North American Spinal Cord Injury Consortium

FDA CDRH Information Meeting - Spinal Cord Injury Community Input

Summary Report – June 5, 2023 at 15:00

AGENDA

Description: The North American Spinal Cord Injury Consortium (NASCIC) is a non-profit organization representing the SCI community of lived experience throughout North America. Our mission is to bring about unified achievements in research, care, cure, and policy by supporting collaborative efforts across the spinal cord injury community. Our organization currently has over 400 members consisting of people with lived experience, organizations that directly represent people living with spinal cord injury and fellow community stakeholders.

Purpose: To inform CDRH reviewers of the community engagement efforts within the spinal cord injury (SCI) community and the known preferences and priorities of those living with the condition.

Panelists: NASCIC members with SCI lived experience

Indication: Spinal Cord Injury

Agenda:

- Introduction to the North American Spinal Cord Injury Consortium and who we represent: Ms. Jennifer French, President of NASCIC, 10 minutes
- Overview of the SCI Research Advocacy Course: a free on-line course to inform about SCI: Mr. Barry Munro, Treasurer of NASCIC, 10 minutes
- Current knowledge of preferences, priorities, and challenges of the SCI community from those with lived experience: Dr. Kim Anderson, MetroHealth Medical Center & Case Western Reserve University, 20 minutes
- Open Discussion and Q&A with panelists: Mr. Ian Burkhart, moderator, 20 minutes
    - Panelists: Mr. Matt Castelluccio, United Spinal Association; Dr. Rex Marco, Christopher & Dana Reeve Foundation; Mr. Jason Stoffer, United to Fight Paralysis; Ms. Tiera McQuatar, Conquer Paralysis Now

North American Spinal Cord Injury Consortium

SUMMARY NOTES

The meeting was segmented into two components: 1) the presentation of SCI community engagement and preferences and 2) group discussion from people with SCI lived experience.

Total attendees: 46

Presentation of SCI Community Engagement & Preferences

- Jennifer French introduced the team of attendees, all with spinal cord injury (SCI) lived experience. She also introduced the North American SCI Consortium (NASCIC) with a mission to bring about unified achievements in research, care, cure, and policy by supporting collaborative efforts across the spinal cord injury community. This is achieved by identifying gaps, communicating resources and being a conduit of collaboration between the SCI community and the many stakeholders. NASCIC is a member of the FDA Patient and Caregiver Connection program.

- Barry Munro introduced the recently released SCI Research Advocacy Course. NASCIC has developed a free online educational course to increase knowledge of the research process so that individuals with SCI and caregivers feel prepared to serve as research advocates and that SCI researchers, healthcare providers, and industry stakeholders are better able to partner with the SCI community effectively. The SCI Research Advocacy Course includes input from leading clinicians and researchers, as well as the guidance of a large community of people with SCI lived experience. It is available via this link: https://nascic.org/courses/nascic-community-engagement-program-cep/

- Kim Anderson delivered a presentation regarding the current knowledge of preferences, priorities, and challenges of the SCI community from those with lived experience.

    - She provided details from specific studies regarding desired functional recovery with recurring priorities of bladder, bowel, and sex; incremental mobility in upper extremity, lower extremity, and trunk stability; exercise; and pain.

    - She also reviewed studies highlighting the SCI community's preferences for meaningful neurological improvement as well as known risk and benefit preferences with respect to specific functions and participating in clinical trials concerning surgery for hand/arm function, cellular therapies, implanted neurotechnology, tendon transfers, neuromodulation for bladder & bowel, and spinal cord stimulation.

    - The summary of published known perspectives of the SCI community regarding risks, benefits & clinical trials were as follows:

- Appropriate consideration of risks and benefits
- Concerns about post-surgical pain and the need for revision surgeries
- Incremental "small" improvements are meaningful
- Individuals with the most to gain may be the most risk averse
- Timing is important
- There are some universal facilitators and barriers to participation.

Group Discussion from People with SCI Lived Experience

- Ian Burkhart facilitated the panel discussion.
- Panelists introduced themselves:
  - **Dr. Rex Marco (C-3)** – Spinal Surgeon, Christopher and Dana Reeve Foundation
  - **Tiera McQuater (C-3)** - Board Member - Conquer Paralysis Now
  - **Matt Castelluccio (C-6)** - Director of Community Support – United Spinal Association
  - **Jason Stoffer (L-1)** - Cure Advocacy Network Manager - Unite 2 Fight Paralysis
- Q: In your experience and as a leader in the community, can you describe what you view as what would be a meaningful improvement?
  - Any improvement gives hope. There is heterogeneity in the community. anything that increases independence, lifespan, and overall health. Anything that provides a better quality of life from access and/or functional ability.
- Q: Viewing the clinical trial (CT) barriers/facilitators, what other barriers have you seen hindering CT participation?
  - Common medications tend to be exclusion criteria. Eligibility requirements are a hurdle. Lack of awareness, financial considerations i.e. travel/accommodation/medical expenses. The opportunity cost to participation is a factor, plus weighing the medications and QOL.
- Q: What perspectives have you seen as the diversity between various levels of injury?
  - Higher-level injuries (tetraplegics) have a greater interest in clinical trials and gaining function back. In contrast, those with lower-level injuries are more interested in quality-of-life improvements of secondary complications for day-to-day life. We tend to avoid the word cure and focus on more attainable gains, but we can't forget there is still a desire for a cure.

- Q: Could you talk about what you have seen to help serve minority, under-served, and rural area people with SCI?
  - Rural access is limited since most studies are conducted in urban centers. Whether it is the level of injury or time post injury, people are cautious due to a fear of lost function. Time commitment is another factor. Time since injury has an impact on interest.

- Q: How do you think the FDA could do better? What would you change?

    - Understanding (and applying) the diversity in the SCI community. The NASCIC course is a great resource to get someone started in understanding their injury and how the research system works.
- Q: Are there any particular aspects of the design of clinical studies (including informed consent forms) that the FDA could help to improve in our reviews?
    - Informed consents can be very long and complicated. The FDA could encourage continual informed consent and continual understanding of the risks. Anything that allows for remote data collection would be helpful. Understanding of when is a good time to go over informed consent.

- Q: What are some innovative or creative ideas we could use to improve the safety of the use of devices that are already in use for people with SCI?
    - Accelerate translation. Minimize revision surgeries and have tools to troubleshoot or correct system issues externally rather than before considering surgery. We need better long-term data for implants and better device contingency plans for when companies go out of business or research ends.
- Q: How can we follow clinical trial participants with implanted devices to improve the devices long term?
    - We need to look at standards of care. There could be an improvement in the longevity of devices. FDA could set up a registry for those with implanted devices, regardless of how long the investigator conducts their study or when it goes to market. FDA has a database of adverse events and could learn from there to improve devices.

The meeting closed at 4:30 pm. We appreciate the FDA extending the meeting time to address the attendees' questions.