

Summary – CCSVI Working Group Meeting, October 3, 2011

The CCSVI Working Group met by teleconference.

Participants

Linda Lumsden, Chair	T.J. (Jock) Murray
Shelley Black	James Orr
Marilyn Lenzen	Brock Winterton
Linda Molyneux	Yves Savoie (ex officio)
Guest	Francine Anne Roy
Staff resource	Deanna Groetzinger

Presentation on Canadian MS Monitoring System

The focus of the meeting was a presentation by Francine Anne Roy, director of Health Spending and Registries for the Canadian Institute for Health Information (CIHI). She is leading the development of the Canadian MS Monitoring System (System).

Ms. Roy provided an overview of the System. Minister of Health Leona Aglukkaq announced the creation of the System in March 2011 and that CIHI would be responsible for its development with funding from the Public Health Agency of Canada. CIHI's responsibility is to develop the System, collect data and provide that data to governments to assist in decisions and policy making regarding health care needs. The System will collect data on MS broadly as well as specifically on the CCSVI procedure.

She noted that CIHI is responsible for 27 databases and many registries. Established in 1994, it is an independent, not-for-profit corporation that is arms-length from government. It is funded by federal, provincial and territorial governments and guided by a board of directors of health leaders from across the country.

Ms. Roy said following the announcement in March, CIHI immediately did an assessment of the current environment to determine what type of data on MS already exists. It was determined there was a gap in information, and it was decided to develop a system that would address the broad information needs related to MS and collect information on individuals living with MS in terms of demographics, geographic distribution, diagnosis, treatments and outcomes. She said the System is not a CCSVI registry per se but information about CCSVI will be collected and included in treatments and outcomes. Those developing the system are being careful not to duplicate other initiatives. CIHI is aware of other data collection initiatives outside of Canada and is working with them.

The objective is to build a relevant and useful System to help manage MS. She described it as a multi-phase approach. The first phase is focusing on building the data system that can access and process data. The System will be built so there is flexibility to add more components during later phases. The System will use recognized best practices, standardized data and sound management.

CIHI is working closely with a number of stakeholders to build the System, including the MS Society, the Canadian Network of MS Clinics, federal, provincial and territorial governments and people with MS. She pointed out CIHI is a secondary data collector. The data is owned by others, i.e., MS clinics and governments. CIHI is working with the clinics to develop the best data collection process. It is important to avoid duplication and not to impede health care professionals providing current care. Participation in the data collection is voluntary at this time. Ms. Roy said privacy concerns are being an important consideration, and CIHI is aware of all privacy and security needs and has developed expertise on safeguarding privacy of individuals through its previous work.

CIHI has established two advisory committees: one involving a number of stakeholders including people with MS and another which involves technical experts. Meetings with the advisory committees had already taken place. A communications strategy is also under development. She said a minimum data set will be created by early November. At that time, it will be possible to see what data already exists and then start to consolidate. She emphasized CIHI is building a longitudinal long-term monitoring system, not a system for just five or 10 years. The ultimate goal is to bring information back to Canadians to improve outcomes for people with MS.

Following is a summary of answers to questions by CCSVI Working Group members:

- Ms. Roy acknowledged there could be a challenge to the collection of data if people do not attend MS clinics or if they do not let clinic neurologists know they have had the CCSVI procedure. She said it is recognized the clinics do not represent the entire MS population in Canada but that they are a starting point. One proposal under discussion is to facilitate people with MS providing information to the system.
- In response to a question about discussions with provincial and territorial governments, Ms. Roy said a provincial-territorial committee has been formed to address the needs of project. The liaison province is Manitoba. The first action has been to share with provinces the assessment done with clinics to let provinces know the cost of participating. She added the advisory committees have provincial and territorial representatives so they can communicate easily.
- In response to a question about access, Ms. Roy said CIHI allows access to data to researchers, clinicians and government health care managers. If they are data providers, they have access to their own data. If they are not a provider, access can be provided to data in aggregate, and the identities of individuals are protected.
- In response to a question as to whether there are experts on CCSVI on the advisory committees, Ms. Roy said as of yet there are no vascular surgeons on the committees right now. In the future, sub-working groups will be created to get that expertise. She added CIHI has contacted other jurisdictions and will do more outreach internationally at meeting such as the upcoming ECTRIMS conference. It was suggested CIHI also do outreach at the upcoming International Society of Neurovascular Disease conference.
- In response to a question about how information would be captured on the existence of CCSVI, where treated, what part of body was treated and whether the treatment involved a balloon and/or stent, Ms. Roy said it was too early to answer that right now. At the advisory committee meetings, it was clear that capturing the answers to these questions was a priority. As yet, the specific questions have not been determined.

- In response to a question as to whether MS clinics have started to gather information on CCSVI as yet, Ms. Roy replied that to her knowledge, they had not.
- In response to a question about the composition of the advisory committee, Ms. Roy said the names of committee members will be posted on the CIHI website.
- In response to a question about what connections will be made between the System and registries and studies in Alberta, British Columbia and Newfoundland and Labrador, Ms. Roy said CIHI officials are aware of the initiatives in those jurisdictions and have made connections with officials and researchers involved in each of them.
- In response to a question as to whether System managers are in contact with CIHR regarding the clinical trial initiative. Ms. Roy said she is in contact with CIHR officials and have established a good relationship. She noted the CIHI System will not duplicate Canadian Institutes for Health Research (CIHR) initiative.
- In response to a comment about privacy needs if clinical trial information were to be included, Ms. Roy said CIHI will not be getting information directly from clinical trial databases since that would be too complicated. Instead CIHI officials, with the MS clinics, will develop a minimum data set that would come from clinic visits, i.e., information on diagnosis, treatment and outcomes.

Advice to board

The chair noted the CCSVI Working Group terms of reference require the national board of directors to review annually the continuation of the group. The input from group members is that the group should continue its work with the focus on monitoring clinical trials and the Canadian MS Monitoring System. This recommendation will be provided to the national board of directors.

CIHR CCSVI clinic trial

There was a general discussion about the design of the CIHR CCSVI clinical trial which is described as a Phase I/II study. A Phase I study is typically small with approximately 30 participants with the objective of establishing safety. A Phase I /II clinical trial probably means the numbers will be in the hundreds, not thousand. Some members wondered why a Phase I was needed since they believed the safety of the CCSVI procedure has been established. Other members said there isn't unanimity that the procedure is safe. It was noted that if the clinical trial is to be a blended Phase I/II study it will have to be designed as double-blind from the beginning.

It was agreed a representative of CIHR will be invited to present to the group about the CCSVI clinical trial as soon as possible.

Possible topics for future meetings

Participants discussed other topics for future working group meetings. These include whether there is sufficient information available to people who are considering treatment; inviting a representative from the Alberta observational study to present to the group; inviting a representative from one of the provincial colleges of physicians and surgeons to present as to how they make decisions.