Designing Health Literacy Measurement Tools: A Critical Review of Common Paths and Probable Mistakes

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ABSTRACT

Background and Objective: Measuring concepts such as health literacy, either generally or specifically, in different populations requires the use of existing standard instruments or the development of new ones by the researcher. The study was conducted to critical review of common methodologies for instrument development in the health literacy.

Materials and Methods: This review article examines health literacy measurement tools with two objectives: 1) methodological review of tool design 2) review of the items used in each tool by posing this question (validity review) "Do the items measure what is intended in relation to the concept of health literacy and its dimensions?". In order to access the health literacy tools, first was referred to the site «Health Literacy Tool Shed».10% of the available tools (20 item) were randomly included in the study for a deep and detailed review.

Results: Finding showed, researchers employed three different approaches to the development of measurement instruments; 1) Review of literature or used the already existing instruments, 2) The qualitative approach to explain a concept and embrace it from different dimensions as well as construct the items and 3) Mix-method approach (a mixture the previous two approaches). Two mistakes include 1) interpretation error (error of qualitative content analysis, creation of categories and sub-categories from codes and meaning units) and 2) program error (error of exploiting subcategories and categories in designing and generating items and different parts of tools) reported.

Conclusions: Paying attention and considering what was indicated regarding different approaches and paths as well as processes and methods can preserve researches to a large extent from the main problem that is the collection of inaccurate data due to instruments with low validity and reliability.

Paper Type: Review Article

Keywords: Health Literacy, Tool, Methodology, Critical Review, Measurement.

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Introduction

Health literacy was a term introduced in 1970s and has become ever more significant in general health and healthcare (1). Health literacy refers to one's capacity of acquiring, processing and understanding basic healthcare information required for appropriate decision-making in healthcare domain (2). Nutbeam et al. divided health literacy to three main categories of basicfunctional, communicative and critical. Such categorizations imply that different levels of health literacy can gradually bring about more personal autonomy and empowerment. In a more extensive definition, the World Health Organization (WHO) defined health literacy as the socio-cognitive skills that determine one's motivation and ability of accessing, understanding and using information to maintain and promote health (3).

Despite the different definitions of health literacy, there are commonalities such as the significance of health literacy as the key social determinant of health. Low health literacy is correlated with the knowledge of disease preventive measures, less participation in healthcare programs (in the case of chronic diseases), lacking knowledge of medical instructions and incorrect interpretation of the information provided (4). Considering health literacy as a key determinant of health would indicate the essentiality of measuring individuals' health literacy and its correlation with different health consequences. Though the existing related literature on health literacy within the past decade has grown dramatically, there is still a lack of an agreed-upon framework for measuring individuals' health literacy and its correlation with different health consequence (5). A number of different measurement instruments have been developed and used in different parts of the world, including the Rapid Estimate of Adult Literacy in Medicine (REALM), the Test of Functional Health Literacy in Adults (TOFHLA), he Short-Test of Functional Health Literacy in Adults (TOFHLA-S) and the Health Literacy for Iranian Adults (HELIA)(6, 7).

Measuring heath literacy requires the use of existing standard instruments or developing new instruments. Besides, collecting data to measure a particular concept is a key step in research procedures and, thus, requires an appropriate instrument. Data collected inaccurately cannot be expected to provide reliable results. Occasionally, the lack of standard instruments leads researchers to develop new instruments. This procedure has certain requirements that if not met can reduce the precision and accuracy of data collection and can eventually disrupt the findings (8, 9).

As the review of the related literature showed, researchers employed different approaches to the development of measurement instruments. Firstly, a body of research has used the review of literature to develop new instruments or used the already existing instruments (10). Secondly, some other studies employed a qualitative approach to explain a concept and embrace it from different dimensions as well as construct the items (6). Thirdly, the instrument development procedure involved a mixture the previous two approaches (review of literature, existing instruments and the data from qualitative studies) (11).

Regardless of the difference among the methodological approaches to instrument development, certain mistakes are probable in the instrumentation procedure in selecting the groups and sub-groups participating in research as well as the steps of exploring the concept and its multiple dimensions as well as item generation (12).

Indeed, at two critical points, the possibility of making mistakes and errors shows itself

stronger. Firstly, in the process of qualitative content analysis, creating of categories and subcategories from codes and meaning units is not done correctly. In this case, the researcher makes interpretive error in the data. Secondly, exploiting subcategories and categories in designing and generating items and different parts of tools is not accurately done. Here, application error is made. In any case, what is occurred as a threat output and main problem is the development of measurement tools - as the key requirements of researches - that do not possess appropriate psychometric properties.

Therefore, this study was conducted to critical review of common methodologies for instrument development in the health literacy.

Materials and Method

This review article examines health literacy measurement tools with two objectives: 1) methodological review of tool design 2) review of the items used in each tool by posing this question (validity review) "Do the items measure what is intended in relation to the concept of health literacy and its dimensions?"

In order to access the health literacy tools, first was referred to the site «Health Literacy Tool Shed» (https://healthliteracy.bu.edu/all URL :), as one of the databases of health literacy tools (13). At the time of the research, this site had 217 tools related to health literacy in various subject areas (general, diabetes, blood pressure, oral hygiene, etc.). First, the authors extracted the general information of the tools. Subsequently, due to the high volume of studies related to tool design, 10% of the available tools (20 item) were randomly included in the study for a deep and detailed review. Then two of the authors (ASM, MGh) reviewed the research objectives by referring to the main article reference of each tool. Items such as: author name, tool

name, tool abbreviation, target group, number of items, country, question format and design method were extracted. In the next step, the authors interpreted the results of this study.

Results

Tools with different languages that were specific to each country were used to measure health literacy. 134 cases were objective and the rest were self-reported. 111 cases were time bound. 4 cases were related to the age group of 0 to 9 years, 36 cases were related to the age group of 10 to 17 years, 184 cases were related to the age group of 18 to 64 years, and the rest were related to the age group of 65 years and older.

25 of the tools were translations method of other tools, 132 were using the target group, 31 were item generation from other tools, and 34 were interview methods from experts. Below some tools have been reviewed (Table 1).

Common methodologies for instrument development in the related literature

In the light of the aforementioned issues, there are three common approaches to instrument development. This categorization is based on applied data sources (review of the related literature, existing relevant instruments and qualitative approaches) (Figure 1).

Approach 1

In a body of research, to develop the required instruments, the related literature was reviewed and the existing instruments were used. In other words, the research team used these sources to explain the concept and embrace it from different dimensions or used these sources in item generation (12, 16).

Due to the fact that qualitative data is not used in this approach, some significant limitations and weaknesses are exist which include disusing of individual's lived experiences and not considering sociocultural experiences

Author (s)	Tool name (Abbreviation)	Target group	Number of	Country	Questions	Designing method
Ochorno D		Adulto: 10 to 64			A point liket time recommended (Ctrongly	
Osborne, R et al, (14)	Health Literacy Questionnaire (HLQ)	Adults: 18 to 64 years	44	China, etc.	4-point Likert-type response scale (Strongly disagree, Disagree, Agree, Strongly agree)	Collect data from the target group
Chinn, D., &	All aspects of health literacy scale	Adults: 18 to 64		United	3-point Likert-type response scale (Often ,	
McCarthy, C (15).	(AAHLS)	years	14	Kingdom	Sometimes, Rarely)	Literature review - Interviews with employees
Tavousi, M., et al,.	Health Literacy for Iranian	Adults: 18 to 64	3	- 	5-point Likert-type response scale (Always ,	
(16)	Adults(HELIA)	years	33	Irdii	Often, Sometimes, Occasionally, Never)	Use available tools
						3 screening items from Chew et al, (18) with
Haun, J., et al, (17)	BRIEF Health Literacy Screening Tool(BRIEF)	Adults: 18 to 64 years	4	USA	5-point Likert-type response scale (Always , Often, Sometimes, Occasionally, Never)	a 4th item added that assesses understanding of what was told to the individual about his/ her health
Nakayama, K et al,(19)	European Health Literacy Questionnaire (Japanese version HLS-EU-Q47(Japanese))	Adults: 18 to 64 years	47	Japan	5-point Likert-type response scale (Very Easy, Somewhat Easy, Somewhat Hard, Very Hard, Don't Know / Not Applicable)	Use of available tools - target group
Ghanbari S, et al,.(6)	The Health Literacy Measure for Adolescents	Adolescents: 10 to 17 years	44	Iran	5-point Likert-type response scale (Always , Often, Sometimes, Occasionally, Never)	Collect data from the target group
Manganello, J., et al,.(20)	Health Literacy Assessment Scale for Adolescents(HAS-A)	Adolescents: 10 to 17 years	15	USA	5-point Likert-type response scale (Never, Rarely, Sometimes, Usually, Always)	Use of available tools - target group
Dumenci et al,.(21)	30-Item Cancer Health Literacy Test (CHLT-30)	Adults: 18 to 64 years	30	USA	Multiple functional options	Use of available tools - target group
Sabbahi, D.A. et al, (22)	Oral Health Literacy Instrument (OHLI)	Adults: 18 to 64 years	57	Canada	38 item the blank Cloze type comprehension questions and 19 numeric calculations	Use of available tools - target group
Osborn, C. et al,. (23)	General Health Numeracy Test (GHNT-21)	Adults: 18 to 64 years	21	USA	blank Cloze type comprehension	A combination of expert opinions, literature review and target group
Zhang, X.H., et al, (24)	Functional Health Literacy Test (FHLT)	Adults: 18 to 64 years	21	Malaysia	Cloze-style reading comprehension of health related content	Maze procedure, expert judgment, and interviews with 55 respondents
Ousseine, Y. M.,(25)	French version of the Functional, Communicative and Critical Health Literacy scale (Fren-FCCHL)	Adults: 18 to 64 years	14	France	4-point Likert-type response scale (Strongly disagree, Disagree, Agree, Strongly agree)	translation from the English version to French

Table 1. Profile description of selected tools

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Table 1. Profile description of selected tools

Collecting qualitative data from target group	sample of Latino adults with diabetes	Translated into Chinese by a bilingual Chinese- native speaker.	Expert panel	Expert panel and target group	Translation -consensus teleconference.	Translated and converted to short form	expert panel
Open-ended and multiple-choice questions (four medical scenarios)	Multiple choice style	5-point Likert scale ranging from "strongly disagree" to "strongly agree"	5-point Likert scale ranging from "strongly disagree" to "strongly agree"	Numeracy	4-point Likert-type response scale (Strongly disagree, Disagree, Agree, Strongly agree)	4-point Likert-type response scale (Strongly disagree, Disagree, Agree, Strongly agree)	 5-point Likert-type response scale (Not important at all ,Not very important , Neutral, ,Somewhat important ,Very important) or (Never , Seldom ,Sometimes, Usually , Always
German	Austria	Taiwan	Taiwan	USA	Germany	France	Iran
72	40	ø	66	15	44	9	46
Adolescents: 10 to 17 years	Adolescents: 10 to 17 years, Children: 0 to 9 years	Adolescents: 10 to 17 years	Adults: 18 to 64 years	Adults: 18 to 64 years	Adults: 18 to 64 years	Adults: 18 to 64 years	Adolescents: 10 to 17 years
Critical Health Competence Test (CHC)	An Instrument for Measuring Health Literacy in Children (QUIGK-K)	Chinese version of the eHealth Literacy Scale (C-eHEALS)	Taiwan Health Literacy Scale (THLS)	Spanish Diabetes Numeracy Test (DNT- 15 Latino)	Health Literacy Questionnaire (HLQ) – German (HLQ – German)	European Health Literacy Survey (HLS-EU-Q6	Food and Nutrition Literacy (FNLIT)
Steckelberg, A. et al(26)	Teufl, L., et al.,(27)	Koo, M., et al. (28)	Pan, F. et al(29)	Richard O White et al,.(30)	Nolte S, et al(31)	Rouquette A, et al, (32)	
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Figure 1. Three Common Approaches for Tool Development Process as Seen in Literature

of the target population for the main study. Indeed, the researcher is restricted to literature and available sources and tools, hence further explanations and identifications is not conceivable. Particularly, this issue becomes more important in developing specific and culturally sensitive health literacy concepts' tools (such as; social health, sexual and puberty issues, etc.). Further, another considerable point which may occur is non-adherence of researchers to preliminarily defined conceptual framework of study during the research process (16).



Figure 2. Two Common Paths for Tool Development Process by Undirected Qualitative Research

Two scenarios are probable in this approach: Scenario A: The core concept such as Health Literacy has been already explained for example in the light of the existing proposed definitions. In this case, the related literature and existing instruments are both used for item generation. Scenario B: The core concept has not been already explained and researcher use the related literature to explain the concept mainly. The existing relevant instruments are usually employed in item generation.

Approach 2

In this approach, the researcher employs qualitative research methods to explain the concept and identify its multiple dimensions. In other words, such methods as content analysis and semi-structured interviews are used. The research population can also be defined in different subgroups or one sub-group (6). It should be noted that the low generalizability of qualitative studies is one of the essential limitations that will affect the expected comprehensiveness in the tool development process.

Here, there are also two scenarios with their probable paths (Figure 2).

Scenario A: Directed qualitative approach is employed. Otherwise, the research framework is adopted to study the core concept (e.g. Health literacy) has been already used based on the existing proposed definitions (e.g. the case of Nutbeam). In this scenario, the qualitative method used is a data collection method rather than some qualitative approach. In fact, this method is used for item generation and not concept explanation.

Scenario B: Here, the core concept is not already explained and undirected qualitative approach is employed (or in other words, the undirected qualitative research) is used to develop the instrument. In this scenario, two common paths are probable.

Path ONE: In this path, qualitative research (e.g. content analysis) is used as a method for constructing items related to the instrumentation. In fact, in this form of content analysis, in the step concerning the extraction of meaning units, the selection and employment of initial codes are abstracted for item generation. In this path, concept explanation is the next step based on machine-like mechanisms such as exploratory factor analysis.

Path TWO: In this path, human factor (e.g. the researcher(s)) plays a key role in concept explanation (e.g. the health literacy concept) which results from qualitative research. That is to say that a full content analysis is done which includes the extraction of meaning units, generation of initial codes and extraction of subcategories and categories. The output of this step is the identification of the multiple dimensions of a concept which is in fact the concept explanation. The second step is to generate items for the subcategories and categories which is immediately followed by the psychometrics of instrument. In construct validation, CFA seems to be preferred as the result expected from EFA has already been obtained from concept explanation. Yet, the use of EFA is optional. Contrary to the first path, here content analysis of gualitative data is used both for concept explanation and item generation.

Approach 3

In this approach, to obtain the instrument, a combination of approach 1 and 2 is used. In other words, to develop the instrument, several sources are used: review of literature, existing instruments and the results of qualitative research. It is rationally expected that comprehensiveness of the instruments which are developed in this approach to be significantly higher than ones are developed in previous approaches.

Here, a combination of scenarios can be conceived together (Figure 3).

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Scenario A: Here, the core concept (e.g. health literacy) is already explained (for instance based on the existing proposed definitions) and then the researcher uses all the three sources for item generation (review of the literature, existing relevant instruments and gualitative methods). Scenario B: The core concept here is not already explained and researchers use the review of literature as the source for concept explanation. Qualitative data and the existing instruments are usually used in the item generation phase. Scenario C: in comparison to Scenario B, here, concept explanation is based on qualitative methods (the probable path is similar to that presented in Fig.2 (Path 2) and researchers use the related literature and existing instruments to generate items.

Scenario D: The three sources (especially

qualitative methods and review of literature) is the basis of identifying concept dimensions and concept explanation as well as item generation. As a routine, qualitative method is followed as the first step for concept explanation and then the findings are completed using the next two sources.

Probable mistakes in health literacy-related TDSs:

Probable mistakes in approach 1

As the researcher explores item generation based on the dimensions of a concept explained in the related literature, in this approach, the weight and contribution of each mistake is higher in the item generation phase. It is also noteworthy that in such an approach any methodological mistake reviewed in the related literature is ignored by the researcher and is taken for granted. If the researcher in item generation does not enjoy a sound understanding of the dimensions of the concept and does not describe the dimensions correctly for him/herself, s/he might construct inappropriate items to measure the concept. In other words, the instrument that is developed does not have the required content validity. For instance, it is possible that the researcher designs the item to measure a variable like "decision making/behavioral intention" in such a way that measures the behavior. For example;

"I use a seat belt when driving - (never = 1, rarely =2, sometimes = 3, usually = 4, always = 5)"(16).

Probable mistakes in approach 2

It is noteworthy that in this approach besides the probable mistake in Approach 1 there are certain probable mistakes as mentioned below:

One probable phase which is seriously prone to deviation and mistake is before achieving the dimensions of the concept and constructing the items (path 1). If the researcher does not follow path 1, s/he may make mistakes in concept explanation. That is because the researcher hands over this fundamental task mostly to computer software and EFA. Otherwise, the researcher needs to be more actively involved in decisionmaking to accept or reject the extracted factors on the one hand (to avoid mistakes in factor categorization or mechanical mistakes) and also appropriate naming of factors on the other (to avoid mistakes in naming factors). Yet, it should be noted that sometimes the mistakes are not related to the software. That is to say that item generation has not been done precisely based on the meaning units and are in fact a kind of path 2 mistake, as explained in the following. In practice, the mechanical diagnosis is accurate for the categorization of factor(s) (34).

The probable mistake in path 2 of approach 2 is known as the content analysis mistake. In

this path, the probable mistake can occur in content analysis and extraction and naming of sub-categories and categories. In fact, in this mistake, the researcher does not add the initial codes to the relevant sub-category and category. Or, s/he makes mistakes in the naming of categories.

Example: the meaning unit or initial code: "one's capability of obtaining information about his/her disease"

Mistake: researcher's incorrect interpretation of a code of a skill-based nature as a perceptual concept such as "belief"

Researcher's interpretation: as if the meaning unit has been stated as: "one's feeling capable of obtaining information about his/her disease" **Other mistakes in instrument development** 1. A review of literature on the development of health literacy instruments similar to those measuring other concepts shows that researchers have somehow made a common unintentional mistake which is probable in each approach to instrument development, known here as the mistake in item generation or content validity mistake.

An instance of the" access" concept has been introduced in the related literature as a major dimension of health literacy (as a concept) (1).

Concerning the above-mentioned concept, researchers in studies attempting to operationalize health literacy (both those that explained the concept itself and also those making reference to the related literature) made mistakes in constructing the items. What this concept embraces is more of a skill nature. Thus, it is perceived entirely skill-based. However, this concept has been taken more as a belief in some other studies. It has been taken as a perceptual variable and as attitude-based. The example of "access" item in several studies:

As it is evident, this items shows that it explores perceived self-efficacy to obtain information about the disease. In fact, what will be measured is not a skill.

Fairly and realistically, we should acknowledge that researchers find it hard to measure such skill-based concepts and thus suffice to selfreport. Despite this difficulty and limitation, we should consider that certain cautions can be taken to avoid such deviations and achieve an acceptable self-rating instrument. One such point to consider is precision in constructing the form of the item. For instance, the above example can be changed to this (35):

I obtain information about my target disease	Always	Often	Sometimes	Hardly ever	Never
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Besides these mistakes which pertained to the methodological paths and such steps as content analysis and the naming of subcategories and categories and item generation (See Fig2), mistakes in selecting the sub-group of participants in research should not be ignored. The eventual goal of measuring health literacy is to examine the current state and meet the educational needs of target population. Here, if the priority goes to normative needs, the selected group for qualitative research should naturally be from among experts. If the perceived needs are addressed, the sample group selected from the population is selected properly. Yet, the best way is to take both types of needs. In other words, participation of both sub-groups is essential to the qualitative phase. It seems that the sub-group of population for item generation of an appropriate face validity is more useful than experts. However, the expert sub-group plays a more significant role in explaining the concept and identifying is multiple dimensions.

Regardless of this analysis, the best way to select the participants is to consider some qualitative research with both sub-groups. As an instance, if the research aims to develop an instrument to measure adolescents' health literacy, an expert sub-group and a sub-group of adolescent population with maximum diversity should participate in collecting qualitative data (12).

One of the most challenging situations in some researches is the low accuracy of researchers in the correct application of psychometric processes and even in some cases ignoring and not considering some important and essential processes. For example, in the psychometrics of health literacy instruments, primary validity processes such as face and content validity are may neglected (36). Normally, these issues in turn will affect the validity and reliability of the tools.

Discussion

Despite the recently of health literacy as a concept in general health literature, we have witnessed copious academic research on this topic in different populations to better understand and explain the concept and develop instruments to measure it. To this aim, researchers use different approaches and sources. As a comprehensive approach, it is recommended to use qualitative methods in such research besides the review of related literature and use of existing instruments. Moreover, using two approaches, expertbased and population-based (proportionate to the purpose of research) seems essential to increase knowledge and experiences of the participants. In other words, sub-groups of participants should be selected in research so as to use all experiences and perspectives of the essential population-based sub-groups. In other words, attempts should be made to use analytic software as aids in the steps of explaining the concept and its dimensions as well as constructing items. Researcher's subjective interpretations and analyses should lie at the core of decision-making on explanations. Naturally, researchers should take great care in concept explanation and item generation so that the measurement instruments can enjoy a precise and appropriate psychometrics as well as a high accuracy and reliability.

Also, considering the extensiveness and variety of the methods of validity and reliability of tools, researchers should pay serious attention to the subtle points in correctly applying of psychometric technical processes, as well as, well equipped themselves with the required skills.

The important point in measuring health literacy is to pay attention to its definition, and a functional view in the evaluation of the studied people (such as TOFHLA). But what is seen in most tools for measuring health literacy is the use of measurement ranges such as Likert, which is not a logical measure for measuring health literacy, Because the questions whose answers are designed in the Likert scale only evaluate the attitude and perceived self-efficacy of the people (and not actual self-efficacy), and does not have the ability to measure performance and skills (which are specific to health literacy tools).

Limitation: This study has some limitations. First, this study randomly included some health literacy tools from the heath literacy tool shed site, which is a relatively comprehensive database. Therefore, since there may be tools that are not indexed on this site, and also for wide access to studies related to the purpose of the research, it is suggested that future studies investigate more tools by conducting a systematic search. The second limitation was the authors' focus on the evaluation of the methodology of the studies (and not the psychometrics and details of the process used by the tools). Therefore, future studies can be done with the aim of filling the gap in this study.

Conclusion

Paying attention and considering what was indicated regarding different approaches and paths as well as processes and methods can preserve researches to a large extent from the main problem that is the collection of inaccurate data due to instruments with low validity and reliability. Also, according to the cases of possible wrong paths mentioned in this study, it is necessary for the authors to avoid these errors in the design of health literacy measurement tools with an objective approach. **Acknowledgments:** The authors would like to thank the research deputy of Shahid Beheshti University of Medical Sciences.

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