Stem cell therapies: Why they're expensive, unproven and often dangerous

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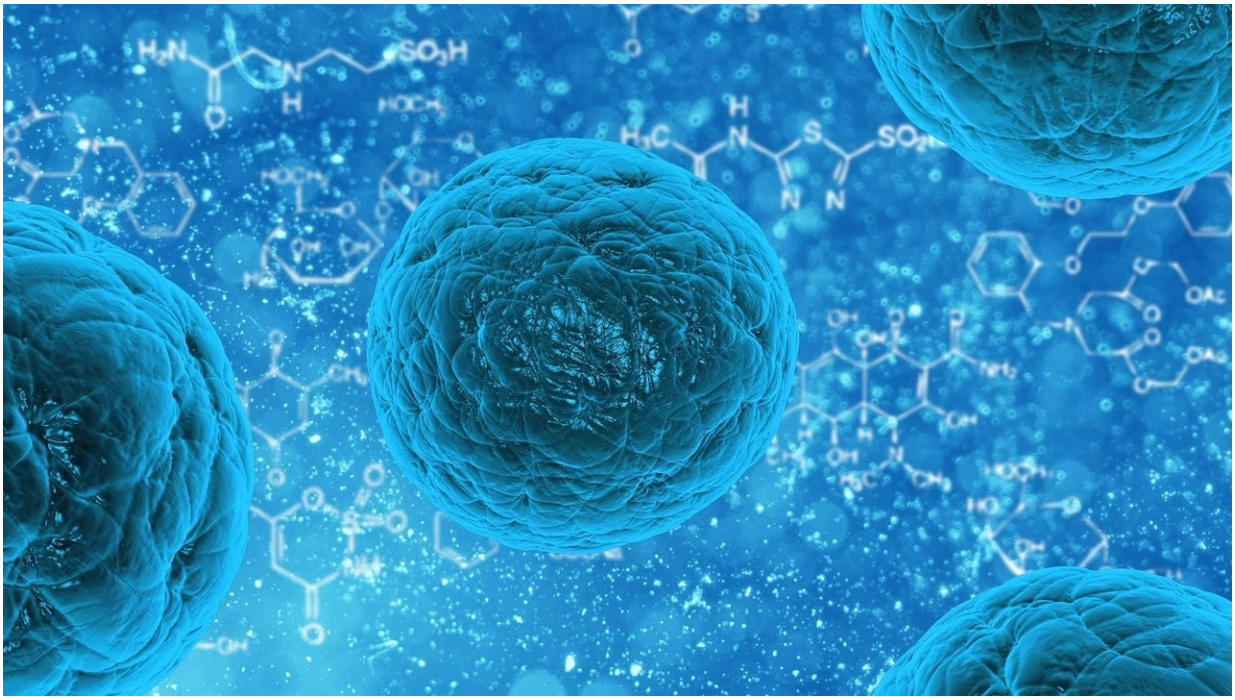

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Rogue clinics selling stem cell therapies are popping up everywhere. There are thousands of them around the world, and they claim to be able to cure everything from autism to cerebral palsy.

The highest concentration of stem cell therapy clinics is in the US, Mexico, India and China. And people are traveling far and wide to get

these treatments, leading to a phenomenon known as stem cell tourism.

Despite warnings from scientists, the media and regulators that these treatments are untested and potentially dangerous, desperate people are forking out thousands of pounds to essentially be guinea pigs for these unproven treatments.

In the US, several patients lost their sight after receiving stem-cell treatment for degenerative eye conditions. The patients, who were treated at an unregulated stem-cell therapy clinic in Florida, paid up to US$20,000 (£15,600) to take part in the "clinical trial."

Other reports have highlighted severe harms associated with unregulated stem cell treatments, including fever, infections, tumors, brain inflammation, life-threatening blood clots, disability and even death.

How stem cells work

Some parts of the human body have the remarkable ability to repair themselves and replace lost or damaged cells. For instance, the human skin renews itself entirely every four weeks, while it takes around four months for all red blood cells to be fully replenished. Unfortunately, some organs are less efficient or unable to repair themselves.

This self-repair or regeneration is a primary function of stem cells. Unlike other cells in our body, stem cells have the unique ability to transform into different types of cells, each serving a specific function.

During early human development, stem cells are called pluripotent, meaning they can develop into any cell type in the body. However, as the embryo develops, stem cells become more specialized and can only develop into certain cell types. In adult humans, these specialized stem cells are referred to as adult stem cells.

Adult stem cells are not as versatile as embryonic stem cells, as they can only develop into cell types similar to their source. For example, stem cells found in the bone marrow can only develop into blood cells, while stem cells in the brain can only replace brain cells.

In addition to their role in replacing specialized cells, all stem cells contribute to the self-healing of cells and organs by releasing beneficial substances stored in small lipid droplets called extracellular vesicles.

Stem cells hold great potential for medical research and treatments because they can help repair damaged tissues and organs in the body. Indeed, thousands of legitimate clinical trials are underway to explore their healing potential.

But it's still early days and only a very few stem cell treatments for a limited range of conditions have been approved by drugs regulators, such as the Food and Drug Administration (FDA) in the US or the European Medicines Agency (EMA) in the EU.

FDA-approved stem cell therapies include those targeting specific cancers, receding gums, cartilage degeneration and spinal muscular atrophy. In all these approved therapies, very specific types of stem cells are used for each targeted condition. Overall, stem cell therapy is still at a very early stage and certainly not a widely used treatment or miracle cure for all disorders or conditions.

Any clinic offering stem cell therapies not authorized by the regulators is selling unproven and potentially dangerous treatments.

Loophole

In the EU and the UK, unethical stem cell clinics are taking advantage of a regulatory loophole. If stem cells aren't modified in any way after

they're extracted and then re-inserted into a person, these procedures fall outside the regulations for so-called advanced therapy medicinal products (medicines based on genes, tissues or cells).

As a result of this lack of regulation, there is no standard quality control—if there is any quality control at all. Consequently, the effectiveness and safety of stem cell therapies cannot be guaranteed.

To persuade potential customers that their stem cell injections work, many of these businesses avoid referring to reliable scientific evidence, such as randomized clinical trials—the gold standard for testing new treatments. Instead, they rely on evidence that has some medical and scientific basis, but has been taken out of context.

These clinics often use written testimonials or testimonial videos from patients who cannot be verified. Or they mention celebrities who have been treated at their clinic. They use their fame and influence to create a perception of legitimacy, despite the lack of scientific evidence or regulatory oversight.

Because of the lack of regulations and undisclosed quality control measures in these stem cell clinics, the risks of dangerous side-effects and complications are significant.

Unproven stem cell treatments may also result in patients delaying or forgoing treatments that have been proven to be safe and effective for their condition. This delay can have serious consequences, as it may allow the underlying condition to progress or worsen without appropriate medical intervention.

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