

Summary – CCSVI Working Group Meeting, October 19, 2010

The CCSVI Working Group held its second meeting on October 19 by teleconference.

Participants:

Linda Lumsden, Chair
Shelley Black
Anthony Feinstein
Marilyn Lenzen
Samuel Ludwin

Linda Molyneux
T.J. (Jock) Murray
James Orr
Brock Winterton
Yves Savoie (ex officio)

Regrets: Lindsay Machan
Julian Spears

Staff resource: Deanna Groetzing

The group had agreed in advance the main topic of discussion would be the question of what is needed to move forward with pan-Canadian therapeutic clinical trials of chronic cerebrospinal venous insufficiency (CCSVI) and MS, if warranted. Before tackling that issue, they reviewed four other priority issues and talked about in which order they should be discussed at future meetings.

Following discussion, consensus was reached quickly that the issues would be discussed in the following order:

1. Can a patient registry be established in Canada to follow those who have had the CCSVI procedure elsewhere?
2. Why compassionate access to the CCSVI procedure is not available to people with multiple sclerosis.
3. What is the true level of risk associated with the CCSVI procedure?
4. Have the lead researchers in the current CCSVI imaging studies been trained appropriately given current disagreement related to the various techniques?

The group discussed the announcement by the Saskatchewan government to commit \$5 million to fund clinical trials of the CCSVI procedure. The government said an advisory panel will be convened in early November, with an expedited call for proposals occurring in early December. It said it is expected that the successful recipient will be chosen in early 2011 and a process leading to clinical trials will be announced by April of 2011.

The group talked about the Saskatchewan initiative in terms of what it meant for other governments and the MS Society waiting for data from studies underway in Canada, the United States and elsewhere. One question was whether Saskatchewan going ahead with a therapeutic clinical trial in April 2011 would constitute sufficient evidence for others to commit funding to a similar therapeutic clinical trial.

The group did not reach consensus as to whether the Saskatchewan government announcement would or should be followed by others. It was noted the imaging studies underway in Canada and the US should contribute useful information for the Saskatchewan clinical trial.

There was discussion about the need for caution relating to people's hopes being raised by the possibility of being treated by a simple procedure and that the downside to hope is major disappointment if that hope is not realized. Caution is needed. While understanding the importance of hope, it is also important to realize how destructive the risk of false hope can be.

Returning to the overall topic of what is needed to move forward with pan-Canadian therapeutic clinical trials of CCSVI and MS, there was agreement CCSVI Working Group members need to monitor what is happening in Saskatchewan as well as studies currently underway and to review and understand published studies. There was a discussion of the importance that CCSVI therapeutic clinical trials are designed in the right way so data will be accepted and acted upon. One member reminded the group the emphasis should be on ensuring data from studies are honest and have integrity since the goal is to find out whether the CCSVI procedure benefits people with MS or not.

The group discussed whether there was a "gold standard" for diagnosing CCSVI at this point. Some members suggested that the methodology Dr. Paolo Zamboni used would be a good place to start noting it was difficult to say right now whether his is the best test or not. There was discussion about different diagnostic methods providing different results and a comment that this problem underscores the need for the current imaging studies.

The group agreed to continue the discussion about what is needed to move forward with pan-Canadian therapeutic clinical trials at its next meeting after receiving summaries of recent scientific meetings. It will also begin to discuss the question of the establishment of a registry of those who have had the procedure.