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Health Literacy and Health Outcomes in Patients with Low Back Pain – A Scoping Review

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Abstract:	<p>BACKGROUND: Low back pain is a leading cause of disability worldwide. Health literacy has been associated with pain intensity and pain control. However, there is a paucity of evidence regarding this association. In the field of low back pain research, inconsistent reporting of outcomes has been highlighted. To address this issue a Core Outcome Set has been developed.</p> <p>OBJECTIVES: The objectives of this scoping review were:</p> <ol style="list-style-type: none"> 1) The health literacy measures currently employed for low back pain and the aspects of health literacy they include. 2) The low back pain health outcomes included in such work. 3) The extent to which these health outcomes reflect the Core Outcome Set for Clinical Trials in Non-Specific Low Back Pain. <p>METHODS: The search included thirteen bibliographic databases, using medical subject heading terms for low back pain and health literacy, and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guidelines. The eligibility criteria were defined by the Joanna Briggs Institute PCC mnemonic. A thematic framework approach was used for analysis.</p> <p>RESULTS: The search yielded ten relevant studies for inclusion, amongst which a total of nine health literacy measures and 50 health outcome measures were used. Most health literacy measures focused on functional health literacy, with few assessing communicative and critical health literacy. The health outcomes assessed by the included studies could be broadly categorised into: Pain, Disability, Behaviour, Knowledge and Beliefs, and Resource Utilisation. Most of these outcome measures studied (36 out of 50) did not directly reflect the Core Outcome Set for Clinical Trials in Non-Specific Low Back Pain.</p> <p>CONCLUSIONS: To allow for comparison across findings and the development of a rigorous evidence base, future work should include the Core Outcome Set for Clinical Trials in Non-Specific Low Back Pain. There is an urgent need to broaden the evidence-base to include regions where low back pain morbidity is high, but data is lacking. Such work demands the incorporation of comprehensive measures of health literacy that have both generic and culturally sensitive components.</p>
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1 **Health Literacy and Health Outcomes in Patients with Low Back Pain – A**
2 **Scoping Review**

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Abstract

BACKGROUND: Low back pain is a leading cause of disability worldwide. Health literacy has been associated with pain intensity and pain control. However, there is a paucity of evidence regarding this association. In the field of low back pain research, inconsistent reporting of outcomes has been highlighted. To address this issue a Core Outcome Set has been developed.

OBJECTIVES: The objectives of this scoping review were:

- 1) The health literacy measures currently employed for low back pain and the aspects of health literacy they include.
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METHODS: The search included thirteen bibliographic databases, using medical subject heading terms for low back pain and health literacy, and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews guidelines. The eligibility criteria were defined by the Joanna Briggs Institute PCC mnemonic. A thematic framework approach was used for analysis.

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CONCLUSIONS: To allow for comparison across findings and the development of a rigorous evidence base, future work should include the Core Outcome Set for Clinical Trials in Non-Specific Low Back Pain. There is an urgent need to broaden the evidence-base to include regions where low back pain morbidity is high, but data is lacking. Such work demands the incorporation of comprehensive measures of health literacy that have both generic and culturally sensitive components.

Keywords: Core Outcome Set, Health outcomes, Chronic Pain, Disability, Musculoskeletal conditions

82 **1. Background**

1
2 83 Low back pain (LBP) is the single leading cause of disability globally and is rising (1,2). In
3
4 84 2017, the point prevalence of LBP was estimated to be 7.5% the global population, or
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6
7 85 approximately 577 million people (3). Financial costs from LBP are estimated to be in the
8
9 86 order of billions of US dollars (USD) (2,4), while the economic burden of members of the
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11 87 workforce suffering from LBP is estimated in the USA alone to be USD 7.4 billion/year (5).
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13 88 Traditionally conceptualised as solely secondary to mechanical injury, LBP is now described
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15 89 within a bio-psychosocial model, resulting from an interaction of physical, psychological and
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17 90 social influences (6). Risk factors for LBP include an older age, increased psychological or
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19 91 psychosocial stress, a lower socioeconomic status, and a lower educational status (7,8).
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27 93 Effective self-management is crucial to improving LBP outcomes (9,10). Studies have also
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29 94 demonstrated the need to focus on health literacy (HL) in order to develop effective patient
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31 95 education materials and/or patient resources to support self-management in such patients
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33 96 (11,12). The concept of HL is extensive and incorporates functional, communicative and
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35 97 critical domains (13). It is defined as “the achievement of a level of knowledge, personal
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37 98 skills and confidence to take action to improve personal and community health by changing
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39 99 personal lifestyles and living conditions” (14). At its core is an observable set of skills that
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41 100 can be developed and improved through effective communication and education to enhance
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43 101 autonomy and empower people to make decisions relating to their health and changing
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45 102 circumstances (14,15). At the inaugural Outcome Measures in Rheumatology Clinical Trials
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47 103 (OMERACT) Health Literacy Special Interest Group workshop, 16 themes at the micro,
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49 104 meso and macro level were identified, including cognitive capacity, access to information,
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51 105 and health systems (16). Independent of other socio-demographic factors, low HL is
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53 106 associated with higher mortality amongst older people, poorer health outcomes, and higher
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107 morbidity (17–19). On the other hand, higher HL is linked to lower pain intensity and better
108 pain control among those with chronic pain (1,20).

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110 Despite the need for a stronger evidence base in LBP management, inconsistent reporting of
111 outcomes in clinical trials of patients with LBP has been highlighted (21). This potentially
112 hinders the comparison of findings across studies and the reliability of systematic reviews. To
113 address this issue a Core Outcome Set (COS) has been developed, led by an International
114 Steering Committee, defining the minimum set of outcomes that should be reported in all
115 clinical trials. The COS includes 'physical functioning', 'pain intensity', 'health-related quality
116 of life' and 'number of deaths' (22).

117
118 There also exists a paucity of research to underpin evidence-based practice of LBP treatment
119 in low- and middle-income countries (LMIC) (23,24). This is a substantial knowledge gap
120 given the significance of LBP in LMICs. Asia alone has the largest number of LBP disability-
121 adjusted life years internationally and the highest risk of occupational LBP is in the
122 agricultural sector – a major sector in Asian economies (25). Existing evidence tends to be
123 from high income countries and cannot be accurately applied to the LMIC context, given that
124 pain reporting, manifestation and management is influenced by socio-cultural and genetic
125 factors (26).

126
127 To develop more evidence-based interventions and guidelines we need to better understand
128 the relationship between HL and LBP outcomes. An initial scoping search of the literature
129 was conducted to assess whether reviews and guidelines on this topic have already been
130 published and what was lacking. This only yielded a single systematic review by Edward et
131 al. in 2018 on the impact of HL on LBP management. The study identified only three relevant

132 studies, all of which were based in high income Western nations. However, the authors of the
133 review acknowledged “possible incomplete retrieval of identified research and reporting
134 bias” (27) as the search was limited to four bibliographic databases and limits were also
135 placed on year of publication, language, and article formats, amongst other search filters (27).

136
137 This scoping review builds on Edward et al.’s work and had three objectives. These were to
138 methodically map evidence on:

- 139
140 1. The health literacy measures currently employed for low back pain and the aspects
141 of health literacy they include.
- 142 2. The low back pain health outcomes included in such work.
- 143 3. The extent to which these health outcomes reflect the Core Outcome Set for
144 Clinical Trials in Non-Specific Low Back Pain.

145
146 Scoping reviews are used instead of systematic reviews where the purpose of the review is to
147 identify knowledge gaps, scope a body of literature, clarify concepts or to investigate
148 research conduct (28). This methodology was chosen in the light of the paucity of existing
149 literature and to reflect and build from the limitations encountered in the work of Edward et
150 al. (27). To do so, this scoping study expanded the search from four to 13 bibliographic
151 databases and did not utilise search limiters or filters such as time or language filters. Unlike
152 the systematic review carried out by Edward et al. (27), this study is a scoping review with
153 the emphasis on identifying the variety of HL and LBP outcome measures employed in
154 existing literature, rather than reporting the degree of association between HL and LBP health
155 outcomes. The aim in doing so is to provide a critique on the choice of outcomes studied and
156 measures used, and to identify implications for future research.

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158 **2. Materials and Methods**

159 **2.1 Literature Search strategy**

160 The searches were conducted in: MEDLINE, Pubmed, Academic Search Complete, The
161 Cumulative Index to Nursing and Allied Health Literature, Education Source, Education
162 Resource Information Centre, PsycINFO, Global Health, Embase (Ovid), Web of Science,
163 Cochrane, Google Scholar, and ClinicalKey.

164
165 MeSH (medical subject heading) terms used included: *Back Pain, Back Ache, Back Pain with*
166 *Radiation, Back Pain without Radiation, Backache, Vertebrogenic Pain Syndrome, Low Back*
167 *Pain, Low Back Ache, Low Back Pain Mechanical, Low Back Pain Posterior Compartment,*
168 *Low Back Pain Postural, Low Back Pain Recurrent, Low Backache, Lower Back Pain,*
169 *Lumbago, Mechanical Low Back Pain, Postural Low Back Pain, Recurrent Low Back Pain.*

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171 The MeSH term used to search for HL was *Health Literacy*. No additional search filters were
172 applied. See Appendix 1 for an example of a search strategy. The search was conducted in
173 August 2019. It was updated in February 2021, reflecting the peer-review process in the
174 context of COVID-19, and no additional studies were identified as meeting the inclusion
175 criteria.

176
177 The search strategy was developed in consultation with the library team at the University, as
178 well as expert opinion within the research team, which consisted of a range of expert
179 researchers and clinicians (29). This included BB (social sciences, primary care research,
180 musculoskeletal research, patient perspectives and health literacy), HES (primary care
181 clinician, health services research, evidence-based medicine), LTC (primary care clinician,

182 health services research, evidence-based medicine, and systematic reviews) and JP (primary
183 care clinician, musculoskeletal conditions, health services research and health literacy).

184

185 **2.2 Inclusion and Exclusion criteria**

186 **Table 1. here**

188 The Joanna Briggs Institute (JBI) manual's PCC mnemonic (30) was used to clarify the
189 research focus in formulating the inclusion and exclusion criteria (Table 1):

- 190 • Population – Patients with LBP ($\geq 10\%$ of study population), of any age, gender, or race
- 191 • Concept – Relationship of LBP health outcomes to HL
- 192 • Context – Any healthcare setting, in any geographical setting

193
194 Only research studies were included in this scoping review as the objectives of this study
195 focused on measures used in LBP research. Hence other sources of evidence (e.g. grey
196 literature, policy documents, expert opinions, guidelines) were not included. In addition,
197 studies for inclusion required the use of specific HL and health outcome measures. Studies
198 were excluded if they only analysed generic literacy, numeracy, and education level not in the
199 context of healthcare. Generic patient education interventions have the potential to influence
200 non-HL related determinants of LBP, hence drawing conclusions about HL's effects on LBP
201 from these studies may be inaccurate (31), and for this reason these studies were excluded.

203 **2.3 Study selection, data extraction and analysis**

204 The search strategy followed the Preferred Reporting Items for Systematic Reviews and
205 Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines (32). An
206 independent review of titles and abstracts from the initial search was conducted by two
207 reviewers (CS and WWC). Any discrepancies were resolved through discussion between

208 reviewers, with a third reviewer (HES) included when necessary. However, no discrepancies
209 which could not be resolved between reviewers were encountered. Studies then underwent a
210 full-text review if they investigated a relationship between HL and LBP outcomes.

211

212 Data extraction included determinants of HL (age, gender, race, and education level) (33),
213 study design, and types of measures used. Thematic analysis as advocated by Levac et al.
214 (34) was done by adopting a framework analysis approach (35,36). The health outcomes used
215 were collated and coded into descriptive themes, and then grouped into overarching
216 categories. These categories were then mapped against the Core Outcome Set for Clinical
217 Trials in Non-Specific Low Back Pain (22), namely 'physical functioning', 'pain intensity',
218 'health-related quality of life' and 'number of deaths'. The HL measures used were categorised
219 according to their validated component of HL, or if absent, the intention of that specific
220 study. This was done using the classification proposed by Nutbeam, namely functional,
221 communicative and critical HL (37,38). The components of this classification have a graded
222 order of complexity, functional HL being the most basic, and critical HL being the most
223 advanced (37). Functional HL encompasses basic skills in reading and writing, which are
224 important for instance in understanding prescriptions or medicine labels. Communicative HL
225 includes social skills and advanced cognitive and literacy skills to actively participate in daily
226 activities. It is important for example in building up rapport with a social support group. It is
227 also crucial in the doctor-patient relationship, as evidenced by HL tools such as Teach Back
228 aiming to facilitate this (39). Critical HL comprises the use of even more advanced cognitive
229 and social skills to exert great control over life events and situations. An example of
230 operationalising critical HL is organising social advocacy health promotion within
231 communities, to enable and empower individuals to 'judge, sift and use' health information in
232 the context of their own lives and social worlds (40).

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2 234 As this was a scoping review, grading of evidence was not conducted. Instead, this study
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5 235 followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension
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7 236 for Scoping Reviews (PRISMA-ScR) guidelines (32), as detailed in Appendix 2.
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11 12 238 **3. Results**

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14 239 **Figure 1.** Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow
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17 240 diagram of the literature review.
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24 243 The initial search yielded 5509 articles. After removing duplicates and reviewing titles and
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26 244 abstracts, 18 articles remained for full-text review. Ten of these were included in the final
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29 245 analysis (Figure 1). The key excluded sources with rationale for their exclusion are listed in
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32 246 Appendix 3. Both 2010 and 2011 papers by Briggs et al. (10,41) were included and recorded
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34 247 as separate studies, as each publication studied different HL measures.
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46 252 Despite no restrictions being placed on the year of publication, all studies meeting the
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49 253 inclusion criteria were published in 2010 or later, and were all cross-sectional in design
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51 254 (Table 2). They utilised structured questionnaires, apart from one mixed methods study which
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54 255 also used interviews. In terms of country of origin, two studies were conducted in Australia,
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56 256 four in the United States of America, three European studies across four centres (Germany,
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58 257 Austria, Switzerland and Italy), one in Saudi Arabia. Five of the cross-sectional studies solely
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5 258 studied patients with LBP, while the other five studies included LBP as a significant portion
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7 259 of their patient population (>10%), one of which provided a subpopulation analysis of
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9 260 patients with LBP.
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12 262 All ten studies focused on adult populations (≥ 18 years) and had a majority female
13 263 population, with one study having entirely female participants. Racial break-down was only
14 264 provided by two USA studies, both of which had predominantly white study populations.
15 265 Nine studies collected data on education level, most reporting an even spread across
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32 271 33 34 272 **3.3 Summary of HL measures used** 35

36 273 Nine different HL measures were used across the ten studies (Table 3). Most HL measures
37 274 assessed functional HL, while the number that evaluated communicative and critical HL were
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39 275 fewer than half (Table 4).
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46 277 In their 2010 paper, Briggs et al. (10) used the Short-form Test of Functional Health Literacy
47 278 in Adults (S-TOFHLA), which comprises of two prose passages and four items testing
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49 279 numeracy. It is a validated assessment of functional HL with good internal reliability -
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51 280 Cronbach's alpha 0.68 for the 4 numeracy items (42) and 0.97 for the reading comprehension
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53 281 items (13,42,43). Spearman's correlation coefficient between the S-TOFHLA and the Rapid
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55 282 Estimate of Adult Literacy in Medicine (REALM) was 0.80 (42). Briggs et al. (10) also used
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3 283 telephone interviews to assess HL by asking participants on how they sought, understood and
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5 284 utilised LBP information.
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9 286 Subsequently in their 2011 paper, Briggs et al. used the Health Literacy Measurement Scale
10 287 (HeLMS) (41), a psychometrically tested tool with good internal consistency (Cronbach's
11 288 alpha > 0.82), and validity (confirmatory factor analysis showing good fit for seven domains
12 289 and moderate fit for one) (44). It goes beyond functional HL to include communication
13 290 skills, computation skills, and social support, thereby overcoming limitations of the S-
14 291 TOFHLA (41,45,46). The HeLMS sets out to assess "overall capacity to seek, understand and
15 292 use health information within the healthcare setting" by asking questions such as "Are you
16 293 able to see a doctor when you need to?" (41). By doing so it attempts to assess all three
17 294 domains of health literacy: functional, communicative, and critical.
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32 296 The Newest Vital Sign (NVS) was the most frequently used HL measure (Table 3), utilised
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34 297 by Devraj, Herndon and Griffin, Al-Eisa, Buragadda and Melam, and Glassman et al.
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36 298 (12,47,48). The NVS is convenient to use and has a sensitivity equivalent to the TOFHLA for
37 299 identifying inadequate HL – with an area under the ROC curve (AUROC) of 0.88, using the
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39 300 TOFHLA as the gold standard (42). It is reported to have a Cronbach's alpha of 0.76 (42,49),
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41 301 and is a widely used assessment of functional HL, with six questions regarding a standardised
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43 302 ice cream nutrition label (50).
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52 304 Farin, Ullrich and Nagl developed the HELP questionnaire (Health Education Literacy of
53 305 Patients with chronic musculoskeletal diseases), an 18-item assessment that aims to
54 306 summarise a patient's reported communication and comprehension difficulties in health
55 307 education and treatment (11). The questions were classified as "comprehension of medical
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308 information” (assessing functional HL), “communicative competence in provider
309 interactions” (assessing communicative HL), and “applying medical information” (assessing
310 critical HL). Questions such as “How much difficulty did you have communicating your own
311 expectations and wishes in terms of your therapy?” were scored on Likert scales anchored
312 from 1 to 5, with lower values indicating a higher HL. The resulting questionnaire’s
313 psychometric properties were deemed to be good (Cronbach’s alpha 0.88 to 0.95,
314 unidimensionality and Rasch model fit established) (11).

315
316 Camerini and Schulz (51) interpreted HL based on scores from the Low Back Pain
317 Knowledge Questionnaire (LKQ). The Questionnaire involved multiple-choice questions on
318 topics such as the aetiology and management of LBP. Although the LKQ did not set out to be
319 a direct measure of HL, its focus was on declarative and procedural knowledge which
320 Camerini and Schulz argued to be acquired using functional HL (51). Hence the LKQ was
321 used as a surrogate measure of functional HL. The LKQ was assessed with both intra-
322 observer and inter-observer reproducibility (Spearman's correlation coefficient and intra-class
323 correlation coefficient ranging from 0.61 to 0.95) and internal consistency (Cronbach’s alpha
324 ranging from 0.71 to 0.77) (52).

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326 Measurement of functional HL alone is also seen in other studies. Burke, Nahin and
327 Stussman used the response option “Never heard of it/Do not know much about it” from the
328 National Health Interview Survey, arguing that this serves as an indicator of health
329 knowledge which in turn is a correlate of functional HL (53). MacLeod et al. used a validated
330 single-item screener “How confident are you filling out medical forms by yourself?” as a
331 measure of functional HL (54). This had an AUROC of 0.82 for detecting limited HL, and

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3 332 0.79 for detecting limited or marginal HL, when referenced against the REALM functional
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5 333 HL measure (55).

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9 335 Köppen et al. used HL questions taken from the Brief Questions to Identify Patients with
10 336 Inadequate Health Literacy (20), a screening tool for functional HL validated against the S-
11 337 TOFHLA (56). These included the questions “how often do you have someone help you read
12 338 hospital materials” (AUROC 0.87), “how confident are you filling out medical forms by
13 339 yourself” (AUROC 0.80) and “how often do you have problems learning about your medical
14 340 condition because of difficulty understanding written information?” (AUROC 0.76) (20,56).
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24 342 In addition to the NVS mentioned above, Glassman et al. also used The Health Literacy
25 343 Assessment, a 10-item self-administered questionnaire using items selected from the
26 344 computerized Health LiTT measure (47). The Health Literacy Assessment (Health LiTT) is a
27 345 validated tool for functional HL that reportedly meets or exceeds psychometric standards,
28 346 with good reliability (Cronbach’s alpha 0.83–0.91) and good evidence for unidimensionality
29 347 (correlation of 0.90–0.95 on confirmatory factor analysis) (57). It assesses HL via three
30 348 sections: Prose, Document and Quantitative (57). The Prose section asks participants to fill in
31 349 missing words in a cloze test passage, while the Document section consists of multiple-choice
32 350 questions regarding images such as a prescription label. The Quantitative section also uses
33 351 multiple-choice questions requiring arithmetic computation.
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52 353 **Table 5 here.**
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56 355 **3.4 Summary of LBP outcomes retrieved from included studies**
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5 358 HL was associated with a wide range of outcomes (Table 5). Five overarching categories
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7 359 summarising the studied LBP health outcomes were identified via framework method
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9 360 analysis (35,36):
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- 12 361 ○ Pain
- 13 362 ○ Disability
- 14 363 ○ Behaviour
- 15 364 ○ Knowledge and Beliefs
- 16 365 ○ Resource Utilisation
- 17 366
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22 365 **3.4.1 Pain**

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24 366 Seven studies involved data on pain (10,12,20,41,47,48,51), using eight different measures
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26 367 (Table 5). Pain intensity was the most frequently measured aspect, with three studies (Briggs
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28 368 et al., Briggs et al., Glassman et al.) using the Numerical Rating Scale and two (Devraj,
29
30 369 Herndon and Griffin, Köppen et al.) using the Visual Analogue Scale (Table 5). Pain
31
32 370 intensity was also quantified as a sub-component of the Chronic Pain Grading (51), the Short-
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34 371 form McGill Pain Questionnaire (20), the Oswestry Disability Index (ODI) (10,41,47,48),
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36 372 and the Euro-QOL5D (47). In addition, the Short-form McGill Pain Questionnaire assesses
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38 373 the nature of pain (58), while other studies looked at pain duration and frequency (10,20).
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41 375 **3.4.2 Disability**

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43 376 Five studies involved data on disability (10,41,47,48,51). Four studies (Briggs et al., Briggs et
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45 377 al., Glassman et al., Al-Eisa, Buragadda and Melam) used the ODI, a spinal disorder-specific
46
47 378 measure of disability which quantifies the difficulty faced in areas such as personal care,
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49 379 movements (e.g. lifting, walking, sitting), and lifestyle (e.g. sex life, travel) (59).
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51 380 Additionally, Glassman et al. (47) used the Euro-QOL5D (EQ-5D) which, in addition to
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1 381 mobility, self-care and activities of daily living, also screens for anxiety and depression. Both
2 382 of Briggs et al.'s studies (10,41) supplemented the ODI with an assessment of disability by
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4 383 asking participants on the amount of intrusion one faces in daily and recreational activities.
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7 384 Lastly, the Chronic Pain Grading Scale also asks about functionality using questions such as
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10 385 "In the past 3 months, how much has this pain interfered with your daily activities (e.g.
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12 386 getting dressed, doing shopping)" (51).
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16 388 **3.4.3 Behaviour**

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19 389 Five studies collected data on patient behaviours (10,41,48,51,53), involving five forms of
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22 390 health outcome measures (Table 5). The Fear Avoidance Beliefs Questionnaire was most
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24 391 commonly used (10,41,48), and asks participants how much they think areas of physical
25
26 392 activity and work would affect their LBP (60). Briggs et al. (10,41) assessed pain
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29 393 catastrophizing with the Coping Skills Questionnaire. Camerini and Schulz (51) assessed
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31 394 patient empowerment and involvement with two scales, the Psychological Empowerment
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34 395 Scale and Modified Patients' Perceived Involvement in Care Scale respectively. Burke,
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36 396 Nahin and Stussman (53) studied the association between HL and health behaviours such as
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39 397 physical activity level and smoking status.
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43 399 **3.4.4 Knowledge and Beliefs**

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46 400 Four studies gathered data on patient knowledge and beliefs (15,16,17,25), utilising five
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48 401 different health outcome measures. Briggs et al. (10,41) used the Back Pain Beliefs
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51 402 Questionnaire, which consists of 14 questions exploring beliefs regarding issues such as the
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53 403 management and prognosis of back trouble (61). They also conducted telephone interviews to
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56 404 understand participant's beliefs regarding the aetiology and course of their LBP. MacLeod et
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58 405 al. (54) used the Modified Consumer Assessment of Healthcare Providers and Systems
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406 survey to assess patient dissatisfaction in areas such as general healthcare and doctors. Farin,
407 Ullrich and Nagl (11) used a single-item measure - “How would you rate your health?” to
408 evaluate participant beliefs on their health status. Finally, Devraj, Herndon and Griffin (12)
409 developed a 12-item survey based on pre-existing pain guidelines and literature to assess the
410 pain awareness and medication knowledge of their participants.

411 412 **3.4.5 Resource utilisation**

413 Four studies involved data on resource utilisation (47,51,53,54). A wide variety of resources
414 were studied, and we broadly grouped these outcomes (Table 5) into utilisation of
415 medications, utilisation of healthcare appointments (e.g. lumbar spine treatment,
416 physiotherapy), and healthcare costs (e.g. expenditure, workdays missed). Of these,
417 utilisation of healthcare appointments was measured the most - in nine occasions, while
418 healthcare costs were measured six times, and utilisation of medications was measured thrice
419 (Table 5).

420
421 **Table 6 here.**

422 423 **3.5 Comparison of included LBP health outcomes against the COS for Clinical Trials in** 424 **Non-Specific LBP**

425 A total of 50 health outcome measures were utilised across the ten studies reviewed. Of these,
426 14 (28%) were deemed to be directly related to those in the COS but were limited to two
427 outcomes “pain intensity” and “physical functioning” (22) (Table 6). The Pain Numerical
428 Rating Scale, Pain Visual Analogue Scale, and Short-form McGill Pain Questionnaire
429 directly addressed the core outcome of “pain intensity”, while the ODI, Euro-QOL5D,
430 Chronic Pain Grading Scale, and questions on intrusion of daily and recreational activities

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431 (10,41) directly addressed the outcome “physical functioning”. Measures on pain duration
432 and frequency were only indirectly related to the COS. The COS outcome “health-related
433 quality of life” had the greatest number of measures indirectly addressing it (Table 6). This
434 was because three of the five overarching categories of health outcomes (behaviour,
435 knowledge and beliefs, and resource utilisation) were found to be assessments of the “impact
436 on physical, psychological and social domains of health” – i.e. the COS’ definition of
437 “health-related quality of life” (22). The COS outcome “Number of Deaths” was not explored
438 in any of the included studies.

439 440 **3.6 Association between HL and LBP health outcomes**

441 Although not a primary aim of this scoping review, we briefly detail here findings on the
442 association between HL and LBP health outcomes as a snapshot of existing literature (Table
443 3). Out of six studies analysing the relation between HL and levels of pain and disability
444 (10,12,20,41,47,48), only two found a significant association, particularly in the area of pain
445 intensity (20,47). On behavioural impact, HL had no significant associations with fear
446 avoidance (10,41), pain catastrophising (10,41), and psychological empowerment (51).
447 However, patients with low HL scores were found to have a less active lifestyle (53).
448 Considering patient knowledge and beliefs, those with lower HL scores had more difficulty
449 identifying types and sources of treatment for LBP (12) and were more dissatisfied with their
450 care (54). However, no significant association was found between HL and beliefs about one’s
451 future with LBP (10,41). Regarding resource utilisation, it appears that low HL scores were
452 associated with higher utilisation of curative or symptomatic treatment (e.g. emergency room
453 visits), and lower utilisation of preventive medicine (e.g. flu vaccinations) (54).

454 455 **4. Discussion**

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456 We will now discuss our results in the context of the three objectives and the implications for
457 evidence and future research i.e. 1) The health literacy measures currently employed for low
458 back pain and the aspects of health literacy they include; 2) The low back pain health
459 outcomes included in such work; 3) The extent to which these health outcomes reflect the
460 Core Outcome Set for Clinical Trials in Non-Specific Low Back Pain.

461
462 The scoping review yielded ten relevant studies. Among the nine different measures of HL
463 used, all involved the study of functional HL. The 50 measures of LBP health outcomes
464 could be grouped into five thematic categories, namely: Pain, Disability, Behaviour,
465 Knowledge and Beliefs, and Resource Utilisation. However, most of these health outcomes
466 did not seek to directly satisfy the COS for Clinical Trials in Non-Specific LBP.

467 468 **4.1 Health literacy measures employed**

469 The studies included in this scoping review adopted a wide variety of measures to document
470 HL (nine measures used) and health outcomes (50 measures used). This hampered the
471 comparison of results across studies and the development of a comprehensive evidence-base
472 despite the development of the COS (22).

473
474 Despite expanding the search and using a more open search criteria, this study only included
475 seven studies in addition to those in the systematic review by Edward et al. (27). The dearth
476 of relevant studies in this scoping review highlights the continuing lack of evidence of the
477 relationship between HL and LBP health outcomes.

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479 Although no restrictions were placed on the year of publication, all relevant studies were
480 published in 2010 or later, suggesting that interest in the association between HL and LBP is
481 relatively recent. This may reflect HL being a relatively new concept within healthcare (62),
482 and the growing interest in LBP as it contributes to rapidly rising healthcare expenditure
483 (2,63). For instance, from 1996 through 2013, US expenditure on low back and neck pain
484 rose by an estimated USD 57.2 billion, becoming the third-highest healthcare spending on a
485 single condition in 2013 (63).

486
487 Despite no language or country restrictions being placed on the search, all studies were
488 conducted in high income countries – as defined by the 2021 World Bank classification of
489 economies (64). This may be a barometer of societal readiness to integrate HL into LBP
490 management. Most pressingly, there is a notable absence of research attempting to draw
491 associations between LBP and HL in LMICs and collectively in Asia, Africa, and South
492 America. This is in keeping with previous epidemiological studies remarking that LBP
493 monitoring and research is largely restricted to high income countries, while being under-
494 researched in LMICs (23,24). Alongside this is an increasing recognition of the need to
495 develop and use culturally sensitive HL tools (65).

4.2 Outcome measures used

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498 Few studies incorporated the four outcome domains of the COS (pain intensity, physical
499 functioning, health related quality of life, and number of deaths); only 14 of the 50 health
500 outcome measures used did so. Moreover, these 14 measures were limited to the two core
501 outcome domains of pain intensity and physical functioning (Table 5). This suggests a
502 divergence of opinions on what is deemed as a key health outcome for people with LBP. This
503 is concerning given that development of the COS incorporated a comprehensive range of

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5 504 views via a Delphi process with patients, care providers and researchers, a review by
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10 505 panellists who had published extensively on LBP, and by a four-continent International
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12 506 Steering Committee (22).

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22 508 Given the methodology in developing the COS, future studies on LBP are strongly
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24 509 recommended to adopt them. The benefit of adopting the COS is two-fold. Firstly, it allows
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26 510 future studies on LBP to have a more robust foundation to build upon. Secondly, the use of
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28 511 common health outcomes allows secondary research to have more compatible data for the
29
30 512 comparison of findings. Overall, this allows for the development of a more rigorous evidence
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32 513 base. Also of note, the authors of the COS have subsequently argued for the inclusion of the
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34 514 24-item Roland-Morris Disability Questionnaire for measuring physical functioning, and the
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36 515 Short Form Health Survey 12 and 10-item PROMIS Global Health form for measuring
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38 516 health-related quality of life (66). However, none of these tools were used in the included
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40 517 studies (Table 2).

4.4 Implications for future research

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51 520 As highlighted in our findings, several limitations were noted in the literature with
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53 521 implications for future research design, specifically regarding study design, measures used
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55 522 and included study populations. It is of utmost importance that future research takes these
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57 523 findings into account in curbing the limitations of future research.

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64 525 By solely employing cross-sectional study designs, the longitudinal relationship between HL
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66 526 and LBP outcomes was not explored. There was also a lack of evidence regarding the
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68 527 efficacy and implementation of HL interventions for people with LBP. Although a mixed-

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3 529 methods approach is preferable to holistically evaluate the complex construct of HL (67),
4 only the 2010 study by Briggs et al. utilised quantitative and qualitative approaches (10).

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7 531 Another limitation of in terms of study design was that the primary studies relied heavily on
8 patient reported outcome measures (PROMs), which may be biased by one's physical and
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10 532 psychological states, along with one's memory, willingness, and ability to answer the
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12 533 questions. This may influence one's ability to give accurate self-assessments of health status
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14 534 (68). This limitation could be overcome by the concurrent use of objective markers (e.g.
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16 535 functional tests), diagnostic imaging (e.g. functional magnetic resonance imaging), and/or
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18 536 observer reported outcomes (69,70).
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26 539 Many studies also had limitations in terms of the HL measure used. Communicative and
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28 540 critical HL measures were under-investigated. HeLMS, and the questionnaires used by
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30 541 Camerini and Schulz (51), MacLeod et al. (54) and Burke, Nahin and Stussman (53) have not
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32 542 been used as widely as the S-TOFHLA and NVS, and their content validity in other settings
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34 543 requires confirmation. We were also unable to find psychometric data for the HL measure
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36 544 used by Burke, Nahin and Stussman (53). It is recommended that future works reinforce their
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38 545 HL data by employing the use of HL measures with good psychometric validity and
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40 546 reliability. While a varied questioning style is likely to result in a more complete assessment
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42 547 of HL, measures tended to focus purely on either objective response (e.g. S-TOHHLA and
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44 548 NVS) or subjective replies (e.g. HeLMS). Ideally future studies on HL should use assessment
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46 549 tools that cover all three domains of HL as well as have vigorous validation in the setting
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3 553 Briggs et al. (10,41) faced a limited distribution of HL, hampering their efforts to analyse the
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5 554 presence of associations between health literacy scores and other outcomes. Studies which
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7 555 excluded patients based on language literacy potentially excluded lower HL participants. If
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10 556 basic language proficiency is required to obtain self-reported patient outcomes, this may
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12 557 come at the cost of excluding certain sectors of the population. The use of translators or
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14 558 pictorial questionnaires need to be explored to enable the inclusion of participants who may
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17 559 be experiencing vulnerability, for example those facing communication barriers or
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19 560 multimorbidity (71,72).
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24 562 Responder bias through self-selection was another common limitation in terms of study
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26 563 population design. This is important in the context of HL studies, as low HL patients with
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28 564 lesser ability to communicate well with their healthcare provider may have a tendency to
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30 565 decline study involvement (73). This limitation may potentially be mitigated using
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33 566 retrospective and anonymised data, rather than depend on the voluntary actions of patients.
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37 568 **4.5 Strengths and limitations**

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39 569 The strengths of this review include the wide search strategy, involving 13 bibliographic
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41 570 databases with no search limiters or filters. By including studies on all forms of LBP health
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43 571 outcomes associated with HL, this review was able to build on the work of Edward et al. (27).
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46 572 This review also followed best practices in the Joanna Briggs Institute methodology for
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48 573 conducting a scoping review, and the PCC mnemonic was adopted (30). Expert opinion in
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50 574 LBP, HL, scoping reviews, and literature searching was also consulted. This was in line with
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52 575 best practice recommendations by the Institute of Medicine (US) Committee on Standards for
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576 Systematic Reviews of Comparative Effectiveness Research (74), as well as Arksey and
577 O'Malley's and Levac et al.'s frameworks for scoping reviews (29,34).

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579 Nevertheless, the search strategy was not without its flaws. The use of MeSH terms was done
580 with the aim of improving reproducibility of results, especially with searches repeated
581 periodically in this study. However, this ran the risk of missing out on recent articles not yet
582 indexed. Furthermore, a more broadly defined strategy using additional synonyms for MeSH
583 terms could have broaden the search even more. Grey literature was also excluded, which
584 given the paucity of evidence in the field, could well have enriched this study's findings (75).

585
586 The studies by Devraj, Herndon and Griffin (12), MacLeod et al. (54), Farin, Ullrich and
587 Nagl (11), and Köppen et al. (20) did not have a solely LBP population, but were included as
588 the LBP population made up at least 10% of the overall study. This was pre-determined as
589 the cut-off percentage for eligibility into this review. This cut off has been used as a marker
590 for significance in other studies (76,77), but caution may be needed when interpreting the
591 results of these studies.

592
593 The heterogeneity of measures employed, as well as the paucity of relevant studies, made it
594 difficult to compare findings across studies and provide firm conclusions on the association
595 between HL and each LBP health outcome. Thus, we were unable to draw strong evidence-
596 based conclusions on this. We also note that classifying measurement tools into functional,
597 communicative and critical HL as proposed by Nutbeam (37) is an imperfect method of HL
598 classification, given the wide range of HL definitions employed and the fact that such a
599 classification may not be the intention of the various measures. However, the benefit of using
600 the classification in this review is that it has an ascending level of "difficulty", thus capturing

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601 a sense of the complexity and dimensions of HL each measurement tool was seeking to
602 assess, whether implicitly or explicitly.

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604 The protocol was not registered a priori, leading to potential bias. However, as stated, no
605 changes to the protocol were necessitated during the review process and data extraction
606 remained per protocol. Piloting of the data extraction form was also not included. However,
607 these are not requirements of a scoping review and were deemed unnecessary to fulfil the
608 study objectives.

609
610 In terms of stakeholder involvement, while experts (clinicians and researchers) in the field of
611 HL and LBP are members of the research team, patients were not consulted. There is growing
612 evidence of the value of patient and public involvement at all stages of the research process
613 (78), and the importance of how best to operationalise this within diverse cultural contexts
614 (79,80). While deemed to be non-essential at this scoping stage, involving patients in the
615 development of research questions would be essential to further work into the impact of HL
616 on LBP health outcomes.

617 618 **5. Conclusions**

619 The ten relevant studies included in this review yielded a total of nine different measures of
620 HL and 50 measures of LBP health outcomes. Most health outcomes evaluated by the
621 included studies did not seek to directly satisfy the Core Outcome Set for Clinical Trials in
622 Non-Specific LBP. The wide variety of measures used hampers efforts to form conclusive
623 relationships between HL and LBP outcomes, and precludes the use of a meta-analysis
624 approach. To allow for comparison across findings and the development of a rigorous
625 evidence base, future work should seek to address the Core Outcome Set for Clinical Trials in

626 Non-Specific LBP. Furthermore, research thus far has focused on a narrow range of
627 populations and there is an urgent need to broaden the evidence-base to include those where
628 LBP morbidity is high, but data is lacking. As noted above, this is especially so in LMICs.
629 Such work demands the incorporation of comprehensive measures of health literacy that have
630 both generic and culturally sensitive components.

631

632 **List of Abbreviations:**

633 HL Health Literacy

634 LBP Low Back Pain

635 COS Core Outcome Set

636 S-TOFHLA Short-form Test of Functional Health Literacy in Adults

637 HeLMS Health Literacy Measurement Scale

638 NVS Newest Vital Sign

639 FABQ Fear Avoidance Beliefs Questionnaire

640

641 **Declarations**

642 **Ethics approval and consent to participate**

643 Not applicable.

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645 **Consent to publish**

646 Not applicable.

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648 **Availability of data and materials**

649 The datasets used and/or analysed during the current study are available from the
650 corresponding author on reasonable request.

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652 **Competing interests**

653 The authors declare that they have no competing interests.

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658 **Authors' contributions**

659 CS provided review on titles and abstracts, full-text reviews of the shortlisted papers, and was
660 a major contributor in writing the manuscript; BB and HES were involved in project
661 conception, analysis and manuscript writing; LTC contributed to analysis and manuscript
662 writing. JP contributed to manuscript writing and acted as the field expert in the consultation
663 process. WWC collected the raw data, provided review on titles and abstracts, and full-text
664 reviews of the shortlisted papers, and contributed to manuscript writing. All authors read and
665 approved the final manuscript.

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937 **Table 1. Inclusion and Exclusion criteria**

Inclusion criteria	Exclusion criteria
Patients with LBP (\geq 10% of study population), of any age, gender, or race	Non-research or Non-peer reviewed sources of evidence (e.g. grey literature, policy documents, expert opinions, guidelines)
Any healthcare setting, in any geographical setting	Studies only analysing generic literacy, numeracy, and education level not in the context of healthcare
Any peer reviewed research study (of any study design)	
Utilisation of specific HL and LBP health outcome measures	

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Table 2. Summary of study characteristics and population.

Author (Year)	Country	Study design	Study size	Age	Gender	Race	Education level
Briggs et al. 2010 (10) Briggs et al. 2011 (41)	Australia	Cross-sectional, mixed methods study	n=117	Mean ages: 38.5 (No CL back pain), 37.4 (CL back pain-low disability), 43.2 (CL back pain-high disability)	Female (n=71)	Unspecified.	≤Secondary school (n=17), Trade certificate or diploma (n=33), University degree (n=30), No response (n=37).
Devraj et al. 2013 (12)	USA	Cross-sectional	n=139	≥18 years	Females (n=105)	White (n=98), African American (n=24), Hispanic (n=8), Asian or Pacific Islander (n=4), Native American (n=4).	≤Secondary school (n=37), Some college (n=48), University degree (n=54).
Farin 2013 (11)	Germany	Cross-sectional	n=577	17-85 years	Females (n~317)	Unspecified	≥Secondary school (77.9%), University-entrance diploma or technical college qualification (20.9%)
Camerini et al. 2015 (51)	Switzerland and Italy	Cross-sectional	n=273	20-89 years	Female (n=159)	Unspecified.	≤Secondary school (n=90), Post-secondary non tertiary educational degree (n=145), University degree (n=38).
Burke et al. 2015 (53)	USA	Cross-sectional, retrospective	n=23393 (back pain sub-sample of 2580)	≥18 years	Unspecified	Included: White, Black, and Others.	Included: ≤High school, ≥Some college.
Al-Eisa et al. 2017 (48)	Saudi Arabia	Cross-sectional	n=227	20-55 years	Female only	Unspecified.	Unspecified.
MacLeod et al. 2017 (54)	USA	Cross-sectional, retrospective	n=7334	≥65 years	Females (n=4384)	Sicker population (Minority/non-white 7.3%, White 92.7%). Healthier population (Minority/non-white 3.4%, White 96.6%).	Sicker population (≤High school 41.8%, ≤2year college 29.0%, ≥4year college 29.2%). Healthier population (≤High school 39.2%, ≤2year college 28.9%, ≥4year college 32.0%).
Köppen 2018 (20)	Austria	Cross-sectional	n=121	18-65 years	Female (n=89)	Unspecified	Compulsory school (17%), School leaving examination/ apprenticeship (61%), University (22%)
Glassman et al. 2019 (47)	USA	Cross-sectional	n=186	≥18 years	Females (n=119)	Unspecified.	≤Secondary school (n=108), University degree (n=51), No data (n=27).

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Table 3. HL and LBP Health Outcome measures used and their relationship.

Briggs et al. 2010 (10)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
Short-form Test of Functional Health Literacy in Adults (S-TOFHLA)	Pain severity	Numeric pain-rating scale	Unspecified.
	Pain impact	LBP episodes (last 1 year), workdays missed, sought health professional advice, medication use, intrusion on regular daily and recreational activities.	Unspecified.
	LBP related disability	Oswestry Disability Index (ODI)	Unspecified.
	Fear avoidance	Fear Avoidance Beliefs Questionnaire (FABQ)	No significant relationship.
	Beliefs about LBP	Back Pain Beliefs Questionnaire (BBQ)	No significant relationship.
	Catastrophising	Coping Skills Questionnaire (CSQ)	No significant relationship.
	Beliefs on “cause and course of low back pain”, and “seeking, understanding and utilising low back pain information”.	Telephone interviews	Unspecified correlation to HL. However, participants reported obstacles in seeking, comprehending and using LBP information, which were not reflected in S-TOFHLA scores.
Briggs et al. 2011 (41)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
Health Literacy Measurement Scale (HeLMS)	Same as Briggs 2010	Same as Briggs 2010	Chronic LBP associated with lower scores in HeLMS domain 1: ‘Patient attitudes towards their health’ and greater difficulty in managing personal health.
Devraj et al. 2013 (12)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
Newest Vital Sign (NVS)	Pain awareness and medication knowledge	12-question survey based on chronic pain guidelines, patient education resources, and previous studies.	Limited HL associated with lower ability to find healthcare providers to manage chronic pain, less likely to know alternative methods to treat pain besides medications alone, and less likely to know over-the-counter medications to take for pain control.
	Pain severity	100mm Visual Analogue Scale (VAS) - (pain severity over the past week).	No significant relationship.
Farin 2013 (11)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
HELP questionnaire (health education literacy of patients with chronic musculoskeletal diseases)	General health status	One-item measure (How would you rate your health?)	Poor self-rated health status was the greatest risk factor for low HL. Study considered this is a causal path in the opposite direction: low HL patients are at a disadvantage and thus experience a less positive disease course.

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Table 3. (continued).

Camerini et al. 2015 (51)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
Low Back Pain Knowledge Questionnaire	Patient empowerment	Psychological Empowerment Scale	No significant relationship.
	Patient involvement	Modified Patients' Perceived Involvement in Care Scale (M-PICS)	Low HL group more inclined to ask healthcare provider for information regarding treatment plan.
	Medication non-adherence	Pain Medication Questionnaire	No significant relationship.
	Health outcomes	6 questions from the Chronic Pain Grading Scale on intensity and functionality	No significant relationship.
Burke et al. 2015 (53)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
"Never heard of it / Do not know much about it" questions from the NHIS (National Health Interview Survey).	Lack of need	"Do not need it" from the NHIS (National Health Interview Survey).	No significant relationship.
	Health Status	Self-reported health status, functional limitation, hospitalization and emergency department attendance (last 12 months).	No significant relationship.
	Health Behaviours	Activity level, smoking status, alcohol consumption level, body mass index, flu immunisation (last 12 months), use of pneumonia vaccine.	Low HL associated lower activity level.
	Healthcare Access	Healthcare provider visits (last 12 months), health insurance coverage, delayed healthcare due to cost concerns, delayed healthcare due to non-cost concerns, ability to afford common supplementary healthcare.	Low HL associated with greater inability to afford ancillary care.
Al-Eisa et al. 2017 (48)			
HL measure	Health Outcome (HO)	HO measure	HO measure
Newest Vital Sign (NVS)	Disability level for LBP	Oswestry Disability Index	Disability was negatively correlated with HL.
	Avoidance behaviour due to pain	Fear Avoidance Beliefs' Questionnaire (FABQ)	Negative correlation between FAB (in terms of Physical Activity) and HL. No significant relationship between FAB (in terms of work) and HL.

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Table 3. (continued).

MacLeod et al. 2017 (54)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
“How confident are you filling out medical forms by yourself?” screening question.	Patient dissatisfaction	Modified Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. 10-point scales measuring dissatisfaction with general healthcare, specialists, physicians, and AARP Medicare Supplement Insurance plans.	Inadequate HL associated with greater dissatisfaction with healthcare system and general healthcare (e.g. physicians, specialists, insurers, and general experiences).
	Preventive services or quality of care	Administrative medical claims databases.	Inadequate HL associated with reduced compliance towards preventive healthcare services and less uptake of flu immunisations.
	Healthcare utilization and expenditures	Administrative medical claims databases.	Inadequate HL associated with higher emergency department attendance, inpatient admission and yearly healthcare expenditure.
Köppen 2018 (20)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
3 screening questions from <i>Brief Questions to Identify Patients with Inadequate Health Literacy</i> : “how often do you have someone help you read hospital materials”, “how confident are you filling out medical forms by yourself” and “how often do you have problems learning about your medical condition because of difficulty understanding written information?”	Pain intensity	Visual Analogue Scale (VAS)	Higher HL associated with lower pain intensity.
	Pain perception	Short-form McGill Pain Questionnaire (SF-MPQ)	No significant relationship.
	Pain duration	Listed in months	No significant relationship.
Glassman et al. 2019 (47)			
HL measure	Health Outcome (HO)	HO measure	Relationship between HO and HL
Newest Vital Sign (NVS) Health Literacy Assessment (HLA)	LBP related disability	Oswestry Disability Index	No significant relationship.
	Pain	Numeric Rating Scales for Back and Leg Pain	Lower HL associated with higher back pain scores.
	Generic health status	Euro-QOL5D (EQ-5D)	No significant relationship.
Utilisation of lumbar spine treatment (last 6 months), physiotherapy attendance, immunisation history, medication use, employment, days of work missed.		Adequate HL group used more medications and consulted a specialist more frequently than limited HL group. Limited HL group reported more individual visits to chiropractor and had lower use of NSAIDs.	

Table 4. HL measures used and the components of HL they cover

HL measure	Functional HL	Communicative HL	Critical HL
Short-form Test of Functional Health Literacy in Adults (S-TOFHLA)	YES	NO	NO
Health Literacy Measurement Scale (HeLMS)	YES	YES	YES
Low Back Pain Knowledge Questionnaire	YES	NO	NO
Newest Vital Sign (NVS)	YES x3	NO	NO
Health Literacy Assessment (HLA)	YES	NO	NO
“How confident are you filling out medical forms by yourself?” screening question	YES	NO	NO
“Never heard of it / Do not know much about it” questions from the NHIS (National Health Interview Survey)	YES	NO	NO
HELP questionnaire (health education literacy of patients with chronic musculoskeletal diseases)	YES	YES	YES
3 screening questions from Brief Questions to Identify Patients with Inadequate Health Literacy	YES	NO	NO
Number of studies - HL component assessed (%)	11 (73.3%)	2 (13.3%)	2 (13.3%)

Table 5. Health outcome measures used by category

Health outcome measures employed (number of times)				
Pain	Disability	Behaviour	Knowledge and beliefs	Resource Utilisation
Numerical rating scale (3)	Oswestry Disability Index (4)	Coping Skills Questionnaire (2)	Back Pain Beliefs Questionnaire (2)	Utilisation of medications (3)
Visual Analogue scale (2)	Euro-QOL5D (1)	Fear Avoidance Beliefs Questionnaire (3)	Modified Consumer Assessment of Healthcare Providers and Systems survey (1)	Utilisation of healthcare appointments (9)
6 item Chronic Pain Grading Scale (1)	6 item Chronic Pain Grading Scale (1)	Psychological Empowerment Scale (1)	One-item measure - How would you rate your health? (1)	Healthcare cost - expenditure/workdays missed/affordability (6)
Short-form McGill Pain Questionnaire (1)		Modified Patients' Perceived Involvement in Care Scale (1)		
Pain duration in months (1)				
Oswestry Disability Index (4)				
Euro-QOL5D (1)				
Others* (2)	Others* (2)	Others* (1)	Others* (3)	
*LBP episodes in last 1 year	*Pain impact (intrusion on regular daily and recreational activities)	*Health Behaviours (Activity level, smoking status, alcohol consumption level, body mass index, flu immunisation in last 12 months, use of pneumonia vaccine)	*Telephone interviews (2), and 12-item survey developed by authors (1)	

Table 6. Summary of number of health outcome measures directly and indirectly related to the COS for clinical trials in non-specific low back pain

COS	Directly related outcomes	Indirectly related outcomes
Pain intensity	6	3
Physical functioning	8	0
Health-related quality of life	0	33
Number of deaths	0	0
Totals (%)	14 (28%)	36 (72%)

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5 **Appendix 1 – Search strategy overviews**

6 Database: Pubmed 1946 to Present.

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12 Syndrome[MeSH Terms]) OR Low Back Pain[MeSH Terms]) OR Low Back Ache[MeSH
13 Terms]) OR Low Back Pain, Mechanical[MeSH Terms]) OR Low Back Pain, Posterior
14 Compartment[MeSH Terms]) OR Low Back Pain, Postural[MeSH Terms]) OR Low Back Pain,
15 Recurrent[MeSH Terms]) OR Low Backache[MeSH Terms]) OR Lower Back Pain[MeSH
16 Terms]) OR Lumbago[MeSH Terms]) OR Mechanical Low Back Pain[MeSH Terms]) OR
17 Postural Low Back Pain[MeSH Terms]) OR Recurrent Low Back Pain[MeSH Terms])
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27 “Health Literacy” AND (“Back Pain” OR “Back Ache” OR “Back Pain with Radiation” OR “Back
28 Pain without Radiation” OR “Vertebrogenic Pain Syndrome” OR “Low Back Pain” OR “Low
29 Back Ache” OR “Mechanical Low Back Pain” OR “Low Back Pain Posterior Compartment” OR
30 “Postural Low Back Pain” OR “Recurrent Low Back Pain” OR “Low Backache” OR “Lower
31 Back Pain” OR “Lumbago” OR “Mechanical Low Back Pain” OR “Postural Low Back Pain” OR
32 “Recurrent Low Back Pain”)
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34 No search filters used (e.g. specifying years, language).

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Appendix 2 – PRISMA-ScR Checklist (Tricco et al. 2018)

Section	Item	PRISMA-ScR checklist item	Reported on page #
Title			
Title	1	Identify the report as a scoping review.	1
Abstract			
Structured summary	2	Provide a structured summary including, as applicable: background, objectives, eligibility criteria, sources of evidence, charting methods, results and conclusions that relate to the review question(s) and objective(s).	2-3
Introduction			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review question(s)/objective(s) lend themselves to a scoping review approach.	4-6
Objectives	4	Provide an explicit statement of the question(s) and objective(s) being addressed with reference to their key elements (e.g., population or participants, concepts and context), or other relevant key elements used to conceptualize the review question(s) and/or objective(s)).	6
Methods			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., web address), and, if available, provide registration information including registration number.	7-10
Eligibility criteria	6	Specify the characteristics of the sources of evidence (e.g., years considered, language, publication status) used as criteria for eligibility, and provide a rationale.	8
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with authors to identify additional sources) in the search, as well as the date the most recent search was executed.	7
Search	8	Present the full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	7
Selection of sources of evidence	9	State the process for selecting sources of evidence (i.e., screening, eligibility) included in the scoping review.	8-9

Appendix 2 – continued

Section	Item	PRISMA-ScR checklist item	Reported on page #
Data charting process	10	Describe the methods of charting data from the included sources of evidence (e.g., piloted forms; forms that have been tested by the team before their use, whether data charting was done independently, in duplicate) and any processes for obtaining and confirming data from investigators.	8-9
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	8-9
Critical appraisal of individual sources of evidence	12	<i>If done</i> , provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	NA
Summary measures	13	Not applicable for scoping reviews.	NA
Synthesis of results	14	Describe the methods of handling and summarizing the data that were charted.	9
Risk of bias across studies	15	Not applicable for scoping reviews.	NA
Additional analyses	16	Not applicable for scoping reviews.	NA
Results			
Selection of sources of evidence	17	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	10
Characteristics of sources of evidence	18	For each source of evidence, present characteristics for which data were charted and provide the citations.	10
Critical appraisal within sources of evidence	19	<i>If done</i> , present data on critical appraisal of included sources of evidence (see item 12).	NA
Results of individual sources of evidence	20	For each included source of evidence, present the relevant data that were charted that relate to the review question(s) and objective(s).	11,14,17
Synthesis of results	21	Summarize and/or present the charting results as they relate to the review question(s) and objective(s).	10-18

Appendix 2 – continued

Section	Item	PRISMA-ScR checklist item	Reported on page #
Risk of bias across studies	22	Not applicable for scoping reviews.	NA
Additional analyses	23	Not applicable for scoping reviews.	NA
Discussion			
Summary of evidence	24	Summarize the main results (including an overview of concepts, themes, and types of evidence available), explain how they relate to the review question(s) and objectives, and consider the relevance to key groups.	19-23
Limitations	25	Discuss the limitations of the scoping review process.	23-25
Conclusions	26	Provide a general interpretation of the results with respect to the review question(s) and objective(s), as well as potential implications and/or next steps.	25-26
Funding			
Funding	27	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	27

Appendix 3 – Key excluded sources with rationale for their exclusion

Author (Year)	Rationale for exclusion
Slater (2012) (81)	Study did not attempt to draw a relationship between HL and LBP health outcomes
Larsen (2015) (82)	Lack of significant LBP population
Khoshnevisan (2010) (83)	Lack of explicit study of HL
Kim (2009) (84)	Lack of significant LBP population
Roth (2001) (85)	Lack of explicit study of HL Lack of significant LBP population
Hardie (2011) (86)	Lack of significant LBP population
Schulz (2010) (87)	Lack of explicit study of HL
Rabenbauer (2021) (88)	Study did not attempt to draw a relationship between HL and LBP health outcomes

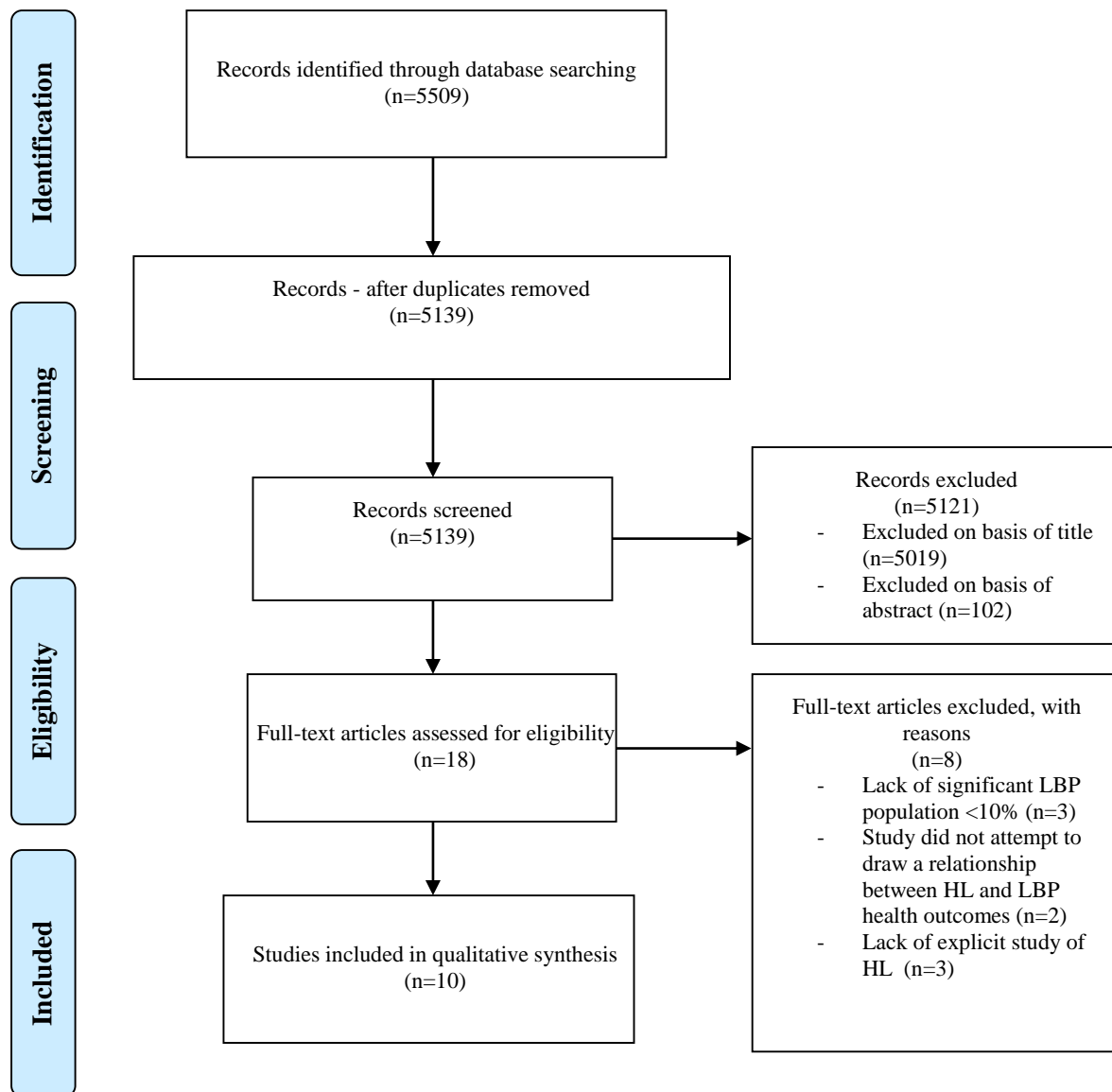


Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram of the literature review.



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