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Hidden insurance crisis: Coverage worse than statistics indicate

Going without insurance not just a problem for the poor

The nation's insurance coverage crisis is even worse than many policy analysts have feared, with nearly 38% of Americans younger than age 65 going without insurance at some point over a four-year period from 1996-1999, according to a study sponsored by the Commonwealth Fund, a private, social research foundation based in New York City.[1]

"The shocking thing about this study is that we are used to thinking of this as a 15% to 17% problem — that roughly 15% to 17% of the population under age 65 is uninsured — and this is telling us that it is a 40% problem," says **Karen Davis**, PhD, the fund's president and former chairman of the department of health policy and management at the Johns Hopkins School of Hygiene and Public Health in Baltimore. "In fact, it is a 70% problem among low-income people."

In August, the U.S. Census Bureau released statistics showing that 2.4 million people lost health care coverage in 2002 — a 6% increase from the previous year. In total, the bureau report indicated, 43.6 million Americans were without health insurance, representing about 15% of the population.

However, the Commonwealth Fund's study of additional data collected by the bureau indicates that cyclical loss of coverage affects almost 40 million more Americans and similarly can have devastating affects on access to care, Davis says.

Researchers at the department of health policy at Pennsylvania State University analyzed data from a survey of 40,000 people conducted by the Census Bureau. The bureau collected monthly data on insurance coverage for these survey respondents between the years 1996 and 1999.

The data indicated that two out of every five people surveyed had been without coverage at some point during the four years. Extrapolating the data to the general population, it indicates that a total of 85 million Americans were uninsured at some point during that time, says **Pamela Farley Short**, PhD, professor in the department of health policy

at Pennsylvania State University in University Park and the lead author of the study report, which was published in the November/December edition of the journal *Health Affairs*.

"The average American faced a 40% risk of being uninsured over those four years," Short says. "That's in the same sense as a 40% chance of rain some time in the day."

The figures 85 million and 40% are double what most people usually hear in discussions about the growing numbers of uninsured, she notes.

"Something in the neighborhood of 40 million people are uninsured on any given day," she says. "But 85 million people are uninsured at some point over four years. The time frame matters because, as studies like ours show, there's a lot of turnover and churning in health insurance. From our study, we estimate that about 2 million people drop out of coverage each month; but 2 million other people, people who had been uninsured, got into a private or public insurance plan."

The poor also are much more likely to go without insurance over a given period of time, the study indicates.

Almost 70% of families with incomes lower than 200% of the federal poverty level went without insurance at some point over the four years. And, when poorer people were uninsured, they were much more likely to get trapped in an on-again, off-again cycle of maintaining insurance.

And of those who lose insurance — even though they regain coverage — typically go without for significant periods of time. Their study also indicates that only about 20 million people were uninsured for four months or less, she says.

"There were 45 million people who were uninsured for more than 24 months out of the four years that we tracked," she adds. "That's at least 24 months out of 48."

Many people cycle in and out of health coverage, what Short refers to as "having battery-powered health insurance" because they have it for awhile then it goes off, then it comes back on again.

"That's in contrast to the situation that most of us would like to be in, where we plugged into a stable source of coverage," she says.

Impact on outcomes and cost

Such churning can have devastating outcomes for the intermittently insured as it does for the uninsured, explains **Benjamin K. Chu**, MD, MPH, president of the New York City Health and Hospitals Corp., the public hospital system for the state of New York.

"The most important thing about health care is continuity, especially when you are talking about illnesses that we can prevent or chronic diseases," Chu says. "It's the worst thing in the world to start a series of treatments, try to get up a head of steam to manage someone, and then all of a sudden have

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them fall out, not be able to come, or not be able to access medications. You tear your hair out trying to figure out why somebody's control of their chronic disease is so off the wall, and that's when you realize that there are economic reasons for this."

And the burden of providing unreimbursed care to uninsured patients also is continuing to strain the resources of the safety nets designed to keep these patients from falling through the cracks, another Commonwealth Fund study indicates.

A national survey of primary care internists, also published in the same edition of *Health Affairs* as the coverage study, indicates that two-thirds of internists in private practice help uninsured patients by reducing or waiving fees for office visits. and more than two-thirds provide some sort of charity care each month.[2]

However, the same group of doctors indicated they felt they were unable to provide an appropriate level of care to these patients because of difficulties obtaining appropriate specialist referrals and medications.

Less than one-third of survey respondents indicated they could get reduced cost medications for the uninsured patients and just 9% indicated they could get reduced-cost lab tests or diagnostic procedures.

Nearly half of the respondents indicated their uninsured patients failed to follow advice or obtain follow-up tests or take prescribed medications because of cost concerns.

Churning also hurts the entire health care system because the administrative costs of enrolling persons into health plans — and for publicly funded plans, the costs of verifying continued eligibility — are so significant, Chu adds.

His hospital system has its own health plan for low-income residents, Natural Plus Health Plan, which has 190,000 enrollees, he says. The cost of enrolling each new person is approximately $280, and the plan has a one-year recertification process. So, at the end of the year, plan administrators must go through another process to determine whether the enrollees stay on. That costs about $80 per person.

"And those costs don't include all of the inefficiencies that come from claims adjudication and other types of reconciliations that we go through on a monthly basis," he notes. "When you look at it, it is almost $400 per year to sign someone up and keep them on. And for a typical child, with annual premiums around $1,200, almost a third of that money in any given year is used for administrative costs."

Repeated cycling on and off plans just means that these administrative start-up costs get wasted when coverage is lost, and additional money is required to re-establish coverage once the person can, again, he says.

Remedies

The only long-term solution to the problem, Davis says, is for the nation to have some type of comprehensive approach to ensure that all Americans can get and maintain affordable health coverage.

Short-term solutions could include changes in eligibility testing by state Medicaid agencies and improvements in the Consolidated Omnibus Budget Reconciliation Act (COBRA) legislation that allow workers to keep health coverage after leaving or changing jobs, she adds.

"More things can be done with employer-based coverage to provide financial assistance to make COBRA affordable," Davis says. "A lot of people are eligible to continue their employer coverage; but when they become unemployed, they simply cannot afford it, so providing premium assistance to pick up 70% to 75% of that premium can also be a way of helping people stay covered."

Studies funded by Commonwealth and other entities indicate that most people who fall off Medicaid rolls still are eligible but have not been able to keep up with repeated requests to verify eligibility and are dropped, she adds.

Involuntary disenrollment in New York Medicaid and Child Health Plus programs is 50%, yet their studies indicated that only 7% actually are ineligible at the time they come up for recertification, she says.

One way to boost re-enrollment or maintenance of coverage would be to require a full eligibility review every other year rather than every year, she notes.

"For example, [recertification] often requires an in-person interview. So, if you've got a low-wage job, you have to take off work to go down to the Medicaid enrollment office, and when you get there, you may find that they want a payroll stub documentation, or they want some other documentation that you don't have with you," she explains.

"You would have to take another day off and go back. A lot of people simply can't find the time

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to go through all of the hoops that are required."

Some states use passive enrollment in which they assume a person still is eligible unless they learn otherwise through employment tax records, etc., she says. But the majority of states do not. In fact, with rising unemployment rates having drastic effects on many states' revenues, most programs are looking at ways to cut enrollment rather than encourage people to stay on, she says.

"Some states have hired more employees to screen out individuals, so we're going in the opposite direction of making it even harder for people to hold on to their coverage."

Health care providers and the public need to be aware that this also is not just an issue affecting the indigent, she continues.

According to the study, while the most pressing coverage problems occurred among poor Americans, almost 34% of people earning between two and four times the federal poverty level (between $30,000 and $70,000 annually) were uninsured during that four-year period as well.

"It's a problem that is particularly serious for low-income people and low-wage workers; but, increasingly, it is a problem for people who work for the big companies and people who think of themselves as middle class," she says. "The dynamics of the problem are changing."

(Editor's note: More information on the studies mentioned in this report, including a detailed issue brief on the four-year census study of insurance coverage, can be found on the Commonwealth Fund's web site at: www.cmwf.org.)

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EDs struggle with mental health emergencies

Funding aims to help patients avoid long waits

In the emergency department (ED) at Palmetto Health-Richland, a 649-bed regional community teaching hospital in Columbia, SC, two waiting rooms have been converted into functional, secure units for patients with behavioral health problems who are waiting for transfer to a mental health treatment facility.

On any given day, an average of seven people with acute behavioral health emergencies remain in the ED because an appropriate treatment bed is not available, reports **John Stewart**, MD, director of emergency medicine and the hospital's chief of staff.

"These patients are stabilized here; but when they remain here, they may not get the proper or appropriate medication or treatment," he says. "As a board-certified emergency physician, I have been trained to recognize and stabilize mental health emergencies, but I do not have the expertise or environment to provide ongoing treatment."

The problem is not unique to Richland or even to the state of South Carolina, says Stewart. Facing funding cutbacks, public and private mental health facilities have reduced the number of available inpatient treatment beds. As a result, people with mental health conditions must seek outpatient treatment in the community and, when they have complications, they seek care in the only available setting — the ED.

EDs across the country are struggling to provide appropriate care for these patients, and the problem has become particularly acute in South Carolina, notes **Shelley McGeorge**, program manager in the Office of the Medical Director of the South Carolina Department of Mental Health.

"In the past few years, there have been 250 public and private psychiatric beds that have been lost in this state," she explains. "Hospitals have been becoming more and more aware that they are not equipped to handle the onslaught of people having to wait for care. Hospitals, by nature, want to provide good-quality care, but were — especially in the past — not equipped to handle the care and needs of patients with behavioral health problems."

Each day, about 50-60 patients statewide seek

psychiatric treatment in EDs, McGeorge estimates.

This past November, the state allocated $1.7 million in grants to local and regional community mental health centers to develop services that would help these patients receive appropriate care and avoid waiting in EDs.

"These grants originated with the awareness that more and more patients were coming to the emergency departments and that two things were happening: They had to wait a very long time to receive appropriate treatment, and other patients seeking medical treatment were being forced to wait because behavioral health patients were taking up so much of the providers' time and resources," McGeorge says.

Collaborative efforts encouraged

To apply for the grants, mental health centers must, in most cases, demonstrate that they have collaborative arrangements in place with local hospitals, alcohol and drug treatment programs, and law enforcement and judicial authorities, she continues.

Last year, the department initiated a large training effort aimed at improving screening and treatment for patients with co-occurring disorders, a coexisting mental health condition, and substance addiction.

"We sponsored a large training event last year with representatives from hospitals, local alcohol and drug treatment facilities, mental health and law enforcement agencies," she says. "As they came together and talked about the problems in their local communities, then they each developed some sort of plan for what they would like to do to solve some of the issues that had to do with co-occurring problems and crisis problems, too."

Four of those initial collaborative efforts were funded through the state and helped pave the way for the $1.7 million in crisis stabilization grants that now are being distributed.

The programs being developed are across the board, from efforts to improve emergency mental health treatments available in hospital EDs, to efforts to improve outpatient mental health case management so that patients with behavioral health conditions do not experience the crisis situations that lead them to the EDs in the first place.

"Some of the funds are used to hire psychiatrists to serve in hospital emergency rooms, as well as providing crisis stabilization units at local hospitals — that might be in an annex or it might be trying to form a system so that bed space would be available at that actual hospital to free up some beds and make them short-term crisis stabilization beds," she explains. "It might also be to hire a social worker or counselor to come in and do on-site assessments of patients who are presenting to give better recommendations should a crisis happen."

The point is, representatives from the different stakeholder agencies are involved in designing programs that help alleviate the problems in their local areas, McGeorge says.

"A collaborative effort is just essential to solving this problem. We believe in that so strongly that we are in the process, statewide, of putting together a performance improvement team with representatives from all of the agencies to take a look at the best way to make crisis stabilization services better in our state."

Complicated cases

Richland's Stewart has been working for years to raise awareness about the problems EDs face in caring for patients with mental health conditions. Yet, he has frequently been the target of criticism from advocates for the mentally ill who believe he, and other emergency medical providers, want to restrict the freedom and civil rights of people with mental illness.

But the majority of mentally ill patients seen in his ED are not people who have regular access to psychiatric care or comprehensive health coverage, he says. Many do have co-occurring disorders.

"Most do not come in voluntarily asking for treatment," he explains. "They are brought in by police, paramedics, sometimes just members of the public."

Patients who don't have regular access to treatment may be noncompliant with taking medications and end up having an acute exacerbation of their condition, he says.

"I look at it in the same way as other chronic medical conditions," Stewart says. "If someone with congestive heart failure stops taking their medication, they will have a complication and require emergency treatment. The same thing happens when someone with a mental illness doesn't take their medication."

The problem is that people experiencing a psychotic episode or other mental health emergency cannot give consent for care or inpatient admission.

Physicians are legally authorized to pursue an involuntary commitment if they believe the

person's condition poses a threat to themselves or to other people.

In South Carolina, physicians can get a court order for a 72-hour involuntary commitment. With the bed shortage, however, patients who need such an admission often have nowhere to go, and EDs are not equipped to manage their conditions.

Although mental health advocates have accused him of wanting to commit people in order to move them more quickly out of the department, Stewart says he has a moral and ethical obligation to ensure that patients in crisis get appropriate treatment, which often means a short-term commitment.

Unlike many hospitals, Palmetto Richland does have an inpatient psychiatric unit, but those beds are often full, both with patients routinely admitted for care and transfers from other hospitals without such units.

Located across the street from a state mental hospital, Richland often sees patients whose conditions have improved enough to be discharged from long-term residential treatment, but do not have good access to follow-up care and remain in the general area, using the hospital as their last safety net.

Stewart has had ED staff knocked unconscious, assaulted and injured by patients who have become violent, and he has had to hire extra security and make the space adjustments to attempt to accommodate the influx of patients. But such measures are stopgap at best and don't adequately address the problem.

"I want to be clear that I don't mean to marginalize the mentally ill even more than already happens too frequently in our society," he says. "I want to be able to treat these patients in the same way I want to treat other patients. But we are only trained and equipped to stabilize emergency conditions until they can be appropriately treated in a specialized setting. When people require more advanced care, we simply aren't equipped to handle them."

Since the crisis stabilization grants have been initiated, Palmetto Richland has seen a small, but significant reduction in the number of mental health patients experiencing extended stays in the ED and has access to psychiatrists who are able to perform rounds in the ED, providing emergency mental health consults and ensuring that the patients who are there receive the appropriate screening and medications.

Stewart says he is hopeful that the effort will both help improve care for people with behavioral health problems and alleviate the stresses on EDs, but says he thinks only time will tell.

SOURCES

- **Shelley McGeorge**, Program Manager, Office of the Medical Director, South Carolina Department of Mental Health, 2414 Bull St., Columbia, SC 29202.
- **John Stewart**, MD, Director of Emergency Medicine and Chief of Staff, Palmetto Health Richland, Five Richland Medical Park Drive, Columbia, SC 29203.

The ultimate goal of the crisis stabilization grants is to address the needs of patients with behavioral health conditions in a number of areas — improving the ability of EDs to handle mental health emergencies, improving community case management so that patients with chronic conditions have fewer acute emergency episodes, and establishing alternative residential treatment options so that patients who have conditions that make it difficult to live independently have an alternative to long-term inpatient admission, says McGeorge.

Through a program known as ACT (Assertive Community Treatment) designated case management professionals, working with a team of other health specialists, would stay in contact with people known to be "frequent flyers" in EDs to ensure they are able to continue to receive the appropriate medication and follow-up treatment.

"You have a team of professionals, including a nurse, mental health professionals, psychiatrists, together involved in a team approach to track whether or not individual people are taking their medications or receiving services, getting appointments, and assist them in that process," McGeorge explains. "If they have crises, they should not have as many, and the ones they do have should be able to be better managed because we have been in contact with that person on a regular basis."

The new programs also are working to develop alternative residential treatment options for patients who may not require long-term inpatient care, but need some type of residential treatment.

"There are people who have needs, but don't need the hospitalization — then we could reserve those beds to be used for more acute care or intermediate care beds," she says. "But, we need placements for long-term patients where their needs could be met, but that would not require hospitalization. One way to say it, is that we are

trying to take care of the front door with the ACT teams beefing up crisis stabilization in the community. Then if someone presents in the ED, we'll have better care for them there, but ultimately making sure there is appropriate care and long-term bed availability for those patients, working our way around the whole system." ■

Protecting children in clinical drug trials

Advocate argues new laws to reduce risk of harm

New federal laws aimed at encouraging drug companies to study how well their products work in children have had the unintended consequence of weakening already vague protections that prevent child research subjects from being exploited, a leading human subjects research advocate claims.

Passage of the Better Pharmaceuticals for Children Act (incorporated into the Food and Drug Administration Modernization Act [FDAMA]) in 1997 and the preceding Prescription Drug User Fee Act (PDUFA) in 1992 have created an environment in which children have become valuable research commodities, says **Vera Hassner Sharav**, MLS, president of The Alliance for Human Research Protection (AHRP), a nonprofit research advocacy organization based in New York City.

These laws, which provide financial incentives to pharmaceutical companies to perform research involving children, set in motion radical shifts in public policy away from protecting children by setting limits on permissible research risks to a policy aimed at broadening the inclusion of children in trials as test subjects, she notes.

In particular, FDAMA provides an additional six months of patent exclusivity for the manufacturer of pharmaceuticals that have undergone testing in children. Such an extension of patent rights can represent millions of dollars in profit.

In a recent report published in the *American Journal of Bioethics*,[1] Hassner Sharav presents case studies detailing incidents in which children have been included in research projects that placed them at significant risk of harm without the potential for direct benefit to the child subject (in violation of federal human subjects research protections laws). In fact, in many instances, children are included as research subjects in trials that do not seem likely to yield scientifically valid information for any population.

"Children are being used in ever more speculative experiments, often in the absence of a therapeutic intent, but with a significant chance of harm and/or discomfort," Hassner Sharav tells *Medical Ethics Advisor*. "The Nuremberg Code provides the best standard for justifying research involving human subjects: 'The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.'"

The code also requires that human subjects give informed consent for participation — that they be informed of all the potential risks and benefits of participation in a given study and then consent to participate free of undue inducement or coercion.

"Children, however, are not capable of exercising the human right to informed consent. Therefore, they need additional protections to prevent their exploitation," she adds.

Institutional review boards (IRBs) and ethics committees, the bodies delegated with the primary task of protecting human subjects under U.S. law, have failed to protect child subjects in many well-documented research studies over the past decade, she argues. Thus, it is time for a national initiative to determine basic protections for child research subjects and a more universal oversight system to ensure the basic protections are enforced.

Animals have more rights

Under federal law, animals used as test subjects have more federal protections than human subjects, Hassner Sharav points out.

Under stipulations of the Animal Welfare Act of 1966, the well-being of research animals must be monitored by an independent veterinarian and documented and safeguarded by study researchers. These researchers must justify any pain inflicted on animal subjects and the U.S. Secretary of Agriculture must provide an annual report to Congress accounting for the outcome of every animal used in research.

However, no one maintains a record of the number or nature of clinical trials involving human subjects in this country, the number of human subjects involved or their disposition following research, Hassner Sharav notes.

While some may argue that humans have the

AHRP Advice for Child Safety in Clinical Research

The Alliance for Human Research Protection (AHRP), a nonprofit research advocacy organization based in New York City, offers the following recommendations for the safety of children involved in clinical research:

1. Federal regulations — 45 CFR 46 Subpart D — restrict the use of children in medical experiments involving greater than minimal risk, if there is no potential medical benefit for them or their condition. These regulations should be strictly enforced.
2. Inasmuch as drugs have unwanted side effects, and medical research involves risks of harm, only children whose narrowly defined, currently diagnosed medical conditions that can potentially be helped, should be recruited to test drugs or other medical devices or procedures.
3. Legislation for the protection of children's health and welfare should put the burden of proof on those seeking to conduct research on minors younger than the age of 18 to establish the existence of "compelling circumstances" that justify such research on children.

   Investigators must provide the criteria for demonstrating that the benefits of the research outweigh severity, duration, frequency and likelihood of the risks. Children must be assured that current "best-medical-practice" standards of treatment will be compared to any new or experimental treatment, and that those consenting on their behalf can be held accountable for making research decisions that are in the child's best interest.
4. Children should not be recruited for experiments involving greater than minimal risk on the basis of vague speculations about them being "at risk" of some unproven condition that may or may not ever materialize.

   Rigorous standards must be established for each study involving children so that the level of risk can be objectively defined by demonstrable, existing factors. Investigators must demonstrate that the nature, severity, duration, and frequency of the risk are greater than the intervention proposed.
5. All clinical trials involving the use of children, as previously defined, should provide no-fault insurance coverage for both short- and long-term adverse effects that may arise from or in the course of participation in the stated clinical trials.
6. The pool of child subjects must not constitute an unfair burden on disadvantaged families who may not have access to current best-practice standards of treatment in their community. Thus, care must be taken to ensure that the population from which sick children shall be recruited represents families from diverse socioeconomic strata. When children are sought from a specific ethnic or socioeconomic population, evidence must be provided demonstrating that the condition under study disproportionately affects that specific population.
7. The recruitment of children with financial enticements to their parents and caregivers should be prohibited.
8. Two-part recommendation:

A. There is a need for oversight by a children protection committee in addition to review by an institutional review board that would serve as the child subjects' advocates, monitoring their selection, assessing the reasonableness of their parents' consent, the adequacy of disclosure in the informed consent documents, and monitoring their continued willingness to participate in the research.

B. The majority of the committee should be drawn from the community, among them representatives from the same socioeconomic strata as the children in the specific clinical trial.

9. All of the members of the ethics review board and the children protection committee should be vetted for complete absence of conflicts of interest.
10. The expenses for the process of safeguarding children's best interest in research — including community members who are involved in implementing the research review and monitoring process — should be paid from a government fund established for that purpose. The government should, in turn, be authorized to recapture its costs, including oversight of all pediatric research, by way of reimbursement from the drug or medical device manufacturers who are eventually licensed to market such drugs or medical devices that result from approved pediatric research.

Source: AHRP, New York City.

ability to refuse to participate in trials that put them at risk of harm — where animals do not — this argument has less weight when the potential research subjects are children, she says.

Parents or guardians must consent to involve children as research subjects, because children are not able to give adequate informed consent themselves. Parents often do not understand the risks

involved in research, and may themselves have conflicts of interest that prevent them from putting the interest of the individual child first.

Definition of minimal risk

Federal regulations adopted in 1983 preclude the inclusion of children in research involving "greater than minimal risk" unless the project poses a potential direct benefit to the child.

However, there are no strict definitions of "minimal risk" or "direct benefit" in the regulations and these terms have been open to wide interpretation, Hassner Sharav argues.

And under the regulations, children may be included in studies that present more than minimal risks to them, if the study will yield generalizable knowledge about the subject's disorder or condition which is of vital importance. And if all of these standards are not met, inclusion of children still is permissible in studies that present significant risk to them if them if the investigator can demonstrate that the proposed project presents "an opportunity to understand, prevent, or alleviate a serious problem affecting the welfare of children."

These standards provide so much room for interpretation that individual IRBs have wide room for discretion in approving studies that pose considerable risks for children, Hassner Sharav says.

"As currently constituted, IRBs cannot claim to be independent," she argues. "IRBs are compromised by an inherent conflict of interest, and their decisions bear this out."

As examples, she cites a 1996 study approved by the IRB at the National Institute of Child and Human Development that approved an obesity experiment conducted on 100 obese and 92 normal-weight children ages 6 to 10. The experiment involving fasting, blood tests, X-rays, and a two-day overnight hospital stay during which the children were subjected to painful, invasive procedures. The procedures included insertion of an intravenous line for 18 hours; a battery of intensive measurements of metabolic rates; a two-hour hyperglycemic claim study involving a second IV line for two hours; blood sampling at five-minute intervals; a three-hour hyperinsulinemic clamp study for two hours with two IV lines; and infusion of glucose and insulin for two hours.

The IRB unanimously approved the study under the federal minimal-risk category justifying its decision by stating to an investigator from the federal Office of Human Research Protections (OHRP) that: "Several members of the committee explored the meaning of minimal risk and what a child might encounter in a visit to the doctor or while playing in traffic. It was felt that spending several hours in the clinical center in a clamp experiment would be safer than playing actively on sidewalks and streets."

The experiment was later suspended by the OHRP.

Defining a medical 'condition'

Under the current system and in the current climate, researchers also have been able to expand the definition of subjects' medical conditions to include conditions the subjects are thought to be at risk for developing in the future.

This argument carries particular weight when the potential subjects are children because children could be considered to be at risk of developing almost any condition at some point in the future, Hassner Sharav notes.

As an example, she cites a study by Pine and colleagues, published in 1997 in the *Archives of General Psychiatry*, which detailed a fenfluramine challenge experiment performed on 34 African-American and Hispanic boys, ages 6 to 11. The child subjects were drawn from a larger study involving 126 brothers who were deemed at risk of following in the footsteps of older brothers who were incarcerated juvenile delinquents.

The investigators stated that there was evidence of a correlation between reduced serotonin activity and aggressive behavior, and hypothesized that measuring the boys biochemical responses to fenfluramine, they would be able to replicate earlier findings and find a predictive biological marker predisposing the children to violence.

The children were required to follow a special diet for four days, fast for 18 hours prior to the challenge, and had an IV catheter inserted in their arm, which remained in place for more than five hours, during which time blood would be drawn.

The researchers were able to justify the risks and discomfort the children would bear by stating: "Research on the relationship between adverse rearing and serotonin may enhance understandings of the association between serotonin and aggression across development."

The parents of the subjects also were paid $125, and the children received $25 gift certificates to a toy store, Hassner Sharav notes.

The drug fenfluramine, she notes, carries the risk of neurotoxicity and heart valve damage.

Although federal regulations prohibit the use of children in research involving greater than minimal risk if there is no potential direct benefit to them, four prominent IRBs approved this admittedly nontherapeutic experiment.

More oversight warranted

These examples and others indicate that more comprehensive protections for children are needed, Hassner Sharav says. "IRBs are not protecting human subjects who have no voice in the research approval process; they are protecting their institution."

The Alliance for Human Research Protection has formulated 10 recommendations for improving research protections for children **(see box, p. 8)** that include a National Review Board to oversee research involving children, and the establishment of a fund — supported by fees from drug and device manufacturers — to cover the cost of research oversight.

A National Review Board could serve in the capacity of a Supreme Court for research by rendering judgments about the appropriateness of specific studies to establish national standards for approval, Hassner Sharav notes.

"The board would be an independent body with one-third of its members nonscientists or not under the influence of industry," she says.

Individual institutions should also have specific child protection committees that function in conjunction with, but independently of, the institutional review boards.

"The majority of this committee's members would be drawn from the community and then be vetted for absence of any conflict of interest," Hassner Sharav explains. "The protection afforded by an independent panel is to monitor, in person, the informed consent process, ensure that the risks are fully disclosed in the consent documents, that parents' permission is reasonable, and to monitor the children's assent and continued willingness to participate in research."

While Hassner Sharav raises some very compelling ethical points in her report, she doesn't give appropriate equal weight to the need to test pharmaceuticals in children to determine their effectiveness and a safe dose, notes **Howard Trachtman**, MD, a pediatrician and clinical researcher at Schneider Children's Hospital in New York City.

Patient advocacy groups, including advocacy groups for children, have driven much of the change in the drug evaluation and approval process that she finds so many faults with, he says. They have done so precisely because they felt that continuing to prescribe drugs for children in the clinical setting, which had previously largely been tested only in adults, was unethical.

"Vulnerable populations can be vulnerable in two ways," Trachtman notes. "One, you can abuse them and take advantage of them, and the other is that you can be overly protective of them."

He also takes issue with the contention that the potential for financial gain is the driving force behind the expansion of clinical research in children. "My sense, in reading [Hassner Shirav's] article, was that she was putting all doctors into this group and that we were all doing this for the same reason, which is to make money," Trachtman notes. "That is not fair to everybody. There are clearly examples you see in the newspaper where investigators get rich off clinical trials in terms of supplementing their income, but I don't think that is very relevant in pediatrics."

The profit motive in pharmaceutical research, while admittedly powerful, is less forceful in the pediatric community because fewer children are ill and pediatric physician investigators are not as sought after as their adult counterparts.

Most pediatric researchers primarily are motivated by the belief that they are doing whatever they can to find good treatments for their patients to find a cure for life-threatening conditions that affect children, Trachtman adds.

In his experience as an investigator, parents also are highly motivated to learn all that they can about a potential drug or treatment, and they are primarily concerned about its potential to benefit their child vs. the risks involved, he notes.

Children are vulnerable to abuse and exploitation in a number of settings — not just research — and improvements in enforcement of existing protections and oversight systems should be sufficient to protect them without depriving them of the benefits of participation in what could be a very helpful and empowering experience, says Trachtman.

Adding more layers to the oversight process would not have the results that Hassner Sharav and others desire, he states. The solution to improving protections for children, he notes, is in strengthening the quality and support for existing oversight structures.

SOURCES

- **Vera Hassner Sharav**, MLS, President, Alliance for Human Research Protection (AHRP), c/o Hospital Audiences Inc., 548 Broadway, Third Floor, New York, NY 10012.
- **Howard Trachtman**, MD, Pediatrician and Clinical Researcher, Schneider Children's Hospital, 269-01 76th Ave., New Hyde Park, NY 11040.

"In industry-sponsored studies, they have quality assurance people who go out all the time to do site visits. In NIH [National Institutes of Health] studies, you have the data safety monitoring boards and you have good, quality people monitor them," Trachtman says. "The oversight responsibility is key. The investigator may not want to do it right; they may not do it in the right way. But the people who are empowered to do it, have to take their responsibility of oversight seriously."

Because research inherently involves experimenting on test subjects, it is easy to demonize human subjects research as being disrespectful and potentially damaging to human beings without seeing the essential benefits it can provide, he notes.

"The view that the research enterprise is this dark force is not fair," Trachtman says. "Most people that I see, they always want what is best for their kid. Well, where did that best drug come from? It had to come from somewhere; it didn't pop out of the sky. The importance of ethical practice and all of the precautions are definitely justified. It is not reigning in some sort of criminal enterprise, but it is needed to make sure that a basically good enterprise is done right."

Reference

1. Sharav V. Children in clinical research: A conflict of moral values. *Am J Bioethics* 2003; 3(1):Infocus. Accessed on-line at: www.bioethics.net. ■

NEWS BRIEFS

Hastings Center issues report on 'reprogenetics'

Ethicists at the Hastings Center have issued a guidance document on the need for and potential of public oversight of "reprogenetics" research, their term for research that involves the intersection of reproductive medicine and the manipulation of gametes and embryos.

The report, *Reprogenetics and Public Policy: Reflections and Recommendations*, is the culmination of a two-year research project by the center. In it, authors Erik Parens and Lori Knowles argue that the complex ethical questions this type of research raises should not be resolved by market forces alone but need to be addressed by broad public discussion and oversight.

The report makes three policy recommendations:

1. The ban on federally funded embryo research should be lifted in order to allow federal oversight of such practices as preimplantation genetic diagnosis, ooplasm transfer, cloning and embryonic stem cell research. If the ban is not lifted, the market will remain the only mechanism regulating development of these technologies.

2. A commission should be established to consolidate the data on this topic and make legislative recommendations about statutory authority for an oversight group. The commission would be able to frame issues through engaging the public and experts and articulating ethical commitments. Ultimately, it would present legislative initiatives to Congress.

3. The commission, when established, should consider calling for a federal Reprogenetics Technologies Board that would have oversight authority of both public and private sectors.

COMING IN FUTURE MONTHS

- ■ Questions about expansion of the federal smallpox vaccination plan
- ■ Patient participation in genetic studies: A question of benefit sharing
- ■ Reporting and handing aggressive/abusive behavior in the workplace: How are hospitals are coping
- ■ New ideas for ethics education

CME Questions

1. The South Carolina Department of Mental Health recently awarded ____ in emergency crisis stabilization grants to help emergency departments (EDs) treat patients with behavioral health problems.
A. $12 million
B. $1.5 million
C. $2 million
D. $1.7 million

2. According to our article, the South Carolina crisis stabilization grants will:
A. fund improvements to EDs that will allow them to better care for patients with behavioral health emergencies.
B. fund additional placement options in communities.
C. fund improved mental health case management services.
D. All of the above

3. According to our article, how many Americans are estimated to have been without health insurance coverage at some point during the years 1999-1996?
A. 40 million
B. 20 million
C. 85 million
D. None of the above

4. According to the article by Vera Hassner Shirav, what federal laws have encouraged the exploitation of children as research subjects?
A. Food and Drug Administration Modernization Act, FDAMA
B. Prescription Drug User Fee Act, PDUFA
C. Both
D. Neither

Answers: 1-D; 2-D; 3-C; 4-C.

The consequences of reprogenetic practice could be far reaching, the authors note, extending from the alteration of individual physiologies to reconfigurations of how a society views and treats its members. For these and other reasons, the direction of the research must not be left up to the market alone and an oversight system is needed.

Copies of the report are available on the center's web site at www.hastingscenter.org. ■

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. ■