



St-Boniface

Hôpital général • General Hospital

Clinical Trial Research News

From the Office of Clinical Research

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This newsletter is published on a quarterly basis and is an information source for anyone interested in Clinical Research. Please contact Terry (237-2226) if you would like to be added to / deleted from our mailing list.

Announcement

Please be advised that August 14, 2009 was **Michael Sinaisky's** last day with the Office of Clinical Research. Michael was with the Office of Clinical Research since November 2008. We wish him well with his future pursuits

Statistics and Medical Research

Non-Parametric Statistics

Most medical researchers are aware of the major parametric tests such as the Pearson correlation, t-test and analysis of variance (ANOVA), but have less familiarity with the non-parametric counterparts of these statistical tests. The non-parametric tests have traditionally been under-represented in published medical studies, partly because they are considered "weaker" than parametric tests. Although non-parametric tests do have less statistical power to detect significant differences between groups and treatments, they are more appropriate for data analysis when the underlying assumptions of the parametric tests are not met. It is important that researchers develop an awareness of the main non-parametric tests and become knowledgeable about their properties and applications.

Levels of Measurement

Traditionally, statisticians have recommended using non-parametric statistical methods to analyze data that is nominal or ordinal in nature and parametric statistical techniques for data which is interval or ratio scaled. Consideration of the level of measurement of data is therefore important in determining the appropriate method of data analysis in a research study. The most common classification of the scales of measurement of variables defines four levels, ranging from the least exact (nominal) to the most precise (ratio).

- Nominal measurement distinguishes between categories (e.g. gender, marital status), but there is no attempt to quantify differences between the categories.
- Ordinal measurement orders or ranks members of a set (objects, people) from most to least with respect to some characteristic (e.g. order of finish in a race). There is no attempt to determine the distance between the rankings.
- Interval measurement occurs when there are equal distances between each pair of adjacent points on a scale, but there is no absolute zero value. An example is the Celsius temperature scale. The difference between 20 degrees and 15 degrees is equal to the difference between 10 degrees and 15 degrees. However 20 degrees is not twice as warm as 10 degrees since there is no absolute zero value (0 degrees is not the absence of temperature).
- Ratio measurement is the most precise level and includes an absolute zero value as well as equal distances along the measurement scale. For example, length is ratio data since 12 cm is twice as long as 6 cm and there is an absolute zero (0 cm).

Although nominal data can only be analyzed with non-parametric statistics, statisticians have determined that ordinal data can be analyzed by both non-parametric and parametric methods. Empirical studies have clearly demonstrated that when ordinal data is treated as if it were interval or ratio data, the parametric analysis results are nearly identical to those yielded by non-parametric procedures. For instance, if data obtained from a 5-point Likert scale (ordinal measurement) is treated as interval data and analyzed with parametric statistics, the results will be almost the same as when the data set is analyzed non-parametrically.

Researchers should keep this in mind since medical data is often ordinal in nature. Applying parametric statistical methods provides a more powerful analysis. However if the data is strongly skewed and deviates significantly from a normal bell-shaped distribution of scores, then a non-parametric analysis is more appropriate.

Parametric versus Non-parametric tests

In general, parametric statistical tests are more powerful and sensitive, and are more likely than non-parametric tests to detect significant differences if they exist. They are also more flexible as they allow the researcher to study the effect of many independent variables on the dependent or outcome variable (e.g. multiple regression analysis) and also make it possible to study the interaction between variables.

Parametric statistical tests such as the t-test and ANOVA assume that the variables under study are normally distributed and the variance in scores is similar between samples (homogeneity of variance). However, numerous theoretical studies using computer modeling techniques have demonstrated that parametric tests are "robust" to substantial departures from the assumptions of normal distributions and homogeneity of variance. So applying parametric tests under these conditions does not seriously affect the validity of statistical inferences. However, when the violations of normality and homogeneity of variance are severe parametric analysis is no longer valid (e.g. data which is highly skewed or bimodal).

Non-parametric tests require no assumptions about the shape and distribution of scores of a variable in a sample or population and therefore are often called 'distribution free.' When data seriously violates the assumptions of normality and equality of variances these test should be applied rather than parametric tests. Non-parametric tests also have the advantage of being appropriate for small sample sizes ($n < 10$). A final advantage is that non-parametric tests handle outliers or extreme scores much better than parametric tests. This is because they rank scores rather than using the actual values in their mathematical procedures, thereby significantly reducing the influence of extreme scores in the analysis.

Non-parametric Measures of Correlation

The linear relationship between two variables that are interval or ratio scaled is measured by the parametric Pearson correlation coefficient. But when data is nominal or ordinal non-parametric correlation techniques should be employed.

- The contingency coefficient measures the relationship between two nominal level variables. The variables can be either dichotomous (e.g. gender) or have multiple levels (e.g. living situation).
- Either the Spearman's rho or Kendall's tau statistics can be used when measuring the correlation between two ranked or ordinal variables.

Non-parametric Tests of Differences Between Means

There are a number of non-parametric statistical methods that can be used to test the difference between the means of two or more groups or treatments.

- The Sign test is used with two related groups (the same or matched subjects, such as in a pre-post design). The Sign test measures the direction but not magnitude of difference between the two groups.
- The Wilcoxon Signed-rank test can also be applied to two related or matched samples and is a stronger test than the Sign test. It measures both the direction and magnitude of difference between two groups and is a counterpart to the parametric related groups t-test.
- The Mann-Whitney U test is one of the most powerful non-parametric tests. It is used to compare the differences between the means of two independent groups and is an alternative to the independent groups t-test when all of its requirements are not met (normal distribution and homogeneity of variance).
- The Kruskall-Wallis test is an alternative to the parametric one-way ANOVA which compares the means of three or more independent groups. It is appropriate when the data is not normally distributed and the variances within groups are significantly different.
- The Friedman test is the non-parametric equivalent of a repeated measures ANOVA which measures the differences between the means of three or more related or matched groups.

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, by email: dstaley@mts.net or directly at 237-2690.

Tri-Council Policy Update

Extension of Release Date and Expanded Opportunities to Comment on Revised Draft 2nd Edition of the TCPS

Ottawa (August 26, 2009)—In December 2008, the Interagency Advisory Panel on Research Ethics released a substantial revision to the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) for public consultation. The consultation period ended on June 30, 2009.

The Panel will release a revised version of the draft to the public for further comment in December 2009, followed by a 60-day period for written comments. The Panel intends to prepare a final draft based on those comments. In April 2010, the Panel will submit the final revision to the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC) and the Social Sciences and Humanities Research Council of Canada (SSHRC) for their consideration.

The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) was jointly developed in 1998 by CIHR, NSERC and SSHRC. The Agencies formed the Panel in 2001 to interpret and promote the TCPS. The Panel's mandate is to ensure that the TCPS evolves to keep pace with changes in research and society at large.

Research Review Committee at St. Boniface General Hospital

Deadlines for RRC Submission

September 30, 2009
October 28, 2009
November 25, 2009

Meeting Date

October 7, 2009
November 4, 2009
December 2, 2009

2010 DATES

January 6, 2010
January 27, 2010
February 24, 2010

January 13, 2010
February 3, 2010
March 3, 2010

Submissions to the RRC must be received in N1004 by 11:00 AM on the deadline date.

Contact the **RRC** at **235-3623** with any questions you may have regarding your RRC submission. Please always refer to the Office of Clinical Research and RRC web site for the most recent submission forms and updates.

<http://www.sbrc.ca/content/blogcategory/87/132/>

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

Deadline for REB Submissions

October 9, 2009 (Friday)
November 9, 2009
November 30, 2009

Meeting date

October 26, 2009
November 23, 2009
December 14, 2009

2010 DATES

January 11, 2010
February 8, 2010
March 8, 2010

January 25, 2010
February 22, 2010
March 22, 2010

Contact **Ethics** at **789-3255** with any questions you may have regarding your REB submission. Please always refer to the Research Ethics Board web site for the most recent submission forms and updates.

<http://www.umanitoba.ca/faculties/medicine/research/ethics/index.html>

Education and Training Events

Clinical Research Lecture Series at St. Boniface General Hospital

Interested in getting involved in Clinical Research? Clinical research refers to all research conducted with human subjects. These comprehensive introductory courses are specially designed for individuals with little to no previous research experience or those wanting a “refresher” on the latest information. The courses will present an overview of the language of clinical research, project design, roles and responsibilities of the Investigator and the research staff, and the regulatory and ethical environment for the conduct of clinical research.

Lecture Title	Date and Time	Location
Introduction to Clinical Research And Research Ethics	Thursday, November 5, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Good Clinical Practice (GCP) and Clinical Research Regulations	Thursday, November 19, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012
Clinical Research Project and Document Management	Thursday, December 3, 2009 1:30 PM to 3:30 PM	St. Boniface General Hospital – N1012

There is no charge to attend the lecture series but registration is required. For more information or to register contact Terry Sawicz-Hanesiak at (204) 237-2226 or tsawicz@sbgh.mb.ca .

SBGH Library kicks off their education sessions for the Fall of 2009

Further Information regarding session descriptions can be found at Education/Training Sessions page on the SBGH Library homepage and as a helpful link to our news page <http://bit.ly/49GXU7>.

PubMed: Basics (CME Credits) - Wednesday, October 28, 2009 1:00 pm-2:30 pm

Learn the basic mechanics of PubMed, the free Internet version of MEDLINE. Discover strategies that can make searches more efficient and your results more targeted.

PubMed: Advanced (CME Credits) - Thursday, November 26, 2009 2:00 pm-4:00 pm

Building from the Pubmed Basics, a graduated level of search techniques are presented. Manipulate medical subject headings (MeSH) and keywords searches in PUBMED to get the results you need.

RefWorks (CME Credits) - Tuesday, December 8, 2009 1:00pm-2:30 pm

RefWorks is a web based citation management program, similar in function to Reference Manager or EndNote, but free for all students and staff. Organize your references with this fantastic citation management tool, capture and share your references, generate a bibliography in any style, and cite with the Write-N-Cite tool.

For registrations, or inquiries, call 237-2807, fax 235-3339, or E-mail sbghlibrary@umanitoba.ca.

Additional Winnipeg Training Events

Recruitment & Informed Consent: Motivations, Challenges and Special Considerations – Researcher and Participant Perspectives (Event Poster Attached)

October 14, 2009, Noon to 4:30 PM

Theatre A, U of M Bannatyne

Video Links at Richardson Centre, U of M Fort Garry **and NG002 St. Boniface General Hospital)**

There is no charge to attend this event however, registration is required. Register on-line at;

www.acrpnet.org/GetInfoFor/InternationalChapters/Canada/UpcomingChapterEvents.aspx

Or

Contact Terry Sawicz-Hanesiak 237-2226 (tsawicz@sbgh.mb.ca) if you would like to attend the video link at St. Boniface General Hospital.

Regulations, Roles and Requirements: An Interactive Monitoring Workshop

November 9 and 10, 2009, 8:00 AM to 4:30 PM (Event Poster Attached)

Life Science Association of Manitoba (LSAM)

1000 Waverly Street

Instructors: ASKA Research Val Willets and Hannelore Vannetta

Fee: \$477.00 LSAM members, \$954 non-members

For additional training information please refer to the on-line LSAM schedule at www.lsam.ca

Canadian and US Training Events

MAGI's Clinical Research Conference - 2009 West

Operations - Regulatory - Contracts - Budgets

October 4-7, 2009 - San Diego, California

More Information Available at:

<http://www.magiworld.org/events/2009-West/>

Clinical Research: Aiming for the Top

October 22, 2009 – Hamilton, Ontario

ACRP – Canadian Chapter, More Information Available at:

<http://www.acrpnet.org/GetInfoFor/InternationalChapters/Canada/UpcomingChapterEvents.aspx>

Clinical Research Training Course: Providing the Tools for Effective Clinical Research

October 26-29, 2009 – Ottawa, Ontario

Ottawa Hospital Research Institute - More Information Available at:

<http://www.ohri.ca/clinicalresearchtraining/>

