life-threatening conditions. However, we do not feel that such treatment is appropriate in self-limiting conditions where it is of dubious benefit (e.g., in cases of poison ivy).

Our goal is not to "embolden lawyers" or increase the number of lawsuits. Rather, we are attempting to alert physicians to what we feel is strong presumptive evidence that some association exists between short-course steroid therapy and the development of avascular necrosis. There is much more to learn regarding this condition, and our series does not provide conclusive proof that there is a cause–effect relationship between the two. However, avascular necrosis is a crippling condition in young adults and the distressing number of cases that we have seen, and continue to see, following the use of steroid medication stimulated this report.

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The ethics of anonymous chart reviews

Although the approach used by Jacques Lemelin and colleagues to measure the effectiveness of a multifaceted intervention to improve preventive care in family practices in Ontario[1] may be methodologically valid, it raises important ethical questions.

Each of the 40 family practitioners in the study provided informed consent to participate, but it appears that repeated chart audits were done by various research personnel without the knowledge of any of the 4000 patients in the trial. In what seems to be an about-face, when telephone interviews were conducted with 1150 of these patients, all were asked for informed consent. Fifty-two (4.3%) of them refused to be interviewed. Why did the family physicians and researchers feel that they had the right to share patients' confidential files without consent as long as the patients did not know about it, but that consent was needed when the patients were to learn about the use of their medical charts for research purposes? Were the patients who were contacted for the telephone interviews told that their charts were being reviewed by strangers and were they given the option to refuse to have their charts used?

Although the study protocol was approved by the Ottawa Civic Hospital Ethics Review Board, we are left wondering whether researchers should obtain explicit consent from patients before they access patient-identifying data. Was the decision not to obtain patient consent made because the logistic difficulties associated with obtaining consent might have compromised the external validity of the study? Do the distinctive features of cluster randomized trials entail new ethical principles, or careful application of existing principles? If a physician gives consent to have his or her behaviour measured in such a trial does this transcend the right of patients to privacy?

Although we agree that outcome measurement is challenging, we feel uneasy about the achievement of research goals at the expense of patients' rights. Our letter should not be interpreted as a personal criticism of Lemelin and colleagues but as an invitation to an open discussion about the issue of obtaining consent in primary care, health services and public health research.

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[The authors respond:]

Janusz Kaczorowski and John Sellors question the ethics of an anonymous chart review. Their concern seems to be the apparent inconsistency in our approach to obtaining consent: we obtained consent from physicians to participate in the study and from patients before their telephone interview but we did not obtain consent for patient chart reviews.[1] Our approach is entirely consistent with the *Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans*, which states that researchers must obtain consent for physician participation in studies and for patient telephone interviews but not for chart reviews.[2] Section 3, paragraph C, states that "secondary use of data refers to the use in research of data contained in records collected for a purpose other than the research itself. Common examples are patient or school records or biological specimens, originally produced for therapeutic for educational purposes, but now proposed for use in research. The issue be-