

Whiplash study remains valid

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Trying to follow the convoluted ethics considerations involving an SGI-sponsored study into medical claims by auto accident victims in the province is enough to give anyone whiplash.

A report last week by the University Committee on Ethics in Human Research said that the 1997 application for an ethics review by U of S researchers conducting the whiplash study didn't make adequate provision to obtain informed consent from participants.

The finding, which runs counter to a determination by an earlier review panel that the 1997 study, as well as a 1994 study for SGI, had been done properly, has led to calls from the public insurer's critics, such as the Coalition Against No Fault, to destroy what they call "tainted" data.

Even SGI, which paid for the study that reportedly cost \$1.5 million, is concerned about the UCEHR finding. Company vice-president Earl Cameron says SGI relied on the expertise of U of S officials to conduct the research and had believed for six years that the study had met ethics guidelines.

While Cameron and everyone else rightly may be concerned, the committee's report isn't a cut-and-dry finding of ethical misconduct by the researchers who either misled or forced claimants into participating by suggesting their SGI benefits would be cut off should they refuse to co-operate.

Rather, UCEHR says, its work was limited to reviewing documents available to the original ethics committee and didn't involve determining if researchers had obtained free and informed consent.

Noting that the "documentation wasn't complete to allow the committee to reach a firm opinion," the panel report goes on to say that "in several places, the researchers reiterate the participants would be allowed to refuse or terminate participation."

Further, it makes reference to a letter that was to be sent to the claimants 10 to 14 days before telephone contact, which clearly informs them of their right to refuse to co-operate without affecting their claims.

"If this letter indeed was sent and received by all participants, the committee judged that participants would have been adequately informed of their right to refuse to participate."

The UCEHR reports notes that it's often difficult to separate a program evaluation (which the whiplash researchers deemed the SGI study) from a research study, and notes that "neither the guidelines at the time, nor the current guidelines speak clearly" on how to differentiate between them.

Given the sentiments of those who've opposed SGI's adoption of no-fault -- the insurer says it keeps rates low and provides injured persons with better rehabilitation coverage -- the reaction to UCEHR's highly qualified findings of ethically questionable practices on the whiplash study is understandable.

Even though SGI now offers Saskatchewan motorists a choice of insurance plans with Canada's only parallel tort/no-fault system, critics aren't about to let go a chance to try to discredit a controversial study, accepted for publication in the prestigious *New England Journal of Medicine*, that found whiplash victims reporting recovery twice as fast under no-fault.

Participants in the study had signed SGI benefits applications that clearly stipulated that information about their claims would be shared with U of S researchers. Even though UCEHR deems that this consent cannot be said to apply to participating in a research study, it also states that "our committee was not in a position to know what constituted common practice at the time the protocol was evaluated."

While in hindsight one can point to many things researchers could have done better in 1997, the reality is that Canada's research ethics process has gone through "sweeping reforms" that have

improved things for today's researchers and their subjects.

In the whiplash study, however, despite calls to scrap the data and even SGI's own concerns, there's nothing to suggest that the findings themselves are off-base.

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