State of the Center

It’s been an interesting year for bioethics. A controversy over the SUPPORT study, and the need for new guidance for research within the standard of care, has been one of the most controversial and divisive topics within bioethics in decades. Here at the Stanford Center for Biomedical Ethics, we’ve been right in the mix of the controversy. (This is partly an outgrowth of interest in previous research we’ve done, which we have talked about in this newsletter, on ethical issues in point of care randomization in comparative effectiveness research more generally.)

As a reminder, the SUPPORT study was a study to try and figure out the best approach to how to provide the best target oxygen levels and treatment for severely premature at-risk newborn infants. The Office of Human Research Protection (OHRP) had an initial finding that there was inadequate informed consent in this case.

The first bioethics opposition to the OHRP decision was published on the bioethics.net blog, run by the center and written by David Magnus. It led to the first publication on the topic by David Magnus and Art Caplan in the New England Journal of Medicine. Several other bioethicists were quickly involved in the debate, as well, including John Lantos writing in the Hastings Center Forum, and Ruth Faden writing on the Berman Bioethics Institute’s blog. David Magnus and Ben Wilfond together organized a very large group of bioethicists and pediatricians to publish a letter criticizing OHRP for its finding and defending the study and the practices of the IRBs at the institutions where this took place.

The OHRP in fact, did suspend its action against Alabama Birmingham, however, another group of bioethicists, including a number of very prominent figures in the field, published a letter criticizing the study and defending the actions of the OHRP. This has left a deeply divided bioethics community regarding how to think about research within the standard of care, leading to a hearing in which very different perspectives on this topic were included. This is likely to be one of the most important and largest issues in bioethics in a long time—about how we should understand risks, how we should think about consent, and what the standards should be for comparative effectiveness research. And in a way, it’s very exciting.

In addition to all those articles, The American Journal of Bioethics, which has its editorial offices at the Stanford Center for Biomedical Ethics, is going to have a special issue coming out that includes both perspectives and both sides in this debate. We look forward to continued debate and insights into developing how to think about this very complicated issue of research within the standard of care.
State of the Center (continued)

RESEARCH
To provide guidance regarding the ongoing SUPPORT debate, we were awarded an administrative supplement for a collaborative project with investigators at the University of Washington, and Seattle Children’s Hospital, to carry out empirical studies of patient, parent, surrogate and IRB attitudes about comparative effectiveness research, or research within the standard of care.

We had a great year at the center publishing in high impact factor journals, including New England Journal of Medicine, Nature, and Science. Katrina Karkazis has a recent new grant from NSF to work on a project related to intersex identity and sports, Science and Sex Segregation: Contemporary Negotiations Over Difference and Fairness.

CHANGES
The Center has bid goodbye to several of our post-docs. Nanibaa’ Garrison has just started her new position at Vanderbilt University. Megan Alyse has started at Duke University, and Lauren Milner has begun her AAAS fellowship, working at NIH in the Office of Science Policy. We are proud of all of our post-docs and very excited to welcome Stephanie Alessi, who joins Marsha Michie, our continuing post-doc at the center. We look forward to seeing them match the very high standards set by previous post-docs.

EDUCATION
Our courses in The Responsible Conduct of Research continue to have record highs in their evaluations, and we have had new people become involved in the teaching of that course. We also are excited about the really interesting publications that our medical students have produced, working with faculty at the center.

We welcome a new program coordinator, Jacqueline Genovese, to the Program in Arts, Humanities and Medicine. Our BEMH scholarly concentration continues to thrive. Our required courses in ethics and medical humanities now include nearly 15% of students taking these courses as electives, which is impressive.

Jessi Bardill, one of our teaching fellows for the bioethics course that is part of the new Thinking Matters freshman course at Stanford, received a tenure track job at East Carolina University at Greenville, North Carolina. Nate Olsen and Nicole Martinez continue as fellows in the program, and we welcome two new fellows, Karola Kreitmair and Ruth Tennen.

CLINICAL ETHICS
Clinical ethics consultation continues to grow in the number of consults. We also continue to revise and develop our training program to develop the clinical ethics competency among our post-doctoral fellows.

It is with great sadness that we have to report that our wonderful colleague and friend, Dr. Clarence Braddock, Director of Clinical Ethics, is leaving Stanford to go to UCLA to become the Vice Dean for Education in the David Geffen School of Medicine. Clarence broke the news to David Magnus fairly early, so he wouldn’t have heard it from any other sources, and he made sure that David was liquored up before he gave him the bad news! Even that wasn’t enough to soften the blow. Clarence will be very badly missed and we are currently working on trying to figure out how we are going to go about replacing all the amazing work he has done for the center and for the hospitals around issues related to clinical ethics and improving patient care.

23rd Annual Jonathan J. King Lectureship

Balancing Hope and Reality: How could physicians do better?

Anthony Back, MD
Clinical Research Division, Affiliate Member
Fred Hutchison Cancer Research Center
Professor, Oncology Division and Adjunct Associate Professor
Medical History and Ethics, University of Washington School of Medicine

Tuesday, October 8, 2013, 5:30 pm
Auditorium, 1st Floor
Lucile Packard Children’s Hospital

The Jonathan J. King Lecture is free and open to the public. No reservations are necessary. LPCH Hospital is located at 725 Welch Road, Palo Alto. A map and parking information can be found at http://bioethics.stanford.edu.
Tell us about your plans for the new center on truth.
This new center addresses all the issues that affect the credibility of what we read in the medical literature, and also those things where the data is reported and analyzed perfectly fine, but the interpretation is likely to be wrong. This encompasses many areas, including both research fraud, falsification, and non-reproducibility, but also many practices that people do routinely, not things that actually involve distortion in a formal way. It also involves different forms of publication and reporting bias.

It’s not really a field right now, even though there are many people working on pieces of this problem. We will be working hopefully in collaboration with many Stanford faculty, as well as people from outside, to bring together all the threads of this field, so it’s seen as a legitimate area for study. The techniques we will be using generally involve looking at empirical results of research, patterns of large bodies of research. The tools we use are those of meta-research, that is, research on research. That will be part of the name of the center, although we haven’t finalized the name. The main plan is to have a Stanford based center that brings together all the people working nationally and internationally on issues related to the credibility and reliability of what we read in the medical literature.

What does the timeline look like?
We’re hoping to get started in the next month or so. The agreement might have been signed today. We’re poised to go, we have the funding, but we have to do all the things that you do before you start up a center. We’ll probably announce it formally in roughly a month. David Magnus is going to be on our internal group, and we hope to involve as many people as are interested. It certainly has ethical dimensions, in that what we do within trials, within interventional studies, depends very much on the ethics of what we know at any given point, what we should be allowed to do to people, and what we call experimental versus non-experimental work. It has ethical implications, in terms of issues related to anything that actively impairs the credibility of the medical literature breaks the implicit contract we have with patients that any sacrifice or burden they endure as part of the medical research process will be for the sake of producing valid or generalizable knowledge. So if for any reason that is not the case, there is an ethical contract that has been broken with the patient. This has manifest epistemological dimensions, it all has practice dimensions, and finally, ethical dimensions.

Is bringing all these pieces together something that has been done in other places, or is this a first?
It’s a first to bring all the pieces together. There are many places that work on pieces of this problem—they work on open science, they work on reporting standards, they work on evidence-based medicine, they work on statistical methodology, they work on all sorts of different aspects, but there is no place that we know of that pulls them all together. It’s not really recognized yet as a field. It’s more a set of activities, and we’re hoping to be the beginning of something that changes that.

What do you see as the major ethical problems or challenges facing clinical research?
Clinical research is a very broad topic. I think that a very big challenge is how to balance the need to learn from every patient, while not imposing ethical barriers to that learning. By that I mean increasingly we are moving towards systems that we call learning healthcare systems, where every patient that walks into a care setting is a patient that potentially we can learn from, so that the next patient can benefit. That patient can benefit from the patient who just walked in before. Everybody is benefitting from everybody.
The potential ethical problem here is that in order to have that level of study, we can’t be having to present in front of every patient a long consent process, particularly when many of the things we are studying are aspects of usual care. That is, if they are being randomized, what they might be randomized to in the setting is the same thing they could have gotten just by walking into another doctor’s office. That’s a random process. If we do that systematically, it requires consent. There is a lot of discussion right now to determine what the areas are where we can minimize the consent process and still protect the interests of patients, and allow them to all be participants in this learning healthcare system. That’s a very tricky area, because we know that in many settings where the thresholds for consent are lowered, somebody somewhere takes advantage of that, or even without mal-intent, things will happen so that people will claim, or legitimately feel afterwards, that they’ve been taken advantage of in some ways by the medical establishment. They’ve been experimented on, like they were guinea pigs. That language is very dangerous to the societal consensus and support for clinical research. How to thread that needle going forward is very challenging.

More and more, we are going to start using the tools of mass data gathering to collect outcomes on people, and recruit people in the same way that information is currently being used to market products to them. People willingly give up their information in those contexts, even though sometimes if they are besieged by targeted marketing, they don’t like it. The point is, can we use the same tools to both gather information about people and to gather information about outcomes without bothering them constantly for consent? The interesting aspect is that when we don’t practice medicine in a manner from which we can learn, we don’t have to garner consent, even though some would say that’s a riskier situation than the context from which we are learning from every patient. The challenges of the new information age, and our desire to get more information than we currently do from all patients or as many patients as possible, is going to be a big ethical conundrum of how to operationalize that going forward.

Is this being done elsewhere?
It’s being done mainly elsewhere right now. It’s being done in many settings, mainly closed healthcare systems, and a few academic centers in limited ways, but we are just at the start of this revolution in how research is done and healthcare is delivered.

Another big challenge is how to take advantage of the information that we have from genetics without overselling it and without making people feel as though their fate is in their genes, and inducing them to pay more than they should for information that, in fact, can’t really affect their future care. I’m on the other side of the wave that currently says that the more we can learn about our genes, the better. I think, depending on what information you are talking about, there is at least as much potential for harm as there is for good, and we have to do a lot of work before we peddle the information, to figure out where the opportunities for reduced suffering are, and where the burden of information is which either produces false alarm, false security, or information that you simply cannot act on. It’s non-actionable information. The genetic information revolution is way ahead of genetic medicine; that is, medicine therapies that actually are driven by information we would get from the genome.

I understand that you are also an opera singer, and were previously very involved in music programs at Johns Hopkins. What would you like to see take place to better integrate music into SCBE’s Arts, Humanities and Medicine Program?
I’m just learning about what the various opportunities are for students, faculty, and staff who are interested in music in the School of Medicine specifically. What is pretty clear right now is that there’s nothing really formally organized at the same level as the writing programs, even though there are many offerings within the institution for performing musicians, usually moderately advanced ones (but not totally), and there are choruses as well, for non-trained singers. I’m currently starting to talk to a lot of people to try to figure out what we can do to bring together people through music, as well as the other things that we do. I’m not just talking about medical students, but the whole medical community here in the School of Medicine. It’s a great thing that breaks down barriers and helps exercise the part of people’s brains they need to exercise to be the best doctors or caregivers they can be.

Tell me about your background as an opera singer.
I would say I’m unusual as a singing doctor, but if you measure me against the Pavarottis and Domingos of the world, I don’t have an alternative career just waiting for me! I started singing a little bit in college. I was actually a clarinetist. If you asked me through my college years and my twenties what my musical outlet was, I would have said playing clarinet. I’d always sung in groups, and usually the
reason I sang in the groups was because most orchestras only take two clarinetists, and I was always the third best, or the fourth best! In college, my roommate was the first best, so I didn’t get as many performing opportunities as a clarinetist as I did being a singer. I was involved in some choruses, then in graduate school I got involved with doing quite a lot of political and social satire, writing songs and performing them, and also a little bit of Gilbert and Sullivan. But I really loved opera, that’s what my real love was, so I wanted to see if I could “do” opera. Most singers, I learned once I got into the business, really start their development in their teens, no later than their twenties. Turns out I was very lucky to have a voice type that peaks in the forties, maybe even fifties, which is sort of a dramatic baritone, or lyric baritone. Towards the end of graduate school, which was after my residency, I started taking lessons. At the time I was at Johns Hopkins and the Peabody Conservatory, which is a major music conservatory, is at Johns Hopkins. Actually, when I first got involved in an opera production there, I just walked into an audition. I had no clue what I was walking into.

Maybe that’s a good thing. You might not have done it otherwise!

Right! I probably wouldn’t. I was told to come before the auditions started, and I walked in and was completely shocked to see that I had arrived smack in the middle! I thought I was coming fifteen minutes early. I watched one extremely polished singer after another audition, and I couldn’t believe it. I did audition and I was cast in my first opera, which was *The Marriage of Figaro*, which has to be one of the great operas to start with. That was in the conservatory.

How do you balance it?

The main way you balance it is, first of all, rehearsals tend to be at night, and performances seem to be at night, so that’s very lucky. I had no spare time and this was challenging, but I found that it was just an astonishing relief to walk out of a professional life where you have to sort of bottle up the right brain. Science is sort of left brain and this was all the things that you have to bottle up. Also, just in interpersonal relations you have to be very rigid, and then all of a sudden you go on the opera stage and literally, it has to pour out. You have to be totally out there and emotionally exposed.

And you have to make the audience cry!

I found it to be exhilarating to go from a somewhat restrained professional existence, which we all have, where you don’t reveal yourself in a personal way, to a night activity where it’s totally laid bare. You deal with a different kind of person as an artist, where again they are totally laying bare who they are to communicate with other people. But also, I love the music, I just simply love the music, and the physical experience of producing the music!

I had started taking lessons a bit before that and I bounced around between teachers, before I had one particular teacher, who just literally overnight transformed how I sang. I was just very lucky to have an instrument. Normal people would call it a voice. The raw instrument I was working with had characteristics that made it very appropriate for opera, and when you are a man, there is not as much competition as when you are a woman. So I was very lucky to be a male singer, and all of a sudden a lot of performing opportunities opened up and I sang small roles with the Baltimore Opera, which was a big regional opera company at the time, and also major roles with small local companies, which I did a lot of, as well as a lot of concertizing, both opera and other stuff. I did that for about ten to fifteen years, and then I had kids and had to slow down a little bit because it’s hard to take off two or three weeks to do opera productions, but also my professional life got rather busy.

It was interesting at the beginning; I wanted to perform on bigger and bigger stages. For someone like me, who wasn’t a superstar, the bigger the stage and the more anonymous it was, the less satisfying. I went on a trajectory in my career from the beginning, where I was mainly performing for
smaller groups and mainly people I knew, to much larger groups of people I didn’t know, and then huge groups, with people I really didn’t know, who didn’t know who I was. I found that totally unsatisfying, and then I went the other way. I decided that the best way if you are lucky enough to do art like this, is to be able to give pleasure to your own community, and it makes them feel better to think that there are artists among them. Now I’m very happy just performing locally and regionally. I left twenty-five years of a music community behind in Baltimore, so I have to see what I can re-establish here.

Do you perform around here?
I’ve done two performances. I was lucky enough to be a soloist in the Bach B Minor Mass performance with the Stanford Singers in Memorial Church, and I was also brought in at the last moment for an ailing soloist to do the Beethoven Mass in C in Bing with the Symphonic Chorus. We’ll see how we go forward.

What about Medicine and the Muse?
First of all, I’ve only been here two years, so there’ve only been two Medicine and the Muse events. Last year I wasn’t here that day, the previous year I’d never seen it before, so I didn’t know anything about it, so maybe I’ll be involved this year. Hopefully, I’ll be able to organize some sort of more musical presence within the School of Medicine, which I’m hoping to do. It can use Medicine and the Muse as a more formal outlet, rather than just be an ad hoc way for musicians to perform who don’t get to perform any other time.

Regarding what you said about accessing both sides of yourself, besides being able to get your emotions out, do you think it benefited your medical career in other ways?
This is a complicated question. It’s part of being a whole person, to be able to express both sides. To the extent that you are in touch with both, if you are a better person, then you are a better doctor. You care for people more. You’re more in tune to that, in some ways. The other part is if it’s institutionalized, which again I would like to see done more here, it sends a message that the institution values that part of you, and wants to see that come out. That you don’t have to maintain this mask of detached, somewhat technocratic, professional. In that sense, it isn’t so much the actual artistic creation that has the effect, but the message you get from your school or employer that they value the expression of this side too, and that, I think, in subtle ways changes the kind of person you are in the workplace, including caring for patients. If you are known as someone who has the capacity to affect people emotionally, those are empathic skills. If you are known for it and appreciated for it, you feel much freer to exercise that in a care setting, particularly for young trainees who are trying to establish their professional and personal identity. For older folks, it’s sort of cast in stone, but for younger ones, I think that is quite important.

Right now, I think the school does this extraordinarily effectively with the writing program. I think there are probably many students out there who are part of the writing program, who if that didn’t exist, would all be bottled up and would not have a chance to express the kinds of things they express through writing. I think there is another bunch of students who would use music. Others would use dance, or other modes of expression. Certainly music is a big chunk of how we communicate directly. What’s interesting about music is that it completely bypasses the analytic side and goes directly to the heart, in a way that sometimes even writing does not. It has unique power in making health professionals understand how non-verbal communication is essential to all healing relationships.

We shouldn’t neglect music. We shouldn’t just see it as a hobby that people can find elsewhere. That’s the other main reason that I want to establish something in the School of Medicine, because it’s not just that the students can find some orchestra or something to participate in. That does not send the message that we think it’s important that you exercise this part of your personality. It’s the messaging from the top that it is as important on some level for you to exercise the empathic muscles, as learning about neuroanatomy and physiology and learning about MRIs. Those are all part of being a terrific doctor, but people need to feel cared for, as well. The arts are one way you continue to stay in touch with that part of yourself and others.
At William and Mary, Jackie and her team earned more than 14 local and national awards, including a CASE Circle of Excellence Silver Medal. Jackie earned a bachelor’s degree in history from the College of William and Mary, where she was a member of the Phi Alpha Theta History Honor Society.

Karola Kreitmair – Teaching Fellow
Karola Kreitmair is a new teaching fellow for the bioethics course that is part of the Thinking Matters freshman course at Stanford. Hailing from the Bavarian Alps, Karola received her PhD in philosophy at Stanford after an MSc in linguistics at Edinburgh and a BA in philosophy at Brown. Her PhD dissertation focuses on the attunement of animals (including humans) to their environments and argues against the symbolic systems approach to mental representation. In addition to philosophy of mind her research interests include cognitive science and Nietzsche. When not philosophizing, Karola likes to write, direct, produce, and perform theater.

Lauren Milner, former postdoctoral fellow at CIRGE since 2010, has moved to Washington, DC, to work in the National Institutes of Health Office of Director (OD), Office of Science Policy (OSP), and the Office of Clinical Research and Bioethics Policy as an AAAS Science and Technology Policy Fellow.

Ruth Tennen – Teaching Fellow
Ruth Tennen received her bachelor’s degree in molecular biology from Princeton University and her PhD in cancer biology from Stanford University. Her graduate work examined the intersection between epigenetics and disease: how human cells squeeze two meters of DNA into their nuclei while keeping that DNA accessible and dynamic, and how DNA packaging goes awry during cancer and aging. As
a graduate student, Ruth shared her love of science by teaching hands-on classes to students at local schools, hospitals, and museums, and by blogging on the San Jose Tech Museum’s website. After completing her PhD, Ruth moved to Washington, DC, to serve as an AAAS Science and Technology Policy Fellow. Working in the Bureau of African Affairs at the U.S. Department of State, she collaborated with colleagues in DC and at US Embassies abroad to promote scientific capacity building, science education, and entrepreneurship in sub-Saharan Africa. She managed the Apps4Africa program, which challenges young African innovators to develop mobile apps that tackle problems in their communities. She also traveled to South Africa and Ghana, where she delivered lectures and workshops designed to spark the scientific excitement of young learners. Ruth is currently a postdoctoral lecturer in the Thinking Matters program, teaching “The Science of MythBusters during fall quarter.

Recent Publications

Colleen Berryessa

Emily Borgelt

Nanibaa’ Garrison

Hank Greely

Katrina Karkazis
Recent Publications (continued)

Sandra Lee

Emily Yang Liu

David Magnus

Marsha Michie

Kelly Ormond

Audrey Shafer
Recent Publications (continued)

Larry Zaroff

SCBE Upcoming Events

**October 1, November 5, December 3, 2013**
7:00 – 9:30 pm
First Tuesday Evening Writing Workshop Series
Facilitated by Elyce Melmon
SCBE Conference Room (62)
1215 Welch Road, Modular A

**January 23, 2014, 5:30 – 7:00 pm**
Moderator: Dr. Richard Shaw
Location: TBD

**March 13, 2014, 12:00 – 1:00 pm**
Grand Rounds with Dr. Paulus Hochgatterer
Location: TBD

**February 1, 2014, 8:45 am – 4:30 pm**
Saturday All Day Writing Workshop
Facilitated by Sharon Bray
Home of Dr. Audrey Shafer

**March 13, 2014, 5:30 – 7:00 pm**
Stanford Med Writers Forum/ Pegasus Physician Readings
Guest Speaker: Dr. Paulus Hochgatterer
Location: TBD

**April 26, 2014, 8:45 am – 4:30 pm**
Saturday All Day Writing Workshop
Facilitated by Sharon Bray
Home of Dr. Audrey Shafer

**April 16, 2014, 5:00 – 7:00 pm**
Medicine and the Muse
Khalid Hosseini, MD
“A Conversation with Khalid Hosseini”
Li Ka Shing Center: Berg Hall
Stanford School of Medicine

**October 8, 2013, 5:30 – 6:30 pm**
23rd Annual Jonathan J. King Lecture
Anthony L. Back, MD
Balancing Hope and Reality: How could physicians do better?
Auditorium, 1st Floor
Lucile Packard Children’s Hospital

**November 9, 2013, 8:45 am – 4:30 pm**
Saturday All Day Writing Workshop
Facilitated by Sharon Bray
Home of Dr. Audrey Shafer

**March 4, April 1, May 6, 2014**
5:30 – 6:30 pm
First Tuesday Evening Writing Workshop Series, Facilitated by Elyce Melmon
SCBE Conference Room (62)
1215 Welch Road, Modular A

**July 10, 2014, 5:30 – 7:00 pm**
Stanford Med Writers Forum/ Pegasus Physician Readings
Moderator: Dr. Audrey Shafer
Location: TBD

**September 25, 2014, 5:30 – 7:00 pm**
Stanford Med Writers Forum/ Pegasus Physician Readings
Location: TBD
Stanford Center for Biomedical Ethics
1215 Welch Road, Modular A
Stanford, CA  94305-5417
http://bioethics.stanford.edu

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**Teaching Fellows:**

Karola Kreitmair, PhD
Nicole Martinez, JD
Nate Olson, PhD
Ruth Tennen, PhD

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