

Study examines direct-to-consumer stem cell clinics in 6 Southwestern states

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This direct-to-consumer stem cell marketplace has come under increasing scrutiny, but relatively little is known about the clinics that deliver these treatments or how the treatments they offer align with the expertise of the practitioners providing them. In a paper published August 1 in the journal *Stem Cell Reports*, investigators offer a detailed characterization of nearly 170 stem cell businesses across six southwestern states. The study focused on Arizona, California, Colorado, Nevada, New Mexico, and Utah, where the researchers estimate that about one-third of all stem cell clinics in the US are located.

"Previous studies have built up a broad picture of the direct-to-consumer stem cell industry," says Emma Frow, an assistant professor in the School for the Future of Innovation in Society and the School of Biological and Health Systems Engineering at Arizona State University, co-first author on the paper along with David Brafman, also an assistant professor of bioengineering at Arizona State University.

"We took a deeper dive into a smaller number of clinics and found that there's a lot of variation among the businesses offering these services," she says. "About 25% focus exclusively on stem cells, but many others are facilities like orthopedic and sports medicine clinics that have added stem cells to their roster of services on offer. For these clinics, it's very difficult to know how much of their business comes from stem cell treatments."

The researchers conducted extensive online searches for stem cell clinics in the six states. "There's no exhaustive list of all the clinics that exist," Frow says. "This is a lively marketplace, with businesses opening and closing and changing their names." For the 169 businesses they identified, they catalogued the treatments being offered, the medical conditions these clinics purported to treat, and the types of cells they claimed to use. For the 25% of clinics focused solely on stem cells, they also looked at the stated expertise of the care providers at these clinics in relation to the medical conditions they offer to treat with stem cells.

The researchers found that orthopedic, inflammatory, and pain conditions were the main types of medical conditions treated with stem cells at direct-to-consumer stem cell clinics in the Southwest. Frow notes that these types of conditions "tend to be chronic problems that often are not curable. The market has really capitalized on targeting conditions that are hard to manage with existing therapies."

Earlier studies have shown a lower percentage of clinics treating inflammatory conditions. "This could mean that the number of clinics treating inflammatory conditions is on the rise or that, in the Southwest, there is more focus on treating inflammatory conditions than in other parts of the US," Frow suggests.

The researchers also found differences in the degree to which the listed expertise of care providers at stem cell clinics matched the medical conditions they treat with stem cells. For example, they identified that specialists in orthopedics and sports medicine were more likely to restrict stem cell treatments to conditions

related to their medical specialties, while care providers listing specialties in cosmetic or alternative medicine were more likely to treat a much wider range of conditions with stem cells.

Public discussions of direct-to-consumer stem cell treatments usually treat clinics as though their business models were all similar, but this study highlights some key differences across these clinics. "We think it makes a difference whether a business is focused solely on stem cells or offers it as one treatment among many," Frow says. "And we think it's important to pay attention to the medical qualifications and expertise of the care providers offering stem cell treatments. Just because someone is board certified doesn't necessarily mean they are qualified to provide stem cell treatments. You really need to ask what they are board certified in and whether their medical expertise is well-matched to the condition you are seeking treatment for."

Recent moves by the FDA to tighten up its guidelines and restrict the practices of these clinics have generated a lot of attention. The authors of this study see their work as contributing to these discussions. "We want to bring more transparency to discussions of the direct-to-consumer stem cell marketplace and to empower consumers to figure out what kinds of questions to ask when they're considering treatment," Frow says. "We also want to help the scientific community get a better understanding of the situation and to help the FDA and state medical boards think through their priorities with regards to regulating the market."

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This research was funded by the Lincoln Center for Applied Ethics and the Institute for Social Science Research at Arizona State University.

Stem Cell Reports, Frow and Brafman et al.: "Characterizing direct-to-consumer stem cell businesses in the Southwest United States." [https://www.cell.com/stem-cell-reports/fulltext/S2213-6711\(19\)30253-X](https://www.cell.com/stem-cell-reports/fulltext/S2213-6711(19)30253-X)

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