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

Clarence Ye King See (clarencesee@gmail.com)
Lee Kong Chian School of Medicine

Helen Elizabeth Smith
Lee Kong Chian School of Medicine

Lorainne Tudor Car
Lee Kong Chian School of Medicine

Joanne Protheroe
Keele University

Wei Cong Wong
Lee Kong Chian School of Medicine

Bernadette Bartlam
Keele University

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Abstract

BACKGROUND: The World Health Organisation highlights low back pain as a leading and growing cause of disability worldwide. In the field of chronic pain, higher health literacy is linked to lower pain intensity and better pain control. However, there remains a paucity of evidence, with a recent systematic review finding only three studies meeting its inclusion criteria.

OBJECTIVES: This scoping review had two objectives in exploring research in chronic back pain, which were to identify:

1) The health literacy measures currently employed for back pain and the aspects of health literacy they include.

2) The back-pain health outcomes included in such work and the extent to which these reflect the core outcome set for clinical trials in non-specific low back pain.

METHODS: The search broadened the search strategy used in the systematic review, with the eligibility criteria defined by the Joanna Briggs Institute PCC mnemonic, namely:

- Population – Patients with LBP (≥ 10% of study population), of any age, gender, or race
- Concept – Relationship of LBP health outcomes to HL
- Context – Any healthcare setting, in any geographical setting

It was conducted using thirteen bibliographic databases, employing medical subject heading (MeSH) terms for low back pain and health literacy, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines. A thematic framework approach was used for analysis.

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. The health outcomes assessed by the included studies could be broadly categorised into: Pain, Disability, Behaviour, Knowledge and Beliefs, and Resource Utilisation. Most outcome measures employed (36 out of 50) were not directly relevant to addressing the core outcome set for clinical trials in non-specific low back pain.

CONCLUSIONS: A dearth of studies in this field of research was noted, especially in Asia and low-middle income countries. Methodological limitations were identified, including in study design and outcome measures. 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. Furthermore, research thus far has focused on a narrow range of populations and there is an urgent need to broaden the evidence-base to include those with characteristics known to be moderators in health outcomes. Such work demands the incorporation of comprehensive measures of health literacy that have both generic and culturally sensitive components.

1. Background

The concept of health literacy (HL) is extensive and incorporates functional, communicative/interactive and critical domains (1). It is defined as “the achievement of a level of knowledge, personal skills and confidence to take action to improve personal and community health by changing personal lifestyles and living conditions” (2). At its core is an observable set of skills that can be developed and improved through effective communication and education to enhance autonomy and empower people to make decisions relating to their health and changing circumstances (2, 3). At the inaugural Outcome Measures in Rheumatology Clinical Trials (OMERACT) Health Literacy Special Interest Group workshop, 16 themes at the micro, meso and macro level were identified, including cognitive capacity, access to
information, and health systems (4). Independent of other socio-demographic factors low HL is associated with higher mortality amongst older people, with poorer health outcomes, and with higher morbidity more generally (5–7), whilst higher HL is linked to lower pain intensity and better pain control among those with chronic pain (8, 9).

Low back pain (LBP) is the single leading cause of disability globally and is rising (9, 10). Financial costs from LBP are estimated to be in the order of billions of US dollars (USD) (10, 11), while the economic burden of members of the workforce suffering from LBP is estimated in the USA alone to be USD 7.4 billion/year (12). Traditionally conceptualised as solely secondary to mechanical injury, LBP is now described within a bio-psychosocial model, resulting from an interaction of physical, psychological and social influences (13). Effective self-management is crucial to improving LBP outcomes (14, 15). Studies have also demonstrated the need to focus on HL in order to develop effective patient education materials and/or patient resources to support self-management in such patients (16, 17). However, inconsistent reporting of outcomes in clinical trials of patients with non-specific LBP has been highlighted, together with the implications for comparing findings and the reliability of systematic reviews. To address this issue a Core Outcome Set (COS) has been developed, led by an International Steering Committee, defining the minimum set of outcomes that should be reported in all clinical trials. The COS includes ‘physical functioning’, ‘pain intensity’, ‘health-related quality of life’ and ‘number of deaths’ (18).

Asia has the largest number of LBP disability-adjusted life years internationally and the highest risk of occupational LBP is in the agricultural sector – a major sector in Asian economies (19). In addition, there exists a paucity of research to underpin evidence-based practice of LBP treatment in low- and middle-income countries (LMIC) (20, 21). Existing evidence tends to be from developed Western nations and cannot be accurately applied to the Asian and LMIC context, given that pain reporting, manifestation and management is influenced by socio-cultural and genetic factors (22).

To develop more evidence-based interventions and guidelines we need to better understand the relationship between HL and LBP outcomes. An initial scoping search of the literature was conducted to assess whether reviews and guidelines on this topic have already been published and what was lacking. This only yielded a single systematic review by Edward et al. in 2018 on the impact of HL on LBP management. The study identified only three relevant studies, all of which were based in Western nations. However, the review acknowledged “possible incomplete retrieval of identified research and reporting bias” (23) as the search was limited to four bibliographic databases and limits were also placed on year of publication, language, and article formats, amongst other search filters (23).

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

1. The health literacy measures currently employed for back pain and the aspects of health literacy they include (Functional, Communicative and Critical).

2. The back-pain health outcomes included in such work and the extent to which these reflect the core outcome set for clinical trials in non-specific low back pain.

Scoping reviews are used instead of systematic reviews where the purpose of the review is to identify knowledge gaps, scope a body of literature, clarify concepts or to investigate research conduct (24). The methodology was chosen in the light of the paucity of existing literature and to reflect and build from the limitations encountered in the Edward’s et al review. As a consequence, this scoping study expanded the search from four to 13 bibliographic databases and did not utilise search limiters or filters such as time or language filters. Unlike the systematic review carried out by Edward et al., this study is a scoping review with the emphasis not on reporting the degree of association between HL and LBP health outcomes, but on identifying the variety of HL and health outcome measures employed in existing literature, while additionally providing a critique on the choice of outcomes studied and measures used in order to identify implications for future research.
2. Materials And Methods

2.1 Literature Search strategy

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

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

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

The search strategy was developed in consultation within the research team, consisting of a range of expert researchers and clinicians (25), i.e. BB (social sciences, primary care research, musculoskeletal research, patient perspectives and health literacy), HES, LTC (primary care clinicians, health services research, evidence based medicine) and JP (primary care clinician, musculoskeletal conditions, health services research and health literacy). Additional advice was sought from the library team at the University.

2.2 Inclusion and Exclusion criteria

| Inclusion criteria | Exclusion criteria |
|--------------------|-------------------|
| Patients with LBP (≥ 10% of study population), of any age, gender, or race | Non-research sources of evidence (e.g. 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 research study (of any study design) | |
| Utilisation of specific HL and LBP health outcome measures | |

The Joanna Briggs Institute (JBI) manual’s PCC mnemonic (26) was used to clarify the research focus in formulating the inclusion and exclusion criteria (Table 1):

- Population – Patients with LBP (≥ 10% of study population), of any age, gender, or race
- Concept – Relationship of LBP health outcomes to HL
- Context – Any healthcare setting, in any geographical setting

Only research studies were included in this scoping review as the objectives of this study focused on measures used in LBP research, hence other sources of evidence (e.g. policy documents, expert opinions, guidelines) were not included. In addition, studies for inclusion required the use of specific HL and health outcome measures. Studies were excluded if they only analysed generic literacy, numeracy, and education level not in the context of healthcare. Generic patient...
education interventions have the potential to influence non-HL related determinants of LBP, hence drawing conclusions about HL's effects on LBP from these studies may be inaccurate (27), and for this reason these studies were excluded.

2.3 Study selection, data extraction and analysis

The search strategy followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines (28). Independent review of titles and abstracts from the initial search was conducted by two reviewers (CS and WWC). Any discrepancies were resolved through discussion between reviewers, with a third reviewer (HES) included as necessary. However, no discrepancies which could not be resolved between reviewers were encountered. Studies then underwent a full-text review if they investigated a relationship between HL and LBP outcomes.

Data extraction included determinants of HL (age, gender, ethnicity, and education level) (29), study design, and measures and types of outcomes used. Adopting a framework analysis approach (30, 31), the health outcomes used were collated and coded into descriptive themes, and then grouped into overarching categories. These categories were then mapped against the core outcome domains for clinical trials in non-specific LBP (18), namely 'physical functioning', 'pain intensity', 'health-related quality of life' and 'number of deaths'. The HL measures used were also categorised according to the components of HL they covered, using the classification proposed by Nutbeam, namely Functional, Communicative and Critical (32, 33). Functional HL encompasses basic skills in reading and writing, Communicative HL includes social skills and advanced cognitive and literacy skills to actively participate in daily activities, and Critical HL comprises the use of even more advanced cognitive and social skills to exert great control over life events and situations.

As this was a scoping review grading of evidence was not conducted. Instead, this study followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines (28), as detailed in Appendix 2.

3. Results

3.1 Articles reviewed

The initial search yielded 5509 articles. After removing duplicates and reviewing titles and abstracts, 18 articles remained for full-text review. Ten of these were included in the final analysis (Fig. 1). The key excluded sources with rationale for their exclusion is listed in Appendix 3. Both 2010 and 2011 papers by Briggs et al. (15, 34) were included and recorded as separate studies, as each publication studied on different HL measures.
| Author (Year)       | Country                  | Study design                              | Study size | Age                      | Gender                  | Ethnicity            | Education level                                                                 |
|---------------------|--------------------------|-------------------------------------------|------------|--------------------------|-------------------------|----------------------|--------------------------------------------------------------------------------|
| Briggs et al. 2010 (15) | 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). |
| Briggs et al. 2011 (34) |                          |                                           |            |                          |                         |                      |                                                                                |
| Camerini et al. 2015 (40) | 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). |
| Glassman et al. 2019 (36) | USA                      | Cross-sectional                           | n = 186    | ≥ 18 years               | Females (n = 119)       | Unspecified.          | ≤Secondary school (n = 108), University degree (n = 51), No data (n = 27).       |
| Al-Eisa et al. 2017 (37) | Saudi Arabia             | Cross-sectional                           | n = 227    | 20–55 years              | Female only             | Unspecified.          | Unspecified.                                                                |
| Devraj et al. 2013 (17) | 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). |
| Author (Year)                  | Country  | Study design                  | Study size          | Age    | Gender | Ethnicity                                                                 | Education level                                                                 |
|-------------------------------|----------|-------------------------------|---------------------|--------|--------|----------------------------------------------------------------------------|---------------------------------------------------------------------------------|
| MacLeod et al. 2017 (41)      | USA      | Cross-sectional, retrospective | n = 7334            | ≥ 65   | Females (n = 4384)             | Sicker population (Minority/non-white 7.3%, White 92.7%).                      | Sicker population (≤ High school 41.8%, ≤ 2 year college 29.0%, ≥ 4 year college 29.2%). |
|                               |          |                               |                     |        |        | Healthier population (Minority/non-white 3.4%, White 96.6%).                | Healthier population (≤ High school 39.2%, ≤ 2 year college 28.9%, ≥ 4 year college 32.0%). |
| Burke et al. 2015 (42)        | USA      | Cross-sectional, retrospective | n = 23393 (back pain sub-sample of 2580) | ≥ 18   | Unspecified | Included: White, Black, and Others.                                   | Included: ≤ High school, ≥ Some college.                                            |
| Farin 2013 (16)               | Germany  | Cross-sectional               | n = 577             | 17–85  | Females (n ~ 317)               | ≥ Secondary school (77.9%), University-entrance diploma or technical college qualification (20.9%). |
| Köppen 2018 (8)               | Austria  | Cross-sectional               | n = 121             | 18–65  | Female (n = 89)                 | Unspecified                                                                     | Compulsory school (17%), School leaving examination/apprenticeship (61%), University (22%). |

### 3.2 Summary of key data retrieved from full-text reviews

Despite no restrictions being placed on year of publication, all the studies meeting the inclusion criteria were published in 2010 or later, and all were cross-sectional in design (Table 2). They employed structured questionnaires, apart from one mixed methods study which also used interviews. In terms of country of origin, two studies were conducted in Australia, four in the United States of America, three European studies across four centres (Germany, Austria, Switzerland and Italy), one in Saudi Arabia. Five of the cross-sectional studies solely studied patients with LBP, while the other five studies included LBP as a significant portion of their patient population (> 10%), one of which provided a subpopulation analysis of patients with LBP.

All ten studies focused on adult populations (≥ 18 years) and had a majority female population, with one study having entirely female participants. Ethnic break-down was only provided by two USA studies, both of which had predominantly
white study populations. Nine studies collected data on education level, most reporting an even spread across participants.
| Briggs et al. 2010 (15) |   |   |   |
|------------------------|------------------------|------------------------|------------------------|
| **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 (34) |   |   |   |
|------------------------|------------------------|------------------------|------------------------|
| **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. |

| Camerini et al. 2015 (40) |   |   |   |
|--------------------------|------------------------|------------------------|------------------------|
| **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. |

| Glassman et al. 2019 (36) |   |   |   |
|--------------------------|------------------------|------------------------|------------------------|
| **HL measure** | **Health Outcome (HO)** | **HO measure** | **Relationship between HO and HL** |
| Briggs et al. 2010 (15) |
|------------------------|
| **Newest Vital Sign (NVS)** | LBP related disability | Oswestry Disability Index | No significant relationship. |
| **Health Literacy Assessment (HLA)** | 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.
| Al-Eisa et al. 2017 (37) | | | |
| --- | --- | --- | --- |
| HL measure | Health Outcome (HO) | HO measure | Relationship between HO and HL |
| 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. |

| Devraj et al. 2013 (17) | | | |
| --- | --- | --- | --- |
| 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. |

| MacLeod et al. 2017 (41) | | | |
| --- | --- | --- | --- |
| 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. |

| Burke et al. 2015 (42) | | | |
| --- | --- | --- | --- |
| 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. |
3.3 Summary of HL measures used

Nine different HL measures were employed across the ten studies (Table 3). Most HL measures assessed functional HL (72.7%), while the number that evaluated communicative and critical HL were fewer than half (27.3% and 36.4%).
respectively) (Table 4).

In their 2010 paper, Briggs et al. (15) used the short-form Test of Functional Health Literacy in Adults (S-TOFHLA), which assesses ‘functional’ HL, defined as reading, writing and numeracy skills in relation to healthcare (1, 35). The S-TOFHLA does so via the use of two prose passages and four items testing numeracy. Briggs et al. (15) also employed telephone interviews to assess HL by asking participants on how they sought, understood and utilised LBP information.

Subsequently in their 2011 paper, Briggs et al. used the Health Literacy Measurement Scale (HeLMS) (34), which goes beyond functional HL to include communication skills, computation skills, and social support, thereby overcoming limitations of the S-TOFHLA (34). The HeLMS sets out to assess “overall capacity to seek, understand and use health information within the healthcare setting” by asking questions such as “Are you able to see a doctor when you need to?” (34). By doing so it assesses all three domains of health literacy, Functional, Communicative and Critical HL.

The Newest Vital Sign (NVS) was the most frequently used HL measure (Table 3), utilised by Glassman et al., Al-Eisa, Buragadda and Melam, and Devraj, Herndon and Griffin (17, 36, 37). The NVS is convenient to use and has a sensitivity equivalent to the TOFHLA for identifying inadequate HL. It assesses functional HL through the asking of six questions regarding a standardised ice cream nutrition label (38).

Besides the NVS, Glassman et al. also used The Health Literacy Assessment, a 10-item self-administered questionnaire using items selected from the computerized Health LiTT measure (36). The Health Literacy Assessment (Health LiTT) assesses HL via three sections: Prose, Document and Quantitative (39). The Prose section asks participants to fill in missing words in a cloze passage, while the Document section consists of multiple-choice questions regarding images such as a prescription label. The Quantitative section also uses multiple-choice questions requiring arithmetic computation. By not assessing social skills and life choice decision making, the Health Literacy Assessment (Health LiTT) confines itself to Functional HL assessment only.

Camerini and Schulz (40) interpreted HL based on scores from the Low Back Pain Knowledge Questionnaire. The Questionnaire involved multiple-choice questions on topics such as the aetiology and management of LBP. This neither quantifies one’s reading, numeracy nor social skills, but arguably involves decision making over treatment options and can be categorised as assessing critical HL. Measurement of critical HL alone is also seen in other studies. MacLeod et al. used a single-item screener “How confident are you filling out medical forms by yourself?” (41), while Burke, Nahin and Stussman used the response option “Never heard of it/Do not know much about it” from the National Health Interview Survey (42).

Köppen et al. used HL questions taken from the Brief Questions to Identify Patients with Inadequate Health Literacy (8). These included the questions “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?” (8). These questions do offer a brief assessment of one’s reading and social skills, hence evaluating functional and communicative HL.

Finally, Farin, Ullrich and Nagl developed the HELP questionnaire (Health Education Literacy of Patients with chronic musculoskeletal diseases), an 18-item assessment that aims to summarise a patient’s reported communication and comprehension difficulties in health education and treatment (16). Questions such as “How much difficulty did you have communicating your own expectations and wishes in terms of your therapy?” were scored on Likert scales anchored from 1 to 5, with lower values indicating a higher HL. This instrument does not directly evaluate control over life events and choices and is categorised as covering only functional and communicative HL.
Table 5

| 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) | |

### 3.4 Summary of LBP outcomes retrieved from included studies

HL was associated with a heterogenous range of outcomes (Table 5). Five overarching categories summarising the studied LBP health outcomes were identified via framework method analysis (30, 31):

- Pain
- Disability
- Behaviour
- Knowledge and Beliefs
- Resource Utilisation

### 3.4.1 Pain
Seven studies involved data on pain (8, 15, 17, 34, 36, 37, 40), using eight different measures. Pain intensity was the most frequently measured aspect, with three studies (Briggs et al., Briggs et al., Glassman et al.) employing the Numerical Rating Scale and two (Devraj, Herndon and Griffin, Köppen et al.) using the Visual Analogue Scale (Table 5). Pain intensity was also quantified as a sub-component of the Chronic Pain Grading (40), the Short-form McGill Pain Questionnaire (8), the Oswestry Disability Index (ODI) (15, 34, 36, 37), and the Euro-QOL5D (36). In addition, the Short-form McGill Pain Questionnaire assesses the nature of pain (43), while other studies looked at pain duration and frequency (Table 5).

### 3.4.2 Disability

Five studies involved data on disability (15, 34, 36, 37, 40). Four studies (Briggs et al., Briggs et al., Glassman et al., Al-Eisa, Buragadda and Melam) used the ODI, a spinal disorder-specific measure of disability which quantifies the difficulty faced in areas such as personal care, movements (e.g. lifting, walking, sitting), and lifestyle (e.g. sex life, travel) (44). Additionally, Glassman et al. (36) used the Euro-QOL5D (EQ-5D) which, in addition to mobility, self-care and activities of daily living, also screens for anxiety and depression. Both of Briggs et al.'s studies (15, 34) supplemented the ODI with an assessment of disability by asking participants on the amount of intrusion one faces in daily and recreational activities. Lastly, the Chronic Pain Grading Scale (40) also asks about functionality using such questions as “In the past 3 months, how much has this pain interfered with your daily activities (e.g. getting dressed, doing shopping)“.

### 3.4.3 Behaviour

Five studies collected data on patient behaviours (15, 34, 37, 40, 42), involving five forms of health outcome measures (Table 5). The Fear Avoidance Beliefs Questionnaire was most commonly used (Briggs et al., Briggs et al., Al-Eisa, Buragadda and Melam), and asks participants how much they think areas of physical activity and work would affect their LBP (45). Briggs et al. (15, 34) assessed pain catastrophizing with the Coping Skills Questionnaire. Camerini and Schulz (40) assessed patient empowerment and involvement with two scales, the Psychological Empowerment Scale and Modified Patients’ Perceived Involvement in Care Scale respectively, while Burke, Nahin and Stussman (42) studied the association between HL and health behaviours such as physical activity level and smoking status.

### 3.4.4 Knowledge and Beliefs

Four studies gathered data on patient knowledge and beliefs (15, 16, 17, 25), employing five different health outcome measures. Briggs et al. (15, 34) used the Back Pain Beliefs Questionnaire, which consists of 14 questions exploring beliefs regarding issues such as the management and prognosis of back trouble (46). They also conducted telephone interviews to understand participant’s beliefs regarding the aetiology and course of their LBP. MacLeod et al. (41) used the Modified Consumer Assessment of Healthcare Providers and Systems survey to assess patient dissatisfaction in areas such as general healthcare and doctors. Farin, Ullrich and Nagl (16) used a single-item measure - “How would you rate your health?” to evaluate participant beliefs on their health status. Finally, Devraj, Herndon and Griffin (17) developed a 12-item survey based on pre-existing pain guidelines and literature to assess the pain awareness and medication knowledge of their participants.

### 3.4.5 Resource utilisation

Four studies (Glassman et al., Camerini and Schulz, MacLeod et al., Burke, Nahin and Stussman) involved data on resource utilisation (36, 40–42). A wide variety of resources were studied, and we broadly grouped these outcomes (Table 5) into utilisation of medications, utilisation of healthcare appointments (e.g. lumbar spine treatment, physiotherapy), and healthcare costs (e.g. expenditure, workdays missed). Of these, utilisation of healthcare appointments was measured the most - in nine studies, while healthcare costs were measured six times, and utilisation of medications was measured thrice (Table 5).
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%)                    |

3.5 Comparison of included LBP health outcomes against the COS for clinical trials in non-specific LBP

A total of 50 health outcome measures were utilised across the ten studies reviewed. Of these, 14 (28%) were deemed to be directly related to those in the COS but were limited to two outcomes “pain intensity” and “physical functioning” (18) (Table 6). The Pain Numerical Rating Scale, Pain Visual Analogue Scale, and Short-form McGill Pain Questionnaire directly addressed the core outcome of “pain intensity”, while the ODI, Euro-QOL5D, Chronic Pain Grading Scale, and questions on intrusion of daily and recreational activities (15, 34) directly addressed the outcome “physical functioning”. Measures on pain duration and frequency were only indirectly related. The COS “health-related quality of life” saw the greatest number of measures indirectly addressing it through outcomes on behaviour, knowledge and beliefs, and resource utilisation since these measures did not directly assess the “impact on physical, psychological and social domains of health” (18). The COS outcome “Number of Deaths” was not explored in any of the included studies.

3.6 Association between HL and LBP health outcomes

Although not a primary aim of this scoping review, we briefly detail here findings on the association between HL and LBP health outcomes (Table 3): out of six studies analysing the relation between HL and levels of pain and disability, only two found a significant association, particularly in the area of pain intensity. On behavioural impact, HL had no significant associations with fear avoidance, pain catastrophising, and psychological empowerment. However, patients with low HL were found to have a less active lifestyle. Considering patient knowledge and beliefs, those with lower HL had more difficulty identifying types and sources of treatment for LBP and were more dissatisfied with their care. However, no significant association was found between HL and beliefs about one’s future with LBP. Regarding resource utilisation, it appears that low HL was associated with higher utilisation of curative or symptomatic treatment (e.g. emergency room visits), and lower utilisation of preventive medicine (e.g. flu vaccinations).

4. Discussion

We will now discuss our results in the context of the two research questions and the implications for evidence and future research i.e. 1) the health literacy measures employed in back pain research and the aspects of health literacy they include (Functional, Communicative and Critical); and 2) the back-pain health outcomes included in such work and the extent to which these reflect the core outcome set for clinical trials in non-specific low back pain.

4.1 Health literacy measures employed

The studies included in this scoping review on the association between HL and LBP adopted a wide variety of measures to document HL (nine measures used) and health outcomes (50 measures used), making comparison across findings and the development of a comprehensive evidence-base challenging despite the development of the COS (18).
Although no restrictions were placed on year of publication, all relevant studies were published in 2010 or later, suggesting that interest in the association between HL and LBP is relatively recent. This may reflect HL being a relatively new concept within healthcare (47), and also the growing interest in LBP as it contributes to rapidly rising healthcare expenditure (10, 48). For instance, from 1996 through 2013, US expenditure on low back and neck pain rose by an estimated USD 57.2 billion, becoming the third-highest healthcare spending on a single condition in 2013 (48).

Despite no language or country restrictions being placed on the search, most studies were conducted in developed Western countries. Besides demonstrating a dearth of evidence in non-Western countries, this may be a barometer of societal readiness to integrate HL into LBP management. Most pressingly, there is a notable absence of research attempting to draw associations between LBP and HL in developing countries and collectively in Asia, Africa, and South America. This is in keeping with previous epidemiological studies remarking that LBP monitoring and research is largely restricted to developed nations, while being under-researched in developing countries (20, 21), countries which are more frequently found in Asia, Africa and South America. Alongside this is an increasing recognition of the need to develop and use culturally sensitive HL tools (49).

This study, despite expanding the search and using more open search criteria, only included seven additional studies on top of that in the systematic review by Edward et al. (23). The dearth of relevant studies in this scoping review highlights the continuing lack of evidence of the relationship between HL and LBP health outcomes.

### 4.2 Outcome measures used

Few studies incorporated the four outcome domains in the COS (pain intensity, physical functioning, health related quality of life, and number of deaths); only 14 of the 50 health outcome measures used did so. Moreover, these 14 measures were limited to the two core outcome domains of pain intensity and physical functioning (Table 5). This discrepancy suggests divergence of opinions on what is deemed as a key health outcome for people with LBP. This is concerning given that development of the COS incorporated a comprehensive range of views, employing a Delphi process with patients, care providers and researchers, a review by panellists who had published extensively on LBP, and by a four-continent International Steering Committee (18). Given the rigour and robustness in developing the COS, future studies on LBP are strongly recommended to adopt them to allow for comparison of findings and development of a rigorous evidence base. Furthermore, the authors of the COS have subsequently argued for the inclusion of the 24-item Roland-Morris Disability Questionnaire for physical functioning, and the Short Form Health Survey 12 and 10-item PROMIS Global Health form for health-related quality of life (50). However, none of these tools were used in the included studies (Table 2).

### 4.4 Implications for future research

Several limitations were noted in the literature with implications for future research design, specifically regarding study design, measures used and included study populations:

All ten studies were cross-sectional with no studies exploring the longitudinal relationship between HL and LBP outcomes, nor the efficacy and implementation of HL interventions for people with LBP. Although a mixed-methods approach is preferable to holistically evaluate the complex construct of HL (51), only the 2010 study by Briggs et al. employed quantitative and qualitative approaches (15).

Another limitation of in terms of design was that the primary studies relied heavily on patient reported outcome measures (PROMs), which may be biased by one's physical and psychological states, along with one's memory, willingness, and ability to answer the questions. This may influence one's ability to give accurate self-assessments of health status (52). This limitation could be overcome by the concurrent use of objective markers (e.g. functional tests), diagnostic imaging (e.g. functional magnetic resonance imaging), and/or observer reported outcomes (53, 54).
Many studies also had limitations in terms of the HL measure used. Most HL measures employed assessed functional
HL, while only a minority assessed communicative and critical HL. For example, both the S-TOFHLA and NVS focuses
solely on functional HL, specifically numeracy and reading comprehension skills, which are merely sub-components of
“understanding health information” in the definition of HL. The HeLMS provides a more holistic measure of HL, for
instance by asking questions on the assessment and usage of health information. HeLMS, and the questionnaires used
by Camerini and Schulz (40), MacLeod et al. (41) and Burke, Nahin and Stussman (42) have not been used as widely as
the S-TOFHLA and NVS, and their content validity in other settings requires confirmation. While a varied questioning style
is likely to result in a more complete assessment of HL, measures tended to focus purely on either objective response
(e.g. S-TOHHLA and NVS) or subjective replies (e.g. HeLMS). Ideally future studies on HL should use measures that cover
the three domains of HL as well as have vigorous validation in the setting employed.

Study population characteristics were also a source of limitation in the studied literature. Briggs et al. (15, 34) faced a
limited distribution of HL, hampering efforts to analyse relationships by HL level. Five of the included studies excluded
patients based on their language literacy, effectively excluding lower HL participants. If basic language proficiency is
required to obtain self-reported patient outcomes, this comes at the cost of excluding certain sectors of the population.
The use of translators or pictorial questionnaires needs to explored to enable the inclusion of participants who may be
considered vulnerable, for example those facing communication barriers or multimorbidity (55, 56).

Responder bias through self-selection was another common limitation in terms of study population design. This is
important in the context of HL studies, as low HL patients with lesser ability to communicate well with their healthcare
provider may have a tendency to decline study involvement (57). This limitation may potentially be mitigated using
retrospective and anonymised data, rather than depend on the voluntary actions of patients.

4.5 Strengths and limitations

The strengths of this review include the wide search strategy, involving 13 bibliographic databases with no search
limiters or filters. By including studies on all forms of LBP health outcomes associated with HL, this review was able to
build on the preliminary work of Edward et al. (23).

The studies by Devraj, Herndon and Griffin (17), MacLeod et al. (41), Farin, Ullrich and Nagl (16), and Köppen et al. (8) did
not have a solely LBP population, but were included as the LBP population made up at least 10% of the overall study,
which was pre-determined as the cut-off percentage for eligibility into this review. This cut off has been used as a marker
for significance in other studies (58, 59), but caution may be needed when interpreting the results of these studies.

In terms of limitations due to the heterogeneity of HL measures and LBP outcome measures employed, as well as the
paucity of relevant studies, it was difficult to compare the findings across studies and provide firm conclusions on the
association between HL and each LBP health outcome.

The protocol was not registered a priori leading to potential bias. However, as stated, no changes to the protocol were
necessitated during the review process and data extraction remained per protocol. Piloting of the data extraction form
was also not included. However, these are not requirements of a scoping review and were deemed unnecessary to fulfil
the study objectives, i.e. detailing the HL measures and LBP health outcome measures employed by pre-existing studies.

In terms of stakeholder involvement, while experts (clinicians and researchers) in the field of HL and LBP are members of
the research team, patients were not consulted. There is growing evidence of the value of patient and public involvement
at all stages of the research process (60), and the importance of how best to operationalise this within diverse cultural
contexts (61, 62). While deemed to be non-essential at this scoping stage, involving patients in the development of
research questions would be essential to further work into the impact of HL on LBP health outcomes in an Asian context.
5. Conclusions

The ten relevant studies included in this review yielded a total of nine different measures of HL and 50 measures of LBP health outcomes. Most health outcomes evaluated by the included studies did not seek to directly satisfy the core outcome domains for clinical trials in non-specific LBP. The wide variety of measures used hampers efforts to form conclusive relationships between HL and the respective health outcomes and precludes the use of a meta-analysis approach. To allow for comparison across findings and the development of a rigorous evidence base, future work should seek to address the core outcome set for clinical trials in non-specific LBP. Furthermore, research thus far has focused on a narrow range of populations and there is an urgent need to broaden the evidence-base to include those with characteristics known to be moderators in health outcomes, in particular Asia which has the largest number of LBP disability-adjusted life years globally. Such work demands the incorporation of comprehensive measures of health literacy that have both generic and culturally sensitive components.

List Of Abbreviations

HL Health Literacy
LBP Low Back Pain
COS Core Outcome Set
S-TOFHLA Short-form Test of Functional Health Literacy in Adults
HeLMS Health Literacy Measurement Scale
NVS Newest Vital Sign
FABQ Fear Avoidance Beliefs Questionnaire

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Availability of data and materials
The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests
The authors declare that they have no competing interests.

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**Figures**
Figure 1

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

Supplementary Files

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- Appendices.docx