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Stem cells: the birth of a new branch of medicine?

Stem cell research is without doubt one of the most exciting and controversial areas of medical science. Since the first bone marrow transplants in the 1960s and the isolation of embryonic stem cells from mice in the 1980s, there have been great advances in understanding the biology of stem cells.

We now know more about where to find stem cells, how to grow them in the laboratory and even how to turn ordinary cells back into stem cells. No longer is it a fantasy that we may one day turn skin into liver and grow tissue for transplants in a petri dish.

The government is seeking to put the UK at the centre of stem cell research and is supporting stem cell scientists to help the UK remain a world leader in this research. The national media have embraced stem cell research, touting it as a “cure” for blindness, deafness and Alzheimer’s disease, a way to grow transplant organs and even a way to “delay menopause”. Although a large proportion of the stem cell studies receiving media coverage are animal and cell culture studies, human clinical trials for a variety of diseases are starting to hit the headlines.

There is no avoiding the fact that stem cell research can be controversial. The US has only recently lifted its ban on government funding for certain types of stem cell research using human embryo tissue. Besides concerns about where the stem cells come from, the ethics of manipulating these cells is hotly debated. As such, each new development in stem cell technology is under intense scrutiny to see whether it is safe and ethically acceptable. A special licence is needed to carry out embryo stem cell research in the UK, and the use of any human tissue for research is tightly regulated.

Stem cell research is global, and what is considered ethical needs to be constantly addressed. Although there have been only a few registered human clinical trials of stem cells, private clinics already offer patients “experimental treatments”. As it becomes easier to travel abroad to receive treatments that might not be allowed in the UK, it’s important to know how to assess the evidence behind what’s currently possible with stem cell treatments and what is merely hopeful or untested.

We are in a pioneering phase of the development of stem cells for medical treatments and there are still many unknowns. Will stem cell science live up to its promise and lead to new medical breakthroughs? Which diseases could it treat? Can the ethical issues be overcome?

This report looks back at stories about stem cells covered by Behind the Headlines since 2007. It gives an overview of the stories and how they were reported in the news, and looks at progress over this time.

About Behind the Headlines

Behind the Headlines provides an unbiased and evidence-based analysis of health stories that make the news. It examines two popular health stories from the national media every day, and looks at whether media claims match the research, as well as the strengths and weaknesses of the scientific studies themselves.
What are stem cells and why are they important?

Stem cells are essentially “building block” cells. They can develop into many different cell types. Stem cells can continue to divide almost indefinitely. However, cells lose this property when they differentiate (develop) into their final cell type.

These properties of stem cells have made researchers investigate them as a potential continual source of any tissue needed. Research has looked at whether these cells can be used to grow new tissue in the body or in the lab for transplant. Stem cells can also be used in the lab to help us understand how diseases work, potentially leading to new drug treatments. Besides looking at how stem cells can be used to grow tissue, scientists have also studied stem cells for cancer research.

Embryonic stem cells

We all develop from one fertilised egg cell. As the fertilised egg develops in the womb, it forms an embryo which contains stem cells that can develop into different cell types. Pioneering research in Cambridge in the early 1980s isolated embryonic stem cells from mice embryos. In humans, embryonic stem cells can be isolated from around five days after fertilisation. At this stage, the embryo consists of around 50 to 100 cells and the embryonic stem cells have the ability to develop into every cell type in the body.

Human embryonic stem cells can be “isolated” from embryos donated from couples who have been through IVF treatments and have extra embryos left over from this procedure. Once embryonic stem cells are grown in the laboratory, a proportion will begin to differentiate into adult cells. These adult cells do not continue to divide in the same way as the embryonic stem cells. There are strict regulations in the UK and other countries governing the type of research the cells can be used for.

In 2003, researchers from King’s College London made the UK’s first embryonic stem cell line. They grew embryonic stem cells in conditions where they would not develop into adult cells and selected cells that could continue to remain in this “non-differentiated” state. As these cells continued to divide, the researchers were able to build up a large supply of stem cells that could be frozen and stored for later use. This was important because we can now continually grow stem cells in the laboratory, reducing the need to use stem cells directly from embryos.

Adult stem cells

Stem cells are also found in adults’ bodies. These adult stem cells, found in human bone marrow, blood, eyes, the brain and muscles, can also differentiate into other types of cells with various specialised functions. However, unlike embryonic stem cells, adult stem cells can only differentiate into a limited number of cell types. Scientists have found ways to expand the number of cells that these stem cells can turn into by exposing them to different chemicals that mimic different conditions in the body. For example, stem cells in...
bone marrow, which normally develop into blood cells, can be made to produce nerve or liver cells under certain chemical conditions. It is now even possible to reprogramme regular fully developed cells to become stem cells in the laboratory.

Spare embryos produced by IVF treatment can be a source of stem cells

Stem cells in the media

Behind the Headlines has covered nearly 40 studies on stem cells since 2007, and the research has used four types of cells:

- embryonic stem cells directly from embryos
- embryonic stem cell lines – cells derived from embryonic stem cells, which can be grown continually in the laboratory without developing into different cell types unless made to do so
- adult stem cells
- induced stem cells – stem cells made from normal cells that have been reprogrammed

We looked at the types of cells used in the research that received media coverage. Most of the studies we covered used human or animal adult stem cells or induced stem cells, rather than embryonic stem cells or cell lines.

Ideally, the media’s reporting of stem cell studies would grab the readers’ interest while avoiding hype or exaggerating the findings of the studies.

Having examined the newspapers’ stem cell headlines, we found that they showed an overwhelmingly positive attitude towards stem cell research. The pioneering nature of this type of research shines through in headlines commonly featuring words like “breakthrough” and “first”. “Hope” and “cure”, “treatment” and “transplant” also commonly appear.

Stem cells have been mooted as a way to repair nerve cells damaged by MS
However, headlines can sometimes be overly optimistic when covering such research. For example, Metro’s headline: “Stem cells ‘cure’ for MS sufferers” (January 29 2009) combined misplaced optimism and a misunderstanding of the research.

Below is a “word cloud” of all newspaper headlines from the stem cell stories covered by Behind the Headlines. The more frequently used words are proportionally larger.

Most of the stem cell stories were animal or laboratory-based studies. Just eight described early clinical trials in people and three stories reported concerns about online and private stem cell clinics. A large proportion of the basic science reports (around 44%) covered new methods of developing specific cell types or growing tissue from stem cells, including “scaffolds” for the stem cells to grow on. About a quarter of these basic science studies looked for new ways to boost stem cell numbers, isolate adult stem cells or find alternative sources of stem cells. Three were trials of treatments in animals, and two looked at ways to get stem cells to particular parts of the body. The idea of injecting or transplanting stem cells to cure disease is clearly enticing, and therefore of enormous interest to the media. However, a lot of stem cell research has aimed to

*Word cloud* of all the headlines from stem cell-related stories covered in Behind the Headlines (the words "stem", "cell" and "cells" have been removed)
Hope and hype help to find drug-based treatment for diseases, rather than considering using stem cells as a treatment for those conditions. Regular readers of Behind the Headlines will know that we like headlines that explain context as well as how close a practical application of the research really is. Good examples include the Daily Mail’s “Blood vessels made from bones offer hope for bypass patients” (July 8 2007) and this from The Times: “Transfusion breakthrough as human blood grown from stem cells” (August 20 2008).

How long will we have to wait for stem cell cures?

A timeline can help us understand when we could expect the basic science research to produce a treatment or a cure in practice. Many media reports attempt to give this context to the science. In some cases, the scientists themselves indicate how long it would take for applications of their research to be available.

“History is littered with perilous predictions and dodgy dismissals”

A trawl of the headlines from the stories we covered have revealed some interesting predictions:

- **Artificial sperm and eggs are “five years away”** (The Times, October 29 2009). As outlined below, this claim was based on a study in which scientists found a way to make embryonic stem cells develop into cells that contain half the number of chromosomes. Therefore, it is almost certain that the figure of five years is highly speculative.

- **Also in five years, you will be able to grow your own transplant liver** (Daily Mail, August 26 2010). The Mail based this claim on research in which induced stem cells were made from the skin of people with inherited liver disease and directed to develop into liver-like cells. However, the scientists did not attempt to make a transplantable liver, so the media’s speculation is suspect.

History is littered with as many dodgy dismissals as there are perilous predictions. Keep reading Behind the Headlines to see if the predictions turn out to be true.

• **A cure for deafness is 10 years away** (Daily Mirror, April 2 2009). This claim was based on research that developed a method to make embryonic stem cells develop into cells that were similar to ear hair cells in the laboratory. However, hair cell damage is only one of several causes of hearing loss. As with many stem cell studies, the work aimed to help researchers understand the condition to pave the way for potential drug treatments.

How stem cell headlines can be misleading

Speculation over the implications of stem cell research is likely to be wide of the mark. A prime example of this is a study that many headlines implied was an attempt to produce functional eggs and sperm from stem cells. The Times claimed that within five years scientists would be able to make “artificial sperm and eggs”. The Daily Mail went further and claimed: “No men OR women needed: Scientists create sperm and eggs...”
Hope and hype from stem cells. The article said that the research "raised a number of moral and ethical concerns including the possibility of children being born through entirely artificial means, and men and women being sidelined from the process of making babies".

These reports were based on a study carried out by scientists at Stanford University. They wanted to see how sperm and eggs developed from embryonic stem cells, and to understand the genes that were involved in this process. Sperm and egg cells are unique as they contain only one set of chromosomes, rather than the two found in all other cell types. Immature versions of these cells are formed very early in the development of an embryo, before the embryo has reached two weeks old. This has made it difficult to study the process in humans.

The researchers wanted to see whether they could get embryonic stem cells to develop into cells with only one set of chromosomes, to understand better how human sperm and egg cells develop in this difficult-to-study period. This could help find clues as to how problems with this process may lead to infertility later. The researchers were not looking to make artificial sperm and eggs for fertility treatments.

Just because something may be possible, it doesn’t mean that it would be ethical.

The Guardian’s headline: “Stem cell study leads to breakthrough in understanding infertility” was therefore slightly closer to the mark, although the research had not yet yielded answers about infertility. Despite the slightly premature nature of the headline, the article appropriately reported that the purpose of this research was to understand the previously “hidden” process of how these cells were made, allowing us to further understand why some people have fertility problems. While a journalist’s job is to highlight potential implications of the research, in this case the purpose of the research was not to make sperm or egg cells for fertility treatment.

Moreover, just because something may be possible, it doesn’t mean that it would be ethical and deemed acceptable as a treatment by fertility treatment regulatory bodies.

Another fertility-related study also showed the importance of giving an appropriate context. On April 13 2009, The Independent reported that “Stem cell treatment may allow women to delay menopause”. The next day, The Sun picked up the story and interpreted it differently, saying “Cure on the way for infertile women”. They were both wrong. So what were scientists looking at, and how can it help with treating fertility?

In this study, researchers found that stem cells in newborn mice ovaries could be used to generate functional eggs and subsequently healthy offspring. This research was important because it was previously thought that the ovaries of most female mammals produce a lifetime’s supply of eggs before they are born, after which no new egg cells can be produced. It is not possible to say from this animal research whether newborn baby girls would have equivalent cells. Clearly, this approach cannot be directly applied to fertility treatment in humans. Ultimately, this animal study is only useful for furthering our basic understanding of how egg cells are made.

Misplaced optimism?

We also need to be careful when reading reports about preliminary human clinical trials of stem cells. Overly optimistic and unproven outcomes can appear in the headlines. The word “hope”
Hope and hype seems almost permanently glued to stem cell studies. But hopeful reporting is not always helpful reporting. One example is coverage of a recent MS stem cell trial, reported on January 30, 2009. The headlines talked about:

- a “cure” for MS (Metro and The Sun)
- “reversing” MS (The Independent and The Daily Telegraph)
- treatment “success” (BBC News)
- “fresh hope” (Daily Mail)
- reducing symptoms of multiple sclerosis (The Times)

These news stories were based on a preliminary study with no control group which looked at the safety of the treatment, not at how effective the treatment was. To test effectiveness, this research needs to be followed by a controlled trial.

Hopeful reporting is not always helpful reporting

This is examined in detail below, but it is worth noting that several people in the trial had a relapse of MS, so to call the treatment a “cure”, as The Sun and Metro did, is a fantasy.

The headlines would have been more accurate if they had focused on the fact that this was one of the first trials of stem cells for MS, and that the treatment seemed to be safe during this period. They could have said that the research opens the door for larger trials. However, such headlines may be less likely to sell papers.

The media can help people understand stem cell research, but scientific researchers must also play their part. Newspaper reports often rely heavily on press releases produced by the researchers and their research institutions. Because these press releases are so useful in helping journalists understand complex science, it is vital that they are written appropriately. They should say why the research is important but also indicate how preliminary or advanced the research is. Indeed, the researchers are usually the experts in knowing where their work fits in the current research field. However, even experts need to avoid indulging in too much speculation.

It will be of growing interest and importance for journalists to investigate any exploitation, quackery and bogus claims

Although the media have largely focused on the supposed success of early trials, they have also been genuinely useful in reporting how stem cells already have an impact on society. For example, The Times covered two studies that looked at claims made on the internet about available stem cell therapies (see page 19). As stem cell science progresses, it will be of growing interest and importance for journalists to investigate any exploitation, quackery and bogus claims that arise on the web or elsewhere.

Although there have been a few early clinical trials, most published stem cell research is basic science, performed using cells in a lab or animals. As with any basic research, one research paper rarely changes the medical field overnight or completely answers a scientific or medical problem in one fell swoop. It should be possible to decide whether a basic science story is newsworthy and present it without tantalising headlines of miraculous cures just around the corner.

Being accurate doesn’t mean that the media have to sacrifice interesting headlines. Looking back, we have found plenty of examples of eye catching headlines that accurately captured the essence of the research, including:

- “Injection of stem cells into stroke victim’s brain is a medical first” (The Independent, November 17, 2010)
- “British doctors' stem cell therapy gives man back his sight” (The Times, December 23, 2009)
- “Mother's life transformed as doctors unveil first ever whole organ stem cell transplant in new dawn for medical science” (Daily Mail, November 19, 2008)
- “Scientists grow new teeth from stem cell seeds planted in mice” (The Times, August 4, 2009)
• “Breakthrough by British scientists could see stem cells made from human skin – NOT embryos” (Daily Mail, March 2 2009)

• “Miracle in a test tube as human skin is turned into heart and brain cells” (The Independent, November 21 2007)

And, although it’s rare to find a stem cell pun, the headline writers at The Sun came up with “New research is skin-credible!” (November 21 2007).

How are stem cells “made”?

One of the great achievements in recent stem cell research has been to “turn back time” and convert normal, fully developed cells back into stem cells. This was heralded in November 2007 by The Independent as a “miracle in a test tube”. Many newspapers covered two research studies, one from Kyoto University, Japan, and one from the University of Wisconsin-Madison, US. Researchers were able to “reprogramme” the genes of human adult cells to convert them into cells that resembled embryonic stem cells.

The Japanese study (PDF, 2Mb) used adult human skin cells. The researchers showed that not only could they make cells that looked like embryonic stem cells, but they were also able to stimulate these to behave like stem cells and become similar to nerve cells or resemble heart cells. They found that by injecting the reprogrammed cells into mice, the cells could develop into tissue resembling that of humans.

The US study used foetal and newborn skin cells, and found that introducing 14 genes could reprogramme these cells to become stem cells. Researchers were then able to narrow down the number of added genes needed to reprogramme the cells to just four. They found that the cells with the four added genes could develop into the three main types of cells found in human embryos.

When The Independent reported the research as a “miracle in a test tube”, it was right to do so, as this was clearly a milestone for stem cell science.
But there was a problem. This research used viruses to reprogramme the cells. There were concerns that these cells would not be safe to use in people, because the viruses might affect the way normal cells function.

However, stem cell technology moves on rapidly. By 2009, research by two teams from Edinburgh and Toronto had found a different way to reprogramme cells to become stem cells. The Daily Telegraph lauded this breakthrough as making “lab-produced stem cells ‘safer for humans’”. The research built on knowledge that to reprogramme adult cells back into induced stem cells required only four genes.

Cord blood stem cells – is banking worthwhile?

The blood that remains in the umbilical cord and placenta after a baby is born is rich in blood stem cells. The types of stem cells are the same as those made by bone marrow, but bone marrow transplants can be difficult and time consuming. Stored cord stem cells, however, are ready for immediate use and do not require invasive procedures for their collection. These cord blood stem cells have been used to treat cancers, immune deficiencies and genetic conditions.

Some NHS hospitals have specialist staff who can collect this blood. It is possible for parents to donate these cells to the NHS Cord Blood Bank. The NHS Cord Blood Bank says that cord blood stem cells have been used to treat cancers, immune deficiencies and genetic conditions.

- cancers of the blood, such as leukaemia or lymphoma
- bone marrow failure
- blood disorders such as sickle cell anaemia or thalassaemia
- immunodeficiencies – when the immune system doesn’t work properly
- metabolic disorders – which affect the breakdown of waste products in the body

Banking stem cells in a public stem cell bank is a generous act that should be applauded.

Private umbilical cord stem cell banking is already available in many parts of the UK. It allows parents to store their own child’s stem cells in case they or a member of their family need the stem cells in the future. The donation is not available for other members of public, as it would be in a public stem cell bank. The NHS Cord Blood Bank says that the probability of an average child requiring a transplant of their own stem cells before the age of 20 is somewhere between 1 in 5,000 and 1 in 20,000.

Cancer Research UK estimates that the total lifetime risk of developing the blood cancer leukaemia is approximately 1 in 71 for men and 1 in 105 for women. In children, the highest risk of developing leukaemia is between birth and four years. After 40 years of age, the risk increases as you get older. However, the NHS Cord Blood Bank service notes that if a child develops leukaemia, it is “extremely unlikely that their own cord blood will be appropriate for transplant due to the nature of the disease. A matched unit from a public cord blood bank is more likely to be of use in this situation”.

If you are considering privately banking your unborn child’s cord blood cells, it is worth seeking information from reliable sources about what conditions can currently be treated with the stored cells and the likelihood of having these conditions. For more information, see the NHS Cord Blood Bank website.
The researchers used a technique that took advantage of a special sequence of DNA found in “jumping genes” called transposons. Transposons are sequences of DNA that can move from one location to another. By adding these DNA sequences to the reprogramming genes, the researchers were able to get them into the cells without using viruses.

**How are stem cells currently used?**

**Bone marrow transplants**

Stem cell treatments have been around for nearly 50 years, in the form of bone marrow transplants. Bone marrow contains stem cells that can produce various types of blood cells, such as red blood cells, white blood cells and platelets. Bone marrow transplants can be given to people with blood cancers, such as leukaemia and non-Hodgkin’s lymphoma, and some genetic blood disorders, such as sickle cell anaemia. Bone marrow transplants require a “matched” donor, normally a brother or sister.

Before the recipient can have the transplant, the existing bone marrow tissue that is not working properly must be destroyed to make room for the new tissue. The person’s immune system is also stopped from working, to make it less likely that their body will reject the transplant. This is usually done with chemotherapy, and possibly radiation, which also destroys any existing cancer cells. For more information about this, see NHS Choices information on [bone marrow transplants](https://www.nhs.org.uk/conditions/bone-marrow-transplants), and [bone marrow donation](https://www.nhs.org.uk/conditions/bone-marrow-donation).

Alternatives to traditional bone marrow transplantation include a technique called peripheral blood stem cell transplant (PBSCT). In PBSCT, the donor is given a drug that causes the blood stem cells to come out of the bone marrow into the bloodstream. Some of their blood can then be taken and the extracted stem cells can be given to the recipient. The other alternative uses blood stem cells from umbilical cord blood, which can be isolated and collected when babies are born. Parents can opt to bank these stem cells either in private or public cord blood stem cell banks (see “Cord blood stem cells – is banking worthwhile?” on page 9).

Although bone marrow transplants have been around for a relatively long time, scientists are still researching ways to improve the procedure. One important area of research is whether it is possible to carry out stem cell transplants without the need to destroy the body’s own stem cells. In 2007, Behind the Headlines covered [a study in mice](https://www.nhs.org.uk/conditions/bone-marrow-transplants) that found that it was possible to lower the number of mouse blood stem cells by injecting them with antibodies that would “block” the stem cells. This was an alternative to using cancer therapies to destroy them, a procedure that can also damage other cells. The researchers found that if they injected donor stem cells while they blocked the mouse’s own stem cells, up to 90% of white blood cells could still be made from the donor stem cells.

At the time (November 22 2007), [The Daily Telegraph](https://www.nhs.org.uk/conditions/bone-marrow-transplants) said that “thousands of patients with ailments such as multiple sclerosis and sickle cell disease have been given new hope that cell transplants could offer a more effective way to treat them”. However, no clinical trials of this approach have been carried out in humans and it is not yet clear whether it would be safe to use.

**Making cell culture models for disease**

Stem cells can be used to make cell culture models for disease, helping researchers understand how diseases work. However, many types of cell, when grown in the lab, do not divide or lose the ability to function properly. For example, it is not possible to grow human adult brain cells in the lab. Researchers have tackled this problem by developing cell lines from a variety of different tumour cells. These “cell lines” have the ability to divide almost indefinitely in the lab, but are not a perfect solution because cancer cells can have different properties from normal cells.

**Models for deafness**

Research published in 2009 elegantly showed the potential of stem cells to allow researchers to grow cells that are otherwise difficult to cultivate in the laboratory. The hair cells in our inner ear are some of the most complex in our body. They move in response to sound waves causing the fluid in the inner ear to move. This movement
causes the hair cells to send an electrical signal to the brain. Loss of these hair cells is a cause of deafness.

British researchers had found stem cells that could turn into ear hair cells in the ears of human foetuses. They wanted to isolate these cells and see whether they could be grown in the laboratory and develop into functioning hair cells and nerve cells. The researchers found a way to grow the cells in the lab. They also found that different chemical conditions switched on genes that are active in hair cells, and made certain proteins arrange as they are in normally developing hair cells. The differentiated stem cells also behaved in a similar way to hair cells. The researchers said that these cells could potentially be used to study the development of ear hair and nerve cells, or to test the effects of drugs. The cells obtained for this study were from foetuses, and this is not a sustainable source for growing hair cells.

Another study covered by Behind the Headlines in 2010 looked at whether hair cells could be developed from other types of stem cells. The researchers found a way to develop hair-like cells from embryonic stem cells or adult induced stem cells from mice. Half of the cells they developed could detect movement and respond by creating electrical activity, which are important properties of hair cells.

Models for Alzheimer’s disease

In 2011, researchers demonstrated a new method to grow the type of nerve cells that are lost in Alzheimer’s disease. The Daily Mirror said: “Alzheimer’s patients could soon have their memory repaired with a transplant”. This was a premature suggestion. The cells were developed to look at what happens to them in Alzheimer’s disease and possibly to use them to identify drugs that would help prevent the processes involved in the condition.

Models for inherited diseases

For some inherited diseases, it may not be straightforward to isolate and grow cells in the lab from the tissue affected by the disease. For example, if researchers want to understand what happens in the cells of people with inherited liver disease, it may not be feasible to take a sample of their liver to grow and study in the lab. The researchers could use an established liver tumour cell line. To make these cells more similar to diseased cells, they could add genes with known liver disease mutations to see how this affects processes in the cell. However, this would still be quite a crude model. What if it was possible to grow cells from people who had the condition? Advances in the field of induced stem cells have made this possible. In 2010, scientists from the University of Cambridge wanted to see whether induced stem cells, which they had made from skin cells, could be made to turn into liver cells. They were particularly interested in whether this was possible using skin cells from people with inherited liver disease. This would allow them to study these people’s disease in the lab. They made 20 induced stem cell lines from 10 people, and 18 were able to differentiate into liver-like cells. They looked at the gene activity in the cells and found that they were not quite fully mature. In terms of their development, they were somewhere between the liver cells of a four-month-old foetus and adult liver cells.

In reporting this research, the Daily Mail claimed that it would be possible to “grow your own transplant liver in a lab” within five years. Although stem cell research is expanding possible avenues for medical research, beyond what could have been imagined 20 years ago, it is still very early days. Whether these induced stem cells will ever be used as treatments is unclear. In this case, the new way to model disease is likely to have an impact on how basic cell research is done, and is newsworthy in its own right.

What stem cell treatments have been tested in humans?

For most people, the truly exciting areas of stem cell research would be those in which the science has been applied to real people. This should, and indeed has, drawn journalists’ attention, leading some of them to herald even the most tenuous results as revolutionary. Yet a truly extraordinary application of stem cell science has
been well established for decades. Transplants of bone marrow (rich in blood stem cells) for blood conditions and cancers are now a successful branch of stem cell medicine (see “Bone marrow transplants”, page 10). In recent years, blood stem cells taken from umbilical cord blood have been used to treat a variety of conditions (see “Cord blood stem cells – is banking worthwhile?” page 9).

“Some journalists herald even the most tenuous results as revolutionary”

Stem cell treatments for other conditions are only just beginning to be assessed in early-stage human trials. These early trials mainly assess safety rather than the effectiveness of the therapy. Because of this, they only recruit a very small number of people, typically fewer than 10 participants.

These are called “phase I” studies, and they don’t usually have a control group. This means it is usually not possible to tell whether any improvements seen during the trial are better than what would have happened over time without the treatment. Nevertheless, these studies can be exciting, because if the treatments are found to be safe, they can then be tried in a wider group of patients.

It is such early days for stem cell science that even the registration of a stem cell trial in humans is newsworthy. Excitingly, a couple of the registered trials that Behind the Headlines has covered should produce safety data in the next year or two. Since 2007, we have analysed early human clinical trials that looked at whether stem cells could be a safe way to treat spinal cord injury, brain damage following a stroke, multiple sclerosis, type 1 diabetes and eye disease. We have also covered a case report of a woman who received a transplant of windpipe tissue, made using stem cell technology.

Spinal cord injury: growing new connections

A spinal cord injury can be devastating. It can limit a person’s sensation or mobility (including paralysis), even if only a very small area of spinal cord tissue is damaged. Most people with spinal cord injuries have enough intact nerves to allow some function, and rehabilitation can help some of them regain function. However, the damage is often irreversible because the nerves in this area are not good at regenerating, and scarring and swelling from the injury can further hinder nerve cells reconnecting, preventing them passing on their signals.

The idea behind stem cell therapy for spinal cord repair is to promote the growth of nerve cells directly or transplant cells that protect the nerves and help them function. In October 2010, much of the media covered the first study using human embryonic stem cells on patients in the US to be approved by the regulatory body the US Food and Drug Administration (FDA).

The trial recruited people who had a recent spinal cord injury (in the past 14 days), and used a human embryonic cell line developed by the biotech company Geron. The length of time that had elapsed since their injury was considered important, as previous animal studies had shown that if the cells were given too late, the formation of scar tissue would stop them from working. The stem cells used in this trial develop into cells that release chemicals that enhance the survival and function of nerve cells and produce myelin. Myelin wraps around nerves, insulating them and allowing them to conduct electrical signals. Without myelin, many nerves in the brain and spinal cord do not work properly.

The researchers injected the stem cells into injured areas of the spine. They hoped that the stem cells would restore the insulation of the nerve cells and stimulate nerve growth, restoring function and feeling. They also wanted to assess whether function improved a year after treatment, and will follow up the participants for 15 years to see whether they have any long-term health problems.

In 2011, Geron presented data from this trial at an international conference. They announced there were currently two patients in the trial with “a very good safety profile” and “no serious adverse events”. Geron said they are now seeking
FDA approval to include people with a wider range of back injuries, affecting different parts of the spine.

**Stroke: promoting rehabilitation**

In November 2010, newspapers reported on the registration of the world’s first fully regulated clinical trial of nerve stem cell therapy for disabled stroke patients. This trial included people who have had an ischaemic stroke (the type of stroke caused when a blood clot blocks blood flow to part of the brain). In an ischaemic stroke, if standard treatments cannot restore blood flow, or if a certain amount of time has passed, brain cells can become damaged and die due to lack of blood supply.

The trial aims to assess whether stem cells could help in rehabilitation after a person’s brain has been damaged by an ischaemic stroke. The trial first assessed the treatment in one man who had brain damage after a stroke. The researchers recruited a further 11 patients who had experienced an ischaemic stroke six to 12 months before. This group would be treated as if the first man to be treated had no side effects after a year. In this pilot trial, the participants will be treated for two years. Doctors at the University of Glasgow are still carrying out the trial, but the company that provided the brain cell stem cell line used in the research recently stated that it was encouraged by the progress of the trial.

**Type 1 diabetes: resetting the immune system**

Type 1 diabetes occurs when the body does not make enough insulin. It can be triggered when the body’s own immune system destroys the insulin-producing cells in the pancreas. Behind the Headlines analysed reports of a Brazilian study which used a novel stem cell treatment for recently diagnosed type 1 diabetes.

This study included 23 people, aged 13 to 31, who received stem cell treatment for new-onset type 1 diabetes. The treatment involved releasing stem cells from the person’s own bone marrow into their bloodstream, then collecting these cells. Participants then underwent chemotherapy to destroy some of their remaining bone marrow stem cells, after which they were injected with the collected stem cells to “re-seed” their bone marrow. Theoretically, this treatment “resets” the body’s immune system and stops it from attacking the pancreas – this attack is a cause of type 1 diabetes. The trial participants were followed for seven to 58 months. Researchers found that 12 people didn’t need insulin injections for an average of 31 months, while eight other people relapsed but started insulin therapy again on a lower dose than before the stem cell treatment.

Although these results looked promising, there were side effects. Two people developed pneumonia, three people had problems with their hormone system and nine men developed extremely low sperm counts. Out of 160 patients who volunteered for the study, only 71 were suitable, as the participants needed to have recently been diagnosed with the condition.
When these people were told about the potential side effects, only 23 opted to participate.

As yet, there have been no major follow-up studies to this one. As it did not have a control group, it is not possible to say whether the treatment was as effective as conventional treatments.

**Multiple sclerosis: preventing nerve damage**

In the UK, multiple sclerosis (MS) affects approximately 100,000 people and is the most common neurological condition among young adults. It is caused when the immune system attacks and damages the myelin that insulates nerve cells. This disrupts the ability of the nerves to send messages effectively.

About 10-15% of people with MS are diagnosed with a form of the disease that gets progressively worse. The remaining 85% of people initially have relapsing-remitting MS, in which symptoms appear and then partially or completely fade away. These people can go on to develop the progressive form of MS after a relapsing-remitting stage.

Behind the Headlines has covered two clinical trials that tested stem cells for the treatment of MS. In January 2009, a trial involving 21 patients with relapsing-remitting MS was carried out at Imperial College London and at research hospitals worldwide. A second trial, in May 2010, investigated stem cell therapy for six people with relapsing-progressive MS. This trial involved researchers at the University of Bristol and Imperial College London. As with most of the stem cell trials in humans so far, both these studies primarily focused on safety and did not include a control group to assess the effectiveness of the treatment.

These studies used two different approaches. In the first study, participants were treated with immune stem cells isolated from their own blood. Researchers thought that new immune cells made by these stem cells might replace the white blood cells that had started to attack the body, causing damage. The participants were studied for an average of 37 months, and their neurological function and any side effects were monitored.

The study found that although the participants’ neurological function improved initially, five participants relapsed within an average of 11 months after the stem cells were transplanted. It is not possible to say with certainty whether the treatment improved MS as there was no control group. As these people had relapsing-remitting MS, it’s likely that a proportion of them would have seen an improvement in their symptoms over the study period without any intervention. Nevertheless, it was promising that no major side effects occurred and the patients also felt that their general health had improved.

**Bone marrow cells may “reset” the immune system**

The second trial used stem cells from bone marrow. The researchers said that these bone marrow stem cells may encourage the repair of myelin as well as “resetting” the immune system. They said some animal studies have suggested that these cells can encourage the repair of myelin and prevent the loss of the cells that insulate the nerves with myelin, reducing or avoiding damage to nerve cells. The bone marrow was removed from the participants and filtered to extract stem cells. These were then injected back into their body. None of the six patients experienced any severe side effects. Three patients had moderate side effects, such as a temporary increase in problems with muscle control in their legs, and a temporary inability to pass urine.
**Injection of these types of bone marrow stem cells is experimental and still unproven**

The MS Society, a key funder of MS research in the UK, has warned that injection of these types of bone marrow stem cells is experimental and still unproven. It is a risky procedure, and the MS Society estimates that there is a 1-2% risk of death. Further clinical trials are needed to assess how effective stem cells are as a therapy for MS and to identify ways to reduce the death rate and other side effects.

The MS Society reported in July 2011 that it is helping to fund an international trial involving around 150 people with MS across the world, including 13 people from the UK. The trial will involve taking stem cells from bone marrow, growing them in a laboratory and injecting them back into the bloodstream.

**Eye disease: renewing the cornea**

Adult stem cells exist in the eye. They help keep the cornea (the transparent part of the eye) smooth, clear and able to focus light into the eye. Cells on the cornea are constantly lost in the tears that lubricate the eye. Because of this, the eye contains a reservoir of stem cells that can replace these cells. Some people are deficient in these cells and experience painful eye problems. Their cornea cannot renew itself appropriately, leading to inflammation and scarring. This can cause loss of vision.

Research covered by Behind the Headlines in December 2009 transferred stem cells from the healthy eye to the diseased eye in people with this condition. The researchers from Newcastle University found a way to grow these cells in the laboratory. They treated eight volunteers who had the condition with their own stem cells. The study had no control group, but the participants’ vision improved and the amount of pain experienced was reduced, compared with before treatment. This was certainly promising. However, the researchers warned that improvement in vision varied between the participants and longer follow-up was required to see whether the improvements continued.

In September 2011, newspapers reported that doctors at Moorfields Eye Hospital in London had been given the go-ahead to conduct a safety trial of retina cells developed from embryonic stem cells for the treatment of Stargardt’s disease. Stargardt’s disease is a genetic condition that affects approximately 1 in 10,000 children and causes an area of the retina, called the macula, to deteriorate over time. The deterioration is gradual, and most people first notice visual problems when they reach adolescence. For more information, see NHS Choices: causes of macular degeneration.

In the trial, retinal cells developed from embryonic stem cells will be transplanted into the eyes of people who have severe vision loss due to Stargardt’s disease, but who are otherwise healthy. The technique of developing embryonic stem cells into retinal cells was developed by a US company called Advanced Cell Technology. It has started similar trials in the US.

**Growing organs in a lab seems like a fantastical plot for a sci-fi movie**

**Tissue grown for transplant**

Growing organs in a laboratory for transplant seems like a fantastical plot for a sci-fi movie. But news of the “first transplant patient to receive an organ grown to order in a laboratory” caused a media sensation in November 2008. In this study, a Spanish patient needed a transplant to replace her damaged windpipe. The researchers developed a technique to take stem cells from
the patient’s own bone marrow and grow them in conditions that would make them turn into cartilage cells. They took a section of windpipe, which was donated from a dead woman, and treated it to destroy the donor’s cells, leaving a tube of cartilage that could act as a scaffold. They then “seeded” the scaffold with the patient’s own cartilage cells, which would grow over the windpipe scaffold. The researchers then gave the patient the windpipe graft.

Using this technique meant that there was a lower chance of the graft being rejected. The woman is still being followed up to make sure the graft tissue survives in the long term. This advance is genuinely exciting and the media are right to be enthused. As always, it is early days.

These trials are all safety trials with no control group. The next stage of clinical trials is a controlled phase called a phase II trial, where safety is still the main measure, but effectiveness can also be measured. A phase II trial may include relatively small numbers of people, and may compare various treatment conditions, such as different doses of treatments.

A phase III randomised controlled trial assesses safety and effectiveness in a larger group of people. Small controlled trials are recruiting for stem cell therapy following a heart attack, and for people with diabetes and Crohn’s disease.

What are the potential future applications of stem cells?

Although there have been limited human stem cell clinical trials, Behind the Headlines often covers innovative research performed in cell culture and in animal studies. Although this research is clearly preliminary and cannot yet be applied to human treatments, it indicates the ultimate goals of stem cell research and showcases scientists’ ingenious ways of overcoming problems.

Growing organs in the lab

Growing tissue or organs in a laboratory for transplantation is a prominent area of stem cell research. Shortages of donors and the need to ensure that tissue is well matched to the recipient to avoid rejection means it can be difficult to obtain a transplant. If it was possible to make viable and functional tissue from stem cells, this would enable more people to be treated sooner. If tissue is made from the patient’s own cells, this may avoid rejection of the tissue and the need for drugs to suppress the immune system.

No-one has yet grown a functioning human heart from stem cells

The news story on the windpipe transplant shows that, at least for some tissues, this may be feasible. Key to the success of the windpipe transplant was having an appropriate scaffold on which to grow the cells so that they formed a suitable structure. Behind the Headlines has covered three other studies that looked at how to make scaffolds for liver, heart and blood vessel tissues. The research into liver bioscaffolds involved stripping a section of rat liver of cells but leaving the connective tissue and blood vessels. The researchers then “seeded” the scaffold with liver cells and reconnected the liver section to the rat’s artery and veins, without causing damage to the new cells.

Heart tissue needs to be able to withstand the mechanical pressure of the beating heart, and heart cells have evolved to cope. In the heart study, the researchers made an artificial scaffold that would mimic the structures and stretching properties of heart cells. The structure allowed the growth of beating rat heart cells within the artificial scaffold in the lab (not in a living body).
Research from 2007, which looked at the feasibility of growing blood vessels from bone marrow stem cells, found that it was possible to create cells that could be grown in the lab to produce vessel-like tubes that could contract. This is an important function of the cells that make up the walls of blood vessels.

With skin tissue, it is already possible to graft adult skin taken from one part of the body to another. However, for people who have had large areas of skin burnt, it may take several weeks to get their graft skin ready for transplant. These people may receive skin from donors in the meantime, but rejection can be a problem.

Researchers from France and Spain looked at whether it was possible to make a ready supply of “skin” using embryonic stem cells to produce temporary grafts. The researchers made the stem cells develop into a type of skin cell on an artificial framework. They grafted the skin they had made on to mice that had defective immune systems and, therefore, would not reject the graft. The artificial skin graft developed into a structure similar to mature human skin. The researchers said that, unlike differentiated cells, embryonic stem cells don’t produce many substances that would cause an immune response. However, further work would be needed to see the extent to which the body rejects tissues made from this and other types of stem cell from another donor.

Scientists from King’s College London and the University of Nottingham have been looking at how to deliver stem cells into the brain using special biodegradable scaffolds. This could help people whose brains have been damaged by a stroke. Animal studies have shown that while some brain function can be regained from transplanting nerve stem cells, some damage remains and recovery is never complete.

The researchers hoped that if the stem cells had good structural support, rather than just being an injected mixture of cells, they would repair the damage more effectively. When they transplanted the stem cell-loaded scaffolds into mice, the scaffold particles allowed the stem cells to migrate while simultaneously giving them structural support. This helped the cells integrate with the tissue at the edge of the damaged area. However, the researchers found a major problem: there was no evidence that a blood supply developed around the graft, casting doubt on whether the grafts would survive in the long term.

Causing stem cells to develop into one particular cell type is an astonishing achievement, but directing stem cells to make multilayer structures is quite another feat. This is what Japanese scientists challenged themselves to do and in 2011, they cracked it. Scientists had previously been able to grow retina-like cells but had not been able to get these cells to develop into the layers of cells seen in a normal retina. The researchers tried to mimic the conditions in the womb that trigger stem cells in an embryo to form eyes. By doing this, they found the stem cells began to align themselves to form a cup-like structure that resembled a developing retina. The inner layer of cells shared similarities with the nerve cells of the retina, and the outer layer was similar to the pigmented cells of the retina.

In 2008, we reported that scientists from the US were investigating the possibility of making embryonic stem cell lines develop into red blood cells. The Daily Telegraph said that this could “make blood donations a thing of the past”. While this may one day be true, it’s still a long way off. The cells that came from this complex procedure shared some features of red blood cells, such as making the protein haemoglobin, which meant they could carry oxygen. As with so many stem cell breakthroughs, however, each advance leads to more questions. In this case, the stem cells were not completely the same as normal red blood cells. They were bigger, and the size difference could make it difficult for the artificial blood to pass through the smallest blood vessels in the body.

The array of cell types that have been grown from stem cells is constantly growing, and work has progressed in making tissue that more closely resembles normal adult tissue. Other research we have covered has explored other potential uses of stem cells. Examples include:
• Could dentures be a thing of the past?
• Will we be able to grow new blood vessels?
• Can stem cells be used to heal a broken heart?

It’s still early days for stem cell science, so it’s not quite time to throw out the dentures. However, this sort of basic research is likely to improve medicine in the future.

Targeting stem cells to damaged tissue

Recent developments may let us use our own adult stem cells for treatments. Work carried out at Imperial College London in 2009 focused on how to stimulate bone marrow to release various types of “progenitor” cells. Progenitor cells are similar to stem cells, but are considered to be at the next stage of development. They have already been programmed to develop into a certain type of cell. It is already possible to make human bone marrow release progenitor stem cells that can make fresh blood cells. The researchers broadly succeeded in making bone marrow in mice release other types of progenitor cells, such as those that make the cells that line blood vessels, and heart cells.

This research aimed to develop methods that encourage the body to release progenitor cells that would repair damaged tissues. One of the study’s authors said: “Inside everybody there are stem cells patrolling around and carrying out repair where it is needed. However, when the damage is severe there is a limit to what the body can do.” Whether it would be feasible to use our own stem cells for repair is a fascinating question that requires further research.

In 2010, US researchers developed an interesting technique, in an animal study, to capture circulating blood stem cells to repair damage to joints. The researchers made an artificial surface that was covered in a protein, called a “growth factor”, which attracts stem cells. These “bioscaffolds” were then attached to the bone surface of rabbits’ shoulder joints. The researchers also used a control scaffold, which did not contain the growth factor. They found that the rabbits with the bioscaffolds were able to perform weight-bearing movement using their shoulders three to four weeks after surgery. When a sample of the scaffold was removed four months after surgery, it was fully covered with a tough but flexible cartilage that naturally lines joints. These positive effects were not seen in the rabbits with the control scaffolds. While this is a marvellous achievement, it remains to be seen whether this technique could be used for other tissues in animals, and whether it would be safe to use in humans.

Other researchers have used different approaches to target the stem cells to where they are needed. Researchers from University College London tagged stem cells with microscopic magnetic iron nanoparticles. In a study covered by Behind the Headlines in 2009, the researchers injected the tagged stem cells into rats in which the carotid artery in the neck had been artificially stripped of its lining. These tagged stem cells had the ability to differentiate into vessel-lining cells. Twelve minutes after the injection, an external magnet was held beside the rats’ carotid artery to attract the tagged stem cells. The technique increased the number of stem cells at the injured site fivefold. While hugely significant, the research did not show whether the repair process itself was improved.
Can we trust the stem cell treatments being offered?

Pioneering scientific and medical advances have to be carefully policed to make sure they are safe and ethical. Stem cell research should be treated no differently, and it has particular ethical considerations of its own.

One prominent debate is whether it is appropriate to use embryonic tissue for scientific and medical research. The debate has focused on the balance between the rights of the embryo and the potential benefits that people may gain from research using these cells and in the future. It is well known that in the US under George W Bush’s administration, federal research funds were limited to research conducted with existing embryonic stem cell lines or adult stem cells, rather than human embryonic stem cells.

An ethical debate has also raged about the extent to which human cells should be manipulated. For example, scientists have explored the possibility of creating artificial embryos by taking the DNA from a human adult cell and transferring it into an animal egg that has had almost all of its genetic material removed. This is a type of cloned cell. If these cloned cells could be made to develop to produce stem cells, this might offer an acceptable alternative to stem cells taken from leftover IVF embryos.

In the UK, the Human Fertilisation and Embryology Act regulates the practice of in vitro fertilisation (IVF) and the creation, use, storage and disposal of embryos produced using this technique. All embryo research in the UK is legally required to have a licence from the Human Fertilisation and Embryology Authority (HFEA). The HFEA determines whether proposals such as the ones described above could go ahead in the UK.

To get the licence from the HFEA, researchers have to demonstrate why their embryo research is necessary. Once embryonic stem cells have been isolated, the UK Stem Cell Bank has custody of stem cell lines, ensuring their purity and provenance and monitoring their use. The European Union Tissues and Cells Directive (EUTCD) was brought fully into force in 2008. It provides a framework to ensure high standards in the procurement, testing, processing, storage, distribution and import and export of tissues and cells across the EU. Alongside these rules, the Human Tissue Act (2004) ensures the quality, safety and traceability of tissue and cells used for human application.

The use of spare embryos from IVF is a source of debate

Private stem cell clinics

Early-phase clinical studies have shown promise for some diseases, and stem cell treatments are becoming more of a realistic prospect. Unregulated stem cell services have already emerged. A few clicks on an internet search engine will uncover services offering stem cell facelifts, injections of animal foetal tissue as an elixir of youth, and stem cell treatments for conditions such as Alzheimer’s disease and autism. But are these claims founded?

“Unregulated stem cell services have already emerged”

As we have seen, bone marrow transplants for blood cancers are well established, but human clinical trials for other conditions or stem cell types are in very early stages. Without evidence
to back up the effectiveness and safety of the treatments that clinics offer, and indeed what exactly the procedures are, it is very risky to have these treatments.

In 2010, BBC News reported the case of a woman with end-stage kidney disease who had been treated in a private clinic in Thailand. The woman underwent a type of stem cell therapy that used stem cells isolated from her own blood. These cells were then injected through the skin into the regions of both kidneys. The woman’s kidney condition did not improve after this treatment and she had to start dialysis three months later.

After six months she went to hospital with pain, and blood in her urine. Scans showed that she had growths on her left kidney and nearby organs. The kidney was removed and inspected and was “shown to have various masses of non-cancerous tissue growths in various parts of the kidney”. The researchers investigating this case suggested that this was caused by her stem cell therapy, although it’s not possible to say this was definitely the reason. The story illustrates one potential concern over stem cell therapies, that the transplanted stem cell could embed elsewhere in the body and grow in an uncontrolled way.

“The basic research is sufficiently pioneering and fascinating to speak for itself without added spin”

Even with treatments that have gone through registered trials, rare side effects may not be seen until many people have received the treatment. Case reports, such as that of the woman with kidney disease, will be useful for identifying rarer side effects that may be missed in small, early-phase clinical trials. The advantage of registered clinical trials, as opposed to non-registered experimental treatments, is that the precise treatment, including how the stem cells have been isolated and handled, will be clear. Therefore, if a side effect emerges, it is easier to trace why it happened and alert other professionals using the same documented technique. Private, non-regulated clinics may not make their methods available and may not, for example, meet the standards of stem cell purification, which licensed treatments would do.

If stem cells are heralded as a potential cure for all ills, this could encourage people to take the risk of going to a private stem cell clinic, especially if they have chronic conditions with no known cure. In 2008, the MS Society warned that although there is no evidence that stem cells are an effective treatment for MS, stem cell companies have approached people with MS and offered stem cell treatments. The Times also reported research carried out in Canada in 2007 that looked at the websites of stem cell clinics. It examined the sort of therapies being offered online and whether there was any clinical evidence to support these therapies. The researchers also looked at how the information was presented. In general, they found that the clinics made inaccurate claims in their advertising to consumers.
A good place to start when assessing online stem cell claims is a guideline produced by the International Society for Stem Cell Research (ISSCR). It says the following claims made by providers of stem cell therapies should be viewed with caution:

- claims based on patient testimonials
- claims that multiple diseases are treated with the same cells
- claims without clear documentation of the source of cells or treatment details
- claims that there is no risk
- high-cost treatments or those where the true cost is hidden

Conclusion

Stem cell treatments for blood disorders have been around for decades, but we have entered a truly exciting time when the use of stem cells is being explored for a whole host of medical problems. We are still in the early stages of this period. While human clinical trials have provided some evidence that stem cell treatments may be safe, it is not yet clear whether they will be effective.

The goal of research using stem cells is not always to produce a stem cell therapy. Basic research over the last four years has shown that stem cells can be used to understand diseases, which may help scientists create new drug therapies.

However, making a stem cell turn into a particular cell type in the laboratory is not easy. Over the last four years, we have seen an explosion in ingenious types of stem cell experiments. The inventive ways that scientists are directing stem cells to develop into different cell types is making them into biological puppeteers.

Using stem cells for transplantation is not simply a matter of injecting the cells into the body. Scientists have been finding ways to get stem cells to settle and grow in the correct place and have created bioscaffolds to make the cells form more functional structures. These techniques have already resulted in the first stem cell tissue transplant of a windpipe graft.

There is no doubt that this technology could lead to new treatments, but most of these experiments have yet to reach the stage of practical application. Newspaper reporting has been generally good, but is prone to overoptimistic interpretation at times. We are still in a time when the registration of a new trial is newsworthy. The basic research is sufficiently pioneering and fascinating to speak for itself without added spin.

Further reading

- Human Tissue Authority: Stem cells (PDF, 1.3Mb)
- MS Society: Stem cell therapies in MS (PDF, 305kb)
- National Institutes of Health: Stem cell information
- Human Fertilisation and Embryology Authority