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Tom Nolan's research reviews—12 January 2023

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Lecanemab infusion confusion

In the same week that the US Food and Drug Administration (FDA) controversially approved the Alzheimer's disease drug lecanemab, the *New England Journal of Medicine* published a letter reporting the case of a patient who received lecanemab and who died after being treated with tissue plasminogen activator (t-Pa) for an acute stroke. Confusingly, the FDA approval of lecanemab is based on the phase II trial data, yet the phase III study was published in November, and the three deaths linked to lecanemab—thought to be related to amyloid related imaging abnormalities (ARIA)—occurred in the open-label extension phase of the trial, so were not included in the published phase III study.

In the *NEJM* case report, the patient had an acute stroke four days after a lecanemab infusion and was treated with a t-Pa infusion. During the infusion the patient became agitated and hypertensive, and computed tomography showed extensive, multifocal intraparenchymal haemorrhages. Postmortem findings included necrotising vasculopathy involving amyloid deposition within blood vessel walls.

N Engl J Med doi:10.1056/NEJMc2215148

Cheers for peers

The days of consultants and GPs playing golf together and all being on first name terms are long gone. Could we use evidence based medicine to bring them back? A study in *JAMA Internal Medicine* asked if the quality of care might be better when a peer relationship between primary care provider and specialist exists. They found a 9% higher rating for quality of care, as judged by a patient rating questionnaire, where there was such a relationship (defined as an overlap in training for a year or more at medical school or postgraduate medical institution). There was an even stronger association when the referrer and specialist were in the same class or year group. The authors suggest that specialists may strive to deliver a higher standard of care when they know their care will be scrutinised or recognised by their peers. Perhaps next year's Quality and Outcomes Framework (QOF) could include points for arranging an annual GPs versus consultants quiz night or sports day?

JAMA Intern Med doi:10.1001/jamainternmed.2022.6007

Patently wrong

A research letter in *JAMA* shines some light on the murky world of patents. A primary patent is the patent of the active ingredient; a secondary patent is a patent of other aspects of the product, such as the propellant or delivery device. These help manufacturers to extend the market exclusivity of a product after the primary patent has expired, often for decades. The authors looked at the revenues of inhaler manufacturers in the US between 2000 and 2021, finding that they earned $67.2bn when primary patents were active, and an inspiring $110.3bn after primary patents had expired but when secondary patents were active—yet only $613m after all patents had expired.

JAMA doi:10.1001/jama.2022.19691

Intervention mention

In a study titled "Trial of an intervention to improve heart failure outcomes" the investigators tested a "strategy to support clinicians in making decisions about discharging or admitting patients, coupled with rapid follow-up in an outpatient clinic." The strategy is not, as some might have hoped, a shared decision making approach harnessing clinical judgment accrued through years of study and experience, but a risk stratification algorithm. The results of the stepped-wedge cluster randomised control trial found a small improvement in outcomes for the intervention versus usual care, including a 20 month risk of death from any cause or hospital admission from cardiovascular causes of 54.4% versus 56.2% respectively.

N Engl J Med doi:10.1056/NEJMoa2211680

Mood disturbance with different intrauterine systems

When discussing contraceptive choices, the possible side effect of mood disturbance often comes up as an important consideration. A cohort study set in France matched 45 736 females who received a 52 mg levonorgestrel intrauterine system with the same number who received a 19.5 mg levonorgestrel intrauterine system. They restricted the study to those aged between 13 and 40 years who had not been prescribed a psychotropic drug in the previous year. There was a small but statistically significant difference in antidepressant use in the subsequent two years: 4% for the 52 mg group versus 3.6% in the 19.5 mg group. The authors concluded these were unlikely to be clinically important at an individual level and that confounding by indication is a possible explanation for the difference.

JAMA doi:10.1001/jama.2022.21471

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