Navigating ethics in the large grey zone of unproven stem cell treatments

Original publiction:
Current and emerging global themes in the bioethics of regenerative medicine: the tangled web of stem cell translation

Author:
Sarah Chan

Ethical and safety concerns are being raised about the increasing number of clinics marketing unproven stem cell therapies around the world. Addressing these issues requires understanding both the scope of what unproven treatments are and how clinics offering these therapies fit into the broader picture of regenerative medicine translation at the interface of research, health care, commercial markets and government policy.

What questions & challenges are raised?

The rapidly growing market of clinics around the world offering unproven stem cell (SC) treatments has prompted many ethical discussions and concerns. Treatments being sold to patients by clinics can be expensive, have safety risks, may offer no benefits and are sometimes based on little to no scientific evidence. This raises concerns of patient vulnerability and exploitation. Dr Sarah Chan from the University of Edinburgh explains in her recent publication that just because a treatment is 'unproven' does not mean it is without scientific merit, just as not all patients are uninformed and vulnerable. Dr Chan points out that "black-and-white" views of unproven SCs don't consider the many complex factors that have built the SC market into its current state. Her examination of this 'large grey zone' of unproven SC treatments illustrates the ever-changing relationships between patients, medical professionals, researchers, businesses, government and the general public in the SC market. Furthermore, understanding this network can guide better approaches to cooperatively managing the international SC market and advancing regenerative medicine research.

What insight & direction does this give for research policies?

Dr Chan's examination into unproven SC treatments illustrates how multiple factors and stakeholders are involved in this market, each with different perspectives and interests. Among these, Dr Chan highlights how patients are playing a growing role as active investigators, consumers, and contributors to their own treatments as well as clinical research to develop better treatments. Dr Chan suggests that the active participation of patients creates new challenges that require reassessing the rights, responsibilities and relationships between patients, researchers, medical professionals, and businesses in the SC market. Effectively managing unproven SC treatments and helping unproven treatments to be approved will likely require a combination of approaches, such as regulations that are adjusted and targeted to specific needs in health care, medical research and the SC market; managing cooperative efforts between patients, researchers and clinicians; and efforts to change professional and personal behaviours.

What background and point are discussed?

Dr Chan begins by emphasising that 'unproven' SC treatments encompass all experimental treatments, from ones in clinical trials to those based on no scientific evidence at all. Unproven treatments cannot simply be banned because testing unproven treatments is essential for developing new medical therapies. Instead, Dr Chan suggests that researchers, patients, businesses, government agencies, and medical providers work together to identify and restrict access to unproven treatments that carry substantial risks. Agreement may not be easy, as researchers who wish to see stricter regulations on SC treatments will likely be standing against the demands of patients and businesses, who want weaker policies to increase patient access and reduce costs on businesses. Many governments have adopted more permissive regulations, such as the US "Right to Try" laws, which temporarily exempt some treatments from the FDA approval process. Unproven therapy supporters claim treatments can be tested for safety and effectiveness while marketed, but Dr Chan notes that once a treatment is on the market, there's less incentive and no guarantee they will be scientifically validated. Regulatory differences between countries can promote 'stem cell tourism', where individuals travel to countries with more permissive laws to get treatments. Dr Chan notes that regulation differences may also encourage businesses to move or expand internationally, or partner with foreign businesses to capitalise on different countries' regulations. An example of this is Cell Therapy Ltd (a UK-based company), which formed a partnership with a Japanese business to take advantage of Japan's new Regenerative Medicine Promotion Law. This law allows businesses to sell regenerative medicine treatments after a small amount of testing to show treatments are generally safe, but without studies to prove they are effective or safe in the long-term. This law also allows some unproven treatments to be paid for by Japan's public health system, which redistributes the costs of testing treatments from businesses onto the public. This means Japan could end up paying foreign businesses to test treatments on Japanese citizens, while they collect clinical data for approval and marketing of their treatment in other countries.

Dr Chan states that charging patients for unproven treatments is another ethical issue being raised, particularly individuals that are required to pay to participate in clinical trials. This situation transfers additional financial risk onto individuals already suffering from medical conditions and taking treatments that could pose physical risks to their health and may offer no benefit at all. Companies selling these treatments have very low risks in this case because they get to test the treatment, collect data and have the patient pay for it. However, Dr Chan remarks that there are some ethical grounds for charging patients. Individuals may feel value in contributing to scientific advancement and others desire a feeling of being in control that is generated by paying for treatments. Dr Chan states that many clinics may be offering treatments they believe are helpful, but that clinics offering treatments with no scientific basis or deliberately misleading patients should be "unambiguously condemned". To address this, she proposes that clinics be required to report all data obtained from treatments – in the interest of creating safer, affordable and effective treatments for patients. Furthermore, she suggests several other unique challenges facing the development of SC treatments might be overcome by adopting alternative and more flexible methods to evaluate the effectiveness and safety of SC therapies.