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Health Literacy education programmes developed for qualified health professionals: A Scoping Review

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Title: Health Literacy Education Programmes developed for qualified health professionals: A Scoping Review

Abstract

Objective: To identify and map health literacy competencies and health literacy related communication skills educational interventions for qualified health professionals. The review was informed by the following questions: which programmes are focused on diabetes care? What are the characteristics of each education programme? What were the barriers and facilitators to implementation? What methods are used to evaluate intervention effectiveness? What are the outcomes of the education programme?

Design: Scoping review.

Methods: This scoping review was informed by the Joanna Briggs Institute (JBI) guidelines. Studies were retrieved using a comprehensive search strategy in the following databases: OVID; Cinahl; Cochrane; EMBASE; ERIC: PsycInfo; RIAN; Pro-Quest; UpToDate. The literature was searched for health literacy education programmes developed for qualified health professionals, in all clinical settings, treating adult patient populations. Articles were not limited by study methodology. Two authors independently screened titles, abstracts and full text articles that met the inclusion criteria. The data was extracted and charted in table format.

Results: In total, fifty-three articles were identified. Twenty-six addressed health literacy education, and twenty-seven addressed health literacy related communication. Thirty-five reported using didactic and experiential methods. One article referred to diabetes care. Forty-seven did not report using educational philosophies. Forty-nine studies evaluated the reported education programmes using outcome measures.

Conclusion: This review mapped existing education programmes regarding health literacy and health literacy related communication skills. Characteristics were identified which will inform future intervention development. An evident gap was identified regarding qualified health professional education in health literacy, specifically in diabetes care.

Strengths and Limitations.

- This study is the first to map characteristics of current education programmes in health literacy and health literacy related communication for health professionals.
- This study is a scoping review which maps the evidence, so it does not assess risk of bias or reporting measures like a systematic review.
- Studies were excluded if they were not in English, which affects the generalisability of the study and relevance to other language speakers and cultures.
- Student populations were not studied in this scoping review. The focus was on qualified health professionals in all clinical settings.

Introduction

Literature has established the need for health literacy (HL) education for qualified health professionals (QHPs) (1-3), with recognition of this need reflected in policy development in European countries (4) where the goal is to improve patient outcomes (1). Although HL research has developed significantly since 1973 (5), limited research has been undertaken on HL interventions and their effectiveness (6), regarding QHP education.

Within the 'oral exchange' between the QHP and patient, interactive/communicative HL takes place (7, 8). Oral literacy and social skills are integral in meeting patients' health needs and understanding. An 'interactive communication loop' has been recommended, whereby the QHP assesses patient understanding and recall (9); an example of this is the 'Teach-Back' tool (10). HL education for health professionals is often directed towards this interactive domain by utilising a range of techniques such as Teach-Back (10), minimising jargon (11) and Ask Me Three to confirm patient understanding (12), and designing health literate reading materials to improve comprehensibility (11). If the HL demand

placed on individuals is reduced, by means of health literate communication from the QHPs, patient outcomes have the potential to improve (13).

In patients with chronic disease, limited HL has been associated with lower health-related quality of life (14), and poorer health outcomes (15). A social gradient can be seen with a higher proportion of those with limited HL experiencing lower socio-economic status, lower educational attainment, and are of older age which mirrors the pattern of inequality of those with chronic diseases (16, 17). In diabetes there is a complex demand on individuals to navigate the health system, especially when complications exist such as diabetic foot disease (DFD) (18). Demands on individuals are characterised by a high level of complexity (19), where effective self-management relies on patients having advanced HL skills to utilise written education material and verbal instructions (6). Interactive HL has been found to be the most important HL domain needed within diabetes self-management (20), consisting of a higher level of oral literacy (communication) needed to extract and discuss information with others (21).

It is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy (22-24), where greater self-efficacy is associated with lower glycaemic levels. Patients that are unable to effectively self-manage are at increased risk of complications, one of the most serious of which is DFD which can result in amputation (25). Individuals living with DFD have been found to have limited comprehension of diabetic foot ulceration (DFU); lack of foot self-care; delayed ulcer detection and seeking of medical attention, which puts the foot at increased risk (26). Similarly, foot self-care was often considered of lower priority than more immediate demands such as taking medication and glycaemic control. However, factors that appeared to motivate engagement in foot self-care included receipt of education and/or training from health professionals, which empowered participants to look after their feet (26). In order to maintain a supportive therapeutic relationship, health professionals must move away from simply focussing on ‘education’ and ‘advice’ but aim to support individuals in achieving effective self-management (27).

This current study adopted a relational concept of HL (28), focusing on organisational health literacy (OHL). The OHL approach makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions for their health (12). Emphasis is not on the individuals’ capabilities to manage their own health but on how their environment and the health services can play a central role in their successful application of their abilities to access and utilise services. Adopting this OHL approach places emphasis on, for example, educating qualified QHPs on health literate practice, to optimise patient-practitioner communication (7, 29) to ultimately empower patients.

Training programmes have been developed, for QHPs, to address HL competencies and HL related communication skills (2, 30-32). The extent and nature of programmes need to be collated in order to assess the potential of undertaking a full systematic review (33) and to inform future development of these complex interventions. This scoping review forms the 1st phase of the MRC framework in the development phase of a complex intervention (34), where focus is on compiling evidence to inform intervention development.

This scoping review aims to identify and map current educational interventions to improve HL competencies and HL related communication skills of QHPs, specifically within diabetes care. This study is situated within a larger research project entitled, Diabetic Foot Disease: from PRevention to treatment to IMproved patient Outcomes (*DFD PRIMO*).

Methods

Review Approach

Protocol development started with preliminary research which did not identify current literature within the population pertaining to those with either diabetic foot disease (DFD) or those with a diabetes diagnosis, therefore it was decided to expand the review to capture all qualified health professionals (QHPs) practicing in primary, secondary and tertiary care settings.

This scoping review was conducted drawing on methods and guidance from the Joanna Briggs Institute (35), which adds to earlier guidance on scoping review methodology (24). The study protocol was published on HRB Open: https://doi.org/10.12688/hrbopenres.13386.2. It was reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist (36) .

Selection Criteria

The "PCC" framework was employed (33, 35), where the population was QHPs of all backgrounds. Concept referred to education programmes for HL competencies and HL related communication skills. Context was primary, secondary, and tertiary care settings.

Five stages of a six stage framework were used to structure this review (33), the optional stage six which comprises stakeholder consultation was not adopted in the context of this current study.

Stage 1: Identifying the research question

The primary research question was:

1. What health literacy competencies and health literacy related communication skills educational interventions exist for qualified health professionals?

The secondary research questions were:

1. Of the qualified health professional education interventions identified which are focused on diabetes care?
2. What health literacy competencies and health literacy related communication skills are integrated into each programme?
3. What are the characteristics of each education programme?
4. What were the barriers and facilitators to implementation?
5. What methods are used to evaluate intervention effectiveness? If any.
6. What are the outcomes of the education programme on qualified professionals and/or patients?

Stage 2: Identifying relevant studies

This study retrieved evidence through a comprehensive search strategy in the following databases: OVID; Cinahl; Cochrane; EMBASE; ERIC: PsycInfo; RIAN; Pro-Quest; UpToDate. This search was performed in September 2021. Grey literature was searched within the references of identified articles. The search strategy was populated from a combination of free text search terms, text words, Medical Subject Headings (MeSH) terms and keywords with Boolean operators. Search terms were used in combination with search filters to tailor for each database. The search was developed with advice from a research librarian with expertise in search strategy development. The selected keywords and search string, relevant to Medline via Ovid, and developed search strategy can be found in the published protocol (37).

Stage 3: Study selection

The search was limited to the English language due to the variation in interpretations of the notion of HL from a cultural and socioeconomic perspective (38, 39). All searches were limited to post - 1973, due to HL research emerging at this time (5). Intervention components must contain HL competencies or HL related communication skills training, as previously defined (40, 41) in order to be included.

In this current study, QHPs identified were not limited by profession or setting. It must be noted that this search is limited to adult patient populations as often foot screening begins in adulthood as diabetes is monitored (42). For this study and the overarching project, health professional students will not be included in the population as the focus is QHPs working in diabetes care. Study selection will be based on the inclusion criteria provided below:

- Qualified health professionals (QHPs)
- Adult patient population (>18 years old)
- Intervention: HL competencies and HL related communication skills education containing competencies as previously defined (40, 41)
- All research methodologies
- All clinical settings

The exclusion criteria include:

- Healthcare students
- Paediatric patient population
- Literature Pre-1973
- Literature not in the English language

Similar to previous research, selection of sources and evidence will take place over four steps (43) :

Step 1: Initial retrieval of sources were performed by one author. Results from the search were imported into Rayyan (44), a scoping review manager software, whereby citations were collated and duplicates removed.

Step 2: Title screening. Titles were screened against the inclusion criteria and retained if they explicitly met the inclusion criteria. This step was performed by two blinded authors, whereby the third author was used to mediate if any disagreements arose.

Step 3: Abstract screening. Abstracts were screened against the inclusion criteria and were retained if they met the inclusion criteria. This step was performed by two blinded authors. Disagreements were mediated by the third author through discussion.

Step 4: Full text review. Articles were retained if compliant with inclusion criteria. This was performed by two authors of the research team and cross-checked with the third if any complications arose. This step was further developed in response to the volume of relevant results at this stage and the variability in the quality and detail of reporting in articles identified. The aim of this development was

to counter any definitional drift, strengthen consistent decision making and increase reliability, specifically in relation to the inclusion criterion, 'intervention'. This was achieved through discussion by the three authors, in two workshop style sessions over two days, where a unanimous decision was made on articles presented. Procedural rules were developed focusing on addressing the questions:

1. Did the article explicitly report details of the intervention?
2. Did the article explicitly report HL competencies OR HL related communication skills?

Therefore, if studies did not follow the procedural rules explicitly then they were excluded, as "a single failed eligibility criterion is sufficient for a study to be excluded from a review" (45) .

Numbers of articles included and excluded were documented using the PRISMA-ScR standardised template (36).

Stage 4: Charting the data

The extraction form was collated based on the JBI template source of evidence details, characteristics and results extraction instrument (35), training programme evaluation methods (46) and insight from previous work (47). A data charting form was developed drawing on categories, as agreed by the research team, such as: Year & Author; Country; Aim; Timeframe; Setting; Patient population; Intervention; Comparator, if any; Programme name; Programme goal; Setting; participants; Programme mode of delivery; Course detail; Programme Length; Who taught the course?; Educational philosophy; Evaluation method; Outcomes assessed; Kirkpatrick level of evaluation (this training evaluation model delineates four levels of outcomes such as reaction, learning, behaviour, and results) (46). An excel spreadsheet was used to chart this data.

Stage 5: Collating, summarizing, and reporting of results

Data was reported for each selected study within the agreed categories. Relevant findings were charted, using the data charting form developed in Stage 4. Subcategories of emerging themes were identified depending on presenting data.

Results

The database search yielded 17036 search results citations post deduplication. Stage 1: Title screening resulted in 610 citations. Stage 2: Abstract Screening resulted in 207 citations where 403 citations were excluded on the basis of wrong population (N=87); not an educational intervention (N=272); no abstract (N=6); Intervention not consisting of HL or HL related communication skills (N=34) and duplicates (N=4). Stage 3: Full text resulted in 131 included citations. Stage 3, step 4 resulted in 53 included citations that were extracted in Stage 4 Data Extraction. The complete process is in Figure 1. One study mentioned diabetes care (48).

Most studies were non-randomised, longitudinal, and undertook pre-post evaluation. The timeframe ranged between immediately post education (49) and 12 months post intervention (50). One study was a randomised controlled trial (HTN outcomes) (51). Of the 53 studies, the majority (N=32) took place in the United States, Denmark (N=5) and Japan (N=3). Intervention participants were reported as health professionals (N=25), some reported specific professions such as doctors (N=13) and nurses (N=9). 38/53 studies did not report the patient population and 10/52 reported oncology.

Educational Techniques

Didactic and experiential methods were reported to be used (N= 35). The use of didactic techniques was reported explicitly (N=11). The educational technique was not reported in one study (52). Specific experiential techniques were reported such as Role-Play (N=23) and Workshops (N=15).

Programme Content

Health Literacy Specific Interventions

All programmes reported educational content (N=26), where sixteen reported teaching written and spoken communication best practices; thirteen reported teaching an overview of HL; five reported self-management and empowerment; and four reported the “Always Use Teach-Back” training toolkit. Specific HL topics were addressed and charted in Table 1: HL Education Programmes.

HL related Communication Skills Interventions

Different HL specific techniques were used, four studies reported confirming understanding using Teach Back; five reported avoiding jargon; four reported using ‘Summarise’; four reported asking open questions; and four reported shared decision making. Specific HL topics were addressed and charted in Table 2: HL communication skills training programmes.

Education Philosophy

The majority of studies (N=47) did not report using an educational philosophy in development or delivering of the intervention, however some studies made reference to using 'adult learning philosophies and instructional methods (e.g., train-the-trainer)' (53); 'comfort theory (54)' and the adult learning theory (55)' (56). 'Bandura's theory of Social Learning (57)' (58); 'Calgary Cambridge (59)' (58, 60); 'COMSKIL conceptual framework (61)' (62) and 'Interaction Adaptation Theory (63) ' (64)

Evaluation

In terms of Kirkpatrick's levels of evaluation (46), 22/53 studies addressed Level 1 evaluation: Reaction; 38/53 studies assessed Level 2 evaluation: Learning; and 35/53 studies addressed Level 3 evaluation: Behaviour. However, 4/53 studies did not report outcome measures therefore a Kirkpatrick Level could not be determined (65-68).

Barriers and Facilitators to implementation

The majority of studies did not report barriers (N=45) or facilitators (N=52) to implementation of knowledge and skills into practice. In this study, implementation was in terms of perceived barriers to implementing learned knowledge, skills and practices in clinical practice.

Barriers reported include feeling unable to translate learning into practice; overestimation of HL understanding; difficulty in changing behaviour; breaking habits and overestimation of competencies; fitting the programme into daily practice; sustainability and lack of resources (2, 69-73). Other barriers to implementation included organisational barriers such as having an internalized or individual pressure to use technical language (71) and environmental barriers (lack of faculty role modelling, time constraints, and/or pressure to address multiple issues during clinic visits) (72, 73). Organisational issues included needing a greater shift in HL thinking by the organisation; lack of resources; limited or no funding; staff retention, and not having HL identified as a priority within the organisation (52).

Facilitators identified included having organisational commitment including managerial and executive support, having someone to champion HL in the organisation, and the organisation already having HL identified as a priority and the support from Primary Care Partnerships Staff (52). Importance of having individuals within the organization who could act as innovators or early adopters of innovation to help champion the change and increase adoption of the innovation (74).

Table 1: Health Literacy (HL) Training Programmes (n=26)

Educational Techniques	Programme Content (HL specific)	Outcomes Assessed
Didactic (2, 31, 48, 49, 53, 69-72, 74-83) Experiential (2, 31, 48, 49, 53, 69-72, 74-77, 79, 80, 82) Workshop (48, 49, 69-71, 84) Patient Video Testimonial (2, 76) Standardised patient encounters (48, 49, 75) Scenario Simulation (79, 80) Lunch and Learn Format (84) Reflection (48, 77) Group discussion (82) Peer supervision (69, 70) Role- play (2, 31, 50, 53, 69-72, 76, 77, 80, 82, 83) Video (31, 77, 80) Active learning component (77) Video and Facilitated discussion (56, 72, 75) Case discussions (53, 77) Feedback (49, 79) Brainstorming exercises (53) "Coaching sessions" (85) NR (52)	Overview of HL (2, 48, 49, 56, 69, 70, 72, 76-78, 80-82) HL importance (50, 53) Universal precautions approach (72, 84) HL Epidemiology (50, 53, 71) HL outcomes (2, 49) Health Disparities (53) Identifying HL (2, 53) HL policies (53) HL Resources (52, 77, 82) Introductory HL forum (52) Attributes of a health literate organisation (52) Teach Back (50) "Always Use Teach-Back" training toolkit (75, 76, 79, 85) Communication Strategies (71) Written and Spoken communication best practices (2, 31, 48, 49, 53, 69, 70, 72, 74, 76-78, 80-83) Clear health communication skills (48, 83) Shared decision making (69, 70) Health Promotion (78) Self-management and empowerment (69, 70, 72, 74, 78) Supportive systems (72) Adult Learning (53) Orem's self-care deficit nursing theory (74) Plain Language Planner for Palliative Care (PLP) (83) COMFORT (83) Brown bag medicine review (74) 'Plan Do Study Act' (PDSA) projects (52)	Acceptability & Usability (50) Satisfaction (53) Patient satisfaction (79) Evaluation (31, 48, 49, 69-71, 77, 81-83) Knowledge (2, 31, 48, 50, 52, 53, 56, 69, 70, 72, 74, 77, 78, 81, 82, 84) Behaviour (72, 74) Self-perceived ability to identify, assess and provide client-centred treatment to low-health literate patients (84) OSCE station score (31) Ability (2) Programme Effectiveness (78) Understanding (52) Plan-DO-Study Act for TB evaluation (76) Skills (48, 53, 69, 70, 74, 81, 83) Attitudes (48, 53, 69, 70, 77, 81) Practice (82, 83, 85) Health Beliefs and Attitudes Survey (HBAS) (53) Self-efficacy (50) Confidence (69, 70) Impact of prior HL training (48) Conviction and Confidence Scale: Conviction in the importance of teach-back; Confidence in the participants' ability to use teach-back (75, 79, 85) Health Professionals Communication Skills Scale (HP-CSS) (80) Press Ganey scores for Communication with Nurses (80)

Table 2: HL Communication Skills Training Programmes (n=27)

Educational Techniques	Programme Content (HL specific)	Outcome Assessed
Didactic (62, 64-68, 73, 86-98) Experiential: (62, 65, 67, 68, 73, 87-91, 95, 96) Workshop (51, 86, 90, 93, 97-101) Video demonstration (73, 86, 90) Facilitated group discussion (86, 96) Role-play (62, 64, 73, 88-91, 94-96) Feedback (90) Visual aids (88) Simulation-based exercises (65, 102) Reflection (102)	Confirming understanding (62, 87, 92, 100) using Teach Back (65, 86) Health Literacy in practice programme (51) Avoiding Jargon (64, 86, 94, 95, 102) Giving only 1-3 key points (86) Summarise (62, 67, 68, 100) Asking open questions (62, 86, 92, 100) Attentive listening (67, 68, 100) Patient centred approach (58, 60, 92, 94, 100, 101) Non-verbal cues (100) Shared decision making (92, 94, 95, 100); Agenda setting, (62, 87, 92) Empathy (87, 93, 100) Building rapport (100) Clarifying responsibility (100) Action planning (100) Handling emotions (100) Resilience and coping (102) Communication Techniques (58, 60) Evidence for communication (73, 100) Impact of communication(97, 98) COMFORT (94) Studor Group's AIDET1 mnemonic (66) Consultation structure of Calgary Cambridge model (58, 60, 67, 68, 90) COMSKIL Communication Skills Training (CST) Programme (87) The 3-Act Model (95) SPIKES methodology (88, 91, 93, 96-98) AIDETVR (Acknowledge, Introduce, Duration, Explanation, and Thank You) principles (65)	Evaluation (62, 64, 87, 89, 90, 92, 96, 102) Learner Feedback (93) Knowledge (86, 88, 94) Attitude (73, 86) Confidence (86, 89, 91) Self-efficacy (62, 87, 92, 100) Psychological distress (89) Burnout (89) Ability to detect patient's distress (97, 98) Decision-making behaviours (99) Client–provider interaction (CPI) checklist (99) Self-perceived ability to identify, assess and provide client-centred treatment to low-health literate patients; Competence (96, 102) Skills uptake (92, 94, 95) Feasibility/ Implementation (73) Behaviour (88) Commitment to change (101) Knowledge using the Health Literacy Assessment Questions (HLAQ) (51) Outcomes not reported therefore Kirkpatrick Level not applicable (65-68)

Discussion

This scoping review maps the current health literacy (HL) and HL related communication skills education programmes in existence for qualified health professionals in all settings. Fifty-three studies were identified that addressed HL or HL related communication skills. Within that sample, 26 studies focussed on HL education, and 27 studies looked at HL communication skills.

A HL education programme consists of a set of competencies including knowledge, attitudes and skills that professionals need to master in order to appropriately address limited HL levels presenting in their patients, by "presenting information in ways that improve understanding and ability of people to act on the information" (103). HL related communication is recognised to be a component of HL, from the point of view of 'oral exchange' and interpersonal communication between the health professional and the patient. They are not seen as synonymous but interlinked (104). HL related communication is the process of information exchange and HL is the application of a skill set (105). This is evident when the aim of communication skills education is to develop competencies that promote HL training of health professionals (1), it's promoting the development of the skills required in the communication process. This has the potential to strengthen the patient-healthcare professional dynamic. If the HL demand placed on individuals is reduced, by means of health literate communication from the health professionals, patient outcomes have the potential to improve (13).

Originally, this scoping review aimed to look at the patient population with diabetic foot disease (DFD) and education of the multidisciplinary team (MDT) involved in its management. A preliminary search revealed that there was no evidence in the area. Similarly, this was the case when broadened to diabetes care for the published protocol (37), therefore, it was decided to do a scoping review due to the inadequate volume of evidence to conduct a systematic review (33). This scoping review found that of the 53 studies only 1 alluded to diabetes (48). The goals of the curriculum did not address diabetes or allude to its applicability to diabetes care and limited reference was made in the standardised patient encounter where the patient case had diabetes. Therefore, to develop an education programme knowledge needs to be drawn from a wider evidence base because of the lack of available literature in the area of diabetes.

The programmes collated in this scoping review have demonstrated the need for appropriately detailed interventions, with wider applicability as most studies focussed on tertiary care or disease specific areas where advanced HL is needed (such as genetic testing). It was noted that no studies reported evaluating education of a disease-specific MDT, which is an area of the utmost importance

when working with chronic diseases such as diabetes, where MDT involvement is vital for optimum patient outcomes.

Minimal detail was reported on each intervention, affecting its reproducibility which is important in health professional education as often a programme will need to be adapted and modified according to the participant and patient demographics and cultural context. This scoping review is a component of a PhD project within a Collaborative Doctoral Award (CDA) focusing on diabetic foot disease, whereby the review forms the initial evidence base in creating a prototype educational intervention for the multidisciplinary team working with patients in the management of DFD. The lack of detail in reporting is a significant barrier to collating the evidence base for a novel programme in disease management. Nevertheless, the evidence base is limited and underdeveloped, specifically in diabetes care. Therefore, the information reported and collated in this current study does not provide sufficient information to replicate implementation of interventions, which is a significant issue for practice development.

Of the 53 studies only 35 reported using a combination of didactic and experiential methods, and 47 did not report using an education philosophy. Similarly, based on programme characteristics noted in this review there is no detail regarding adult education and how adults learn which may be beneficial to a new education programme. This suggests a lack of input from those with expertise such as educationalists, or it simply suggests lack of reporting. Underreporting and insufficient detail were common issues encountered throughout this review as one of the secondary research questions was to detail the 'characteristics of each programme'. Within complex interventions, the role of theory has been identified and recognised in the MRC framework (34) and yet has not been reported by identified papers as to how their intervention was developed. Similar to diabetes care which lacked detail, the broader literature base will need to be addressed in terms of instructional design and what educational philosophies or theories can form the basis of an education programme.

Interestingly, barriers and facilitators were not reported in 85% of studies identified in this scoping review. The way in which the education is delivered is integral, as it has the potential to mitigate issues. Various studies identified barriers such as a lack of resources, environmental barriers, and organisational barriers. Such barriers need to be noted and addressed by investigating long-term outcomes such as behaviour, to support the current evidence base which is lacking.

In terms of education delivery, the reporting was vague, and no detail was given as to how the delivery method was chosen. It is difficult to determine the most preferential delivery method from the results of this review so liaising with qualified health professionals enables accessibility and can mitigate potential barriers.

It was found that the majority of outcomes assessed were self-reported, this can create difficulty in determining the volume of learning that took place as often individuals can over-estimate or underestimate their skills (106). Focus was placed on participant outcomes such as self-perceived knowledge, skills, or attitudes and not on patient outcomes. This suggests the need for evaluation and feasibility assessment prior to integrating patient outcomes into the initial phase of a project.

Although, some studies evaluated Level 3: Behaviour, organizational impact wasn't reported (Level 4: Results). Most interventions only focused on levels 1, 2 and 3 of Kirkpatrick's evaluation model. In the context of the development of organisational HL, HL education aims to address areas that health professionals can be trained to respond to and address limited levels of HL. Health professionals have an impact on overall organisational HL, in confirming understanding and interpersonal communication (8, 12). Therefore, by targeting health professionals there will be an organisational impact. In terms of professional outcomes it is intended that if an organisation is health literate that individuals working within it will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (107). Therefore, assessing Level 4 of evaluation: Results would provide valuable insight into the effect of the education programmes on the wider context.

In conclusion, future educational HL interventions need to describe in depth the methods used to develop the programme while providing a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used to enhance reproducibility. The results from this scoping review will form the basis of a Delphi consensus study where the aim will be to build consensus on the theoretical and practical elements, design, delivery and evaluation of a HL education programme aimed towards health professionals working in diabetes care.

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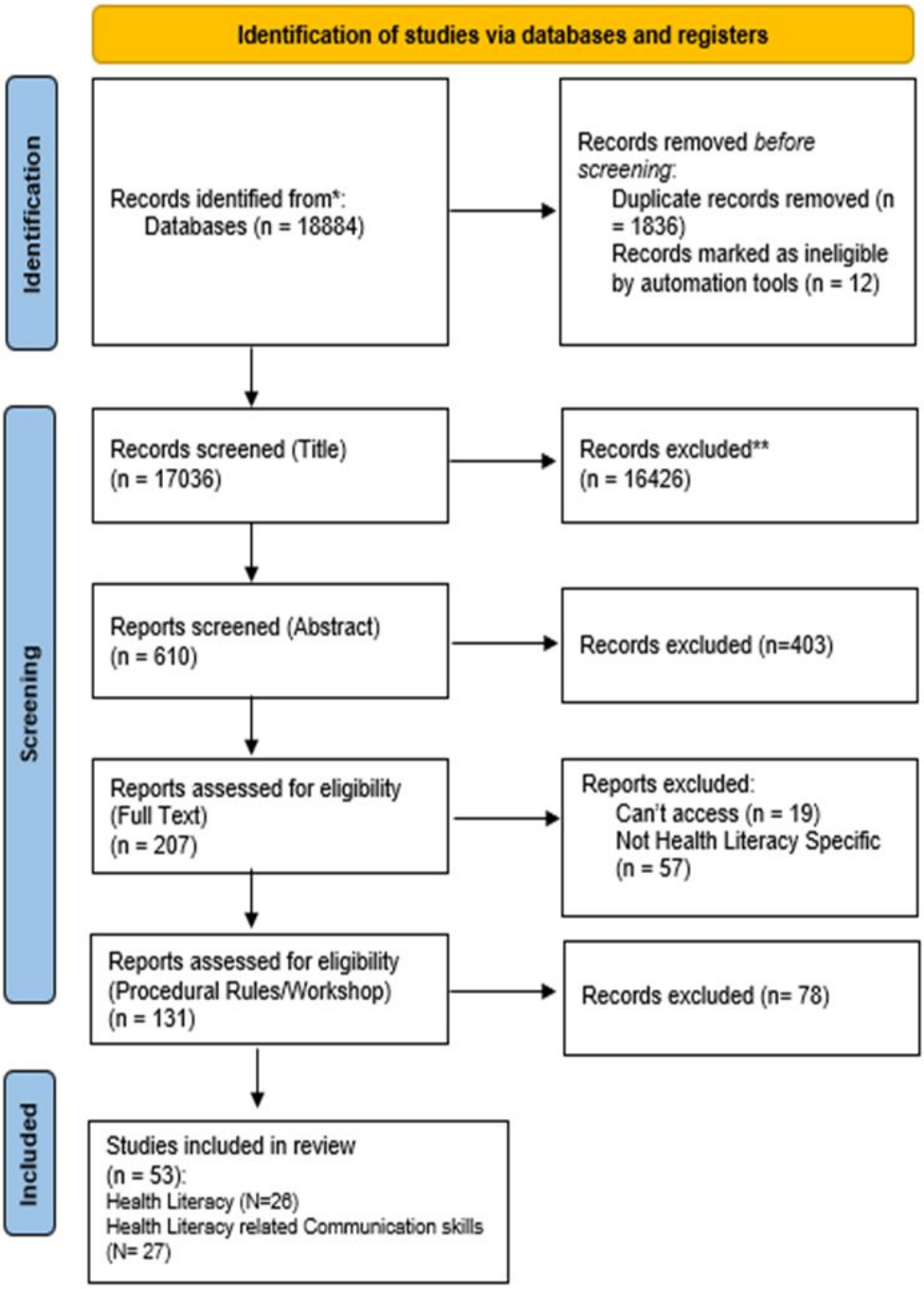
PRISMA 2020 flow diagram for new systematic reviews which included searches of databases and registers only



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Figure 1: PRISMA Flow Diagram

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STUDY PROTOCOL

REVISED Health literacy education programmes developed for qualified health professionals: a scoping review protocol [version 2; peer review: 2 approved]

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Abstract

Introduction: Health literacy education, for health professionals, has been identified as having the potential to improve patient outcomes and has been recognized as such in policy developments. Health literacy, as a relational concept, encompasses individuals' skills and how health information is processed in relation to the demands and complexities of the surrounding environment. Focus has been predominantly on the dimension of functional health literacy (reading, writing and numeracy), although increasing emphasis has been placed on interactive and critical domains. Such dimensions often guide the development of health professional education programmes, where the aim is to enhance the patient-practitioner relationship, and ultimately reduce the health literacy burden experienced by patients navigating health services. Currently little is known about qualified health professionals' education in health literacy and communication skills, and development, implementation or evaluation of such interventions.

Aim: To identify and map current educational interventions to improve health literacy competencies and communication skills of qualified health professionals.

Methods: A scoping review will be conducted drawing on methods and guidance from the Joanna Briggs Institute, and will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist. This study will retrieve literature on health professional education for health literacy and communication skills through a comprehensive search strategy in the following databases: CINAHL; Medline (Ovid); the Cochrane Library; EMBASE; ERIC; UpToDate; PsycINFO. Grey literature will be searched within the references of identified articles;

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 11 Jan 2022	✓ view	✓ view
version 1 02 Sep 2021	? view	? view

1. **Susie Sykes**, London South Bank University, London, UK
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Any reports and responses or comments on the article can be found at the end of the article.

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Lenus; ProQuest E-Thesis Portal; RIAN and OpenGrey. A data charting form will be developed with categories including: article details, demographics, intervention details, implementation and evaluation methods.
Conclusion: Little is known about the extent and nature of the current evidence base therefore a scoping review will be conducted, in order to identify programme characteristics in relation to health literacy competencies and communication skills.

Keywords
health literacy, health professional education, communication skills

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REVISED **Amendments from Version 1**

Following peer review the protocol has been revised. Protocol version 2 contains changes made in response to reviewers' feedback on version 1. We have actioned all of the changes suggested by the reviewers such as: describing what we interpret to be health literacy education, the worldview of the project, how communication skills relate to health literacy and their role within interactive health literacy, refinement of the inclusion criteria, refinement of chosen literature sources, and the relational concept of health literacy and its conceptual framework i.e., organisational health literacy.

Any further responses from the reviewers can be found at the end of the article

Introduction

The need for health literacy (HL) education, for qualified health professionals (QHPs), to improve patient outcomes has been identified[1], is supported by research literature[1–3] and is recognised in policy development in European countries[4]. This protocol is for a scoping review which aims to identify and map current educational interventions to improve HL competencies and communication skills of QHPs. Focus will be applied to diabetes care, as this study is a component of a larger research project entitled, Diabetic Foot Disease: from PRevention to treatment to IMproved patient Outcomes (*DFD PRIMO*).

HL has been described as an 'evolving' concept[5], developing over time with multiple definitions identified in the literature[6,7]. This is an identified limitation to research and can negatively impact the measurement of HL[8]. Nevertheless, there is increasing consistency in the use of a typology of HL comprising of three core domains: functional, communicative/interactive and critical[5]. At an individual level, functional HL leads to improved awareness of health risks, health services and treatment adherence; interactive HL, also referred to as communicative HL, leads to improved independence, motivation and self-confidence; whereas critical HL leads to better resilience to antecedents such as social adversity[9].

A relational concept of HL will be used[10], focusing on an organisational health literacy (OHL) approach which makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions and take informed actions for their health[11]. In this conceptualisation, emphasis is not on the individuals' capabilities to manage their own health but on how their environment and the health services can play a central role in their successful application of their abilities to access and utilise services. This approach is informed by the identification of the ten attributes of a HL friendly organisation[12], specifically that the organisation 'uses health literacy strategies in interpersonal communications and confirms understanding at all points of contact'. By adopting this approach, educating QHPs on HL competencies, to optimise patient-practitioner communication[13,14], has the potential to strengthen the patient-healthcare professional dyad. Such competencies include the knowledge, attitudes and skills that professionals need to master in order to appropriately address limited HL levels presenting in their patients[15]. As a result health professional education in HL is often directed towards improving HL related communication skills by utilising a range of techniques such as teach-back[16], minimising jargon[17], Ask Me Three, which helps confirm patient understanding[11], and designing health literate reading materials to improve comprehensibility[17].

For the purpose of this research, the relational characteristic of HL is recognised and informs the choice of definition used which is that HL is 'People's ability to find, understand, appraise and communicate information to engage with the demands of different health contexts to promote health across the lifecourse'[10].

In Ireland, 1 in 7 adults have been found to have limited HL skills[18], and at a European level almost every second respondent within the European health literacy survey (HLS-EU) had limited HL[19], which is associated with increased hospitalization, higher all-cause mortality, poor health related knowledge, self-care behaviour and other outcomes[20]. A social gradient can be seen with a higher proportion of those with limited HL experiencing lower socio-economic status, lower educational attendance and attainment, and are of older age which mirrors the pattern of inequality of those with chronic diseases[21,22].

For people with chronic disease, limited HL has been associated with lower health-related quality of life (HRQoL)[23], and poorer health outcomes[24]. In chronic disease such as diabetes, demands on individuals are characterised by a high level of complexity[25], where self-management relies on patients' having advanced HL skills, in order to utilise written education material and verbal instructions[26]. Diabetes has a profound effect on individuals with varying complications: macrovascular complications such as cardiovascular disease, stroke, peripheral vascular disease; and microvascular complications such as nephropathy, retinopathy, peripheral neuropathy, and diabetic foot disease[27].

Inadequate HL has been shown to be an independent predictor of poor glycaemic control, being associated with a lower likelihood of achieving tight control[28]. Also, it is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy[29–31], where greater self-efficacy is associated with lower glycaemic levels. It is implied that a positive relationship between HL and improved diabetes control. Interactive and critical HL have been found to be more influential than functional HL in influencing self-efficacy in those with diabetes[32–34]. In contrast, some studies have not found HL to have a statistically significant relationship with diabetes-related health outcomes such as wound healing[24] and other complications[35]. But, when interactive HL or critical HL are considered some relationships have been found to be positive[32,33,36].

The majority of the literature focuses on functional HL, however, there has been increasing emphasis on the development of the interactive dimension of HL. This has been particularly evident within health professional education, where programmes have been developed to improve HL competencies

and HL related communication skills[15,37]. If the HL demand placed on individuals is reduced, by means of improved communication and health literate communication from the QHPs, patient outcomes have the potential to improve[38]. Limited evidence has shown that confirming patient's understanding of new concepts can increase glycaemic control in those with diabetes[39].

Although HL research has developed and grown since at least 1973[40], limited research has been undertaken on HL interventions and their effectiveness[17], particularly in regards to qualified health professional education, despite the identification of such education programmes being relevant to mitigating potential health outcomes[1]. More recently, some training programmes have been developed, for QHPs, to address HL competencies and Hl related communication skills[2,37,41,42]. Although there is emerging evidence of these interventions, the extent and nature of programmes need to be collated in order to assess the potential of undertaking a full systematic review[43] and to inform future development of these complex interventions.

A HL education programme consists of a set of competencies to be addressed and achieved. Such competencies include the knowledge, attitudes and skills that professionals need to master in order to appropriately address limited HL levels presenting in their patients[15]. Although often recognized as a separate entity[10], communication plays a significant role in the development of interactive and critical HL, whereby effective communication maintains the patient-practitioner relationship[13,14].

Interactive HL has been found to be the most important HL domain needed within diabetes self-management[44], where interactive HL consists of a higher level of communication (oral literacy) and socials skills needed to extract and discuss information with others[5]. Patients with these skills are characterized by the self-confidence to act independently on advice, and to interact effectively with the health system. Interactive/communicative HL takes place within the 'oral exchange' in the QHP and patient interaction[14,45]. Oral literacy and social skills are integral to the interactive HL domain and in meeting patients' health needs and understanding. An 'interactive communication loop' has been recommended, whereby the QHP assesses patient understanding and recall[39]; an example of this is the 'Teach-Back' tool[16]. Other forms of communication within a health literate organisation include communicating: using social media and other digital forms, at an interprofessional level, with external stakeholders and at a community level.

Current educational health literacy interventions aimed at qualified health professionals need to be identified accordingly to collate the current evidence base and provide a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used. Currently, there are no universally accepted guidelines in relation to development of HL curricula for qualified health professionals, although there are general outlines to help guide development such as the Calgary Charter on Health Literacy[46]. Established HL competencies have been defined more recently for health professionals in areas such as general HL knowledge; HL related communication skills; and attitudes in practice[47,48].

Methods

The extent and nature of research in relation to health literacy education programmes for qualified health professions is currently unknown. A configurative scoping review was chosen as it aims to 'seek concepts to provide enlightenment through new ways of understanding'[49]. A preliminary review of research identified limited literature in the area. As a consequence, a scoping review design is appropriate to develop an overview of what is known[50] and to assess if a systematic review is possible[34]. An iterative approach will be used in this study to allow authors to develop the inclusion and exclusion criteria while considering the presenting evidence[49,51]. This scoping review will be conducted drawing on methods and guidance from the Joanna Briggs Institute[52], which adds to earlier guidance on scoping review methodology[31]. It will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist[53]. Protocol development started with preliminary research which did not identify current literature within the population pertaining to those with either diabetic foot disease (DFD) or those with a diabetes diagnosis, therefore it was decided to expand the review to capture all qualified health professionals (QHPs) practicing in primary, secondary and tertiary care settings.

The "PCC" framework was employed in this scoping review to determine the research question, whilst drawing on methods from Joanna Briggs Institute[52] and Arksey and O'Malley's (2005) scoping review framework[43]. The PCC framework, where PCC stands for Population, Concept and Context[52], helps construct a title without the need for outcomes, interventions or phenomena of interest[52]. The PCC framework provides the core detail on the inclusion criteria related to the review topic, but acknowledges the need for more detail when planning the screening phases. In this scoping review the population is qualified health professionals of all backgrounds. Concept refers to education programmes for health literacy competencies and health literacy related communication skills. The context is in terms of qualified health professionals working clinically in primary, secondary and tertiary care settings.

Five stages of a six stage framework will be used to structure this review[43], the optional stage six which comprises stakeholder consultation will not be adopted in the context of this stage of this current study. Nevertheless, this research is the first stage of a three stage project with the results of this scoping review informing stakeholder engagement activities and further research.

Stage 1: Identifying the research question

The primary research question is:

1. What health literacy competencies and health literacy related communication skills educational interventions exist for qualified health professionals?

The secondary research questions are:

1. Of the qualified health professional education interventions identified which are focused on diabetes care?

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2. What health literacy competencies and health literacy related communication skills are integrated into each programme?

3. What are the characteristics of each education programme?

4. What were the barriers and facilitators to implementation?

5. What methods are used to evaluate intervention effectiveness? If any.

6. What are the outcomes of the education programme on qualified professionals and/or patients?

Stage 2: Identifying relevant studies

This study will retrieve evidence through a comprehensive search strategy (Table 1) in the following databases: CINAHL; Medline (Ovid); the Cochrane Library; EMBASE; ERIC; UpToDate; PsycINFO.

Grey literature will be searched within the references of identified articles; Lenus; ProQuest E-Thesis Portal; RIAN and OpenGrey. The search strategy was populated from a combination of free text search terms, text words, Medical Subject Headings (MeSH) terms and keywords with Boolean operators. Search terms will be used in combination with search filters to tailor for each database. The search was developed with advice from a research librarian with expertise in the area of strategy development. The selected keywords and search string, relevant to Medline via Ovid, can be found in Table 1 below.

Results from the search will be imported into Rayyan[54], a scoping review manager software, whereby citations will be collated and duplicates will be removed. Although no current studies exist regarding the reliability and efficacy of using such automation tools, users have noted that the use of these tools saved time and increased accuracy[55].

Stage 3: Study selection

The search will be limited to the English language due to the variation in interpretations of the notion of HL from a cultural and socioeconomic perspective[56,57]. All searches will be limited to post- 1973, due to the history of HL research emerging at this time[40]. Intervention components must contain health literacy competencies or health literacy related communication skills training, as previously defined[47,48] in order to be included. For the purpose of this research, the relational characteristic of HL is recognised and informs the choice of definition used which is that HL is 'People's ability to find, understand, appraise and communicate information to engage with the demands of different health contexts to promote health across the lifecourse' as developed by Kwan (2006)[10]. In this current study, qualified health professionals identified will not be limited by profession in which they work. It must be noted that this search is limited to adult patient populations as often foot screening begins in adulthood as diabetes is monitored[58]. For the purpose of this study and the overarching project, health professional students will not be included in the population as the main focus is qualified health professionals working in diabetes care. Study selection will be based on the inclusion criteria provided in Table 2.

Table 1. Search Strategy for Medline (Ovid).

1	(("healthcare" or "health care") adj2 (professional* or provider* or personnel or worker*)).tw. or health personnel/
2	exp education/
3	(education adj2 (continuing or "competency based" or "competency-based" or health or program or programme*)).tw.
4	(workshop* or (problem-based adj (curricul* or learning))).tw. or ("problem based" adj2 (curricul* or learning)).mp. or (learning adj2 (active or experiential or problem-based or "problem based or case-based" or "case based")).tw.
5	(training adj2 (course* or module* or program or programme*)).tw.
6	training.tw. or inservice training/ or intervention*.tw. or course*.tw. or module*.tw.
7	staff development/ or clinical competence/ or program evaluation/ or program development/ or continu* professional development.tw.
8	2 or 3 or 4 or 5 or 6 or 7
9	exp Health Literacy/ or "health literacy".mp. or exp "health promotion"/ or "health literacy education".tw.
10	("health literacy" or ("health literacy" adj2 (competenc* or skill* or knowledge or attitudes))).tw.
11	communication skill*.tw.
12	(communication* adj2 ("teach back" or "teach-back" or method* or personal or program or social or personnel or health or nonverbal or non-verbal)).tw.
13	(skill* adj2 (interpersonal or social)).tw.
14	9 or 10 or 11 or 12 or 13
15	1 and 8 and 14
16	limit 15 to (english language and yr="1973 – 2021")

Table 2. Inclusion/Exclusion Criteria.

Inclusion criteria	Exclusion criteria
Population: Qualified health professionals.	Population: Healthcare students
Adult patient populations (>18 years old)	Patient population: Paediatric (<18 years old)
Intervention: HL competencies and HL related communication skills education containing competencies as previously defined[47,48]	Literature pre 1973
Study Methods: All research methodologies	Not in the English language
Limited to 1973- September 2021	
Settings: primary, secondary and tertiary care	

Similar to previous research, the selection of sources and evidence will take place over four steps[59]:

Step 1: Initial retrieval of sources, which will be performed by one author.

Step 2: Title screening. Titles will be screened against the inclusion criteria and will be retained if they explicitly meet the inclusion criteria. This step will be performed by two blinded authors, whereby the third author will mediate if any disagreements arise.

Step 3: Abstract screening. Abstracts will be screened against the inclusion criteria and will be retained if they meet the inclusion criteria. This step will be performed by two blinded authors. Disagreements will be mediated by the third author through discussion.

Step 4: Full text review. Articles will be retained if compliant with inclusion criteria. This will be performed by two authors of the research team and cross-checked with the third if any complications arise. Numbers of articles included and excluded will be documented using the PRISMA-ScR standardised template[53].

Stage 4: Charting the data

The extraction form will be collated based on the JBI template source of evidence details, characteristics and results extraction instrument[52], training programme evaluation methods[60] and insight from previous work[61]. A data charting form will be developed drawing on categories, as agreed by the research team, such as: article details, demographics, intervention details, such as adult education approaches, HL domain implementation and evaluation methods. An excel spreadsheet will be used to chart the data.

Stage 5: Collating, summarizing, and reporting of results

Data will be reported for each selected study within each category as agreed on in the previous stage. Findings will be presented in a table that outlines the research demographics as defined in Stage 4. Any subcategories of emerging themes will be identified depending on presenting data. Entries will be checked by all authors.

Dissemination

The findings of this scoping review will be published in a peer-reviewed journal and made available on ARAN, an NUI Galway open access repository, subject to the open-access policies of the original publishers.

Study status

Not yet initiated.

Conclusions

Although some training programmes have been developed to address HL competencies and HL related communication skills[37,41,42], the extent and nature of programmes, needs identifying and collating to assess the potential of undertaking a full systematic review[43]. This will inform future development of these complex interventions. Current educational health literacy interventions aimed at qualified health professionals need to be identified accordingly to collate the current evidence base and provide a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used.

Data availability

No data are associated with this article.

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 25 February 2022

https://doi.org/10.21956/hrbopenres.14699.r31170

✔ **Sarah Barry**

Centre for Health Policy and Management, Trinity College Dublin, Dublin, Ireland

The authors have responded to the points raised in my peer review report. The updates explain to a greater extent the theoretical underpinnings and operational elements of the original study protocol. Hopefully the queries raised have helped clarify the general frameworks that will drive the full programme of investigation envisaged. The full study can make a really useful contribution, especially for improved outcomes for diabetes patients.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: integrated care, organisation science, policy implementation, health services

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 24 January 2022

https://doi.org/10.21956/hrbopenres.14699.r31169

✔ **Susie Sykes**

Institute of Health and Social Care, London South Bank University, London, UK

Catherine Jenkins

Institute of Health and Social Care, London South Bank University, London, UK

We are happy that the authors have addressed all of the points we raised in our review and that

this protocol is now suitable for indexing.

The authors may wish to note that one of the sources that they include in their protocol, OpenGrey, is being decommissioned and may not therefore be available to them.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health literacy, critical health literacy, health literacy education for health professionals and students, scoping review design.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 15 October 2021

https://doi.org/10.21956/hrbopenres.14580.r30201

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Sarah Barry
Centre for Health Policy and Management, Trinity College Dublin, Dublin, Ireland

The paper is a protocol for a scoping review of health literacy (HL) literature, with a particular focus on HL training for healthcare professionals working in all clinical settings, although some focus on professionals working with diabetes patients is suggested.

The rationale for the scoping review is to map interventions (programmes, etc.) currently not evident in the literature as a starting point in considering the viability of a systemic review. A link between healthcare professional's HL competency and positive outcomes for patients is asserted. Subsequent study aims to inform better design and implementation of HL interventions based on a systematic review of the evidence scoped here.

One of the important premises is that most HL interventions are functional in nature, e.g. better awareness of risks, services and adherence, whilst interactive and critical domains of HL are less evident. The methods for the review are comprehensively described and referenced in several stages, nonetheless, I find a few overall study design elements could be further developed.

In essence, I think the protocol and planned review would be strengthened if the general worldview underpinning the study were more evident. This means clarifying something like a relational framework for HL competencies and skills, contexts, etc., and how that functions in the patient-healthcare professional dyad (or system).

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Such a framework (encapsulating a worldview) would help for clarifying questions arising here such as, what would more critical HL add to this relationship and/or better outcomes for patients and/or professionals; or why focus on diabetes care and outcomes as a good case?

Interactive and critical HL are linked to communication skills and greater relational competency, but other aspects could be explored including adult learning approaches. I think more detail on critical HL is needed, especially given the authors include all clinical settings in their inclusion criteria. Without knowing this literature in-depth I imagine critical HL would have to consider some of the institutionalised and systemic aspects of professional-patient interactions and outcomes given a relationship-based framework. I guess there is potential here for clinicians and patients together to become better system navigators.

A qualification of the secondary research question No. 2 (What are the characteristics of each education programme?) could suggest categorising programmes as 'functional', 'interactive' or 'critical' as a way to better understand the nature of these differences or the outcomes they generate.

A second element of the study design somewhat missing is evidence on HL among healthcare professionals. HL among diabetes patients is reported here, but how this evidence links to HL outcomes among professionals is not developed sufficiently.

Given the focus here is on health professionals and the HL interventions available to them, or indeed accessed by them - I am missing the literature that says something about this population in particular - even if scant and shows some sort of context-mechanism-outcome pattern. Some examples of positive outcomes from HL for healthcare professionals might include leadership skills development, skills in policy advocacy, or access to career development opportunities.

As per above, some more descriptions of why it is a good idea to focus on the relationship between diabetes patients and diabetes care (providing) professionals would add to the overall rationale. I imagine this can be easily asserted given the size of the population in question.

I thought the use of population, concept and context (PCC) as a frame for the review is a useful focusing plan. I'm not sure how this is a mnemonic (as stated), or how it functions to operationalise the study. I would expect a brief outline of the plan to report findings that corresponds to the PCC approach, and maybe explaining what this adds.

I also wondered why the authors are not planning a 'stage 7' stakeholder engagement as part of the scoping review - especially given their sub-question on implementation. The reason may be lack of funding, time, etc. If this is the case it would be good to say so.

Overall, the protocol positively outlines the rationale, design and next steps for studying HL among healthcare professionals as an addition to both the literature and practice. Mapping current interventions is a positive contribution that will build development of better interventions. The protocol would gain from more exploration of its ontological approach - I think this is implied but not fully stated or its implications drawn out.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: integrated care, organisation science, policy implementation, health services

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 15 Dec 2021

Lauren Connell, National University of Ireland, Galway, Galway, Ireland

Dear Dr Sarah Barry,
Thank you for reviewing our protocol submission, and for your constructive feedback. As a result, revisions have been made and are individually addressed below, please see reviewer's comments in bold. The revisions suggested from your comments certainly enhance the overall protocol.

The paper is a protocol for a scoping review of health literacy (HL) literature, with a particular focus on HL training for healthcare professionals working in all clinical settings, although some focus on professionals working with diabetes patients is suggested. The rationale for the scoping review is to map interventions (programmes, etc.) currently not evident in the literature as a starting point in considering the viability of a systemic review. A link between healthcare professional's HL competency and positive outcomes for patients is asserted. Subsequent study aims to inform better design and implementation of HL interventions based on a systematic review of the evidence scoped here. One of the important premises is that most HL interventions are functional in nature, e.g. better awareness of risks, services and adherence, whilst interactive and critical domains of HL are less evident. The methods for the review are comprehensively described and referenced in several stages, nonetheless, I find a few overall study design elements could be further developed.
Thank you for your positive comments, please see responses below.

In essence, I think the protocol and planned review would be strengthened if the general worldview underpinning the study were more evident. This means clarifying something like a relational framework for HL competencies and skills, contexts, etc., and how that functions in the patient-healthcare professional dyad (or system).

This study is part of a larger project focussed on diabetic foot disease (DFD) prevention, and this project aims to improve interactive health literacy (HL) from a communicative point of view. A relational concept of health literacy will be used (1), focusing on an organisational health literacy (OHL) approach which makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions and take informed actions for their health (2). By adopting this approach, increasing HL competencies and communication has the potential to strengthen the patient-healthcare professional dyad. Please see amended protocol introduction that introduces OHL and the relational concept of HL. Reference to this is now included in the update protocol. See introduction paragraph 3.

Such a framework (encapsulating a worldview) would help for clarifying questions arising here such as, what would more critical HL add to this relationship and/or better outcomes for patients and/or professionals; or why focus on diabetes care and outcomes as a good case?

The concept of OHL is an important one that helps us determine the relevance and understanding of where interactive HL comes into the overall study. Predominately the literature focuses on functional HL, and the literacy proficiency needed to navigate the health system. In the overall PhD project the objective is to target interactive HL by addressing patient-practitioner communication and the therapeutic relationship. This will be achieved by developing an education programme to improve the interactive domain of HL, and introduce a shift in understanding for professionals whereby HL is often an under/overestimated concept when it comes to patient interaction. Attaining critical HL is the ultimate goal in creating an accessible and inclusive health system, where individuals can evaluate and critique relevant health information. Therefore, by attaining critical HL at a community level, individuals have the potential to use the patient-professional consultation to its full capacity in promoting health creating a cultural shift.

The worldview is addressed within the protocol introduction (paragraph 3) where the reason for the focus on diabetes is included. Reference to this is now included in the updated protocol, see introduction paragraphs 5,6 and 7.

Interactive and critical HL are linked to communication skills and greater relational competency, but other aspects could be explored including adult learning approaches.

Adult learning approaches and methodologies will be reported in the results when charting the retrieved data. It is intended to explore this in the next stages of intervention development, where experiential learning (3) will be explored in further detail. Reference to the inclusion of adult learning approaches and methodologies is now explicitly included in the protocol methodology stage 4: charting the data.

I think more detail on critical HL is needed, especially given the authors include all clinical settings in their inclusion criteria. Without knowing this literature in-depth I imagine critical HL would have to consider some of the institutionalised and systemic aspects of professional-patient interactions and outcomes given a relationship-based framework. I guess there is potential here for clinicians and patients together to become better system navigators.

This current study is focused on the interactive aspects of HL and the patient practitioner interaction, therefore the chosen settings, primary, secondary and tertiary, aim to capture all qualified health professionals where patient communication is needed. However, it must be noted that critical HL is attributed to having advanced personal and social skills enabling one to access, manage, assess the credibility, understand and critically appraise information on health related issues (4). Critical HL is seen to arise from the relationship between individuals and services, being able to navigate and advocate for themselves in the healthcare setting. Reference to this is now included in the updated protocol, see methodology paragraphs 1 and 2.

A qualification of the secondary research question No. 2 (What are the characteristics of each education programme?) could suggest categorising programmes as 'functional', 'interactive' or 'critical' as a way to better understand the nature of these differences or the outcomes they generate.
Thank you for this suggestion. It is anticipated that such categories will be recorded, as it will demonstrate meaningful information when carried out in charting the results and is explicitly included in Stage 4: Charting the data.

A second element of the study design somewhat missing is evidence on HL among healthcare professionals. HL among diabetes patients is reported here, but how this evidence links to HL outcomes among professionals is not developed sufficiently.
The need for health professionals HL education, to improve patient health outcomes, has been identified (5), is supported by research literature (5-7) and is recognised in policy development in European countries (8). Educating health professionals has the ability to make an impact in reducing health inequalities in populations at the highest risk of limited HL levels, particularly within diabetes. It is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy (9-11), where greater self-efficacy is associated with lower glycaemic levels. Inadequate HL has been shown to be an independent predictor of poor glycaemic control, being associated with a lower likelihood of achieving tight control (12). Similarly, HL was associated with a higher prevalence of retinopathy and other self-reported complications of diabetes (12). This is now included in the protocol Introduction paragraph 7.

Given the focus here is on health professionals and the HL interventions available to them, or indeed accessed by them - I am missing the literature that says something about this population in particular - even if scant and shows some sort of context-mechanism-outcome pattern. Some examples of positive outcomes from HL for healthcare professionals might include leadership skills development, skills in policy advocacy, or access to career development opportunities.
In terms of professional outcomes it is intended that if an organisation is health literate that individuals working within will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (13)

As per above, some more descriptions of why it is a good idea to focus on the relationship between diabetes patients and diabetes care (providing) professionals would add to the overall rationale. I imagine this can be easily asserted given the size

of the population in question.
The evidence base for interventions to prevent diabetic foot disease is lacking. Therefore, to address this unmet and critical need, this Collaborative Doctoral award programme of research is focusing on primary and secondary prevention of DFD and novel treatment approaches to improve patient outcomes for those with DFD. The overall goal of DFD PRIMO is to train a multidisciplinary cohort of health care professionals to doctoral level in order to increase internationally competitive DFD research activity in Ireland, to provide a strong evidence-base for prevention and treatment provision decisions and improved patient outcomes.

I thought the use of population, concept and context (PCC) as a frame for the review is a useful focusing plan. I'm not sure how this is a mnemonic (as stated), or how it functions to operationalise the study. I would expect a brief outline of the plan to report findings that corresponds to the PCC approach, and maybe explaining what this adds.
The PCC (Population (or participants)/Concept/Context) is a framework recommended by the Joanna Briggs Institute. It enables one to identify the main concepts in the primary review question to allow for added structure within development of the study's aims and criteria. This is now addressed in Methodology paragraph 2. However, the PCC framework is designed to be utilised in creating the review title and the planning of the review, therefore it will not be used as a tool to report findings.

I also wondered why the authors are not planning a 'stage 7' stakeholder engagement as part of the scoping review - especially given their sub-question on implementation. The reason may be lack of funding, time, etc. If this is the case it would be good to say so.
The optional stage which comprises stakeholder consultation will not be adopted in the context of this current study. However, this research is the first stage to a three stage project which aims to incorporate stakeholder engagement informed by and using data collated from this review. This is noted within the updated protocol under Methodology paragraph 3.

Overall, the protocol positively outlines the rationale, design and next steps for studying HL among healthcare professionals as an addition to both the literature and practice. Mapping current interventions is a positive contribution that will build development of better interventions. The protocol would gain from more exploration of its ontological approach - I think this is implied but not fully stated or its implications drawn out.
In terms of ontological approach, the UK Medical Research Council (MRC) framework on developing and evaluating complex interventions (14) will be used to guide this research programme, whereby the four stage process will be used to develop a complex intervention informed by a gap analysis (scoping review), expert consultation and review. This framework recommends a phased development process, which is indeed the case for this research. It allows a continuum of increasing evidence in order to assist with intervention development (14). This approach uses systems theory which is a foundation for OHL, in order to structure intervention development. HL is a relational concept whereby focus is on individual interaction with services and systems, from an OHL point of view. As the focus is

on OHL, it is anticipated that a more health literate organisation will result in reduced barriers for individuals accessing and utilising healthcare.

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health literacy with diabetes outcomes. Jama. 2002;288(4):475-82.

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14. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, *et al.* A new framework for developing and evaluating complex interventions: update of Medical Research Council guidance. bmj. 2021;374.

Competing Interests: No competing interests were disclosed.

Reviewer Report 16 September 2021

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Susie Sykes
Institute of Health and Social Care, London South Bank University, London, UK

Catherine Jenkins
Institute of Health and Social Care, London South Bank University, London, UK

Thank you for the opportunity to review this protocol which we feel forms the basis of an important and useful scoping review. This protocol for a scoping review addresses an important area of inquiry of an emerging area of research that addresses a practice-based problem. The review is well-planned and largely methodologically sound but issues of replicability could be enhanced. This is discussed below. It is aligned with the PRISMA ScR guidance and has benefitted from the inclusion of a librarian to design the search strategy. We agree that a scoping review is the most appropriate review type to explore the research objectives outlined here and to assess the need for undertaking a systematic review in the future. The inclusion of grey literature will enrich the review. Incorporating grey literature coverage also provides further justification for the choice of review type.

The authors provide a clear rationale for conducting a scoping review to address their research objectives, which are clearly-defined.
Some points that the authors may wish to consider:

- While the rationale for the study clearly states the prevalence and implications of low health literacy amongst patients and the public, there is a slight leap between this and the specific problem the scoping review seeks to address of health professional training/education. While it is perhaps implicit, a clear delineation of exactly what is included in your understanding of health literacy education for professionals would be helpful. Is it to improve the health literacy of professionals themselves, their understanding of how to

respond to low and varied health literacy levels of patients or how to create a health literate environment. We think that there is value in drawing on some of the literature around health literacy as a relational concept that explores the relationship between the health literacy competencies of individuals and the demands of the environment.

- The research questions are clear and helpful but a secondary question around diabetes is introduced and the rationale for this over other types of subject-specific health literacies is not clearly made.

- We feel there is a chance that a bias could be introduced at the study selection stage stemming from the intervention inclusion criteria (and this links with our first point). The health literacy competencies have not been clearly articulated and are open to interpretation. There also appears to be a conflation between health literacy education and communication skills education and this needs clarity. They are not synonymous. It is not clear to us exactly what you are including in your intervention criteria and why. This undermines the replicability of this study.

- It is not clear why the study excludes health care students or pediatric patient populations.

- Is the HSE health research repository distinct enough from Lenus to be included as a separate grey literature source? Perhaps Carrot2, OpenGrey or Google Scholar UK (in an incognito browser) could be substituted (providing a more balanced mix: two Irish and two international grey literature sources).

- There is a pre-1973 source related to HL which you may wish to take into account in your date range, although it does not focus on education: Dixon, J.P. (1959). The community responsibility for medical care. Am J Public Health 49, 76–81. https://doi.org/10.2105/AJPH.49.1.76.[1]

- Will your end-date of 2021 in the search strategy capture preprints and reviews-in-progress in e.g. PROSPERO?

- The PCC stipulates a clinical setting, but the inclusion criteria stipulate all settings. Is this a discrepancy?

References

1. DIXON JP: The community responsibility for medical care.*Am J Public Health Nations Health*. 1959; **49** (1): 76-81 PubMed Abstract | Publisher Full Text

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health literacy, critical health literacy, health literacy education for health professionals and students, scoping review design.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 15 Dec 2021

Lauren Connell, National University of Ireland, Galway, Galway, Ireland

Dear Dr Susie Sykes,
Thank you for reviewing our protocol submission, and for your very constructive feedback. As a result, revisions have been made and are individually addressed below, please see reviewer's comments in bold. The revisions suggested from your comments certainly enhance the overall protocol.

Thank you for the opportunity to review this protocol which we feel forms the basis of an important and useful scoping review. This protocol for a scoping review addresses an important area of inquiry of an emerging area of research that addresses a practice-based problem. The review is well-planned and largely methodologically sound but issues of replicability could be enhanced. This is discussed below. It is aligned with the PRISMA ScR guidance and has benefitted from the inclusion of a librarian to design the search strategy. We agree that a scoping review is the most appropriate review type to explore the research objectives outlined here and to assess the need for undertaking a systematic review in the future. The inclusion of grey literature will enrich the review. Incorporating grey literature coverage also provides further justification for the choice of review type.
Thank you for your positive comments. Please see responses below.

While the rationale for the study clearly states the prevalence and implications of low health literacy amongst patients and the public, there is a slight leap between this and the specific problem the scoping review seeks to address of health professional training/education. While it is perhaps implicit, a clear delineation of exactly what is included in your understanding of health literacy education for professionals would be helpful. Is it to improve the health literacy of professionals themselves, their understanding of how to respond to low and varied health literacy levels of patients or how to create a health literate environment.
Thank you for this important observation. This has been clarified within the updated manuscript where a more explicit connection has been made between the problem statement and the background of health literacy.

In the context of the development of organisational health literacy, health literacy education aims to address areas that health professionals can be trained in order to appropriately respond to and address limited and variable levels of health literacy in the patient population, this can be achieved by using techniques to encourage adequate HL, such as Teach-Back and avoiding medical jargon, which confirm understanding (1), whilst designing health literate reading materials to improve comprehensibility (2). Health professionals have an impact on overall organisational health literacy, in confirming understanding and interpersonal communication (1, 3). Therefore, by targeting health professionals there will be an organisational impact. In terms of professional outcomes it is intended that if an organisation is health literate that individuals working within will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (4).

The research questions are clear and helpful but a secondary question around diabetes is introduced and the rationale for this over other types of subject-specific health literacies is not clearly made.
Thank you for this observation, focus on diabetes is something that has been addressed in the manuscript. This particular review is a component of a larger funded research project comprising multiple doctoral students with multiple projects that focuses on diabetic foot disease and its prevention. Therefore, it was decided to scope the literature for any relevant health literacy education programmes that have been implemented within diabetes care. Sequentially, a prototype health literacy intervention will be developed and increasing focus will be placed on professionals working in the diabetes multidisciplinary team as the project progresses. Where the scoping review is situated in the study as a whole and the context of the larger research programme are now included in the manuscript.

We feel there is a chance that a bias could be introduced at the study selection stage stemming from the intervention inclusion criteria (and this links with our first point). The health literacy competencies have not been clearly articulated and are open to interpretation. There also appears to be a conflation between health literacy education and communication skills education and this needs clarity. They are not synonymous. It is not clear to us exactly what you are including in your intervention criteria and why. This undermines the replicability of this study.
Thank you for this comment, this is a clear limitation of the protocol. The health literacy competencies have been defined in line with previous research (5, 6) whereby competencies have been established and are articulated clearly. Similarly, key attributes of a health literate organisation have been established (4).

Communication skills education is recognised to be a component of HL education from the point of view of 'oral exchange' and interpersonal communication between the HP and the patient. They are not seen as synonymous but they are interlinked, in particular when the aim of communication skills education is to develop competencies that promote health literacy training of health professionals (7). In teaching HPs HL techniques the goal is to enhance the patient's understanding, not to change, explain or understand behaviour but to encourage the absorption of health information in order that the patient can make informed decisions and take informed actions.

It is not clear why the study excludes health care students or pediatric patient populations.
Because this study is a part of a larger project, it was decided to look at qualified health professional education, as it is emerging; the author recommends a separate review to explore health literacy education in the health professions' student curricula. Patient populations that encompass those most at risk of diabetic disease i.e. adult patient populations, as often diabetic foot screening begins in adulthood and continues to be monitored throughout adulthood (8). The Collaborative Doctoral Award (CDA) in which this project is a part is focused on diabetic foot disease. The reason for excluding healthcare students and paediatric populations is now included in the protocol within the methodology section Stage 3: Study selection.

Is the HSE health research repository distinct enough from Lenus to be included as a separate grey literature source? Perhaps Carrot2, OpenGrey or Google Scholar UK (in an incognito browser) could be substituted (providing a more balanced mix: two Irish and two international grey literature sources).
Thank you for this comment, amendments have been made to remove the HSE health research repository, and include a more balanced mix of grey literature sources as suggested.

There is a pre-1973 source related to HL which you may wish to take into account in your date range, although it does not focus on education: Dixon, J.P. (1959). The community responsibility for medical care. Am J Public Health 49, 76–81. https://doi.org/10.2105/AJPH.49.1.76.1
Thank you for this, it has been insightful to read. However, it does not meet the study's inclusion criteria or address health literacy education in health professionals.

Will your end-date of 2021 in the search strategy capture preprints and reviews-in-progress in e.g. PROSPERO?
September 2021 was used and there is no exclusion criteria regarding study type therefore it is possible that the search strategy will capture those studies. Although, the study aims to capture characteristics of education programmes and feasibility outcomes, which may not be accessible when including a review in progress.

The PCC stipulates a clinical setting, but the inclusion criteria stipulate all settings. Is this a discrepancy?
Settings will include primary, secondary and tertiary care settings. The protocol has been amended to reflect this change.

Reference List:

1. Brach C. The journey to become a health literate organization: a snapshot of health system improvement. Studies in health technology and informatics. 2017;240:203.

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Competing Interests: No competing interests were disclosed.

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	
Limitations	20	Discuss the limitations of the scoping review process.	
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

BMJ Open

Health Literacy education programmes developed for qualified health professionals: A Scoping Review

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Diabetes and endocrinology, Medical education and training
Keywords:	PUBLIC HEALTH, EDUCATION & TRAINING (see Medical Education & Training), Diabetic foot < DIABETES & ENDOCRINOLOGY, DIABETES & ENDOCRINOLOGY, MEDICAL EDUCATION & TRAINING

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Title: Health Literacy Education Programmes developed for qualified health professionals: A Scoping Review

Abstract

Objectives Both the literature and policy has identified the need for health literacy education for qualified health professionals. This study aimed to identify and map health literacy competencies and health literacy related communication skills educational interventions for qualified health professionals. The research questions included: Of the qualified health professional education interventions identified which are focused on diabetes care? What health literacy competencies and health literacy related communication skills are integrated into each programme? What are the characteristics of each education programme? What were the barriers and facilitators to implementation? What methods are used to evaluate intervention effectiveness, if any?

Design Scoping review, informed by the Joanna Briggs Institute (JBI) guidelines.

Data Sources The following databases: OVID; CINAHL; Cochrane; EMBASE; ERIC: PsycInfo; RIAN; Pro-Quest; UpToDate were searched.

Eligibility criteria Articles were included if the education programme focussed on qualified health professionals, in all clinical settings, treating adult patient populations, of all study types.

Data extraction and synthesis Two authors independently screened titles, abstracts and full text articles that met the inclusion criteria. The third author mediated any discrepancies. The data was extracted and charted in table format.

Results In total, fifty-three articles were identified. One article referred to diabetes care. Twenty-six addressed health literacy education, and twenty-seven addressed health literacy related communication. Thirty-five reported using didactic and experiential methods. The majority of studies did not report barriers (N=45) or facilitators (N=52) to implementation of knowledge and skills into practice. Forty-nine studies evaluated the reported education programmes using outcome measures.

Conclusions This review mapped existing education programmes regarding health literacy and health literacy related communication skills, where programme characteristics were identified to inform future intervention development. An evident gap was identified regarding qualified health professional education in health literacy, specifically in diabetes care.

Strengths and Limitations.

- This study is the first to map characteristics of education programmes in health literacy and health literacy related communication for qualified health professionals.
- A scoping review methodology was used in order to map the current evidence, therefore, it does not assess risk of bias or reporting measures like a systematic review methodology.
- Studies were excluded if they were not in the English language, which affects the generalisability of the study and relevance to other language speakers and cultures.
- Student populations were not studied in this scoping review. The focus was on qualified health professionals, which is an identified limitation of this research.

Introduction

Literature has established the need for health literacy (HL) education for qualified health professionals (QHPs) (1-3), with recognition of this need reflected in policy development in European countries (4) where the goal is to improve patient outcomes (1). Although HL research has developed significantly since 1973 (5), limited research has been undertaken on HL interventions and their effectiveness (6), specifically within QHP education.

Within the 'oral exchange' between the QHP and patient, interactive/communicative HL takes place (7, 8). Oral literacy and social skills are integral in meeting patients' health needs and enabling patient understanding. An 'interactive communication loop' has been recommended, whereby the QHP assesses patient understanding and recall (9); an example of this is the application of the 'Teach-Back' tool (10). HL education for QHPs is often directed towards this interactive domain by utilising a range of techniques such as 'Teach-Back' (10), minimising jargon (11) and 'Ask Me Three' to confirm patient understanding (12), and designing health literate reading materials to improve comprehensibility (11). If the HL demand placed on individuals is reduced, by means of health literate communication from the QHPs, patient outcomes have the potential to improve (13).

In patients with chronic disease, limited HL has been associated with lower health-related quality of life (14), and poorer health outcomes (15). A social gradient can be seen with a higher proportion of those with limited HL experiencing lower socio-economic status, lower educational attainment, and are of older age which mirrors the pattern of inequality of those with chronic diseases (16, 17). For those with diabetes there are complex demands put on them in navigating the health system, especially when complications exist, such as diabetic foot disease (DFD) (18).

Demands on individuals, with diabetes, are characterised by a high level of complexity (19), where effective self-management relies on patients having advanced HL skills to utilise written education material and verbal instructions (6). Interactive HL has been found to be the most important HL domain needed within diabetes self-management (20), where a higher level of oral literacy (communication) is required to extract and discuss information with others (21).

It is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy (22-24), where greater self-efficacy is associated with lower glycaemic levels. Patients that are unable to effectively self-manage are at increased risk of complications. One of the most serious of which is DFD which can result in amputation (25). Individuals living with DFD have been found to have limited comprehension of diabetic foot ulceration (DFU); lack of foot self-care; delayed ulcer detection and seeking of medical attention, which puts the foot at increased risk (26). Similarly, foot self-care was often considered of lower priority than more immediate demands such as taking medication and glycaemic control. Factors that appeared to motivate engagement in foot self-care included receipt of education and/or training from health professionals, which empowered participants to look after their feet (26). In order to maintain a supportive therapeutic relationship, health professionals must move away from simply focussing on 'education' and 'advice' and instead aim to support individuals in achieving effective self-management (27).

This current study adopted a relational concept of HL (28), focusing on organisational health literacy (OHL). The OHL approach makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions for their health (12). Emphasis is not on the individuals' capabilities to manage their own health but on how their environment and the health services play a central role in their successful application of their abilities to access and utilise services. Adopting this OHL approach places emphasis on educating qualified QHPs on health literate practice, to optimise patient-practitioner communication (7, 29) to ultimately empower patients.

Training programmes have been developed for QHPs to address HL competencies and HL related communication skills (2, 30-32). The extent and nature of programmes need to be collated in order to assess the potential of undertaking a full systematic review (33) and to inform future development of these complex interventions. This scoping review forms the first phase of the Medical Research Council (MRC) framework in the development phase of a complex intervention (34), where focus is on compiling evidence to inform intervention development. In this scoping review the core concept is that of education programmes for HL competencies and HL related communication skills for the population comprising QHPS of all backgrounds, in the context of primary, secondary or tertiary health care settings (33, 35). These key elements comprising concept, population and context inform the

primary research question which is: what HL competencies and HL related communication skills educational interventions exist for qualified health professionals?

The overall aim of the scoping review was to identify and map current educational interventions to improve HL competencies and HL related communication skills of QHPs, specifically within diabetes care. This study is situated within a larger research project entitled, Diabetic Foot Disease: from PRevention to treatment to IMproved patient Outcomes (*DFD PRIMO*).

Methods

Patient and public involvement

None

Review Approach

Protocol development started with preliminary research which did not identify current literature within the population pertaining to those with either DFD or those with a diabetes diagnosis. Therefore, it was decided to expand the review to capture all QHPs practicing in primary, secondary and tertiary care settings.

This scoping review was conducted drawing on methods and guidance from the Joanna Briggs Institute (JBI) (35), which adds to earlier guidance on scoping review methodology (24). The study protocol was published on HRB Open: https://doi.org/10.12688/hrbopenres.13386.2. This study protocol can be found in Supplementary File 1. It was reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist (36) .

Selection Criteria

The "PCC" framework was employed (33, 35), where the population was QHPs of all backgrounds. Concept referred to education programmes for HL competencies and HL related communication skills. Context was primary, secondary, and tertiary care settings.

Five stages of a six-stage framework were used to structure this review (33), the optional stage six which comprises stakeholder consultation was not adopted in the context of this current study.

Stage 1: Identifying the research question.

The primary research question was:

What HL competencies and HL related communication skills educational interventions exist for qualified health professionals?

The secondary research questions were:

- Of the QHPs education interventions identified which are focused on diabetes care?
- What HL competencies and HL related communication skills are integrated into each programme?
- What are the characteristics of each education programme?
- What were the barriers and facilitators to implementation?
- What methods are used to evaluate intervention effectiveness? If any.
- What are the outcomes of the education programme on QHPs and/or patients?

Stage 2: Identifying relevant studies

This study retrieved evidence through a comprehensive search strategy in the following databases: OVID; CINAHL Cochrane; EMBASE; ERIC: PsycInfo; RIAN; Pro-Quest; UpToDate. This search was performed in September 2021. Grey literature was searched within the references of identified articles. The search strategy was populated from a combination of free text search terms, text words, Medical Subject Headings (MeSH) terms and keywords with Boolean operators. Search terms were used in combination with search filters to tailor for each database. The search was developed with advice from a research librarian with expertise in search strategy development. The selected keywords and search string, relevant to Medline via Ovid, and developed search strategy can be found in the published protocol (37) and in the Supplementary File 2, to which further details have been added.

Stage 3: Study selection

The search was limited to the English language due to the variation in interpretations of the notion of HL from a cultural and socioeconomic perspective (38, 39). All searches were limited to post 1973, due to HL research emerging at this time (5). In order to be included the educational intervention, components had to contain HL competencies or HL related communication skills training, as previously defined (40, 41) in order to be included.

In this current study, QHPs identified were not limited by profession or setting. It must be noted that this search was limited to adult patient populations as often foot screening begins in adulthood as diabetes is monitored (42). For this study and the overarching project, health professional students

were not included in the population as the focus is QHPs working in diabetes care. Study selection was based on the inclusion criteria provided below:

- Qualified health professionals (QHPs)
- Adult patient population (>18 years old)
- Intervention: HL competencies and HL related communication skills education containing competencies as previously defined (40, 41)
- All research methodologies
- All clinical settings

The exclusion criteria include:

- Healthcare students
- Paediatric patient population
- Literature Pre-1973
- Literature not in the English language

Similar to previous research, selection of sources and evidence will take place over four steps (43):

Step 1: Initial retrieval of sources were performed by one author. Results from the search were imported into Rayyan (44), a scoping review manager software, whereby citations were collated, and duplicates removed.

Step 2: Title screening. Titles were screened against the inclusion criteria and retained if they explicitly met the inclusion criteria. This step was performed by two blinded authors, whereby the third author was used to mediate if any disagreements arose.

Step 3: Abstract screening. Abstracts were screened against the inclusion criteria and were retained if they met the inclusion criteria. This step was performed by two blinded authors. Disagreements were mediated by the third author through discussion.

Step 4: Full text review. Articles were retained if compliant with inclusion criteria. This was performed by two authors of the research team and cross-checked with the third if any complications arose. This step was further developed in response to the volume of relevant results at this stage and the variability in the quality and detail of reporting in articles identified. The aim of this development was to counter any definitional drift, strengthen consistent decision making and increase reliability, specifically in relation to the inclusion criterion, 'intervention'. This was achieved through discussion

by the three authors, in two workshop style sessions over two days, where a unanimous decision was made on articles presented. Procedural rules were developed focusing on addressing the questions:

1. Did the article explicitly report details of the intervention?
2. Did the article explicitly report HL competencies OR HL related communication skills?

Therefore, if studies did not follow the procedural rules explicitly then they were excluded, as "a single failed eligibility criterion is sufficient for a study to be excluded from a review" (45).

Numbers of articles included and excluded were documented using the PRISMA-ScR standardised template (36), as demonstrated in Figure 1.

Stage 4: Charting the data

The extraction form was collated based on the JBI template source of evidence details, characteristics and results extraction instrument (35), training programme evaluation methods (46) and insight from previous work (47). A data charting form was developed drawing on the following characteristics, as agreed by the research team, such as: Year & Author; Country; Aim; Timeframe; Setting; Patient population; Intervention; Comparator, if any; Setting; participants; Programme mode of delivery; Course detail; Educational philosophy; Evaluation method; Kirkpatrick level of evaluation (this training evaluation model delineates four levels of outcomes such as reaction, learning, behaviour, and results) (46). An excel spreadsheet was used to chart this data and a full list of the characteristics charted is available in Supplementary File 3.

Stage 5: Collating, summarizing, and reporting of results.

Data was reported for each selected study within the agreed characteristics. Relevant findings were charted, using the data charting form developed in Stage 4. Subcategories of emerging themes were identified depending on presenting data, as seen in Results.

Results

The database search yielded 17036 search results citations post deduplication. Stage 1: Title screening resulted in 610 citations. Stage 2: Abstract Screening resulted in 207 citations where 403 citations were excluded on the basis of wrong population (N=87); not an educational intervention (N=272); no abstract (N=6); Intervention not consisting of HL or HL related communication skills (N=34) and duplicates (N=4). The remaining 131 citations from Stage 2 moved to Stage 3 with full text screening undertaken which resulted in 53 included citations that were extracted in stage 4, Data Extraction.

Study Characteristics

Most studies were non-randomised, longitudinal, and undertook pre-post evaluation. The timeframe ranged between immediately post education (48) and 12 months post intervention (49). One study was a randomised controlled trial, looking at hypertension outcomes) (50). Of the final 53 studies, the majority (N=32) took place in the United States, Denmark (N=5) and Japan (N=3). Intervention participants were reported as health professionals (N=25), some reported specific professions such as doctors (N=13) and nurses (N=9). Thirty eight out of the fifty-three studies did not report the patient population and ten reported oncology.

Educational Techniques

Didactic and experiential methods were reported to be used (N= 35). The use of didactic techniques was reported explicitly (N=11). The educational technique was not reported in one study (51). Specific experiential techniques were reported such as Role-Play (N=23) and Workshops (N=15).

Programme Content

One study mentioned diabetes care (52).

Health Literacy Specific Interventions

All programmes reported educational content (N=26), where sixteen reported teaching written and spoken communication best practices; thirteen reported teaching an overview of HL; five reported self-management and empowerment; and four reported the "Always Use Teach-Back" training toolkit. Specific HL topics were addressed and charted in Table 1.

HL related Communication Skills Interventions

Different HL specific techniques were used, four studies reported confirming understanding using Teach Back; five reported avoiding jargon; four reported using 'Summarise'; four reported asking open questions; and four reported shared decision making. Specific HL topics were addressed and charted in Table 2.

Education Philosophy

The majority of studies (N=47) did not report using an educational philosophy in development or delivering of the intervention, however some studies made reference to using 'adult learning philosophies and instructional methods (e.g., train-the-trainer)' (53); 'Comfort Theory' (54) and the 'Adult Learning Theory' (55, 56). 'Bandura's Theory of Social Learning' (57, 58); 'Calgary-Cambridge

model (58-60); 'COMSKIL conceptual framework' (61, 62) and 'Interaction Adaptation Theory' (63, 64).

Evaluation

In terms of Kirkpatrick's levels of evaluation (46), 22/53 studies addressed Level 1 evaluation: Reaction; 38/53 studies assessed Level 2 evaluation: Learning; and 35/53 studies addressed Level 3 evaluation: Behaviour. However, 4/53 studies did not report outcome measures therefore a Kirkpatrick Level could not be determined (65-68).

Barriers and Facilitators to Implementation

The majority of studies did not report barriers (N=45) or facilitators (N=52) to implementation of knowledge and skills into practice. In this study, implementation was in terms of perceived barriers to implementing learned knowledge, skills and practices in clinical practice.

Barriers reported include feeling unable to translate learning into practice; overestimation of HL understanding; difficulty in changing behaviour; breaking habits and overestimation of competencies; fitting the programme into daily practice; sustainability and lack of resources (2, 69-73). Other barriers to implementation included organisational barriers such as having an internalized or individual pressure to use technical language (71) and environmental barriers (lack of faculty role modelling, time constraints, and/or pressure to address multiple issues during clinic visits) (72, 73). Organisational issues included needing a greater shift in HL thinking by the organisation; lack of resources; limited or no funding; staff retention, and not having HL identified as a priority within the organisation (51).

Facilitators identified included having organisational commitment including managerial and executive support, having someone to champion HL in the organisation, and the organisation already having HL identified as a priority and the support from Primary Care Partnerships Staff (51). Importance of having individuals within the organization who could act as innovators or early adopters of innovation to help champion the change and increase adoption of the innovation (74).

Table 1: Health Literacy (HL) Training Programme (n=26)

Characteristics		
Educational Techniques	Programme Content (HL specific)	Outcomes Assessed
Didactic **(2, 31, 48, 52, 53, 69-72, 74-83)** Experiential **(2, 31, 48, 52, 53, 69-72, 74-77, 79, 80, 82)** Workshop **(48, 52, 69-71, 84)** Patient Video Testimonial **(2, 76)** Standardised patient encounters **(48, 52, 75)** Scenario Simulation **(79, 80)** Lunch and Learn Format **(84)** Reflection **(52, 77)** Group discussion **(82)** Peer supervision **(69, 70)** Role- play **(2, 31, 49, 53, 69-72, 76, 77, 80, 82, 83)** Video **(31, 77, 80)** Active learning component **(77)** Video and Facilitated discussion **(56, 72, 75)** Case discussions **(53, 77)** Feedback **(48, 79)** Brainstorming exercises **(53)** "Coaching sessions" **(85)** NR **(51)**	Overview of HL (2, 48, 52, 56, 69, 70, 72, 76-78, 80-82) HL importance (49, 53) Universal precautions approach (72, 84) HL Epidemiology (49, 53, 71) HL outcomes (2, 48) Health Disparities (53) Identifying HL (2, 53) HL policies (53) HL Resources (51, 77, 82) Introductory HL forum (51) Attributes of a health literate organisation (51) Teach Back (49) "Always Use Teach-Back" training toolkit (75, 76, 79, 85) Communication Strategies (71) Written and Spoken communication best practices (2, 31, 48, 52, 53, 69, 70, 72, 74, 76-78, 80-83) Clear health communication skills (52, 83) Shared decision making (69, 70) Health Promotion (78) Self-management and empowerment (69, 70, 72, 74, 78) Supportive systems (72) Adult Learning (53) Orem's self-care deficit nursing theory (74) Plain Language Planner for Palliative Care (PLP) (83) COMFORT (83) Brown bag medicine review (74)	Acceptability & Usability (49) Satisfaction (53) Patient satisfaction (79) Evaluation (31, 48, 52, 69-71, 77, 81-83) Knowledge (2, 31, 49, 51-53, 56, 69, 70, 72, 74, 77, 78, 81, 82, 84) Behaviour (72, 74) Self-perceived ability to identify, assess and provide client-centred treatment to low-health literate patients (84) OSCE station score (31) Ability (2) Programme Effectiveness (78) Understanding (51) Plan-DO-Study Act for TB evaluation (76) Skills (52, 53, 69, 70, 74, 81, 83) Attitudes (52, 53, 69, 70, 77, 81) Practice (82, 83, 85) Health Beliefs and Attitudes Survey (HBAS) (53) Self-efficacy (49) Confidence (69, 70) Impact of prior HL training (52) Conviction and Confidence Scale: Conviction in the importance of teach-back; Confidence in the participants' ability to use teach-back (75, 79, 85) Health Professionals Communication Skills Scale (HP-CSS) (80) Press Ganey scores for Communication with Nurses (80)

	'Plan Do Study Act' (PDSA) projects (51)	

Table 2: HL Communication Skills Training Programmes (n=27)

Characteristics		
Educational Techniques	Programme Content (HL specific)	Outcome Assessed

Didactic (62, 64-68, 73, 86-98) Experiential: (62, 65, 67, 68, 73, 87-91, 95, 96) Workshop (50, 86, 90, 93, 97-101) Video demonstration (73, 86, 90) Facilitated group discussion (86, 96) Role-play (62, 64, 73, 88-91, 94-96) Feedback (90) Visual aids (88) Simulation-based exercises (65, 102) Reflection (102)	Confirming understanding (62, 87, 92, 100) using Teach Back (65, 86) Health Literacy in practice programme (50) Avoiding Jargon (64, 86, 94, 95, 102) Giving only 1-3 key points (86) Summarise (62, 67, 68, 100) Asking open questions (62, 86, 92, 100) Attentive listening (67, 68, 100) Patient centred approach (58, 60, 92, 94, 100, 101) Non-verbal cues (100) Shared decision making (92, 94, 95, 100); Agenda setting, (62, 87, 92) Empathy (87, 93, 100) Building rapport (100) Clarifying responsibility (100) Action planning (100) Handling emotions (100) Resilience and coping (102) Communication Techniques (58, 60) Evidence for communication (73, 100) Impact of communication(97, 98) COMFORT (94) Studor Group's AIDET1 mnemonic (66) Consultation structure of Calgary Cambridge model (58, 60, 67, 68, 90) COMSKIL Communication Skills Training (CST) Programme (87) The 3-Act Model (95) SPIKES methodology (88, 91, 93, 96-98) AIDETVR (Acknowledge, Introduce, Duration, Explanation, and Thank You) principles (65)	Evaluation (62, 64, 87, 89, 90, 92, 96, 102) Learner Feedback (93) Knowledge (86, 88, 94) Attitude (73, 86) Confidence (86, 89, 91) Self-efficacy (62, 87, 92, 100) Psychological distress (89) Burnout (89) Ability to detect patient's distress (97, 98) Decision-making behaviours (99) Client–provider interaction (CPI) checklist (99) Self-perceived ability to identify, assess and provide client-centred treatment to low-health literate patients; Competence (96, 102) Skills uptake (92, 94, 95) Feasibility/ Implementation (73) Behaviour (88) Commitment to change (101) Knowledge using the Health Literacy Assessment Questions (HLAQ) (50) Outcomes not reported therefore Kirkpatrick Level not applicable (65-68)

Discussion

This scoping review maps the current HL and HL related communication skills education programmes in existence for QHPs in all settings. Fifty-three studies were identified that addressed HL or HL related

communication skills. Within that sample, 26 studies focussed on HL education, and 27 studies looked at HL communication skills.

A HL education programme consists of a set of competencies that professionals need to master in order to appropriately address limited HL levels presenting in their patients, by "presenting information in ways that improve understanding and ability of people to act on the information" (103). HL related communication is recognised to be a component of HL, from the point of view of 'oral exchange' and interpersonal communication between the health professional and the patient. They are not seen as synonymous but interlinked (104). HL related communication is the process of information exchange and HL is the application of a skill set (105). This is evident when the aim of communication skills education is to develop competencies that promote HL training of health professionals (1). In other words, it is promoting the development of the skills required in the communication process. This has the potential to strengthen the patient-healthcare professional dynamic. If the HL demand placed on individuals is reduced, by means of health literate communication from the health professionals, patient outcomes have the potential to improve (13).

Initially, this scoping review aimed to look at the patient population with diabetic foot disease (DFD) and the education of the multidisciplinary team (MDT) involved in its management. A preliminary search revealed that there was no evidence in the area. Similarly, this was the case when broadened to diabetes care for the published protocol (37), therefore, it was decided to do a scoping review due to the inadequate volume of evidence to conduct a systematic review (33). This has been identified as both a strength and a limitation as the population chosen is specific yet broad. Therefore, this allows for the full scope of the chosen population to be explored by means of a scoping review. Similarly, this is the case with the chosen population where student health professionals were excluded. Learner needs and motivation for learning differ. If QHPs are working fulltime their need for flexibility in learning must be accounted for.

This scoping review found that of the 53 studies only 1 referred to diabetes (52). The goals of the curriculum did not address diabetes or allude to its applicability to diabetes care and limited reference was made in the standardised patient encounter where the patient case had diabetes. Therefore, to develop an education programme knowledge needs to be drawn from a wider evidence base because of the lack of available literature in the area of diabetes. However, this can be identified as a limitation to the research as one could allude to the role of generalised education programmes with focus on chronic disease.

The programmes collated in this scoping review have demonstrated the need for appropriately detailed interventions, with wider applicability as most studies focussed on tertiary care or disease

specific areas where advanced HL is needed (such as genetic testing). It was noted that no studies reported evaluating education of a disease-specific MDT, which is an area of the utmost importance when working with chronic disease such as diabetes, where MDT involvement is vital for optimum patient outcomes.

Minimal detail was reported on each intervention, affecting its reproducibility which is important in health professional education as often a programme will need to be adapted and modified according to the participant and patient demographics and cultural context. This scoping review is a component of a PhD project within a Collaborative Doctoral Award (CDA) focusing on diabetic foot disease, whereby the review forms the initial evidence base in creating a prototype educational intervention for the multidisciplinary team working with patients in the management of DFD. The lack of detail in reporting is a significant barrier to collating the evidence base for a novel programme in disease management. Nevertheless, the evidence base is limited and underdeveloped, specifically in diabetes care. Therefore, the information reported and collated in this current study does not provide sufficient information to replicate implementation of interventions, which is a significant issue for practice development and methodological rigour. Similarly, the scoping review methodology did not allow for quality appraisal or risk of bias, therefore, it was not assessed.

Of the 53 studies only 35 reported using a combination of didactic and experiential methods, and 47 did not report using an education philosophy. Similarly, based on programme characteristics noted in this review there is no detail regarding adult education and how adults learn, which may be beneficial for novel programme development. This suggests a lack of input from those with expertise such as educationalists, and/or a lack of reporting. Underreporting and insufficient detail were common issues encountered throughout this review as one of the secondary research questions was to detail the 'characteristics of each programme'. Within complex interventions, the role of theory has been identified and recognised in the MRC framework (34). In this study, chosen articles did not elaborate explicitly as to how their intervention was developed. The broader literature base will need to be referenced for detail on instructional design and educational philosophies, particularly if a novel programme is to be developed.

Interestingly, barriers and facilitators were not reported in 85% of studies identified in this scoping review. The way in which the education is delivered is integral, as it has the potential to mitigate issues. Various studies identified barriers such as a lack of resources, environmental barriers, and organisational barriers. Such barriers need to be noted and addressed by investigating long-term outcomes such as behaviour, to support the current evidence base which is lacking.

In terms of education delivery, the reporting was vague, and no detail was given as to how the delivery method was chosen. It is difficult to determine the most preferential delivery method from the results of this review so liaising with QHPs enables accessibility and can mitigate potential barriers.

It was found that the majority of outcomes assessed were self-reported. This can create difficulty in determining the volume of learning that took place as often individuals can over-estimate or underestimate their skills (106). Focus was placed on participant outcomes such as self-perceived knowledge, skills, or attitudes and not on patient outcomes. This suggests the need for evaluation and feasibility assessment prior to integrating patient outcomes into the initial phase of a project.

Although, some studies evaluated behaviour using Level 3 evaluation (46), organizational impact wasn't reported using Level 4 evaluation. Most interventions only focused on levels 1, 2 and 3 of Kirkpatrick's evaluation model. In the context of the development of organisational HL, HL education aims to address areas that QHPs can be trained to respond to and address limited levels of HL. Health professionals have an impact on overall organisational HL, in confirming understanding and interpersonal communication (8, 12). Therefore, by targeting QHPs there will be an organisational impact. In terms of professional outcomes, it is intended that if an organisation is health literate then individuals working within it will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (107).

Conclusion

In conclusion, future educational HL interventions need to describe in depth the methods used to develop the programme while providing a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used to enhance reproducibility. The results from this scoping review will form the basis of a Delphi consensus study where the aim will be to build consensus on the theoretical and practical elements, design, delivery, and evaluation of a HL education programme aimed towards QHPs working in diabetes care.

Contributorship statement: LC,YF and JS have contributed to the conception and design of the study. LC,YF and JS have contributed to the establishment of search and scoring criteria. Article reviewing and data analysis has been performed by LC,YF and JS. LC,YF and JS have made contributions to the drafting and revising of the article. LC,YF and JS have approved the final version to be published and its accuracy and integrity.

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Table 1: Health Literacy Training Programme Characteristics, including Educational Techniques; Programme Content; and Outcomes Assessed.
Table 2: Health Literacy Related Communication Skills Training Programme Characteristics, including Educational Techniques; Programme Content (Health Literacy specific); and Outcomes Assessed.

Supplementary File 1: Scoping Review Protocol.
Supplementary File 2: Search Strategy.
Figure 1: PRISMA Flow Diagram.
Supplementary File 3: Data extraction characteristics.

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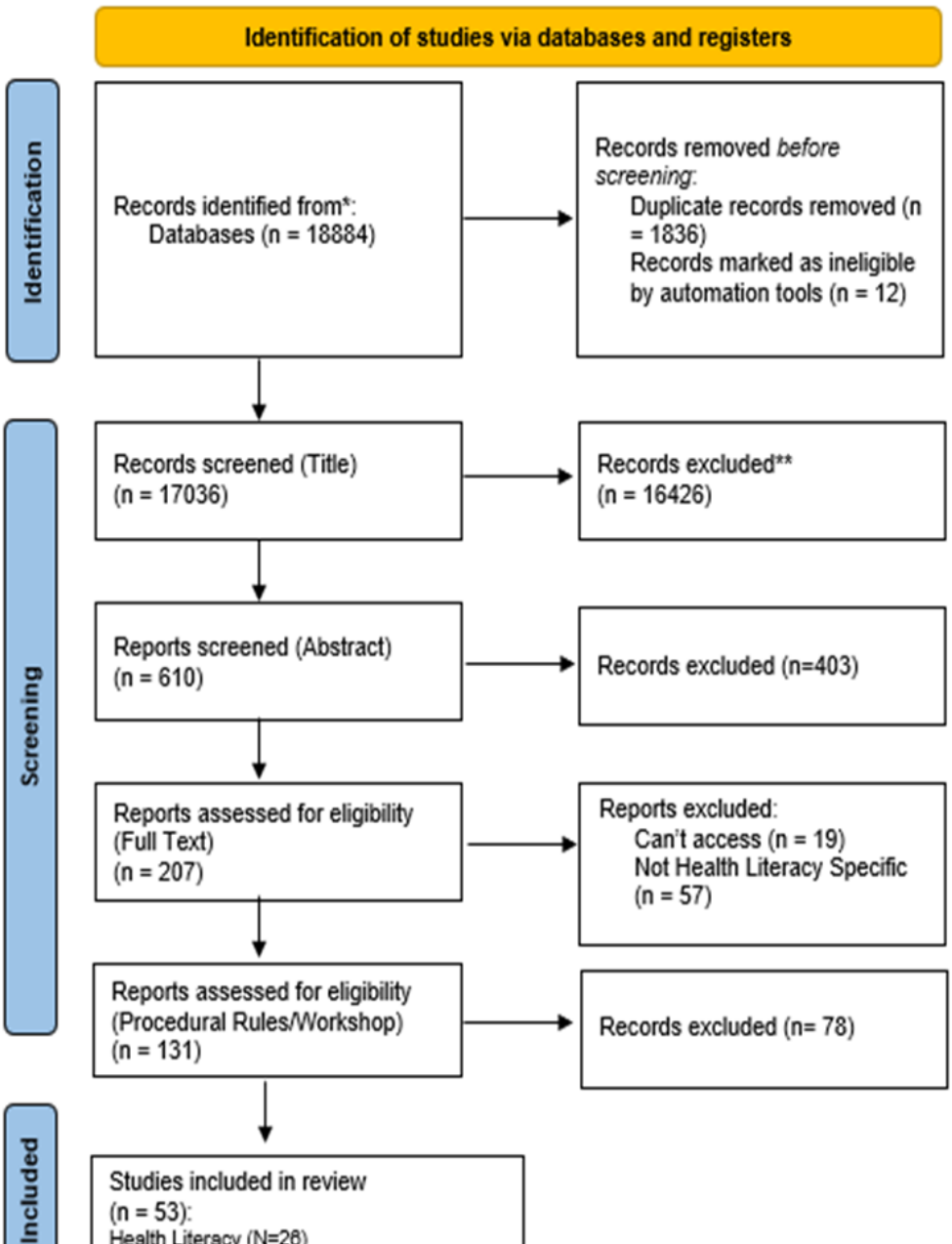

*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).

**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

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STUDY PROTOCOL

REVISED Health literacy education programmes developed for qualified health professionals: a scoping review protocol [version 2; peer review: 2 approved]

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Abstract

Introduction: Health literacy education, for health professionals, has been identified as having the potential to improve patient outcomes and has been recognized as such in policy developments. Health literacy, as a relational concept, encompasses individuals' skills and how health information is processed in relation to the demands and complexities of the surrounding environment. Focus has been predominantly on the dimension of functional health literacy (reading, writing and numeracy), although increasing emphasis has been placed on interactive and critical domains. Such dimensions often guide the development of health professional education programmes, where the aim is to enhance the patient-practitioner relationship, and ultimately reduce the health literacy burden experienced by patients navigating health services. Currently little is known about qualified health professionals' education in health literacy and communication skills, and development, implementation or evaluation of such interventions.

Aim: To identify and map current educational interventions to improve health literacy competencies and communication skills of qualified health professionals.

Methods: A scoping review will be conducted drawing on methods and guidance from the Joanna Briggs Institute, and will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist. This study will retrieve literature on health professional education for health literacy and communication skills through a comprehensive search strategy in the following databases: CINAHL; Medline (Ovid); the Cochrane Library; EMBASE; ERIC; UpToDate; PsycINFO. Grey literature will be searched within the references of identified articles;

Open Peer Review

Approval Status ✓ ✓

	1	2
version 2 (revision) 11 Jan 2022	✓ view	✓ view
version 1 02 Sep 2021	? view	? view

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Any reports and responses or comments on the article can be found at the end of the article.

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Lenus; ProQuest E-Thesis Portal; RIAN and OpenGrey. A data charting form will be developed with categories including: article details, demographics, intervention details, implementation and evaluation methods.

Conclusion: Little is known about the extent and nature of the current evidence base therefore a scoping review will be conducted, in order to identify programme characteristics in relation to health literacy competencies and communication skills.

Keywords

health literacy, health professional education, communication skills

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REVISED **Amendments from Version 1**

Following peer review the protocol has been revised. Protocol version 2 contains changes made in response to reviewers' feedback on version 1. We have actioned all of the changes suggested by the reviewers such as: describing what we interpret to be health literacy education, the worldview of the project, how communication skills relate to health literacy and their role within interactive health literacy, refinement of the inclusion criteria, refinement of chosen literature sources, and the relational concept of health literacy and its conceptual framework i.e., organisational health literacy.

Any further responses from the reviewers can be found at the end of the article

Introduction

The need for health literacy (HL) education, for qualified health professionals (QHPs), to improve patient outcomes has been identified[1], is supported by research literature[1–3] and is recognised in policy development in European countries[4]. This protocol is for a scoping review which aims to identify and map current educational interventions to improve HL competencies and communication skills of QHPs. Focus will be applied to diabetes care, as this study is a component of a larger research project entitled, Diabetic Foot Disease: from PRevention to treatment to IMproved patient Outcomes (*DFD PRIMO*).

HL has been described as an 'evolving' concept[5], developing over time with multiple definitions identified in the literature[6,7]. This is an identified limitation to research and can negatively impact the measurement of HL[8]. Nevertheless, there is increasing consistency in the use of a typology of HL comprising of three core domains: functional, communicative/interactive and critical[5]. At an individual level, functional HL leads to improved awareness of health risks, health services and treatment adherence; interactive HL, also referred to as communicative HL, leads to improved independence, motivation and self-confidence; whereas critical HL leads to better resilience to antecedents such as social adversity[9].

A relational concept of HL will be used[10], focusing on an organisational health literacy (OHL) approach which makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions and take informed actions for their health[11]. In this conceptualisation, emphasis is not on the individuals' capabilities to manage their own health but on how their environment and the health services can play a central role in their successful application of their abilities to access and utilise services. This approach is informed by the identification of the ten attributes of a HL friendly organisation[12], specifically that the organisation 'uses health literacy strategies in interpersonal communications and confirms understanding at all points of contact'. By adopting this approach, educating QHPs on HL competencies, to optimise patient-practitioner communication[13,14], has the potential to strengthen the patient-healthcare professional dyad. Such competencies include the knowledge, attitudes and skills that professionals need to master in order to appropriately address limited HL levels presenting in their patients[15]. As a result health professional education in HL is often directed towards improving HL related communication skills by utilising a range of techniques such as teach-back[16], minimising jargon[17], Ask Me Three, which helps confirm patient understanding[11], and designing health literate reading materials to improve comprehensibility[17].

For the purpose of this research, the relational characteristic of HL is recognised and informs the choice of definition used which is that HL is 'People's ability to find, understand, appraise and communicate information to engage with the demands of different health contexts to promote health across the lifecourse'[10].

In Ireland, 1 in 7 adults have been found to have limited HL skills[18], and at a European level almost every second respondent within the European health literacy survey (HLS-EU) had limited HL[19], which is associated with increased hospitalization, higher all-cause mortality, poor health related knowledge, self-care behaviour and other outcomes[20]. A social gradient can be seen with a higher proportion of those with limited HL experiencing lower socio-economic status, lower educational attendance and attainment, and are of older age which mirrors the pattern of inequality of those with chronic diseases[21,22].

For people with chronic disease, limited HL has been associated with lower health-related quality of life (HRQoL)[23], and poorer health outcomes[24]. In chronic disease such as diabetes, demands on individuals are characterised by a high level of complexity[25], where self-management relies on patients' having advanced HL skills, in order to utilise written education material and verbal instructions[26]. Diabetes has a profound effect on individuals with varying complications: macrovascular complications such as cardiovascular disease, stroke, peripheral vascular disease; and microvascular complications such as nephropathy, retinopathy, peripheral neuropathy, and diabetic foot disease[27].

Inadequate HL has been shown to be an independent predictor of poor glycaemic control, being associated with a lower likelihood of achieving tight control[28]. Also, it is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy[29–31], where greater self-efficacy is associated with lower glycaemic levels. It is implied that a positive relationship between HL and improved diabetes control. Interactive and critical HL have been found to be more influential than functional HL in influencing self-efficacy in those with diabetes[32–34]. In contrast, some studies have not found HL to have a statistically significant relationship with diabetes-related health outcomes such as wound healing[24] and other complications[35]. But, when interactive HL or critical HL are considered some relationships have been found to be positive[32,33,36].

The majority of the literature focuses on functional HL, however, there has been increasing emphasis on the development of the interactive dimension of HL. This has been particularly evident within health professional education, where programmes have been developed to improve HL competencies

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and HL related communication skills[15,37]. If the HL demand placed on individuals is reduced, by means of improved communication and health literate communication from the QHPs, patient outcomes have the potential to improve[38]. Limited evidence has shown that confirming patient's understanding of new concepts can increase glycaemic control in those with diabetes[39].

Although HL research has developed and grown since at least 1973[40], limited research has been undertaken on HL interventions and their effectiveness[17], particularly in regards to qualified health professional education, despite the identification of such education programmes being relevant to mitigating potential health outcomes[1]. More recently, some training programmes have been developed, for QHPs, to address HL competencies and Hl related communication skills[2,37,41,42]. Although there is emerging evidence of these interventions, the extent and nature of programmes need to be collated in order to assess the potential of undertaking a full systematic review[43] and to inform future development of these complex interventions.

A HL education programme consists of a set of competencies to be addressed and achieved. Such competencies include the knowledge, attitudes and skills that professionals need to master in order to appropriately address limited HL levels presenting in their patients[15]. Although often recognized as a separate entity[10], communication plays a significant role in the development of interactive and critical HL, whereby effective communication maintains the patient-practitioner relationship[13,14].

Interactive HL has been found to be the most important HL domain needed within diabetes self-management[44], where interactive HL consists of a higher level of communication (oral literacy) and socials skills needed to extract and discuss information with others[5]. Patients with these skills are characterized by the self-confidence to act independently on advice, and to interact effectively with the health system. Interactive/ communicative HL takes place within the 'oral exchange' in the QHP and patient interaction[14,45]. Oral literacy and social skills are integral to the interactive HL domain and in meeting patients' health needs and understanding. An 'interactive communication loop' has been recommended, whereby the QHP assesses patient understanding and recall[39]; an example of this is the 'Teach-Back' tool[16]. Other forms of communication within a health literate organisation include communicating: using social media and other digital forms, at an interprofessional level, with external stakeholders and at a community level.

Current educational health literacy interventions aimed at qualified health professionals need to be identified accordingly to collate the current evidence base and provide a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used. Currently, there are no universally accepted guidelines in relation to development of HL curricula for qualified health professionals, although there are general outlines to help guide development such as the Calgary Charter on Health Literacy[46]. Established HL competencies have been defined more recently for health professionals in areas such as general HL knowledge; HL related communication skills; and attitudes in practice[47,48].

Methods

The extent and nature of research in relation to health literacy education programmes for qualified health professions is currently unknown. A configurative scoping review was chosen as it aims to 'seek concepts to provide enlightenment through new ways of understanding'[49]. A preliminary review of research identified limited literature in the area. As a consequence, a scoping review design is appropriate to develop an overview of what is known[50] and to assess if a systematic review is possible[34]. An iterative approach will be used in this study to allow authors to develop the inclusion and exclusion criteria while considering the presenting evidence[49,51]. This scoping review will be conducted drawing on methods and guidance from the Joanna Briggs Institute[52], which adds to earlier guidance on scoping review methodology[31]. It will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist[53]. Protocol development started with preliminary research which did not identify current literature within the population pertaining to those with either diabetic foot disease (DFD) or those with a diabetes diagnosis, therefore it was decided to expand the review to capture all qualified health professionals (QHPs) practicing in primary, secondary and tertiary care settings.

The "PCC" framework was employed in this scoping review to determine the research question, whilst drawing on methods from Joanna Briggs Institute[52] and Arksey and O'Malley's (2005) scoping review framework[43]. The PCC framework, where PCC stands for Population, Concept and Context[52], helps construct a title without the need for outcomes, interventions or phenomena of interest[52]. The PCC framework provides the core detail on the inclusion criteria related to the review topic, but acknowledges the need for more detail when planning the screening phases. In this scoping review the population is qualified health professionals of all backgrounds. Concept refers to education programmes for health literacy competencies and health literacy related communication skills. The context is in terms of qualified health professionals working clinically in primary, secondary and tertiary care settings.

Five stages of a six stage framework will be used to structure this review[43], the optional stage six which comprises stakeholder consultation will not be adopted in the context of this stage of this current study. Nevertheless, this research is the first stage of a three stage project with the results of this scoping review informing stakeholder engagement activities and further research.

Stage 1: Identifying the research question

The primary research question is:

1. What health literacy competencies and health literacy related communication skills educational interventions exist for qualified health professionals?

The secondary research questions are:

1. Of the qualified health professional education interventions identified which are focused on diabetes care?

2. What health literacy competencies and health literacy related communication skills are integrated into each programme?

3. What are the characteristics of each education programme?

4. What were the barriers and facilitators to implementation?

5. What methods are used to evaluate intervention effectiveness? If any.

6. What are the outcomes of the education programme on qualified professionals and/or patients?

Stage 2: Identifying relevant studies

This study will retrieve evidence through a comprehensive search strategy (Table 1) in the following databases: CINAHL; Medline (Ovid); the Cochrane Library; EMBASE; ERIC; UpToDate; PsycINFO.

Grey literature will be searched within the references of identified articles; Lenus; ProQuest E-Thesis Portal; RIAN and OpenGrey. The search strategy was populated from a combination of free text search terms, text words, Medical Subject Headings (MeSH) terms and keywords with Boolean operators. Search terms will be used in combination with search filters to tailor for each database. The search was developed with advice from a research librarian with expertise in the area of strategy development. The selected keywords and search string, relevant to Medline via Ovid, can be found in Table 1 below.

Results from the search will be imported into Rayyan[54], a scoping review manager software, whereby citations will be collated and duplicates will be removed. Although no current studies exist regarding the reliability and efficacy of using such automation tools, users have noted that the use of these tools saved time and increased accuracy[55].

Stage 3: Study selection

The search will be limited to the English language due to the variation in interpretations of the notion of HL from a cultural and socioeconomic perspective[56,57]. All searches will be limited to post- 1973, due to the history of HL research emerging at this time[40]. Intervention components must contain health literacy competencies or health literacy related communication skills training, as previously defined[47,48] in order to be included. For the purpose of this research, the relational characteristic of HL is recognised and informs the choice of definition used which is that HL is 'People's ability to find, understand, appraise and communicate information to engage with the demands of different health contexts to promote health across the lifecourse' as developed by Kwan (2006)[10]. In this current study, qualified health professionals identified will not be limited by profession in which they work. It must be noted that this search is limited to adult patient populations as often foot screening begins in adulthood as diabetes is monitored[58]. For the purpose of this study and the overarching project, health professional students will not be included in the population as the main focus is qualified health professionals working in diabetes care. Study selection will be based on the inclusion criteria provided in Table 2.

Table 1. Search Strategy for Medline (Ovid).

1	(("healthcare" or "health care") adj2 (professional* or provider* or personnel or worker*)).tw. or health personnel/
2	exp education/
3	(education adj2 (continuing or "competency based" or "competency-based" or health or program or programme*)).tw.
4	(workshop* or (problem-based adj (curricul* or learning))).tw. or ("problem based" adj2 (curricul* or learning)).mp. or (learning adj2 (active or experiential or problem-based or "problem based or case-based" or "case based")).tw.
5	(training adj2 (course* or module* or program or programme*)).tw.
6	training.tw. or inservice training/ or intervention*.tw. or course*.tw. or module*.tw.
7	staff development/ or clinical competence/ or program evaluation/ or program development/ or continu* professional development.tw.
8	2 or 3 or 4 or 5 or 6 or 7
9	exp Health Literacy/ or "health literacy".mp. or exp "health promotion"/ or "health literacy education".tw.
10	("health literacy" or ("health literacy" adj2 (competenc* or skill* or knowledge or attitudes))).tw.
11	communication skill*.tw.
12	(communication* adj2 ("teach back" or "teach-back" or method* or personal or program or social or personnel or health or nonverbal or non-verbal)).tw.
13	(skill* adj2 (interpersonal or social)).tw.
14	9 or 10 or 11 or 12 or 13
15	1 and 8 and 14
16	limit 15 to (english language and yr="1973 – 2021")

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Table 2. Inclusion/Exclusion Criteria.

Inclusion criteria	Exclusion criteria
Population: Qualified health professionals.	Population: Healthcare students
Adult patient populations (>18 years old)	Patient population: Paediatric (<18 years old)
Intervention: HL competencies and HL related communication skills education containing competencies as previously defined[47,48]	Literature pre 1973
Study Methods: All research methodologies	Not in the English language
Limited to 1973- September 2021	
Settings: primary, secondary and tertiary care	

Similar to previous research, the selection of sources and evidence will take place over four steps[59]:

Step 1: Initial retrieval of sources, which will be performed by one author.

Step 2: Title screening. Titles will be screened against the inclusion criteria and will be retained if they explicitly meet the inclusion criteria. This step will be performed by two blinded authors, whereby the third author will mediate if any disagreements arise.

Step 3: Abstract screening. Abstracts will be screened against the inclusion criteria and will be retained if they meet the inclusion criteria. This step will be performed by two blinded authors. Disagreements will be mediated by the third author through discussion.

Step 4: Full text review. Articles will be retained if compliant with inclusion criteria. This will be performed by two authors of the research team and cross-checked with the third if any complications arise. Numbers of articles included and excluded will be documented using the PRISMA-ScR standardised template[53].

Stage 4: Charting the data

The extraction form will be collated based on the JBI template source of evidence details, characteristics and results extraction instrument[52], training programme evaluation methods[60] and insight from previous work[61]. A data charting form will be developed drawing on categories, as agreed by the research team, such as: article details, demographics, intervention details, such as adult education approaches, HL domain implementation and evaluation methods. An excel spreadsheet will be used to chart the data.

Stage 5: Collating, summarizing, and reporting of results

Data will be reported for each selected study within each category as agreed on in the previous stage. Findings will be presented in a table that outlines the research demographics as defined in Stage 4. Any subcategories of emerging themes will be identified depending on presenting data. Entries will be checked by all authors.

Dissemination

The findings of this scoping review will be published in a peer-reviewed journal and made available on ARAN, an NUI Galway open access repository, subject to the open-access policies of the original publishers.

Study status

Not yet initiated.

Conclusions

Although some training programmes have been developed to address HL competencies and HL related communication skills[37,41,42], the extent and nature of programmes, needs identifying and collating to assess the potential of undertaking a full systematic review[43]. This will inform future development of these complex interventions. Current educational health literacy interventions aimed at qualified health professionals need to be identified accordingly to collate the current evidence base and provide a comprehensive narrative pertaining to the characteristics, including their generic or any disease specific focus, methodologies and assessments used.

Data availability

No data are associated with this article.

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Open Peer Review

Current Peer Review Status: ✔ ✔

Version 2

Reviewer Report 25 February 2022

https://doi.org/10.21956/hrbopenres.14699.r31170

✔ **Sarah Barry**

Centre for Health Policy and Management, Trinity College Dublin, Dublin, Ireland

The authors have responded to the points raised in my peer review report. The updates explain to a greater extent the theoretical underpinnings and operational elements of the original study protocol. Hopefully the queries raised have helped clarify the general frameworks that will drive the full programme of investigation envisaged. The full study can make a really useful contribution, especially for improved outcomes for diabetes patients.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: integrated care, organisation science, policy implementation, health services

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 24 January 2022

https://doi.org/10.21956/hrbopenres.14699.r31169

✔ **Susie Sykes**

Institute of Health and Social Care, London South Bank University, London, UK

Catherine Jenkins

Institute of Health and Social Care, London South Bank University, London, UK

We are happy that the authors have addressed all of the points we raised in our review and that

this protocol is now suitable for indexing.

The authors may wish to note that one of the sources that they include in their protocol, OpenGrey, is being decommissioned and may not therefore be available to them.

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health literacy, critical health literacy, health literacy education for health professionals and students, scoping review design.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Version 1

Reviewer Report 15 October 2021

https://doi.org/10.21956/hrbopenres.14580.r30201

?

Sarah Barry
Centre for Health Policy and Management, Trinity College Dublin, Dublin, Ireland

The paper is a protocol for a scoping review of health literacy (HL) literature, with a particular focus on HL training for healthcare professionals working in all clinical settings, although some focus on professionals working with diabetes patients is suggested.

The rationale for the scoping review is to map interventions (programmes, etc.) currently not evident in the literature as a starting point in considering the viability of a systemic review. A link between healthcare professional's HL competency and positive outcomes for patients is asserted. Subsequent study aims to inform better design and implementation of HL interventions based on a systematic review of the evidence scoped here.

One of the important premises is that most HL interventions are functional in nature, e.g. better awareness of risks, services and adherence, whilst interactive and critical domains of HL are less evident. The methods for the review are comprehensively described and referenced in several stages, nonetheless, I find a few overall study design elements could be further developed.

In essence, I think the protocol and planned review would be strengthened if the general worldview underpinning the study were more evident. This means clarifying something like a relational framework for HL competencies and skills, contexts, etc., and how that functions in the patient-healthcare professional dyad (or system).

Such a framework (encapsulating a worldview) would help for clarifying questions arising here such as, what would more critical HL add to this relationship and/or better outcomes for patients and/or professionals; or why focus on diabetes care and outcomes as a good case?

Interactive and critical HL are linked to communication skills and greater relational competency, but other aspects could be explored including adult learning approaches. I think more detail on critical HL is needed, especially given the authors include all clinical settings in their inclusion criteria. Without knowing this literature in-depth I imagine critical HL would have to consider some of the institutionalised and systemic aspects of professional-patient interactions and outcomes given a relationship-based framework. I guess there is potential here for clinicians and patients together to become better system navigators.

A qualification of the secondary research question No. 2 (What are the characteristics of each education programme?) could suggest categorising programmes as 'functional', 'interactive' or 'critical' as a way to better understand the nature of these differences or the outcomes they generate.

A second element of the study design somewhat missing is evidence on HL among healthcare professionals. HL among diabetes patients is reported here, but how this evidence links to HL outcomes among professionals is not developed sufficiently.

Given the focus here is on health professionals and the HL interventions available to them, or indeed accessed by them - I am missing the literature that says something about this population in particular - even if scant and shows some sort of context-mechanism-outcome pattern. Some examples of positive outcomes from HL for healthcare professionals might include leadership skills development, skills in policy advocacy, or access to career development opportunities.

As per above, some more descriptions of why it is a good idea to focus on the relationship between diabetes patients and diabetes care (providing) professionals would add to the overall rationale. I imagine this can be easily asserted given the size of the population in question.

I thought the use of population, concept and context (PCC) as a frame for the review is a useful focusing plan. I'm not sure how this is a mnemonic (as stated), or how it functions to operationalise the study. I would expect a brief outline of the plan to report findings that corresponds to the PCC approach, and maybe explaining what this adds.

I also wondered why the authors are not planning a 'stage 7' stakeholder engagement as part of the scoping review - especially given their sub-question on implementation. The reason may be lack of funding, time, etc. If this is the case it would be good to say so.

Overall, the protocol positively outlines the rationale, design and next steps for studying HL among healthcare professionals as an addition to both the literature and practice. Mapping current interventions is a positive contribution that will build development of better interventions. The protocol would gain from more exploration of its ontological approach - I think this is implied but not fully stated or its implications drawn out.

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Yes

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: integrated care, organisation science, policy implementation, health services

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 15 Dec 2021

Lauren Connell, National University of Ireland, Galway, Galway, Ireland

Dear Dr Sarah Barry,
Thank you for reviewing our protocol submission, and for your constructive feedback. As a result, revisions have been made and are individually addressed below, please see reviewer's comments in bold. The revisions suggested from your comments certainly enhance the overall protocol.

The paper is a protocol for a scoping review of health literacy (HL) literature, with a particular focus on HL training for healthcare professionals working in all clinical settings, although some focus on professionals working with diabetes patients is suggested. The rationale for the scoping review is to map interventions (programmes, etc.) currently not evident in the literature as a starting point in considering the viability of a systemic review. A link between healthcare professional's HL competency and positive outcomes for patients is asserted. Subsequent study aims to inform better design and implementation of HL interventions based on a systematic review of the evidence scoped here. One of the important premises is that most HL interventions are functional in nature, e.g. better awareness of risks, services and adherence, whilst interactive and critical domains of HL are less evident. The methods for the review are comprehensively described and referenced in several stages, nonetheless, I find a few overall study design elements could be further developed.
Thank you for your positive comments, please see responses below.

In essence, I think the protocol and planned review would be strengthened if the general worldview underpinning the study were more evident. This means clarifying something like a relational framework for HL competencies and skills, contexts, etc., and how that functions in the patient-healthcare professional dyad (or system).

This study is part of a larger project focussed on diabetic foot disease (DFD) prevention, and this project aims to improve interactive health literacy (HL) from a communicative point of view. A relational concept of health literacy will be used (1), focusing on an organisational health literacy (OHL) approach which makes health services easier for patients and their families to access, navigate and engage with so that they can make informed decisions and take informed actions for their health (2). By adopting this approach, increasing HL competencies and communication has the potential to strengthen the patient-healthcare professional dyad. Please see amended protocol introduction that introduces OHL and the relational concept of HL. Reference to this is now included in the update protocol. See introduction paragraph 3.

Such a framework (encapsulating a worldview) would help for clarifying questions arising here such as, what would more critical HL add to this relationship and/or better outcomes for patients and/or professionals; or why focus on diabetes care and outcomes as a good case?
The concept of OHL is an important one that helps us determine the relevance and understanding of where interactive HL comes into the overall study. Predominately the literature focuses on functional HL, and the literacy proficiency needed to navigate the health system. In the overall PhD project the objective is to target interactive HL by addressing patient-practitioner communication and the therapeutic relationship. This will be achieved by developing an education programme to improve the interactive domain of HL, and introduce a shift in understanding for professionals whereby HL is often an under/overestimated concept when it comes to patient interaction. Attaining critical HL is the ultimate goal in creating an accessible and inclusive health system, where individuals can evaluate and critique relevant health information. Therefore, by attaining critical HL at a community level, individuals have the potential to use the patient-professional consultation to its full capacity in promoting health creating a cultural shift.

The worldview is addressed within the protocol introduction (paragraph 3) where the reason for the focus on diabetes is included. Reference to this is now included in the updated protocol, see introduction paragraphs 5,6 and 7.

Interactive and critical HL are linked to communication skills and greater relational competency, but other aspects could be explored including adult learning approaches.

Adult learning approaches and methodologies will be reported in the results when charting the retrieved data. It is intended to explore this in the next stages of intervention development, where experiential learning (3) will be explored in further detail. Reference to the inclusion of adult learning approaches and methodologies is now explicitly included in the protocol methodology stage 4: charting the data.

I think more detail on critical HL is needed, especially given the authors include all clinical settings in their inclusion criteria. Without knowing this literature in-depth I imagine critical HL would have to consider some of the institutionalised and systemic aspects of professional-patient interactions and outcomes given a relationship-based framework. I guess there is potential here for clinicians and patients together to become better system navigators.

This current study is focused on the interactive aspects of HL and the patient practitioner interaction, therefore the chosen settings, primary, secondary and tertiary, aim to capture all qualified health professionals where patient communication is needed. However, it must be noted that critical HL is attributed to having advanced personal and social skills enabling one to access, manage, assess the credibility, understand and critically appraise information on health related issues (4). Critical HL is seen to arise from the relationship between individuals and services, being able to navigate and advocate for themselves in the healthcare setting. Reference to this is now included in the updated protocol, see methodology paragraphs 1 and 2.

A qualification of the secondary research question No. 2 (What are the characteristics of each education programme?) could suggest categorising programmes as 'functional', 'interactive' or 'critical' as a way to better understand the nature of these differences or the outcomes they generate.
Thank you for this suggestion. It is anticipated that such categories will be recorded, as it will demonstrate meaningful information when carried out in charting the results and is explicitly included in Stage 4: Charting the data.

A second element of the study design somewhat missing is evidence on HL among healthcare professionals. HL among diabetes patients is reported here, but how this evidence links to HL outcomes among professionals is not developed sufficiently.
The need for health professionals HL education, to improve patient health outcomes, has been identified (5), is supported by research literature (5-7) and is recognised in policy development in European countries (8). Educating health professionals has the ability to make an impact in reducing health inequalities in populations at the highest risk of limited HL levels, particularly within diabetes. It is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy (9-11), where greater self-efficacy is associated with lower glycaemic levels. Inadequate HL has been shown to be an independent predictor of poor glycaemic control, being associated with a lower likelihood of achieving tight control (12). Similarly, HL was associated with a higher prevalence of retinopathy and other self-reported complications of diabetes (12). This is now included in the protocol Introduction paragraph 7.

Given the focus here is on health professionals and the HL interventions available to them, or indeed accessed by them - I am missing the literature that says something about this population in particular - even if scant and shows some sort of context-mechanism-outcome pattern. Some examples of positive outcomes from HL for healthcare professionals might include leadership skills development, skills in policy advocacy, or access to career development opportunities.
In terms of professional outcomes it is intended that if an organisation is health literate that individuals working within will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (13)

As per above, some more descriptions of why it is a good idea to focus on the relationship between diabetes patients and diabetes care (providing) professionals would add to the overall rationale. I imagine this can be easily asserted given the size

of the population in question.
The evidence base for interventions to prevent diabetic foot disease is lacking. Therefore, to address this unmet and critical need, this Collaborative Doctoral award programme of research is focusing on primary and secondary prevention of DFD and novel treatment approaches to improve patient outcomes for those with DFD. The overall goal of DFD PRIMO is to train a multidisciplinary cohort of health care professionals to doctoral level in order to increase internationally competitive DFD research activity in Ireland, to provide a strong evidence-base for prevention and treatment provision decisions and improved patient outcomes.

I thought the use of population, concept and context (PCC) as a frame for the review is a useful focusing plan. I'm not sure how this is a mnemonic (as stated), or how it functions to operationalise the study. I would expect a brief outline of the plan to report findings that corresponds to the PCC approach, and maybe explaining what this adds.
The PCC (Population (or participants)/Concept/Context) is a framework recommended by the Joanna Briggs Institute. It enables one to identify the main concepts in the primary review question to allow for added structure within development of the study's aims and criteria. This is now addressed in Methodology paragraph 2. However, the PCC framework is designed to be utilised in creating the review title and the planning of the review, therefore it will not be used as a tool to report findings.

I also wondered why the authors are not planning a 'stage 7' stakeholder engagement as part of the scoping review - especially given their sub-question on implementation. The reason may be lack of funding, time, etc. If this is the case it would be good to say so.
The optional stage which comprises stakeholder consultation will not be adopted in the context of this current study. However, this research is the first stage to a three stage project which aims to incorporate stakeholder engagement informed by and using data collated from this review. This is noted within the updated protocol under Methodology paragraph 3.

Overall, the protocol positively outlines the rationale, design and next steps for studying HL among healthcare professionals as an addition to both the literature and practice. Mapping current interventions is a positive contribution that will build development of better interventions. The protocol would gain from more exploration of its ontological approach - I think this is implied but not fully stated or its implications drawn out.
In terms of ontological approach, the UK Medical Research Council (MRC) framework on developing and evaluating complex interventions (14) will be used to guide this research programme, whereby the four stage process will be used to develop a complex intervention informed by a gap analysis (scoping review), expert consultation and review. This framework recommends a phased development process, which is indeed the case for this research. It allows a continuum of increasing evidence in order to assist with intervention development (14). This approach uses systems theory which is a foundation for OHL, in order to structure intervention development. HL is a relational concept whereby focus is on individual interaction with services and systems, from an OHL point of view. As the focus is

on OHL, it is anticipated that a more health literate organisation will result in reduced barriers for individuals accessing and utilising healthcare.

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Competing Interests: No competing interests were disclosed.

Reviewer Report 16 September 2021

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Susie Sykes
Institute of Health and Social Care, London South Bank University, London, UK
Catherine Jenkins
Institute of Health and Social Care, London South Bank University, London, UK

Thank you for the opportunity to review this protocol which we feel forms the basis of an important and useful scoping review. This protocol for a scoping review addresses an important area of inquiry of an emerging area of research that addresses a practice-based problem. The review is well-planned and largely methodologically sound but issues of replicability could be enhanced. This is discussed below. It is aligned with the PRISMA ScR guidance and has benefitted from the inclusion of a librarian to design the search strategy. We agree that a scoping review is the most appropriate review type to explore the research objectives outlined here and to assess the need for undertaking a systematic review in the future. The inclusion of grey literature will enrich the review. Incorporating grey literature coverage also provides further justification for the choice of review type.

The authors provide a clear rationale for conducting a scoping review to address their research objectives, which are clearly-defined.
Some points that the authors may wish to consider:

- While the rationale for the study clearly states the prevalence and implications of low health literacy amongst patients and the public, there is a slight leap between this and the specific problem the scoping review seeks to address of health professional training/education. While it is perhaps implicit, a clear delineation of exactly what is included in your understanding of health literacy education for professionals would be helpful. Is it to improve the health literacy of professionals themselves, their understanding of how to

respond to low and varied health literacy levels of patients or how to create a health literate environment. We think that there is value in drawing on some of the literature around health literacy as a relational concept that explores the relationship between the health literacy competencies of individuals and the demands of the environment.

- The research questions are clear and helpful but a secondary question around diabetes is introduced and the rationale for this over other types of subject-specific health literacies is not clearly made.

- We feel there is a chance that a bias could be introduced at the study selection stage stemming from the intervention inclusion criteria (and this links with our first point). The health literacy competencies have not been clearly articulated and are open to interpretation. There also appears to be a conflation between health literacy education and communication skills education and this needs clarity. They are not synonymous. It is not clear to us exactly what you are including in your intervention criteria and why. This undermines the replicability of this study.

- It is not clear why the study excludes health care students or pediatric patient populations.

- Is the HSE health research repository distinct enough from Lenus to be included as a separate grey literature source? Perhaps Carrot2, OpenGrey or Google Scholar UK (in an incognito browser) could be substituted (providing a more balanced mix: two Irish and two international grey literature sources).

- There is a pre-1973 source related to HL which you may wish to take into account in your date range, although it does not focus on education: Dixon, J.P. (1959). The community responsibility for medical care. Am J Public Health 49, 76–81. https://doi.org/10.2105/AJPH.49.1.76.[1]

- Will your end-date of 2021 in the search strategy capture preprints and reviews-in-progress in e.g. PROSPERO?

- The PCC stipulates a clinical setting, but the inclusion criteria stipulate all settings. Is this a discrepancy?

References

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Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Health literacy, critical health literacy, health literacy education for health professionals and students, scoping review design.

We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however we have significant reservations, as outlined above.

Author Response 15 Dec 2021

Lauren Connell, National University of Ireland, Galway, Galway, Ireland

Dear Dr Susie Sykes,
Thank you for reviewing our protocol submission, and for your very constructive feedback. As a result, revisions have been made and are individually addressed below, please see reviewer's comments in bold. The revisions suggested from your comments certainly enhance the overall protocol.

Thank you for the opportunity to review this protocol which we feel forms the basis of an important and useful scoping review. This protocol for a scoping review addresses an important area of inquiry of an emerging area of research that addresses a practice-based problem. The review is well-planned and largely methodologically sound but issues of replicability could be enhanced. This is discussed below. It is aligned with the PRISMA ScR guidance and has benefitted from the inclusion of a librarian to design the search strategy. We agree that a scoping review is the most appropriate review type to explore the research objectives outlined here and to assess the need for undertaking a systematic review in the future. The inclusion of grey literature will enrich the review. Incorporating grey literature coverage also provides further justification for the choice of review type.
Thank you for your positive comments. Please see responses below.

While the rationale for the study clearly states the prevalence and implications of low health literacy amongst patients and the public, there is a slight leap between this and the specific problem the scoping review seeks to address of health professional training/education. While it is perhaps implicit, a clear delineation of exactly what is included in your understanding of health literacy education for professionals would be helpful. Is it to improve the health literacy of professionals themselves, their understanding of how to respond to low and varied health literacy levels of patients or how to create a health literate environment.
Thank you for this important observation. This has been clarified within the updated manuscript where a more explicit connection has been made between the problem statement and the background of health literacy.

HRB Open Research

HRB Open Research 2022, 4:97 Last updated: 10 MAR 2022

In the context of the development of organisational health literacy, health literacy education aims to address areas that health professionals can be trained in order to appropriately respond to and address limited and variable levels of health literacy in the patient population, this can be achieved by using techniques to encourage adequate HL, such as Teach-Back and avoiding medical jargon, which confirm understanding (1), whilst designing health literate reading materials to improve comprehensibility (2). Health professionals have an impact on overall organisational health literacy, in confirming understanding and interpersonal communication (1, 3). Therefore, by targeting health professionals there will be an organisational impact. In terms of professional outcomes it is intended that if an organisation is health literate that individuals working within will display OHL attributes such as leadership, HL integration into planning, community engagement, use of HL strategies in communication, designing accessible resources and clear communication (4).

The research questions are clear and helpful but a secondary question around diabetes is introduced and the rationale for this over other types of subject-specific health literacies is not clearly made.
Thank you for this observation, focus on diabetes is something that has been addressed in the manuscript. This particular review is a component of a larger funded research project comprising multiple doctoral students with multiple projects that focuses on diabetic foot disease and its prevention. Therefore, it was decided to scope the literature for any relevant health literacy education programmes that have been implemented within diabetes care. Sequentially, a prototype health literacy intervention will be developed and increasing focus will be placed on professionals working in the diabetes multidisciplinary team as the project progresses. Where the scoping review is situated in the study as a whole and the context of the larger research programme are now included in the manuscript.

We feel there is a chance that a bias could be introduced at the study selection stage stemming from the intervention inclusion criteria (and this links with our first point). The health literacy competencies have not been clearly articulated and are open to interpretation. There also appears to be a conflation between health literacy education and communication skills education and this needs clarity. They are not synonymous. It is not clear to us exactly what you are including in your intervention criteria and why. This undermines the replicability of this study.
Thank you for this comment, this is a clear limitation of the protocol. The health literacy competencies have been defined in line with previous research (5, 6) whereby competencies have been established and are articulated clearly. Similarly, key attributes of a health literate organisation have been established (4).

Communication skills education is recognised to be a component of HL education from the point of view of 'oral exchange' and interpersonal communication between the HP and the patient. They are not seen as synonymous but they are interlinked, in particular when the aim of communication skills education is to develop competencies that promote health literacy training of health professionals (7). In teaching HPs HL techniques the goal is to enhance the patient's understanding, not to change, explain or understand behaviour but to encourage the absorption of health information in order that the patient can make informed decisions and take informed actions.

It is not clear why the study excludes health care students or pediatric patient populations.
Because this study is a part of a larger project, it was decided to look at qualified health professional education, as it is emerging; the author recommends a separate review to explore health literacy education in the health professions' student curricula. Patient populations that encompass those most at risk of diabetic disease i.e. adult patient populations, as often diabetic foot screening begins in adulthood and continues to be monitored throughout adulthood (8). The Collaborative Doctoral Award (CDA) in which this project is a part is focused on diabetic foot disease. The reason for excluding healthcare students and paediatric populations is now included in the protocol within the methodology section Stage 3: Study selection.

Is the HSE health research repository distinct enough from Lenus to be included as a separate grey literature source? Perhaps Carrot2, OpenGrey or Google Scholar UK (in an incognito browser) could be substituted (providing a more balanced mix: two Irish and two international grey literature sources).
Thank you for this comment, amendments have been made to remove the HSE health research repository, and include a more balanced mix of grey literature sources as suggested.

There is a pre-1973 source related to HL which you may wish to take into account in your date range, although it does not focus on education: Dixon, J.P. (1959). The community responsibility for medical care. Am J Public Health 49, 76–81. https://doi.org/10.2105/AJPH.49.1.76.1
Thank you for this, it has been insightful to read. However, it does not meet the study's inclusion criteria or address health literacy education in health professionals.

Will your end-date of 2021 in the search strategy capture preprints and reviews-in-progress in e.g. PROSPERO?
September 2021 was used and there is no exclusion criteria regarding study type therefore it is possible that the search strategy will capture those studies. Although, the study aims to capture characteristics of education programmes and feasibility outcomes, which may not be accessible when including a review in progress.

The PCC stipulates a clinical setting, but the inclusion criteria stipulate all settings. Is this a discrepancy?
Settings will include primary, secondary and tertiary care settings. The protocol has been amended to reflect this change.

Reference List:

1. Brach C. The journey to become a health literate organization: a snapshot of health system improvement. Studies in health technology and informatics. 2017;240:203.

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Competing Interests: No competing interests were disclosed.

	Search Strategy
1	(("healthcare" or "health care") adj2 (professional* or provider* or personnel or worker*)).tw. or health personnel/
2	exp education/
3	(education adj2 (continuing or "competency based" or "competency-based" or health or program or programme*)).tw.
4	(workshop* or (problem-based adj (curricul* or learning))).tw. or ("problem based" adj2 (curricul* or learning)).mp. or (learning adj2 (active or experiential or problem-based or "problem based or case-based" or "case based")).tw.
5	(training adj2 (course* or module* or program or programme*)).tw.
6	training.tw. or inservice training/ or intervention*.tw. or course*.tw. or module*.tw.
7	staff development/ or clinical competence/ or program evaluation/ or program development/ or continu* professional development.tw.
8	2 or 3 or 4 or 5 or 6 or 7
9	exp Health Literacy/ or "health literacy".mp. or exp "health promotion"/ or "health literacy education".tw.
10	("health literacy" or ("health literacy" adj2 (competenc* or skill* or knowledge or attitudes))).tw.
11	communication skill*.tw.
12	(communication* adj2 ("teach back" or "teach-back" or method* or personal or program or social or personnel or health or nonverbal or non-verbal)).tw.
13	(skill* adj2 (interpersonal or social)).tw.
14	9 or 10 or 11 or 12 or 13
15	1 and 8 and 14
16	limit 15 to (english language and yr="1973 – 2021")

Data Charting Categories
1. Title
2. Author
3. Year
4. Country
5. Study aim
6. Timeframe
7. Study setting
8. Patient population
9. Intervention
10. Comparator, if any
11. Programme name
12. Programme goal
13. Setting
14. Programme participants
15. Programme mode of delivery
16. Course detail
17. Programme Length
18. Who taught the course?
19. Educational philosophy
20. Was the programme evaluated?
21. Evaluation methods
22. Outcomes assessed (Patient & Participant)
23. Kirkpatrick level of evaluation