Dean's Newsletter
March 7, 2011

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Patient Care, Innovation and Research

One of the most distinguishing features of Stanford Medicine is innovation – in research, education and patient care. Innovations in clinical care not infrequently take place around the diagnosis and management of individual patients, guided by the physician's assessment of the unique clinical presentation of the patient under her or his care. Conventional wisdom suggests that as many as 80% of patients who present with a specific set of clinical symptoms or findings can be treated in a standard or protocol-driven manner. However, a number of patients with complex disorders or a unique presentation require a novel approach that may include the use of a drug or biological agent in an "off-label" fashion or a surgical or interventional procedure that is uniquely modified or designed for a specific patient. Observations from the care of a single patient can spawn new insights and promote new directions in research and patient care. At Stanford we want to foster a spirit of collaborative innovation to improve the care of an individual patient – but that innovation might also trigger a new direction and even a paradigm shift in medical care. And just as we want to foster innovations in the diagnosis and management of disease, we also want to stimulate innovations that will prevent disease or better define or refine the process of healthcare delivery.

We all recognize that whenever innovation involves patients we must be cognizant of both the ethics surrounding human subjects and the interfaces among standard patient care, innovation and research. These relationships are not linear and sometimes do not follow a logical progression. We certainly do not want to over-manage them, but we do want to be sure that our faculty and medical staff are aware of the boundaries between innovation and research and that we do all that we can to protect the patients we serve and the physicians who care for them.

As I have written in prior Newsletters, some guidance is important in defining "innovative care" and determining whether it is best undertaken under specific and limited circumstances or whether it is really "research" and thus best carried out with Institutional Review Board (IRB) approval. Although these distinctions are nuanced, the Task Force led by Drs. Frank Longo, George E. and Lucy Becker Professor in Medicine

and Chair of the Department of Neurology and Neurological Sciences, and Norm Rizk, Berthold and Belle N. Guggenhime Professor in Medicine and Senior Associate Dean, Clinical Affairs, offered these definitions of innovative care and research:

> ***Innovative patient care*** is care that departs in a significant way from standard or accepted care. The primary purpose for innovative care is to benefit the patient, not to collect data to support a hypothesis or theory. Further, it is expected that innovative care will enhance the well-being of the patient even though it is recognized that there is limited prospective evidence of safety and efficacy.

In contrast:

> ***Research around patient care*** is defined as an activity (e.g., drug, biological, surgery, procedure) that is designed to test a hypothesis with the goal of collecting data to reach an answer, result or conclusion. This almost always requires an IRB approved protocol since the goal is to seek new knowledge, to reorder existing knowledge or to apply existing knowledge to a new (clinical) situation.

To guide physicians in assessing proposed innovative treatments, the Task Force developed a process that was presented and discussed at the School of Medicine's Executive Committee on February 4th and that was presented to the Stanford Hospital & Clinics Medical Executive Committee (of the Medical Board) on March 2nd. It will be presented to the Medical Board at the Lucile Packard Children's Hospital on March 10th. The guidelines recommended by the Task Force can be summarized as follows:

- The process begins with a consultation by the treating physician with the Vice Chief of Staff at SHC or the President of the Medical Staff at LPCH [Med Staff Leader], who will consult with the relevant service chief and Senior Associate Dean for Clinical Affairs (Adult or Pediatric). ***Note that it is the responsibility of the treating physician to initiate the process.***
- If the issues that prompted the consultation are resolved, the process concludes at that point.
- If they remain, the Med Staff Leader convenes a review committee consisting of several standing members plus *ad hoc* members with expertise in the specialty of the proposed treatment. Outcomes of the review may include such recommendations as:
    - The treatment is not innovative and should be considered under an existing privileging process.
    - The physician should consider carrying out the treatment as a research project and developing a research protocol for submission to the IRB.
    - The treatment should not be undertaken at all.
    - The treatment should be undertaken as innovative care for a small number of patients. In this case the Med Staff Leader will continue to provide support and will monitor the outcomes of the treatment.

To monitor this process records will be kept of the requests that come forth including how they are triaged, and how many innovative treatments become research.

The Task Force also developed a Fact Sheet to help physicians and care providers who have questions or concerns. This will be modified over time, but here is what they put together to date:

A Brief Fact Sheet Q&A

Q. Is what I am doing research or innovative care?

A. *Federal regulations define research as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. The purpose of research is primarily to seek new knowledge, to reorder existing knowledge, or to apply existing knowledge to a new situation.*

In contrast, the primary purpose of innovative care is to benefit a patient(s), not to collect data to support a hypothesis or theory. Innovative care is a non-standard procedure or treatment that is solely attempted to enhance the wellbeing of a patient. Innovative care is sometimes called 'nonvalidated' treatment, since it has not been formally evaluated for safety or effectiveness.

Q. What kind of oversight is required for research?

A. *Procedures and therapies that are determined to be research require review by the Institutional Review Board (IRB) in the Research Compliance Office. If you are uncertain if your proposed treatment should be considered research, contact the IRB to ask or begin with a consultation with the appropriate Medical Staff Leader (Vice Chief of Staff for SHC and President of the Medical Staff for LPCH).*

Q. What kind of review and monitoring is required for innovative care?

A. *Innovative care requires engagement with the Medical Staff Organization. For innovative therapy/procedures that present a significant increase in risk over other acceptable alternatives or if the therapy/procedure is so novel or unique that it is not possible to evaluate the risk or benefit, a consultative committee of the Medical Staff Organization will be organized to review the reasonableness of the proposed treatment and the patient's situation, and to make recommendations to the Medical Staff Organization and to you.*

Q. Does every procedure that deviates from the 'Standard of Care' require oversight?

A. *Whenever you plan a treatment or procedure that is significantly different from the accepted Standards of Care, you should consult with the appropriate Medical Staff Leader (Vice Chief of Staff for SHC and President of the Medical Staff for LPCH). . The Medical Staff Organization, in consultation with the appropriate Senior Associate Dean for Clinical Affairs (Adult or Pediatric) and*

the relevant service chief, is ultimately responsible for determining what kind of monitoring, support or oversight (if any) your activity requires.

Q. What if my approved innovative treatment/procedure is successful and I want to repeat it?

A. *If you want to repeat the treatment beyond the number of times initially authorized, you should consult with the appropriate Medical Staff Leader, who will consult with the Committee that initially reviewed your treatment plan under these guidelines. The Committee will consider whether the treatment should no longer be considered "innovative." If so, the Credentialing and Privileging Committee will be asked to develop privileging criteria in consultation with the appropriate service and/or division chiefs. However, you should continue to follow these guidelines for approval of further treatments pending establishment of those privileging criteria. Alternatively, the Committee may recommend to the Credentialing and Privileging Committee that any further treatments would be best undertaken as research carried out with IRB approval. The Credentialing and Privileges Committee will make the final determination about continuing the treatments.*

Q. What if I want to publish the outcome of or describe the procedures I've done in a medical journal article?

A. *The Federal Office of Human Research Protections (OHRP) has said that "the intent to publish is an insufficient criterion for determining whether an activity involves research." Planning to publish an account of an activity does not necessarily mean that the project fits the definition of research. People seek to publish descriptions of clinical activities that are not research for a variety of reasons. In fact, Kennedy and Eaton (2007)[1] feel that "all innovating physicians should assume a duty…to educate about the impact of their changes on patient care." They go on to say that "If formal research is not conducted…the least that innovating physicians can do is to collect outcome data on their patients and use it to inform themselves and other physicians."*

This Q&A is not inclusive and both it and the guidelines will evolve over time. Importantly, we are interested in your comments and reactions. Please send them to Kathy Gillam, Senior Advisor to the Dean, at k.gillam@stanford.edu, so that they can be shared with the Task Force. The actual Innovative Care Guidelines will be available in their entirety on line in the next weeks, and if, after reviewing them, you have further reactions, please do share them with us. I want to again thank the leadership of Drs. Longo, Rizk and Gillam and the outstanding task force members for their work on this important issue. In closing, I want to underscore that our goal in developing these guidelines is to emphasize our commitment to fostering innovation while doing all we can to protect patients and those providing their care.

Healthcare Reform and New Models for the Delivery of Patient Care

[1] Eaton, Margaret L. and Donald Kennedy. Innovation in Medical Technology. Ethical Issues and Challenges. Baltimore: Johns Hopkins Press, 2007.

Much has been written about the impact of healthcare and its reform, including in past issues of this Newsletter. At Stanford we have put together a Healthcare Reform Planning Committee with the goal of developing novel approaches to healthcare delivery. The group includes leadership from the School of Medicine, Stanford Hospital & Clinics and the Lucile Packard Children's Hospital, and it receives critical input from clinical department chairs and faculty. We also benefit from the new Clinical Research Excellence Center that Dr. Arnie Milstein leads and that will develop important partnerships with other leaders in the University (especially from the Business School and the School of Engineering). The primary task of the group is to consider ways of improving clinical care delivery that is coupled with innovation, clinical excellence, and outstanding quality, safety and patient experience, and that achieves these goals with attention to cost and value.

Over the last months we have been engaged in discussions with the Stanford University Benefits Group led by Randy Livingston, Vice President for Business Affairs, and Less Schlaegel, Associate Vice President for Benefits. This planning group has faculty and staff leadership representation and has been focusing on improving the health of Stanford University employees and dependents while also being attentive to controlling and slowing the costs of healthcare – which have continued to rise at an unsustainable pace. Given this financial reality, and coupled with the expectation that various components of the 2010 Affordable Care Act (ACA) will be instituted between 2011-2018, it is imperative that we all be proactive in planning for the future. A presentation of the impact of the ACA on faculty and staff benefits was given to the University Academic Senate on February 17th by Randy Livingston and Arnie Milstein, and their comments are available at the website for the Faculty Academic Senate (see: http://facultysenate.stanford.edu/).

In his presentation to the Academic Senate as well as to the Council of Clinical Chairs on February 25th, Dr. Milstein highlighted some of the unique ways in which Stanford faculty, in conjunction with SHC and LPCH, could develop a distinctive model of care based on its special expertise and on the recognition that in most populations approximately 10% of the patients account for 60% or more of the healthcare costs. These are often medically unstable chronic illness patients. Before joining Stanford, Dr. Milstein developed a unique model to care for such patients that has been described as an "Ambulatory ICU" – not because it comprises intensive care *per se* but rather because it uses an efficient care delivery system that, like an inpatient ICU, is available to high-risk patients 24/7. This system is based on a close relationship with the patient's main care provider and selected specialists. It has been successfully employed in several ambulatory settings, including at least one academic center. A readable description of this model appears in the January 17th issue of ***The New Yorker*** by Dr. Atul Gawande and is entitled *"The Super-Utilizers"* (see: http://www.newyorker.com/online/blogs/newsdesk/2011/01/atul-gawande-super-utilizers.html).

Dr. Milstein proposes that we establish an A-ICU at Stanford that will offer 24/7 care to Stanford employees who are likely to benefit from this model. These individuals

would be cared for by defined clinicians who would focus on keeping them well and out of the hospital by coordinating care and using "design discipline" approaches to affect change in patient behavior.. Dr. Milstein and our team are in the midst of identifying the care providers, and the Stanford benefits group will be responsible for identifying the patients with the goal that this will be available in 2012. While this will be a data driven pilot experiment, we have every intent of seeking ways to extend the model to other regional employers.

Clearly this is just one example of how we will respond to the changing landscape of healthcare reform. There will be countless others – but in the end we will seek to the best of our ability to define approaches that capitalize on what makes Stanford Medicine unique and that focus on how we can shape the future rather than just react to it.

Changes Coming in the MCAT Exam

The Medical College Admissions Test (MCAT) is well known to undergraduates contemplating application to medical school and is actively used by nearly every medical school admission committees as one of the tools to guide admission. Interestingly, the format of the MCAT in use today was introduced in 1991 – twenty years ago. While this test measures knowledge across a number of domains, it has a number of limitations and may not be well suited to assessing all the qualities needed to be an excellent physician.

In the January 25, 2010 issue of this Newsletter I gave a preview of the work underway in revising the MCAT under the auspices of the MR5 Committee of the AAMC. The MR5 is a 22-member advisory committee that was appointed in 2009. Dr. Steven Gabbe, Senior Vice President for Health Sciences at The Ohio State University and Chair of the Committee, provided an update on its work at the February 24th AAMC Board of Directors meeting, which I attended. The committee will preview its recommendations at the 2011 Annual Meeting, after which they will make a final recommendation to the AAMC. At the same time, the MR5 Committee has been quite transparent in sharing its thinking and planning and in soliciting comment from medical schools and the broader community.

The major goals of the MR5 are to develop a new MCAT that identifies students who are academically qualified to succeed in medical school and beyond. There is also a strong desire to better identify students who have the personal characteristics to make them excellent professionals. I certainly concur that these are important objectives, but I pointed out in the discussion that a broader cultural transformation is also needed. In fact, most incoming medical students have the altruistic and humanistic values that make for excellent physicians, but these important attributes get blunted during medical school, residency training and beyond. Thus, if we want to develop highly knowledgeable physicians who are also humanistic and professional, considerable work needs to be done to improve these values among our residents, fellows, faculty and community colleagues.

While the MR5 work is clearly "in progress," one of the intriguing aspects of Dr. Gabbe's presentation was the possibility that in the next MCAT exam equal weight will be given to knowledge in the biosciences, physical sciences, critical analysis and

reasoning and the behavioral and social sciences. The critical reasoning section could have questions, problems and scenarios similar to the ones being used this year in our "Multiple-Mini Interview" process for medical student admissions, which also test reasoning in different domains. (see http://med.stanford.edu/ism/2011/january/interview-0110.html).

There will be more to share in November after the AAMC meeting. At this point the earliest date the new MCAT could be in use is 2014.

US Economics and the NIH

While the actual budget numbers for FY11 and FY12 for science and technology, including biomedical research, are still uncertain, there is considerable and understandable concern and anxiety about how they will play out. While the President's budget proposal for FY11 called for a 3.2% increase in the NIH budget (to $32.007 billion), this is most unlikely, especially since the FY House Continuing Resolution calls for a 5.2% decrease (to $29.376 billion). The potential impact of such a decrease would be even greater than it would otherwise be since it would be implemented halfway through the year, prior to the end of September of 2011. The showdown underway in the Congress leaves the entire discretionary budget (including NIH, NSF and other agencies) at a very concerning point. And while the President's budget for NIH for FY12 (which begins October 1, 2011) proposes the NIH budget at $31.7 billion, all bets are off since the budgetary battles are likely to be fierce. Obviously our various advocacy and professional organizations continue to emphasize the positive impact of investments in science, innovation and technology. But the focus on the national debt and the fierce divides between the Republicans and Democrats pose major threats and challenges.

I have noted in prior Newsletters that our faculty have competed well for NIH and other grants and that we have been judicious in our investments, but there is no denying that the years ahead will be extremely challenging and will require even more judicious financial management as well as efforts to find new or additional sources to support our mission in research. I remain confident that we will succeed given the excellence of our faculty and students – but it will be a time of serious challenge.

Graduate Student Admissions and Stanford Diversity

The last days have brought hundreds of potential PhD students applying to the Bioscience Graduate Programs to campus for interviews, meetings and tours. I have heard from a number of faculty how pleased they are with this year's applicants. I was also pleased to note that this year the Biodiversity Event went "mainstream" and was included as part of a luncheon event for graduate students. The message was clear: diversity is part of our mission and culture and not a separate event or grouping. Special thanks for hosting this event go to Dr. Melanie Bocanegra, our newly appointed Assistant Dean for Graduate Education and Director of the Biosciences Diversity Program. The luncheon event featured a wonderful presentation by Dr. Carlos Bustamante, Professor of Genetics, who joined Stanford a year ago and who offered his perspective on why it is such an extraordinary institution. This was complemented by an exciting presentation from Antonia Dominguez, President of BioAIMS and PhD student in Genetics. Thanks

also to the various groups who participated in the Diversity Mini-Resource Fair. It was a day when Stanford Biosciences shined brightly.

A Perspective from the UK on Postdoctoral Scholars

I suspect that the "World View" Perspective by Dr. Jennifer Rohn, a cell biologist at University College London in the March 3rd issue of *Nature* will engender a range of views and reactions. Entitled "Give Postdocs a Career, Not Empty Promises" (see http://www.nature.com/news/2011/110302/full/471007a.html), Dr. Rohn addresses concerns that are global and that relate specifically to postdocs in the biosciences. While her basic thesis is that a viable career pathway for postdocs or bioscience graduates in research staff positions should be developed, she also touches on the important issue of the numbers of individuals being trained for too few jobs over too long a period of time. A number of these themes were touched on in our July 17th Think Tank on Postdocs and in our January Leadership Retreat. While the proposals by Rohn are important, they are not new and will need to be considered in the broader context. But Dr. Rohn's perspective is certainly worth reviewing.

Bike Safety: Yes and No

It was nice to learn about the student sponsored "Helmet Hookup" event that was held on February 25th, in which students promoted the use of bike helmets by fellow students. Elise Marie Geithner, ASSU Chair of Campus Organizing, is leading this effort. And we always appreciate the work of Ariadne Scott and her office on Bike safety. I am also pleased that a number of our medical students, led by Anthony Kaveh (SMS I) are eager to take on the issue of bicycle safety on campus. These are all good things.

At the same time, it is concerning to see students dressed in blue scrubs or white coats riding bikes without helmets or lights. And I must admit that every night when I drive the short distance to our campus home I encounter multiple student bikers whom I put in the "near miss" category. By this I mean students who ride recklessly, never stop at traffic signs, cross in front of moving vehicles and often have neither helmets nor lights. The lack of lights remains one of the biggest safety hazards.

So while I am encouraged by student-to-student engagement, bike safety on campus remains an ongoing and I think still major health and safety problem. I realize I have written about this frequently and also tried various advocacy approaches, none really having the kind of impact one hopes for. But it is still worth trying!

Upcoming Event

Mind Bugs: The Ordinary Origins of Bias, Dr. Brian Nosek

Thursday, March 17, 2011
4-6 pm

Munzer Auditorium, Beckman

Dr. Brian Nosek is a renowned social psychologist and scholar of unconscious bias, i.e. thoughts and feelings that are outside of a person's conscious awareness. In this talk, Dr. Nosek will explain what research has to say about where unconscious biases come from and how to measure them. He will also discuss how such biases can affect our perceptions, thinking, and behavior. His talk will explore the implications of unconscious bias on real-world behaviors such as hiring and evaluation decisions.

Please register for this event at:
https://www.onlineregistrationcenter.com/register.asp?m=275&c=6

Awards and Honors

- A special thank you to the SMSA (Stanford Medical Student Association) and the Gardner Mentorship Fund for hosting a reception for faculty who have served as mentors for students. This is all the more special since students initiated it, and I am sure it was very meaningful to faculty who work hard to guide and mentor students.

- The recipients of the 2010 School of Medicine SPIRIT Award and the new Inspiring Change Award were announced this week and will be formally celebrated (along with our valued staff) at the Recognition Celebration on Friday May 20th in the Li Ka Shing Center for Learning and Knowledge from 4-7 pm. This years SPIRIT recipients include:
    - ***Chris Shay***, Project Manager/Planner for the Office of Facilities Planning and Management and
    - ***Vuong Quoc Vu***, Human Health and Disease Coordinator for the Department of Pathology

  In addition, the winners of Inspiring Change Leadership Awards include
    - ***Sonia Barragan***, Associate Director, Research Management Group and
    - ***Nancy Lonhart***, Associate Director and Administrative Manager for the Department of Medicine and PCOR

  Congratulations to each – they are incredible individuals.

- ***Dr. David Spiegel***, The Jack, Samuel and Lulu Willson Professor in Medicine, has been awarded the 2011 Arthur M. Sutherland Award from the International Psycho-Oncology Society (IPOS). This award "honors an IPOS or psycho-oncology community member with a lifetime achievement in the field of psycho-oncology. This is a late career award and recognizes sustained and distinguished output in psycho-oncology over their whole career. This is the Society′s most important award and reflects the international standing of the recipient." Congratulations to Dr. Spiegel.

- ***Dr. Abraham Verghese***, Senior Associate Chair for the Theory and Practice of Medicine, was honored at a special event hosted by Dr. Linda Boxer, Interim

Chair of the Department of Medicine, for a unique honor. In addition to his many other talents, Dr. Verghese is a world-renowned writer of non-fiction and fiction. The most recent event celebrated the fact that his novel, *Cutting for Stone*, has been on the New York Times Best Seller List for more than a year. While Stanford faculty boast many honors, few will achieve this one. And while I don't want to convey this as marketing, if you haven't read *Cutting for Stone* you should. It is fantastic!

- ***Dr. George Yang,*** Associate Professor of Surgery**,** has been elected President of the Society of University Surgeons. He will assume office in Feb 2012 and deliver his Presidential Address at the Society meeting in Feb 2013. The SUS presidency is a singular honor; please join me in congratulating Dr. Yang.

- ***Stephanie Weber,*** PhD candidate in Biochemistry, is one of 12 students who has been chosen to receive the 2011 Harold M. Weintraub Graduate Student Award sponsored by the Basic Sciences Division of Fred Hutchinson Cancer Research Center. Nominations were solicited internationally; the winners were selected on the basis of the quality, originality and significance of their work. The recipients, all advanced students at or near the completion of their studies in the biological sciences, will participate in a scientific symposium May 6 at the Hutchinson Center consisting of scientific presentations by the awardees. Congratulations.

- ***The Glenn Foundation for Medical Research*** has awarded a $5 million grant to Stanford University to launch a new center on the biology of aging, focusing on the role of stem cells in the aging process. ***Thomas Rando, MD, PhD***, Professor of Neurology and Neurological Sciences, will serve as the director of the new laboratories**.** ***Steven Artandi, MD, PhD***, Associate Professor of Hematology, and ***Anne Brunet, PhD***, Associate Professor of Genetics, will serve as associate directors.

Appointments and Promotions

Arlina Ahluwalia has been promoted to Clinical Associate Professor (Affiliated) of Medicine, effective 1/1/2011.

Ingrid Bossen has been reappointed as Clinical Assistant Professor (Affiliated) of Obstetrics and Gynecology, effective 9/1/2010.

K.S. (Casey) Crump has been reappointed as Clinical Assistant Professor of Medicine, effective 10/1/2010.

Christopher Gonzalez has been reappointed as Clinical Assistant Professor of Pathology, effective 1/1/2011.

Kevin Graber had been reappointed as Clinical Assistant Professor of Neurology & Neurological Sciences, effective 4/1/2011.

Stephen Harris has been promoted to Clinical Professor (Affiliated) of Pediatrics, effective 3/1/2011.

Paul Helgerson has been reappointed as Clinical Assistant Professor (Affiliated) of Medicine, effective 11/1/2010.

Gary Hsin has been promoted to Clinical Assistant Professor (Affiliated) of Medicine, effective 1/1/2011.

Annie Hsu has been promoted to Clinical Assistant Professor of Radiation Oncology, effective 2/1/2011.

Robert T. Isom has been appointed to Clinical Associate Professor of Medicine, effective 3/1/2011.

Amul Jobalia has been reappointed as Clinical Assistant Professor (Affiliated) of Medicine, effective 2/1/2009.

Michael S. Krathen has been appointed to Clinical Assistant Professor of Dermatology, effective 8/1/2011.

John Kugler has been promoted to Clinical Assistant Professor of Medicine, effective 1/15/2011.

Wilma Lee has been reappointed as Clinical Assistant Professor (Affiliated) of Obstetrics and Gynecology, effective 9/1/2010.

Jin (Billy) Li has been appointed to Assistant Professor of Genetics nter, effective 3/01/11.

June Lugovoy has been reappointed as Clinical Associate Professor (Affiliated) of Medicine, effective 9/1/2009.

Jana Mannan has been reappointed as Clinical Assistant Professor (Affiliated) of Obstetrics and Gynecology, effective 9/1/2010.

Fernández-Viña, Marcelo has been appointed to Professor of Pathology at the Stanford University Medical Center, effective 2/01/10.

Sean McGhee has been appointed to Clinical Assistant Professor of Pediatrics, effective 3/1/2011.

Madhur Rani Saxena has been reappointed as Clinical Assistant Professor (Affiliated) of Medicine, effective 3/1/2011.

Nigam Shah has been appointed to Assistant Professor of Medicine, effective 3/01/10.

Vanila M. Singh has been promoted to Clinical Associate Professor of Anesthesia, effective 1/1/2011.

Annie Talbot has been promoted to Clinical Assistant Professor of Medicine, effective 2/16/2011.

Wendy Bick-Ling Wong has been promoted to Clinical Associate Professor of Pediatrics, effective 2/1/2011.