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ORIGINAL ARTICLE

Transparency, openness, and reproducible research practices are frequently underused in health economic evaluations

Ferrán Catalá-López[a,b,c,*], Manuel Ridao[d,e,f], Laura Tejedor-Romero[a,g,h], Lisa Caulley[c,i,j], Brian Hutton[c,k], Don Husereau[k,l], Adolfo Alonso-Arroyo[m,n], Enrique Bernal-Delgado[e,f], Michael F. Drummond[o], David Moher[c,k]

[a]*Department of Health Planning and Economics, National School of Public Health, Institute of Health Carlos III, Madrid, Spain*
[b]*Department of Medicine, University of Valencia/INCLIVA Health Research Institute and CIBERSAM, Valencia, Spain*
[c]*Clinical Epidemiology Program, Ottawa Hospital Research Institute (OHRI), Ottawa, Ontario, Canada*
[d]*Institute for Health Research in Aragon (IISA), Zaragoza, Spain*
[e]*Data Science for Health Services and Policy Research, Aragon Health Sciences Institute (IACS), Zaragoza, Spain*
[f]*Research Network on Chronicity, Primary Care, and Health Promotion (RICAPPS), Institute of Health Carlos III, Madrid, Spain*
[g]*Preventive Medicine Unit, La Princesa University Teaching Hospital, Madrid, Spain*
[h]*Division of Pharmacoepidemiology and Pharmacovigilance, Spanish Medicines and Healthcare Products Agency (AEMPS), Madrid, Spain*
[i]*Otolaryngology-Head and Neck Surgery Department, Ottawa Hospital, Ottawa, Ontario, Canada*
[j]*Department of Clinical Medicine and Otolaryngology-Head and Neck Surgery, Aarhus University, Aarhus, Denmark*
[k]*School of Epidemiology and Public Health, Faculty of Medicine, University of Ottawa, Ottawa, Ontario, Canada*
[l]*Institute of Health Economics, Edmonton, Alberta, Canada*
[m]*Department of History of Science and Documentation, University of Valencia, Valencia, Spain*
[n]*Information and Social and Health Research (UISYS) Joint Research Unit, Spanish National Research Council (CSIC), University of Valencia, Valencia, Spain*
[o]*Centre for Health Economics, University of York, York, UK*

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Abstract

Objectives: To investigate the extent to which articles of economic evaluations of healthcare interventions indexed in MEDLINE incorporate research practices that promote transparency, openness, and reproducibility.

Study Design and Setting: We evaluated a random sample of health economic evaluations indexed in MEDLINE during 2019. We included articles written in English reporting an incremental cost-effectiveness ratio in terms of costs per life years gained, quality-adjusted life years, and/or disability-adjusted life years. Reproducible research practices, openness, and transparency in each article were extracted in duplicate. We explored whether reproducible research practices were associated with self-report use of a guideline.

Results: We included 200 studies published in 147 journals. Almost half were published as open access articles (n = 93; 47%). Most studies (n = 150; 75%) were model-based economic evaluations. In 109 (55%) studies, authors self-reported use a guideline (e.g., for study conduct or reporting). Few studies (n = 31; 16%) reported working from a protocol. In 112 (56%) studies, authors reported the data needed to recreate the incremental cost-effectiveness ratio for the base case analysis. This percentage was higher in studies using a guideline than studies not using a guideline (72/109 [66%] with guideline vs. 40/91 [44%] without guideline; risk ratio 1.50, 95% confidence interval 1.15−1.97). Only 10 (5%) studies mentioned access to raw data and analytic code for reanalyses.

Conclusion: Transparency, openness, and reproducible research practices are frequently underused in health economic evaluations. This study provides baseline data to compare future progress in the field.

Keywords: Cost-effectiveness analysis; Data sharing; Economic evaluation; Methodology; Quality; Reporting; Reproducibility

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* Corresponding author. Department of Health Planning and Economics, National School of Public Health, Institute of Health Carlos III, Avda. Monforte de Lemos 5, 28029 Madrid, Spain. Tel.: +34-9182-22239.
E-mail address: ferran_catala@outlook.com (F. Catalá-López).

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What is new?

Key findings

- Authors reported the data needed to recreate the incremental cost-effectiveness ratios for the base case analysis, in only 56% studies. This percentage was higher in studies using a guideline than studies not using a guideline (66% vs. 44%).
- 16% studies reported working from a protocol, and only 5% of studies mentioned access to raw data and analytic code for reanalyses.

What this adds to what was known?

- To our knowledge, no study has quantified how often authors of health economic evaluations report the data needed to recreate all incremental cost-effectiveness ratios (including baseline, subgroup, and sensitivity analyses) nor investigated whether completeness of reporting varies by self-reported use of any guideline (e.g., for study conduct or reporting). In addition, no study has investigated how often reproducible research practices, such as the sharing raw datasets and analytic methods (e.g., code), are used in health economic evaluations.

What is the implication and what should change now?

- These results could potentially be used to inform the process of developing and implementing best practices for transparent reporting of health economic evaluation, sharing of datasets and analytical code so that others can recreate the findings or perform secondary reanalyses.

1. Introduction

There is a growing need for rigorous and transparent reporting of health research to ensure that studies can be reproduced [1−3]. The value of health research can be improved by increasing transparency and openness of the processes of design, conduct, analysis, and reporting [4,5]. For example, sharing data and materials from studies allows for the conduct of additional analyses to further explore data and generate new hypotheses, but also encourages reproducibility and transparency. Recognizing the potential impact of open science practices, journals are increasingly supporting the use of reporting guidelines, as well as data-sharing policies and technologies that help to improve efficiency and enhance credibility of the published literature [6−10].

Health economic evaluations, which compare alternative interventions or programs in terms of their costs and consequences, can help inform resource allocation decisions [11]. Cost-effectiveness analyses, a specific form of health economic evaluation that compares alternative options in terms of their costs and their health outcomes, have been established globally as an important methodology for assessing value for money of healthcare interventions. Efforts to increase transparent conduct and reporting of health economic evaluations have existed for many years [12−22]. Complete and accurate reporting of health economic evaluations, starting with an unambiguous description of study methods, enhances transparency and reproducibility. For example, the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) statement [13] and the US Panel on Cost-Effectiveness in Health and Medicine [14−17] provide recommendations for authors, peer reviewers, and journal editors regarding how to conduct and report health economic evaluations.

Several studies have evaluated the reporting [23−35] and potential biases [36,37] in health economic evaluations. However, many of these studies were narrow in scope (e.g., focusing only on specific countries/regions [29−32], interventions [33] or methodological issues [34−37]). In other studies, the sample of health economic evaluations examined was more diverse, but contained studies published over a decade ago [24,25,28] or was evaluated against a small set of reporting items [34,35]. The few studies [25,29,38] examining the impact of health economic evaluation guidelines and the reporting of published articles suggest that some items (e.g., justification of discount rate for costs and outcomes) improved after its introduction, but that reporting of others (e.g., description of analytic methods) [25,29] did not change. To our knowledge, no studies have evaluated how often reproducible research practices such as sharing of study protocols, data, and analytic methods (which allow others to recreate study findings) in health economic evaluations. Given the accumulating literature on reproducibility across scientific disciplines [39−44], we were interested in advances in health economic evaluations.

The objective of this metaresearch study was to investigate the extent to which articles of health economic evaluations of healthcare interventions indexed in MEDLINE incorporate transparency, openness, and reproducible research practices.

2. Materials and methods

2.1. Study design

This study is a baseline cross-sectional analysis of a metaresearch project on reproducibility and transparency of health economic evaluations. We published [45] and registered a protocol for the project (Open Science Framework: osf.io/gzaxr). Our methods are briefly described here

(and explained in more detail in the Electronic Appendix 1−5). Deviations from the protocol for the present study are outlined in the Electronic Appendix 2.

2.2. Eligibility criteria

We included articles that we considered to meet the definition of a full health economic evaluation measuring health effects in terms of prolongation of life and/or health-related quality of life. In particular, we considered cost-effectiveness analysis of healthcare interventions in humans reporting an incremental cost-effectiveness ratio (ICER) in terms of costs per life years gained, quality-adjusted life years (QALYs), or disability-adjusted life years. We selected this specific form of health economic evaluation because many decision-makers and researchers have recommended this framework as the standard reference for cost-effectiveness in health and medicine.

Publications of health economic evaluations were limited to journal articles written in English with an abstract available. We excluded editorials, letters, narrative reviews, systematic reviews, meta-analysis, methodological articles, retracted publications, and health economic evaluations that do not quantify health impacts in terms of prolongation of life and/or health-related quality of life.

2.3. Searching

On August 20, 2020, an information specialist (A.A-A.) searched MEDLINE through PubMed (National Library of Medicine, Bethesda, USA) to identify articles of health economic evaluations indexed during 2019. The search strategy is available in Electronic Appendix 3.

2.4. Screening

Screening was undertaken using online review software, Rayyan (Rayyan Systems Inc., Cambridge, USA). Two researchers (M.R. and F.C-L.) screened all titles and abstracts using the method of liberal acceleration, whereby both researchers needed to independently exclude a record for it to be excluded, although only one researcher needed to include a record for it to be included. We retrieved the full-text article for any citations meeting our eligibility criteria or for which eligibility remained unclear. Two researchers (M.R. and F.C-L.) independently screened each full-text article.

2.5. Data extraction

We performed data extraction on a random sample of 200 of the included health economic evaluations, which were selected using the random number generator in Microsoft Excel (Microsoft Corp, Seattle, USA). Data were collected using a standardized data extraction form including 75 items (see forms in Electronic Appendix 4). Briefly, to enable description of the general characteristics and the reporting in each article, we gathered year and journal of publication, journal impact factor (according to 2021 Journal Citation Reports), journal type (e.g., subscription-based vs. fully open access), number of authors, gender and country of corresponding author, type of disease condition, type of intervention (e.g., pharmacological, nonpharmacological, both), type of comparator, type of health economic evaluation (e.g., model-based vs. single-study), study design (e.g., randomized trial, observational study, mathematical model), number of participants, perspective (in terms of which costs are considered, e.g., society, healthcare system, others), time horizon, type of costs (e.g., direct or indirect) and sources of information, health outcomes used, measurement of clinical effectiveness (e.g., a description of the design features of the single effectiveness study and why the study was a sufficient source of effectiveness; and for synthesis-based estimates a description of the methods used for identification of included studies and synthesis of effectiveness data using systematic reviews and meta-analyses), discount rates, discussion of all analytical methods supporting the analyses, sensitivity analyses, subgroup analyses, results for the primary outcome in the base case scenario (e.g., ‘‘more costs, more outcomes’’, ‘‘less costs, more outcomes’’), ICERs, hypothetical willingness-to-pay threshold, and study conclusions. Disclosures of funding source and conflicts of interest were also evaluated.

We collected data on enablers for reproducibility, transparency, and openness as follows: open access article (or free availability in PubMed), citation/mention of a guideline (e.g., for study conduct or reporting), use of CHEERS statement (e.g., appropriate, inappropriate, or unclear use) [46], study protocol/registration mentioned, health economic analysis plan mentioned, sharing of raw data used in the analyses, access to analytic methods and algorithms (e.g., ‘‘code,’’ ‘‘script,’’ or ‘‘model’’), usage of software, methods for sharing data and materials (e.g., open access repository), data made available to recreate the index ICERs (e.g., base case), data made available to recreate all core ICERs (e.g., base case and subgroup analyses), data made available to recreate all ICERs (e.g., base case, sensitivity/subgroup analyses) according to reporting standards [13] and statement on novelty or rigorous independent replication and reproducibility checks [43]. Health economic evaluations reporting ICERs needed to meet the following criteria to be judged as ‘‘recreatable’’: (a) it was clear which studies were included as source of clinical effectiveness data, the effect estimates (e.g., risk ratio) with measures of precision (e.g., 95% confidence intervals [CIs]), methods used to elicit preferences for outcomes (if applicable), approaches used to estimate resource use, and associated costs and (b) the relative costs and effectiveness of the alternative interventions being compared were presented numerically or could be calculated from the study.

All data extractors piloted the form on 10 articles to ensure consistency in interpretation of data items.

Subsequently, data from each health economic evaluation were extracted by two researchers (M.R., L.T-R., and/or F.C-L.) independently in duplicate. Any discrepancies were resolved via discussion or adjudication by a senior researcher (F.C-L.).

2.6. Data analysis

Data were summarized as frequency and percentage for categorical items and median and interquartile range (IQR) for continuous items. We analysed general, methodological, and reproducibility indicators of all health economic evaluations. We also explored the association between reproducibility indicators and self-reported use (citation/mention) of any reporting guideline, defined as a document specifying essential items to report in a health economic evaluation (such as the CHEERS statement [13] and/or the US Panel on Cost-Effectiveness in Health and Medicine [14–17]). We quantified associations using the risk ratio (RR), with 95% CIs. All analyses were performed using Stata version 17 (StataCorp, College Station, Texas, USA).

3. Results

3.1. Search results

Our search retrieved 6,336 records (Fig. 1). Screening of title and abstracts led to the exclusion of 4,780 records. Of the 1,556 full-text articles retrieved, 772 were excluded; most articles were not a full health economic evaluation. A total of 200 studies were included in the analyses (see references in Electronic Appendices 5). Citations of all records identified, screened, and included are available on the Open Science Framework (osf.io/gzaxr).

3.2. General characteristics of health economic evaluations

We evaluated 200 articles published in 147 journals. Most of the studies (116/200 [58%]) were led by researchers based in the United States, United Kingdom, Canada, and China (Table 1). The studies covered a wide range of conditions, with particular emphasis on neoplasms, infectious and parasitic diseases, diseases of the circulatory system and endocrine, and nutritional and metabolic diseases (125/200 [63%]). Most studies were model-based economic evaluations (150/200 [75%]). The interventions evaluated were nonpharmacological in 93/200 (47%), pharmacological in 84/200 (42%), or both in 23/200 (12%). The studies included (or simulated) a median of 1,000 participants (IQR: 186–20,000). In 109/200 (55%) studies, authors cited/mentioned a guideline (e.g., for study conduct or reporting). Almost half of the studies were published as open access articles (93/200 [47%]). Most authors declared whether they had any conflicts of

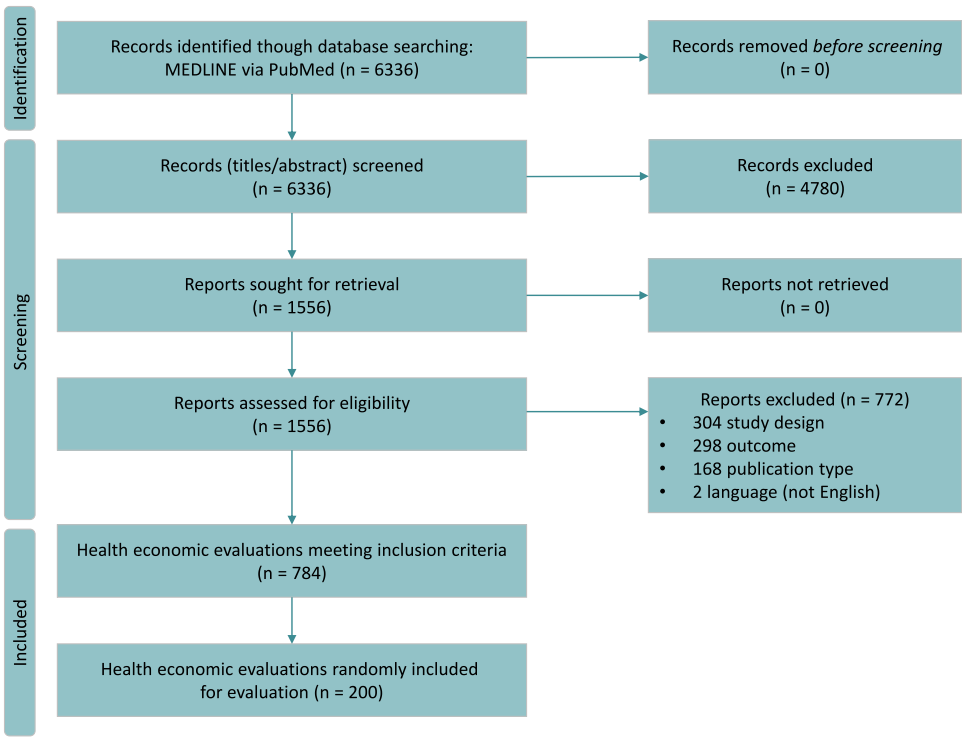

Fig. 1. Flow diagram of identification, screening, and inclusion of health economic evaluations. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Table 1. Descriptive characteristics of health economic evaluations

Characteristics	All (N = 200)
Total number of journals	147
Journal impact factor (JCR 2021)	
0.0–5.0	118 (59%)
5.1–10.0	50 (25%)
10.1–15.0	17 (9%)
>15.0	15 (8%)
Journal type[a]	
Subscription-based (including hybrid journals)	153 (77%)
Fully open access	47 (24%)
Number of authors	6 (4–9)
Country of corresponding author	
United States	58 (29%)
United Kingdom	26 (13%)
Canada	17 (9%)
China	15 (8%)
Other	84 (42%)
Gender of corresponding author	
Men	120 (60%)
Women	80 (40%)
Type of condition addressed (ICD-10 category)	
Neoplasms (including cancers, carcinomas, tumors)	55 (28%)
Infections and parasitic diseases	37 (19%)
Diseases of the circulatory system	21 (11%)
Endocrine, nutritional, and metabolic diseases	12 (6%)
Other	75 (38%)
Type of health economic evaluation	
Model-based	150 (75%)
Single study-based	50 (25%)
Types of interventions addressed	
Nonpharmacological	93 (47%)
Pharmacological	84 (42%)
Both	23 (12%)
Number of participants (included or simulated)	1,000 (186–20,000)
Citation/mention of any guideline (e.g., for study conduct or reporting)	109 (55%)
CHEERS statement (2013)	37 (19%)
Second Panel on Cost-Effectiveness in Health and Medicine (2016)	25 (13%)
Panel on Cost-Effectiveness in Health and Medicine (1996)	9 (5%)
Other (e.g., HTA national organisations, scientific societies)	48 (24%)
None	91 (46%)
Source of funding	
Nonprofit	116 (58%)
For-profit/mixed	39 (20%)
Authors specified there was no funding	21 (11%)
Not reported/unclear	24 (12%)
Conflicts of interest	
Authors declare no competing interests	112 (56%)
Authors declare competing interests	74 (37%)
Not reported/unclear	14 (7%)
Open access articles (or free available in PubMed Central)	93 (47%)

(*Continued*)

Table 1. Continued

Data given as number (percent) or median (interquartile range). Some percentages do not add to 100% because of rounding.

Abbreviations: CHEERS, Consolidated Health Economic Evaluation Reporting Standards (published in 2013); HTA, Health Technology Assessment; ICD-10, International Classification of Diseases, 10th Revision; JCR, Journal Citation Reports.

[a] Journal type: Hybrid, subscription-based: 144/200 (72%); Gold open access: 44/200 (22%); Platinum open access: 3/200 (2%); Not specified/unclear: 9/200 (5%).

interest (186/200 [93%]). Funding source was disclosed in 176/200 (88%).

3.3. Methodological aspects and reporting of health economic evaluations

Table 2 shows methodological and reporting practices. With regard to framing, most studies presented an adequate description of interventions and comparators (168/200 [84%]). Studies have focused on treatment (121/200 [61%]), prevention (65/200 [33%]), and diagnostic procedures (12/200 [6%]). Nearly half of studies considered usual care (92/200 [46%]) as the comparator, 61/200 (31%) used active alternatives (e.g., drug, device, procedure, or program), and 47/200 (24%) placebo or "do nothing". Overall, most of the studies (163/200 [82%]) were conducted in the adult population. With regard to study design, nearly half of studies (93/200 [47%]) were Markov models. In 128/150 (85%), model-based studies described the specific type of decision-analytical model and 132/150 (88%) listed assumptions. The perspective was clearly stated in 176/200 (88%) studies. The time horizon was clearly reported in most studies (192/200 [96%]), with the long-term (lifetime) horizon applied in 107/200 (54%). Most studies (170/200 [85%]) used QALYs as the measure of benefit. Only 75/200 (38%) studies provided a full description of the methods used for the measurement of clinical effectiveness. Most studies (160/200 [80%]) appropriately reported measurement and valuation of resources and costs; 184/200 (92%) clearly stated the currency and the year in which monetary units were valued. With regard to reporting of results, a total of 643 ICERs were reported for the base case (with a median of 2; IQR 1–4). Most studies (191/200 [96%]) reported sensitivity analyses, but only 98/200 (49%) reported subgroup analyses. Most studies (134/200 [67%]) reported that the intervention produced "more costs

Table 2. Methodological aspects and reporting of the health economic evaluations

Characteristics	All (*N* = 200)	With any guideline (*N* = 109)	With CHEERS (*N* = 37)	With panel CEA (*N* = 32)	Without guideline (*N* = 91)
Adequate description of interventions and comparators	168 (84%)	93 (85%)	33 (89%)	24 (75%)	75 (82%)
Focus of the intervention					
Treatment/therapeutic	121 (61%)	62 (57%)	25 (68%)	15 (47%)	59 (65%)
Prevention	65 (33%)	40 (37%)	11 (30%)	13 (41%)	25 (28%)
Diagnosis	12 (6%)	6 (6%)	0 (0%)	3 (9%)	6 (7%)
Rehabilitation	2 (1%)	1 (1%)	1 (3%)	1 (3%)	1 (1%)
Type of comparators					
Usual care	92 (46%)	53 (49%)	22 (59%)	16 (50%)	39 (43%)
Active alternative(s)	61 (31%)	31 (28%)	11 (30%)	10 (31%)	30 (33%)
Placebo or do nothing	47 (24%)	25 (23%)	4 (11%)	6 (19%)	22 (24%)
Population analysed					
Adults	163 (82%)	89 (82%)	29 (78%)	28 (87%)	74 (81%)
Children (including newborn) and adolescents	18 (9%)	11 (10%)	4 (11%)	3 (9%)	7 (8%)
Mixed	15 (8%)	6 (6%)	4 (11%)	0 (%)	9 (10%)
Not reported/unclear	4 (2%)	3 (3%)	0 (0%)	1 (3%)	1 (1%)
Study design of the health economic evaluation					
Markov model	93 (47%)	48 (44%)	14 (38%)	13 (41%)	45 (49%)
Deterministic decision analysis	33 (17%)	23 (21%)	7 (19%)	9 (28%)	10 (11%)
Randomized controlled trial	25 (13%)	11 (11%)	9 (24%)	2 (6%)	14 (15%)
Observational study (e.g., cohort)	20 (10%)	7 (6%)	2 (5%)	2 (6%)	13 (14%)
Microsimulation model	9 (5%)	6 (6%)	2 (5%)	5 (16%)	3 (3%)
Discrete event simulation model	5 (3%)	4 (4%)	1 (3%)	0 (0%)	1 (1%)
Not reported/unclear	5 (3%)	4 (4%)	2 (5%)	0 (0%)	1 (1%)
Other	10 (5%)	6 (6%)	0 (0%)	0 (0%)	4 (4%)
Perspective of the analysis					
Healthcare system only	129 (65%)	72 (66%)	23 (62%)	14 (44%)	57 (63%)
Societal only	29 (15%)	16 (15%)	5 (13%)	11 (34%)	13 (14%)
Societal and healthcare system	18 (9%)	13 (12%)	7 (19%)	6 (19%)	5 (5%)
Not reported/unclear	24 (12%)	8 (7%)	2 (5%)	1 (3%)	16 (18%)
Type of costs					
Direct costs only	152 (76%)	81 (74%)	25 (68%)	18 (56%)	71 (78%)
Direct and indirect costs	39 (19%)	24 (22%)	11 (30%)	12 (37%)	15 (16%)
Not reported/unclear	9 (5%)	4 (4%)	1 (3%)	2 (6%)	5 (5%)
Time horizon					
Long time (lifetime)	107 (54%)	62 (57%)	19 (51%)	19 (59%)	45 (49%)
Short time (<5 yr)	57 (29%)	31 (28%)	15 (40%)	7 (22%)	26 (29%)
Intermediate (5–10 yr)	28 (14%)	13 (12%)	3 (8%)	5 (16%)	15 (16%)
Not reported/unclear	8 (4%)	3 (3%)	0 (0%)	1 (3%)	5 (5%)
Discounted costs and/or outcomes	149 (75%)	90 (83%)	27 (73%)	25 (78%)	59 (65%)
Type of outcome measure					
QALYs only	150 (75%)	82 (75%)	26 (70%)	28 (87%)	68 (75%)
QALYs and LYGs	20 (10%)	10 (9%)	2 (5%)	3 (89%)	10 (11%)
DALYs only	17 (9%)	12 (11%)	6 (16%)	1 (3%)	5 (5%)
LYGs	13 (7%)	5 (5%)	3 (8%)	0 (0%)	8 (9%)
Stated currency and year for costs	184 (92%)	100 (92%)	36 (97%)	27 (84%)	84 (92%)
Described measurement of effectiveness	75 (38%)	53 (49%)	21 (57%)	11 (34%)	22 (24%)
Described measurement/valuation of resources and costs	160 (80%)	93 (85%)	35 (95%)	25 (78%)	67 (74%)

(*Continued*)

Table 2. Continued

Characteristics	All (*N* = 200)	With any guideline (*N* = 109)	With CHEERS (*N* = 37)	With panel CEA (*N* = 32)	Without guideline (*N* = 91)
Described all analytical methods supporting the evaluation	157 (79%)	92 (84%)	36 (97%)	24 (75%)	65 (71%)
Statistical analyses reported					
Number of ICERs estimates for the base case	2 (1–4)	2 (1–4)	2 (1–4)	2 (2–4)	2 (1–4)
Sensitivity analysis reported	191 (96%)	106 (97%)	37 (100%)	31 (97%)	85 (93%)
Subgroup analysis reported	98 (49%)	58 (53%)	19 (51%)	22 (69%)	40 (44%)
Main results for the base case					
More costs, more outcomes	134 (67%)	70 (64%)	23 (62%)	22 (69%)	64 (70%)
Less costs, more outcomes	42 (21%)	25 (23%)	8 (22%)	5 (16%)	17 (19%)
More costs, comparable outcomes	10 (5%)	6 (6%)	1 (3%)	4 (12%)	4 (4%)
More costs, less outcomes	7 (4%)	5 (5%)	4 (11%)	0 (0%)	2 (2%)
Other (e.g., less costs, comparable or less outcomes)	7 (4%)	3 (3%)	1 (3%)	1 (3%)	4 (4%)
Conclusions					
Favourable	153 (77%)	85 (78%)	28 (76%)	23 (72%)	68 (75%)
Unfavourable	34 (17%)	18 (17%)	6 (16%)	7 (22%)	16 (18%)
Neutral/unclear	13 (7%)	6 (6%)	3 (8%)	2 (6%)	7 (8%)
Reported a hypothetical willingness-to-pay threshold	187 (94%)	104 (95%)	34 (92%)	30 (94%)	83 (91%)

Data given as number (percent) or median (interquartile range). Some percentages do not add to 100% because of rounding.

Abbreviations: CHEERS, Consolidated Health Economic Evaluation Reporting Standards (published in 2013); DALYs, Disability-adjusted life years; ICERs, Incremental cost-effectiveness ratios; LYGs, Life-years gained; QALYs, Quality-adjusted life years; Panel CEA; Recommendations of the US Panel on Cost-Effectiveness in Health and Medicine (published in 1996 and 2016).

and more outcomes''. Conclusions favored interventions in 153/200 (77%) studies. The vast majority of studies (187/200 [94%]) reported a hypothetical willingness-to-pay threshold. All these characteristics were similar in studies using a guideline and those without a guideline, except for the description of measurement of effectiveness, which was less frequent in studies not using a guideline.

3.4. Openness and reproducible research practices in health economic evaluations

Table 3 shows openness and reproducible research practices. Of the 200 studies, 31 (16%) reported working from a protocol—of which, 20 were randomized trials and five were observational studies. Only 5/200 (3%) health economic evaluations indicated an analysis plan was available, and in all cases were developed for randomized trials.

Only 10/200 (5%) studies mentioned access to raw data and analytic methods/algorithms used to perform reanalyses. Most studies (147/200 [74%]) reported the usage of software for analyses, being the most common: TreeAge Pro (54/147 [37%]), Microsoft Excel (51/147 [35%]), Stata (27/147 [18%]), and R (22/147 [15%]). In 112/200 (56%) studies, authors reported the data needed to recreate the ICERs for the base case analysis. This proportion decreased to 21/200 (11%) when considering all core ICERs (e.g., base case and subgroup analyses) and to 5/200 (3%) when considering all ICERs (e.g., base case, subgroup/sensitivity analyses) in the study.

All reproducible research practices were observed more often in studies using a guideline compared with those not using a guideline (Fig. 2 and Table 3). This was largely driven by more frequent reporting of indicators in studies mentioning CHEERS (Table 3). However, only three RR associations that favored the use of a guideline had 95% CIs that excluded the null. These included the reporting of the data needed to recreate the index ICERs (72/109 [66%] with guideline vs. 40/91 [44%] without guideline; RR 1.50, 95% CI 1.15–1.97), the reporting of the data needed to recreate all core ICERs (17/109 [16%] with guideline vs. 4/91 [4.4%] without guideline; RR 3.55, 95% CI 1.24–10.17), and reporting a statement on novelty or rigorous independent replication/reproducibility checks (55/109 [50%] with guideline vs. 28/91 [31%] without guideline; RR 1.64, 95% CI 1.14–2.35) (Fig. 2).

4. Discussion

In this metaresearch study, we investigated the extent to which articles of health economic evaluations incorporate transparent, openness, and reproducible research practices. Based on our analysis of a random sample (n = 200) of health economic evaluations indexed in MEDLINE, we observed reproducible research practices are frequently

Table 3. Reproducible research practices in health economic evaluations

Characteristics	All (*N* = 200)	With any guideline (*N* = 109)	With CHEERS (*N* = 37)[a]	With panel CEA (*N* = 32)	Without guideline (*N* = 91)
Protocol/registration mentioned					
Protocol publicly available	23 (12%)	13 (12%)	8 (22%)	2 (6%)	10 (11%)
Partly, but protocol is not publicly available (e.g., available on request)	8 (4%)	5 (5%)	1 (3%)	1 (3%)	3 (3%)
No protocol/unclear	169 (85%)	91 (83%)	28 (76%)	29 (91%)	78 (86%)
Health economic analysis plan					
Analysis plan publicly available	4 (2%)	4 (4%)	4 (11%)	0 (0%)	0 (0%)
Partly, but analysis plan is not publicly available (e.g., available on request)	1 (1%)	1 (1%)	1 (3%)	1 (3%)	0 (0%)
No analysis plan/unclear	195 (98%)	104 (95%)	32 (86%)	31 (97%)	91 (100%)
Sharing of raw data used in analyses					
Provided access to raw data for reanalyses	4 (2%)	3 (3%)	3 (8%)	0 (0%)	1 (1%)
Partly, but raw data are not publicly available (e.g., available on request)	31 (16%)	19 (17%)	9 (24%)	3 (9%)	12 (13%)
No data sharing mentioned	165 (83%)	87 (80%)	25 (68%)	29 (91%)	78 (86%)
Access to analytic methods and algorithms (e.g., 'code', 'script', 'model') used					
Provided access to analytic methods	3 (2%)	2 (2%)	2 (5%)	0 (0%)	1 (1%)
Partly, but analytic methods are not publicly available (e.g., available on request)	7 (4%)	4 (4%)	1 (3%)	0 (0%)	3 (3%)
No access to analytic methods	190 (95%)	103 (95%)	34 (92%)	32 (100%)	87 (96%)
Reported the usage of software	147 (74%)	85 (78%)	30 (81%)	28 (87%)	62 (68%)
Reported the usage of an open-source software (such as R, Python, JAGS, OpenBUGS)	23 (12%)	16 (15%)	5 (13%)	5 (16%)	7 (8%)
Methods of sharing data and materials					
Open access repository	3 (2%)	2 (2%)	2 (5%)	0 (0%)	1 (1%)
Supplementary files/journal repository	3 (2%)	3 (3%)	3 (8%)	1 (3%)	0 (0%)
Institutional/project repository	1 (1%)	1 (1%)	1 (3%)	0 (0%)	0 (0%)
None	193 (97%)	103 (95%)	31 (84%)	31 (97%)	90 (99%)
Reported data needed to recreate the index ICERs (e.g., base case)	112 (56%)	72 (66%)	25 (68%)	21 (66%)	40 (44%)
Reported data needed to recreate all core ICERs (e.g., base case and subgroup analyses)	21 (11%)	17 (16%)	7 (19%)	6 (19%)	4 (4%)
Reported data needed to recreate all ICERs (e.g., base case, sensitivity/subgroup analyses)	5 (3%)	5 (5%)	3 (8%)	1 (3%)	0 (0%)
Statement on novelty or replication/reproducibility checks					
Novel findings	47 (24%)	31 (28%)	9 (24%)	7 (22%)	16 (18%)
Replication	18 (9%)	11 (10%)	6 (16%)	3 (9%)	7 (8%)
Novel findings and replication	18 (9%)	13 (12%)	6 (16%)	5 (16%)	5 (5%)
No statement	117 (59%)	54 (50%)	16 (43%)	17 (53%)	63 (69%)

Data given as number (percent). Some percentages do not add to 100% because of rounding.

Abbreviations: CHEERS, Consolidated Health Economic Evaluation Reporting Standards (published in 2013); ICERs, Incremental cost-effectiveness ratios; Panel CEA, Recommendations of the US Panel on Cost-Effectiveness in Health and Medicine (published in 1996 and 2016).

[a] Of the health economic evaluations citing and/or mentioning CHEERS, 14/37 (38%; 95% CI: 23–54%) made an appropriate use, 7/37 (19%; 95% CI: 9–34%) the use was inappropriate, and 16/37 (43%; 95% CI: 29–59%) was unclear o neutral.

underused in health economic evaluations. Overall, our study showed that the quality of reporting of health economic evaluations was reasonable. Several methodological and transparency items were reported frequently (e.g., reporting of conflicts of interest, funding source, description of interventions and comparators, population analysed, perspective, type of costs, time horizon). Almost half (47%) of studies were published as open access articles, but some essential components of research methods were missing in many articles, such as the use of study protocols

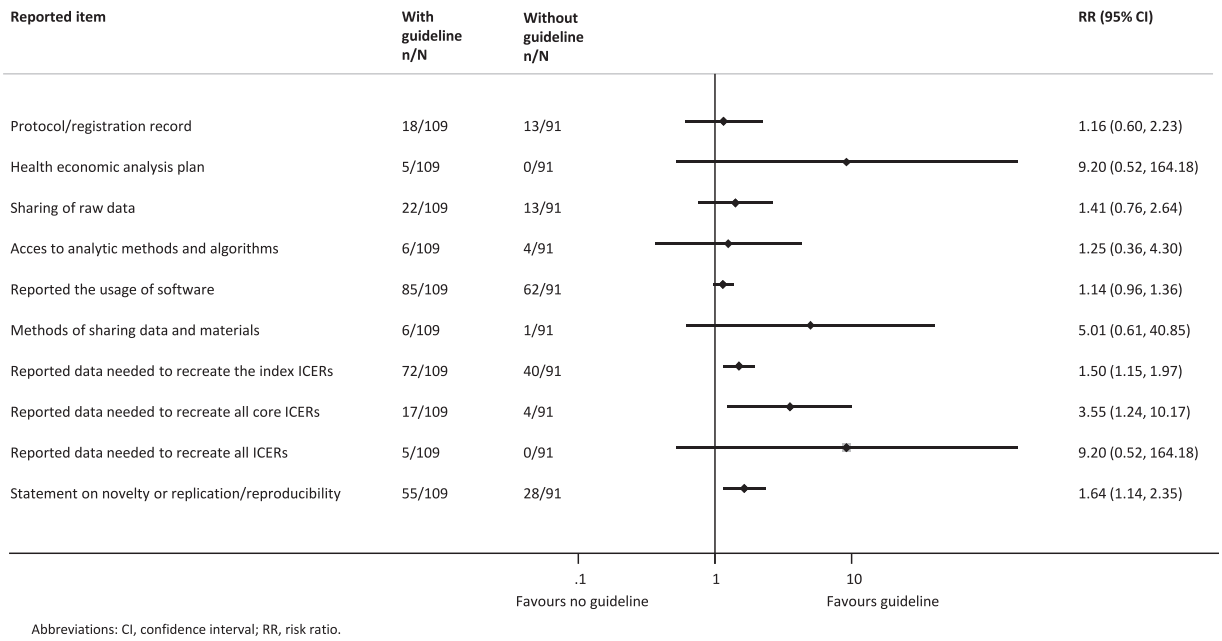

Fig. 2. Association between self-reported use of any guideline and reproducible research practices in health economic evaluations. Abbreviations: CI, confidence interval; RR, risk ratio.

and health economic analysis plans, access to raw data and analytic code for reanalyses, but also the description of measurement methods for clinical effectiveness (e.g., using a systematic review process). Authors reported the data needed to recreate the index ICERs (for the base case analysis), in 56% of studies. This percentage was higher in studies using a guideline than studies not using a guideline (66% vs. 44%). In contrast, the data needed to recreate all ICERs, including base case, subgroups, and sensitivity analyses, were available in only 3% of studies.

An important element in assessing transparency, openness, and reproducibility is the registration of a study protocol and (health economic) analysis plans. Study registration, protocols, and analysis plans are now routine in clinical research, being critically important in planning, conduct, interpretation, and external review of randomized trials and systematic reviews. When clearly reported protocols and analysis plans are made available, they enable knowledge users to identify deviations from planned methods and whether they bias the interpretation of results [1,5]. Nevertheless, registration of study protocols and analysis plans remain uncommon outside of randomized trials and systematic reviews. In our sample, and despite being recommended by some reporting guidelines (such as the US Second Panel on Cost-Effectiveness in Health and Medicine [14] and more recently the CHEERS 2022 statement [47]), analysis plans were reported only in 3% of health economic evaluations. This percentage was somewhat higher for studies that reported working from a study protocol, but only 16% in our sample. In view of these results, scarcity of study protocols and analysis plans in health economic evaluations could warrant pragmatic actions. For example, recent initiatives are still in the process to improve the transparency and content health economic analysis plans for trial-based health economic evaluations [48] that could be useful for all types of economic evaluations (e.g., model-based, observational study−based).

Analytic methods (e.g., code and algorithms) and data sharing are critical elements of transparency and reproducibility [2]. This sharing is an essential part of most studies as it allows the reanalysis and the assessment of the analytic methods for potential errors or nondisclosed approaches that may affect study results and conclusions. The absence of sharing data and code may affect the trustworthiness of the published articles. Nevertheless, only 5% of studies in our sample mentioned access to raw data and analytic code for reanalyses which is within the range of previously reported results in other study designs [41,49,50]. For example, in a 2020 sample of published systematic reviews and meta-analyses of interventions [50], 7% (20/300) of reviews mentioned access to datasets, analytical code, and materials used. In addition, we observed the vast majority of published health economic evaluations (75% in our sample) used decision-analytic modeling as the main methodology. Issues regarding model transparency and approaches to facilitating model-sharing continue to be important [19,51−53]. Current recommendations state that authors should provide enough detail about model structure and parameterization to allow reproducibility [13,14,47]. Although many reporting guidelines did not reach a consensus on this, some authors have called for open-source approaches that would require making the models (“source code”) available [18,19,21]. On this regard, the CHEERS 2022 statement [47] recently added

recommendation to report where publicly available models can be found and that sharing of unlocked models with editors and reviewers is encouraged. Similarly, it is essential for health economic evaluations to use all relevant evidence on the clinical effectiveness of health interventions under evaluation. Rarely will all relevant evidence come from a single study, and typically, it will have to be drawn from several clinical studies. On this regard, a disappointing finding of our study is that few health economic evaluations provided a full description of the methods used for the measurement of effectiveness. As such, most health economic evaluations, and particularly model-based, seemed to make arbitrary decisions about what studies to use to inform clinical effectiveness data. Future studies should be more transparent in reporting these important aspects.

In our study, it was encouraging that the data needed to recreate the index ICERs (for the base case analysis) were available in more than half (56%) of health economic evaluations, although somewhat disappointing that this was not the case for all ICERs. In our opinion, there are several possible explanations. Some authors may consider it sufficient to report data fully for the base case analysis only from running a decision-analytic model with the preferred set of assumptions and input values given that this is likely to be the most important to decision-making and perceived as the primary study outcome. Others may argue space constraints of scientific journals (e.g., word limits and restrictions on the numbers of tables and figures) may force authors to be selective about which data they present in an article. Nevertheless, multiple options exist to present the relevant data for all analyses. For example, most journals allow online and supplementary appendices for complete descriptions of analytic methods, and we observed several examples of such appendices providing complete data and analytical code (e.g., an economic evaluation of potentially inappropriate prescribing and related adverse events in older people [54]). If online and supplementary appendices are not allowed by journals, authors can upload the relevant data to public repositories (such as the Open Science Framework, Dryad, or Zenodo). With these options, reproducible research practices should become routine in health economic evaluations.

Half (55%) of included studies in our sample self-reported use of a guideline (e.g., for study conduct or reporting). Mention or citation of a guideline (such as the CHEERS statement [13] and/or the US Panel on Cost-Effectiveness in Health and Medicine [14−17]), perhaps a surrogate for actual use [46], appears to be potentially associated with some reproducible research practices. For example, guideline users were statistically significantly more likely to report the data needed to recreate the index ICERs, but not all ICERs in the health economic evaluation. There are several possible reasons for this. Some authors may still be unaware of reporting guidelines for health economic evaluations or assume that they already know how to report the methods and results transparently. The extent to which journals endorse reporting guidelines in health economics is highly variable [55], with some explicitly requiring authors to submit a completed checklist at the time of manuscript submission, others only recommending its use in the instructions to authors, and many not referring to it at all. Some authors may assume that they have adequately addressed an item if they report at least one element. One way to improve matters is for journals, authors, and peer-reviewers to follow existing guidelines and checklists to improve editorial management and transparency of published articles.

There are several strengths of our methods. We did not restrict inclusion based on the scope of the economic evaluation and, thus, unlike previous studies [24,29−34], were able to collect data on a broader cross-section of health economic evaluations. The studies in our sample covered a wide range of disease conditions, or time-based health outcomes (not only QALYs), but predominantly addressed questions about the cost-effectiveness of therapeutic interventions. We collected data from both the published articles and supplementary appendices. Our sample consists of health economic evaluations published before the CHEERS 2022 statement [47] was released, and thus provides a useful benchmark for future metaresearch studies to explore whether changes in transparency and reproducibility occurred after the release of the updated version. There are also some limitations to our study. Potential information bias, although innate to the use of retrospective data, is less likely due to the level of training implemented for data extractors and the use of piloted and standardized extraction forms. Our results reflect what was reported in the articles, and it is possible that some health economic evaluations were conducted (and reported) more rigorously than was specified in the report, and vice versa. Our findings may not necessarily generalize to health economic evaluations indexed outside of MEDLINE or written in languages other than English. Similarly, only health economic evaluations of the medical field were included. Therefore, reporting cost-effectiveness analyses of other health and social science areas might be worse (or different) than the results found here, considering that medicine has pioneered evidence-based practice. Some items were reported by less than 10 studies, so the 95% CIs of RR associations are imprecise. In some health economic evaluations, it was unclear how particular subgroup/sensitivity analyses were performed or whether they were performed for all or only some treatment comparisons or outcomes. By not contacting the authors to resolve these uncertainties, we were only able to determine whether analyses that were evidently performed had the data necessary for users to recreate them. Another possible limitation is that the health economic evaluations were published in 2019, before COVID-19 pandemic. Although the quality and openness of research has not improved during the COVID-19 period [56−58], it is possible that more recent health economic evaluations use reproducible research practices more often given the

increasing number of publications discussing reproducibility [39,41−43].

5. Conclusion

Transparency, openness, and reproducible research practices were suboptimal in our sample of health economic evaluations. Strengthening the reproducibility, openness, and reporting of methods and results can maximize the impact of health economic evaluations by allowing more accurate interpretation and use of their findings. In our opinion, strategies are needed to facilitate the provision and implementation of detailed descriptions of data gathered and data used for analysis, transparent reporting of the methods and results of the health economic evaluations, and sharing of datasets, analytical code, and models so that others can recreate the study results or perform secondary reanalyses. Moreover, our study provides a useful baseline against which the impact these data-sharing statements have on future health economic evaluations can be assessed, but also could further be used in discussions to strengthen reproducible research practices of health economic evaluations.

CRediT authorship contribution statement

F.C-L., M.R., L.C., B.H., D.H., M.F.D., and D.M. contributed to conceptualizing and designing the study. F.C-L. supervised the study. M.R., A.A-A., and F.C-L. conducted searches. M.R., L.T-R., and F.C-L. curated data. F.C-L. performed data analysis and visualizations. F.C-L., M.R., L.T-R., L.C., B.H., D.H., M.F.D., A.A-A., and D.M. interpreted the study findings. F.C-L. drafted the first version of the manuscript. M.R., L.T-R., L.C., B.H., D.H., M.F.D., A.A-A., and D.M. commented for important intellectual content and made revisions. All authors read and approved the final version of the manuscript. All authors meet the ICMJE criteria for authorship. F.C-L. accepts full responsibility for the finished manuscript and controlled the decision to publish.

Declaration of transparency

F.C-L. affirms that this manuscript is an honest, accurate, and transparent account of the study being reported, that no important aspects of the study have been omitted, and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Data availability

With the publication of this manuscript, the dataset will be freely available online in the Open Science Framework (osf.io/gzaxr), a secure online repository for research data.

Declaration of competing interest

L.C., D.H., M.F.D., and D.M. are authors of the CHEERS statement. All other authors declare that they have no competing interests to declare.

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Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.jclinepi.2023.10.024.

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