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Peer-Review

Zwei Studien des Basel Institut für klinische Epidemiologie und Biostatistik ceb

(1) Surveillance of Physicians Causing Potential Drug-Drug Interactions in Ambulatory Care: A Pilot Study in Switzerland

(2) Personalized Prescription Feedback Using Routinely Collected Data to Reduce Antibiotic Use in Primary Care: A Randomized Clinical Trial.

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Background

Santésuisse is running with 2 of 3 persons (Reto Guetg (MD), Mr Stefan Kaufmann) the Board of Trustees of the Foundation Institute for Clinical Epidemiology, which is responsible for the CEB Institute, where Mr. Heiner Bucher, MD, is the head: "Our mission is to improve decision making in health care." Some of the studies issued by CEB are financed by santésuisse. Therefore, some activities of CEB may rather reflect a mission of santésuisse, which is an umbrella organisation of Health Care Insurers representing about 60% of health care insured (OKP). Some large Health Care Companies (Helsana, CSS) run their own "health supply" research. Therefore, santésuisse might aim at running similar activities using CEP. This cooperation started in fact several years ago and santésuisse is paying regular amounts of at least CHF 200'00 per year until 2014 to CEB. The two above mentioned studies are probably designed within a contract framework between CEP and santésuisse, which is however not explicitly declared. Santésuisse and its allied organisation SASIS dispose of health insurance claims that cover around 96% of claims annually for Switzerland. SASIS receives the data from virtually all health care insurers. Using these claim data, CEP designed the two studies mentioned above.

SASIS BIG DATA Problems

Before thinking of doing studies, the quality of the database is a central inssue. SASIS receives the claim data from most health care insurers. The problems with SASIS database are as follows:

- Database contains aggregated data, not individual data at the patient level.
- There is no possible data linkage between a patient and pharmaceutical cost groups due to aggregation of data.
- Physicians are identified by a unique registration number (Zahlstellenregister ZSR), however, ZSR numbers may be used by several doctors. To overcome this shortcome, the Global Location Number GLN should be known instead.
- The Database is poorly validated, which could be exemplified in regress requirements and in direct controls of SASIS Database with respect to relevant problems regarding physician profiling.

Therefore, any results and conclusions from SASIS database might not fulfill scientific requirements. CEP did not validate the quality of the SASIS database before using it, as far as can be seen from the published papers. These problems were also not addressed in the limitation sections of the two papers.

STUDY DESIGN USING GEP (good epidemiological practice)

The two above mentioned studies contain a scientific question, which is clinically relevant in supply research:

- How can clinically important drug interactions be avoided?
- How can unnecessary antibiotic treatment be reduced?

There is now doubt, that these problems exist and the possible prevalence of these problems has been described extensively in the observational literature. However, when it

comes to the level of reasons, that have to be identified in order to prevent these problems, the literature is mute.

The question is, if the two CEB/SASIS studies add relevant information in order to avoid drug interactions and antibiotic over medicalisation.

Analysis of the Drug-Drug Interaction (DDI) Study (CEB)

The claim data do not exclude, that a physician interrupted drugs temporarely, that might have caused DDI.

Physicians were not properly identifyable based on the ZSR number.

Group practices had higher DDI.

Analysis of the possible overuse of antibiotics study (CEB)

The paper does not allow to address the question, whether the use of antibiotics at the individual level was indicated or not. Nor does it allow to correctly identify a prescribing MD. Further, it is not clear, how many patients received potentially unnecessary antibiotics, since the SASIS database only allowed to calculate the prescription of antibiotics per 100 consultations, for potentially several patients. the "councelling reistance" in this randomised study may therefore be an artefact.

Discussion

The study designs are observational, not analytical. Generated numbers are prone to severe bias from data aggregation, regression to the mean and problems with the quality of the SASIS database and the problem with correct identification of individual prescribing doctors and omitted variable bias (e.g. temporal interruption of DDI by the treating physician). Therefore, the observational data contain neither novelty nor are they sufficiently trustworthy in order to generate a scientific hypothesis.

In order to overcome these shortcomings, one would need on site verification at the clinical level, as outlined in an accompanying editorial written by Mitchell H. Katz, MD, for the second study: "Commonsense doesn’t always prove to be right. Preintervention-postintervention observational designs can be mistaken, especially when there is no concurrent control. Just as we would not accept a drug as efficacious without a randomized clinical design, quality improvement interventions benefit from rigorous evaluation methodology. As the Russian proverb says: trust but verify."

For a pilot study it is indispensable to first verify the presence of a clinically relevant problem and only then to look, how good SASIS big data are capable to detect such problematic signals defined by the reality. If this step is avoided - because it is costly to generate such sound scientific evidence - then we are left with a basket of senseless numbers.

Conclusion

Health Care Insurers aim at influencing medical practice by supply research. They try to create a scientific environment for their databases by the use of public health institutes or own research centers. By the use of scientific methods they aim to gain a certain credibility,

which should then be acknowledged by the press and stakeholders. The analysis of the two CEB papers on the other hand, casts serious doubts on the aims of private health insurers to create sound scientific work that has the potential to improve health care. The main problem here is the mislabeling of correctly functioning doctors and therefore increasing the malaise of treating physicians. Ultimately, health insurers abuse science and waste their money. They do not contribute to any improvements in health care quality.

When Alan Niederer wrote in the NZZ 06.01.2017 about the second study: "Studies with health insurers databases are the future of supply research (Studien mit Krankenkassendaten sind die Zukunft in der Versorgungsforschung)", we get an idea about the magnitude of confusion that health care insurers create with their observational activities. Improvements in decision making in health care, the goal of CEB, can be perverted by such studies.

Key message

Supply research has to answer important questions. GEP is able to identify pathological signals based upon high-quality real-world assessments. Frequentists should verify, if the signals they obtain from big data are artefacts, therefore creating a pseudo reality. Pseudo reality in social science is an increasing problem in health care, creates unnecessary uncertainties and mislabels correct health care delivery.

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