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REVIEW ARTICLE

Health literacy in type 2 diabetes patients: a systematic review of systematic reviews

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Abstract *Aim* To summarize, critically review, and interpret the evidence related to the systematic reviews on health literacy (HL) amongst type 2 diabetes mellitus (T2DM). *Methods* The methodology for this study consisted of a systematic review of systematic reviews, using the PRISMA statement and flowchart to select studies, and searching on PubMed, CINAHL, Scopus, and Cochrane. The search covered the period between January 2006 and June 2016. *Results* From the 115 identified record by the queries, only six systematic reviews were included, following a quality evaluation using AMSTAR. The included systematic reviews content was analyzed by the independent work of two authors, using a narrative synthesis approach. The findings of this study (i.e., main themes) are areas of consensus and gaps in knowledge. Areas of consensus are HL definition, HL measurement tools, and the relationship between T2DM patient knowledge (or literacy) and his/her HL. The gaps in knowledge were the assessment of the relations between HL and health outcomes and self-efficacy, the gender differences, the effectiveness of interventions to improve HL, the cost-effectiveness study of interventions to improve HL, and the understanding of the influence of organizational environment on HL. *Conclusion* This review provides a current state of knowledge to address clinical practice and research proposals. HL could be useful to personalize patients' follow-up and it should be routinely assessed in its three dimensions (i.e. functional, interactive and critical) to enhance patients' ability to cope with clinical recommendations. Future research should be mainly aimed to test the effectiveness of evidence-based interventions to improve HL amongst T2DM patients.

Keywords Health literacy · Type 2 diabetes mellitus · Diabetes mellitus · Systematic review · Diabetes knowledge · Health outcomes

Introduction

Type 2 diabetes mellitus (T2DM) affects the 90–95% of the overall population of patients with diabetes mellitus, being an important health issue for more than 380 million people worldwide [1]. Currently, more than 8.5% of the adult European population has a diagnosis of T2DM, while International Diabetes Federation (IDF) estimates the growing of its prevalence, rising over the 10% of the global adult population within the 2040 [2]. In fact, many studies clearly highlighted how T2DM represents an important challenge for the health systems sustainability, especially considering its negative impact on patients' outcomes and their clinical trajectory [2, 3]. Considering that T2DM is a chronic condition, patients have to cope lifetime with the clinical recommendations to optimize their health and quality of life and to reduce their complications [4–7]. Therefore, the attention to define strategies to enhance T2DM patients' coping

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ability has been increased over the last 10 years [8, 9]. With regard to this, many authors indicated that T2DM patients' health literacy (HL) has a key role to achieve best health outcomes, guide their follow-ups, and define educational strategies [10–12].

HL was defined as an individual's capacity to obtain, understand and function the basic information and services to best manage his or her health and engage in proper decision-making [13, 14]. HL includes three different levels: functional, interactive or communicative, and critical [15]. The 'functional' level focuses on basic skills of daily life functioning (e.g., reading and writing) [15]. The 'interactive' level, also known as 'communicative' level, refers to cognitive skills and literacy [15]. The 'critical' level refers to proper health decision-making [15]. Overall, HL was shown to be a key element for patients with chronic illness both for the management of the disease and for the achievement of positive health outcomes and quality of life [16–20]. Specifically, previous results found that limited functional HL is associated with low diabetes knowledge [11, 12, 21]. This is important because glycemic control is associated with disease knowledge [22], treatment adherence [23], self-efficacy [24], and self-care behaviors [4, 25].

Despite this key role of HL to manage and achieve best health outcomes in T2DM patients, clinicians and researchers must face a diverse and complex scenario provided by miscellaneous conceptualizations and tools that make difficult to identify implications both for healthcare interventions and further research on the topic [26]. In fact, the multitude of primary studies and the increasing number of available systematic reviews confirm the diversity of available knowledge [27]. Specifically, the literature showed contrasts in both the measured outcomes and in the findings of previous studies focused on HL of T2DM patients [26]. Indeed, the study of HL in T2DM patients could benefit of a broad critical review and synthesis of the available systematic reviews encompassing the continuous adjustment of HL definitions and the use of multiple tools to measure it in clinical and research fields [6, 27]. So far, the framework shaped by evidence emerging from the available systematic reviews is a current issue and it has not been described yet. According to many authors, a critical analysis on the available systematic review (i.e., systematic review of systematic reviews) could help to define the current state of knowledge, highlighting the areas of consensus and the weakness still present in research [28, 29].

Coherently with this gap, the aim of this study was to summarize, critically review, and interpret the evidence related to the systematic reviews on HL among T2DM patients. The need of a systematic review of systematic reviews is also enhanced by the clinical demand to dispose of an handy evidence-based framework to orient health professionals in T2DM care [28].

Methods

The methodology for this study consisted of a systematic review of systematic reviews [28]. A systematic review of systematic reviews helps to provide a summary of evidence from different systematic reviews within the same field, including the combination of outcomes, different conditions, and problems [29]. According to Smith et al. (2011), this study aims to summarize, critically review, and interpret the evidence on the role of HL in T2DM patients. Details of the adopted methodology and the strategies used to minimize possible review bias are described below.

Search strategy

We used the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement and flowchart to select studies for inclusion in this review and to provide a systematic search [30]. The PRISMA statement is an evidence-based minimum set of items to ensure the rigor of systematic searches and decrease selection bias [8]. The PRISMA flowchart helpfully maps the number of records identified by crossing the previous phases of identification, screening, and eligibility [31] (Fig. 1). Electronic searches on PubMed, CINAHL, Scopus, and Cochrane were performed. Inclusion criteria were: (a) systematic reviews published between 2006 and 2016, (b) written in English, (c) with the availability of the abstract and (d) the full text, focused on (e) HL in (f) T2DM patients. Exclusion criteria were: (a) without the abstract and (b) the full text available, (c) with low-quality appraisal of the eligibility papers (i.e., phase 3 of PRISMA, Fig. 1). As described below, to assess the quality papers in the eligibility phase (i.e., phase 3), the authors used A Measurement Tool to Assess Systematic Reviews (AMSTAR) [32]. The search queries are shown in "Appendix 1."

Evaluation of eligibility

Two authors (AM, IB) independently conducted the process of including systematic reviews. Consensus discussions solved potential disagreements for each phase as shown in Fig. 1. In the first phase (i.e., identification) the search queries were developed for PubMed, CINAHL, Scopus, and Cochrane ("Appendix 1") and 115 records were identified. In the second phase (i.e., screening), the duplicates were removed ($n = 13$) and 90 papers were excluded by reading titles and abstracts because they did not meet the inclusion criteria ($n = 69$ were not focused on T2DM patients and HL; $n = 21$ were not systematic reviews). In the third phase (i.e., eligibility), the full texts were retrieved, read, and assessed by using AMSTAR [32] by the independent work of two authors (AM, IB). A consensus discussion was

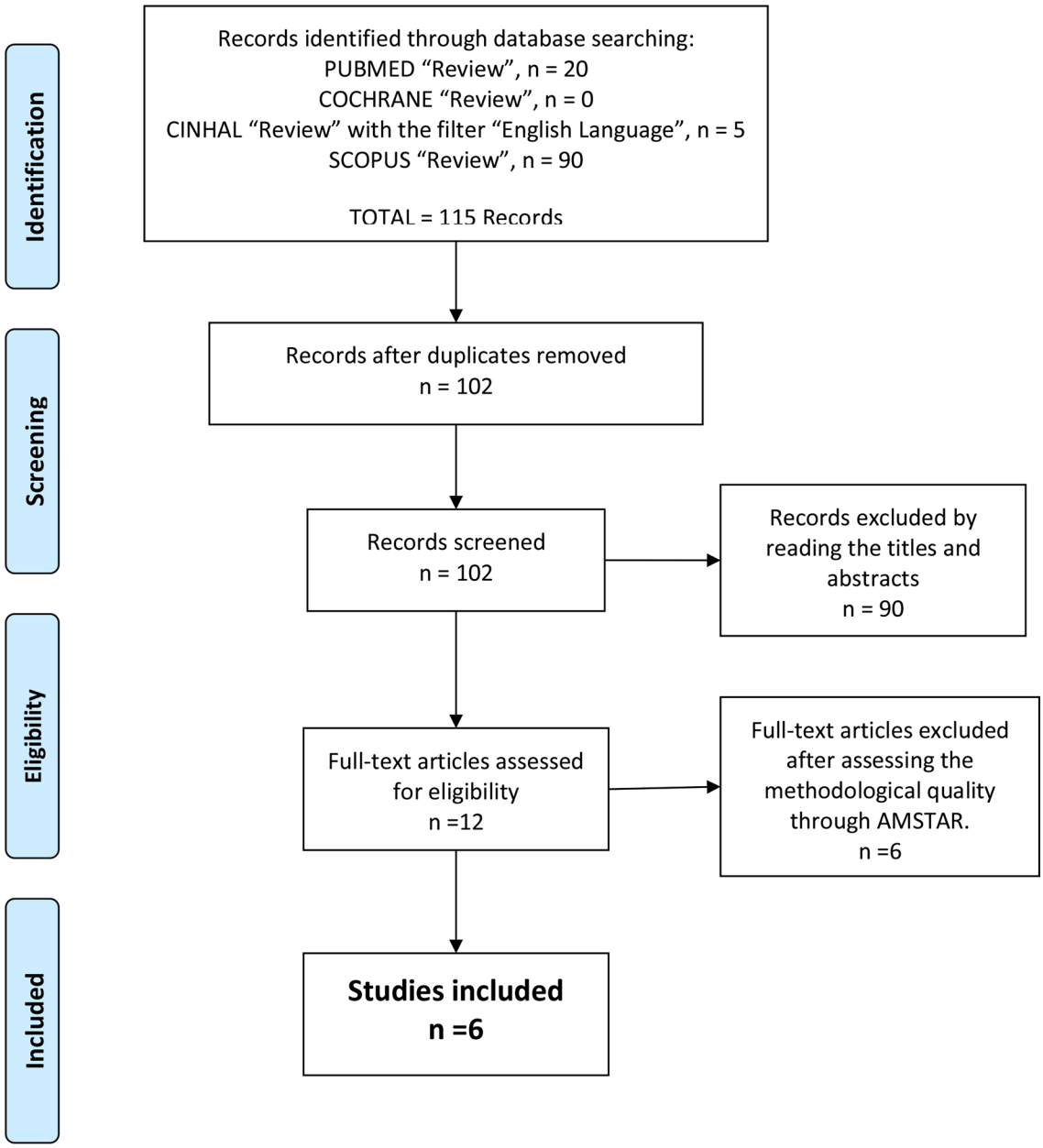

Fig. 1 PRISMA flowchart

performed for each AMSTAR items, covering the following main aspects: (a) foreground question elements (i.e., PICO components), (b) review methods (i.e., search and synthesis strategies), (c) selection bias, (d) synthesis of the included studies, (e) quantitative synthesis evaluation (when available), (f) conflict of interest and funding statements. Overall, the total AMSTAR score guided the final inclusion/exclusion decision, and its cutoff has been set at the achievement of a score equal or superior to eight. Six papers were excluded due to their weakness, as highlighted by the AMSTAR assessment (Table 1). The main causes of weakness were related to the evaluation of an unclear foreground question, the review methods for both search and synthesis strategies, and the presence of selection bias. None of the 12 eligible systematic reviews presented a quantitative synthesis. Then, the Cohen's Kappa index was used to objectively assess the degree of agreement among authors' AMSTAR assessment of each paper, considering two raters (i.e., the independent work of the authors) and two categories, which were the positive AMSTAR items' assessment versus the negative/partial AMSTAR items' assessments. According to the literature, authors considered a score > .70 as a cutoff of a good agreement [33] (Table 1). Therefore, the fourth phase (i.e., inclusion) included six systematic reviews (Fig. 1).

Table 1 AMSTAR evaluation of systematic reviews performed during the eligibility phase

AMSTER's items														
	Authors	ITEM 1	ITEM 2	ITEM 3	ITEM 4	ITEM 5	ITEM 6	ITEM 7	ITEM 8	ITEM 9	ITEM 10	ITEM 11	TOTAL	Cohen's K
AlSayah, 2016	AM	1	1	1	1	1	1	2	1	4	1	1	**9**	0.836
	IB	1	1	1	1	2	1	2	1	2	1	1	**8**	
Davey, 2015	AM	1	2	1	1	2	1	1	1	4	1	1	**8**	0.850
	IB	1	2	1	1	2	1	1	1	4	1	1	**8**	
Bailey, 2014	AM	1	2	2	1	2	1	3	1	4	1	3	5	0.770
	IB	1	2	2	1	2	1	3	2	4	1	2	4	
Aponte, 2013	AM	1	2	2	1	2	1	2	3	4	3	2	3	0.881
	IB	1	2	2	1	2	1	2	3	4	2	2	3	
AlSayah, 2012	AM	1	1	1	1	2	1	1	1	1	1	1	**10**	1.000
	IB	1	1	1	1	2	1	1	1	1	1	1	**10**	
Fransen 2012	AM	1	1	2	1	2	1	1	1	4	1	1	**8**	0.854
	IB	1	1	2	1	2	1	1	1	4	1	1	**8**	
Loke, 2012	AM	3	1	1	1	2	1	1	1	4	1	1	**8**	1.000
	IB	3	1	1	1	2	1	1	1	4	1	1	**8**	
White, 2010	AM	3	3	3	3	3	3	3	3	3	3	3	0	1.000
	IB	3	3	3	3	3	3	3	3	3	3	3	0	
Wallace 2010	AM	3	2	3	3	2	3	3	3	3	3	3	0	0.765
	IB	2	2	3	3	3	3	3	3	3	3	3	0	
Eichler 2009	AM	1	1	1	1	2	1	1	1	1	1	1	**10**	0.765
	IB	1	1	1	1	2	1	1	2	1	1	1	**9**	
Boren, 2009	AM	1	2	1	1	2	1	2	2	2	2	3	4	0.862
	IB	1	2	1	1	2	1	2	2	2	2	1	5	
Nath, 2007	AM	3	3	2	2	2	2	2	2	2	2	2	0	0.800
	IB	1	3	2	2	2	2	2	2	2	2	2	1	

Final grading of the methodological quality of each SR was based on the overall score and reported as either 'high' (score ≥ 8), 'medium' (score 4–7) or 'low' (score ≤ 3)

Systematic reviews with higher AMSTER evaluation are in bold, representing the included records for this study

1 = Yes; 2 = No; 3 = Cannot answer; 4 = Not applicable

Data extraction and synthesis

After selecting the literature, the authors read the full texts several times to get an overview of the content of each paper (Table 2) in accordance with the following format: (a) first author, (b) year of publication, (c) population/geographic area, (d) aim, and (e) results. Considering that none of the six included systematic reviews presented a meta-analysis, it was not possible to perform a pool meta-analysis. In each included review, the authors clearly discussed that they found considerable heterogeneity between methodologies, samplings, and measures of their included primary studies. For this reason, the authors of this systematic review of systematic reviews considered the main and common results of each included study, and synthesized it with narrative techniques according to the following four phases: (a) defining the theoretical framework of the synthesis, (b) developing a preliminary synthesis, (c) exploring relationships within and between studies, and (d) assessing the robustness of the synthesis [34]. Indeed, the authors assessed their consensus (i.e., degree of agreement among raters) related to their independent narrative synthesis by using inter-rater agreement [33], where a value of .80 or greater was considered an acceptable value of consensus. According to methodological recommendations, the narrative synthesis represents the results of this paper [28, 29]. A .95 inter-rater score was obtained, showing good authors agreement on the narrative synthesis.

Results

Of the six systematic reviews (Table 2), two were conducted in the United States; one involved samples from the USA and the UK, and three used a multinational sampling. We obtained a good agreement (i.e., .95 inter-rater score) in considering two main themes that summarize the evidence concerning HL in T2DM patients. The first theme (a) is given by the 'areas of consensus', while the second theme (b) is given by 'the gaps in available knowledge' described by the authors of the included systematic reviews and also identified by our critical analysis of the included reviews (Fig. 2).

Areas of consensus

There are three subthemes in which the authors found consensus among the different perspectives of the included systematic reviews. The subthemes related to (a) the HL definition, (b) HL measurement tools, and (c) the relationship between T2DM patient knowledge (or literacy) and his/her HL (Fig. 2).

Different authors consider HL a multidimensional concept related to a skills set that patients need to function effectively in the health care environment [5, 13, 27, 35–37]. Indeed, the authors have a good consensus in operationalizing HL into three levels (i.e., functional, interactive or communicative, and critical). This consensus arose from the definition proposed by Nutbeam [38]. There is agreement in considering numeracy a subelement of HL, because it refers to the patient's skill to use numeric information for specific tasks, such as understanding medication dosages or blood glucose measurements, even if numeracy often is considered a proper construct in empirical studies [27].

The literature presents many tools to assess HL in T2DM patients, giving a diverse scenario [17]. Considering the findings of the selected systematic reviews, however, it is possible to categorize the tools as (a) generic or disease-specific (i.e., diabetes-specific), and (b) with a direct or indirect assessment of numeracy skills [6, 17, 35]. There is consensus in considering how each tool presents strengths and weaknesses as the result of its structure and measurement scope, and in relation to its validity proprieties [35]. The indirect assessment tools (i.e., self- or clinician-administered measures) seem to be the most useful in clinical and research fields, because they are less influenced by bias in data collection (e.g., writing ability, concentration, sight).

Finally, there is strong consensus on the positive effect of a patient's knowledge on his/her HL [13, 17, 35, 37, 39]. The literature consistently shows that greater diabetes-specific knowledge is associated with higher HL. These results are confirmed in different populations, different approaches of analysis, and even by the use of different tools [13, 27, 36].

Gaps in knowledge

This theme includes six main subthemes: (a) relations between HL and health outcomes, (b) relations between HL and self-efficacy, (c) gender differences, (d) effectiveness of interventions to improve HL, (e) cost-effectiveness of interventions to improve HL, and (f) influence of organizational environment on T2DM patients' HL.

The health outcomes assessed by the included systematic reviews were glycemic control, self-care, self-management, therapeutic adherence, or other clinical parameters (e.g., blood pressure, body weight). The findings of the included systematic reviews indicate a poor understanding of how and the degree to which HL influences health outcomes of T2DM patients [13, 27]. Some authors argued that HL plays a mediator role between patient knowledge and behavior, such as self-care or self-management [13, 37]. However, the findings of these studies are not consistent enough to understand the role of HL for health outcomes of T2DM patients [13, 17, 37].

Despite the literature showing the important role of patient self-efficacy to achieve health outcomes (e.g., 40, 41), there inconsistencies in the findings of studies aiming to

Table 2 Summary of the main contents of the included systematic reviews on health literacy in type 2 diabetes patients

First author	Year of publication	Population/geographic area	Aim	Results
Al Sayah F	2013	Patient with diabetes (type 1 and 2). Studies conducted in United States	The aim of these review was identified the instruments used to measure HL, evaluated their measurements scope & properties, and proposed recommendations for their use	Description of several instruments to assess the skills of HL (direct and indirect instruments). They have been identified 12 instruments: (a) one, diabetic specific (LAD) (b) eight, general measures of HL (REALM, REALM-R, TOFHLA, s-TOFHLA, NVS, 3-brief SQ, 3 level HL Scale, SILS) (c) two, generic measures of numeracy (SNS, WRAT), (d) one overall diabetic specific (DNT). Indirect self- or clinically administered measures are the most useful in both clinical and research setting
Davey J	2015	Multinational samplings of patients with ischemic heart disease and T2DM (mainly men)	This review was aimed to address the knowledge gap that exists in the identification and understanding of the correlates of men's HL and its components in relation to major lifestyle related chronic disease	The limited body of research identified has resulted from a lack of consensus about the definition of HL, and a concordant set of validated HL measures. Only a bivariate analysis presented their results for knowledge of heart disease or stroke. Only six empirical studies found an association between educational attainment and components of HL, the direction of association was positive in all cases. Then there is a little attention to HL as an enabler of preventive action to reduce disease burden in men
Al Sayah F	2013	Patients with diabetes (type 1 and 2). Studies conducted in United States	The aim was to synthesize research evidence on relationship between HL (functional, interactive, and critical) or numeracy and health outcomes (i.e., knowledge, behavioral and clinical) and understanding their interaction	Consistent and sufficient evidence showed a positive association between HL and diabetes knowledge but there was an unbound or poor evidence on the relationship between health literacy or numeracy and clinical outcome (e.g., hypoglycemia, blood pressure, diabetes complications, low-density lipoprotein). It may be premature to routinely screen for low HL as a means for improving diabetes-related health-related outcomes
Fransen M	2012	Patients with diabetes (type 1 and 2). Studies conducted in Unit State and United Kingdom	To review studies on the associations between HL, diabetes self-management and possible mediating variables	From studies examined is emerged mainly a positive relationship between HL and knowledge and self-efficacy and social support. There is only limited evidence for a significant association between health literacy and diabetes self-managements, and for mediating role of socio-cognitive variables in this pathway; on nine total studies, only three of these have shown a positive direct relationship between HL and SM. These relations were described in a conceptual framework and promote empirical reports to study these relationship

Table 2 (continued)

First author	Year of publication	Population/geographic area	Aim	Results
Loke Y	2012	Older adults taking drugs for cardiovascular diseases and T2DM. Multinational samplings	The aim was to study the relationship between HL and adherence to medications in these key patient groups, because the levels of HL are found to have a strong influence on adherence	HL had some correlation with diabetes knowledge but no correlation with medical adherence. There is an urgent need for robust studies outside of US with wider, generalized recruitment of participant
Eichler K	2009	Multinational samplings (US, Norway, Italy, Canada, Bermuda, Mexico and Switzerland) of patients with T2DM	The aim to systematically review the economic implications of limited HL by collecting evidence about costs of limited HL and cost-effectiveness of interventions to improve limited HL	It would seem that a low HL would determinate a major expense to the health care system despite no studies reported cost- effectiveness. More research is needed to better understand the economic aspect of limited HL and the cost-effectiveness of interventions to improve HL

HL health literacy; *T2DM* type 2 diabetic mellitus; *SM* self-management

understand the relations between T2DM patient self-efficacy and HL [17, 35, 37]. For instance, some authors found no significant interactions between self-efficacy and HL [42], while others found a significant positive interaction [7]. At any rate, there is little empirical research studying this relation. Furthermore, available findings come from studies with a diversity of samplings, measurements, and analytical approaches.

Another topic requiring deeper study is the gender differences related to HL in T2DM patients [25, 36]. Davey et al. [36, 39] have highlighted how little is known about this topic. Even though their paper focused on the correlation of men's HL and components, Davey et al. [36, 39] have clearly shown how the evidence supporting the understanding of gender differences in T2DM patients HL is poor.

To the best of our knowledge (see Table 2), there are no systematic reviews assessing the effectiveness of interventions to improve HL among T2DM patients. Little research was conducted with experimental design (i.e., Randomized Controlled Trials) to assess the effectiveness of interventions. Considering the empirical studies included in each analyzed systematic review, the majority of the papers had a cross-sectional design. For the same reasons, there is a shortage of primary studies assessing the cost-effectiveness of interventions to improve HL in T2DM patients [9]. There are no systematic reviews assessing the influence of the organizational environment (e.g., hospital organizational well-being) [43] and health professionals' characteristics (e.g., competencies, staffing levels) [44] on HL in T2DM patients.

Discussion

This study examined published systematic reviews on HL in T2DM patients. To the best of our knowledge, this is the first systematic review of systematic reviews on this topic providing a broad framework on HL among T2DM patients and defining both strengths and limitation of previous research. The areas of consensus were: HL definition, HL measurement tools, and the association between T2DM patients' knowledge (or literacy) and HL. Good evidence exists about the three levels of HL (i.e., functional, interactive and critical) and about the influence of patients' knowledge (or literacy) on their HL [27]. However, although several tools to measure HL in T2DM patients were found, there is only one diabetes-specific tool measuring the three HL levels [21]. Furthermore, it is available only in the Japanese language and a brief version for clinical practice is still lacking [35].

The gaps in knowledge were: the association between HL and health outcomes and self-efficacy, the gender differences, the effectiveness of interventions to improve HL, the cost-effectiveness of interventions to improve HL, and the understanding of the influence of organizational

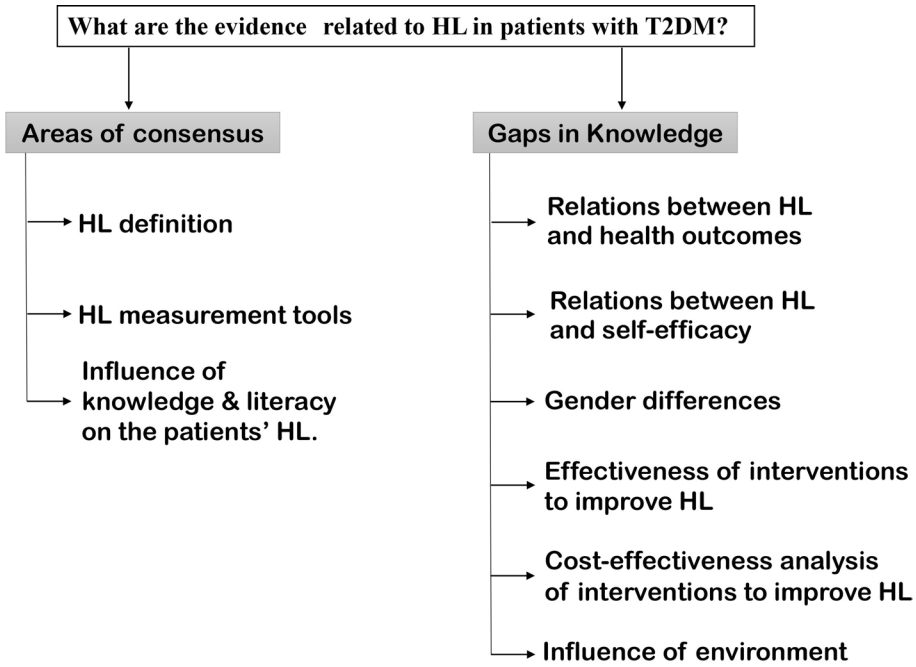

Fig. 2 Results synopsis

environment on HL. The impact of HL on health outcomes is unclear [13, 17, 37]. Indeed, the literature presents the following contradictions: (1) some studies show an association between HL and self-care [45–47], while other studies did not [48]; (2) some authors find a relation between HL and adherence [49], while others do not find any significant association between them [50]; (3) the evidence for the association between HL and self-management in T2DM patients is limited. Furthermore, self-efficacy mediates the relationship between knowledge and behavior [51] representing a strategic element to achieve positive outcomes in T2DM population (e.g., self-care, glycemic control). However, also the evidence showing the association between HL and self-efficacy are poor in T2DM [37]. Little is known also about HL gender differences in T2DM population [39]. This gap is relevant considering that the disease-management burden for men was shown to be higher than for women [52]. Furthermore, men seem more likely to engage in risky lifestyle behaviors (e.g., smoking, physical inactivity, and poor diet) [53]. Interventions to improve HL require multi-disciplinary knowledge, adequate skill-mix, competencies, and staffing levels [54]. Particularly, some authors have shown that competency is performance-specific and influenced by organizational environments [44]. However, both the effectiveness of interventions to improve HL and the influence of the organizational environment on HL are unclear in T2DM. Finally, some authors show that limited HL in T2DM patients represents an additional 3–5% cost to the total health care cost per year [5]. Due to the little interventional research, data on the cost-effectiveness of interventions to improve HL are also few. Considering that the prevalence of T2DM is growing worldwide, more research is strongly needed to study the economic implications of HL in this population [55].

Strengths and limitations

The main limitation of this systematic review of systematic reviews is the diversity of aims and methods of the included systematic reviews. Moreover, none of the included reviews presented a quantitative synthesis, due to issues related to methodological, samplings, and measurement heterogeneity. Thus, based on the current state of the art, nor data aggregation neither pool meta-analyses were performed. For the same reason, the narrative synthesis to obtain the findings of this study was difficult. However, at the end of the narrative analysis, the study findings (Fig. 2) have obtained a very good agreement among authors (inter-rater score = .95), describing the current and broad portrait of the evidence available on HL in T2DM patients.

Conclusion

Adequate HL is strategic to achieve best outcomes for T2DM patients. So far, it has not yet been possible to perform meta-analysis, due to the available primary studies are mainly aimed to describe—using different measurements and methodologies—the relationships between HL,

behaviors (e.g., patients' self-care) and health determinants (e.g., self-efficacy), with a lack of randomized controlled trial (RCT) to test interventions aimed to enhance HL in T2DM patients. Otherwise, the literature presented a number of systematic reviews on different aspects of HL published in the last few years, such as the relationships between HL and clinical outcomes or HL measurement tools. Although those systematic reviews are useful to understand specific nuances of HL, they drove the literature toward a fragmentary and diverse scenario. For those reasons, our study—highlighting the areas of consensus and gaps in knowledge—shapes the framework of the current state of knowledge on this topic, driving hints for both health care providers and academic researchers.

Considering the growing interest to move toward personalization in many different areas of science, HL plays a bright role to facilitate a paradigmatic shift in clinical practice, being a framework that could address patients' education, enhancing their ability to cope with the clinical recommendations. For this reason, our results could be useful to drive HL from academic contexts into practice environments, due to our synthesis itself represents a tip to understand the current state of knowledge. De facto, this study helps health care providers in their decision-making related to the care paths personalization. Noticeably, personalization should be intended in its macrosense, which is given by the customization of pathways, education, health promotion, and broadly T2DM patients' follow-ups, as well as the understanding of the micro/biological aspects of the human beings (e.g., genomics and omics). In this regard, this study helps health care providers to find more clearness in the broad HL scenario. Hence, HL could act as a driver to guide tailored follow-ups, encompassing the important role of patients' engagement and empowerment. For this reason, based on our results, our main recommendation is to routinely assess HL during follow-ups in all its three dimensions: functional, interactive and critical.

This study also gives a number of tips for future researches. Those are mainly showed by the subthemes of the highlighted gaps in knowledge, which are the study of the relations between HL and health outcomes, the relations between HL and self-efficacy, the gender differences, the effectiveness of interventions to improve HL, the cost-effectiveness of interventions to improve HL, and the influence of organizational environment on T2DM patients' HL. Furthermore, we have to acknowledge that the contemporary technology (e.g., telemedicine, Web apps, mobile machineries, high-tech spreading) can also be used to easily collect data for research purposes in an intensive and longitudinal way, overcoming the main limits of the majority of the available empirical research on HL, which still have mainly a cross-sectional design. The longitudinal and intensive approach to collect data from remote could be given by patients' diaries, using standardized and validated measurements. Those datasets could be analyzed using new methodological approaches (e.g., intensive longitudinal analyses) to valorize the patients' personal trajectory within their follow-up, adding value to the current understanding of health predictors, such as HL. This future research could be useful to personalize follow-ups, owing to the possibility to monitor the personal trends in maintaining an adequate HL over time. Furthermore, robust RCTs to test the effectiveness of evidence-based interventions to improve HL are strongly needed.

Finally, all future directions of both research and clinical practice related to HL in T2DM patients should be supported by the shared use of valid and theory-driven measurement tools, otherwise the evidence on HL will continue to be undermined by gaps. The achievement of adequate and widespread HL in T2DM patients will be strategic to save public money, due to its potentiality in enhancing patients' ability to cope with clinical recommendations, preventing complications and optimizing the clinical management over the time. Accordingly, HL is a valuable driver to face the challenges brought by T2DM population, such as the need of tailored management strategies for a chronic and aging population.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Human and animal rights This article does not contain any studies with human or animal subjects performed by the any of the authors.

Informed consent Not applicable.

Appendix 1. Queries used for the systematic review of systematic reviews search

Database	Query	Date of the search	Number of papers
PubMed	((systematic review [ti] OR meta-analysis [pt] OR meta-analysis [ti] OR systematic literature review [ti] OR this systematic review [tw] OR pooling project [tw] OR (systematic review [tiab] AND review [pt]) OR meta synthesis [ti] OR meta synthesis [ti] OR integrative review [tw] OR integrative research review [tw] OR rapid review [tw] OR consensus development conference [pt] OR practice guideline [pt] OR drug class reviews [ti] OR cochrane database syst rev [ta] OR acp journal club [ta] OR health technol assess [ta] OR evid rep technol assess summ [ta] OR jbi database system rev implement rep [ta]) OR (clinical guideline [tw] AND management [tw]) OR ((evidence based[ti] OR evidence-based medicine [mh] OR best practice* [ti] OR evidence synthesis [tiab]) AND (review [pt] OR diseases category[mh] OR behavior and behavior mechanisms [mh] OR therapeutics [mh] OR evaluation studies[pt] OR validation studies[pt] OR guideline [pt] OR pmcbook)) OR ((systematic [tw] OR systematically [tw] OR critical [tiab] OR (study selection [tw]) OR (predetermined [tw] OR inclusion [tw] AND criteri* [tw]) OR exclusion criteri* [tw] OR main outcome measures [tw] OR standard of care [tw] OR standards of care [tw]) AND (survey [tiab] OR surveys [tiab] OR overview* [tw] OR review [tiab] OR reviews [tiab] OR search* [tw] OR handsearch [tw] OR analysis [ti] OR critique [tiab] OR appraisal [tw] OR (reduction [tw]AND (risk [mh] OR risk [tw]) AND (death OR recurrence))) AND (literature [tiab] OR articles [tiab] OR publications [tiab] OR publication [tiab] OR bibliography [tiab] OR bibliographies [tiab] OR published [tiab] OR pooled data [tw] OR unpublished [tw] OR citation [tw] OR citations [tw] OR database [tiab] OR internet [tiab] OR textbooks [tiab] OR references [tw] OR scales [tw] OR papers [tw] OR datasets [tw] OR trials [tiab] OR meta-analy* [tw] OR (clinical [tiab] AND studies [tiab]) OR treatment outcome [mh] OR treatment outcome [tw] OR pmcbook)) NOT (letter [pt] OR newspaper article [pt]))) AND ((((“diabetes mellitus”[MeSH Terms] OR (“diabetes”[All Fields] AND “mellitus”[All Fields]) OR “diabetes mellitus”[All Fields]))) AND ((health[ti] AND literacy[ti]) OR (“health literacy” OR “health literate” OR “medical literacy”) OR (functional[tw] AND health[tw] AND literacy[tw]) OR numeracy OR ((low literate[ti] OR low literacy[ti] OR literacy[ti] OR illiteracy[ti] OR literate[ti] OR illiterate[ti] OR reading[mh] OR comprehension[mh]) AND (health promotion[major] OR health education[major] OR patient education[major] OR Communication Barriers[major] OR communication[major:noexp] OR Health Knowledge, Attitudes, Practice[major] OR attitude to health[major])) OR (comprehension[major] AND educational status[major]) OR (family[ti] AND literacy[ti]) OR ((“drug labeling” OR Prescriptions [mh]) AND (“comprehension” OR “numeracy”)) OR ((cancer[ti] OR diabetes[ti]) AND (literacy[ti] OR comprehension[ti])) OR “adult literacy” OR “limited literacy” OR “patient understanding”[ti] OR (self care [major] AND perception[mh]) OR (comprehension AND food labeling[mh]) OR (comprehension AND informed consent) OR (comprehension AND insurance, health) AND English[la]))	08 June 2016	20
Cinahl	(Health literacy) AND (diabetes)—Limiters—Publication Type: Review; Language: English—Search modes—Boolean/Phrase	8 June 2016	5
Scopus	TITLE-ABS-KEY-AUTH ((health literacy) AND (diabetes)) AND DOCTYPE (re) AND PUBYEAR > 2005 AND PUBYEAR < 2017 AND (LIMIT-TO (LANGUAGE, “English”))	8 June 2016	90
Cochrane	(Health literacy) AND (diabetes)- Title, Abstract, Keywords—Publication Year from 2006 to 2016	8 June 2016	0

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