

## The Columbia “miracle” study

A plethora of lessons about medical research, evidence-based medicine, and the peer-review system.

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The Cha/Wirth/Lobo study claimed to demonstrate, using meticulous scientific methodology, that supernatural or paranormal phenomena actually exist. (1) These mysterious phenomena apparently caused a 100% increase in the success rate of complex infertility treatments. How did a bizarre study claiming extraordinarily unlikely and apparently supernatural results end up in a peer-reviewed medical journal? The following are some of the many important lessons that can be learned from this incredible research saga.

1. **Always be suspicious of outrageous claims.** The Columbia 'miracle' study is an excellent example of what Dr. C.N. Reckens, chairman of the Dutch Union Against Quackery calls a, “seemingly impeccable paper proving absurd claims.” (2) A related phrase cherished by most scientists is, “extraordinary claims demand extraordinary evidence.” Thus, the first lesson this paper teaches us is that we should be highly suspicious of studies that appear to show astonishing results. Of course, every once in a while someone will discover something that is truly astonishing! Nevertheless, such results wave a red flag indicating extreme caution should be taken as the study is reviewed.
2. **One red flag should prompt a search for others.** The extraordinary claims of the Cha/Wirth/Lobo study should have prompted reviewers to look for other red flags. In this case the peer review system completely failed. For example, an obvious red flag was that one of the authors, Daniel Wirth, had no medical degree but rather a degree in para-psychology, a dubious field that deals with ghosts and supposed psychic phenomena. A five-minute Google search of this author yields dozens of red flags that researchers at Columbia University as well as the peer-reviewers and editors at the Journal of Reproductive Medicine obviously missed. (3) If anyone had taken a moment to look, they would have found that Mr. Wirth had already published many papers claiming bizarre healing phenomena in paranormal magazines and alternative medicine journals.

3. **An overly complex study design is a red flag.** The Cha/Wirth/Lobo study involved a complex and convoluted study design involving various groups, levels, and tiers of overlapping and intertwining intervention groups. Multiple glaring red flags in the Cha/Wirth/Lobo manuscript should have caused reviewers to at least glance at prior publications by Daniel Wirth, the author with no medical credentials. This would have revealed a long pattern of similarly unusual study designs and bizarre healing methods. For example, one prior Wirth study involved only 15 patients yet evaluated some eight different interventions in various groups and combinations. (4) The strange study included LeShan “elevated state of consciousness” healers, Reiki “life force transferring” healers, Intercessory Prayer healers, Non-contact therapeutic touch “energy field altering” healers, Guided imagery, biofeedback, visualization and relaxation techniques. There were almost as many study interventions as study participants! For comparison, imagine a study with only 15 study patients that claimed to evaluate the safety and efficacy of eight different investigational drugs!
4. **Lack of informed consent is a red flag.** The Cha/Wirth/Lobo study clearly states that patients undergoing treatment were not aware of the fact that they were being used as study subjects. This was a shocking revelation, particularly in light of current governmental laws governing research and strict HIPAA regulations. One would think that this would give reviewers a good reason to look very carefully at the study design and methodology. However, reviewers at Columbia University along with peer-reviewers and editors of the Journal of Reproductive Medicine were apparently not alarmed by this information.
5. **Investigation of a study by the Federal Government is a red flag.** The Columbia University press release announcing the publication of this study mentioned the fact that study patients did not know they were taking part in a study. This fact was subsequently mentioned in the New York Times in an article that caught the attention of the U.S. DHHS Office of Human Subjects Protection. This prompted a Federal investigation of Columbia University. Limited information about this investigation has been made public and can be viewed at the DHHS Internet site given below. During the investigation Columbia department chairman Dr. Rogerio Lobo, who had been listed in the Columbia University press release and the New York Times as the study's lead author, claimed to have not been involved with the study until 6 to 12 months *after* its completion. Three years later Dr. Lobo formally removed his name from the study. Concerns about a study that are sufficient to spark a Federal investigation should clearly have been sufficient to concern peer reviewers and editors. However this red flag that was ignored.
6. **Studies claiming absurd results should be replicated before they are taken seriously.** If the claimed results are not only astonishing but also

- defy the known laws of physics then we are faced with the reddest of all red flags. Before such a study is accepted for publication it would be wise to await replication by an independent research group. A fundamental rule of scientific research is that a valid study can always be replicated by other researchers. Conversely, if other research groups are not able to replicate a study then it is almost certain that the original results were not valid.
7. **Letters to the Editor serve an important peer-review role.** In some cases even the most cautious peer-reviewers and editors may miss important errors in a manuscript. Letters to the editor often correct such problems. In this case peer-reviewers and editors at the Journal of Reproductive Medicine missed an entire array of red flags. Worse yet, they undermined evidence-based medicine's system of checks and balances by refusing to publish even a single letter critical of the study. For three years letters from concerned physicians and scientists were completely ignored by the Journal of Reproductive Medicine. The JRM editors' stonewalling serves as an excellent example of exactly how editors of medical journals should never behave. At the other end of the spectrum, the British Medical Journal publishes rapid responses from readers on their Internet site within 24 hours of their submission. Selected letters are then published in the paper version of the British Medical Journal. This open and public peer review system serves as an excellent example of how editors of medical journals should behave.
  8. **Studies claiming supernatural results may defeat peer-review systems.** The Cha/Wirth/Lobo study involved spectacular outcomes apparently related to distant Christian prayers. Religion is a very sensitive subject and may create a serious 'blind spot' in evidence-based peer-review systems. Some journal peer-reviewers may be unable to function objectively when faced with religious claims. If psychic healers or fortune tellers had claimed to have doubled the success rate of infertility treatments by utilizing Tarot cards or Ouija boards their manuscript would have been immediately rejected as utter nonsense by any legitimate medical journal. Yet, the apparently supernatural results of the Cha/Wirth/Lobo study were accepted and published by a supposedly evidence-based peer-reviewed medical journal. Why?
  9. **Once a flawed medical study is published in a peer-reviewed medical journal, the damage has already been done.** In the winter of 2001, newspapers and magazines around the world announced the astounding results of the Columbia 'miracle' study. By June of 2004, a Google search for the terms, "Wirth, Columbia, prayer" revealed more than 600 links, many to sites touting the supposedly miraculous results. For almost three years the public had no knowledge of the study's serious flaws. During those years the study was cited many times, even in peer-reviewed medical journals, as strong scientific evidence for the power of faith

healing.

10. **The peer-review system can continue to fail even when serious flaws and problems are made public.** As of January, 2005, in spite of all the flaws and problems delineated above, Columbia University apparently stands by the 'miracle' study and has concluded its investigation of the matter. The publication was briefly removed from the Journal of Reproductive Medicine Internet site but has now been reinstated and can be viewed at the JRM Internet site at the link given below. Amazingly, after ignoring readers concerns about the study for three years, the JRM published a letter in the October 2004 issue in which co-author Kwang Cha was allowed to defend the bizarre study. However, as of January 2005, the editors of the JRM have refused to publish even a single letter critical of the Cha/Wirth/Lobo study.

Internet Links for more information about the Columbia 'Miracle' study

**Scientific Review of Alternative Medicine on-line articles**

<http://www.sram.org/online-articles.html>

**The Complete Cha/Wirth/Lobo 'miracle' study**

<http://www.reproductivemedicine.com/Features/2001/2001Sep.htm>

**Skeptical Inquirer**

**The Columbia University Miracle Study: Flawed and Fraud**

<http://www.csicop.org/si/2004-09/miracle-study.html>

**The Federal Indictment of Daniel Wirth**

<http://www.quackwatch.org/11Ind/wirthindictment.html>

**Time Magazine July 2004**

<http://www.time.com/time/columnist/jaroff/article/0,9565,660053,00.html>

**Time Magazine December 2004**

<http://www.time.com/time/columnist/jaroff/article/0,9565,982245,00.html>

**Chronicle of Higher Education June 2004**

<http://chronicle.com/free/2004/06/2004060801n.htm>

**DHHS Investigation of Columbia University and Cha/Wirth/Lobo Study**

[http://64.233.161.104/search?q=cache:2l-PN4lzt78J:www.hhs.gov/ohrp/detrm\\_lettrs/dec01f.pdf+wirth+dhhs+daniel&hl=en&ie=UTF-8](http://64.233.161.104/search?q=cache:2l-PN4lzt78J:www.hhs.gov/ohrp/detrm_lettrs/dec01f.pdf+wirth+dhhs+daniel&hl=en&ie=UTF-8)

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4. Complementary Healing Therapies. Wirth DP, Barrett, MA. *International Journal of Psychosomatics*. 1994;41;1-67
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