Can randomised trials rely on existing electronic data?

Can randomised trials rely on existing electronic data? A feasibility study to explore the value of routine data in health technology assessment

JG Williams[1*]
WY Cheung[1]
DR Cohen[2]
HA Hutchings[1]
MF Longo[2]
IT Russell[3]

[1] Centre for Postgraduate Studies, The Clinical School, University of Wales Swansea, UK
[2] School of Care Sciences, University of Glamorgan, Pontypridd, UK
[3] Department of Health Sciences and Clinical Evaluation, Alcuin College, University of York, UK

* Corresponding author

Executive summary

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Executive summary

Background

Data are widely collected routinely in healthcare and increasingly held in electronic form. These data are used for a wide variety of purposes, such as health technology assessment without randomisation, although the value of this has been disputed. The randomised controlled trial (RCT) is the design of choice for health technology assessment, but data are usually collected for the sole purpose of evaluation. The value of using routinely collected data for prospective health technology assessment by RCTs has not previously been explored.

Objectives

The objectives were to estimate the feasibility, utility and resource implications of electronically captured routine data for health technology assessment by RCTs, and to recommend how routinely collected data could be made more effective for this purpose.

Methods.

The project assessed the feasibility of extending the practice of health technology assessment through the use of routine data by replicating the analysis of four RCTs. The original trials were taken as designed, and the trial population as randomised. The research process was then modelled from data definition to final writing up, substituting routine for designed data activities throughout. In other words, the project simulated a novel form of health technology assessment by RCTs, using existing electronic data. The four exemplars addressed different interventions (shared care for inflammatory bowel disease, home assessment of obstructive sleep apnoea, urethral sling surgery for female urinary incontinence, and autologous blood transfusion during total knee replacement). For each of these four RCTs, two analyses were undertaken, one using designed data and the other routine data. The analyses were carried out independently before discussion and reconciliation of the findings. This led to conclusions about the feasibility, validity, utility and cost of using routine data for health technology assessment.

Results

The study has shown that some of the research questions posed by health technology assessment through RCTs can indeed be answered using routinely collected data. Where these questions require analysis of NHS resource use, data can usually be identified. Clinical effectiveness can also be judged, using proxy measures for quality of life (QoL), provided clinical symptoms and signs are collected in sufficient detail. Patient and professional preferences cannot be identified from routine data but could be collected routinely by adapting existing instruments.

Routine data are potentially cheaper to extract and analyse than designed data. In addition, they facilitate recruitment. They also have the potential to identify patient outcomes captured in remote systems that may be missed in designed data collection.

Notwithstanding these potential benefits, the study confirmed previous evidence that the validity of routinely collected data is suspect, particularly in systems that are not under clinical and professional control. There are also potential difficulties in identifying, accessing and extracting data, and in the lack of uniformity in data structures, coding systems and definitions. While data validity remains suspect there is likely to be resistance among researchers to the use of routine data for health technology assessment by RCTs.

Conclusions

Routine data have the potential to support health technology assessment by RCTs. The cost of data collection and analysis is likely to fall, although further work is required to improve the validity of routine data, particularly in central returns. Better knowledge of the capability of local systems and access to the data held on them is also essential. Routinely captured clinical data have real potential to measure patient outcomes, if the data were collected in detail and with precision.

Research recommendations

There is a need for further research to:

- test prospectively the feasibility of health technology assessment by RCTs through routine data
- classify the research data needed for health technology assessment, and to map these data to potential routine sources
- assess the feasibility, cost and effects of greater clinical ownership and responsibility for hospital episode statistics
- explore the feasibility and cost of local information laboratories aimed at maximising access to, and the utility of, routine data
- understand and change clinicians' and researchers' attitudes to routine data, particularly as validity and availability improves
- define standards to ensure the uniformity and validity of data collected by different local and national systems
- explore the use of surrogate clinical data for measuring patient-focused outcomes
- explore the feasibility and cost of routine completion of health-related QoL questionnaires in clinical practice
- explore the feasibility and cost of routine capture of patient preference data.

Publication

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NHS R&D HTA Programme

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This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure was replaced in 2000 by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme will continue to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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