Lecture Series – Pitfalls and Solutions

Good Experimental Design

Complete, transparent and unbiased reporting as a requisite in research in the health sciences

Speaker: Prof. Dr. Willi Sauerbrei (Institute of Medical Biometry and Statistics)

Wednesday, 09.10.2019

17:00-18:00

Seminar room window, ZTZ, Breisacher Str. 115

Abstract:
For many years the quality of research in the health sciences has been heavily criticized. It is argued that serious improvement would be possible if biomedical research is better chosen, designed, executed, analyzed, regulated, managed, disseminated, and reported. Serious improvements are far from being simple for many of the issues mentioned, but suitable guidance documents have been developed to improve on the reporting of research. Severe weaknesses in this area are unnecessary and can be avoided. Concerning issues in reporting of health science the EQUATOR (Enhancing the QUAlity and Transparency Of health Research, https://www.equator-network.org/) network acts as an umbrella organization.

Unfortunately, many reviews of publications have clearly shown that the quality of reporting of studies is still bad. Problems seem to be less severe for RCTs than for observational studies. In the latter even basic items of the study population and relevant details of statistical analyses are often not provided. In general, there are plenty of conceivable approaches to statistically analyze data that both make sense from a substantive point of view and are defensible from a theoretical perspective. It is not uncommon that several approaches are conducted, the analysis with the 'most satisfactory' result is selected and published. Consequently, the published literature gives a seriously biased impression, causing severe harm for the results of systematic reviews and meta-analyses. An unbiased assessment of the importance of many factors relevant for decision making in areas like risk assessment, prognosis or treatment is often impossible.

In this talk I give a general impression about the seriousness of bad reporting and problems it causes for research in the health sciences and for the care of patients. I will present a brief overview of guidelines for many different types of studies. To illustrate more specific issues I will consider randomized controlled trials (CONSORT statement) and prognostic factor studies (REMARK recommendations).

References:

Moher D, Altman DG, Schulz KF, Simera I, Wager E (editors) (2014). Guidelines for Reporting Health Research: A User's Manual, John Wiley & Sons

Sauerbrei W, Taube SE, McShane LM, Cavenagh MM, Altman DG (2018). Reporting Recommendations for Tumor Marker Prognostic Studies (REMARK): An Abridged Explanation and Elaboration. J Natl Cancer Inst. 110(8): 803-811

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Simera I, Moher D, Hoey J, Schulz KF, Altman DG (2009): The EQUATOR Network and reporting guidelines: Helping to achieve high standards in reporting health research studies. Maturitas 63 (1): 4–6. doi: 10.1016/j.maturitas.2009.03.011

Target group:
Clinician scientists, scientists involved in clinical research and interested readers of medical publications

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