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INSTRUMENTOS PARA A AVALIAÇÃO DA QUALIDADE DE ESTUDOS DE PREVALÊNCIA: REVISÃO SISTEMÁTICA DA LITERATURA

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Trabalho de conclusão de curso de graduação apresentado ao Instituto de Ciências Básicas da Saúde da Universidade Federal do Rio Grande do Sul como requisito parcial para a obtenção do título de Bacharela em Biomedicina.

Orientador: Dr. Maicon Falavigna Co-orientadora: Dra. Verônica Colpani

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RESUMO

As estimativas de prevalência têm um papel importante para a saúde pública, subsidiando decisões relacionadas a políticas de saúde. Apesar de sua importância, e considerando que revisões sistemáticas de estudos de prevalência são cada vez mais publicadas na literatura, ainda há incertezas e falta de padrões quanto à avaliação da qualidade desses estudos. O objetivo desta revisão sistemática é identificar os instrumentos existentes para avaliar estudos de prevalência, descrever suas principais características e classificar seus componentes. Para identificar as ferramentas disponíveis, foi realizada busca sistemática nas bases de dados MEDLINE, Embase e Web of Science. Além disso, foram realizadas buscas no Google Scholar e em websites de instituições relevantes, além da revisão manual de listas de referências de artigos relacionados. Ainda, revisões sistemáticas de prevalência publicadas no último ano foram avaliadas para identificar outras ferramentas utilizadas para a avaliação do risco de viés dos estudos individuais. Foram incluídos estudos metodológicos ou manuais descrevendo métodos (ex. formulários, *checklists*) para a avaliação de estudos de prevalência. Para cada instrumento identificado, foram extraídas informações sobre desenvolvimento, aplicabilidade, estrutura e conteúdo da ferramenta. Em seguida, as questões de cada ferramenta foram classificadas em itens e domínios. Os itens representam o objetivo principal de cada questão. Os domínios são: 'população e contexto', 'mensuração do desfecho' e 'estatística'. Eles foram previamente definidos com base nos dois principais componentes de uma questão de pesquisa de estudos de prevalência (população e desfecho) e considerando a importância da análise estatística dos dados. Além disso, foi criado o domínio 'outros', que engloba itens não relacionados diretamente ao risco de viés (como redação do manuscrito e protocolo e metodologia do estudo). A seleção dos estudos, extração de dados e classificação das questões em itens e domínios foram realizados por dois revisores de forma independente. A busca resultou em 1378 referências únicas. Trinta e dois artigos foram incluídos na revisão, reportando 30 instrumentos. Oito instrumentos (26,7%) foram desenvolvidos especificamente para avaliar estudos de prevalência e 22 (73,3%) são adaptáveis para esse fim. Entre todas as ferramentas, foram identificados 119 diferentes itens; 12 classificados no domínio 'população e contexto', 16 no domínio 'mensuração do desfecho' e 14 no domínio 'estatística'. Além disso, 77 itens foram classificados como 'outros'; grande parte desses itens (62%) avaliam questões de redação do manuscrito. A maior parte dos itens classificados entre os domínios chaves foi encontrada apenas nas ferramentas específicas para estudos de prevalência (59,5%), enquanto os itens classificados como 'outros' foram majoritariamente identificados apenas nos instrumentos não específicos (68,8%). Existe grande variabilidade entre as ferramentas em relação a sua estrutura e componentes. Nem todos os domínios foram avaliados por todas as ferramentas, e muitas ferramentas apresentavam sobreposição de questões, o que pode levar a penalização dos estudos pelo mesmo motivo mais de uma vez. O conjunto de itens e domínios desenvolvido é um sumário abrangente que pode ajudar na avaliação de estudos de prevalência, desenvolvimento de estudos primários de prevalência e construção de novas ferramentas para avaliar esse tipo de estudo.

Palavras-chave: Prevalência. Estudos transversais. Risco de viés. Qualidade metodológica.

ABSTRACT

Prevalence estimates has an important role in public health, supporting decisions related to health policies. Despite its importance, and considering also that systematic reviews of prevalence studies have increasingly been published in the literature, there is still uncertainty and lack of standards regarding quality assessment of these studies. The objective of this systematic review is to identify tools and frameworks used to assess methodological quality of prevalence studies. In order to identify available tools, we systematically searched MEDLINE, Embase and Web of Science. We also searched for instruments on Google Scholar and websites of relevant institutions, and screened reference lists of related articles. Moreover, we retrieved systematic reviews of prevalence of clinical conditions published in the last year to identify tools used to assess the risk of bias of individual studies. We included methodological studies, manuals or handbooks describing a methodology (e.g. questionnaires, checklists, frameworks) to critically appraise prevalence studies. For each tool identified, we extracted information about development, applicability, structure and content. The questions or statements of each tool were classified into items and domains. Items represent the aim of each question or statement. The domains are 'participants and setting', 'outcome measurement' and 'statistics'. They were developed a priori based on the two main components of a question of prevalence studies (population and outcome) and considering the importance of statistical analysis. Besides, we created a domain 'other', which includes items not directly associated with risk of bias (such as reporting and methods). Study selection, data extraction and classification of questions were performed by two independent reviewers. The search resulted in 1378 unique abstracts. We included 32 articles in our review, reporting a total of 30 instruments. Eight tools (26.7%) were developed specifically for prevalence studies and 22 (73.3%) can be adapted for this purpose. Among all tools, we identified 119 different items; 12 were classified in the domain 'population and setting', 16 in the domain 'outcome measurement' and 14 in the domain 'statistics'. Moreover, 77 items were classified as 'other'; the majority of these items (62%) evaluated manuscript writing and reporting. Most items classified among the three key domains were identified only on the specific tools (59.5%), while most items classified as 'other' were identified only in the non-specific tools (68.8%). There is great variability among tools in relation to their structure and content. Not all domains were assessed by all tools, and there was an overlap among questions in the same tool, which may lead to penalization of the study for the same reason more than once. We provide a comprehensive set of items and domains that can be useful for the assessment of prevalence studies, conduction of primary studies of prevalence and development of new tools to assess this type of study.

Keywords: Prevalence. Cross-sectional studies. Risk of bias. Methodological quality.

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1 INTRODUÇÃO

Prevalência é uma medida epidemiológica que pode ser definida como a proporção da população que apresenta uma determinada característica (como uma doença ou uma condição clínica) em um certo momento ou período de tempo (FLETCHER; FLETCHER; FLETHCER 2014). Essa medida é de grande valor epidemiológico pois reflete a relevância que determinada condição clínica possui para a sociedade (WAGNER, 1998).

No âmbito da saúde pública, a prevalência tem grande importância para a tomada de decisões. O conhecimento sobre a prevalência de diferentes condições clínicas auxilia na definição de prioridades para o sistema: em geral, condições com maiores prevalências são mais relevantes para a saúde pública, e quando tratadas como prioridades causam maior impacto na saúde da população (OXMAN; SCHÜNEMANN; FRETHEIM, 2006).

A prevalência também pode ser utilizada para avaliar a carga de doenças, e assim dimensionar necessidades como hospitais, serviços de saúde, equipamentos e profissionais. Um exemplo disso é o programa *Global Burden of Disease*, criado pela Organização Mundial da Saúde. Esse projeto utiliza dados epidemiológicos, como a prevalência, para avaliar a carga de diversas doenças em diferentes regiões do mundo e analisar tendências temporais, buscando identificar as necessidades atuais e projetar as necessidades futuras no âmbito da saúde.

Dados de prevalência podem também ser utilizados para avaliar o impacto de programas e ações relacionadas à saúde pública (WAGNER, 1998). Ademais, a prevalência é utilizada para estimar o impacto orçamentário de intervenções em saúde. Assim, é de grande importância para avaliações de tecnologia em saúde, auxiliando a tomada de decisões em relação à implementação de novas tecnologias no sistema (ROTILY; ROZE, 2013).

Para estimar a prevalência de condições clínicas, pode-se utilizar bases de dados (como o DATASUS) ou realizar estudos observacionais. Essas duas estratégias fornecem informações diferentes, mas que podem ser complementares; todavia, ambas possuem vantagens e limitações. Bases de dados geralmente possuem maior representatividade e maior volume de informações; contudo, os dados são coletados com qualidade variável e normalmente há grande nível de subnotificação (IEZZONI, 1997). Estudos observacionais, quando bem executados, podem fornecer informação com menor grau de viés; contudo, sabese que há alta variabilidade da qualidade dos estudos realizados. Além disso, a representatividade pode ser limitada, visto que muitas vezes esses estudos são conduzidos em

cenários específicos e não representativos, como ambulatórios especializados e hospitais terciários, dificultando a transposição dos dados dos estudos para a vida real (NEDEL; SILVEIRA, 2016).

A utilização de estudos de prevalência vem ganhando espaço na literatura e espera-se que esses dados sejam cada vez mais aplicados para a tomada de decisões relacionadas à saúde pública. Um exemplo desse aumento de importância é o fato que a publicação de revisões sistemáticas de estudos de prevalência vem crescendo nos últimos 20 anos; entre 2007 e 2016, houve um aumento no número de publicações indexadas na base de dados PubMed em mais de 10 vezes (Figura 1).

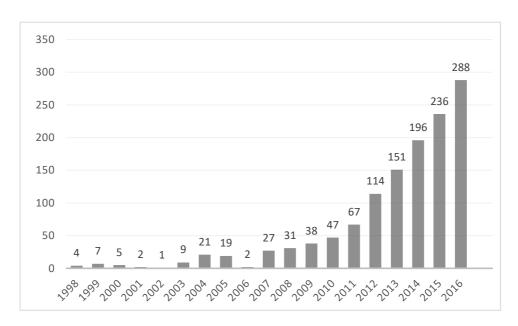


Figura 1: número de artigos indexados na base de dados PubMed com os termos "systematic review" e "prevalence" no título.

Entretanto, apesar do aumento em publicações sobre prevalência, há incertezas e falta de padronização em como avaliar a qualidade dessa informação para adequada transposição ao cenário de interesse. Em revisão sistemática abrangente sobre o tópico, foram encontrados na literatura cinco instrumentos construídos para esse objetivo; todavia, todos eles apresentaram limitações de aplicabilidade, além de haver falta de consenso sobre os domínios dos estudos que devem ser avaliados (SHAMLIYAN; KANE; DICKINSON, 2010). A avaliação da qualidade de estudos é um aspecto de grande importância para a saúde pública, porque esse fator deve ser ponderado durante a tomada de decisões. Enquanto há dúvidas

sobre a avaliação da qualidade de estudos de prevalência, para outros delineamentos já existem ferramentas de qualidade que são amplamente utilizadas. Como exemplo, pode-se citar o QUADAS (para estudos de acurácia diagnóstica), o RoB 2.0 (para ensaios clínicos randomizados) e o ROBINS-I (para estudos não randomizados) (WHITING et al., 2011; HIGGINS et al. 2016; STERNE et al., 2016).

Tendo em vista os aspectos observados, e a necessidade de aprimorar a avaliação da qualidade dos estudos de prevalência, o presente trabalho se propôs a avaliar os instrumentos disponíveis na literatura, identificando e classificando seus componentes. Com isso, espera-se assegurar que as informações sobre prevalência de condições clínicas sejam melhor aproveitadas no cenário da saúde pública.

1.2 OBJETIVOS

1.2.1 Objetivo geral

O objetivo desse estudo foi identificar e caracterizar instrumentos disponíveis para a avaliação da qualidade de estudos de prevalência, assim como identificar e classificar os seus principais componentes.

1.2.2 Objetivos específicos

- Identificar os instrumentos existentes aplicáveis para a avaliação de estudos de prevalência;
- Descrever as principais características dos instrumentos encontrados, como: desenvolvimento, aplicabilidade, estrutura e domínios avaliados;
- Identificar, sumarizar e classificar os componentes relacionados à avaliação da qualidade de estudos de prevalência.

2 ARTIGO CIENTÍFICO

QUALITY ASSESSMENT OF PREVALENCE STUDIES: A SYSTEMATIC REVIEW

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Abstract:

Objective: To identify instruments applicable for the quality assessment of prevalence

studies, describing and classifying their components.

Study design and setting: We systematically searched health electronic databases and grey

literature in order to identify tools or guides about the quality assessment of prevalence

studies. After study selection, questions / statements applicable for prevalence studies were

classified into at least one of the following domains: 'population and setting', 'outcome

measurement', 'statistics' and 'other'. Study selection, data extraction and classification of

questions / statements were conducted by two independent reviewers. PROSPERO register

number CRD42018088437.

Results: We identified 30 tools: 8 (26.7%) specifically designed to appraise prevalence

studies tools and 22 (73.3%) adaptable for this purpose. There was a great variability among

tools regarding their structure and content. We identified 119 different items: 12 in the

domain 'population and setting'; 16 in the domain 'outcome measurement'; 14 in the domain

'statistics'; and 77 were classified as 'other'.

Conclusions: We provide a comprehensive set of items classified by domains that can be

used for the assessment of prevalence studies. Moreover, it can guide the conduction of

primary prevalence studies and the development of new tools to appraise this type of study.

Keywords: prevalence; cross-sectional; risk of bias; critical appraisal; methodological

quality.

Running title: Quality assessment of prevalence studies

1. Introduction

Prevalence is an epidemiological measurement that represents the proportion of the population affected by certain condition [1]. Since they reflect the importance of different diseases for the society, prevalence estimates are of great importance for health-related decision making. For instance, these estimates are used to assess the burden of different conditions, define priorities for interventions and research, evaluate the impact of health interventions, and conduct health technology assessments [2-4].

Despite the importance of prevalence studies, the risk of bias assessment of this type of study is heterogeneous, usually inappropriate and often neglected. A systematic review conducted in 2010 identified five tools specifically develop to appraise prevalence studies, but they all presented several limitations specially regarding applicability and lack of consensus about which domains should be assessed [5]. In comparison, there are standard, recommended, and widely used tools for other study designs, such as RoB 2.0 for randomized clinical trials, ROBINS-I for observational studies and QUADAS 2 for diagnostic studies [6-8].

In light of the exposed, the objective of this study is to systematically review, evaluate and compare available tools to assess risk of bias of prevalence studies, in order to identify the domains and items evaluated on this type of study.

2. Methods

2.1. Protocol and registration

The study protocol was prospectively registered on PROSPERO, under the registration number CRD42018088437.

2.2. Search strategy and data sources

We searched MEDLINE (via PubMed), Embase and Web of Science up to January 2018 using terms such as "prevalence", "cross-sectional studies" and "critical appraisal". The search was not limited by date or language of publication.

In order to identify studies not indexed by these databases, we also screened the first 200 results on Google Scholar. We also manually searched the reference list of relevant studies, and searched for instruments on websites of institutions related to the topic. Moreover, we conducted a systematic search for systematic reviews of prevalence of clinical

conditions published between February 2017 and February 2018 and indexed in MEDLINE, to identify further instruments used to assess the quality of individual prevalence studies.

For each instrument found, we conducted an internet search for complementary material, including handbooks or manuals for the instrument in question.

2.3 Study selection

We included methodological studies, manuals or handbooks with general guidance or specific tools applicable for the critical appraise of prevalence studies. First, we reviewed the title and abstracts of all records identified in our search in order to select all potentially relevant studies. Then, we assessed the full text of selected studies and included studies meeting the eligibility criteria. Study selection was conducted by two reviewers independently (CBM and CS). Disagreements were solved by consensus or arbitrated by a third reviewer (VC or MF).

A tool was eligible if (1) it was developed to critically appraise prevalence studies or (2) the authors stated it could be applied to appraise prevalence studies or (3) it was used by systematic reviews authors to appraise the quality of individual prevalence studies.

2.4 Data extraction

We extracted relevant information for each tool using pre-designed and piloted tables. Data extracted included: process of development of the tool, applicability, structure of tool and content. Data extraction was conducted by two independent reviewers (CBM and CS). Disagreements were solved by consensus or arbitrated by a third reviewer (VC or MF).

2.5 Data analysis

We classified each question or statement of the instruments into items, which represented the objective of assessment. Afterwards, we classified the items into three key domains: 'population and setting', 'outcome measurement' and 'statistics'. These domains were defined a priori based on the main components of a prevalence research question (population and outcome) and considering the importance of appropriate statistical data analysis. If a question was applicable to appraise prevalence studies but covered a different domain (such as reporting or study methods), it was included under the classification 'other'.

As described, we included not only tools specifically designed to assess prevalence studies but also tools that could be adapted for this purpose. Thus, not all questions from non-specific tools were applicable for prevalence studies, and we only categorized the applicable ones. If the instrument provided guidance about which questions should be used to assess prevalence studies, we followed these instructions. If not, before we classified the questions into items and domains, we evaluated if they were applicable for prevalence studies or not. If classified as applicable, the question was categorized into items and domains as previously described. Questions classified as not applicable were not further evaluated.

The process of selection and classification of questions / statements into items and domains was conducted by two reviewers independently (CBM and CS). Discrepancies were solved by consensus or arbitrated by a third reviewer (VC or MF).

3. Results

3.1. Study selection

Our search resulted in 1378 unique references. After selection of titles and abstracts, we assessed 100 full-text for eligibility. Finally, we included in the review 32 studies reporting a total of 30 tools [9-40]. Figure 1 presents the flowchart of study selection.

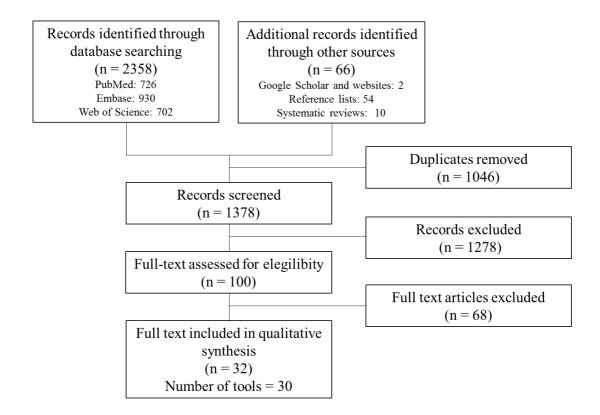


Figure 1: Flowchart of study selection

3.2 Tools specific for prevalence studies

Out of the 30 tools, eight (26.7%) were specifically designed to appraise prevalence studies [9-17]. Table 1 summarizes the main characteristics of these tools. The median number of questions in the tools was 10, ranging from 7 to 32. Four tools (50%) were scales, with numeric results [9, 11, 13, 15], and four (50%) were descriptive checklists [10, 12, 14, 16-17]. Among the scales, only one suggested cut-off values to define the overall quality of the study [11]; among the checklists, two had an overall appraisal question, but they were answered based on rater's judgement, without clear guidance of how to consider the previous questions to define a summary assessment [12, 16-17].

Regarding the domains assessed, seven tools (87.5%) covered all key domains [10-17], and there was great variability on the items assessed by each tool. In the domain 'population and setting', the main items assessed were 'appropriate sampling' (7 tools, 87.5%), 'appropriate response rate' (5 tools, 62.5%) and 'representative sample' (4 tools, 50%). In the domain 'outcome measurement', the main items assessed were 'valid measurement of condition' (6 tools, 75%), 'standard measurement of condition' (6 tools, 75%) and 'reliable measurement of condition' (5 tools, 62.5%). In the domain 'statistics', the main items assessed were 'precision of estimate' (6 tools, 75%), data analysis considering sampling (3 tools, 37.5%), 'appropriate sample size' (2 tools, 25%) and 'subgroup analysis' (2 tools, 25%). Overall, these tools provided 25 different items related to the assessment of quality of prevalence studies, six related to 'population and setting', nine related to 'outcome measurement' and ten related to 'statistics'. In addition, 24 items were classified as 'other', mainly related to reporting.

3.3 Tools adapted for prevalence studies

Among the 30 included tools, 22 (73.3%) were not specific for prevalence studies. These tools provided six additional items for the domain 'population and setting', 7 items related to 'outcome measurement' and 4 items related to 'statistics'. Moreover, these tools provided 53 items classified under the domain 'other'.

3.4 Items related to quality assessment of prevalence studies

Overall, we identified 119 different items. Forty-two were classified under the three key domains: 'population and setting' (12 items), 'outcome measurement' (16 items) and 'statistics' (14 items); of those, 25(59.5%) were identified only in the eight specific tools and

Table 1: Tools specifically designed to appraise prevalence studies – main characteristics.

Instrument	Structure	Summary and reporting of results
Al-Jader, 2002 [9]	7 questions, with different answer options; each answer option with an associated score.	Maximum score: 100 points. No cut-off point defined.
Boyle, 1998 [10]	10 questions, split in 3 sections. No pre-defined answer options.	No overall summary. Descriptive reporting of results.
Giannakapoulos, 2012 [11]	11 questions, split in 3 sections, plus a question about ethics. Each question with two or three answer options; each answer option with an associated score.	Maximum score: 19 points. Studies are classified according to their total score in poor (0-4), moderate (5-9), good (10-14) or outstanding (15-19).
Hoy, 2012 [12]	10 questions with 2 standard answer options (<i>High risk of bias / Low risk of bias</i>).	Question for overall appraisal with three answer options (Low risk of bias / Moderate risk of bias / High risk of bias), based on rater's judgment.
Loney, 1998 [13]	8 statements, one point for each criterion achieved.	Maximum score: 8 points. No cut-off point defined.
MORE, 2010 [14]	32 questions, with different answer options; each answer option is classified as 'minor flaw', 'major flaw' or 'poor reporting'.	No overall summary. Descriptive reporting of results.
Silva, 2010 [15]	19 questions, split in 3 sections. Two or three answer options, with an associated score.	Maximum score: 100 points. No cut-off point defined.
The Joanna Briggs Institute Prevalence Critical Appraisal Tool, 2014 [16-17]	9 questions with 4 standard answer options (Yes / No / Unclear / Not applicable) ¹ .	Question for overall appraisal with three answer options (<i>Include / Exclude / Seek further info</i>), based on rater's judgement.

NR: not reported. ^{1.} 10 questions in previous versions.

17 (40.5%) were identified only in the additional 22 non-specific tools. In the domain other, we identified 77 items; of those, 24 (31.2%) were identified in the eight specific tools and 53 (68.8%) were identified in the additional 22 non-specific tools. Table 2 summarized the items assessed in each domain among all tools.

4. Discussion and conclusions

In this systematic review, we identified, summarized and compared 30 instruments used for the quality assessment of prevalence studies. Our results, similar to what was found in reviews assessing tools for other study designs, show that there is great variability among instruments [41-42]. We classified all questions or statements into items and domains, creating a comprehensive set of 119 items useful for the assessment of prevalence studies.

Not all domains were covered by all tools, and even when they were covered, they were not always properly assessed. Some tools did not consider important aspects inside each domain, such as representativeness of sample, estimation of sample size and appropriate measurement of condition; and there was an overlap among questions in the same instrument, which may lead to penalization of the same study for the same reason more than once. Moreover, many instruments assessed not only risk of bias but also reporting and manuscript writing. Although related, with adequate reporting being usually a proxy for good methodological quality, it is important to distinguished between these two concepts, with risk of bias consisting on methodological aspects prone to result on distorted findings.

We conducted a broad literature search, using important databases and alternative data sources. Our search was very sensitive to identify tools specifically designed for prevalence studies, but we probably have not included all instruments that could be adapted for this purpose. This could be a limitation of our study; however, we expect our results are representative of the items and domains used to appraise prevalence studies. Of note, most items from key domains were identified through the eight specific tools; most items identified through non-specific tools were not relevant for bias assessment or were similar to items already included.

Another possible limitation of our review is that data abstraction and classification of questions into items and domains required judgment, which can lead to different decisions by

Table 2: Items identified among all included tools and classified into a key domain.

Population and	Outcome	C	
setting (n = 12)	measurement (n = 16)	Statistics (n = 14)	Other (n = 77)
 Appropriate sample Unbiased sample Representative sample Appropriate sample source Appropriate size of population source Ethnic characteristics of population source Appropriate sampling Random sampling Standard selection of participants Participation rate of eligible persons Appropriate response rate Assessment of non-responders 	 Type of prevalence estimate (point or period) Appropriate length of prevalence period Appropriate definition of condition Appropriate measurement of condition Accurate measurement of condition Precise measurement of condition Quality control of measurement methods Valid measurement of condition Reliable measurement of condition Standard measurement of condition Unbiased measurement of condition Reproducible measurement of condition Assessment of disease severity and frequency of symptoms Data collection performed by investigators unrelated to patient Face validity Selective outcome reporting 	 Sample size estimation Appropriate sample size Appropriate statistical analysis Appropriate numerator and denominator parameters Appropriate exclusion from analysis Adjustment of estimates Data analysis considering sampling Data analysis considering response rate Data analysis considering special features Missing data handling Random error Precision of estimate Subgroup analysis Data fishing 	 Clear reporting of authors and affiliations Appropriate title Appropriate abstract Study justified by literature review Description of the problem Theoretical framework Clear hypothesis Clear study questions Description of study objectives Description of condition of interest Description of study design Description of study design Description of study design Description of methods Reporting of size of population source Description of eligibility criteria Reporting of year of conduction of study Description of statistical analysis Appropriate data reporting Appropriate reporting of results Reporting of inclusion flowchart Reporting of sample size Reporting of data collection procedures Description of missing data Reporting of satistical significance Reporting of statistical significance Reporting of discussion

		Appropriate discussion
		Discussion based on results
		Reporting of all possible
		interpretation of resultsDiscussion of bias
		Discussion of biasDiscussion of limitations
		 Discussion of minitations Discussion of strengths
		 Comparison of results with
		existing literature
		 Description of study conclusions
		 Appropriate conclusions
		 Conclusion based on results
		 Reporting of additional
		information source
		 Description of funding
		 Reporting of conflict of
		interest
		 Clear references
		 Recommendations for future research
		 Specific objectives
		 Study protocol
		 A priori statistical analysis plan
		 Appropriate study design
		 Appropriate review of existing literature
		 Appropriate methods
		 Appropriate data collection
		Standard data collection
		 Consideration of important
		variables
		 Consideration of privacy
		and sensitivity of condition
		Objective criteria for
		subgroup definitions
		 Quality control of data Importance of study
		Importance of studyRelevance of research
		question
		Relevance of outcomes
		Identification of bias
		 Consistent results
		 Believable results
		 Conclusion plausible
		Possible alternative
		conclusions
		Relevance of conclusion Applicability of results
		Applicability of resultsGeneralizability of results
		Generalizability of resultsEthics
		Effect of conflict of
		interest
		Role of funding
1	I	<i>5</i>

	•	Bias due to funding
	•	Reader's interpretation of
		study
	•	Other

different assessors. We tried to overcome this by conducting the classification independently by two reviewers with the assistance of third reviewers in case of discrepancies.

In summary, we provide a set of instruments, domains and items for quality assessment of prevalence studies. For end-users working with prevalence evidence synthesis (e.g. systematic reviews), that want to apply a standardized instrument for quality assessment, it is not possible to strongly recommend a tool, because there is great variability in their structure, content and comprehensiveness - no single tool covered all potentially relevant items for quality assessment. However, among the tools specific for prevalence studies, the Joanna Brigs's Institute Prevalence Critical Appraisal Tool has a higher methodologic rigor and addresses what we consider the most important items related to the methodological quality of prevalence studies, and currently may be considered the most appropriate tool [16-17]. We provide a set of items that is comprehensive and may contain almost all quality criteria, being helpful as a guide for a broader quality assessment, development of a new tool or development of primary prevalence studies.

5. References

- [1] Fletcher, R., Fletcher, S., Fletcher G., (2014). Epidemiologia clínica: elementos essenciais, 5th ed. ArtMed.
- [2] Wagner, M. (1998). Medindo a ocorrência da doença: prevalência ou incidência? Jornal de Pediatria, 74, pp.157-162.
- [3] Oxman, A., Schünemann, H. and Fretheim, A. (2006). Improving the use of research evidence in guideline development: 2. Priority setting. Health Research Policy and Systems, 4(1), pp.4-14.
- [4] Rotily, M. and Roze, S. (2013). What is the impact of disease prevalence upon health technology assessment? Best Practice & Research Clinical Gastroenterology, 27(6), pp.853-865.
- [5] Shamliyan, T., Kane, R. and Dickinson, S. (2010). A systematic review of tools used to assess the quality of observational studies that examine incidence or prevalence and risk factors for diseases. Journal of Clinical Epidemiology, 63(10), pp.1061-1070.
- [6] Higgins JPT, Sterne JAC, Savović J, Page MJ, Hróbjartsson A, Boutron I, Reeves B, Eldridge S. (2016). A revised tool for assessing risk of bias in randomized trials in: Chandler J, McKenzie J, Boutron I, Welch V (editors). Cochrane Methods. Cochrane Database of Systematic Reviews, Issue 10 (Suppl 1).
- [7] Sterne, J., et al. (2016). ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. BMJ, 4919.
- [8] Whiting, P et al. (2011). QUADAS-2: A Revised Tool for the Quality Assessment of Diagnostic Accuracy Studies. Annals of Internal Medicine, 155(8), p.529.
- [9] Al-Jader, L., Newcombe, R., Hayes, S., Murray, A., Layzell, J. and Harper, P. (2002). Developing a quality scoring system for epidemiological surveys of genetic disorders. Clinical Genetics, 62(3), pp.230-234.
- [10] Boyle, M. (1998). Guidelines for evaluating prevalence studies. Evidence-Based Mental Health, 1(2), pp.37-39.
- [11] Giannakopoulos, N., Rammelsberg, P., Eberhard, L. and Schmitter, M. (2011). A new instrument for assessing the quality of studies on prevalence. Clinical Oral Investigations, 16(3), pp.781-788.
- [12] Hoy, D., Brooks, P., Woolf, A., Blyth, F., March, L., Bain, C., Baker, P., Smith, E. and Buchbinder, R. (2012). Assessing risk of bias in prevalence studies: modification of an existing tool and evidence of interrater agreement. Journal of Clinical Epidemiology, 65(9), pp.934-939.

- [13] Loney, P., Chambers, L., Bennett, K., Roberts, J. and Stratford, P. (1998). Critical Appraisal of the Health Research Literature: Prevalence or Incidence of a Health Problem. Chronic Diseases in Canada, 19(4), pp.170-176.
- [14] Shamliyan, T., Kane, R., Ansari, M., Raman, G., Berkman, N., Grant, M., Janes, G., Maglione, M., Moher, D., Nasser, M., Robinson, K., Segal, J. and Tsouros, S. (2011). Development quality criteria to evaluate nontherapeutic studies of incidence, prevalence, or risk factors of chronic diseases: pilot study of new checklists. Journal of Clinical Epidemiology, 64(6), pp.637-657.
- [15] Silva, L., Ordúñez, P., Rodríguez, M., Robles, S. (2001). A tool for assessing the usefulness of prevalence studies done for surveillance purposes: the example of hypertension. Revista Panamericana de Salud Pública 10, pp.152-160.
- [16] Munn, Z., Moola, S., Lisy, K., Riitano, D. and Tufanaru, C. (2015). Methodological guidance for systematic reviews of observational epidemiological studies reporting prevalence and cumulative incidence data. International Journal of Evidence-Based Healthcare, 13(3), pp.147-153.
- [17] Munn, Z., Moola, S., Riitano, D. and Lisy, K. (2014). The development of a critical appraisal tool for use in systematic reviews addressing questions of prevalence. International Journal of Health Policy and Management, 3(3), pp.123-128.
- [18] Academy of Nutrition and Dietetics (2016). Evidence Analysis Manual: Steps in the Academy Evidence Analysis Process. Chicago: Academy of Nutrition and Dietetics, pp.1-1106.
- [19] Avis, M. (1994). Reading research critically. II. An introduction to appraisal: assessing the evidence. Journal of Clinical Nursing, 3(5), pp.271-277.
- [20] Downes, M., Brennan, M., Williams, H., Dean, R., (2016). Development of a critical appraisal tool to assess the quality of cross-sectional studies (AXIS). BMJ Open 6, e011458.
- [21] Berra, S., Maria Elorza-Ricart, J., Estrada, M. and Sánchez, E. (2008). Instrumento para lalectura crítica y laevaluación de estudios epidemiológicos transversales. Gaceta Sanitaria, 22(5), pp.492-497.
- [22] Research.bmh.manchester.ac.uk. (2018). Critical appraisal (COEH University of Manchester). [online] Available at: http://research.bmh.manchester.ac.uk/epidemiology/COEH/undergraduate/specialstudymodul es/criticalappraisal/ [Accessed 14 Dec. 2018].
- [23] Downs, S. and Black, N. (1998). The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. Journal of Epidemiology & Community Health, 52(6), pp.377-384.
- [24] Durant, R. (1994). Checklist for the evaluation of research articles. Journal of Adolescent Health, 15(1), pp.4-8.

- [25] Fowkes, F. and Fulton, P. (1991). Critical appraisal of published research: introductory guidelines. BMJ, 302(6785), pp.1136-1140.
- [26] Gardner, M., Machin, D. and Campbell, M. (1986). Use of check lists in assessing the statistical content of medical studies. BMJ, 292(6523), pp.810-812.
- [27] Genaidy, A., LeMasters, G., Lockey, J., Succop, P., Deddens, J., Sobeih, T. and Dunning, K. (2007). An epidemiological appraisal instrument a tool for evaluation of epidemiological studies. Ergonomics, 50(6), pp.920-960.
- [28] Glynn, L. (2006). A critical appraisal tool for library and information research. Library Hi Tech, 24(3), pp.387-399.
- [29] Kmet, L., Lee, R., Cook, L., (2004). Standard quality assessment criteria for evaluating primary research papers from a variety of fields. Alberta Heritage Foundation for Medical Research, Edmonton
- [30] Law, M. (1998). [online] Available at: https://www.coursehero.com/file/20139171/Critical-Review-Form-Quantitative-Studies-English/ [Accessed 14 Dec. 2018].
- [31] Margetts, B., Vorster, H. and Venter, C. (2002). Evidence-based nutrition Review of nutritional epidemiological studies. South African Journal of Clinical Nutrition, 15(3), pp.68-73.
- [32] Slim, K., Nini, E., Forestier, D., Kwiatkowski, F., Panis, Y. and Chipponi, J. (2003). Methodological index for non-randomized studies (MINORS): development and validation of a new instrument. ANZ Journal of Surgery, 73(9), pp.712-716.
- [33] Hong, Q. (2018). [online] Mixed methods appraisal. Available at: http://mixedmethodsappraisaltoolpublic.pbworks.com/w/file/fetch/127916259/MMAT_2018_criteria-manual_2018-08-01_ENG.pdf [Accessed 14 Dec. 2018].
- [34] Wells, G., Shea, B., O'Connell, D., Peterson, J., Welch, V., Losos, M., Tugwell, P. (2018). [online] The Newcastle-Ottawa Scale (NOS) for assessing the quality of nonrandomised studies in meta-analyses Available at: http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp [Accessed 14 Dec. 2018].
- [35] NIH. Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies [online] Available at: https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools [Accessed 14 Dec. 2018].
- [36] Public Health Wales Observatory, (2004). Critical appraisal checklist: Cross sectional study.
- [37] Wong, W., Cheung, C. and Hart, G. (2008). Development of a quality assessment tool for systematic reviews of observational studies (QATSO) of HIV prevalence in men having sex with men and associated risk behaviours. Emerging Themes in Epidemiology, 5(1), p.23.

- [38] Viswanathan, M. and Berkman, N. (2012). Development of the RTI item bank on risk of bias and precision of observational studies. Journal of Clinical Epidemiology, 65(2), pp.163-178.
- [39] Viswanathan, M., Berkman, N., Dryden, D., Hartling, L., (2013). Assessing Risk of Bias and Confounding in Observational Studies of Interventions or Exposures: Further Development of the RTI Item Bank. Agency for Healthcare Research and Quality, Rockville.
- [40] Cardiff University. (2018). Cardiff University. [online] Available at: http://www.cardiff.ac.uk/insrv/libraries/sure/checklists.html [Accessed 14 Dec. 2018].
- [41] Jarde, A., Losilla, J., Vives, J., (2012). Methodological quality assessment tools of non-experimental studies: a systematic review. Anales De Psicología, p. 28.
- [42] Sanderson S, Tatt I, Higgins J. Tools for assessing quality and susceptibility to bias in observational studies in epidemiology: a systematic review and annotated bibliography. International Journal Of Epidemiology 2007;36:666-676.

3 CONCLUSÕES

A revisão sistemática realizada resultou na identificação de 30 diferentes ferramentas para a avaliação da qualidade de estudos de prevalência. Houve grande variabilidade entre elas, principalmente em relação a estrutura e conteúdo.

Dessas 30 ferramentas, foram identificados e caracterizados 119 diferentes itens, que foram classificados em domínios. Quarenta e dois itens foram classificados no que consideramos os domínios chaves – população e desfecho (n=12), mensuração do desfecho (n=16) e estatística (n=14). Os outros 77 itens foram classificados como 'outros', e englobavam principalmente questões de redação do manuscrito.

Conduzimos uma busca abrangente, sensível para os instrumentos específicos para estudos de prevalência. Entretanto, é possível que nem todos os instrumentos que podem ser adaptados para a avaliação desse tipo de estudo tenham sido identificados. Isso pode ser uma limitação do estudo; todavia, acreditamos que os nossos resultados são abrangentes e representativos em termos de itens e domínios avaliados pelas ferramentas, especialmente em relação a itens classificados nos três domínios chaves. É importante ressaltar que grande parte dos itens classificados nos domínios chaves foram provenientes das ferramentas específicas para estudos de prevalência, enquanto a maioria dos itens identificados nas ferramentas não específicas foram classificados como 'outros'.

Uma possível limitação do nosso estudo é a necessidade de julgamento para classificar os itens em domínios, o que pode levar a decisões diferentes entre os avaliadores. Para evitar que isso se tornasse um problema, a avaliação foi realizada por dois revisores independentes com o auxílio de um terceiro revisor sempre que necessário; e os julgamentos foram disponibilizados para aumentar a transparência do processo.

A lista de itens construída a partir dessa revisão sistemática possui ampla abrangência e utilidade. Esses itens podem ser utilizados para avaliar estudos primários de prevalência, para guiar a condução de estudos primários de prevalência e para o desenvolvimento de ferramentas para avaliar a qualidade desse tipo de estudo.

REFERÊNCIAS

FLETCHER, Robert H; FLETCHER, Suzanne W; FLETCHER, Grant S. Epidemiologia Clínica: Elementos Essenciais. 5. ed. [n.i.]: Artmed, 2014. 296 p.

HIGGINS Julian PT, et al. A revised tool for assessing risk of bias in randomized trials. In: CHANDLER, J., MCKENZIE, J., BOUTRON, I., WELCH, V (Ed.). Cochrane Methods: Cochrane Database of Systematic Reviews, v.10 (Suppl 1), 2016.

IEZZONI, L. I. Assessing quality using administrative data. Annals of Internal Medicine, [s.l.], v. 127, n. 15, p.666-674,1997.

NEDEL, Wagner Luis; SILVEIRA, Fernando da. Os diferentes delineamentos de pesquisa e suas particularidades na terapia intensiva. Rev. bras. ter. intensiva, São Paulo, v. 28, n. 3, p. 256-260, Sept. 2016

OXMAN, Andrew D; SCHÜNEMANN, Holger J; FRETHEIM, Atle. Improving the use of research evidence in guideline development: 2. Priority setting. Health Research Policy and Systems, [s.l.], v. 4, n. 1, p.4-14, 29 nov. 2006.

ROTILY, Michel; ROZE, Stéphane. What is the impact of disease prevalence upon health technology assessment? Best Practice & Research Clinical Gastroenterology, [s.l.], v. 27, n. 6, p.853-865, dez. 2013.

SHAMLIYAN, Tatyana; KANE, Robert L.; DICKINSON, Stacy. A systematic review of tools used to assess the quality of observational studies that examine incidence or prevalence and risk factors for diseases. Journal of Clinical Epidemiology, [s.l.], v. 63, n. 10, p.1061-1070, out. 2010.

STERNE, Jonathan Ac et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. Bmj, [s.l.], p.i4919, 12 out. 2016. BMJ.

WAGNER, Mario B. Medindo a ocorrência da doença: prevalência ou incidência? Jornal de Pediatria, v. 74, p. 157-162, 1998.

WHITING, Penny F, et al. QUADAS-2: A Revised Tool for the Quality Assessment of Diagnostic Accuracy Studies. Annals of Internal Medicine, [s.l.], v. 155, n. 8, p.529-536, out. 2011

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