

## listening to the messages of patients and stakeholders : where stem cell therapy, spinal cord injury and neuroethics meet

Just over a decade ago, two scientists, Thomson<sup>1</sup> and Gearhart,<sup>2</sup> isolated human embryonic stem cells. These experiments generated intense excitement about the potential therapeutic promise of stem cells for a wide range of diseases and conditions such as diabetes, Parkinson's disease, and spinal cord injury, as well as controversies about moral, legal, ethical, social, and cultural issues. The areas of controversy are many and nuanced, and are so dynamic that they are in a constant state of flux. Debates about them focus on the challenges of procurement, derivation, banking, and distribution of stem cells; the impact of intellectual property and patents on collaboration and innovation among scientists; hurdles created by different jurisdictional and national policies and practices that impede the development of international regulatory and ethical guidelines for research<sup>3</sup>; concerns about human stem cell intervention and medical tourism in advance of scientific evidence<sup>4</sup>; and, the balance between speed and caution in progressing from research in animal models to human clinical trials<sup>5</sup>.

At the heart of the debates lie the hopes and expectations of persons desperate for a cure for a range of diseases and concerns about exploitation. However, despite a decade of extraordinary attention in the scientific and public realm, the potential for stem cells still awaits translation into standard medical therapies.

Several international initiatives have been launched to promote the understanding and delivery of stem cell research to patients in a safe, effective and fair manner. For example, the International Society for Stem Cell Research (ISSCR) has published two documents in this regard: Guidelines for the Clinical Translation of Stem Cells<sup>6</sup> and the Patient Handbook on Stem Cell Therapies<sup>7</sup>. The Guidelines document highlights scientific, clinical, regulatory, ethical and social issues that must be addressed for stem cell research. The Patient Handbook provides answers to frequently asked questions (FAQs) and delves into important underlying

elements of many issues of concern. These resources are invaluable for scientists, regulators, policy makers, and patients.

How can neuroethics build on these international initiatives and contribute meaningfully to progress in the clinical translation of stem cells? Neuroethics aims to tackle the ethical, legal, policy and social implications of frontier technological developments in the neurosciences. The objective is to align innovations in the brain sciences with societal, cultural and individual human values through high impact research, education, and outreach. At the National Core for Neuroethics in Vancouver, Canada, some of our recent work has been focused on the critical importance of the voice of stakeholders in the translational roadmap of human neuroscience research. Nowhere is this more true than for individuals with chronic neurological disabilities who have completely intact intellectual abilities such as is the case in spinal cord injuries (SCI). While significant research has been devoted to defining the scientific feasibility of SCI transplantation, the identification of SCI populations for whom this procedure would initially be well matched – given risks and benefits, and contextual features such as a network of care, culture and values – has received little attention. Instead, individuals with SCI have held on to hope where it does not yet exist, and have even been lured to risky procedures at international sites where procedures have not been validated scientifically<sup>8</sup>.

Our work specifically addresses these issues by gathering empirical data from focus groups and interviews with persons with SCI, family members and others in primary relationships with them, and their physicians. Our objectives are to identify: (i) the first segments of the SCI population who, given physiologic and psychosocial predictors of success, are the best candidates for early clinical trials of an invasive stem cell transplantation, (ii) the barriers, incentives, and readiness for translational stem cell research, and (iii) the tools that will be needed to meet

these challenges.

Early findings with physicians in acute care and rehabilitation settings suggest shared perceptions that the perceived benefit of stem cell therapy to persons with SCI will be a function of individual goals and priorities. They also reveal common concerns about the risks and abundance of misinformation, fear of doing more harm than good by causing aberrant recovery and pain, and risky allocation of resources, time and money. Rehabilitation physicians express additional challenges related to the time required in educating patients, ensuring that patients engage fully in validated methods to improve function, and keeping a focus on care versus cure.

By directly harnessing the voices of all stakeholders in the stem cell debate, the scientific and neuroethics communities join together to draw upon the intimate knowledge of people living with SCI and of physicians who will be gatekeepers to clinical trials and therapy. We believe that the collective voice of all people vested in the research-to-translation trajectory for SCI will be an important force in identifying realistic and meaningful eligibility criteria for clinical trials when they are ready to be launched. Results will guide assessment and balance of risk and benefit, and inform the development of innovative and effective educational and outreach resources both for pre- and post-intervention.

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