

# The Worst 'Healthcare': 'Stem Cell' Clinics Wrought with Red Flags, Insincerity and Blindness



By *Jamie Wells, M.D.* — March 20, 2017



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The [New England Journal of Medicine \(NEJM\)](#) [2] just published distressing accounts of three patients who endured irreparable damage to their vision after seeking treatment at the same unnamed “stem cell” clinic in Broward, Florida.

Shortly, we will address where things went very, very wrong and how such situations can be avoided. But, first, let’s discuss what happened.

The women aged 72-88 years old suffered blindness to near blindness as a direct result of untested “stem cell” therapies being injected into their eyes while being fleeced \$5000 for the procedures. Promised “revolutionary” therapy, they were left with catastrophic reminders of the unfortunate and unnecessary ordeal.

Each patient had age-related macular degeneration (aka the leading cause of vision loss in those over 75) and were told these injections of supposed autologous “stem cells” into both of their eyes on the same day would prompt improved outcomes. “Stem cells” are in quotations as it is presumed (not confirmed) that is what was reconstituted from the cells acquired from their own adipose (aka fatty) tissue obtained by “staff” through peri-umbilical liposuction just before the eye injections.

Subsequently, each sought emergent care due to disastrous complications in the ensuing days. The end result: irreversible blindness to virtual blindness for a condition that without intervention would not yield such extreme progression.

Theirs is a cautionary tale of the hazards of poor and irresponsible practice at a private “stem cell”

clinic, unfixable medical interventions with no scientific evidence to back claims, sales over substance, marketing hype lacking in meaning and actions taken by seemingly complicit personnel that took advantage of the most vulnerable and in need.

Let's break down what was unacceptable and egregious in the experience of these three patients at a private "stem-cell" clinic:

- **All "stem cells" are not the same. The promise of their potential to treat or cure many diseases needs to be further unpacked.**

"Stem cells" are being used and studied for a host of medical conditions. Many in the medical community are enthused about their promise and rightfully so as some advancements are already underway. This is a good and hopeful thing for those with certain life-threatening and limiting conditions. In fact, my recent article [Did Gene Therapy Cure Sickle Cell Disease?](#) [3] discusses the promising work in autologous stem cell transplantation obtained from bone marrow for this and other hemoglobinopathies. This is further explored in this television appearance: [Dr. Jamie Wells On Al Jazeera TV Discussing Sickle Cell Anemia](#) [4].

The [safety and efficacy](#) [5] of their use when derived from bone marrow or your peripheral blood is well-established, but stem cells are now being increasingly derived from alternate sources like adipose tissue and put in use for orthopedic to neurological disorders. (1) Facilities offering false hope often based on the most minimal of clinical evidence are popping up all over the country without well-controlled clinical trials or having met any regulatory standards. In the cases of autologous use especially—since they are your own cells, advocates affirm they are safe. These [private "stem cell clinics"](#) [6] are typically patient-funded at nonacademic centers, are not based on preclinical research or sound design and lack investigational new drug application with the FDA—because, again, they are your own cells despite the fact what the facility mixes them with are unknown agents that have not been tested to confirm safety. (2)

In a [perspective written by the U.S. Food and Drug Administration](#) [5] in the NEJM, the FDA maintains: "Outside the setting of hematopoietic reconstitution and a few other well-established indications, the assertion that stem cells are intrinsically able to sense the environment into which they are introduced and address whatever functions require replacement or repair—whether injured knee cartilage or a neurologic deficit—is not based on scientific evidence." The piece goes on to inform about misadventures of their use and the worrisome lack of evidence in particular in circumstances where therapies proved harmful or ineffective when properly studied.

- **"The patients paid for a procedure that had never been studied in a clinical trial, lacked sufficient safety data..."**

At least one of the patients believed the procedure was taking place as an official clinical trial (NCT02024269) though the consent forms lacked this detail for all three patients. Apparently, what gets listed as a trial on [ClinicalTrials.gov](#) [7] is not formally vetted so the appearance itself on the site does not mean it is legitimate, well-designed or been approved by an independent review board or the FDA.

According to the [New England Journal of Medicine report](#) [6], as of November 2, 2016, 13 trials of

“intravitreal injections of various stem-cell populations were registered on [ClinicalTrials.gov](#) [7]” of which 4 were taking place in the United States. The fourth (NCT02024269) was “withdrawn on September 15, 2015, before enrollment had begun, focused on the use of intravitreal autologous adipose tissue-derived stem cells in patients with non-neovascular AMD” and was the site center for the stem-cell clinic of these three patients.

Translation: A person’s own fat cells procured from another location were processed into “stem cells” and injected into the vitreous of the eye for those afflicted with acute macular degeneration. “Stem cells” is in quotations because it is presumed or assumed they were derived from the patient and processed as such, but this cannot be confirmed as the authors of the report cared for the patients after their ill-fated procedures and managed their complications not what caused their original injury.

- **“ Many stem-cell clinics are treating patients with little oversight and with no proof of efficacy.”**

[Thomas Albin, M.D.](#), [8] associate professor of clinical ophthalmology at Bascom Palmer Eye Institute, part of UHealth – the University of Miami Health System, and co-author of the NEJM study [warns](#) [8], “Patients seeking stem cell treatments for medical problems should only consider a carefully controlled clinical trial at an academic medical center. Paying thousands of dollars to a local clinic for an unproven stem cell treatment – as these patients did – is extremely risky with a low probability of a successful outcome. Some clinics are claiming that treatments using the patient’s own stem cells don’t require FDA oversight or clinical trials, even though there is no evidence the treatments are safe or effective. Almost all legitimate research is funded by an institution or company with an established protocol, lots of pre-clinical data and extensive pre-trial and post-trial evaluations.”

- **“The patients paid for a procedure...performed in both eyes on the same day. Experimental bilateral intravitreal injections are both atypical and unsafe.”**

Ophthalmologists do not typically operate on both eyes on the same day. It is customary for them to perform a procedure on the worst one first and see how the patient responds so as to decipher what essential adjustments need to be made. Additionally, if there is an untoward event, then the untouched eye can still provide sight.

- **The [NY Times reports](#) [9] that though two of the patients and their attorney, Andrew B. Yaffa of Coral Gables, FL are prohibited from discussing the case “a publicly available complaint he filed in July 2016 details one patient’s story, and states that the injections were performed by a nurse practitioner who was introduced as a physician.”**

The published report in the NEJM speculates about the likelihood of profound flaws in the reconstitution or preparation itself as being a likely culprit in the blinding outcomes since it appears they assume ophthalmologists did the injecting. But, the NY Times article quoted above raises other suspicions of who administered said injections. If a nurse practitioner masqueraded as a doctor and misled the patients, then the ethical implications alone are disconcerting.

A nurse practitioner is a nurse practitioner. A doctor a doctor. An optometrist an optometrist. An ophthalmologist an ophthalmologist. A staff member a staff member. They must identify themselves precisely and prominently display their identification tag. When someone says he or she is a doctor, they may be a PhD not an MD or the type of “doctor” that does not mean what most people believe it to mean. Huge disparities in levels of education (or training) exist.

Additionally, intentional confusion is rampant as terms like “provider,” “clinician” and “advanced or mid-level practitioner” serve to perpetuate these false perceptions.

A Doctor of Optometry (O.D.) is not a Medical Doctor. An individual with an O.D. went to optometry school and is well-educated about refracting eyes and making glasses, for instance. He did not learn about all organ systems in the body, what disease states and surgical interventions warrant treatment, or pharmacology, to name a few. Generally, his license does not extend to surgical procedures or medication prescriptions -- though challenges to these restrictions are being made by their lobby.

An ophthalmologist possesses an M.D. (aka medical doctor degree) having gone to medical school, completed an internship and residency for many years caring for ambulatory and hospitalized patients engaging in routine care to urgent and emergent operations. He can perform surgery, understands anesthesia and the ever important fluid balance, treats systemic conditions like retinopathy from diabetes, foreign body ocular impailment and so forth as well as can refract and fit for contact lenses or glasses.

Both an optometrist or ophthalmologist might be called “doctor” but the nature of their respective training is vastly different. A plastic surgeon is a physician who performs liposuction after years of specialized training after four years of medical school— other “staff” might learn from a weekend course or truncated certification. There are many reasons these invasive procedures require years of training and understanding of the complexities of different anatomy and diseases to minimize and entirely avoid complication risks.

An ophthalmologist should be the only person injecting into an eyeball. A nurse practitioner would be grossly under-trained to do so responsibly, especially in the absence of an ophthalmologist.

- **Practitioners of whatever kind are ethically and duty-bound to identify themselves precisely without ambiguity. ONLY a Board-Certified Ophthalmologist should ever perform a procedure with your eyeball itself. It would not be standard-of-care for anyone to inject anything into the eye without being a Board-Certified Medical Doctor.**

Expecting this level of transparency is your right as a patient. To review further how to protect and advocate for yourself or a loved one when undergoing medical care, review [10 Ways to Save Your Life or the Life of a Loved One](#) [10].

Not all levels of training are equivalent and substitutable albeit on the medical doctor track to the physician assistant track to the nursing track. For example, there is a marketing campaign afoot to bundle all who provide primary care under one umbrella and it is misleading to patients. This is wonderfully addressed in this recent JAMA article which underscores the importance of properly labelling those who deliver primary care: [Eliminating the Designation of Primary Care “Provider”](#) [11].  
[12]

Institutions, academic and otherwise, are universally stretching non-doctors beyond the scope of their training. One CEO of a major center recently acknowledged their use of such practitioners “at the top of their ticket” in efforts to control cost. This is a penny-wise dollar foolish endeavor that I further address in [Unhealthiest Reality of Obamacare—Lack of Doctor Choice](#) [13]. Poorer outcomes are well-documented with inexperienced and less trained professionals, here is one example of such a consequence [To Survive the Hospital, Make Sure Your Heart Stops on a Weekday](#) [14].

As I have consistently maintained, everyone— albeit doctors, nurses, nurse practitioners, physician assistants and so on...— when practicing within the scope of their respective training contributes extraordinary and invaluable things to the team in the best interest of the patient. When stretched well beyond such parameters, the ensuing path can be wrought with danger.

The lobbying groups for nurse practitioners and optometrists, for example, are also culpable as they are petitioning with increasing momentum in varying states to be able to practice independently without the supervision of physicians. Nursing as well as optometry advocates claim untethering expands access to health care in rural areas, for instance, where there are physician shortages. The lack of critical experience and training, however, does not prioritize patient safety and expansion of these blurred lines often misleads patients.

Now, optometrists are battling to urge state legislatures to be able to extend their services so they may operate and prescribe medications. Fortunately, most states are rejecting such increases in autonomy given the profound lack of adequate training to perform such advanced procedures. An [article detailing their progress or lack thereof](#) [15] includes this statement by "Dr. Daniel Briceland, a highly rated ophthalmologist in Sun City, Ariz., and secretary for state affairs with the American Academy of Ophthalmology, "They want to practice medicine without going to medical school. This is how people get hurt.""

- **Beware of these buzzwords or expressions that are usually red flags: groundbreaking, revolutionary, rejuvenation, game-changing, regenerative, restoring balance, or disruptive.**

A good rule of thumb in medicine is to be suspicious when you are being overtly sold. The consummate practitioner will readily present their findings and reasoning, have the self-confidence not to be threatened by seeking other opinions and answer all of your questions to your level of satisfaction.

### **In summary...**

Such recklessness as demonstrated in the initial “healthcare” of these three patients does not merely serve to damage physically, emotionally, and spiritually these individuals and their loved

ones; but also, undermines and puts at risk genuine medical progress in the field of stem cell research. The tremendous potential these types of therapies hold is invaluable for those with devastating disease. When such poorly designed “experimentation” like that orchestrated here takes place, it threatens legitimate and sound science being done for those in greatest need.

When greed trumps science, we all lose.

#### SOURCES:

1. Marks M.D., Peter W. et al. [Clarifying Stem-Cell Therapy’s Benefits and Risks](#) [5]. N Engl J Med 2017; 376:1007-1009.
2. Kuriyan, M.D., Ajay E.; Albin, M.D., Thomas A. et al. [Vision Loss after Intravitreal Injection of Autologous “Stem Cells” for AMD](#) [6]. N Engl J Med 2017; 376:1047-1053.

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#### **Links**

- [1] <https://www.shutterstock.com>
- [2] <https://www.nejm.org/doi/full/10.1056/NEJMoa1609583>
- [3] <http://www.acsh.org/news/2017/03/07/did-gene-therapy-cure-sickle-cell-disease-10950>
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