

Developing a good practice guideline

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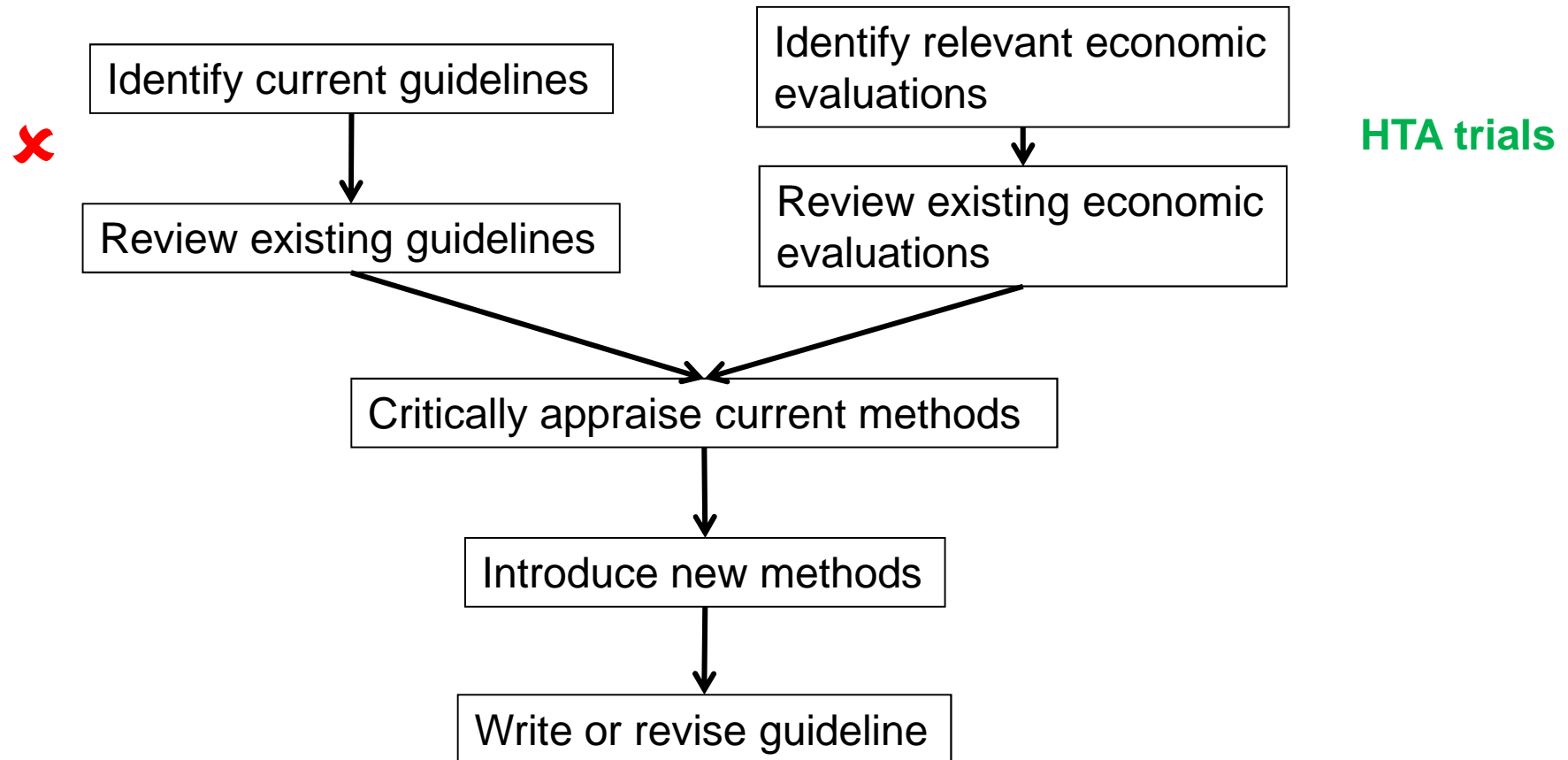
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Guideline development



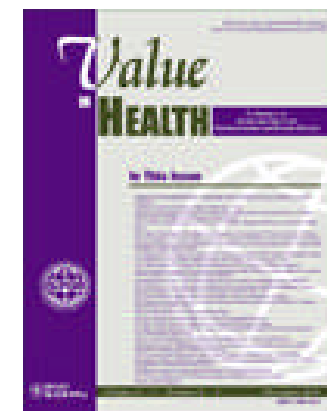
Review of trial-based economic evaluations

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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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Review of HTA-funded trials

- 85/95 studies collected patient-level data
- 61 used at least 2 methods
- Diaries used in 20 studies
- 63 studies used questionnaires / forms / interviews



Data collection methods

Method	Number
Data on patient-level resource use captured as part of the study	85/95
Patient (or carer/guardian)-completed forms	48/85
Patient (or carer/guardian)-completed diary	10/95
Researcher/healthcare practitioner-completed forms based on patient/carer recall	23/85
Researcher/healthcare practitioner-completed. Not routinely collected data; not based on patient recall	22/85
Routinely collected medical or other records	59/85



Item identification

- Evidence of resource identification at the planning stage
 - n=22 out of 95
- Consulting with health care professionals or conducting a review of published economic literature



Piloting

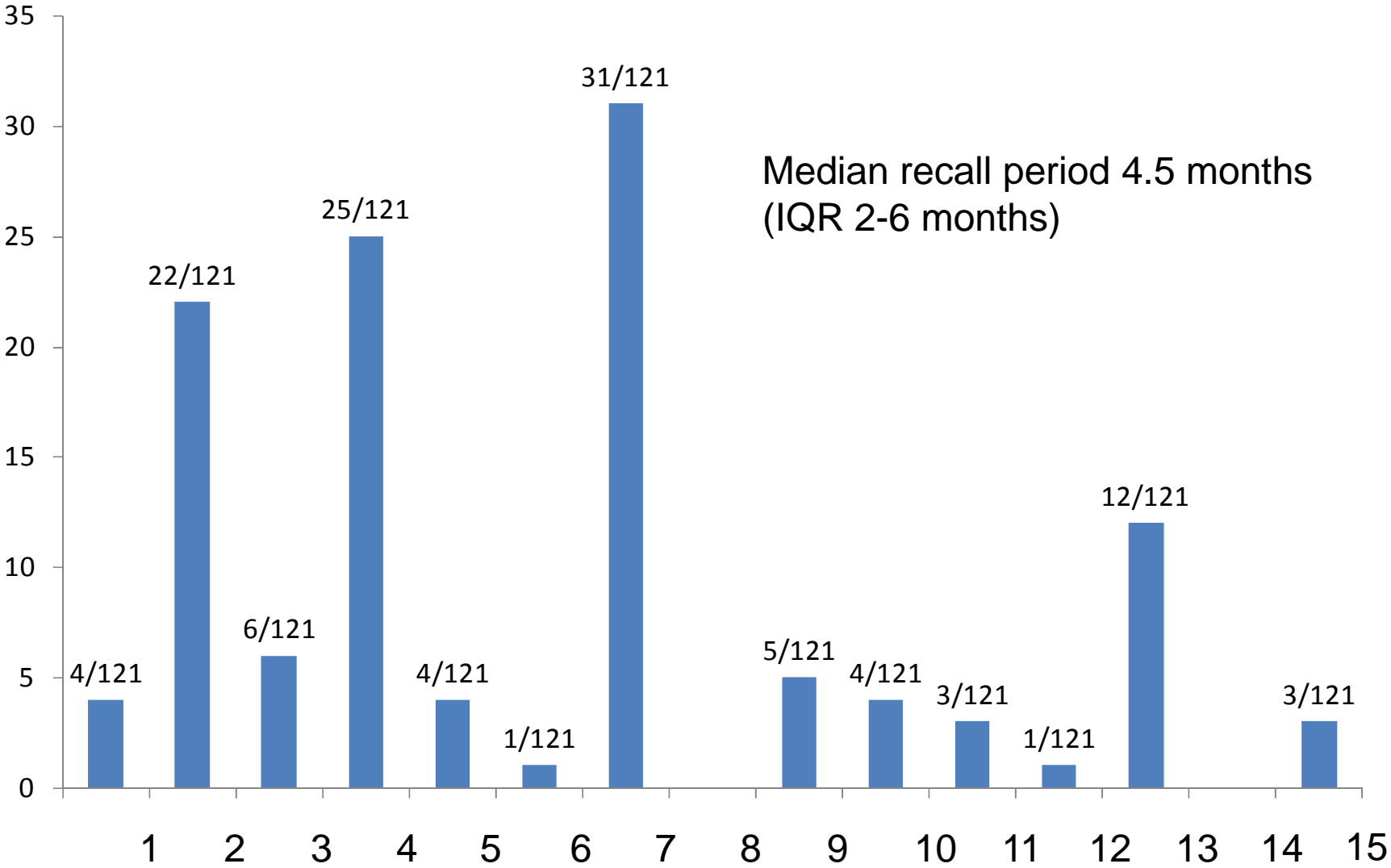
- Piloting
 - n=21 out of 63
- Adopting formats that had been piloted in previous studies
- Asking patients, carers or research nurses to test a resource use diary



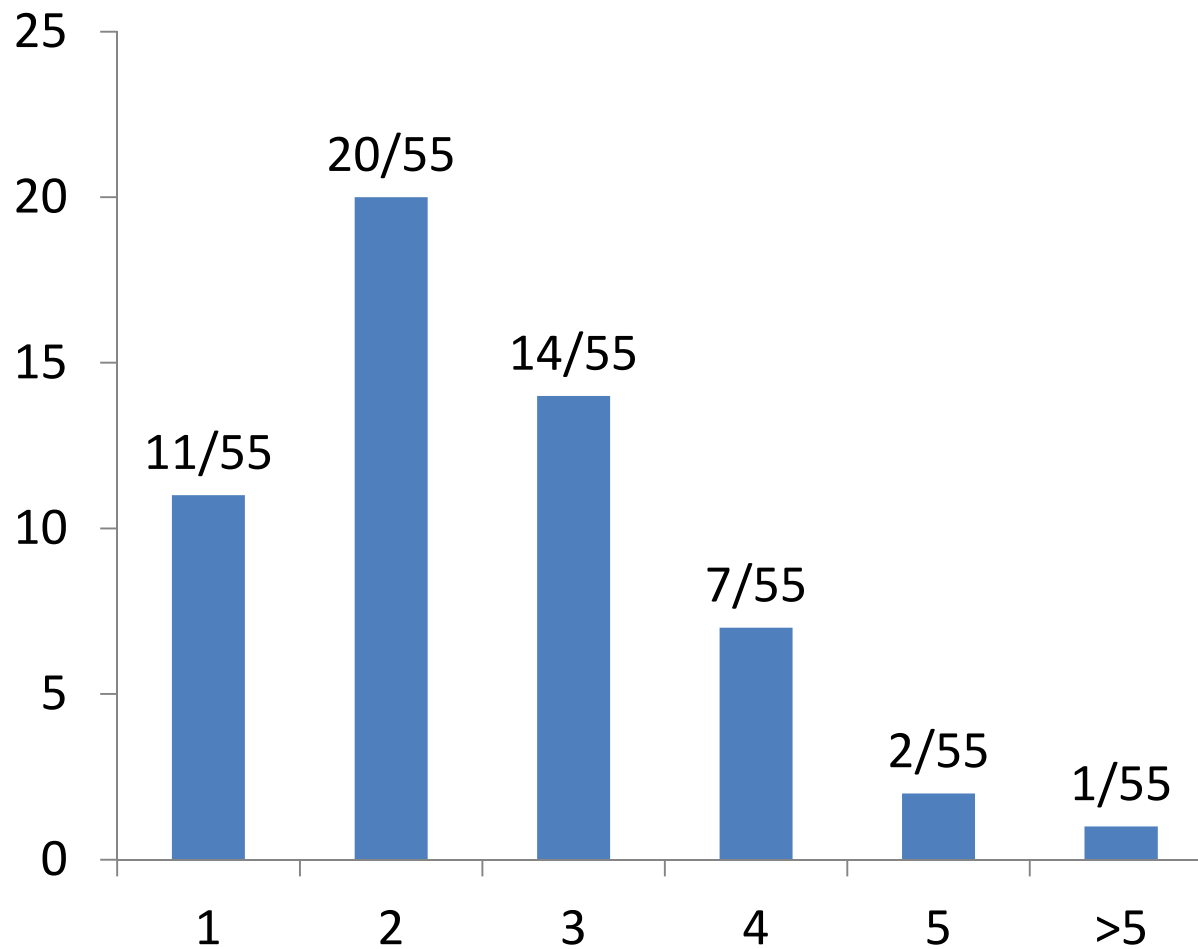
Validation

- Validation of data collection methods
 - n=28 out of 85
- Questionnaire responses compared to routinely collected data such as hospital or GP notes
- Pre-“validation” from previous literature or pilot studies

Recall periods



Questionnaire burden



Number of recall-based resource use questionnaires deployed per patient per study

Good practice checklist for resource use data capture alongside HTA clinical trials

Practice	Recommendation
Perspective	Should be aligned with that of the decision maker (e.g., NHS and /or Personal Social Services, multi-agency public sector, societal). Avoid inappropriate use of the phrase “societal perspective.”
Identify resources for measurement	Items for costing should be identified a priori from consultation with health-care professionals, pilot studies, or literature searches. It is important to identify the expected main cost-driving events and to justify the range of resource items that are to be valued. Issues for consideration: (i) What are the consequences of not collecting these data?; (ii) What information is available on the key events within the study?; (iii) Which baseline data are needed?; (iv) What data are needed to maximize external validity?; (v) Protocol-driven resource use should be identified, and adjusted for, accordingly.
Data collection/analysis plan	A plan detailing how cost and resource use data will be obtained is essential—paying particular attention to: (i) the frequency of resource data collection; (ii) identifying if data collection needs to be resource-, effects- or schedule-driven [6]; (iii) considering whether the methods of resource use data collection will impact on the trial outcome (e.g., diaries may improve adherence to intervention); (iv) single-site or multi-site sources; (v) the time horizon within which resource use data are needed; (vi) statistical analysis.
Resource use data collection	The choice depends on the balance between factors that include: (i) reliability of patient recall; (ii) burden on the researcher/health-care practitioner; (iii) completeness and appropriateness of routinely collected data; (iv) information technology systems; and (v) the cost of research (i.e., acquiring the data). The method selected, and frequency of data capture, should be informed by previous studies or pilot studies [4].
Baseline cost data	Should be collected as an important predictor of future costs. In studies with a small sample size, baseline characteristics need to be balanced [44]. Costs can be adjusted for baseline differences for example by use of appropriate regression-based modelling.
Piloting	Patient-/carer-completed forms should be piloted to test clarity, ease of use and completion rates [11]. Piloting is also useful in determining the main cost-driving events related to the health technology.
Validation	Where possible, alternative methods of resource use data collection should be employed to test for validity [28,37].
Non-trial estimates of resource use	If nontrial resource use estimates are used to supplement trial-based data, there needs to be a documented and systematic approach to their selection. Resources used as a result of the trial protocol should be excluded.
Method of costing	Top-down microcosting, applying national costs to patient-level units of resource use where they exist. This increases generalizability.
Unit costs	Valued using national costs for the most recently available year [7]. If national costs do not exist for items of resource use, apply unit costs sourced locally.
Standardized reporting format	A common reporting format for economic evaluations would improve transparency and enhance benchmarking between similar studies [45].



Practice	Comment
Perspective	Aligned with that of the decision maker (NHS +/- Personal Social Services, Societal)
Identify resources for measurement	Items for costing should be identified <i>a priori</i> from consultation with health care professionals, pilot studies or literature searches
Data collection & analysis plan	A plan detailing how cost and resource use data will be obtained is essential (e.g. frequency, sources, time horizon, statistical analysis, methods)
Resource use data collection	Choice depends on: reliability of patient recall, burden on the researcher/ healthcare practitioner, completeness and appropriateness of routinely collected data, information technology systems, cost of acquiring the data. The method selected, and frequency of data capture, should be informed by previous studies or pilot studies



Practice	Comment
Piloting	Patient / carer completed forms should be piloted to test clarity, ease of use and completion rates
Validation	Alternative methods of resource use data collection should be employed to test for validity
Non trial estimates of resource use	Documented and systematic approach to their selection
Method of costing	Top-down micro-costing, applying national costs to patient-level units of resource use where they exist
Standardised reporting format	To improve transparency and enhance benchmarking between similar studies

