

## **Submission to Standing Committee on Health – 24 July 2015**

### **A submission on behalf of the consumer organisations CCSVI Australia and the Multiple Sclerosis Network of Care Australia**

#### **Part 1 – An Overview**

**Committees Terms of Reference:** The Standing Committee on Health will inquire into and report on Chronic Disease Prevention and Management in Primary Health Care.

**Chronic Diseases encompassed by this Submission.** Multiple Sclerosis, Chronic Cerebro Spinal Venous Insufficiency and more than 20 other chronic disabilities associated with these conditions – including;

Extreme fatigue, progressive muscle function deterioration (including spasticity, lack of mobility, weak hands/arms and lack of coordination), bowel and bladder problems, temperature intolerance (including extremely cold extremities), visual and speech problems, cognitive problems (including 'brain fog', concentration, memory, mood, frustration and depression), abnormal sensory symptoms (including numbness, pain, headache, pins and needles).

Sometimes described as a 'slow stroke' and to varying degrees, a person diagnosed with MS will progressively experience any or all of these conditions.

**Australia has no NHMRC endorsed MS Guidelines.** While not necessarily directly related to this submission there is a broader, and potentially over-arching issue whereby NHMRC has re-affirmed that "Australia has no NHMRC endorsed clinical guidelines for the primary and secondary care of people with multiple sclerosis nor is it aware of any plans for their development.

It went on to say "starting points" to initiate the development of such guidelines could include the State Chief Health Officers, the CEO of NHMRC or Australia's Chief Medical Officer and that funding is always an issue, so if there is a funding source, that makes it easier.

**Purpose of this Submission.** There is an avalanche of new knowledge associating vascular irregular irregularities with the foregoing disabilities. This is attracting significant debate amongst medical researchers. However that is not what this submission is about (or relies upon).

**This submission is about seeking the support of the Parliament to assist in accelerating the processes whereby what is being learnt is better translated into benefits for patients and reduced government outlays.**

Simplistically, but by way of example, in excess of 80% of pwMS (properly tested) have vascular irregularities with approximately the same population percentage experiencing significantly disabling MS fatigue. 70% of all people leaving the workforce report doing so because of this fatigue. Time after time treating underlying vascular irregularities (via angioplasty) not only eliminates/significantly minimises MS fatigue but can also give rise to significant improvements in most of the other MS related disabilities identified above..

This report seeks the assistance of the Parliament in accelerating these outcomes across the Australian MS community.

**About the Australian MS Community.** 24,000 Australians are currently diagnosed with Multiple Sclerosis (MS). It is a progressive condition the cause of which is not known and for which there is no cure or long term effective containment. Its presence frequently becomes apparent during early to middle adulthood from which point, and over an extended time spans (up to 20 years) wide ranging disabilities can progressively develop.

Since 1993 people with relapsing remitting forms of MS have been offered access to a range of subsidised pharmaceuticals intended to provide relief by suppressing the activity of the immune system. Subsequent long term studies confirm that none of these drugs impact on long term MS progression.

**Treatment Delayed is Treatment Lost.** It is demonstrated that around 80% of those with MS have vascular irregularities that slow the flow of deoxygenated blood back to the heart. For over 5 years it is being consistently shown that treatment of this condition, by long established medical practice, frequently provides significant relief from many of the chronic disabilities associated with MS. The most common form of treatment (angioplasty) is a safe, minimally invasive, drug free one hour day surgery procedure.

**Reference Group.** On 1 July 2015 a Reference Group drawn from the Australian Multiple Sclerosis community provided an evidenced based report titled "Treatment Delayed is Treatment Lost". Covering the period May 2011 to June 2015 the Executive Summary says "It seems extraordinary that, after five years, less than 3% of the Australian MS population has been able to gain access to treatment - something is seriously wrong. Apart from potentially providing significant relief to seriously ill people, substantial economic benefits are being forgone". The report is at Part 2 of this submission. A number of elected representatives with an interest in health have expressed interest in this Report - which gave rise to this submission.

The authors say "the purpose of their recommendations is to add weight to a referral, to the Parliament's Health Committee, of multiple sclerosis matters reported by Hansard on 30 May 2011. While groundwork for a bipartisan referral commenced in 2012 the calling of the Federal Election made it impracticable to progress. It remains important unfinished business.

The report identifies the role of the Australian Parliament as "putting in place policies, programs and practices that support the advancement of CCSVI medical knowledge while, at the same time, addressing the ongoing CCSVI needs of Australians living with MS". It goes on to identify six associated key result areas - the achievement of which can be significantly enhanced via appropriately targeted Government policies and/or support. They are.

### **The Six Key Result Areas**

1. Fully funding of the already commenced trial at the Alfred Hospital in Melbourne - \$250.000 already raised by Australians with MS - needs a further \$200.000.
2. Additional clinical trials with a specific focus on the role of Percutaneous Venoplasty in addressing vascular irregularities and the consequential relief of most common CCSVI symptoms frequently experienced by many diagnosed with MS,

3. The implementation of an Australian National Monitoring System (ANMS) that includes retrospective opportunities for the registration/recognition of those that have/are being treated and captures relevant information. Also flagged by HealthPACT
4. Ensuring the availability of Medicare rebates for all recognised CCSVI related procedures.
5. The ANMS to also enable screening and treatment to be offered to those who may so benefit from symptom relief – over and above those participating in more comprehensive clinical trials.
6. Screening for possible vascular irregularities be undertaken during the diagnostic stages of MS as a prerequisite to qualifying for immunotherapy subsidies. Also flagged by HealthPACT

### **What are the anticipated Outcomes of Such Policies?**

Parliament's role as a stakeholder in the care and support of families living with these chronic diseases will be enhanced by;

1. Encouraging/facilitating improvements in the prevention and management of chronic outcomes through the provision of more appropriate primary care.
2. Better targeting of Medicare services
3. Better access to CCSVI diagnostic services
4. Expanded education for general practitioners and those diagnosed with MS
5. Appropriate access to specialist medical practitioners in the field of neurovascular medicine

On the fiscal side of things there are significant benefits associated with

6. A diminishing reliance on welfare, pharmaceuticals and NDIS
7. Increased workforce participation
8. Revisiting research funding priorities for these and associated chronic diseases

There is also a need for appropriate infrastructure/expertise, particularly in regional and rural Australia to support this transition - especially for the seriously disabled.

There will be some offsetting costs associated with early interventions, treatment and monitoring

In the overall scheme of things, there will be progressive but significant reductions in Government outlays - even if the benefits were confined to 20% of the Australian MS population (around 60% is a conservative estimate).

Not all of these changes will necessarily be well received. All change impacts differently upon different stakeholders.

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Next - Part 2 'Treatment Delayed is Treatment Lost'

A Gateway into the evidence that supports this Overview

## Part 2 – Treatment Delayed is Treatment

### Supporting a Submission to Parliaments Standing Committee on Health

Last Revised 21 July 2015

**Recommendations by the Reference Group established by  
Multiple Sclerosis Network of Care Australia and CCSVI Australia – July 2015**

#### **Executive Summary - Treatment Delayed is Treatment Lost**

The purpose of these recommendations is to add weight to a referral, to the Parliament's Health Committee, of multiple sclerosis matters reported by Hansard on 30 May 2011. While groundwork for this bipartisan referral commenced in 2012 the calling of the Federal Election made it impracticable to progress. It remains important unfinished business.

The Summary says "It seems extraordinary that, after five years, less than 3% of the Australian MS population has been able to gain access to treatment - something is seriously wrong. Apart from potentially providing significant relief to seriously ill people, substantial economic benefits are being forgone'

#### **Multiple Sclerosis**

24,000 Australians are currently diagnosed with Multiple Sclerosis (MS). It is a progressive condition, the cause of which is not known and for which there is no cure or long-term effective containment. Its presence frequently becomes apparent during early to middle adulthood from which point wide ranging disabilities can progressively develop.

Since 1993 people with relapsing remitting forms of MS have been offered access to a range of subsidised pharmaceuticals intended to provide relief by suppressing the activity of the immune system. Subsequent long-term studies confirm that none of these drugs impact on long term MS progression. More about MS Needs Issues and Expectations - <http://www.msnetwork.org/roadmap/issues.htm>

#### **Vascular Irregularities and Multiple Sclerosis**

By way of contrast, it is demonstrated that around 80% of those with MS have vascular irregularities that slow the flow of deoxygenated blood back to the heart. For over 5 years it has been consistently shown that treatment of this condition, by long established medical practice, frequently provides significant relief from many of the most common symptoms of MS. The most common form of treatment (angioplasty) is a safe, minimally invasive, drug free, one hour day surgery procedure.

**"Time flies when you've got your health back. Has it really been 5 years since people with MS started having angioplasty to clear their blocked jugular veins? I personally went from being unable to work for 12 months (and rapidly declining) to having the majority of my symptoms recede. I've been able to go back to full time employment, and enjoy my free time pain free, for all these years...Helen – Australia"**

This condition is known as Chronic Cerebrospinal Venous Insufficiency - CCSVI. The nature and scope of the underpinning vascular irregularities can present differently between individuals. Despite the high prevalence

Access detailed research references at <http://www.msnetwork.org/advocacy/healthcommittee.htm>

of this condition amongst those with MS, access to diagnosis and determination of appropriate treatment is extremely limited.

It seems extraordinary that, after five years, less than 3% of the Australian MS population has been able to gain access to treatment. Apart from potentially providing significant relief to seriously ill people, substantial economic benefits are also being forgone. Given that no new medical procedures are involved, and having regard to Australia's acknowledged excellence in the field of interventional radiology, something seems terribly wrong. More about Neurovascular Issues and MS - <http://www.msnetwork.org/ccsvihistory.htm>

### **Objective**

The purpose of this paper is to provide the Australian Parliament with information sufficient for it to proceed with an undertaking (25 June 2012) to the Australian MS community, that it would facilitate a referral to the Parliament's Health Committee of the matters raised in the House by the Member for Page on 30 May 2011 (in conjunction with World Multiple Sclerosis Day). Events leading to the calling of the 2013 Federal Election made it impracticable to progress this issue, which remains important unfinished business.

The recent emergence of an avalanche of new knowledge, relating to the involvement of the vascular system in multiple sclerosis progression, is also a motivating factor in asking for the continuance of this important undertaking. One example is the June 2015 stunning discovery that the brain is directly connected to the immune system by vessels previously thought not to exist.

Overturning decades of textbook teaching, these developments fit well with what is being learnt regarding CCSVI - potentially providing a completely new body of clinical evidence to support accelerating vascular interventions for many of those with MS. More about Parliamentary involvement - <http://www.msnetwork.org/advocacy/ccsvistrategy.htm>

### **About the Reference Group**

This group was established to progress issues identified in the Hansard record of the 30 May 2011. To facilitate this, a briefing note was provided to all of Australia's Federal Parliamentary representatives (and beyond) requesting that "the Australian Parliament put in place policies, programs and practices that support the advancement of CCSVI medical knowledge while, at the same time, addressing the ongoing CCSVI needs of Australians living with MS".

What followed was wide ranging feedback, discussion and research. Involved were the MS community, MS Australia, peak organisations, parliamentary representatives, advisory bodies and medical specialists (both in Australia and internationally).

For example Australia's peak Health Policy Advisory Committee on Technology (HealthPACT) identified a key question, as "Does Percutaneous Venoplasty make a difference in relieving the symptoms of multiple sclerosis by improving cerebrospinal venous drainage?" and went on to say that properly designed clinical trials would help to answer this question. More about the Reference Group - <http://www.msnetwork.org/trials.htm>

### **Research Capability**

One of the enduring legacies of this process is the HORIZONScan database. Developed to underpin the Reference Group's global research role, it is arguably one of the most comprehensive multiple sclerosis research databases across the globe. At least once every 24 hours several thousand global MS reference sites are screened (via leading edge search engine and database technology).

Access detailed research references at <http://www.msnetwork.org/advocacy/healthcommittee.htm>

What makes it different is that all of the parameters by which information is analysed are patient-cantered. It is proving to be a unique resource for families living with MS, service providers, researchers, policy advisors and parliamentary representatives. More about HORIZONSScan - <http://www.msnetwork.org/roadmap/index.htm#horizon>

### **The Six Key Result Areas**

The consultative processes, associated with the Reference Group's fact finding, have encompassed more than 500 individuals and organisations over a period of nearly 5 years - with the HORIZONSScan database currently identifying more than 900 associated titles. This process has enabled the identification of six key result areas - the achievement of which can be significantly enhanced via appropriately targeted Government policies and/or support. They are

- 1. Fully funding of the already commenced trial at the Alfred Hospital in Melbourne.**
- 2. Additional clinical trials, with a specific focus on the role of Percutaneous Venoplasty in addressing vascular irregularities, and the consequential relief of most common CCSVI symptoms frequently experienced by many diagnosed with MS.**
- 3. The implementation of an Australian National Monitoring System (ANMS) that includes retrospective opportunities for the registration/recognition of those that have/are being treated and captures relevant information. Also flagged by HealthPACT.**
- 4. Ensuring the availability of Medicare rebates for all recognised CCSVI related procedures.**
- 5. The ANMS to also enable screening and treatment to be offered to those who may so benefit from symptom relief – over and above those participating in more comprehensive clinical trials.**
- 6. Screening for possible vascular irregularities to be undertaken, during the diagnostic stages of MS, as a prerequisite to qualifying for immunotherapy subsidies. Also flagged by HealthPACT.**

### **Treatment Delayed is Treatment Lost**

The Reference Group noted that sole reliance on awaiting the outcomes of potentially long term, and/or protracted, clinical trials does not fit well in addressing the here and now well-being of many of those with MS. It said, "significantly enhanced understandings, including internationally recognised Australian expertise, now support a progressive but staggered approach (as illustrated above) - whereby details of all "standards based interventions" are routinely aggregated and analysed... Nationally and/or globally".

It went on to say, "it may well be that the environment supporting the Alfred trial evolves into a much needed Australian Centre for Neurovascular Medical Excellence with affiliations with the International Society of Neurovascular Disease (ISNVD)". It identified Mem-NET, a highly sophisticated database technology, as potentially underpinning this process. It also recommends that the Health Minister refer this issue to HealthPACT for guidance...

**Beyond the business model there is the issue of how best to protect vulnerable often seriously ill people with MS, from potentially overzealous commercial marketing practices. The Reference Group anticipated this eventuality in 2011 when it recommended that 'screening for possible vascular irregularities be undertaken during the diagnostic stages of MS as a prerequisite to qualifying for immunotherapy subsidies'.. HealthPACT also referenced this recommendation. While this is clearly an important role for government regulatory bodies nothing has yet transpired.**

## Peak Organisations

Australia's peak health advisory bodies (NHMRC and HealthPACT), along with MS Australia, all highlighted the role of properly designed clinical trials in guiding the diffusion of this new knowledge. The Australian Parliamentary response focused upon a bipartisan presentation to the Parliament's Health Committee with the aim of obtaining agreement from the Health Minister and NHRMC to fast track appropriate action. None of these bodies have yet facilitated funding support to fast track appropriate clinical trials

## Clinical Trials - Progress in Australia

The Australian MS community itself, in collaboration with the Alfred Hospital, Service Organisations and Charitable Bodies, have raised \$250,000 towards the \$450,000 needed to fully fund Australia's first (already commenced), internationally acclaimed, CCSVI clinical trial at the Alfred Hospital in Melbourne. More is needed. When commenting on the trial, Alfred Hospital's Dr Helen Kavnoudias said,

**'We hope to provide viable and valuable alternative to pharmaceuticals and provide new opportunities to greatly improve quality-of-life in at least two-thirds of MS patients'**

More about this trial - <http://www.msnetwork.org/advocacy/questions.htm>

## Importance of Standardised Protocols

In November 2014, the Journal of Vascular and Interventional Radiology published standardised protocols relating to non-invasive and invasive imaging protocols for detection of extracranial venous abnormalities indicative of Chronic Cerebrospinal Venous Insufficiency (CCSVI).

These protocols were developed under the auspices of the International Society for Neurovascular Disease (ISNVD). In July 2014, the Italian National Epidemiological Observatory on CCSVI made available, as a "gift to humanity" a free web accessible computer based global database called MEM-net. Incorporating the aforementioned protocols, MEM-net acts as a blind control eliminating a possible source of human error and subjective interpretation of CCSVI examinations.

It also enables the standardised storage, retrieval and analysis of patient medical data relating to all aspects of examinations and treatments. Included are the outcomes of past and present procedures and examinations including Neurological, MRI, CT Scans, Phlebography, Surgical, Echo Doppler Ultrasound (ECD), MRV, Angioplasty and other Therapies. Developers said, "We hope that in the future, everyone will use this data collection tool for all scientific work on this topic."

More about MEM-net - <http://www.msnetwork.org/ccsvihistory.htm#memnet>

## Addressing Discordant Feedback

The foregoing emphasis on the importance of standards well addresses feedback received by the Reference Group - especially regarding a spate of apparent divergent research outcomes. The reasons for such divergence were summed up in a 2014 meta-analysis by Dr Mariam Simka who said, 'considering the many faces of CCSVI, it becomes more comprehensible why the results of prevalence studies have been so discordant.'

**" Not only were the authors using different diagnostic modalities and distinct protocols, but (probably more importantly) they were not looking for the same pathology."**

Access this Analysis - <http://www.msnetwork.org/abstracts/ccsvi-overview-simkaMar-2014.pdf>

Access detailed research references at <http://www.msnetwork.org/advocacy/healthcommittee.htm>



## Discordant Reporting

Hansard referenced an example of this discordancy in the following terms, "the MS Australia website has a page on CCSVI headed 'Your questions answered' and there are differences between what MS Australia says and what the MS Network of Care says." The information on this page was subsequently removed when MS Australia and CCSVI Australia provided a United Statement to the Parliament.

Another reported example is a page on the website of MS Research Australia. Dated [26 June 2014](#) and originally titled "New studies from key international research groups question the validity of the CCSVI diagnosis and its usefulness in MS". Following criticism, this page was retitled, "New evidence on the rates of CCSVI in people with MS". Unfortunately the authors did not also readdress the substance of their conclusions to reflect the earlier research by Dr Simka. Also not referenced was the most significant research that concluded:

**"This pilot study shows that both a non-invasive and invasive multimodal imaging diagnostic approach should be recommended to depict a range of extracranial venous anomalies indicative of CCSVI. The findings from the 2 invasive techniques confirmed the existence of severe extracranial venous anomalies that significantly impaired normal blood outflow from the brain in this group of MS patients".**

The report of 26 June is understood to be the latest public commentary by MS Research Australia on the topic of CCSVI. It is noted that by early 2013 MS Australia and all of its State Branches had removed nearly all (apart from some very dated) CCSVI references from their web sites. Shortly thereafter MSA unexpectedly stepped back from the substance its United Statement commitments.

The reported reasons for this included that CCSVI was not a causal factor in MS (supporting research at the Austin Hospital has been questioned) and that Australia's strengths in MS research were better served elsewhere - potentially discounting the expertise of some of Australia's leading vascular specialists. See also footnotes.

## Emergence of CCSVI Australia

In the event, CCSVI Australia became a registered charity in its own right for the purpose of ensuring that the interests of people with CCSVI have continued representation and that the understanding and treatment of CCSVI continues to advance. Since that time, and Chaired by Bill Younger, former CEO of MS Australia NSW/VIC/ACT, it has also been catalytic in raising \$250,000 towards the \$450,000 needed to fund Australia's first CCSVI clinical trial at the Alfred Hospital in Melbourne - more is needed.

## Find Out More - Quick Reference Guide

On an ongoing basis, the Reference Group highlights representative abstracts from the global CCSVI knowledge base. This information is then broadly classified according to a range of "subject matter areas" relating to issues regularly discussed across MS consumer networks. These classifications comprise 10 broad subject matter areas and 10 "emerging questions" - Access the Quick Reference Guide - <http://www.msnetwork.org/advocacy/questions.htm#questions>

## Disclosures

Participation in the Network of Care, CCSVI Australia and the Reference Group is entirely voluntary - largely comprising Australian families living with MS, their friends and others entrusted with their care. There are no known no affiliations with pharmaceutical organisations or associated entities.



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#### Footnotes

- 1 MS Australia identifies itself as the national voice for MS on behalf of State Member organisations - to the benefit of people affected by MS across the country. It also works closely with MS Research Australia to fund research into better detection, treatment and cure of MS. These organisations do not provide individual medical advice - that being a matter entirely between an individual and their medical advisers.
- 2 The web sites of MS Research Australia acknowledge support by pharmaceutical organisations for unrestricted research and educational grants. A further example is that a representative of the pharmaceutical company (Biogen) is one of the four members of MSRA influential International Research Review Board. Genzyme and Novartis are referenced on the web site of MS Australia in relation to their sponsorship of the 2014 National Advocates Conference.
- 3 People with MS have minimal direct representation on the Boards of MS Australia, MS Research Australia or the represented State Bodies.
- 4 When commenting upon the future relationship between those with MS and the State based bodies operating under the MSA banner MS Ltd said, in the light of NDIS "We're stepping away from a charitable/welfare model, into a competitive marketplace" On 21 July 2015 and in response to complaints the Chairman of the MS Ltd Board said 'I have instructed the CEO to remove from the website the statement. The sentence is misleading'

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