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The Protection of Human Subjects in Clinical Research

by Ruby H. Greene

In the biomedical context, therapy ordinarily refers to a set of activities whose primary purpose is to relieve suffering and to restore or maintain health. The foremost goal is for the recipient to benefit medically from the new drug, vaccine, treatment or diagnostic procedure being tried. By contrast, research or experimentation refers to a set of activities whose primary purpose is to develop or contribute to generalized knowledge about the chemical, physiological or psychological processes involved in human functioning. Its aim is to provide information required by the researchers.

Biomedical experimentation using human subjects falls into four broad categories: therapy, research, therapeutic treatment, and non-therapeutic treatment. All such experimentation, whatever its purpose, raises serious ethical challenges and concerns. These include recruitment and payment of human research subjects, justification for payment, payment models, finder's fees, and risks to subjects. The question raised by all these practices is: Does informed consent adequately protect the patient, especially the disadvantaged patient, from economic exploitation? (Lind, 1990)

Recruitment of and payment to human research subjects is thought to exert undue influence on subjects, particularly subjects from disadvantaged populations, to assume an excessive share of risks and burdens. Many research subjects are in public institutions such as prison wards, homes for the mentally retarded, and public hospital wards. It may put disinterested subjects at risk for injury, and it surely changes the investigator-subject relationship. Payment has typically been justified as being necessary, even vital, to the recruitment of subjects. The thinking has been that though participation requires little skill on the part of subjects, it does take time and effort and requires the endurance of uncomfortable procedures, so it should not require financial sacrifice. (Dickert & Grady, 1999)

Three groups of potential research subjects present especially troubling ethical issues: children (CFR 46.401, 1991) – can they really give consent? does parental consent (CFR 46.408, 1991) apply?; prisoners (CFR 46.301, 1991) – does their situation make it so that their consent cannot be sufficiently free and informed?; and paid research subjects – does payment for research take advantage of the economically deprived? (CFR, 1991).

Too many researchers look at informed consent as a document they have to get signed, a hurdle they have to leap over. They don't appreciate that it is a bedrock principle that defines the relationship between the subject population and the researchers. As such it is a process that must be taken seriously. This is true for all parties participating in the research but it is doubly true for people who might justifiably be skeptical of what the researcher is doing.

Minority populations and research investigators: a relationship of mistrust

It is no secret that among minority populations there has been a long-standing and historically warranted mistrust of research investigators. Prior to World War II, most researchers in medicine operated virtually alone. It was only after the war that the modern research laboratory was born, a place where researchers worked together on common problems

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In This Issue

Casey E. Warren is HAP's 2002 Porrath Fellow in Cancer Patient Advocacy

The Health Advocacy Program is pleased to announce this year's Porrath Fellow in Cancer Patient Advocacy, Casey E. Warren of Fort Montgomery, New York. Casey will be working this summer at the Zalmen A. Arlin Cancer Institute at the Westchester Medical Center, under Executive Director Constance Engelking. She will be helping to create a model pilot cancer patient advocacy program that could be replicated elsewhere. To develop the program, Casey will be researching the best practices of cancer patient advocacy in clinical care settings. Casey, a first year HAP student, is the ideal Porrath Fellow. In her application for the $10,000 fellowship, she wrote the following:

At the age of 32, I found myself in the unimaginable position of being a cancer patient. The mother of two small children, I had been an extremely active and healthy individual. Being diagnosed with Hodgkin's lymphoma felt like being thrown into a small rowboat and told to row across the Atlantic. The route was choppy, filled with danger, fraught with frustration and made me prone to bouts of nausea. The worst part about the trip was being alone.

Casey's goal is to become a professional cancer patient advocate and help others navigate the difficult, frustrating, complicated and often lonely path of a cancer patient. Both Casey's goal and her summer project fit the vision of the Porrath Foundation for Patient Advocacy: "Every person diagnosed with cancer, regardless of personal resources or geography, will have access to the vital information, tools and trained Cancer Patient Advocates they need to proactively manage the cancer process. These resources will immediately help cancer patients address their fears and effectively sort through the overwhelming array of information to: get answers, make decisions and outwit cancer."

Connie Engelking, the Executive Director of the Arlin Cancer Institute, is also the Vice President for Clinical Research and Grants Administration at the Arlin Cancer Institute. In fact, the Resource Center for cancer patients and families at the Arlin Cancer Institute was developed by Connie and a Health Advocacy Program intern, now graduate, Eleanor Scarcella. ■

CALENDAR

October 2. Lecture by Pulitzer Prize-winner Laurie Garrett, author of The Coming Plague: Newly emerging diseases in a world out of Balance and Betrayal of Trust: The Collapse of Global Public Health, [Co-sponsored by Center for Continuing Education and Health, Science, and Society]

October 14. *"Positive Exposure," a video/photographic presentation by photographer Rick Guidotti and epidemiologist Diane McLean, challenging public fears about difference and celebrating the richness of genetic variation. [Co-sponsored by Human Genetics, Health Advocacy and Center for Continuing Education]

October 22. "From Corsets to Body Piercing: An Historical Perspective on Female Adolescence," a lecture by Joan Jacobs Brumberg, professor of Feminist, Gender, and Sexuality Studies at Cornell University. [Co-sponsored with Center for Continuing Education, Women's History, Psychology, Health Services]

Theresa Foster: First Porrath Fellow in Patient Advocacy

Last year, dual Health Advocacy and Human Genetics student Theresa Foster of New York City was awarded the very first Porrath Fellowship in Patient Advocacy (see *Health Advocacy Bulletin* Spring 2001 for further background on the Porrath Fellowship).

Theresa used her $10,000 fellowship to intern for the summer of 2001 at the Breast Examination Center of Harlem (BECH), a community program of Memorial Sloan Kettering Cancer Center, under the supervision of Director Diana Godfrey. Theresa worked with patient navigators and patient educators at the Center, learning how to advocate for women who screen positive for cancer. She also helped codify procedures for following up with women who screen positive.

Theresa got interested in advocacy early by watching her mother advocate for her younger sister, who was born with cerebral palsy. "My mother was a health advocate for my sister before we even knew what that was," said Theresa in the *New York Times Magazine* education supplement last year. Even as a child, Theresa was helping her sister with her motor skills and helping her mother research medical terms. When Theresa's mom was herself diagnosed with a brain cyst, Theresa had to step up and become a self-directed health advocate as well.

Theresa, who is spending the summer of 2002 interning at Memorial Sloan-Kettering Cancer Center. will receive her M.S. in Human Genetics in September 2002 and her M.P.S. in Health Advocacy in December 2002. She intends to combine health advocacy and genetic counseling in a cancer care setting. Through her experience as a Porrath Fellow at BECH, Theresa says she gained "a lot of respect for the amount of work and empathy needed to provide quality, community-based care. I'm now even more motivated to help women with cancer."

The Porrath Fellowships for Patient Advocacy allow one Sarah Lawrence health advocacy student every year to work as an unpaid intern in a clinical cancer setting. These fellowships allow students who could not otherwise afford to work in this field during their studies to do so. Students interested in applying for the 2003 Porrath Fellowship for Patient Advocacy should contact HAP director Marsha Hurst at mhurst@slc.edu. ■

http://slc.edu/~health

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Fly on the Wall: My Visit to the Downstate IRB

By Deborah Hornstra

Have you ever wondered what goes on during a meeting of an Institutional Review Board? Are you even sure you know what an Institutional Review Board does? Though it is essentially concerned with ethics, the IRB has a more specific charge than a hospital's ethics committee. The IRB exists for one purpose only: to monitor and safeguard the rights and welfare of human subjects participating in clinical research. To this end the IRB regularly reviews research protocols to ensure compliance with all laws, regulations and institutional policies.

I was privileged to be permitted to attend a meeting of the IRB at the State University of New York/Downstate Medical Center in Brooklyn this spring. Downstate actually has two IRBs, known as Board A and Board B. They each meet monthly and divvy up the cases between them. I was there as the guest of Alice Herb, a lawyer by training who now teaches ethics to both aspiring health advocates at Sarah Lawrence and aspiring physicians at Downstate. Alice represents the Humanities in Medicine division of the hospital on the IRB. Mine was a rare opportunity to be the proverbial fly on the wall and see how an IRB functions behind normally closed doors.

The mix of people in the conference room was striking in its diversity and its uniformity. Federal regulations require that IRB members have a variety of backgrounds, education and experience. Like many hospitals, Downstate tries to include an expert in each medical discipline on each of its IRBs. So there's a pathologist, an endocrinologist, an emergency room doctor, a pediatrician, a psychiatrist, a neurologist, a surgeon, an ob/gyn, and a couple of internists. There is also one community member, who is typically a non-scientist with no current affiliation with the institution.

HAP graduate Donna Gentry serves as the IRB's Associate Administrator. As part of the three-person IRB staff, Donna manages the review of proposed research projects and ensures that all relevant information has been submitted to the IRB and forwarded to the appropriate reviewer (not every member reviews every case). The IRB administrators also serve as the liaisons between clinical researchers and the board, and help to train principal investigators in the rules and regulations applicable to research with human subjects.

"For example," says Donna, "a physician comes into the office wanting to do a study. First we have to make sure he's done the educational component required of the institution in order to do research on human subjects. We have an online course for investigators and all other individuals involved in research, and we have a database to track those who complete it and those who don't.

"If they've done their education," Donna continues, "we have to look through their paperwork and make sure it contains all the necessary documents and proper signatures. We then do a first review to decide if the request has to go to the full board or if it can go through an "expedited" procedure, which allows the chair to approve the study without board discussion. This decision is based on federal regulations that outline exactly what has to be reviewed by the full board and what doesn't."

Back in the stark, completely unadorned conference room, chairs are arranged in a square so everybody can see everybody else. There is a cheerful camaraderie as the meeting begins. Though it is still only mid-morning, almost everybody helps themselves to the thick New York-style sandwiches, potato chips and sodas available up front. (I am always amazed at the type of food available in health care institutions!)

Donna hands out the meeting agenda and related paperwork. Again I notice that the board is diverse in the sense that nearly all medical disciplines are represented. There are seven women and ten men. But still, 11 of the board's 17 members are medical doctors. Among the remaining six members, there are two lawyers (including the community representative), one nursing administrator, one pharmacist, and one person who holds a master's in public administration. Only two board members do not hold an advanced degree. Most members are in their fifties or older. The board is overwhelmingly white.

A few minutes are given over to small talk while members wait for a quorum, then the Board quickly reapproves a series of ongoing studies (all studies must be reapproved annually or more frequently). The only controversy among the ongoing studies concerned a study of melatonin in which the potential side effects were not clearly delineated in the consent form. The IRB members expressed collective disbelief that the study could have been ongoing for five years without this.

It is actually the IRB administrators who help investigators write their consent forms. "The consent forms have to be written at a sixth grade level," explains Donna, "and very often they need a lot of work before they're comprehensible by a lay person." By federal law, consent forms must give potential study participants enough information to make an "informed decision."

"We usually read the entire protocol, so we have to be comfortable with scientific language," says Donna. "We then try to help investigators condense the information into readable, understandable language. We try to use simple language, short sentences and the active voice. But no matter how much we try, it will often take months before a consent form is approved. Either the investigator doesn't make the changes promptly, or very often, the changes have to go back through the study sponsor who can object to all or part of what the IRB wants, typically for legal reasons. Usually we can work out a compromise, but it can take time."

Most of the new studies are quickly approved, but there are two controversial items on the day's agenda that provide a chance to see how the board operates in deliberative, collaborative fashion. The first concerns a new laser-type device for monitoring blood pressure in patients who have suffered traumatic brain injury. The study's principal investigator, a young physician who has apparently been waiting in the hallway, is about to answer some questions from the board about his study. The questions come from all over the room in an orderly fashion. First off, Will you be collecting clinical data? Yes, answers the P.I.

A board member asked the P.I. to explain exactly how the device is used, which he did. The researcher gave a few

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examples of how the new device was an advance over the existing technology for monitoring blood pressure.

But isn't the device also more intrusive? he was asked. The device is exactly the same as the old device except for a 5 mm fiber extension, and the way the old device is inserted, you get practically the same result with this one. The researcher reminded the board that this device is typically used during an emergency, life-saving procedure. It may sound like we're violating informed consent but these are very acute situations. Alice pointed out that there are emergency exemptions from informed consent requirements and that these situations either do or they do not fall under those emergency exemptions.

Clearly the board had issues with this study: the collection of clinical data (for what purpose?), the invasive nature of the procedure performed with the device, and the inability of most potential study participants (or even their family members, in many cases) to give informed consent to the use of the experimental device due to the emergency nature of its indications for use. The doctor was thanked and asked to leave the room. After some discussion, the Board agreed the study was not necessary as the indications for use of the experimental device fell under the emergency exemptions.

The other controversial study on the agenda involved a new medication for children with hypertension. Of course research with children as subjects always presents additional ethical (and legal) considerations. Most researchers do not want to do research on children for these reasons and there is a serious shortage of medical research on children.

As an IRB member pointed out, almost all medications are therefore not officially approved for children, and almost all medications (including psychiatric medications) prescribed to children are prescribed "off-label." It's "standard practice," this doctor said, and no one there disagreed with him.

The federal government recently enacted a law meant to motivate pharmaceutical companies to sponsor research on children. Companies are now allowed a potentially lucrative six-month patent extension if they will perform the research. This study involved a researcher who wanted to take a group of hypertensive kids off the medication they were currently on (which was controlling their condition) and put them on either a new medication he was testing or a placebo.

The P.I. was brought out of the "soundproof booth" (the hallway), greeted politely and immediately asked, Why take people off their meds if they're doing well on those meds? He replied it was standard practice to take people off these meds periodically anyway to see if they still needed them. An IRB member said that does not address our concerns about taking people off their meds, it just tells us that other people are doing it as well.

This study had been turned down once before. A board member noted that it is rare they turn something down, so it's an indication they are "unusually concerned." The P.I. said the participants' parents would monitor their blood pressure once a week using kits provided by the drug manufacturer. If it spiked above a certain level, the child would be brought in for immediate treatment. The P.I. reiterated that the study involved patients with only mild hypertension and no endocrine damage. He added that many doctors would not even medicate patients with this level of hypertension; instead they would treat it by prescribing exercise and change of diet.

Asked the purpose of the study, the P.I. said We're trying to figure out what the starting dose is for a child. We don't know so we're starting with a very small dose, a baby dose. And yes, the drug's manufacturer was sponsoring the study because they want the six-month patent extension. The P.I. said nobody will pay for a study of the proper dose of the medication currently being prescribed because it is already off patent and available in generic form.

The board wanted to know whether the FDA required a placebo in this type of research. Clearly their concern was with the stopping of the medication for up to 24 days in the case of participants receiving the placebo. The researcher explained that doing it without a placebo would require a much larger sample which would increase the general risk. Additionally, he noted that there is a lot of "white coat hypertension" in kids, and that hypertension is a totally different disease in kids and we have virtually no data. He also mentioned that the FDA has issued a general directive encouraging research in kids.

Another member raised an issue everyone on the board agreed was problematic: a proposal to pay a $50 payment per needlestick to each participant. This was readily seen by most (but not all) board members as far too attractive to a child and therefore coercive. The board also raised concerns about the monitoring process. What will make the mother do the monitoring, they wanted to know. What will make the child cooperate? How do we know the mother knows how to do this? Many studies call for monitoring at home, responded the P.I. If we doubt this can be done we doubt all such studies.

Again, the board members had had their chance to ask questions and the researcher was thanked and politely shown the door. One member proposed some changes to the study, including monitoring three times a week by staff, not parents, education for the parents, and a modest payment to participants of $10 per needlestick. A vote was taken which ended in a tie, defeating the motion to approve the study. But a second vote to establish a committee comprised of pediatricians and cardiologists, to be chaired by Alice and charged with studying these issues further, passed easily.

The meeting went an hour over its scheduled length and concluded with people either rushing out of the room or falling into small groups to talk. The meeting demonstrated to me the strength of the idea of Institutional Review Boards and the importance of their mission. The members took their responsibilities very seriously and were in no sense pushovers. That said, I do believe more diversity must be encouraged, if not mandated. We need not only a diversity of medical viewpoints, but a diversity of viewpoints in general, including those from outside the medical community.

Perhaps IRBs should be mandated to include at least one patient advocate. Donna says that advocates should argue for more oversight and monitoring of the process, especially with the growing awareness of clinical research among the general public. "By protecting human subjects in a particular research study in a particular place, we are practicing a type of advocacy," Donna suggests. "We try and look at each study and each consent form with the eye of a potential participant, asking, Would I understand what this means? Are these people being coerced in some way to do something unsafe? Is this a feasible thing to ask people to do?" ■

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and where the research model for medicine was developed.

After discovery of the medical atrocities committed by the Nazis during World War II, the Nuremberg Code (The Nuremberg Code, 1949) was developed under the auspices of the US military. The Code is a ten-point statement on medical ethics. Subtitled "Directives for Human Experimentation," the Nuremberg Code established the importance of voluntary consent to research participation. The first sentence of the Code reads "The voluntary consent of the human subject is absolutely essential." The Code also called for avoidance of the physical and mental suffering of participants.

Unfortunately, researchers have not always adhered to the precepts of the Nuremberg Code. Minority mistrust of research investigators is traced to incidents such as the infamous Tuskegee Syphilis Study (Jones, 1981) in which four hundred African-American men from rural Macon County, Alabama were lied to by the United States Public Health Service. They were neither told they had syphilis nor treated for it, even after the discovery (ironically in 1949, the year the Nuremberg Code was published) that penicillin would cure it.

The Tuskegee Study (Wolinsky, 1997) began in 1932, before adoption of the Nuremberg Code, but it continued until 1972, when a journalist made public the fact that curative therapies were being deliberately withheld from the participants. In fact, according to Dr. James Jones of the University of Houston, author of *Bad Blood: The Tuskegee Syphilis Experiment*, as awareness of the benefits of penicillin grew, the researchers saw greater urgency in continuing a "never-to-be-repeated opportunity." When Dr. Jones interviewed Dr. John Heller, who at the time was the director of the Public Health Service's Division of Venereal Diseases, Dr. Heller said that he saw no connection between the Nazi atrocities and the Tuskegee study. "For the most part, doctors and civil servants simply did their jobs. Some merely 'followed orders,' others worked for 'the glory of science.'"

1979: The Belmont Report

The 1979 Belmont Report (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979) was a milestone in thinking about clinical research subjects. It set forth three principles or judgments that are generally accepted in our cultural tradition and are relevant to human research. The first is *respect* for persons, which incorporates two ethical convictions:

- that individuals should be treated as autonomous agents; and
- that persons with diminished autonomy are entitled to respect.

So we not only acknowledge autonomy but we also *protect* autonomy. That means we give weight to that person's considered opinions, and refrain from obstructing their actions unless they are clearly detrimental to others. Some persons may need protection even to the point of excluding them from activities which may harm them, while others may only require protections that ensure they undertake activities freely and with awareness of the possible adverse consequences. The extent of protection should depend upon the risk of harm and the likelihood of benefit.

The second principle espoused in the Belmont Report is *beneficence.* This principle holds that individuals are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well being. The term is often understood to cover acts of kindness or charity that go beyond strict obligation. In the Belmont Report, beneficence is formulated as complementary expressions of:

- Do no harm, which has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying one should not injure one person regardless of the benefits that might come to others.
- Maximize possible benefits and minimize possible harms.

The obligations of beneficence affect both individual investigators and society at large. Investigators must give forethought to the maximization of benefits and the reduction of risk. Members of the larger society are obliged to give forethought to the longer term benefits that might result from the improvement of knowledge.

The third and final principle expressed in the Belmont Report is *justice*. Who should receive the benefits of research and who should bear the burdens? This is the question of justice, in the sense that it concerns fairness in distribution or the issue of what is deserved. An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unfairly.

If the concept of justice also means that equals ought to be treated equally, what would be a just way of distributing burdens and benefits?

- Everyone an equal share
- Each according to need
- Each according to effort
- Each according to societal contribution or
- Each according to merit

During the 19th and 20th centuries, the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. We have seen the exploitation of unwilling prisoners as research subjects, with the activities conducted in the Nazi concentration camps a particularly flagrant injustice. And we have seen how in this country the subjects in the Tuskegee syphilis study were deprived of treatment long after it was known to be effective so as not to interrupt the project. Against this historical background, we can see how conceptions of justice are relevant to research. (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

Trust, Risk and Access

Tuskegee has become a symbol of ethical misconduct in human research. In 1997, President Clinton officially apologized on behalf of the U.S government for the Tuskegee study, but we should not be surprised that there is still an underlying element of distrust between poor populations and minority populations who may be the subjects of research and the research establishment. The outrage over the Tuskegee study led to the requirement of informed consent and to other safeguards, such as the creation of institutional review boards (see "Fly on the Wall," p. 3), data and safety monitoring boards, and continuing ethics education for researchers.

Research investigators must regain the trust not only of minority populations, but of all people who care about the protection of human subjects in clinical research. As cross-cultural research is extraordinarily difficult, one very effective way to do this is to use researchers and physicians who are part of the minority,

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who will naturally be trusted more. Of course, much more needs to be done to increase the participation of women, minorities, and persons with disabilities in science and engineering programs. Additionally, researchers themselves need to conduct community outreach programs. Investigators must understand that mistrust is there and that there are historical bases for misconceptions and wrongly held beliefs, such as the belief that HIV was created by the government and introduced into the black community as a means of genocide (Tuskegee Syphilis Study Legacy Committee Report, 1996).

Because minority access to health care is restricted by so many barriers, minorities may be very concerned when they are asked to participate in research. The feeling seems to be, All of a sudden, a research group is interested in me. Why are you interested in me now? Even when minorities do participate in studies that yield advances in treatment, too often they can't afford to pay for those same benefits once they hit the market. This is something that has not been completely eliminated in the minds of the disadvantaged.

If you're asked to be a research subject, but you aren't going to reap the benefits of the research, why should you participate? The issue is ultimately one of the structure of our health care system and the uneven lack of access to it.

The fact is research subjects place themselves at risk. The risk of participation in research may be part of the research design or it may be a consequence of the research procedures, or both. For example, the risks of an adverse reaction to an investigative drug are part of the research design, while the risk of a hematoma from blood drawn in the research is not part of the design but a consequence of the research procedures. Risks may be a consequence of the methods of recording, maintaining or reporting data, and they may be a consequence of the methods of obtaining informed consent.

Federal regulations governing research with human subjects define "minimal risk" as a situation in which "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests."(Weijer, 1999).

Broadly defined, minimal risk can be said to entail the following:

- The participant experiences no pain or physical danger.
- The participant experiences no emotional arousal or psychological stress beyond the levels normally to be expected in daily life.
- The project neither induces nor attempts to induce long-term significant change in the participant's behaviors, including attitude toward others and self.
- The data would not embarrass or socially disadvantage the participant, were confidentiality to be violated.
- Any concealment on the part of or misinformation provided by the investigator with regard to the specific purpose of the project is such that there is no basis for believing that the participant would choose not to participate had the true state of affairs been made known to him/her.

While it is difficult to develop a rule that can be applied across all disciplines and in all situations, the researcher must apply the customs and practices associated with his/her discipline, such as would be outlined in a code of ethics, in making this initial determination.

We take as a given that researchers have an ethical and moral obligation to safeguard the rights and welfare of all subjects involved in research. Examples of physical risks include physical discomfort, pain, injury, illness or disease brought about by the methods and procedures of the research. It may result from the involvement of physical stimuli such as noise, electric shock, heat, cold, etc. Engaging the subject in a social situation which could involve violence may also create a physical risk.

Examples of psychological risks include the production of negative affective states such as anxiety, depression, guilt, shock and loss of self-esteem and altered behavior. Sensory deprivation, sleep deprivation, the use of hypnosis, deception or mental stresses are examples of psychological risks.

Psychological risks should be addressed in the cover statement to the consent form: *If you feel uncomfortable answering any of the questions, you may discontinue at any time or skip to the next question. If you experience any stress, anxiety or psychological discomfort as a result of participation in this research, you may contact* _____. Psychological risks should also be mentioned in the debriefing statement: *Answering personal questions about one's life can be a disconcerting experience. If answering any of these questions has upset you, or made you think of your own questions, or if you have experienced any stress or discomfort as a result of participation in this research, you may contact* _____.

Occasionally, some degree of deception is involved in a research study (National Health and Medical Research Council, 1992). Minor deception, such as failing to tell the subject what the specific points of interest are in an attempt to prevent biasing the results, could be acceptable provided the subject is fully debriefed after participating. Major deceptions, such as leading a subject to believe that s/he has committed a crime or has a disease, must be counterbalanced by the benefits of the research.

Researchers need to show why deception is needed, how the potential benefits justify its use, and how debriefing will be done. The key to all of this is that *withholding information cannot be used as a means to secure the participation of subjects in research.* If information was temporarily withheld from the subject during the study, or if deception was employed, a separate debriefing statement should be presented at the end of the procedure. This statement should clearly state why information was withheld during the study, and/or the purpose of the deception.

Risks are not limited to the physical and the psychological. Research participants are also subject to social risks, including alterations in their relationships with others that are to the disadvantage of the subject, including embarrassment, the loss of others' respect, the labeling of the subject in a way that will have negative consequences, or the diminishing in some way of the opportunities and powers a person has by virtue of his or her relationship with others.

Risks to subjects may also be economic. They include payment by subjects for procedures not otherwise required, loss of wages or other income, and any financial costs, such as damage to their employability, that may be a consequence of their participation in the research.

Loss of confidentiality is another risk to research participants. In all research involving human subjects, confidentiality of identifiable information is presumed and must be maintained unless

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Gender and Quality of Care—Comparing East and West

by Judith F. Helzner

When "Quality of Care" was introduced as a concept worthy of explicit attention by family planning programs in the late 1980s, it was considered by many practitioners and researchers to be vague and subjective rather than capable of being standardized and measured. Over time, a variety of tools and indicators have been developed to ground the assessment of quality of care in concrete medical and social terms. More recently, the concept of "gender analysis" has been introduced into family planning and reproductive health, with a number of the same concerns – lack of understanding of its basic components, suspicion of its usefulness in evaluation, and skepticism regarding the possibility of generalizing beyond a specific cultural context. The question of how "reproductive and sexual rights" can be implemented or assessed in programs is still generating questions and doubts.

Yet, in all three areas, instruments and tools can put fuzzy ideas into measurable terms and can help lead to recommendations for action. One such tool has been developed by International Planned Parenthood Federation/Western Hemisphere Region (IPPF/WHR) in collaboration with the Latin American and Caribbean Women's Health Network (LACWHN).

Working with a team of feminists, evaluators and program managers from Latin America and the Caribbean, key concepts of gender, sexual and reproductive health and rights, and quality of care were identified and the *Manual to Evaluate Quality of Care from a Gender Perspective* was developed, starting in 1995. Field experience in a number of Latin American countries including Brazil, Colombia, the Dominican Republic, Honduras, Peru and Bolivia, has shown the methodology to be effective at assessing the extent to which both public and private sector organizations are sensitive to gender issues and in identifying areas for improvement.

In 2000, the Manual was translated into Chinese. It is in the process of being adapted and pilot-tested in one urban and one rural district, both participating in China's quality improvement efforts. In July 2001, a workshop allowed me to review the methodology with colleagues in

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GENDER ISSUES	LATIN AMERICA	CHINA
1. Women's practical gender needs based on child care	Have area with toys/staff with a watchful eye for children in waiting room	Not relevant due to small family size (usually 1 child) and fact that mothers usually have someone with whom to leave the child
2. IEC material review to find gender-based images	Watch for men doctors, women nurses	Mostly women doctors but watch for images of boys as single child
3. Gender sensitive language a) Written language b) Spoken language	a) The existence of masculine and feminine words in Romance languages means the need to examine male words used for women b) Using "Mrs." (Sra.) is respectful; diminutives/ nicknames can show contempt/disdain/lack of respect (mijita, mamita) (In both places, waving and pointing, avoiding 'please/thank you,' not using courteous tone, can be problems)	a) Language does not have gendered words (even he/she as pronouns) [but characters used can have meanings based on male/female gender stereotypes, or be more neutral (sounds)] b) Referring to women as Auntie/ Big sister in law may be <u>more</u> respectful than using the equivalent of "Mrs." with the woman's last name
4. Rights approach	Charter and poster available in Spanish and Portuguese; relatively little use of rights approach in client education; some lessons from Colombia e.g. • Legal service • Brochure with pictures • New tripartite project	China has translated IPPF Charter on Sexual and Reproductive Rights and poster. Has its own interpretation of some of the rights e.g. to freely decide number of children
5. Providers' views of service program's mission or goal and client-provider interaction as a power dynamic	From family planning to reproductive health (sexual health) per ICPD	"2 reorientations" – i.e., from one child policy with little method choice or client orientation to more concern for method choice and information, and alternatives to sterilization

The Protection of Human Subjects in Clinical Trials

Continued from page 6

the investigator obtains the express permission of the subject to do otherwise. Subjects have the right to be protected against injury or illegal invasions of their privacy and to preservation of their personal dignity. The more sensitive the research material, the greater the care that must be exercised in obtaining, handling, and storing data (NIH, 1993).

There are two legal ways in which research subjects may lose their confidentiality and/or anonymity. Loss of confidentiality can occur when a court requires that research files be submitted as evidence in a legal matter. The court has access to the files and determines whose identity will be revealed. Loss of confidentiality can also occur under the Freedom of Information Act. Under this Act, citizens can gain access to the files of federal agencies, except where this is expressly disallowed by law.

So how can researchers circumvent these two legal threats to confidentiality and anonymity? If research files are arranged so that the investigators cannot know the identity of the participants, then loss of confidentiality cannot occur by court order. This can be accomplished by routinely destroying master code lists. Locating the master code lists outside the country may not be sufficient to preserve confidentiality. Anonymity may be assured when there are no identifiers whatsoever on project materials which could link the data with individual subjects.

It is important to note that investigators can be held in contempt of court for failing to submit research files or for destroying master code lists only because they had knowledge of the intent of the court. However, investigators *will not* be held in contempt of court for not revealing the identity of subjects when they routinely take steps to keep the identity of subjects unknown to themselves (i.e. subjects' responses are kept anonymous). *Additionally, if identifying information is not sent to a federal agency, loss of confidentiality cannot occur under the Freedom of Information Act.* All federal files are subject to the Act.

The 1970s: The development of IRBs and other oversight mechanisms

Since 1971, FDA regulations have required that studies involving investigational new drugs and biologics performed on human subjects in institutions receive review and approval by an Institutional Review Board (IRB). This regulation includes hospitals, nursing homes, mental institutions, and prisons. Medical devices have required IRB review since 1976.

An IRB reviews and has the authority to approve, require modifications in or disapprove all research activities in the institution. The IRB ensures that information given to subjects as part of the informed consent process is in accordance with the requirements for informed consent, and notifies investigators and the institution in writing of the approval or disapproval of each proposed research activity, or of modifications required to secure IRB approval.

If the IRB decides to disapprove a proposed research activity, a statement of the reasons for the decision must be given to the investigator. The investigator must be permitted to respond either in person or in writing. The IRB also conducts continuing reviews of research at periodic intervals appropriate to the degree of risk but not less than annually.

Various entities are responsible for monitoring and improving protections for human subjects in clinical research, among them the Food and Drug Administration and the Department of Health and Human Services. Corporations engaged in this work will have a corporate code of conduct and some method of ensuring compliance with that code. The guiding principles for the protection of research subjects are:

- protection of confidentiality;
- minimizing of competing or conflicting interests;
- protection of special subject populations;
- ensuring access.

In 1977, the FDA developed the Bioresearch Monitoring Program and began to expand their review of IRB operations. This program now encompasses IRBs, clinical investigators, research sponsors, monitors, and non-clinical (animal) laboratories. The program's primary responsibility is to ensure the quality and integrity of data submitted to the FDA for regulatory decisions. For this reason IRB regulations permit the FDA to inspect, review, and copy IRB records.

The FDA is the largest IRB oversight of any federal agency and the only federal program for oversight of radioactive drug research committees. The FDA performs periodic on-site inspections of all IRBs that are known to review FDA-regulated studies. In cases of serious non-compliance, FDA suspends approval of new studies and accrual of new subjects into ongoing studies. Such sanctions are imposed on more than twenty IRBs each year.

The DHHS coordinates interagency requests for applications from researchers to develop new knowledge related to the informed consent process. They offer expanded technical assistance to IRBs at institutions receiving DHHS research funds (an additional12-24 visits per year). DHHS has also increased its activities to improve procedures to protect human subjects. For example, the Centers for Disease Control are developing an online education system in research integrity and ethics that will be mandatory for investigators.

Since October 2000 the National Institute of Health has required education for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or competing awards for research involving human subjects. Additional educational resources are to be developed: The Offices for the Protection of Research Subjects (OPRS) and Clinical Research and Training (OCRT) are in the process of developing a series of training courses to comply with this new NIH requirement.

These mandatory training requirements for researchers and their support teams and the ongoing commitment and vigilance of consumer advocates are first steps in protecting the rights of human research participants in the decision-making process.

References

Links to these references can be found on the HAP website.

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. (1979). *The Belmont report: Ethical principles and guidelines for the protection of human subjects of research.*

Code of Federal Regulations. (1991). Title 45, part 46. In Department of Health and Human Services Rules and Regulations.

Dickert, N., & Grady, C. (1999). What's the price of a research subject? Approaches to Payment for research participation. *New England Journal of Medicine*, *341*, 198-203.

Jones, J. *Bad blood: The Tuskegee syphilis experiment: A tragedy of race and medicine.* New York. The Free Press, 1981.

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Report from the SHCA Annual Conference, Spring 2002 Washington, D.C.

by Marlene Gallo

It was a glorious time of the year to be in our nation's capital. Cherry blossoms were in full bloom in spite of the cool temperatures. Two hundred fifty patient advocates attended this year's conference, which was held in April in conjunction with the AHA. We were invited to join the AHA in their installation of new officers, as well as on visits to our legislators on Capitol Hill.

Friday, pre-conference sessions were held and all agreed that these were some of the best sessions offered during the conference. Hopefully, they will be incorporated into next year's general schedule. The sessions themselves were informative, enlightening and sometimes very thought provoking. One session in particular left me hungry for more information and training on a very timely issue, "Cultural Issues in Pain Management." Jerri Scarzella opened up a whole new way of viewing the diverse populations we work with and their normal reactions to pain. I truly hadn't thought about the particular characteristics in various cultures that influence patients' reactions to pain. This is a topic that should be discussed at every level of patient care by everyone from nurses' aides to physicians.

Networking is my favorite part of any conference. Many of us are the only patient reps in our hospitals and the feeling of professional isolation can be overwhelming. The annual conference gives us an opportunity to see that we are not alone and our problems are very common. Over coffee, in our hotel rooms, in the hallways we talked about the increasing complexity of the issues we handle on a day to day basis. We are all being asked to do more and more tasks that aren't necessarily related to patient issues. And we discussed the fact that numerous institutions lack the funding for our basic needs, let alone money to send us to conferences and workshops and provide us with educational materials.

This commonality creates bonds very rapidly among the attendees. I left Washington feeling like I'd made some friends for life. Armed with some new perspectives and lots of phone numbers, I returned to my job with my battery recharged.

Marlene Gallo is a patient relations representative at the SUNY Upstate Medical Center in Syracuse, New York. Previously she worked as the director of various community residences for juvenile offenders and children and adults with mental and physical disabilities. She has three grown sons and loves to dance, read, travel, and refinish furniture. ■

Gender and Quality of Care—Comparing East and West

Continued from page 7

China, including sharing some of the results from Latin America. I had the privilege of making comparisons between the meanings of gender sensitivity in Latin America and China. This article describes the basic instruments and their uses, and shares some of the differences found in the interpretation of gender in the two very different continents where the Manual is being used.

The Manual includes a variety of topics that were based on gender realities in Latin America, but that make less sense in the Chinese context (see box, page 7). For example, our Latin American colleagues were very pleased with our focus on women's need for child care, or at least on women's possible worries about where their children will be while they themselves are having the counseling or examination they need. Hence the concern in the clinic observation guide for observing the physical plant for space for children. But the fertility policies in China have meant that small family sizes are the norm, and that it is not common for women to bring their children with them to a clinic. Thus, the questions about child care are much less relevant in China.

Another example is the instruction in the "document review" to look for gender-biased language and images in IEC (information, education and communication) materials. While the issue in Latin America is whether men are usually depicted as doctors (and women as nurses or lower level staff), in China the predomi-

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Lind, S.E. (1990). Finder's fees for research subjects. *New England Journal of Medicine*, 323, 192-194.

National Health and Medical Research Council. (1992). Research involving deception of participants, concealment or covert observation. *NS* 17.1.

National Institutes of Health/Office for Protection From Research Risks. (1993). *Protecting human research subjects: Institutional review board (IRB) guidebook.*

The Nuremberg Code. (1949). *Trials of war criminals before the Nuremberg military tribunals under control council law no. 10, 2* (pp.181-182). Washington, DC: U.S. Government printing Office.

The Tuskegee Syphilis Study Legacy Committee Report: A request for redress of the wrongs of Tuskegee, 1996.

Weijer, C. (1999). Thinking clearly about research risk: Implications of the work of Benjamin Freedman. *IRB*, 21 (6), 1-5.

Wolinsky, H. Steps still being taken to undo damage of "America's Nuremberg." *Annals of Internal Medicine.*

Ruby H. Greene is the founder and President of RHG Consulting Services, a healthcare consulting and training firm. Prior to establishing her own firm, Ruby was the Director of Patient Relations at Long Island College Hospital. In that role she served as a member of the Institutional Review Board and was listed on all IRB consent forms as the individual for research participants to contact with questions regarding their rights as a research participant. She is currently a lecturer at New York University, teaching a variety of courses in the Health Administration and Health Services Policy and Planning programs. ■

The Paradox of Cuba

A field journal by Cathey Bienkowski

They say if you go for a week, you can write a book about Cuba. If you go for two weeks, you can write a paper about Cuba. If you go for longer than this, you will become so confused and bemused you will never write anything about Cuba. You'll continue visiting though just in case you can learn some more.

I went to Cuba for the third time with the Health Advocacy Program last winter. I felt I was coming back to a familiar but surreal place. Cuba is a paradox; I question my ability to comprehend a government that limits information yet cherishes education. Yet I have respect for the ethics of the health care providers I have encountered there.

This trip was co-sponsored by Medical Education Cooperation with Cuba (MEDICC) and the National School of Public Health (ENSAP). We were a group of four students, four graduates and two faculty, accompanied by two translators and Clarivel Presno, MD, President of the Cuban Society of Family Medicine and Professor, National School of Public Health.

Gail Reed, International Director of MEDICC and Dr. Presno gave the introduction on the first day of the program. Basically the information was the same as I had heard on both my previous trips. The medical ladder starts with the family doctor, goes to the polyclinic, to the subspecialist, to the hospital, and then to the specialty hospital. The emergency room is used for emergent situations. Since everyone has coverage and a family doctor, the emergency room does not have to deal with non-emergent care.

The next day was spent exploring the city after hearing from Miguel Coyula discuss the Comprehensive Development Plan for Havana.

On the third day we visited the Polyclinic Lawton, the very first family medicine clinic, which was founded eighteen years ago. Lawton serves 22,833 patients, has twenty-four hour emergency coverage and is located in the most populated neighborhood in Havana. Specialists in comprehensive care are always on call. Rosa Maria Báez Dueñas, MD, Polyclinic Director, provided a tour. Here I saw some progress in information technology, the clinic had six computers with limited Internet access.

Dr. Báez told us of the clinic's efforts to offer home hospitalization for certain illnesses, taking into account the possibility of infection and other dangers to the patient. The clinic providers met frequently to discuss mortality and morbidity issues in the community and to identify ensuing problems. One problem identified was low birth weight and what to do about it. Not doing anything is not considered an option.

That afternoon was spent in the Ethics Department of the Victoria de Girón Medical School discussing patient's rights (or lack thereof) in Cuba. Dr. José Acosta presented a difficult paper on ethics in Cuba. Our translator found it almost impossible to translate, since the concepts were so involved.

And so an interesting discussion ensued. In Cuba, individual responsibility and social responsibility are closely intertwined. Informed consent serves as a function of a certain educational perspective and body of knowledge, and is less of an ethically charged issue. The criteria for death in both countries are based on neurological criteria. But at times the value of life is viewed differently, e.g. Cuba does not consider conception as the start of life. They use as a standard an embryo's capacity for self-sufficiency. Assisted suicide does not exist in Cuba, but palliative care based on family medicine is being introduced. At this time Cubans typically want family members to die in the hospital, receiving all possible care. Educational programs are being introduced that will encourage families to take their dying relatives home.

Everything that is not futile is done when a neonate weighs less than 500 grams. We never got a clear response as to who determines futility—doctors, family or both. And we never got a proper definition of futility. The medical response has been to do whatever can be done, but the ethicists are trying to implement an understanding that doing nothing is sometimes the better alternative for some patients. One issue we did discuss was how to pay for these infants. Without the proper equipment and supplies, the concept of "doing everything" becomes moot.

Ethics is coming of age in Cuba. Informed consent is also part of the medical training now. Before 1990 the MDs made most decisions, but today, the MDs

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HAP in Cuba January 2002

Together with Medical Education Cooperation with Cuba (MEDICC) and the National School of Public Health (ENSAP), the Sarah Lawrence College Health Advocacy program sponsored a unique study program in Cuba in January 2002.

The objectives of the program were threefold:

1. To offer theoretical background and practical experiences to familiarize students with Cuba's National Health System.
2. To develop particular understanding among students of the Family Doctor-and-Nurse Program, as a prioritized strategy within the Cuban health system.
3. To exchange information, experiences and opinions with providers and users of the Cuban health system, through site visits to healthcare institutions.

The group's first full day in Cuba began with an "Orientation and Presentation on the Cuban Approach to Family Medicine" by program co-coordinator Gail Reed, MS, International Director, MEDICC. The HAP group was then treated to a tour of a scale model of Havana by Miguel Coyula, City Planner with the Capital's Comprehensive Development Plan.

Principles of the Cuban medical system and the concepts of the family doctor program and the polyclinic were introduced on the second day, in the community of Lawton. Rosa María Báez Dueñas, MD, Director of the Lawton Polyclinic, and Clarivel Presno, President, Cuban Society of Family Medicine and Professor, National School of Public Health, and co-coordinator of the HAP program, were the featured speakers. Later that day Dr. José Acosta, Director of the Ethics Curriculum at the Victoria de Girón Medical School, introduced the group to current thinking on medical ethics in Cuba.

Other highlights of the week-long program included visits to the National Center for Sex Education (CENESEX), tours of an adolescent health center and a maternity center, and presentations and discussions with leading Cuban experts on AIDS, fertility, acute care, medical education and complementary medicine. ■

The Paradox of Cuba

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are discussing options with patients and families. The family remains a constant in all hospital scenarios.

The Victoria de Girón Medical School is located in the old Sacred Heart School for Girls. This school has historical significance as after the revolution, the nuns attempted to train the girls to fight the revolution. This was discovered, the school was closed, and the nuns were sent abroad. Interestingly the buildings and their stained glass windows were preserved. The school has been carefully maintained, even during the so-called special period after the fall of the USSR. My cynical reasoning says it is because too many international visitors and physicians visit it.

The National Center for Sex Education (CENESEX) was the first meeting on the following day. All sexual health issues were covered. Cuba's resources are aimed at the health professional and cover the psychosocial as well as the biological. Among the concerns studied at the center are the aging of the community and the negative birth rate. These issues raise the question of who will provide support. Life expectancy is increasing, but the population is decreasing.

Cuba has an abortion tradition. Dr. Gomez told us that before 1959 it was illegal, but women came from the U.S. and other countries, went to the Tropicana for the evening, had an abortion the next day and went back home to the States or wherever. Physicians providing the service were very accomplished and after the revolution most of them left. Those left behind had no experience and maternal mortality went up. This resulted in abortion becoming legal around 1964-65 so that doctors could be trained and the maternal mortality rate lowered. Guidelines for abortions include:

- consent of the woman;
- if < 16 parental consent is needed;
- parents cannot force an abortion;
- father cannot force an abortion;
- it must be performed by a qualified professional in an accredited institution;
- it must be free.

The system books older women to have their abortions on different days than adolescents. In the 1970s there were approximately 62 abortions per 100 births; in 1999-2000 there were approximately 71 abortions per 100 births. (In a country that keeps volume of statistics on everything, I find it interesting that this is reported as "approximate" information. Data at PAHO and WHO sites is not more specific.) In 1959 abortion was the main form of contraception; it is still a major method today. It is felt that the abortion problem is at the macro level and has social as well as economic implications. The goal is to have family planning replace abortion.

In school, students are taught the relationship between reproduction; STDs; affection; relations with family, friends, colleagues, couples and groups; gender; and eroticism. Homosexuality is considered a regular part of this picture.

One evening a gay friend took three of us to see a bit of gay and lesbian life in Cuba. The cruising scene, where one comes to pick up a date or to find a party, is usually concentrated on La Rampa after 10 p.m. What I saw revolved around *jineterismo*, i.e. sex for admission to clubs or for dollars. This is different from "professional" street prostitutes. These participants are just trying to increase their material possessions above and beyond what their day jobs provide. Clubs will only allow entrance to heterosexual Cuban couples, so gays and lesbians team up to get inside. My contact said that most conservative or older gays find it very hard to be open about their sexuality in Cuba. In fact he was amazed that this group knew he was gay without asking. We assured him that it was because many of us work with gays. The cruising reminded me of Greenwich Village in New York in the 1980s.

We visited the Adolescent Mental Health Clinic the next day, where Elsa Gutiérrez, MD, Director; Ricardo González, MD; and Michelle Frank, MD, spoke on mental health in Cuba. The clinic has 22 beds and handles over 40,000 outpatient visits per year. Psychiatrists have unlimited access to and unlimited visits with their patients. Patients are always accompanied by a parent. Parents get food and a chair to sleep in. While they do not get paid, they do not lose their jobs while caring for their mentally ill teenager.

Before the 1990s, little to no substance abuse problems were observed in Cuba, but since then there has been an increase in the use and abuse of alcohol, marijuana, cocaine and designer drugs. Heroin is not common. (On my second trip, I saw Ecstasy being handed out on the dance floor in the Habana Club in Varedero. Young Cubans were present as they had been hired or allowed entrance to dance with tourists.)

Cuba: Against terrorism, against war

At the time of our January visit, the clinic was treating nine cases of anorexia and none of bulimia. The low numbers were thought to be due to the fact that Cuban men appreciate "a little flesh" on women. (The lack of excess food and the difficulty in obtaining it were not considered a reason for the low numbers.) The Cubans also claimed to have little autism, but hard numbers were not offered.

Medications have been a problem to obtain. Doctors must choose which patients get pharmacological treatment as there are not enough medications to go around. The Cubans have most first generation Rxs but few fourth generation drugs. The biotechnology industry is attempting to make generic versions of more recent drugs like Prozac.

All polyclinics offer mental health services. Emergency treatment is sometimes determined by how frantic a parent is and whether the doctor feels the *parent* can handle the situation.

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Sarah Lawrence College Health Advoc

Sponsored by Medical Education C
National School of Pu

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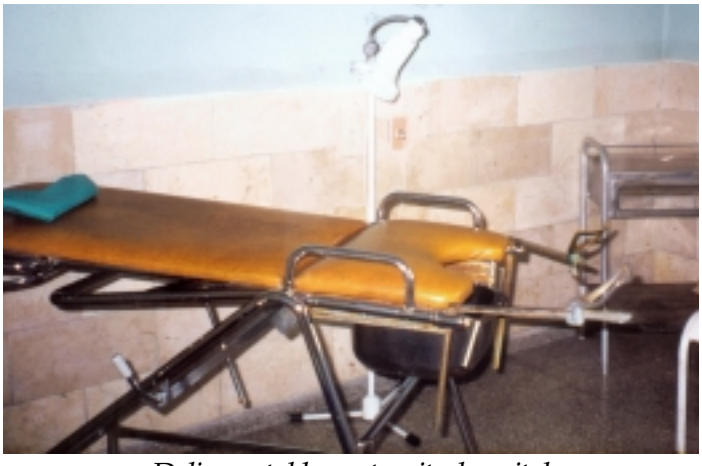
Co-Coordinator:
Clarivel Presno, MD
President, Cuban Society of Family Medicine
Professor, National School of Public Health

HAP group in Old Havana

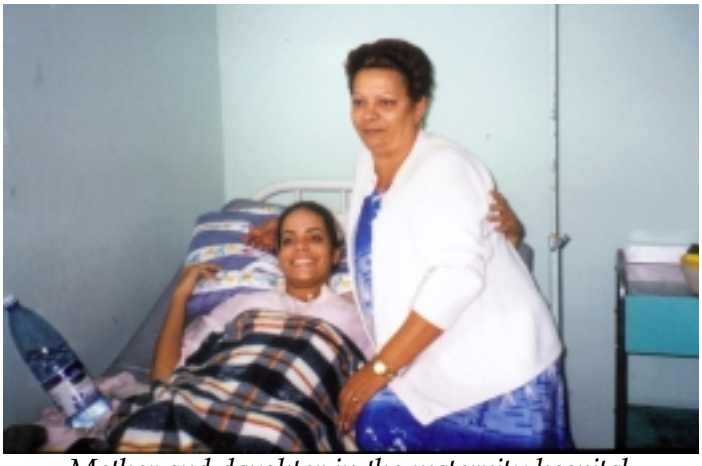
Havana is filled with old cars

HAP Group outside the Lawton Polyclinic

Girón Medical School, in a gorgeous old Catholic girls' school



Delivery table, maternity hospital



Mother and daughter in the maternity hospital. The daughter had an ectopic pregnancy.

cacy Program Study Program in Cuba

Cooperation with Cuba (MEDICC)
ublic Health (ENSAP)
y 2002

Co-Coordinator:
Gail Reed, MS
International Director, MEDICC

Our host Clarivel Presno outside an AIDS sanitarium in a beautiful old hacienda

Newly built housing for AIDS patients

Alternative medicine hospital

Taking a break, with Havana in the background

By the statue of John Lennon

Ché lives!

The Paradox of Cuba

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The clinic was in Playa, near the ocean and in a formerly exclusive neighborhood. It was a big, airy facility and while Spartan, did not seem dismal or depressing. We were constantly being led into patients' rooms without a second thought. Informed consent and asking a patient's permission did not seem to be issues. While this was distressing to us, it is important to remember that the value system in Cuba is different. Patients trust their doctors and are used to doing what doctors tell them; this seems right and comfortable to them.

The next day we were taken to the Ramón González Coro Maternity Hospital for a tour and to hear from Frank Tobey, MD, Director. While any hospital can provide services in an emergency, each municipality has its own maternity hospital. Coro was a private clinic that was turned into a maternity hospital in 1971. As I walked in, my initial response was that either this clinic is a showpiece or the economy has turned. The facility was dramatically different from Hospital Maternidad Obrera, which I had visited on my first trip. The space was cleaner, better equipped and much more cheerful.

As a high-risk facility, Coro serves people from every Cuban province. Only 50% of the patient population comes from the neighborhood. Coro has residents in obstetrics, gynecology, neonatology and general medicine. It produces research and has published 19 papers in Cuba. The hospital has 208 beds: 122 ob/gyn, 30 neonate, 12 general wards, and 1 NICU with 5 beds and a 24-hour emergency outpatient service. When a patient needs inpatient services the hospital cannot provide, they are transferred.

Dr. Torbey offered the following statistics: 4005 births in the facility per year or 10 per day; a 4.2 per thousand maternal mortality; a 6.2 per thousand neonate mortality; 30% of births are Caesarian (the country average is 26%).

We toured the facility and walked through patient rooms and around the NICU. The equipment seems sparse and old compared to what I see in the Jacobi Medical Center in the Bronx. While in need of paint and maintenance everything seems surprisingly clean.

As we toured Dr. Tobey introduced us to Nelson Rodriguez Hidalgo, MD, a fertility specialist. Eager to share his work with us, Dr. Rodriguez marched us into a patient's room, showed us her small incision and began a mini grand round describing the young woman. She had presented with an ectopic pregnancy and needed immediate attention. He performed a laparoscopy and was able to remove the fallopian tube and pregnancy safely. He was very happy to be able to tell the young woman that she would survive and with the one healthy fallopian tube could still have children.

This interlude presented many issues to us. First, would the young woman be told she could have another ectopic pregnancy? She was. Second, we were standing in front of the woman and her mother having this long conversation about what he had been able to do for her. What about her right to privacy? What about her right to know what was being said since much was in English? What about her right to be included in the conversation? The woman was quite comfortable and was pleased to have visitors who were interested in her case. She and her mother accepted that doctors train people with case discussions. Patients' rights and privacy issues are perceived differently and this was a major insight into another system. Our intrusion was met with interest and a perhaps a bit of system obedience. Privacy issues need to be discussed further.

As we meandered through this maternity hospital, walking down both a high risk unit and a medical unit, I quietly asked family members, "Why are you here with the patient?" The family almost always looked at me as if I was crazy. "Why wouldn't we be here, where we are needed?" We were told that an employer cannot fire an employee who is staying in the hospital with a family member. The rationale is that the employee would not be productive at work anyway under the circumstances, and that the patient would heal faster with a family member attending to her. I found this very enlightened. One could probably even show that it is cost effective as well. What started as necessity may have developed into effective patient advocacy. Having someone with you means you can focus on getting well and not dealing with the bureaucracy.

The next afternoon we traveled to an HIV/AIDS clinic in Santiago de las Vegas, where our group was welcomed by an entirely new cohort of young Cuban physicians. New apartments were being built to accommodate the growing and aging population.

These doctors informed us that Cuba never tested its entire population for HIV and that only residents of certain high risk barrios and people of certain "persuasions" were tested.

I did not have my field notes from my first visit when Dr. Rosaval said that everyone over the age of 14 was tested between 1986 and 1989. We did have Feinsilver's *Healing the Masses* , where on page 83 she quotes MINSAP as saying that by 1989, the entire population would be tested. History is being rewritten or perhaps erased. One hopes that the very young doctor made a mistake, but the reality is this may be the new public policy.

We then went to Matanzas to the National Reference Center for Natural and Traditional Medicine, where Juventino Acosta, MD explained the use of complementary medicine in Cuba. He essentially said what I had heard on previous visits, with one notable difference: patients were present. One elderly couple was waiting patiently to be called and I asked for permission to photograph them. They began talking and I learned that the gentleman had just had bypass surgery the week before and was in the clinic for his rehabilitation. Was this a signal that things were indeed changing? On my previous trips I was told that even though the Cuban surgeons had the capability to do the surgery, it wasn't done because it was too expensive and monies were spent on prevention instead. For this man to have had the surgery means either things have changed or he was able to finance it on his own. Perhaps he had family in the US that sent him enough dollars to cover the procedure. Not knowing how to inquire this of him politely, I refrained from asking it at all.

The afternoon encounter that day was at the Matanzas Medical School, where we received a description of Cuban medical education from Cristobal Mesa Simpson, MD, Dean and Ester Báez, MD, Director of Women's Health. Matanzas is a province with a population of 650,000. There are 20,000 health care workers, one doctor for every 195 patients, and 1,685 primary care providers.

The medical school has 1,665 students (185 of them non-Cuban) and divisions of medicine, nursing and dentistry. The first two years are spent on basic sciences and patient contact begins in the third year. The students currently receive information on malpractice, default, mistakes and

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October College 2002: Focus on Wellness and Illness

This year, the series of mini-courses known as October College will showcase Sarah Lawrence's new interdisciplinary program in Health, Science and Society. What defines a disease? Do films tell us the "truth" about science? What does literature have to tell us about illness? How do adolescents understand their own sexuality—and how do writers represent it? How does—how can—the apparently universal experience of dying change from one culture to another? These are among the questions that will be addressed at October College 2002, a series of non-credit liberal arts courses taught by Sarah Lawrence faculty. The focus this fall is wellness and illness as these are represented, understood, and interpreted in literature, history, anthropology, film and the health sciences.

Karen Rader from Science, Technology and Society will join with faculty from Mathematics, Physics, and Biology to consider "Science Fiction, Science Facts." This course will revolve around four films—from *Forbidden Planet* to *A Beautiful Mind*—and will take up the many questions surrounding film as a vehicle for scientific knowledge. Anthropologist **Robert Desjarlais** will consider dying, death, and bereavement as these are experienced and understood across cultures. Author and psychotherapist **Kathlyn Conway** will lead an exploration of the illness narrative, an increasingly popular literary genre. **Marsha Hurst**, Director of the Health Advocacy Program, will challenge our very definitions of disease in "Making Sense of Symptoms." Psychologist **Linwood Lewis** and fiction writer **Carolyn Ferrell** will, together, explore sex and sexuality in the lives of adolescents and in the literature of adolescence. Bioethicist **Alice Herb** will take up—and take on—the ethical dilemmas that attend the beginning and end of life and, more broadly, the ethics of health care in America.

In addition to these mini-courses, the Center for Continuing Education, in cooperation with various programs on campus, is currently planning a variety of public events—from a practical workshop on advocating for the elderly, to lectures about the impact of hospital architecture on health and about tattooing and body piercing practices among adolescent girls, to a film series focused on expressions of health and illness, and a photographic exhibition about genetics, culture, and difference. Join us in October for some or all of this exciting program. For more information, please contact the CCE at 914-395-2205 or at cce@sarahlawrence.edu, or the college website at www.slc.edu. ■

The Paradox of Cuba

Continued from page 14

patients' rights. Communication skills and relating to the patient have gained much importance in the last few years. Two residents were present and spoke of the same issues one might hear in the US, long hours, little sleep, and always the need for more knowledge. They were frustrated in their attempts to get information and recognized that they need to publish as well. They had limited access to journals and to the Internet because of the expensive subscription prices.

Women's health is studied separately since women are seen as having legitimately different medical needs. Only recently have pharmaceutical companies in the US realized that clinical trial information on men does not necessarily apply to women.

Members of the group requested a visit to a general hospital and on the next day we went to Hospital Dos Hermanos Almejeiras in Vedado, near the US Special Interest Section. The Public Relations Director and a chief resident met with us. Dos Hermanos was founded in 1982. Last December 884 residents graduated, with 60% coming from other provinces and 80 residents from other countries.

The faculty includes 215 attendings of whom twenty are full time professors. The hospital undergoes a three-year accreditation process using a quality control committee and patient surveys. An analysis of the quality of clinical services is done monthly, with cost being the main concern.

The facility has 950 beds, with ten in ICU/non specialized, one unit for CCU, one unit for the burn unit, and one stepdown unit with the same nursing ratio as the ICU. Almejeiras is one of five facilities accredited to do bypass surgery. There is no separate neurological unit.

There is a dining hall on each wing and the patients, doctors, nurses, family members and staff all eat together. There are 2,008 employees, 500 MDs, 480 nurses, 26 engineers, and a multitude of auxiliary support personnel serving a population of 300,000. Patients can come from anywhere in Cuba but need to be referred by their family doctor. Since the family doctor works to prevent illness, admissions are down and there is no waiting for a bed. There is no emergency room as there is one three blocks away.

This was an almost overwhelming amount of information essentially thrown at us by the Director of Public Relations. What we really wanted to see and hear about ethics, patients' rights and futility were somehow lost in this storm of words.

I had spent some time reading up on this hospital before this trip and had visited their website. The hospital is world known for "health tourism," which means it actively recruits cash paying patients from around the world to come here for procedures. Both necessary and optional procedures are available. One can come for a kidney transplant, a facelift or to dry out in an alcoholic rehab program. If family comes with the patient, a restful, pleasant four-star facility in Playa is available—for a fee, of course. It has all the amenities of a luxury hotel including a pool. Celebrities from around the world come for the privacy. Prices are occasionally listed on the website. (It would be interesting to compare them with Columbia Presbyterian in New York. They too actively recruit patients who pay cash.) Diego Maradona, the Argentine soccer star, publicly credits the hospital as saving his life when by "curing" him of his cocaine dependence. *(Editor's Note: Maradona is currently back in Cuba for further treatment.)*

The 22nd, 23rd, and 24th floors are reserved for the international clientele. They have a separate admission area and elevator. In general the hospital seems in better condition than others I have seen. However, we were not allowed to see the separate floors or the floors for the Cubans. This is where we would have been

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nance of women physicians is reflected in many of the photos and drawings. One Chinese gender expert pointed out, however, that gender indicators might include whether a girl or a boy is depicted in the images of a happy family with one child. Given the traditional son preference in China, a conscious effort to promote the image of a girl as completing a family could be considered an effort to promote gender equity.

Gender-sensitive language has been an important issue in Spanish- and Portuguese-speaking countries, where nouns and adjectives are masculine and feminine. The idea of ensuring that words use the feminine form (usually designated by an ending of *a* rather than *o* in those languages), or a neutral form, when women are included in the group being described is one that has been addressed in various ways in those countries. For example, "usuarios" can be used for male, or male and female "users" of services; but the preferred gender-sensitive term would be "usuarias," the version designating women. In the written language, some Spanish-speakers have begun to use the @ symbol at the end of a word to represent both *o* and *a*, both men and women, for example "usuari@s" for clients of both sexes. Others use both endings separated by a slash mark, as in "usuarios/as." Written materials in those Romance languages can be reviewed to determine the degree and type of gender bias or gender sensitivity in these terms. But in China, the language does not have gendered words, even for pronouns such as "he" and "she" which use the same term. So a document review of written materials would not need to include this same aspect for analysis. Of interest is the way that the concept of gendered language was explained during the workshop in China. I asked for and was given a Chinese name, sounding like "Her Ju-Di," and learned that those sounds can be written with a variety of different characters. One set of characters includes the symbol for the

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Manual to Evaluate Quality of Care from a Gender Perspective

Purpose: To apply a broader gender perspective in assessing the quality of sexual and reproductive health services in a variety of clinical settings.

Intended Users: Private or public sector sexual and reproductive health organizations, and non-governmental organizations (NGOs) providing reproductive health services.

Description: *The Manual to Evaluate Quality of Care from a Gender Perspective* is an evaluation and quality improvement tool that describes how to conduct an assessment of quality of care from a gender perspective. The evaluation methodology was originally designed for clinics providing reproductive health counseling and clinical services for female clients. However, it can also be adapted for services targeting male clients. The methodology is guided by six tools described below:

1) Observation of Physical Aspects of the Clinic (A simple and quick assessment of the physical space and its utilization)

2) Observation of Client Reception (An examination of what happens from the moment a client enters a clinic until she begins a consultation with a service provider)

3) Observation of Consultation and Counseling (An examination of client-provider interactions with respect to both traditional quality factors and gender-specific issues)

4) Client Exit Interview (An assessment of clients' perceptions of the information and services provided)

5) Service Provider Interview (An examination of staff attitudes and perceptions regarding their role and that of the institution within a sexual and reproductive health context)

6) Document Review (An assessment of institutional policies and practice regarding gender, as well as the degree to which the organization's educational materials are gender-neutral)

Each tool contains data collection and tabulation forms. It has surveys and questionnaires with detailed guidelines on how to and who should conduct the observation and how long an observation might take to be completed. The tools can be applied in any order in its entirety or can be applied in parts depending on the issues the institution wishes to address, the time, and the availability of personnel permit.

Developed by: International Planned Parenthood Federation/ Western Hemisphere (IPPF/WHR) in January 2000.

Advantages: The methodology represents the first time that the concepts of gender have been operationalized in a way that allows sexual and reproductive health organizations to assess their programs for gender-sensitivity and quality simultaneously. The methodologies are straightforward and simple, and can be done with local expertise in most countries. The methodology can be used at any time during the life of a program or can be used as a baseline study prior to the initiation of gender-related activities. In all of the applications of the tool to date, the local research teams have carried out the study with no external international technical assistance.

Limitations: The methodology looks largely at the supply side of the quality issues. It does not focus as much on the demand for gender-sensitive, quality services. In addition, it is designed for women sexual and reproductive health clients, and it does not currently address the gender-specific need of men.

Recommendation for Users: The methodology should be used in an environment where there is an interest in changing at the higher management levels because the standards of quality from a gender perspective implicit in the manual are very high. In most cases, organizations might find that they have significant issues to address if they were to have the highest levels of quality from a gender perspective. In addition, the methodology is designed primarily for sexual and reproductive health service providers even though the methodology can be adapted for other types of organizations. Institutions are encouraged to adapt the tools to meet their local needs, but they should maintain a certain level of standardization of the methodology and modify the tools only if their usefulness to the institution is enhanced by the process.

Availability: The manual is available in English, Spanish, and Chinese.

Contact: Victoria Ward, Ph.D., International Planned Parenthood Federation/ Western Hemisphere Region, Inc (IPPF/WHR), 120 Wall Street, 9th Floor, NY, NY 10005-3902. Phone: (212) 214-0214. E-mail: info@ippfwhr.org or vward@ippfwhr.org.

To access the tool online: The Manual is available in PDF format at: http://www.ippfwhr.org/resources/QCGPtoc.htm ■

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chrysanthemum flower, a feminine image, while another set holds no traditional symbolism but simply represents the sounds. This type of analysis may or may not be appropriate for Chinese materials, but it indicates the vast differences between languages that require adaptation of the Manual's methodology.

Spoken language is another area that can be observed, and the Manual's guide for observing client-provider interaction in reception areas and during the medical consultation offer suggestions to determine gender-sensitivity. In Latin America, the most respectful way of addressing a woman is "Señora" (the equivalent of the title "Mrs.") plus her last name. Instead, some staff members use common diminutives that in that culture can have a connotation of lesser status, even contempt: "mamita" (little mother), "mijita" (little sister), etc. When this part of the observation guide was discussed in China, the workshop participants were puzzled and asked what was wrong. In that culture, the use of terms such as "Auntie" or "Big Sister-in-Law" may actually be considered *more* respectful than using the woman's name, so again the Manual needed to be adapted. In both cultures, of course, there can be problems of tone of voice (e.g., saying sternly "sit down and wait!" rather than politely requesting "please have a seat, ma'am, we'll be with you as soon as we can"), or problems of staff pointing and waving rather than speaking at all.

The implementation of people's sexual and reproductive *rights*, not just the promotion of health, is part of the analysis in the IPPF/WHR Manual. The IPPF has published a Charter of Sexual and Reproductive Rights that interprets twelve international rights for their application to health topics. These include the right to choose whether or not to marry and to found a family, the right to information and education, the right to privacy, etc. The Charter's rights have been adapted into a Clients' Bill of Rights, which is available as a poster in many languages, including Spanish, Portuguese, and Chinese. The Manual's observation guide includes checklists for the availability of such materials. Clinics can go further than simply publicizing the list of rights. For example, PROFAMILIA/Colombia has been the leading proponent of the rights approach in the Western Hemisphere Region, with its legal services unit established 15 years ago, its adaptation in the recent years of the full Charter to colorful materials for lay people, and its current efforts to promote rights by forging links in four cities among its own clinics, women's groups, and government officials. In China, the workshop on the Manual included a discussion of adapting the rights approach to the country's services. There was general agreement that the clients' version of the rights could be a useful set of ideas to disseminate, though the interpretation of some of the rights was acknowledged to be different in China than in some other places.

The Manual includes a guide for interviews with service providers, in an attempt to learn their personal understanding of their work's objectives and their feelings about their work sites. In Latin America, the specific questions include the staff members' definitions of terms such as "reproductive health," and their level of knowledge about issues in the International Conference on Population and Development's Programme of Action. In China, the questions will be adapted to ask about individual providers' understanding of the reorientation being promoted by the government's family planning program, for example, offering

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Faculty Spotlight: Sayantani Das Gupta

There's a new course in the Health Advocacy program called **Illness Narratives: Understanding the Experience of Illness**. Taught by Sayantani Das Gupta, a writer who holds both M.D. and M.P.H. degrees from Johns Hopkins, this powerful course concentrates on the intersection between illness and personal, social, political, and cultural realities.

In order to relate effectively and work productively with patients, health care advocates must be able to not only empathize with but also interpret and understand illness narratives. In addition, advocating for patients in the modern health care system requires a real knowledge of how physicians and other health care professionals conceptualize and explain disease.

The primary objective of the new course is to understand how the experience of illness is influenced and interpreted through the lens of an individual's physical and emotional realities, their families, and their communities. A second objective is to understand and be able to critically analyze the perspectives of physicians versus the perspectives of the patients, and how the medical system itself might promote disease narratives that impact patients' experiences of illness. The course ends with a focus on how narrative can be utilized in health advocacy and activism.

Sayantani came to the course with a pre-existing appreciation for narrative. While at Johns Hopkins she wrote a series of evocative essays on attending medical school as an Indian-American woman; in 1999 they were published as *Her Own Medicine: A Woman's Journey from Student to Doctor*. Sayantani has also written numerous essays and articles on health, gender, race and sexuality and together with her mother, she has published a collection of Bengali folk tales, *The Demon Slayers and Other Stories*.

"To me it's all a continuum," says Sayantani, a highly animated, self-confident woman. "From being able to understand the characters on a page, it's not so much of an extension to understand and empathize with the experience of someone in whose life you are a health professional.

"Narrative is not just a nice story," Sayantani explains. "It's also practical, it helps us to understand the larger issues and understand other people. AIDS, for example, is a collective national narrative. Everyone old enough remembers before and after." In her teaching, Sayantani likes to address issues of stigma and power. "Whose story is it here? Who's in control of the way we think about illness? Narrative is a tool to make sense of what's happening."

Sayantani is also teaching versions of this course to Sarah Lawrence summer school students (graduates and undergraduates) and to second-year medical students at Colombia, where it forms part of their required humanities symposium. "I think there's a lot of room for all the different health professions to train together," she says with conviction. "We need more mutual understanding of our professional philosophies. We could be much more effective health professionals with more cross-fertilization." ■

Health Advocacy and 9/11

A First-Hand Account of the Catastrophe in NYC

by Sandy Burke

You all saw the pictures and heard many of the stories of the horror that came to us on September 11th. I need to tell of our experiences.

The Patient Representative Office at NYU Medical Center ran a phone bank—ten lines—24 hours a day until the Friday night after the tragedy and then 12 hours on Saturday and Sunday. We collected lists of patients treated from all the hospitals in the city so that we were able to give the families and friends information from multiple sources. The staff of this office offered to alternate staying overnight to provide supervision and support to those who volunteered to answer the phones. We also assisted the Volunteer Office however we could, by providing information and supplies and helping to orient all new volunteers.

During all those hours, every person who called in looking for a missing person expressed only appreciation for our efforts. And here are some of the people who contributed to our small effort.

The young man from Australia, never before in New York, who spent 12-14 hours a day in the Emergency Room—answering phones, running errands and generally endearing himself to the ER staff.

The innumerable individuals who closed their businesses and came to answer phones—we even had too many people for the 4 a.m. to 8 a.m. shift!

The medical school student who offered help on Wednesday, and when told by a frazzled Director that I couldn't think of anything at the moment, stood quietly for a few minutes and then disappeared. A half hour later, he reappeared with an updated list of patients from Bellevue. He accepted our thanks and left. Several hours later, he and two of his fellow students reappeared with updated patient lists from all the hospitals in the city. I learned later that they had walked to many of those institutions in order to obtain the most recent information for us. The next day, this same student found, somewhere in the city, a master list in alphabetical order which decreased the amount of time we had to spend looking up names (and the amount of paper we had to use to make copies). He also brought us cookies.

Our Food Service Director never let our volunteer office go hungry. Coffee and Danish in the morning, sandwiches and cookies throughout the day. She also kept our phone volunteers well supplied with bottled water as their throats dried out regularly.

We had volunteers from everywhere doing everything. In many cases, the individuals created the jobs before we knew they were needed. For instance, when the Family Center opened for registration of missing persons, the volunteers were on the lines—just reassuring and supporting the family members waiting. As the photos of the missing on the walls outside and inside our institution increased in number, volunteers were there to stand with those who came to look and provide a shoulder to cry on and tissues to wipe their eyes.

An older couple from the building across the street arrived one morning with four pans of coffee cake, cookies and brownies, still warm from the oven, to be shared by the volunteers, staff and rescue workers.

We had no trouble whatsoever finding people to report at midnight to act as runners, which we needed as our hospital information computer system was based in a building downtown and was not functional.

Students from Stern College cut classes in order to give more time to us—I offered to write excuse notes and sign them "Mom," but they all declined.

A professor from the Medical School apologized for leaving at 9:15 a.m. after she had spent five hours answering phones, as she had to teach a class. She came back when her class was over. Staff from physicians' office came to give time and energy after working a full day in their regular jobs.

And the phone calls we received—mental health counselors from Canada who wanted to drive down, and other health care professionals from all over the country prepared to get in a car or on a bus or train to come and do anything.

Our own nurses went to the site as a triage team on 9/11 and came back looking tired and depressed from what they had seen and how little there was for them to do—and then went to work another shift upstairs.

The head nurses from the floors told their staff NOT to call the Patient Rep office unless they absolutely had to as the work we were doing should not be interrupted.

The hugs everyone gave to everyone in the hallways, the elevators, the street, the cafeteria contributed to the ability to go back to our assignments.

There are so many other people who should be acknowledged for the personal sacrifices they made in order to assist total strangers—those they came to work for and with and of course, the victims—it is impossible to acknowledge them all.

I have often thought of myself as a cynical New Yorker but not any more—at least not for a while. I have in my Rolodex the names and numbers of people I would never have met, who have come to be very precious to me. I am unable to think of a way to say thank you to all of them for the parts they played in helping me personally, my departments and this institution and interestingly, most of them have told me not to even try.

And to you, my family, friends and colleagues—a huge thank you for your support during those trying days. Your calls, emails and constant "checking up" on us made us realize that although the city in which we were living was much like an armed camp, there was a "normal" life somewhere out there. We needed that.

Sandy Burke is Director of the Patient Representative Department at New York University Medical Center. She has been a patient rep for 26 consecutive years, starting at a community hospital, "traversing" the South Bronx, taking a respite in outpatient dialysis for five years. and then returning to acute care in her current position in the early 90s. ■

Foundation Honors Judy Keane's Husband

The health advocacy program extends its condolences to the family of 1994 HAP alumna Judy Keane of Weathersfield, Connecticut. Judy lost her husband Dick, father of five and grandfather of two, in the World Trade Center tragedy.

Dick's family and friends have established the Richard M. Keane Foundation to honor his memory and raise funds to build a much-needed community center in Weathersfield. Judy is serving as president of the Foundation. For more information or to make a contribution, email Judy at judy@ keanefoundation.org or visit the website at http://www.keanefoundation.org/index.html. ■

My Experience at Ground Zero

by Pat Stanley

I volunteered to go with my church, St. Matthew's, to St. Paul's Chapel which had been turned into a refuge for the emergency workers at the Ground Zero site. What an incredible transformation. The chapel is the oldest public building in continuous use in Manhattan and the only remaining colonial church. It was built in 1766 and has 14 cut glass Waterford chandeliers. The church is Georgian Classic revival with blue and pale pink walls, hand carved pillars and intricate woodwork. It is simply beautiful. It was totally unscarred by the 9/11 attack in spite of the fact that the towers were right outside its back doors. George Washington worshipped there and his pew was temporarily turned into the podiatrist's corner!

As you entered the chapel (after going through security to make sure you were a legitimate emergency worker) you were greeted by volunteers who were manning all the stations for medicines, clothing, food, reading materials, chiropractic and massage. The pews of the church were filled with pillows, teddy bears, blankets and assorted inspirational reading material. Many times workers napped there or ate a meal or just meditated or talked with a friend.

There were additional cots with blankets and special pillowcases with loving messages spread all around the pews and on the second floor. The church was covered with banners, letters, wall hangings, flowers—all proclaiming words of sympathy and encouragement. You could not believe the effect when we arrived (13 of us with a rector).

We were at first given instructions for our 12-hour stint and then we all went our separate ways to man the stations. I of course volunteered to give out medical supplies which meant dispensing aspirin, Tums ®, cough medicine and throat lozenges (and occasionally candy and cigarettes). The men and women who came through the door were so thankful and so very nice. We would chat with them about their day but most just wanted to rest a bit.

One guy sat down and played the piano....can you imagine going from the work site to the piano! Another guy told me about his buddy who he lost in the attack, and the remembrances he was gathering for the surviving family. Many workers came from places far across the country, including Seattle, California, and New Mexico. The masseuse had come from Ohio, the chiropractor from California, and the banners and signs covering the inside and outside of the church were filled with expressions of love and support from all over the world. Sewannee loves NY, Holland loves NY…and all the papers from school children with drawings. It was as if the entire world was expressing its sorrow through art and writing.

On the outside of the church there were gates and fencing which became enormous canvases for expressions of grief and love. Flowers were everywhere and I spent some time throwing out the dead ones and rearranging the somewhat spent bouquets. Large sheets were put up on the exterior fencing and within an hour were filled with the words of passersby who could not resist adding their own thoughts to the wailing wall. The chapel must have thousands of these literary sheets which hopefully will be transformed into a collection that goes out to all the churches all over the country for display to their congregations.

Other people dropped off handmade pins and badges for the workers to have as mementos of their contribution to the event. Form time to time musicians would arrive to play either piano, flute or violin…so soothing and relaxing for all of us.

Upstairs on the second floor of the church was an open gallery which served as storage for all the donated supplies and a bedroom for the regulars, who spent many nights there. Teddy bears and special blankets and quilts had been donated for their beds. The supplies were all organized and a chart put on the wall so that any new volunteer could find the masks at pew 6 or the sweatshirts at pew 5 or the extra eyewash at pew 4. Amazing! I must have made 25 trips upstairs to replenish my stock of over-the-counter meds.

The food stations were truly amazing. In addition to every sort of candy and beverage and power bar were gourmet sandwiches from Eli's (bought at cost) and donated hot meals from many of the city's top restaurants. My dinner was catered by the Waldorf Astoria and it was outstanding. We were also allowed to bring trays of water and hot drinks, cans of Red Bull (a caffeine drink that is very popular) and candy out to the police who were guarding the streets off Broadway. They were so appreciative of the support and generous with their explanations of what was going on behind the barriers. No one was rude or pushy ... New York was definitely transformed by this event.

One of the highlights of the day was the noon service which our rector conducted

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Things Will Never be the Same

by Cathy Handy

Things will never be the same here after September 11. I went to work one day and my patients and I looked out our windows and saw thousands of people being murdered.

I was assigned to one of the satellite EDs and was terribly busy for hours, and then sickeningly not busy. I was overwhelmed by the courage and kindness of the community. That day people brought food and drink to us. They came and offered their homes to any of us who needed a bed or just a shower.

I looked out the window at one point and saw hundreds of people waiting to give blood. When we put out a sign saying we needed clothing we were inundated. Some of the clothes were still on hangers. I was moved to sobs by the posters of the "missing." I read as many as I could, feeling it disrespectful not to.

St. Vincent's moved all of the posters to a "Wall of Hope and Remembrance" outside the ER that served as a shrine. I understand when nurses I have met from other parts of the country admit they wish they had been there with me. I was one of the lucky ones in that I didn't lose anyone and I was able to feel as if I had helped. I have never been prouder to be a nurse or a New Yorker.

Unlike Congress during the anthrax scare, all of the health care workers stayed in their posts despite being in a war zone, and they returned to that war zone day after day. If you asked any of them why they did it they would say what I say: "But that's what you do."

Cathy Handy is an Oncology Clinical Nurse Specialist at St. Vincent's Hospital in New York City. She holds M.A. and Ph.D. degrees from New York University and has 25 years nursing experience in such diverse specialties as bone marrow transplantation, home care, AIDS care, and education. Cathy's special interests include pain management and ethics. She is a frequent speaker on oncology and AIDS nursing issues and joined the HAP faculty in 2000. Since 9/11, Cathy has completed both the New York City and the Boston Marathons. ■

From the Ethics Files

This feature will highlight cases that present unusually difficult ethical issues. Readers are invited to respond to the questions raised by email: health@slc.edu.

By Alice Herb

Case I

A 57-year-old woman with end stage renal failure refused dialysis. The staff and family believed that patient lacked capacity to make a decision, although two psychiatric consultations had concluded that patient was "competent." (They merely concluded that she was oriented to time and place, not whether she could rationally make decisions.)

The ad hoc ethics consultation began at the patient's bedside and included the attending physician, three house officers, the patient relations director, the patient's sister, her two sons and the ethicist. The patient was obviously very swollen and now bedridden. She complained that she had not been allowed to get out of bed. Although clearly able to respond to questions and the discussion, she maintained that the physicians were mistaken, that she did not need dialysis and that her swelling was "going down" because she was urinating. She also claimed that she was four months pregnant and that dialysis would hurt her fetus.

The sister related the patient's 20-year history of mental health problems, of being in and out of psychiatric facilities. The sons believed that she was bipolar and that when she took her medication, she seemed to calm down. However, all three agreed that when she "felt better," she stopped taking medication whether for mental or physical illnesses. The family was fully aware of her serious medical condition and that continued refusal to be dialyzed would result in her death. All three wanted to know how to go forward with treatment in spite of her resistance. They were informed that while patient did not appear to have capacity, dialysis could not be done over her resistance.

Discussion on how to persuade patient to cooperate was continued without the patient. The family, extremely supportive, was dismayed at the grim outlook but stated realistically that the patient would probably remain intractable; she had already signed out against medical advice from two other hospitals.

Another psychiatrist was called, spoke to patient and concluded that she was not decisionally capable, that she did not appreciate the severity of her illness. The psychiatrist, noting that patient was on Haldol, prescribed another anti-psychotic medication that could possibly be more calming. The meeting ended with a recommendation that:

- if patient could not be persuaded to cooperate, she would be discharged to a nursing home with the understanding that when she was re-admitted in delirium, emergency dialysis could take place. The reasoning was that since patient was incapable of refusing treatment she could be dialyzed if she was no longer resisting and was emergent. Her resistance would have stopped once she became delirious from her renal disease.
- the long term outcome remained poor since patient's history of adhering to medical prescription was so poor but it would give the family another opportunity to convince patient to accept treatment.

Follow-up: Patient remained in the hospital receiving no treatment for a period of one week. Because of her refusal to accept treatment and to agree to nursing home placement, no nursing home placement was possible. Continued efforts to persuade her to accept treatment have so far failed. Yet she is still alive and still resisting dialysis.

Case II

This consultation involved a 60-year-old woman with end stage lung cancer who was no longer fully conscious and was unresponsive. Her attending physician discussed a Do Not Resuscitate (DNR) order with one of her daughters who agreed to consult her sisters. However, each time he asked for her decision, she insisted they were not yet ready. When the one daughter agreed to discuss the situation, the ad hoc Bioethics Committee team assembled: the ethicist, the house staff, a medical student and the patient representative.

The patient had four daughters, three living in New York and one stationed with the US Army in Europe. The daughter explained that it was difficult to grasp that their mother was so close to death since only two months earlier, she had been "perfectly fine," working fulltime and taking care of herself and her affairs. How could she be so terminal so quickly. The diagnosis and prognosis were carefully explained again. The discussion emphasized that resuscitation would be needlessly hurtful to patient because of the large mass in her lung and that such resuscitation attempts would undoubtedly be futile. The principle of "best interest" and "do not harm" were repeated many times over the course of an hour but the daughter once again only agreed to talk to her sisters and would not agree to a DNR. The attending physician arrived toward the end of the consultation and he, too, failed to get any commitment. Although one of the daughters was the Health Care Agent, the family never agreed to a DNR. They wanted everything for their mother.

These cases are in a way opposite sides of the coin – but in reality, in both cases the family wanted to keep their patient alive. In the first, the family was realistic in accepting the diagnosis and prognosis while in the second, the daughters were not yet able to accept that their mother was in fact dying.

Ethics consults are most often useful in identifying the issues. In the first case, the issue of not being able to strap someone down and treat them over their objections is sometimes hard for families to accept. The dignity and basic autonomy of the patient needs to be underlined and emphasized. The outcome may be tragically unnecessary but the patient had apparently always made poor choices and this time was no different – a bitter fact of life that the family already knew. In the second case, the problem was that the daughters remained in denial and were unable to see the damage their mother could sustain. However, here an ethics evaluation could help the attending physician to decide that resuscitation would be infinitely more burdensome than beneficial and therefore an inappropriate treatment – in effect a "futile" treatment – if we could agree on a definition of futility. He could therefore withhold the resuscitation effort, while documenting the burden/benefit ratio. Explaining his medical decision to the family might help them as well because it allows the children to opt out of making this very hard decision.

Alice Herb, J.D., L.L.M, teaches Ethics and Advocacy at Sarah Lawrence College. She is also Assistant Clinical Professor of Family Practice and Humanities in Medicine SUNY Health Science Center at Brooklyn, and Ethics Consultant to the Brooklyn Hospital Center. Alice's special interests include clinical ethics, particularly in channels/barriers between health care professionals and patients/families; cultural diversity and its effect on physician/patient interaction; the role of palliative care in a high tech environment; and the continuing dilemmas in human subject research. ■

News for Advocates:

What you don't know can hurt you . . .

We welcome readers to submit brief information from news reports that are of importance to advocates and patients, but that may not be widely circulated. Our "heads up" report this month has to do with conflicts of interest that affect both hospital finances and patient care.

In a multi-part investigative series, the *New York Times* has been reporting on "Medicine's Middlemen," the relationship between hospitals and the buying groups they entrust to purchase the best quality medical products for the lowest price. The *Times* reporters describe how two large buying groups—Premier and Novation—control purchasing for 1500 hospitals each. These purchasing groups are funded by the very companies they are suppose to evaluate. Their fees are a percentage of the millions of dollars in hospital purchases they arrange. The more the hospital buys, the more the middlemen—the hospital purchasing groups—get from the suppliers. In some cases Premier and Novation also hold shares or options in the supplier's company, or individuals top executives in buying groups hold these options. Small companies that produce a new and improved technology may be shut out of the market, especially if they cannot afford—or refuse to pay fees or give options to the large buying groups. In these cases, Premier or Novation will contract exclusively with a competitor, even if the competitor does not produce a product of comparable value. Not only is the small company then put in financial jeopardy, but patients may be harmed because the better product was not promoted by the purchasing group.

Large purchasing groups for hospitals will also actively promote companies in which they have a large investment. Premier helped establish American Pharmaceutical, one of the nation's largest suppliers of injectable drugs, and made sure it succeeded financially. Individual executives of Premier held stock options in American Pharmaceutical. Better quality drugs or, in some cases, cheaper generic cancer drugs may have been kept out of the market because of Premier's connection to American Pharmaceutical.

These conflicts of interest are not confined to buying groups. Child Health Corporation of America, with 28 member pediatric hospitals, evaluates medical supplies for children's' hospitals and gives a "seal of approval" to those products it endorses. Unlike independent evaluation groups like Consumers Union, however, Child Health *sells* its product endorsements. Endorsements are based on evaluations that are unscientific and secretive: products are not always tested against each other and nor are results of any comparative tests published. Like the large buying groups, Premier and Novation, Child Health both receives fees from medical product companies and invests money in these companies. Until recently it also manufactured pediatric supplies.

Why do hospitals support this system? Often they have cut their own buying staff, so must rely on contracts with an outside purchaser. More insidious is the practice of hospitals themselves getting thousands of dollars as their share of manufacturers' payments to the purchasing groups. And the hospitals that purchase through Premier and Novation include some of the most prestigious and trusted teaching hospitals in the country: Mount Sinai Medical Center in New York City, Georgetown University Hospital in Washington, D.C. and Yale University Medical Center in New Haven, Connecticut. Similarly the children's hospitals that rely on Child Health Corporation include the well known Boston and Philadelphia

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Gender and Quality of Care—Comparing East and West

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women a choice of contraceptive methods instead of requiring the IUD or sterilization under specific circumstances. In both regions, there is interest in assessing client-provider communications for both their content and their power dynamics.

The Manual has been used as a diagnostic tool in several countries in Latin America already, and plans for testing it in selected health districts in China are underway. While the two cultures are clearly very different, there are some fundamental human principles that will make possible comparisons of the results in the future. From our IPPF/WHR experience, we have learned that a client-centered approach means that, in a meeting between a service provider and a user, "there are two experts in the room." This illustrates in simple terms the concept of reproductive rights, i.e., the fact that a woman client is deserving of respect and dignity in her treatment by the provider. In simple terms, this concept – far from the one-way provision of information or instructions moving from provider to client that has been the hallmark of many services in the past – this simple but powerful phrase describes an ideal vision of what quality of care from a gender perspective really means.

References

International Planned Parenthood Federation. *Charter on Sexual and Reproductive Rights*. London, 1996.

International Planned Parenthood Federation/Western Hemisphere Region. *Manual to Evaluate Quality of Care from a Gender Perspective.* New York, 2000. (Also available in Spanish as *Manual para Evaluar la Calidad de Atención desde una Perspectiva de Género*; both versions available in PDF format on the website http://www.ippfwhr.org.)

Newman, Karen and Judith F. Helzner. "IPPF Charter on Sexual and Reproductive Rights." *Journal of Women's Health and Gender-Based Medicine*, Vol. 8, No. 4, 1999, pp. 459-463.

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From The Director:

The Cuban Health System and the American Public's Health

by Marsha Hurst

This winter I was asked by the Westchester Health Action Coalition to give a talk on the American public health system. Having recently returned from our Health Advocacy educational trip to Cuba (see *The Paradox of Cuba*, p. 10), I couldn't help but think comparatively about the two systems. The differences are, as expected, striking—but so are the similarities.

Ironically, what these two systems have in common are significant health problems and similar health outcomes. Cuba's population, like ours, is aging, which presents new, multidimensional and expensive demands on the health care system. Infectious disease as a cause of mortality has given way to diseases of the heart, cancer and stroke, and these 20th century killers are becoming the 21st century chronic conditions. Cubans also struggle with the high cost of medications, and have additional problems of drug availability because of the American embargo.

The differences between the two health systems include almost everything else—the structure of care, financing of care and right to care. Cuba is a poor third world country with a first world health care system. While the country has few resources, and the institutions of care are threadbare, there is one doctor for every 172 people[1], health and medical care are free, medical education is free, and health care is a right—not a privilege.

The structure of care in Cuba is a pyramid, with the foundation resting on family doctor-nurse teams practicing in the community in which they live. They hold office hours in the morning and the afternoons are reserved for home visits, accompanying patients to the hospital, or meeting with specialists and specialist teams at the polyclinic—the community health center at the next level up on the pyramid. The family doctor is the patient's advocate, and is expected to practice the elements of "boutique" or "concierge" medicine for which our physicians are now charging those who can afford it thousands of dollars extra. These elements include extra time with patients, continuity with hospital care, joint meetings with specialists, patient education, and help navigating the system. For economic reasons Cuba has been doing more "home hospitalization" (although we still found much longer hospital stays and more hospitalization than we have come to expect in the US), which is built on the availability of family doctors for home visits, as well as on the strong family support and intergenerational living situations. With an extremely high literacy rate (96% in 2000), Cuba can and does rely extensively on patient education. To bolster the family role, employers are required to give time off with pay for any family member who stays in the hospital with a sick relative (and no one goes to or stays in the hospital alone).

Physicians in Cuba are not only plentiful, but they are well-educated. There are medical schools in every province, and a Latin America program accepts low income students from countries in the region (now including the US) for free Cuban education. Although specialty care is readily available, the system is built on primary and preventive care. All doctors (with a few exceptions in areas of great need) who want to specialize are required to go through a family medicine residency before doing a specialty residency. While patients can bypass the family doctor and go right to a specialist—and they can also bypass their neighborhood family doctor to go to another family practitioner—most people use the family doctor, feeling that she (and most are women) is more an advocate than a gatekeeper.

Cuban medical care is widely considered to be high quality. Patients come from all over central and south America, as well as from parts of Europe, to receive complicated treatments, diagnostic procedures and surgeries in Cuban hospitals. They pay with dollars (and stay in separate hospital areas) and this "health tourism" helps support the free care and medical training available to Cuban nationals. Cuban doctors, particularly family doctors, are "exported" to third world countries in need. This medical service brings added respect and a "pension" supplement to the normally very low salary of the participating doctors.

In terms of health status of the population, Cuban life expectancy is 76 years as compared to American 77[2]. The infant mortality rate in both Cuba and the US was 7.2 in 2000 and Cuba reports a 2001 drop to 6.2. Cuban infant vaccination rates are higher than ours.

While we know that health status of a population is not a simple product of either medical interventions or health care spending, it is still interesting to note that the US reports spending twice the proportion of its GDP on health (13%) that Cuba spends (6%).

So what did this mean for us as health advocates visiting Cuba for the first time? Our trip was organized as a "course" about the Cuban health care system. We spend a week meeting with Cuban health professionals, visiting providers and educators, and asking endless questions, particularly of our exceptional host, Dr. Clarivel Presno, President of the Cuban Society of Family Medicine and Professor at the National School of Public Health. As a learning experience, the visit was not easy. First, we had to adjust to a system in which health care *is* public health. A healthy population is a national goal and a public responsibility. Second, we had to get past the contradictions, par-

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[1] Cuban health data for this article come from the Pan American Health Organization (www.paho.org, accessed 4/10/02). This ratio is from 1999 data. US ratio for the same period is one doctor per 358 inhabitants.

[2] PAHO, 2001 data.

My Experience

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with the aid of Sister Grace, one of the angels who runs the refuge program at the chapel. We were allowed to participate and I was selected to read the gospel (unusual since only the clergy do that). Our rector spoke totally off the cuff and we were all quite moved by his words in that special place. I just could not believe that I was there. It has been a long time since I have so felt the presence of God and, for sure, angels.

I have to say that this experience was so valuable that I truly gained so much more than I probably gave. I met some incredible people who gave selflessly , some having taken off from work just to be there, and some who just kept bringing in endless amounts of donated supplies. This opportunity made me feel so much more connected to the tragic event , to New York, to fellowship and love, and hopefully to God.

Pat Stanley is a student in the Health Advocacy Program. She was her husband's advocate during his decade-long battle with cancer; that experience was her motivation to become a professional health advocate. Pat also has an MBA and was an investment banker. She has two grown children and a grandchild and rides her horse daily. ■

From the Director

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ticularly the high quality of medical care in a threadbare and resource-bare system. Third, we needed to learn to look for advocacy within the structure and practice of medical care and within the context of a family and community-oriented society. Fourth, although health care is free, the health care system, like much of the Cuban economy, now rests on a dual economy—pesos for the Cubans and dollars from the tourists. In our short time we could not determine the impact of the crossover—and the social significance of some Cubans having access to dollars.

We left with many more questions than we arrived with; and our hope is to bring our host, Clarivel—and perhaps others—to the States so that we can continue this learning process. Cubans are proud of their health care system, and there are many opportunities for American health care professionals to visit Cuba legally on educational trips. Go if you possibly can—and then let's continue our learning experience together. ■

The Paradox of Cuba

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taken if we, as tourists, had been injured or fallen ill while in Cuba.

Feinsilver talks about health tourism as an important source of much needed dollars. By providing this health service, the country earns hard currency that allows it to provide some care for its people. Without the monies the Cuban people would have much less.

Before one gets upset at the idea of a double standard one needs to look at health care at home. If I choose to have a facelift, I have to pay for it. With the money earned from these optional procedures, surgeons and hospitals make enough money to allow/encourage them to do charity work. The child with a birth defect and no insurance receives care. While it would be nice for everyone to be equal, it doesn't happen that way.

The unfortunate side to this is Cubans with dollars from family in the States can buy this care. The division between the people is increasing again. This is often a color division as well. Most of the immigrants to the US were white and they are the ones sending dollars back.

I have not studied enough economics or political theory to understand how decisions are made on spending. Athletes in Cuba live well and enjoy privileges with respect to housing and material possessions. The money comes from the state, not from capitalist fans willing to pay for outrageous salaries. Party leaders do not live in Santo Suarez. Privileges exist for some while others do with less. Perhaps this is not socialism, but it is human.

After a debriefing and summation we returned home, more than ever intrigued by the Cuban paradox of health care.

How do they get the same outcomes as the developed world? The data show such surprising results.

Perhaps I need to return to ask more questions.

Cathey Bienkowski received her M.A. in Health Advocacy in May 2002. She has been a consultant in women's health care for 20 years. Cathey is continuing to explore advocacy in the Cuban health care system and is involved in Peace Corps advocacy issues. ■

What You Don't Know Can Hurt You

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Children's Hospitals.

As I talk to advocates, to administrators, to doctors, to nurses, to almost everyone in health care delivery, and listen to the incessant theme of how hospitals are squeezed by reimbursement rates and required to lay off staff and reduce non-profitable programming, I can't help but think about the millions of dollars that go into purchasing kickbacks, executive stock options, and overpriced supplies. A General Accounting Office study of these buying groups concluded that often hospitals got better prices negotiating with vendors on their own. This GAO study was a very limited preliminary study. Nevertheless, the day before the study was released, Premier Inc. took out a full-page ad in *Roll Call* (http://www.rollcall.com), an influential newspaper covering Capitol Hill, stating that it was holding down the cost of health care for business, taxpayers and health consumers. A more comprehensive GAO study is promised to determine whether millions of health care dollars may be wasted due to the practices of large and market-controlling buying groups.

There is no public accountability for the actions of these purchasing companies. A 1986 law passed by Congress allows suppliers to pay fees to purchasing groups without being subject to federal antikickback laws (wonder how that passed through our legislators!).

The antitrust subcommittee of the Senate, chaired by Democrat Herb Kohl of Wisconsin, is now investigating financial links between hospital buying groups and suppliers, but even Kohl claims to have first learned about these conflicts through the *Times*' reporting.

For more information about "Medicine's Middlemen," see articles in the *New York Times* by Walt Bogdanich, Berry Meier or Mary Williams Walsh on March 4, March 26, April 23, April 27 and April 30, 2002. Watch for additional *New York Times* reports in the future, for the promised GAO investigation and for reports of or transcripts from the Senate hearing. And, in the meantime, do you know who does your hospital's purchasing and how that buying is structured? Find out!

Compiled by HAP Bulletin staff. Please submit your own news items of interest. ■

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