Commentary: Use of registries to investigate the past and develop the future.
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Opportunities and limitations of registries

Clinical evidence should primarily be based on results of appropriately designed randomised clinical trials. However, their results are often limited by including selected populations, and they are expensive and cumbersome to perform. Furthermore, for many subsets of patients randomised trials will never be (and can never be) performed. In this case observational studies are often the only option.

Retrospective analyses of prospectively collected registry data are inexpensive—the only costs relate to the analyses—and reflect the true clinical situation. They are ideal for descriptive studies and for outcome analyses but have limited value for comparisons between therapeutic options. Nevertheless, registries can be used as a platform for randomisation and thus allow large scale studies to be done at low cost. For example, the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) is being used to prospectively evaluate mortality in patients given manual thrombus aspiration before primary percutaneous coronary intervention compared with that in patients given no aspiration.3

Postmarketing surveillance

Registries also have great potential for postmarketing surveillance. In Europe devices receive approval for use and CE marking from notified bodies and national competent authorities based on limited clinical documentation. Reports of problems with devices should be submitted to notified bodies, but it has been estimated that voluntary reporting may capture less than 10% of relevant events. We recommend that approval for commercial use of devices without adequate clinical data should be conditional on rigorous postmarketing surveillance studies to prove safety and efficacy in broad populations.4 It is the manufacturer’s responsibility to monitor the performance of their devices, for as long as they are in use, and to ensure these devices continue to be safe and suitable for clinical use. It is also important that the European database on medical devices (EUDAMED) should be in the public domain.
Although all countries are required to submit safety data—including CE certification, clinical data, and device failures—to the database from this month, the information will be available only to marketing surveillance authorities.

Large scale postmarketing studies are costly, require specially designed web based clinical report forms, and are often funded and driven by industry. Instead postmarketing studies should be done within existing large registries developed by professional organisations. This will ensure broad unselected populations and avoid competition between randomised trials and registries. It would also stimulate input from academia and support the development of large continuous quality registries. When licensing authorities request postmarketing surveillance studies, the manufacturers should have to provide financial support to the registry.

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