

Education can improve clinician confidence in information sharing and willingness to refer to stem cell clinical trials for cerebral palsy

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ABSTRACT

To progress stem cell therapies for cerebral palsy, clinicians need to openly engage with patients about emerging evidence and be willing to refer to relevant clinical trials, if and when appropriate. To assess whether education can change clinicians' confidence in information sharing and willingness to refer to relevant clinical trials, an online questionnaire was distributed at a scientific conference before and after a professional workshop on cell therapies for cerebral palsy. Of the 42 participants who completed the survey, 26 self-identified as clinicians. Of these, 81% had had patients ask about stem cells, yet in the pre-workshop questionnaire indicated they were not confident answering questions about cell therapies. Clinicians were most commonly asked about stem cell treatments provided by private clinics, stem cell research and current evidence. Post-workshop, knowledge and confidence regarding stem cells, as well as likelihood to refer to clinical trials using therapies with a strong evidence base (eg, umbilical cord blood/placental cells), significantly increased ($p < 0.001$). This study highlights that by offering resources and education, clinician confidence and willingness to refer to cell therapy trials can improve; this may help drive the stem cell research landscape and support patient decision-making.

INTRODUCTION

Cell therapies for cerebral palsy

Cerebral palsy describes a group of disorders of movement and posture, attributed to injury to the developing brain.¹ Evidence for stem cells as a beneficial intervention for cerebral palsy is emerging. Some stem cell therapies have been shown to improve motor function, with a robust safety profile observed in clinical trials.^{2,3} Many cell types are currently being investigated, with cells from the placenta or umbilical cord blood, as well as bone marrow, the most widely researched. Generally, cells from these sources release paracrine factors with trophic and immunomodulatory properties that contribute indirectly to brain repair.^{4,5} There is also significant interest in harnessing the regenerative potential of neural stem cells, which may directly repair the brain. However, transplantation of neural stem cells requires additional procedural risks such as neurosurgery and the use of adjuvant

Significance of this study

What is already known about this subject?

- ▶ Stem cell therapies for the treatment of cerebral palsy show promise; research supports that some treatments are safe and can improve motor function.
- ▶ Clinicians have an important role in progressing stem cell research and clinical trials by assisting consumers in making decisions about accessing novel treatments.
- ▶ It is unclear if relevant clinicians are confident in sharing information regarding stem cells or willing to refer patients with cerebral palsy to stem cell clinical trials.

What are the new findings?

- ▶ In our sample, clinicians are often asked by patients about stem cells for cerebral palsy.
- ▶ Clinicians report low knowledge and confidence providing stem cell information to patients.
- ▶ Stem cell knowledge and confidence can be improved by an educational workshop.

How might these results change the focus of research or clinical practice?

- ▶ By offering relevant resources and education, clinician confidence and willingness to refer to cell therapy trials for cerebral palsy can improve.
- ▶ Clinician education may help to better support patient decision-making and translation of stem cell research for the treatment of cerebral palsy.

immunosuppression. It is therefore essential that factors like the route of administration, cell type and its mechanism are considered in parallel to the proposed therapeutic effect and expected benefits.

Relevant stakeholders in cell therapies for cerebral palsy

There are a number of key stakeholders to consider when discussing cell therapies for cerebral palsy. These include 'patients', those with

cerebral palsy receiving direct care or services by a medical professional, and ‘consumers’, those with cerebral palsy and/or their family members or carers, pursuing information or access to treatments. There is overlap in the definition of patients and consumers, and we acknowledge that different individuals may have a preferred identifier. Other key stakeholders include clinicians, which for the treatment and management of cerebral palsy may include both medical professionals (eg, pediatrician or neurologist) or allied health professionals (eg, occupational therapist or physiotherapist). Scientists and researchers are other stakeholders, playing a pivotal role in progressing stem cell therapies for cerebral palsy. Any one individual may identify with a number of stakeholder groups. Importantly, there is interplay between all groups and each remains essential in cell therapy translation and implementation.

The essential role of clinicians in cell therapy translation and implementation

In order to progress stem cell research and clinical trials, clinicians must stay abreast of current research and related considerations, or at least feel confident in seeking this information from reliable sources. In turn, this may assist consumers and patients in engaging in clinical trials via consultation with trusted healthcare professionals. Support of consumers and patients becomes even more important as unregulated private clinics promote stem cell treatments, and interest in stem cell and medical tourism increases.⁶ Clinical trials of stem cell and regenerative therapies are an important, legitimate option for patients and separate to unregulated clinics. Australia’s contribution to stem cell research for cerebral palsy and relevant causal pathways (eg, preterm birth) has been significant, leading to the establishment of multiple world-first clinical trials.^{7–10} Harnessing results from these trials to influence changes in clinical practice and policy will be the next major hurdle.

As Australia and New Zealand face a new frontier of treatment options for cerebral palsy, it is crucial to understand clinician confidence and willingness to refer patients to stem cell clinical trials. This knowledge is an important step in understanding the feasibility of progressing stem cell clinical research and for gaining insights about how to accelerate treatment options for people with cerebral palsy.

This study aimed to survey clinicians attending a professional conference, to gauge clinician confidence in discussing stem cells and the acceptability and readiness to refer patients with cerebral palsy to stem cell clinical trials. A 90-minute workshop was conducted to provide delegates with up-to-date information on the current state of the evidence and equip clinicians with the tools to answer patient questions on stem cell therapies. We hypothesized that after interactive delivery of relevant, high-quality and critically reviewed stem cell information, clinician confidence and likelihood to refer patients to cell clinical trials for cerebral palsy would be significantly increased, on a 10-point and 5-point Likert scale, respectively.

METHODS

An online questionnaire was administered via Typeform (www.typeform.com/) during a workshop held at the Australasian Academy of Cerebral Palsy and Developmental

Medicine (AusACPDM) 10th Biennial Scientific Conference in March 2020. This AusACPDM conference, with the theme of *Visionaries*, encouraged participants to seek future-focused research, practice and outcomes, with the conference providing scientific education targeted to medical professionals, researchers and consumers. The title of this workshop was ‘Stem cell therapies for cerebral palsy: the what and how of handling difficult questions’. All workshop attendees were provided with study information and invited to participate in the survey. Consent was expressed by completion of the prequestionnaire and/or postquestionnaire. Those not participating in the survey could still participate in the workshop.

Workshop details

The workshop aimed to be educational and ran for 90-minutes with the following objectives for attendees:

- ▶ Understand the current landscape of stem cell therapies for cerebral palsy.
- ▶ Identify the existing and emerging evidence in clinical trials.
- ▶ Identify barriers and explore facilitators to implementation.
- ▶ Gain confidence addressing common questions from the public about stem cells.

The workshop had several components, including traditional oral presentation of materials from the authors listed in this manuscript, as well as interactive panel discussions and a question and answer segment.

Survey content

Our survey comprised two questionnaires: one administered before and one after the workshop. Each questionnaire was administered via the distribution of a study URL which directed participants to Typeform. The pre-workshop questionnaire comprised 17 questions: 3 open-ended and 14 Likert-scale categorized-response questions. The post-workshop questionnaire comprised a maximum of 13 Likert-scale categorized-response questions (depending on branching logic prompted by the professional role selected).

Data analysis and statistics

Due to the nature of the questionnaires, pre-workshop and post-workshop participant responses could not be paired; all data were aggregated. Qualitative questions relating to demographics were summarized, with ordinal responses analyzed by frequency. Non-parametric statistical analyses (Wilcoxon signed-rank) were conducted to analyze differences in Likert scale responses before and after the workshop, expressed as median±IQR. A p-value of <0.05 was considered statistically significant. Statistical analysis was conducted using SPSS V.25.

Confidence on a 10-point Likert scale was interpreted as ‘not confident’ if below or equal to 5 and ‘confident’ if above 5. Likelihood was interpreted as ‘unlikely’ if below or equal to 5 and ‘likely’ if above 5. This terminology reflects the response options provided in the survey.

RESULTS

A total of 42 people participated in the survey. The survey (consisting of both questionnaires) took on average less

Table 1 Participant demographics and clinicians' professional specialty

| Demographics | Total (N) |
|------------------------------------------------------------------------------------------------------------------------|-----------|
| Family member/carer of someone with a disability/chronic health condition | 5 |
| Researcher/scientist | 4 |
| Person with a disability/chronic health condition | 1 |
| Clinicians including medical professionals and allied health professionals | 32 |
| Clinicians (n=25) | |
| Clinician and family member/carer of someone with a disability/chronic health condition (n=3) | |
| Clinician and researcher/scientist (n=3) | |
| Clinician and researcher/scientist and family member/carer of someone with a disability/chronic health condition (n=1) | |
| Clinician specialty (n=32) | |
| Physiotherapist (n=13) | |
| Occupational therapist (n=8) | |
| Pediatric rehabilitation specialist (n=6) | |
| Neurologist (n=2) | |
| Other (n=3) | |

Total participant demographics, n=42. Clinician-indicated area of specialty by free text, n=32.

than 4 minutes to complete (3 minutes 50 \pm 1 minutes 32 s). **Table 1** displays participants' demographics, including clinicians' professional specialty (n=32/42). The leading occupations for these participants were physiotherapists (41%, n=13), occupational therapists (25%, n=8) and pediatric rehabilitation specialists (19%, n=6). Only 12.5% (n=4) of the clinicians also identified as a researcher or scientist. More than 80% (n=26) of the clinicians nominated themselves as being in a 'patient-facing' role, which enabled subsequent questions related to patient consultation and referral to clinical trials.

Frequently asked clinician–patient themes

The majority of patient-facing clinicians indicated that they had previously been asked about stem cells by their patients (81%, n=21). From a preset option list, these clinicians indicated they had been asked about the following: 46% (n=12) stem cell treatments offered by private clinics; 31% (n=8) stem cell research and current evidence; 27% (n=7) collection and storage of stem cells (eg, cord blood and tissue banking); 27% (n=7) stem cell clinical trials and potential involvement; 19% (n=5) stem cell basics (ie, what is a stem cell therapy?); and 12% (n=3) clinical opinion on stem cell treatment (**figure 1**).

Clinician knowledge and confidence about stem cells

Before the workshop, clinicians indicated a low level of knowledge (defined as a score ≤ 5 out of 10) about stem cells, with a median of 4 (range 2–5; **figure 2**). This score significantly increased immediately following the workshop ($p<0.001$). Before the workshop, clinicians indicated low-level confidence in a variety of patient-based scenarios when asked about stem cells (score ≤ 5 ; **figure 2**). Participating in the workshop significantly increased the confidence of clinicians in answering questions about stem cells with their patients ($p<0.001$), discussing the latest research

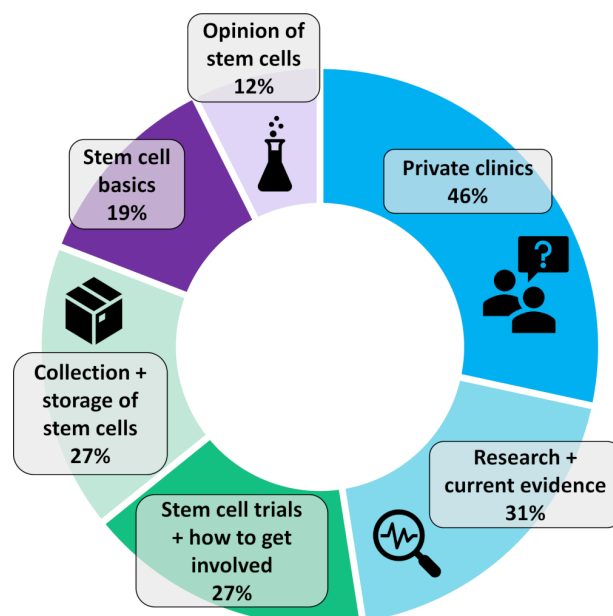


Figure 1 Frequently asked questions about stem cells by patients to clinicians. Analysis of common stem cell queries indicated by clinicians via a preset list of themes (n=32).

($p<0.001$) and trials ($p<0.001$), and participating in open conversations with patients seeking to access stem cell treatments from private clinics ($p<0.001$).

Referral to stem cell clinical trials

When asked about their previous referral experience, 62% (n=16) of clinicians indicated that they would refer patients for a clinical trial in their current role and that 56% (n=9) had previously. Of the patient-facing clinicians, the majority (92%, n=24) would refer patients to trials in Australia or New Zealand, whereas only 27% (n=7) would refer to overseas trials.

Prior to the workshop, clinicians indicated that they would be likely to refer patients with cerebral palsy to an Australian or New Zealand clinical trial using intravenously administered umbilical cord blood or placental cells, or a patient's own bone marrow cells given intrathecally (score >5 ; **figure 3**). This attitude was in contrast to those expressed about referral to higher-risk clinical trials, such as those using neural stem cells transplanted neurosurgically or requiring immunosuppression (preworkshop score ≤ 5). After the workshop, clinicians were significantly more likely to refer to trials requiring immunosuppression ($p=0.017$) and indicated a relatively higher likelihood to refer to trials using intravenous umbilical cord blood or placental cells ($p=0.003$).

DISCUSSION

In this study, we highlight the pivotal role clinicians play in communicating the latest stem cell research to their patients, to support decision-making and involvement in clinical trials. We demonstrate that by delivering current information on stem cells for cerebral palsy during a 90-minute workshop, we can increase clinician confidence in providing evidence-based information to their patients.

Rate your **knowledge** of
stem cells....



I feel **confident**...



...answering **questions about
stem cells** with my patients

...discussing **the latest stem
cell research** with my patients



...discussing information on
stem cell clinical trials with
my patients

...having an open conversation with
patients interested in seeking stem
cell treatment from **private clinics**

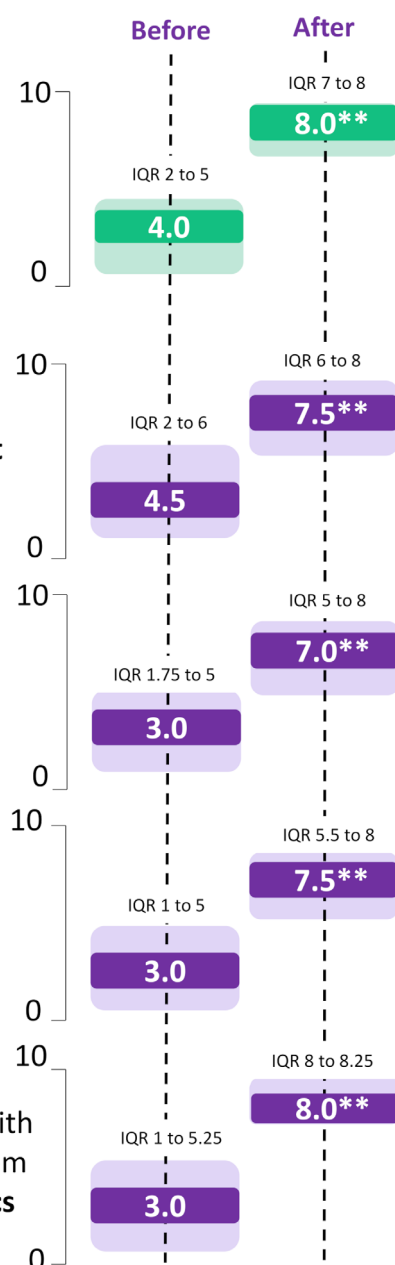


Figure 2 Clinician knowledge of stem cells and confidence in relevant patient interactions. Responses expressed as median with IQR before and after the workshop (n=26). For both knowledge and confidence, 0 indicates 'none' or 'not confident at all' and 10 indicates 'extensive' or 'extremely confident', respectively. **P<0.001.

We have also shown that clinician education may help to promote patient referrals to local clinical trials, which is an important factor in the successful and feasible translation of cell therapies.

A staggering 81% of clinicians in a patient-facing role have previously been asked about stem cells, highlighting a high-level of engagement with this topic by patients and consumers. This study also reveals that clinicians are often asked about private clinics offering stem cell treatments for cerebral palsy. Similar results were found in a study of academic neurologists; the majority had been asked about obtaining stem cell treatments related to private clinics, and notably 65% had patients who had already been treated.¹¹ Interestingly, our clinician respondents indicated

that speaking about private clinics with patients in an open conversation was an area of low confidence. Private clinics offering cell therapies for those with cerebral palsy and other neurological conditions are abundant, commonly using direct-to-consumer marketing to draw customers from across the world, who then travel to receive treatment.¹² These clinics have been known to use information from preclinical research to justify clinical application and appear to sell cell therapies without robust data to support safety and efficacy. For instance, one study showed that 67% of all websites offering stem cell treatment do not mention that the therapy is experimental or unproven, and 94% fail to state the specific risks involved with the therapy.¹³ Despite

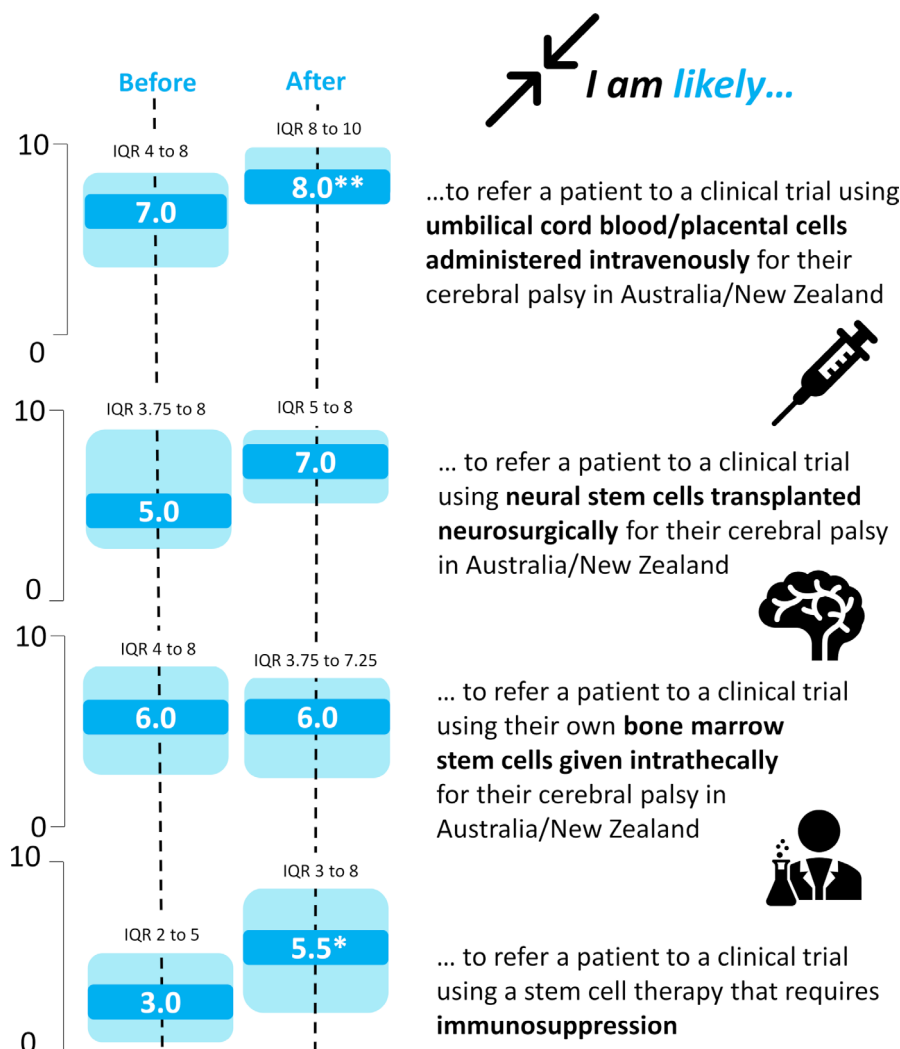


Figure 3 Likelihood of clinician referrals to stem cell trials. Responses expressed as median with IQR before and after the workshop (n=26). For likelihood, 0 indicates 'not likely at all' and 10 indicates 'extremely likely'. *P<0.05, **P<0.001.

this, the number of unregulated clinics offering treatment globally, as well as those traveling for treatment, is rising.¹⁴

While regulatory bodies help mitigate risks associated with private clinics, clinicians also have a vital role to play in supporting patients seeking alternative treatment options, acting as a source of evidence-based information. Ideally, clinician-patient interactions will be free from conflicts of interest, such as financial gain, and thus clinicians can safeguard patient well-being by supporting informed decision-making.⁶ Through a short 90-minute workshop, we demonstrate improvements in clinician willingness and confidence in discussing stem cell research and engaging in open conversations about private clinics, which should ultimately help support patients.

The number of clinical trials investigating the use of stem cells for cerebral palsy is increasing.¹⁵ However, the demand for access to clinical trials still far exceeds availability.¹⁶ Our study sample mainly comprised physiotherapists and occupational therapists, which are two types of professionals known to make the highest number of referrals to cerebral palsy trials. The majority of clinicians at this workshop had prior experience referring a patient to a trial; yet before the

workshop, clinicians' likelihood to refer to local (Australian and New Zealand) trials using stem cells was highly variable and dependent on the cell type. Strikingly, the majority of clinicians highly preferred local trials (92%), whereas far fewer clinicians (27%) would refer to clinical trials overseas. This preference may have a variety of explanations, one being clinician familiarity of local regulators and the public health system.

Following the workshop, clinicians were significantly more likely to refer a patient to clinical trials with a strong evidence base, such as umbilical cord blood/placental cells. This outcome was unsurprising as the workshop presented a large amount of content on this intervention, reflecting its substantial and growing evidence base.² Consistent with our observation that clinician decision-making is guided by available evidence, referral likelihood remained unchanged for other cell types like neural stem cells and bone marrow that have limited published clinical data in cerebral palsy. Thus, we anticipate that more evidence of safety or efficacy will be needed before opinion is altered for these cell types. Despite the lack of clinical evidence suggesting the benefits of these cell therapies for cerebral palsy, these

interventions still remain highly sought after by the cerebral palsy community¹⁷ for several reasons. For example, neural stem cells are the only cell type with known regenerative capacity when implanted directly into the brain,¹⁸ and private clinics often promote bone marrow as a safe and autologous method of cell therapy.¹⁹ It is therefore vital that clinicians feel confident in discussing the evidence base, together with their professional concerns, while acknowledging a patient's motivations for seeking information and access to experimental treatments.

A striking finding from this study was the change in clinician likelihood to refer patients to clinical trials using immunosuppression. Before the workshop, clinicians were unlikely to refer when the trial involved the use of immunosuppression. This opinion was unsurprising since long-term immunosuppression carries significant risks to patient health, including infections and other complications associated with immune deficiency.²⁰ However, immunosuppression is a necessary adjuvant for transplantation of donor neural stem cells to ensure cell engraftment and efficacy. After an explanation in the workshop, clinicians were willing to refer to trials using this therapy, demonstrating how information sharing between researchers and clinicians can influence clinician opinion and decision-making regarding referral to stem cell clinical trials. These post-workshop score changes are also likely to reflect the safety data presented at the workshop, with more supportive evidence of stem cells and immunosuppression than first assumed. Again, it should be noted, however, that the majority of clinicians surveyed were physiotherapists and their familiarity with immunosuppression prior to this event is potentially more limited than other specialists and neurologists. Nevertheless, to progress stem cell clinical trials for cerebral palsy, broad clinician education must be a priority, and this is expressed consistently in the literature when highlighting the essential role of healthcare professionals in being a primary source of evidence-based information for patients.^{6 11 21} There should also be an emphasis on ongoing education and awareness among clinicians in stem cells for cerebral palsy as this area is rapidly changing. The need to provide specific and ongoing education for clinicians has already been identified by the cerebral palsy community and documented in the recent Australian and New Zealand Cerebral Palsy Strategy.²² A specific example of this is the inclusion of evidence-based education on cerebral palsy in nationally accredited training degrees. Stem cells are an area of interest that could benefit from being incorporated. Importantly, this ongoing education and awareness will need to be tailored for each clinician demographic to ensure that the material is appropriate and meaningful.

There are some definite limitations to this study as our survey only captured responses and opinion from those in attendance at a professional conference, before and immediately following the workshop. While there were improvements in knowledge, confidence and likelihood to refer, due to the workshop being a once-off event we cannot infer any long-term, sustained changes to opinion or behavior. However, we can confirm that this educational medium is effective and that clinicians' confidence, willingness and clinical trial referral likelihood can be improved. It should be noted that clinicians in attendance at this conference are also highly likely to be interested

in research and evidence-based practice due to the nature of the event. Therefore, our respondents are likely to be receptive to new information and have already demonstrated active information seeking by participating in the professional conference. The sample was also small and responses biased by the nature of self-reporting. Within this sample are a high number of physiotherapists, who may not be the most appropriate population for referrals to stem cells trials for cerebral palsy compared with, for example, neurologists. More research will determine if these results will extrapolate to a larger and more relevant population of clinicians.

Clinicians are frequently asked about stem cells for cerebral palsy. More education and resources should be provided to clinicians so they can appropriately and confidently handle these interactions. Importantly, education should be tailored and relevant for different clinician demographics. In turn, this may improve clinician willingness and readiness to refer to trials using stem cells for cerebral palsy and support the rapidly advancing stem cell research landscape. Importantly improving clinical knowledge and confidence may help patients make more informed choices about their involvement in stem cell research and accessing stem cell treatments for cerebral palsy.

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