

Private Foreign Stem Cell Clinics: Most Are Not Doing Hard Science Yet -- Though Some Are Working On It

By

[Anthony G. Payne, Ph.D.](#)

Biogenesis Institute affiliated clinics is the focus of this article as Dr. Payne is very familiar with their operation and has found the challenges facing them fairly common among many other foreign private stem cell clinical programs. He ceased his work with BI at the end of July 2010.

One of the charges leveled at private foreign stem cell clinics and institutes is that they do little if any legitimate science and primarily rely on anecdotal material to vouchsafe for their therapies. I basically do not disagree with this contention at all. Most foreign stem cell facilities I have surveyed do by-and-large lean heavily on anecdotal (case history) data and documentation to support their treatment approaches. There are exceptions, yes, but on-a-whole solid objective data obtained in a scientifically rigorous fashion is lacking when it comes to most of the stem cell clinics I am acquainted with.

I cannot speak to why most of the foreign (especially second and third world) clinics I am familiar with do not pursue evaluating their treatments using the proven tools of clinical research, but suspect the reasons are many and varied and include but are not limited to: Lack of resources especially funds to engage the services of experienced clinical researchers and biostatisticians, lack of patient cooperation (I know from experience that many patients prefer to “get treated and get on with life”), concern that doing any sort of study that includes a placebo when it comes to terminally ill patients is unethical – and in some instances such negative players as greed, ignorance, indifference, or incompetence.

With respect to Biogenesis Institute which I served as a patient educator-liaison and biomedical theoretician for three years (July 2007-2010): Like most private stem cell enterprises the website put up by Biogenesis is geared to attract browsers, especially prospective patients – and hopefully get them to ask questions and probe the science that informs what the physicians and scientists abroad are doing. One of these draws is posted case histories (Anecdotal material). Mind you, no one at Biogenesis would ever contend that these ultra-summarized posted case histories or other promotional information constitutes hard, objective scientific proof of efficacy or claim they constitute rigorous proof in the hard science sense.

Biogenesis Institute affiliated clinics, like many other foreign clinical stem cell facilities, is very much committed to making available treatment approaches whose clinical costs/benefits to the patient favors the latter over the former. Safety is a major concern, which is why virtually all patients being treated are those saddled with terminal or intractable illnesses or medical conditions, as well as those who have a narrow window for improvement that will close in short order. Mind you, the physicians and scientists involved do not suggest trying stem cell therapy

on medical conditions whose nature is so poorly understood as to make it difficult to determine if or how stem or progenitor cells would confer benefit (Nor is stem cell therapy advocated for conditions that conventional medicine can ably manage with the exception of diseases and conditions in which the patient's quality of life is declining appreciably or so compromised as to lend them to a species of despair that is resistant to standard medical and/or psychological intervention). For example, autism apparently arises on the heels of various neurologic defects which are yet to be fully characterized and for which no evidence – not even animal studies – indicates will be in any way remediated by any extant form of adult stem cell therapy. As such, Biogenesis affiliated clinics will not entertain treating people with autism.

There is of course a judgment call aspect to all this – an informed weighing of what science exists with clinical insight and concern for the patient (beneficence) – and thus not all calls turn out to be as well-founded in the scientific sense as one might like. And then too even groups of medical and scientific professionals can reach a consensus that is wrong.

Critics, of course, point out that the best way to approach adult stem cells and their use in clinical medicine is to do randomized, placebo-controlled [clinical studies](#). This is certainly the ideal way to sort wheat from chaff and discern what is effective or not. However, many suffering people do not have the luxury of awaiting the outcome of future clinical studies as they will either be dead or could sacrifice their shot at an optimal response to the ravages of their disease or to aging or such ([There are published studies that indicate that the microniche or biological tissue milieu in the human body becomes less conducive to supporting stem cells with age](#)). The people who founded Biogenesis believe it is not be in the best interests of terminal or intractably ill folks to sit back and await the outcome of controlled clinical trials in the USA or elsewhere before offering various forms of adult stem cell therapy.

This is not to say that Biogenesis staffers and affiliated clinic personnel deny the value of rigorous scientific studies nor disdain doing them. However, the fact is that Biogenesis and the clinics it serves face a problem common to many if not most private stem cell operations: Limited resources. This said the Institute and clinics are doing what they can to insure that some scientifically meaningful information and data comes out of its ongoing work. This includes:

- (1) Accrual of well-documented anecdotal case histories including having patients do standardized tests before and (at regular intervals) following their stem cell treatment. And yes, we are all well aware of the limitations of anecdotal material in science, but this is not to say it is without merit. Let me illustrate this using these published articles:
 - a. <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030423> - “Anecdotal Evidence”: Why Narratives Matter to Medical Practice
 - b. <http://www.sciencebasedmedicine.org/?p=33> - The Role of Anecdotes in Science-Based Medicine by Steven Novella, MD (Yale University School of Medicine)

“But should anecdotes play any role in medical evidence? Yes, but a very minor and clearly defined one. Anecdotes, with all their weaknesses, are real life experience. It is possible that a treatment does in fact work and personal experience may be the first indication that there

is a meaningful biological effect in play. But here are two limiting factors in how anecdotes should be incorporated into medical evidence:

The first is that anecdotes should be documented as carefully as possible. This is a common practice in scientific medicine, where anecdotes are called case reports (when reported individually) or a case series (when a few related anecdotes are reported). Case reports are anecdotal because they are retrospective and not controlled. But it can be helpful to relay a case where all the relevant information is carefully documented - the timeline of events, all treatments that were given, test results, exam findings, etc. This at least locks this information into place and prevents further distortion by memory. It also attempts to document as many confounding variables as possible.

The second criterion for the proper use of anecdotes in scientific medicine is that they should be thought of as preliminary only - as a means of pointing the way to future research. They should never be considered as definitive or compelling by themselves. Any findings or conclusions suggested by anecdotal case reports need to be later verified by controlled prospective clinical studies.

Understanding the nature and role of anecdotes is vital to bridging the gap between the proponents of science-based medicine and believers in dubious or sectarian health practices (as well as the public at large). In my experience it is often the final point of contention between these two camps.”

(2) Collaboration of major private stem cell R & D firms that are working with a number of renown US university stem cell research centers.

Of course, Biogenesis affiliated researchers and clinicians would dearly love to carry out or facilitate the conduct of randomized controlled clinical studies but, as indicated above, is hamstrung in what it can pull off due to limited resources (Monies tendered by investors have been exhausted on lab R & D work with little left over for funding any kind of decent controlled study or studies. And the small profits generated by each patient treatment, though to a great extent invested back into the ongoing R & D effort, are not yet substantial enough to carry the day in terms of funding rigorously designed and executed controlled studies). This is frustrating for all involved.

The dilemma facing Biogenesis as of the time I left (July 2010) is, as I've indicated above, a familiar one for small private stem cell clinics and institutes, especially those in second and third world countries; that is, namely stretching ultra-limited resources to extract valid data from patient treatments. Since pulling together the resources to conduct even a small scale randomized clinical study would be difficult to pull off for Biogenesis and the clinics its works with and serves, I suggested a poor man's solution: Doing a [N=1 crossover study](#) on select patients, which essentially entails the patient being their own control. That is, he or she will randomly receive a placebo and the “Real McCoy” (in blinded fashion, i.e., neither patient nor those administering the treatment knows which is being given, done or administered – placebo

or the treatment in question). This said I can't imagine any terminally or intractably ill patient who is paying (say) \$9K USD for a treatment opting to possibly receive a placebo – even though he or she would receive the “Real McCoy” down the line (Some do not have life expectancies that allow for this). I am mindful too of the fact that such a study would require the patient to undergo real v. sham treatments in a blinded fashion repeatedly. How many small clinic-lab operations can stretch (say) a \$9K payment to cover repeated medical procedures such as catheter or intrathecal delivery of stem cells or such on the same patient? And how many patients can afford to fly from distant locales to a foreign country several times over to participate in such a study? Yes, it gets daunting to try to pull off the kind of hard science that needs to be done on a shoestring budget in a third world country with an unstable currency or economy.

Biogenesis affiliated clinics are doing the best they can with what they have to work with. They could suspend operations and wait for the outcome of clinical studies done in America and elsewhere, but those involved deemed staying the course the “lesser of two evils” when it comes to terminally and intractably ill patients (The more ethical choice all things considered). Some critics and skeptics will undoubtedly dispute this choice and toss “the baby out with the dirty nappy”, i.e., infer or declare that by not doing hard science these clinics have to be engaging in charlatanism, quackery or such. Sadly, I have read posts on various cyber-forums on the Internet in which a handful of MDs and MD/PhDs have basically characterized everything being done by private foreign stem cell operations as quackery, pseudoscience, con artistry or worse. Many of these are, in my opinion actually less charitable in their assessment of what is going on in foreign stem cell clinics than many of the bench and clinical researchers I routinely interact with face-to-face and by phone and e-mail (A few of these more charitable contacts are, in fact, FDA scientists). More than a few indulge in the very kind of hyperbole, hype and fallacies of logic they accuse those they attack of. Sadly, many are also condescending when tackling those they criticize or their supporters.

The question of what works and what doesn't in the fledgling field of stem cell medicine is not going to be settled by expert pronouncements, generalizing from the bad apples to all the apples in the barrel, debate, scare tactics, biased reporting and writing or such. These matters will ultimately be settled in the arena of science, i.e., by consensus on what is efficacious based on a confluence of scientific evidence that in some instances will originate with a body of well documented anecdotal case histories that inspires the conduct of randomized controlled clinical trials by firms who possess the wherewithal to pull this off. As this all unfolds, it is vital that nothing can or should be dismissed *a priori* unless it violates well established natural laws of physics, chemistry and such. And again, while skeptics and critics are right to insist that stem cell therapeutics be based on rigorous science, they must also temper their often hard line stance with the realization that not all private foreign stem cell clinics who agree with this can readily pull this off. Hopefully they will also come to realize and acknowledge that the clinical offerings of these facilities are not necessarily predicated on pseudoscience, opportunism, the exploitation of sick people, or charlatanism -- nor necessarily indulge in predicating their patient treatments on shady ethical standards or the reported clinical outcomes on hyperbole, selective reporting or intentional sidestepping of doing rigorous science. Yes, some foreign stem cell facilities are guilty of one or more of these failings though this is not necessarily the end result of

some devious premeditated agenda but, rather is sometimes due to lack of human, financial or technological resources to do the kind of hard science which critics favor and expect.

Naturally and not unexpectedly critics often point to the aforementioned shortcomings as justification for condemning all private stem cell clinical operations and vociferously steering all suffering people away from them. I appreciate their reasoning and motives, but believe they do a great disservice to the public they seek to protect when their actions or words wind up actually turning terminally and intractably ill people away from genuinely promising forms of adult stem cell intervention. Admittedly, in the absence of hard scientific proof of efficacy it is hard to determine what is genuinely promising; difficult, but not impossible. A number of well documented case histories showing that stem cell treatment x substantially benefits disease y, while weak at the evidential level in science can nonetheless be persuasive enough at the clinical cost-benefit level to compel patients to favor “taking the plunge”.

And speaking of patient conducted evaluations of various stem cell treatment offerings: It has been pointed out by various critics and medical consumer advocates that patients are usually not equipped with the scientific skills and knowledge to weight even anecdotal evidence. This is true in many instances. However during over seven (7) years of dealing with people considering doing adult stem cell therapy at various clinics and treatment centers abroad, I have found that most emphatically *do not* make an uninformed decision. That is, they read what skeptics have to say, tackle scientific papers with the help of their physicians or people who have the training to accurately interpret published studies and relevant technical material, and spent countless hours on the Internet examining everything they can lay their hand on both pro and con. Very few people I have ever run across took off to a stem cell clinic abroad on the basis of superficial study or based solely on a handful of testimonials or patient video clips.

Interestingly, a great many of these people (I have dealt with) are scientific or medical professionals including at least a dozen MDs, several dentists, more than ten research scientists including one former NIH R & D laboratory supervisor, a number of applied and research engineers, plus chemists, pharmacists, and others – all of whom have at least a modicum of training in the methods of doing clinical research.

But whether steeped in the ways of science or not, the people I have tracked who ultimately elected to head abroad for adult stem cell therapy did so after concerted study, investigation and analysis. Few among them ever expressed regrets about the particular stem cell treatment they elected to undergo or disappointment with the results. This is not to say they invariably saw results or even impressive ones after doing their treatment (Though a great many did) – only that these folks by-and-large had their adult stem cell therapy of choice knowing that such treatments are experimental and thus carry no guarantees, which prepared them mentally for the possibility of a lackluster response or none at all.

In addition, of the hundreds of patients I have kept tabs on in terms of their foreign adult stem treatments (2003-present), none experienced profound negative side effects or wound up worse off as a result of their treatment. Yes, some got demonstrably worse, but this was tied by both the patients and their physicians to the progressive nature of their medical conditions and not to their adult stem cell treatment. And on top of this, a survey of the medical literature and

painstaking Google search I did back in 2006 underscored what I was seeing in the patients I tracked and still see to this day; namely that reports of severe side effects or stem cell spawned medical complications or conditions were scant.

This is not to say stem cell therapy is not without risk. Most who are reading this article have heard or read about the [little boy who had fetal cell therapy in Moscow](#) for [ataxia telangiectasia](#) (AT) and wound up with slow growing tumors in his brain (glioneuronal neoplasm). However, if adult stem cell therapy is to be swept aside on the basis of a single dire outcome case or two, should we then apply this standard to standard or experimental (approval track) medical drugs and therapies that result in rare instances of malignancy or other physical or mental complications? Of course not, you say – this is overkill. And yet some critics essentially embrace this kind of “toss the baby out with the dirty bathwater” approach when it comes to foreign private clinics doing adult stem cell therapy.

But wait. The drugs and therapies referred to above have been through clinical studies or are in-process and enjoy or will enjoy FDA approval. The side-effects and risks are basically known and quantified. The same cannot be said of most adult stem cell therapies outside of the sanctioned ones such as chemoablation of bone marrow and reconstitution using autologous peripheral stem cell, bone marrow stem cell or matched stem cell –rich donor cord blood transplant. This is basically true. And with this we come full circle to the issues delved into previously: Namely, that formal safety and efficacy studies need to be carried out involving specific adult stem cells, e.g., autologous bone marrow derived stem cells, allogenic cord blood stem cells, etc. for medical challenges such as sporadic ALS, congestive heart failure, cerebral palsy, and traumatic brain injury, but are unlikely to be carried out by the vast majority of small private stem cell clinics and such abroad due to various factors including resource limitations. But while short- and long- term safety as well as efficacy studies are lacking when it comes to infusion or implantation of various kinds of adult stem cells for many vexing medical diseases and conditions, the fact that the clinical use of a wide range of adult stem cells by private foreign medical facilities has been going on for a while and has not produced medical horror stories, nor has anything of this sort emerged from animal studies or from what human clinical pilot and other studies that have been done to-date, suggests that these treatments do not pose a major safety risk. But again, this isn't certain because the formal studies have not been carried out in most instances. And as such patients considering doing any form of adult stem cell therapy that has not undergone a formal scientific evaluation must carefully weigh what is known v. unknown (as in possible/probable costs/risks v. benefits). This includes being leery of any clinic or center that offers stem cell therapy for a disease or condition that is imminently remediable via conventional medical care (provided quality of life is not sacrificed in the process or costs outweigh benefits) or which does not compromise the patient's quality of life or lifespan in a way that makes non-treatment more inimical than forging ahead and being treated.

In light of what has been discussed and explored in this article, foreign stem cell clinics certainly owe to their patients to make sure that they avoid the pitfalls outlined in the preceding pages while working diligently to document each case history thoroughly including having patients undergo standardized, validated pre- and post- treatment testing germane to their particular medical condition or illness (Biogenesis affiliated clinics adhere to this approach). Critics and

medical consumer advocates owe it to the public they wish to protect not to use scare tactics or the very forms of hyperbole or fallacious reasoning they accuse stem cell operations of employing or relying on. And terminally and intractably ill patients as well as their physicians owe it to themselves and each other to use the best available information combined with the tools of skeptical thinking to determine which form of adult stem cell therapy, if any, is most likely to be both safe and effective for their particular afflictions.

Anthony G. Payne, Ph.D. literally wrote the book on [Umbilical Cord Stem Cell Therapy](#), which is to say he co-authored one of the first lay level books on the subject ever in the English-speaking world (Basic Health Publications). He is currently doing consultancy work for a number of clinics and firms. Readers can get a feel for his passion to help those working with the sick and dying by reading ["Embracing the Disenfranchised"](#). Payne can be readily reached by e-mail at attachi-mailbox@yahoo.com.

Additional/Supplemental Reading

[For Those Considering Doing Stem Cell Therapy Abroad by Dr. Anthony G. Payne](#)

[International Society for Stem Cell Research](#)

[American Stem Cell Therapy Association](#)

[Stem Cell Pioneers \(Moderated cyber-discussion board\)](#)

[The Stem Cell Blog \(David Granovsky - Repair Stem Cell Institute\)](#)

[Dr. Payne's Cerebratorium \(Blogsite\)](#)

[Do No Harm: The Coalition of Americans for Research Ethics](#)

[Snake Oil Science](#) by R. Barker Bausell, Ph.D.

[Fads & Fallacies in the Name of Science](#) by Martin Gardner

[Any and All Books by James Randi](#)

[Carl Sagan's "The Demon Haunted World"](#)

[Operation Clambake presents: Baloney Detection Kit](#)

[The Critical Thinking Community](#)

[Free online Critical Thinking Test](#)

[Muscle Nerve](#). 2009 Jun;39(6):858-60.

A placebo arm is not always necessary in clinical trials of amyotrophic lateral sclerosis.

[Gordon PH](#).

The Eleanor and Lou Gehrig MDA/ALS Research Center, Department of Neurology, Columbia University Medical Center, 710 West 168th Street, New York, New York 10032, USA.

Riluzole is currently the only approved medication for amyotrophic lateral sclerosis (ALS). While other potential neuroprotective agents have been tested in clinical trials, none has been effective, and few symptomatic treatments have been studied. Randomized placebo-controlled trials are necessary to establish the effectiveness of a drug, but an increasing number of potential therapies combined with limited resources means that only a few drugs at a time can be tested for efficacy in ALS. Therefore, priority must be given to agents that show an advantage in early phase trials before proceeding to Phase III efficacy trials. New strategies are being used to screen different agents, along with their correct dose, in a variety of neurological illnesses, including ALS. **Early phase trial designs conducted without a placebo arm improve efficiency, reduce cost, and appeal to patients.** Dose-ranging, futility, and selection trials are examples of Phase I and II trial designs that can be conducted without placebo groups. Muscle Nerve, 2009.

PMID: 19382169

http://symptomresearch.nih.gov/chapter_6/sec1/csss1pg1.htm

Cross-over trials are trials in which patients are allocated to sequences of treatment with the purpose of studying differences between individual treatments ([Senn, 1993](#)). **N-of-1 studies are special cases of cross-over trials in which the same patient is repeatedly randomised to receive either the experimental treatment or its control ([Senn, 1993](#)).** The distinction between these types of trials has more to do with presumed purpose than with statistics, traditionally cross-over trials have been seen as efficient alternatives to parallel group trials for the purpose of investigating typical effects of treatments, **whereas n-of-1 trials have been developed by medical researchers with the express purpose of extending the methodology of the clinical trial to the treatment of the individual patient.** These distinctions, however, are less important than has commonly been supposed. We shall look at cross-over trials initially and then consider what further matters are raised by n-of-1 trials.

<http://www.annals.org/cgi/content/full/133/6/474> - Annals of Internal Medicine, 'Are Placebo-Controlled Clinical Trials Ethical or Needed When Alternative Treatment Exists?'

Richard

Simon,

D.Sc.

19 September 2000 | Volume 133 Issue 6 | Pages 474-475

The randomized clinical trial was a major methodologic breakthrough in medicine. For conditions having no effective treatment, the control regimen to which the new treatment is compared is usually either observation or administration of placebo. In some cases, untreated or placebo control groups are used even though effective treatment exists for the condition. Rothman (1) has challenged the ethics of such clinical trials; in the current issue, Temple and Ellenberg (2,3) address this challenge.

There is general agreement that placebo or untreated controls are not appropriate in trials of therapy for life-threatening conditions if a treatment that prolongs or preserves life is available. The disagreement centers on trials of therapy for non-life-threatening conditions, in which a delay in administration of the effective treatment is unlikely to cause permanent harm.

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