Overcoming barriers to Hispanic participation in clinical trials

It's more than language; trust, finances, practical issues all come into play

In the past few years, Hispanics have become the largest minority group in the United States, numbering nearly 41.3 million in the most recent U.S. Census estimates.

But they still make up a relatively small portion of the participants in clinical research. That gap is important and troubling, since diseases such as diabetes, hypertension, and heart disease are more prevalent among Hispanics and minorities in general than in the population as a whole.

The barriers that stand between Hispanics and research are varied and require a multifaceted approach to overcome, say those who work to improve minority participation in human subjects research.

At the University of Michigan (UM), an outreach program that seeks to involve minorities of varied ethnic backgrounds in research has begun to make progress in winning the trust of the Latino community and to overcome logistical barriers to Hispanic participation in clinical trials. But there are no quick fixes, warns Louise Hahn, BSN, MSA, research subject advocate for the university’s General Clinical Research Center (GCRC) in Ann Arbor.

““We believe that if we’re successful, it will be many years before our accrual numbers are as high as we’d like them to be,” she says. “We don’t expect to have a three-year program and have high numbers of participants. We really expect this will be slow. We want the community to know that we’re here, we’re interested, we’re reliable.”

Providers need to be ready with the basics

Hahn says institutions that want to beef up Hispanic participation need to be ready with the basics, particularly providing translators to decipher informed consent documents and to speak with potential participants. But they also must educate themselves about the cultures in their community and how to ensure the views of different ethnic groups are represented.
“If you have a population that’s diverse, then your IRB should be too,” she says.

While lack of proficiency in English comes to mind immediately as a barrier to participation in research, it’s not the only problem encountered by researchers in recruiting the Hispanic population.

Amelie G. Ramirez, DrPH, a cancer researcher and deputy director of the Chronic Disease Prevention and Control Research Center at Baylor College of Medicine in San Antonio, says Hispanics are severely underrepresented on available registries.

And once patients have been identified, many are ineligible for studies because of existing comorbidities.

“Our some of them may have diabetes or other health problems that may keep them from being able to participate in a clinical trial,” Ramirez says. “The numbers get really small — by the time you go through all these different steps, the population that could potentially be accrued becomes much, much smaller.”

David Gordon, MD, associate dean for diversity and career development at the UM Medical School, heads up the school’s Minority Health Research Program.

He says he sees difficulty in identifying a cohesive Latino population — that Hispanics more often organize themselves into groups such as Mexican Americans or Puerto Ricans.

“That makes it administratively harder to identify who the key people are who have a sense of the Latino community that we can appeal to,” Gordon explains.

Undocumented Hispanics often harbor mistrust

He also notes the difficulty in getting Hispanics to trust a government entity such as a university, particularly when they may be in the country without proper documentation.

“When we say we’re looking for Latino/Latina individuals to participate in research, there’s the barrier of: What is this institution? Is it part of the police? What are you really looking for?” Gordon asks.

“Particularly when you’re doing something like signing people up for registries, where you’re asking people to identify by name, you find more concern from Hispanic individuals feeling comfortable with that. Don’t get me wrong, African-Americans don’t feel comfortable about it, either,” says Gordon, who is African American. “But I can see this being accentuated a bit with certain groups, particularly with the issue of immigration or citizenship status.”

Other barriers can be financial or logistical, such as the cost of transportation to the research site or finding a babysitter to care for children, he says.
And Gordon and Ramirez both note that Hispanics raise the same trust issues that many other research participants do: Am I being used as a guinea pig? Why are you trying out this drug on me? Both say participants need to get basic information about clinical trials, emphasizing the amount of research that’s already been done on the treatment, and noting that patients will receive the best standard care in addition to experimental treatment.

**Strategies for success**

Joel Escobedo, a third-year UM medical student, recently conducted interviews with elderly residents of a Hispanic community in Chicago to discern their attitudes about participating in research. Despite lower education levels (most had only completed elementary school), most of the elders he interviewed knew about clinical research and believed it to be valuable.

The barriers most identified to participating in studies were logistical rather than cultural or psychosocial, says Cathy C. Lee, MD, assistant professor of internal medicine, with a focus on geriatrics, at the UM Medical School.

The participants said they would be more willing to participate if clinical research studies were conducted on weekends. While it was important to most that the researchers spoke Spanish, their ethnicity was not as important to these seniors. And nearly all said they would be more willing to participate if there was personal benefit or benefit to the Hispanic community as a whole.

**Hector M. Gonzalez,** PhD, assistant research scientist in epidemiology at UM, currently is conducting research among elderly Latino residents of both California’s Central Valley and southwest Detroit.

“We’re quick to point out whenever we talk to community groups that we hope the information we collect would be of benefit to them, but would also serve as a legacy to their family and their community, to better the health of the community and their family,” he says.

Gonzalez says that providing bilingual services — everything from the consent forms to the support staff — is essential for recruitment and retention of participants whose first language may not be English. For example, the group he’s following in a longitudinal cohort study in California is older than 60 years old, and more than 60% prefer speaking Spanish.

“Many of them have lived in the country for 40-odd years, and they can communicate in English,” he says. “But we want to ensure, starting with the informed consent, that they fully understand the relationship they’re engaging in as a partner in research.”

**Going beyond the trial**

In addition to fluency in Spanish, Gonzalez says staff need to be people-oriented and attentive to the needs of the participants — for example, being able to help put people in touch with other health care services as needed.

That kind of “giving back” can help researchers gain and keep the trust of the Latino community, especially in an atmosphere where contact with the government isn’t always seen as welcome.

Gonzalez notes that when he began his work in California, the state had just been through a series of propositions that were seen as anti-immigrant, and community leaders were concerned that people wouldn’t be interested in volunteering for research through a state university.

“There was concern that participants would be fearful that we were working for the government and turning in people with questionable immigration status,” he says.

Gonzalez says he dealt with the issue simply by not asking about a participant’s immigration status. “I think from an ethical perspective, it wasn’t really relevant,” he notes.

And while participation in the research did require people to give his staff a lot of personal identifiable information, staff always explained the purpose of the questions and tests.

“We had an all, or almost all-Latino staff, and I think it helps in getting away from that kind of barrier,” Gonzalez says. “I think it’s important to have people from the community, people they can relate to. We’ve had the same study nurse since day one, and she’s developed these very good working relationships with the participants.”

**Community advisory boards**

As part of its effort to increase diversity in clinical research, UM’s Minority Health Research Program set up a small extension program at a health center in Ypsilanti, MI, which has a more diverse population, Hahn says. It also set up a community advisory board with representatives from various community, religious, and other
Steps IRBs can take to increase Hispanic participation

What can IRBs do to help reach out to the Hispanic population in their own communities?

- **Make sure necessary outreach is funded.**

  Amelie G. Ramirez, DrPH, a cancer researcher and deputy director of the Chronic Disease Prevention and Control Research Center at Baylor College of Medicine in San Antonio, says IRBs need to ensure that an investigator has a budget appropriated for doing community education and outreach for their trials. In a cancer trial, for example, there should be plans to reach out to those Latinos with cancer in their own communities, through community clinics and local doctors.

  “You need to make sure they aren’t just relying on their traditional data sources such as different types of registries,” she says. “The numbers aren’t going to be there.”

  Funding should extend to covering necessary expenses for participants who may need help with transportation or baby-sitting costs, says Louise Hahn, BSN, MSA, research subject advocate for the University of Michigan’s General Clinical Research Center in Ann Arbor.

  She says the Ypsilanti community advisory board frequently takes investigators to task, asking for more compensation for participants.

- **Get community leaders involved.** Particularly if an institution is in an area with a large Hispanic population, it’s important to seek out community leaders such as clergy or educators to serve on the IRB or on community advisory boards that work with the institution.

- **Translators for documents and patients.**

  Hahn says the standard procedure at UM is to have a document translated into Spanish by one translator, then translated back into English by a second translator, to make sure the original translation was correct.

  In addition, there must be staff available who can communicate with the patients in Spanish, if necessary.

  “If at all possible, there should be a cultural match, in terms of the person who’s doing the outreach and recruitment,” Ramirez says. “And if not, definitely someone who’s culturally sensitive and bilingual would be the minimal requirement.”

  She and others note that in addition to providing a Spanish translation, documents should be written as simply as possible to address participants with less education.

  - **Make every step easier.** Institutionalize practices that make it easier for all participants to understand and become comfortable with research.

    Make sure researchers give adequate time to explaining trials and answering questions. Look at institutional barriers to participation — issues as small as parking and finding research facilities can hurt enrollment, particularly among people who don’t have much money or time.

    “What we’re trying to teach our PIs to do is to look at these things as real barriers,” says Nancy Lowenbergh, BSN, RN, a community research nurse for the Ypsilanti (MI) Health Center. “Not just: ‘Oh yeah, it’s hard to park up there,’ But this will stop people from coming to you.”

  - **Require follow-up with the community.**

    Lowenbergh says when her health center completes its first protocol, “We’re going to have a party to thank everybody, and tell people what the preliminary results are.

    “That’s another way we’re not going to drop the community,” she says. “We will also be reporting back to the community advisory board because they OK’d the protocol in the first place. Those PIs need to come back and say, here’s what I found, thanks to your work and your permission.”

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groups in the Ypsilanti area.

Protocols accepted by the GCRC also are reviewed for suitability by the board; if the advisory board approves them, patients can be recruited at the Ypsilanti site.

Nancy Lowenbergh, BSN, RN, a community research nurse for the Ypsilanti Health Center, says she extends the university’s reach into Ypsilanti’s various minority communities. She speaks at churches and health fairs, and passes out multilingual brochures at festivals and other community events.

“It’s very hard to touch our Latino community,” Lowenbergh says. “That’s why I’ve been so active with [a local Latino festival], advising them on their health tent, so I can get to be known. Now, enough people have told other people, ‘Yes, you can trust her,’ and they’ll talk to me now.”

Lowenbergh says there’s a grocery store in town where it has taken two years for her to be given permission to post notices on a community bulletin board.

She and Hahn are adamantly opposed to so-called “helicopter” studies — where a researcher descends on a community, does a study, and disappears without ever coming back to let participants know the results of the work.

“These people are used to being used; therefore,
they have no trust,” Lowenbergh says. “And one of the things I’m doing is proving to them that I’m here to stay, and I’m not going anywhere.”

IRB costs are greater than previous estimates

New figures include indirect costs

The cost of operating institutional review boards is higher than previous estimates had indicated, according to a survey published recently in the New England Journal of Medicine.

The survey of 63 U.S. academic medical centers found annual operating costs ranging from $171,014 to $4,705,333, with a median operating cost of $741,920.

It’s a finding with implications for IRBs, as they seek to make their institutional officers aware of the real price tag that comes with protecting human subjects in research.

“I think that the activity has significant costs — that’s not a surprise,” says Jeremy Sugarman, MD, MPH, MA, professor of bioethics and medicine at the Phoebe R. Berman Bioethics Institute at Johns Hopkins University in Baltimore. “But the costs are real, and as additional mechanisms are put into place to protect the rights and interests of participants, we need to understand that there are costs associated with the activities of IRBs.”

Getting at the true costs

Sugarman, the lead author for the article that ran in the April 28 issue of the publication, says that to arrive at the true costs of IRBs, his group made an effort to calculate costs that often don’t get attributed to IRB activities.

For example, 43% of the institutions surveyed don’t provide monetary compensation to faculty members and others who serve as IRB members. But Sugarman says the time faculty spends doing the work should be seen as an opportunity cost: It prevents them from doing other work. So his group calculated the amount of time spent reviewing protocols, the amount of training needed to perform the task and arrived at a calculation of the cost of that activity. Using that method, they found that board salaries ranged from $23,303 to $2,476,471, with a median of $219,349.

“Just because it is not a direct cost doesn’t mean it’s not a true cost,” Sugarman says. “We have to account for those costs, and so that’s what we did. We asked people, who is doing the job? What is their degree and experience? We found out what the average cost of paying someone like that would be and then figured out how much time they spent on those activities and then did the math.”

Other costs, such as office space or information technology, which may not have been covered in budgets as direct costs, were calculated in a similar way, he says. Some of the results:

- staff salary — $85,246 to $3,103,397, with a median of $463,107;
- space — $504 to $226,800, median $37,800;
- outside services — $0 to $275,469, median $13,347;
- equipment — $0 to $19,500, median $4,817.

The researchers also calculated how IRB staff time was apportioned: 29% on general administration, 27% to review protocols, 12% to monitor compliance, 11% on training, 9% on adverse-event reporting, and 7% on compliance with HIPAA.

Sugarman says the HIPAA result was likely as high as it was because institutions were surveyed in 2002, as they were preparing for the new privacy rule to take effect in April 2003.

“That was the HIPAA panic — no one knew what to do with it,” he says. “If you looked around medical centers, the amount of attention people were placing on that new privacy rule was enormous.”

Marjorie Speers, PhD, executive director of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), agrees that IRBs probably spend less time these days complying with HIPAA than they did at the time of this survey.

“I think institutions are still spending a fair amount of time on it,” she says. “I don’t know how much now, but they wouldn’t have as much of the start-up costs that they were experiencing in 2002.”

The researchers used their cost information to calculate the costs per protocol, based on three different categories of institution: low volume (fewer than 350 new protocols a year), intermediate volume (350-699 protocols) and high volume (more than 700 protocols).

Expedited reviews costlier?

They also broke down the costs according to type of review: full, expedited, or continuing. That
breakdown led to a notable finding: For low-volume institutions, and for all the institutions as a group, the average cost per protocol was higher for expedited reviews than for full reviews.

At first glance, Sugarman says, that result may seem counterintuitive, but it makes sense when you examine how the expedited reviews are conducted.

"Federal rules require that that's done by a chair or one of his or her designates, and that's likely more expensive," says. "If the work isn't done by less expensive people, it's probably done by more expensive people."

Speers notes that expedited reviews also require all the pre-review activities that an IRB does with any protocol.

Even though previous studies have indicated that expedited reviews can also take longer to complete than full reviews, she says that doesn't necessarily indicate a problem with expedited reviews.

**Improve efficiency, save money?**

"I think IRBs have spent a lot of time in the last few years trying to put all the policies and procedures in place to have a program that's compliant with the regulations," Speers says. "I think that what IRBs need to do now is look at whether what they're doing is the most efficient way to do it.

"In the past, there's been major concentration on compliance and not necessarily on streamlining and efficiency. I think once they have a system in place that meets federal regulations, then they can begin to address questions around efficiency," she says.

The survey's breakdowns of IRB staff — ranging from an average of six staff members at low-volume institutions to 14 at high-volume centers — can begin to give IRBs a better idea of how their own institutions stack up, Speers says.

But she says more surveys like this one are needed to help refine that process.

"Everybody in the field would like to have some benchmarks, to have a good idea how many staff you need per X number of protocols, but that's very difficult to get," Speers says. "It's very dependent on the type of system you use, the qualifications or the competency of the IRB, the number of IRBs, a lot of factors that influence those figures.

"I do think that if I were an institution trying to gauge where I am, I would look to these numbers to see if they feel right, if I feel like I'm in the range of similar institutions."

Sugarman says his group will continue to analyze the data from this survey. In the future research, he hopes to concentrate more on the relationship between the cost of IRB activities and the quality of the resulting reviews. But he concedes that will be a tough nut to crack.

"It's an enormous challenge to evaluate quality of review," he says. "There aren't really good metrics yet for quality of review."

**Reference**


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**Fear about side effects hinder trial participation**

Physicians discussing clinical trials with their patients may not realize the importance of patients' fears about side effects in making a decision about whether to participate.

That's the conclusion of a survey of oncologists and cancer patients that looked at their attitudes about various psychosocial barriers to clinical trial participation.

Neal J. Meropol, MD, a medical oncologist at Fox Chase Cancer Center in Philadelphia, studies decision making and communication regarding research. His group presented their findings in May to the American Society of Clinical Oncology's annual meeting in Orlando.

**Importance of informed consent discussions**

Meropol says IRBs reviewing the protocols should keep patients' concerns about side effects in mind when looking over informed consent documents.

"I think that special care has to be taken in the informed consent process to strike an appropriate balance between complete disclosure of potential side effects and over weighting of potential harm," he says.

Meropol says in the past five years, there has been a lot of interest in determining the importance of barriers to research participation, both
among patients and doctors. He says much of the previous focus has been on practical barriers to doctors’ participation, including lack of access to trials, not enough office time, not enough staff or reimbursement.

“The conclusion from that research has been that we have to improve access to clinical trials — we have to make the eligibility criteria looser to make more people eligible, and we’ve got to get people comfortable talking about them and we have to get doctors to recommend them. That’s what will influence patients,” Meropol explains.

He says his group came at the question from another angle, looking at the psychosocial barriers that patients experience and how those barriers influence decisions to participate or not participate in research.

**Methodology**

Using a grant from the state of Pennsylvania, researchers mailed out a survey to every oncologist in the state, receiving 137 surveys back. Each physician also was given a package of 10 patient surveys that they could either distribute themselves or could leave in their offices for patients to pick up. There were 170 patient responses to those surveys, Meropol reports.

Each group was asked about patients’ attitudes toward research — how they would rank the following psychosocial barriers to research participation:

- uncomfortable with random assignment;
- don’t trust the medical establishment and fear of being a guinea pig;
- fear of receiving a placebo;
- don’t understand what clinical trials are;
- fear of side effects.

Meropol says both the oncologists and the patients were interested in clinical trials, particularly for advanced stages of disease, after standard treatments had failed. Eighty-four percent of the cancer patients had heard of clinical trials, with white patients and more educated patients being more likely to have knowledge about trials.

**Differences were striking**

When asked whether patients would benefit from participating in clinical trials, 79% of doctors agreed, but only 57% of patients said yes.

When asked specifically about the barriers to participation, the difference in the doctors’ responses and the patients’ responses was striking.

Doctors, on average, ranked fear of side effects as the least important psychosocial barrier to participation in a clinical trial. Meanwhile, more than a third of patients ranked it as the most important barrier — the highest ranking of all the barriers cited in the survey.

Meropol says this result, while surprising, is consistent with previous studies of patients that showed they care as much about the quality of their lives as the remaining length of their lives.

“In a previous study of 328 patients considering Phase 1 studies, 96% of people ranked quality of life as at least as important as length of life,” he says. “I don’t think doctors realize this. That even people who are in the most desperate straits — everything’s failed, they’re thinking about a Phase 1 study — believe quality of life is still really important.”

**Fears overlooked**

Meropol says doctors may be so focused on the possibility that clinical trials could extend patients’ lives that they underestimate the patients’ fear of side effects from treatment.

While there were few demographic differences in patients’ rankings, he says oncologists from academic medical centers seemed to recognize a fear of side effects as more of a barrier than oncologists from community or nonacademic medical centers.

Conversely, Meropol says, doctors perceived lack of trust in the medical establishment as one of the most important barriers to participation, while patients ranked it as one of the least important.

“It may be that just the patients who filled out the survey are more trusting,” he says. “But it does raise a concern that the doctors don’t understand where the patients are coming from.”

Meropol says doctors may be overly hesitant to suggest clinical trials, believing that they must overcome severe trust issues that aren’t really that severe.

Meropol did note that some of the patients had difficulty answering the ranking questions. “A ranking question is tough for some people to understand,” he says.

In responding to patients’ concerns about the possibility of side effects, Meropol says IRBs need to strike an appropriate balance of ensuring patients get the information they need during informed consent while making sure that information is put in the proper context.
A long laundry list of possible side effects “can freak people out,” he says. “In the consent process, it’s important to stratify those side effects by both severity and their likelihood of occurrence. The challenge for those involved in consent is to devote the time necessary to really put in perspective the potential for harm and the potential for benefit.”

Meropol says he wants to confirm these findings in a larger group of patients and doctors, as well as develop tailored delivery of information to patients that can address the specific concerns they have about research.

“We need to identify who the patient is you’re dealing with and tailor your presentation to that individual, to their particular decision-making calculus,” he says. “That’s the major thrust of my research.”

Should administrators be voting members?

Yes, but beware of potential conflicts

Particularly at smaller institutions, IRB administrators who also serve as voting members can offer many benefits. They attend and coordinate all meetings, so counting them as members helps the board achieve quorum. The additional knowledge and experience with federal research regulation — as well as their familiarity with many of the protocols and principal investigators — helps improve efficiency and function.

But there are also some potential drawbacks to allowing administrators to serve as voting members, says Erica Heath, CIP, MBA, president of Independent Review Consulting (IRC) Inc., a private institutional review board and consulting company in San Anselmo, CA.

“First, it’s important not to compare apples and oranges. A CIP in a university is at a different level than a medical staff coordinator working 25% of the time on the IRB,” she says. “When there is an integrated program with sufficient staff, I see few problems. The problems I have seen and heard about are almost always in smaller institutions where the administration and IRB is taking advantage of the goodwill of a staff member.”

At smaller institutions, the administrator may be the frontline person bearing the brunt of enforcing IRB rules or giving unwelcome news to investigators. If the administrator is also a voting member, he or she may feel pressure to help certain applications get approved.

Administrators often help investigators develop their submissions — interpreting IRB questions or helping draft consent document language, Heath adds. “As the person in the middle, the administrator should not be in the position of voting on their own work or of explaining to the investigator why the vote went the way it did.”

Make expedited reviews off-limits?

The potential conflicts are particularly acute when it comes to expedited reviews. These are typically conducted by a single IRB member representing the entire board. First, says Heath, the potential for objective decision making may be compromised — since an administrator may be tempted to exceed his or her expertise or appropriate level of authority.

“The issue of membership is negligible until the administrator is asked to serve as the primary expedited reviewer making decisions for the IRB,” she states. “Then, it is easy to take on more and more power if there is a vacuum of authority. The administrator, who is often someone who is ineligible for tenure but perhaps reviewing the work of someone who is tenured or has a higher position, may feel more pressure to have an efficient process or to exceed his or her appropriate authority or expertise.”

Beware of overloading

There also is the potential for the administrator to unfairly bear the brunt of doing all expedited reviews.

“In a smaller institution [like a community hospital with a few protocols] there is likely to be only one staff member who does everything. It is a part-time job, and the administrator with very little training about IRB functions may be the best-trained person there. This person may be asked to serve in multiple roles,” Heath says. “This definitely has the potential for exploiting the administrator, asking more of the person than should be asked. It may be to the detriment of the person — without tenure — who is vulnerable to being made the scapegoat. It may be to the detriment of the research community if the person is exceeding their level of expertise. Many of the expedited review applications are trivial and should be dealt with administratively, rather than wasting the time of the
members,” she says. “But knowing when to pass the review to another reviewer is critical.”

To insulate the administrator from potential conflicts or inappropriate influence, Heath suggests the following steps:
- Have a good job description in which roles and authorities and chain of command are clearly laid out.
- Only extend the function to a mature adult.
- Offer some administrative protection for the person.
- Ensure proper supervision and oversight.
- Make the standard operating procedures SOPs clear about extent of authority.

**Clarifying the issue**

A conference call with officials at OHRP helped members of the IRB at the Community Medical Center in Toms River, NJ, decide that it was OK for their IRB coordinator to serve as a voting member.

“My institution had assumed that someone involved in the day-to-day activities of the protocols may have a perceived conflict of interest due to that relationship,” says coordinator Lucinda Girtain, CIM. “In order to avoid any unforeseen conflict of interest, my institution played it safe. I was told from the beginning that I wouldn’t vote due to the possible conflict of interest.”

However, during a transition to a new IRB director, they sought advice from OHRP via a “mock audit.”

The representative clarified that having Girtain as a member offered the IRB some substantial benefits, and that there was no automatic prohibition against someone in that position serving, she says. After a great deal of discussion and examination by the full IRB, she was recently appointed as a voting member.

“After giving it a lot of thought, I don’t think a person in my position has a conflict of interest with being a voting member,” Girtain says. “Other than the medical professionals on the board, I probably know more about the informed consent process than anyone since it is my job to scrutinize the entire submission, including the consent.

“My job is not to push for research approval at my facility, it is very simply to protect research participants, put myself in their shoes, and see that every possible courtesy is extended to them. I feel that being able to cast a vote — other than just sharing my thoughts — helps me ensure that human subject participant protection is fully considered,” she adds.

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**NEWS BRIEFS**

25% of patients don’t complete clinical trials

Only 75% of patients that begin clinical trials for drugs fully complete, according to a recent study by Cutting Edge Information in Research Triangle Park, NC, noting several reasons for this low completion rate.

The reasons for departure from a study vary from boredom to inability to get to the examination sites to feelings that the trials are not helping their ailment. Additionally, patients often complain that the risks and requirements of the study were not adequately reported to them prior to enrollment.

With the average per-patient cost of clinical trials ranging from about $5,500 in Phase I to $7,600 in Phase III, pharmaceutical companies stand to lose a great deal from such high patient turnover rates.

One way companies have been trying to improve retention of participants is through communication initiatives. The study said that at the beginning of a trial patients must be fully aware of the parameters and have access to communication avenues for questions. The best results involved treating patients as clients. Companies must treat patients with respect, define the trial for them, and keep them informed throughout the process.

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**Critic: Trial transparency system doesn’t need law**

With a bill kicking around the halls of Congress related to clinical trial transparency, some are scratching their heads over
a need for such legislation.

"The bill would mandate public disclosure of not only active clinical trials," says Dan McDonald, the vice president of Thomson CenterWatch in Boston, "but also clinical trial result information, which is in itself a very noble cause."

He's not sure the proposed law is essential. McDonald agrees that companies should make data available for consumers, but many already do just that through various registries, and his chief concern lies in the bill's requirement of posting on a central internet registry.

Such an effort already has created the www.clinicaltrials.gov web site, though that has had light usage at best. The national registry, which went live in 2000 after being established through a $215 million appropriation, has yet to receive full compliance. McDonald says not quite half the trials that should be on the www.clinicaltrials.gov web site are posted.

"There have been no FDA crackdowns on pharmaceutical companies that we know of, to get them to post this information," McDonald says. "So our point is that it really hasn't worked, not the way it was intended."

Instead, companies have posted clinical trial data on commercial registries, and have done so for about a decade. With a system already in place, McDonald says there isn't necessarily a need for legislation such as the Fair Access to Clinical Trials (FACT) Act of 2005, which Sens. Christopher Dodd (D-CT) and Charles Grassley (R-IA) introduced in February.

Its authors have proposed that the law create a registry on information for all clinical trials conducted to test the safety or effectiveness of any drug, biological product or device, including approved products, intended to treat serious or life-threatening diseases and conditions.

McDonald adds that pressure for a government-mandated clinical trials registry also is coming from the International Committee of Medical Journal Editors.

But the FACT Act is of concern to companies that fear submitting proprietary information to the registry.

"It would disclose detailed information about the design of studies, the indication targeted and a little bit about the molecules themselves to competitors," McDonald says. "Obviously, that's a big concern."

Other worries for companies relate to gathering the volumes of data to comply with requirements for such a registry, as well as determining which results, positive or negative, are worth reporting.

The FACT Act, also labeled S.470, has been referred to the Senate's Committee on Health, Education, Labor, and Pensions. In addition to Dodd and Grassley, other co-sponsors include Sens. Ron Wyden (D-OR), Tim Johnson (D-SD) and Lincoln Chafee (R-RI).

More pediatric device development needed

As part of last year's Medical Devices Technical Corrections Act, which came out in April and clarified language in the Medical Device User Fee and Modernization Act of 2002, the FDA was asked to issue a report to Congress on barriers of availability to devices intended for treatment and diagnosis of diseases that affect children.

After publishing a notice in the Federal Register asking industry for comments on what the sector needed. Additionally, last fall the FDA began meeting with professional organizations, healthcare providers, academia, consumers and other stakeholders, including a series of meetings sponsored by AdvaMed.

Overwhelmingly, according to Joanne Less, PhD, associate director of clinical research and government affairs in the FDA's Center for Devices and Radiological Health, the barriers identified by participants fall into three categories: economic, clinical, and regulatory.

Less spoke during the annual Device Submissions Workshop sponsored by the Advanced Medical Technology Association (AdvaMed) in May in Washington, DC.

Companies feel that the development costs are much too prohibitive, she explained, adding that companies perceive considerable added liability issues in the pediatric market.

"Some of the smaller manufacturers would say that if they could make a million dollars, they'd be interested in exploring the market," Less said. "Some of the larger companies would say that they weren't even interested for a million."

Other issues include a lack of reimbursement from Medicare and Medicaid, combined with an absence of a mechanism for patent exclusivity.

Drug companies often are able to take advantage
of the Pediatric Research Equity Act, or PREA. If a company conducts studies to show how its drug works in a pediatric population, PREA allows FDA to grant some level of exclusivity on the drug’s indication — for both adult and pediatric populations.

“As a result, so many companies feel that it is not worth their time or money cost to bring pediatric devices to market,” Less said.

On the clinical side, she said there is a belief that pediatric trials are unethical and that enrollment is limited by parental reluctance, concerns about testing exposure — X-rays and blood samples, for example — and geographic constraints because the populations are so small and so spread out around the country.

“It is much harder to get pediatric patients to come back on a regular schedule when they’re not hospitalized,” Less said.

When it comes to government’s role, Less said companies think that regulatory requirements aren’t clear and there needs to be more device-specific guidance for new devices and modifications to existing devices.

Frequent size changes are needed for smaller anatomy, requiring additional regulatory activity, retooling and manufacturing.

Some of the proposed solutions include more government grants for research and development for companies deciding to enter the market.

Also mentioned as a possible incentive are tax credits, as well as expedited reimbursement decisions from the Centers for Medicare & Medicaid Services.

In the regulatory arena, industry says it is looking for more guidance from FDA and perhaps even revised regulatory requirements in the form of new 510(k) applications specifically for pediatrics.

Less said the FDA currently is working on a targeted survey to see what can be done to facilitate development under current laws and how to encourage invention through changes to policy.

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**OHRP telephone numbers change**

In June, the Office of Human Research Protections (OHRP) of the U.S. Department of Health and Human Services announced new phone numbers for all its employees.

The main OHRP phone number is (240) 453-6900. The area code has changed as well as the office number. Other organizational phone numbers are available at the office’s web site. Go to www.hhs.gov/ohrp/about/phonstfa.htm to see an alphabetical listing by staffers’ last names.

Callers using the old numbers will hear a recorded message directing them to the new numbers.

OHRP’s toll-free phone number, (866) 447-4777, is unchanged.

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**COMING IN FUTURE MONTHS**

■ When government is the guardian — protecting wards of the state in research

■ Compensating research subjects: How much is too much?

■ Overcoming cultural barriers in overseas research

■ An ethicist argues for incentives to increase research participation
Physicians, nurses, and others participate in this continuing education program by reading the article, using the provided references for further research, and studying the questions at the end of the issue. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to test their knowledge.

To clarify confusion surrounding any questions answered incorrectly, please consult the source material. After completing this activity at the end of each semester, you must complete the evaluation form provided and return it in the reply envelope provided to receive a certificate of completion. When your evaluation is received, a certificate will be mailed to you.

1. Which of the following is NOT a barrier to Hispanic participation in clinical research?
   A. Language barriers
   B. Distrust of government entities such as state universities
   C. Lack of interest in clinical trials
   D. Concern about immigration status

2. At which sized institutions was the cost of expedited review greater than the cost of full review, according to a recent survey of IRB costs?
   A. Low-volume institutions
   B. Intermediate-volume institutions
   C. High-volume institutions

3. In a survey of Pennsylvania oncologists and their patients, doctors ranked concern about side effects as a greater barrier to participation in clinical trials than patients themselves did.
   A. True
   B. False

4. OHRP guidelines prohibit IRB administrators from being voting members.
   A. True
   B. False

Answers: 1-C; 2-A; 3-B; 4-B.