Controversy Continues Over Prayer, IVF Study

BY JOYCE FRIEDEN
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A prominent reproductive health researcher has removed his name from the list of authors of a study on prayer and in vitro fertilization published in 2001, but the controversy over the study continues.

The study "Does Prayer Influence the Success of In Vitro Fertilization–Embryo Transfer?" was published in the September 2001 issue of the Journal of Reproductive Medicine (J. Reprod. Med. 2001;46:781-7). The authors studied the use of prayer on 219 Korean women who underwent IVF over a 4-month period. The pregnancy rate was nearly twice as high in the women who had been prayed for, compared with those who had not been prayed for (50% vs. 26%), a statistically significant difference.

The study was removed from the Web site nearly 3 years later after the journal received a number of letters and e-mails critical of the research. The journal's editor-in-chief, Lawrence Devoe, M.D., said the study was removed from the Web site because it generated more traffic than the office could handle. Critics of the study questioned its methodology—involving several "tiers" of people, some praying for the study subjects and others praying for those doing the praying—as well as the fact that no informed consent was obtained.

The study recently was returned to the Web site, and the journal also published a defense of the work by one of its authors, Kwang Y. Cha, M.D. (J. Reprod. Med. 2004;49:944-5).

Dr. Cha noted that the study was approved "by our local institutional review board with full knowledge that patients would not be signing informed consent forms. ... We thought that the requirement of written informed consent would introduce a bias or variable in the study by encouraging patients to pray for themselves or not, depending on their own religious persuasion. This might have interfered with the potential effects, if any, of intercessory prayer as an independent variable in our study."

Dr. Cha also noted that some people doubted whether the prayer groups were actually ever established. "While this author did not have information about the composition and conduct of the prayer groups during the study (a design consideration to avoid potential investigator bias), there is no reason to think that [my colleague] would have been motivated not to organize prayer groups when such groups are his area of interest," he said.

Dr. Cha's colleague, Daniel Wirth, is a lawyer with a background in paranormal studies. Last May, Mr. Wirth pled guilty in a federal court in Pennsylvania to several counts of bank and mail fraud. He was sentenced last November to 5 years in prison and 3 years of probation.

In his letter, Dr. Cha called Mr. Wirth's legal troubles "regrettable" but said they were "entirely unrelated" to the study. "The study was completely blinded, and it is impossible for Mr. Wirth to have influenced the outcome," he added.

But Bruce L. Flamm, M.D., area research chairman at the Kaiser Permanente Medical Center in Riverside, Calif., and a longtime critic of the study, maintained that Mr. Wirth's fraud conviction does cast doubt on the believability of the data.

"Dr. Cha defended the study's design by stating that Mr. Wirth thought it was the best design to use. This is an argument from authority," he wrote in a letter published in the journal's January issue. "However, in this case the authority is a convicted felon" (J. Reprod. Med. 2005;50:71).

The third coauthor of the study, Rogerio Lobo, M.D., professor of ob.gyn. at Columbia University, New York, recently decided to remove his name from the paper. Columbia University Medical Center issued a press release saying that it "supported" Dr. Lobo's decision. "Dr. Lobo decided to remove his name in order to more accurately represent his role in the study," the release noted. "Although listed as a senior author, Dr. Lobo provided only stylistic guidance and editorial review."

The release also noted that as a result of Dr. Lobo's move, the medical center was dropping its investigation into the matter. Dr. Lobo declined to be interviewed for this article. Dr. Devoe did not return a phone call seeking comment, and Dr. Cha could not be reached.

Dr. Flamm said he was concerned that both Columbia and Dr. Lobo seemed to feel that removing Dr. Lobo's name from the paper ended the controversy. "The flawed, and possibly fraudulent, paper is apparently not going to be retracted, it will stay on the journal's Internet site, and it will be cited as a valid scientific study that supposedly proves that supernatural or paranormal phenomena occurred." ■

More Data Needed for Consumer-Driven Health Care

BY JOYCE FRIEDEN
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WASHINGTON — Consumer-driven health care may be the "next big thing" in health insurance, but it won't go anywhere until more data on plans, providers, and outcomes become available, George Halvorson said at a health care congress sponsored by the Wall Street Journal and CNBC.

A consumer-driven health plan typically involves a high-deductible health policy combined with a health savings account. Patients initially use money from their account to pay for the first few thousand dollars of health care before the catastrophic policy kicks in.

Many major and expensive trends in care 'too often lack scientific backing.'

Although the popularity of such plans may be on the rise, Mr. Halvorson, chairman and CEO of Kaiser Foundation Health Plan, Oakland, Calif., cautioned that many major and expensive trends in care "too often lack scientific backing." He cited the examples of hormone therapy for heart attack prevention in women, knee surgery to relieve osteoporosis pain, and cyclooxygenase-2 (COX-2) inhibitors for arthritis pain, where the therapy turned out not to work as well as expected.

"Because there's no consistent database in health care, people did not realize this kind of outcome was happening with something that was a very popular treatment," he said.

Mr. Halvorson recommended that health care executives follow the example of other industries. For example, General Electric instituted a program of "measure, analyze, improve, and control" to weed out errors in its manufacturing process.

Health care doesn't do any of those four steps with any great consistency, Mr. Halvorson continued. "Where does health care get the data that are used? We get it from paper medical records, which are not even complete per patient." For instance, he said, "we have one patient, four doctors—four unrelated, unconnected, noncommunicative, nonintuitive, noninteractive, too often inaccessible, and often illegible, paper medical records from which to derive the database."

In addition to the well-known data-collection tools such as electronic medical records (EMRs) and computerized physician order-entry systems, the health care system also should be systematically collecting other information, such as whether patients fill their prescriptions, he said.

Another subject about which more data are needed is the hospital shift change. "It takes an average 43 minutes to do a shift change [and exchange information about patients], and during that time, patients are hitting their buzzer and taking their own steps to the restroom and falling," Mr. Halvorson said. "By automating that process, you can take the shift change from 43 minutes down to 12 [and] improve patient safety."

Although the U.S. health care system is better than it's ever been, and the technology is better than it has ever been, "we will not be able to realize the full potential of it until we can get an information flow, and the flow has to come from an EMR," he said. ■