

## Standard-of-Care in Obstetrics: An Advantage or A Hindrance?

Alexander D Kofinas\*

NY Methodist Hospital-Weill Cornell Medical College, USA

**\*Corresponding Author:** Alexander Kofinas, Kofinas Perinatal PC, Weill Cornell Medical College, 901 Stewart Av. Suite 245, Garden City NY, 11530, USA.

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Standard of care in medicine refers to treatment modalities of specific diseases that are widely accepted by the majority of physicians, insurance companies and certain health care related organizations. Such standard treatments have evolved over the years as a result of clinical experience, basic science research, customary practices, clinical research and technical innovation with the goal of leading to uniformly acceptable outcomes. Despite this effort, some of the outcomes are unsatisfactory to many physicians and researchers; nevertheless these outcomes are accepted because they are the “best” that can be achieved given available knowledge and expertise. Most physicians practice according to established standard practices. Doing so gives a sense of safety and comfort; this reduces the stress of going against the majority and the stress from taking risks that could be criticized by others, despite the potential benefits. Failing within the standard and acceptable norms is permitted, but failing outside the standard practices is considered dangerous and potentially medical malpractice, regardless of the quality of achieved outcomes.

There are many definitions for the term standard, but the following, I believe, best conveys the essence of the word in the medical community: “A standard is something considered by an authority or by general consent as a basis of comparison; an approved model”. The important point to recognize here is that a *standard* process is not necessarily the *best* process. Building on this premise, innovation requires deviation from the norm, and in this case, the norm is the “standard-of-care”.

When a physician practices medicine in a manner that deviates from the “standard of care” and patients’ outcomes are inferior to the average doctor’s outcomes, this physician does not practice according to acceptable standards and his care is *substandard*. In such cases it is quite easy to identify poor quality of care by physicians, but what about when a physician does not deviate from the standard of care, and his or her outcomes are still unacceptable? This, in fact, occurs often since many conditions in medicine have not been well defined in terms of diagnosis, prevention and treatment and the standard-of-care is an inferior choice albeit acceptable by necessity. When the standard-of-care is deficient as is the case in many obstetrical problems, the need for innovation is clear but not necessarily evident to the majority of practitioners. Innovation, however, does not come from repeating ineffective standard treatments or by clinical randomized trials of ineffective treatments. A physician, who treats patients with non-conventional means and experiences *consistently* superior outcomes in comparison to those achieved by standard-of-care approaches, is doing something right and should not be reprimanded for deviating from the standard-of-care.

This is not the case however in today’s increasingly regulated practice of medicine. Such novel medical practice approaches outside the standard-of-care should become the impetus for further research and advancement of our knowledge, not the focal point of argument and regression.

Innovation comes from great ideas that come out of brilliant and experienced clinicians and researchers. Such ideas, if allowed to become known and widespread, can then become the spark that will ignite other equally brilliant minds to take this idea and advance it to the next level. It is this kind of discourse and cross-pollination that advances scientific discovery and not clinical randomized trials. Unfortunately, the spread of ideas and new treatments that have shown promise and the need to be further investigated have a hard time obtaining any publicity from the current prestigious medical journals. Most of the top quality medical journals will not consider publication of any clinical study that is not a clinical randomized trial or an extensive case-control study. Some of them would not even accept

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simple case-control studies. High-quality non-controlled clinical studies executed by clinicians in private practice are extremely unlikely to see the light of publication. This limitation discourages clinicians from even attempting to publish their experience and leaves a number of great ideas in the darkness; this impedes the spread of ideas and advancement. It seems that editorial boards have forgotten that the role of any randomized study is to simply reduce bias and not to innovate.

The physician's freedom to innovate and replace ineffective standard-of-care treatments should not be robbed by authoritative and dysfunctional guidelines established by bureaucratic health care organizations and governmental agencies. Standard-of-care practices are frequently the result of a collective group mentality and not necessarily based on valuable, verifiable and most importantly, up-to-date scientific evidence. This creates a status quo that becomes entrenched. Resistance to change in the medical community is immense and pervasive. As a result of such resistance, a time honored but scientifically unproven treatment may, due to pure inertia, be employed for many years despite strong contradictory evidence. In addition, old and usual practices provide comfort and anything new creates fear and anxiety. Past century's philosopher Bertrand Russell describes this succinctly [1].

*"If a man is offered a fact that goes against his instincts, he will scrutinize it closely, and unless the evidence is overwhelming, he will refuse to believe it. If on the other hand, he is offered something that affords a reason for acting in accordance with his instincts, he will accept it even on the slightest evidence. The origin of myths is explained in this way...."*

One of the most impressive examples in modern obstetrics has been the use of intravenous Magnesium Sulfate as tocolytic for over three decades. The use of Indomethacin was superior but unable to dethrone Magnesium due to Magnesium's entrenchment by means of guidelines and acceptable standards. It is true that Indomethacin can be risky due to fetal cardiac effects but it is also true that well-trained perinatologists should be comfortable and able to use this drug efficiently and safely. Even now, Indomethacin is the only treatment that has been proven to reduce prematurity and not just delay delivery. The same is true for Nifedipine [2-5]. The lack of a widely acceptable alternative and resistance to change allowed the comfortable majority to continue using a harmful and unethical treatment. Dr. Grimes, in an editorial he published in 2006, called the use of Magnesium Sulfate "a North American anomaly" and went on to say "the fact that it remains the most common tocolytic in the US today is unexplained but reflects inadequate progress toward *rational therapeutics in obstetrics*". Further more, he calls such treatment "*shaky, poor science and worse ethics*". Dr. Grimes attributed such anomalies in part to the unjustifiable, ill-conceived and irrational support for such treatments by authoritative organizations, institutions and poorly critiqued announcements (editorials) in prestigious journals [6].

The use of electronic fetal monitoring (EFM) for the assessment of fetal wellbeing is another ostentatious example. Despite able evidence to the contrary, EFM is the standard-of-care for fetal wellbeing at the detriment of hundreds of thousands of fetuses globally. The only evidence we have after more than four decades is that EFM is valueless and rather harmful, because it increases the occurrence of unnecessary and dangerous procedures without the ability to prevent fetal harm [7-10]. In contrast, fetal Doppler studies have been shown to be the only antenatal tests that reduce fetal adverse outcomes and yet, fetal Doppler has been and remains a "second-class" citizen to EFM thanks to inertia and resistance to change [11-15].

Health care policy today conforms mostly to the utilitarian approach. For the most part this means that we try to achieve the greatest health and financial benefits with the least effort and interventional cost for the whole. This approach requires that we group individual patients into general categories; treat them according to population based statistical commonalities and reject the uniqueness of individual patients. Such an approach has failed utterly because it does not respect the uniqueness of each patient singularity. It puts life, disease, pain, disability etc. in one basket and attempts to value such qualities collectively without respect for what these qualities mean to each and every one of us. In addition, such an approach ignores completely the fact that the same disease more often than not displays itself in very different ways from patient to patient. Human bodies are chaotic (non-linearly dynamic systems) in terms of functionality, and a minor change in one body function or region might cause immense and completely unpredictable effects on other bodily functions. Sometimes such influences are beneficial to the individual, but sometimes harmful. Beyond our unique biology however, we are individuals with unique characteristics, psyche, values, and needs. When we become ill we expect our doctor to provide us with the highest

level of care, the best possible drugs, the best diagnostic technology and the highest level of individual attention, anything less is simply unacceptable, but the standard-of-care does not always provide this.

No patient will ever accept to be treated as a solitary member of the “uniform” whole with total disregard for particular and unique characteristics. The incidence and quality of pregnancy related complications are as unique as each individual patient. Grouping together all patients that suffered recurrent pregnancy loss or any other pregnancy complication can only lead to a treatment failure and nothing more. The creation of guidelines and standards-of-care over the last few decades have not helped obstetricians reduce the incidence of prematurity, preeclampsia, intrauterine growth retardation, and preterm rupture of membranes, cerebral palsy and fetal and neonatal death [16,17]. Do we need more evidence those regulatory activities no matter how well intended are not helpful? To the contrary, there is strong evidence that they have inhibited innovation by restricting the ability of intelligent clinicians to try to break away from the “group” for fear of reprimand and even right out ridicule. It is an evolutionary advantage in breaking the rules. During our evolution, individuals that broke the rules aided the group to discover new environments and new strategies that helped the group survive its hostile environment [18]. It is time therefore to show some divine discontent and break the rules as the great ultrasound innovator Dr. Ian Donald has reminded us.

*“Anyone who is satisfied with his diagnostic ability and with his surgical results is unlikely to contribute much to the launching of a new medical science. He should first be consumed with a divine discontent with things as they are. It greatly helps, of course, to have the right idea at the right time, and quite good ideas may come, Archimedes fashion, in one’s bath”.*

To conclude, it would help if established medical journals reserved a part of their print space for new ideas, opening discussion and allowing the medical community to evaluate their significance and viability. It should be left to the rest of us to either reject and move on to the next idea or accept them and try to improve upon them with further collaboration. It is this kind of cross-pollination that can take great ideas and transform them into great solutions for our obstetrical problems. The evolution of open-access online medical journalism presents a great opportunity to both, publishers and authors alike, to create a new paradigm and a new forum for such ideas and new treatments to be presented for what they are: new *ideas*. Hundreds of randomized clinical trials have failed to elucidate the pathology of our Great Obstetrical Syndromes and help us find ways to prevent them. Has the obstetrical community ever wandered why? The answer to this question is not intricate; our research and academic communities seem confused about the differences between bias reduction and innovation. Is this a surprise?

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