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Spina bifida clinical trial brings unexpected ethical dilemmas

A study, *The Management of Myelomeningocele Study* (MOMS), that appeared in *The New England Journal of Medicine* found that if a baby suffering from spina bifida is operated on while still in the uterus, the most common and serious complication, myelomeningocele (MMC), can be greatly reduced.[1] According to the study, prenatal repair of MMC might result in better neurologic function than repair delayed until after the baby is born.

"The primary ethical issue is related to the fact that MMC [myelomeningocele] is in general not a lethal disorder. Therefore, fetal surgery might not only put the mother at risk for a non-life threatening fetal condition, but might also replace disability caused by the disease, with death due to extreme prematurity of other causes," says **Alan W. Flake**, MD, director of the Children's Institute for Surgical Science and the Pediatric Surgery Residency Training Program, director of the Children's Hospital of Philadelphia (CHOP), and professor of surgery and obstetrics/gynecology, University of Pennsylvania School of Medicine, all in Philadelphia.

Mark J. Bliton, PhD, associate professor, Department of Medicine, Department of Obstetrics and Gynecology, Vanderbilt University Medical Center, Center for Biomedical Ethics & Society in Nashville, TN notes that the woman is under general anesthesia, and major surgery, a C-section, in order to provide surgeons access to her fetus. "She does not benefit from this surgery, so a good analogy would be a genetically related live kidney donation for a family member," Bliton says.

EXECUTIVE SUMMARY:

Fetal surgery for myelomeningocele might not only put the mother at risk for a non-life threatening fetal condition, but it also might cause death.

- The clinical trial produced groundbreaking results in addition to drawing attention to ethical dilemmas in research.
- Ethicists familiar with the ethical issues surrounding fetal therapy were involved in the early discussions of the trial and the meetings directed toward design of the trial at the National Institutes of Health (NIH) and other locations.
- Patients were not referred to a surgical center unless they expressed willingness for randomization during the initial evaluation and counseling.

Curiously, the ethics board at CHOP was not consulted when planning the surgeries. However, ethicists familiar with the ethical issues surrounding fetal therapy were involved in the early discussions of the trial and the meetings directed toward design of the trial at the National Institutes of Health (NIH) and other locations. "There was a tremendous amount of discussion about those legal issues at the meetings of professional societies for maternal-fetal medicine and fetal surgery, as well as at the NIH," says Bliton. There were also trained individuals at each of the three trial sites that interviewed the patients preoperatively and raised any social or ethical concerns on a case-by-case basis. The trial was conducted at three hospitals: Vanderbuilt University in Nashville, TN, Children's Hospital of Philadelphia (PA), and University of California, San Francisco. "The issue about only offering the surgery at selected medical centers is complex," notes Bliton. "The main point to convey is that the study was research on surgery. Surgical research of this kind requires a team of specialists that can work together, and have worked well together, in order to manage the inevitable complexities of such an ambitious study," says Bliton.

Interestingly, the researchers assumed that only a small number of women would consent to be involved in the trial if the surgery was available elsewhere, so they persuaded other hospitals that were not participating in the trial to stop performing the procedure. According to Bliton, given the time, effort and expense that the study would require, the leaders wanted to achieve a clear answer. "Limiting the number of medical centers who could enroll subjects and perform the interventions and collect the data was a reasonable way to reduce some obvious complexity," says Bliton.

Flake says, "The argument was based on true equipoise for a randomized trial existing in the medical community and the ethical obligation to prove efficacy of a surgical procedure prior to dissemination of the procedure as standard or accepted care." Flake continues to say, "there are many examples of harm to patients from early widespread application of unproven surgical procedures such as intestinal bypass for morbid obesity."

The randomization of the trial was a significant issue for accrual of patients for the trial, according to Flake. "Patients were not referred to a surgical center unless they expressed willingness for randomization during the initial evaluation and counseling at the Data and Study Coordinating Center [DSMC]," he says. Counseling was based on principles of equipoise, and attempts were made to objectively dispel biases within the patients regarding the efficacy of prenatal surgery, Flake says. "Nevertheless, accrual was much slower than anticipated, undoubtedly in part due to resistance," he says.

Surprisingly for some, there were few ethical objections from the various oversight bodies for the trial, according to Flake. "Those oversight bodies included the Maternal Fetal Medicine Network Advisory Board, the DSMC, the Steering Committee, the hospital IRBs, and our own Fetal

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EDITORIAL QUESTIONS

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Treatment Oversight Committee at CHOP. This suggested that there was agreement among these bodies that the disability related to MMC warranted the risks of prenatal treatment, that there was true equipoise with respect to efficacy justifying randomization, and that it was important to determine efficacy unequivocally before the procedure became widely disseminated," he says.

The trial was a success, says **N. Scott Adzick**, MD, pediatric surgeon, The Division of Pediatric General and Thoracic Surgery, The Children's Hospital of Philadelphia, and lead author of the study. "The current study reports data on 158 patients who were followed at least one year after surgery," Adzick explains. "At one year of age, 40% of the children in the prenatal surgery group had received a shunt, compared to 83% of the children in the postnatal group."

There were additional positive outcomes. "During pregnancy, all the fetuses in the trial had hindbrain herniation. However, at age one year, 36% of the infants in the prenatal surgery group no longer had any evidence of hindbrain herniation, compared to only 4% in the postnatal surgery group," says Adzick.

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For more information about spina bifida and the clinical trial, visit:
http://www.spinabifidaassociation.org, then on the right side of the page, click on "MOMs Study Results."

To view a video about fetal surgery for myelomeningocele, go to http://www.chop.edu/video/fetal-surgery/spina-bifida-video.html. ■

Survey targets ethics in mental health field

The moral struggles and ethical controversies encountered in physician practices all over America can be considered insurmountable at times. A recent study published in *Psychiatric Times* focused on a range of ethical dilemmas encountered in daily practice. More than 700 psychiatrists and other mental health professionals including nurses, psychologists, and students took part in the survey.[1]

The multiple-choice moral struggles survey asked participants to respond to a range of ethical dilemmas encountered in daily practice.

"Medscape had done an ethics survey in 2010 with their readership. I thought a similar survey geared to psychiatry would be of interest," says **Cynthia M.A. Geppert**, MD, PhD, MPH, chief of consultation psychiatry and ethics, New Mexico Veterans Affairs Health Care System, Albuquerque, associate professor in the Department of Psychiatry and director of ethics education, University of New Mexico School of Medicine, Albuquerque.

The survey uncovered a high level of ethical obstacles and other issues that physicians face, says Geppert. The respondents were all subscribers and readers of *Psychiatric Times* which has a readership of about 40,000, according to Geppert. When she asked how often the respondents had encountered ethical dilemmas in their practice, of the 640 participants who answered the question, 34% reported facing ethics issues once or twice a week, 43% once or twice a month, and 23% hardly ever.

Participants were also asked about their level of comfort and preparedness when faced with ethical dilemmas in daily practice. Clearly from the responses, psychiatrists recognize and reflect on ethi-

EXECUTIVE SUMMARY

A recent study published in *Psychiatric Times* focused on a range of ethical dilemmas encountered in daily practice. More than 700 psychiatrists and other mental health professionals including nurses, psychologists, and students took part in the survey.
• The survey uncovered a high level of ethical obstacles and other issues that physicians face.
• Psychiatrists recognize and reflect on ethical problems in the profession.
• Psychiatrists indicated that they are pressured by managed care and insurance companies, the pharmaceutical industries, legislative and regulatory demands, and institutional policies.

cal problems in the profession. Of the 633 participants who responded to that question, 29.4% felt they had adequate skills and knowledge to analyze and resolve ethical dilemmas; 47.2% said they occasionally needed ethical consultation but knew where to find such assistance; and 23.4% said they occasionally needed help, but did not know who to turn to for an ethics consult.

When asked to what extent participants would benefit from expert ethics consultation, of the 644 respondents, a mere 4.1% replied they would never benefit from consultation, and 9.8% said they would often benefit. Some (35.7%) said they seldom needed an ethics consult, and more than half (50.4%) said they could occasionally use a consultation.

"The most surprisingly result [of the study] was that so many psychiatrists and other mental health professionals took the time out of their busy schedules to respond. Not so much surprising, but inspiring, was the moral seriousness of the responses, which showed the daily efforts of psychiatrists to do the right thing despite considerable pressure to compromise ethical values," says Geppert. Pressures usually come from managed care and insurance companies, the pharmaceutical industries, legislative and regulatory demands, and institutional policies, Geppert says. "In sum, there are now many third-party forces that are involved in the practice of psychiatry that present conflicts of interest that may compromise the patient-centered therapeutic alliance."

For example, according to Geppert, a number of respondents commented that there are pressures from insurance and managed care companies to discharge patients before they are ready to leave the hospital. "Psychiatrists often feel pressure to over document the acuteness of a patient's psychiatric condition, say continuing to be suicidal, in order to obtain the extra hospital days the patient clinically needs to be appropriately treated," says Geppert.

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SOURCE

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Ethics mentoring — lead by example

Students need specific training

Research institutions that make it a goal to improve ethical conduct among staff, researchers, and students engaged in research should focus on providing better ethics education, developing sound policies & procedures, and leading by example, an expert says.

Mentors and their own ethical principles and behaviors are critical to the ethical development of student researchers, says **Celia Fisher**, PhD, professor of psychology, Marie Ward Doty university chair and director of the Center for Ethics Education at Fordham University in The Bronx, NY. Fisher received a lifetime achievement award as part of the Awards for Excellence in Human Research Protection for 2010 from the Health Improvement Institute of Bethesda, MD. Fisher and co-investigators have studied the impact of mentoring on psychology graduate student preparedness in conducting research responsibly. The research was funded by the National Institute of Neurological Disorders and Stroke and the Office for Research Integrity.

Their research has found that students need a good mentor to help them feel prepared for responsible conduct of research practices. And the mentor's own ethical behavior is as important as what the mentor teaches the student.[1,2]

"Graduate students conducting research are not going to pick up responsible conduct of research practices simply by reading guidelines," Fisher says. "If they have a good mentor, they'll feel prepared; if they have a poor mentor they'll feel unprepared."

The mentor's role is to demonstrate ethical conduct and reinforce institutional and national ethical conduct of research policies. And it's the research institution's job to have explicit policies about research ethics and conduct, she adds.

"Students won't feel prepared unless they're in a department with specific policies and that demonstrates expectations," Fisher says. "And they need a mentor who is willing and able to provide specific, didactic information and who acts ethically."

The mentor's behavior matters: "If you don't practice what you preach, then what you preach might be diluted somewhat in terms of its effect,"

Fisher says.

Departmental or institutional ethical policies and procedures can be based on national research guidelines for ethical conduct, as well as on specific guidelines by organizations such as the American Psychological Association (APA). So for ethical training in psychology departments, the APA's ethics code is a good model to follow, Fisher notes. *(See resource, right, for link to APA's code of ethics.)*

"Have your policies and procedures updated and passed out to each student, requiring students to be familiar with these," Fisher advises. "The student handbook that everyone gets should include the APA ethics code, or the ethics code for the students' discipline, and the federal regulations, departmental procedures for making ethics complaints, and research conduct rules."

It's important that students feel safe in discussing ethical violations or asking questions about the research in which they are participating, so departments need to have explicit and formal procedures for students to follow. Requiring ethics coursework for student researchers also is important, Fisher notes. "All accredited clinical psychology programs that train practitioners are required to have an ethics course, but programs that train researchers are not required to have an ethics course, so students studying clinical programs feel more prepared, according to our research," she explains. "Research programs should require a course in research ethics to help give students more confidence in responsible conduct of research."

Medical schools also often require ethics courses for clinicians, but not in research, she adds. "Even if doctors never do their own research, they should have to read about responsible conduct of research," Fisher says. "If they don't have some knowledge about research ethics, then they won't be very good consumers of medical research, and that will limit the effectiveness of their clinical practice."

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RESOURCE

• To access "Ethical Principles of Psychologists and Code of Conduct" go to http://www.apa.org/ethics/code/index.aspx. ■

Hospice cap changes evaluated by CMS

Managers should monitor cap deficit risk

After two district courts struck down the Centers for Medicare and Medicaid Services' (CMS) regulations for calculating hospice caps, CMS issued an unprecedented rule that allowed all hospices with appropriately filed hospice cap repayment demand appeals to avoid going to court.

"This ruling is a big deal," says **Carel T. Hedlund**, principal, Ober Kaler Attorneys at Law, in Baltimore, MD. "If a hospice has a repayment demand based on exceeding the cap and has taken the appropriate steps to file an appeal, the cases go back to the CMS intermediaries to be recalculated using the patient-by-patient proportional methodology."

Losing judgments in two district courts was a major blow to CMS and suggested that as other cases reached district courts, similar decisions would be made to enjoin CMS from calculating hospice caps with the methodology currently used, she says. CMS has also included a proposal included in the 2012 Wage Index that allows a hospice to choose between the patient-by-patient proportional methodology and the current methodology to calculate their hospice cap, she adds.

The hospice cap was introduced in 1983, but appeals of the repayment demands did not occur regularly until about five years ago, points out Hedlund. The cap was established to limit the amount of Medicare payments a hospice receives in a fiscal year. Simply described, the cap is determined by multiplying the number of beneficiaries in an individual hospice by the fiscal year's cap amount, which is adjusted each year by CMS, she explains. "I don't know if the repayment demands were not high enough to justify appeals prior to the 2005 fiscal year, or if hospices just did not consider it worthwhile to appeal," she says. "I do know that around 2005 we saw lengths of stay increasing as hospices provided care for longer term patients with a wide range of diagnoses, rather than the typical short-stay cancer patients."

A longer length of stay does increase a hospice's risk of exceeding the hospice cap, especially if the hospice's case mix does not include enough short-term patients to offset the long-term stays, she adds.

Kyle Terry, MBA, consultant and principal at Hospice CAP Consultants in Owasso, OK, learned everything he knows about hospice cap repayment demands the hard way. When working as an administrator for two hospices, he faced hospice cap deficits of $1.5 million and $800,000. Although the hospices were responsible for repayment demands for previous years, Terry was able to implement business strategies that prevented the hospices from continuing to accrue cap deficits on an ongoing basis. "I was able to eliminate the $1.5 million deficit in 12 months and the $800,000 deficit in nine months," says Terry.

Even with the CMS ruling, hospices must pay close attention to their hospice cap exposure and hospice managers need to understand how the cap works, says Terry. "I hate to tell clients that if they've received one repayment demand letter, they will get a second, and it will probably be for more money," he says. *(For more information about monitoring cap deficit exposure monthly, see story, right.)* Because the repayment demands are for fiscal years that ended two years earlier, it is likely that the hospice did nothing to adjust the case-mix to address cap deficits for the year between the year addressed in the first repayment demand and the current year, he says. For example, a hospice manager won't receive a repayment demand letter for fiscal year (FY) 2009 until FY 2011, he explains. "If the hospice manager wasn't monitoring cap exposure in FY 2010 and addressing issues contributing to the cap deficit, the hospice will almost always receive a repayment demand for FY 2010," he says.

SOURCES/RESOURCES

For more information about the hospice cap, contact:

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• To see the April 14, 2011, Centers for Medicare and Medicaid Services ruling related to hospice cap appeals based on validity of calculation methodology, go to www.cms.gov/Rulings/downloads/CMS1355R.pdf.

• To see the proposed Hospice Wage Index for 2012, which includes changes to the hospice cap calculation methodology, go to www.cms.hhs.gov/hospice. On the left navigational bar, select "Hospice Regulations and Notices," then choose "CMS-1355-P." ■

Monthly monitoring of hospice cap deficit risk

Although the key to reducing hospice cap deficits is to monitor cap deficit exposure on a monthly basis, the first step is to understand the issues that can increase your hospice's risk, suggests **Kyle Terry**, MBA, consultant and principal at Hospice CAP Consultants in Owasso, OK.

"The larger the number of hospices in a single market, the greater the risk of exceeding the cap amount," he says.

Competition increases awareness of the hospice benefit, improves education about the benefits of earlier admission to hospice, and encourages longer lengths of stay as hospices seek patients who have a wide range of diagnoses, he explains.

The first step for a hospice manager to take when a repayment demand letter is received is to compare the list of beneficiaries included in the calculation to their own information, says Terry. Sometimes a patient whose benefit period started in one fiscal year but continued into the next year is counted as a full patient for the first year, he says. In other cases, a hospice manager or administrator might not realize that a patient received care from another hospice during the year, and that care adjusts how the cap is calculated, he adds.

"I've had clients who immediately ask about the lawsuits filed by other hospices challenging the calculation methodology, but I've found that for most hospices, the repayment amount is usually accurate, and if it's based on incorrect information, the intermediaries are willing to listen and adjust if needed," he says.

If your hospice administrator does believe your repayment demand is not accurate, he or she has 180 days to file an appeal, says **Carel T. Hedlund**, principal, Ober Kaler Attorneys at Law, in Baltimore, MD. "The CMS [Centers for Medicare and Medicaid Services] ruling automatically sends any appeals back to intermediaries for recalculation if the appeal was filed appropriately," she says. For that reason, hospices that receive repayment demands should make sure they file their appeals in a timely manner to ensure their cap is calculated in a proportionate manner, she adds. Hedlund advises that before the administrators file the appeal, they should make sure the new calculation is appropriate for the particular

hospice. "Some hospices, based on case-mix, may prefer the current calculation." The only way to know which method is best is to evaluate your data and conduct your own calculation, she says.

Once you've addressed the immediate concern of the first repayment demand letter, take a look at the fiscal year following the year addressed by the letter, suggests Terry. "There's nothing you can do to change the hospice cap deficit for that year because it is in the past, but you can get an idea of how much you might be asked to repay," he says. "Some of my clients were able to plan ahead to set aside extra funds or make financial arrangements for loans to repay CMS when the demand letter arrived."

The analysis also gives hospice managers a good picture of the issues that contributed to the hospice cap deficit, he adds. This analysis enables the hospice management team to make changes to their business strategy to avoid or minimize cap deficits in the current and future years, he adds.

In addition to making sure the hospice cap and each hospice's individual risk of exceeding the cap is understood, managers also should review the proposed changes to hospice cap calculation carefully, suggests Hedlund. ■

The infinite power of personal health records

Is the possibility of a person having total access to their individual health records too much power for the person? If given such access, could a person incorrectly alter or add information to the record?

Although this is a generation of computer literate and electronics-savvy people, ethical questions have been raised as to how much access a layperson should have to their medical records and just how secure are the files.

The personal health record (PHR) is defined as an electronic application through which individuals can access, manage, and share their health information, and that of others for whom they authorize, in a private, secure and confidential environment. In the United States market, a plan for the widespread acceptance of this tool is being worked out.

Information in a Personally Controlled Electronic Health Record (PCEHR) can be accessed by the patient and the authorized healthcare provider. According to a survey published by *The New England Journal of Medicine*,[1] about 4% of physicians have a fully functional electronic records system (ERS), and 13% have a basic system. Thirty-four percent had ordered a system but had not installed it or planned to purchase one in the next couple of years.

With patient health information available to them, healthcare providers will be able to make better decisions about a patient's health and give better treatment advice, proponents say. Where the controversy comes in is that over time the patient will be able to contribute to the information and add to the recorded information stored in the PCEHR. At what ethical cost will physicians as well as patients possibly have to pay for having this system in place?

Public concerns about privacy and security are a major barrier to the complete adoption of PHRs. A recent survey found that two-thirds of the public is concerned about the privacy and security of their health information.[2]

Ethics questions arose from a like e-health system that was started in Australia. The Australian Personally Controlled Electronic Heath Record system (PCEHR) is a secure, electronic record of each patient's medical history that is stored and shared in a network of connected systems. The PCEHR brings key health information from several systems together and presents it in a single view.

Although **Merle Spriggs**, MBioeth, PhD, research fellow at The Royal Children's Hospital, Children's Bioethics Centre in Australia, is a strong advocate for the PCEHR system, she recognizes the ethical ramifications that could possibly arise from using this system. "The ethical concerns are the same for any country," says Spriggs. "They involve issues such as consent, privacy, the degree of control that people will have over who can access the record, etc." Questions must be resolved regarding the legitimate use of data in the PCEHR and by whom, Spriggs says.

Cost is also an issue. "There is a question of who should pay," says Spriggs. "Participation for consumers and health providers in the Australian PCEHR system is voluntary, so this raises questions about the implications for individuals and the record system of lower-than-expected rates to uptake," she says.

As part of the 2010/2011 federal budget, the Australian government announced a $466.7 million investment over two years for a national PCEHR system for all Australians who choose to register online in 2012-2013.

Ethical issues notwithstanding, the benefits possibly outweigh the negatives, some ethics experts say. "Potentially, there are enormous benefits in having such a system and in having our own personally

controlled record. Electronic records could improve outcomes for patients by improving safety and quality in healthcare. It is believed that that they will fix the problems of paper records, which are notorious for being difficult to read, incomplete, sometimes unavailable, and not all in the one place," says Spriggs.

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SOURCE/RESOURCE

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Discussion of EOL care helps patients, families

For patients with severe heart failure, an implanted mechanical pump known as a Left Ventricular Assist Device (LVAD) can be a life-sustaining treatment. Even though the technology involves risks, few patients and their families tend to talk explicitly about the "what ifs" before surgery takes place. In the June issue of *Mayo Clinic Proceedings*, a team of Mayo Clinic researchers found that careful discussions at the bedside about patients' end-of-life preferences brought relief to families and eased subsequent medical care.

"Previous studies have looked at the ethics of LVAD surgery and the role of patient and family members when it comes to turning the device off," says lead author **Keith Swetz**, MD, an internist and specialist in palliative medicine. "But these are complex patients, and many things can happen. To our knowledge, this was the first study to investigate how to help patients and families to be proactive in decision-making before patients' quality of life is compromised."

The study looked at 19 patients dependent on LVAD as a long-term survival strategy rather than as a "bridge" to a heart transplant. Among them, 13 patients and their families discussed advanced care wishes with a palliative care team that included physicians and social workers. The study found the conversations provided guidance when adverse events occurred, such as when a patient fell after surgery and suffered brain damage. The study also found LVAD patients often presumed family members were aware of their end-of-life wishes, when, in fact, spouses and children were grateful to be guided in a conversation.

The study affirms the effectiveness of palliative care discussions before LVAD surgery and provides guidelines for clinicians and hospitals about how to address end-of-life decision-making. "It can be a tough conversation for families to have but we found it didn't cause stress or loss of hope," Swetz says. "Instead, having the conversation brought relief and was ultimately reassuring for families and patients."

RESOURCES

For more information about Left Ventricular Assist Device (LVAD), visit the Mayo Clinic web site at http://www.mayoclinic.com/health/lvad/MY01077.

A video titled "Palliative Medicine for Preparedness Planning in Patients Receiving LVAD as Destination Therapy" from Keith Swetz, MD, is available at http://www.youtube.com/watch?v=EYwUVCyToL0. ■

R&D center adapts for multicenter studies

As a research institution's human subjects research increases, so must the work. In some cases this work means expanding to handling multicenter protocols, which might result in new challenges. For example, the review board handling these multicenter studies will need to provide some guidance on regulatory and human subjects protection issues to the satellite sites.

Review board offices will need to develop new policies and procedures, as well as staff roles and tasks to handle the influx of new work that comes with multicenter protocol reviews, an expert says.

"At our site, these types of studies have been increasing for the past 10 years," says **Stephanie A. Skoler-Karpoff**, MPH, manager of the Research Support Office in the Office of Clinical Research at Memorial Sloan-Kettering (MSK) Cancer Center of New York City.

In 2000, Memorial Sloan-Kettering had two studies in which a Memorial Sloan-Kettering investigator wrote the protocol for a multicenter study. By 2010, there were 87 such studies, Skoler-Karpoff says. "Every year these increase, and there are a couple of reasons," she adds. "We can accrue subjects faster and get results to transfer into practice faster."

MSK opened its Office of Clinical Research's multicenter protocols group (MCPG) at the end of 2009 to provide this guidance and support.

"Our goal for starting this office was to provide institutional support and a repository for all of the common tools and best practices involving oversight, safety, and compliance," Skoler-Karpoff says.

Multicenter studies require more resources and staff time than single-site studies, she notes. Having a specific office handle the training and oversight of these studies can result in improved regulatory compliance and reduce duplication of effort, Skoler-Karpoff says. "In addition, people are just happier, having a central place to ask questions about multicenter studies," she adds. She describes how oversight of multicenter protocol reviews works:

• **Develop new standard operating procedures (SOPs).** Research oversight and review board offices will need new SOPs to describe regulatory requirements for multicenter study principal investigators (PIs) as well as for participating sites.

"We developed an institutional SOP that defines the responsibilities for the PI, describing what the PI's responsibilities are in a multicenter study," Skoler-Karpoff says. "It sets requirements for document language and submissions."

The SOP also sets regulatory and data submission timelines, such as describing when researchers have to submit data and amendments, she adds.

• **Create training module.** Skoler-Karpoff provides training and inservices based on the SOPs.

The training sessions last an hour and are held regularly because there are new multicenter studies beginning on a regular basis, she says. Research staff also has access to tools and templates that help reinforce the training.

• **Use standard protocol language.** Research sites that are part of a multicenter study need to use some of the same language for therapeutic and non-therapeutic studies, coordinated by Memorial Sloan-Kettering Cancer Center. For example, sites should include language pertaining to deadlines of when data and the case report forms (CRFs) are submitted, Skoler-Karpoff says.

"We have something posted on our web site that is our suggested language, and they can cut and paste these to the protocol," she says. "This way the site will know exactly what our expectations are."

• **Collect best practices.** "One thing we're doing is collecting all regulatory documents, IRB documents from outside institutions, including their informed consent form, continuing review approvals, and amendments," Skoler-Karpoff says.

Also, MSK has an intranet page that posts best practices, definitions, and templates that are useful in multicenter protocol management. "We created processes and guidelines for sites," Skoler-Karpoff says. "We have guidelines for auditing participating sites and best practices for communication."

Also, there is a computerized graphic presentation available to use at start-up meetings, she says. "It's a skeleton that they can fill in with details as needed, so it's a lot easier for them, and there is no reason to reinvent the wheel," she adds.

• **Track each site's protocol life cycle.** "We have a sophisticated system that tracks all review board documents, including serious adverse events [SAEs], and other data, and it's available for all research studies," Skoler-Karpoff says. "The system, which was not part of the multicenter initiative, allows us to see each site's information, including their accrual information."

The tracking system also allows the oversight office staff to look at the study's latest amendments and continuing review data. And it can send out automatic e-mail reminders to the different sites about upcoming deadlines. "We can see all the documents associated with that [review board] approval, any correspondence and documents," she says.

The system will show the timeline for each site's local review board approvals, and it e-mails the MSK oversight staff information about continuing reviews. "It will send an e-mail to me that says, 'In 30 days, this institution's site's [review board] approval is expiring,'" Skoler-Karpoff says.

The tracking system also enables oversight staff to easily look up the names of consenting officials at each site, which saves them the time and trouble of calling coordinators for this information, she adds. Investigators benefit from this assistance.

"We remind them each week of documents that are pending and need to be submitted for approval," Skoler-Karpoff says. ■

Genetic review finds common ground

Survey: Researchers, review boards agree on issues

In response to concerns raised about review boards' evaluation of genetic research, a group of investigators, ethicists, and other stakeholders has surveyed genetic researchers and review board professionals to discern what issues are complicating review.

The results have shown that the two groups are in accord on many points, particularly regarding which issues are most important to address,[1] says **Karen L. Edwards**, PhD, MS, professor of epidemiology at the University of Washington (UW) and director of the university's Center for Genomics and Public Health in Seattle. "The most surprising result was the fact that it's not really us versus them," Edwards says. "Actually, both groups are dealing with the same challenges and unsure in some situations about what to do. I think both groups would like guidance, and I think part of the tension has been that researchers look to the review boards for guidance, and where do the review boards go for guidance?"[2]

Edwards says the effort grew out of complaints she and others were hearing from colleagues about the difficulty of getting genetic research approved by review boards. Recognizing a need to address the question more empirically, members of UW's Center of Excellence in Ethical, Legal and Social Implications Research teamed with the Center for Genetic Research Ethics and Law at Case Western Reserve University in Cleveland, OH, and the American Society of Human Genetics and Public Responsibility in Medicine and Research (PRIM&R) Boston, to examine investigators' and review boards' attitudes about genetic research. They formed the Genetic Research Review and Issues Project (GRRIP) and obtained NIH funding to survey both groups.

'Considerable discussion'

The GRRIP group first conducted in-depth interviews with researchers and review board professionals, then used the information to develop questionnaires asking about the issues that most frequently caused "considerable discussion" between them during review.

The two groups reported spending the most time on roughly the same set of issues:

- **consent documentation;**
- **protection of subjects' personal information or samples;**
- **return of genetic research results to participants;**
- **reconsent from research participants for a new study or a change in study purpose.**

Researchers' opinions were surprising similar to review board professionals' answers on many of these issues. For example, 78% of review board professionals and 82% of researchers thought there is a duty to return results from genetic research to participants if those results would affect a participant's health or health care. Only 44% of review board professionals and 43% of researchers thought it was necessary to obtain reconsent from a participant to share his or her deidentified data with a researcher at another institution.

Despite these agreements, researchers reported problems with their studies' assessment by review boards. Fifty-four percent of researchers said that review board evaluation resulted in "excessive delay of a project," while nearly 30% said their experiences with review board analysis dissuaded them or their colleagues from pursuing a similar project in the future.

Edwards says that it can be quite frustrating for researchers to speak to colleagues at other institutions who seem to be having an easier time of it than they are. "When somebody else at another institution gets something through easily and you can't get it through, then people go crazy," she says.

Researchers also sometimes think that review boards tend to focus on risks that are theoretically possible but unlikely, such as harm occurring because of reidentification of a subject, while they themselves are struggling with more immediate problems, such as working out the wording of a consent document, Edwards says.

The survey notes that researchers who had themselves served on a review board were about 80% more likely to report positive consequences of review board assessment than those who had not.[1] Taken together with reports from review board professionals that these studies take more time because of their complexity, Edwards suggests that recruiting genetic researchers to review boards might result in a win for both groups.

"I think that's actually an important message," she says. "If the review board does need expertise, I think there are certainly many researchers out there who would happily volunteer, but they don't know how, or have never been asked. In working on this project, I thought many times, 'Gosh, I've never been asked, I wonder how this works.'"

With the completion of the surveys, Edwards says she hopes the stakeholders her group brought into the

project, including PRIM&R, can move forward with efforts to bridge the gap.

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2. Lemke AA, Trinidad SB, Edwards KL, et al. Attitudes toward genetics research review: results from a national survey of professionals involved in human subjects protection. *J Empir Res Hum Res Ethics* 2010; 5:83-91. ■

Public prefers limited informed consent

A team of University of Iowa (UI) researchers conducted a study to determine people's preferences with respect to informed consent for biobanking. Forty-one percent of people surveyed, and 54% of those in focus groups, were in favor of the broad approach to providing consent.

The study, "Active choice but not too active: Public perspectives on biobank consent models," was published in the online edition of the journal, Genetics in Medicine.[1] It was led by **Christian Simon**, PhD, associate professor of bioethics and humanities in the Department of Internal Medicine at the UI Roy J. and Lucille A. Carver College of Medicine, Iowa City, IA.

The study involved 751 telephone surveys and seven focus groups with the public who were randomly sampled from counties across Iowa. More than half the study participants were female.

Most study participants had not heard of a "biobank" before, but when it was explained to them what biobanks were and that they could help advance research on genetic and nongenetic aspects of disease, most study participants were enthusiastic.

The majority (95%) of survey participants rejected the idea of deriving and banking samples without first obtaining informed consent. Sixty-seven percent of those surveyed and 63% of those who participated in the focus groups said they would prefer an opt-in consent process.

Study participants then were asked to consider whether they would prefer a broad description of how their samples and health information might be used in future research, whether they wanted to control what research their samples and health information are used in via "menu-type" consent forms, or whether they wanted to be contacted for their permission every time their samples and health information became eligible for research.

Broad consent was preferred by more people when compared to the menu or study-specific types of consent. Forty-one percent of people surveyed, and 54% of those in focus groups, were in favor of the broad approach to providing consent.

The study was supported by the UI Institute for Clinical and Translational Sciences, the UI Carver College of Medicine, and the UI vice president for

CME INSTRUCTIONS

To earn credit for this activity, please follow these instructions.
1. Read and study the activity, using the provided references for further research.
2. Log on to www.cmecity.com to take a post-test; tests can be taken after each issue or collectively at the end of the semester. First-time users will have to register on the site using the 8-digit subscriber number printed on their mailing label, invoice or renewal notice.
3. Pass the online tests with a score of 100%; you will be allowed to answer the questions as many times as needed to achieve a score of 100%.
4. After successfully completing the last test of the semester, your browser will be automatically directed to the activity evaluation form, which you will submit online.
5. Once the completed evaluation is received, a credit letter will be e-mailed to you instantly.

CME OBJECTIVES

Upon completion of this educational activity, participants should be able to:
- Discuss new developments in regulation and health care system approaches to bioethical issues applicable to specific health care systems.
- Explain the implications for new developments in bioethics as it relates to all aspects of patient care and health care delivery in institutional settings.
- Discuss the effect of bioethics on patients, their families, physicians, and society.

COMING IN FUTURE MONTHS

- Cost concerns of medical ethics
- Disaster preparedness for the mentally impaired
- Is there a new Hippocratic Oath?
- Ethical issues in palliative sedation

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medical affairs, all in Iowa City, IA. The study was conducted with the assistance of the Center for Social and Behavioral Research at the University of Northern Iowa, Waterloo.

REFERENCE

1. McGowan M, Burant C, Moran R, et al. Patient education and informed consent for preimplantation genetic diagnosis: Health literacy for genetics and assisted reproductive technology. *Genetics in Medicine* 2009; 11:640-645. ■

CME QUESTIONS

5. What is a possible outcome of the fetal surgery performed on fetuses diagnosed with spina bifida?
   A. Put the mother at risk for a non-life threatening fetal condition
   B. Death of the mother
   C. Better neurologic function for the fetus
   D. All of the above

6. After studying the impact of mentoring on psychology graduate student preparedness in conducting research responsibly, what did researchers uncover?
   A. That students need a good mentor to help them feel prepared for responsible conduct of research practices.
   B. The mentor's own ethical behavior is as important as what the mentor teaches the student.
   C. Both A and B
   D. None of the above

7. What are some of the ethical considerations being raised regarding personal health records (PHRs)?
   A. Patients will soon be able to contribute to the information and add to the recorded information stored in the PHR.
   B. Public concerns about privacy and security of health information.
   C. PHRs will fix the problems of paper records, which are difficult to read, incomplete, unavailable, and not in one place.
   D. All of the above

8. The end-of-life study published in the Mayo Clinic Proceedings affirms the effectiveness of palliative care discussions before Left Ventricle Assist Device (LVAD) surgery and provides guidelines for clinicians and hospitals about how to address end-of-life decision-making.
   A. True
   B. False