STATISTICAL APPLICATIONS IN HEALTH RELATED QUALITY OF LIFE

Editorial

This special issue of the Italian Journal of Applied Statistics is devoted to issues and innovation in Health Related Quality of Life. Submissions that advance the current state of the literature and/or promote methodological developments in this field were retained. In the same manner of regular issues, all papers were peer-reviewed, by anonymous reviewers (thanks to everyone!), and revised before final editing and acceptance. Although this process was quite time consuming, we believe that it greatly improved the volume as a whole, making this special issue a valuable contribution to the field of "Health Related Quality of Life" research.

Patient Reported Outcomes (PRO) studies measure any aspect of a patient's health status that is reported directly from the patient without any influence from a physician or outside agent. PROs can be used to measure the impact of a treatment on one or more aspects of patients' health status, ranging from symptomatic to complex concepts such as quality of life. PRO instruments that are demonstrated to effectively measure a particular concept may generate evidence of a treatment benefit and may be used to support claims in approved product labeling.

In Health Sciences, Quality of Life studies (HRQoLs) are PROs that aim to evaluate how a treatment or disease affects a patient psychologically, socially, and physically. These studies take into consideration the patients' own perspective of their treatment or disease. HRQoLs can identify specific healthcare needs, provide evidence that can lead to improved quality of care, and provide a rapid screening test to identify populations or individuals who might need a more detailed health needs assessment.

It is not by chance that all the articles in this special issue, deal with, whether it's near or far, Item Response Theory or/and Rasch models. The main purpose of QoL or PRO studies is to produce individual measures having an excellent metrological quality, using mainly self-administered questionnaires, as instruments specifically developed to measure unobserved latent traits, yet conceptually known. Most of the time, those questionnaires consists of set of dichotomous or polytomous questions (items). Item Response Theory was developed mainly for the design, analysis, and scoring of tests, questionnaires, and similar instruments *measuring* abilities in educational research, attitudes in sociological research, or other variables

in various fields. The Rasch model is known as the most achieved measurement model within the family of Item Response Theory models. Its use in Health research is in continual increase ([1], [2], [3]).

It is not by chance also, that all the articles in this special issue deal with Longitudinal Analyses: modern causal inference and treatment effect research require prospective studies.

In their paper entitled "*Longitudinal Analysis of the Health-Related Quality of Life in Oncology Integrating the Occurrence of The Health Related Shift Effect*", Anota et al explore several methods to take into account the occurrence of the recalibration component of the response shift effect according to three statistical methods for the longitudinal analysis: the linear mixed model for repeated measures, the time to HRQoL score deterioration and the longitudinal partial credit model (LPCM) based on the IRT approach. All these methods were applied on data from a multicenter prospective cohort study on early breast cancer patients where the then-test method was used as a standard to identify recalibration.

In their paper entitled "*Analysis of longitudinal Patient Reported Outcomes Data with CTT and Rasch-Based Methods: an Application on Health-Related Quality of Life in Breast Cancer Patients*", Blanchin et al compares two methods of analysis of longitudinal PRO data using a real breast cancer patients data, where, HRQoL was evaluated at three time points with the cancer specific questionnaire European Organisation for Research and Treatment of Cancer Quality if Life Questionnaire (EORTC QLQ-C30).

In their paper entitled "*Analysis Longitudinal and Cross-Sectional Modelling of Health Related Quality of Life in People with Cystic Fibrosis"*, Hurley et al, based on direct modelling of the empirical data followed by a computer simulation, provides a comparison of the advantages of longitudinal over cross-sectional studies in terms of HRQoL model estimation and the assessment of the contribution of demographic and clinical changes to changes in HRQoL.

Boisson et al, in "*Log-rank-type Test for Evolution of Health Related Quality of Life"*, build a global log-rank test to compare the time to HRQoL score deterioration (or degradation), between treatment groups. Time to HRQoL score deterioration methods usually consider the event of first time when deterioration of HrQoL is over a prefixed threshold x. Thus, for each value x, there corresponds a time variable, which may be censored if the deterioration does not occur below x for the entire study period. This effectively converts the longitudinal observations into survival times. In particular, a log-rank test for treatment difference, by choosing a fixed threshold x of deterioration of HrQoL, can be derived. By varying the relative deterioration threshold x, Boisson et al obtained a group of survival data

sets, which naturally contain more information than any individual one with a single *x*. They proposed non and semiparametric methods for simultaneously incorporating the entire group of data sets. The theoretical properties of the resulting methods are studied for the continuous time version using empirical process theory. Under their formulation, analysis of degradation with HrQoL data lies in the interface of survival analysis and longitudinal data analysis. They focused on the problem of testing the effect of an observed covariate and then bypass the physical degradation process to directly deal with the log-rank statistics construct.

All the papers in this special issue reveal a very active field of research, in the interface of various scientific disciplines. The methods presented are based on theoretical results, simulations and are illustrated with real problems and data for which they were developed.

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Co-editors of this issue

Preface Additional References:

[1] Christensen, K.B. , Kreiner, S. and Mesbah, M. (2013). Rasch Models in Health. John Wiley & Sons, Hoboken, NJ USA.

[2] Mesbah, M. (2012). Measurement and Analysis of Quality of Life in Epidemiology. In "*Bioinformatics in Human Health and Heredity* (Handbook of Statistics, Vol. 28)". Eds: Rao, C.R., Chakraborty, R. and Sen, P.K. North Holland. Chapter 15.

[3] Mesbah, M. (2013). Preface. *Pub. Inst.Stat. Univ. Paris* Vol 57- Fasc 1-2 45-58.