



Ringseminar

„Statistische Methoden der Epidemiologie, Medizinischen Biometrie und Versorgungsforschung“

Einladung

Sehr geehrte Kolleginnen und Kollegen,

hiermit möchten wir Sie ganz herzlich einladen zu unserem Ringseminar, das sich der Vorstellung und Diskussion statistischer Methoden und Prinzipien in verschiedenen Bereichen der medizinischen Forschung widmet.

Am **27. Juni 2016** wird **Dr. Arthur Allignol** (Institut für Statistik, Universität Ulm) sprechen über

Statistical Issues in Studies on Drug Exposed Pregnancies: Experiences from the "Surveillance of A(H1N1) Vaccination During Pregnancy" Study

Das Ringseminar findet statt von **16.00 – 17.00 Uhr in N25/2103**. Alle Interessierten sind herzlich willkommen, eine Anmeldung ist nicht erforderlich.

Abstract:

The study "Surveillance of A(H1N1) Vaccination During Pregnancy" aimed at assessing the potential risks associated with vaccination against A(H1N1) during pregnancy. The outcomes of main interest were major malformation, spontaneous abortion and preeclampsia. This talk presents some of the challenges met while analyzing this study and explains the choices made for analyzing the data.

For instance, the outcomes are seldom observed in the general population, e.g. 10 major malformations were observed in the vaccinated group. Second, as is the case for all observational studies, the groups being compared are likely to be different due to the lack of randomisation, hence leading to biased estimates of the exposure effect.

Another problem analysis has to deal with is that entry times into the cohort, taken as week of gestation, are usually several weeks after conception. Entry times are moreover highly variable between pregnant women. Methods appropriate for dealing with such delayed entry are thus mandatory. Besides, vaccination has been observed virtually at every time of gestation. As a change in risk is expected only after vaccination having taken place, exposure has to be modelled as time-dependent. These aspects are considered for the analysis of spontaneous abortion, induced abortion, and gestational week at birth.

Mit freundlichen Grüßen

Prof. Dr. med. Dietrich Rothenbacher und PD Dr. Benjamin Mayer
Institut für Epidemiologie und Medizinische Biometrie

Prof. Dr. Jan Beyersmann
Institut für Statistik