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Treating substance abuse during pregnancy: What approach works?

Coercive legal measures are ethically problematic

In recent years, efforts to address substance abuse among pregnant women have moved from being barely visible public health initiatives to controversial political battlegrounds.

A recent survey from the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) indicates that approximately 12% of pregnant women and girls between the ages of 15 and 44 used alcohol in the month prior to being surveyed, and 3% used illegal drugs.[1]

Over the past decade, a number of states have passed laws requiring health care providers to report substance abuse by pregnant women, compelling pregnant women to undergo treatment for substance abuse problems or face incarceration, and allowing addicted pregnant women to be charged with child abuse and endangerment.

Most professional medical societies have condemned such legislation as compromising the provider-patient relationship and violating the civil rights of the women involved.

Now, some researchers argue, these laws not only are unsound ethically, but largely ineffective at addressing the problem of substance abuse during pregnancy.

"Society does have a compelling interest in preventing substance abuse during pregnancy as a public health issue, but the criminalization approach is inadequate and wrong," says **Mary Faith Marshall**, PhD, professor of medicine and bioethics at the School of Medicine at the University of Kansas Medical Center in Kansas City. "This is such a complex problem, and research into addiction medicine is showing more and more that it is not just a social construct in the sense of someone being able to say, 'I want to stop being addicted today.'"

Marshall and several colleagues published a paper in the *Journal of Law, Medicine, and Ethics* questioning not only the ethics of laws attempting to coerce treatment, but also the suitability of clinical treatment encounters to sufficiently address the problem.[2]

Forcing women into treatment implies that addressing the clinical

aspects of addiction will be enough to stop the drug abuse — an assumption that Marshall and others say has been shown to be questionable.

"Most of the factors that contribute to addiction, such as poverty, level of education, job skills, and the like are outside anything the clinical encounter can effect," Marshall says.

Experts in substance abuse treatment generally agree that effective programs should include residential care, combine inpatient and outpatient services, are gender-specific, and offer vocational and educational services, transportation, and childcare. Yet, most of the public policy initiatives designed to address substance abuse in pregnant women have no support for these additional services, and pregnant women most at risk of substance abuse and addiction do not have access to such programs.

If society really were interested in addressing the problem, why not spend public funds on improving treatment rather than incarceration for addicted pregnant women, Marshall asks.

Financial constraints and political support for punitive approaches have limited the spread of such treatment facilities and created concerns about cuts in addiction treatment and services, she adds. And empirical evidence continues to suggest that drug addiction resists a clinical solution, even when measures are taken to provide appropriate social supports.

It doesn't help that most women who end up in the criminal justice system for addiction during pregnancy come from poor, minority populations that are easy for the rest of society to marginalize, Marshall adds.

"There was a really interesting study several years ago down in Pinellas County, FL, where they anonymously screened every pregnant woman presenting at three different medical centers, to see whether they had a positive screen for drugs or alcohol," she recalls. "They followed up on that and found that the people who fell into the social welfare system or who were brought to the attention of authorities were poor women of color, even though the data were there that showed that other women, too, tested positive. The only ones gone after were the ones who were politically not in a position to make a whole lot of fuss."

A public health angle

A more comprehensive, public health approach to address the core influences of substance abuse and addiction could be much more effective, but will be much more difficult, in terms of political will, to implement, Marshall argues.

Efforts to place treatment centers in at-risk communities could reach some women before they become pregnant. Training lay health advisors to educate peers about healthy and unhealthy behaviors has been shown to be effective in other public health initiatives, such as anti-smoking programs. Job training and

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Editorial Questions

Questions or comments?
Call **Christopher Delporte** at (404) 262-5545.

education programs also could play a role.

However, Marshall notes, the current U.S. health system overall emphasizes individual clinical care at the expense of public health initiatives and substance abuse treatment continues to focus on improving access to clinicians — albeit through coercion — rather than pursuing larger, population-based initiatives.

"In terms of bioethics in general, we tend to concern ourselves with sexy issues like genetics, which are important, but access to health care and substance abuse is a huge public health issue, and people in the bioethics world have not paid a whole lot of attention to it," she says.

Some health systems, however, have decided to alter their clinical models for treating addiction in pregnant women, adding social supports and tailoring interventions specifically for this at-risk population, says **Mary Anne Armstrong**, MA, a biostatistician and researcher at Kaiser Permanente Medical Care Program's Division of Research in Oakland, CA.

In the late 1980s, physicians at Kaiser Permanente Medical Center in Oakland became concerned about the number of babies born there who had been exposed to alcohol and drugs.

They designed several different interventions aimed at easing referrals for pregnant women into existing treatment programs, but few of the efforts were successful, she says.

In 1990, the hospital designed a new approach, known as Early Start, which combined substance abuse screening and treatment with obstetric and prenatal health services.

Under Early Start, pregnant patients complete a screening questionnaire on their first prenatal visit, and undergo a urine toxicity screen if they consent, and about 95% of patients do, she notes.

If the questionnaire and/or urine test indicate substance abuse, the patient is referred to a social worker who is stationed in the obstetricians' office full time.

The social worker conducts an in-depth assessment of the patient and designs an individual diagnosis and care plan. Women at moderate to high risk of substance abuse during their pregnancy are seen for follow-up visits by the social worker at subsequent prenatal checkups. The follow-up visits are designed to be similar to other brief intervention treatment programs and use a number of different therapies, including motivational therapy, cognitive/behavioral therapy and psychodynamic therapy.

Early Start clients also receive routine follow-up toxicology screens and are referred to other available treatment programs.

Studies conducted by Armstrong and colleagues indicate that women who undergo screening and treatment through the Early Start program have babies with fewer drug-related complications than women who do not participate in the program.[3]

Combining screening and treatment with prenatal care was a key element in successfully treating many women where previous efforts had failed, Armstrong notes.

"Early Start was developed because referral to treatment in the psychiatry department — where substance abuse treatment takes place in the Kaiser system — wasn't working," she explains. "The women weren't going there; it wasn't convenient to go and make appointments at another clinic in another building, and there is also the stigma of being pregnant and a substance abuser. Most substance abuse treatment is in a group setting, and nonpregnant patients look down on pregnant substance abusers."

The most unique feature of Early Start is its location of a treatment provider in the obstetric clinic and the linking of treatment appointments with prenatal appointments.

"And certainly, all information obtained by the Early Start specialist in the course of treatment is confidential," Armstrong adds. "The fear of criminal prosecution does not prevent patients from participating. On the contrary, they know that participation will prevent them from being prosecuted."

Armstrong and others in the research division currently are involved in more follow-up studies on substance abuse in pregnancy, including: a study to determine how women utilize inpatient and outpatient services before and after treatment during pregnancy and their substance use postpartum; research on why some women deny substance abuse on the screening questionnaire but have a positive toxicology screen; and a method

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of tracking cases of fetal alcohol syndrome in the northern California Kaiser Permanente region. And she is finishing a five-year study examining ways to help women who drink alcohol during pregnancy better quantify how much they actually drink.

"The two most important things health care systems can do are to provide adequate screening and convenient treatment," she contends. "In general, individual clinicians need to become more comfortable discussing substance abuse with their patients and support innovative programs like Early Start."

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Ethical questions raised by emergency blood trial

No opportunity for prior informed consent

Paramedics in the Denver area will be administering an experimental blood substitute to patients who meet certain criteria under an unusual research protocol that allows patients to be recruited without giving informed consent.

Denver Health Medical Center is one of 20 hospitals nationwide participating in the study of PolyHeme, a substitute blood product manufactured by Evanston, IL-based Northfield Laboratories.

PolyHeme is made from chemically modified hemoglobin derived from human blood and is designed to be an alternative to transfused blood in the treatment of acute blood loss. According to information published by the manufacturer, PolyHeme is universally compatible and does not require blood typing prior to its use. And unlike stored donated blood, which can only be stored for 28-42 days, the experimental product has an estimated shelf life of 12 months under refrigerated conditions. If proven effective, PolyHeme could dramatically improve outcomes for trauma patients. Donated blood cannot be carried on ambulances because of problems with storage and the need to match a patient's blood type.

People who suffer severe blood loss in the field normally are given transfused saline to maintain blood volume and pressure during their transport to a medical facility. An oxygen-carrying blood substitute however, could better maintain blood oxygen levels and help reduce the incidence of hemorrhagic shock.

PolyHeme previously has been tested in surgical patients and used during in-hospital resuscitations with no reported adverse events.

But investigators believe it is essential to test the product in emergency patients to determine how they will respond.

The problem, however, is that patients who suffer severe blood loss in the field are unable to give informed consent prior to participation in a study. Often, the patients are unconscious. But even if they are not, paramedics cannot take time out from performing lifesaving procedures to explain the potential risks and benefits.

The research is being conducted under 1996 federal exemption from consent regulations for research into emergency, lifesaving procedures.

For trauma patients meeting certain criteria, paramedics will randomly administer the PolyHeme product or the standard treatment, infusion of plain saline.

To be eligible for the exemption, investigators must demonstrate:

- Patients who would be included face a life-threatening situation.
- Currently available treatments are unproven or unsatisfactory.
- Consent from the patient would not be feasible because of the patient's condition, and because treatment must be initiated before an appropriate representative can be reached.
- Research cannot reasonably be conducted otherwise.
- Risks and benefits of the experiment are considered reasonable in light of the patient's condition and what is known about other therapies.
- Participation in the research holds the potential for direct benefit of the subject.

If these conditions are met, federal regulations also require investigators to develop methods to publicly communicate information about the study in the community where it will be conducted and to publish the results of the study once it is complete,

use an independent data safety monitoring board, and have the protocol approved by the U.S. Food and Drug Administration.

Critics fear abuse

Some patient advocates say the exception is unethical because it permits experimentation on human subjects without their prior consent.

The study "is another one along that slippery slope that's essentially demolishing your individual right not to become experimental subjects unless we give prior, voluntary, informed, comprehending consent," **Vera Sharav**, president of the New York-based Alliance for Human Research Protections, told the Associated Press on Feb. 20.

But many medical ethicists say there are important characteristics of emergency care that warrant exemptions to standard research practices.

"Emergency medicine and critical care are the two areas most in need of clinical research, but it is very difficult to conduct study protocols in this setting," says **Norman Fost**, MD, MPH, director of the program in medical ethics at the University of Wisconsin Medical School.

Emergency and critical care specialists frequently don't have the time to design and conduct randomized clinical trials of new procedures or therapeutics. Yet they often want to employ innovative new therapies if they believe they offer their patients the best chances of survival and recovery.

Because patients in emergency settings often face unexpected, life-threatening conditions, prior informed consent for experimental procedures is not always a viable option.

Clinical trials, approved by an institutional review board and supervised by data safety monitoring boards, actually may offer patients with emergency conditions more protections — even without their informed consent — than they would enjoy outside a research protocol.

"Informed consent is a process not a means to an end," Fost says.

Its purpose, he contends, is to prevent people from being enrolled in research that they would not want to be involved in if they were aware of the risks and benefits.

However, prior informed consent is not always necessary to accomplish these goals, Fost adds.

Federal regulations require investigators to publicize the research in the community and seek public input, he says. And the informed consent exemption only applies to emergency research in areas where there is not an effective treatment available.

In many cases, community members where such research takes place indicate that they would welcome the opportunity to have access to the experimental treatment, he continues.

Investigators at Denver Health, in fact, designed an extensive public education campaign in advance of seeking permission to test the PolyHeme product, says **Jeffrey Long**, clinical research specialist and the PolyHeme study coordinator at that site.

"A team of representatives from Denver Health, including the principal investigator, co-investigators, emergency room physicians, EMS personnel, and representatives from our public relations department, and myself met with several local community groups and provided a 20-minute presentation, detailing the study design and federal regulations as well as previous experience with the product," he reports. "The presentation was followed by a question-and-answer period that lasted between 15 and 20 minutes."

At the meetings, the team provided an anonymous survey to be filled out and returned. In addition, they placed notices in several local publications and got local coverage of the proposed study on local TV stations and newspapers.

"We also created a web site and offered both a call-in number, as well as e-mail and mailing addresses for correspondence concerning questions and comments regarding the study," Long adds.

They developed print and radio advertising in both English and Spanish and scheduled the principal investigator, Ernest E. Moore, MD, to give a presentation before the city council, which was then featured on public access television.

"The reaction during our community consultation was positive," Long says. "I was pleasantly surprised by the enthusiasm surrounding the trial that was witnessed during our community consultation efforts. Multiple attendees told us that, should the situation arise, they hoped the PolyHeme product would be available for them and their families."

In the event that community members did not want to participate in the study, they could let investigators know through one of the established avenues of communication and would be provided with a small bracelet to wear, indicating they refused participation.

"The regulations don't require this measure to be taken; however, we felt obligated to provide

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everyone with the opportunity to express their wishes to refuse participation," Long says.

Fears that the federal exemption from informed consent requirements in emergency research would lead to a rash of no-consent protocols have proved to be unfounded, adds Fost.

Since its implementation, only 15 such studies have been approved.

Fost attributes this to the stringent requirements and some confusion among research sponsors and would-be investigators about what the requirements for community consultation and public disclosure really are, he notes.

The federal regulations are not specific about the extent of public information required and, thus many sponsors are wary of attempting such research, Fost claims. The result, he says, is that many beneficial studies never get performed, leaving emergency critical care patients with fewer options. ■

Should dying patients be research subjects?

Ethicists worry research would erode respect

An experimental blood oxygenation device has the potential to help thousands of patients with severe emphysema or other lung conditions. The device has been thoroughly tested in laboratory animals, but human trials would involve major invasive procedures for research participants and place them at very high risk of death or serious complications.

Instead, researchers have tested the device in brain-dead patients just prior to the withdrawal of mechanical ventilation. Researchers gathered information about how well the device improved oxygen levels in the subjects' blood, without conducting painful experiments in living patients expected to recover and continue their lives.

At a noted cancer hospital, researchers needed to test an innovative therapeutic designed to target tumor growth, yet leave healthy tissue undamaged. Instead of injecting the product into research volunteers — which would have necessitated multiple tissue biopsies to ascertain whether intended tissue targets were affected — researchers first tested it on "terminal wean" patients, those who were being removed from mechanical ventilation and respiration and expected to die within the next few hours.

These are just a few examples of research being conducted nationwide using dead and nearly dead patients as subjects. Such investigations allow researchers and clinicians to study new and risky procedures and treatments in a realistic way, without putting patients at risk of harm.

However, some ethicists worry that more oversight is needed to ensure pursuit of this type of research doesn't erode respect for human beings, both living and dead.

Viewing deceased or dying patients as possible subjects in research in which they cannot possibly benefit raises the potential risk that patients at the end of life — or very ill patients — will be seen as a means to an end, rather than retaining the respect they should have as individuals, notes **Jacqueline Glover**, PhD, associate professor in the Center for Bioethics and Humanities and the Department of Pediatrics at the University of Colorado Health Sciences Center in Denver.

She and other experts in bioethics and medical research participated in a seminar on developing ethical guidelines for research including patients at the end of life, held Feb. 24 at Emory University in Atlanta.

Institutions and researchers considering such protocols need guidance on the unique issues these projects pose, Glover adds. "We have to be concerned with protecting vulnerable populations, but also promoting public health and needed research. What are the societal implications, conflicting interests in this, and what is the role of bioethics in fostering dialogue in the community?"

A wide variety of research using deceased and dying subjects has been proposed in several different medical specialties, says **John Kavanagh**, MD, professor at the University of Texas M.D. Anderson Cancer Center in Houston.

Particularly in highly technological fields such as interventional radiology or laparascopic surgery, where new techniques, procedures, and

instruments emerge quickly and clinicians are pressed to develop proficiency, practicing on deceased patients first can prevent the occurrence of serious errors later.

Animals, because they do not have the same anatomy, often are not appropriate substitutes, Kavanagh notes. Currently, clinicians often use flash-frozen human cadavers, but these models also do not provide a realistic simulation of what performing an actual procedure is like or how living human tissues and systems will react to a procedure or treatment.

Research into the pharmacodynamics of new medications also could be improved using brain-dead patients or terminal-wean patients prior to the withdrawal of life support, he continues.

One of the first thing clinical investigators need to know about a new drug is how it reacts once it is inside the human body. Researchers must give the drug, then collect numerous biopsies and blood samples to determine where the medication went and whether it acted as researchers believed it would, he says.

"These studies rarely, if ever, benefit the patient — the information is needed for future patients," Kavanagh says. "Usually, these are part of Phase I trials — which are dose-determining trials. Participants in these trials usually receive less-than-optimal doses of the drug, and participation in the trial frequently requires subjects to travel and stay in a hotel near the hospital. Morbidity from participation is not usually very bad. But the majority of Phase I trials fail and never progress to Phase II."

The administration of an experimental drug into a nearly dead patient with intact major organ systems could yield the same information.

A number of institutions and ethics committees have examined the ethical issues these protocols present and are developing guidelines for allowing certain projects to proceed while prohibiting others, and what subject protections need to be in place, says **Rebecca D. Pentz**, PhD, associate professor and research ethicist for hematology and oncology at the Winship Cancer Institute at Emory.

If institutions want to allow protocols involving the dead or dying patients, there are a number of issues to consider:

1. How important is the research? Several authors have stipulated that the proposed investigation must address an important clinical problem, and usually one that would be difficult to study in any other population, Pentz says.

2. Which patients are eligible? Some institutions permit research involving brain-dead patients, but not patients that others define as nearly dead — those patients who physicians believe to be within a few hours of death. And some institutions feel that these populations should be used only as a last resort. Opinions also differ about whether organ donors and autopsy candidates should be included or excluded from consideration.

3. Should informed consent be obtained? Almost all ethicists agree that investigators should obtain informed consent from family members and some have added that subjects should have previously indicated to family or to caregivers some willingness to participate in research or have their body and/or tissues used for research purposes after their deaths.

4. What are the time limits? A particularly thorny issue is the duration of the proposed research intervention, Pentz notes. Almost all of the published guidance indicates that the intervention should be of short duration and that deceased patients not be maintained on life support for long periods of time solely for the purpose of conducting a research protocol, she explains.

5. What if patient dies during the protocol? For research involving terminal-wean patients and patients who are near death, the possibility exists that death will occur during the intervention, Pentz notes. Ethics committees must decide what investigators and clinicians will do if this happens. For example, must investigators halt the intervention? Will family members be allowed to be present during the protocol, etc.?

Conflicts of interest, affect on the living

One of the most difficult quandaries posed to medical ethicists involves the need to separate decisions about inclusion in research from the decision to terminate life-support measures, notes Glover.

Some institutions require that a death certificate be issued prior to inclusion of the patient in a research protocol, and some also require that the decision about placing the patient on a terminal wean be made by a clinician independent of the research protocol.

The impact of participation in the research protocol on the deceased person's family also must be considered.

Family members are not always in agreement about whether their loved one would have wanted to be included and they are not always of one mind in terms of knowing what to expect, Glover adds.

Research protocols involving the nearly dead

present unique ethical dilemmas, she adds. Where is the distinction between a living person and one who is "nearly dead" or should there even be a distinction, she asks.

Although in particular situations, clinicians may feel that they can predict with some certainty that a person will not live longer than a few hours, it's difficult to argue that these patients should somehow be considered "less than alive," she says.

Research involving deceased patients actually falls into a gray area in terms of federally mandated human subjects' protections, says **Michael A. DeVita**, MD, FACP, assistant professor of anesthesiology and critical care medicine at the University of Pittsburgh Medical College and chair of the college's ethics committee.

According to federal regulations, institutional review boards only are authorized to monitor research involving living human subjects. Many are understandably reluctant to evaluate protocols involving the dead because of fears that a federal audit of their records would reveal different criteria used to judge protocols involving dead participants and those involving living subjects.

Medical center ethics committees usually only consider issues related to the clinical treatment of patients at their facility and, typically have no jurisdiction over organs, tissues, or other materials that may come into a facility from somewhere else, but involve investigators at that center.

After receiving a request from a clinician to study an artificial blood oxygenation device in brain-dead patients, the University of Pittsburgh College of Medicine decided to form a separate committee, the Committee on Research Involving the Dead (CORID), to evaluate such protocols.

University officials said that such protocols did present some difficult human subjects concerns that were separate and distinct from the concerns posed by research involving living subjects.

Officials noted that researchers aren't able to quantify all the potential risks to subjects well, that abuses of potential subjects could occur and that they would not easily be discovered if they did occur, DeVita says. Thus, the separate committee was formed. The goals of CORID are:

- to protect deceased patients;
- to protect family members of deceased and dying patients;
- to provide guidance to investigators;
- to provide ethical standards on how similar research should be monitored.

Among the issues that CORID has had to consider is when to seek consent for a research protocol from family members of organ donors, since the Uniform Anatomical Gift Act permits research on donated organs and tissues if the person has consented to organ donation.

However, the committee determined that investigators must seek additional consent from family members if the study involves an unusual procedure or degree of bodily invasion.

In determining the need for family consent,

More info on research involving the dead

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CORID considers the degree of invasion the protocol would involve, the potential for benefit to be obtained by the information found in the study, and whether the potential for benefit outweigh the degree of invasion involved.

The committee also has developed guidance about research processes and procedures. For example, how will tissue samples be collected and stored, whether family visitation can occur during the study procedure, and whether participants in the study still may be able to have an open-casket funeral.

CORID also established time limits on how long study interventions could take, and where brain-dead patients could be maintained during the study intervention and what health care personnel would be involved in providing clinical care. ■

Study questions true extent of 'trial effect'

No evidence to support long-held belief

A new study from researchers at the Dana-Farber Cancer Institute in Boston indicates that a long-held belief among oncologists — that patients who participate in clinical trials have better outcomes overall than those who do not — may not be supported by empirical evidence.

In a report published in the Jan. 24 issue of the journal *Lancet*, investigators reviewed 26 studies that compared outcomes among trial and non-trial participants. Fourteen studies showed some evidence that trial participants had better outcomes, but just nine of the trials were designed to compare the outcomes of the participants with those nonparticipants who also would have been eligible for the trials. Of these, only three studies suggested better outcomes among trial participants than among nonparticipants. No studies showed that participants had worse outcomes than nonparticipants.

The findings seem to indicate there is little strong evidence of a "trial effect" in cancer research, the researchers say.

"Clinical trials are critical to the advancement of cancer care, but it is important that people who enroll in a study understand that their participation is intended primarily to benefit future patients," says lead author **Jeffrey M. Peppercorn**, MD, MPH, a clinical research fellow at Dana-Farber.

Many clinicians believe that patients who participate in clinical trials frequently have better outcomes than nonparticipants regardless of the efficacy of the experimental treatment involved. Known as the trial effect, it's believed that the increase in clinical monitoring and supportive care can help improve outcomes among research participants.

Although investigators found a few instances in which trial participants may have had better outcomes than nonparticipants, the limitations of the data did not allow for a definitive link between participation and improved outcomes, adds study co-author **Steven Joffe**, MD, MPH, instructor in pediatrics at Dana-Farber and Children's Hospital in Boston.

Although about half of the studies found some evidence of a trial effect, methodological difficulties with the studies' design makes the resulting interpretations questionable, the authors state.

They contend that there are four possible reasons that trial participants could experience an improved outcome vs. nonparticipants:

1. Experimental treatment effect — the experimental treatment offered is an improvement over standard therapy.

2. Participation effect — aspects of trial participation other than the investigational treatment improve outcomes (changes in doctor-patient relationship, improved monitoring, etc.).

3. Confounding case characteristics — differences in baseline characteristics (age, gender, socioeconomic status) that might influence both outcome and trial participation.

4. Bias in collection of data — follow-up might be more complete in trial participants that nonparticipants, or publication bias might result in dissemination of studies that find an effect in certain populations whereas researchers have little incentive to publish investigations that show no effect.

Collection bias and reporting bias can work both ways, the researchers note, concealing some trial effects while indicating effects where none truly exist.

To accurately evaluate a trial effect, it is particularly important to identify an appropriate comparison group — that participation be the only difference between participants in a trial and nonparticipants.

This might best be accomplished by comparing outcomes among participants in a trial and those who were offered study participation, but declined. This strategy is not foolproof, but offers several advantages over the other methods used, they said.

SOURCE

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"More research is still needed to determine whether trial participation can confer a predictable benefit," Joffe reports.

However, oncologists should be sure to emphasize the true goals of research trials when recruiting patients and not any perceived direct benefit of participation, say Joffe and Peppercorn.

Public statements that indicate trial participation is a key in obtaining better outcomes for patients can be misleading for both patients and their physicians, they add.

However, the belief that clinical trials offer the best treatment for patients with cancer is widespread in the oncology community, the authors note.

For example, the American Federation of Clinical Oncologic Societies states, "Treatment in a clinical trial is often a cancer patient's best option."

Such claims suggest that trials are viewed not only as a way to improve future treatment, but also as the best treatment for current patients. The view that trials lead to better outcomes, if correct, has important implications. First, that more than 95% of adults and perhaps 40% of children with cancer do not enroll in trials would constitute evidence of substandard care, the authors add. ■

AMA releases report on insurance coverage ethics

Program outlines criteria for ethical decision making

Removing financial incentives to providers and employers that are designed to influence coverage decisions and recruiting patient representatives to participate in designing health care benefit packages are two measures that can help ensure that health care coverage decisions are fair and equitable, says a new report from an independent research arm of the American Medical Association (AMA) in Chicago.

The report, "Ensuring Fairness in Health Care Coverage Decisions," was issued in February by the AMA's Institute for Ethics' Ethical Force Program, a collaborative group charged with developing systemwide performance measures for ethics in health care. The panel includes representation from patient groups, providers, health care delivery organizations, accrediting bodies, government agencies, purchasers, academics, and others.

"This report is groundbreaking because of the diversity of the group that came to consensus on these difficult issues, the clarity of the agenda the report sets out, and the actionable steps it recommends organizations take to ensure that coverage decisions are credible, understandable, and fair for patients," says **Myrl Weinberg**, CAE, president of the National Health Council and chair of the Ethical Force Program.

The report outlines five basic criteria for making ethical coverage decisions and then includes specific recommendations for each criterion. The criteria state that health care coverage decisions should be participatory, equitable and consistent, compassionate, sensitive to value (consider available resources and the existing limits on them), and transparent.

The report features more than 70 specific recommendations in these key areas, including:

- Financial incentives should not be placed on decision makers to affect coverage decisions.
- Special monitoring is needed to ensure that vulnerable people, such as the elderly, disabled, and those with health literacy problems, receive appropriate care.
- Coverage denials should be explained in writing, using basic and direct language that patients can easily understand.
- Organizations should have an ombudsman to explain coverage decisions.
- Patient representatives should be involved in designing health benefit packages.

Founded in 1997, the Ethical Force Program is charged with developing ethical standards and performance measures for the entire health care system, not just providers, says AMA spokesman **Ross Fraser**.

Although AMA members are bound by the association's code of ethics, and other participants in the health care system may be bound by other individual professional codes of ethics, leaders at the Institute of Ethics felt that there needed to be some set of shared, fundamental ethical principles that could be agreed upon by all stakeholders.

The program's Fair Coverage Decisions Initiative is the second ethical focus area for the group; the first involved developing patient privacy and confidentiality standards.

SOURCE

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The program's oversight committee decided to examine ethics in coverage decisions because it felt that ensuring the integrity and fairness of the processes for making health coverage decisions were the cornerstone of fostering trust in health care organizations, the authors of the report explained.

However, coverage decisions can be ethically complex in that each group involved in designing and administering health care benefits packages has unique and, sometimes, conflicting responsibilities that must be weighed against one another.

For example, employers, unions, government and other purchasers generally decide what sorts of benefits packages to offer, the authors state. They design packages for beneficiaries.

And health plans and clinicians are charged with administering these packages — thus, making coverage decisions for individuals.

But sometimes purchasers are involved in administration issues, especially when they self-insure and perform both administration and payment functions, the report states. And health plans frequently negotiate with purchasers, brokers, unions, and others about benefit package designs that they must then administer.

Added to these overlapping responsibilities, each participant in the health care system may recognize different competing demands on available resources as well as different ethical standards as to what are considered "good" decisions.

"Valid distinctions often exist between professional ethics, business ethics, public health ethics, and personal ethics," the report states. "Given the varying standards and priorities (ethical and otherwise) within organizations, deciding how to apply different criteria when designing and administering health benefits packages is one of the most complex and potentially divisive challenges health care leaders now face."

The program members felt that questions about the fairness of coverage decisions tended to arise in three basic areas: access to care, benefits package design, and benefits administration.

However, the final report focuses only on package design and benefits administration when developing recommendations, the authors note.

The issue of access to health care coverage — basically, the problem of large numbers of uninsured Americans — presented unique ethical and social challenges that were beyond the scope of the report and recommendations and deserved separate consideration.

In the context of this report, "coverage decisions" are decisions about which products and services are covered for which population, not decisions about which populations or people are eligible for coverage.

Hiding underlying inequalities?

By only focusing on covered populations, some members felt the report would inappropriately hide underlying inequalities in the health care system and conceal large, unethical coverage decisions.

"Improving the ethical legitimacy of coverage decisions within small, isolated pieces of a structurally unfair system could lead to complacency about the system as a whole, especially if it fails to challenge, or, worse, masks the inequities of the underlying system," the report states. "For example, an organization might do a very good job of allocating resources for health care within its covered population, but intentionally exclude from this population, the ill, the infirm, or those at higher risk of illness."

Although many think of coverage decisions as the sole responsibility of third-party payers and employers, the report emphasizes the role that other participants in the health system play.

Often, practitioners and patients demonize third-party payers and others involved in benefit administration roles, which reinforces distrust in the health care system as a whole, and also fails to acknowledge their responsibility for plan design and administration, the report states.

Some groups are becoming scapegoats, while

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others are escaping scrutiny. For example, they note, the important role of health care purchasers in designing benefits packages may not be recognized when insurers and practitioners are seen implementing restrictions on benefits.

Important trade-offs between cost and coverage may not be apparent to consumers/patients who ultimately pay for benefits packages but have no role in designing them.

Copies of the program's final report are available for download from the AMA's Ethical Force program web site at www.ama-assn.org/ama/pub/category/2558.html. The report also will be published in the June 2004 issue of the *American Journal of Bioethics*. ■

CME Questions

13. The product to be tested on emergency trauma patients in Denver is:
A. A blood substitute
B. An experimental lung assist device
C. A new cancer drug
D. None of the above

14. Which managed care organization initiated a new program in 1990 aimed at addressing substance abuse in pregnant women?
A. BlueChoice
B. Allina
C. Kaiser Permanente
D. Aetna

15. Researchers at Dana-Farber Cancer Institute have questioned the scientific support for:
A. The placebo effect
B. The treatment effect
C. The "trial effect," a predictable benefit from clinical trial participation
D. Informed consent

16. According to our article, the first initiative from the AMA's Institute for Ethics Ethical Force Program examined:
A. Racial disparities in access to care
B. Privacy and confidentiality issues
C. Ethical insurance coverage decisions
D. Medical profiling

Answers: 13-A; 14-C; 15-C; 16-B.

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. ■