Thursday June 9, 15:45-17:05

Parallel session 4

Fringe Session

Chairs: Rolf Groenwold & Femmie de Vegt

15:45 Looking back to move forward: a reflection on traditions in research methodology (F1)
Maike Imkamp

16:05 Propensity scores: a holy grail in epidemiological research? (F2)
Marissa van Maaren

16:25 Post COVID-19 condition (PCC) epidemiology in a multi-island and low resource setting: Comparison of research methodologies between Caribbean and European Netherlands' long-COVID studies (F3)
Danytza Berry

16:45 The art of rapid safety evaluation studies in the context of COVID-19 vaccines; balancing a need for speed with reliable and robust research (F4)
Sophie Bots

F1. Looking back to move forward: a reflection on traditions in research methodology.

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Van Kuijk S., Department of Clinical Epidemiology and Medical Technology Assessment (KEMTA), Maastricht University Medical Centre
Wee L., Department of Radiation Oncology (MAASTRO), GROW School for Oncology and Reproduction (GROW), Maastricht University Medical Centre.
Seiler C., Department of Data Science and Knowledge Engineering, Maastricht University.

Nowadays, clinical research is strongly based on statistics. However, the opportunities of data science appear skyrocketing. And, raise questions. Since, some parts of data science, such as machine learning, seem highly intertwined with statistics. What sets one field apart from the other can be quite confusing and may complicate a thorough model choice. So, then, how to make your choice of methodology? We welcome you to join us on a journey. A journey to unravel the cultural and philosophical differences between statistics and data science. Both statistics and data science have their own culture and traditions, resulting in unique perspectives how to approach science. This journey encourages you to become aware of the traditions of the methodology you use and of alternative perspectives. To examine the traditions and their becoming in statistics and data science, we start our journey with some key moments throughout the history of each field. Since, after all, we are standing on the shoulders of giants, and their perspectives have become ours. Then, we will dive deeper into the fundamental philosophical differences of the two cultures concerning assumptions, beliefs, explainability, and modelling aim. While we all know that “all models are wrong, but some are useful”, we will now learn that our model choice is, eventually, based on a cultural choice. A choice that influences our daily research practices and, even, the research questions we ask.

F2. Propensity scores: a holy grail in epidemiological research?

van Maaren M.C., Netherlands Comprehensive Cancer Organisation (IKNL), Utrecht, the Netherlands / University of Twente, Utrecht, the Netherlands

As epidemiologists we work a lot with observational data. We all know about confounding and we all know that we should correct for it. Many methods have been developed that allow us to properly correct for confounding. One of these methods concerns the use of propensity scores. The use of these scores sounds simple, but when is a propensity score good enough? There are multiple ways to include propensity scores in your analyses, including matching, inverse probability weighting, using it as a confounder in your model and propensity trimming can be performed. What are the advantages and disadvantages of each method, and when do you use them? In what cases is the use of propensity score analysis better dan conventional multivariable analysis?

In this session I will shortly introduce the relevance of observational research in the estimation of treatments or exposures on outcomes, and explain the concepts of confounding and selection bias – terms that are used interchangeably – to be able to better understand the purpose and effect of propensity score analysis. Subsequently I will guide you through the concepts of propensity score analysis, including a clear explanation of the abovementioned methods that are used to include propensity scores in analyses.

In the end, you will have a complete overview of the use of propensity score analysis, including its advantages and disadvantages, and you will know how and when to use it.

This session is relevant both for researchers who never worked with propensity scores as for researchers who already have experience with it, but are interested in more in-depth information on the concepts of propensity score analysis, including a comparison between different methods of analysis.

F3. Post COVID-19 condition (PCC) epidemiology in a multi-island and low resource setting: Comparison of research methodologies between Caribbean and European Netherlands' long-COVID studies.

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Dalhuisen T,, RIVM
Marchena G., Publieke Gezondheid Bonaire
Krijgsman A., Publieke Gezondheid Bonaire
Tiemessen I., Mobilito Bonaire
van der Maaden T., RIVM
Geubbels E., RIVM
Jaspers L., Publieke Gezondheid Bonaire

Background: In May 2021, having just experienced a second wave of SARS-CoV-2 infections, epidemiologists and clinicians in Bonaire expressed the need for researching PCC epidemiology in the Caribbean Netherlands setting. As the health status and burden of chronic disease in the Caribbean Netherlands differ largely from the European Netherlands, it could not be assumed that what will be found through Dutch Long-COVID-studies would be similar in Bonaire, St. Eustatius and Saba (the BES islands), a group of overseas municipalities of the Dutch Kingdom. A retrospective cohort study was designed, aiming to answer urgent questions about PCC occurrence, predictors, healthcare use and needs of PCC patients while strengthening local capacity in setting up and conducting research on the BES islands. Concurrently, the RIVM set up a Long-COVID-study in the European Netherlands with similar research aims, predictors and outcomes. In this fringe session, we will contrast the process of developing the Caribbean and European Netherlands Long-COVID studies whilst finetuning methodology to locally available resources, capacity, and implementation amidst another (Omicron) wave of infections.

What we will be doing: During this 20-minute interactive session, we will take you on a Caribbean journey into the challenges faced while designing and implementing the study on the BES islands, and how these can be solved using creative strategies. We will compare these with solutions available in the European Netherlands. We will walk through each step of the study design and data collection process with the audience to explore alternative strategies to overcome methodological challenges.

F4. The art of rapid safety evaluation studies in the context of COVID-19 vaccines; balancing a need for speed with reliable and robust research.

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Knowledge about the safety of COVID-19 vaccines was limited to pre-licensure clinical trials at the time national vaccination programmes were initiated. Therefore, comprehensive surveillance of the real-world safety of these vaccines was essential to detect and rapidly evaluate any signals that warranted regulatory action. Due to the nature of post-marketing surveillance, vaccination roll-out and safety evaluation occur simultaneously. Consequently, any potential safety signal needs to be evaluated rapidly to inform regulatory agencies on post-approval benefit/risk assessment of vaccines. In short, time is of the essence. However, reliability is also key because findings will directly inform regulatory action. How to balance this need for speed with making sure findings are robust to bias, especially in a vaccination setting where such issues are likely to occur? And what about collecting sufficient events for meaningful analyses given the short timeframe? This fringe session will discuss these issues using work from the European Medicines Agency (EMA)-funded Covid Vaccine Monitoring project on myo- and pericarditis as a case study. In July 2021, myocarditis was raised as a potential adverse effect of mRNA-based COVID-19 vaccines, especially in younger men after the second dose. Combining real-world data from four European countries, we applied both a cohort and a nested self-controlled risk interval design to evaluate the effect of four EMA-approved COVID-19 vaccines on myo-/pericarditis risk. Only four months after the signal was first raised, we

confirmed an increased incidence of myo-/pericarditis after the second dose of both mRNA vaccines, especially in individuals aged 12-29 years. This fringe session will present the project in real time, encouraging the audience to think along, come up with solutions, and discuss the findings and decisions made. The aim is to interactively introduce the audience to safety evaluation study designs and methods and challenges surrounding observational COVID-19 vaccine safety research.