

ORIGINAL ARTICLE

Perspectives on strategies and challenges in the conversation about stem cells for spinal cord injury

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Study design: Qualitative study.

Objective: To examine how trusted communication between individuals with spinal cord injury (ISCIs) and physicians who care for ISCIs is affected by the discussion of advances in stem cell research and interventions locally and abroad.

Setting: Canada and the United States (US).

Methods: Semi-structured interviews with ISCIs and physicians. A thematic analysis approach was applied to more than 12 h of data to derive prominent themes and describe relationships between them.

Results: A convergence of factors involving transparency impact trusted communication between ISCIs and physicians about stem cells and spinal cord injury (SCI). ISCIs expressed that trusted communication is strengthened when physicians exhibit caring, attentive and positive attitudes that are underpinned by domain-specific knowledge and scholarship. Perceived reluctance to communicate or lack of knowledge poses significant challenges. Physicians also emphasised the importance of transparency for trusted communication but expressed that the still limited clinical reality of treatment choices for SCI and the pressures imposed by external resources are significant stressors that complicate the communication landscape. Both groups cited the range and variable quality of information sources, and the difficulty associated with navigating them, as priorities for action that would remediate these tensions.

Conclusions: (1) Epistemic transparency should be privileged over silence. (2) A new generation of innovations in research and clinical trial dissemination about stem cells for SCI is needed to remedy the perceived inadequacies of existing information content and accessibility.

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INTRODUCTION

Researchers have been interested for many decades in the therapeutic potential of transplanting cells into the spinal cord to bridge an injured area and promote recovery. The emergence of stem cell technologies since the 1960s has led to much excitement among researchers and individuals living with spinal cord injury (SCI). Not all cell therapies for SCI technically involve stem cells, but the discourse around regenerative therapies for SCI is invariably dominated by interest in stem cells, particularly among those who are injured.

Although the pace of advancement in stem cell biology is accelerating and has resulted in an abundance of discoveries, translation into human treatments has been frustratingly slow. Indeed, there is a fine line between offering treatments too soon—before adequate appreciation of the full spectrum of risks and benefits of any intervention are known—and delaying treatments for too long with the possibility of subsequent denial or reduction in benefit. Starting with the Geron clinical trial of oligodendrocyte precursors from embryonic stem cells, other neural stem cell approaches have more recently reached human testing in regulated and highly scrutinised clinical trials.¹ The outcome of these trials and the determination of

the safety and efficacy of these approaches are still many years down the road.

Meanwhile, for-profit centres around the world are offering individuals with spinal cord injury (ISCIs) experimental options using stem cell interventions that have no formal regulatory approval and have limited or no preclinical or clinical substantiation of their effectiveness. Many of these for-profit stem cell interventions are advertised over the Internet and are accompanied by patient testimonials that resonate with other ISCIs. ISCIs who are interested in experimental stem cell interventions abroad may also be influenced in their decisions by other factors such as the media, their families, for-profit stem cell clinics and their doctors at home.^{2,3} Ultimately, ISCIs must decide where and in whom to place their trust to make choices about health, quality of life and well-being. The hopes and desires of ISCIs to improve their spinal cord function combined with the current lack of conventional medical therapies and the availability, albeit at cost, of novel stem cell interventions from seemingly reputable stem cell clinics around the world create an awkward dynamic between the ISCI and their physicians: What information should ISCIs seek? Who should they trust? Whose advice should they heed?

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Table 1 Sample interview questions

Individuals with spinal cord injury	Physicians
'Have you ever asked a health care provider about experimental therapy options such as stem cell interventions for your spinal cord injury (SCI)?'	'Under what set of circumstances do conversations about stem interventions generally emerge with your patients?'
'Did receiving this information have any influence on your relationship with any of these individuals? If so, how?' (Positive or negative)	'Would you say that talking to your patients about stem cell interventions affects your relationship with any of them at all?'
'What is most important to you when it comes to trust with regard to your physician (and stem cells)?'	'Do you generally feel trusted by your patients?'
'How much of an influence did your physician have on your decisions about travelling for experimental stem cell interventions for your SCI?'	'Do you currently have patients who are considering the possibility of travelling for stem cell interventions? What kind of information do you think would help them make a final decision?'
'What advice would you give someone else who was thinking about speaking to a physician about travelling abroad for stem cell interventions?'	'What advice would you give to other health care providers in your position?'

Trust is built upon the expectation that competence and good will govern decisions of a trustee to act in the interest of a trustor. In the fiduciary relationship in health care, this translates to the belief that a trusted physician will act in the best interest of the trusting patient and puts the health and well-being of the patient under the discretion of the physician.⁴ Along with trust, effective communication between both parties is an essential part of a successful patient–physician relationship. Trust and effective and trusted communication in the patient–physician relationship have been linked to positive patient behaviours involving treatment decisions, compliance and information disclosure.⁵ In the present study, one of a series on readiness for clinical trials,⁶ decision making,⁷ expectation of benefit and risk,⁸ advocacy⁹ and risk,¹⁰ we sought to examine how these trusting relationships specifically are fostered and threatened in the context of the conversation about stem cell interventions for SCI.

MATERIALS AND METHODS

Participants

We recruited ISCI from across British Columbia, Alberta and the Yukon, Canada. Eligibility criteria for ISCI required that they be at least 19 years of age, able to converse fluently in English and be at least 1 year post injury. ISCI were recruited from a registry of individuals who pre-consented to be contacted for study participation and through an article published in a popular magazine devoted to lifestyle after SCI. In addition, notices were posted online by four major spinal cord advocacy groups, at the largest rehabilitation facility in British Columbia, and on the authors' website under a dedicated study recruitment tab. Printed notices were also placed in health care facilities in the Vancouver area that offer services to ISCI, and direct emails were sent to relevant patient groups and to members of the professional networks of physicians and researchers in Canada and the United States (US) involved with SCI. All participants who expressed interest in the study were sent a consent form prior to enrolment.

We recruited English-speaking physician specialists in rehabilitation or SCI, from across Canada and the US. Physicians were recruited through announcements of the study in the professional community of the authors, direct contact with expert participants from previous studies with interest in further participation and snowball sampling. All participants who expressed interest in the study were sent a consent form prior to enrolment.

Interview development and data collection

A tailored semi-structured interview guide was developed for each of the two participant cohorts. The guides were formulated from results from the prior suite of studies on stem cells and ISCI conducted by our group. Interview questions were developed, vetted and refined through piloting and testing, with a final guide yielding a target time of ~30 min to complete. Each included baseline questions about participant backgrounds, such as time post injury or years in practice, as relevant to each group. Interview guides were further refined during data collection as interviews informed new insights. Interviews

were conducted either over the phone or in person depending on the participant's preference and were one-time, audio-recorded events that were transcribed verbatim, verified to ensure accuracy and made software ready.

The ISCI interview guide probed for sources of care, sources of information about stem cells for SCI, sources of advice about treatment options, perception of trust in sources of information and advice and strategies for decision making (Table 1). Participants were also invited to provide open comment on issues not explored by the interview guide.

The physician interview guide explored communication strategies, perceptions of trust in sources of information and advice provided to ISCI by outside sources, factors related to trust in the patient–physician relationship and details of patient's pursuits of stem cell interventions. The guide also contained questions to gauge how many of the physicians' patients had discussions about stem cells with them and the perceived effects of these discussions (Table 1). These participants were also given the opportunity to provide feedback on issues not probed *a priori* in the interview guide.

Data analysis

Transcripts were managed using NVivo 10 software (QSR International, 2012). Using methods from past studies, we applied a thematic analysis approach to the data, involving a rigorous and an iterative process in which portions of raw data are labelled and examined for broader themes across the data set.¹⁰ To develop the initial coding frame, two coders who were trained in qualitative research methods acted independently to examine the transcripts and came together to compare codes until a consensus was reached. These codes were continuously revisited, revised and added to as analysis went on. Initial codes were then clustered together under major themes. With the coding scheme finalised, one coder independently coded all of the transcripts, whereas the other double coded ~20% to check reliability. Discrepancies between coders were discussed until an agreement was reached. Results are reported in the form of major themes as defined by their prominence in the discourse.

Statement of ethics

The authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of the research.

RESULTS

Eighteen ISCI and 12 physicians were enrolled in the study, consented and interviewed. Tables 2 and 3 provide participant demographics. Interviews ranged from 20 to 40 min. Taken together, ISCI and physician interviews contributed over 12 h of audio-recorded data for analysis, divided approximately equally between the two groups.

Factors favoring trusted communication

Of the seven ISCI who had conversations with their physician about stem cell interventions for spinal cord injury, the majority reported a

Table 2 Participant demographics: individuals with spinal cord injury

<i>Gender</i>	<i>n</i>
Male	15
Female	3
<i>Age range (years)</i>	<i>n</i>
20–30	4
31–45	2
46–60	8
61–75	3
76+	1
<i>Time from injury (years)</i>	<i>n</i>
1–5	8
6–10	1
26–30	2
31–35	1
36–41	3
Unknown	3
<i>Level of injury</i>	<i>n</i>
Cervical	5
Thoracolumbar	13
<i>Educational level</i>	<i>n</i>
Some high school	1
Trade school	1
High school degree	4
Post secondary degree	9
Doctoral degree	3

Table 3 Participant demographics: physicians

<i>Gender</i>	<i>n</i>
Male	7
Female	5
<i>Location of practice</i>	<i>n</i>
Canada	8
United States	4
<i>Age range (years)</i>	<i>n</i>
30–50	9
51+	3
<i>Clinical practice or research with spinal cord injury (years)</i>	<i>n</i>
5–10	2
11+	10

positive experience. ISCIs expressed the importance of caring, attentive and positive physician attitudes. As one ISCI described, for example:

‘...you can see it in their actions that they really care about their patients. And that they want to do everything to improve their lives and quality of lives of all their patients.’ (ISCI08)

ISCI also indicated that trust was improved by perceptions of physician knowledge and scholarship. Such credibility was derived from the involvement in research, the manner in which they spoke about the stem cell field and experimental interventions and referrals to resources deemed trustworthy that empowered ISCI to make informed choices. For example:

‘...the main reason to be trust in the doctor [sic] is his background...and experience in that field.’ (ISCI18)

Physicians highlighted the importance of being transparent and forthright when communicating with ISCI about stem cell interventions. They described the virtues of open knowledge sharing about

emerging biotechnologies, including discussion around the costs associated with stem cell tourism. For example:

‘There are financial risks, there are the travel risks, there’s the emotional risk.’ (P08)

‘...they would be on the hook for those medical expenses that they wouldn’t pay for in Canada. I have some of those discussions with them.’ (P12)

Physicians also described the duty to recognise and be truthful about knowledge limits. For example:

‘I think it builds trust to admit that there’s gaps in my knowledge and that there are things that I don’t know. And I think being honest with patients...that helps them...believe that...you will engage in an honest conversation with them.’ (P10)

Physicians also highlighted the value of empathy and the value of refraining from critical or negative judgment of their patients’ perspectives:

‘I think it’s really important that you approach stem cells with an open attitude when you’re talking to patients so that you don’t just say, you know, ‘No, don’t do it.’ But you explore why a patient is thinking about doing it and what their motivation is and what their current belief and perceptions are, so that you can understand where they’re coming from so that you can help guide their decision making.’ (P02)

‘...having discussion [sic] about what is it about your life that’s really upsetting you, is really a much more useful conversation than discussing stem cell therapy...oftentimes we have to address the emotional content of the message as well as the factual content of the message.’ (P12)

Factors stressing trusted communication

Several ISCI had not discussed stem cells with their physicians despite the interest they expressed in the interview in learning more about new discoveries and clinical applications. One factor was the perception of physician reluctance to engage in the conversation. For example:

‘Doctors don’t seem to be very open about talking about [stem cells]...’ This ISCI later goes on to add: ‘If doctors were more open about...talking about it, that would be kind of cool...’ (ISCI13)

Although some ISCI felt that their physicians were experts in stem cell interventions, this was not shared by all of the participants, some of who perceived that the physician did not have adequate knowledge of stem cell interventions to engage in the conversation:

‘It seems to be like, you know, stem cells on the positive side, for the positive doctors, they seem to think there’s a lot of future in it. The ones that seemed kind of negative...they don’t know or are not keeping current.’ (ISCI03)

This perceived lack of knowledge left some ISCI unsure where to turn to for more information:

‘I wouldn’t know anyone right now that I’d get more information from.’ (ISCI11)

Some physicians clearly shared the views that the avoidance of stem cell conversations could be misconstrued as a lack of knowledge, as an unwillingness to engage or even as a form of information withholding. For example:

‘...when it comes to the relationship with my patients, it...also set[s] up, the possibility of competing expectations or competing agendas or perceptions that a treatment is being withheld.’ (P08)

‘Bring [stem cells] up before they do...that way...when they find out that there’s things going on they’re not going to think that you kept something from them’ (P09).

‘...these patients may go away thinking, ‘Well, this surgeon never discussed anything about the stem cells, he probably doesn’t know anything about it.’ This physician later goes on to add ‘by not educating them they may go home and be susceptible to, you know, wrong information.’ (P07)

Communicating the clinical reality of treatment choices was a prominent internal stressor that physicians reported when navigating through stem cell discussions. For example:

‘I don’t want to really discuss something that I can’t offer...’ (P07)

By being in the critical path of queries about stem cell interventions and having to highlight these clinical realities, some physicians felt vulnerable and at risk of damaging the patient–physician trust relationship, as the following physician describes:

‘...when you’re...the bearer of bad news...you’re taking away hope...it can affect the relationship...it does put a bit of strain. And then...I kind of have to work hard to regain that.’ (P05)

The vast range, variable quality and sometimes conflicting information from external sources such as the Internet, peers, family members and others were further stressors for physicians:

‘...the information [from stem cell clinics abroad] is completely and totally unreliable because people are running a business.’ (P03)

‘...you really want to be positive for your loved ones and...you’re very selective at your interpretations and you interpret all the good things but you don’t actually consider all the sort of cautionary points.’ (P07)

ISCIs likewise commented on the variability of information sources about stem cell interventions, and the difficulty that they have navigating them. ISCIs recognised that not all information on the Internet is trustworthy. Still, some highlighted the difficulty in knowing where to place their trust:

‘... there’s a lot of junk out there that’s hard to filter through to find the real stuff.’ (ISCI17)

All physicians reported that their strategy is educational when responding to queries about stem cells, and many urged others to keep up to date on new advances in the field to do the same. However, as the following quotes illustrate, the majority of physicians expressed that far better and more readily accessible resources are needed both for their own educational benefit as well as for the educational benefit of their patients than are currently available:

‘I think anyone who’s dealing with spine trauma and spinal cord injury should, you know, keep themselves relatively well informed of the technology...and I don’t think there is a cohesive way of doing that.’ (P07)

‘What would be helpful is having better access to up to date information on what trials may be available...if we work more collaboratively that way, and if we have up to date lay level materials that we can utilise for educating our patients.’ (P09)

Indeed, the ‘less reputable are widely available and the very reputable are highly regulated and there’s less access to them’ (P12).

DISCUSSION

In this study, ISCIs and physicians described factors that promote and tax trusted communication about stem cells and SCI. Similar to studies by others,¹¹ we found that physician demeanour, knowledge, openness, straightforward honesty and understanding are key elements in the discourse that preserve and promote trusting patient–physician relationships. The stresses that ISCIs and physicians feel when communicating about stem cells, however, coupled with the lack of a satisfactory way to get and stay informed, threaten this essential and delicate relationship.

From the ISCIs in this study who had conversations about stem cells with their physicians, we learned that the conversation posed little risk to the patient–physician relationship. In fact, it is silence that may be the greater obstacle. This finding is consistent with previous research showing that physician silence may be interpreted as physician indifference or as implicit endorsement for stem cell tourism.^{12,13} Silence may also be interpreted as a lack of knowledge or information withholding, leaving ISCIs unsure where to turn for information or shared decision making. Dialogue about stem cell clinical trials and activity abroad is favourable to the alternative, especially within a framework of epistemic transparency in which both the extent and boundaries of knowledge are expressed.¹⁴

Individuals with a serious medical condition such as SCI can be susceptible to hopeful promises of recovery even if the risks and potential for therapeutic benefit are unknown.^{2,13,15} The ISCIs who reported that they were reluctant to talk about stem cell interventions were left to navigate often confusing and conflicting information available on stem cells without the guidance of physician expertise available to them locally. The benefits of this expertise, however limited or extensive, are downplayed in the direct to consumer world of stem cell interventions, in which ISCIs may be encouraged to bypass conventional approaches in favour of experimental interventions purchased privately from providers abroad. A growing body of literature shows that many for-profit providers downplay risks, do not provide sound safety and efficacy data and lead prospective consumers to develop trust and false hope.¹⁶ The practice of selling unproven stem cell interventions is condemned by the international scientific community.¹⁵ The legitimate involvement of other sources external to the health care system such as family, friends and the Internet can also complicate this already fragile landscape,^{2,13} although the involvement of peers and other affected individuals may provide still untested benefits.⁷ A summary of the balances and tensions is shown in Table 4.

Table 4 Major emergent themes

	<i>Perspectives of individuals with spinal cord injury (n = 18)</i>	<i>Perspectives of physicians (n = 12)</i>
Factors favouring trusted communication	Physician attitude Physician expertise	Transparency Understanding ISCI perspective
Factors stressing trusted communication	Hesitation of physicians to engage Lack of physician knowledge Difficulty with resources	Patient misconceptions Communicating clinical realities Pressure from external information sources Challenges of resource content quality and accessibility

Abbreviation: ISCI, individual with spinal cord injury.

Guidelines set out by the International Society for Stem Cell Research (ISSCR) and the International Campaign for Cures of Spinal Cord Injury Paralysis (ICCP) advise physicians to stay informed of the latest developments in stem cells in order to communicate with interested patients effectively. Even though there have been attempts to improve the availability to stem cell resources,¹⁷ this study and others highlight that the user go-to or information-pull strategy of existing resources is simply inadequate.¹⁸ The time is ripe for a physician-oriented mobile app or a similar resource that regularly pushes out specific updates about discoveries or trial results to subscribers to remediate this persistent gap. Scott's¹⁹ proposal for a new cadre of professionals in the stem cell arena—stem cell counsellors akin to genetic counsellors—could also offer much needed additional clinical intervention resources to address the full range of factors, including not only ISCI interest in the details of potential procedures but also underlying emotional interests in them. Until these resources are widely available, clinicians will continue to be faced with the very real world challenge of desperate patients who are craving authentic and authoritative insights into stem cell technologies.

The findings from this study are based on affected individuals from western Canada only and a broader but still relatively small sample of physicians from across North America. Physicians who were interviewed see patients at various points along the continuum of care and were speaking on the basis of their experiences. The cohort sizes are common to qualitative research and, similarly consistent with this approach, the results are limited to their meaningful transferability to other groups but not generalisability. Although we recognise that there are considerable disparities in health care systems and medicolegal landscapes between the US and Canada, physicians in both nations practice within comparable regulatory frameworks within which stem cell technologies for SCI are completely experimental and have the same regulatory status to physicians in the US and Canada. Hence, although we acknowledge significant differences in the health care systems, we contend that there are reasonable similarities on the issue of how clinicians and ISCI interact on the topic of stem cell interventions.

It has been argued that open, multidirectional communication is the new way in the biomedical sciences and may well be the way for the stem cell and SCI conversation between the individuals who are affected and the people who care for them. It offers both a direct and indirect pathway to trust in legitimate sources, to consideration of the full range of health values and assets of affected individuals and to both informed decision making and informed hope.²⁰

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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