



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;

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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<sup>1</sup>, is supported by research literature<sup>1-3</sup> and is recognised in policy development in European countries<sup>4</sup>. 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<sup>5</sup>, developing over time with multiple definitions identified in the literature<sup>6,7</sup>. This is an identified limitation to research and can negatively impact the measurement of HL<sup>8</sup>. Nevertheless, there is increasing consistency in the use of a typology of HL comprising of three core domains: functional, communicative/interactive and critical<sup>5</sup>. 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<sup>9</sup>.

A relational concept of HL will be used<sup>10</sup>, 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<sup>11</sup>. 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<sup>12</sup>, 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<sup>13,14</sup>, 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<sup>15</sup>. 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<sup>16</sup>, minimising jargon<sup>17</sup>, Ask Me Three, which helps confirm patient understanding<sup>11</sup>, and designing health literate reading materials to improve comprehensibility<sup>17</sup>.

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'<sup>10</sup>.

In Ireland, 1 in 7 adults have been found to have limited HL skills<sup>18</sup>, and at a European level almost every second respondent within the European health literacy survey (HLS-EU) had limited HL<sup>19</sup>, which is associated with increased hospitalization, higher all-cause mortality, poor health related knowledge, self-care behaviour and other outcomes<sup>20</sup>. 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<sup>21,22</sup>.

For people with chronic disease, limited HL has been associated with lower health-related quality of life (HRQoL)<sup>23</sup>, and poorer health outcomes<sup>24</sup>. In chronic disease such as diabetes, demands on individuals are characterised by a high level of complexity<sup>25</sup>, where self-management relies on patients' having advanced HL skills, in order to utilise written education material and verbal instructions<sup>26</sup>. 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<sup>27</sup>.

Inadequate HL has been shown to be an independent predictor of poor glycaemic control, being associated with a lower likelihood of achieving tight control<sup>28</sup>. Also, it is suggested that when HL is considered in isolation it is associated with greater diabetes self-efficacy<sup>29-31</sup>, 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<sup>32-34</sup>. In contrast, some studies have not found HL to have a statistically significant relationship with diabetes-related health outcomes such as wound healing<sup>34</sup> and other complications<sup>35</sup>. But, when interactive HL or critical HL are considered some relationships have been found to be positive<sup>32,33,36</sup>.

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<sup>15,37</sup>. 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<sup>38</sup>. Limited evidence has shown that confirming patient's understanding of new concepts can increase glycaemic control in those with diabetes<sup>39</sup>.

Although HL research has developed and grown since at least 1973<sup>40</sup>, limited research has been undertaken on HL interventions and their effectiveness<sup>17</sup>, particularly in regards to qualified health professional education, despite the identification of such education programmes being relevant to mitigating potential health outcomes<sup>1</sup>. More recently, some training programmes have been developed, for QHPs, to address HL competencies and HI related communication skills<sup>2,37,41,42</sup>. 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<sup>43</sup> 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<sup>15</sup>. Although often recognized as a separate entity<sup>10</sup>, communication plays a significant role in the development of interactive and critical HL, whereby effective communication maintains the patient-practitioner relationship<sup>13,14</sup>.

Interactive HL has been found to be the most important HL domain needed within diabetes self-management<sup>44</sup>, where interactive HL consists of a higher level of communication (oral literacy) and social skills needed to extract and discuss information with others<sup>5</sup>. 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<sup>14,45</sup>. 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<sup>39</sup>; an example of this is the 'Teach-Back' tool<sup>16</sup>. 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<sup>46</sup>. 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<sup>47,48</sup>.

## 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'<sup>49</sup>. 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<sup>50</sup> and to assess if a systematic review is possible<sup>34</sup>. An iterative approach will be used in this study to allow authors to develop the inclusion and exclusion criteria while considering the presenting evidence<sup>49,51</sup>. This scoping review will be conducted drawing on methods and guidance from the Joanna Briggs Institute<sup>52</sup>, which adds to earlier guidance on scoping review methodology<sup>31</sup>. It will be reported according to the Preferred Reporting Items for Systematic Review and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist<sup>53</sup>. 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<sup>52</sup> and Arksey and O'Malley's (2005) scoping review framework<sup>43</sup>. The PCC framework, where PCC stands for Population, Concept and Context<sup>52</sup>, helps construct a title without the need for outcomes, interventions or phenomena of interest<sup>52</sup>. 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<sup>43</sup>, 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<sup>54</sup>, 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<sup>55</sup>.

### 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<sup>56,57</sup>. All searches will be limited to post-1973, due to the history of HL research emerging at this time<sup>40</sup>. Intervention components must contain health literacy competencies or health literacy related communication skills training, as previously defined<sup>47,48</sup> 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)<sup>40</sup>. 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<sup>58</sup>. 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 <sup>47,48</sup>	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<sup>59</sup>:

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<sup>53</sup>.

#### 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<sup>52</sup>, training programme evaluation methods<sup>60</sup> and insight from previous work<sup>61</sup>. 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<sup>37,41,42</sup>, the extent and nature of programmes, needs identifying and collating to assess the potential of undertaking a full systematic review<sup>43</sup>. 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

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**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>

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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

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

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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

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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?**

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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.**

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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

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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>.<sup>1</sup>
- 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?

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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.

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.

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