

Research practices must be changed to minimize fraud, deception

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In 1998, a study linking the measles, mumps and rubella (MMR) vaccine to autism in children appeared in a respected medical journal. For a decade, the study grabbed headlines worldwide. Worried parents rejected the life-saving vaccine for their children and those with autistic children agonized that they allowed an injection that caused the condition.

But the vaccine-autism research was a fraud. The paper was retracted 12 years later, denounced as an elaborate deception.

"The fraud in that MMR study epitomizes how fabricated research can lead to a <u>domino effect</u> of tragic consequences," says Vineet Chopra, M.D., F.A.C.P., F.H.M., assistant professor of Internal Medicine at U-M. "Patients fear potentially lifesaving interventions, clinicians alter practice and scientists and governments waste precious resources to evaluate researchers' claims."

Chopra expresses these concerns in a commentary published in the Journal of the American Medical Association March 23 with Matthew Davis, M.D., M.A.P.P., associate professor of pediatrics and communicable diseases, internal medicine and public policy at the University of Michigan Medical School and Gerald R. Ford School of Public Policy. They call for changes throughout the research process to adjust expectations for researchers that conduct studies, the journals that publish results and the public that responds to the findings.



Chopra and Davis emphasize the critical importance of equipoise—a state of genuine uncertainty on the part of the researcher as to what a study will reveal.

"In an era of increasing competition for funding and publication, researchers face mounting pressure to report the results they wish to see," says Davis. "Of course, it's natural for the public to want unequivocal advances in understanding and the latest accomplishments in medical research. But research doesn't always yield those results.

"The key is for funders, journals, the media and the public to value equipoise in the research process, rather than only the results."

In their *JAMA* commentary, Chopra and Davis recommend steps to reach research equipoise:

- 1. Mandate the public release of all available data in connection with a study, as opposed to specific data associated with outcomes.
- 2. Reduce publication bias, in which medical journals accept and publish chiefly those studies with statistically significant results. This jeopardizes consideration and dissemination of research pertaining to findings on both sides of an issue, and influences investigators before research begins.
- 3. Shift the focus of public and private sponsors of research from outcome to process, affirming that study veracity is more valuable than results.
- 4. Train researchers to recognize, appreciate and root out biases in their work.



"Researchers may lie about their research for personal or political gain. They make front page news when they get caught, but they represent a small part of the overall picture. A broader problem occurs when a researcher conducts a study with an answer to their question already in mind. Their certainty, rather than genuine uncertainty, influences their investigation and reporting, leading to results that may not be accurate," says Chopra.

More information: "Society demands research that is moral, ethical and honest. When this is not the case, both the public and researchers, even those telling the truth, lose." *JAMA*, March 23/30, 2011, Vol. 305, No. 12

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