

Clinical Trial Research News

From the Office of Clinical Research

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This newsletter is published on a bi-monthly 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.

Announcement

Please note that Trish Berry has recently accepted a newly created Administrative Secretary position within the Asper Centre. We will do our best to accommodate all requests but ask that you please be patient with us until this position is refilled. We wish Trish the best of luck in her new endeavors and at her new office.

Statistics and Medical Research

Graphical Presentation of Data: Correlation and Regression

Two of the most common statistical procedures are correlation and regression. Both techniques are widely used in medical research to analyze the relationship between two or more variables and, in the case of regression, to predict the values of one variable based on the scores of another variable. With both procedures the initial step is the creation of a graph or plot of the relationship between two variables.

Scatter Plot or Scatter Diagram

Correlation is a bivariate statistic which measures the strength and direction of relationship between two variables. Correlation can be computed for data that is nominal (categorical), ordinal (ranked) or interval/ratio (continuous). Different types of correlation coefficients (r) are used depending on the numerical scale of the data:

- Phi coefficient is used with two dichotomous variables (i.e. only two levels such as male-female or yes-no);
- Point biserial r is used to compute the relationship between a dichotomous variable and one continuous variable;
- Spearman r and Kendall's tau are applied to ordinal or ranked data;
- Pearson r is used when both variables are continuous (i.e. based on scales which are interval or ratio such as blood pressure or heart rate).

The first step in any correlation analysis is the construction of a scatter plot or scatter diagram to depict graphically the relationship between two variables. A scatter plot of cholesterol versus triglyceride levels of 30 male medical students is shown in Figure 1. The two variables are delineated by the vertical (or Y) axis and the horizontal (or X) axis and each dot represents a pair of values taken on the same person.

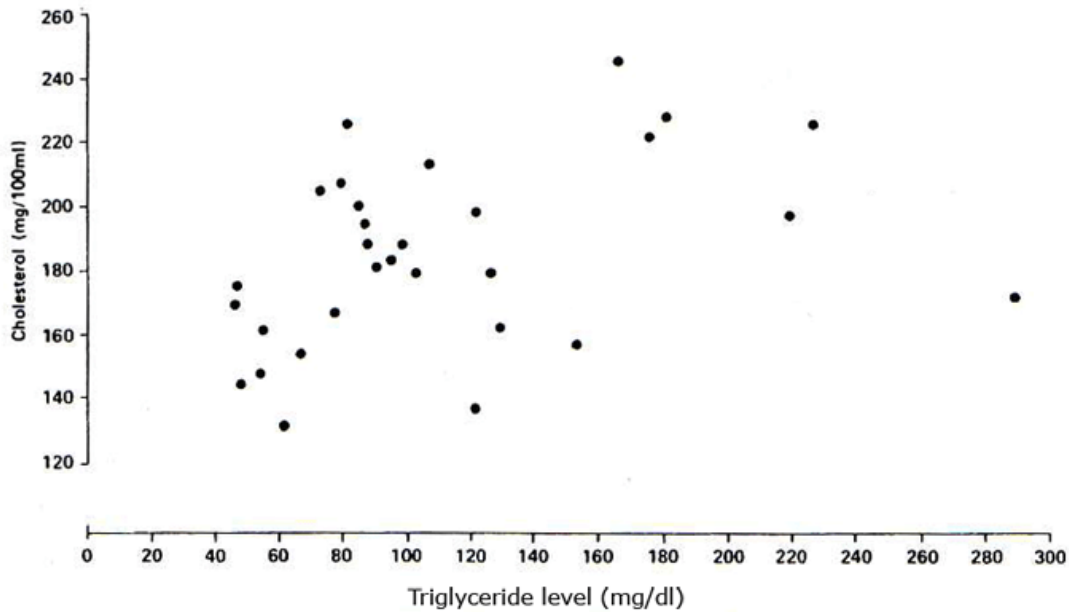


Figure 1

Examination of the scatter plot in Figure 1 indicates a slight tendency for one measure (cholesterol level) to be related to the other measure (triglyceride level) leading to a low positive correlation between the two variables. The scatter plot is also useful in highlighting outliers or extreme scores in the data. For instance, in Figure 1 one subject had a triglyceride level > 280 which was much higher than the values of the rest of the sample. The identification of outliers in a data set can have significant implications in interpreting the data and choosing further appropriate statistical procedures.

Construction of a scatter plot also allows the researcher to detect non-linear patterns of relationship between two variables. Figure 2 provides examples of several curvilinear relationships between two hypothetical variables.

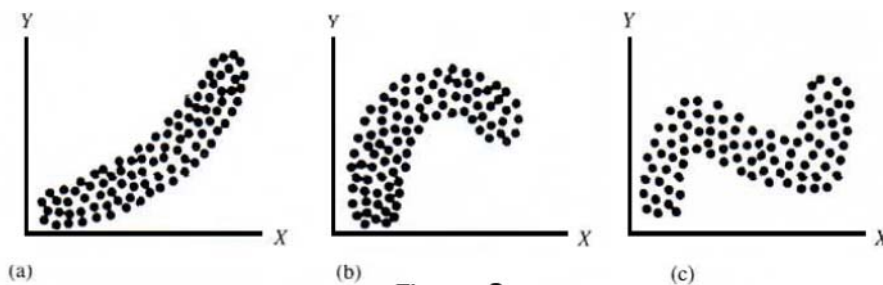


Figure 2

With non-linear relationships the Spearman r is the appropriate index of correlation rather than the Pearson r which only measures linear relationships. Examination of a scatter plot will alert the researcher to the presence of non-linear relationships between variables and lead to a correct choice of statistical tests.

Regression Lines

Simple linear regression is an important statistical procedure which allows a researcher to predict values on one variable from knowledge of the values of a correlated variable. Regression analysis is based on the pattern of scores between two variables depicted in a scatter plot. For a perfect correlation between two variables (i.e. $r = + 1.0$ or $r = - 1.0$), the scatter plot is a perfect straight line and the values of one variable will precisely predict the values of the other variable. However, in almost all instances, there is variability in the distribution of paired scores and a regression line needs to be fitted to the data.

Mathematically, a best-fitting straight line is determined by a least sum squares algorithm which minimizes the squared deviation of scores around the line. The best fit line is called a regression line. Figure 3 shows a regression line for a scatter plot of anxiety and task performance scores.

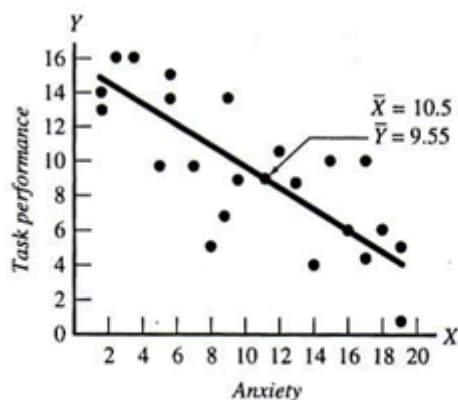


Figure 3

The regression line allows the researcher to predict task performance on the basis of anxiety level. In Figure 3 the scatter plot indicates that there is a negative correlation between the two variables (i.e. task performance increases as anxiety scores decrease). The regression line allows precise prediction of one variable from another. For example, an anxiety score of 10.5 predicts a task performance score of 9.55 (Figure 3). The accuracy of this prediction can be stated as the standard error of estimate and expressed as 95% or 99% confidence intervals.

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.

Lectures, Workshops and Conferences

Fall 2007 Clinical Research Lecture Series - U of M Bannatyne Campus

Interested in getting involved in Clinical Research? Clinical research refers to all research conducted with human subjects. These comprehensive lectures are specially designed for individuals with little or no previous research experience. The lectures will present an overview of the language of clinical research, project design and management, roles and responsibilities of the Investigator and the research staff, and the regulatory and ethical environment for the conduct of clinical research.

Guidelines, Policies and Regulations in the Conduct of Clinical Research

This 2 hour lecture will review the regulatory environment that directs the developmental process for taking a drug from bench discovery through human research and on to market. An overview of the historical evolution of today's regulatory environment will serve as the basis for why the regulations exist as they do. Quality control/monitoring and quality assurance/auditing will also be discussed.

Lecturers: Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Second Lecturer: TBD

Date: Thursday, November 8, 2007

Time: 10:00 AM to Noon

Location: Theatre C, Basic Medical Sciences Building, U of M Bannatyne Campus

Project and Documentation Management for Clinical Research

Rules, Roles and responsibilities will serve as the basis for project and documentation management of clinical research studies, be they drug, device or outcomes research. Topics covered will be:

- Pre-Study Planning, REB and Institutional Approvals
- Study Documents (Protocol, ICF, etc.)
- Source Documents and Data Collection Forms
- Informed Consent Process, Subject visits
- Study Close out

Lecturers: Terry Sawicz-Hanesiak, Regulatory Affairs/Quality Assurance
Second Lecturer: TBD

Date: Thursday, November 8, 2007

Time: 1:30 PM to 3:30 PM

Location: Theatre C, Basic Medical Sciences Building, U of M Bannatyne Campus

If you would like to register for these FREE lectures on November 8, 2007 contact Terry Sawicz-Hanesiak, SBGH – Office of Clinical Research (204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

Good Clinical Practice Workshop – DATE CHANGED TO November 15, 2007

Date: Thursday, November 15, 2007

Time: 8:30 – 4:00 pm

In response to several requests, the Office of Clinical Research is presenting another full day Good Clinical Practice workshop.

The cost to attend the one day workshop is \$150 (breakfast, lunch and break refreshments are included).

Registration is limited to **20** participants. For more information, please contact Terry Sawicz-Hanesiak, (204) 237-2226 or e-mail tsawicz@sbgh.mb.ca

Research Review Committee at St. Boniface Hospital

Deadlines for RRC Submission

October 31, 2007

November 28, 2007

January 2, 2008 (**tentative**)

Meeting Date

November 7, 2007

December 5, 2007

January 9, 2008

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

Deadline for REB Submissions

November 9, 2007 (Friday)

November 26, 2007

January 14, 2008

Meeting date

November 26, 2007

December 10, 2007

January 28, 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. Please always refer to the Research Ethics Board web site for the most recent submission forms and updates.

SoCRA Certification – Are you Interested in Writing your Exam in Winnipeg?

The Society of Clinical Research Associates, Inc. (SoCRA) is a non-profit, professional organization dedicated to the continuing education and development of clinical research professionals. The express aim of SoCRA is to provide training and continuing education for clinical research professionals and to establish and maintain an international certification program for clinical research professionals.

To become certified

- In order to be considered for SoCRA certification, the applicant must be a current member of SoCRA working with GCP guidelines under IRB/EC/REB approved (or specifically exempted) protocols.
- SoCRA will not be able to consider candidates who are unable to provide the requested supporting documentation regarding their experience in clinical research.
- Any questions regarding the eligibility requirements should be directed to the SoCRA Administrative Office.

NOTE: Most candidates will be eligible under **Category 1**. If you have completed two (2) years of full-time employment as a clinical research professional in the past five years, you will **NOT** need to provide supporting documentation for your educational experience.

ELIGIBILITY CATEGORIES – The applicant’s experience must fall under one of the following categories:

Category 1: Candidates having completed a **minimum of 2 years of full time employment** (or 3500 hours of part-time employment) during the past five years as a clinical research professional.

Category 2: Candidates holding a **degree in “Clinical Research”** from an Associate, Undergraduate or Graduate Degree Program **AND** having completed a **minimum of one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional.

Category 3: Candidates holding an **Undergraduate or Graduate Certificate in “Clinical Research”** with a curriculum of no less than 12 semester (credit) hours or totaling a minimum of 144 credit hours from an academic institution of higher learning (community college, college or university) **AND** holding an **Associate’s or Bachelor’s Degree in a science, health science, pharmacy or related field AND** having completed a minimum of **one year of full-time experience** (or 1750 hours part-time) during the past two years as a Clinical Research Professional.

More information is available at <http://www.socra.org>

We are considering hosting another exam writing for SoCRA Certification here in Winnipeg at St. Boniface General Hospital. SoCRA requires a minimum of 10 people to write the exam so if you are interested in obtaining your certification, please contact Terry Sawicz-Hanesiak at 237-2226 tsawicz@sbqh.mb.ca to register.

