

PRESS RELEASE

Opportunities and Risks of Routine Data in Medicine

International guidelines on the use of routinely collected data set new quality standards

Bonn/Munich, June 02 – The increasing availability of routinely collected health data (RCD) which is increasingly being used for research purposes, opens up numerous opportunities to answer more questions about health and disease – and to do so in less time. However, researchers often lack knowledge about how the data was generated, as well as control over how it was collected. An international research consortium has now published a groundbreaking guide on the use of RCDs, which is the first comprehensive guide of its kind. The goal is to sustainably improve the quality, validity, and transparency of studies based on such data, thereby strengthening the foundation for reliable evidence-based medicine. The study is now published in the renowned journal *The BMJ*.

Routine data – such as that from electronic health records, registries, or billing data – offers enormous opportunities for medical research, as it reflects large patient populations under real-world care conditions. At the same time, it presents significant methodological challenges. The newly published guidelines systematically analyze these challenges and describe key problem areas, including lack of representativeness, insufficient data quality, lack of temporal alignment between measurements and interventions, non-randomized treatment decisions, and the multitude of possible analytical approaches.

“Routine data open up enormous possibilities for investigating medical questions more quickly and broadly. At the same time, we must be aware of the methodological challenges in order to achieve valid and trustworthy results,” explains lead author and head of the Statistical Consulting Laboratory at LMU Munich, Dr. Sabine Hoffmann, regarding the motivation behind creating the guidelines for the use of RCDs.

The goal is to improve research quality

The researchers placed particular emphasis on the risk of biased results as well as on problems associated with missing and erroneous data. Furthermore, the role of modern, high- e analytical methods – particularly those involving artificial intelligence – is critically assessed. The guide demonstrates that while these methods hold great potential, they can also lead to misleading results without methodological rigor.

As a key innovation, the study presents a structured roadmap and concrete recommendations for action that researchers can use to improve the quality of their analyses. These include strategies for ensuring data quality, correctly defining time points,

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and reporting studies in a transparent and reproducible manner. Through these comprehensive recommendations, the guide makes a decisive contribution to improving research quality. It helps prevent misinterpretations, increase the reproducibility of studies, and sustainably strengthen trust in results derived from routine data.

Interdisciplinary Collaboration for Practical Guidance

The guidelines for the use of RCDs are the result of a unique interdisciplinary collaboration among internationally renowned statisticians, methodologists, experts in artificial intelligence, and cardiologists. Several of the contributing authors are members of the internationally recognized STRATOS initiative (STRengthening Analytical Thinking for Observational Studies), which is dedicated to improving statistical methods and their application in medical research. This work is part of a growing body of initiatives to promote high-quality evidence, including those led by institutions such as the Institute for Quality and Efficiency in Health Care (IQWiG), which emphasize the importance of methodologically robust studies for health policy decisions.

“With this guide, we are providing, for the first time, comprehensive, practical guidance that combines clinical and methodological expertise. Our goal is to sustainably improve the quality of research based on routine data and to responsibly harness its potential,” state the Director of the Department of Cardiology at the UKB, Prof. Dr. Georg Nickenig, and the Director of the Department of Cardiology at the Leipzig Heart Center, Prof. Dr. Holger Thiele. The study’s corresponding author and cardiologist at the UKB Heart Center, Prof. Dr. Enzo Lüsebrink, adds: “With its publication in *The BMJ*, the guideline sets a new international benchmark for the analysis of routine data. It provides researchers, clinicians, and decision-makers with a central framework and makes an important contribution to the further development of evidence-based medicine in the digital age.”

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Image:



Caption: Prof. Enzo Lüsebrink and Dr. Sabine Hoffmann

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About the University Hospital Bonn: As one of Germany's leading university hospitals, Bonn University Hospital (UKB) combines excellence in medical care and research with high-quality teaching. Every year, UKB treats more than half a million outpatients and inpatients. Around 3,500 students are enrolled in medicine and dentistry, and over 600 individuals receive training in healthcare professions annually. With around 9,900 employees, UKB is the third-largest employer in the Bonn/Rhein-Sieg region. In the „Focus hospital rankings“, UKB is rated the top university hospital in North Rhine-Westphalia and has the second-highest case mix index (an indicator of treatment complexity) of all university hospitals nationwide. In 2025, UKB secured nearly €100 million in third-party funding for research, transfer, and teaching. For the fourth consecutive year, the F.A.Z. Institute recognized UKB as both “Germany's Training Champion” and “Germany's Most Desirable Employer.” For current figures and further information, please refer to the annual report at: geschaeftsbericht.ukbonn.de