A Call for Maintaining Ethical Behavior in Bariatric Surgery

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A few recent events have reminded me of the importance of maintaining a high level of ethical behavior in our bariatric practices. As we all know, the bariatric world is spinning like a large top. Our significant successes in reducing surgical risk and our willingness to report these great accomplishments have propelled our field into the international limelight. We as a community are no longer viewed as scientifically and academically inferior to other surgical specialties, and we as individuals are no longer seen as mercenaries out only to earn money. Our research is getting published in prestigious journals, our clinical results increasingly quoted by non-bariatric surgeons, and our opinions counted. So, why the concern?

This “Golden Age” for field of bariatric surgery has also led to a greater societal acceptance that has revealed a great unmet need and a nearly inextinguishable thirst for better, safer, and less invasive operative procedures. As we speak, countless new procedures, technologies, and devices are undergoing human experimentation. So, once again, why the concern?

The concern is warranted because some of these innovations are not being investigated ethically and following the proper conduct for human experimentation. In some settings, no IRB approval was obtained. In others, little pre-clinical experimentation was performed. No less shockingly, training courses are being offered to train surgeons to perform procedures not yet considered acceptable. The driving forces for this phenomenon are several: industry support, academic pressures, enticement of fame and fortune for the

first “expert” with a new procedure, patient pressures to deliver safer therapies, and the potential financial reward of being marketed as the region expert.

Human experimentation is nothing new. It probably dates all the way back to the cave-dwelling people. It took on a rather sinister face during World War II. Following the war, the World agreed that human experimentation should be highly regulated to be safe and humane. Several regulations and guidelines were adopted. These include the Nuremberg Code (1947), the Declaration of Helsinki (1975–2008), and the Belmont Report of 1976. These were all established not to retard or restrict innovation and progress but to safeguard the subjects undergoing these procedures. All require a sufficient preclinical investigation. Human research should only occur if there is reasonable evidence for beneficial outcomes. Informed consent should be thorough. Subjects should be made aware of the risks and the reversibility of the study procedures. If the experimental procedure is not reversible, the research volunteer must be given some explanation of the possible ramifications. Data collection and reporting must be honest. The rush to publish has led a few investigators to knowingly or unknowingly report inaccurate, exaggerated, or even false data.

New procedures require the appropriate vetting. Adequate patient sample size, valid study design, and the appropriate follow-up period are essential. We all know that many new procedures resulted in respectable weight loss in the short term, but failed to maintain meaningful long-term weight loss. Until these procedures have survived rigorous evaluation, and the so-called test of time, they must not be performed in clinical practice, much less aggressively taught to others. Our societies, including the ASMBS and IFSO, have mechanisms for evaluating new

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procedures and determining whether they can be added to our surgical armamentarium or whether they must remain investigational. It is our duty to respect the opinions of our colleagues tasked to evaluate these procedures.

In summary, I believe that those clinicians who practice bariatric surgery (and for that matter, all clinicians) owe it to our patients, and to our discipline in general, to conduct our research and clinical practices with the

highest level of ethical standards. After all we have accomplished, we must not return to the Dark Ages of Bariatric Surgery. Let us not give our naysayers the fire with which to burn us.

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