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TITLE PAGE

Title: 'Self-management skills in chronic disease management: what role does health literacy have?'

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ABSTRACT

Background:

Self-management based interventions can lead to improved health outcomes in people with chronic diseases, and multiple patient characteristics are associated with the development of self-management behaviors. Low health literacy (HL) has been implicated in poorer self-management behaviors and increased costs to health services. However, the mechanisms behind this relationship remain unclear. Therefore, the aim of the current review is to assess the association between HL and patient characteristics related to self-management behaviors (i.e. disease-related knowledge, beliefs, and self-efficacy).

Methods

The review comprised three phases: (i) database searches, (ii) eligibility screening, and (iii) study quality assessment and strength of evidence. Inclusion criteria specified that a valid HL screening tool was utilized, that at least one self-management behavior was assessed, and that patients had a chronic condition.

Results

An initial search generated a total of 712 articles, of which 31 studies fulfilled the eligibility criteria. A consistent association was found between low HL and poorer disease-related knowledge in musculoskeletal and renal diseases, diabetes, and multiple disease categories. A significant association between low HL and poorer self-efficacy was reported in cardiovascular diseases, diabetes,

HIV, and multiple disease categories. HL was significantly associated with poorer beliefs in respiratory, musculoskeletal, and cardiovascular diseases.

Discussion

The findings from the current review suggest that low HL may impact on behaviors necessary for the development of self-management skills. Given that self-management strategies are core components for effective treatment of a range of chronic diseases, low HL poses a considerable health concern. Further research is needed in order to understand the mediating influence of HL on disease-related knowledge, self-efficacy, and beliefs. From this, HL-sensitive, self-management interventions ought to be devised and implemented.

1. INTRODUCTION

It has been established that self-management strategies can result in improved health outcomes, particularly for those with chronic diseases (1). Self-management is defined as ‘the ability of an individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, and lifestyle changes’ (2). The development of chronic conditions such as cardiovascular disease and diabetes is largely associated with unhealthy lifestyle behaviors (3, 4), and have surpassed infectious diseases as the leading causes of mortality worldwide (2, 5). A consequence of the traditional biomedical approach has resulted in patients often having a passive role in their healthcare choices (6), which has been proven to be less effective in treating such ‘lifestyle acquired’ conditions (7). Managing chronic conditions requires individuals to choose healthier behaviors of their own volition, and self-manage using a skill-set developed through information and support obtained from various educational and healthcare resources (8). Much research exists on a variety of self-management based interventions, such as disease-related education sessions, and community initiatives (3, 8). However, the effectiveness of these interventions is mixed (2, 9), and further research on potential facilitators and barriers to attaining self-management skills is required.

More recently, researchers and policy makers have identified health literacy (HL) as a potential facilitator or barrier to improved health outcomes (10-12). HL is defined as ‘the cognitive and social skills which determine the motivation

and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health' (13). Low HL has been linked to health outcomes such as poorer quality of life (14), increased emergency service use and mortality risk (15), which results in an increased burden on health budgets worldwide (16). Furthermore, low HL is associated with poorer health-related behaviors - namely self-management skills (17-19). However, despite the myriad of research in this area, the causal pathways behind this association remains unclear, and current recommendations from the literature suggest that further investigation is warranted (20, 21).

Deconstructing self-management may provide a basis for understanding how HL influences the development and maintenance of self-management behaviors. Newman et al (22) proposed three models which describe the development of self-management behaviours in those with chronic diseases – The Common Sense Model (CSM) by Leventhal et al (23), Bandura's Social Cognitive Theory (SCT)(24), and Ajzen's Theory of Planned Behavior (TPB)(25). At the foundation of these models are three distinct patient attributes – knowledge (CSM), self-efficacy (SCT), and beliefs (TPB), and previous literature corroborates the importance of these attributes combined for effective self-management (8, 26-30). For example, disease-related knowledge is integral to actively engaging in decision-making processes (26, 27), and is key to understanding health markers for disease control – a fundamental component of self-management (29, 30). In addition, poorer beliefs can result in poorer adherence to self-management strategies (28), whereas improving self-efficacy levels in patients can result in

increased confidence in making lifestyle changes, which is inherent to self-management (8).

To date, no review has considered the impact of HL on factors associated with self-management behaviors, as described by these three behavioral models.

Interestingly, a HL model developed by Passche-Orlow and Wolf (21) describes possible causal pathways between HL and health outcomes, highlighting knowledge, self-efficacy, and beliefs as mediating factors (Figure 1). Therefore, the current review aims to investigate the impact of HL on self management skills, with reference to the initial stages of behavioral change, as described by the CSM, SCT, and TBP - i.e. disease-related knowledge, self-efficacy, and attitudes and beliefs.

2. METHODS

2.1. Overview

The review comprised three phases: (i) a systematic search of the literature, (ii) study selection and data extraction, (iii) quality assessment of papers, and grading the strength of evidence.

2.1.1. Phase (i): Search Strategy

Chronic non-malignant diseases were included based on two reports by The World Health Organisation. The first included the top 10 diseases of greatest mortality risk, reporting cardiovascular diseases, diabetes, HIV, and respiratory diseases among the leading causes of death worldwide (5). The second report ranked cardiovascular diseases, respiratory diseases, diabetes, renal diseases, and musculoskeletal diseases highest in terms of global burden of disease (31). From this initial inclusion criterion, keywords were chosen and reviewed by two researchers (L.M.M., B.M.F.), and a database thesaurus was developed and used where possible (see appendix). A search string of keywords was generated and electronic searches of PUBMED, CINAHL, EMBASE, Cochrane Central Register of Controlled Trials (Central), and PEDro were conducted (inception – November 2013), and additional hand searches were conducted where suitable. The search was subsequently updated up to June 2015.

2.1.2. Phase (ii): Study Selection and Data Extraction

Potentially relevant articles were identified from the titles, abstracts and keywords provided, and were scrutinized by two researchers (L.M.M., B.M.F.). It

was not necessary to include a third reviewer, as there were no disagreements regarding the selection of appropriate studies. The full papers of accepted abstracts were retrieved, and relevant data were extracted using a detailed proforma developed to capture, and subsequently categorize the methodology and results of each paper. Initial inclusion criteria specified that studies were written in English, were observational in design (cross-sectional, longitudinal/cohort), included adults only (>18 years), that a validated HL tool was utilized, and that patients had at least one chronic condition. In addition, only papers that included assessment of at least one of the following were included in the current review: disease-specific knowledge, self-efficacy, and beliefs. In the revised search (i.e. to June 2015), the search extended to interventional studies (experimental, randomized control trials), to allow for potential causal relationships to be assessed. Accepted papers were categorized by chronic condition.

2.1.3. Phase (iii): Quality assessment and Strength of Evidence

The Effective Public Health Practice Project (EPHPP) quality assessment tool was chosen to assess the quality of eligible articles (32). This tool has been identified as one of the most appropriate for assessing both randomised control trials (RCTs) and non-RCTs (33), and has been used in 29 previous systematic reviews (34). The tool comprises six components that are rated as strong, moderate, or weak (see Table 1 for detailed information). The studies included in the current review were split evenly between all authors, with L.M.M. and C.D. co-reviewing the first half, and B.M.F. & E.L.W co-reviewing the remainder. No disagreements occurred regarding the quality appraisals. From this, the strength of evidence

(Level A to E) was reported using The Agency for Health Care Policy and Research (AHCPR) Guidelines (35). To calculate the strength of evidence, the consistency between findings from included studies was assessed (i.e. a consistent association was allocated when findings from all studies were in agreement, whereas an inconsistent association was allocated when findings from included studies were conflicting). Then the quality ratings of studies were considered before a final strength on evidence was graded. Minor amendments were made to include a Level B category for trials of moderate quality (36) (see Table 2 for further information).

3. RESULTS

3.1. Overview

In total 31 papers were included in the current review: cross-sectional (n=24), cohort/longitudinal (n=4), and randomized control trials (RCT) (n=3). Details of the search strategy are summarized in Figure 2.

Seven chronic disease categories were included: cardiovascular, respiratory, renal, musculoskeletal, HIV, diabetes, and multiple diseases. HL was assessed in primary care (n=10), tertiary care (n=13) and community settings (n=8), and six validated HL tools were utilized: The Short Test of Functional Health Literacy (s-TOFHLA) (37), The Rapid Estimate of Adult Literacy in Medicine (REALM) (38), The Test of Functional Health Literacy (TOFHLA) (39), The Newest Vital Sign (NVS) (40), the Korean TOFHLA (41), and The Three-Item Literacy Questionnaire by Chew et al (42). Studies varied in how they presented HL data, with some reporting HL as two categories (i.e. adequate or inadequate), or three categories (i.e. adequate, marginal, or inadequate). Furthermore, HL levels were most commonly described in percentages, although some studies provided mean and standard deviation values.

Included studies were rated as: strong (n=6), moderate (n=12), or weak (n=13), none of which were excluded on the basis of quality, as all provided sufficient information to be assessed by the EPHPP tool. Most studies utilized multivariate analyses, controlling for various demographic factors such as race, education and income. Three studies included structural equation modeling to further

investigate potential mediating relationships between HL and health outcomes. The study methodologies and findings are summarized in Table 3.

3.2. Respiratory Diseases

Three studies assessed the impact of HL on asthma (43, 44), and COPD and asthma (45).

3.2.1. Knowledge

Two studies found a consistent association (Level B) between low HL and lower disease-related knowledge (44, 45). Mancuso and Rincon found a correlation between lower HL levels and poorer scores on the 'Check Your Asthma IQ' knowledge assessment tool, with bivariate analysis ($r=0.39$, $p<0.0001$). Those with low HL were significantly less likely to correctly answer questions about asthma, for example, that breathing problems are dangerous (89% vs. 66%, $p=0.003$), and people with asthma should exercise (95% vs. 75%, $p=0.001$). The second study (45) found that HL remained the strongest predictor of asthma knowledge in multivariate analysis (adjusted diff. -1.1, CI 95% -1.7, -0.5, $p<0.001$).

3.2.2. Beliefs

One study (43) found that lower HL was associated with suboptimal beliefs about asthma (Level D), i.e. no symptoms–no asthma: 60% adequate HL versus 34% inadequate HL ($p = 0.01$); asthma is temporary: 23% versus 9% ($p = 0.07$); asthma is curable: 54% versus 25% ($p = 0.004$); medication works better if not used all the time: 44% versus 21% ($p = 0.03$).

3.2.3. Self-Efficacy

One study found no correlation between HL and patient self-efficacy (Level D), with bivariate analysis ($r=0.05$, $p=0.66$) (44).

3.3. Musculoskeletal Diseases

Six studies assessed HL and its impact on those with musculoskeletal diseases: chronic pain (46), rheumatoid arthritis (47, 48), osteoporosis (49), chronic low back pain (50), and osteoarthritis (51)

3.3.1. Knowledge

There was inconsistent evidence from three studies (Level D) that HL and disease-related knowledge were associated (46, 48, 49). One paper (46) found that after controlling for race, education, and income, that chronic pain patients with higher HL had better knowledge about over-the-counter medications, alternatives to medication for pain management, and knowing where to get medical assistance (F change (1,70) = 4.48, $p=0.038$) - overall, HL explained 36% of variance in medication knowledge. The second reported that HL was independently associated with arthritis knowledge ($B=0.266$, $p=0.002$) (48). However, Levinson et al (49) found no association between HL and osteoporosis knowledge ($p>0.05$). It is noteworthy that 97% of participants in this study had adequate HL.

3.3.2. Beliefs

There was inconsistent evidence from two studies (47, 50) regarding the impact of HL on beliefs in people with musculoskeletal diseases (Level D). One paper reported that HL and disease specific beliefs such as fear avoidance and catastrophizing were not associated ($p>0.05$) (50). However, all participants in this study had adequate levels of HL as measured by the S-TOFHLA, therefore, making comparisons between HL levels difficult. Martin et al (47) found that low HL was associated with greater risk perceptions regarding disease modifying anti-rheumatic drugs ($B=0.82$, $p<0.01$), and therefore, a reduced willingness to take these medications in rheumatoid arthritis patients ($B=0.86$, $p<0.01$).

3.3.3 Self-efficacy

One RCT found that changes in self-efficacy post intervention were not associated with baseline HL (51).

3.4. Cardiovascular Diseases

Fifteen papers assessed the impact of HL in cardiovascular diseases: heart failure (52-57), hypertension (58-62) stroke (63, 64), and general cardiovascular diseases (65, 66).

3.4.1. Knowledge

Disease-related knowledge was assessed using both validated and non-validated tools, with the majority focusing on patients' knowledge regarding medications and disease characteristics. Of the 15 papers included, an inconsistent association (Level D) between low HL and poorer knowledge was found (52-66). All but one paper (53) reported a significant association between HL and

disease-related knowledge. Hwang et al (53) identified barriers and factors to promoting self-care in health failure patients utilising analysis of variance methods. They stratified the sample into four different groups based on knowledge and self-care levels (see table 3), finding no differences in HL levels ($p=0.59$). One study reported bivariate findings only (56), finding that lower HL was associated with poorer dietary sodium knowledge in patients with heart failure. A further two studies utilized analysis of variance methods, with one (54) finding a significant association between low HL and poorer heart failure knowledge scores ($F(2,92)=12.7, p<0.001$), and the other (57) reporting that HL predicted 27% of variance in stroke education recall ($B=0.53, p<0.01$). Two studies (52, 59) utilized structural equation modeling to explain potential mediating pathways between HL and disease-related knowledge. Chen et al (52) found HL predicted 36.6% variance in knowledge as assessed by The Heart Failure Knowledge Questionnaire ($B=0.46, p<0.05$). Whereas Osborn et al (59) assessed knowledge using a set of questions derived from a validated questionnaire, and reported a 5% variance in knowledge according to HL ($B=0.22, p<0.001$). The remaining papers analyzed data using multivariate regression techniques (55, 60-64, 66), reporting significant associations. One paper (64) found conflicting results regarding patients' stroke knowledge - that while HL did not impact on patients knowing why they take warfarin (AOR 2.2, 95% CI 0.8-5.7), it was associated with discordant stroke perceptions (i.e. when asked 'what is a stroke') (AOR 5.8, 95% CI 2.1-15.6), after controlling for demographic factors. Two RCTs found that while HL scores was not associated with improvements in disease-related knowledge, participants in both studies showed improvements in post-test knowledge scores after completing a HL-

sensitive intervention, regardless of baseline HL. In contrast, one of the RCTs found no improvements in knowledge scores for participants assigned to the control group, regardless of HL (i.e. usual care).

3.4.2. Self-efficacy

Three papers reported on the relationship between HL and self-efficacy with conflicting results (Level D). Macabasco et al (55) found that patients with higher HL also had higher self-efficacy levels regarding the management of their condition (adjusted diff. 0.99, 95% CI 1.55-0.43, $p=0.01$), whilst the other papers found no association (59). Similarly, the third paper found that HL was neither directly ($B=0.19$, $p>0.05$) or indirectly ($B=0.02$, $p>0.05$) associated with self-efficacy levels (52).

3.4.3. Beliefs

Hwang et al (53) found a significant correlation between low HL and beliefs about the degree of control patients have regarding their condition ($r=0.095$, $p<0.05$).

3.5. Diabetes

Three studies assessed the impact of HL in diabetes patients (62, 67, 68).

3.5.1. Knowledge

Two papers found a consistent association (Level C) between patients HL scores and disease-related knowledge (62, 68). One paper found that after controlling for demographic variables, HL significantly predicted diabetes knowledge

($p < 0.001$) (62). The other paper found that despite patients attending a diabetes education class, repeat analysis at three months found that those with lower HL had significantly lower diabetes knowledge (19.9 ± 0.51 vs. 18.0 ± 1.08 , $p < 0.001$) (68).

3.5.2. Self-Efficacy

One paper found that patients with higher HL had more self-efficacy regarding diabetes self-care using structural equation modeling ($r = 0.14$, $p < 0.01$) (67).

3.6. Renal Diseases

One study reported on the impact of HL on kidney transplant knowledge (69), finding no association between HL and knowledge ($p > 0.05$) (e.g. 'do they know what a transplant is') with bivariate analysis. Whereas a second study found that low HL was independently associated with poorer knowledge of chronic kidney disease ($B = -0.21, -0.36, -0.06$; $p = 0.006$) in adjusted analysis (70), (Level D).

3.7. HIV

One study (71) assessed the impact of HL in HIV patients, and multivariate analysis found that low HL significantly predicted self-efficacy levels (AOR 5.8, 95% CI 2.0-15.7) and disease-related knowledge, as assessed by the subsequently validated 'Brief Estimate of Health Knowledge and Action' questionnaire (72) (AOR 2.4, 95% CI 2.2-2.6), (Level D).

3.8. Multiple Chronic Diseases/Multi-Morbidity

Three studies investigated the impact of HL on multiple chronic diseases collectively (62, 73, 74). Conditions included cardiovascular, respiratory and musculoskeletal diseases, and diabetes. One study (62) reported on conditions separately (i.e. diabetes and hypertension), and therefore, were included in the diabetes and cardiovascular results sections respectively.

3.8.1. Knowledge

Gazmararian et al (74) found that patients' level of HL was independently associated with knowledge of chronic disease (Level D), after controlling for demographic factors ($p < 0.001$).

3.8.2. Self-Efficacy

One paper reported that HL indirectly affected physical and mental health via self-efficacy ($B = 0.41$, $SE = 0.13$, $p = 0.001$), as measured by The General Self-Efficacy Scale (73).

4. DISCUSSION

4.1. Overview

The current review assessed the impact of HL on characteristics associated with self-management, in the most prevalent and costly chronic diseases (5, 31).

Three distinctive characteristics that are considered core to supporting self-management, via well-established behavioral models were evaluated - disease-related knowledge (CSM), self-efficacy (SCT), and beliefs (TPB). The findings were based on 31 studies, the majority of which were reported as either moderate or weak quality. Out of 25 studies that reported on the relationship between low HL and poorer disease-related knowledge, all but one reported significant findings. In addition, four out of eight papers found a significant association between low HL and poorer self-efficacy, and three out of four studies found an association between low HL and beliefs. According to the proposed behavioral models outlined by Newman et al (22), possessing such attributes is key to the development of self-management abilities, particularly for the conditions included in the current review. Therefore, these findings highlight a potential deleterious association between HL and self-management. As most best practice guidelines for chronic conditions support the use of self-management, it is vital to understand the behavioural processes required to ensure patients adopt these practices.

Deconstructing health behaviors associated with self-management may highlight further areas for Departments of Health to further incorporate the concept of HL as part of public health campaigns, to support engagement in self-management

practices. Several countries have initiated such programmes, e.g. the U.S. National Action Plan to improve Health Literacy (12); the Scottish 'Making it Easy: A health literacy Action Plan for Scotland' (75); and Ireland's 'Health literacy and Primary Care' (76). A study by Kiser et al (77) assessed the effectiveness of a HL-sensitive, self-management intervention with chronic obstructive pulmonary disease patients, finding that self-management practices significantly improved, regardless of HL levels. Similar findings have been reported in studies assessing HL-sensitive interventions in diabetes (78) and hypertension (79). Therefore, self-management interventions that are HL-sensitive may not only improve health outcomes for patients, but may also have a positive impact on healthcare cost. Currently in the U.S.A, the cost of poor HL is between 3-5 per cent of the health budget a year (16). Additional expenditures per year for each person with limited HL compared to an individual with adequate HL range from \$143 to \$7,798. In England, the NHS budget is £95.6 billion (80) - a saving of 3-5 per cent from adequate patient HL would be in the range of £2.87 billion to £4.78 billion – equivalent to the whole of the current skills budget for England and Wales (81).

4.2 Main Findings

4.2.1. Knowledge

While the majority of studies that assessed the relationship between low HL and poorer disease-related knowledge reported a significant association, not all disease categories had multiple papers from which conclusions could be drawn. Also, methods of assessment varied between studies, as a range of both validated and non-validated tools were utilized. This made synthesizing data between

studies difficult, and could also explain the conflicting reports regarding the impact of HL on disease-related perceptions (82). Furthermore, only two studies investigated the mediating effect of HL on disease-related knowledge and development of self-management skills (52, 59), despite previous reviews highlighting the need for more in-depth studies that investigate causal pathways between HL and self-management (20, 83). Future research should include newly developed disease-related knowledge assessment tools, that are validated in a range of chronic conditions, e.g. COPD (84), cardiovascular diseases (85), and diabetes (86).

4.2.2. Self-efficacy, and Beliefs

Few studies included self-efficacy and beliefs in their assessments. Four out of seven studies reported that those with higher HL had more self-efficacy, and three out of four studies reported that patients with lower HL had suboptimal beliefs, regarding the management of their condition. While these characteristics are posited in SCT and the TPB models as fundamental to behaviour change, and have been implicated in poorer health outcomes (87, 88), their relationship with HL is limited given the findings from the current review.

4.3 Limitations

The findings of the current review must be considered with the following limitations in mind. Only studies written in English were included, and as the majority of these studies were cross-sectional in design, caution must be taken when assuming direct causal relationships. In addition, 13 papers were rated as weak according the EPHPP quality assessment tool. Lastly, given the

heterogeneity of the studies included, it was not possible to categorize the results section by self-management characteristics, as the findings were not generalizable to all chronic diseases included.

4.4. Conclusions

The literature suggests that there is an association between HL and self-management skills. However, more robust research, particularly studies with interventional components is needed, to understand the direction and magnitude of the relationship between HL and disease-related knowledge, self-efficacy, and beliefs. More importantly, HL researchers should consider utilising HL frameworks (e.g. Passche-Orlow and Wolf), to gain a greater appreciation of the mediating influence of HL on health outcomes. This may serve as a more accurate method of analysis, as the use of multivariate regression techniques risks 'over-adjustment' - given that HL may develop from a range of patient demographics and attributes. Techniques such as structural equation modeling as utilized by Chen et al (52) and Osborn et al (67), or mediational analysis techniques conducted by Wolf et al (71), may provide more accurate representation of the impact of HL on self-management behaviors.

4.5. Practice Implications

Low HL can be difficult to detect and it can be embarrassing for patients, leading to further stigma and unwillingness to attend or seek out health services.

Previous research found that HL-sensitive interventions resulted in significant improvements in self-care practices, regardless of HL levels. Therefore healthcare professionals should consider adopting HL-sensitive interventions,

regardless of their patients' backgrounds. Furthermore, as outcomes from typical education based interventions have been reported as modest or inconclusive, HL must not be solely viewed as a patient issue, but must be addressed holistically by health services, ensuring disease-related knowledge is disseminated efficiently, that discordant beliefs regarding chronic diseases are eliminated, and that self-efficacy levels are improved or maintained. A HL-sensitive approach may foster an environment that promotes patient empowerment, which could ultimately lead to improved adherence to self-management strategies.

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6. CONFLICT OF INTEREST

The authors do not have any conflicts of interest to disclose.

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8. TABLES

Table 1: Components and scoring method of Effective Public Health Practice Project (EPHPP) Quality Assessment Tool

	STRONG	MODERATE	WEAK
Selection bias and Sample size	Very likely to represent target population and $\geq 80\%$ participation.	Somewhat likely to represent target population and 60-79% participation.	Not likely to represent target population or $< 60\%$ participation.
Design	Randomized control trials or controlled clinical trials.	Cohort analytical studies, case control studies, or interrupted time series.	Any other method used, or if method is not stated.
Confounders (list provided in accompanying document)	Controlled for $\geq 80\%$.	Controlled for 60-79%.	Controlled for $\leq 60\%$.
Blinding	Assessor not aware of participant status, and participant not aware of research question.	Assessor not aware of participant status, or participant not aware of research question, or blinding not described.	Assessor is aware of participant status, and participant is aware of research question.
Data collection methods	Tools are valid and reliable	Tools are valid but not shown to be reliable.	Tools are not shown to be valid or reliable.
Withdrawals and dropouts	Follow-up rate is $\geq 80\%$.	Follow-up rate is 60-79%, or question is non-applicable.	Follow-up rate is $\leq 60\%$, or withdrawals and dropouts not described.
Calculating overall score:	Study is rated as STRONG if there are no weak ratings.	Study is rated as MODERATE if there is one weak rating.	Study is rated as WEAK if there are two or more weak ratings.

Thomas et al, 2004

Table 2. Level of evidence

Level	Type of evidence
A	Generally consistent findings provided by (a systematic review of) multiple high quality studies (STRONGLY rated)
B	Generally consistent findings provided by (a systematic review of) multiple moderate quality studies (MODERATELY rated)
C	Generally consistent findings provided by (a systematic review of) multiple low quality studies (LOW rated)
D	One diagnostic study (either high or low quality), or inconsistent findings from (a systematic review of) multiple studies (LOW rated)
E	No diagnostic studies

The Agency for Health Care Policy and Research (AHCPR) Guidelines.

Table 3: Summary of included studies.

RESPIRATORY DISEASES					
Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
43. Federman et al, 2010. U.S.A. Primary Care.	Asthma. C/S study. n=100.	Understand the relationship between HL & disease beliefs in older, inner-city dwelling adults.	1. HL: S-TOFHLA. 2. Beliefs: CSM.	1. HL scores: 35% (n=35) inadequate, 65% (n=65) marginal or adequate. 2. Low HL associated with poorer beliefs: no symptoms-no asthma (AOR 2.5, 95% CI 1.0-6.1, p=0.01); that asthma can be cured (AOR 3.3, 95% CI 1.3-8.3, p=0.05); medication works better when not taken regularly (AOR 3.8, 95% CI 1.3-11.2p=0.02).	Moderate
44. Mancuso & Rincon, 2006. U.S.A. Primary Care.	Asthma. C/S study. n=175.	Measure the association between HL & patients' assessment of care, desire to be informed about, & participate in treatment.	1. HL: TOFHLA. 2. Asthma knowledge (Check your Asthma IQ). 3. Self-efficacy.	1. HL scores: 82% (n=143) adequate, 18% (n=32) marginal/inadequate. 2. HL levels correlated with asthma knowledge (r = 0.39, p<0.0001). 3. HL levels did not correlated with: self-efficacy (r=0.05, p=0.66).	Moderate
45. Williams et al, 1998a. U.S.A. Hospital.	Asthma. C/S study. n=483.	Measure reading ability of asthma patients presenting to the ED or during routine care.	1. HL: REALM. 2. Asthma knowledge.	1. HL scores: 27% (n=130) adequate, 33% (n=158) marginal, 27% (n=130) inadequate, 13% (n=65) essentially illiterate. 2. Low HL associated with poorer knowledge (adjusted diff. -1.1, CI 95% -1.7, -0.5, p<0.001).	Moderate
MUSCULOSKELETAL DISEASES					
Author &	Disease &	Aims/Hypothesis	Tools /Outcome	Results	Quality

46. Devraj et al, 2013.	Chronic pain. C/S study. n=139.	Examine the relationship between patient's HL level, pain awareness, & pain medication knowledge.	1. HL: NVS. 2. Knowledge: pain medication.	1. HL scores: 56.1% (n=78) limited, 43.9 (n=61) adequate. 2. Low HL associated with poorer medication knowledge (F change (1,70) = 4.48, p=0.038).	Weak
47. Martin et al, 2013	RA C/S study n=1009	Risk perception could be a unique patient attribute that might be influenced by background factors as well as modified by various formats of a risk presentation in a decision aid.	1. HL: 3 item literacy questionnaire (Chew et al, 2008) 2. Beliefs: Risk Perception and willingness to take DMARDS	1. HL scores: 8.8% (n=89) inadequate. 2. Low HL associated with increased risk perception (B=0.82, p<0.01) and reduced willingness for taking medication (B=0.86, p<0.01)	Moderate
48. Quinlan et al, 2012.	RA. C/S study. n=125.	Determine if HL is a predictor of health knowledge in RA patients.	1. HL: TOFHLA. 2. Arthritis knowledge: AKQ.	1. HL levels: 3% (n=4) inadequate, 4% (n=5) marginal, 93% (n=116) adequate. Mean (SD) HL scores 90.8 (13.8) 2. HL and knowledge significantly and independently associated (B=0.266, p=0.002)	Moderate
49. Levinson et al, 2012	Osteoporosis Cohort study n=60	To measure HL and osteoporosis knowledge in older adults with MTF.	1. HL: REALM 2. Knowledge: disease related (OKAT).	1. HL scores: 97% (n=58) adequate. 2. HL not associated with OKAT scores (p= not given).	Weak
50. Briggs et al, 2010.	CLBP.	Explore the relationship between HL & LBP-	1. HL: S-TOFHLA.	1. HL scores: All participants had adequate HL.	Strong

Australia. Community	C/S study. n=117.	disability, & the association between LBP & LBP-related beliefs.	2. Beliefs: (i) Fear avoidance (FABQ), (ii) Catastrophizing (CSQ), (iii) Beliefs about pain (BBQ).	2. HL not associated with: (i) Fear avoidance (p=0.43PA; p=0.35work), (ii) catastrophizing (p=0.85), beliefs (p=0.48).	
51. Sperber et al, 2013	Osteoarthritis	Explore whether a 12-month telephone-based self-management support intervention yielded differences in outcomes according to HL.	1. HL: REALM	1. HL scores: 70% (n=323) adequate.	Strong
U.S.A Primary Care	RCT. n=461		2. Self-efficacy: Arthritis self-efficacy scale	HL not associated with changes in self-efficacy post intervention (p>0.05).	

CARDIOVASCULAR DISEASES

Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
52. Chen et al, 2014. U.S.A. Primary care.	HF C/S study. N=63.	To test a model examining relationships between HL, HF knowledge, self-efficacy and self-care. *Structural Equation Modeling.	1. HL: S-TOFHLA 2. Knowledge: HFKQ. 3. Self-Efficacy: SCHFI	1. HL scores: 15.9% (n=10) inadequate, 15.9% (n=10) marginal, 68.2% (n=43) adequate. Mean (SD) HL = 27.4 (9.3). 2. Low HL significantly associated with knowledge (B=0.46, p<0.05). 3. HL not associated with self-efficacy (B=0.19, p>0.05).	Moderate
53. Hwang et al, 2014 USA	HF C/S study n=612	Identify barriers to, and factors promoting self-care among HF patients with high or low knowledge.	1. HL: S-TOFHLA 2. Beliefs: Perceived control (CAS-R)	Mean (SD) scores of 4 groups: low knowledge & good self-care = 24.9 (9.1), low knowledge & poor self-care = 25.1 (9.2), high knowledge & good self-care, = 25.6 (8.7), high knowledge & poor self-care 26.4 (8.5). Perceived control significant correlation (r=0.095, p<0.05)	Moderate

			Knowledge: HFKS	No significant findings between knowledge/self-care combined in 4 groups.	
54. Dennison et al, 2011.	HF. C/S study. n=95.	Determine prevalence of inadequate HL, & differences by HL levels in relation to self-care & knowledge.	1. HL: S-TOFHLA. 2. Knowledge (DHFKS).	1. HL scores : 42% (n=40) inadequate, 19% (n=16) marginal, 39% (n=35) adequate. 2. Low HL associated with lower knowledge (F(2,92)=12.7, p<0.001).	Weak
U.S.A. Hospital.					
55. Macabasco et al, 2011.	HF. C/S study. n=605.	Examine potential mediators of HL development (e.g. knowledge, self-efficacy, self-care behaviors).	1. HL: S-TOFHLA . 2. Knowledge. 3. Self efficacy.	1. HL scores: 37% (n=225) low, 63% (n=380) adequate. Mean (SD) scores = 24.2 (12.3). 2. Adequate HL associated with better knowledge: mean 6.6 vs. 5.5 (adjusted diff. 0.63, 95% CI 0.97-0.29 p=0.01). 3. Higher HL associated with higher self-efficacy: 5.0 vs. 4.1 (adjusted diff. 0.99, 95% CI 1.55-0.43, p=0.01).	Moderate
U.S.A. Hospital.					
56. Kollipara et al, 2008.	HF. C/S study. n=97.	Examine risk factors associated with deficiencies in dietary sodium knowledge in HF patients.	1. HL: TOFHLA. 2. Knowledge of dietary sodium (PDSKT).	1. HL scores: 29% (n=14) inadequate, 71%(n=83) adequate. 2. Low HL associated with less sodium knowledge (p=0.01).	Moderate
U.S.A. Hospital.					
57. Morrow et al, 2005	HF Cohort study n=32	Investigate whether patient-centred instructions for HF medications increase comprehension and memory for medication information in older adults.	1. HL: S-TOFHLA 2. Knowledge: recall of information in medication leaflet	1. HL scores: 34% (n=11) inadequate. Mean (SD): 26.3 (9.4) 2. HL predicted recall (B=0.53,p<0.01).	Strong
U.S.A Community					

58. Guise et al, 2012	HTN RCT n=196	Investigate whether appealing to HL level alone, or in conjunction with preferred learning style enhances educational outcomes	1. HL: S-TOFHLA 2. Knowledge: Hypertension Knowledge Test	1. HL scores: 83.7% (n=164) adequate, 8.7% (n=17) marginal, 7.7% (n=15) inadequate. 2. HL not associated with improved knowledge in HL only intervention. HL sensitive intervention resulted in improved pre versus post-test knowledge scores (p<0.001), in comparison to control group (P>0.05).	Strong
59. Osborn et al, 2011.	HTN. C/S study. n=330.	Examine pathways associated with self-care behaviors (e.g. demographics, knowledge, self-efficacy), & HL. *Structural Equation Modeling.	1. HL: S-TOFHLA. 2. Knowledge. 3. Self-efficacy.	HL scores: 30.3% (n=100) inadequate, 69.7% (n=230) marginal/adequate. 2. Higher HL associated with higher knowledge (B=0.22, p<0.001). 3. HL not associated with self-efficacy (p>0.05).	Weak
60. Pandit et al, 2009.	HTN. C/S study. n=330.	Examine if HL mediated the association between education &, HTN knowledge.	1. HL: S-TOFHLA. 2. Knowledge.	1. HL scores: 28.2% (n=93) inadequate, 71.8% (n=237) adequate. 2. Low HL associated with poorer HTN knowledge (Adj. diff. -0.89, 95% CI -1.79-0.02, p<0.001).	Weak
61. Persell et al, 2007.	HTN. C/S study. n=119.	Determine prevalence of medication discrepancies, & whether HL was associated with reconciliation problems.	1. HL: S-TOFHLA. 2. Medication knowledge: naming them.	1. HL scores: 31% (n=37) inadequate, 69% (n=82) adequate. 2. Low HL associated with having more difficulty naming medications (AOR 2.9, 95%CI 1.3-6.7, p=0.03).	Moderate

63. Sanders et al, 2014 USA	Stroke Prospective C/S study n=92	Examine the relationship of HL to retention of knowledge after recommended stroke education	1. HL: S-TOFHLA 2. Knowledge: retention of post stroke education provided in hospital (SPER).	1. HL scores: % 57.6 (n=53) inadequate. Mean (SD): Inadequate 5.58 (2.06), adequate 7.31 (1.76). 2. HL associated with poorer recall (adjusted difference 1.87, 95% CI 0.63-3.12, p=0.001)	Strong
64. Fang et al, 2009. U.S.A. Hospital.	Stroke. C/S study. n=146.	Assess stroke related HL in patients at risk of stroke, & perceptions of stroke.	1. HL: S-TOFHLA. 2. Knowledge: (i) medication knowledge ('why take warfarin'), (ii) definition of stroke & mechanisms ('what is a stroke').	1. HL scores: 35.6% (n=52) adequate, 12.3% (n=18) marginal, 52.1% (n=76) inadequate. Mean HL score = 17 2. Low HL: (i) not associated with warfarin knowledge (OR 2.2, 95%CI 0.8-5.7, p>0.05), (ii) is associated with discordant answers regarding stroke perception (AOR 5.8, 95% CI 2.1-15.6, p<0.001).	Moderate
65. Eckman et al, 2012 U.S.A. Hospital	CVD. RCT. n=170	Investigate whether appealing to HL level alone, or in conjunction with preferred learning style enhances educational outcomes	1. HL: S-TOFHLA 2. Knowledge: Hypertension Knowledge Test	1. HL scores: 83.7% (n=164) adequate, 8.7% (n=17) marginal, 7.7% (n=15) inadequate. 2. HL not associated with improved knowledge in HL only intervention. HL sensitive intervention resulted in improved pre versus post-test knowledge scores (p<0.001), in comparison to control group (P>0.05).	Strong
66. Kripalani et al, 2006. U.S.A. Primary care.	CVD C/S study. n=152.	Examine the association of HL with medication management capacity in an inner-city medical clinic.	1. HL: REALM. 2. Knowledge: Medication regimen complexity (DRUGS).	1. HL scores: 50.7% (n=70) inadequate, 28.9% (n=44) marginal, 20.4% (n=31) adequate. 2. Low HL associated with poorer ability to identify medications (AOR 12, 95% CI 0.97-23.75, p<0.001).	Weak

DIABETES

Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
67. Osborn et al, 2010. U.S.A. Primary care.	DM. C/S study. n=383.	Examine the association between HL, numeracy, & diabetes self-efficacy. *Structural Equation Modeling.	1. HL: REALM. 2. Diabetes self-efficacy: PDSMS.	1. HL scores: 31% (n=120) ≤9th grade (inadequate), 69% (n=263) ≥9th grade (adequate). 2. HL had direct affect on self-efficacy (r=0.14, p<0.01).	Weak
68. Kim et al, 2004. U.S.A. Hospital.	DM. Prospective study. n=92.	Assess the association of HL with self-management behaviors, & if diabetes education improves self-management in low HL patients.	1. HL: S-TOFHLA. 2. Knowledge: DKQ.	1. HL scores: 77% (n=71) adequate, 23% (n=21) limited. 2. Lower HL associated with lower knowledge (19.9±0.51 vs. 18.0±1.08, p<0.001).	Weak

RENAL DISEASES

Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
69. Grubbs et al, 2009. U.S.A. Hospital.	Kidney disease. C/S study. n=62.	Inadequate HLIT in dialysis population is common & associated with poorer access to kidney transplant wait list.	1. HL: S-TOFHLA. 2. Knowledge: transplant awareness.	1. HL scores: 32.3% (n=20) inadequate, 67.7% (n=42) adequate. Mean (SD) HL scores = 25.6 (9.4). 2. HL not associated with preference for transplant (p = 0.7), or certainty about the decision (p = 0.5).	Weak
70. Wright-Nunes et al,	Kidney disease.	Perceived knowledge is low in patients with	1. HL: REALM.	1. HL scores: 18% (n=71) <9th grade, 83% (n=328) ≥9th grade.	Moderate

2011.		chronic kidney disease.	2. Knowledge: of chronic kidney disease.	2. Low HL (<9 th grade) associated with poorer knowledge
U.S.A	C/S study.			
Primary Care	n=399.			

HIV					
Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
71. Wolf et al, 2007.	HIV.	Investigate whether HIV treatment knowledge, self-efficacy, or both mediate the literacy-adherence relationship	1. HL: REALM.	1. HL scores: 68.6% (n=140) adequate, 20.1% (n=41) marginal, 11.3% (n=23) low.	Weak
U.S.A.	C/S study.		2. Knowledge (BEHKA - HIV).	2. Low HL significant predictor of poorer knowledge (AOR 2.4, 95% CI 2.2-2.6).	
Hospital.	n=204.		3. Self-efficacy.	3. Low HL significant predictor of poorer self-efficacy (AOR 5.8 95% CI 2.0-15.7).	

MULTIPLE CHRONIC DISEASES

Author & Country	Disease & Design	Aims/Hypothesis	Tools/Outcome measures	Results	Quality
73. Kim and Yu, 2010.	OA, DM, Pulmonary disease, & CVD.	Investigate whether HL is mediated through self-efficacy on influencing the health status in Korean older adults.	1. HL: Korean TOFHLA.	1. HL scores: mean score (SD) = 5.48 (3.53). Mean (Weak
South Korea.	C/S study.		2. Self-efficacy: GSE.	2. HL predicted self-efficacy (B=0.67, SE=0.28, p=0.001).	
Community.	n=103				
74. Gazmararian	DM, HF, Asthma,	Explore the relationship between HL & knowledge	1. HL: S-TOFHLA.	HL scores: 24% (n=157) inadequate, 11.8% (n=77) marginal, 64.2% (n=419) adequate.	Weak

et al, 2003.	HTN.	of chronic disease among medicare managed care patients.	2. Knowledge.	2. Patients with low HL were less likely to answer multiple questions related to overall knowledge of condition correctly (p<0.05).	
U.S.A.	C/S study.				
Community.	n=653.				
62. Williams et al, 1998b.	HTN & DM.	Examine the relationship between HL & chronic disease (HTN and DM), its relationship with disease knowledge.	1. HL: TOFHLA.	1. HL scores: HTN: 49% (n=196) inadequate, 12% (n=50) marginal, 39% (n=156) adequate. DM: 44% (n=50) inadequate, 11% (n=13) marginal, 51% (n=45) adequate.	Weak
U.S.A.	C/S study.				
Hospital.	HTN: n=402.				
	DM: n=114.		2a. HTN knowledge.	2a. Low HL associated with poorer HTN knowledge (p<0.01).	
			2b. DM knowledge.	2b. Low HL associated with poorer DM knowledge (p<0.05).	

AKQ: Arthritis Knowledge Questionnaire; BEHKA - HIV: Brief Estimate of Health Knowledge and Action - HIV Version; C/S: Cross-Sectional; CLBP: Chronic Low Back Pain; CSM: Common Sense Model of Self-Regulation; CSQ: Coping Skills Questionnaire; CVD: Cardiovascular Disease; DHKFS: Dutch Heart Failure Knowledge Scale; DKQ: Diabetes Knowledge Questionnaire; DM: Diabetes; DRUGS: Drugs Regimen Unassisted Grading Scale; FABQ: Fear Avoidance Beliefs Questionnaire; GSE: General Self-Efficacy Scale; HC: Healthcare; HF: Heart Failure; HeLMS: The Health Literacy Management Scale; HFKQ: Heart Failure Knowledge Questionnaire; HIV: Human Immunodeficiency Virus; HL: Health Literacy; HTN: Hypertension; LBP: Low Back Pain; NVS: Newest Vital Sign; OA: Osteoarthritis; PDSKT: Parkland Dietary Sodium Knowledge Test; PDSMS: Perceived Diabetes Self-Management Scale; RCT: Randomized Control Trial; REALM: Rapid Estimate of Adult Literacy in Medicine; -S-TOFHLA: Shortened Version -Test of Functional health literacy in Adults; TOFHLA: SCHFI: Self-Care Heart Failure Index; Test of Functional health literacy in Adults.

9. FIGURES

Figure 1: Passche Orlow and Wolf (21), health literacy model.

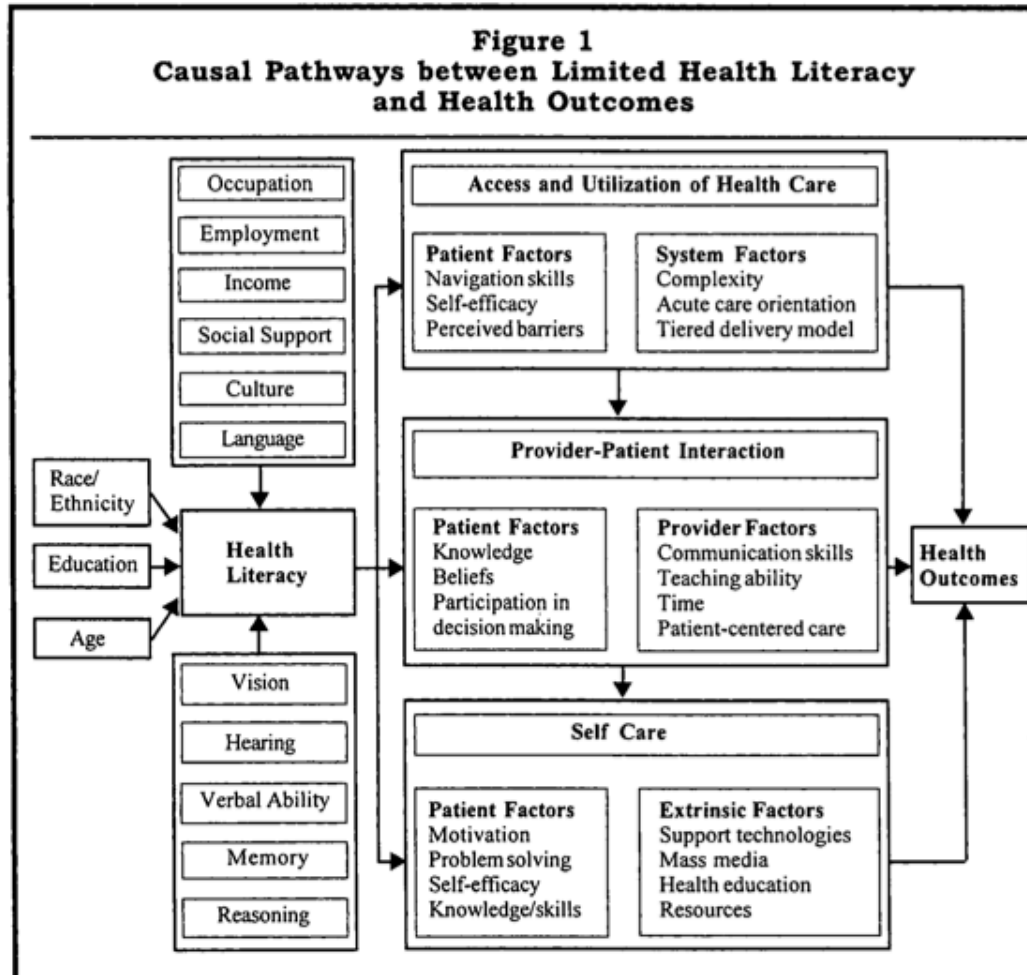
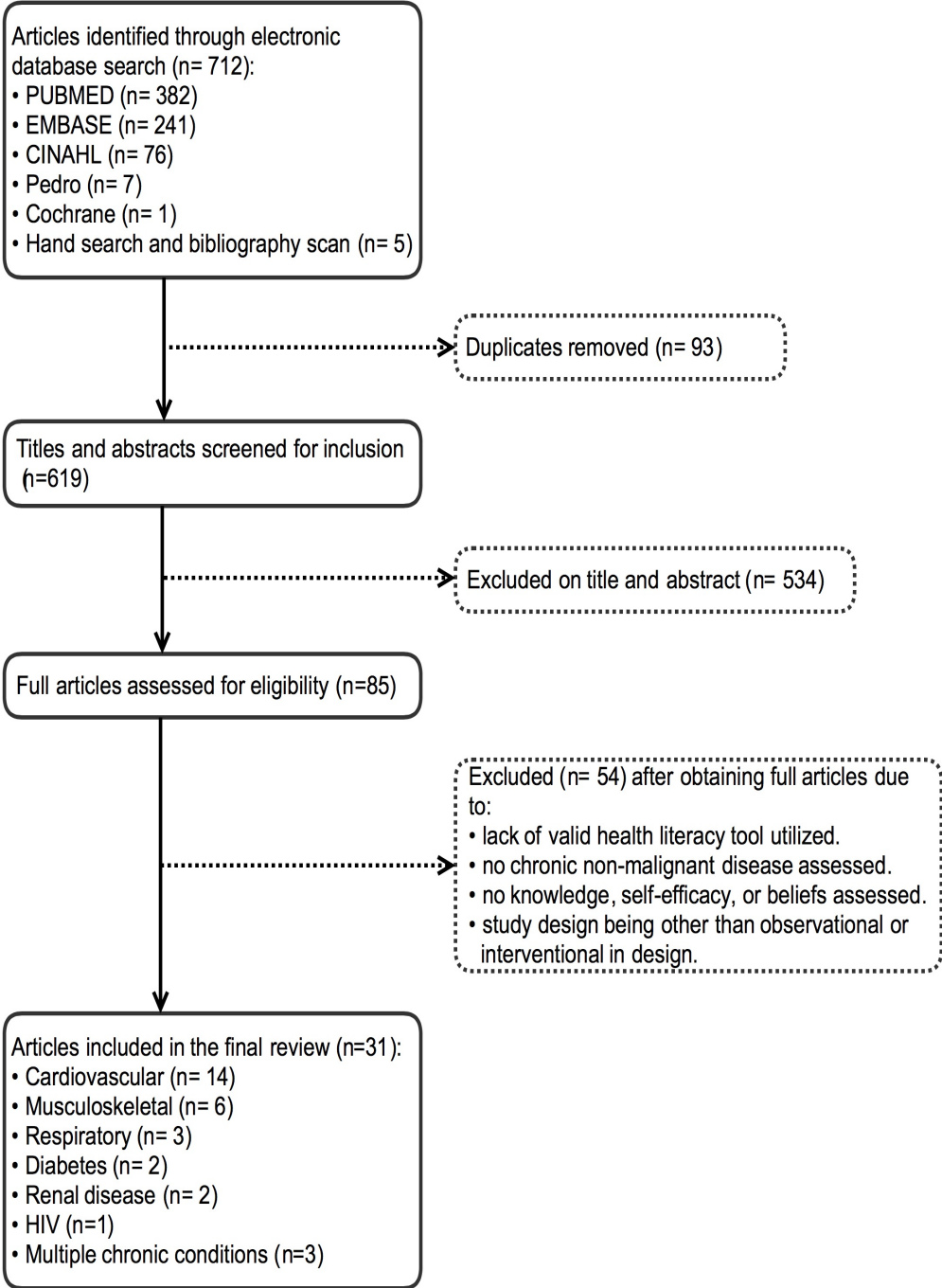


Figure 2: PRISMA flow chart.



10. APPENDIX

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