REVIEW

Methodological guidance for rapid reviews in healthcare: A scoping review

Christian Speckemeier¹ | Anja Niemann¹ | Jürgen Wasem¹ | Barbara Buchberger² |

¹Institute for Healthcare Management and Research, University of Duisburg-Essen, Essen, Germany

²Centre for International Health Protection, ZIG2, Evidence-based Public Health, Robert Koch Institute, Berlin, Germany

Correspondence

Christian Speckemeier, Institute for Healthcare Management and Research, University of Duisburg-Essen, Thea-Leymann-Straße 9, 45127 Essen, Germany.

Email: christian.speckemeier@medman. uni-due.de

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Silke Neusser¹⁰

Abstract

The aim of the present work was to identify published methodological guidance for rapid reviews (RRs) and to analyze the recommendations with regard to timesaving measures. A literature search was performed in PubMed and EMBASE in November 2020. In addition, a search based on Google Scholar and websites of governmental and non-governmental organizations was conducted. Literature screening was carried out by two researchers independently. A total of 34 publications were included. These describe 38 distinct RR types. The timeframe to complete the identified RR types ranges from 24 h to 6 months (mean time 2.2 months). For most RR types a specific research question (n = 21) and a prioritizing search (n = 25; preference for e.g., systematic reviews and meta-analyses) is employed. Different approaches such as reduced personnel in literature screening (n = 21) and data extraction (n = 21) are recommended. The majority of RR types include a bias assessment (n = 28) and suggest a narrative report focusing on safety and efficacy. The included RR types are heterogeneous in terms of completion time, considered domains and strategies to alter the standard systematic review methods. A rationale for the recommended shortcuts is rarely presented.

KEYWORDS

evidence synthesis, guideline, methodology, rapid review, recommendations, scoping review

Highlights

- To our knowledge, this scoping review is the first attempt to systematically analyze rapid review methodology with a specific focus on published method papers.
- · Published methodological guidance recommends a large variety of methodological shortcuts to achieve time savings.
- A rationale for the choice of specific shortcuts is rarely presented.
- · Further research should also and more deeply investigate the effects of particular limiting techniques on the validity of reviews.

Barbara Bucherger and Silke Neusser share senior authorship.

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• Review authors and authors of review methods papers should be encouraged to fully and transparently display their methods.

1 | INTRODUCTION

Evidence-based information is needed to support decision-makers in healthcare with regards to new technologies. Health technology assessment reports (HTAs) provide this information. HTA are typically based on a systematic review of the evidence. Systematic reviews attempt to identify, appraise and synthesize the best available evidence in order to answer a specific research question¹ and are accepted as the gold standard in evidence-based medicine.² Due to the high degree of scientific rigor,³ the production is time-consuming and resource-intensive and it often takes more than a year to complete an HTA report.⁴ However, to support urgent and emergent decisions evidence is needed within shorter periods of time.⁵ According to the Transparency Directive (Directive 89/105/EEC), member states of the European union need to perform relative effectiveness assessments in a limited timeframe (90 days for pricing or reimbursement decisions or 180 days for pricing and reimbursement decisions).⁶ In response to the incongruence between the time needed to produce evidence syntheses and the time within policy and other decision makers must reach decisions, abbreviated types of evidence syntheses have emerged.⁷ Frequent terms to describe these approaches are "rapid review" (RR), "rapid evidence assessment," "rapid systematic review" or "rapid health technology assessment" (hereinafter, the term RR is used as an umbrella term).⁸ In an attempt to define RRs, Hamel et al.⁹ have lately proposed to define RRs as "a form of knowledge synthesis that accelerates the process of conducting a traditional systematic review through streamlining or omitting a variety of methods to produce evidence in a resource-efficient manner.9"

In order to create RRs, the methodology will represent a departure from the standard systematic review process.¹⁰ A range of methodological alterations can be applied to save human and financial resources and to ultimately avoid the risk of drawing a conclusion which is out of date by the time the review is finalized.¹¹ Methodological approaches for RRs differ largely with respect to timescale, rigorousness and scope.¹⁰ In a number of publications, RRs were analyzed regarding the methodological shortcuts that have been applied. A large variability in abbreviated methods was identified but at the same time, possible effects of the alterations (e.g., with regards to bias) are rarely mentioned.^{2,8,12–15} In addition, many RRs do not explicitly state their methods.^{8,12} In a recently published systematic scoping review, studies assessing methodological shortcuts for undertaking RRs have been examined. The authors conclude that few studies formally evaluated methodological shortcuts and while some abbreviations may be valid for the conduct of RRs, limitations within the included studies may impede applicability in the RR context.¹⁶ At the time of writing this article, no agreed methodology like the Cochrane Handbook for Systematic Reviews for the conduct of RRs exists.

Lately, the emergence of COVID-19 has made RRs an even more topical issue as it has driven the need for timely evidence syntheses and has led to an explosion of publications.¹⁷ This has created several challenges throughout the entire process, including the urgency of the requests, conceptualization of question and scope, identification and access to relevant evidence, screening, data abstraction, synthesis and interpretation, and dissemination of the results.^{18,19} Lately, publication processes have been expedited for COVID-19-related research, in order to share new findings in a timely manner. This led to an acceleration of the time to publication from several months to a few days in many cases, with these fast turnarounds often being at the expense of thorough peer review processes.^{20,21}

Due to these challenges, the objective of the present review was to offer an overview on methodological guidance for RRs in healthcare. The method of scoping review was found feasible, as we were interested in identifying, reporting and discussing different concepts and their characteristics.²² The measures to achieve time savings are analyzed and if possible, methods are compared taking into account the time needed to produce the respective RR.

2 | METHODS

Conduct of this scoping review was guided by the JBI guide for scoping reviews²² and reporting was guided by the PRISMA extension to scoping reviews.²³ No review protocol was published in advance.

2.1 | Literature search

In order to identify and analyze published methodological guidance for RRs, a literature search was conducted in bibliographic databases as well as in Google Scholar and on websites of governmental and non-governmental organizations. Prior to the main literature search, a search in EMBASE and PubMed was conducted to identify terms for RRs. For this purpose, terms were extracted from titles, abstracts and indexing of the articles and transferred to a search strategy. A combination of keywords and text words represented by "technology assessment", "review", "evidence synthesis", "knowledge translation", "evidence map", "evidence format", "short", "rapid", "timely", "fast", "quick", "guideline", "guidance", "methodology", "checklist" and "protocol" was used. The search was then pilot tested and refined. The search strategy was reviewed by a senior researcher. The main search was conducted on November 18th, 2020 in EMBASE and PubMed. Results were downloaded into the EndNote reference management program (version X9) and duplicates removed. In addition, a search in Google Scholar and on websites of governmental and nongovernmental organizations was carried out in November 2020. The search strategy for the database and website searches is presented in Appendix S1.

2.2 | Inclusion and exclusion criteria

Methodological guidance describing the development of RRs (i.e., abbreviated forms of systematic reviews) was included. Further, the recommendations had to include adjustments to general systematic review methods, that is, methodological papers were not included, if the time savings solely arose from additional deployment of personnel or by omitting certain steps in the development (e.g., no consultation after development). In order to generate a broad information basis, no restriction was applied regarding the publication period. Publications in English or German language were included. No authors or institutions were contacted to identify additional sources.

2.3 | Selection and extraction of relevant recommendations

First, the titles and abstracts of identified publications were screened in terms of their potential relevance. Documents considered to be potentially eligible were examined in full text. Both review steps were conducted independently by two persons. Any disagreements were resolved by consulting a third person. Characteristics of the included documents and recommendations for the development of RRs were extracted in pre-specified tables comprised of the following aspects: search strategy, number of databases, search timeframe, languages, inclusion of grey literature, study design, inclusion of easily obtainable literature, full-text analysis, number of reviewers involved in screening, number of reviewers involved in extraction, and risk of bias assessment. These criteria have been developed and refined based on a sample of method papers. In case enough information on a set of pre-defined criteria (at least on five of eight development steps, see Appendix S3) was contained in the included documents, methods were compared taking into account the time needed to produce the respective RR. Data extraction was performed by one person and quality-checked by a second person. The focus of this review was to present an overview of methodological guidance and thus, the methodological quality of the included documents was not assessed and the evidence underlying the recommendations was not reviewed.

3 | RESULTS

The selection process is shown in Figure 1. A total of 17 articles from the database search met the inclusion criteria and another 17 documents were included from the additional search in Google Scholar and on the websites of governmental and non-governmental organizations.^{10,18,24–55} Three articles described more than one RR type.^{24–26} Thus, a total of 34 publications were included, in which 38 distinct RR types are described.

3.1 | Characteristics of included publications

The number of published methods papers about RRs has increased in recent years, with 76% of the included papers having been published between 2014 and 2020. The majority of papers are from Canada (n = 7), the United States (n = 6), and Australia (n = 5). A total of three papers in German language could also be identified.^{27–29} Most of the included papers are targeting policy makers (n = 19) and clinical decision-makers (n = 8). The majority has been published by governmental agencies or developed as part of government-funded research projects. The remaining papers have been developed by non-profit organizations,^{24,30} multi-national organizations such as the World Health Organization,³¹ non-academic research societies²⁸ and healthcare organizations²⁵ (see Appendix S2). Information on the time needed to produce the respective RR type is provided in 27 of the 34 papers (79%). On average, the development of RRs as reported takes 2.2 months (24 h to 6 months, median: 2 months) and half of the RRs take between 0.5 and 3.5 months. In 31 papers, information on the included

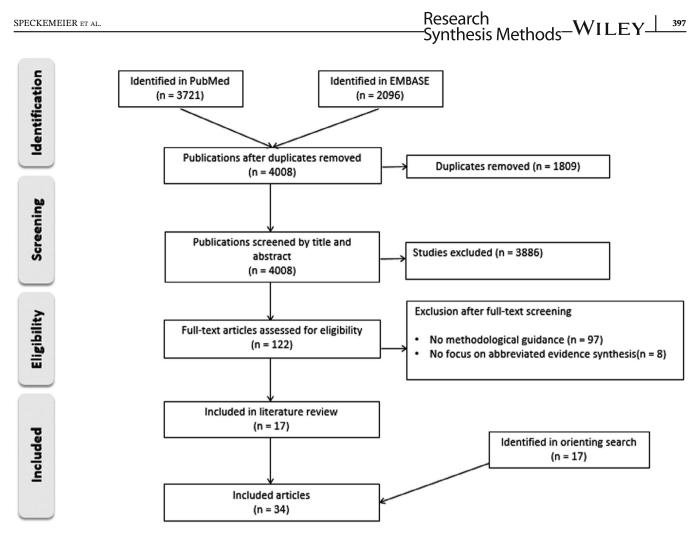


FIGURE 1 Study selection flow chart

domains (safety, effectiveness, ethical, social, organizational, and legal aspects) is given. In most RR types (n = 16), safety and efficacy are assessed. In 10 RR types, clinical and economic questions are addressed and in five RR types, further domains (e.g., ethical and social) are investigated. The extent of information on type and scope of the report varies widely. A narrative report is recommended by 22 methodological papers, often based on predefined templates and comprising just a few pages. In five RR types, evidence tables are part of the report.

3.2 | Recommendations for methodological shortcuts

In most RR types information on the risk of bias assessment (n = 35), full-text analysis (n = 34), the inclusion of a specific study design (n = 33), included databases (n = 31), and the number of reviewers involved in the process of literature screening is provided.

In Table 1, the number of RR types containing information on specific steps in the development is reported. Furthermore, the relative frequency of the specific categories related to the number of RR types giving information on the process step is shown. Most of the RR types (n = 21) recommend a specific search strategy to answer a clearly defined research question. Recommendations regarding the number of databases are heterogeneous. While 12 RR types recommend a search in at least three databases, seven RR types recommend to search in one or two databases. Different recommendations are also given with regard to the search timeframe, with one RR type limiting the search to the last 3 years, four RR types limiting the search to the last 5 years, and three RR types limiting the timeframe to the last 10 years. The majority of RR types recommend to customize the timeframe according to the research question. Furthermore, 20 RR types recommend limiting the search to English articles, while two RR types recommend searching in English and one further language and five RR types recommend an individual language restriction. Furthermore, the majority of RR types recommend including gray literature (n = 12), eight RR types propose to not include gray literature and seven RR types recommend a customized

TABLE 1 Recommendations for methodological shortcuts

Development step	Recommendation	n (%)
Search strategy	Rapid review types containing information on search strategy	29 (100%)
	Specific search strategy	21 (72%)
	Sensitive search strategy	5 (17%)
	Individual adapted search strategy	3 (10%)
Databases	Rapid review types containing information on databases	31 (100%)
	Search in 3 or more databases	12 (39%)
	• Search in 1 or 2 databases	7 (23%)
	• Search in limited number of databases	5 (16%)
	Preliminary search to identify databases	5 (16%)
	Individual choice of databases	2 (6%)
Search timeframe	Rapid review types containing information on search timeframe	21 (100%)
	• Search timeframe limited to 10 years	3 (14%)
	• Search timeframe limited to 5 years	4 (19%)
	• Search timeframe limited to 3 years	1 (5%)
	• Individual limitation of the search timeframe	10 (48%)
	No restriction	3 (14%)
Languages	Rapid review types containing information on language	27 (100%)
	Limited to English and one further language	2 (7%)
	Limited to articles in English language	20 (74%)
	Individual restriction	5 (19%)
Inclusion of gray literature	Rapid review types containing information on gray literature	27 (100%)
	Inclusion of gray literature	12 (44%)
	No inclusion of gray literature	8 (30%)
	Customized approach	7 (26%)
Study design	Rapid review types containing information on study designs	33 (100%)
	Search without restriction of study design	1 (3%)
	 Prioritizing search strategy with a preferred search for systematic reviews, meta-analyses, HTA reports and guidelines 	25 (76%)
	• Exclusive search for systematic reviews and for RCTs published after the most recent systematic review	6 (18%)
	Individual choice of study design to include	1 (3%)
Inclusion of easily obtainable literature	Rapid review types containing information on the inclusion of easily obtainable literature	18 (100%)
	Only easily obtainable literature is included	12 (67%)
	• All available literature is included	4 (22%)
	• Customized approach depending on availability of evidence	2 (11%)
Full-text analysis	Rapid review types containing information on full-text analysis	34 (100%)
	• Full-text analysis	30 (88%)
	Analysis on abstract level	2 (6%)
	Customized approach	2 (6%)
Screening: number of reviewers	Rapid review types containing information on screening	30 (100%)
	• Screening is carried out by two persons and uncertainties are clarified through discussion	8 (27%)

TABLE 1 (Continued)

Development step	Recommendation	n (%)
	• Screening is carried out by one person and 20%–25% of articles are reviewed by a second person. If the match is <95%, all articles will be screened independently by a second person	5 (17%)
	• Screening is carried out by one person and a second person screens excluded articles (in some cases only for title and abstract screening, while the full text is screened by two people)	3 (10%)
	• Screening is carried out by one person and a second person is consulted in case of uncertainties	13 (43%)
	Customized approach	1 (3%)
Extraction: number of reviewers	Rapid review types containing information on extraction	29 (100%)
	• Extraction is carried out by one person and all results are verified by a second person	6 (21%)
	• Extraction is carried out by one person and results are partially verified by a second person	7 (24%)
	• Extraction is carried out by one person	14 (48%)
	Customized approach	2 (7%)
Risk of bias assessment	Rapid review types containing information on risk of bias assessment	35 (100%)
	Risk of bias assessment	20 (57%)
	No risk of bias assessment	7 (20%)
	• No independent assessment of the risk of bias but bias potential reported in the included evidence is incorporated	5 (14%)
	Customized approach depending on availability of evidence	3 (9%)

Abbreviation: RCTs, randomized controlled trials.

approach. The majority of RR types suggest a prioritizing search for systematic reviews, meta-analyses, HTA reports and guidelines (n = 25). If no such publications can be identified, the search strategy is to be expanded to incorporate primary studies. In other RR types, an exclusive search for systematic reviews and randomized controlled trials (RCTs) published after the most recent systematic review is performed (n = 6). In 12 RR types, only easily obtainable literature is included. A full-text analysis is carried out in most RR types (n = 30).

In most RR types, screening is carried out by one person and either a second person is consulted in case of uncertainties (n = 13), a second person reviews 20%-25% of articles (n = 5), or a second person screens excluded articles (n = 3). Extraction is in most cases carried out by one person (n = 27), and either no second person is involved (n = 14), parts of the results are checked by a second person (n = 7) or the complete results are checked by a second person (n = 6). An independent risk-of-bias assessment is carried out in most RR types (n = 20). In some cases, the information on risk of bias is based on the bias potential reported by the included reviews (n = 5). Further aspects could not be identified in sufficient detail in the methods papers.

3.3 | Analysis taking into account the time needed to produce the RRs

Due to the often incomplete information contained in the included methods papers, a comparison of the process steps while taking into account the time needed to produce the RR types is only possible to a limited extent. Only 25 of the included 38 RR types provide information on the intended timeframe and contain sufficient information on particular steps of production. Ten RR types are developed within 4 weeks and were compared to 15 RR types with a process time greater than 4 weeks and up to 6 months (see Appendix S3). Even RR types with similar process periods show strong differences in the choice of particular development steps. However, it is noticeable that a specific search strategy is recommended by the methods papers for all included RR types in which the RR is to be conducted within 4 weeks. Nevertheless, more than half of the RR types with a process time of between more than 4 weeks and 6 months recommend a specific search as well. In addition, only easily obtainable literature is included in all RRs which are produced within 4 weeks, while this is true for only 63% of RRs with a longer process time. A full-text analysis is carried

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out in all RRs with a process time of more than 4 weeks, whereas this is the case in only 70% of RRs with a shorter process time. Comparable adaptations depending on the process time could not be seen for other development steps (e.g., risk of bias assessment, language restrictions, and personnel use in literature screening).

4 | DISCUSSION

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This review identified 38 types of guidance for RRs and analyzes similarities and differences. Despite the great variability in terms of process time, considered domains, target groups and the respective methodological shortcuts, certain techniques to save time and resources appear frequently. In 72% of methods papers, a specific search strategy is recommended and 76% of methods papers recommend a prioritizing search (e.g., with a prioritizing search for systematic reviews, meta-analyses, HTA reports and guidelines). In 67% of methods papers, only easily obtainable literature is included. Further, the majority of methods papers (74%) recommend to include English articles only.

This review analyzes RR methodology with a specific focus on published methods papers. Prior publications on the topic of RR methodology have predominantly extracted methods from published RRs. However, our findings confirm several results of these previous works. We agree with Mattivi and Buchberger,⁵⁶ who found notable differences between RR types with regard to extent, publication type and terms used for RR methods. Most RR types seem to be specifically tailored to the respective context and the developing organization^{13,14} and have a strong focus on the individual needs of decision-makers.^{57,58}

It is worthwhile to mention that the ability of RRs to flexibly react to the needs of requestors is often seen as a major advantage of the concept which inhibits the development of an explicit and standardized methodology for RRs.^{12,32,59} There is common agreement in the literature that the impact of using certain methodological shortcuts is unclear and that few approaches are used consistently.^{2,8,12,13,15} There seems to be no consensus as to which limitations should be used in which research area.^{14,15} This is also reflected in the process time mentioned for the different types of RRs. Ranging from 24 h to 6 months, 2.2 months are needed on average. In contrast, according to a rule of thumb mentioned by Schünemann and Moja⁶⁰ RRs should be completed in less than 8 weeks, resulting in a time-saving of about 75% compared to what most researchers would propose as standard timeline for systematic reviews. Hartling et al.¹³ found that reviews with a longer development period have less methodological limitations. However, this finding cannot be fully confirmed by our results.

In our review, no overarching rationale for selection of certain methods could be identified. Even RR types with similar process time show marked differences in their choice of particular process steps. One potential reason for this might be that, in our exclusive consideration of published methodological guidance for the conduct of RRs, the recommendations are strongly tailored to the respective field of application. It can be assumed that methodological alterations in early process steps of RR preparation lead to impactful reductions in workload along the whole development sequence.⁶¹ A retrospective comparison of RRs and systematic reviews found that, due to a narrow focus, RRs generally included a smaller number of studies than systematic reviews.⁶² Employing a limited search strategy is known to increase the risk of selection, retrieval and publication bias.^{12,13,28} Frequent methodological shortcuts also appear in the areas of literature screening and extraction, with differing ways to implement these recommendations. Screening is not being performed by two persons in 73% and extraction is not being performed by two persons in 87% of methods papers. Performing screening and extraction by one person can lead to selection bias remaining undetected.¹² A RCT has shown that single-reviewer abstract screening missed 13% of relevant studies, while dual-reviewer abstract screening missed 3% of relevant studies.⁶³ Similarly, Taylor-Phillips et al.⁶⁴ found that a basic RR approach involving a single reviewer led to important inaccuracies in data extraction compared to a systematic review. On the other hand, an enhanced RR approach with a second reviewer checking 20% of titles/abstracts and data extraction performed better and, according to the authors, may be an appropriate tool to expeditiously assess evidence. Of note, only 17% of RR types identified in our analysis recommend a screening approach in which 20%-25% of articles are reviewed by a second person. In general, the conclusions drawn from inaccurately conducted RRs bear the risk of leading to wrong decisions which might be hazardous for human life and health.

Of note, only two of the included methods papers include recommendations on automation steps to reduce the resources needed for screening and extraction.^{31,55} In two other papers, automation techniques are mentioned in the discussion sections, but are not part of the recommendation.^{18,49} Software engineering methods such as Natural Language Processing have been used to screen articles, analyze their content, chart results, and so forth.^{65,66} For example, a substantial reduction in screening burden with corresponding time savings could be shown by using an artificial intelligence supported software tool.⁶⁷ Although automation may be particularly interesting for the time-

critical production of RRs, there is little evidence on the validity of these techniques.⁶⁸ While steps like the initial screening process may be easier to automate, other steps such as risk of bias assessment, where subtle differences may be decisive, may be difficult to automate.⁶⁹ Thus, future research should address the impact of individual automation steps on the validity of RRs.

Despite the aforementioned limitations due to methodological shortcuts, decision-makers have high expectations on the validity of RRs. Research has shown that healthcare decision-makers and guideline developers expect RRs to provide answers similar to systematic reviews in at least 9 out of 10 cases.⁷⁰ Further, a discrete choice experiment showed that healthcare decisionmakers and people involved in the preparation of evidence syntheses have high preferences for quality standards in the process of literature screening and data extraction.⁷¹ Although consensus exists that methodological shortcuts in the conduct of a review can lead to bias, retrospective comparisons of systematic reviews and RRs indicate that both types of reviews apparently lead to comparable conclusions. Affengruber et al.⁷² found that, when compared to Cochrane reviews, a RR approach that combines abbreviated literature searches and singlereviewer abstract screening had low accuracy. However, this seems to depend on the research area. The RR approach would have led to comparable conclusions as the original Cochrane review for oncological topics, but not for public health topics.⁷²

Furthermore, the varying quality of systematic reviews has to be taken into account, hampering the identification of marked differences between the RRs and systematic reviews in general.⁷³ For example, in an analysis of the methodological restrictions of RRs compared to systematic reviews, a duplicate study selection and data extraction was only performed in 37% of reviews labeled as "systematic."⁵⁶ Furthermore, many reviews labeled as "systematic."⁵⁶ Furthermore, many reviews labeled as "systematic."^{47,75} Interestingly, a systematic review in which studies assessing methods for selecting studies, abstracting data, and appraising quality in systematic reviews have been included found diverse approaches and few studies."⁷⁶

To estimate the validity of RRs, a detailed analysis of the applied methodological restrictions is needed. A reliable and valid tool for the assessment of systematic reviews is the AMSTAR 2 checklist, which considers the major potential sources for bias within 16 items.⁷⁷ The prerequisite for using AMSTAR is that RRs contain sufficient information on the single items. However, we found in our review that most method papers contain incomplete information on methodological steps in the conduct of RRs and thus offer incomplete guidance for review authors.

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The present review has some limitations. We searched in two databases and it cannot be ruled out that a more extensive search might have led to different results. Due to the non-inclusion of RR types in which the time savings solely arise from additional deployment of personnel or by omitting certain steps in the development, some publications might have been dismissed. For example, the HTA Core Model for Rapid Relative Assessment, which was developed by the member organizations of the European Network of Health Technology Assessment (EUnetHTA) from 2010 onwards to enable the production of rapid assessments within 3 months, was not taken into account, as no methodological shortcuts are applied. Time savings arise as four evaluation elements are considered whereas the full HTA Core Model consists of nine evaluation elements and thus, no methodological shortcuts are taken.⁶ The quick reports written by the German HTA authority, the Institute for Ouality and Efficiency in Healthcare (IOWIG) were also not included, since their development largely corresponds to that of ordinary reports, with the only deviation being that no intermediate products are published and no consultation takes place.⁷⁸ Potential uncertainties can also arise from the increasing variety of review types. According to a typology of Grant and Booth, 14 different types of reviews exist, while in three types (RRs, scoping reviews, and mapping reviews) an abbreviated literature search is performed.⁷⁹ However, since scoping reviews and mapping reviews are mainly used to identify parameters and gaps in the literature, particularly RRs are used to provide timely information for a specific research question.^{32,80} Thus, these related types of reviews have been omitted in this work. Finally, limitations might arise because of the sole inclusion of English and German publications.

In summary, a large number of different RR types exist in which a variety of different time-saving measures are employed. No common rationale for the choice of certain methods in relation to production time could be detected. This might be due to the fact that recommendations are tailored to specific application areas and decision-makers' needs. On the other hand, it underlines the need for further investigation related to the validity of these formats. In addition, most methods papers contain incomplete guidance for the conduct of RRs. Considering the increased number of published RRs during the COVID-19 pandemic, an acceptable quality has to be ensured in order to maximize credibility and impact. COVID-19 in particular shows how far-reaching public health concerns are and that the procedures are also very important for other sciences. Future research should further investigate the effects of particular methodological shortcuts on the validity of reviews, with the aim to derive specific recommendations and offer review authors a rationale when choosing their methods.

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Further, authors of rapid and systematic reviews and authors of corresponding method papers should be encouraged to fully and transparently display their methods. This would help to determine the validity, appropriateness and, ultimately, the utility of the RR products and thus prevent from decisions which are potentially hazardous for human life and health.

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CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

AUTHOR CONTRIBUTIONS

The review was conceptualized by BB, SN and CS. Searches, screening and extraction have been conducted by CS, AN and SN. BB, SN and JW reviewed and discussed the results. CS, SN, BB, AN and JW contributed to the manuscript and approved the final version of the manuscript.

DATA AVAILABILITY STATEMENT

The data generated during the study are available from the corresponding author on reasonable request.

ORCID

Christian Speckemeier ^b https://orcid.org/0000-0001-7507-4432

Barbara Buchberger ^b https://orcid.org/0000-0002-8596-740X

Silke Neusser b https://orcid.org/0000-0001-9077-7005

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