PRIFYSGOL BANGOR UNIVERSITY

Resource use measurement in trial based economic evaluations

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MRC Hubs for Trials Methodology Research

Background

- Resource use data is required in order to calculate costs for economic evaluations.
- Resource use data can be obtained from routine data, or medical records but this is not always practicable, and may not always contain relevant data (e.g. out of pocket costs) …
- … and therefore many trial-based economic evaluations rely on resource use questionnaires.
- Resource use questionnaires are based on recall and are hampered by inconsistent methods and a lack of validation.

‘Current’ (2010) State of Play: Review

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VALUE IN HEALTH

Methods for the Collection of Resource Use Data within Clinical Trials: A Systematic Review of Studies Funded by the UK Health Technology Assessment Program

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ABSTRACT

Background: The UK Health Technology Assessment (HTA) program funds trials that address issues of clinical and cost-effectiveness to meet the needs of the National Health Service (NHS). The objective of this review was to systematically assess the methods of resource use data collection and costing; and to produce a best practice guide for data capture within economic analyses alongside clinical trials.

Methods: All 100 HTA-funded primary research papers published to June 2009 were reviewed for the health economic methods employed. Data were extracted and summarized by: health technology assessed, costing perspective adopted, evidence of planning and piloting, data collection method, frequency of data collection, and sources of unit cost data.

Results: Ninety-five studies were identified as having conducted an economic analysis, of which 85 recorded patient-level resource use. The review identified important differences in how data are collected. These included: a priori evidence of analysts having identified important cost drivers; the piloting and validation of patient-completed resource use questionnaires; choice of costing perspective; and frequency of data collection. Areas of commonality included: the extensive use of routine medical records and reliance on patient recall; and the use of standard sources of unit costs.

Conclusion: Economic data collection is variable, even among a homogeneous selection of trials designed to meet the needs of a common organization (NHS). Areas for improvement have been identified, and based on our findings and related reviews and guidelines, a checklist is proposed for good practice relating to economic data collection within clinical trials.

Keywords: clinical trials, cost analysis, economic evaluation, health technology assessment.

- Review of HTA-funded research papers published prior to 2009
- 95 identified as including economic analysis
- 85 recorded patient level resource use
- Methods varied
  - A priori evidence to identify cost drivers
  - Piloting and validation of resource use questionnaires
- Some common areas
  - Choice of perspective
  - Routine medical records
  - Reliance on patient recall

Value in Health 2010; 13(8): 867-872

Database of Instruments for Resource Use Measurement (DIRUM)

- Network of HTMRs with collaborators from: Bristol, Birmingham, LSE, Vancouver and Bangor
- Examined feasibility of establishing an open-access Database of Instruments for Resource-Use Measurement
- Identified relevant fields for data extraction
- Outlined database design.

DIRUM: Survey of health economists

VALUE IN HEALTH 15 (2012) 650–655

Available online at www.sciencedirect.com

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Development of a Database of Instruments for Resource-Use Measurement: Purpose, Feasibility, and Design

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ABSTRACT

Background: Health economists frequently rely on methods based on patient recall to estimate resource utilization. Access to questionnaires and diaries, however, is often limited. This study examined the feasibility of establishing an open-access Database of Instruments for Resource-Use Measurement, identified relevant fields for data extraction, and outlined its design. **Methods:** An electronic survey was sent to authors of full UK economic evaluations listed in the National Health Service Economic Evaluation Database (2008–2010), authors of monographs of Health Technology Assessments (1998–2010), and subscribers to the JISCMail health economics e-mailing list. The survey included questions on piloting, validation, recall period, and data capture method. Responses were analyzed and data extracted to generate relevant fields for the database. **Results:** A total of 143 responses to the survey provided data on 54 resource-use instruments for inclusion in the database. All were reliant on patient or carer recall, and a majority (47) were questionnaires. Thirty-seven were designed for self-completion by the patient, carer, or guardian, and the remainder were designed for completion by researchers or health care professionals while interviewing patients. Methods of development were diverse, particularly in areas such as the planning of resource itemization (evident in 25 instruments), piloting (25), and validation (29). **Conclusion:** On the basis of the present analysis, we developed a Web-enabled Database of Instruments for Resource-Use Measurement, accessible via www.DIRUM.org. This database may serve as a practical resource for health economists, as well as a means to facilitate further research in the area of resource-use data collection.

Keywords: clinical trials, cost analysis, data collection methods, economic evaluation, health technology assessment.

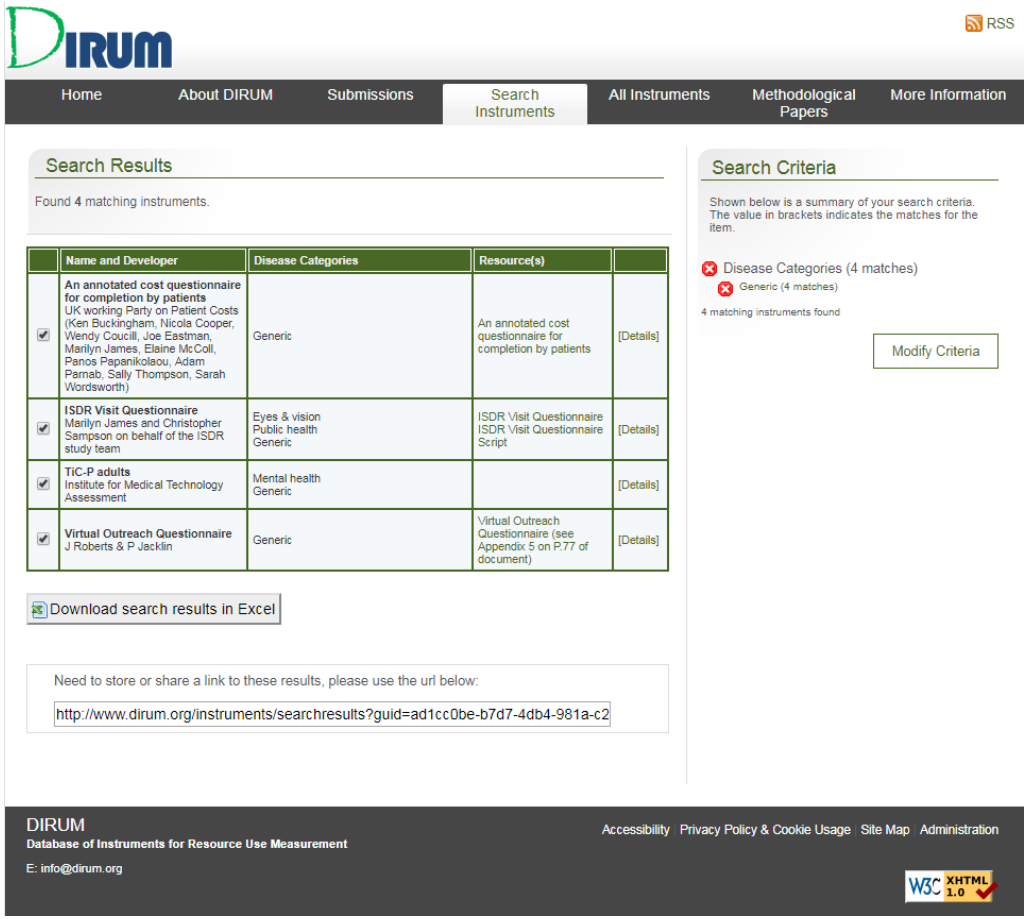
- Electronic survey of UK health economists
- Questions on piloting, validation, recall period, and data capture method.
- 143 responses
- Data on 54 resource-use instruments.
- All instruments reliant on recall.
- Thirty-seven designed for completion by the patient, carer, or guardian
- Remainder for completion by researchers or health care professionals during patient interviews.

Value in Health 2012; 15(5): 650-655

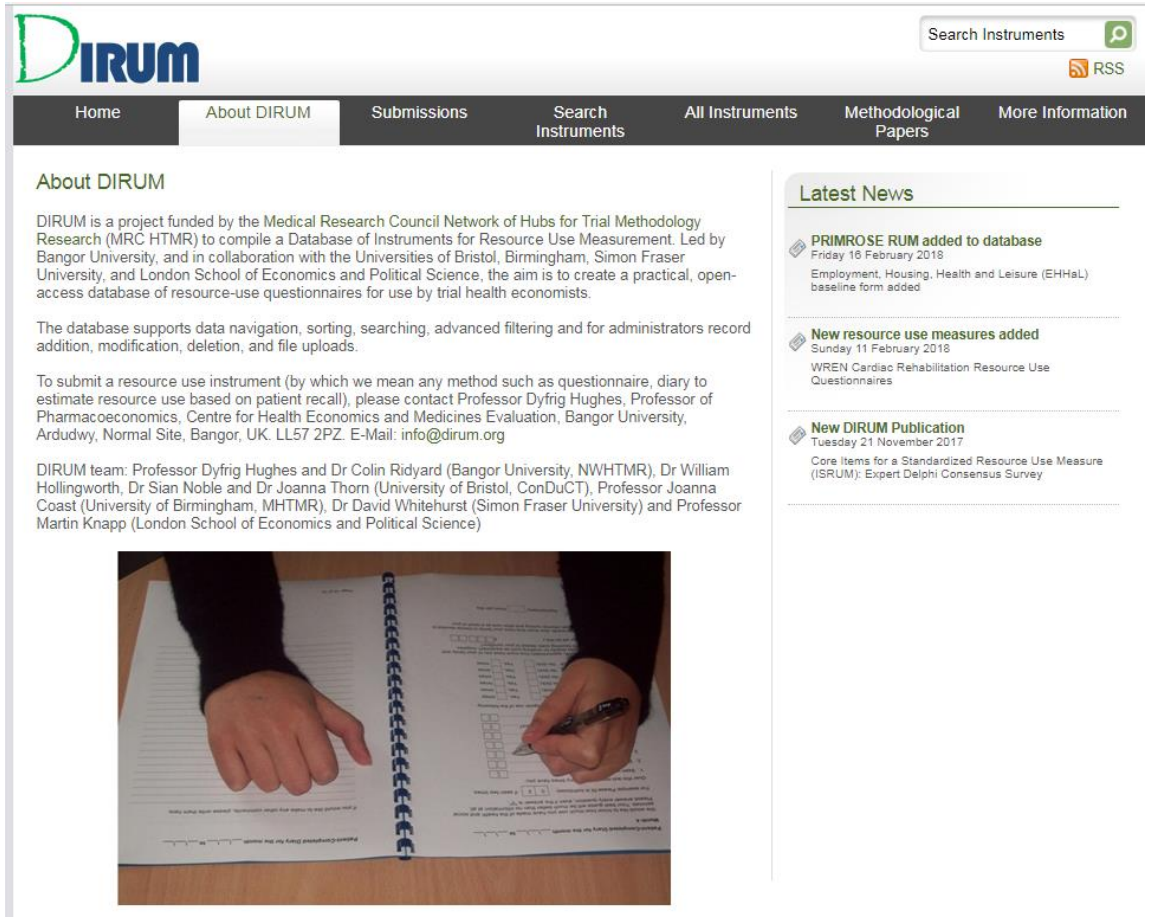
DIRUM: Website

On this basis developed Web-enabled Database of Instruments for Resource-Use Measurement, accessible via www.DIRUM.org.

DIRUM serves as a practical resource for health economists, and a means to facilitate further research in the area of resource-use data collection.



DIRUM: Updates

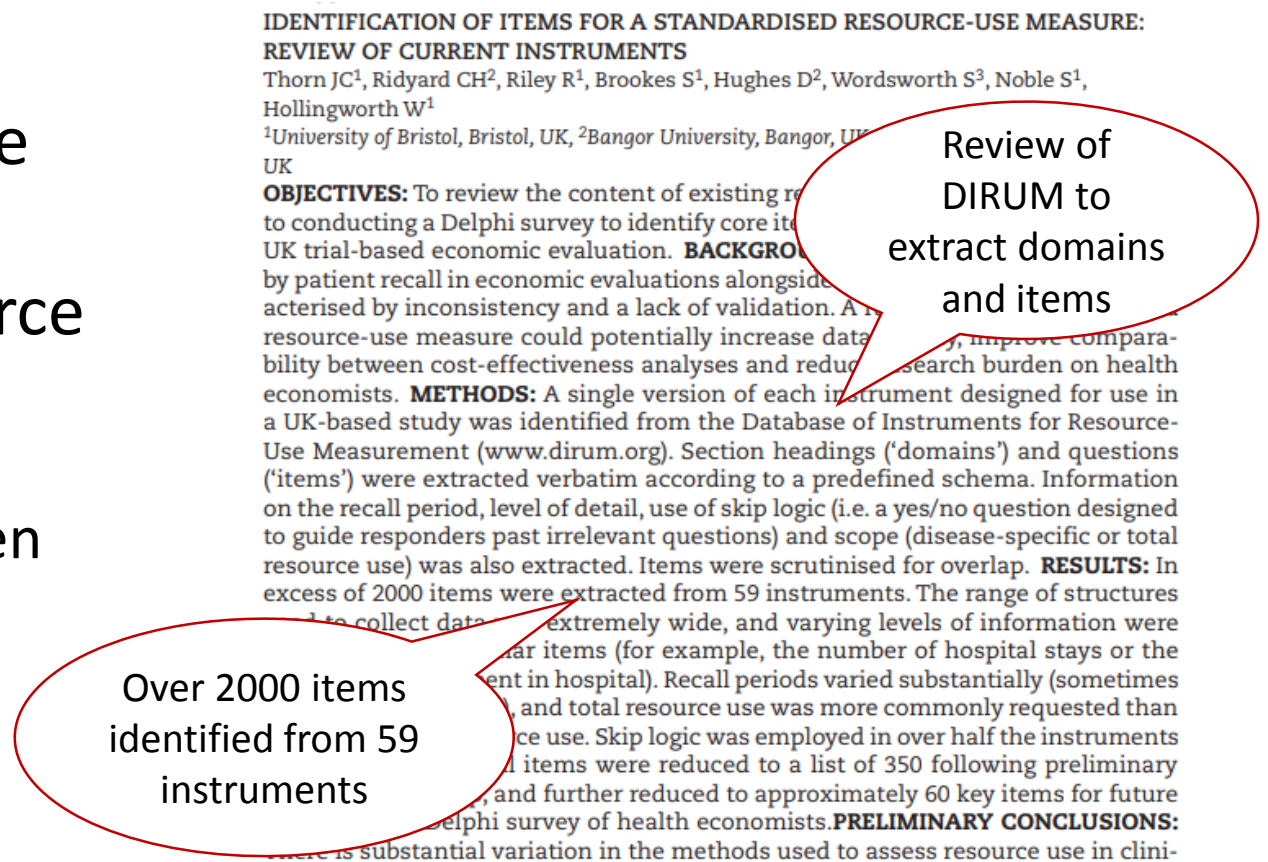


- 84 resource use instruments
- ~ 20,000 visits (68% from outside of the UK)
- ~ 6,000 instrument downloads

(December 2017)

ISRUM: Motivation

- Led by Bristol
- Minimum set of core resource use items
- Validated standardized resource use measure
  - Increase data quality
  - Improve comparability between studies
  - Reduce research burden.
- Standardised resource use instrument



IDENTIFICATION OF ITEMS FOR A STANDARDISED RESOURCE-USE MEASURE: REVIEW OF CURRENT INSTRUMENTS

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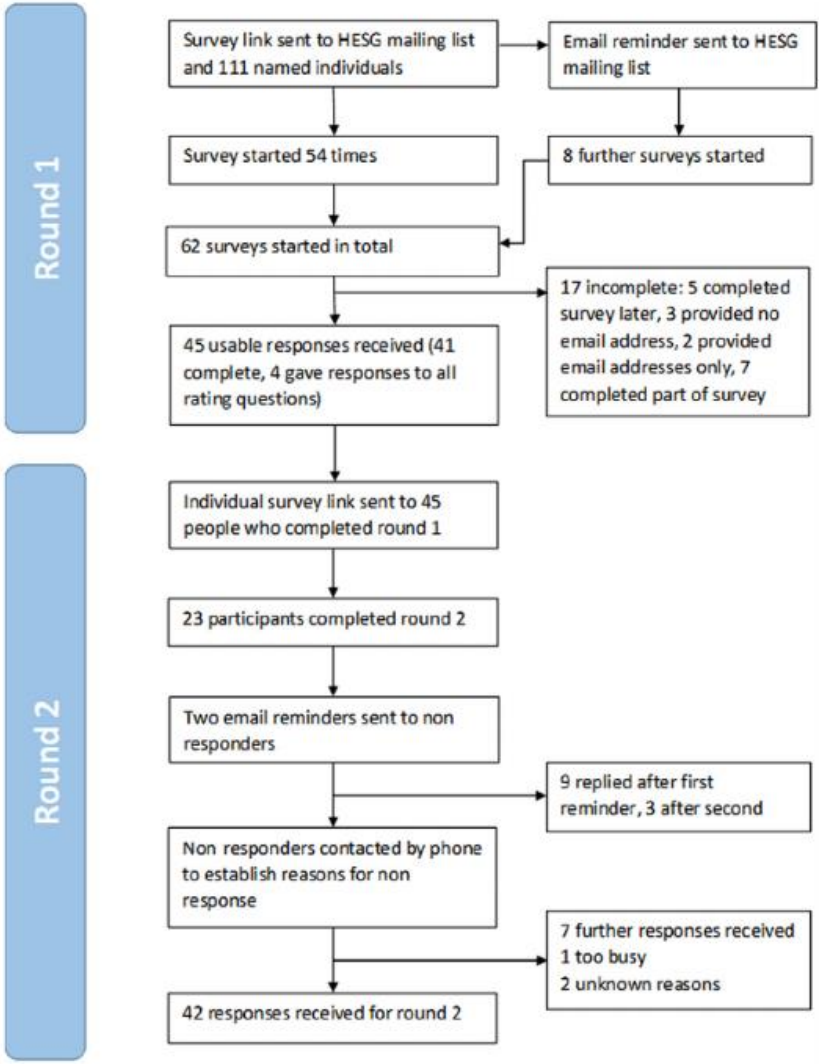
OBJECTIVES: To review the content of existing r… to conducting a Delphi survey to identify core it… UK trial-based economic evaluation. **BACKGRO…** by patient recall in economic evaluations alongside… acterised by inconsistency and a lack of validation. A … resource-use measure could potentially increase data … bility between cost-effectiveness analyses and reduc… economists. **METHODS:** A single version of each instrument designed for use in a UK-based study was identified from the Database of Instruments for Resource-Use Measurement (www.dirum.org). Section headings ('domains') and questions ('items') were extracted verbatim according to a predefined schema. Information on the recall period, level of detail, use of skip logic (i.e. a yes/no question designed to guide responders past irrelevant questions) and scope (disease-specific or total resource use) was also extracted. Items were scrutinised for overlap. **RESULTS:** In excess of 2000 items were extracted from 59 instruments. The range of structures … to collect data … extremely wide, and varying levels of information were … ar items (for example, the number of hospital stays or the … ent in hospital). Recall periods varied substantially (sometimes … , and total resource use was more commonly requested than … ce use. Skip logic was employed in over half the instruments … l items were reduced to a list of 350 following preliminary … , and further reduced to approximately 60 key items for future … elphi survey of health economists.**PRELIMINARY CONCLUSIONS:** … is substantial variation in the methods used to assess resource use in clinical trials. Further work is in progress to prepare and administer the Delphi survey.

Review of DIRUM to extract domains and items

Over 2000 items identified from 59 instruments

Value in Health 2015; 18(7): A668

ISRUM: Delphi survey



- Round 1: Respondents rated 60 resource use items. Less important items were dropped and a second survey developed.
  - 45 respondents
  - 26 items were dropped
  - 34 items were retained
  - No new items added
- Round 2: Respondents rerated items. For each item, respondents given median score, their own score and summarized comments from Round 1.
  - 42 respondents completed
  - Greater consensus observed
- Final meeting
  - 10 core items selected
  - Further items identified as suitable for “bolt-on” questionnaire modules.

Value in Health 2018; 21(6): 640-649

ISRUM: Core items 1/2

- Hospital care
  - Number of hospital admissions (inpatient stay or day case)
  - Length of stay (e.g. dates or number of nights)
  - Number of hospital outpatient appointments
- Emergency care
  - Number of visits to A&E
  - Number of appointments

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Core Items for a Standardized Resource Use Measure: Expert Delphi Consensus Survey

Joanna C. Thorn, BSc, MSc, PhD[1,], Sara T. Brookes, BSc, PhD[1], Colin Ridyard, PhD[2], Ruth Riley, BSc, MSc, PhD[1], Dyfrig A. Hughes, BPharm, MSc, PhD[2], Sarah Wordsworth, BSc, PhD[3], Sian M. Noble, BSc, PhD[1], Gail Thornton, BSc, MRes(Psych)[1,a], William Hollingworth, BSc, MSc, PhD[1]*

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ABSTRACT

Background: Resource use measurement by patient recall is characterized by inconsistent methods and a lack of validation. A validated standardized resource use measure could increase data quality, improve comparability between studies, and reduce research burden. **Objectives:** To identify a minimum set of core resource use items that should be included in a standardized adult instrument for UK health economic evaluation from a provider perspective. **Methods:** Health economists with experience of UK-based economic evaluations were recruited to participate in an electronic Delphi survey. Respondents were asked to rate 60 resource use items (e.g., medication names) on a scale of 1 to 9 according to the importance of the item in a generic context. Items considered less important according to predefined consensus criteria were dropped and a second survey was developed. In the second round, respondents received the median score and their own score from round 1 for each item alongside summarized comments and were asked to rerate items. A final project team meeting was held to determine the recommended core set. **Results:** Forty-five participants completed round 1. Twenty-six items were considered less important and were dropped, 34 items were retained for the second round, and no new items were added. Forty-two respondents (93.3%) completed round 2, and greater consensus was observed. After the final meeting, 10 core items were selected, with further items identified as suitable for "bolt-on" questionnaire modules. **Conclusions:** The consensus on 10 items considered important in a generic context suggests that a standardized instrument for core resource use items is feasible.

Keywords: cost measurement, patient-reported, randomized clinical trial, resource use.

Value in Health 2018; 21(6): 640-649

ISRUM: Core items 2/2

- Care at a GP surgery or health clinic or other community setting
  - Number of appointments
  - Type of professional seen
- Health care at home
  - Number of health care professional visits at home
  - Type of health care professional seen at home
- Medication
  - Name / class of medication

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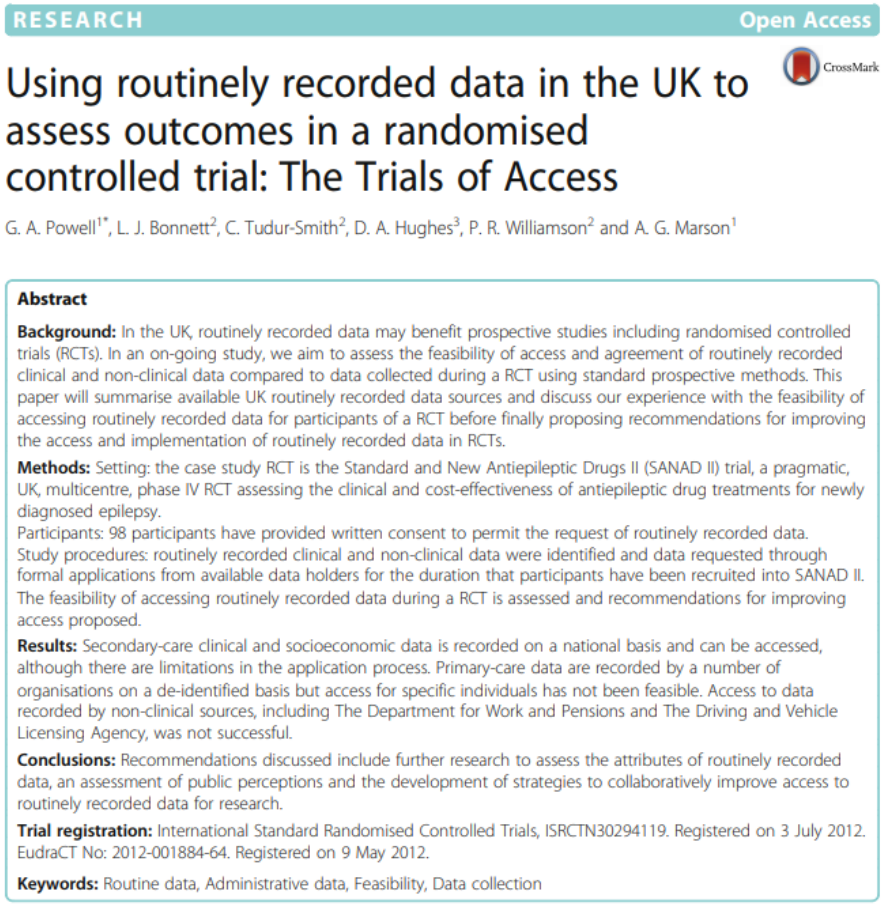
Value in Health 2018; 21(6): 640-649

Looking forward, future challenges 1/2



RESEARCH Open Access

Using routinely recorded data in the UK to assess outcomes in a randomised controlled trial: The Trials of Access

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Abstract

Background: In the UK, routinely recorded data may benefit prospective studies including randomised controlled trials (RCTs). In an on-going study, we aim to assess the feasibility of access and agreement of routinely recorded clinical and non-clinical data compared to data collected during a RCT using standard prospective methods. This paper will summarise available UK routinely recorded data sources and discuss our experience with the feasibility of accessing routinely recorded data for participants of a RCT before finally proposing recommendations for improving the access and implementation of routinely recorded data in RCTs.

Methods: Setting: the case study RCT is the Standard and New Antiepileptic Drugs II (SANAD II) trial, a pragmatic, UK, multicentre, phase IV RCT assessing the clinical and cost-effectiveness of antiepileptic drug treatments for newly diagnosed epilepsy.
Participants: 98 participants have provided written consent to permit the request of routinely recorded data.
Study procedures: routinely recorded clinical and non-clinical data were identified and data requested through formal applications from available data holders for the duration that participants have been recruited into SANAD II. The feasibility of accessing routinely recorded data during a RCT is assessed and recommendations for improving access proposed.

Results: Secondary-care clinical and socioeconomic data is recorded on a national basis and can be accessed, although there are limitations in the application process. Primary-care data are recorded by a number of organisations on a de-identified basis but access for specific individuals has not been feasible. Access to data recorded by non-clinical sources, including The Department for Work and Pensions and The Driving and Vehicle Licensing Agency, was not successful.

Conclusions: Recommendations discussed include further research to assess the attributes of routinely recorded data, an assessment of public perceptions and the development of strategies to collaboratively improve access to routinely recorded data for research.

Trial registration: International Standard Randomised Controlled Trials, ISRCTN30294119. Registered on 3 July 2012. EudraCT No: 2012-001884-64. Registered on 9 May 2012.

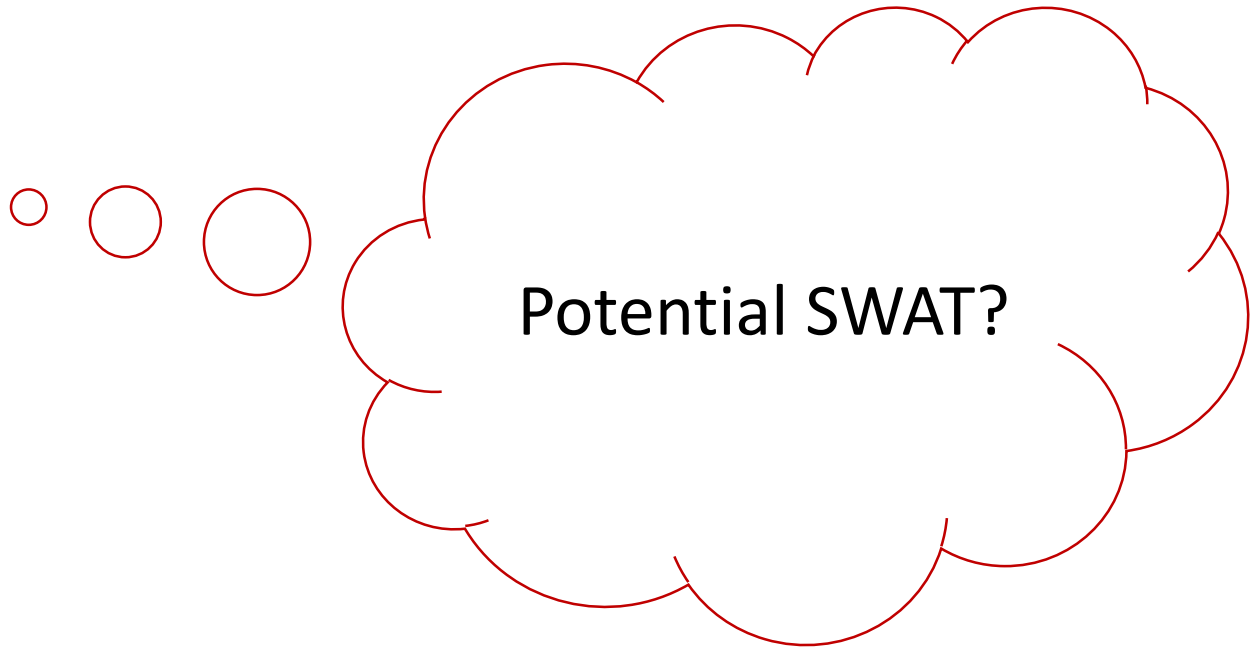
Keywords: Routine data, Administrative data, Feasibility, Data collection

- Based on subset of participants from SANADII RCT
  - 3 sources of clinical routine data from secondary care
  - 5 sources of clinical routine data from primary care
  - 4 sources of non-clinical data
  - 2 ‘linked’ routine data sources
- Secondary care data could be accessed, but limitations in application process.
- Primary care data are recorded but access of data for specific individuals was not feasible.
- Access to non clinical data was not successful

Trials 2017; 18(1): 389

Looking forward, future challenges 2/2

- Return rates for questionnaires
  - Self-complete
    - Postal
    - Online
  - Interviews
    - Face to face
    - Telephone



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- University of Oxford: Sarah Wordsworth
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- The London School of Economics and Political Science: Martin Knapp