

Title:

Development of a Database of Instruments for Resource Use Measurement (DIRUM):
Purpose, feasibility and design

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ABSTRACT

Aims: Health economists frequently rely on methods based on patient-recall to estimate resource utilisation. However, access to well-designed and validated questionnaires and diaries is often limited. This study examines the feasibility of establishing an open-access Database of Instruments for Resource Use Measurement (www.DIRUM.org), identifies relevant fields for data extraction and outlines its design.

Methods: A targeted electronic survey was distributed among health economists asking questions about piloting, validation, recall period and data capture method, amongst others; as well as respondents' willingness to share their resource use instruments. Responses were analysed and data extracted to generate relevant fields for the database.

Results: 143 responses to the survey provided data on 54 resource use instruments eligible for inclusion in the database. The majority (47) were questionnaires, with the remainder being diaries. Thirty-seven were designed for completion by patient, carer or guardian; and 17 were designed for completion by telephone or face-to-face interviewing by researchers or healthcare professionals. Instruments showed evidence of disparate methods of development in areas such as the planning of resource itemisation (evident in 25 instruments), piloting (25) and validation (29).

Conclusion: A database would help facilitate improvements in the methodology and reporting of resource use instruments, as well as providing a valuable resource for health economists. The positive response to the survey indicates a willingness to share resource use instruments and suggests compiling such a database would be a worthwhile endeavour. We outline an agenda for further research in the development, refinement, application and analysis of resource use instruments.

BACKGROUND

Health economists use a variety of methods to estimate patient-level resource use for the determination of costs and cost-effectiveness. These typically include a combination of one or more of the following: routine medical records (e.g. patient notes, databases); case report forms completed by trial researchers or healthcare professionals; and patient (or carer) completed logs, questionnaires or diaries.

In a recent review of the methods of resource use data collection within UK National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme-funded trials, we identified those based on patient-recall as being the most common [1]. We found important differences in whether and how analysts: identified important cost drivers *a priori*; piloted their methods (including testing for reliability and validity); selected recall periods and timing of administration. Of note was the frequency with which questionnaires were re-used, re-cycled and re-invented. This confirmed anecdotal evidence that health economists rely on a few oft-used methods and modify their own methods for different settings of care or clinical application, and contrasts with other patient-reported measures—such as health outcomes—whose rigorous testing for reliability, validity, responsiveness and interpretability is considered essential.

The choice of appropriate health-related quality of life and patient-reported outcome instruments is aided by the existence of an internet-based database, ProQolid (Patient-Reported Outcome and Quality of Life Instruments Database) [2]. We hypothesised that a comparable open-access database of resource use instruments based on patient-recall would not only be a valuable resource to health economists, but would encourage further research in providing an evidence base for resource use measurement techniques, as there are no existing guidelines on the development or assessment of the appropriateness of such instruments.

The aims of the present study were to determine the feasibility of accessing resource use instruments and to determine the appropriate fields of data for extraction. The objectives were: (i) to conduct a survey of health economists; (ii) to identify a sample of recent resource use instruments based on patient-recall; (iii) to extract information on a range of variables, including: economists' selection of resource items, evidence on piloting, validation, costing perspective, frequency of data collection and period of recall; and (iv) to gauge health economists' willingness to provide copies of their resource use instruments with a view to include in an open-access database.

METHODS

Sample

Subscribers to the JISCMail health economics e-mailing list [3], whose membership is open to all health economists (and all those interested in health economics) worldwide, were invited to complete an on-line survey. The mailing list is the recommended discussion list for members of the International Health Economics Association (iHEA) and the UK Health Economists' Study Group (HESG), and has a membership of over 750. This list was advertised widely, via the HealthEconomics.com newsletter, which has an international circulation of 5,500.

We also screened abstracts for potential use of resource use instruments based on patient-recall, and contacted the corresponding authors (or the health economists, where identified) of: (i) UK-based economic evaluations published between January 2008 and March 2010 and listed in the NHS Economic Evaluation Database (NHS EED) (n=159); (ii) HTA reports of primary research, published between January 1998 and March 2010 (n=56); and (iii) on-

going HTA studies (as of March 2010) (n=99). Screening involved examining the titles and abstracts of articles and excluding any reviews, models or secondary data analysis. Authors were invited to complete the on-line survey, and non-responders were contacted by e-mail with reminders at 3 and 6 weeks.

All survey respondents who agreed to be contacted directly were asked to share a copy of their resource use instrument(s) and permission for its inclusion in the database. Those who replied, but who did not complete the survey, were invited to share a copy of their resource use instrument(s) for inclusion in the database.

Exclusion criteria

All identified resource use instruments were included except those where patient recall was not seen as a factor in resource identification (for example, case report forms used to abstract data directly from hospital notes).

Survey

The survey was administered through SurveyMonkey, an internet-based system which enables users to create their own web-based surveys [4]. The survey asked for information on the following:

1. Details on respondents' names, e-mail address and affiliations
2. Reference for identification purposes (e.g. reference(s), title of trial, authors, trial registration number such as ISRCTN, NCT)
3. Publications arising from the study that make reference to the resource use data collection instrument
4. Description of the data collection instrument, from a drop-down menu of: patient-completed questionnaire, patient-completed internet-based questionnaire, patient-completed diary, researcher-completed questionnaire based on face-to-face patient interview, researcher-completed questionnaire based on telephone interview, other (with option to specify)
5. Maximum patient recall period (1 day, 2 days to 7 days, >1 week to 1 month, >1 month to 3 months, >3 months to 6 months, >6 months to 12 months, >12 months)
6. Costing perspective (one or more of: health service, personal social services, patient (and carer) out-of-pocket costs, education sector, employers, societal, voluntary, social security benefits / contributions, other with option to specify)
7. Piloting (not piloted, piloted by patient group within trial, piloted by separate patient group, piloted by healthy volunteers, piloted by health care professionals, used previously or other, with an option to specify)
8. Validation (option to specify)

Prior to distribution, five health economists were invited to complete the survey and provide their comments. Responses were received from three, who gave favourable comments, and the questions remained unchanged.

Assessment

Based on the instrument provided and associated publications, we extracted information on potentially important elements, based on a good practice checklist for resource-use data capture alongside clinical trials [1]. These were divided into: *characteristics* such as content, completion method, population, setting of care, disease area, resource use area, recall period and periods of administration; *qualities* such as reliability, validity, responsiveness, development, piloting, cognitive preparation; and *supporting material* such as instructions. Data were taken from each instrument, from publications (journals and protocols) relating to each instrument, and from responses to the on-line survey. Following data extraction and review, we determined a list of fields for the database.

RESULTS

One hundred and forty three electronic SurveyMonkey questionnaires were returned, of which 79 (55%) carried useful information such as literature references, instrument details and contact e-mail address. Of these, 26 respondents came from the NHS EED category, 12 were from the published HTA category and 23 responded from the unpublished HTA category. The remaining 18 respondents may have come from the JISCMail group but could equally have been prompted to respond by members of the other three groups. Questionnaire responses yielded data on 80 instruments. Of these, 16 were unavailable as the respondents specifically indicated an unwillingness to share. Follow-up of willing-to-share respondents and other subsequent contacts yielded a total of 54 resource use instruments considered suitable for the database (once exclusion criteria and non-responses were taken into account). The majority (36/54) were from NIHR HTA-funded trials. The Department of Health and NHS Trusts each funded 4 studies, 2 were from drug company-funded research and 2 were European Union-funded. Forty-seven (87%) of instruments took the form of questionnaires with the remainder being diaries. A full list of the instruments eligible for inclusion in the database is provided in Appendix 1.

As well as the key identification fields such as instrument name and instrument developer, the following database fields are defined, based on a structured review of the 54 instruments.

Resource-use instrument characteristics

Administration

Thirty-seven instruments were designed for completion by patients, their carers or guardians. The remainder were designed for completion by researchers or healthcare professionals whilst conducting telephone or face-to-face interviews. The distinction between patient/carer/guardian-completion and researcher/healthcare professional-led interview was not always clear. For example, the designers of the annotated cost questionnaire [5] recognised patient-completion alone was not always appropriate, whereas the Client Service Receipt Inventory [6] whilst originally designed for trained interviewers and directed at client carers, has been adapted for administration in multiple contexts (e.g. for completion by patients [7], parents [8] and healthcare professionals/carers [9]).

We identified the most important administrative descriptors for the resource-use instruments as: patient-completed form (reported in 26 out of 54), parent/carer-completed form (7/54), patient/carer diary (7/54), researcher/healthcare-professional-completed based on patient recall (23/54), face-to-face interview (22/54), telephone interview (9/54) and computer administration (1/54). It was clear from the sample of instruments that a combination of these categories often applied to a single questionnaire or diary (mean 1.76, SD 1.06) making administration a nominal categorical variable for the database.

Resource categories

Twenty-five of the 54 resource-use instruments had identified items for costing at an early stage in their development. This was usually done by consultation with healthcare professionals, pilot studies or literature searches but details on the extent to which this was done were not always clear. The principal resource categories included: general practitioner (GP) (47/54), inpatient (46), outpatient (38) and community/practice nurse services (45). Use of dental, optician, dietician and the services of other professions allied to medicine were measured in 36 instruments, while medications were captured in 32 instruments, physiotherapy (30), employer costs (29), patient incurred costs (27), informal carer costs (28), social services (27), day hospital (27) and accident and emergency (29). Non-NHS services included state benefits (11), criminal justice system (7) and education (6). In general, the layout of all instruments made them particularly amenable to costing with

standard sources of UK unit cost [10], NHS Reference Costs [11, 12], and medicines' unit costs [13]. Most instruments (50) covered 4 or more categories (mean 8.87, SD 3.82), which would need to be reflected in the coding for the database.

Disease

Disease classification was modelled on the Cochrane Library listing [14]. All disease areas of the 54 instruments could be mapped to this listing, although 5 (under the category "other") needed a further free-text disease category field to explain their application; typically because these instruments were designed generically for measuring resource use in a wide variety of medical conditions, an example being the Expert Patients Programme questionnaire [15].

Setting of care

Setting of care was not always defined explicitly, and in such cases, it was difficult to distinguish between (for example) primary care and community care; and to specify a single setting for healthcare interventions that spanned many. Unless the setting of care was stated explicitly, difficulty was also experienced in understanding where it ended (e.g. community) and began (e.g. hospital inpatient). We identified the most common 'setting of care' descriptors for the resource-use instruments as: community (30/54), GP practice (19/54), inpatient (16/54) outpatient (16/54). Other lesser-used categories included accident and emergency, day hospital, residential care and specialist tertiary centres. A combination of these settings of care was often captured within questionnaires or diaries (mean 1.83, SD 1.30), indicating setting of care would be coded as a nominal categorical variable in the database.

Population

Categories of population ages were initially considered as mutually exclusive groups: paediatric, adult and elderly; however, it became clear these were not practicable as mutual exclusion could not always be inferred or assumed. We therefore recorded the upper and lower age limits of the populations in which the instruments were administered.

Specified recall period

Within the study sample, 53 (of 54) instruments clearly stated recall periods and of these, 46 were less than 6 months. Median recall period was 3 months (IQR, 0.5 to 6 months). A specified recall period would constitute a categorical ordinal variable within the database and utilise descriptors of 0-3 months, 4-6 months etc. The likelihood is that many were determined by study protocols and follow-up for clinical assessments rather than based on empirical evidence on optimal (or maximum) recall periods.

Frequency of data collection (diaries excluded)

Data collection periods were specified in 42 of the 47 instruments, and ranged from a few weeks to 10 years with up to 12 resource data collecting episodes per instrument. The median number of data collection episodes was 3 (IQR 1 to 4) with a median data collection interval of 4 months (IQR 3 to 6 months). Data collection intervals did not necessarily equate to recall periods, but as with recall periods, may be determined by the clinical protocol. The frequency of data collection would constitute another categorical ordinal variable within the database and utilise a similar range of ordered descriptors.

Resource-use instrument qualities

Reliability

Reliability refers to the consistency with which a resource use instrument correctly measures what it is supposed to be measuring [16]. There was, however, very little evidence of any

reliability testing (4 out of 54 instruments) and, therefore, very little opportunity to assign descriptors for a reliability field within the database.

Validity

Whilst not necessarily reported as such, varying degrees of three specific validative descriptors were observed in a number of resource use instruments (29 out of 54). For example, expert panel review and literature comparisons were evident in 12 cases, representing a degree of content validation; acceptance of scale by patients or healthcare professionals was evident in 18 instances, showing a degree of face validation; and comparisons with GP and hospital notes (16 out of 54) were demonstrated as an acknowledgement of criterion validation (if based on an assumption that healthcare professionals' notes provide a gold standard) or convergent validation (if exploring different methods to gain the same information).

Cognitive interview development

Evidence of cognitive questionnaire development, present in 5 (out of 54) instruments within the sample, demonstrated steps had been taken in a few studies to ensure patients understood the questionnaires. No evidence existed, however, for the presence of readability measures such as the Gunning Fog Index in either instructions or instruments. Database fields to reflect this information would be appropriate since patient comprehension is a prior requisite to recall.

Pilot testing

Within the sample, a number of instruments (25/54) were considered piloted, although as observed in a previous review [1], authors used a variety of methods ranging from direct application of an annotated system [5, 17]; inclusion in specifically designed pilot programmes [18]; and reliance on previously used questionnaires from similar [19] and dissimilar [15] studies. Because of the importance of pilot testing, it would be necessary to include details of the methods employed within the database.

Questionnaire completion

Attempts were made to assess patients' acceptability of instruments including the number of returned resource use questionnaires, the number of unanswered questions and completion times. There was, however, little evidence of any widespread analysis (4 out of 54 instruments) in these areas—especially since some studies were still ongoing—and therefore no opportunity to assign descriptors within the database. In addition, a resource use questionnaire may only form a part of the overall patient-reporting package and may typically appear alongside health-related quality of life measures. This makes it difficult to assess whether the completion rates are due to the resource use questionnaire *per se* or due to other questionnaires/tasks within the package, or indeed, the overall length of the package itself. Nevertheless, as patient-acceptability is an important criterion for judging the effectiveness of a resource use questionnaire it would be useful for the database to include relevant details where these are available.

Resource-use instrument supporting materials

Instructions for completion were available to 24 out of 54 instruments. These ranged from a short paragraph at the top of a postal questionnaire to multi-page manuals of instructions for interviewers.

DISCUSSION

There is general agreement that in the absence of cognitive and /or physical impairments, patients are an important source of information on the use of healthcare and other resources [20, 21]. Diaries and questionnaires offer a structured means of gathering information on the use of a wide range of health, out-of-pocket, informal and social care resources that may not

be possible by other methods. When used alone, or to complement other methods—such as routine medical records and case report form entries—they provide valuable data to inform economic evaluations of healthcare interventions.

Comparing data based on patient recall with data from hospital notes or other secondary source abstraction allows for correlative corroboration to improve validity [21, 22, 23]. However, there are clear limitations to estimating resource-use based on patient-recall. These are related to the length of recall period, questionnaire design, mode of data collection, impact on patient, frequency of administration, level of social desirability and patient cognition and demographics, which affect the validity of reported results [20, 24]. Nevertheless, because clinical records are often fragmented across different health system sectors and established for clinical and /or payment purposes rather than research, and because sufficient information for accurate costing may not always be readily available from these sources, patient-reported resource use instruments are unlikely to be superseded in the short term. The balance between data accuracy and the costs of alternative methods should always be considered during the design of a trial-based economic evaluation.

Key steps in the process of questionnaire development involve the identification of key cost-driving elements (e.g. based on expert opinion, use of focus groups, literature reviews), piloting, validation and reliability testing. However, methods vary from study to study and there is no acceptable gold standard methodology for the development of resource use instruments. Researchers relying on patient-recall are normally left with a choice of either designing their own resource use data collection instruments or adapting instruments from previous studies. Reliance on instruments developed by others may facilitate this process but access to such instruments is often limited, and reliability and validity may not be generalisable to different populations or contexts. Herein lies the challenge of developing generic patient-reported RUIs (cf. generic patient-reported outcome and quality of life instruments).

Our analysis represents a first step in the development of a repository of resource-use instruments based on patient-recall. We have shown that such an endeavour is feasible (response rates and agreement to share data collection instruments were acceptable), and have identified the pertinent fields for data extraction (Appendix 2). The Database of Instruments for Resource Use Measurement (accessible via www.DIRUM.org) will support data navigation, sorting, searching, advanced filtering, record addition, modification, deletion, and file uploads. A conceptual structure of the database and field content is presented in Figure 1. Different levels of access will be allowed, depending on authors' levels of permission granted. An author submission form will allow questionnaire developers to submit their questionnaires for inclusion on the database.

The ability to access resource use instruments, and to choose among validated and reliable instruments or parts of instruments which are applicable to specified areas of disease, population or settings of care, will provide a valuable resource to health economists, and a basis for much-needed further development.

An agenda for future research in this field would include:

- (a) fundamental questions on how resource use questionnaires are to be assessed for validity and reliability (e.g. is test-retest relevant? What are the best approaches for assessing construct and content validity? etc.). These are areas where there is currently little or no published guidance. An important component of the database, therefore, will be to also include relevant methodological papers, which would be identified through a systematic search of the literature.

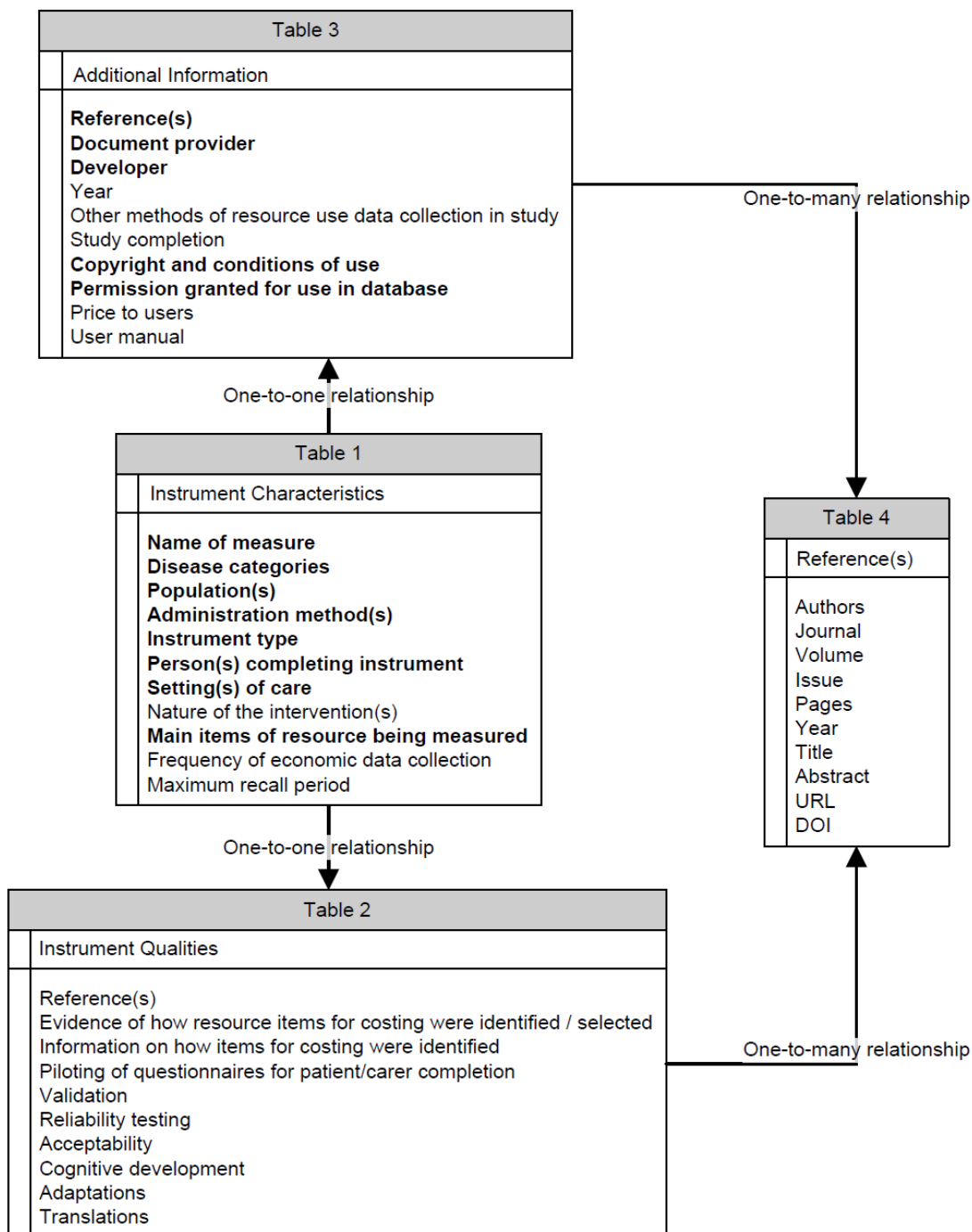
- (b) use of DIRUM to quickly yield lists of likely candidate instruments for review within development focus groups and expedite the preparation of first draft questionnaires with high degrees of content validation;
- (c) investigating the longer-term advantages in applying reliability measures to these draft instruments and recording those developments in DIRUM;
- (d) investigating the benefit in applying cognitive and readability measures to enhance face validation and patient comprehension of text, applying these measures to drafts and capturing the gains in DIRUM;
- (e) detailing and recording the piloting of these validated and reliability-tested draft instruments in DIRUM to gain a longer-term understanding as to what constitutes a good pilot test;
- (f) longer term, detailing and recording in DIRUM the acceptabilities of piloted drafts to include, for example, records on missingness e.g. rates of uncompleted questionnaires, unreturned questionnaires and completion times.

High acceptability rates of questionnaires with fully-documented development histories would reflect the most effective instrument development and piloting paths for resource use questionnaires. A conceptual path is outlined in Appendix 3, which shows the points at which questionnaires could be inputted into DIRUM along with the important fields for consideration. For example, a first draft instrument that has undergone focus-group review and content validation on population and items of resource use would not necessarily be as ready for piloting as the same instrument had it undergone reliability testing and cognitive and administrative optimisation.

SOME SUGGESTED DISCUSSION POINTS

- Are we on the right track for developing the database and setting an agenda for further research in the development, refinement, application and analysis of resource use instruments?
- How important is cognitive and readability development at an early stage in the questionnaire preparation?
- What would be the best methods of testing reliability and validity in resource use questionnaires?

Figure 1: Conceptual structure of database and field content



Notes: Items in bold are essential criteria needed for each instrument. Without these, an instrument will not be able to go on the database. The first three tables are split between the instrument's characteristics, qualities and additional information. The characteristics such as "name of measure" are set for each instrument and are therefore fixed in a one-to-one relationship with the 'qualities' and 'additional information' tables. Qualities such as "validation" and "translations" may involve multiple references and are thus fixed in a one-to-many relationship with the fourth 'reference(s)' table. Each instrument will be characterised by at least one (but sometimes more) essential reference (journal or internet) relating to its previous use/development; the 'additional information' table is also therefore linked in a one-to-many relationship with the fourth table.

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Appendix 1: References to resource use instruments eligible for inclusion in database

Name of measure(s)	Reference	Instrument*
FoIATED use of health and social-service questionnaire	Roberts SH, Bedson E, Hughes D, et al. Folate Augmentation of Treatment – Evaluation for Depression (FoIATED): protocol of a randomised controlled trial. <i>BMC Psychiatry.</i> 2007; 7: 65.	Q
Self-report questionnaire for use of health and social service (used in AHEAD Trial)	Peveler R, Kendrick T, Buxton, et al. A randomised controlled trial to compare the cost-effectiveness of tricyclic antidepressants, selective serotonin reuptake inhibitors and lofepramine. <i>Health Technol Assess.</i> 2005; 9: 1-134.	Q
An annotated cost questionnaire for completion by patients	Wordsworth S, Thompson S. An annotated cost questionnaire for patients: results of piloting. <i>HERU Discussion Paper 03/01.</i> 2001: 91.	Q
Lifelax daily diary/ telephone questionnaire /baseline questionnaires	Speed C, Heaven B, Adamson A, et al. LIFELAX – diet and LIFEstyle versus LAXatives in the management of chronic constipation in older people: randomised controlled trial. <i>Health Technol Assess.</i> 2010; 14: 1-221.	2Q,D
Household and individual costs of living, health and illness	Fox M, Voordouw J, Mugford M, et al. Economic Costs of Food Allergies in Europe: Development of a Questionnaire to Measure Costs and Health Utility. <i>Health Serv Res.</i> 2009; 44: 1662-78.	Q
BROSG diary/ BROSG travel and time costs questionnaire / BROSG healthcare service utilisation form	Symmons D, Tricker K, Roberts C, et al. The British Rheumatoid Outcome Study Group (BROSG) randomised controlled trial to compare the effectiveness and cost-effectiveness of aggressive versus symptomatic therapy in established rheumatoid arthritis. <i>Health Technol Assess.</i> 2005; 9: 1-78.	2Q,D
BECCA: baseline interview questionnaire / follow-up interview	Charlesworth G, Shepstone L, Wilson E, et al. Does befriending by trained lay workers improve psychological well-being and quality of life for carers of people with dementia, and at what cost? A randomised controlled trial. <i>Health Technol Assess.</i> 2008; 12: 1-58.	2Q
ELEVATE resource data collection sheet (nurse and patient) / resource data collection sheet (patient) / resource diary	Wilson E, Price D, Musgrave S, et al. The cost-effectiveness of leukotriene receptor antagonists versus long acting beta-2 agonists as add-on therapy to inhaled corticosteroids for asthma: a pragmatic trial. <i>Pharmacoeconomics.</i> 2010; 28: 597-608.	2Q,D

Name of measure(s)	Reference	Instrument*
Treating Interstitial Pneumonia with the Addition of Co-Trimoxazole (TIPAC) Study - baseline cost questionnaire / follow-up questionnaire / health service use and personal expenditure resource diary	Treating Interstitial Pneumonia with the Addition of Co-trimoxazole. ISRCTN22201583. ISRCTN Register. Available from http://www.controlled-trials.com/ISRCTN22201583 [Accessed March 1, 2011].	2Q,D
AESOP service use questionnaire	Coulton S, Watson J, Bland M, et al. The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care (AESOPS) – A randomised control trial protocol. BMC Health Services Research. 2008; 8: 129.	Q
Verteporfin resource use questionnaire	Grieve R, Guerriero C, Walker J, et al. Verteporfin Photodynamic Therapy Cohort Study Group. Verteporfin photodynamic therapy cohort study: report 3: cost effectiveness and lessons for future evaluations. Ophthalmology. 2009; 116: 2471-77.	Q
BASIL clinical follow up form	Bradbury AW, Adam DJ, Bell J, et al. Multicentre randomised controlled trial of the clinical and cost-effectiveness of a bypass-surgery-first versus a balloon-angioplasty-first revascularisation strategy for severe limb ischaemia due to infrainguinal disease. The Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial. Health Technol Assess. 2010; 14: 1-210.	Q
PD REHAB healthcare usage questionnaire	Randomised controlled trial to assess the clinical- and cost-effectiveness of physiotherapy and occupational therapy in Parkinson's disease (PD REHAB). NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1748.asp [Accessed March 1, 2011].	Q
PDMED resource usage	A large randomised assessment of the relative cost-effectiveness of different classes of drugs for Parkinson's disease (PD MED). NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1119.asp [Accessed March 1, 2011].	Q
BRUM resource use questionnaire	Jolly K, Taylor R, Lip GY, et al. Birmingham rehabilitation uptake maximisation study (BRUM). Home-based versus hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence. Health Technol Assess. 2007; 11: 1-98.	Q
CUTLASS economic patient questionnaire	Lewis SW, Davies L, Jones PB, et al. Randomised controlled trials of conventional antipsychotic versus new atypical drugs, and new atypical drugs versus clozapine, in people with schizophrenia responding poorly to, or intolerant of, current drug treatment. Health Technol Assess. 2006; 10: 1-165.	Q

Name of measure(s)	Reference	Instrument*
HOPEFUL study patient questionnaire	Hirst A, Dutton S, Wu O, et al. A multi-centre retrospective cohort study comparing the efficacy, safety and cost-effectiveness of hysterectomy and uterine artery embolisation for the treatment of symptomatic uterine fibroids. The HOPEFUL study. <i>Health Technol Assess.</i> 2008; 12: 1-227.	Q
P3MC headache and health diary	A double blind parallel group randomized placebo controlled trial of Propranolol and Pizotifen in preventing migraine in children. NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1526.asp [Accessed March 1, 2011].	D
SNAP Trial 6 month follow up questionnaire	Coleman T, Thornton J, Britton J, et al. Protocol for the Smoking, Nicotine and Pregnancy (SNAP) trial: double-blind, placebo-randomised, controlled trial of nicotine replacement therapy in pregnancy. <i>BMC Health Services Research.</i> 2007; 7: 2.	Q
PDSURG questionnaire	Williams A, Gill S, Varma T, et al. Deep brain stimulation plus best medical therapy versus best medical therapy alone for advanced Parkinson's disease (PD SURG trial): a randomised, open-label trial. <i>Lancet Neurol.</i> 2010; 9: 581–91.	Q
CESAR patient cost questionnaire / events diary	Peek G, Mugford M, Tiruvoipati R, et al. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. <i>Lancet.</i> 2009; 374: 1352-63.	Q,D
Escitalopram and duloxetine resource use questionnaire	Wade A, Fernández JL, François C, et al. Escitalopram and duloxetine in major depressive disorder: a pharmaco-economic comparison using UK cost data. <i>Pharmacoeconomics.</i> 2008; 26: 969-81.	Q
BCST receipt of services	Donnelly M, Power M, Russell M, et al. RCT of an early discharge rehabilitation service; the Belfast Community Stroke Trial. <i>Stroke.</i> 2004; 35: 127-133.	Q
MAPS questionnaire / participants cost questionnaire	Conservative treatment for urinary incontinence in men after prostate surgery (MAPS). NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1417.asp [Accessed March 1, 2011].	2Q
PROMISE assessment booklet	A single blind randomised controlled trial to determine the effectiveness of group cognitive behaviour therapy (CBT) in the prevention of depression in high risk adolescents. NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1667.asp [Accessed March 1, 2011].	Q
Specialist behaviour therapy team CSRI	Hassiotis A, Robotham D, Canagasabay A, et al. Randomized, single-blind, controlled trial of a specialist behavior therapy team for challenging behavior in adults with intellectual disabilities. <i>Am J Psychiatry.</i> 2009; 166: 1278-1285.	Q

Name of measure(s)	Reference	Instrument*
PRaCTICaL health service utilisation questionnaire	Cuthbertson BH, Rattray J, Campbell MK, et al. The PRaCTICaL study of nurse led, intensive care follow-up programmes for improving long term outcomes from critical illness: a pragmatic randomised controlled trial. <i>BMJ</i> . 2009; 339: b3723.	Q
CONSTRUCT questionnaire	COmparison of iNfliximab and ciclosporin in STeroid Resistant Ulcerative Colitis: a Trial (CONSTRUCT). NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1737.asp [Accessed March 1, 2011].	Q
SHIFT young person questionnaire booklet / carer or parent questionnaire	SHIFT. Self-Harm Intervention, Family Therapy: a randomised controlled trial of family therapy vs. treatment as usual for young people seen after second or subsequent episodes of self-harm. NIHR Health Technology Assessment Programme. Available from: http://www.hta.ac.uk/project/1733.asp [Accessed March 1, 2011].	2Q
CSSRI - EU / UK	Chisolm D, Knapp M, Knudsen H, et al. Client Socio-Demographic and Service Receipt Inventory - European Version : development of an instrument for international research. <i>Br J Psychiatry</i> 2000; 177: s28-33.	Q
CSRI (original version)	Beecham J, Knapp M. Costing Psychiatric Interventions. 1999; Discussion Paper 1536: 22.	Q
REACT study CSRI	Killaspy H, Bebbington P, Blizard R, et al. The REACT study: randomised evaluation of assertive community treatment in north London. <i>BMJ</i> . 2006; 332: 815.	Q
CSRI - childrens version	Knapp M, Scott S, Davies J. The cost of antisocial behaviour in younger children. <i>Clin Child Psychol Psychiatry</i> . 1999; 4: 457-73.	Q
UEA-IFG health service use baseline questionnaire	Delivering the Diabetes Prevention Programme in a UK community setting: UEA-IFG Study. ISRCTN06589959. ISRCTN Register. Available from: http://www.controlled-trials.com/ISRCTN06589959 [Accessed March 1, 2011].	Q
BoTULS one month assessment questionnaire	Shaw L, Rodgers H, Price C, et al. BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. <i>Health Technol Assess</i> . 2010; 14: 1-113.	Q
MINT recovery after neck injury questionnaire	Lamb S, Gates S, Underwood M, et al. Managing Injuries of the Neck Trial (MINT): design of a randomised controlled trial of treatments for whiplash associated disorders. <i>BMC Musculoskeletal Disorders</i> . 2007; 8: 7.	Q
RCT lap cholecystectomy patient questionnaire	D Macafee, D Humes, G Bouliotis, et al. Prospective randomized trial using cost-utility analysis of early versus delayed laparoscopic cholecystectomy for acute gallbladder disease. <i>Br J Surg</i> . 2009; 96: 1031-40.	Q

Name of measure(s)	Reference	Instrument*
VENUS II questionnaire	Dumville JC, Worthy G, Soares MO, et al. VenUS II: a randomised controlled trial of larval therapy in the management of leg ulcers. <i>Health Technol Assess.</i> 2009; 13: 1-182.	Q
The Scottish back trial time and travel questionnaire	Gilbert FJ, Grant AM, Gillan MGC, et al. Does early magnetic resonance imaging influence management or improve outcome in patients referred to secondary care with low back pain? A pragmatic randomised controlled trial. <i>Health Technol Assess.</i> 2004; 8: 1-131.	D
PRIME patient diary	Prescott RJ, Kunkler IH, Williams LJ, et al. A randomised controlled trial of postoperative radiotherapy following breast-conserving surgery in a minimum-risk older population. The PRIME trial. <i>Health Technol Assess.</i> 2007; 11: 1-149.	Q
NESSTAC parent's questionnaire	Lock C, Wilson J, Steen N, et al. North of England and Scotland Study of Tonsillectomy and Adeno-tonsillectomy in Children (NESSTAC): a pragmatic randomised controlled trial with a parallel non-randomised preference study. <i>Health Technol Assess.</i> 2010; 14: 1-164.	Q
EPP questionnaire	Richardson G, Kennedy A, Reeves D, et al. Cost effectiveness of the Expert Patients Programme (EPP) for patients with chronic conditions. <i>J Epidemiol Community Health.</i> 2008; 62: 361-367.	Q

* Q=questionnaire; D=diary; 2Q = 2 questionnaires

Appendix 2: Data fields for resource use instrument database

Instrument Characteristics

Name of measure

Gives the title appearing on the instrument or, if this is absent, the name given to the instrument by the document provider.

Disease categories

Indicates the disease group the named instrument is measuring resource use for. The disease categories are identical to the ones used in the Cochrane Library¹ to aid harmonisation between this and the Medical Research Council (MRC) Core Outcome Measures in Effectiveness Trials (COMET) initiative². Generic questionnaires and other miscellaneous disease groups will be listed as Other (specify). Listing of descriptors includes: Anaesthesia & pain control, Blood disorders, Cancer, Child health, Consumer & communication strategies, Dentistry & oral health, Developmental, psychosocial, & learning problems, Ear, nose, & throat, Effective practice/health systems, Endocrine & metabolic, Eyes & vision, Gastroenterology, Genetic disorders, Gynaecology, Heart & circulation, Infectious disease, Kidney disease, Lungs & airways, Mental health, Methodological & diagnostic, Neonatal care, Neurology, Orthopaedics & trauma, Pregnancy & childbirth, Public health, Rheumatology, Skin, Tobacco, drugs, & alcohol dependence, Urology, Wounds, Other (specify)..

Population(s)

Refers to the population whom the named instrument is measuring and in line with the COMET initiative is defined according to two subsections; Namely:

- (i) Population comprising two numerically discrete descriptors of upper age limit and lower age limit,
- (ii) Gender comprising one nominal category made up with descriptors of male, female and both.

Intervention

Refers to a multicode variable comprising the following binary (yes/no) descriptors - Drug, Vaccines, Cellular, Gene therapy, Immunotherapy, Surgery, Radiotherapy, Device, Imaging, Psychological & behavioural, Physical, Rehabilitation, Educational/self-management, Dietary, Complementary therapy, Complex intervention, Management of care, Active monitoring, Other (specify), Not specified

These interventions are based on the intervention descriptors found in the National Institute for Health Research (NIHR) Clinical Research Network Portfolio database.

Setting(s) of care

Refers to the setting(s) of care in which the named instrument is being utilised. Multiple-choice menu of descriptors includes: Community, GP practice, inpatient, outpatient A&E, day hospital, residential care, specialist tertiary centres; other (specify).

Main items of resources being measured

Identifies the main resource-use items being covered by the measure. Multiple-choice menu of descriptors includes: GP, inpatient, nurses (community and practice), outpatient, other NHS, medication, A&E, employer, informal carer, day hospital, social services, patient incurred, physiotherapy, occupational therapy, social services day care, psychologist, residential care, healthcare aids, state benefits, NHS phone-in centres, criminal and other (specify).

Administration

Methods of administration will be split into three multiple-choice menus of descriptors to include: administration method (in person, via telephone, via computer, via post, other); instrument type (diary, recall questionnaire, log, other); and person completing instrument (patient, patient/carer, healthcare professional, researcher, other).

Frequency of economic data collection

As reported in studies employing the instrument.

Maximum recall period

As reported in studies employing the instrument.

Instrument Qualities

Evidence of how resource items for costing were identified / selected

This will indicate whether there is evidence of prior identification of the likely types of resource to be utilised in the study. This can take place in several ways and is reflected in a

multiple-choice menu of descriptors which includes: Referral to similar studies, Consultation with patient groups, Consultation with healthcare professionals, Other (specify). Evidence of how resource items for costing were identified / selected is an important part in the defining of the face and content validity of the named instrument.

Information on how items for costing were identified

This text field will be used to provide references to prior identification studies involving the instrument.

Piloting of questionnaires for patient/carer completion

Indicates whether the instrument was reported as having been piloted. References to prior piloting studies will be included, if applicable.

Validation

To include details of whether the instrument was validated, and the methods employed.

Reliability testing

Details of reliability testing, including references to prior validation studies involving the instrument

Acceptability

To indicate whether the instrument has been tested for user acceptability, to include, for example, records on rates of uncompleted questionnaires, unreturned questionnaires and completion times. References to acceptability studies involving the instrument will be listed.

Cognitive development

References to any cognitive development studies involving the instrument will be noted

Adaptations

To indicate if the instrument is based on another, and details of main adaptations

Translations

An indication of whether the instrument exists in other languages

Supplementary Information

Document provider

Name of the person who originally provided the instrument. This person may be contacted on behalf of the instrument developers.

Reference(s)

Details the initial reference of the study that used the named instrument.

Developer(s)

This will give the name of the person(s) from whom permission needs to be sought for using the named instrument (and also for publication in the compendium).

Year

This gives the year the named instrument was first used

Copyright and conditions of use

This gives details on the availability of the instrument, copyright, who to contact for permission to use, whether a fee is applicable and whether a contract is applicable.

Permission granted for use in database

Taken from document provider or developers

User manual

Identifies whether a manual or set of instructions accompanies the instrument

Other methods of resource use data collection in study

This addresses whether the resource use questionnaire is the only means of collecting resource use data within the study it is designed for, and if not, identify what other methods were used e.g. use of patient notes, use of GP records, and use of patient administration systems etc.

Study completion

An indication of whether the study is ongoing or not.

References

1. The Cochrane Library. Available from:
<http://www.thecochranelibrary.com/view/0/index.html> [accessed April 6, 2011].
2. The COMET Initiative. Available from:
http://www.methodologyhubs.mrc.ac.uk/upcoming_workshops/comet_initiative.aspx [accessed April 6, 2011].

Appendix 3: A conceptual development path for designing resource use questionnaires

