

Clinical Trial Research News

From the Office of Clinical Research

Volume 10, Issue 1

January 2008

To Contact Us:

Noreen Allsopp, CCRP
Assoc. Research Coordinator
Ph: 235-3813

Lorie Forbes
Admin. Manager
Research Enterprise
Ph: 258-1044

Terry Sawicz-Hanesiak
Regulatory Affairs / QA Assoc.
Ph: 237-2226

This newsletter is published on a quarterly basis and is designed to provide an information source for anyone interested in Clinical Research. Please contact Noreen if you would like to be added to / deleted from our mailing list.

Announcements

Change in Publication

Please note that the Clinical Trial Research News will be published quarterly now as opposed to bi-monthly. If you have anything you'd like to add to our newsletter, we'd love to hear from you. Please contact Noreen at 235-3813 or at nallsopp@sbgh.mb.ca

Statistics and Medical Research

Evaluating Meta-Analysis Studies

Meta-analysis emerged in the medical literature in the early 1980s as a specialized type of review article and has since gained increasing recognition and significance as an important research method. Many important medical decisions and the allocation of financial, personnel and technological resources are based on the findings of meta-analysis research.

Meta-analysis is sometimes described as an overview or a "pooled" analysis in which formal statistical methods are applied to combine outcome results from multiple studies of a similar nature. Meta-analysis is a specialized technique which serves as an adjunct to the more traditional review article which examines published studies on similar topics from a more descriptive perspective.

- Although systematic reviews of clinical trials often provide an objective and condensed picture of a complex topic, they are subject to various biases which that can undermine their findings. The most common bias is the element of subjective judgment whereby authors may selectively highlight or downplay individual studies. Meta-analysis was developed, in part, to overcome subjective biases and provide a more objective analysis of medical studies which examine similar clinical issues and treatments.

Advantages of Meta-analysis

- Combining clinical trial results from many studies increases the overall sample size for the analysis which, in turn, increases the statistical power for evaluating treatment effects. The increase in sample size means that more moderate treatment effects, which may be clinically important, have a greater chance of being detected and declared statistically significant.
- Meta-analysis, by pooling the results from a large number of studies, tends to neutralize extreme findings (positive or negative) from individual clinical trials.
- By pooling large numbers of studies, meta-analysis can more accurately identify subgroups of

patients who may respond favorably (or unfavorably) to a given treatment regime.

- By combining related trials from different geographical regions or countries, meta-analysis enriches the variability of patient groups, providing greater generalizability of the treatment efficacy

Disadvantages of Meta-analysis

- Combining all clinical trial results means that data is pooled from studies that may vary greatly in methodological quality and sophistication.
- Retrieval bias is another problem with meta-analysis. Studies may not be included in the pooled findings if they are published in foreign-language journals or in non-medical disciplines.
- Publication bias arises when negative or neutral clinical trial results are not included in the meta-analysis because they lack statistically significant positive results and were either not submitted for publication or were rejected for publication by leading medical journals. Studies with smaller sample sizes may be overlooked as they are less likely to be published than larger clinical trials.
- Many published clinical studies may not report the data related to the particular outcome measures relevant to the meta-analysis. Attempts to acquire this data from the study investigators may not always be successful.
- Combining apparently similar clinical trials in the meta-analysis may be problematic. Individual studies may differ greatly in terms of patient selection, characteristics, compliance, treatment intervention and time points for assessing treatment effects.
- Establishing rigorous standards and criteria for including studies in the meta-analysis (such as specific patient groups, treatment intervention and duration) may introduce systematic bias by excluding relevant studies that do not meet the strict criteria of the meta-analysis.

The above considerations need to be kept in mind when reviewing the results of meta-analyses and when making important clinical or public policy decisions based on the findings of a meta-analysis. Although meta-analysis is a powerful statistical tool, it is based on certain assumptions and inherent biases that should be carefully examined before concluding that the findings of the meta-analysis are sound and definitive.

This article is authored by OCR statistical consultant Doug Staley. Doug teaches statistics at the School of Medical Rehabilitation, University of Manitoba and has conducted medical research at SBGH for more than 25 years. Readers are welcome to submit questions or suggest topics of interest.

Doug can be contacted through the OCR or by email: dstaley@mts.net or extension 2690.

Research Review Committee at St. Boniface Hospital

Deadlines for RRC Submission

January 2, 2008
January 30, 2008
February 27, 2008
March 26, 2008

Meeting Date

January 9, 2008
February 6, 2008
March 5, 2008
April 2, 2008

The Biomedical (BREB) / Health Research Ethics Board (HREB) Submissions

Deadline for REB Submissions

January 14, 2008
February 11, 2008
March 17, 2008

Meeting date

January 28, 2008
February 25, 2008
March 31, 2008

Contact **Ethics** at **789-3255** with any questions you may have regarding your REB submission. Noreen is available to assist you with consent form development and the submission process at SBGH. Please always refer to the Research Ethics Board web site for the most recent submission forms and updates.

Options for Submission of Annual Approvals for Full Board Review (HREB/BREB)

In the past when annual approvals required full board review, hard copies of all documents were the only method for submission. For some time, the REB has been accepting and encouraging when possible electronic submission of Annual Approvals for full board review.

CCMB and other sites have been facilitating this trial whenever possible. The process has been beneficial for efficiency of the board meetings which will help us all. The REB realizes that not all sites have the technology to facilitate this process however; if you are interested and able to submit full board submission of annual approvals electronically, please contact Lorna in the Ethics office for details.

There were some inconsistencies in the website re: number of copies of documents for full board submission of annual approvals. This has now been corrected along with the number of copies required for annual approval submission (full board) for hard copy submissions. Let Lorna know if you find a web page with errors. If you'd like further information, please contact Lorna Pankratz, REB Secretary, (204) 789-3255 or at pankratl@cc.umanitoba.ca.

Call for Research Review Committee Members

If you or someone you know would consider becoming a member on the Research Review Committee (RRC), please let us know. The RRC is currently looking for a Research Nurse to fulfill the duties required of a voting member. You should be available on the 1st Wednesday of each month (except July) to attend meetings. If you would like more information, please contact Terry Sawicz-Hanesiak at 237-2226 or at tsawicz@sbgh.mb.ca

Research Informed Consent Forms in the Main Hospital Charts

This is again a reminder of your obligation to include a photocopy of the current approved Research Informed Consent Forms in the main hospital charts of patients involved in research studies.

The only time this would not apply would be if the Research Ethics Board requested that there be no mention of the study in the subject's medical charts. This exception would be made to comply with TriCouncil Policy Statement, Article 8.2. "The researcher must ensure that the results of genetic testing and genetic counseling records are protected from access by third parties (e.g. insurers, employers), unless free and informed consent to do so is given by the subject)."

If you have any questions or concerns do not hesitate to contact Terry Sawicz-Hanesiak at 237-2226 or at tsawicz@sbgh.mb.ca

Patient Registration Forms

The Office of Clinical Research has recently looked into patient registration through HISP. At this time, Research Nurses do not have the ability to register research subjects through the system. Therefore, all research subjects being seen at SBGH that have not been registered through another area in the hospital (i.e. Emergency, ACF, etc.), must be registered using the proper forms required by Patient Registration. This is for initial visits and any follow-up visits. A copy of the policy for Registration of Research Patients (VI-15) is attached for your review. The forms that are required can be obtained through the Office of Clinical Research or ordered on a Stock Requisition as per below:

7102-3182-2 N "Registration Form For Research Patients"

7102-3180-8 N "Return Registration Form"

7102-3181-5 N "Discharge Form"



SoCRA Certification – Saturday, May 10, 2008

We will be hosting another exam for SoCRA Certification here in Winnipeg at

St. Boniface General Hospital on Saturday, May 10, 2008 from 9 AM to 1 PM.
(Registration deadline is March 28, 2008).

SoCRA requires a minimum of 10 people to write the exam so if you are interested be sure to register before the deadline. You can find more information about the SoCRA certification and registration process at: <http://www.socra.org/html/certific.htm>

If you have any other questions, please contact Terry Sawicz-Hanesiak at 237-2226 tsawicz@sbgh.mb.ca.

New CIHR Guidelines for Research in Aboriginal People

(2007-11-02) The Governing Council of CIHR has recently endorsed [Guidelines for Health Research Involving Aboriginal People](#) (the "Guidelines"). The aim of the Guidelines is to facilitate research involving Aboriginal people, and to provide important safeguards for Aboriginal communities. They will foster an environment that integrates scientific excellence with priorities relevant to Aboriginal people by offering clear guidance on how to plan, initiate and conduct such research.

The Guidelines apply only to research projects to which CIHR has made financial contributions and in which Aboriginal people are recruited because they are Aboriginal.

The Guidelines will come into effect as of the **June, 2008**, funding competition. In the meantime, researchers, institutions and Aboriginal communities have the opportunity to familiarize themselves with the Guidelines' intent and requirements.

