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Review Article

Routinely collected data and patient-centred research in anaesthesia and peri-operative care: a narrative review

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Summary

Randomised controlled trials are the gold standard in clinical research, but remain rare due to their expense and a perceived lack of 'real-world' applicability. At the same time, there has been an exponential increase in routinely collected data which presents opportunities for audit, quality improvement, adverse event reporting and more efficient clinical research. Registry-based research benefits from reduced cost, large sample size and real-world applicability, with methodological developments, particularly registry-based randomised controlled trials and causal inference techniques, showing promise. Limitations include data quality and validity, the need for data linkage, the restrictions of fixed data fields, regulatory barriers, and privacy and security concerns. However, the principal factor hampering current efforts is a lack of anaesthesia-specific datasets in the UK and the fact that most surgical registries do not collect any anaesthetic data. This presents an opportunity for anaesthetists, through enhanced engagement and collaboration, to influence and improve the design of these datasets and increase the value and volume of data collected. Better datasets, coupled with a growing appreciation of new analysis methodologies, would allow significant progress towards realising the potential of routinely collected data for patient benefit. At the same time, work should begin on the development of a minimum dataset for anaesthesia to underpin new data sharing networks and, ideally, a national registry of anaesthesia.

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Introduction

An increasing volume of administrative and clinical registry data is now routinely collected for patients undergoing anaesthesia. A registry is "an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure" [1]. The terms 'registry' and 'database' are often used interchangeably, though a stricter definition might hold that "registries are a functional subset of databases (i.e. all

registries are databases, but not all databases are registries)" [2]. The defining characteristics of a registry are: the existence of a merged centralised dataset; a standardised dataset for each patient; a protocol for prospective data collection; the presence of longitudinal data for each patient; and the collection and inclusion of follow-up and outcome data [2].

Administrative systems, such as the Hospital Episode Statistics database for England [3], exist for non-clinical purposes, most often to facilitate billing or revenue

generation. Clinical registries by definition have a more clinical focus and are frequently established to support processes such as audit, quality improvement and benchmarking. Such sources, alone or in combination, provide opportunities for research through secondary use of the data they contain. The gold standard of clinical research, the randomised controlled trial (RCT), has potential limitations, including high cost and a perceived lack of real-world applicability, which have led to increasing calls for improved efficiency in research design. Registry-based research has the potential to address this need with cost effective studies of routine clinical practice, although there are well-described concerns and limitations.

The aims of this review were firstly to describe the current anaesthesia and peri-operative care registries which exist in the UK, the potential advantages and unique opportunities they might offer compared with traditional RCTs, and the practicalities and barriers preventing their routine use for clinical research. We also wished to explore recent methodological developments which are being deployed to overcome some of the historic limitations of registry-based research and future implications.

Methods

Current anaesthesia, surgery and peri-operative care registries in the UK were identified using a PubMed search using combinations of the following search terms (MeSH where appropriate): 'register*', 'registry', 'registri*'; 'database*', 'dataset*'; 'anaesth*'; 'Surgical Procedures, Operative'; 'United Kingdom'. Results were supplemented by manual searching, and intensive care registries were not included.

Results

The literature search revealed a marked contrast between the lack of UK-based, anaesthesia-specific registries, and the increasing number of international examples. In Denmark, the Danish Anaesthesia Database is a comprehensive, population-wide anaesthesia registry with mandatory data entry [4]. The USA has many disparate registries and databases covering specific insurance providers or healthcare schemes, some of which member hospitals pay to participate in. One of the largest, the American College of Surgeons' National Surgical Quality Improvement Program contains the basic anaesthetic data and important complications of over 6.6 million cases from over 700 hospitals, despite being 'built by surgeons for surgeons' [5]. Such registries contain a wealth of information but primarily exist to collect accurate, detailed billing codes.

In the UK, multidisciplinary programmes such as the National Emergency Laparotomy Audit (NELA) and the Perioperative Quality Improvement Programme (PQIP), led by the Royal College of Anaesthetists in collaboration with the Royal College of Surgeons and others, are promising examples of multidisciplinary efforts [6, 7]. There are several UK-specific surgical registries, the majority of which do not collect data on anaesthesia provision (Table 1). Those that do display substantial variation in the breadth and depth of information captured (online Supporting Information Table S1).

Discussion

Randomised controlled trials remain the gold standard in clinical research. However, RCTs in anaesthesia are rare and there are well-described limitations to the paradigm, including expense, restrictive inclusion and exclusion criteria, and strict protocols which may not be reflective of day-to-day clinical practice. In response to this there has been a growth in pragmatic trial design, to better emulate clinical reality, and increasing efforts to improve the efficiency of trial conduct and data collection. One such approach is the registry-based randomised trial which draws upon the infrastructure of existing registries to facilitate one or more components of the trial: identifying and consenting potentially eligible participants; randomisation and allocation; data capture; and/or patient follow-up (Table 2). The study may be run entirely within the registry platform or alongside it, thus merging the strengths of traditional RCTs and observational registries. Such studies have been reported from Scandinavian healthcare systems since the 1970s and North America from the 1980s [8]. The FLO-ELA trial is a UK example of this approach, in which the existing NELA infrastructure for patients undergoing emergency laparotomy is used to facilitate a randomised study of a peri-operative intervention (<https://www.floela.org/>). An exciting new development is the Volatile vs. Total intravenous Anaesthesia for major non-cardiac surgery (VITAL) study that will use the PQIP database [9]. Similarly, recent UK trials in critical care have utilised the existing Intensive Care National Audit and Research Centre (ICNARC) infrastructure to great effect [10, 11], as will the National Institute for Health Research-funded UK-ROX trial [12].

One of the factors limiting RCTs in anaesthesia is the requirement for large sample sizes to detect differences in relatively low adverse outcome rates. Registry-based RCTs make it easier to enrol large numbers of patients, for example, the 94,006 patients enrolled in a trial of systematic airway assessment using the Danish Anaesthesia Database

Table 1 A list of UK surgical registries with or without anaesthesia fields included.

With anaesthesia fields	Without anaesthesia fields
National Vascular Registry	UK Registry of Endocrine and Thyroid Surgery
National Joint Registry	British Association of Urological Surgeons
National Ligament Registry	Non-arthroplasty Hip Registry
National Hip Fracture Database	National Oesophago-gastric Cancer Audit
Cataract National Dataset	National Bowel Cancer Audit
Transcatheter Aortic Valve Implantation (TAVI) Dataset	UK Liver Transplant Audit
	Breast and Cosmetic Implant Registry
	National Neurosurgical Audit Programme
	National Adult Cardiac Surgery Audit
	National Congenital Heart Disease Audit
	National Prostate Cancer Audit

Table 2 Examples of the advantages and disadvantages of prospective registry-based trials.

Advantages	Disadvantages
Large sample sizes	Data quality
Lower cost	Ethical and legal issues
Enhanced generalisability	Privacy concerns
Completeness of follow-up	Methodological challenges
Embed alongside routine care	Operational and infrastructure

[13], and are thus well-suited to anaesthesia. Registry-based RCTs are also cheaper than conventional RCTs, with some estimates of the relative cost being as low as 2%. These savings come from a reduction in patient visits, administrative costs, staff training and time, and the removal of the need to build new platforms or infrastructure to run the trial (though these 'hidden' costs are borne elsewhere)[14].

However, some have argued that pragmatic prospective study designs are not the best approach for peri-operative care due to the complex, often unmeasured, interactions that contribute to a patient's outcome. They are relatively slow, and the interventions under study are time-sensitive as 'standard care' develops over time [15]. There will always be conditions for which it is not ethically or morally feasible to perform a prospective RCT due to the risk of deviation from standard care and consenting patients adds time to already constrained clinics and operating lists[16].

The reality is that the current landscape of anaesthesia registries in the UK is insufficient to support this

methodology at scale. This is further compounded by difficulty in adapting or updating existing registries to facilitate the collection of novel or additional data. The FLO-ELA and VITAL studies are promising examples utilising the two existing peri-operative registries, NELA and PQIP [14, 15]. However, given the lack of other opportunities, another strategy is to pursue the application of innovative methodologies to existing datasets.

Methodological developments using routinely collected data

Retrospective, observational analyses of routinely collected clinical data are increasingly common. The principal limitations of such research relate to different forms of bias and confounding, which the prospective RCT is designed to eliminate. Observational studies employ a variety of statistical methods to minimise the influence of these factors, examples of which can be seen in studies investigating mode of anaesthesia for hip fracture surgery (Table 3). These studies all examine the same question, in larger sample sizes than are feasible in a RCT, and all reach the same conclusion (i.e. no difference in the primary outcome) via different methodologies.

The 'traditional' method is multivariable regression, in which patient outcomes are adjusted for measured covariates and known confounders within the data, such as a patient's age and ASA physical status [17]. Propensity score matching extends this approach by using the covariates to calculate a propensity score for each individual, and then matching patients with similar characteristics (e.g. the same age and sex) in the different treatment 'arms' of the trial[18].

Only covariates which are specified in the dataset can be adjusted for using these methods, which therefore remain prone to unmeasured confounding. Causal inference methods, for example, the use of instrumental variable analyses, attempt to minimise the effect of unmeasured confounding, thus allowing better exploration of causal relationships between exposures and outcomes [19, 20]. An 'instrument' affects the treatment a patient receives, but has no other impact on their outcome. As an example, hospitals differ in their usage of regional and general anaesthesia (RA and GA) for hip fracture surgery. As patients with hip fractures will typically present to their nearest hospital, a patient living nearer a hospital which performs more RAs is more likely to receive a RA than a patient who lives nearer a hospital which performs more GAs. The 'instrument' is thus calculated as the difference in distance between a patient's nearest 'RA hospital' and their nearest 'GA hospital'. Patients who live nearer RA hospitals

Table 3 Observational studies of mode of anaesthesia for hip fracture surgery

Methodology	Data source and sample size	30-day mortality (RA vs. GA)	p value
Multivariable regression	National Hip Fracture Database (n = 65,535) [17]	7.0% vs. 7.5%	0.23
Propensity score matching	Nottingham Hip Fracture Database (n = 7164) [18]	Odds ratio 0.97 [95% CI 0.8–1.15]	0.76
Instrumental variable	New York Statewide Planning and Research Cooperative System (n = 56,729) [21]	Risk difference –1.1% [95% CI –2.8–0.5]	0.20

RA, regional anaesthesia; GA, general anaesthesia.

can then be matched with patients who are similar on measured confounders, for example, sex and fracture type, but who live nearer GA hospitals. The resulting analysis therefore compares patients whose mode of anaesthesia varied as a result of their proximity with specific hospitals, rather than a process of clinical selection [21].

Another approach is target trial emulation in which a prospective trial is simulated using retrospective data. The value of this approach is illustrated by a blinded analysis in which existing data from previous trials was used to emulate an ongoing, novel prospective trial (e.g. PreVent; Preventing Hypoxemia with Manual Ventilation during Endotracheal Intubation) and produced similar results for the primary outcome [22]. However, this approach requires that all relevant confounders are measured and available such that statistical adjustment for potential selection bias and immortal time bias can be performed. That was possible in this case as the existing trial datasets contained more detailed, accurately collected, patient information than is typically found in routinely collected clinical datasets.

These examples illustrate the extent to which the combination of subject-matter knowledge, high-quality data and sound methodology can help to overcome the limitations of observational research [23] while including much larger sample sizes than a RCT could feasibly recruit.

Challenges in registry research

Successful research commonly requires linkage of multiple sources, for example, administrative and clinical datasets, to produce new, clinically meaningful, data [16]. This is particularly true for anaesthesia in the UK because anaesthesia provision is not coded in the Hospital Episode Statistics data [24]. The process of data linkage is time consuming, often requiring multiple, distinct approvals and increases the risk of errors. Linkage may also highlight deficiencies in the quality and completeness of routinely collected data, requiring an approach to dealing with missing data in analyses, and measures of data quality are inconsistently reported [8]. Substantial differences in case

numbers between administrative and clinical registries have been reported [25], particularly when local level data are scrutinised against national records [26], which may in part represent a lack of clinician involvement in routine clinical data capture [27].

Existing datasets are subject to the limitations imposed by the data fields specified in that data and the necessarily reductionist approach to data collection may fail to meet the needs of more complex retrospective studies [28]. This is compounded by a lack of flexibility in adding fields or modules to existing registries. The design of any given registry will be influenced by the primary purpose for which it was established: it is reasonable to expect that a registry set up to detect adverse events or generate billing data would not contain the same data items as one designed to allow the clinical outcomes of individual hospitals to be benchmarked against one another. This is particularly true when registries designed for one purpose are used to fulfil another, secondary aim, which is often the case in registry-based research. For example, a registry developed to audit performance against specific targets might be missing clinically important confounders relevant to an additional outcome of interest, thus rendering comparative analyses misleading and inappropriate [29]. The alternative, manual data collection, is labour intensive and more expensive than relying on existing sources, but the elements collected can be aligned with the intended purpose [16] as the National Audit Projects of the Royal College of Anaesthetists have demonstrated (<https://www.nationalauditprojects.org.uk/>).

There are several layers of approvals and permissions which are required for research using registry data, the specifics of which will vary depending on the project. Examples include the NHS Research Ethics Committees [30], which assess whether research proposals are ethical, and the Health Research Authority Confidentiality Advisory Group, which oversees approvals under Section 251 of the NHS Act 2006 to enable the common law duty of confidentiality to be temporarily lifted so that patients' confidential information can be used for research purposes,

where seeking individual consent or anonymising data is not practical (<https://www.hra.nhs.uk/about-us/committees-and-services/confidentiality-advisory-group/>). These safeguards are necessary to protect patient data and ensure research integrity; however, they do pose a logistical barrier to research and may deter potentially interested collaborators [31]. They also impose lengthy timelines on observational projects, which may negate the benefit of timeliness compared with prospective trials. Applications to access national data sources in the UK increasingly attract fees [32, 33] and there may also be overhead costs for the setting up of registry research, though in prospective trials these are often offset by later cost savings due to a reduction in monitoring and follow-up visit requirements [34].

There are understandable concerns regarding the privacy and security of patients' healthcare data and its potential misuse, as well as a lack of clarity over safe and ethical secondary use of routinely collected data [35]. Patient groups tend to show a broad appreciation of the potential benefits to quality and safety of healthcare that the use of electronic health information might permit [36] and the altruistic benefits of sharing anonymised electronic patient records for research tend to outweigh the risks [37]. Most patients had no preference or would prefer not to be asked their permission for doctors to use anonymised data from their records, although a minority definitely did want to be asked [38]. There is a supportive attitude towards data linkage without consent, provided they are de-identified and used for research that aims to benefit society [39, 40]. Patients would value educational materials and an opportunity to discuss the risks and benefits of sharing their data [36]. However, willingness to share data is not universal and certain groups of patients, for example, under-represented minorities or those with particular privacy and confidentiality concerns, are less supportive. Additionally, not all usage purposes receive consistent support, with reluctance to share data described when large pharmaceutical companies would have access [41]. The national data opt-out, introduced in England in 2018, allows patients to choose not to allow their confidential information to be used for research and planning purposes (<https://www.nhs.uk/your-nhs-data-matters/>).

Future implications

Improving anaesthetic data collection in existing surgical registries through enhanced collaboration could be a short-term, achievable goal. Those which currently collect no anaesthetic data represent a missed opportunity and we should engage collaboratively to start including anaesthetic data. Those with existing anaesthesia fields should seek

engagement and feedback in order to update and adapt their dataset to maximise the potential benefits, as the National Vascular Registry has done in conjunction with the Vascular Anaesthesia Society [42]. Increased clinician involvement in data entry would help to improve the quality of data collected. However, any additional time commitment is unlikely to be feasible in the longer term, and it may be that the automated data capture provided by electronic health records and anaesthesia information systems is the ultimate solution for efficiency and accuracy [17, 27, 43]. Ideally, routinely collected data would be of the same standard as research grade data and so readily employed to provide the endpoints, both clinical and patient-reported, of clinical trials. However this will require substantial investment and infrastructure changes alongside collaboration on regional and national scales between healthcare providers, academic institutions, industry and patient groups [44, 45].

In the longer term, efforts to develop a standardised minimum dataset for anaesthesia would be welcomed, although there is no consensus as to what that might contain [46]. This would align with ongoing efforts to standardise endpoints in peri-operative trials [47] and allow standardisation of how anaesthesia is defined and reported, as has been achieved for surgical interventions [48]. The need for such consistency will only increase as electronic health records and anaesthesia information systems become more widespread. A central repository of registries and databases through infrastructure, such as the Health Data Research Innovation Gateway (<https://www.healthdatagateway.org/>), might make this standardisation easier to achieve.

Additional research is needed for data quality and validation, novel research designs and how they affect outcome assessment, and aspects of reporting and transparency [34]. Written consent is resource intensive and not feasible for identifying consecutive eligible patients for an extended registry [35]. New models of consent have been proposed, for example, dynamic consent [49] and broad consent [41, 50]; alternatively, an electronic interface could be developed to allow individual control over consent choices and provide feedback on data recipients and research results [37].

Ultimately, there is a need for new, multicentre or national data-sharing networks within UK anaesthesia, akin to the Multicenter Peri-operative Outcomes Group in the USA [51] or the critical care arm of the National Institute for Health Research Health Informatics Collaborative [52]. The National Institute of Academic Anaesthesia Health Services Research Centre data science stream is an encouraging

development [53] but it would ultimately be aided by a national anaesthesia registry. Any new registry should have inbuilt procedures to ensure integrity and quality of data; capture key baseline characteristics and hard clinical endpoints, collect identifiable information to permit linkage, have appropriate security and governance arrangements and seek participant consent for future research [14]. Patient and public involvement should inform design from the outset and clinical trialist input could facilitate embedding of RCTs in the future [8].

In conclusion, a change in the approach to registry-based research in anaesthesia in the UK is needed in order to harness the opportunities for patient benefit. Despite encouraging signs, the UK is lagging behind other countries and healthcare systems in this domain. As electronic health records and anaesthesia information systems become more widespread, we have an opportunity to establish comprehensive, high quality, registries which will allow improvements to anaesthesia care in this country for the foreseeable future. In the short term, there is an opportunity for enhanced collaboration between anaesthesia and surgery to increase the volume and value of data collected. The resulting datasets, coupled with innovative statistical methodologies, would allow significant progress towards realising the potential of routinely collected data for patient-centred research. Concurrently, work should begin towards a standard minimum anaesthesia dataset with the ultimate aim of establishing a national registry of anaesthesia.

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Supporting Information

Additional supporting information may be found online via the journal website.

Table S1. Data items relevant to anaesthesia in existing UK surgical registries.