Letter to the Editor

(Answer to Dr Pelz and Professor Milne):

**Re: Raymond J, Mohr JP. The Prevention of Hemorrhagic Stroke.
Interventional Neuroradiology 14: 365-373, 2008**

Where is the problem with trials on Unruptured Aneurysms and AVMs

We thank Dr Pelz and Professor Milde for expressing interest in our article. We regret they did not like it, concerned that philosophically naïve physicians could read our text and be 'confused' or 'troubled'. Their intention is to reassure them, but how and more importantly, why?

First, how: Their first strategy is to label everything controversial; we suppose they would claim there is no Truth, everything being relative. They claim 'some studies are flawed' but we 'mislead the reader into believing that the matter of their validity has been settled'. Alternatively, 'RCTs are established methods to address medical uncertainty, but this subject is not without controversy'. Hence they show a lot of uncertainty regarding what could count as medical knowledge; it is strange how quickly this uncertainty can vanish when time comes to make a recommendation to a particular patient. Painful or not to admit, there is nothing controversial about the superiority of the methodology of RCTs, or the lack of validity of natural history studies in the way they have been executed; the latter evidence has always been classified as class IIb, level C¹.

A second strategy is to pinpoint was lacking in this article: a discussion of the shortcomings of the available evidence and arguments that use 'understandable science and logic'. Our assumption was that most readers of *Interventional Neuroradiology* are familiar with the literature and needed no repeat of the obvious, nor proof that the need for the trials was clear. We had many opportunities to discuss scientific issues with Dr Pelz and many others in meetings and articles and will gladly offer a lengthy

bibliography on these points²⁻⁶. What has kept us in a permanent state of wonder is how slow have been the recruitment to these two trials given the array of publications and their unsettling nature indicating the interventions may be more hazardous than what is believed to be the natural history.

Scientific validity is not the subject matter here.

A third strategy is to imply that by quoting Galen or Dewey, we have trespassed our area of expertise, to enter the territory of Philosophy, 'a profession with its own history, methods, and literature'. But Aristotle or Galen are not, as Professor Milde and Dr Pelz suggest, the 'framework' of these trials; evidence-based medicine is. There was a time when Dewey or Aristotle were part of a general education. We are sorry to learn they are now reserved to professional philosophers. We could remind our critics that Galen was a doctor, or that Greek empiricists are an important part of the history of ancient medicine. This would be a silly fight if it did not reveal a deeper problem: according to the authors of this letter, we should have referred to specialized journals or institutes (and perhaps be ethicists), if we wished to have the authority to discuss ethics. We should be philosophers to quote Galen. Now if ethics is reserved to ethicists, Dewey to philosophers, perhaps science belongs to scientists, thinking to thinkers, and clinical practice to practitioners. There is great peril if doctors are kept on the sidelines, cannot understand, interpret, or discuss the jargon of experts, the science of their devices, the ethics of their practice, or the methods of their trials.

The problem is that for all we know, decades of studies in research institutes or at the Hastings Centre may never reach that privileged,

private moment when individuals, physicians and patients, decide what to do with what they have.

The major problem is located in this gap between what is recognized, by some specialized scientific and ethical groups as to what should be done, and what actually happens in clinical practice. This brings us to the second question we introduced: Why would our critics want to reassure the reader? What is so troubling about 'troubled' physicians? What is so subversive about trials constructed on the principle that risky preventive actions must first show evidence that they are beneficial before recommending them on as large a scale?

This article was written by physicians for their colleagues, in an attempt to convince them to participate in these trials. We hoped to stir the thoughtful replies of those currently unsettled by the uncertainty of whether to treat or not, how to present the uncertainty to a concerned patient, and how to feel comfortably among

those colleagues who join in the same effort. Progress and answers to the most vexing problems of modern medicine cannot come from secluded research or ethics institutes; they can only come from clinical practice. This is why practitioners should be allowed to discuss science, ethics, Dewey, Chinese philosophy, or whatever could help bridge the gap between what is scientifically sound, ethically respectable and clinically applicable. Dr Pelz and Professor Milde were appalled by the caricature we drew of the divorce between clinicians and scientists. We must have written awkwardly if we do not converge here: we aim at a reconciliation between science, ethics, clinical trials and practice. Science and ethics, the way we understand them, are not the privileges of an elite. If they are meant to be vehicles of freedom from ignorance, fashion, habits and human error, they belong to patients and their physicians in their constant struggle for better care and better outcomes.

References

- 1 Meyers PM, Schumacher HC et Al: American Heart Association. Indications for the performance of intracranial endovascular neurointerventional procedures: a scientific statement from the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. *Circulation*. 119(16): 2235-2249, 2009.
- 2 Raymond J, Molyneux AJ et Al: Safety and efficacy of endovascular treatment of unruptured intracranial aneurysms in the prevention of aneurismal hemorrhages: A randomized comparison with indefinite deferral of treatment in 2002 patients followed for 10 years. *Trials*. 9(1): 43, 2008.
- 3 Raymond J, Guillemin F, Proust F, Molyneux AJ, Fox AJ, Johnston SC, Meder JF, Rouleau I, and the Trial on Endovascular Aneurysm Management (TEAM) collaborative group. Unruptured Intracranial Aneurysms A Critical Review of the International Study of Unruptured Intracranial Aneurysms (ISUIA) and of Appropriate Methods to Address the Clinical Problem. *Interventional Neuroradiology* 14(1): 85-96, 2008.
- 4 Stapf C: Endovascular management of unruptured intracranial aneurysms: the dawn of a multidisciplinary treatment paradigm. *J Neurol Neurosurg Psychiatry*. 2006 Jun;77(6):e1. Erratum in: *J Neurol Neurosurg Psychiatry*. 77(6): 804, 2006.
- 5 Hartmann A, Mast H, Choi JH, Stapf C, Mohr JP. Treatment of arteriovenous malformations of the brain. *Curr Neurol Neurosci Rep*. 7(1): 28-34, 2007. Review.
- 6 Fiehler J, Stapf C. ARUBA—beating natural history in unruptured brain AVMs by intervention. *Neuroradiology* 50(6): 465-467, 2008.

Jean Raymond, M.D.
CHUM Notre-Dame Hospital
Montreal, Canada
E-mail: jean.raymond@umontreal.ca

J.P. Mohr, M.D.
Columbia University Medical Centre
New York, USA
E-mail: jpm10@columbia.edu