End-of-life research: IRBs queasy about studies with dying patients

Broad restrictions and concern for family often impede research

The goals of palliative and end-of-life research are unimpeachable — discovering methods to ease the suffering of dying patients and their families.

But there are obstacles to achieving those goals. Patients in such studies are only available to researchers for a short time. They may lose the ability to participate in research due to incapacitation. Family members may not wish to burden them with research activities when time is short and hours are precious.

Experts in the field say another significant obstacle to end-of-life studies is the reluctance of IRBs to allow them or their tendency to unnecessarily restrict them in the name of protecting a vulnerable population. They argue that the issues involved in dealing with dying patients are often no different than those that arise with other vulnerable populations, such as mentally ill patients or cancer patients recruited for Phase 1 trials. And they say that patients in hospice and other end-of-life settings may actually benefit from the knowledge that their experience will help others.

“There can be a risk of assuming that they are too sick to participate, and that’s not true,” says Charles von Gunten, MD, PhD, FACP, editor-in-chief of the Journal of Palliative Medicine and medical director of the Center for Palliative Studies at San Diego Hospice and Palliative Care. “The reason people in a palliative care population participate in research is strongly related to their desire to give back, to want to be of service, particularly at a time of life when they are thinking about final gifts and ‘What was my life worth?’ Participation in research is a very important part of that for some patients.”

Von Gunten’s hospice has its own IRB and works with researchers, both inside and outside the institution as part of its mission to improve end-of-life care. The need for good evidence-based information about palliative care is great, he says.

“This is a population that has by and large been neglected and yet it’s large — 2 ½ million people in the country die every year,” von Gunten
says. “Their medical care is important and most of the medical evidence base rests on extrapolation from other populations.”

David Casarett, MD, MA, assistant professor of medicine at the University of Pennsylvania’s Division of Geriatric Medicine and a researcher into end-of-life decision-making, says that in general, IRBs do a “pretty awful job” when presented with protocols for patients in hospice or other end-of-life settings.

Too often, he says, they place overly broad restrictions on access to such patients out of fear of distressing them or their families.

“As we all know from our personal lives, the idea of talking to somebody who is dying is kind of scary,” he says. “I think we’re all sort of queasy at getting too close and causing distress. So we tend to avoid situations like that in our own personal lives. And as people become IRB members, they worry about actually talking to a family member about the death of their loved one and the possibility that those conversations might cause somebody to break down and cry. IRBs just think that’s the most awful thing in the world.”

However, the following are serious concerns that IRBs should rightly weigh when presented with end-of-life protocols, von Gunten and Casarett say.

Time burden. Dying patients do face risks, including the simple passage of time. A survey that takes too long to administer isn’t just an inconvenience, it robs the patient of precious time spent with family and friends.

“To some degree, time and inconvenience are burdens for anybody,” Casarett says. “But hour for hour, it may be a bigger burden for somebody who has fewer hours.”

He notes that patients and their families are usually very straightforward about telling researchers when the study for which they’re being recruited would take more time than they’re willing to give.

Von Gunten says his institution’s IRB focuses more on instrumental burden than other IRBs might. A long survey instrument that might take hours to complete might be considered too burdensome in this population, he says.

He says his IRB also is willing to take on the science of a proposed protocol.

“Our IRB would say that they are supposed to protect patients from risk,” von Gunten says. “And if the science is not good, then no risk, even if it’s a minimal risk, is worth it, because it’s a vulnerable population, which has limited time, and they don’t want to waste subjects’ time on studies that won’t produce good research. I’ve never encountered that with other IRBs.”

Causing distress. Many end-of-life studies are surveys in which patients and their families are asked about issues related to death and dying. A common concern of IRBs reviewing these studies is the possibility that they might cause patients or family members emotional distress. Casarett believes that concern is overblown by many IRBs.

While he says that it’s true that patients and family members may respond to a survey about their feelings and attitudes by crying, it doesn’t necessarily mean that the questions are unwelcome or the emotions are viewed negatively.
“Family members may say, ‘Yes, it was really distressing to talk about my father’s last weeks of life, but it was also really valuable, because it gave me a chance to talk those things over with somebody. It was really valuable to know that his experiences would help other patients. And overall, I’m really glad I did this interview,’” Casarett says. “But IRBs don’t see those parts; they just see the fact these interviews might cause distress.”

Von Gunten says the San Diego Hospice IRB requires that the researcher present a plan for how he or she will deal with a situation in which a person being surveyed becomes distraught.

“A researcher is not absolved of responsibility for the distress they might cause,” he says. “So even if the interview is over and the researcher leaves, and the study is done, they have to have a plan for ensuring there’s counseling and support in the wake of the study.”

Although counseling is among the services offered to all patients at the hospice, “they have to have a system or a plan for how it would get operationalized,” von Gunten says. “You can’t just assume that somebody will do it. That’s really not taking responsibility for your actions.”

**Informed consent.** Von Gunten says informed consent issues in end-of-life care are not any different than they are in other settings.

“We use the same standards as everybody else, which reduces the size of the population, because they have to be able to give consent,” he says.

Casarett says that informed consent creates challenges among dying patients because of the high prevalence of conditions that impair decision-making judgment. But the issues themselves are no different than in other vulnerable populations, and the same rules apply.

“If you’re concerned about informed consent in end-of-life populations and you take seriously concerns about decision-making capacity, then you should exercise exactly those same concerns with Phase 1 trials, oncology trials and other similar trials,” he says. “Psychiatry research, dementia research – there are plenty of other situations in which there are significant problems with informed consent.”

He says that a little-used method of gaining advance consent for specific studies could help facilitate the trickiest of all end-of-life research – working with patients who are only days, or even hours from death.

“There are a lot of terminal symptoms, such as terminal delirium in the last days of life,” Casarett says. “We don’t know much about how to manage that effectively because it’s very hard to enroll people. If somebody has to be delirious and dying to be enrolled, you can’t wait until they’re delirious and dying and then try to get consent.”

In advance consent, a patient could sign a study-specific consent form stating that in the event the patient develops a particular condition during a hospitalization or hospice admission, he or she consents to participation in the study.

“The study has been explained to me, I understand exactly what would happen, I understand who’s doing it,” Casarett says. “It’s very specific to this hospitalization, or nursing home admission. And it’s very study-specific.”

Casarett says more IRBs soon may be introduced to the challenges of handling end-of-life research proposals, as interest grows in this area of research.

Last year, the NIH held a three-day state-of-the-science conference on improving end-of-life care. A panel of experts recommended increased federal funding for end-of-life research, creating new networks of researchers in the field and supporting existing networks.

“They really see end-of-life research now as a priority,” Casarett says. “And I think in the very near future, that will trickle down to more funding and more good research, so it’s something that IRBs really need to become familiar with and comfortable with very quickly.”

Among those existing networks currently engaged in end-of-life studies is the Population-Based Palliative Care Research Network (PopCRN), a Denver-based research group that links organizations providing hospice and palliative care.

Its director, Jean Kutner, MD, MSPH, works with both university-based IRBs and hospice IRBs such as San Diego Hospice’s board to conduct multi-site studies of end-of-life issues.

She says relations with both types of IRBs have been smooth, although she notices that the hospice-based IRB understands some nuances of end-of-life care that a more general IRB might not.

For example, her university IRB’s consent form contains standard language offering medical care to anyone injured by research. Kutner notes that some patients may not want such treatment, if they have advance medical directives limiting interventions at the end of life.

“I can’t get them to let me modify it to say, ‘consistent with palliative care goals,’” she says.
“San Diego Hospice templated forms contain standard language that is more relevant for the population.”

Von Gunten and Casarett say that IRBs approaching end-of-life studies should be sure to seek out the right expertise for the board.

“It doesn’t necessarily have to be a physician, but it needs to be somebody who knows the clinical field, knows the patient population and has clinical experience,” Casarett says.

Von Gunten suggests bringing other stakeholders to the conversation as well, including family members of patients, or nursing representatives for a study that focuses on hospice nursing.

He says seeking out IRBs that do a lot of end-of-life care can help provide a better idea of logistical issues that may come up. For example, he says, IRBs should be prepared for large numbers of serious adverse event (SAE) reports from end-of-life, because of the unique characteristics of the study population.

“It’s a unique challenge to us, particularly in new drug studies, where all adverse events need to be reported and death is a serious adverse event by definition, and you’re working in a population where death is expected,” von Gunten says.

“We have lots of SAEs that have to be processed. They all are thought to be not related to the therapy but it’s still a huge paperwork burden. This is a group that only lives on average 41 days.”

Casarett says that ideally, he’d like to see a national IRB, set up by national organizations devoted to end-of-life care, which could handle multisite studies.

While such an undertaking might be expensive, “it would pay off in the long run because it would make possible a lot of research that is really pretty prohibitive to do right now,” he says.

As IRBs grapple with the issues raised by social-behavioral research, they may also want to consider the concerns of researchers who in a recent study charged that delays in processing proposals and overly intense risk aversion have impeded valuable research. T. Gregory Barrett, MBA, MA, PhD, assistant professor of educational leadership at the University of Arkansas-Little Rock, says he and colleague Jim Vander Putten, MS, PhD, assistant professor of higher education and IRB chair at UALR, did a series of studies of social science researchers and IRB officials.

Their goal, Barrett says, was to understand the attitudes of researchers regarding climate of human subjects research at their institutions. Barrett presented early results from his work last year to a conference sponsored by the Department of Health and Human Service’s Office of Research Integrity.

Barrett says he and Vander Putten felt it was important to look specifically at the attitudes of researchers he terms “outliers” — “folks who are frustrated with IRB rules, regulations, policies, practices and so forth,” to get a better overall picture of the research climate.

They identified 12 individuals, who conducted a range of different types of social and behavioral research at different institutions, both public and private.

“The interesting thing about this study is that all 12 participants are active researchers and all 12 of them believe strongly in the role of the IRB in protecting human subjects,” Barrett says. “Their issues revolved around policies and practices they felt had become onerous, or had caused difficulties in getting prompt IRB approvals, or situations in which they felt the IRB had been overly cautious with their assessment of risk, that sort of thing.”

**Regulation-bound, overloaded?**

Barrett says many of the researchers felt overly regulation-bound, particularly at institutions that were heavily dominated by biomedical research. Researchers speculated that the IRB was worried a mistakenly approved study might get an entire research operation shut down.

Barrett says those concerns were expressed even at institutions with separate social-behavioral IRBs.

“The whole concern revolves around protection of institutional reputation,” he says. “The federal government doesn’t differentiate between social science IRBs and biomedical IRBs. If something’s done in a psychological study, through the social science IRB, it can still shut down the entire research operation, potentially.”

**Social scientists take issue with IRB aversion to risk**

Researchers also concerned about IRB workloads

---

124 IRB ADVISOR / November 2005
Another concern raised by the researchers was that the IRBs reviewing their studies were overloaded with work, which led to critical delays in approval.

"As research expectations and research productivity have increased exponentially, the number of people employed by IRBs and the number of people engaging in volunteer work for IRBs has not kept pace, so they get bogged down in research overload," Barrett says.

Researchers in the outliers study complained that IRBs have become overly risk-averse, applying reasonable federal regulations in ways they were not intended to be used. Some researchers also believed that IRBs had crossed the line in reviewing the methodology of studies.

Barrett says participants gave some specific examples of cases in which these disagreements hampered their work:

- One organizational behaviorist reported that he had been given permission to conduct a study in a corporation and was given a period of time in which he could conduct his research. Because of IRB concerns about his study, its review was put on hold repeatedly, for more than six months. In the end, Barrett says, the researcher lost his opportunity to do the work at the corporation.

- A community psychologist, who was doing research related to HIV at a prison, saw her proposal approved by the prison’s IRB with no problem. However, when she attempted to gather other information at a local community hospital, a different IRB wanted to make changes to the consent form indicating that some data for the study had been collected in a prison.

“They felt like that would give a stigma, and that perhaps prevent women from participating in the study at the community hospital,” Barrett says.

- The same psychologist gave another example, that of a student of hers who wanted to interview victims of sexual assault. The IRB insisted that she interview the women in a clinic setting so that there could be a psychological intervention if the subject became distraught. The psychologist noted that the student wasn’t a clinical student, and that they felt doing the interviews in a clinical setting gave subjects the impression that they were too fragile to confront the facts of their assault.

“As we thought further about recovery from trauma,” the psychologist said in her interview, “we began to theorize more about how the requirement of the IRB worked against what is necessary to be a successful survivor of sexual assault. That is, not to convey the message that someone is damaged goods or someone who the minute you ask them about sexual assault is going to fall apart or go to pieces.”

Vander Putten says that as he looked at the outliers’ comments through his eyes as an IRB chair, he sees an atmosphere in which researchers often don’t understand the role of the IRB – or their own responsibility to submit to the board’s judgment.

“Part of it may be faculty viewing themselves as independent contractors,” he says. “Faculty love their autonomy, and I think that’s important, but it’s also important to note that there are limits to that autonomy and faculty cannot always act as free agents.”

He says that many researchers harbor the opinion that IRB restraints are a violation of academic freedom, a stance that’s been rejected by the American Association of University Professors. And he notes that the time pressure researchers report is often of their own making, and could be avoided with planning. For example, he says many researchers at his college are working within the preschool-high school academic calendar, and wait until late in the year to seek necessary approvals of their work.

“I always kind of cringe about April or so because I know IRB proposals are going to come screaming in because people are going to want to collect data before the kids get out of school for the year,” he says. “The researchers place much more emphasis on getting the data than they do on protecting the rights of prospective participants.”

**Bridging the gap**

The researchers Barrett interviewed did have ideas about ways in which IRBs could bridge the gap with social scientists while still preserving a commitment to protecting research subjects:

- Find ways to manage workload and turn proposals around more efficiently.
- Create IRBs that are specific to individual academic units, which would have more understanding of their methodological approaches.
- Create an atmosphere in which IRBs see it as part of their mission to encourage good research, while still abiding by the regulations.

One participant suggested more active presentations by the IRB to inform the research community of how to conduct research properly.
Both Barrett and Vander Putten say that their experiences on the other side of the IRB review table have helped broaden their understanding of the tensions between social-behavioral researchers and IRBs.

As part of their study into attitudes regarding research, Vander Putten says he wrote IRB proposals for the different institutions at which they wanted to survey faculty and staff.

Several of those proposals were rejected by IRBs at the other institutions, despite the fact that his own IRB had approved it. It's a problem Vander Putten calls "double jeopardy," and he sees it as an emerging point of conflict in social-behavioral research review.

"I was surprised at the reasons given for the IRB proposal rejections," he says. "These other institutions were using much higher levels of scrutiny than the IRB does here for the lowest risk social science research."

Vander Putten says one proposal was rejected because the consent document wasn't written in the past tense; another was turned back because the pages lacked consecutive pagination (Page 1 of 3, Page 2 of 3, etc.).

By comparison, he says, his own IRB focused attention on what he considers to be more substantive issues, such as readability levels of consent documents or conflicts between consent forms and data collection documents.

For his part, Barrett recently began serving on a behavioral IRB at the University of Arkansas for Medical Sciences in Little Rock. He says his experiences there have helped him see the situation from the IRB's point of view.

For example, he says, he now sees some of the problems with turnaround can be caused by investigators not submitting all the necessary materials. Barrett says he also has more concerns about issues of identifiability of subjects and the readability of consent forms after seeing those issues from the IRB's side of the table.

"I think it's a two-way street," he says. "I've become more sensitized to the issues that the IRBs face as well as the issues that researchers face. I think I have more of a balance now."

Vander Putten says studies such as this one don't address instances in which the relationship between IRB and researcher does work. He worries that horror stories about "heavy-handed" IRBs have become the prevailing impression.

He'd like to see more research done on a national level to see how social-behavioral IRBs function in areas such as staffing, workload and turnaround time. While there have been some studies looking at biomedical IRBs, Vander Putten says there's a dearth of information about social science IRBs.

"What I've seen indicates to me that there are such wildly varying practices in IRB work that it's time for national data to be collected to begin empirically look at what's going on and where there need to be some standards set so there can be some semblance of consistency across institutions."

---

**EPA proposes new human subjects protection rule**

Some studies of pregnant women, children banned

The Environmental Protection Agency has released a draft of its proposed rule limiting the use of intentional dosing research on human subjects. The rule would outlaw all new intentional dosing studies involving children or pregnant women and establish a Human Studies Review Board (HSRB) to review study protocols.

But critics of the EPA's controversial pesticide study that was shelved earlier this year after raising the issue of pesticide studies involving children, say the proposed rule still isn't stringent enough.

"It must be changed dramatically from the version EPA forwarded to OMB... If not, it will still be an attack on our most vulnerable citizens," Sen. Barbara Boxer, D-CA, said in a statement released shortly after the EPA unveiled the proposed rule in September.

The proposed rule, available for review on the agency's web site (www.epa.gov/pesticides/) bans inclusion of pregnant women, infants and children in intentional dosing studies, or studies in which individuals are deliberately exposed to a substance to determine its safety.

The ban applies to EPA-conducted or EPA-supported studies, as well as so-called third-party studies, which are conducted by outside entities, often pesticide manufacturers, in hopes of winning looser restrictions on pesticide use by demonstrating safety.

Under the proposed rule, all proposed intentional dosing studies would have to comply with the requirements of the Common Rule and would have to be reviewed by an IRB prior to
submission to the EPA’s new Human Subjects Review Board.

**John Carley**, PhD, program analyst for the EPA’s Office of Pesticides Programs and one of the principal authors of the proposed rule, says the Human Subjects Review Board was one recommendation made by the National Academy of Sciences when the EPA asked for guidance on this issue.

The NAS report suggests that the board be comprised of a “small but broadly knowledgeable group of experts, with core expertise in human toxicology, biostatistics, and research ethics.” It would not, however, function as the EPA’s IRB, Carley says. “It would complement and supplement oversight by local IRBs but not supersede it.”

The NAS report suggests that the HSRB review proposed studies before the IRBs, lending their guidance to subsequent IRB review. But Carley says the proposed rule calls for IRB review first, with the HSRB serving as a final check on the process.

Although the proposed rule would ban new studies that intentionally expose pregnant women and children to pesticides, it does leave open the door for EPA to consider such studies in their regulatory actions in cases where public health would benefit. Carley says the intention would be to only do so in cases where considering a non-complying study would lead to a tougher regulatory standard for a pesticide.

“The idea is that yes, we want to discourage unethical research, but we also want to protect public health,” he says. In the case of a completed study that doesn’t comply with the rules, “no action that we do could change the conduct of the study or how the subjects were treated.”

Some critics of the proposed rule have suggested that its wording would allow use of an unethical study that could weaken an existing regulatory standard for a pesticide.

“We never had anything like that in mind, and we will do our very best to make it impossible to misunderstand in the final rule,” Carley says.

The issue of pesticide studies involving children got national attention earlier this year, when the EPA canceled the Children’s Health Environmental Exposure Research Study (CHEERS), which would have measured pesticide exposure of children in everyday residential settings. Critics including Boxer raised ethical concerns over the study.

CHEERS was not designed as an intentional dosing study, but as an observational study of pesticide use in homes with small children.

Carley says he believes a study of that kind could be designed in compliance with the proposed rule, as long as the study did not alter families’ decisions about pesticide use. He declined to say whether the CHEERS study met that criterion, saying changes were made to the design of that study as it went through the review process.

Comments about proposed changes must be received by December 12 and may be submitted in one of the following ways:

— online (go to www.epa.gov/oppfead1/guidance/comment.htm and follow the directions for online submissions);

— by e-mail, at opp-docket@epa.gov (Attention Docket ID No. OPP-OPP-2003-0132);


---

**IRBs say there’s too much work, not enough help**

*Results of 2005 Salary Survey*

There are federal regulations that are supposed to ensure IRBs have appropriate staffing levels, but respondents to the **IRB Advisor** 2005 Salary Survey could easily make one believe there are very few IRBs that meet that regulation.

Of the 80 comments offered by respondents, 45 deal directly with staffing levels, appropriate types of staff, or having the resources to pay for enough of the right kinds of staff.

In fact answers to the question, “What is your biggest personnel issue?” included:

- “Lack of resources! Can’t get my organization to understand that I need more staff.”
- “Research volume is up…They want me to decrease staff by 0.5 FTE.”
- “Finding professionals for the low rate of pay we can offer.”
- “We have over 300 studies and only 1.25 FTEs!”
- “Never enough qualified help because of institutional belief that the job requires ‘clerks.’”
Is it just the luck of the draw that so many comments related to this issue? No, says Katrina A. Bramstedt, PhD., Director of the GCRC Research Subject Advocate Program at the Cleveland Clinic Foundation. “I would say that it is a pervasive issue. In my own experience I have had to change the title of a position just so that I could get someone who was qualified for what I really wanted. You just can’t pay someone with a master’s degree $10 an hour.”

**Show, don’t tell**

Bramstedt says she was able to get more resources just by showing that the job required someone with more than clinical skills. “I went to the administrator of the department and said that what we have won’t work,” she recalls. “I showed them what I needed, and explained that the previous person had only stayed three months — the length of time it takes just to train someone. I

*continued on page 130*
2005 Salary Survey Results

A significant number of respondents are relatively new to the field; nearly 47% report working in the field one to six years.

Number of People in Department on Administrative Side

IRB staffs tend to be small — 73% reported 1-3 staff members.

Gained or Lost Staff?

Nearly 15% lost staff, but 54% reported no change in staffing levels.

How Many Hours a Week Do You Work?

Only a quarter (25%) of respondents report working a 40-hour week; 54% reported working 41-50 hours. Nearly 12% reported working 51+ hours.
outlined what the job really entailed, which was beyond what the duties in the job description said. Once I redefined the job in a more accurate manner, I was able to get more resources. I now have a great person in that position."

She says that people at a higher level don’t always understand what it is people in human research protection do. “They may hear things passively. But show them. Itemize it in a report. Detail all your tasks. Be an eye opener. And be sure you update your job descriptions regularly.”

Burning through people is a waste of time and money, she says. It is a powerful argument you can make to the folks who set the budgets for more people.

Not that it will necessarily pay off, says John Isidor, JD, the CEO of Shulman Associates IRB in Cincinnati. “My gut feeling is that most people understand staffing is an issue, but there are other competing priorities for the money,” he says.

He likens it to the situation with levees in New Orleans. There were plenty of people who knew and said that they needed to be reinforced, that a disaster was bound to occur. “The way our society works, though, is that no one wants to pay for anything until they are forced to. That includes staffing for IRBs.”

The best of them, he says, are places like Duke, Johns Hopkins, and the University of Pennsylvania, where regulators have come in and forced the issue.

Part of the problem with the regulations about appropriate staffing is that they do not define what it is, says Marjorie Speers, Ph.D., executive director of the Association for the Accreditation of Human Research Protection Programs, a calculated move. “I agree with the wording because there is no one way to staff an IRB or human research office,” says Speers.

AAHRPP has accredited 27 organizations, representing 87 entities. Another 200 are in the pipeline, she says. She says that staffing issues have turned up at some of those organizations whose applications have been denied.

More importantly, she says that the self assessments or site visits for those who have been accredited often turn up problems with appropriate staffing — either the right kinds or the right numbers of staff — and those organizations are able to use that information to justify increased funding. The accreditation process becomes a means to an end, she says.

One of the issues, says Speers, is that things have changed so greatly in the field over the last two decades. “If you go back 20 years, it was an administrative person who helped the IRB chair manage a couple hundred protocols that an institution was involved in. That staff person was a clerical person.” In addition, there was no real awareness of federal regulations, nor was there much guidance about those regulations.

That same institution is now doing maybe 10 times as many studies, and there is awareness of government rules, as well as guidance on those rules, Speers says. “Now, that clerical person is not sufficient for the job. Directors of IRBs need to have a master’s degree or even a doctoral degree. The field has professionalized.”

Change is hard, she says, and many institutions have been slow to adapt. They also have greater demand on them. They have to fund radiation safety, bioterrorism, and follow animal research regulations. “There are many competing needs,” says Speers.

There are some clear clues to whether you have enough staff or not, she says. “If it’s taking a couple weeks for a protocol to get on the IRB agenda, you’re probably fine. If it is taking a few months, that’s not reasonable.”

Keep track of your staff’s hours, and their morale level. Most importantly, pay attention to what they are saying and be proactive. “It’s not a good idea to wait until you have a serious problem,” Speers concludes.

Med students cite lack of training in medical ethics

Survey highlights shortcomings in key areas

More than one-third of American medical students are not required to study medical ethics, according to survey results compiled by the American Medical Student Association (AMSA).
Medical students told the association they are receiving traditional education but are not required to study medical ethics.

"Medical education should provide students with the information and skills they need to enter medicine as physicians worthy of the public trust," says Leana S. Wen, AMSA national president. "It is a constant challenge for medical schools to teach the traditional medical curriculum while also incorporating new, timely topics. However, it is absolutely necessary that medical schools recognize this challenge and strive to develop physicians who can effectively provide care in this modern health care environment."

"To ensure that future physicians are properly prepared and curricula are all-encompassing, students and educators must collaborate and continue to refine medical education," Wen says. "AMSA continues to work with educators to develop the best curriculum possible that not only reflects the clinical skills future doctors need but also the other aspects of being a socially responsible physician in our modern and diverse society."

The survey was conducted as a general assessment of medical students' attitudes toward medical school curricula. AMSA designed the on-line survey and solicited member response to it; 322 students responded.

For more information, visit AMSA's web site at www.amsa.org.

---

Genetic Privacy Act gains energy; Gingrich weighs in

Former House Speaker Newt Gingrich threw his weight behind a bill that would preclude genetic-based discrimination, a measure that its backers have called integral to the future of personalized medicine.

During a gathering in September on Capitol Hill, the one-time congressional leader, who these days frequently comments on health care matters in his capacity as the founder of the Center for Health Transformation in Washington, agreed with other speakers in noting that "people have every reason to be worried about genetic discrimination." His address was made to several current House members, including co-sponsors of the Genetic Information Non-Discrimination Act, as well as representatives from the Personalized Medicine Coalition and others in related spaces.

A version of the bill to prevent genetic-based insurance or employment prejudice cleared the Senate, 98-0, early this year, and a movement is afoot to bring it to a vote in the House of Representatives before this congressional session ends.

Presently, most states have some law against genetic-based discrimination for health insurance, and 33 have measures in place to prevent workplace discrimination, but previous work to enact federal regulations on both fronts has stalled.

But according to a recent poll conducted by Christy White of Cogent Research, almost three-quarters of those asked said the government should protect the privacy of genetic information. Also according to the poll, Americans are extraordinarily in favor of using genomics to improve health care, with large majorities saying that they would like to see pharmacogenomic data used to improve drug safety and efficacy. But they also fear the manipulation of their genetic information without federal regulations in place.

Among the poll’s negative findings, 68% said they are concerned about the storage of personal information and access to it, and almost a third said their concern would prevent them from having a genetic test. Further, 69% felt that insurance companies would deny coverage if a genetic profile indicated a low chance of response.

Brian Munroe, president and founder of the Personalized Medicine Coalition in Washington, who works as the vice president of government relations and public policy at Cambridge, Mass.-based Millennium Pharmaceuticals Inc., also noted recruitment slowdowns in clinical studies.

---

COMING IN FUTURE MONTHS

- The latest on federal and state rulemaking in human subjects protections
- Providing results to research participants: Should IRBs require it?
- Tailoring web-based applications to social-behavioral research
- OHRP’s updated guidance on clinical trial web sites
that employ genetic testing because participants fear signing informed consent documents.

The Genetic Information Non-Discrimination Act, H.R. 1227, was authored by a bipartisan
syndicate that includes Reps. Judy Biggert (R-Ill.), Anna Eshoo (D-Calif.), Bob Ney (R-Ohio) and
Louise Slaughter (D-N.Y.). It has nearly 130 co-sponsors and is identical to S. 306, which passed
unanimously in the Senate in February.

17. Which of the following is not considered a special challenge to research involving end-
of-life care?
A. A higher-than-usual number of SAEs, from patients who die of causes unrelated to
   the research.
B. The possibility that a lengthy survey instrument may impose an undue time risk on
dying patients.
C. Less concern about therapeutic misperception.
D. A prevalence of conditions that impair decision-making capacity.

18. In the Outliers study of social-behavioral researchers’ attitudes toward IRBs,
researchers reported that social-behavioral IRBs did not pose the same concerns that
general IRBs did.
A. True
B. False

19. Under the Environmental Protection Agency’s new proposed rule on human
testing, which body would review a proposed pesticide study first?
A. the EPA’s Human Studies Review Board
B. individual IRBs
C. both
D. neither

20. Some strategies for improving chances of adding IRB staff members include:
A. detail tasks
B. record hours worked
C. update job descriptions
D. all of the above