Improving the design of clinical and observational studies to optimize data quality assessments

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Abstract-Text :

Introduction: A key objective in clinical and epidemiological studies is the assurance of a high data quality. Examiners, devices, readers of images, but also environmental factors such as room temperatures, ambient light, or examination times may introduce variability or measurement errors. This presentation discusses issues related to the design and implementation of observational studies aiming to improve the detection of potential sources of errors from a theoretical and applied point of view.

Methods and results: The design of a study must be optimized in such a way to establish causal links between detected data irregularities and underlying sources of error such as those mentioned above. Confounding between participant characteristics and study design factors must be avoided by achieving statistical independence between them. A major challenge remains the unknown inter-individual variability of participant characteristics over time, which may be associated with population based time trends or the study design, e.g. changing invitation procedures. From an applied perspective, we analyze organizational aspects that complicate an ideal implementation of study design factors, for example, clustered designs. Selected examples will be presented based on experiences within the Study of Health in Pomerania (SHIP).

Conclusion: Many design elements such as examiners and devices can be implemented appropriately to allow for correct inferences on sources of errors. However, handling some study design factors is difficult in practice due to a necessary tradeoff between efficient resource allocation and study design demands. Most importantly, the inter-individual temporal variability of study outcomes is only partially under control, which poses a serious issue especially in long term studies.