International Journal of Nursing Studies 113 (2021) 103785

Contents lists available at ScienceDirect

International Journal of Nursing Studies

journal homepage: www.elsevier.com/ijns

Instruments assessing medication literacy in adult recipients of care: A systematic review of measurement properties ☆

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ARTICLE INFO

Article history:
Received 28 April 2020
Received in revised form 6 August 2020
Accepted 27 September 2020

ABSTRACT

Objectives: The assessment of medication literacy in patients is an important step in assisting clinicians to plan for education, prescription simplification, assistance and/or medication aids. There have been several attempts to develop a standardised, objective measure of medication literacy. The objectives of this systematic review were to critically appraise, compare and summarise the measurement properties of existing instruments that assess medication literacy in adult recipients of care.
Design: A systematic review was performed. Search methods: Structured searches were conducted in Embase, MEDLINE PubMed, CINAHL, APA PsycINFO and Web of Science Core Collection in March 2020. Additional searches were performed in ProQuest Dissertations and Theses, DART Europe, and Google Scholar, followed by citation tracking of included studies.
Review methods: Two researchers independently identified eligible studies. Two researchers then assessed the methodological quality of the studies and quality of measurement properties, using the Consensus-based Standards for selection of health Measurement Instruments (COSMIN) guidelines. A best-evidence synthesis for each instrument was performed.
Results: From the 5035 citations, 17 studies were included that concerned 13 instruments using different administration methods (i.e., performancebased or self-report), medication type (i.e., prescribed or nonprescribed) and context of use (i.e., clinical or community settings). Very low- to moderate-quality evidence supported satisfactory content validity regarding relevance and comprehensibility, while comprehensiveness remained inconsistent. Other measurement properties were less frequently examined and were supported by moderate-quality evidence (i.e., structural validity) to low- or very low-quality evidence (i.e., internal consistency, reliability, construct validity). The bestvalidated instrument is the unidimensional 14-item Medication Literacy in Spanish and English assessment tool (MedLitRxSE), based on direct testing of participant performance regarding four hypothetical scenarios on medication use. Nine instruments have the potential to be recommended but require additional research, while for others, their psychometric soundness is too limited and they require content revisions.
Conclusion: This is the first systematic review to identify instruments for medication literacy. None of the identified instruments had all measurement properties properly assessed and none reported measurement invariance, measurement error and responsiveness of the instrument. Further research is necessary for a better theoretical understanding of medication literacy in order to assist health professionals in identifying patient needs for education, regimen simplification, assistance and/or medication aids. Such research will help conceptualise new instruments that not only cover relevant domains dedicated to specific populations (e.g., polymorbid and/or older individuals), but also exhibit satisfactory measurement properties.

☆ Funding: This project was funded by Lausanne University Hospital, Switzerland.
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https://doi.org/10.1016/j.ijnurstu.2020.103785

What is already known about the topic?

- Medication literacy refers to the necessary cognitive and social abilities to follow through with medication information (e.g., how to interpret medication dosing and measurements, how to understand instructions, what actions are required in the case of a missed dose or side effects), and must not be restricted to reading medication labels and remembering medication names.
- In the last decade, the development of standardised and objective measures of medication literacy has become an important step in supporting clinicians to plan interventions tailored to a patient's medication literacy (i.e., education, regimen simplification, assistance and/or medication aids).
- A variety of instruments is available to evaluate medication literacy in patients, but no systematic review is available.

What this paper adds

- This paper provides a comprehensive overview of the content of medication literacy instruments and their measurement properties for adults.
- A critical appraisal of the methodological quality of the studies, in combination with a best-evidence synthesis and instrument characteristics (domains, number of items and response options), could support clinicians and researchers to choose the most suitable medication literacy instrument to use in care and research.
- There is a need for research to enhance the quality of the evidence for existing instruments and to conceptualise new comprehensive instruments in specific adult populations (e.g., polymorbid and/or older individuals).

1. Introduction

Medication literacy is the manifestation of health literacy in the context of medication use. It was defined as "the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medications to make informed medication and health decisions in order to safely and effectively use their medications, regardless of the mode by which the content is delivered (e.g., written, oral and visual)" (Pouliot et al., 2018). Medication literacy underlines the necessary competencies for an individual to deal with different, often complex, medication-related information (i.e., name of medicine, dosages, timing of administration, instructions) and messages coming from various sources (i.e., drug containers, outer packaging, information leaflets, oral instructions given by health professionals) (Ng et al., 2017). Medication literacy competencies should not be restricted to the capacity of an individual to read information leaflets or to list his/her prescribed drug regimen; rather, they involve specific abilities such as how to interpret medication dosing and measurements, how to follow prescription instructions, and what to do in the case of a missed dose or the occurrence of side effects (Yeh et al., 2017; Sauceda et al., 2003).

Pharmacotherapy represents one of the biggest achievements of modern medical interventions, in particular in the control of chronic disorders (Topinkova et al., 2012). However, it also results in adverse events, including drug-drug and drug-disease interactions, which are an important public health concern because they are a frequent cause of hospital admissions and increased morbidity and mortality (Khalil and Huang, 2020). For example, about 30% of visits to the emergency department are directly related to medication problems (i.e., misuse, overuse or underuse (Shehab et al., 2016; Mira et al., 2015)), of which one-third are deemed preventable (Tache et al., 2011). Previous studies stated that inappropriate prescribing could affect up to 59% of community-dwelling people (Mira et al., 2015; Pouliot and Vaillancourt, 2016). Other studies reported that, amongst the contributing factors, up to 75% of primary care patients were not able to describe the details of their own treatment regimen, and 46% misinterpreted either the dosage or the right timing of administration (Kenning et al., 2015; Wolf et al., 2007; Perez-Jover et al., 2018). Conversely, patients' therapeutic adherence and prevention of medication-related problems were associated with the patients' capacity to understand information about their own prescriptions (Mira et al., 2015; Bailey et al., 2013; Chesser et al., 2016).

Thus, assessing medication literacy competencies could be considered an important step in identifying a patient's specific inabilities and needs in order to improve self-care skills and to promote the safe and appropriate use of medication. Most studies that aimed to describe medication literacy in patients have considered general health literacy instruments (e.g., Rapid Estimate of Adult Literacy in Medicine [REALM] and Test of Functional Health Literacy in Adults [TOFHLA]) (Liang et al., 2018). However, such instruments do not capture the specific skills related to medication. This raises concern for clinical practice. Administering flawed measurement instruments burdens patients needlessly and raises uncertainty about the quality of the collected data, which in turn may generate a risk that healthcare workers will provide inappropriate care (Polit and Yang, 2015). Several attempts have been made to develop a standardised, objective measure of medication literacy. Therefore, a critical appraisal of the properties of medication literacy instruments is necessary so that clinicians and researchers can select the best-validated one. This study provides a psychometric review of existing medication literacy instruments designed for adult care recipients, including instruments dedicated to informal caregivers who are often responsible for preparing medication and/or administering it to ill proxies.

2. Objectives

The objectives of this systematic review are to critically appraise, compare and summarise the measurement properties (i.e., content validity, structural validity, internal consistency, cross-cultural validity, construct validity/hypotheses testing, test-retest reliability, measurement error, and responsiveness) of existing instruments that assess medication literacy in adult recipients of care.

3. Methods

This review was conducted in accordance with the Consensus-based Standards for the Selection of health Measurement Instruments (COSMIN) guidelines (Prinsen et al., 2018;

Mokkink et al., 2018; Terwee et al., 2018b; Mokkink et al., 2018; Terwee et al., 2018a) and follows the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (Moher et al., 2009). For each included study, three assessments were made. First, the risk of bias of each study was assessed (i.e., methodological quality). Second, the results of a measurement property were rated against established criteria for satisfactory measurement properties. Third, the results from all studies on the same measurement property were summarised and the quality of evidence graded. Both patient-reported outcome measures and objective performance-based outcome measures were considered. As the established COSMIN standards were applicable to the latter outcome measures, no deviations were made from the guideline. This systematic review was registered on the international prospective register of systematic reviews (PROSPERO, CRD42019126548 – https://www.crd.york.ac.uk/prospero/).

3.1. Search strategy

The search strategies were designed in collaboration with a qualified health librarian (CJ). The correctness and the comprehensiveness of these strategies were peer reviewed by means of the Peer Review of Electronic Search Strategy (PRESS) guidelines (McGowan et al., 2016).

An initial search was undertaken in Embase and PubMed, followed by the analysis of the title and abstract terms, as well as the index terms of the retrieved papers. Structured searches were then conducted in Embase.com, Medline Ovid SP, PubMed (search limited to non-MEDLINE articles), CINAHL Complete, APA PsycInfo Ovid SP and Web of Science Core Collection on March 12, 2020. A validated search filter for studies on measurement properties developed for PubMed was used (Terwee et al., 2018a) and adapted (CJ) for all other databases. Additional searches were carried out in ProQuest Dissertations and Theses, DART Europe, and Google Scholar. Full search strategies are provided as supplementary material (Appendix A). The search was complemented by backward and forward reference tracking of included studies by using the Web of Science Core Collection. References were integrated into Endnote X8 software for deduplication.

3.2. Selection criteria

Eligible studies, written in French or English, had to evaluate at least one of the measurement properties identified by the COSMIN taxonomy: content validity, structural validity, internal consistency, cross-cultural validity, construct validity/hypotheses testing, test-retest reliability, measurement error, responsiveness. Studies presenting the development of such instruments were also selected for the assessment of content validity. Criterion-related validity was not considered, as there is no reasonable gold standard for medication literacy. Emphasis was placed on psychometric studies, but other types were also included if they provided sufficient information to evaluate the quality of at least one measurement property.

This review included all types of instruments, measures (e.g., generic, specific) and measurement methods (i.e., self-reported, performance based) designed to quantify medication literacy and medication illiteracy or concepts used as synonyms: pharmacotherapy literacy, pharmacy health literacy, pharmaceutical literacy and illiteracy, health literacy in the context of medication use. The focus was on adult care recipients (i.e., $\geq$18 years), including the informal caregivers who are responsible for preparing medication and/or administering it to ill proxies, irrespective of the type of medication (i.e., prescribed or non-prescribed). No restriction was placed on the setting of care or the year of publication. Exclusion criteria concerned posters, abstracts, editorials, opinions or any publications in which the development phase of an instrument or measurement properties were reported. Nevertheless, these resources were reviewed for additional instruments and publications and 10 experts were contacted, but no other studies could be identified. Studies designed to measure medication literacy in healthcare professionals or students were not considered. Two researchers (JG, JH) independently screened titles, abstracts and full texts to select studies by using Rayyan software (Ouzzani et al., 2016). Disagreements were resolved through discussion (JG, JH) and, if necessary, by a third researcher (CM).

3.3. Methodological quality of the included studies

The methodological quality of each study was assessed with the COSMIN Risk of Bias checklist (Mokkink et al., 2018b; Terwee et al., 2018a). Seven of 10 lists of criteria were applicable to this review (i.e., instrument development, content validity, structural validity, internal consistency, cross-cultural validity, reliability and construct validity), including up to 35 criteria. Detailed information on these criteria is provided elsewhere (Mokkink et al., 2018b; Terwee et al., 2018a). A 4-point rating scale (i.e., very good, adequate, doubtful or inadequate) was considered for rating each criterion. The overall rating was determined by "the worst score counts" principle. For content validity studies, we reported separate ratings for relevance, comprehensiveness and comprehensibility because more information was available on some aspects of content validity (e.g., comprehensibility) but less on others (e.g., comprehensiveness) (Terwee et al., 2018a). Two researchers (JG, JH) independently assessed the risk of bias and achieved a consensus through discussion; when necessary, a third researcher (CM) was consulted to resolve remaining disagreements. At this stage, the developers of the instrument were contacted by email to give them an opportunity to provide additional information: six researchers provided additional information or a copy of their instrument.

3.4. Data extraction

For all included studies, the following data were extracted and collected in standardised form: (a) characteristics of the instruments, (b) study design and (c) domains explored by each instrument. The extraction of content domains of medication literacy was performed through subjective assessment of each instrument by using existing definitions of medication literacy (i.e., attributes). One researcher (JG) extracted information, and a second (JH or CM) checked content for accuracy. Any disagreements were resolved through discussion.

3.5. Quality of the results and evidence synthesis

Results of each study were rated according to established criteria for satisfactory measurement properties (i.e., satisfactory results (+), unsatisfactory results (-), inconsistent results ($\pm$) and indeterminate results (?)), where 75% of the results were expected to meet the criteria (Mokkink et al., 2018a; Mokkink et al., 2018b; Terwee et al., 2018a). These criteria were amended to allow the assessment of other results (i.e., exploratory factor analysis for multidimensional scaling, confirmatory factor analysis using incremental fit index, normed fit index and goodness-of-fit index, internal consistency with Kuder-Richardson formula 20, cross-cultural validity using Wald statistics, reliability based on Cohen's Kappa) (Appendix B). For construct validity assessment, the review team formulated a priori hypotheses about the expected relationships between the instruments under review and comparator instruments used across included studies. More specific information on how to apply these criteria is provided elsewhere (Mokkink et al., 2018b; Terwee et al., 2018a).

Finally, the overall rating was accompanied by a grading of the quality of the evidence (i.e., high, moderate, low or very low) (Mokkink et al., 2018a; Mokkink et al., 2018b; Terwee et al., 2018a). Three researchers (JG, JH, CM) contributed to the rating and the quality of the evidence per measurement property through discussion. The data synthesis provides recommendations synthesised into three categories: (i) most suitable instruments to assess medication literacy, (ii) instruments that need further validation studies and (iii) instruments not recommended. The most suitable instruments had evidence for sufficient content validity (any level) and at least low quality evidence for sufficient internal consistency, while instruments not recommended had high quality evidence for an insufficient measurement property. The instruments that need further validation studies showed unsatisfactory content validity and/or absence of evaluation of internal consistency.

4. Results

4.1. Study inclusion

The literature search and study selection process is detailed in Fig. 1. Of the 5035 references initially identified by the literature search, 134 were selected for full-text screening according to selection criteria and 116 were excluded. At this stage, several instruments to measure medication literacy were identified, for which the measurement properties were not evaluated,not reported or in other languages (Horvat et al., 2018; O'Neal et al., 2013; Calamusa et al., 2012; Sahril et al., 2012), and therefore have been excluded. After a critical appraisal of the full texts of the included references, one study was secondarily excluded because the information to evaluate the methodological quality was insufficient (Cordina et al., 2018). Moreover, the Medication Literacy Questionnaire for Discharged Patients, which was initially developed in English (Maniaci et al., 2008) and then translated into Chinese (Zheng et al., 2016), underwent substantial changes during its transcultural adaption (Zhong et al., 2019). Thus, the review team considered the Chinese version original and included it. As no study reporting the measurement properties of the original English version could be found, this version was not further considered (Maniaci et al., 2008). Finally, 17 studies reporting the measurement properties of 13 different instruments were included for methodological quality assessment.

4.2. Characteristics of instruments and studies

The characteristics of the 13 instruments are presented in Table 1a and 1b (Yeh et al., 2017; Sauceda et al., 2003; Zhong et al., 2019; Emmerton et al., 2012; Jang et al., 2019; Sayekti et al., 2018; Shi et al., 2019; Shreffler-Grant et al., 2014; Stilley et al., 2014; Vervloet et al., 2018; Ubavic et al., 2019). Nine instruments were developed to assess medication literacy regarding a specific medication type (e.g., immunosuppressant drugs, diabetic drugs, complementary medicine, paediatric medicine, herbal products) and four were designed to be applicable across a wide range of medicines, namely generic measures (Yeh et al., 2017; Zhong et al., 2019; Vervloet et al., 2018; Zhang et al., 2019). The administration mode chosen was self-reported (patient-reported outcome measures) by respondents for three instruments (Shreffler-Grant et al., 2014; Ubavic et al., 2019; Zhang et al., 2019), from performance through direct testing (objective performance-based outcome measures) for seven instruments (Yeh et al., 2017; Sauceda et al., 2003; Zhong et al., 2019; Jang et al., 2019; Sayekti et al., 2018; Stilley et al., 2014) and from a combination of both approaches for three instruments (Emmerton et al., 2012; Shi et al., 2019; Vervloet et al., 2018). Instruments were composed of 6 to 37 items, which were generally divided into different domains. Depending on the instrument, this varied from three to five dimensions, except for the medication literacy instrument focused on non-steroidal anti-inflammatory drugs (MedLit-NSAID) (Jang et al., 2019), the Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019), the 14-item Medication Literacy in Spanish and English assessment tool (MedLitRxSE) (Sauceda et al., 2003) and the Literacy of Cold Medication labelling questionnaire (Sayekti et al., 2018), all of which explored a single dimension. The item-response type was either dichotomous, based on Likert scales with three to five points, or a mixed combination of these types. None of the identified instruments used a recall period; instead, the assessment of medication literacy was based on real-time or hypothetical scenarios. The comparisons of the medication literacy aspects that were explored demonstrated that the Chinese Medication Literacy Scale for Hypertensive Patients (C-MLSHP) (Shi et al., 2019), the Health Literacy of Pharmacy Consumer questionnaire (Emmerton et al., 2012) and the 14-item MedLitRxSE (Sauceda et al., 2003) instruments covered the broadest spectrum of domains, as shown in Table 1b, i.e., six to seven of the eight potential domains found in the literature. The instrument that covered the fewest dimensions was The Literacy of Cold Medication labelling questionnaire (Sayekti et al., 2018), which included one dimension and based the assessment on reading ability only. Completion time was specified for only three instruments (Yeh et al., 2017; Sauceda et al., 2003; Ubavic et al., 2019), ranging from 10 to 25 min.

Concerning the characteristics of the included studies (Table 2), the publication dates were extended from 2010 to 2020. Eight of the 14 included studies were psychometric studies, focusing on the development or evaluation of an instrument (Yeh et al., 2017; Sauceda et al., 2003; Shreffler-Grant et al., 2014; Stilley et al., 2014; Vervloet et al., 2018; Ubavic et al., 2019; Weinert et al., 2019; Koster et al., 2018). Nine cross-sectional studies were also integrated in the review that did not primarily aim at validation but contained some information about the development or the evaluation of the instruments (Zhong et al., 2019; Emmerton et al., 2012; Jang et al., 2019; Sayekti et al., 2018; Shi et al., 2019; Zhang et al., 2019; Zheng et al., 2017; Ma et al., 2019; Zheng et al., 2019). Original instruments were mostly developed and tested in Asia and the United States, with fewer studies conducted in Europe and only one in Australia. Samples were adults, with a mean age of 39.7 to 68.0 years. A summary of findings per instrument is provided in Table 3, including the methodological quality per study, the quality of the results and the level of evidence. Content validity (including the development phase) was the measurement property most frequently tested, followed by internal consistency, reliability, structural validity and construct validity, whereas only one study reported cross-cultural validity. None of the included studies reported evaluation of measurement invariance, measurement error and responsiveness.

4.3. Methodological quality of studies

The methodological quality of instrument development was inadequate for all studies, related either to a conceptual mismatch or to the fact that developers failed to include target group participants during the development phase, except for the 20-item and 14-item MedLitRxSE (Sauceda et al., 2003) and the Pharmacotherapy Literacy questionnaire (PTHL-SR) (Ubavic et al., 2019)), which included patients for concept elicitation and tested the first draft of the instrument through cognitive interviews or pilot testing. However, their aims and procedures were not clearly described, such as the data collection method, leading to doubtful ratings. In addition, content validity studies overall had poor methodological quality, as

Table 1a
Medication literacy instrument characteristics.

Instrument	Name abbreviation	Type	Administration method	Number of items, (sub)scale(s) (number of items)	Response options, range of scores	Original language (translation)
Health literacy of pharmacy consumer questionnaire (Emmerton et al., 2012)	None	Specific (Actapress©)	Performance-based and self-reported	10 items Functional (Shehab et al., 2016), interactive (Ng et al., 2017), critical (Pouliot et al., 2018)	Incorporate different combinations of options (match/mismatch/no; yes/no/unsure; open-ended responses). No information	English
Pregnant Women's Medication Information Literacy Scale (Zhang et al., 2019)	PWMILS	Generic	Self-reported	23 items Medication information needs (Sauceda et al., 2003), medication information sources (Sauceda et al., 2003), medication information quality discrimination (Yeh et al., 2017), medication information source awareness (Shehab et al., 2016) and medication-taking behaviour (Topinkova et al., 2012)	Dichotomous scoring system and 5-point Likert scale 0–37	Chinese
Medication label literacy instrument focused on non-steroidal anti-inflammatory drugs (Jang et al., 2019)	MedLit-NSAID	Specific (over-the-counter NSAID labels)	Performance-based	8 items Literacy and numeracy in multiple domains (single dimension)	Not detailed but assumed to be a dichotomous score 0–8	English
Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019)	None	Generic	Performance-based	9 items Name, dose, frequency of use, therapeutic effect, and major side effects (single dimension)	Dichotomous score 0–7 (items 7 and 9 do not contribute to the total score)	Chinese
Medication Literacy in Spanish and English assessment tool (20 items) (Sauceda et al., 2003)	20-item MedLitRxSE	Specific (4 hypothetical scenarios: (Pouliot et al., 2018) injectable medication, (Ng et al., 2017) paediatric dose of non-prescription medication for fever, (Yeh et al., 2017) tablets, (Sauceda et al., 2003) active ingredients on a non-prescription product)	Performance-based	20 items Document literacy (Kenning et al., 2015), numeracy (Khalil and Huang, 2020) and prose (Yeh et al., 2017)	Dichotomous score 0–20	Spanish and English
Medication Literacy in Spanish and English assessment tool (14 items) (Sauceda et al., 2003; Zheng et al., 2017)	14-item MedLitRxSE	Specific (4 hypothetical scenarios), same as MedLitRxSE (20 items)	Performance-based	14 items Document literacy and numeracy (unidimensional scale)	Dichotomous score 0–14 Inadequate literacy (<4), marginal literacy (Sauceda et al., 2003; Topinkova et al., 2012; Khalil and Huang, 2020; Shehab et al., 2016; Mira et al., 2015; Tache et al., 2011; Pouliot and Vaillancourt, 2016), adequate literacy (>10) (Zheng et al., 2017)	Spanish and English (Chinese)

(*Continued on next page*)

Table 1a (*Continued*).

Instrument	Name abbreviation	Type	Administration method	Number of items, (sub)scale(s) (number of items)	Response options, range of scores	Original language (translation)
Literacy of Cold Medication labelling questionnaire (Sayekti et al., 2018)	None	Specific (hypothetical scenario with Mixagrip Flu©)	Performance-based	7 items To read and pronounce medication labels (single dimension)	Dichotomous score 0–7 Illiterate (0–3), literate (Sauceda et al., 2003; Topinkova et al., 2012; Khalil and Huang, 2020; Shehab et al., 2016)	Indonesian
Chinese Medication Literacy Scale for Hypertensive Patients (Shi et al., 2019; Ma et al., 2019)	C-MLSHP	Specific (any antihypertensive medication)	Performance-based	37 items Medication knowledge literacy (Tache et al., 2011), skill literacy (Shehab et al., 2016), attitude literacy (Mira et al., 2015) and practice literacy (Perez-Jover et al., 2018)	Dichotomous scoring system and 5-point Likert scale 0–37	Chinese
Montana State University complementary and alternative medicine Health Literacy Scale (Shreffler-Grant et al., 2014; Weinert et al., 2019)	MSU CAM	Specific (herbal products)	Self-reported	21 items Safety and information (Shehab et al., 2016); effect, safety and dose (Khalil and Huang, 2020); availability and quality (Mira et al., 2015)	4-point Likert scale 21–84	English
Medication Health Literacy measure (Stilley et al., 2014)	None	Specific (Prograf© or Metformin©)	Performance-based	6 items Document literacy (Ng et al., 2017), numeracy (Ng et al., 2017) and prose (Ng et al., 2017)	Dichotomous score 0–6	English
Pharmacotherapy Literacy questionnaire (Ubavic et al., 2019)	PTHL-SR	Specific (paediatric medicines)	Self-reported	14 items Knowledge (Topinkova et al., 2012), understanding health information (Yeh et al., 2017), numerical skills (Topinkova et al., 2012) and access to information (Pouliot et al., 2018)	Dichotomous score 0–14	Serbian
Recognition and Addressing of Limited Pharmaceutical Literacy interview guide (Vervloet et al., 2018; Koster et al., 2018)	RALPH	Generic	Performance-based and self-reported	10 items Functional (Yeh et al., 2017), communicative (Yeh et al., 2017) and critical (Sauceda et al., 2003)	Incorporate different combinations of options (yes/no/doesn't know; pointing out actions; 4-point Likert scale). No information	Dutch
Chinese medication literacy measure (Yeh et al., 2017)	ChMLM	Generic	Performance-based	17 items Vocabulary (Topinkova et al., 2012), non-prescription drug (Topinkova et al., 2012), prescription drug (Sauceda et al., 2003) and drug advertisement (Yeh et al., 2017)	Dichotomous score + multiple-choice questions 0–17	Chinese

Table 1b
Content domains of the instruments measuring medication literacy.

Instrument	To read[a]	To find[b]	To understand[c]	To communicate[d]	To calculate[e]	To interpret[f]	To process information[g]	To take action[h]
Health literacy of pharmacy consumer questionnaire (Emmerton et al., 2012)	YES	YES	YES	YES	YES	YES		
PWMILS (Zhang et al., 2019)		YES	YES	YES		YES		
MedLit-NSAID (Jang et al., 2019)		YES	YES		YES	YES		
Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019)			YES		YES			
14-item MedLitRxSE assessment tool (Sauceda et al., 2003; Zheng et al., 2017; Zheng et al., 2019) (the 20-item version was not available)	YES	YES	YES		YES	YES	YES	
Literacy of Cold Medication labelling Questionnaire (Sayekti et al., 2018)	YES							
C-MLSHP (Shi et al., 2019; Ma et al., 2019)	YES	YES	YES	YES	YES		YES	YES
MSU CAM (Shreffler-Grant et al., 2014; Weinert et al., 2019)			YES			YES	YES	YES
Medication Health Literacy measure (Stilley et al., 2014)			YES		YES	YES	YES	
PTHL-SR (Ubavic et al., 2019)		YES	YES		YES	YES	YES	
RALPH interview guide (Vervloet et al., 2018; Koster et al., 2018)	YES	YES	YES	YES		YES		
ChMLM (Yeh et al., 2017)	YES	YES	YES			YES		

Note. PWMILS, Pregnant Women's Medication Information Literacy Scale; MedLit-NSAID, Medication label literacy instrument focused on non-steroidal anti-inflammatory drugs; 14-item MedLitRxSE, Medication Literacy in Spanish and English (14 items); C-MLSHP, Chinese Medication Literacy Scale for Hypertensive Patients; MSU CAM, Montana State University complementary and alternative medicine Health Literacy Scale; PTHL-SR, Pharmacotherapy Literacy questionnaire; ChMLM, Chinese medication literacy measure.

[a] To read, to pronounce words (Yeh et al., 2017; Zhang et al., 2019)).

[b] To obtain, to access, to find (reliable) information, to locate information (e.g., in a prescription) (Pouliot et al., 2018; Sauceda et al., 2003; Zhong et al., 2019; Emmerton et al., 2012; Sayekti et al., 2018; Shi et al., 2019; Ubavic et al., 2019; Zhang et al., 2019; Zheng et al., 2017).

[c] To understand, to demonstrate knowledge (e.g., based on a simulated prescription or on one's own medication), to remember, to recall information (e.g., medication names) (Pouliot et al., 2018; Yeh et al., 2017; Sauceda et al., 2003; Zhong et al., 2019; Emmerton et al., 2012; Sayekti et al., 2018; Shi et al., 2019; Ubavic et al., 2019; Zhang et al., 2019; Zheng et al., 2017).

[d] To communicate, to express, to ask, to contact, to interact with healthcare professionals (e.g., take an active part in decisions) (Pouliot et al., 2018; Sayekti et al., 2018; Shi et al., 2019).

[e] To calculate, to measure, to prepare medication (e.g., dosages, number of pills) (Pouliot et al., 2018; Sayekti et al., 2018; Shi et al., 2019).

[f] To interpret (e.g., warning label meaning), to compare, to evaluate, to critically analyse (e.g., information reliability and relevance) (Ubavic et al., 2019; Zhang et al., 2019).

[g] To process information, to adapt information to one's own situation, to make decisions, to solve problems (Pouliot et al., 2018; Yeh et al., 2017; Sayekti et al., 2018; Shi et al., 2019; Ubavic et al., 2019; Zhang et al., 2019; Zheng et al., 2017).

[h] To take action (e.g., monitor potential side effects of a new medication), to apply, to use, to follow the instructions (e.g., to adhere) (Pouliot et al., 2018; Sauceda et al., 2003; Zhong et al., 2019; Emmerton et al., 2012; Sayekti et al., 2018; Shi et al., 2019; Zheng et al., 2017).

they included only professionals and/or provided insufficient information on methods.

The structural validity studies based on confirmatory factor analysis were very good for the 20-item MedLitRxSE (Sauceda et al., 2003) and in one study for the Pregnant Women's Medication Information Literacy Scale (PWMILS) (Zhang et al., 2019). Structural validity was rated adequate when based on exploratory factor analysis for the Montana State University complementary and alternative medicine Health Literacy Scale (MSU CAM) (Shreffler-Grant et al., 2014)), the Medication Health Literacy measure (Stilley et al., 2014) and in another study for the PWMILS (Zhang et al., 2019). Other studies used samples that were too limited in size to conduct item response theory analysis (Sauceda et al., 2003), or failed to report their procedures and results (Yeh et al., 2017; Zheng et al., 2017). The absence of a rating on the structural validity devalued the internal consistency of the PTHL-SR (Ubavic et al., 2019), the C-MLSHP (Shi et al., 2019), the MedLit-NSAID (Jang et al., 2019) and the Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019), resulting in doubtful ratings. An internal consistency statistic was computed for each (sub)scale separately and rated as very good for the PWMILS (Zhang et al., 2019), the Medication Health Literacy measure (Stilley et al., 2014), one study of the MSU CAM (Shreffler-Grant et al., 2014) and the 14-item MedLitRxSE (Sauceda et al., 2003). The alpha per subscale was lacking in other studies, leading to an inadequate rating.

For the remaining measurement properties, cross-cultural validity was performed only for the 14-item MedLitRxSE (Sauceda et al., 2003) in comparing the English and Spanish language versions, using differential item functioning analysis. However, relevant characteristics between the two groups appeared with differences (i.e., age and educational level), and the analysis was performed in a sample size that was too small for item response theory. The reliability studies had overall poor methodological quality, as details on test conditions and procedures were lacking in most. The appropriate time interval ($\geq$ 2 weeks) and similar test conditions were made explicit only for MSU CAM (Weinert et al., 2019), but in this study, information was lacking on the statistics used. The MedLit-

Table 2
Characteristics of included studies.

Instrument	Construct definition (paraphrase)	Study design and references	Country	Study population and setting	Mean age (SD or min-max)[a]	Gender% female[a]	Others[a]	Score distribution[a]	Response rate
Health literacy of pharmacy consumer questionnaire (Emmerton et al., 2012)	Health literacy competencies in community pharmacies, health literacy of pharmacy consumers = the ability of health consumers to obtain, understand and use information regarding their health	Cross-sectional survey (Emmerton et al., 2012)	Australia	Pharmacy consumers (≥16 y)	?	?	?	Not reported	Not reported
PWMILS (Zhang et al., 2019)	Medication information literacy = the combination of medication literacy and information literacy (…) and refers to medication-related information behaviour, including needs, seeking and use of information related to the medication. It involves the ability to read and understand medication instructions.	Cross-sectional survey (Zhang et al., 2019)	China	Pregnant women visiting an obstetric clinic	?	?	?	Not reported	Not reported
MedLit-NSAID (Jang et al., 2019)	Health literacy relevant to medication labels, medication literacy = no definition given.	Cross-sectional pilot study (Jang et al., 2019)	USA	Adult individuals (>18 y) of a primary care practice at the time of post-visit	Less than 65 y = 68% 65 y or older = 32%	52.0%	Estimated glomerular filtration rate > 60 mL/min/1.73 m^2 (88%), ⩽ 60 mL/min/1.73 m^2 (12%), ≥ college educational level (72%), Caucasians (86%), self-managing medication (99%), number of medications <5 (72%), 5–10 (25%), 11–15% (1%), ≥15 (1%).	MedLit-NSAID mean score = 6.8 out of 8 (SD = 1.4) Correct answers = 85% (SD = 18%)	86.6%
Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019)	Medication literacy = the ability of individuals to obtain, correctly understand and use medication information in order to take that medication safely and appropriately.	Cross sectional study (Zhong et al., 2019)	China	(Adult) patients discharged from hospital, after a coronary stent implantation	?	?	?	Not reported	Not reported
20-item MedLitRxSE assessment tool (Sauceda et al., 2003)	Medication literacy = the ability of individuals to safely and appropriately access, understand and act on basic medication information.	Psychometric study (Sauceda et al., 2003)	USA	General population of English- and Spanish-speaking individuals (>18 y), in community health centres, pharmacies and non-clinical settings	English speakers: 46.9 y (SD = 15.2) Spanish speakers: 46.8 y (SD = 13.3)	English speakers: 68.1% Spanish speakers: 76.7%	English sample: Hispanic/Latino ethnicity (70.3%), and non-Hispanic white (23.2%), income <10,000 USD (15.4%), education level < high school (81.4%) Spanish sample: Hispanic/Latino ethnicity (98.9%), income <10,000 USD (45.6%), education level < high school (36.6%)	English version mean score = 13.09 out of 20, SD = 3.88, min-max = 2–18 Spanish version mean score = 8.8 out of 20, SD = 4.17, min-max= 0–16	Not reported

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Table 2 (*Continued*).

Instrument	Construct definition (paraphrase)	Study design and references	Country	Study population and setting	Mean age (SD or min-max)[a]	Gender% female[a]	Others[a]	Score distribution[a]	Response rate
14-item MedLitRxSEassessment tool (Sauceda et al., 2003; Zheng et al., 2017; Zheng et al., 2019)	Same as above	Psychometric study (Sauceda et al., 2003)	USA	General population of English- and Spanish-speaking individuals (>18 y), in community health centres, pharmacies and non-clinical settings	English speakers: 39.7 y (SD = 14.7) Spanish speakers: 46.5 y (SD = 15.9)	English speakers: 71.0% Spanish speakers: 80.6%	English speakers: Hispanic/Latino ethnicity (83.9%), and non-Hispanic white (12.9%), income <10,000 USD (9.7%), education level ≥ high school (90.3%) Spanish speakers: Hispanic/Latino ethnicity (100%), income <10,000 USD (22.6%), education level ≥ high school (41.9%)	English version mean score = 10.7 out of 14, SD= 3.10, min-max = 1–14 Spanish version mean score mean =7.9 out of 14, SD = 3.34, min-max = 0–14	Not reported
		Cross-sectional study (Zheng et al., 2017)	China	Ambulatory care patients (>18 y) of tertiary hospitals	?	?	?	Not reported	Not reported
Literacy of Cold Medication labelling questionnaire (Sayekti et al., 2018)	Medication literacy = the degree to which individuals can obtain, comprehend, communicate, calculate and process patient-specific information about their medication to make informed medication and health-related decisions in order to safely and effectively use their medications, regardless of the mode by which the content is delivered (e.g., written, oral, visual).	Cross-sectional survey (Sayekti et al., 2018)	Indonesia	Hypertensive outpatients (>18 y) of primary healthcare centres	?	?	?	Not reported	Not reported
C-MLSHP (Shi et al., 2019; Ma et al., 2019)	Medication literacy, health literacy in the context of medication use = obtain, comprehend, communicate, calculate and process patient-specific information about their medication to make informed medication and health-related decisions in order to safely and effectively use their medications, regardless of the mode by which the content is delivered (e.g., written, oral, visual).	Cross-sectional survey (Shi et al., 2019)	China	Hypertensive outpatients (>18 y) of tertiary and secondary hospitals and community healthcare services, taking antihypertensive treatment for at least 2 weeks	?	?	?	Not reported	Not reported

(*Continued on next page*)

Table 2 (*Continued*).

Instrument	Construct definition (paraphrase)	Study design and references	Country	Study population and setting	Mean age (SD or min-max)[a]	Gender% female[a]	Others[a]	Score distribution[a]	Response rate
MSU CAM (Shreffler-Grant et al., 2014; Weinert et al., 2019)	Complementary and alternative medicine literacy = the information needed about CAM to make informed self-management decisions regarding health.	Psychometric study (Shreffler-Grant et al., 2014)	USA	Community-dwelling older adults using CAM (herbal products)	Summarised results: 68–68.2 y (min-max = 55–97)	Summarised results: 55.80 – 66%	Summarised results: Currently married or partnered (51–55.2%), > high school education (52–75%), having used CAM in the past (58–82%), and having one or more significant acute or chronic health problems (49.5–52.4%)	Summarised MSU CAM mean = 61.1–68.5 (range 25–82)	Not reported
		Psychometric study (Weinert et al., 2019)	USA	Adult and senior individuals of living centres using CAM (herbal products)	Summarised results: 59.9 – 60.5 y (min-max = 21–95)	Summarised results: 76.8 –77.1%	Currently married or partnered (47.3%), high school education (68.8%)	Mean score = ?	Not reported
Medication Health Literacy measure (Stilley et al., 2014)	Medication health literacy = not defined. Based on health literacy = the degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.	Psychometric study (Stilley et al., 2014)	USA	Liver transplant recipients and diabetic patients of a transplant institute and community sites (ambulatory care)	55.6 y (SD = 9.0)	35.30%	White (94.1%), completed education > high school level (47.1%)	Not reported	Not reported
PTHL-SR (Ubavic et al., 2019)	Pharmacotherapy literacy = to obtain, evaluate, calculate and comprehend basic information about pharmacotherapy and pharmacy-related services necessary to make appropriate medication-related decisions, regardless of the mode of content delivery (e.g., written, oral, visual images and symbols).	Psychometric study (Ubavic et al., 2019)	Serbia	Parents, guardian or step-parent of preschool children (1–7 y), kindergarten	18–29 *y* = 5.7% 30–40 *y* = 75.3% 41–50 *y* = 15.3% 51–60 *y* = 3.8%	80.70%	Currently married (84%), higher level of education was university degree (53%), being employed (86.7%), non-smokers (70%), one's own health status perception as very good and excellent (22%), having 2 children (66%), breastfeeding of the first child up to 12 months (40.7%), absence of chronic diseases in children (87%)	Not reported	66.7%

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Table 2 (*Continued*).

Instrument	Construct definition (paraphrase)	Study design and references	Country	Study population and setting	Mean age (SD or min-max)[a]	Gender% female[a]	Others[a]	Score distribution[a]	Response rate
RALPH interview guide (Vervloet et al., 2018; Koster et al., 2018)	Health literacy = refers to the skills to obtain, process and apply health information needed to make appropriate health decisions (…). In the context of medication use, specific skills are required, e.g., skills to understand and apply the instructions on how to use the medication, to understand what the medication is for, and to know what its adverse effects can be. These specific skills are referred to as pharmaceutical literacy skills.	Psychometric study (Vervloet et al., 2018)	Netherlands	Participants (>18 y) who visited a community pharmacy to fill a prescription for themselves	?	?	?	Not reported	Not reported
		Psychometric study (Koster et al., 2018)	Netherlands	Participants (>18 y) who visited a community pharmacy to fill a prescription for themselves	67.6 y (SD = 15.2)	46.10%	Educational level: no formal/low (40.6%), middle (34.8%), high (20.1%), other (4.5%). Native origin (91%)	% of correct answers for functional domain = 74.7–95.9%, ease level regarding the communicative domain = 60.6–90.9% and critical domain = 36–64.7%. In addition to the critical domain: ability to search the information in reliable source = 70.1%	Not reported
ChMLM (Yeh et al., 2017)	Medication literacy = the ability to read, understand and process medication-related information.	Psychometric study (Yeh et al., 2017)	Taiwan	General population in the community (friends, relatives, neighbours and customers of pharmacies approached as potential participants)	42.2 y (SD = 16.5)	63.6%	College or graduate school (63.3%), income < 150,000 NTD (46.3%), speaking Chinese and Taiwanese frequently (47.7%)	Mean of correct answers = 13.0 (SD=2.8) (min-max = 0–17)	95%

Note. PWMILS, Pregnant Women's Medication Information Literacy Scale; MedLit-NSAID, Medication label literacy instrument focused on non-steroidal anti-inflammatory drugs; 20-item MedLitRxSE, Medication Literacy in Spanish and English (20 items); 14-item MedLitRxSE, Medication Literacy in Spanish and English (14 items); C-MLSHP, Chinese Medication Literacy Scale for Hypertensive Patients; MSU CAM, Montana State University complementary and alternative medicine Health Literacy Scale; PTHL-SR, Pharmacotherapy Literacy questionnaire; RALPH, Recognition and Addressing of Limited Pharmaceutical Literacy; ChMLM, Chinese medication literacy measure.

[a] Characteristics of the study population corresponding to the sample in which measurement properties were evaluated. When the medication literacy instrument was used to describe outcomes in another sample, the results were no longer considered.

Table 3
Summary of findings per instrument.

PROM/PerBOM	Development study	Content validity[a]										Structural validity			Internal consistency			Cross-cultural validity			Reliability			Construct validity					
		Relevance				Comprehensiveness			Comprehensibility															Convergent			Discriminant		
Instrument	Study reference	MQ	MQ	QM	Evidence[a]	MQ	QM	Evidence[a]	MQ	QM	Evidence[a]	MQ	QM	Evidence	MQ	QM	Evidence	MQ	QM	Evidence	MQ	QM	Evidence	MQ	QM	Evidence	MQ	QM	Evidence
Health literacy of pharmacy consumer questionnaire	(Emmerton et al., 2012)	I	D	+	Moderate	D	+	Moderate	D	+	Moderate																		
PWMILS	(Zhang et al., 2019)	I	I	+	Very low	I	–	Very low	I	+	Very low	A	±	NA	V	?	NA												
												V																	
MedLit-NSAID	(Jang et al., 2019)	I	I	+	Very low	I	–	Very low	I	+	Very low				D	?	NA						I	?		A	–	Moderate			
Medication Literacy Questionnaire for Discharged Patients	(Zhong et al., 2019)	Ø	D	+	Moderate	D	–	Moderate	D	+	Moderate				D	?	NA						D	?	NA						
20-item MedLitRxSE assessment tool	(Sauceda et al., 2003)	D	D	+	Moderate	D	+	Moderate	D	+	Moderate	V	+	High	I	?	NA												
14-item MedLitRxSE assessment tool	(Sauceda et al., 2003)	D	Ø	+	Low	Ø	+	Low	Ø	+	Low	D	+	Low	V	+	High	I	+	Very low							A	–	Low
	(Zheng et al., 2017; Zheng et al., 2019)											D			V								D	?	NA			
Literacy of Cold Medication labelling questionnaire	(Sayekti et al., 2018)	I	I	–	Very low	I	–	Very low	I	?	(NA)												D	+	Very low						
C-MLSHP	(Shi et al., 2019; Ma et al., 2019)	I	D	+	Moderate	D	+	Moderate	D	+	Moderate				D	?	NA						D	?	NA						
MSU CAM	(Shreffler-Grant et al., 2014)	I	D	+	Moderate	D	–	Moderate	D	+	Moderate	A	+	Moderate	V	–	High									I	±	NA	I	+	Very low
	(Weinert et al., 2019)														I								D	?	NA	I			I		
Medication Health Literacy measure	(Stilley et al., 2014)	I	I	+	Very low	I	–	Very low	I	+	Very low	A	+	Moderate	V	–	High												A	+	Low
PTHL-SR	(Ubavic et al., 2019)	D	D	+	Moderate	D	±	Moderate	D	+	Moderate				D	?	NA						D	+	Low						
RALPH interview guide	(Vervloet et al., 2018)	I	I	+	Very low	I	–	Very low	D	+	Moderate																				
	(Koster et al., 2018)																									D	?	NA			
ChMLM	(Yeh et al., 2017)	I	I	+	Very low	I	–	Very low	D	+	Moderate	D	?	NA	I	?	NA														

Note. PROM, patient-reported outcome measure; PerBOM, objective performance-based outcome measure; MQ, methodological quality per study; V, very good; A, adequate; D, doubtful; I, inadequate; NA, not applicable; QM, quality of measurement (summarised results across studies when possible); +, satisfactory results; -, unsatisfactory results; ±, inconsistent results; ?, indeterminate results; Evidence = quality of evidence, certainty in the findings. High quality of evidence = very confident that the true measurement property lies close to estimate. Moderate = moderately confident; there is a possibility that the estimate of the measurement property is substantially different. Low = confidence is limited. Very low = very little confidence. Downgrading the quality of evidence occurred in the case of (i) risk of bias (methodological flaws in the studies); (ii) inconsistency between studies, or between the study results and the subjective evaluation of the instrument by the researchers (only for content validity); (iii) imprecision, when the sample size was too small (applicable to internal consistency, reliability and construct validity). PWMILS, Pregnant Women's Medication Information Literacy Scale; MedLit-NSAID, Medication label literacy instrument focused on non-steroidal anti-inflammatory drugs; 20-item MedLitRxSE, Medication Literacy in Spanish and English (20 items); 14-item MedLitRxSE, Medication Literacy in Spanish and English (14 items); C-MLSHP, Chinese Medication Literacy Scale for Hypertensive Patients; MSU CAM, Montana State University complementary and alternative medicine Health Literacy Scale; PTHL-SR, Pharmacotherapy Literacy questionnaire; RALPH, Recognition and Addressing of Limited Pharmaceutical Literacy; ChMLM, Chinese medication literacy measure. Empty cells indicate that the measurement property was not evaluated or not reported.

[a] For content validity, the evaluation considered the results of content validity studies, together with the development study and the subjective researchers' rating of the instrument.

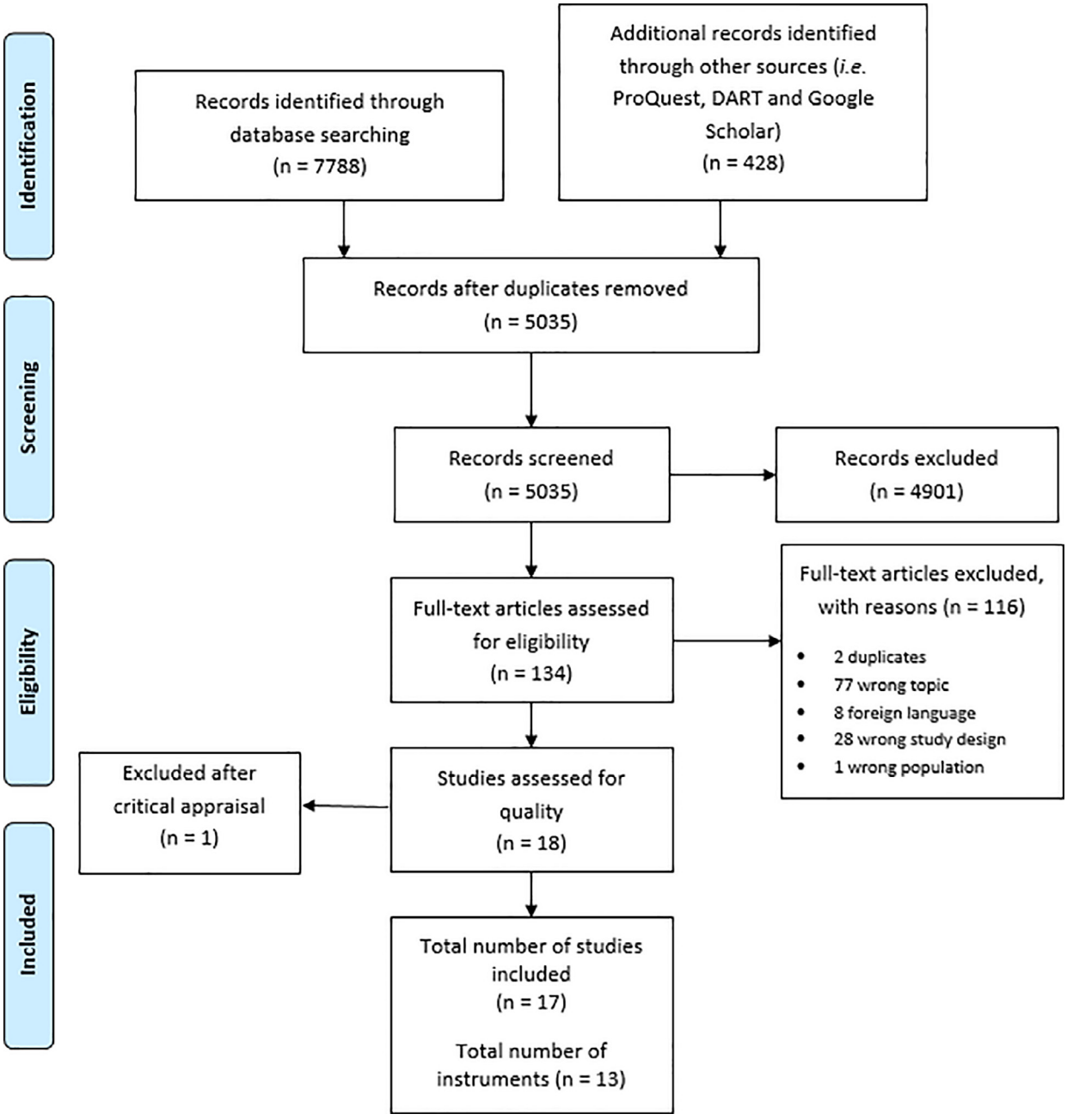

Fig. 1. Flow diagram of the study selection process.

NSAID (Jang et al., 2019) had an inadequate rating, as the statistics used appeared to be insufficient (i.e., weighted Kappa, unweighted Kappa or intraclass coefficient tests are preferred over t-testing or correlation analysis). For construct validity, consideration of correlations with demographic variables provides very limited evidence (Mokkink et al., 2018b). Thus, the research team decided to ignore the results reported in two studies (Yeh et al., 2017; Jang et al., 2019). Adequate methodological quality was found for the MedLit-NSAID (Jang et al., 2019), the 14-item MedLitRxSE (Sauceda et al., 2003) and the Medication Health Literacy measure (Stilley et al., 2014), as their studies provided sufficient information on comparator instruments and procedures such as the statistical method. For the Recognition and Addressing of Limited Pharmaceutical Literacy (RALPH) interview guide (Koster et al., 2018)), insufficient information was found about categorisation and a justification given in terms of an appropriate level of agreement, leading to a doubtful rating. All other studies failed to provide enough information on the comparator instrument in terms of justification or reporting of their measurement properties.

4.4. Quality of the results and evidence synthesis

The detailed information on study results and the quality of evidence, including reasons for downgrading, is available as supplementary material (Appendix C and D).

The content validity, taken together with the development study and the subjective researchers' rating of the instrument, showed overall satisfactory results for aspects on relevance and comprehensibility of most instruments, but less satisfactory results on aspects of comprehensiveness. The Literacy of Cold Medica-

tion labelling questionnaire (Sayekti et al., 2018) had unsatisfactory results on its relevance and comprehensiveness and indeterminate results regarding its comprehensibility, as the instrument was available only in Indonesian. For the research team, reading ability and word pronunciation, regardless of any other domain, are a reflection of literacy, not medication literacy. The results were supported by either moderate or very low-quality evidence, depending on the risk of bias in their studies, rated as being of doubtful or inadequate quality. For the 14-item MedLitRxSE, certainty in the findings was downgraded to "low," as the content validity was conducted only for its longer version, namely the 20-item MedLitRxSE (Sauceda et al., 2003), and not repeated for its shorter version.

Structural validity across studies was satisfactory for all, except for the Chinese medication literacy measure (ChMLM) (Yeh et al., 2017)), for which the results remained indeterminate because of not having enough information, and the PWMILS (Zhang et al., 2019)), for which the results were inconsistent because the exploratory factor analysis results were satisfactory but not those for the confirmatory factor analysis. High-quality evidence for satisfactory factor structure was found for the 20-item MedLitRxSE (Sauceda et al., 2003), while a serious risk of bias downgraded the quality of evidence to moderate for the MSU CAM (Shreffler-Grant et al., 2014) and the Medication Health Literacy measure (Stilley et al., 2014). For the 14-item MedLitRxSE, the developers of the instrument found satisfactory item response theory (Sauceda et al., 2003), but one cross-sectional study reported unsatisfactory confirmatory factor analysis (Zheng et al., 2017). In the latter, the authors failed to report complete results of the model fit, and thus the results from this study (Zheng et al., 2017) were ignored and the overall quality of evidence was downgraded for risk of bias and for inconsistency between studies. Furthermore, in the absence of structural validity (e.g., either not conducted or inconclusive results), the quality of internal consistency remained indeterminate for the PWMILS (Zhang et al., 2019), the MedLit-NSAID (Jang et al., 2019), the Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019) and the C-MLSHP. Similarly, the ChMLM (Yeh et al., 2017), the PTHL-SR (Ubavic et al., 2019) and the 20-item MedLitRxSE (Sauceda et al., 2003) failed to report alpha per subscale, also leading to an indeterminate rating. High-quality evidence for unsatisfactory internal consistency was found for the MSU CAM (Shreffler-Grant et al., 2014; Weinert et al., 2019) and the Medication Health Literacy measure (Stilley et al., 2014)), which reported alphas of < 0.7. Finally, the only instrument to reach high-quality evidence for satisfactory internal consistency was the 14-item MedLitRxSE with a Kuder-Richardson formula 20 of ≥ 0.7 (Sauceda et al., 2003; Zheng et al., 2017; Zheng et al., 2019).

For the remaining measurement properties, the cross-cultural validity of the 14-item MedLitRxSE (Sauceda et al., 2003) showed satisfactory results, namely non-significant differences between the English and Spanish language versions ($p = 0.13$), but the too-small sample size was considered an extremely serious risk of bias, downgrading the evidence to very low. For reliability, satisfactory results were found for two instruments, the PTHL-SR (Ubavic et al., 2019) with an intraclass coefficient of ≥ 0.7 and the Literacy of Cold Medication labelling questionnaire (Sayekti et al., 2018) with a Kappa of ≥ 0.7. These results are supported by low to very low-quality evidence, downgraded for imprecision because the sample size was not reported for one instrument and for very serious risk of bias for both instruments regarding the poor methodological quality of their studies. For all other instruments, reliability remained indeterminate (Zhong et al., 2019; Jang et al., 2019; Shi et al., 2019; Weinert et al., 2019; Zheng et al., 2017).

Finally, satisfactory discriminant validity was found for two comparator instruments, the REALM and the Single Question for Health Literacy Measure (Shreffler-Grant et al., 2014; Stilley et al., 2014; Weinert et al., 2019). These results are supported by low and very low quality of evidence regarding the risk of bias in the methodological quality of their studies and the imprecision related to samples that were too small in size (<100). For other instruments, the construct validity results remained inconclusive (Sauceda et al., 2003; Jang et al., 2019; Shreffler-Grant et al., 2014; Weinert et al., 2019; Koster et al., 2018).

5. Discussion

This systematic literature review identified 13 instruments to assess medication literacy or illiteracy, irrespective of the type of medication and the setting of use. To the best of our knowledge, this is the first systematic review to critically appraise the methodological quality and the results of the studies on instruments for medication literacy. It was conducted by applying extensive and standardised guidelines – the COSMIN methodology.

5.1. Best-validated instruments and recommendations

The unidimensional 14-item MedLitRxSE (Sauceda et al., 2003) is currently the only instrument recommended as suitable for assessing medication literacy in adult care recipients, including their informal caregivers. The results provided for this instrument are valuable with satisfactory content validity, structural validity and internal consistency, but indeterminate reliability. Satisfactory results on the differential of item functioning calculation, namely cross-cultural validity, underlines that this instrument could be used either in its original English version or the Spanish version. However, its discriminant validity against the TOFHLA showed unsatisfactory results. It appeared that both correlates were higher than expected. Therefore, the construct validity of this instrument needs further investigation with probably a better theoretical justification of patterns of inter-correlations with other comparator instruments. In terms of feasibility and interpretability aspects, as this assessment is based on four hypothetical scenarios about certain types of medication (i.e., injectable medication, paediatric non-prescription dose, medication for fever, tablets, and active ingredients on a non-prescription product), the MedLitRxSE could have a limited scope of applicability in practice. Nevertheless, the certainty in the findings are supported by low- to very low-quality evidence (except for internal consistency, which is supported by high-quality evidence), indicating that it is likely that further research could have an important impact on the study results and may change them (Prinsen et al., 2018).

Other instruments identified in this review have potential for recommendation, but at their current stage of development, they require complementary studies to further investigate their quality. The broader content coverage of the C-MLSHP (Shi et al., 2019) and the health literacy of pharmacy consumer questionnaire (Emmerton et al., 2012), as well as the satisfactory results for the content validity of the PTHL-SR (Ubavic et al., 2019) and the MedLit-NSAID (Jang et al., 2019), provide a good basis for further psychometric analysis of these instruments. Complementary content validity studies should include the systematic involvement of members of the target population, with a particular focus on the evaluation of comprehensiveness (i.e., exhaustiveness). This would improve the quality of content validity by providing measures that address the full range of domains of the medication literacy construct. The PWMILS (Zhang et al., 2019), the ChMLM (Yeh et al., 2017), the RALPH interview guide (Vervloet et al., 2018; Koster et al., 2018) and the Medication Literacy Questionnaire for Discharged Patients (Zhong et al., 2019) provided inconclusive evidence and thus more studies must be conducted. With respect to the Literacy of Cold Medication labelling questionnaire

(Sayekti et al., 2018), which had unsatisfactory results for its content validity, it is likely that a conceptual revision would be necessary prior to any further testing.

Finally, in their current state, the MSU CAM (Shreffler-Grant et al., 2014; Weinert et al., 2019) and the Medication Health Literacy measure (Stilley et al., 2014) showed high-quality evidence of unsatisfactory internal consistency, and thus they cannot be recommended as suitable to assess medication literacy. The internal consistency of the MSU CAM (Shreffler-Grant et al., 2014; Weinert et al., 2019) presented satisfactory results for the total scale, but not when the subscales were considered, while the Medication Health Literacy measure (Stilley et al., 2014) had overall low alphas. As certainty in the findings is high, additional testing is very unlikely to change the confidence in these results (Prinsen et al., 2018). For these instruments, revision of their content should be considered. For instance, developing more items for the Medication Health Literacy measure (Stilley et al., 2014), which comprises only six items for a three-factor structure, could be beneficial prior to future testing of its dimensionality and internal consistency. Additionally, several instruments of medication literacy were not critically appraised during this systematic review, as their measurement properties were not evaluated, not reported or in other languages (Horvat et al., 2018; O'Neal et al., 2013; Calamusa et al., 2012; Sahril et al., 2012). Psychometric studies for these instruments are deem necessary prior to recommend their use in research and practice.

This systematic review aimed to identifying all instruments for medication literacy, regardless of the context of use. However, an important issue in using the same instrument in different clinical settings is the reliability. Reliability is not a fixed property of a test; it can vary depending on the characteristics of the group completing it, and the circumstances under which it is filled out (Streiner et al., 2015). Reliability studies help to estimate the influence of different sources of variation on scores, such as the time or occasion when the measurement was taken, the instructions that were given to patients, the type of device or the settings that were used (Mokkink et al., 2018b). High quality studies on measurement error and reliability of existing medication literacy instruments are needed in different healthcare settings, and different populations. Importantly, comparing people from different countries and different sociocultural groups require reliable and valid version of the instrument. A necessary assumption when comparing individual differences towards an underlying construct of interest is that the items quantifying the construct function in the same way across samples from different cultures or languages (Beckstead et al., 2008). Therefore, sufficient evidence concerning the quality of measurement properties of instruments in their original language must be available prior to evaluate the performance of the items in a translated or culturally adapted version. This review underlines that medication literacy lacks a robust theoretical foundation. For example, the included studies used a variety of definitions that were sometimes incomplete or even inadequate when referring to health literacy, and no instrument referred to a conceptual framework or a theory, except for the MSU CAM (Shreffler-Grant et al., 2013). Across publications several core skills are widely admitted to be defining attributes of medication literacy (i.e. to understand information, to find it to calculate), while others appear more ambiguous (i.e., reading skills, the ability to interpret information, apply it and follow through instructions). Consequently, most of the included instruments remain conceptually narrow and mostly focus their assessment on the ability to recall and understand information, find it, interpret it, critically analyse its reliability, and calculate dosages. Only a few instruments evaluate reading ability, the way that individuals process the information, or the ability to communicate, take action or effectively follow a prescription. In accordance with mainstream health literacy studies, future development of these instruments should seek a more comprehensive assessment of medication literacy, including *interactive* and *critical literacy* (Nutbeam et al., 2018). This is congruent with previous studies on instruments for health literacy and medication literacy, highlighting the contradiction between a widespread call for more comprehensive instruments and dependence on functional literacy measurement (Nutbeam et al., 2018; Altin et al., 2014; Pantuzza et al., 2020).

One of the greatest threats to content validity is an unclear conceptual match between the items of an instrument and the definition of the construct. A recent scoping review (Pantuzza et al., 2020) provide an overview of the definitions for medication literacy and its evolution. To date, the general definition of medication literacy proposed by Pouliot et al. achieved through a Delphi process including international experts, is the most comprehensive and elaborate one (Pouliot et al., 2018). However, given the requirements and the specific tasks involved with appropriately and successfully consuming medications, to group all populations and healthcare environments under a single umbrella definition of medication literacy is inappropriate. Medication literacy is influenced by a broad range of personal, educational, cultural and social factors, which are in turn influenced by healthcare interactions, such as the way services are organized and delivered (e.g., how easily educational materials and communication may be understood and followed) (Raynor, 2009; King et al., 2011). It is therefore warranted to further develop this definition and provide clinicians and researchers with a more operational one, adjusted for the population of interest and a particular healthcare context. Concept development is especially useful when studying vague concept. It can be defined as the dissection of a concept into simpler elements (i.e. attributes, antecedents, consequences) to promote clarity while providing mutual understanding within healthcare professionals (Schwartz-Barcott and Kim, 2000). In concept development, theoretical analysis of the literature and the analysis of the empirical data are combined to refine the concept of interest, including a description of its nomological network, namely its surrogate terms and how medication literacy is conceptually related to other concepts (Tay and Jebb, 2017). The findings are very useful for developing a new instrument or a way to examine existing ones.

The complexity of the medication literacy construct does, however, raise the question of the applicability of comprehensive measures. Drawn from health literacy research, the development of a universal measure that can be applied to diverse populations is proving to be very challenging (Jordan et al., 2011; Haun et al., 2014). Thus, it seems of utmost importance that during future development of these instruments, researchers justify their content domains, as well as their administration method based on a clear rationale. For instance, multiple factors may interfere with the level of older individuals' performance, such as decline in attention, working and prospective memory, and executive functions (Stilley et al., 2010; Elliott et al., 2015). In addition, poor vision has been shown to be associated with worse medication management (Advinha et al., 2017; Leat et al., 2016). Thus, tailored medication literacy instruments that assess the ability to read and to remember, using an objective performance-based outcome measure, could be more important in older individuals. This is congruent with previous health literacy studies that underline the importance of considering hearing and/or visual limitations, cognitive impairment and language barriers in measurement instruments (Findley, 2015) and of specifically developing instruments for older individuals (Chesser et al., 2016). From the same perspective, medication literacy instruments tailored to individuals with cumulative chronic diseases and/or more complex medication regimens remain a significant shortfall. As these individuals deal with different and often difficult medication-related information and messages coming from various sources (Ng et al., 2017), generic measures that use

their own prescribed medication regimens (versus hypothetical) while also taking into account newly introduced medicines and/or prescription changes may be more accurate.

5.2. Limitations

This review was subject to some limitations. First, the literature search was restricted to studies written in English and French, and therefore studies in other languages could not be included (Horvat et al., 2018). To be as exhaustive as possible with this limitation, we considered a large panel of electronic sources to locate unpublished work, such as ProQuest, DART and Google Scholar. Moreover, 10 authors were contacted directly to find further relevant studies or to obtain additional information, although not all of them replied. The lack of good reporting of primary studies is a problem when conducting a systematic review, and to date reporting guidelines for studies on measurement properties are scarce (Mokkink et al., 2016; Streiner and Kottner, 2014).

Second, medication literacy appears to be closely related to other concepts, such as *medication understanding, medication knowledge, medication self-management* and *medication capacity*, for which several instruments already exist (e.g., Hopkins Medication Schedule, Drug Regimen Unassisted Grading Scale, Medication Administration Task, Self-medication Assessment Tool, Medication Management Performance Evaluation) (Advinha et al., 2017; Farris and Phillips, 2008; Elliott and Marriott, 2009). These instruments were not included, but several of them seem conceptually relevant (i.e., similar domains to medication literacy).

6. Conclusion

This systematic review identified a paucity of instruments that measure medication literacy in adult care recipients. None of these instruments have had all measurement properties properly assessed and none of the studies identified reported measurement invariance, measurement error and responsiveness of the instruments. Amongst the 13 instruments identified, the best-validated was the 14-item MedLitRxSE (Sauceda et al., 2003). It has, however, a limited scope of applicability in practice. For other instruments, findings showed limited psychometric soundness. Further research is necessary for a better theoretical understanding of medication literacy in order to assist health professionals in identifying patient needs for education, regimen simplification, assistance and/or medication aids. This research will help conceptualise new instruments that not only cover relevant domains dedicated to specific populations (e.g., polymorbid and/or older individuals), but also exhibit satisfactory measurement properties.

Conflict of Interest

None

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijnurstu.2020.103785.

CRediT authorship contribution statement

Jenny Gentizon: Conceptualization, Formal analysis, Writing - original draft. **Julian Hirt:** Formal analysis, Validation. **Cécile Jaques:** Resources, Investigation. **Pierre-Olivier Lang:** Conceptualization, Writing - review & editing. **Cedric Mabire:** Supervision, Validation, Writing - review & editing.

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