

What Do They Mean by 'Stem Cells'? Recommended Guidelines for Reporting on Cell Therapies

May 15, 2019 – Cell therapies including so-called "stem cells" are increasingly being marketed and used for the treatment of musculoskeletal disorders – despite questions about these treatments and their effectiveness. A new tool for standardizing communication about cell therapies is presented in the May 15 issue of [The Journal of Bone & Joint Surgery](#). The journal is published in the Lippincott portfolio in partnership with [Wolters Kluwer](#).

Called "DOSES," the new tool provides standards for describing the characteristics and use of cell therapies. Developed by an international expert panel, "The use of this tool may allow clinicians and patients to better understand the characteristics of current and future cell preparations," according to the new report's senior author, Robert F. LaPrade, MD, PhD, of The Steadman Clinic, Vail, Colo.

Consensus Tool Seeks to Clarify 'Misleading, Ambiguous' Terminology

The DOSES tool was designed to meet the need for more transparent, standardized communication in describing cell therapies – often marketed as "stem cells" – for musculoskeletal conditions. "Misleading or ambiguous terminology can result in mistaken assumptions regarding cell origins and characteristics, making interpretation of studies difficult," Dr. LaPrade and colleagues write. "A lack of standards for conveying the characteristics of cell therapies is being increasingly exploited with misinformation of unproven treatments."

An expert working group of 34 clinicians and researchers followed a formal process to reach a consensus (more than 80 percent agreement) on the essential information needed when communicating about cell therapies. The resulting DOSES tool addresses five areas that should be included whenever cell therapies are described or reported on:

- *Donor*: The source of cells – for example, from a donor (allogeneic) or from patients themselves (autologous).
- *Origin*: The type of tissue from which cells were obtained – for example, fat or bone marrow.
- *Separation*: The methods used to prepare the cells or separate them from other tissues.
- *Exhibited cell characteristics*: Referring to biologic activity that is believed to affect the therapeutic behavior of the cells.
- *Site of delivery*: Referring to where the cells are administered – for example, intravenously or into a joint (intra-articularly).

These five elements should be used in describing cell therapies at every step: from initial scientific reports through product marketing and clinical use. "The DOSES tool can be utilized by researchers, clinicians, regulators, and industry professionals to improve standardization and transparency when describing cell therapies," Dr. LaPrade and coauthors write. They also believe that research journals should make these "core descriptors" mandatory in studies reporting cell therapies.

The DOSES tool provides a much-needed set of standard descriptors, at a time when "stem cells" and other cell therapies are being aggressively marketed to consumers and professionals - often without meaningful supporting data. "Clinical research and practice are being undermined by ambiguous terminology that acts as a barrier to understanding the basic attributes of cell therapies," Dr. LaPrade and coauthors write. "The present study has established consensus on the requirement for a descriptive tool to improve cell therapy communication."



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