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Class action lawsuit misses mark, say not-for-profit hospitals

Suit unlikely to address higher payments for uninsured patients

Mississippi attorney **Richard Scruggs** has targeted not-for-profit hospitals in his latest class action effort, accusing them of overcharging uninsured patients and using harassment to collect overdue bills.

But while the lawsuits are bringing fresh attention to a long-simmering problem, health policy experts and hospital officials say, they are not likely to help the uninsured.

"This lawsuit is totally baseless, without merit, and will serve only to line the pockets of the trial attorneys," says **Cheryl Iverson**, vice president for business development at DeKalb Medical Center in Decatur, GA, one of the hospitals named in the actions. "They have only gone after the not-for-profits with the largest cash reserves. All of their allegations are completely contrary to our day-to-day business practices. We in no way use harsh collection practices, and we provide seven times the value of our tax exemption in uncompensated charity care."

Scruggs and several other attorneys, including some who also collaborated with him in his precedent-setting attack on the tobacco industry, filed class action suits June 16 in federal court in eight states against 13 not-for-profit hospital systems.

A week later, the same group filed five more class action suits in three more states and, on July 7, added six new lawsuits, bringing the

total number of suits to 27 involving 15 states.

The lawsuits allege that the systems have entered into explicit or implicit contracts with their communities to provide charity care in return for significant tax breaks. The hospitals have breached these contracts, the suits contend, by charging uninsured patients premium prices while negotiating steep discounts with insurers, HMOs, and government payers such as Medicare and Medicaid. Some hospitals also use aggressive tactics to collect unpaid bills, pursuing liens on property, and assessing interest on late payments.

All lawsuits also name the American Hospital Association (AHA) as a "conspirator" with the hospitals for providing "substantial advice to the defendant nonprofit hospitals on billing and collection practices as well as other aspects of hospital operations."

"The defendant nonprofit hospitals and the AHA know full well that the uninsured patients are being charged sticker-shock prices for hospital health care. They know full well that the true fair-market value for their services are the discounted prices they have arranged for those patients with Medicaid and private health insurance. [And] they know full well that they are distorting the figures they are reporting as charity care, and that practices such as taking unpaid hospital charges as both bad debt and charity care is not appropriate," the plaintiffs' attorneys state in a press release accompanying the lawsuit filings. "The defendant nonprofit hospitals know full well that, given the vast liquid assets they hold, they can afford to honor their contractual obligations with governmental authorities as well as live up their own mission statements. These obligations and those missions are to provide charity health care for uninsured patients, the patient group which needs it the most."

The hospitals also engage in deceptive practices by overstating losses due to investments, and claiming uncompensated care as both charity care and bad debt, Scruggs and colleagues allege.

This is not the first time that attorneys have challenged the practice of charging uninsured patients higher rates than those covered by third-party payers, notes **Jay Wolfson**, DrPH, JD, professor of public health and medicine at the University of South Florida Health Sciences Center in Tampa.

Over the past decade, Wolfson has published research on the arguments for and against not-for-profit hospitals' tax-exempt status and on legal challenges to hospital charging structures and billing practices.

"For the most part, the courts have not ruled that pricing practices of hospitals are subject to judicial interaction," Wolfson says. This has occurred because some of the cases used to bring the actions have been so weak that they did not qualify (for example, using a Medicaid patient as a plaintiff — when that person would have no standing as somebody with residual financial liability). The efforts to certify a class have failed,

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Editorial Questions

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and the individual actions have not succeeded through trial."

The lawsuits are drawing new attention to the relatively hidden fact that hospital charges are often not reflective of the costs it requires to provide a needed service or procedure. For example, health care organizations frequently add to the charge for routine and frequently used health services to offset the high cost of infrequently used, expensive, yet essential services — such as maintenance of trauma and burn units and neonatal intensive care.

Certain health care charges are inflated beyond what it costs to provide the actual service. Third-party payers also negotiate across-the-board discounts for their members. Thus, the charges to insured patients are lower, while the full charge assessed to uninsured patients, in many cases, is unrelated to the cost of care provided.

However, says Wolfson, this is an issue that must be addressed on a societal level.

Burn units, for example, don't treat enough patients to pay for themselves. But communities have decided that they want these services available and it has been up to the health systems to find a way to pay for them.

"Costs have not been relative to charges for nearly 20 years," notes Wolfson. "And the concept of cost-shifting has been endorsed by many state legislatures as essential to the sustenance of health care organizations. It has been adopted as public policy. It makes sense — particularly as it relates to expensive, essential, less intensely used services — such as burn and trauma and neonatal services."

Hospitals in a tight squeeze

It also is common for large-volume purchasers of certain goods and services to negotiate discounts from the provider of such services, he adds.

"This makes fundamental business sense, the way that early-bird discounts for dinners make sense to some people," Wolfson continues. "But the way charges are constructed and included in complex billing systems may create challenges."

However, the volume discounts given to Medicare, Medicaid, and other private payers are often way below the cost of the goods or services provided, he admits. So, not only are uninsured patients bearing the brunt of paying full charges, their charges also reflect below-cost discounting given to payers that control large portions of the market.

"The prospective payment reimbursement system [used by government payers] and managed care plans literally cap payments regardless of the complexity or actual cost of an individual case," Wolfson says. "Hospitals that have large unfunded bases without any public offset face the problem of cost shifting the losses — since the historical margins enjoyed from old-style Medicare reimbursements disappeared years ago."

The Scruggs lawsuits may lead some hospitals to change their charging structures, but this could actually hurt consumers in the long run, says **Timothy D. McBride**, PhD, professor of health management and policy at St. Louis University's School of Public Health.

During managed care's heyday, hospitals had little power to charge covered patients the same rate, he notes. Managed health plans covered so much of the market that they could force systems to accept slashed fees in return for remaining on preferred provider lists.

Now, however, with many plans facing financial crises of their own, hospitals might be able to force plans to pay more.

But this also could result in substantial increases in premiums, driving more employers to reduce or drop health coverage for the employees or induce employees to give up available coverage.

"The biggest factor driving the increase in the number of uninsured people, in recent years, has been decreases on the employer insurance side — employers are dropping coverage," McBride says. "We have seen pretty good news on Medicaid side, [i.e., the State Children's Health Insurance Program] has reduced the number of uninsured kids. But the whole percentage is going up, mostly due to drops in employer-sponsored coverage — a combination of employers dropping coverage and employees not accepting the coverage when it is offered to them, but both of those trends are related to price."

Squeezed by reductions in private payer and government-sponsored health insurance reimbursements, hospitals have borne the brunt of rapidly rising health care costs in this country. These lawsuits could induce hospitals to start pushing the burden back onto the taxpayers, McBride says.

"It is a vicious cycle," he notes.

This is a problem that should be addressed at a societal level, says Wolfson. "As more people are without benefits, there are going to be more uninsured, and they require care. The cost of the care they seek has increased due to inflation, pharmaceutical and device costs, and the other forces that increase the costs of health care," he says. "Many

not-for-profits are experiencing higher rates of unfunded care, and sometimes they reasonably and truly find that a sizable portion of that population does have the means to afford some payment. Sometimes, they can afford payment of the entire amount. There is a dilemma for many policy pundits as well who allege that some portions of the uninsured population have no difficulty paying for cigarettes, expensive cars, electronic goods, etc., but are unable to pay for health care."

Health care tends to be thought of, by most people, as something that should be a purchasable commodity — until they need it, or someone they know needs it, and then they want it to be readily available and affordable, Wolfson says.

"Communities have to decide how they are going to address the needs of the uninsured," he says. "This means taking responsibility — something communities don't want to do, unless it is to fund a football stadium. We give lip service but little real credence to being our brothers' keepers. We are a crisis-oriented culture. We want instant gratification, not investment in the health and welfare and productivity of our communities."

While a societal debate over how to provide health care to the needy may be desperately needed, the problems will not be solved by this avalanche of lawsuits, says Iverson, noting the hospital administration found out about the allegations when they were called by a reporter from *The Wall Street Journal*. The official legal notification came a week later.

DeKalb Medical Center's annual tax exemption amounts to about $4.5 million; however, the hospital provides almost $40 million in uncompensated care each year.

"The hospital has a well-established policy of providing charity care to patients who truly cannot afford to pay," she says. "We work with everyone to find out whether they are eligible for any public assistance, or government-sponsored health plans, then we look to see if they meet our guidelines for charity care. If they do, we write it off, they never even get a bill. If they don't, we offer to set up a payment plan and work with them to see how much of it they can pay."

Even then, only 7% of those patients pay their bills, she says. Ninety-three percent do not pay at all, and the hospital absorbs this as bad debt.

Medicare requires, as a condition of the hospital's participation, that it make reasonable attempts to collect bad debt, she notes.

The hospital receives no support from county revenues and must find a way to keep the facility running, Iverson says, emphasizing that they do so without threatening the patients who cannot pay. "Some of the people who are uninsured can afford [health coverage] but most cannot," she notes.

Iverson says she believes the hospital will be exonerated, but notes that they have already spent a great deal of money, time, and other resources preparing to defend themselves against the charges.

"I don't know what the ultimate impact of the lawsuits will be nationwide," she says. "But, whatever the outcome, it will likely be millions of dollars that could have been spent on providing care that will instead be consumed by the legal system." ■

SOURCES

- **Cheryl Iverson**, DeKalb Medical Center, 2701 N. Decatur Road, Decatur, GA 30033.
- **Timothy McBride**, St. Louis University, School of Public Health, 3545 Lafayette Ave., St. Louis, MO 63104.
- **The Scruggs Law Firm**, PA, 708 Watts Ave., Pascagoula, MS 39567.
- **Jay Wolfson**, DrPH, JD, CPH 1126, Dept. of Environmental and Occupational Health, USF College of Public Health, Health Sciences Center, 13201 Bruce B. Downs Blvd., Tampa, FL 33612.

Public programs crowd out private insurance

Study examines impact on public health care system

Expansions in public health insurance programs are designed to offer a safety net to vulnerable Americans unable to obtain basic health insurance and regular access to medical care.

In recent years, expansions of state Medicaid programs under the State Children's Health Insurance Program have reduced the number of uninsured children in this country.

But such efforts come with a price.

For every expansion that covers those previously uninsured, some people may drop coverage, or not seek coverage they are eligible for to participate in the public program. This phenomenon is known as "crowd-out" — the public assistance program crowding private insurance out of the market.

Policy-makers are concerned about crowd-out because it limits the impact of public coverage

expansions. When crowd-out occurs, some of the scarce resources are used to cover people who would have purchased private insurance anyway.

The Robert Wood Johnson Foundation (RWJF) recently asked researchers from the State Health Access Data Assistance Center (SHADAC) at the University of Minnesota in Minneapolis to study the incidence of crowd-out.

The problem, says **Gestur Davidson**, PhD, senior research associate at SHADAC and the lead author of the RWJF's *Synthesis Report* on crowd-out,[1] is that no one really knows the best way to measure public program crowd-out, and many efforts at doing so have used different definitions and methods, thus making comparisons difficult.

"Quite a few conceptualizations of crowd-out are used in the literature, and then, within individual ways of defining the concept, there can be some differences in the way it gets measured," he notes.

There are three ways that crowd-out can occur:

• **People drop private coverage for public:** A person or family drops private insurance — either employment-based or individually purchased — to enroll.

• **A public program enrollee refuses an offer of private coverage:** Someone with public coverage refuses an employer's offer of insurance, which that person would have accepted in the absence of the public program. This phenomenon is known as "within enrollment" crowd-out.

• **An employer changes coverage offerings in response to the existence of a public program:** An employer changes elements of its insurance offerings — for instance, dropping dependent coverage or increasing employee premiums — resulting in an employee losing or deciding to drop private coverage and enroll in a public health insurance program.

Researchers measure crowd-out by examining changes in public and private coverage after the creation or expansion of public programs. However, it is difficult to determine whether changes in private coverage are directly related to public-program expansions (i.e., would not have occurred if the public program expansion did not exist). Estimates are imprecise and vary greatly depending on the type of coverage expansion and the assumptions, methods, and data used, as well as the time period covered by the study.

Researchers often measure crowd-out by observing the total change in health insurance coverage occurring over a period of time due to all possible causes — including those independent of the expansion of a public program and those related to it. Then, using sophisticated statistical models, they construct likely scenarios to estimate how much private and public insurance coverage would have changed in the absence of the expansion. Their estimate of crowd-out, presented as a range rather than a single number, is the difference between these model-based estimates of the changes that would have occurred without the program and those that did occur when the program was introduced.

However, researchers also often use different definitions of crowd-out, which contributes to confusion when differing estimates of crowd-out are compared. The most common definition compares the reduction in the share of the population with private coverage to the increase in the share of the population with public coverage due to the expansion.

A less restrictive definition focuses on the amount of crowd-out that occurs throughout the public program following an expansion — not just among the newly eligible population. This definition usually produces lower estimates of crowd-out than the previous one.

Still other studies compare the decline in private coverage associated with program expansions to the overall decline in private coverage during the period, rather than to the increase in public coverage. This approach tends to also produce lower estimates of crowd-out.

Some estimates focus on the extent to which program expansions reduce the number of uninsured. However, this broad definition can, and often does, produce a larger crowd-out estimate than the narrow definition, which focuses on how much private coverage fell as a result of the expansions.

Definitions specific to questions

Although the variety of definitions and methodologies can be confusing, it is important to understand that different definitions are used to answer different questions, Davidson tells *Medical Ethics Advisor*.

"The different definitions/conceptualizations, in fact, serve different purposes," he notes. "And one could say they yield different perspectives on how important crowd-out might actually be.

For example, using one definition, a researcher might determine that a certain number of people enrolled in a newly expanded public assistance program would have access to private insurance. However, that number might include both people

enrolling in the new program with less strict requirements and people dropping coverage who are only eligible for the older portion of the plan with stricter enrollment requirements.

Another strategy one might use, Davidson continues, is to express how much of the total public program enrollment growth over the period might have been the result of people who otherwise would have had some private insurance. This method is likely to show less crowd-out than the previous one, but researchers may have specific reasons for using this method over the other.

"Policy-makers examining different studies need to be aware of the different ways that crowd is measured and defined so that they don't make inadequate comparisons, he notes.

According to the report's findings, the potential for crowd-out is greater among families with income above the federal poverty level that are more likely than poor families to have private insurance coverage. Crowd-out rates also may be higher if whole families can enroll together in public coverage.

External factors of crowd-out

Crowd-out rates are likely to change over time, influenced by the economy, labor market conditions, characteristics of private coverage, and attitudes toward public coverage.

Examining the raw data also does not tell the entire story behind public program crowd-out, Davidson adds. "In some cases, people who drop their private insurance to enroll in the public program can substantially lower out-of-pocket costs since their premium contributions — if they are participating in an employer-sponsored program or, if they are directly purchasing private, non-group insurance coverage — can actually be quite high, relative to their available income," he says. "Moreover, many who drop private insurance might gain in the services and benefits covered as well as access to care that they now have with the public program."

This is an important point for policy-makers worried about crowd-out to consider, Davidson contends. Crowd-out can mean important benefits to some with very low incomes.

"I'm sure policy-makers do not like to think that those who could afford private insurance are taking some of the available public monies," Davidson continues. "But it is not clear how much of the crowd-out that public programs are experiencing comes from those who could easily afford good private coverage and don't buy it, but enroll in the public program, instead."

Unfortunately, there is no good way to measure the last phenomenon.

"Even if we had a single definition of crowd-out and method for measuring, it is technically so very difficult to estimate the amount of crowd-out that might be present," he says. "You cannot look at an individual case that enrolls — knowing what insurance they had just before enrolling — and confidently predict that they would have had private insurance for all or even good parts of their enrollment in the public program if the public program had not existed. People drop private insurance coverage all the time, for all kinds of reasons — enrolling in a less expensive public program is just one of them."

Just because someone drops private insurance and then later enrolls in a public program does not mean the program was the motivating factor.

"There is a similar problem with identifying cases of no crowd-out from those who are uninsured and then enroll in the public program," he says. "Some of them might have enrolled in private insurance without the public program's availability. In other words, knowing where someone came from, doesn't tell you where they would have been."

States have most commonly used waiting periods and, more recently, cost-sharing as tools to limit crowd-out in SCHIP, the authors state. While, no real evidence exists on the effectiveness of waiting periods, logically they are likely to reduce some forms of crowd-out.

To ease problems for families facing serious hardships, some states exempt families from waiting periods if they have high medical expenses, experience an involuntary loss of coverage, or purchase coverage in the individual market.

Cost sharing also may limit crowd-out by reducing the difference in out-of-pocket costs between public and private coverage, but may also discourage the uninsured from enrolling in or using health benefits offered by public programs.

Measures to control crowd-out, though hard to evaluate, are likely to result in some reductions, but they may also discourage the uninsured — those the program expansions are designed to help — from participating.

"There is an inherent trade-off between targeting efficiency [keeping crowd-out at low levels] and making significant inroads in reducing the number of uninsured," Davidson says. "You could define a program that could probably

SOURCE

- **Gestur Davidson**, Senior Research Associate, State Health Access Data Assistance Center, 2221 University Ave., Suite 345, Minneapolis, MN 55414. Telephone (612) 624-4802.

achieve very low levels of crowd-out — say, restricting it to only those who are currently unemployed or who have very low cash reserves and no possibility of using a COBRA program. That would yield a very low crowd-out, but also have very low numbers enrolling compared to the total number of uninsured."

Policy-makers should consider the trade-offs between limiting crowd-out and covering the uninsured. Crowd-out limits the impact of public coverage efforts, but lower-income families enrolling in public programs may gain a more stable source of insurance.

While anti-crowd-out measures will probably reduce the substitution of public for private coverage, they also may lower participation in public programs and raise equity concerns. They can also be costly and require substantial effort to implement.

To achieve meaningful reductions in the number of uninsured, some amount of crowd-out seems inevitable.

"This trade-off will exist, to some extent, no matter what the specific policy approach is to reducing the number of uninsured. It is not restricted to the direct expansions of public programs," Davidson says. "Programs that would provide refundable tax credits to individuals to purchase private, non-group coverage would also entail public dollars [in the form of taxes not collected], [thus] displacing private dollars, which is the essence of crowd-out. There is no getting around it."

The RWJF report and other information on public program crowd-out is available on the web at www.policysynthesis.org

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Medical research lacks female participants

Women should be recruited for clinical trials

Patients who participate in clinical trials not only have access to newer, experimental treatments, they also have access to more routine medical checkups and state-of-the-art technologies.

For people with serious illnesses, and those without access to routine medical care, participation can make a significant difference in their care.

Yet for many women, participation in medical research studies is still not an option. More than a decade after the National Institutes of Health (NIH) issued guidelines encouraging the inclusion of women as subjects in clinical research, they still are not fully represented in clinical trials that determine which drugs and treatments get marketed in this country.

Although progress is being made, advocates say, women still have a lot of catching up to do after decades of historical, cultural, and legal barriers that excluded them from both the benefits and risks of participation in medical research.

Many women are still reluctant to participate in clinical trials. And many clinical investigators are reluctant to recruit them, fearing additional complications if a female subject becomes pregnant during the course of treatment or experiences reproductive complications later.

In fact, until 1993, regulations by the U.S. Food and Drug Administration (FDA) prohibited the inclusion of women of childbearing age as subjects in early clinical trials. Those regulations have since been changed and the restriction removed, thus allowing more women to be included in clinical trials, but the results are only now being felt.

"Even though the guidelines changed in 1993, it's been like turning a battleship," says **Sherry Marts**, PhD, vice president for scientific affairs for the Society for Women's Health Research, a Washington, DC-based nonprofit organization that encourages the inclusion of women as research participants and research into gender-linked differences in health and medicine. "You have to consider trial design and finding ways to recruit and retain women into studies — that took a few years. It is really only in the last few years that some of the data are starting to emerge. That shows you how long it takes to change the system. Data that you collect today will be in front of the FDA in 10 years."

Though more women are being recruited and are participating in clinical trials, there is little

evidence that researchers are examining the data to look for any differences in response that might be linked to gender, Marts says.

"That is sort of the follow-up issue to inclusion," she notes. "What's the point if you are not going to at least look to see if there is a difference?"

The 'male norm'

Historically, women were excluded from participation as research subjects because of the risk untested agents posed to their future children, says **Georgia Sadler**, MBA, PhD**,** clinical professor of surgery in the Cancer Prevention and Control Program at the University of California-San Diego, and director of the center's community outreach program. Even today, investigators must take painstaking steps to ensure that participants are not pregnant when a trial starts and they understand the importance of not becoming pregnant during the course of the trial.

"There is always the concern about doing harm. You want to weigh the risks and benefits," Sadler says. "You want more benefit than risk — that is the goal, especially when there could be another person involved, namely the child."

Prior to the change in regulation, women of "childbearing potential" (i.e., those who had not yet reached menopause or not undergone a sterilization procedure) were excluded from early trials of drugs that had not been tested for the potential to cause birth defects.

Exceptions were made in instances in which a patient had a life-threatening condition and no other source of treatment was available, Marts adds. "It meant that there were some women in cancer clinical trials, but it did keep them out of trials of most drugs, and it certainly kept them out of the early phase trials," she says.

For many years, the medical community assumed that what worked in men would work — and work in the same way — for women, and vice versa. Drugs not proven effective in male subjects were assumed to have no value for women either.

"For a long time in medicine, we had this thing called the 'male norm,'" Marts continues. "I say this in my talks and it always gets a laugh, but it is true. It was just assumed that the male was 'normal' and women were just small men with different plumbing and a hormone problem. Come to find out, we are not. Our biologies are very different, and that has an impact on our health."

Recent experience has borne this out.

For example, the only two drugs currently marketed specifically to treat irritable bowel syndrome seem to be more effective in women. And there are drugs that metabolize differently in men and women.

"There are some drugs that women break down faster than men, so they may need a higher dose or more frequent dosing, and there are some where it is the other way around," Marts says. "It is very challenging to kind of break the data out and figure out exactly what is going on."

Pharmaceutical manufacturers have an understandable disincentive to discovering the need for different doses for different populations, she adds. It is great if one dose works for everyone, but that's not always the case.

And although more women are being included in clinical trials, there is some residual perception that trials are easier with men as subjects.

"We understand perfectly that manufacturers have a profit disincentive to doing this because if they look for a difference, and they find one, then they are going to have to label the drug to say, 'These people should take it,' or, 'These people should not,'" Marts says. "When Drug Company X is looking for the next blockbuster 'everybody's-gonna-take-this' drug, then some advocacy group comes along and says, 'But does this work differently in women than in men?' The reaction we get is, 'We don't want to know.'"

There still is an issue of the risk should a female subject be in the early stages of pregnancy and not know it, or, equally dangerous, become pregnant during the course of the trial.

However, both Sadler and Marts say this potential complication is overblown in the minds of some researchers.

"You can ask a woman, 'Is there any chance you might become pregnant?' By definition, that means, 'Have you missed your period?" says Sadler. "Once you have determined that she is not pregnant right now. The next question would be, 'Are you trying to get pregnant, or do you have any plans to get pregnant? If you have someone who says they are, then you could exclude them because of the potential to do more harm than good."

The riskier the product being tested, the more solid assurance the investigators will want that subjects are not going to become pregnant, she continues. "If you are doing things that are relatively safe, you might say, 'Well, being on birth control is probably adequate, but if you are testing a new drug for the first time in humans, and [the drug] was highly toxic in animal models, you might say that, unless the person has had her

tubes tied or some other procedure, you might not want to take the chance."

During the informed consent process, it also is important to emphasize this risk, the importance of not becoming pregnant, and — should an unplanned pregnancy occur — stress that the investigators need to be notified immediately.

Even with the change in the guidelines and attempts by many investigators to recruit female participants, women are not exactly knocking down clinic doors to get into trials.

Recruitment woes

Almost any conference involving research professionals will feature a session on recruiting women and minorities — and usually, it's a single session titled, 'Recruiting Women and Minorities,' as if they were one population, Marts notes.

"You still tend to hear investigators say, 'Oh, but it is so hard to recruit and retain women," she says. "I always ask them, first of all, 'Are you listening to your site staff?' Maybe they have some ideas about how to do this better."

There are some recent examples of large-scale clinical trials involving women and other populations who were thought difficult to recruit that can provide helpful lessons about how to recruit and retain study subjects.

The first, says Marts, is the Women's Health Initiative, which recruited many older women and followed them for several years. "People said it could never be done. You could never recruit that many older women and keep them in the trial," she points out. "But, as we know, they did."

Other examples can be found in the HIV prevention trials that involve women who are either drug users, partners of drug users, or are professional sex workers.

There are some study sites that have had 98% retention rates over two-year periods with these populations, she says. The sites developed unique ways of maintaining contact with these women, even though the subjects may have been moving frequently, sometimes in and out of homeless shelters, or work in dangerous and illegal conditions — not exactly conducive to regular follow-up visits.

"What they are finding is that it takes more than just herding people into the clinic, performing the visit, writing the next appointment on a note card, patting them on the head, and sending them out," Marts says.

Because women typically shoulder the lion's share of responsibility for child care and household maintenance, clinics that offer weekend and evening hours, and those that combine multiple services (blood draws, X-rays, other monitoring) at a single visit are often more amenable to female participants, she adds.

They also may be concerned about the safety of the clinic's location, and whether security is provided.

Obviously, this is not a sole concern for female participants, Marts adds, and researchers may find that concessions they make to attract female participants may recruit more participants overall, as well.

Working on a contract with one of the HIV vaccine trials, Marts helped produce a video featuring the subjects talking about the benefits of participating in the study. "There was one interview with a drug addict — who, in this instance, happened to be a man — and the interviewer asked, 'Why are you doing this? Why agree to be in the trial?'" she relates. "The guy looked at her and said, 'Lady, I'm a junkie. No one has ever asked me for nothing. These people came, and they asked me to do something for other people. How could I say no?'"

Because clinical trials have, in the past, focused exclusively on men, it's possible that many women simply don't recognize this as something that is possible for them — they don't realize they are able to contribute, Marts notes.

"It is sort of a truism in the not-for-profit world that people don't volunteer unless they are asked. One of the things that occurred to us early on after they changed the guidelines was that half the population had been reading about medical research and seeing reports in the news, and it was always about men," she says. "Heart disease in men; men should take aspirin, etc. We imagined that women simply don't feel asked. They don't feel welcome to participate in these studies."

To help remedy that problem, the society initiated its "Some Things Only a Woman Can Do" campaign, which included a web site, brochures, and other educational materials that encourage women to consider participating in clinical trials.

"It emphasizes that you don't necessarily have to have a disease or condition to participate, and women are really intrigued to find this out," Marts says.

Conducting clinical research on essentially one population — white men — has handicapped medical research in a number of ways. Studies that include diverse groups of people can yield better information, faster, notes Sadler, whose research focuses on improving recruitment of both women and minorities. "It is important, for example, to

SOURCES

- **Sherry Marts**, Society for Women's Health Research, 1025 Connecticut Ave., Suite 701, Washington, DC 20036.
- **Georgia Sadler**, UCSD-La Jolla Campus, 9500 Gilman Drive, La Jolla, CA 92093-0658.

have women of childbearing age represented in clinical trials. Let's say you are looking at blood pressure medication for hypertension. You would not want to exclude women between the ages of 18 and 50 [because] that is a large segment of the population that will eventually take this medication," she says. "Would you want them to take it without it ever having been tested in that population? That is essentially what happens now. If you have a study, and you don't have a large enough representation of African Americans, Hispanics, or Asians, it is the same thing."

The issues go beyond just genetics and gender, she continues. For example, say a particular drug does really well in subjects who are Asian women, but none of the other participants. Researchers would then look to see why. Perhaps it is something in the diet that these women all had that enhances the drug's efficacy? Once that is determined, that information could be included in the drug's labeling.

Conversely, say a certain group does poorly in a trial. For example, all of the Hispanic men don't respond. Perhaps there is a reason there. Once the likely cause is found, then researchers can recommend a possible solution.

However, if these people are never represented in clinical trials, this information is likely to never be found. For example, say the drug that worked so well for Asian women only is tested in groups of Caucasian men, is found to not work well, and is dropped. Researchers would never know its true potential.

Or suppose a drug that has significant complications for people with certain dietary habits or genetic differences makes it to market. Patients who do not respond to the drug, or worse, experience a poor reaction, are rarely noted.

Outside a clinical trial, Sadler says, individual complications or adverse events occur too far apart for their significance to be noted.

Sadler and her colleagues at the University of California-San Diego have initiated several projects attempting to improve the recruitment of women as clinical research participants.

First, they have written articles in several different professional journals advocating the benefits to patients who participate.

"The media has given clinical trials a bad public reputation," Sadler says. "There are a lot of good things you can say about clinical trials, but you don't hear about it in the media. You only hear about the bad cases, where someone is injured or a participant dies."

The public, at large, has no idea that development of new drugs and treatments would not happen if patients did not sometimes agree to be subjects. "You may read an article about a new exciting drug that has now been found to reduce cancer mortality by 10%, but you never hear about the clinical trial that yielded this information," she continues. "It looks like it just appeared out of the clear blue sky — someone figured it out, and it worked. No, it was actually 10 different studies and 895 people took part in those various studies. They were Phase 1, Phase 2, and Phase 3 studies; and now, eight years later, here are the results [that] they are very excited to bring that to you. You never see that information in a newspaper article or TV report."

Sadler has written articles for nurses, physical therapists, chaplains, and even nurse-midwives.

"We wanted to reach people, in addition to physicians — who may not have enough time to talk with patients at length about clinical trials in general — [and whom] patients might seek advice from," Sadler says. "We want those professionals to know about clinical trials so that they can pass on reliable information."

Sadler's group also works to enroll women in small research studies that are very low risk, such as opinion surveys, to acquaint them with the informed consent process. At a later time, some of these people may have a chance to be a trial subject, and will hopefully find the

COMING IN FUTURE MONTHS

- Peer review of expert witness testimony
- Informed consent for telephone calls to physicians
- Addressing requests for inappropriate or unnecessary care
- Hospital policies on incapacitated patients without surrogates
- International bodies examine organ transplant ethics

process less intimidating.

"One of the reasons we spend so much time educating health professionals and the public is to try to help communities understand that 'no participation' is really 'no voice,'" Sadler says. "Someone has to step up to the plate. Obviously, we are not saying everyone should do everything, but keep your eyes and ears open, and don't have a knee-jerk negative response." ■

Some journals fail to enforce disclosures

Report finds lax conflict-of-interest disclosures

Several leading medical and science journals fail to enforce their own policies for disclosing financial conflicts of interest among contributing authors, according to a study released July 12 by the nonprofit Center for Science in the Public Interest (CSPI).

The study examined 163 articles in the *New England Journal of Medicine (NEJM),* the *Journal of the American Medical Association (JAMA), Environmental Health Perspectives (EHP),* and *Toxicology and Applied Pharmacology.* It identified at least 13 articles where authors did not disclose relevant conflicts of interest that should have been disclosed according to the journals' policies. CSPI found another 11 articles where there were undisclosed conflicts of interest that might not have directly related to the subject at hand, but should have been disclosed nevertheless.

"Published research that fails to disclose authors' ties to drug companies threatens the credibility of scientific journals and rightly undermines public confidence in studies about the safety or efficacy of various drugs or chemicals," said **Merrill Goozner**, director of the Integrity in Science Project at CSPI and the author of the study.

Nondisclosure of financial conflicts of interest was a problem at all four journals, the study found, but *JAMA* had the highest rate of nondisclosure of conflicts at 11.3% (six out of 53 articles). The undisclosed conflicts in *JAMA* ranged from consulting fees from companies immediately involved in the subject of the study to authors holding patents on technologies that may one day prove valuable because of information contained in the study.

CSPI recommends that journal editors require authors to disclose any financial arrangements they have had with private firms within the past three years, regardless of whether those arrangements relate to the subject of the article, and that the conflicts be published if they are in any way related to the article's subject. CSPI also says that authors should be required to disclose any patent applications, or intentions to apply for any patents. To encourage authors to comply with journals' policies, CSPI also recommends that editors adopt strong sanctions for failing to disclose conflicts of interest, such as a three-year ban on publication imposed on authors who fail to make complete disclosures.

"Some of the blame for the failure to disclose these conflicts rests with the individual scientists, who clearly feel comfortable withholding fairly glaring conflicts," Goozner said. "But much of the blame must rest with the journal editors themselves, who, for the most part, have created disclosure policies that too narrowly define what conflicts are relevant."

When asked about the study, some journal editors said the CSPI report unfairly implied that prior corporate consulting relationships were an inherent conflict of interest and defended their monitoring of compliance.

Gregory Curfman, executive editor of *NEJM*, told *The Wall Street Journal* that the center's criticism levied against the two researchers in the journal was "underwhelming," noting that their article didn't involve assessments of any drugs or products. He added that, while the *NEJM's* disclosure policies may not be perfect, "we spend a lot of time on this."

Editors of some of the other journals covered, however, told the newspaper they welcomed the report. "We really rely upon scrutiny of these disclosure statements by other scientists and outside organizations," said **Tom Goehl**, editor-in-chief of *EHP*, who added that his editorial board plans to discuss whether to impose sanctions on researchers who fail to disclose conflicts.

SOURCE

- **Merrill Goozner**, Center for Science in the Public Interest, 1875 Connecticut Ave. N.W., Suite 300, Washington, DC 20009.

Reference

1. Tomsho R. Report faults scientific journals on financial disclosures. *The Wall Street Journal,* July 12, 2004: p. 3/section D. ■

CME instructions

Physicians participate in this continuing 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, you must complete the evaluation form provided at the end of each semester 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. ■

CME Questions

5. According to our article, class action lawsuits against several not-for-profit hospitals accuse the institutions of:
   A. Unfairly charging higher prices to uninsured patients.
   B. Using overly aggressive tactics to collect unpaid bills.
   C. Distorting financial information to hide profits.
   D. All of the above

6. According to our article, legal challenges to hospital charging structures have:
   A. Been successful in the past.
   B. Resulted in some limited change
   C. Not been successful in the past
   D. None of the above

7. Public program "crowd-out" of private coverage occurs when:
   A. Public programs institute policies that are much less expensive than private insurance in a given area.
   B. People drop private coverage in order to enroll in a public program.
   C. Public program expansions result in employers limiting or adjusting their health plans in order to encourage employees to enroll in the public program.
   D. B and C

8. According to our article, prior to 1993, women were:
   A. Not allowed to participate in clinical trials at all.
   B. Only allowed to participate in clinical trials if they could demonstrate they were incapable of becoming pregnant or suffered from a life-threatening condition for which no suitable alternative treatment was available.
   C. Were allowed in Phase 1 and 2 trials but not Phase 3
   D. None of the above

Answers: 5-D; 6-C; 7-D; 8-B.