ADVANCED
MEDICAL INTEGRATION

THE SCIENCE OF REGENERATIVE MEDICINE

REGENERATIVE MEDICINE, THE FUTURE OF HEALTHCARE

“There is a vast difference between treating effects and adjusting the cause.”
-Daniel D. Palmer

The Science of
Regenerative Medicine

Regenerative medicine is one of the most talked-about subjects healthcare has ever known, and for good reason. It could hold the solution to the puzzle of America's failed healthcare system.

Regenerative Medicine

"Regenerative medicine may be defined as the process of replacing or 'regenerating' human cells, tissues or organs to restore or establish normal function." *(source -American Association of Blood Banks.)*

This field holds the promise of regenerating damaged tissues and organs in the body by stimulating previously irreparable tissues to heal themselves.

Regenerative medicine also empowers scientists to grow tissues and organs in the laboratory and safely implant them when the body cannot heal itself. Importantly, regenerative medicine has the potential to solve the problem of the shortage of organs available through donation compared to the number of patients waiting for a life-saving organ transplant. *(source: NIH. U.S. Department of Health and Human Services)*

Stem Cells

Everyone has heard of stem cells, but few understand fully what they are, where they come from, and how they may benefit healthcare.

Regenerative medicine science is still in its infancy, a field with an ever-increasing number of incredible results. Once the potential of stem cells began to be realized, they have experienced unparalleled growth in research and discovery.

Regenerative medicine is the path to follow for chiropractors as they are leading the pack in healing without drugs or surgery. Many are becoming experts at this emerging science and will provide the opportunity for which we went to school – to be real healers.

The Basic Cell

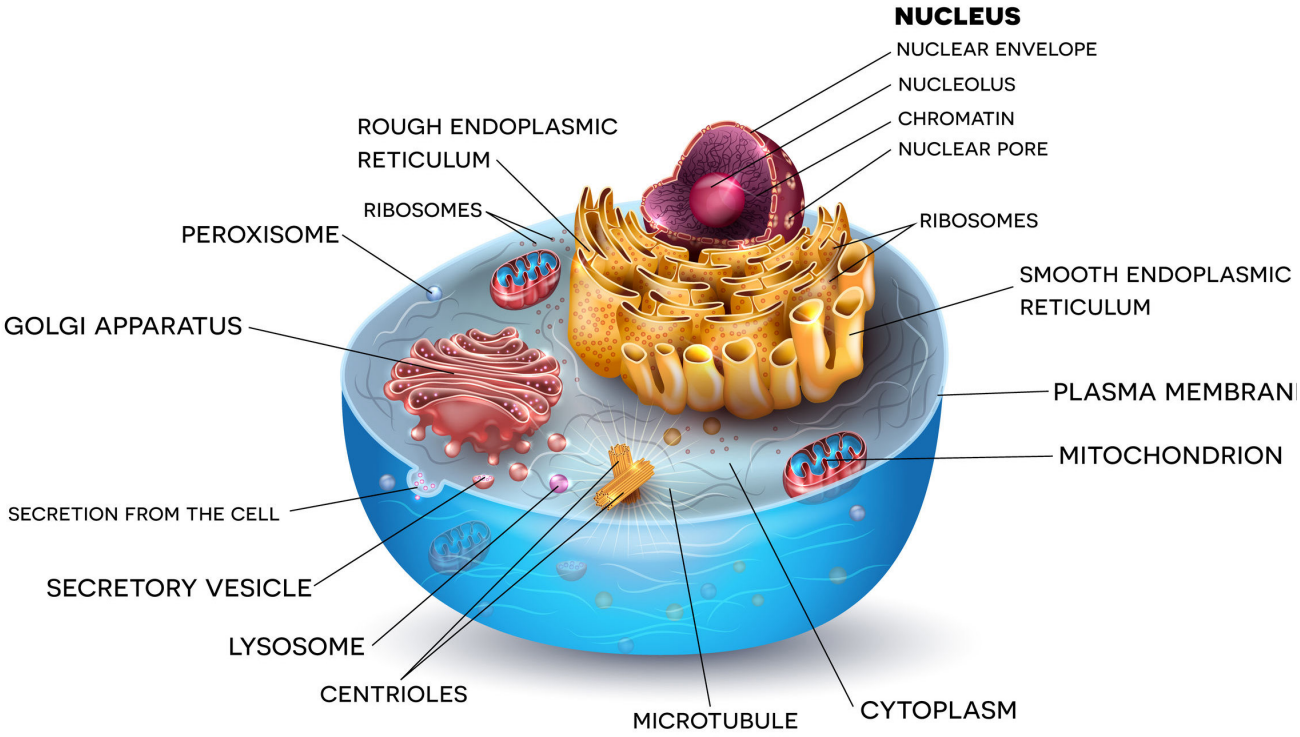
Before refining this discussion on stem cells, let's look at the structure and function of the basic cell itself. *(source: closerlookatstemcells.org)*

Cells in the Human Body

The human body is comprised of more than 200 cell types, and every one of these cell types arises from the *zygote*, the single cell that is formed when an egg is fertilized by a sperm.

Within a few days, that single cell divides over and over again until it forms a *blastocyst*, a hollow ball of 150 to 200 cells that gives rise to every single cell type a human body needs to survive, including the umbilical cord and the placenta that nourishes the developing fetus.

ANATOMY OF A CELL



Basic Cell Biology

Each cell type has its own size and structure appropriate for its job. Skin cells, for example, are small and compact, while nerve cells that enable you to wiggle your toes, have long, branching nerve fibers called axons that conduct electrical impulses.

Cells with similar functionality form tissues, and tissues organize to form organs. Each cell has its own job within the tissue in which it is found, and all of the cells in a tissue and organ work together to make sure the tissue or organ function properly.

Regardless of their size or structure, all human cells start with these things in common:

- A *nucleus* that contains DNA, the genetic library for the entire body. Different cells read and carry out different instructions from the DNA, depending on what those cells are designed to do. Your DNA determines virtually everything about your body, from the color of your eyes to your blood type and even how susceptible you are to certain diseases (some diseases and conditions, such as color blindness are also passed down through DNA).

- *Cytoplasm* – the liquid outside the nucleus. The cytoplasm contains various components that make the materials that the cell needs to do its job.

- The *cell membrane* – the surface of the cell, a complex structure that sends and receives signals from other cells and lets material in and out of the cell (cells have to be able to communicate to work together in tissues and organs).

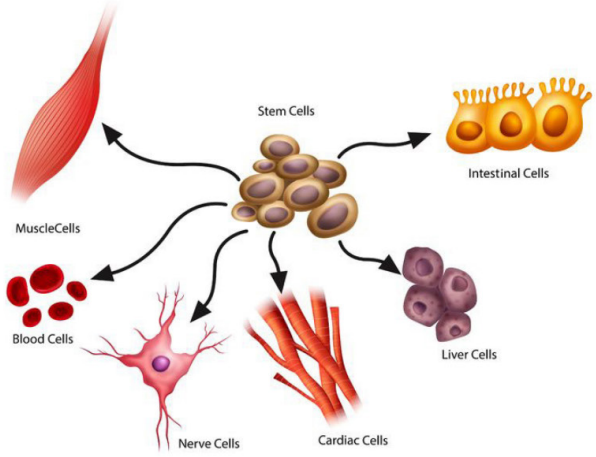
Most cells divide. Shortly before division, the DNA replicates and then the cell divides into two *daughter cells*. Each has a complete copy of the original cell's DNA, cytoplasm and cell membrane.

"During the early stages of embryonic

development, the cells remain relatively undifferentiated (immature) and possess the ability to become, or differentiate, into almost any tissue within the body. For example, cells taken from some section of an embryo that might have become part of the eye can be transferred into another section of the embryo and could develop into blood, muscle, nerve, or liver cells." *(source: medicinenet.com)*

STEM CELLS, WHAT ARE THEY?

Stem cells are unspecialized cells that have not yet "decided" what type of adult cell they will be.	They can self-renew and make two new identical stem cells.
They can differentiate to make multiple types of cells.	They ultimately amplify by expanding the number of differentiated & mature cells.



(source: University of Nebraska Medical Center)

The Boss Stem Cell

Here is a more simplified way of looking at it: as described above, the female egg is fertilized by the male sperm. Now we have a fertilized cell called a zygote.

It is the founder, the master, or the boss cell from which the rest of the embryo is formed. Specifically, it is called a "*totipotent*" stem cell.

The Embryo

"Embryonic stem cells are *pluripotent*, meaning they can give rise to every cell type in the fully formed body, but not the placenta and umbilical cord. These cells are incredibly valuable because they provide a renewable resource for studying normal development and disease, and for testing drugs and other therapies.

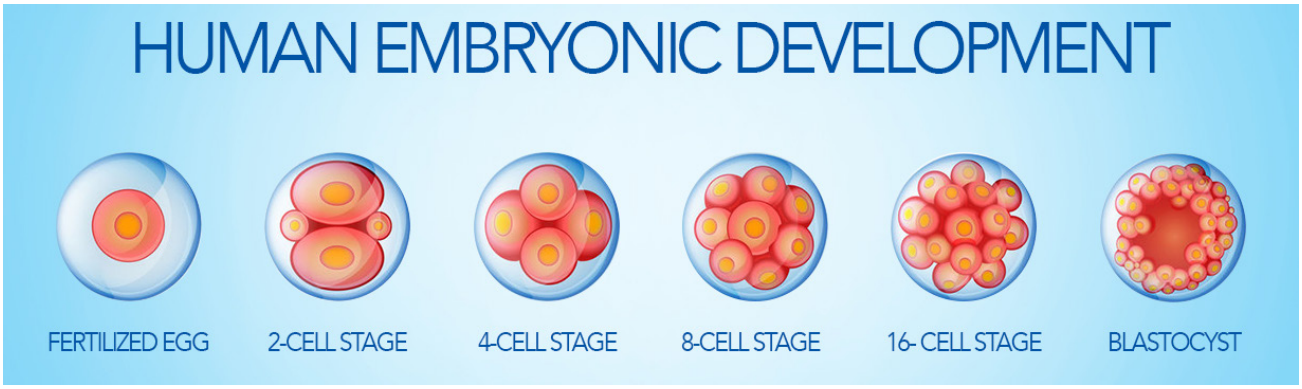
Human embryonic stem cells have been derived primarily from blastocysts created by in vitro fertilization (IVF) for assisted reproduction that were no longer needed." *(source: closerlookatstemcells.org)*

These are "undifferentiated" stem cells, which have no identity. They then become partially undifferentiated. Before they assume the identity of a body part, they can still be assigned to any job to repair or replace anything elsewhere in the body.

Originally designed and destined to become a particular body part, they are freelance handymen ready to go to work and become what is needed. They will go on to their destination and become a nose, eye, blood, a pancreas, or a toenail on the left big toe - all according to plan.

Blastocyst and the Placenta

The trophoblast, a layer of cells that forms the outer ring of the exterior of the blastocyst, attaches to the endometrium and forms the placenta. The placenta is the connection to



the uterine wall, providing a connection to the fetus through the umbilical cord.

The umbilical cord is the lifeline to the fetus. It carries oxygen-rich cells and nutrients from the mother to the fetus and then allows it to pump deoxygenated and nutrient-depleted blood back out. Its structure consists of one vein and two arteries. The vein carries blood rich in oxygen and nutrients from the mother. The arteries return deoxygenated blood and waste products, such as carbon dioxide.

What is the Difference Between Totipotent, Pluripotent, and Multipotent?

"Totipotent cells can form all the cell types in a body, plus the extraembryonic, or placental cells. Embryonic cells within the first couple of cell divisions after fertilization are the only cells that are totipotent. Pluripotent cells can give rise to all of the cell types that make up the body; embryonic stem cells are considered pluripotent. Multipotent cells can develop into more than one cell type, but are more limited than pluripotent cells; adult stem cells and cord blood stem cells are considered multipotent. These cells are usually limited to repairing and replenishing one particular type of tissue." *(source: Department of Health, Wadsworth Center, NYSTEM, New York Stem Cell Science)*

Role of Stem Cells

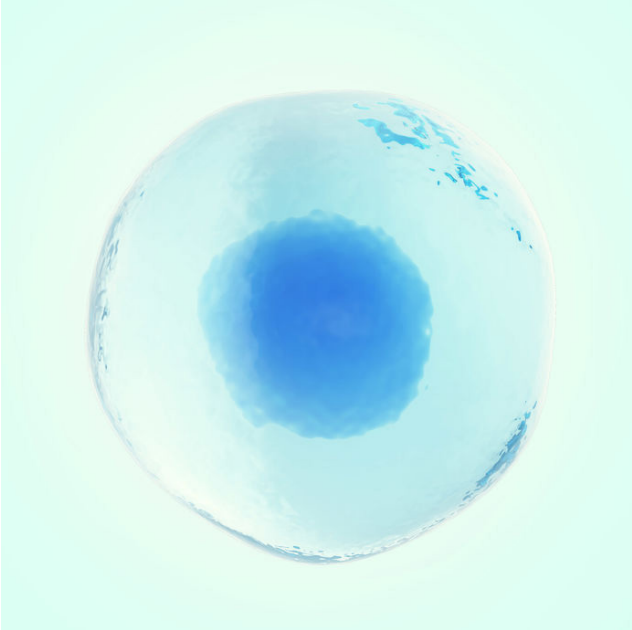
They guide the development from embryo to a living baby and then help that body heal itself throughout its lifetime. There is an abundance of stem cells during the early growth period and during the period the human is more active and in need of repair from use or accident. Over the years they become less and less as the body ages. This is why the young heal right away and the elderly heal so slowly. In the younger period of the organism, Mother Nature is right there with stem cells at the ready to heal. They fix what is wrong with the tissue injured for that is their specific ability and job to do. They cannot go heal a neighboring muscle if their job is repairing some other body part. With the lessening of availability of stem cells as the body ages, it is a blessing and a tribute to man's continuous effort to discover better ways to solve age old problems, and I mean old age problems as well. Thus, the role of pluripotent stem cells becomes important to the healing at all ages. But the availability of pluripotent stem cells is limited by ethical considerations in using embryonic cells. Although this would solve any ethical issues, this has not yet been fully done - but much has been accomplished. Some areas of research include stimulating an adult stem cell in the host to revert back to a pluripotent stem cell.

Ethical Considerations of Embryonic Stem Cells (HES)

Regenerative medicine is not new. Bone marrow transplants have been performed for decades, but when scientists learned how to remove stem cells from human embryos in 1998, as much controversy as excitement resulted.

The huge potential of employing these cells to cure human disease was the driving force behind an explosion of research and the hope of miracles to come. In short order it was discovered that a patient's own cells could be stimulated or induced to behave like embryonic stem cells. This led to the discovery that umbilical and placental stem cells were almost as pluripotent as embryonic stem cells. *(Sources: nih.gov)*

This breakthrough provided a source that was no longer controversial and available everywhere. With the availability of mesenchymal stem cells from non-embryonic sources, researchers, doctors, and ethicists alike are breathing easier.



Induced Stem Cells, Pluripotent Umbilical Cells, or Embryonic Stem Cells?

Evidently, embryonic stem cells are better, but the issue is, how much better - and how much are we losing in curing of human diseases and ills because the use of embryonic cells for research is forbidden?

As we become more and more familiar with the identification and use of various sources of stem cells, the limitations become less and less. The frontier for the study and use of stem cells in the near future remains very bright. *(source: academic.oup.com)*

The History of Stem Cells

In 1910, Dr. Maximilian Stern, M.D. used amniotic tissue on burn victims with great success. In the 1960's, Ernest McCulloch and James Till discovered the blood forming stem cell. By definition, a stem cell must be capable of both self-renewal (undergoing cell-division to make more stem cells) and differentiation into mature cell types. But the cells they discovered could differentiate only into blood stem cells. This is called *tissue specific* stem cells that only grow to other types of blood cells.

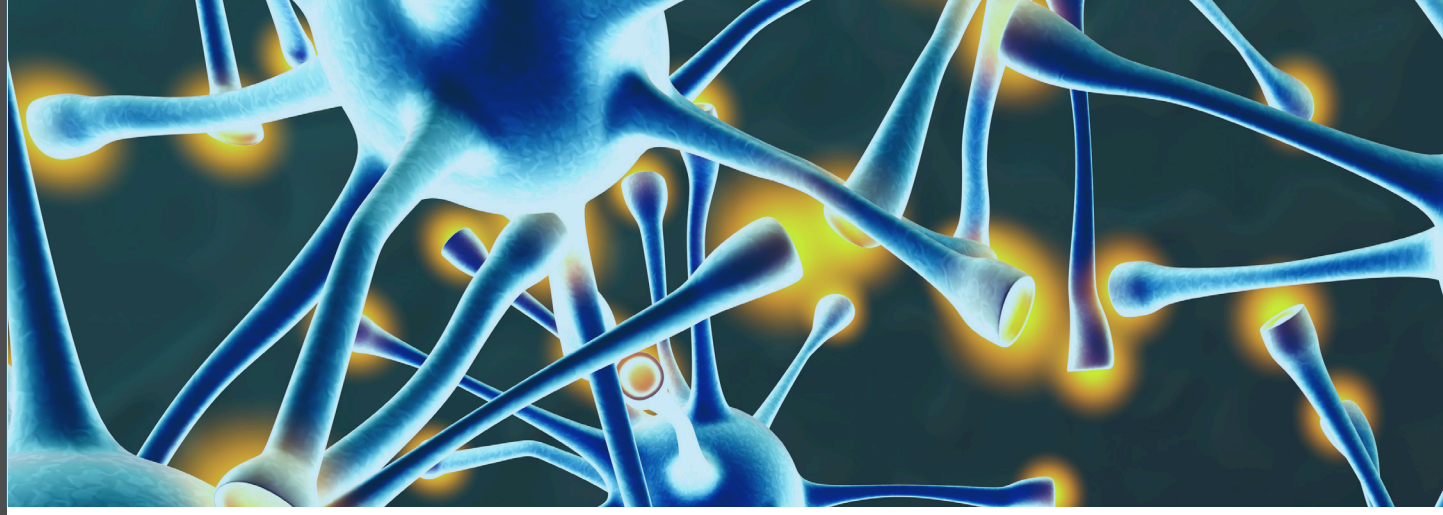
They are one of the many examples of "adult stem cells", or are "*unipotent*" giving rise to only one cell type, muscle cell or blood cell. But what is sought are *pluripotent stem cells* – the "I can be anything" stem cell.

The Big Discovery

Over the years a number of scientists gradually moved the process forward. In the early 1960's, Sir John Gurdon FRS FMedSci MAE, showed that cells are not locked in their differentiation state and can be reverted to a more primitive state with higher developmental potential.

Then, finally, Dr. Shinya Yamanaka and colleagues shocked the world when they were able to convert skin cells into pluripotent stem cells. This represented the birth of "*induced pluripotent stem cells*" or IPS cells. Gurdon and Yamanaka shared the Nobel Prize in Physiology or Medicine.

Pluripotent stem cells hold promise in the field of regenerative medicine. Because they can propagate indefinitely, as well as give rise to every other cell type in the body (such as neurons, heart, pancreatic, and liver cells), they represent a single source of cells that could be used to replace those lost to damage or disease. *(source: Wikipedia)*



On the Cusp

We are on the edge of a monumental change in personalized regenerative medicine. With IPS cells, research, experimentation and exploration in stem cells has leaped ahead.

These cells can facilitate the generation of all the cells in our body. This means diseased, deteriorated, and damaged organs or other parts of the body can be repaired or replaced with no fear of donor incompatibility causing immune rejection.

Old Age May Be at an End

A little more development and old age, with its inevitable degenerative consequences, may become a thing of the past. With stem cells, the worn out connective tissues around joints that are usually the target of inflammation and pain may be renewed, and we may eventually be able to grow new organs essential to life.

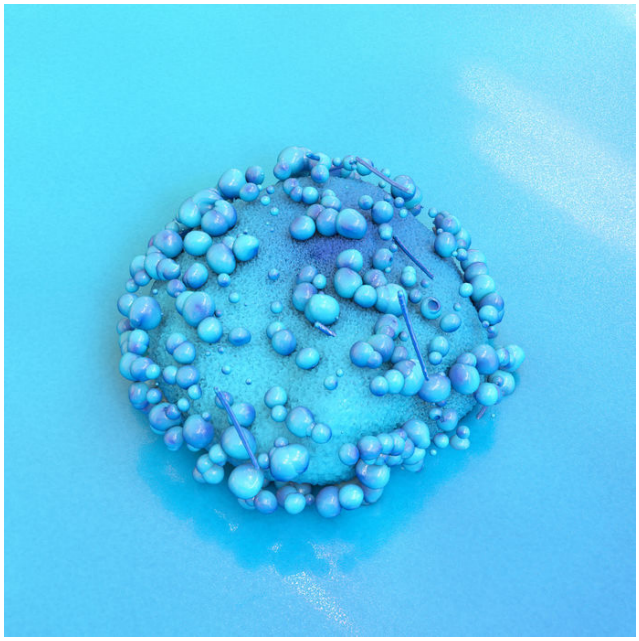
Present-day healthcare's reliance on medication and surgery has been failing. It is a disease maintenance system that can only attempt to keep a patient pain free. Remedies that employ regenerative medicine could very well be the future, repairing degenerated or damaged tissues.

Adult Stem Cells

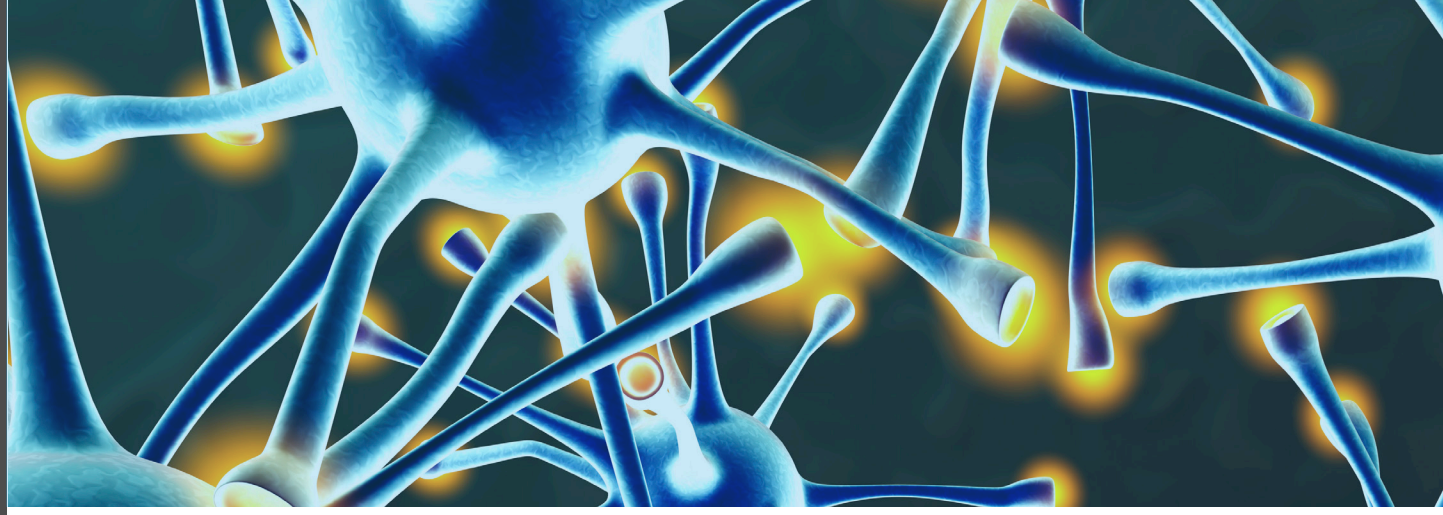
As science progresses, we have learned that there are stem cells in the brain and heart. The body is loaded with stem cells that act as an on-site handyman to fix a particular organ or body part to which it is assigned.

Sixty years ago, it was discovered that bone marrow contained two kinds of stem cells: Hematopoietic, that forms all kinds of blood cells, and Stromal, (mesenchymal) or skeletal stem cells, which can generate bone, cartilage, and fat cells that support the formation of blood and fibrous connective tissue. *(source: National Institutes of Health)*

Currently, these cells are limited to that specific area of tissue involvement. They are found among differentiated cells in tissues and organs - they are literally everywhere.



An adult stem cell can renew itself and can differentiate to produce some or all of the major cell types of tissue or organs. Their role is to maintain and repair the tissue in which



they are found. If the differentiation of adult stem cells can be managed and produced in laboratories, many transplantation-based therapies may soon become possible.

Use of Mesenchymal Stem Cells

Recently it was discovered that *mesenchymal stem cells are the most effective in repairing and replacing damaged and deteriorated knee, hip, and other joints that experience heavy wear and tear. The richest source of this pluripotent stem cell is from the umbilical cord and placenta. (**mesenchymal (meh-ZE-kih-mul) cells develop into connective tissue, blood vessels, and lymphatic tissue.)*

It is a treasure trove, with enough stem cell potential to heal the world over and over. With every child that is born there is an umbilical cord and placenta that are usually discarded.

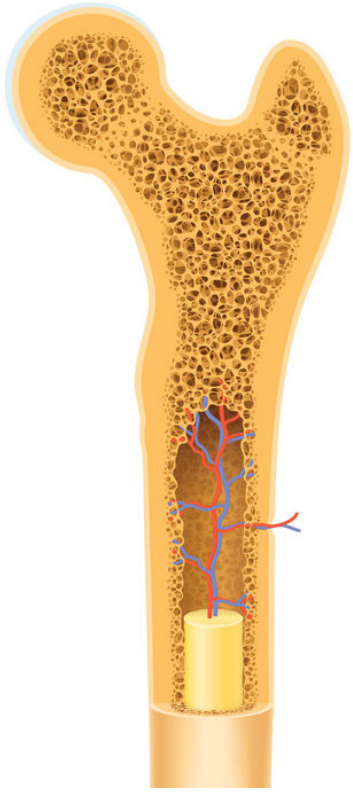
Every birth delivers with it an abundant source of regeneratvie medicine. Parents are encouraged to have their newborn's cord blood banked in case it is needed for the future treatment of a blood-borne disease. Regenerative medicine science is one of the most exciting frontiers of health science simply because of the potential that it holds.

First Bone Marrow, Now Cord Blood

Bone marrow transplantation has been the traditional treatment for certain diseases such as leukemias, a variety of aplastic anemias, and certain immunodeficiencies. It has been the only treatment to achieve successful, long-term patient survival.

Could There be a Better Way?

The transplantation of bone marrow and the process of taking cord blood and using or banking for future use is very complex. By comparison, harvesting stem cells directly



from the umbilical cord, processing them, and then injecting them is much simpler.

More and more uses are developing with research, and these therapies can be a part of what's offered in the medically integrated practice.

The Umbilical Cord and Wharton's Jelly

The umbilical cord runs from an opening in the stomach of the fetus to the placenta which is attached to the lining of the womb wall during pregnancy. The cord has one vein and two arteries. The vein carries blood rich in oxygen and nutrients from the mother to the fetus. The arteries return deoxygenated blood and waste products, such as carbon dioxide back through the placenta.

Surrounding and protecting these vital blood vessels is a sticky, gel-like substance called Wharton's Jelly. It was discovered that Wharton's Jelly is rich in mesenchymal stem cells, which may be harvested in abundance for they are present in every umbilical cord.

Amniotic Tissue and Fluids

Amniotic tissue and fluids are taken from the amniotic fluid and sac that surrounds the embryo. These membranes have been shown to improve the healing of damaged tendons and other connective tissues. Authors disagree if it contains mesenchymal stem cells that come from the surrounding amniotic membrane. An advantage of amniotic tissues and fluid is that they can be obtained easily at the time of birth without harming the mother or baby and cryopreserved until they are needed. They contain many cytokines that aid in healing.

Reduce Rejection Risk, Inflammation, and Pain

When mesenchymal stem cells derived from umbilical cord tissue are placed in an osteoarthritic knee joint, they can potentially form cartilage cells. In addition to containing mesenchymal stem cells, the fluid contains many other growth factors (such as cytokines, hyaluronic acid) that benefit healing and regeneration. These growth factors can recruit other stem cells to the area, causing

the existing cells to divide and stimulate the growth of nerves, blood vessels, and other supporting tissues. *(source: nih.gov)*

Studies have also found that amniotic tissue grafts used during spine surgeries lead to improved healing and less pain. When these grafts are applied to flesh wounds, they have

been found to speed up healing and wound closure. *(source: nih.gov)*

Osteoarthritis of the knees, hips, and shoulders affects millions of people in the U.S. and can cause chronic, debilitating pain. An ongoing study of 170 patients with arthritic knees found that injections of amniotic fluid significantly reduced their pain and reduced disability at 13 weeks after injection. *(source: Pain Doctor)*

PRP (Platelet Rich Plasma) Therapy Injections

"PRP therapy involves drawing a small volume of blood from the patient and spinning this blood in a centrifuge. This separates the blood into different layers, each containing concentrated amounts of the substances naturally found in blood: serum in the top layer, white blood cells and platelets in the middle layer, and red blood cells in the bottom layer.

The middle layer, known as PRP concentrate, is then separated from the rest of the blood. This PRP concentrate contains three to five times the normal concentration of the platelets and growth factors that are used in the body's own healing process. This PRP concentrate is then injected back into the patient's body at the site of their injury, for example, into the site of an injured tendon or ligament. This process is then repeated over the course of weeks with additional PRP concentrate being drawn and injected each time.

The platelets injected release hundreds of different proteins involved in the regeneration of tissues. Though research on this treatment continues, existing research has shown increased promotion of healing of several different types of tissues. Because the patient is injected only with concentrate from their own blood, PRP therapy avoids safety issues of ensuring donor compatibility when using blood and tissue donation." *(source: Pain Doctor)*

The PRP technique was developed in the 1970s and has been adopted in orthopedic surgery, plastic surgery, and sports medicine. Many top athletes around the world use it to help recover following major surgery. In 2009, Hines Ward, a wide receiver for the Pittsburgh Steelers used it to help heal a sprained ligament in his right knee before Super Bowl XLIII. *(source: scientificamerican.com)*

Regenerative Medicine Around the World

At the World Stem Cell Summit in 2018, hosted by the regenerative medicine Foundation, representatives from around the globe gathered to share challenges, discuss cures, treatment advances and collaborate on progress made in many areas.

210 organizations were represented by over 1500 attendees from over 30 different nations. Innovations in the identification of causes of certain diseases, the engineering of tissues and organs, the reversing of the aging process, acceleration of wound care and healing were all on the event's agenda.

The medical world is waking up to the increasing impact of regenerative medicine and cell-based therapies on healthcare. Scientists, philanthropists, government leaders, bioethicists, regulators and companies from across the globe gathered to share breakthroughs and forge collaborations.

China, India and Brazil, considered developing countries by the World Bank represent 40% of the world's population. These three countries have made a commitment to developing regenerative medicine therapies and treatment.

While Brazil is conducting one of the largest regenerative medicine clinical trials in the world, India is repairing the corneas of hundreds of patients using limbal stem cells. China, now the fifth largest publisher on regenerative medicine in peer-reviewed literature, has become a world leader in the field.

Brazil has invested approximately $40 million (US) in regenerative medicine research and cell therapies since 2005. In Japan's historic capital of Kyoto a global race is on to become the world's regenerative medicine equivalent of Silicon Valley. *(source: Financial Times)* Though accurate numbers are hard to come by, some estimate that China has made investments of nearly $300 million (US) to gain an advantage. *(source: Future Medicine)*

"Regenerative medicine (RM) uses the body's own power to "heal from within" to repair and replace damaged tissues and organs at the cellular level. In a recent Drugs and Biologics Update on this topic, we noted that Japan has taken a leading role in RM research and development (R&D), resulting in the development of a large number of technological advances, in particular in the areas of regenerative medicine technology, devices, and manufacturing. The field of RM is considered critically important in Japan because of concern that health care costs associated with its large aging population

will financially devastate its social support system by mid-century. In most developed countries around the world, medicines comprise 5% to 10% of total health care costs, whereas in many developing countries that figure can be as much as 60%." *(source: Clinical Therapeutics)*

How Big is it?

"Global regenerative medicine market is expected to reach USD $79.8 billion by 2024, at a CAGR (Compound Annual Growth Rate) of 20.5% from 2018 to 2024. Factors driving the growth of the market are: increasing prevalence of degenerative and chronic diseases, technological advancements in nanotechnology, bioengineering and stem cell therapy, and increasing geriatric population across the globe." *(source: Energias Market Research - March 18, 2019)*

Regenerative Medicine's Potential

Shortages of tissues and organs has been identified as a major public health challenge with only a small percentage of patients in need receiving transplantations. Regenerative medicine is an emerging field in the healthcare sector that aims to repair, replace, and regenerate damaged organs and tissues.
Emerging technology, including cell therapy, small molecules and biologics, tissue engineering, and gene therapy, offer the potential for lifetime cures of unmet medical challenges. In many ways regenerative medicine has become the leading edge of clinical practice and biomedical research.

Moreover, in the last decade, there has been increased government support for funding and approval of regenerative medical products and procedures. The industry has witnessed an increasing number of clinical trials, and various companies are working on products that should reach clinics in the next five years. In addition, regenerative medicine could potentially be applied towards improving health in developing countries.

Coming to Their Senses

The cost of American Healthcare is $3.3 trillion a year, ($10,000 per person – 16.9% of America's GDP), which is far more per capita than the next most costly nation, which is France. Yet the World Health Organization (WHO) ranks American healthcare 37th

KEY FINDINGS OF THE REPORT:

North America held the largest share of the global market in 2017. Asia-Pacific region is expected to register highest CAGR from 2018 through 2024.

Based on technology, the cell therapy segment held the major share of the market in 2017.

The oncology segment is likely to augment at the fastest rate over 2018-2024 due to the increasing number of cancer patients across the globe, and a growing number of clinical trials in oncology indications. Approx. 53% of all current clinical trials are in oncology, such as lymphoma, leukemia, and cancer of breast, colon, brain, pancreas, cervix, bladder, and esophagus, among others.

The global regenerative medicine market is expected to reach USD $79.8 billion in 2024, at a CAGR of 20.5% during 2018 -2024.

among 180 nations, 26th in longevity, and 29th in infant mortality.

What is wrong with this picture?

The answer is waste, government corruption, the influence of Big Pharma, the AMA, as well as Big Insurance and Big Food. Place them in a TV sitcom, and the name could be "The Greedy Bunch".

Healthcare by Pill

Add this to the idea most patients leaving a doctor's office are gripping a prescription for some kind of drug as the favored solution to his or her problem. If it's for pain, it will likely be an addictive drug – which is how we've gotten ourselves to the current opioid crisis.

Americans have been trained to think that this is the way it should be. Contrary to common perception, in nearly every instance there is a means of treating pain and curing ailments without a single drug needed.

The weight of these facts, are born out in the new book *The Death of American Healthcare*, by Dr. Mike Carberry, DC. It will shock readers with the revelation that our failing healthcare system will bankrupt our country unless something is done immediately.

Regenerative Medicine is the Unequivocal Answer

It is now internationally recognized that regenerative medicine is the direction in which modern healthcare is moving. Another motivating factor is the economic incentive for finding a rational and sane solution to the insanity we call healthcare in America.

The paradigm shift will occur as integrated medical clinics consisting of a variety of disciplines treat patients as a whole not a symptom. Joining in on a collaborative goal to permanently change the landscape of healthcare will result in there no longer being simple treatments for symptoms by just giving relief and prolonging illness. The disease maintenance model of American healthcare is soon to be a thing of the past.

Opportunities and the Rise of Medical Clinics Offering Regenerative Medicine

From the Cajun Country of Louisiana to 8 clinics within a three block area on the famous Rodeo Drive in Beverly Hills, California, medical clinics offering regenerative medicine is proliferating across the United States. They are growing internationally as well, and thousands of Americans seek inexpensive treatments by traveling overseas every day for regenerative medicine tourism.
The most common area of treatment is the knee. Osteoarthritis (OA) affects more than 27 million Americans and an estimated 9.9 million adults suffer from OA in the knee. Risk factors include age, sex, genetics, being overweight, and repetitive knee bending or heavy lifting. Women have an increased risk of OA in the knee as they age, leading to pain, stiffness, and decreased movement.

80% Success Rate

The average price per treatment is $5,000, but some clinics may charge over $25,000. They commonly claim to have an 80% success rate, citing "improved conditions" and increased mobility.

Just the mere hope of pain being alleviated for chronic sufferers of the condition combined with an improvement in mobility has stirred optimism in an entire subset of the population. "A simple injection even at five grand is cheap compared to having to undergo serious surgery to replace a knee even if you have no real proof of what the result may be," says one hopeful patient. *(source: https://projects.sfchronicle.com/2018/stem-cells/clinics/)*

Opportunity

Many orthopedic surgeons, having performed hundreds of knee replacements and other joint surgeries, are adding regenerative medicine to their practices. Patients and providers alike are increasingly turning to joint pain, and many other kinds of soft tissue problems.

Integrating your practice, establishing a clinic to provide a full array of regenerative healthcare services is the next frontier for your business. Becoming thoroughly familiar with the complexity of regenerative medicine treatments and the pertinent laws and regulations is critical.

FDA

There are regulations regarding the use and marketing of regenerative medicine products. This section will give a short background and basic understanding of some key aspects in regard to these regulations.

Sections 351 and 361 of the Public Health Service Act (PHSA) provides the authority for the FDA to establish regulatory requirements for marketing traditional biologics and human cells, tissues, and cellular and tissue-based products (HCT/Ps). These two pathways differ markedly in terms of the time, effort and expense required to bring these products to market in the U.S.

Basically section 351 products are regulated as drugs or biologics and involves the application for clinical trials and ultimately approval as a drug by the FDA.

Human cellular tissue products would be categorized as section 361 products. It is not approved but rather "cleared" as safe and not misleading by the FDA. Regenerative medicine usually falls under the 361 rule because it is NOT A DRUG.

Section 361 of the PHSA does not identify a specific class of products. Rather, it gives the FDA the authority to make and enforce such regulations that are necessary to prevent the introduction, transmission or spread of communicable diseases from foreign countries into the States.

In 1993, pursuant to Section 361, the FDA published an interim rule concerning human tissue intended for transplantation, which required testing for certain communicable diseases, along with donor screening, and record-keeping. *(source: 58 Fed. Reg. 65514 December 14, 1993)*.

The FDA then issued a final rule entitled, "Human Tissue Intended for Transplantation" on July 29, 1997 creating Part 21 CFR 1270, which requires certain infectious disease testing , donor screening, and record keeping. In 2001 the FDA published 21 C.F.R. Part 1271 and subpart A contains definitions and general provisions pertaining to the scope and purpose of the HCT/P regulations. In particlar, 1271.10(a) sets out the criteria that

form the foundation of a tiered, risk-based approach to regulating HCT/Ps.

Human cells, tissues, or cellular or tissue-based products (HCT/Ps) means articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

Under this tiered approach human tissue products that meet the defined criteria provided in 21 CFR Part 1271.10 are regulated solely under Section 361 of the PHSA.

361 products that meet all the criteria outlined in 21 CFR 1271.10(a) are regulated as HCT/Ps and are not required to be licensed or approved by the FDA.

Combine Multiple Specialties Under One Roof

When a chiropractor and an MD collaboratively work together under one location, you've got a medically integrated practice. You can then focus all treatment efforts on treating the root cause of a patient's ailments and develop an all-encompassing plan of care.

Focusing a team's attention on the problem instead of referring to another doctor keeps the patient in the hands of the providers who know them best and allows for collaboration on treatment. By combining physical medicine, rehab, and regenerative medicine, you are able to help the patient resolve the problem.

Doctor, Integration is For You...

When you integrate and collaborate with another discipline you are able to provide more services to help your patients. Bringing multiple disciplines under one roof will enable you to deliver these successful regenerative therapies with your other physical medicine therapies to each and every patient that needs it.

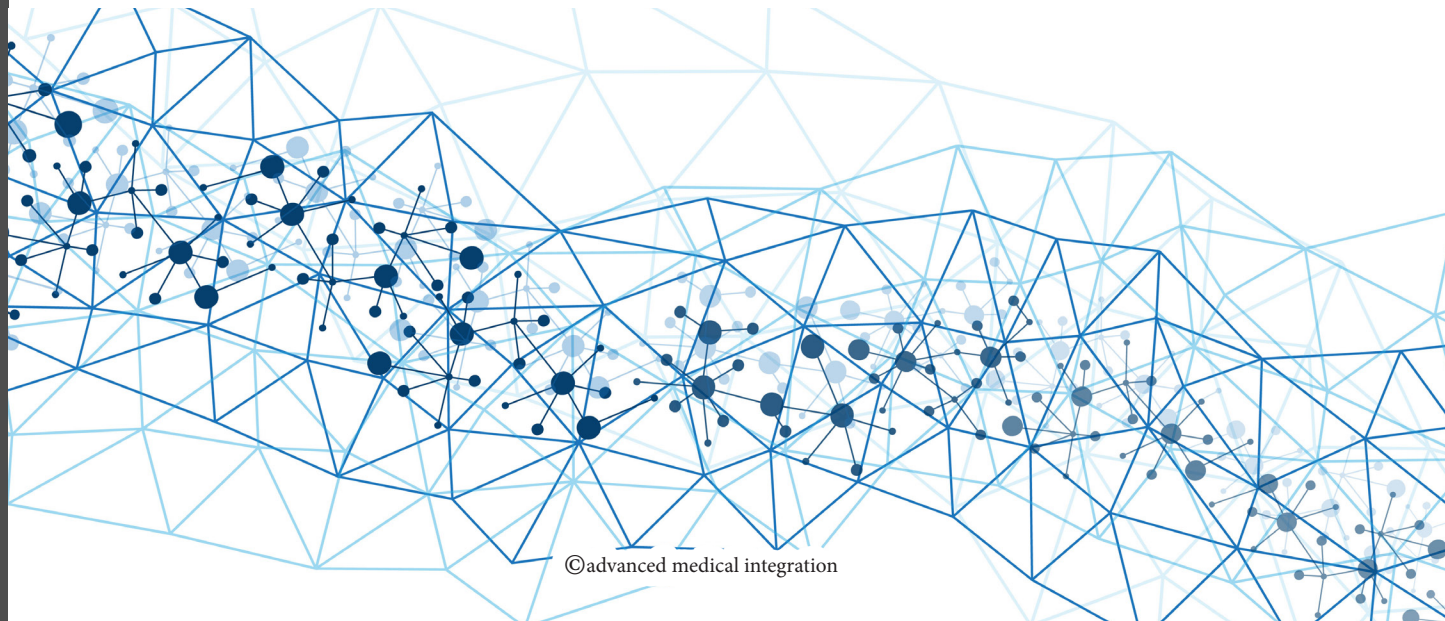
At AMI we have three rules:

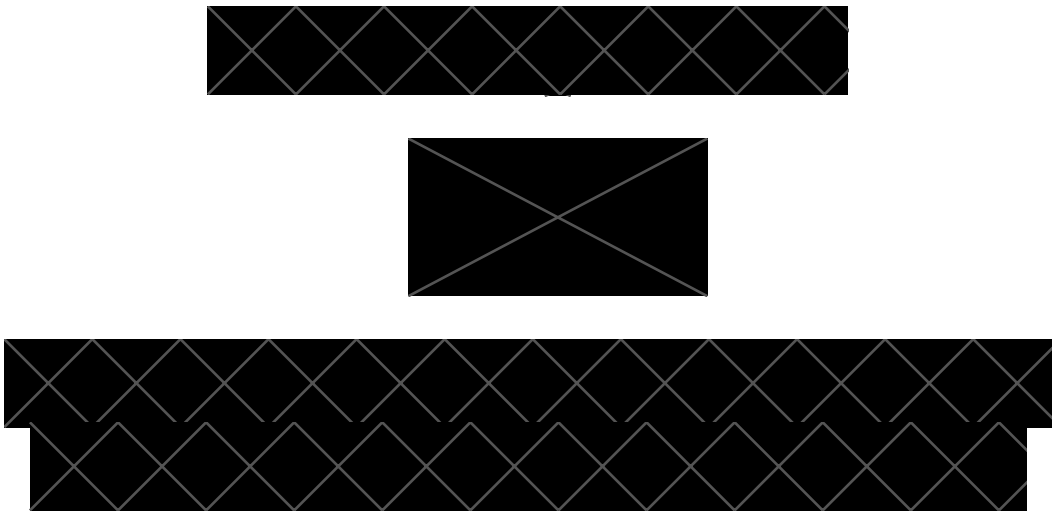
1. At all times, do what's best for the patient
2. Always assure compliance with the law
3. Make it profitable for the owner

In that order!

Success

There are thousands of successful cases of regenerative medicine, and their stories are amazing. Most of them involve clinics that have delivered cases of real advances in alleviating the suffering of patients with acute, chronic pain. Your practice can be one of them – helping the people who truly need it.





ADVANCED
MEDICAL INTEGRATION

Regenerative medicine is one of the most talked about subjects healthcare has ever known, and for good reason. It could hold the solution to the puzzle of America's failed healthcare system.

-Mike Carberry, DC

Want to learn more? Call (888) 777-0815 to begin your medical integration story today!