



Title	Can Randomized Trials Rely on Existing Electronic Data? A Feasibility Study to Explore the Value of Routine Data in Health Technology Assessment
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Reference	Health Technol Assess 2003;7(26). Sept 2003. www.ncchta.org/execsumm/summ726.htm

Aim

To estimate the feasibility, utility, and resource implications of electronically captured routine data for health technology assessment (HTA) by randomized controlled trials (RCTs), and to recommend how routinely collected data could become more effective for this purpose.

Conclusions and results

The study shows that routinely collected data can answer some research questions posed by HTA through RCTs. Data to analyze NHS resource use can usually be identified. Clinical effectiveness can be judged using proxy measures for quality of life (QoL) if clinical data are sufficiently detailed. Patient and professional preferences cannot be identified from routine data, but could be collected by adapting existing instruments. Routine data can facilitate recruitment and may be cheaper to extract and analyze than designed data. Also, they can potentially identify patient outcomes that may be missed in designed data. Despite the potential benefits, the study confirmed that the validity of routinely collected data is suspect, particularly in systems not under clinical and professional control. Other problems include identifying, accessing, and extracting data, and the lack of uniformity in data structures, coding systems, and definitions. If data validity remains suspect, researchers are likely to resist using routine data for HTA by RCTs.

Recommendations

Routine data can potentially support HTA by RCTs. Although the cost of data collection and analysis is likely to fall, the validity of routine data needs to improve. Better knowledge of the capability of local systems, and access to the data, is essential. Routinely captured clinical data, if detailed and precise, could potentially measure patient outcomes.

Methods

The original 4 RCTs were taken as designed, and the trial population as randomized. The research process was modeled from data definition to final writing, sub-

stituting routine for designed data activities throughout. The project simulated a novel form of HTA by RCTs, using existing electronic data. The 4 examples addressed different interventions. For each, two analyses were undertaken (one using designed data and the other routine data). The analyses were done independently before discussion and reconciliation of the findings.

Further research/reviews required

Further research is needed to: test prospectively the feasibility of HTA by RCTs through routine data; classify research data needed for HTA and map the data to potential routine sources; assess feasibility, cost, and effects of greater clinical responsibility for hospital episode statistics; explore the feasibility and cost of local information labs maximizing access to, and utility of, routine data; understand and change clinician/researcher attitudes to routine data, particularly as validity and availability improve; define standards to ensure uniformity and validity of data; explore surrogate clinical data for measuring patient-focused outcomes; explore the feasibility and cost of routine completion of health-related QoL questionnaires in clinical practice; and explore the feasibility and cost of routinely capturing patient preference data.