CLINICAL TRIALS
ADMINISTRATOR
An essential resource for managers of clinical trials

AHC Media LLC

IN THIS ISSUE

Financial Disclosure:
Editor Melinda Young, Associate Publisher Coles McKagen, Managing Editor Gary Evans, and Nurse Planner Elizabeth Hill, DNSc, report no consultant, stockholder, speaker's bureaus, research or other financial relationships with companies having ties to this field of study. Physician Reviewer Stephen Kopecky, MD, is a consultant to GlaxoSmithKline and has a research affiliation with Bristol-Myers Squibb.

JANUARY 2009
VOL. 7, NO. 1 • (pages 1-12)

Shortage of nurses, docs hurts CR staff hiring, retention rates

Salary is chief obstacle

Clinical research sites are continuing to struggle finding and retaining trained staff in an environment in which physicians, researchers, and nurses are in ever shorter supply.

The United States will need one million new nurses by 2016, and it appears that the nation's nursing schools will have difficulty keeping up with the demand, according to reports at 2008 meetings of the U.S. Senate committee on health, education, labor, and pensions.

Government and industry groups now project a physician shortfall in coming years. The Health Resources and Services Administration (HRSA) has projected that the nationwide supply of primary care physicians will be about 65,000 fewer than needed by 2020.[1]

It appears that both similar and separate marketplace trends may impact the supply of clinical trial researchers.

According to testimony at a U.S. Senate committee on health, education, labor, and pensions meeting in March, 2008, years of underfunding the National Institutes of Health (NIH) has made it far more difficult for young physicians and scientists to receive research grants. And this has had a compounding affect of discouraging a generation of researchers and, ultimately, leading to fewer treatments being tested in clinical trials.[2]

The research field also is struggling with having difficulty finding clinical trial staff to work with investigators.

Research directors continue to struggle to hire and retain clinical research associates who have the training and experience necessary to work for a clinical trial site, despite some recent increase in interest in these jobs, experts say.

"There has been a trend of people that want to get into the clinical trial field, and they truly don't have any experience," says **Tamara Dowd Owen**, RN, MSN, MBA, director of clinical trials at Pinehurst Medical Clinic in Pinehurst, NC. Owen is a member of the editorial board of Clinical Trials Administrator.

"We have had a big influx of nurses who are interested in going into research, but when you read their resumes you see that they really don't have any experience in trials," Owen adds. "It's increasingly difficult to

find experienced staff."

For clinical trial jobs that are entry level and which traditionally have been good places for nurses and other health care professionals to make a transition to research, there appears to be the opposite trend of too little interest among health care professionals.

Clinical Trials Administrator (ISSN# 1544-8460) is published monthly by AHC Media LLC, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Periodicals Postage Paid at Atlanta, GA 30304 and at additional mailing offices.

POSTMASTER: Send address changes to ***Clinical Trials Administrator***, P.O. Box 740059, Atlanta, GA 30374.

AHC Media LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media LLC designates this educational activity for a maximum of 18 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

AHC Media LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 15 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider # 14749, for 15 Contact Hours.

This activity is intended for research nurses and physicians. It is in effect for 36 months from publication.

Subscriber Information

Customer Service: (800) 688-2421 or fax (800) 284-3291, (customerservice@ahcmedia.com). Hours of operation: 8:30 a.m. -6 p.m. Monday-Thursday; 8:30 a.m.- 4:30 p.m. Friday.

Subscription rates: U.S.A., one year (12 issues), $299. Add $17.95 for shipping & handling. Outside U.S., add $30 per year, total prepaid in U.S. funds. Discounts are available for group subscriptions, multiple copies, site-licenses or electronic distribution. For pricing information, call Tria Kreutzer at 404-262-5482. **Back issues**, when available, are $50 each. (GST registration number R128870672.)

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Editor: **Melinda Young**.

Associate Publisher: **Coles McKagen**, (404) 262-5483 (colesmckagen@ahcmedia.com).

Managing Editor: **Gary Evans**, (706) 310-1727 (gary.evans@ahcmedia.com).

Production Editor: **Ami Sutaria**.

AHC Media LLC

Editorial Questions

Questions or comments? Call **Gary Evans** at (706) 310-1727.

"These jobs aren't paying well enough to convince nurses to take those positions and stay in them," says **Elizabeth E. Hill**, PhD, RN, an associate chief of staff for research at the VA Sierra Nevada Health Care System in Reno, NV.

So as research sites try to grow their research programs, a chief obstacle emerges in how to find people who know what they're doing in clinical trials, she adds.

"There's no formal education for people who will manage clinical trials at the baseline," Hill says. "I think that's a real problem because you need more expertise at this level."

Two of the main reasons why there are increasing hiring problems are because the clinical trial jobs are becoming more complex due to increased regulations, and, secondly, the salaries are not on par with the expected workload, says Ramesh Gunawardena, MBA, director of clinical trial operations in the clinical trial office of Beth Israel Deaconess Medical Center in Boston, MA. Ramesh and Hill also are members of the editorial board of Clinical Trials Administrator. (See the CTA salary survey story, inserted in this issue.)

Clinical trial coordinators are expected to complete a lot of paperwork, and they have a huge burden to learn a lot of information in a short period of time, Gunawardena adds.

This is why there is such a great turnover of employees at clinical trial sites, he says.

"One of the reasons we've identified for the high turnover rate is because clinical trial work is identified as a transitional job," Gunawardena says. "It's not seen as a professional career path, unfortunately."

Another issue is matching an employee's educational level with the job and career track, Hill notes.

"I came here from an academic environment at a big university, and I was managing a master's program in clinical research," Hill says.

"I think there's a missing piece there," she explains. "If you have people educated at the master's level, then they're not people who want to be on the frontline managing a clinical trial; they'll want to manage their career and move up."

The problem is that the clinical research industry doesn't recognize the difference between these master's level professionals who have additional research education and people who move into the field in the more traditional way of shifting from clinical work to trying research work,

Hill says.

"I have a former student who has a job at a big clinical research organization, and he says, 'I'm not using anything I learned; they start everyone at the same place, and then they move people up,'" Hill recalls. "He said he was bored because he wasn't doing what he was trained to do."

There soon might be either a solution or another contributor to the clinical trial site staffing shortage, depending on CR directors' preferences.

"One trend that I've seen is there seem to be contract services now, a new business sprouting up," Gunawardena says. "Two companies have called me to say they have a pool of study coordinators at different levels, and they could provide us with these coordinators for a certain fee."

It seems these new contracting companies are training staff themselves and creating a new career path for entry-level CR associates, he notes.

"That's a good reason why we're seeing less direct applications to us," Gunawardena adds.

Probably the best way CR directors can improve their staffing problems is by working harder to retain employees once they hire them, the experts say.

Retention is a huge issue, Owen says.

"Some people don't stay more than a couple of years at the job -- if that long," Owen says. "It might be because they came in here and decided research is too complex and harder than they thought."

Some nurses will try to treat the CR coordinator job as though they were continuing to work in a clinical setting, Owen adds.

So the million dollar question is how to attract the best and keep them. **(See story on strategies for recruitment and retention of staff, right.)**

"If you can get good people in, how do you get them to stay?" Owen says. "One thing we've discussed is trying to create some incentive within the department, such as a career ladder where staff could see some progression."

Reference

1. Steinwald AB. Primary care professionals, recent supply trends, projections, and valuation of services. Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. Feb. 12, 2008; GAO-08-472T.

2. Faust DG. Why consecutive years of flat funding of the NIH is putting a generation of science at risk. Testimony before the Committee on Health, Education, Labor, and Pensions, U.S. Senate. March 11, 2008. ■

Improve your CR site's staff recruitment and retention by following these tips

Put some added-value into career

Most clinical trial managers face the familiar problem of finding the right employees to handle increasingly difficult clinical research work and then keeping the best employees for more than a year or two.

While this is a challenge, it's not insurmountable.

Several experienced CR managers explain some of their strategies for improving staff recruitment and retention. Here are their suggestions:

• Constantly watch for the right person: It's a good idea to advertise and interview for jobs, even when there are no openings, suggests **Tamara Dowd Owen**, RN, MSN, MBA, director of clinical trials at Pinehurst Medical Clinic in Pinehurst, NC.

Although the Pinehurst CR associate staff numbers five, Owen has conducted a job interview about every three months and has frequently advertised for employees.

"What we've tried to do is be proactive," Owen says. "So even if we don't have a spot, we'll interview candidates."

You never know when the ideal candidate will come along and when a clinical research associate will resign, Owen says.

"We've talked about creating back-up PRN positions, but we haven't had any luck with those because they're hard to fill," Owen adds.

• Fight for higher salaries: The biggest obstacle to finding the best clinical research associate is a salary that's too low for the potential employee's experience and training level, Owen says.

It's worth pushing for higher salaries since CR sites have to compete with CROs and pharmaceutical companies who are larger and have the resources to offer higher salaries.

"One thing we've done is revisit our pay scales and we requested the human resources department to do a market analysis and make the necessary changes based on that analysis," says **Ramesh Gunawardena**, MBA, director of the clinical trial operations in the clinical trial office of Beth Israel Deaconess Medical Center in

Boston, MA.

"That strategy has narrowed the gap between industry and ourselves, as well as eliminating geographic differences, as well," Gunawardena says.

Another strategy is to offer bonuses.

Some CR sites will offer incentive bonuses to staff when the site meets its goals for the year, and others might offer sign-on bonuses.

"We haven't offered sign-on bonuses yet, but we've had that discussion," Owen says.

Even nursing salaries vary across the United States, so CR sites will have to come up with a salary that's competitive for their regions, suggests **Elizabeth E. Hill**, PhD, RN, associate chief of staff for research at the VA Sierra Nevada Health Care System in Reno, NV.

"If you want to hire strong nurses for research, then you'll have to offer them a little more than what they're paid in basic nursing," Hill says.

• Give CR staff some added value to jobs: "The other thing we've tried to do is enhance the value of the job, as opposed to having CR associates just come in and do the protocol and submit paperwork," Gunawardena says.

"We've tried to add some value to the job," he explains. "We've done that by adding more internalized training programs, mentoring programs, full career development, and add some value to the job so that the work won't seem to be unappreciated."

Beth Israel Deaconess Medical Center also has a program called the study coordinator round, which is like grand rounds for medical professionals, Gunawardena says.

Study coordinators and also physicians will present information about certain research topics related to clinical trials, he explains.

Conducting the educational session is appealing to study coordinators, and the lunch time event typically has a good attendance, Gunawardena adds.

"It gives coordinators a speaking engagement to put on their resume to add value, and it's a great opportunity to have the experience of public speaking," he says. "It's something they can learn from as well."

With this type of added value to the CR job, the employee might decide to stay a little longer.

"Even those people who are coming into the job knowing they might go to nursing school or medical school, maybe they'll postpone it for a year or two," Gunawardena says.

Educational sessions add value to CR staff jobs, and they also ensure that employees are knowledgeable and well-trained.

"We've revamped our training program a couple of times, and we're working on it again," Owen says. "We're putting in some measurable criteria so that within a 90-day period, staff can sign-off on certain tasks."

The idea is to have metrics in place and to make certain CR employees are exposed to everything on the priority list, she adds.

• Develop a career track for new employees: "We've changed the structure within our department, so if you started out as a research assistant you can be at levels one or two, and then you move to CRC-1," Owen says. "If you started working here without any experience, then this has been good for your career."

For senior clinical research coordinators, there's the option of giving them their own site to manage, Owen adds.

"A lot of people like that if they've wanted the opportunity and have not had that before," Owen says. "The good employees will stay, and those who are unsure will go."

The Beth Israel research site has traditionally had an extremely high turnover rate with a vacancy rate once of about 12 employees, Gunawardena says.

This experience led to changes in how the CR job track was structured.

"Over the course of two years, we've added value to these programs and created another level within the job category to improve the career path," Gunawardena says.

Now there are four job levels with adjusted pay scales according to those levels, he adds.

"This gives employees a chance to stay here for four years and maybe jump up a pay level each year," he says.

The entry level is called clinical research associate 1, and it's followed by clinical research associate 2. After that, there is a clinical research coordinator, and the final level is a clinical trials specialist, Gunawardena says.

"The clinical trials specialist is in the top tier, and at that level the person is managing a portfolio within his or her group and is contributing to the entire center, as well in terms of mentoring and training," he explains. "We have a pool of projects made available to the specialist so that he can opt to enhance his career path."

Gunawardena says his site has filled all of its job openings and has had very good success in retaining employees too.

"It's been very successful, and morale has gone up," he adds. ■

Compliance Corner

Common problems can have major consequences

Tips and strategies to prevent pitfalls

It's important to stress to clinical research staff and investigators that regulation compliance is a goal that everyone in the CR enterprise works hard to achieve, an expert says.

"We are all into this together, and we need to work on it," says **Jan Hewett,** BSN, JD, director of the University of Michigan Medical School institutional review board in Ann Arbor, MI.

Hewett tries to show investigators how it doesn't take much to create a noncompliance problem.

One small and even unintended act in noncompliance could create a big problem, Hewett notes.

For instance, supposed a young investigator didn't realize that he couldn't change his research approach without obtaining prior approval of the IRB, Hewett says.

The mistake might have been that the protocol included a procedure that the researcher failed to realize was part of standard care. So the researcher didn't need to include the procedure in the protocol. As a result, the researcher removed the procedure from the protocol, but he did so without first seeking IRB approval of the change, Hewett says of the hypothetical situation.

"In this situation you had a study design that had a subject enter the trial with a required number of lab tests and a required number of office visits for a physical," she explains. "And during the course of the study, the investigator realized the labs were not required to follow the clinical condition, in part, because during the course of the study, the tests became part of standard care that would be reimbursed by insurance companies."

This meant the young researcher could eliminate these lab tests and, instead, turn the study into an observational study, Hewett says.

"The research design didn't need to continue in the way it had," she says. "So the researcher decided to not have patients come in to have their blood work done, and as a result, 70 percent of subjects enrolled had protocol deviations."

This meant subjects' time was wasted because the study wasn't done the way it was supposed to be done, Hewett says.

When the IRB intervenes after the fact, it takes a great deal more effort to straighten out than it would have taken if the researcher had sought approval for the change before it occurred, she adds.

"The researcher should have come to the IRB for an amendment and changed the informed consent," Hewett says.

In this scenario, the investigator's lack of knowledge about the IRB process caused a study coordinator to report his noncompliance, which resulted in an investigation and remediation efforts, she adds.

This is only one example of how a well-intentioned CT change can have a ripple effect because of noncompliance with regulations.

Research institutions can help prevent such noncompliance scenarios by providing better regulatory education and training to investigators and staff and by providing investigators with support in completing documentation, Hewett suggests.

"Many institutions now have electronic human subjects research applications rather than the old method of submitting 20 written questions on paper," she says. "Within the text of questions for applications there are a large number of opportunities to provide links to regulatory guidance materials."

These serve as quick ways to educate investigators and to answer questions as they complete the protocol application form, Hewett says.

"Questions on the application have a help icon next to it," Hewett says.

As the institution has developed and improved the electronic application, the questions have been more robustly addressed, he says.

When the application was rolled out, investigators made suggestions for changes, and these were incorporated into the final product.

"We wanted to make sure they understood it, and we wanted to make sure we included all elements from the main campus and the medical campus," Hewett says.

It's more effective to make regulatory references available to investigators and to distill the information in language to which researchers can

relate, she adds.

"A large part of an IRB's and institution's role is to distill information enough that researchers know what they need and where to go for more information," Hewett says. "And they need to know how they got into noncompliance and how to not get in that state again."

One way to do this is to make certain the IRB's questions for principal investigators are well-crafted and incorporate regulatory requirements without overtly showing which direction they're going, Hewett suggests.

"When IRBs give an explanation to investigators about why they may need to amend a contingency, it's important to give a background on why this is being asked and telling them how they could prevent this from being a contingency," she adds.

It's also a good idea to provide investigators with a practice application in which they can see all of the questions that will be asked, but none of their answers will be submitted to the IRB until they complete the actual application form, Hewett says. ■

Informed consent and biorepositories

Most are okay with controversial aspects

Research participants are more open to sharing their medical tissue for research than is commonly thought, but they also do expect to hear about the results of any health findings, a researcher says.

A study of 40 people in the Durham, NC, area found that most people were comfortable with some of the more controversial elements of an informed consent document relating to tissue collected for a biorepository, says **Laura Beskow**, MPH, PhD, an assistant research professor at the Duke Institute for Genome Sciences & Policy in Durham, NC.

"We developed a biorepository consent form and recruited 40 people to have them read the form," Beskow says. "Then we interviewed them about what they thought of the form and recorded their opinions."

Participants mostly were okay with some of the issues that sometimes are debated in research ethics forums. For instance, most of the subjects were fine with informed consent language that discusses using the tissue for unspecified future research, indefinite storage time-frame for the tissue, and even for the potential of their tissue being used for commercial purposes, Beskow says.

More than half of the interviewees also were comfortable with being contacted periodically to update their personal information and to be informed of additional research opportunities.1

A majority of those who read the IC document also were willing to provide continuous access to their medical records, and most said they would not expect profits from any commercial use of the specimens to be shared with them.[1]

Although most people approved access to their medical records, this was one item that caused major concern among other members of the group, Beskow says.

The other thing that people expressed concern about was whether they would have access to their individual results, she says.

In the informed consent template, there is a bold-faced question of "Will I find out the results of the research?"[1]

The answer given in the IC template is as follows: "You should not expect to get individual results from research done with your blood. Researchers must study samples from many people over many years before they can know if the results have meaning. The results will not affect your care right now. They will be given to your doctor and will not be put in your medical record. You can get general news about studies being done through the Biorepository at this [Web site….]"[1]

"Most people understood and were comfortable with this language in the informed consent," Beskow says. "But when we asked, 'If researchers did happen to find something serious about your health, would you expect them to tell you about it?' more than three-quarters of the people said, 'Yes.'"

They wanted researchers to tell them about it as a matter of routine, Beskow says.

"I can't think of a more hotly debated topic in the research policy and ethics world," she adds. "The people we were interviewing were saying, 'I'm helping you out with this research by giving you my sample, so you should help me out if there's something you find about my health.'"

For other participants, this was considered a common courtesy, Beskow says.

"Arguments on the other side of this debate

are that if we're talking about genetic results, then even if it looks like someone is at increased risk for their condition, often times there's not something you can tell them about what to do with this information," Beskow says.

"Also, people say that giving subjects' their individual medical information is not the purpose of the research, and expecting resources to be spent on giving people advice is not the way research resources should be spent," Beskow adds.

"We also asked people in our interview if the researchers did find something serious, would they prefer the investigators contact them directly or whether they preferred to have the investigator go to their doctor with the results," Beskow says. "And I believe their preferences were pretty evenly split: some say they'd rather hear the information from their physician, and other people said, 'Oh, doctors offices are so busy they'll lose the message and forget to tell me.'"

This debate likely will continue, she notes.

On the positive side, the study's findings were good news for investigators who worry about people wanting to share in the profits of their tissue's use for commercial purposes, Beskow says.

"There's been a lot of discussion in ethics literature about this idea that commercial products could be developed," Beskow says. "And the discussion about that generally suggests that participants would be unhappy about that and wouldn't want their biologic specimen to be used to develop a commercial product that someone will derive a profit from."

This isn't as big a controversy with subjects as ethicists might expect, however.

"Not only were people comfortable with the commercial use, but some were very positive about that," Beskow says. "They said, 'That's why you do this; you do it to help people and to develop drugs and tests.'"

Beskow continues to study informed consent and biorepositories with her next study focusing on how to simplify biorepository consent documents.

"We're doing a three-part study where the first part is to ask research participants what information in the consent form is the most important in helping them make a decision about whether to take part in a biorepository study," Beskow says. "We're essentially asking people to read the consent form and highlight the sentences that are important to them if they're making a decision."

The second part is to ask IRB members and researchers to do the same thing, highlighting the IC language they think is most important for making a decision, she adds.

"We think it will be interesting to see the difference between what they say and what the participants say," Beskow says.

"And the third part of the study is to evaluate the simplified consent form as compared with a traditional consent form and having people read one version or another to test their comprehension of what they're reading," Beskow adds.

Reference

1. Beskow LM, Dean E. Informed consent for biorepositories: assessing prospective participants' understanding and opinions. *Cancer Epidem Biomark*. 2008;17(6):1440-1451. ■

Monitoring program finds common mistakes

CR site's audits show trends

The University of Virginia in Charlottesville, VA, identifies clinical trial compliance deficits and other trends fairly quickly because of a post-approval monitoring program.

"The post-approval program has been in place for around four years, and it's amazing to watch," says **Susie Hoffman**, RN, BSN, CIP, director of the IRB for health sciences research.

"Once we get a report we get together and review reports, looking for trends and the types of things a lot of people might get wrong," Hoffman explains. "Maybe investigators didn't understand an issue, or maybe there's confusion about the information we're giving them and so we need to provide more education on a topic."

Sometimes there will be a new person at the CT helm, and this person doesn't fully understand the process and might need one-on-one educational support.

"So we might go in a lot of different directions with the information we find out," Hoffman says. "Then, depending on the seriousness of the findings, we might revisit the study team and make sure they understand the information we're sharing with them."

The post-approval monitoring process has identified some of the more common mistakes investigators and CT staff make. They are as

follows:

• Failing to obtain two parent/Guardian signatures: Federal regulations, under 45 CFR 46.408(b), require both parents or guardians to sign the informed consent when a child is enrolled in a clinical trial that has more than minimal risk and no potential for benefit, Hoffman says.

Investigators might submit informed consent forms with only one signature or signatures from at least one person who is not a legal guardian.

The regulations state that both parents must give permission where "research is covered by 46.406 and 46.407 [for research with greater than minimal risk and no prospect of direct benefits to individual subjects and research that is not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affect the health or welfare of children].

Exceptions can be made in cases where one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the child's care and custody.

So if investigators obtain only one parental signature, then the reason why it qualifies as an exception should be well-documented.

• Confusion about privacy plans: Under HIPAA, investigators are asked to have a privacy plan if there's an informed consent waiver, Hoffman says.

"When HIPAA went into effect, we instituted a privacy plan for those studies with waivers of consent, and we started audits on those 1.5 years ago," Hoffman says. "We found that people didn't really understand this, so we put together education on the topic, which we call Learning Shots." **(See story on Learning Shots, right.)**

Later, the institution required that all protocols have privacy plans.

"But we feel it's important to have a privacy plan for all of your protocols, and we want the plan to be similar to the template for HIPAA privacy plans," she says.

For instance, CT staff and investigators are asked to answer these questions:

— How will identifiers be stored?

— Does it include health information?

— Where is the information kept?

— Are the identifiers kept separate from the health information so that even if the computer is hacked into the identifiers won't be found?

— Is the information stored on a computer behind a firewall and password encryption, or is it on a laptop or memory stick?

"We don't recommend investigators keep the information on their laptop or on a memory stick because they'll run into issues if it's stolen," Hoffman says.

• Enrolling subjects in more than one protocol: "In some situations this is fine," Hoffman says. "You might have a situation where one study is a drug study, and the other study involves a questionnaire that doesn't affect the first study."

But in some cases the protocols do not permit dual enrollment, she adds.

"Also, you might have a subject in two IND studies, which could really cause a lot of difficulty with the results and reliability," Hoffman says.

So investigators need to make certain that potential subjects are not already enrolled in another clinical trial, particularly when a study protocol prohibits dual enrollment as part of the exclusion criteria.

And researchers conducting investigator-initiated studies should think about writing into inclusion/exclusion criteria a requirement regarding dual enrollment, Hoffman suggests.

• Deviating from protocol: Protocol deviations vary in seriousness, but minor protocol deviations are common, Hoffman notes.

If the investigator miscalculated the investigational dose of the drug and gave the subject three times the dose, the protocol deviation would be serious.

More commonly, a subject may miss a study visit date by one day, or the CT site might fail to obtain lab results at one visit, which could be benign or serious, depending on the study, she adds.

"If we find that a study has a lot of deviations, we'll probably ask our post-approval, compliance monitors to go in and do a visit and then to send a report to the IRB," Hoffman says. "Then we'd determine what action would be required." ■

"Learning Shots" provide just-in-time education

Each is 7-15 minutes long

Research institutions often find one of the biggest educational challenges is finding times or forums that work for researchers and clinical trial staff.

Although electronic educational programs provide flexibility, there still is the problem with

researchers finding enough time to visit the educational Web sites and using the Web site to receive institution-specific policy and guidance.

So one research institution has created a model that addresses these issues. It's called Learning Shots, which are brief, voiced-over, online educational segments that are specific to the institution.

The University of Virginia in Charlottesville, VA, has developed this aspect of their continuing education model. The Learning Shots were started in May, 2007.

Learning Shots presentations provide IRB and post-approval monitoring information, says **Sarah Blackman**, an IRB education coordinator at the University of Virginia.

These targeted educational presentations range from four minutes to 17 minutes in length and cover a variety of topics. **(See list of Learning Shot topics, p. 10.)**

Like most research educational programs, this one evolved before becoming Learning Shots.

"We decided early on that one thing we could do was post PowerPoint presentations on line," Blackman says.

"Everybody does that, but we didn't know if that was doing the best job we could be doing," she adds. "Also, we couldn't always bring people to a class every time we wanted to give them new information."

Both researchers and IRB members didn't have the time for regular inservice meetings.

"So we were struggling with finding a creative way to get information out to people when they needed it," Blackman says. "Our IRB staff had a brainstorming session and decided it would be interesting to take those PowerPoint presentations and provide a voice-over for them."

The point was to create something that could be viewed on-line and which would be specific to the University of Virginia, she adds.

Using software for the voice-over, they experimented with ways to develop content that was in direct response to a message or new information that the IRB wanted the research community to know, Blackman says.

"One Learning Shot responds to the confusion some researchers had about de-identifying data and HIPAA waivers," Blackman says.

"With some minimally-risky research, you're allowed a waiver," she explains. "The key to a successful protocol in those cases is to be able to store the data in a way that reflects what you said you'd do in the protocol."

The IRB office found that research staff had some commonly-held misunderstandings of what this meant, and often there was a disconnect between what the protocol said they would do and what they actually were doing, Blackman says.

"The purpose of this Learning Shot talk is to clarify those misunderstandings," she adds. "The purpose is not to be punitive, but to provide education that will help researchers be and stay compliant with their own research protocols."

This type of just-in-time education gives the research institution the flexibility of directly addressing issues raised during internal reviews, Blackman notes.

"If everyone is confused about something, then we'll create a presentation to share with them," she says. "We'll let them know what the issue is and advise them to visit the Learning Shot, which attempts to clarify the issue."

The Learning Shots do not have to replace inservices, but they add to the menu of options available to human subjects research staff, Blackman notes.

"The on-line sessions complement the in-person mentoring we offer in our school of medicine," she says. "The research team might watch the 11-minute Learning Shot on informed consent before the mentor arrives, if they know that's a topic they'll be discussing with the mentor."

This way, the on-line education prepares staff for more comprehensive educational sessions.

Learning Shots are a service to busy researchers who might need a little help on a targeted topic, Blackman says.

Also, as researchers fill out the new protocol application form, they will see references to the Learning Shots in the electronic protocol application, Blackman says.

"If they are confused about identified versus de-identified data, then they can follow a link right there, and they're connected with Learning Shots," she adds. "Also, there are tips for international research and a process for monitoring a protocol after it's approved."

The institution's IRB staff will send Learning Shots links to researchers whenever they feel a particular lesson might prove useful, Blackman says.

"We provide the Learning Shots free-of-charge, without password protection, and if people don't like it, they don't have to use it, or if something is incorrect, I want to know about it," Blackman says. "We try to do the best we can to provide educa-

tion to researchers without asking them to give us an unreasonable amount of time in the classroom."

So far, the Learning Shots have been popular.

"We're always receiving suggestions for new topics, so we have a long list of Learning Shots topics we're trying to develop right now," Blackman adds. ■

Here's a list of Learning Shots

The University of Virginia in Charlottesville, VA, has created brief, on-line, educational sessions for the human subjects research community, including investigators and clinical trial staff.
Some of the "Learning Shots," located at http://www.virginia.edu/vpr/irb/hsr/education_online.html include these topics:

- HIPAA & Waiver of Consent Part 1: Terminology (15 min);
- HIPAA & Waiver of Consent Part 2: Privacy Plan (15 min);
- Safety Reporting Part 1: Adverse Events (8 min);
- Safety Reporting Part 2: Protocol Violations and Unanticipated Problems (12 min);
- Use of consent and assent forms to enroll minors (12 min);
- Use of short forms for non-English speaking subjects (8 min);
- Recruitment, advertising and HIPAA (10 min);
- Process for modifying IRB-approved protocols (7 min);
- The informed consent process for clinical research (11 min);
- Tips for writing better research consent forms (13 min);
- Using bullets and tables in your research consent form (4 min);
- IRB-HSR protocol submission requirements for international research (13 min);
- Continuing review and five year updates (8 min);
- Post-approval monitoring (PAM) program overview (7 min);
- Source documentation (14 min);
- Clinical researcher roles and responsibilities (14 min);
- New protocol review process for non-scientists (11 min);
- Continuations (9 min);
- Modifications (7 min).

Weigh the vulnerability of clinical research subjects

Economic, power vulnerability exist

Investigators and clinical trial associates sometimes miss the more subtle signs of vulnerabilities among potential study participants.

There are times when participants are vulnerable for economic reasons or for coercive pressures that the investigator has not fully considered.

Even when physicians who also are investigators ask their patients to consider participating in a study, this can be a situation involving vulnerability, says **Helen McGough**, who works with the Collaborative IRB Training Initiative (CITI) as a writer and editor of modules. McGough is retired from the office of research at the University of Washington in Seattle, WA, and she speaks about vulnerability and research at national conferences, including the recent PRIM&R conference on advancing ethical research, held Nov. 17-19, 2008, in Orlando, FL.

"I think researchers don't recognize that potential subjects may view the invitation to participate in research as weighted," McGough says. "If I say, 'No,' what will my doctor think of me?"

Patients have more invested in their relationship with their doctors than do the doctors, particularly if they have a life-threatening illness, she adds.

"If I have a condition that's life-threatening, then I'm a lot more vulnerable than I am with male pattern baldness," McGough says.

Vulnerability associated with powerlessness can be associated with various aspects of life, depending on a potential subject's physical health, psychological/social conditions, language differences, cultural orientation, or it can be an entirely individual matter, she says.

It's investigators' responsibility to be aware of subjects' vulnerabilities, even when the participants are unaware that they are vulnerable to making a decision without fully understanding their options, says **Monika Markowitz,** PhD, director of the office of education and compliance oversight in the vice president's office of research at Virginia Commonwealth University in Richmond, VA. Markowitz also spoke about vulnerabilities at the PRIM&R conference.

For example, a student might enroll in a study that is not specifically targeting college students. And the student might be limited in providing

informed consent because his status as a student could mean that he doesn't fully appreciate the risks to which he is susceptible, Markowitz suggests.

The student might feel pressure to please his professor, so he volunteers for a study he has heard that the professor is leading, she adds.

"It's a matter of considering the individual and having more focus on the circumstances that an individual brings to a project," Markowitz says.

Sometimes research subjects decide to participate for reasons related to their vulnerability, which poses an ethical dilemma to researchers.

"How do you make sure people understand they really are under no obligation to take part in this research, especially if they have no other choices?" McGough says. "They could be so sick that they are easily pressured into thinking the research is the only opportunity for them to receive care."

And yet if the study might offer them direct benefit, their vulnerability could be balanced by fairness and equity in research.

"I have an acquaintance who participated regularly in studies of experimental antidepressants," McGough says. "She suffered from depression and had no money, so her way of obtaining care was to enroll serially in clinical research trials of antidepressants."

This woman's economic vulnerability made it difficult for her to fully weigh the risks of clinical trials since she put so much weight on the potential benefits of receiving treatment she otherwise could not obtain.

But whether this vulnerability meant she should be disqualified from a clinical trial is an ethical question IRBs and investigators need to fully consider.

"Given our society and the way our current government is structured, there are a lot of people who don't have access to care," McGough says. "So clinical trials can be a win-win situation."

There are caveats to this approach: for instance, if CT sites discover that some participants are enrolling for these economic reasons, then they should be extraordinarily careful that the participants meet all of the exclusion/inclusion criteria for the study, McGough says.

The key is to make sure the informed consent is clear about the participant's right to not enroll or drop out of the study at any time and about how an investigational treatment is different from standard medical care.

Also, there are vulnerable populations beyond what are outlined in federal regulations.

For example, a study that enrolled gay and lesbian couples for research about domestic violence would involve a double vulnerability, perhaps, Markowitz says.

"So investigators need to be very aware of the possible vulnerability, and IRBs need to help them ensure as much as possible that risks are understood and that consent is informed and voluntary," Markowitz says.

"Investigators also need to think about vulnerabilities in an ongoing way, so that part of what they consider is what is necessary to provide ongoing protections for privacy and confidentiality," she adds. ■

CNE/CME Objectives / Instructions

The CNE/CME objectives for *Clinical Trials Administrator* are to help physicians and nurses be able to:

- **review** pertinent regulatory mandates;
- **develop** practical clinical trial oversight strategies;
- **review** best practices shared by facilities that successfully conduct clinical trials.

Physicians and nurses participate in this medical education program by reading the issue, 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 letter of credit. When your evaluation is received, a letter of credit will be mailed to you. ■

COMING IN FUTURE MONTHS

■ Use these tactics to enhance subject recruitment

■ Explore these models for PI mentoring

■ FDA answers questions about latest regulations

■ How will research funding and progress fare under

CNE/CME *questions*

1. Which of following is a good strategy for recruiting and retaining trained employees for a clinical trial site?
   A. Compare regional salaries and convince research institution to provide a more competitive starting salary
   B. Offer value-added features to the position, such as opportunities to attend and present at study coordinator rounds
   C. Develop a career track so employees hired at entry level can move up in responsibility and pay grade at least once a year
   D. All of the above

2. Which of the following is not a good way to help principal investigators improve regulatory compliance?
   A. Give investigators a reference guide with citations for all of the regulatory documents they will need to read and understand
   B. Make certain IRB questions for PIs are well crafted and incorporate regulatory requirements
   C. Use electronic IRB applications and include links to regulations and guidance at each point where a PI might have a question.
   D. None of these are good methods to help PIs

3. True or False: A recent study shows that potential research subjects were very comfortable with the idea that their tissues might be stored in a biorepository, used for research, and possibly result in commercial uses for which the tissue donor would receive now financial compensation.
   A. True
   B. False

4. Which of the following are common mistakes made by investigators, according to post-monitoring conducted at one institution?
   A. Failing to obtain two parent/Guardian signatures
   B. Enrolling subjects in more than one protocol
   C. Deviating from the protocol
   D. All of the above

Answers: 1. D; 2. A; 3. A; 4. D.

2008 SALARY SURVEY RESULTS

CLINICAL TRIALS ADMINISTRATOR

An essential resource for managers of clinical trials

Survey shows some wage growth, but experts say industry still lagging

More money needed to find, keep experienced staff

Salaries remain strong for readers of *Clinical Trials Administrator*, according to the 2008 Salary Survey.

The survey found that more than 94% of respondents reported making $60,000 or more per year. And more than 22% reported making more $100,000 or more per year.

The salary findings are not surprising given the responsibilities and experience level of the survey respondents, notes **Tamara Dowd Owen**, RN, MSN, MBA, director of clinical trials at Pinehurst Medical Clinic in Pinehurst, NC.

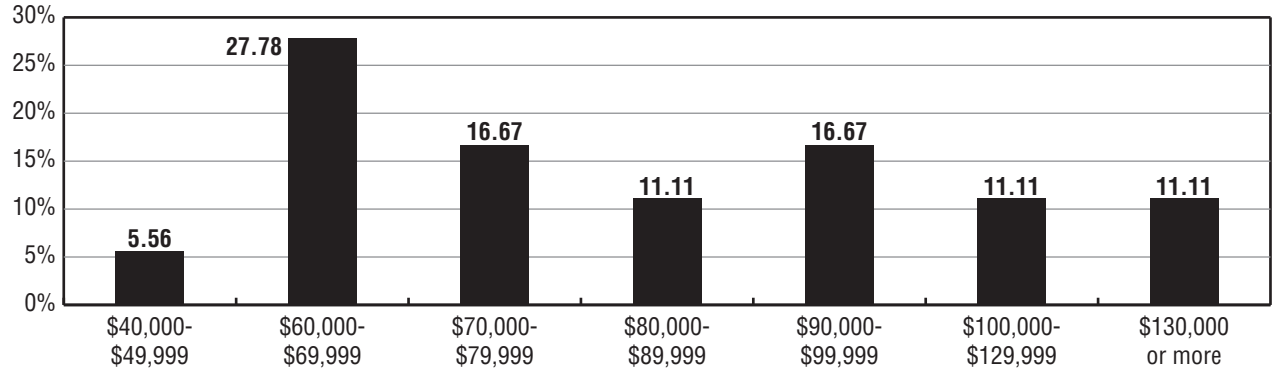
"It's an age group trend," Owen says.

Survey respondents tend to be older, with nearly 94% reporting their ages to be 36 years or older, and nearly 70% reporting an age of 51 years or older. "Salaries tend to be a little higher if you're at a director level," Owen says. "Some monitors also are making between $80,000 and $90,000 a year."

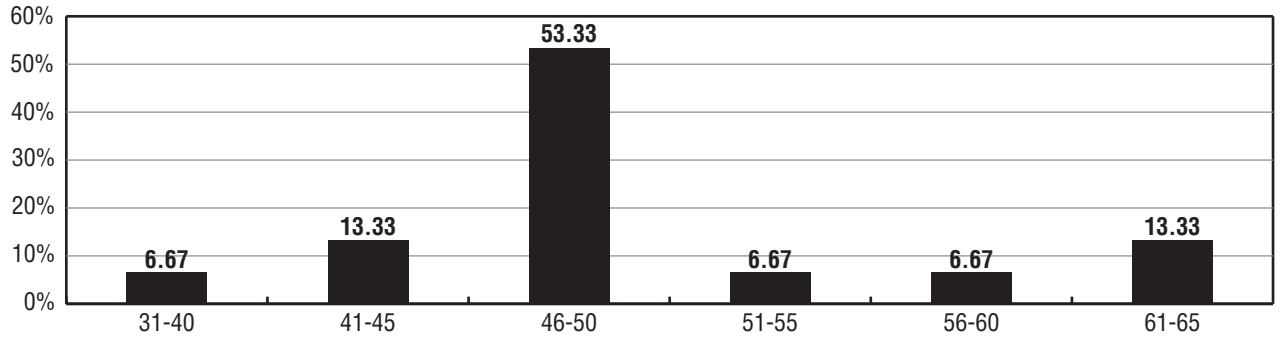
Also, the survey found that nearly 90% of respondents reported receiving a raise last year, with a little more than half reporting a modest 1% to 3% raise. Survey respondents tend to be an experienced and educated group of clinical research leaders.

Close to 95% of the people responding to *CTA*'s salary survey have worked in health care for 13 or more years, with two-thirds reporting having had health care careers of 25 or more years.

What Is Your Annual Gross Income?



How Many Hours a Week Do You Work?



Survey respondents also reported having a supervisor role with close to three-quarters reporting having four or more employees to supervise. One-half of those surveyed said their staffing levels stayed the same last year, and a little more than one-fifth said they had lost staff, while more than one-quarter said they had gained staff.

The clinical research workload for respondents meant long work weeks. According to survey results, nearly 94% of respondents work more than 40 hours per week, and a little more than half work between 46 and 50 hours per week, with one-quarter reporting having work weeks that are 51 hours or longer.

These hard-working, highly-paid, well educated, and very experienced clinical research professionals are, perhaps, the very same directors and managers who are finding it difficult to come up with salary packages that will help them recruit and retain the best qualified clinical trial associates.

"Increasingly, it's difficult to find experienced staff," Owen says. "How do you lure those people?"

About 90% of the CT associate applicants to Pinehurst Medical Clinic are coming from a nursing background, Owen estimates.

The problem is that a research site might only be able to pay a new clinical research associate $35,000 per year, which makes it difficult to recruit the most capable and bright research field newcomers, particularly if they are accustomed to higher salaries, she adds.

"For us, it's case-by-case, and we have a little bit of latitude with regard to salaries," Owen says.

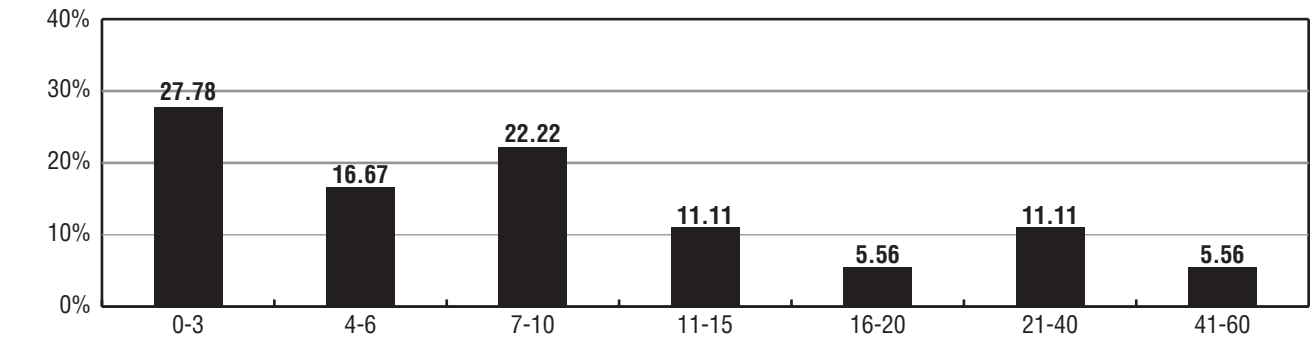
But there are times when the best qualified candidate is out of reach because of salary limitations, she notes.

"We had a job candidate from New Hampshire who was making $75,000 there and had tons of experience," Owen recalls. "We couldn't get her a salary that high — the best we could do was $65,000."

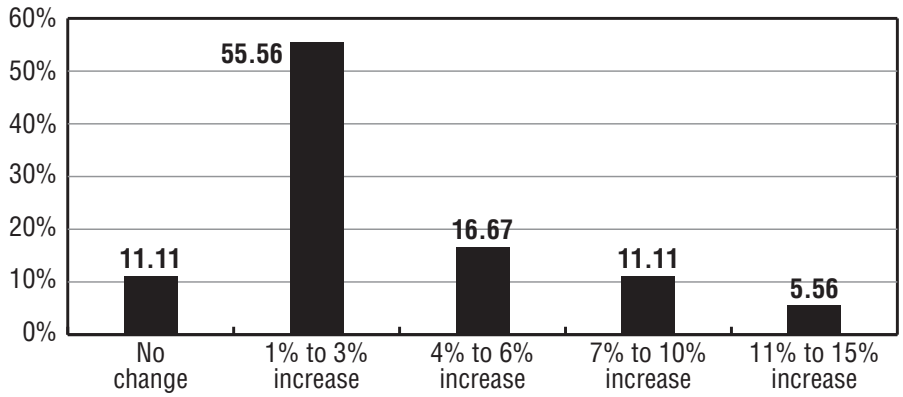
Although, the North Carolina site has a lower cost of living, the job applicant could not be convinced to take the pay cut, Owen says.

"We were at a place where we couldn't offer more, and she couldn't see how it would happen," she adds.

How Many People Do You Supervise?



In the Past Year, How Has Your Salary Changed?



One of the problems for clinical trial sites is that they compete for employees with pharmaceutical companies and clinical research organizations that sometimes can pay more for experienced staff.

"From an academic perspective, we're constantly competing with industry for staff," says **Ramesh Gunawardena**, MBA, director of clinical trial operations in the clinical trial office of Beth Israel Deaconess Medical Center of Boston, MA.

New CR associates quickly find that the workload piles up quickly at a CR site, Gunawardena says.

"You're dealing with patients and running protocols, and at the same time you have all of these requirements for submitting forms to the IRB, sponsor, handling paperwork, IND safety reports, etc.," he explains. "The workload requirement is huge, and it's not on par with what the pay scale is."

Salaries are a drawback to finding good clinical trial employees because so many of these professionals come from health care backgrounds where they were making more money, says **Elizabeth E. Hill,** PhD, RN, an associate chief of staff for research at the VA Sierra Nevada Health Care System in Reno, NV. Hill previously was the director of the clinical research management program at Duke University School of Nursing in Durham, NC.

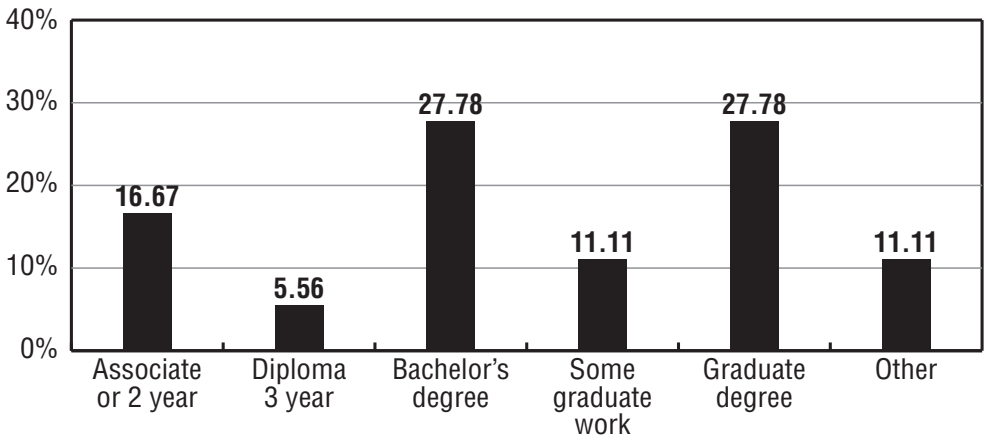
The ideal clinical trial managers are people who have been educated in clinical trial management after having some experience working in health care as a nurse or some other discipline, Hill says.

Duke University has a master's degree program in research for nurses or post-graduate certificate in research for people with master's degrees or doctorates.

Duke's model is the new trend of training research associates in an academic setting before they venture out into the CR world for on-the-job training.

Of course, these CR professionals start out their research careers at an advanced level when com-

What is Your Highest Degree?



pared with those who enter at the bottom rung.

The Duke program doesn't address basic CR training, Hill notes.

Education and training are limited for CR staff at the one or two clinical trial level, she says.

"There is a real lack of education for people at the study coordinator level," Hill notes. "It's almost all on-the-job training."

It might have worked in the past to hire nurses with no research experience and expect them to learn about clinical research on the job, but Hill says this is no longer the best strategy.

"I feel like we're past this now," she says. "You need people with some background and education in research because someone could have a PhD and not keep up with it."

However, the CR industry will have to recognize that with the updated model of hiring people who have either CR experience or advanced education in clinical research, there comes the obligation of higher salaries, Hill says.

"I've had students [with experience as nurses and] with master's degrees in research who were offered salaries of $40,000 to $50,000 or less," Hill says. "And they could make more than that as a staff nurse somewhere with no other responsibilities than getting their work done each day."

One time, a research director called Hill to find a master's level research student who had extensive health care experience.

"He wanted to offer the person $55,000, and I said, 'This is not going to happen,'" Hill recalls.

Hill had another student with a doctorate, who earned a post-doctoral degree in clinical research management, and one research site offered him $50,000. "So he went somewhere else," she says.

Since CT directors often must hire employees who have very little or no CR experience, the key is to provide thorough training, Owen notes.

"We've gotten back to the basics," Owen says. "We review regulatory pieces, things that need to be filed, IRB submissions, protocol violations, policies on reporting adverse events, and other things that people should know."

While it sounds elementary, it's necessary to go over the basics when your staff is new to research, she adds.

"Those are the things we've never felt like we needed to tell people who were experienced," Owen says.

The *CTA* survey findings come in as the health care system — normally considered a safe haven in an economic storm – starts to feel the impact of the recession. For example, fewer patients are seeking hospital care while at the same time a growing proportion of patients need help paying for care, according to a recent report from the American Hospital Association (AHA). The report also noted that hospitals — which employ 5 million people nationwide — could be facing uncertain times as their financial health falters and ability to borrow funds for improving facilities and updating technology is squeezed.

The report is based on survey results from 736 hospitals and information from DATABANK, a web-based reporting system used in 30 states to track key hospital trends. Many hospitals are beginning to see the effects of the economic downturn, with more than 30% of survey respondents reporting a moderate to significant decline in patients seeking elective procedures, and nearly 40% of respondents reporting a drop in admissions overall. The majority of hospitals surveyed also noted an increase in the proportion of patients unable to pay for care. Uncompensated care was up 8% from July to September versus the same period last year, according to the report. ■