

KOFINAS PERINATAL

Providing care to the unborn

UPDATES ON PERINATAL ISSUES AND NEWS ABOUT KOFINAS PERINATAL

Standard of Care in Medicine

Why medical controversies will continue to exist for as long as patients and physicians maintain their individuality

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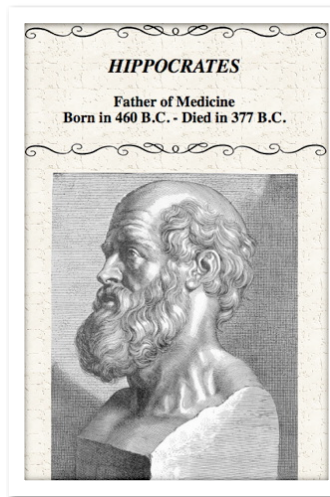
Kofinas Perinatal baby of the month

We are cherishing every moment with our son. Joseph loves to giggle and have fun. He enjoys bouncing up and down in his exersaucer and he is entertained watching the fish move on his aquarium swing. Joseph is sitting up now and likes exploring with his toys. He also is determined to crawl. Whenever he is on his belly, he tries to wiggle forward. Most of all, Joseph likes interacting with his big brother Nicholas. He gets a good laugh watching him zip around the house. He can't wait to do the same! We are so excited and blessed to watch Joseph grow and accomplish these milestones in his life.
Proud Parents



Hippocrates first established medicine as a scholarly and scientific endeavor approximately 2,500 years ago. He was the first ever healer who employed the method of observation and recording of symptoms, signs and outcomes of patients who were under his care. He thus developed a database of information, which was published in a comprehensive text "The Hippocratic Writings". Prior to this, there was no comprehensive recording of any medical

knowledge with some exceptions in Egyptian



hieroglyphics (ancient Egyptian alphabet). The practice of medicine before the time of Hippocrates was very similar to what is known as witchcraft today than the medical discipline created by Hippocrates; medicine as we know it today. We have come a long way since then and the science component in the practice of medicine has grown to be at least half of the whole. The other half remains to be the part of the artistic

component of medicine. Medical art represents the individualistic approach and uniqueness of the particular physician who examines and treats a particular patient. There is an increasing tendency in the medical community to remove the artistic component and standardize medicine to a “one size fits all” mentality. This will never succeed for as long as humans remain individual and unique creatures unlike humanoids. Medicine is a science and as such it can be precise with minimal deviation and pluralism. However, the practice of medicine is a totally different issue. The practice of medicine incorporates the science as well as the human artistic aspect of the particular physician. There are no two physicians that are alike in the way they learn, think, analyze, feel, love etc. and for this reason the practice of medicine will always be individualistic and much dependent on the qualities of the physician and the patient. It is the physician’s role to adapt his care to the particular needs of each patient and not to try to fit all patients into a predefined mold. The development of standards of care is nothing more than the creation of generic molds in order to fit in them all the patients regardless of their unique problems. For these reasons, all attempts to standardize the practice of medicine will fail to help most of the doctors and their patients. The development of standards of care is an attempt to reduce quality to the lowest common denominator. By doing so, we allow incompetent physicians to practice acceptable medicine but we limit excellent physicians from applying new and



innovative ways to provide superior health care to their patients. In addition, the attempt to standardize medical practice creates a mentality of disrespect for all physicians who step out of the box of the “standard of care” in an effort to find new and innovative treatments. Physicians, who utilize their knowledge, clinical skill, innovative attitude etc. and blaze new paths, become frequently the target of ridicule by their colleagues who practice according to the “standard of care”. Of course, the fact that the outcomes produced by the ‘standard of care’ crowd are dismal is totally ignored. Such an example is a prominent academic institution in New York City that teaches their obstetricians that when the cervix is short during the second trimester of the pregnancy, the standard of care is to do nothing because “nothing works”. The result of such policies is a 60% prematurity among such patients. We believe otherwise, and found a treatment that reduces prematurity in such patients by 10 times to only 6%. We simply stepped out of the box of the “standard of care” and blazed a new path to save countless lives.



The question that is always asked in such instances is, “why most physicians reject and object to new ideas?” The answer is not simple because the reasons physicians behave in this manner are complex. For starters, the most common reason is pure and simple inertia. When an object is motionless or moving in a given direction, it would take tremendous energy to start it moving or to make it change direction. In the

case of obstetrical practice, it is very difficult for any obstetrician who has been practicing in a particular manner for several years to suddenly change and practice in a new way. One reason is the inability of any physician to admit and accept that up to the moment of change, he was practicing in a manner that was “wrong”. This is incomprehensible considering that most physicians are more or less quite egotistical and proud of themselves for the excellent work they do. I accept this as part of the character of a physician and I do not see it necessarily as a negative trait. Such attitude in most circumstances helps the particular physician be agonistic and always try to keep up with the medical advances and thus remain competitive and provide the best possible care to his patients. Such attitude becomes problematic when the physicians believes that because he practices in a particular manner for several years, he has

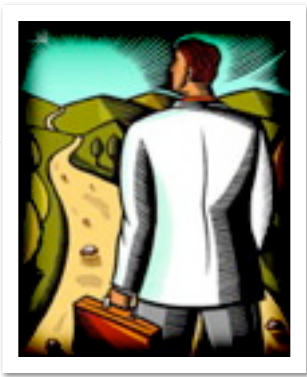
the right to reject any new methods that contradict his believes. The science of medicine changes significantly every year.



Old ideas and methods are proven incorrect or even harmful and new ones are introduced. It usually takes many years for a new idea to become the prominent one. The pioneers in new medical breakthroughs meet tremendous resistance when they try to introduce new ideas. New ideas have to be tested in studies involving human subjects. Such studies can range from difficult to impossible to complete and this adds to the difficulties in the acceptance of any new method or idea. Clinical trials are frequently inconsistent in their conclusion due to poor design, poor execution, poorly controlled confounding factors, selection

bias, interpretation bias, etc. One needs only to watch the news to see how a health related subject moves from one extreme to the other over a short period of time. One day we hear that hormone replacement is life saving in postmenopausal women and a few months later we hear the opposite. These changes of opinion are not always real but the result of the factors mentioned above. It should be no surprise to anyone that such extreme changes of opinion on various controversial subjects are indicative of the fact that the truth regarding the subject at hand is not clear and further elucidation is necessary. Most of the medical advances over the last century were the result of simple inquisitive thinking and plain old curiosity on the part of very few physicians who had the courage to step out of the box and question the existing knowledge status quo. Performing research on human subjects a few years ago was a very easy process. Now, with the extensive regulations in place, it is frequently impossible to test a new idea in humans. Without a doubt, some of the limitations in today’s clinical research are necessary to protect human subjects from unethical and dangerous research. Never the less, such regulations put the brakes on the exploration process and

make it difficult to move new ideas forward and advance medicine at a faster clip. “There is no free lunch” and unless we are prepared to take calculated risks with human subjects, medical progress will be inhibited. The early signs of such problems have already become evident and there is no easy solution in the horizon. In other words, when there is no specific knowledge regarding a medical



problem, innovative physicians should be encouraged to look forward, see things unseen to others and to come up with solutions even if this means that their patients might be exposed to some risk. This is acceptable as long as the benefits to the patient exceed the risks by far. For example, if a patient has lost 7 babies from a condition that is still controversial and for which there is no known successful treatment, then innovative physicians with strong research and clinical background should not be ostracized for trying to create new solutions to help such a patient. Such attempts to find solutions to existing problems, can lead to new pathways in treating otherwise untreatable problems. Once enough data are gathered from such efforts, then additional studies can confirm or reject the original solutions proposed by the pioneers. Randomized clinical trials are considered to be the gold standard for clinical studies defining what is appropriate treatment and what is not. However, such randomized trials are only used to test a hypothesis that has been tested before in observational or case-controlled studies. A pioneer physician who applies a new treatment can only publish his observations in an observational study. Subsequently, the same physician or other scientists will contact a case controlled study and finally, if the case controlled study confirms the findings of the observational study, a randomized controlled clinical trial will be in order. This last kind of study removes the bias of the scientists and is supposed to remove any confounding factors from the subjects under study. Ideally, a randomized clinical trial is the study that will set the record straight and express the final and indisputable statement regarding the value of the treatment under examination. However, the quality of all randomized clinical trials is not the

same. There are a lot of factors that can make or break a randomized clinical trial. Many randomized clinical trials have studied the same subject and came to different conclusions. This is very common and it is the result of the complexity of the process of medical decision-making. For this reason, there are many controversies in medicine and there are going to be as many controversies in the future. For as long as individuals continue to be individuals (patients as well as physicians), controversies regarding medical treatments and outcomes will continue to exist. Unfortunately, in addition to the above differences, there are reasons that may affect the conclusions of any given study. This is truer when the outcome of a study affects the financial gains or losses of a corporation that “happened” to fund the study under consideration. For example, scientist whose research has shown that it is not dietary fat that causes cardiovascular disease but carbohydrates, have been ostracized from their medical community and their research is usually rejected in favor of studies that show that carbohydrates are good for our health. If you suspected that the major corporations that provide us with 90% of the refined carbohydrates funded such studies, you guessed it right. Most of the studies that favor the use of refined carbohydrates are funded through funds provided to the National Institute of Health (NIH) and the Center for Disease Control (CDC) by corporations such as Coca-Cola, Kraft Foods, Tyson Foods, General Mills, Cargil Corp. etc. It is difficult to prove the presence of collusion among these huge multinational corporations that stand to make multibillion dollar profits from peddling their high fructose corn syrup and highly processed carbohydrate-derived foods, by funding unscrupulous scientists who help them prove their

“sick points”. In addition, most of the FDA and USDA executives were previously employed by these corporations. With a few million dollars to a few politicians, it is very easy to place former industry executives in key positions in the organizations that control what we eat and how much of it. One of the problems clinicians face today is limited access to publish in the medical journals. In recent years, most of the medical journals are willing to publish only clinical studies that have been randomized. Randomization of the subjects of the study is expected to eliminate biases that otherwise might lead to erroneous conclusions about the data of the studies. Medical journals prefer to publish only randomized clinical trials. There is a great number of very intelligent physicians who have a lot to say about new treatments that could help other physicians help their patients. However, because their findings have not been produced as a result of a randomized clinical trial, their knowledge will never see the light of publicity. Can



we then change physicians so they can accept change and try new treatments? Woodrow Wilson (27th US president) once said “If you want to make enemies, try to change something”. He meant of course political change but this quote applies to all aspects of life and more so in the medical profession. Physicians are for the most part intelligent individuals and think highly of themselves. This gives them the perception that their opinion is more valuable than any other opinion. It is easy to understand then why change is very difficult and if one tries to bring about change, one can only hope to gain a lot of new enemies.

During my long journey over the last 35 years in the Medical field, I have been a student, a researcher and a teacher. I had the fortune to meet some wonderful teachers who were enjoying giving away their wisdom to those willing to get it; here is however the problem. There are very few physicians willing to assume the role of the student again and convince themselves that it is time to part with the old ideas and embrace the new ones. As a teacher, I met a few physicians who were truly insatiable students. They were courageous enough to understand and come to terms always with the fact that we all know very little in the context of what is to be known and what is yet to be discovered. Looking forward to new innovative and out of the box solutions is the only way we can solve current problems and provide help our patients who felt helpless. Helping desperate mothers-to-be, achieve the dream of their lives, is one of the noblest things one can do as a physician. Fortunately there are enough physicians who still try hard against all odds to find innovative solutions for the benefit of their patients. This is the kind of physicians who create the medical practice of the future. One thing that has changed in the last few years, is the evolution of our patients into knowledgeable and assertive individuals, who increasingly take responsibility for their health care choices. I believe this is a wonderful thing and it is transforming the medical field irreversibly. Educated patients will force physicians out of mental stagnation or get them out of the way to make space for the more open-minded ones. The goal of our news letter is to help such patients become more educated for better medicine.

