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Anti-doping of Clinical IT

After a magnificent ride up l'Alpe d'Huez, Floyd Landis came within 89 seconds of the leader Oscar Pereiro after the 15th Stage of the 2006 Tour de France. During Stage 16, another steep ride, Landis "bonked" and fell an insurmountable 8 minutes behind Pereiro.

In one of the most epic rides ever seen in cycling, Landis sprinted solo on the 120 km, mountainous 17th Stage to come within 30 seconds of Pereiro. During Stage 19 he took the overall lead for good, affording him the opportunity to drink champagne under the Arc de Triomphe in Paris wearing the "malliot jaune" or yellow jersey worn by all Tour de France champions.

A short time later, Tour officials notified Landis that his urine sample was positive for a banned performance enhancing substance. A second sample taken the same day as the first was then tested and found also to be positive. Currently, the United States Anti-Doping Authority is in charge of the appeal filed by Landis to clear his name and allow him to reclaim his "malliot jaune."

Also in 2006, world-class sprinter Marion Jones tested positive for banned substances after competing in the USA Tack and Field Championships in Indianapolis. Her second sample tested negative, and her name was cleared.

Major League Baseball lacked robust testing for performance enhancing drugs prior to the 2006 Championship Season. Barry Bonds, the current holder of the single season home run record and second on the list to Hank Aaron for career home runs, remains mired in controversy concerning his alleged use of anabolic steroids.

Cheating by Researchers

While all these allegations of "cheating" swirled around the world of sports, the *Journal of the American Medical Association (JAMA)*, among others, faced serious charges of undisclosed conflicts of interest among authors published in the Journal. In one article published in *JAMA* advocating the continued use of antidepressants in pregnant women, a majority of the authors were paid consultants or lecturers for the pharmaceutical company that manufactured the antidepressant drug mentioned in the study. According to a July 2006 editorial in *The New York Times*, this financial arrangement was not disclosed to the editors of *JAMA* because the authors believed it not to be relevant.

Ironically, in an article published in *JAMA* in 2005, Wears and Berg criticized much of the research work that evaluated clinical decision support and clinical information technology tools stating, "grading oneself was the only factor that was consistently associated with good evaluations."

The entire basis of clinical decision support and effective use of clinical information technology tools is focused on reliable, accurate, and honest evidence-based medicine. Clinicians rely on and trust these tools as the database of clinical knowledge that they use to heal their patients. Clinician adoption of clinical decision support is based on the belief that the embedded clinical content is accurate, defensible, and free of bias. Any whiff of "cheating" around these tools or the clinical content they contain puts the adoption of clinical information technology at great risk.

Conflict of Interest Is Not New

Conflict of interest, bias, and cheating by researchers is not a new problem. Unfortunately, the increasing dependence of researchers and institutions on private funding creates great temptation, whether conscious or not, for the research to reflect a predetermined outcome consistent with the expectations of the funding source. Peer review of articles for academic journals works fairly well at identifying research worthy of publication, but performs less well at identifying cheating among researchers.

Much valuable research is funded by entities other than the government and independent foundations, so banning private funding of research is both a short-sighted and unworkable solution. Instead, a strong and powerful deterrent must be put in place to strongly discourage cheating and lack of full disclosure by investigators.

Anti-doping Policy Needed

As doping is fundamentally contrary to the spirit of sport, dishonesty in research is contrary to the spirit of medical research. An "anti-doping" policy modeled loosely upon that created for sport by the World Anti-Doping Agency must be developed for clinical research published in peer review journals. Of course, clinical research and IT issues are far removed from the factors that impact sports, but the key tenets are the same: ethics, excellence, and fairness.

The decade-long drop in crime in the United States, according to law enforcement officials, is due mostly to deterring crime rather than catching more criminals. To reduce the prevalence of cheating in research, journals require a powerful deterrence factor that motivates authors to police themselves. To be effective, this deterrence factor requires cooperation from the research institutions, as employers and supporters of these investigators.

Any anti-doping research policy must allow researchers to maintain relationships with various funding sources and influential partners. At the same time, the policy must strong-

ly motivate the researchers to accurately and fully disclose all conflicts of interest to journal editors, peer reviewers, and readers. Therefore, the following principles should be part of any clinical research anti-doping policy:

- All researchers must submit a conflict-of-interest declaration with the submission of their research for publication.
- All journals must subscribe to a standard, comprehensive disclosure form used for a conflict-of-interest declaration.
- Any researcher found to knowingly hide information of financial ties to an entity that is relevant to the research presented for publication, or falsify any portion of the declaration, should be subsequently banned from appearing in that publication and all other publications that sign on to the "anti-doping" policy.
- In addition, guilty researchers should be negatively sanctioned by their affiliated institution with possible actions including loss of academic tenure, demotion, or termination of employment.
- A just and reliable process is required to ensure that all researchers charged with "doping" receive robust due process.
- A non-profit private entity should be formed by journal publishing companies, academic institutions, government, and other interested parties to both monitor this issue while functioning as the independent entity that ensures due process and responds to appeals by researchers who disagree with any levied sanctions.

As clinicians rely increasingly on clinical content presented through clinical information technology tools, the validity of the information presented and utilized by these clinicians becomes ever more critical. Only through a transparent process of vetting clinical content can clinicians learn to trust the clinical decision support and the underlying information technology tools deployed for their use. Failure to prevent doping by clinical researchers in published research undermines efforts to make clinical decision support a commonplace tool used by clinicians to enhance quality of care and patient safety. PSQH

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