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Educational Advisory Board Report: The Science of Simulation



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Simulation-based medical education (SBME) refers to the use of different modalities to recreate elements of the clinical encounter. It is used to teach, train and/or assess.^{1,2} This innovative educational technique emerged from efforts begun in the 1920s by anesthesiologists in an effort to improve patient safety.^{3,4} While many different simulation modalities may be used (part-task trainers, virtual reality simulators, standardized patients, virtual patients, and computerized full-body mannequins), the goals remain improved patient care and safety.¹

“He observed that surgical fellows who studied in the laboratory before assisting with patients in the OR were better able to identify anatomic structures and perform surgical techniques on real patients than their colleagues who did not study in the laboratory.”⁴

Interest in this innovative instructional technology continues to grow. Medical schools and hospitals are building simulation programs, and, at the same time, credentialing and governing bodies are beginning to require the addition of simulation to both educational and certification processes.^{5,6} This review

discusses the science of simulation. It provides an overview of a field that incorporates a wide spectrum of educational tools and techniques but is not intended to be comprehensive.

History of Simulation: Anesthesiologists at the Forefront

Anesthesiologists were the first to develop simulation technology and incorporate simulation into medical education. The earliest record of the use of simulation to train physicians can be traced to the *anatomy laboratory* launched by Dr. John Lundy in the 1920s at the Mayo Clinic. He developed a method to educate surgical fellows about anatomic structures to improve their application of regional anesthesia techniques and to interest them and other physicians in the field of anesthesiology. He created an anatomy laboratory using cadavers so the fellows were able to practice procedures. Initially used by surgical residents, it ultimately became a multidisciplinary laboratory.⁴

Lundy conducted research to identify whether this approach to education was effective. He observed that surgical fellows who studied in the laboratory before assisting with patients in the OR were better able to identify anatomic structures and perform surgical techniques on real patients than their colleagues who did not study in the laboratory.⁴ He also developed a simulation program that recreated the OR environment so residents could learn about performing procedures under conditions similar to the real clinical setting. This enabled surgical fellows to practice procedures, learn anatomy and receive feedback about their performance, which was not possible in the operating room.³

Simulation and Anesthesia Crisis Management

In the 1980s, anesthesiologists developed the mannequins currently used for training and assessment. One was created by David Gaba, MD and colleagues at Stanford⁷ and another, the Gainesville Anesthesia Simulator was developed by Drs. Michael Good and Joachim S. Gravenstein at the University of

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Florida.⁸ Both groups targeted use of these mannequins to help teach the recognition and management of critical anesthetic events.⁹ Dr. Gaba also developed Anesthesia Crisis Resource Management (ACRM) as a model to manage perioperative crises. This approach was based on Crew Resource Management in aviation. ACRM significantly impacted patient safety efforts and simulation-based training in anesthesia and other medical disciplines.¹⁰ The Stanford group demonstrated improvement in the ability of physicians to recognize and manage critical events using the basic principles of CRM: calling for help early, establishing role clarity, using available resources and communicating effectively with the team.⁹

Simulation for Education and Training: State of the Science

While most studies demonstrate that simulation-based medical education programs are well received by students, trainees and physicians, learner perceptions are inadequate to determine whether the session enhanced learning or changed patient outcomes. Over the past several decades, significant research in this area has been conducted.

Studies using simulation demonstrated gaps between ideal and actual performance. In one study using simulation, anesthesiologists performed less than 20 percent of the indicated key actions during two (hyperkalemia and malignant hyperthermia) of 12 scenarios.¹¹ Applications of simulation also demonstrated that skills learned in the laboratory transfer to improved patient care during routine, complex events (such as cardiopulmonary bypass)¹² and during life-threatening events that require teamwork and communication (adult and pediatric codes).¹³

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Deliberate Practice and Simulation

Deliberate Practice (DP) requires highly motivated learners and is defined as repetitive performance of cognitive or psychomotor skills combined with specific feedback and rigorous skills assessment in an effort to achieve better performance.¹⁴ The goal of DP is continuous skill improvement. It has been demonstrated to improve ability in many domains including sports, commerce, performing arts, science, and writing. Research shows that DP is a more powerful predictor of successful skill acquisition than experience or academic aptitude.¹⁴

DP has been used with simulation to achieve sustained improvement in skills, often leading to improved patient outcomes (Barsuk, Grantcharov, Burden, Park, Wayne).¹⁵⁻¹⁷ These positive results were reported to occur through enhanced physician cognition, psychomotor skills in performing procedures,¹⁵⁻¹⁸ and leadership developed by managing critical incidents in the simulation laboratory¹³ and during cardiac arrests in patients.¹⁸

“As anesthesiologists championed patient safety and the development of medical simulation, simulation has developed as a means for practicing anesthesiologists to learn and improve their skills in resource management and team building and to stimulate meaningful practice improvement.⁶”

Simulation and Physician Practice Improvement

As anesthesiologists championed patient safety and the development of medical simulation, simulation has developed as a means for practicing anesthesiologists to learn and improve their skills in resource management and team building and to stimulate meaningful practice improvement.⁶ Course evaluations identified that 95% of participants would recommend the simulation programs to their colleagues, and 98% felt the course was relevant to their practice. Course participants have identified relevance to their practice as the most important element of the simulation program.¹⁹ Communication with these practicing physicians after the simulation course revealed that 95% of participants had successfully completed changes in their practice based on their experiences during the course. These implemented practice improvement plans revealed initiatives that overcame barriers and often exceeded the scope of the original plans. Examples include plans demonstrating direct benefits for patients and widespread dissemination of management guidelines (treatment checklists) across departments and hospital networks.¹⁹

Simulation: Future Directions

Evidence that skills learned in the simulation laboratory translate to patient care continues to mount. Simulation-Based Medical Education has been demonstrated to improve physicians' skills and performance in a variety of patient care settings. It offers a dynamic educational approach and allows physicians to practice and improve their crisis management skills. Further research is needed to identify opportunities to improve the skill of practicing physicians and to address medical errors.

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ASA Academic Caucus

You are invited to a meeting of academic anesthesiology!

When: Saturday, October 24, 2015, 7:30 am to 8:30 am

Where: Anesthesiology® 2015; Hilton San Diego Bayfront, Cobalt Level, Room 5001, San Diego, California

Why: Provide organized feedback to ASA Leadership to support the needs of academic anesthesiologists. Refreshments will be served (Sponsored by SAAA).

Questions:

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AUA President's Column: Age-Related Requirements for NIH Funding



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I have read with interest an Op-Ed contribution in the October 2, 2014 issue of *The New York Times* by our colleague Dr. Andrew Harris, a John Hopkins-trained anesthesiologist and currently a member of the U.S. House of Representatives. His piece leads to a follow-up article in the October 10, 2014 issue of *Science*. He asserted that the average age of a first-time recipient of an R01 is 42 and the median age is 52.

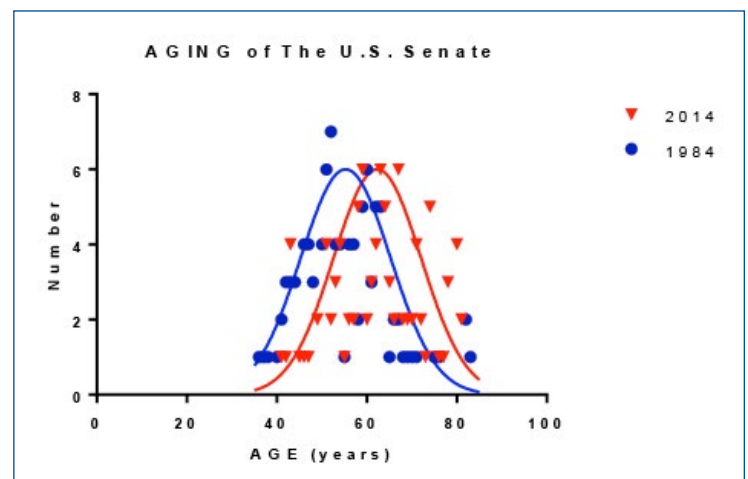
In an opinion reminiscent of the movie, *Logan's Run*, wherein one's life has a mandatory 30-year limit (<http://goo.gl/2wC405>), he proposed that NIH should “mandate that the median age of first research awards to new investigators be under 40 within five years, and under 38 within 10 years.” I, too, am concerned about the prolongation of graduate and post-doctoral training of our gifted young scientists. However, mandating an age-related change in NIH funding without evidence that it will improve the quality or innovation of science is potentially dangerous.

Many aspects of our society have demonstrated a gradual shift toward an older population. A prime example of this can be found in the U.S. Senate. In 1984, the average age of a senator was 55.3 years, in 2014, it was 62.3 years. This difference is statistically significant at the $p < 0.0001$ level (unpaired t-test). Furthermore, the median age of a senator in 1984 was 54 while the median age in 2014 is 63, demonstrating a comparable degree of aging in the senate to the increase noted in first R01 grant recipients over 30 years.

“However, mandating an age-related change in NIH funding without evidence that it will improve the quality or innovation of science is potentially dangerous.”

As Sarah Harper, Professor and Director of the Oxford Institute of Population Aging, points out in *Science* (2014) 346; 589, “concern arises from an assumption that the older labor forces of the future will be less productive and less innovative.” In fact, this is the assumption that Dr. Harris had made in his Op-Ed in *The New York Times*. However, this has not been proven and does not take into account the change in demographics of the current research community nor has there been any quantification of productivity of our current funded investigators compared to those of 30 years ago. It also ignores the many examples of innovative contributions by older people. These examples include Grandma Moses (<https://goo.gl/ySREY2>), seven examples listed in the *MIT Technology Review* (<http://goo.gl/bqOOgK>), Henri Rosseau (<https://goo.gl/mV94J5>) and, of course, our own John Severinghaus who continued to make scientific contributions into his ninth decade.

Is Dr. Harris also concerned about the innovative thinking of our legislators? We in the scientific community and the population in general have not been impressed with the recent productivity of our Congress. Should there be an age limit on holding elected federal office? There was a similar concern at the founding of the AUA as noted in Emmanuel Papper's recollection in 1992 in *Anesthesia & Analgesia*. The founders of the AUA ultimately decided that we should not have any age limits to membership. The recent decision by the AUA membership to develop an Associate Membership for newly funded investigators will infuse continued vigor and research focus into the AUA.



*Senator ages were obtained from Wikipedia.

**Editor's note: I got my first R01 at 62 years...WAK

Scientific Advisory Board Report: Physician-Scientist Pathway in Anesthesiology



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After years of hard work, you have finally completed your clinical training. You will inevitably have to make one of the most important decisions in your professional career: to choose between academic medicine and private practice. In the U.S., a majority of MDs enter private practice after their clinical training. They take care of patients in offices and in small community hospitals, and represent an important part of the U.S. healthcare delivery system. In most cases, they do not have teaching or research responsibilities.

A small number of physicians choose to work in medical school-affiliated hospitals, where they carry out three core missions of major teaching hospitals – patient care, teaching, and innovative research.

This article outlines the research career pathways for academic physicians. Of note, these pathways are mainly for MDs conducting basic science research. Physicians pursuing clinical research may have different pathways in terms of the funding sources and necessary training that they may need to fulfill. For clinical research, industry and private foundation funding play a major role. Although the National Institutes of Health (NIH) has increasingly committed funding to translational and clinical research.

As illustrated in Fig. 1, the post-graduate physician-scientist pathway can be divided into four stages: 1) Residency, 2) Post-residency research fellowship, 3) Transition to independence, and 4) Principal Investigator.

Stage 1: Residency

Without a doubt, the most important goal of any residency training is to obtain sufficient clinical skills that are essential for you to become a competent physician. Having solid medical knowledge and proficient clinical skills is the foundation and pre-condition for anyone who wants to pursue a future research career as a physician. Considering how much you have been invested in medical school and clinical training, you should become a competent doctor first and then a researcher.

“To identify a good mentor, you need to talk to people around you, in your department, hospital, and medical school, and do some searches about your faculty members.”

1. Stay connected

Having said that, it is important to stay connected with research during your residency if you do consider a research career after the clinical training. Many top residency programs in the U.S. have various research/career-related components built in their residency curriculum, such as 1) Research mentorship, 2) Career advice and development, 3) Lecture series on faculty research. It is important to discuss with your program director your career goals and to have his or her advice and support.

2. Good mentorship

Having a good mentor is extremely important for your career development. A mentor acts as your advocate who is genuinely interested in promoting your career. To identify a good mentor, you need to talk to people around you, in your department, hospital, and medical school, and do some searches about your faculty members. Regardless what stage in your career you may be, you need a mentor(s).^{1,2} Given the nature of the career pathway (i.e. research), you need to have a mentor who is a well-established and NIH R01-funded investigator and who shares similar research interests with you. It would be preferable that the mentor is a MD and has had prior mentoring experience with MD researchers, but that is not absolute.

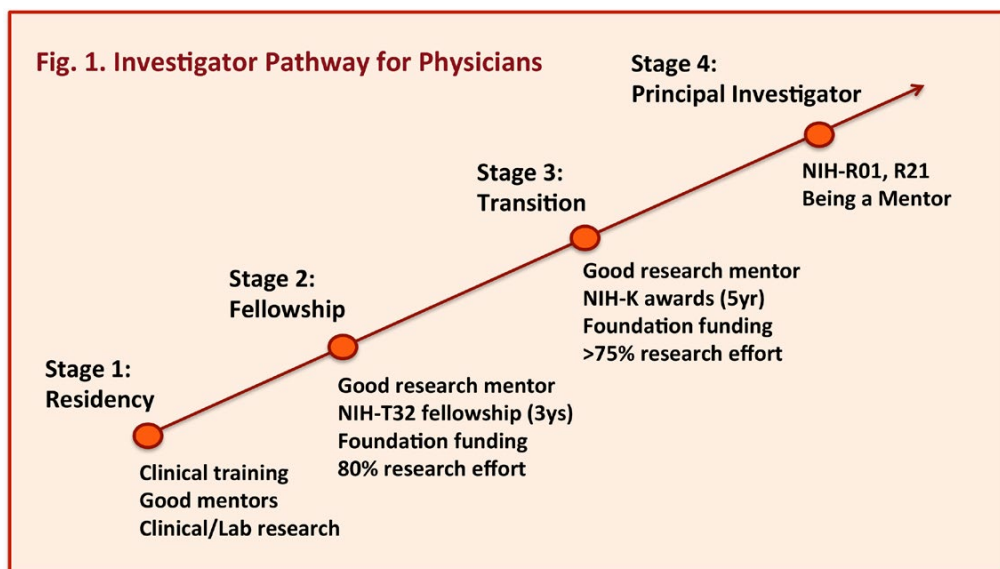


Figure 1.

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3. Consider research block

Many specialty programs such as anesthesiology and surgery offer a block of protected research time to residents. For example, The American Board of Anesthesiologists (ABA) offers residency credit to residents who pursue 6 months of full-time research during the CA (Clinical Anesthesia)-3 year. Recently this research opportunity has been expanded by the ABA under the discretion and direction of your program director to allow for up to 25% of your residency devoted to research during a 3- or 4-year residency program and up to 35% of your training during a 5-year training program (<http://goo.gl/cycjym>). While it is debatable as to what advantage the research block during the residency may offer, it clearly gives one an early start to generate preliminary data that may be critical for your post-residency research fellowship applications.

Stage 2: Post-Residency Fellowship

This is a critical and also most vulnerable period as many MD researchers “drop out” during this period for a variety of reasons. You are now an attending physician practicing medicine part-time and at the same time, trying to establish your own research capability as a fellow in your mentor’s lab. If your department has a strong academic track record, most likely there is a NIH-sponsored Institutional Training Grant (T32) in place (Fig. 2) (<http://goo.gl/glxnk1>). In that case, you just need to apply for the T32 fellowship within your department and do not have to deal with the NIH.

The NIH T32 training program mandates at least 80% of research effort from awarded trainees. This period is critical as the T32 fellowship provides necessary funding for your

protected research time. However, it only provides up to 3 years of support. You have to make good progress within the 3 years in order to move on to the next stage.

Again, it is important to have a good mentor who understands you (being a part-time physician and researcher) and are familiar with the issues specifically associated with physicians, such as absence from the lab on your post-call days and your clinical responsibilities at the hospital. The post-residency research training is intense and you have to work hard and be productive.

“While it is debatable as to what advantage the research block during the residency may offer, it clearly gives one an early start to generate preliminary data that may be critical for your post-residency research fellowship applications.”

In our department at the MGH, T32 awardees’ salary is supported by the combination of clinical service, the T32 fellowship, and the departmental research fund, and is near the level of a full-time clinician. If your department does not have a T32 program in place, the department would need to use additional departmental funds to support you. In any case, it is extremely important to have some protected research time to pursue your research career, and that, of course, costs money. Your departmental support is the key. Without the support from your mentor(s) and chief, you will have a hard time succeeding.

A lack of the departmental support is one of the most common causes for the “drop-out.” This is the period when you are most vulnerable.

Stage 3: Transition to Independence

In most cases, the three-years of T32 fellowship training isn’t sufficient to lead you to become an independent investigator. Additional research training is often needed to make the transition to independence. There are a few foundations and NIH funding mechanisms that are specifically designed to support such a transition, such as Career Development Awards from NIH (i.e. K awards), the Mentored Research Training Grants from The Foundation for Anesthesia Education and Research (FAER) and the International Anesthesia Research Society (IARS), The Society for Cardiovascular Anesthesiologists (SCA), The Anesthesia Patient Safety Foundation

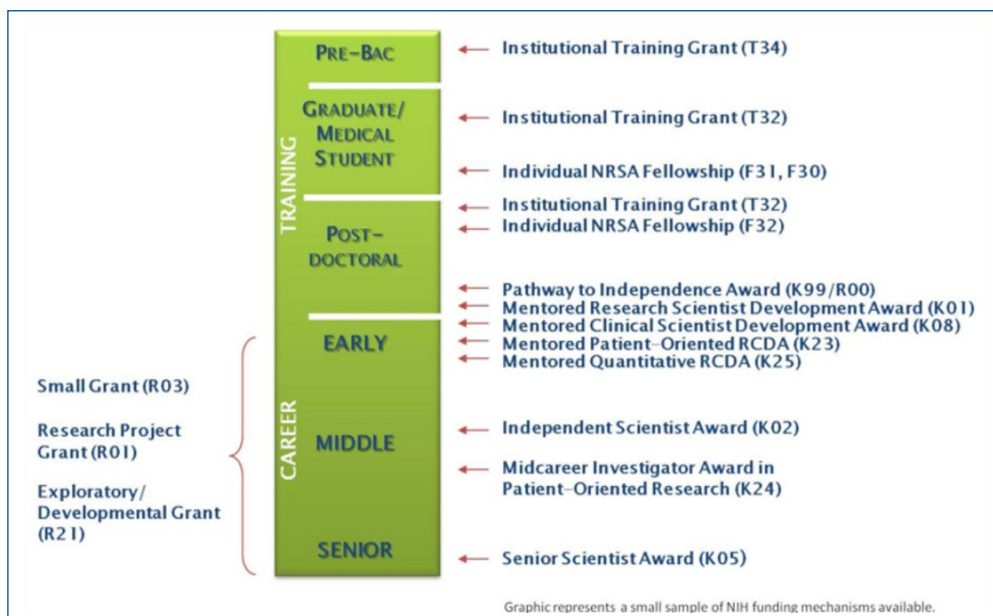


Figure 2. NIH offers different funding mechanisms to researchers at different stages and different career pathways. For MD or MD/PhD researchers, T32, K08, K23 are very popular. To PhD researchers, F32, K01, and K99/00 are popular. K99/00 is also available to MD researchers.

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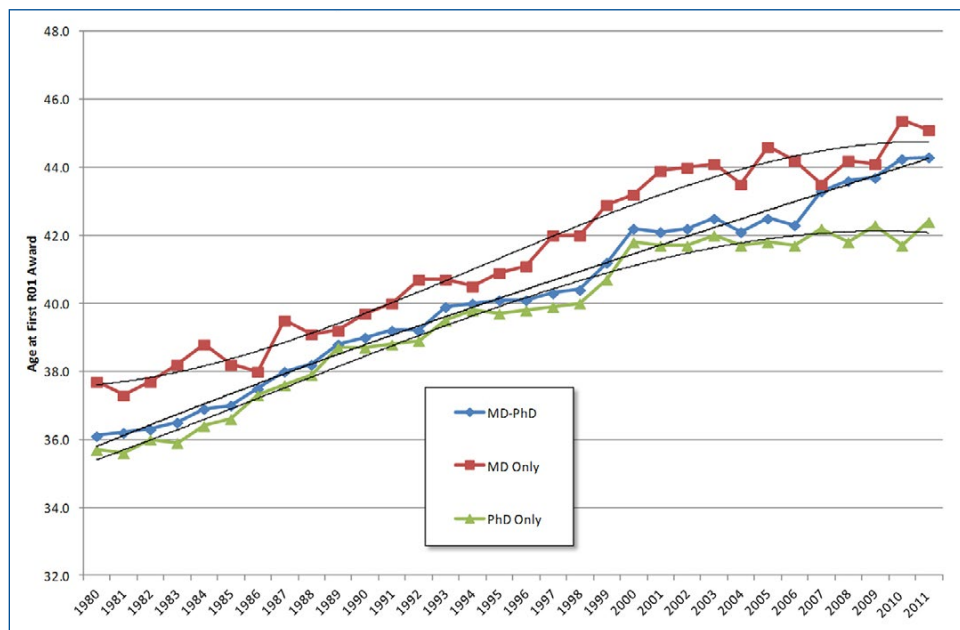


Figure 3. Average Age of Principal Investigators with MD, PH-PhD, or PhD at the time of First R01 Equivalent Award from NIH, Fiscal Years 1980 to 2011.

(APSF) or Career Development Awards from the American Heart Association (AHA), to name a few.

“The K08 is important in two ways: 1) It provides the “protected time” so you can intensely focus on your research project with a very limited clinical responsibility, and 2) It provides an opportunity for you to further strengthen your research capability and to develop your own independent project(s), the two key elements for you to make a successful transition from a mentored physician-scientist to an independent investigator.”

Of all these awards, the most popular award among junior physicians is NIH’s “Mentored Clinical Scientist Research Career Development Awards” (<http://goo.gl/lrhcxK>) or the commonly known K08 award. A K08 equivalent for clinical investigators is the K23 or “Mentored Patient-Oriented Research Career Development Award” (Fig. 2). Table I (see page 9) compares three different career development awards. The K08 award provides up to \$100,000 in salary support plus fringe benefits per year to MD or MD/PhD investigators for up to five years. PhD researchers are not eligible for a K08, but can apply for a K01. In addition, it provides up to \$30,000 of research support. In return, the K08 award mandates at least 75% of professional effort being devoted to conducting research.

“While many researchers have had vigorous research training during medical or graduate school, very few have been taught grant writing.”

The K08 is important in two ways: 1) It provides the “protected time” so you can intensely focus on your research project with a very limited clinical responsibility, and 2) It provides an opportunity for you to further strengthen your research capability and to develop your own independent project(s), the two key elements for you to make a successful transition from a mentored physician-scientist to an independent investigator.

The K99/R00 award is designed to help senior postdocs make a smooth transition to independence and is popular among PhD researchers. It provides \$75,000 of annual salary support for the first two years. Pending the working progress (e.g. new papers and a faculty job offer), the awardee will get \$250,000/year of research support for the latter 3 years as an independent investigator.

You may also apply for support from various foundations and societies, such as Foundation for Anesthesia Education and Research (FAER), International Anesthesia Research Society (IARS), The Society for Cardiovascular Anesthesiologists (SCA), the Anesthesia Patient Safety Foundation (APSF) or American Heart Association (AHA). FAER offers grant support in three categories: 1) Mentored Research Training Grant (for junior faculty), 2) Research in Education Grant, and 3) Research Fellow Grant (for residents/fellows). IARS offers similar awards. These grants provide generous financial support and mandate protected research time. You can find the details of eligibility, funding levels, required research effort, and application procedures on their websites (www.faer.org; www.iars.org; www.scahq.org; www.apsf.org; www.heart.org).

In addition to developing an innovative research project, another important goal during this transition period is to develop grant-writing skills. While many researchers have had vigorous research training during medical or graduate school, very few have been taught grant writing. Writing a winning grant proposal is a necessary skill for any successful principal investigator. Learn the skills from your mentors, your advisors, your collaborators, and in workshops. This is a big topic that is beyond the scope of this article. I have included two papers on the topics of research funding and grant writing for your reference.^{3,4}

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Table 1. Comparison of three career development (K) awards

NIH Program	K08	K23	K99/R00
Title	Mentored <i>Clinical Scientist</i> Research Career Development Award	Mentored <i>Patient-Oriented</i> Research Career Development Award	NIH Pathway to Independence Award
For Whom	Clinical doctoral degrees (MD, DO, DMD, PharmD, DVM...)	Clinical doctoral degrees (MD< DO, DMD, PharmD, DVM...)	Clinical/Research doctorate (MD or PhD)
% Effort	75%	75%	
Duration	3-5 years	3-5 years	2 years (K99) + 3 years (R00)
\$\$\$ per year, (NHLBI)	\$75K salary + fringe \$25K research support	\$75K salary + fringe \$30-50K research development support	K99: \$75K + fringe R00: \$249K
Deadline (NHLBI)	Feb 12, June 12, October 12	Feb 12, June 12, October 12	Feb 12, June 12, October 12

NHLBI: National Heart, Lung, and Blood Institute. Other NIH institutes offers similar awards with some minor differences.

The R01 award provides a large sum of money (\$250,000 or more of direct cost per year) for up to five years. With this grant and hopefully the support from your department in the form of a start-up fund, you will finally be able to have your own laboratory and enjoy your independent and innovative research.

Some Perspectives

Challenges: The pathway to become an independent investigator as a physician is long and challenging. The average time from the completion of residency to the first R01 award is approximately eight years assuming that everything goes smoothly. Given the economic downturn during the past 5-10 years, the NIH budget has been declining. The paylines for most NIH institutes/centers are around 10%. The situation is challenging for all researchers but even more so for physicians as many of us have to devote at least 20-40% of our professional effort to patient care and resident teaching. Despite the challenges, many academic physicians enjoy their careers in teaching hospitals as clinicians, teachers, and researchers.

“The ultimate goal of research is to improve human health.”

Opportunities: The ultimate goal of research is to improve human health. There are advantages as well as opportunities for academic physicians. Physicians have the first hand of knowledge of human diseases. We take care of patients, identify underlying clinical issues and challenges, ask critical questions, form hypotheses, and then test the hypotheses in well-controlled experimental settings. In doing so, we advance our knowledge of human diseases, translate the knowledge to novel treatments, and ultimately, improve the patients’ outcome.

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Stage 4: Principal Investigator

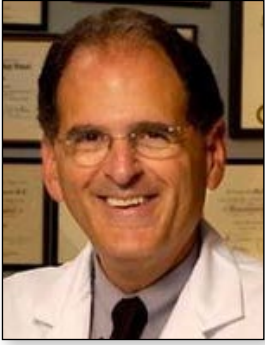
To become an independent researcher or principal investigator (PI), you need to have an adequate level of funding to support your projects. This is true for both basic and clinical investigators. For a basic researcher, that means you’ll need to obtain your own independent funding, most likely from NIH. The most common funding mechanism for most PIs is the Research Project Grant or better known as R01 (Figure 2) (<http://goo.gl/i0a8Ee>).

The increasing complexity of science and thus demand on our scientific knowledge and skills has resulted in a steady increase between 1980 and 2010 in the age at which the new investigator obtains their first R01s. As illustrated in Fig. 3, the average age of new PhD R01 investigators increased from 36 in 1980 to 42 in 2010. This number is even higher for researchers with an MD or an MD/PhD.

“The increasing complexity of science and thus demand on our scientific knowledge and skills has resulted in a steady increase between 1980 and 2010 in the age at which the new investigator obtains their first R01s.”

The good news is that NIH realizes the enormous challenge of such transition and has thus designed a set of policies to encourage and promote new investigator’s first R01 applications (<http://goo.gl/ud7I50>).

Academic Medicine Survival Guide*



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Boston, Massachusetts

The History European University (e.g. Italy, Germany, France, England) descended from the Church. The academic hierarchy, reflected in the regalia, has its roots in organized religion. The American University was a phenocopy of the European University, but the liberal arts college was a unique American contribution, wherein teaching was considered a legitimate academic pursuit. Even the closest analogues in Europe (the colleges of Cambridge and Oxford) are not as purely an educational institution as the American liberal arts college. The evolution of American medical education (adapted and updated from: Ludmerer KM. *Time to Heal*, Oxford University Press, Oxford, 1999) may be divided into five eras.

The pre-Flexnerian era (1776- 1910) was entirely proprietary in nature. Virtually anyone with the resources could start a medical school. There was no academic affiliations of medical school and no national standards.

“The Harvard model in which the hospitals grew up independently with only a loose alliance with the medical school, represented a hybrid between pre- and post-Flexnerian medical education.”

The inter-war period (1910-1945) was characterized by an uneasy alliance between hospitals and universities. Four major models emerged. In the Johns Hopkins model, led by William Osler, the medical school and the hospital were married and teaching of medicine took place at the bedside. The Harvard model in which the hospitals grew up independently with only a loose alliance with the medical school, represented a hybrid between pre- and post-Flexnerian medical education.

The Massachusetts General Hospital grew from a pre-Flexnerian prototype, while the Brigham was founded in 1913 just after the 1910 Flexner report and more closely approximated the Hopkins model, to a large extent because of Cushing's experience under the influence of Osler at Hopkins. The State University Model consisted of a group of hospitals (city, county, VA, university) that were allied with a medical school under the leadership of a powerful dean. The Special Interest Medical School model arose when a specific group (African Americans, women, Jews) created their own schools out of the perception and often reality of prejudice.

The post-WWII period (1945-1985) was marked by the dramatic rise in the influence of the National Institutes of Health (NIH), which made research profitable, combined with the advent of Medicare (1965), which made clinical work and residency training profitable for academic medical centers. These events had two effects. One was the rise of the “submarine,” meaning the biomedical scientist-physician, who spent greater than 80% of the time engaged in research and then “surfaced” to behave like a doctor, one day a week or one month a year. The second effect was the orphanage of medical student education. This occurred because research was profitable as a result of the growth of the NIH extramural program and clinical work and residency training was profitable because of Medicare. Nothing was earmarked for medical students.

“One can never tell whether the person next to you is “one of them” without looking carefully for the telltale electrode in the back of the neck. There are many signs that the “invaders from mars” actually have taken control of organized medicine.”

The paradoxical era of cost containment and scientific mania followed (1985-2000). The concept of “translational research” is born. Physicians-scientists proclaimed that the current era was the most unique in the history of humanity and that we are on the threshold of solving the major mysteries of disease. Cancer, heart disease and neurodegeneration are thought to be soluble with the tools of molecular biology. Despite this hubris, society is not convinced that the era of the growth of the NIH has yielded enough “cures” to justify the cost, so the era of cost containment frustrates the physician-scientists who believe that this “false economy” will risk our losing the opportunity to solve the major human diseases, but their protestations smack of self-interest.

A replay of the era of proprietary medicine is upon us (2000- ?), almost exactly a century after the Flexner report brought an end to the last such era in 1910. Business models now dominate the hospitals. Some of these hospital leaders are trained as doctors, but they have been transformed into something very different. Recall the William Cameron Menzies film, *Invaders from Mars* (a precursor of *The Body Snatchers*), where beings from outer space come to earth but have no bodies in which to live, so they kidnap people, and replace their brains with computers that are controlled via a small antenna that one can find by inspecting carefully at the nape of the neck. Gradually, more and more people are turned into these evil automatons. One can never tell whether the person next to you is “one of them” without looking carefully for the telltale electrode in the back of the neck. There are many signs that the “invaders from mars” actually have taken control of organized medicine. The following is a compilation of words I have heard in real hospital meetings over the past few years.

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Words Heard in Real Hospital Meetings

I'm afraid that if we don't drill down on our brand equity on the front end, we'll have to model it out on the back end to align our seamless incentives or pad our ask regarding the co-branding deliverables on the horizon. As an FYI, this empowerment is going to require an elbow to elbow champion getting under the covers for a 360° of the eRoom to facilitate a paradigm shift in order to achieve buy-in among the stakeholders if we're going to tip our toe into that water and get the low hanging fruit before our clients incentivize the burning platform with new metrics.

After all, you are the process owner who needs to reach out in the proper bandwidth to push back on the KOL's or we'll have to sunset your blue ribbon committee for not trimming the fat on the real-time escalation project. We need to do more due diligence before we hitch our wagon to that indexed outcome measure, and let's be careful how we message it and roll it out to the core constituency. We can model that projected gap, but we don't want to get out ahead of our audience before sensitizing them to the moving target. Let's not drop the meat in the dirt but rather vet a pause point, collapse it up to a high level statement and assess the current state in order to connect the dots to achieve the ideal state and have you weigh in at the portal for service-oriented architecture. After all, at the end of the day, we'll have more skin in the game and be in a better space if you walk the stakeholders through it so that they can leverage their halo to birddog that from 10,000 feet.

If you could create a placeholder to move the needle in the continuous quality improvement initiative, some heavy lifting might give us a report card so that there can be the accountability for a decent ROI, unless the co-branding produces a choke point so severe that the balanced score card causes a culture change, one by each. Just between you and I, you need to parking lot that issue, take the deep dive and put the rubber to the road with a degree of commonality that will re-engineer a sea change in our SWOT analysis so that we bake it into the budget of the high level implementation group. We have to move the ball down the field and prevent leakage. Net-net there is value added for a win-win, rather than a zero-sum game. You can manage the matrixed organization on the frontline and in the back office. With central discipline and local control we can achieve savings and margin, while penetrating that segment of the market. A lot of what we have to do to reduce our trend is blocking and tackling in different spaces. Bottom line on top, if I don't report to myself, we could really take a haircut before we can trim the fat out of the box and shift the culture beyond this pilot demonstration program. That having been said, the PEST analysis shows that if you step up to the plate and evangelize the brand, we can be about the business of creating a placeholder of new buckets with more vertical silos so that we can finally tell whether we are on foot or on horseback.

Comparing apples to apples, it is clear that this is not a plug and play culture, so that you'll have to hold your nose and jump in order to filter the noise and incentivize the process owners in a more granular fashion before it becomes a major mission drag. A bread crumb has been forming so let's put some stakes in the ground to leverage our insights as enablers of change to circle back on a more granular view, and tee up our clinical levers to mine insights from the benchmarks and beat the waste out of this process. We will cleanse our application platform and get ready for the first wave of ambulatory e-care go-live across the family and take advantage of the elbow-to-elbow support of the super-users and be back to 100 percent productivity by the second week. Having said that, we traffic-lighted that report so you can optimize the outcome metrics. If we can get the whole group on board in this arena we can try to boil the ocean with a six sigma culture change. We mean to hit this one out of the park and get some substantive returns in the coin of our realm to avoid any mission creep. It's a non-starter to analyze the dashboard for crosswalking noise, so we need to slice and dice our organic growth, peel the onion and hardwire the initiative with more boots on the ground. If this could be the pause point for a new value initiative, that's where the metal meets the road. Let's reach out, using our optimized tool kit to go anything north of zero and put a hard stop on this turn-key operation. If you would like to get some trend lines and traction from this piece, I can ping you a copy of my deck.

If you hear any of these terms come from the mouth of someone who looks like a doctor, carefully check at the nape of the neck for the telltale antenna.

The Institute of Medicine's 1999 report entitled "To Err is Human" heralded the beginning of this new era, in which we are still ensconced. The report declared that 98,000 Americans die annually from inpatient medical errors and that these errors were the leading cause of death in the U.S., exceeding motor vehicle accidents, breast cancer and AIDS. The report, meant as a self-critical professional analysis, became public and took on a life of its own, spawning an enormous "movement", only a few examples of which are the Institute for Healthcare Improvement (IHI), the Leapfrog Group, hospital and doctor "report cards" (*Consumer Reports, US News & World Report's lists, Consumer's Checkbook, Healthgrades, Inc.*). Buying into the self-hatred of the culture of error and blame, creating elaborate guidelines and systems to prevent error, believing it to be the major enemy, only avoids the uncomfortable fact that it is **disease** that is the enemy against which the forces of medicine should be aligned and that mortality is a fact of the human condition. The death rate remains one per person; unchanged from ancient times. We should, of course, try to prevent error, but we should realize that the patient safety movement is a self-fueling industry, in which the solutions to the patient safety problem are sold by the very people who declared that the problem exists; a classic conflict of interests that undermines the social contract

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between doctors and society and de-professionalizes medicine; hardly different from the proprietary snake oil salesmen who, almost exactly a century earlier, called themselves doctors in pre-Flexnerian America.

A new era of physician-scientists from the heyday of the NIH era lead the medical school departments by propagating the myth of the triple (quadruple if one includes the capacity to run the business that is now an academic department) threat. This is a cruel hoax, which makes young doctors believe that they are not living up to the monumental accomplishments of their predecessors unless they “do everything well.” If you were a fly on the wall of our promotions and search committees you would be shocked to learn that we are surrounded by veritable Supermen, combining the skills of the great scientist with the brilliance and empathy of the wizened clinician, while running the marathon, raising a family and playing the clarinet.

Clinicians succeed by servicing the rich (witness the birth of concierge practices). The wealthy, but medically unsophisticated, clientele are encouraged to believe that error is avoidable, that their intellectual contributions to the boards of trustees of hospitals are actually substantive, that life can be extended virtually forever and that the cures for major illnesses (cancer, heart disease, neurodegeneration and even ageing itself) are close at hand requiring only more money.

“Thus, if one believes that the leaders of academic medicine are actually quadruple threat Supermen, one is constantly putting them into positions wherein they must opine about ‘matters of which they are to some degree ignorant.’”

The myth of our specialness (“never in the history of humanity has there been a more exciting era of science with its potential to eliminate disease”) is used to cynically harness personal fear of disease and death to extract resources from philanthropists and government, yet there is no reason to believe that this is true. When in history have we not been at the advancing edge of the accumulated knowledge of all that went before us. When Hooke first gazed down his compound microscope, was he not also at the cutting edge? Did he not also believe that the new world that he visualized would hold the solutions to all of medicine? The following quotation has been attributed to William James, the psychologist and philosopher: “There is no doubt that great revolutions of human scientific thought will occur in the next century and in the century after that and in a thousand of centuries afterward; so which of our current pet scientific dogmas will be among the first trashed away by new facts and sudden clarities?”

This proclamation about the perceived uniqueness of ourselves and our time is the subject of Princeton philosophy

professor Harry G. Frankfurt’s little book entitled, *Bullshit*. Its opening words are: “One of the most salient features of our culture is that there is so much bullshit.” Frankfurt argues that it is likely, though not certain, that there is more bullshit today than ever before, if only because there is more communication of all kinds than ever before. Thus, even if the proportion of bullshit is about the same as ever, the total amount is enormously greater. Email is certainly a good example of this phenomenon. “Bullshit is unavoidable,” Frankfurt argues, “whenever circumstances require someone to talk without knowing what he is talking about.” Thus, if one believes that the leaders of academic medicine are actually quadruple threat Supermen, one is constantly putting them into positions wherein they must opine about “matters of which they are to some degree ignorant.” Watching the submarine wax eloquent about a clinically complex patient comes to mind as an example familiar to all of us. Gourmet clinical medicine and teaching are further orphaned and the word education comes to mean re-education (indoctrination).

The Natural History of the Great Physician in the Academy

Academic life is not the smooth trajectory that it appears in retrospect. Joseph Babinski (1857-1932) was denied associate professorship by the Board of Medical Examiners of Paris in 1892 (age 35) by one of his former students, Charles Bouchard, who was president of the board and in competition with Babinski for leadership of the faculty. This made it impossible for Babinski to ever obtain the chair in neurology. He made four unsuccessful attempts to become responsible for a medical department before taking a position at La Pitié, a peripheral hospital that moved next door to the Salpetriere in 1911, where he stayed for his entire career, retiring at age 65 in 1922. His department had no administrative links to the university, so he was limited to rare medical students on electives and a few residents. “The (*Babinski*) sign” was described in 1896 in a 26 line single authored paper entitled: “About the cutaneous plantar reflex in some organic diseases of the central nervous system.” It is unarguable now that Babinski is the most recognizable name in all of neurology. He was also interested in treatment when everyone else in neurology was obsessed with phenomenology (“diagnose and adiose”).

Furthermore, he was actually a nice guy; good to his students and friends, philanthropic, cultured (a serious opera buff), modest, kind, productive, insightful, loyal to his teachers, to Poland, where his father was born, and to France, for which he served twice in the military, including in WWI at the age of 60.

Babinski’s experience highlights one of the major challenges in academic medicine: dealing with assholes. It sometimes appears that narcissistic, mean spirited, self-righteous, overconfident assholes have the right formula for success in the academe. If you believe this is true, you must read a

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little book entitled, *The No Asshole Rule*, written by Stanford Business School professor, Robert I. Sutton, published in 2007 by Warner Business Books. In it Sutton outlines the reasons that management should allow only a few assholes in a business and why behaving like a creep actually does not pay.

The Efforts to Reform the Promotions System in Academic Medicine

The concept of tenure, created to protect academic freedom, has undergone a fundamental change because of its inordinate costs. The fall of tenure is a salient feature of the new academic era. Medical schools' struggle with their role in the larger university is epitomized by efforts to describe the academic roles of physicians. Harvard Medical School is one such leading institution, whose history reflects the ambivalence that marks the role of the medical faculty in the context of the university. The Harvard promotion tracks resulted in a struggle with the rest of the university. One track was replaced by two (clinician, investigator), which were replaced by four criteria (laboratory investigator, clinical investigator, teacher-clinician, clinician-scholar), which were replaced by two criteria (teacher-clinician, investigator). A caste system of prefixes attempts to maintain the hierarchy of the ancient university order in many universities (e.g. Professor of Clinical Medicine and Clinical Professor of Medicine). At Harvard, then President Bok was only willing to accept Dean Daniel Tosteson's proposal to have a clinician-scholar track if the prefix "Clinical" was placed in front of the title. Dean Tosteson engineered a compromise whereby that prefix would be removed at the level of full professor but remain in place for the lower levels. The newest iteration is a system that requires a major in one of three areas (investigation, teaching and educational leadership, clinical expertise and innovation), with an optional minor in one or both of the others.

The bottom line is the same: At Harvard, the titles mean the following:

Instructor: Entry level

Assistant Professor: Local reputation

Associate Professor: Regional reputation

Professor: National & International reputation (international without national does not count)

In the words of Hillel: "All the rest is commentary"

Professionalism

Justice Louis Brandeis defined a learned profession as one with a specialized body of knowledge that it passes on to the next generation, which sets its own standards that it self-regulates and is altruistic (i.e. puts the needs of others over one's own). In return for maintaining professional values, doctors are afforded a number of tangible benefits including financial reward, societal respect, access to the most sensitive and intimate information, and broad freedom to carry out research, even involving other human beings. The Charter on

Medical Professionalism, which was published simultaneously in the *Annals of Internal Medicine* and *The Lancet* in February, 2002, was developed by a task force of the Medical Professionalism Project, sponsored by the American Board of Internal Medicine Foundation, the American College of Physicians-American Society of Internal Medicine Foundation and the European Federation of Internal Medicine. The three basic principles of professionalism in medicine are: primacy of patient welfare, patient autonomy, and social justice, supported by ten professional responsibilities: professional competence, honesty with patients, patient confidentiality, maintenance of appropriate relations with patients, improving quality of care, improving access to care, just distribution of finite resources, scientific knowledge, maintenance of trust by avoiding conflicts of interest, and professional responsibilities.

The transition to becoming a professional is gradual but begins at the start of medical school. Medical students are junior colleagues. Simulations are fine for learning technical skills (e.g. tying knots, learning CPR), but using simulations in place of real patients transmits the idea that the students cannot be trusted with patients. This infantilizes what is really a mature graduate student and deprofessionalizes medicine. Excessive dependency on artificial core competencies and guidelines changes medicine from a profession into a trade.

A Checklist for Surviving Clinical Medicine

- Decide who you are and don't kid yourself.
- Don't bluff; the triple (quadruple, i.e., triple + businessperson) threat is an illusion.
- Know your subject; teaching is not a trick; you must have something real to transmit. Don't replace substance with gimmicks (e.g. fancy PowerPoint).
- Simulated patients produce simulated doctors and de-professionalize students.
- Respect your teachers but don't believe in the Days of the Giants; they have feet of clay. Don't become "one of them."
- Develop a reputation beyond the local environment.
- Train people, but remember that some will not respect you (remember Bouchard).
- Stand proudly for clinical excellence.
- Write briefly, simply and parsimoniously (remember Babinski).
- Be a professional.
- Don't be an asshole.
- Don't bullshit.

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Creating Leverage: The Roles of Operations Researchers in Academic Anesthesiology



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Anesthesia departments, especially those at academic medical centers, play an influential role in the overall operational performance of the perioperative arena. The increasing focus on perioperative surgical homes is extending this sphere of influence to include outpatient and hospital inpatient areas as well. Anesthesia departments therefore have to be efficient in allocation of faculty time and measurement of faculty performance. They have to also ensure that involvement in non-clinical hospital administration activities results in anesthesia faculty providing the greatest value to the group. This is both an opportunity and a challenge. On the one hand, involvement in administrative leadership roles leads to faculty's professional development and improved job satisfaction. On the other hand, inability to make stellar contributions among the peer group comprised of surgeons, nurses, and non-clinical administrators can be demotivating. Anesthesia departments and anesthesia faculty can get a comparative advantage in this arena by learning and applying the well-developed concepts from the area of business research called "operations research."

Operations Researchers model real-world systems in an analytical way, often through mathematical modeling and simulations, with the objective of helping make better decisions. Management Science and Decision Sciences are often used synonymously with Operations Research (OR). The engineering disciplines of Industrial and Systems Engineering rely heavily on OR techniques to model engineering problems. In the business domain, operations management and process improvement rely heavily on OR methods. OR therefore provides a good analytical toolkit for understanding and solving real-world business questions in the perioperative system.

The Operations Research (OR) term was first used in 1936 by British military¹ and played an immense role in giving the allied forces their military advantage in WWII.² The genesis of OR, however, can be traced back to 1654 when Pascal and Fermat (working independently of each other) came up with the idea of "expected value" of a random variable – that, *the value of a future gain should be directly proportional to the chance of getting it*. This then led to the evolution of the field of Probability Theory and later the field of Statistics. Today, OR techniques of mathematical optimization, stochastic and Markov processes, decision analysis, etc. are employed in all sectors of the economy, including healthcare delivery.³

"Variability in daily surgical volume leads to mismatch between the labor capacity planned for the day and the actual labor-hours needed. We developed a technique to predict the case volume from the developing elective schedule up to 30 days in advance, and with sufficient confidence to be able to flex nurse and anesthesia staffing."

The Department of Anesthesiology in Vanderbilt University School of Medicine, along with the Perioperative Enterprise began a program three years ago to build our in-house operations research capabilities. The objective was four-fold: help faculty in their clinical research as well as in their administrative pursuits, improve the perioperative team and hospital leadership's decision-making, and strengthen the collaboration and credibility between anesthesiology faculty and perioperative & hospital leadership. The OR expert has a dual faculty appointment in the Department of Anesthesiology and an operational leadership role in the Perioperative Enterprise. This assures that initiatives informed by OR analyses both provide academic value for the Department *and* achieve operational implementation and provide real benefit to the organization. This initiative has been largely successful, and we provide some examples next.

Variability in daily surgical volume leads to mismatch between the labor capacity planned for the day and the actual labor-hours needed. We developed a technique to predict the case volume from the developing elective schedule up to 30 days in advance, and with sufficient confidence to be able to flex nurse and anesthesia staffing.⁴ The same methodology has been expanded to predict future daily surgical inpatient bed needs. Developing the OR methods further, using computer simulation model and Bayesian analysis the prediction of daily case volume at individual surgeon and service as far out as 42 days has been tested. These applied OR implementations impact areas of operations across the medical center, and has

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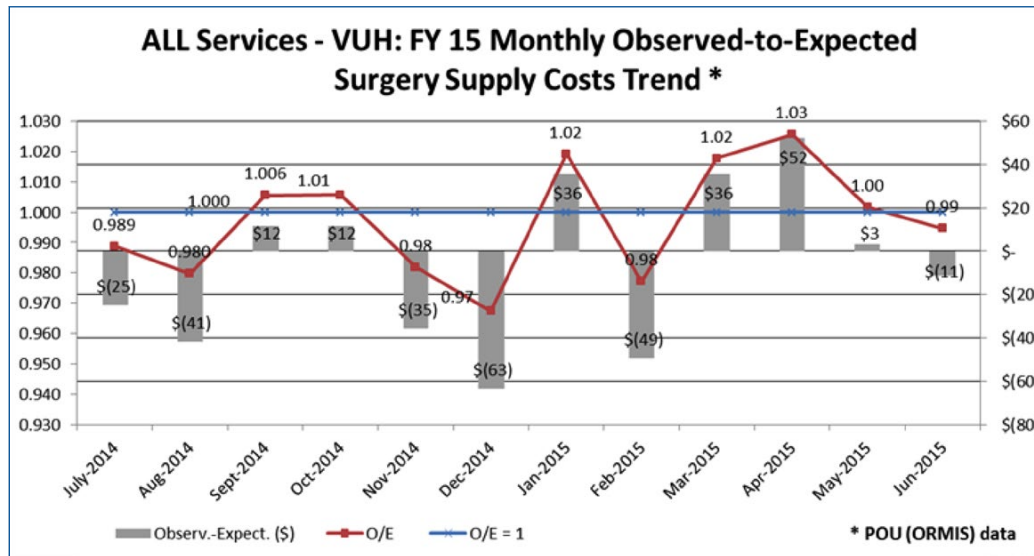


Figure 1: CPT Adjusted Variable Surgical Supply Observed-to-Expected Costs – July 2014 to June 2015.

solidified the anesthesia department’s position of being at the forefront of innovative research.

Surgical chairs tasked with reducing surgical supplies expenses for their services struggled to prove any reduction in costs per case, even after instituting several proven cost reduction strategies in collaboration with perioperative services. To help the hospital administration and the finance department interpret this conundrum, we analyzed millions of lines of supply cost data spanning over several years and determined that simple cost per case was an inadequate metric. Using variability analysis concepts we proved the outsized impact of few cases on monthly supply expenses. We conceptualized, socialized, developed, and then implemented a new metric based on grouping of similar procedures to get an “observed to expected” supply expense ratio (Figure 1). We developed real-time web-based reports that help surgical departments quickly isolate procedures causing monthly variances, and then drill-down to case and item-level data. The new metric put to rest hospital administrators’ (unfounded) concern that supply expenses were uncontrollably trending up.

Factors that contribute to the success of individual fellows within a critical care fellowship have not been well studied. Most programs place significant emphasis on summative evaluations to assess whether fellows are meeting ACGME milestones. We used data envelopment analysis (DEA)⁵ to compare and rank peers and assess what aspects of the educational program and work characteristics contribute to fellows’ success in our program. DEA is a non-parametric, OR technique that uses linear programming to calculate an efficiency score based on the relative usage of multiple resources, by each unit under evaluation, in producing multiple outputs. It can also potentially

be a tool to forecast the level of effort needed by a trainee to achieve the same level of results as their top performing peers.

Some other applied research projects currently under way wherein OR is helping anesthesiology and other faculty around the school of medicine include: (1) cost comparison among alternate treatment pathways using decision trees, (2) anesthesia faculty productivity evaluation using DEA, (3) optimal policy for medical decision making of neuro ICU patients on external ventricular drainage for intracranial pressure monitoring, using the OR technique of stochastic dynamic programming.⁶

Analytical thinking comes effortlessly to most anesthesiologists, but medical school education and residency training do not provide adequate exposure to the analytical and modeling techniques they need to answer complex pragmatic analytical questions in clinical practice. Operations Research techniques are well suited to addressing such questions, but most OR experts do not have sufficient clinical grounding to be optimally effective. Creating a multidisciplinary capability by bringing a faculty-level operations researcher into the Department and the Perioperative Enterprise bridges this divide to the benefit of everyone. This was a self-funding initiative, as the case-count prediction project allowed the Department of Anesthesiology to increase its case load without the expected 2 full-time employee increase in the clinical faculty count. Hence, broadening an anesthesiology department’s problem-solving toolkit to include operations research techniques offers low setup costs, additional collaborative faculty productivity and development, all for high marginal returns.

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APSF Accepting Applications for the Safety Scientist Career Development Award

Deadline to Submit Applications is February 1, 2016

The Anesthesia Patient Safety Foundation (APSF) is soliciting applications for training grants to develop the next generation of patient safety scientists. APSF intends to fund one Safety Scientist Career Development Award (SSCDA) to the sponsoring institution of a highly promising new patient safety scientist with funding starting July 1, 2016.

The grant has the following key attributes:

- An award up to **\$75,000** per year for a period of 2 years (\$150,000 total) to develop the academic career of a new patient safety investigator.
- A grant mechanism will be used and funds will be awarded to a single institution. The award will be made to a sponsoring institution, not to individuals or to departments. However, should the awardee leave the funded institution, the SSCDA award could be moved to the awardee's new institution contingent on appropriate commitments from the new institution acceptable to the APSF.
- Applications that comply with this RFA will be evaluated by a special SSCDA Subcommittee chosen by the APSF Executive Committee and Scientific Evaluation Committee. Proposals will be assessed for merit, based primarily on the likelihood of the Applicant meeting the objectives outlined in the RFA with a particular emphasis on the potential of the Applicant to become a federally funded independent patient safety scientist.
- Proposals that cannot be initiated by **July 1, 2016** and be in compliance with the stipulations of this RFA will not be considered.
- Funding will be contingent on acceptable modifications to the proposal based on feedback from the APSF SSCDA Subcommittee as well as appropriate IRB and institutional approvals.
- The initial grant payment (\$75,000) will be made upon initiation of the grant. The second payment (\$75,000) will be made upon receipt of a satisfactory progress report within 12 months of the initiation of the grant.

Award Requirements

Applicant Requirements

- Holder of an accredited doctoral level degree (i.e., MD, DO, DNP, PhD, EdD, PsychD) or equivalent.

- A documented interest in and aptitude for a career as a Patient Safety Investigator. Prior authorship of peer-reviewed journal publications relevant to the field would be considered evidence toward this requirement.
- Holder of or eligible for a full-time faculty position in a Department of Anesthesia (primary appointments only) at an academic institution in North America by the start of the second year of the grant award.
- No prior receipt of federal-level peer-reviewed grant or contract funding as a PI or Co-PI with the exception of Early Stage Investigator grants (<http://goo.gl/7JWRp3>).

Mentor Requirements

- Commitment to mentor the applicant with a minimum of 5% dedicated effort.
- Prior evidence of successful mentorship of doctoral students, post-doctoral fellows or junior faculty.
- Tangible evidence of substantial experience as a patient safety (or related field) scientist including peer-reviewed extramural funding and peer-reviewed publications.
- Holder of an accredited doctoral level degree (i.e., MD, DO, DNP, PhD, EdD, PsychD).
- Full-time faculty appointment (preferably tenure track) in an accredited North American academic institution.
- At the time of the award, the mentor must have a faculty appointment in the Applicant's Department of Anesthesia but this need not be the mentor's primary faculty appointment. NOTE: Special exceptions may be made for this requirement if the mentor has an appointment in a Department of Anesthesia at an affiliated academic institution – *Contact APSF for further information in this situation.*

Departmental and Institutional Requirements

- Commitment to provide the Applicant with *at least* 40% unencumbered research and non-clinical career development time during the duration of the award.
- Commitment to provide the Mentor with *at least* 5% unencumbered time to mentor the Applicant.

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APSF Accepting Applications for the Safety Scientist Career Development Award

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- Unencumbered provision of the facilities and resources required for successful completion of the Applicant's proposed Career Development Plan and Research Project, as specified in the Application and Budget.

Application Process

Applications that fail to comply with the content and formatting requirements will be returned without review. All applications must use Times New Roman 12-point font. All application pages will be single-spaced and use 1-inch margins on all sides. For this RFA, no supplemental materials, appendices, addenda, websites, or additional documents will be accepted. Number all pages (bottom right corner) sequentially, starting with the cover page. Application requirements are enumerated further in the following section.

All applications must be submitted electronically to Stoelting@apsf.org

The application deadline is 5:00 pm EST on Friday, February 1, 2016

REQUIRED APPLICATION ELEMENTS

A. Cover Page (1 page).

The Cover Page shall include the following in this order:

1. Title of research project
2. Name of applicant (Principal Investigator) with academic degrees, office address, phone number, fax number and e-mail address
3. Names and affiliations of the applicant's mentor
4. Name and affiliations of any other investigators or consultants
5. Name, office address, and phone number of departmental chairperson
6. Sponsoring institution and name, office address, phone number and e-mail address of the responsible institutional financial officer
7. Total amount of funding requested (including institutional overhead)
8. Start and end dates of proposed project

B. Project Abstract (≤ 100 words). The Abstract should explain the proposed research study in language understandable to the average clinical anesthesiologist. The abstract will be used primarily for promotional purposes.

C. Applicant Career Plan Summary (≤ 250 words). The Career Plan Summary should explain the applicant's current situation, proposed career development activities, and future career plans in language understandable to the average clinical anesthesiologist. The Career Plan Summary must include at least the following elements:

- Applicant's preferred full name and degrees.

- The submitting academic institution (and medical center if different).
- The preferred full name, degrees, and primary affiliations of the Applicant's mentor
- The title of the research project and a summary sentence about the proposed project.
- The patient safety topic area(s) and research methods that will be the focus of the Applicant's career.
- The Applicant's long-term goals for improving perioperative patient safety.

D. Candidate Background (Do not exceed 3 pages)

1. Career Goals and Objectives (include specific plans for post-award research activities, extra-mural funding and further career development)
2. Career Development/Training Activities During Award Period
3. Training in the Responsible Conduct of Research
4. Timeline of Proposed Activities

E. Research Plan (Do not exceed 8 pages)

1. Significance (~ 1 page recommended). Why is the proposed research important? How will it advance our understanding of and improvements in patient safety? How will it advance the Applicant's long-term goals for improving patient safety? This section typically includes evidence that the Applicant has a strong fundamental understanding of the relevant patient safety knowledge and evidence.
2. Innovation (~ 1 page recommended).
3. Approach (~ 6 pages recommended). The Approach must include the following sections presented in the following order:
 - a. *Hypothesis and Specific Aims* (≤ 1 page recommended). After a brief introduction, this section must articulate the Aims of the study and the hypotheses to be tested. All hypotheses must be stated in a way that they can be tested with empiric data.
 - b. *Detailed Proposed Methods* (< 2.5 pages). This section must include a detailed description of the proposed experimental design, the numbers and nature of study participants, the procedures to be employed, the independent variables to be manipulated, the dependent variables to be measured, and any covariates that will be included. The description should include a rationale for the choice of each dependent variable.
 - c. *Statistical Plan and Power Analysis* (< 1 page). This section must include a detailed analytical plan and a sufficiently robust power analysis to convince the reviewers of a low likelihood of either Type 1 or Type 2 errors. In addition to total sample size, the plan should include a statement of the number of eligible subjects

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in the study site's patient population and the feasibility of adequate recruitment during the study period. It would be prudent to provide evidence of the initial and planned ongoing involvement of an experienced biostatistician.

d. *Interpretation of Results* (0.5 page). This section should describe how the results will address the stated hypotheses, how alternative findings will be interpreted, what the investigator will do if the findings do not confirm the original hypotheses (this is especially important in multi-part studies or aims that depend on each other), and the patient safety significance of the expected results.

e. *Study Limitations* (0.5 page). This critical section must provide a comprehensive and realistic description of the study limitations and the methods by which the investigators have (or will) mitigate these limitations.

f. *Future Directions* (<0.5 page). This brief section should describe what future studies are anticipated to flow from APSF's investment in the conduct of the proposed study and why such future studies are important to long-term improvements in patient safety. Do not duplicate content in the Significance section above.

g. *Project Management and Detailed Timeline* (< 1 page). This section must describe how the PI will organize, plan, and oversee the proposed research. When a team of scientists will be involved, the Project Management plan should describe how the team will communicate and interact. Finally, this section should describe how the team will assure that the project is completed on time and within the proposed budget. The project timeline should be presented in a Gantt chart that includes specific detailed milestones and deliverables.

F. Cited References (Do not exceed 2 pages). This section should provide evidence that the Applicant is very familiar with the most current relevant literature and will take a rigorous and scholarly approach to the proposed research. Please cite only the most relevant and important literature. References should be cited in the order in which they appear in the Research Plan and should use the format approved by the journal *Anesthesia & Analgesia*.

G. Mentor's Letter (Do not exceed 4 pages). The mentor's letter may be the most critical part of the application. The letter must be a PDF scan of a signed original on institutional stationary. The mentor's letter must contain all of the following elements:

1. Training and Research Career Development Plan
2. Mentoring Plan

3. Progress Assessment
4. Anticipated Sources of Research Project Support
5. Nature and Extent of Supervision and Mentoring
6. Anticipated Non-Award Activities
7. Plan for Transition to Independence
8. Mentor Qualifications
9. Mentoring History

H. Facilities and Resources (≤2 pages). This section describes the readily available relevant institutional facilities and resources that will support the Applicant's career development and proposed research project. Please provide evidence (i.e., specific examples) of how the institution has invested in and supported prior patient safety research projects that have led to peer-reviewed journal publications. The Review Committee considers the institutional infrastructure very important to the success of new patient safety investigators.

I. Human Subjects (≤3 pages).

1. This section should succinctly address all of the elements typically found in an institutional human subjects committee (or IRB) application.
2. **Data Management Plan.** Describe how your data will be collected, handled, stored and analyzed with respect to HIPPA compliance, participant and patient privacy, confidentiality, and data security.

IMPORTANT NOTE: By the time of application review, the Applicant must provide APSF with evidence that they have undergone and are current with their institution's approved human subjects/responsible conduct of research training.

FDA and Other Regulatory Compliance (if applicable). If medical devices are to be used on patients in the proposed study in ways that are not currently FDA-approved, the investigators must confer with their IRB regarding the need for an IDE. Similarly, if drugs are to be used in the proposed study in ways that are not currently FDA-approved, the investigators must confer with their IRB regarding the need for an IND. The relevant issues should be addressed in this section.

J. Current NIH Format Biosketches of the Applicant and of the Mentor (≤4 pages each including all Active Support).

K. Budget (no page limit).

1. **Budget for each individual year and in total.**
2. **Itemized budget justification.** The application should provide sufficient explanation and rationale for each budget item to fully justify the proposed expenditure. Please explain all changes in item-level budgeted amounts between Years 1 and 2.

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3. **Budgeting limitations.** The following items can **NOT** be paid for from funds provided by this grant:
- Salary or benefits of the Applicant that exceed 25% of the current NIH salary cap.
 - Construction, Renovations, or Furniture.
 - Capital equipment exceeding \$10,000.
 - Any item considered an Indirect Cost by any Federal granting agency.

IMPORTANT NOTE: No indirect cost will be covered by this grant.

IMPORTANT NOTE: Violations of any of this grant's financial stipulations will be grounds for immediate revocation of the award and full repayment of the total award by the sponsoring institution.

- L. Chair's Letter containing Affirmations** (Do not exceed 3 pages). This letter must be from the Chair of the sponsoring institution's Department of Anesthesiology. The letter must be a PDF scan of a signed original on institutional stationery. The letter must include the following elements:
- Application's significance to Anesthesiology;
 - Guaranteed regular (preferably tenure) track faculty appointment of the Applicant by the start of the second year of funding;

- Departmental commitment to provide to the Applicant 50% research and academic time for the two-year project duration;
- Departmental commitment to provide a minimum of 5% dedicated effort of the designated mentor;
- Resource availability and commitment;
- Internal peer review completed;
- Management of awarded funds;
 - No use of awarded funds for Investigator's salary or benefits that covers more than 25% effort at the NIH salary cap.
 - Commitment to provide specified facilities and resources
 - Return of unused funds to APSF.

NOTE: *No Appendices or supplemental material will be accepted.*

NOTE: *Applications that do not conform to all of the application requirements will not be considered.*

The SSCDA application must be submitted electronically to Stoelting@apsf.org no later than 5:00 pm (EST) on Monday, February 1, 2016.



SAVE THE DATE!

May 19 - 21, 2016

Association of University Anesthesiologists
63rd Annual Meeting

SAN FRANCISCO, CALIFORNIA

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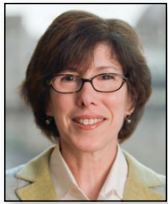
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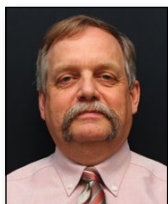


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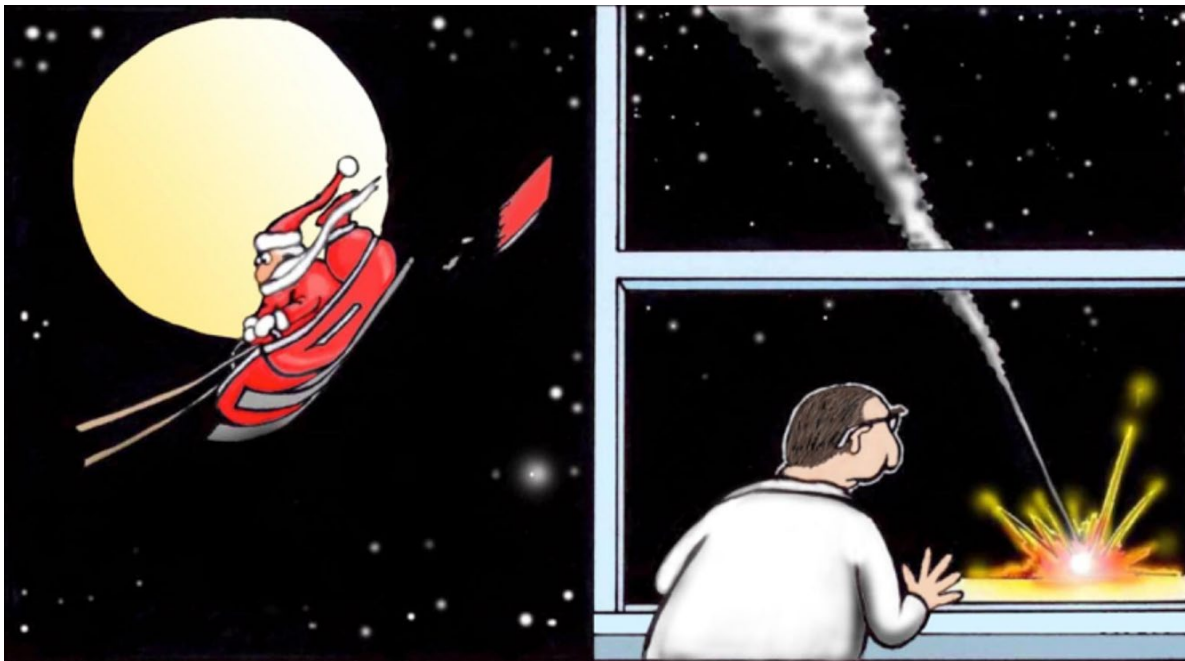
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Biggins watched incredulously as Santa's sleigh, port stabilizer torn away, flipped gracefully over and entered a terminal dive to destruction.

Oh just great, thought Biggins, the night before Christmas and there goes my last chance at getting research funding.

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