Recycling existing data: a greener future for clinical registries

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"*It is only by collecting data and using them that you can get sense*"

William Osler (1)

From modest origins, as personal case-series published for educational purposes, clinical registries – organised datasets of clinical and demographic information about patients with particular health needs – have grown in both influence and importance. They illuminate what is actually happening in the 'real world' of disordered and complex practice.

Utility of Clinical Registries

Registries have many uses. (2,3) Depending on the information therein, registries allow quantification of 'disease burden' and the use of health services, and so can aid planning and commissioning of care. They can serve to chart the implementation of new technologies and form a repository for the long-term surveillance of implanted devices. Those with rich datasets may provide material for observational research, including international comparisons. They have a role in risk modelling and prognostication. Registries that contain (or link to) outcomes or 'vital status' may be used to support interventional randomized controlled trials by providing a 'pool' of potential participants and forming the means of following-up the participants during such studies. Importantly, because they contain information about variations in processes and outcomes they have become intertwined with quality assurance and performance management and play a central role in a "Cycle of Quality Improvement". (4)

With respect to quality of care they have a 'Janus-like' capability. They offer a backwards look, and so inform the development of performance indicators and clinical guidelines, and, through showing where care is most deficient or variable, identify where, and which, quality improvement (QI) initiatives are likely to have the greatest impact. They can also be used to look forwards, providing a tool to audit actual care against agreed standards, to identify missed opportunities to deliver recommended care, to reward optimal care, and to measure the effect of QI interventions.

Data quality

However a prerequisite to these many functions, and underpinning the validity of all subsequent analyses, interpretations and presentations of findings, is that the registry contains accurate, reliable and sufficiently detailed information. It should encompass the generality of clinical cases rather than being highly selective. Information on each case should be as complete as possible. The dataset should be updated to take account of changes in practice and be flexible enough to capture information about episodes of care that include transfer between hospitals. Such data should be carefully collected and curated – 'cleaned' and validated – stored and handled in accordance with relevant legal strictures.

These more functional aspects of the management of clinical registries require considerable resources and present significant challenges. (5) Chief amongst them is a trade-off between *case ascertainment* – the inclusion of all eligible cases – and *data timeliness/completeness* – the timely recording of all available information about each case. Interestingly, there is an association between the extent of missing data and 30-day mortality in acute coronary syndrome (ACS), (6) suggesting that centres that make efforts to maintain the quality of their data are also more likely to provide good clinical care. However, in general, as the number of data items per case increases 'data fatigue' begins to affect those responsible for collecting and submitting data. This leads to a tendency to submit incomplete data on individual cases or to exclude some cases altogether. For example, the national clinical audit of ACS in England and Wales – MINAP: a 'rich dataset' of 130 data fields per case, completed by hospital-based clinical or clerical staff often some weeks after the index event – under-reports cases when compared both with extensive resource-intensive hospital-based search strategies triggered by laboratory troponin estimates, (7) and with linked primary care and hospital admissions coding systems. (8)

Reducing this burden of data collection can be achieved by minimizing the volume of data collected on each case, collecting only a sample (e.g. the first 10 cases per month) of cases, or performing highly detailed snapshot surveys (as in the case of the nationwide French FAST-MI programme – one month of data collection every 5 years). (9)

e-Registry

In this issue of *European Heart Journal – Quality of Care and Clinical Outcomes* Iain Findlay *et al*. (10) present a further solution to these challenges of adequate data collection and high data quality, and, in so doing, neatly leapfrog over many larger more mature registries.

Having formed a collaborative of clinicians, university academics and analysts/project managers from a biopharmaceutical company, these researchers produced a reliable, useful and validated electronic clinical register (e-Registry) using data extracted from existing service-related electronic data bases, without the need for additional registry-specific electronic or manual data collection, and so avoiding additional work for those clinicians caring for patients. This is certainly not the first time that administrative data has been used for this purpose. (11,12) However the Scottish group have taken advantage of a unique national personal health number, the Community Health Index, to link information on 2327 individual patients (2472 episodes of care) managed for ACS over 12 months in a large health region: consisting 7 acute hospitals and a cardiothoracic unit providing coronary angiography, invasive cardiology and surgery. This linkage established connections across databases that served clinical, administrative, and epidemiological purposes – more specifically, a common electronic patient administration system that also documented aspects of clinical care, a system used to refer patients to the interventional centre, and a bespoke catheter laboratory system within that centre. The dataset was further enriched through linkage to a national record of death certificates – this latter linkage taking place within a virtual 'Safe Haven' within NHS Scotland.

Through analysis of the resultant dataset Findlay *et al*. describe the characteristics of the patients, the types of ACS they experienced, and which of six distinct pathways of care they followed – successfully tracking those patients transferred between hospitals within the cardiac network. They also present information about the use and timeliness of cardiac interventions, the durations of hospitalizations and 30-day and 12 month all-cause mortality.

Early findings

This yields interesting observations on practice in the West of Scotland, some of which warrant further investigation and could form the focus of future QI initiatives. For instance, the median delay to primary percutaneous coronary intervention (PCI) in cases of ST-elevation myocardial infarction (STEMI) is 95 minutes from first calling for medical attention and 22 minutes from arrival at hospital. These findings suggest that this Scottish interventional centre is among the best performing centres in the United Kingdom. (13) Yet, given that 20% of cases of STEMI are not offered primary PCI, might anything be done to improve the rate of reperfusion therapy within the network? Further, there are potentially important and modifiable differences in management by gender – men with non-ST-elevation myocardial infarction (nSTEMI) are more likely to be referred for, and to receive, angiography, and to undergo PCI, than women, despite tending to have lower GRACE risk scores.

Finally, most patients with nSTEMI who are referred for urgent inpatient angiography, with a view to proceeding to PCI, do not undergo angiography within the recommended interval of 72 hours from admission to hospital – 25% of patients wait at least 6 days – albeit those with higher GRACE scores receive earlier angiography. During the same period, similar sub-optimal care was reported (in MINAP) from other parts of the UK. (13) However, MINAP only presented reliable data for those patients admitted directly to interventional centres whilst the Scottish e-Registry includes those transferred between hospitals for angiography.

Other lessons

Importantly, a meticulous validation exercise involving assessment of 200 individual patient episodes is detailed within the paper. In doing this the authors satisfy one of the recommendations of the RECORD guidelines for promoting transparency and completeness of reporting of observational research using routinely collected health data. (14) They also demonstrate almost complete accuracy of the coded diagnosis – a very low 'false-positive' rate – but are unable to report on the 'false negative' rate – the proportion of patients with ACS who do not appear in the e-Registry by virtue of being wrongly assigned another diagnostic code. This is an important point as it has been suggested that the more expensive approach of individually/manually verifying disease diagnoses in each case is less prone to error than the mass application of identification criteria used in extracting cases *en masse*. (15) Disease misclassification in routinely collected electronic data may lead to significant bias.

The authors make no claim that their findings are unique, nor even of great importance outside their own clinical network. Rather, the interesting lesson is how their e-Registry was forged, with indirect Governmental support and managerial approval, strict governance and legal agreements between the NHS and academia, and with an industry partner playing an enabling and priming role. Findlay *et al*. have succeeded in developing a useful e-Registry that has the potential to become a major driver for QI in their region, and indeed throughout Scotland. In so doing they have made prudent use of existing data without distracting practising clinicians from their primary purpose of providing care. To paraphrase Osler (above) they have been able to make secondary use of collected data to get a sense of their own real world practice and the experiences of the patients they serve.

Funding: No external funding

Conflict of Interest: I am Clinical Director of the Myocardial Ischaemia National Audit Project.

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