Title	ABCs of Stem Cell Research
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Purpose

The goal of this course is to help health care professionals understand and educate their patients regarding stem cell research.

Objectives

1. Identify how cell therapies are being used today.
2. Discuss what are some of the challenges of those therapies.
3. State three types of stem cells.
4. Describe how cell therapy works.
5. State where stem cells comes from.
6. Discuss how stem cell therapy helps different disease states.
7. Identify three safety concerns regarding stem cell therapy.

Stem Cell Research

Cell therapy can be defined as a group of new techniques, or technologies, that rely on replacing diseased or dysfunctional cells with healthy, functioning ones. These new techniques are being applied to a wide range of human diseases. Including many types of cancer, neurological diseases such as Parkinson's and Lou Gehrig's Disease, spinal cord injuries, and diabetes. Replacing dead cells in the retina with new ones may someday cure even presently incurable eye diseases such as glaucoma and macular degeneration. To understand how cell therapy works, it helps to understand the role of cells in the body.

Cells are the basic building blocks of the human body. These tiny structures compose the skin, muscles, bones and all of the internal organs. They also hold many of the keys to how our bodies function. Cells serve both a structural and a functional role in the body, performing an almost endless variety of actions to sustain the body's tissues and organs.

There are hundreds, perhaps thousands, of different specialized cell types in the adult body. All of these cells perform very specific functions for the tissue or organ they compose. For example, specialized cells in the heart muscle "beat" rhythmically through the conduction of electrical signals, while the cells of the pancreas produce insulin to help the body convert food to energy. These mature cells have been differentiated, or dedicated, to performing their special tasks. Conventional wisdom has long maintained that under normal conditions, once a cell has become specialized, it cannot be changed into a different type of cell.

Like the body itself, cells have a finite life span; they eventually die. Most of the body's cells divide and duplicate throughout life, but some cells either don't replenish themselves or do so in such small numbers that they cannot replace themselves fast enough to combat disease.

While cells are indispensable in performing vital functions for the body, they can also exist outside the body. They can live and divide in "cultures", special solutions in test tubes or Petrie dishes. This ability of certain cell types to live isolated from other cells under controlled conditions has allowed scientists to study them independently of the organ or system they are normally a part of. Through the isolation and targeted manipulation of cells, scientists are finding ways to identify young, regenerating ones that can be used to replace damaged or dead ones in diseased organs. This therapy is similar to the process of organ transplant, only the treatment consists of the transplantation of cells rather than organs. The cells that have shown by far the most promise of supplying diseased organs with healthy new ones are called stem cells.

Simply put, stem cells are primitive cells that give rise to other types of cells. Also called progenitor cells, there are several kinds of stem cells. Totipotent cells are considered the "master" cells of the body because they contain all the genetic information needed to create all the cells of the body plus the placenta, which nourishes the human embryo. Human cells have this capacity only during the first few divisions of a fertilized egg. After 3-4 divisions of totipotent cells, there follows a series of stages in which the cells become increasingly specialized. The next stage of division results in pluripotent cells, which are highly versatile and can give rise to any cell type except the cells of the placenta. At the next stage, cells become multipotent, meaning they can give rise to several other cell types, but those types are limited in number. An example of multipotent cells is hematopoietic cells – blood stem cells that can develop into several types of blood cells, but cannot develop into brain cells. At the end of the long chain of cell divisions that make up the embryo are "terminally differentiated" cells – cells that are considered to be permanently committed to a specific function.

Scientists have long held the opinion that differentiated cells cannot be altered or caused to behave in any way other than the way in which they have been naturally committed. New research, however, has even called that assumption into question. In recent stem cell experiments, scientists have been able to persuade blood stem cells to behave like neurons, or brain cells. Scientists now believe that stem cell research could reveal far more vital information about our bodies than was previously known.

In addition, it was recently discovered that some stem cells also occur in the bodies of adults, rather than exclusively in embryos. Many kinds of multipotent stem cells have been discovered in adults, and scientists believe that many more will be discovered. Research is now being conducted on both adult and embryonic stem cells to determine the characteristics and potential of both to cure disease. (1)

In the early 1980s it was validated that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells. Over the past decade, thousands of cord blood stem cell transplants have been successfully performed worldwide. As doctors learn more about the power of stem cell therapy, it may become one of the greatest medical breakthroughs of our generation.

According to Viacord Inc., "in Miami, Florida, a seven-year-old girl faced a long, uphill battle with leukemia. But since the mother was expecting another child, Viacord was able to offer them a rare opportunity by preserving the newborn's cord blood at birth. Turns out, her little sister was a perfect match. Two months later, the frozen cord blood was thawed and infused into the ailing child to help restore her immune system. Shortly after, she was released from the hospital with no evidence of ever having leukemia." (2)

A Child's Cord Blood

A pregnancy provides an opportunity to do something extraordinary for a baby and entire family. By choosing to preserve a newborn's cord blood, you could preserve a family's chance to potentially use it as part of a treatment therapy for over 40 diseases, including various cancers, genetic diseases, blood disorders and immune system deficiencies.

Today, cord blood banking is one of the fastest growing obstetrical procedures. Every year, thousands of new parents with no family history of disease choose to preserve their baby's cord blood stem cells. They understand that as medical researchers continue to discover new uses, the value of their baby's cord blood stem cells may increase dramatically. In truth, scientists have not even begun to realize the full potential of cord blood stem cells. Imagine what we'll learn in the coming decades about this remarkable gift of nature. However, if you don't preserve your baby's stem cells at birth, you can never take advantage of its future potential – which is why more and more physicians are recommending cord blood preservation for their patients. (2)

Potential Treatment

Imagine a potential treatment for life-threatening diseases for your baby, for siblings, parents and grandparents. Cord blood stem cells are a perfect match for your baby have a high probability of being a viable match for a sibling and can potentially be used for parents and grandparents.

In addition, research and development is demonstrating that stem cells may someday change the way many more diseases are treated. Cord blood research is continually being conducted to understand its full potential in stem cell transplantation. (2)

What Doctors Are Saying

"There are a number of things we know that make cord blood valuable. There are things that we can only predict that it will be used for in the future. But right now there are things called stem cells which are building-block cells, which are building-block cells that can become anything, so in the future, if a baby needs certain transplants, like, say, for bone marrow for leukemia. There are a lot of things that we don't even know yet that they could be used for." (3)

"If a cord blood company is committed to research, it's a good indication that it is also committed to the future, which means they are more likely to have financial stability. Another potential benefit is that any medical breakthroughs developed by their R & D division will have been conducted using their own processing and cryopreservation methodology. In other words, you may be in a better position to benefit from their discoveries by using their processing techniques as opposed to methods used by other cord blood companies." (4)

"For the last two centuries of medicine, doctors have used surgery or drugs as tools to help our patients and to treat disease. Drugs, however, do not alter the underlying disease. They treat the symptoms, but generally they aren't cures. Today we stand on the threshold of curing disease. Curing disease by transplanting stem cells is a huge change." (5)

Stem Cells

Stem cells can renew themselves indefinitely and differentiate into any of a number of types of specialized cells. These properties make stem cells different from the body's other mature cells, which are permanently committed to their fate – for example, a skin cell can only divide and generate new skin cells. The ability of stem cells to become other types of cells – their "plasticity" – makes them essential for repairing and renewing body tissues throughout our lives.

Stem cells are formed at conception and specialize to become the various tissues of the growing embryo. After we are born, our body retains stem cell reserves in various organs and, throughout our lives, we tap into those reserves to repair and replace injured or diseased tissues. Unfortunately, our stem cell reserves are finite and, as they become depleted, we succumb to diseases, disorders and the ravages of aging. Thus, stem cell therapy offers the potential to replenish our reserves and fight a wide variety of diseases and disorders.

Scientists first discovered pluripotent stem cells in mice in the 1970s. Soon they began to recognize the amazing versatility of these primitive cells, which exist for only a short time before differentiating into the many cell types of the body. Mouse studies continued to reveal the extraordinary promise of these cells, but it wasn't until 1998 that the first human pluripotent stem cells were isolated. James Thomson at the University of Wisconsin and John Gearhart at The Johns Hopkins University, working independently, were the first scientists to isolate human pluripotent stem cells and to maintain them in their pluripotent state.

Since then, scientists have discovered several types of stem cells from different sources and at different stages of differentiation. The sources of these cells are:

- Adult stem cells are generated in the different organs and tissues of the fully developed human body. These cells can be harvested from donors and isolated in the laboratory, where scientists hope to grow "fresh supplies" of desired cell types to implant into people. However, adult stem cells are only multipotent – limited in that they will only turn into a certain number of cell types.
- Another source of multipotent stem cells is umbilical cord blood, which is usually disposed of after the birth of a baby. Scientists have found that this blood is rich in blood stem cells and is multipotent, but so far it has not been found to contain pluripotent stem cells.
- One source of pluripotent stem cells – that is, cells that can differentiate into any cell type of the human body – are fetal germ cells. Following the termination of a pregnancy of about 5-9 weeks, some women donate the fetal material, which would otherwise be disposed of, to research. Pluripotent stem cells can then be extracted from the part of the fetus that would have developed into either testicles or ovaries.
- Frozen embryos that were created by fertility clinics and are no longer needed by the couple are another source of pluripotent stem cells. These fertilized eggs can be thawed and allowed to go through a limited number of cell divisions to produce the pluripotent cells. Extracting the cells destroys the embryo before the cells can differentiate into any specific cell type.
- Therapeutic cloning is another way to obtain pluripotent cells. In this procedure, which is also called nuclear transplantation, DNA from an individual patient is inserted into an egg and the egg is activated to divide. After only a few cell divisions, scientists extract the pluripotent stem cells. This destroys any possibility that the embryo could ever develop into a person. The advantage of this technique is that it may help scientists create stem cells that are genetically matched to the recipient, posing little or no risk of rejection. (6)

Stem Cell Therapy

Embryonic Stem Cells

When a sperm fertilizes an egg, it becomes what is known as a "zygote". Many scientists view the zygote as the ultimate stem cell because it can develop into any cell – not only of the embryo, but also of the surrounding tissues, such as the placenta. Because the zygote has the highest degree of plasticity, it is referred to as a "totipotent" stem cell.

Thirty hours after fertilization, the zygote begins to divide, and by the fifth or sixth day, the cells form a kind of a bubble or "blastocyst". These stem cells are somewhat less plastic and more specialized than totipotent zygote stem cells. Those on the outer surface of the blastocyst develop into the placenta and other tissues that surround the fetus, while those inside, referred to as "embryonic stem cells", become the cells of all the fetal organs and tissues. Such stem cells that can become any of the more than 200 types of cells in the body are called "pluripotent".

Between the seventh and ninth day, the blastocyst attaches to the uterus, and begins to develop and grow. From this point until about eight weeks it is generally referred to as an "embryo". From eight weeks on it is referred to as a "fetus". (7)

Fetal Stem Cells

As the embryo grows, it accumulates additional embryonic stem cells in the yolk sac. As the fetus grows from weeks 8 to 12, it accumulates "fetal stem cells" in the liver. Both embryonic and fetal stem cells generate the developing tissues and organs. At this stage, the stem cells are more tissue-specific rather than generating all of the body's 200 different cell types. For example, fetal stem cells in the liver tend to generate liver and blood cell families. Such stem cells are generally designated as "multipotent". However, some research suggests that at least some multipotent stem cells may be more plastic than first thought and may, under the right circumstances, become pluripotent.

Fetal liver tissue has been shown to be a rich source of stem cells. Indeed, in studies in which stem cells from human fetal liver tissue, cord blood or adults were transplanted into mice, fetal liver tissue was shown to be the richest source of very primitive progenitor cells.

Up until week 12, fetal stem cells (as well as the embryonic stem cells which preceded them) have a very important property. They can be transplanted into an individual without being rejected. This is because they have little to none of a certain type of protein on their surface (Class II HLA) which otherwise can trigger a rejection reaction if the cells were transplanted into another individual. Ordinary cells carry this protein, which is why physicians must carefully match donors and recipients in blood transfusion or organ transplants. Such matching is not necessary when transplanting embryonic or fetal stem cells. These cells are also hypoallergenic, so side effects are rare.

After the 12th week, fetal stem cells acquire these immune-triggering proteins, and they remain present on stem cells from this point on, including on adult stem cells. Thus, while some advocate therapeutic use of stem cells derived from cord blood, adult bone marrow or the blood stream, these sources pose the problem of possible rejection reactions. Therefore, stem cells derived from these sources may have therapeutic potential only when given to the individual from whom they were derived ("autologous" transplantation) or from an immunologically matched donor ("allogenic" transplantation).

Fetal tissues are derived from elective abortions. In the U.S., scientists have proposed methods for preparing and cryopreserving stem cells from fetal tissue for later clinical use, and recommended procedures that separate the abortion decision from the donation decision and preserve confidentiality between donor and recipient. (7)

Adult Stem Cells

Currently, the chief sources of adult stem cells are bone marrow, the bloodstream, and cord blood. The stem cells derived are blood (hematopoietic) precursor cells, i.e., they generate the major blood cell types: red blood cells, white blood cells and platelets. Some research suggests that these blood stem cells may, under the right circumstances, be “pluripotent” and able to generate other cell families. Other types of multipotent stem cells exist in different tissues, but scientists have not been able yet to extract them in sufficient quantities for therapeutic use.

In addition to the possible challenges of immune reactivity, adult stem cells can be difficult to collect. The richest source is the bone marrow. Harvesting bone marrow involves surgically inserting a needle into the pelvis, can be somewhat painful, and typically requires the donor four to six weeks to fully regenerate the donated marrow tissue. The bloodstream also contains adult stem cells (referred to as peripheral blood stem cells or PBSCs), but their concentration is significantly lower than in bone marrow, making harvesting them a slow process. Recent advances, however, have made the procedure more efficient and it is becoming more common. Finally, adult stem cells can be extracted from cord blood, which is collected, with the mother’s prior permission, at birth. However, cord blood units provide a fixed amount of adult stem cells, and may not be enough for a patient, and a second donation is not available if the patient needs more. There is also a chance that a genetic disease might be transmitted through cord blood. (7)

How It Works

Most diseases and disorders are caused by or at least involve damaged body tissues and insufficient repair. For example:

- Cancer chemotherapy and radiation therapy destroy many other non-cancerous cells in the body, including those of the immune system
- Disorders of the blood involve abnormal growth and/or destruction of certain types of blood cells
- Heart failure, which is currently incurable, involves damage to heart muscle, which the body cannot repair
- Liver failure involves progressive destruction of liver cells
- Stroke involves damage and/or death of brain cells resulting from a lack of oxygen and nutrient-carrying blood
- Type 2 diabetes, the most common form of the disorder, involves a progressive decrease in the ability of the pancreas to produce insulin. Its complications are due to progressive destruction of tissues in the eye (diabetic retinopathy, which can lead to blindness), kidney (diabetic nephropathy, which can lead to kidney failure), and nerves (diabetic neuropathy, which can lead to decreased sensation in the limbs and limb amputation)
- Osteoarthritis involves destruction of cartilage tissue around joints
- Parkinson’s disease, Alzheimer’s disease and other central nervous system disorders involve destruction of certain neurons in the brain
- Various autoimmune disorders involve immune system attack and destruction of the lining around nerves (multiple sclerosis), the cells lining the intestine (ulcerative colitis), cartilage in joints (rheumatoid arthritis), and other specific tissues for specific diseases
- Spinal cord injuries involve trauma and destruction of nerve tissue in the spinal cord
- Aging involves a general deterioration throughout the body’s tissues

Stem cell treatment offers the potential to help repair and renew the damaged tissues associated with these and other diseases and disorders. This promising potential of stem cell therapy has fueled an enormous explosion in scientific research, and initial clinical results are encouraging. It should be noted that, in the U.S. and Western Europe, stem cell therapy remains an area of research, and its benefits are in the process of being rigorously studied. However, stem cell therapy has been practiced routinely for more than 20 years in other countries such as the Ukraine. Given the recognized theoretical potential of stem cell therapy, and the collective results of its clinical use from non-western countries, many people believe it is appropriate, even morally responsible, to make stem cell treatment available to people who need it now. (8)

Summary of Clinical Experience with Fetal Stem Cell Therapy, Institute for Cryobiology and Cryomedicine, Ukraine

		Treatment Results: Degree of Improvement			
Diseases	**No. of Patients**	**Significant**	**Partial**	**None**	**Duration of Observation**
Acquired aplastic anemia	18	14	2	2	1-8 yrs.
Secondary anemic states	246	230	16	0	6 mo.- 6 yr.
Thrombocytopenia	38	19	8	11	3 mo.- 5 yrs.
Diabetes	222	0	206	16	1- 8 yrs.
Diabetic retinopathy	230	194	36	0	1- 5 yrs.
Macular degeneration	86	74	10	2	1 - 7 yrs.
Cytostatic disease (hemosupression after chemotherapy and/or radiation therapy)	118	94	18	6	1- 7 yrs.
Gynecological pathologies					
- Endometriosis	12	10	2	0	1- 5 yrs.
- Septic complications	16	12	4	0	short term
- Anemia during pregnancy	39	39	0	0	short term
Neurology					
- Spinal cord trauma	16	0	14	2	1- 5 yrs.
- Nervalis fascialis	7	4	3	0	1 year
- Parkinson's disease	19	13	6	0	3 years
- Multiple Sclerosis	23	16	5	2	1-3 years
- Trigeminal neuralgia	46	46	0	0	1 year
- Cerebral palsy	13	0	13	0	9 mo.- 4 yrs.
- Amyotrophic lateral sclerosis	11	0	11	0	3 years
- Multiple organ trauma	8	8	0	0	short term
- Chronic fatigue syndrome	32	30	2	0	1-5 yrs.
- Arthritis	29	22	7	0	1- 5 yrs.
- Psoriasis	12	9	2	1	1- 8 yrs.
- Rejuvenescence (anti-aging)	139	120	19	0	1- 7 yrs.
- Sexual pathology	88	52	22	14	1- 8 yrs.
- Ulcerative colitis (Crohn's Disease)	28	14	8	6	1- 5 yrs.
- Abdominal adhesions	24	21	3	0	short term
- Aesthetic application	140	140	0	0	1- 5 yrs.
Totals	1740	1181	494	62	
Percents	100%	68%	28%	4%	

Note: "Degree of improvement" generally refers to changes in one or more key clinical indicators of patients' disease status, as assessed by the treating physician(s). "Significant" improvement means a marked improvement in disease status and/or normalization of one or more disease indicators. "Partial" improvement means the progression of the disease was halted, as reflected by the clinical indicators. (9)

Stem Cell Therapy Today

Even though most of the work done in this field has been experimental, most scientists find cell therapy so promising that they believe it is only a matter of time before its use becomes routine. And while many of the hoped-for uses of cell therapy sound futuristic, there are a few forms of this technique that have already been in use for years. Bone marrow transplants are an example of cell therapy in which the stem cells in a donor's marrow are used to replace the blood cells of the victims of leukemia and other cancers. Cell therapy is also being used in experiments to graft new skin cells to treat serious burn victims, and to grow new corneas for the sight-impaired. In all of these uses, the goal is for the healthy cells to become integrated into the body and begin to function like the patient's own cells. So far, the results of such experiments have exceeded expectations. In a recent advance, pancreatic cells grown from stem cells were implanted into the body of a diabetic and began to produce insulin. Even though cell therapy is a new science, early results like the above have caused great optimism in the scientific community. However, there are several scientific challenges that must be overcome before we can truly harness the power of stem cells.

One of the first challenges that must be overcome for stem cell therapies to become more commonplace is the difficulty of identifying stem cells in tissue cultures, which contain numerous types of cells. While scientists are discovering new cell types almost every day, they estimate that there could literally be thousands of human cell types. The process of identifying any desired type of stem cell will involve painstaking research. Second, once stem cells are identified and isolated, the right biochemical solution must be developed to cause these progenitor cells to differentiate into the desired cell type. This too will require a great deal of experimentation.

Assuming that the above obstacles have been overcome, new issues arise when the cells are implanted into a person. The cells must be integrated into the patient's own tissues and organs and "learn" to function in concert with the body's natural cells. Cardiac cells that beat in a cell culture, for example, may not beat in rhythm with a patient's own heart cells. And neurons injected into a damaged brain must become "wired into" the brain's intricate network of cells and their connections in order to work properly.

Yet another challenge is the phenomenon of tissue rejection. Just as in organ transplants, the body's immune cells will recognize transplanted cells as "foreign", setting off an immune reaction that could cause the transplant to fail and possibly endanger the patient. Cell recipients would have to take drugs to temporarily suppress their immune systems, which in itself could be dangerous.

Yet another concern is the possible risk of cancer. Cancer results when cells lose their internal "brakes" and keep dividing when further proliferation is no longer desirable. Researchers must find a delicate balance between fostering the growth of new cells to replenish damaged tissues and making sure that cells don't overgrow and become cancerous. However, most scientists believe that, with the appropriate research, these obstacles can be overcome and the power of stem cells can be harnessed. (10)

Safety Concerns

Safety is always a concern with any therapy. Data from the Institute of Cryobiology and Cryomedicine in the Ukraine show no serious adverse effects in any of the total 2925 patients given fetal stem cell therapy since 1986 and followed for one to the maximum of ten years. In rare instances, patients experience brief, transitory reactions such as swelling and redness near the infusion site, rash or dizziness, but such effects soon resolve.

It is important to note, however, that stem cells are biological materials and, just as with blood transfusions and organ transplantations, they carry a very small potential risk of transmitting known or unknown pathogens. To minimize such risk, rigorous standard screening tests are performed on both the donor and the stem cells, similar to tests used with blood donations. There are also safety screening, testing and preparation procedures that must be done according to standard requirements of tissue banks.

One of the key concerns about embryonic stem cells is that, because they constitute such early progenitor cells (derived from a blastocyst, the ball of cells that forms 5-6 days after an egg is fertilized), they have a greater potential to grow uncontrollably. An example would be a type of tumor called a teratoma. The Institute for Cryobiology and Cryomedicine in the Ukraine found no cases of teratoma in any of their patients given fetal stem cell treatment since 1986 and followed for a maximum of 10 years. (7)

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Course Exam

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1. Stem cell therapy has been practiced routinely in the United States for more than five years.

   ○ True ○ False

2. One challenge for stem cell therapy is the difficulty of identifying stem cells in tissue cultures.

   ◯ True ◯ False

3. When a sperm fertilizes an egg it becomes known as an embryo.

   ◯ True ◯ False

4. Fetal liver tissue has been shown to be a rich source of stem cells.

   ◯ True ◯ False

5. Fetal germ cells are not a source of pluripotent stem cells.

   ◯ True ◯ False

6. By the fifth or sixth day after fertilization, the cells form a kind of a bubble or 'blastocyst'.

   ◯ True ◯ False

7. Stem cells are formed at conception.

   ◯ True ◯ False

8. Stem cell reserves are finite and can become depleted.

   ◯ True ◯ False

9. Scientists first discovered pluripotent stem cells in mice in the 1990s.

   ◯ True ◯ False

10. In 1998 the first human pluripotent stem cells were isolated.

    ◯ True ◯ False

11. Adult stem cells cannot be harvested from donors.

    ◯ True ◯ False

12. One source of multipotent stem cells is umbilical cord blood.

    ◯ True ◯ False

13. Cord blood can potentially be used as part of a treatment therapy for over ten diseases.

    ◯ True ◯ False

14. Therapeutic cloning is another way to obtain pluripotent cells.

    ◯ True ◯ False

15. Very few physicians are recommending cord blood preservation for their patients.

    ◯ True ◯ False

16. Therapeutic cloning is also called nuclear transplantation.

    ◯ True ◯ False

17. The ability of stem cells to become other types of cells is called 'plasticity'.

○ True ○ False

18. Cord blood banking is one of the fastest growing obstetrical procedures.

○ True ○ False

19. In the early 1990s it was validated that the blood remaining in the umbilical cord after birth is rich in a precious resource called stem cells.

○ True ○ False

20. Stem cells are the building blocks of our blood and immune systems.

○ True ○ False