Quality of Reporting and Publication Bias in Early Phase Oncological Trials

A study of publication practices of pharmacodynamic studies in phase I and II cancer trials.

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Introduction: Early phase trials in cancer are increasingly incorporating pharmacodynamic study components in trial design. The typical aims of such studies are demonstrating proof of principle, gathering evidence of biological activity, or guiding dosing decisions in later trials. Pharmacodynamic studies often require collection of tumor tissue through biopsy.

The aim of our research is to determine the extent to which pharmacodynamic studies involving biopsy are not reported. As many as a third of phase I cancer studies go unpublished after seven years; similar trends have been described for phase II trials as well. Though many trials are now registered, pharmacodynamic studies within them are not always recorded in registries. In addition to estimating the frequency of PD nonreporting, we would like to investigate why this occurs. Our ultimate aim is to establish an evidence base for improved pharmacodynamic reporting practices.

Design: Our study consists of two components:

a) Empirical study of incomplete or non-publication: Pharmacodynamic studies are identified using AACR and ASCO conference abstracts. PubMed is used to identify the proportion of these that end up as full publications. Questionnaires are sent to the corresponding authors on publications where pharmacodynamic studies are not published or are incompletely published.

b) Nonpublication Survey: Questionnaires regarding publication practices are sent to investigators who have led phase I cancer trials with a pharmacodynamic component. These investigators are identified using PubMed.

Protections for Survey Respondents: Our protocol has been reviewed and approved by McGill’s Institutional Review Board (IRB). Questionnaires will be sent initially by email. Positive responses will be interpreted as consent. When responses are received, the email will be converted into a text file and immediately deleted. Text file will be stripped of identifiers and assigned a numeric, which will be linked to identifiers with a key. The key for the purposes of making sure that multiple questionnaires are not sent to the same investigator. The key will be retained in a locked filing cabinet, and destroyed immediately upon completion of data collection. No demographic information about investigators will be collected. No identifying information will be published.

Who we are: This study is being led by Jonathan Kimmelman, a researcher in the Biomedical Ethics Unit / Social Studies of Medicine at McGill University. You can learn more about Kimmelman at http://www.mcgill.ca/biomedicalethicsunit/faculty/kimmelman/. The team also includes a research assistant, Georgina Freeman, and an oncologist consultant, Janet Dancey.

Questions: Should you have questions or concerns about our study, please contact jonathan.kimmelman@mcgill.ca or georgina.freeman@mail.mcgill.ca.