横浜市立大学大学院 データサイエンス研究科
ヘルスデータサイエンス専攻　博士前期課程
サンプル問題（「英文」）

〔Ⅰ〕

文献：Mette Nørgaard et al. Confounding in observational studies based on large health care databases: problems and potential solutions – a primer for the clinician Clinical Epidemiology 2017; 9: 185–193.

以下の観察研究の限界に関する文章を読み、問いに答えなさい。

‘Observational studies based on large existing health care databases have a well established role in clinical research. Nevertheless, there are controversies regarding the validity of observational studies based on such databases. Among limitations is the fact that the data collection methods are predetermined and not controlled by the researcher. Misclassification constitutes a frequent limitation of registry-based research. In addition, as with any type of nonrandomized epidemiological research, the absence of confounding cannot be assumed in studies of associations between a given exposure and a given outcome using large databases. The value of these population-based databases for interpreting observed associations as causal will therefore also depend on how effectively confounding can be controlled. Confounding is the situation in which the difference in the risk of the outcome (or lack thereof) between exposed and unexposed can be explained entirely or partly by imbalance of other causes of the outcome in the contrasted groups. Ideally, to directly observe a causal (ie, confounding-free) exposure–outcome relation, we would like to examine the occurrence of a given outcome in the same group of people over the same period of time under two contrasted exposure conditions. In reality, this is impossible, as for each person only the outcome under one exposure condition is observed; the outcome under the counterfactual exposure condition is not observed. Thus, one will need to find ways to control confounding or at least assess its potential impact.’

(ア)交絡(confounding)とは何か、日本語で説明せよ。

(イ)観察研究において交絡の影響を考慮することの意義を日本語で説明せよ。

〔 II 〕

文献：Manuj Sharma et al. Observational studies of treatment effectiveness: worthwhile or worthless? Clinical Epidemiology 2019; 11: 35–42.

以下のバイアス（bias）に関する文章を読み、問いに答えなさい。
‘Although it is common practice in RCTs, estimating the effectiveness of treatments by comparing treated and untreated individuals in a cohort study can lead to bias as treatment may be indicated only for those with a specific prognosis. The results may suggest that treatment is ineffective if an untreated group has a better prognosis or, conversely, may exaggerate effectiveness if the untreated group has a worse prognosis. This type of bias, which often occurs in observational studies, is known as channeling bias or confounding by indication, and arises when the indication for choosing a particular treatment also affects the outcome. Treated and untreated groups commonly differ in terms of disease severity, which can be difficult to measure in a cohort study.’

(ア)文章内で記載されているバイアスについて日本語で説明せよ。

以下の効果比較研究　（Comparative Effectiveness Research；CER）に関する文章を読み、問いに答えなさい。
‘In any cohort study comparing the effectiveness of different treatments, all groups at baseline must have an equal chance of recording the outcome being investigated. A thorough consideration of whether individuals receiving one treatment may have longer follow-up, or are more likely to be screened for an event, to be intensively managed or to have better data recorded, must be made at the outset. For example, individuals prescribed the anticoagulant warfarin, which requires regular international normalized ratio blood testing, as opposed to direct oral anticoagulants, which do not, may have more frequent health care contacts and thus greater opportunity to report symptoms that lead to identification of an outcome being considered.’

(イ)コホート研究において、薬剤の有効性を比較するうえで留意するべき点を日本語で説明せよ。