

"Dr. Jean-Paul Collet, a scientist with the government of Quebec, Canada has submitted for publication a study on the efficacy of Hyperbaric Oxygen Therapy in children with cerebral Palsy. We, as parents, were extremely disappointed in Dr. Collet presentation and have since discovered that Dr. Collet acted under orders of the government of Quebec, Canada to sabotage the study in order to find or reportedly find little beneficial effect of hyperbaric oxygen therapy in order that the government not have to pay for this therapy. A newspaper in Quebec reported that one of the researchers, Dr. Pierre Marois of Quebec could not stand back and watch this travesty in medical study go unanswered. He reports that the results were sabotaged and when contacted by other medical doctors he bravely admits how the results were a fraud. I urge The Lancet to thoroughly review and investigate the study before publishing the report. The Lancet does not need to entertain a report whose sole purpose was a predetermined deceit and cover-up This is not a radical parent talking, it is the truth and should be tested."

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Dear Dr. Butcher,

Thank you for bringing to my attention the letter sent to the Lancet by a group of parents regarding the Hyperbaric Oxygen Therapy for Cerebral Palsy Study. Whereas in principle, I am empathetic with the dedication of this group to find effective treatment for the children, I am disturbed by the accusations they have made. To say that I acted "under orders from the government of Quebec, Canada to sabotage the study in order to find or repeatedly find little beneficial effect of hyperbaric oxygen therapy in order that the government not have to pay for this therapy" and that "the results were a fraud" is untrue, unsubstantiated totally inappropriate, is a distortion of the truth and can be considered libellous.

These allegations are completely unfounded. The malicious personal attack on my integrity appear to be made with the objective of destroying my credibility as an independent researcher. Should you choose to give further consideration to this letter I would obviously request that you ask the parents to substantiate their remarks before you give such defamatory statements any consideration. I have forwarded the letter to Fonds de la Recherche en Santé du Québec (FRSQ) and the head of the Scientific Advisory Committee established at our request to independently review the quality of the study and the results. a completely independent manner (report is available)

In order to put this 'situation' in perspective I feel it is necessary to provide you with some background information with regard to my training and my work. As you can see from my CV which I attached I am a pediatrician with a PhD in epidemiology and MSc in health economics. I am Associate professor at McGill and director of the randomized Clinical Trial Unit (RCTU) at the Jewish General Hospital in Montreal. The RCTU team has had extensive experience conducting both publicly funded (MRC) and pharmaceutical industry funded RCT's (including IND submissions). All studies adhere to International Conference of Harmonisation (ICH) good clinical practice guidelines. I am committed to 'good clinical practice' based research which I also teach at McGill University in the Department of Epidemiology and Biostatistics (Faculty of Medicine) in a course entitled "Randomized Clinical Trial: from regulation to practice".

I expect that it is due to the RCTU's excellent reputation and standing with the scientific community that FRSQ approached us to investigate this question. That I was not 'emotionally' involved with this issue and did not have a vested interest in child rehabilitation or HBO therapy research allowed me to maintain professional objectivity. We at the RCTU accepted this project with my encouragement. I am sensitive to the needs of these children and the desperate

situation their parents are in, searching for a treatment for CP. I understand their desire to try anything that could improve the condition of their children. It is because of the social and emotional climate surrounding the study and the strong public health aspect of the question that I felt the need to get involved to help provide a clear answer.

The huge expectation of the parents in the benefit of HBO therapy has led to heated and unfortunately acrimonious exchanges when the results that was no effect. This great false hope has been fuelled by misleading publicity posted on the web by hyperbaric centers and because of the personal conviction of physicians like Dr. Pierre Marois, who are also owners of hyperbaric centre (as acknowledged in the article). In their letter, parents refer to the position of Dr. Marois who "could not stand back and watch this travesty in medical study go unanswered". This statement is also a distortion of the truth. You will note that Dr. Marois accepted to sign the authorship agreement and is co-author of the article. The present conflict stems from a situation where parents and a few physicians are unable to accept the results of the study that unequivocally indicate that HBO therapy for cerebral palsy is ineffective.

I hope this information useful for you to make a decision; should you have any question, please do not hesitate to contact me.

If there is any question regarding the quality of the study and the conclusions, the whole study process as well as the source documents, database, statistical analysis can be audited at any time.

Sincerely,