

2012 UPDATED CHAPTER J: ADDRESSING HEALTH LITERACY

(Original Title: Using Plain Language)

SECTION 1: AUTHORS/AFFILIATIONS

Kirsten McCaffery (co-lead)	University of Sydney	Australia
Stacey Sheridan (co-lead)	University of North Carolina	USA
Don Nutbeam (co-lead)	University of Southampton	UK
Marla Clayman	Northwestern University	USA
Karen Kelly-Blake	Michigan State University	USA
Margaret Rovner	Michigan State University	USA
David Rovner	Michigan State University	USA
Sian Smith	University of Sydney	Australia
Mike Wolf	Northwestern University	USA

NOTE

The original title for this dimension (“Using Plain Language”) is now considered inadequate to capture the interface between health literacy and decision aids. While plain language presentations of the information within decision aids is still critical, skills-based conceptions of health literacy provide important insight into the need for decision aids to address individuals’ variable cognitive and social skills as they clarify values and interact with the health system to achieve the best health outcomes.

Therefore, this updated dimension chapter presents entirely new sections regarding definition, theoretical rationale, evidence base, and references.

The original dimension chapter is included here as an Appendix.

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SECTION 2: CHAPTER SUMMARY

What is this quality dimension?

Health literacy is at its simplest the “capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions”. Broader definitions extend beyond reading and writing skills (functional health literacy) to include communicative and social skills (interactive/communicative health literacy) and advanced literacy, cognitive and social skills to analyze information and make informed decisions (critical health literacy). We propose that each of these forms of health literacy is required for patients to effectively use decision aids. Attending to these levels of health literacy in decision aid design, and supporting consumers not only to read and understand decision aids but also to have the confidence to communicate with health professionals and their families, to negotiate decisions, and to think critically in order to make an informed decision, is an important objective in PtDA development.

What is the theoretical rationale for including this quality dimension?

A large proportion of people living in developed countries have inadequate health literacy. It is particularly common among the elderly, ethnic minorities, and socially disadvantaged populations. These same populations experience higher rates of preventable disease and poorly managed chronic disease and engage frequently with the health system. Lower health literacy is independently associated with poor health across a wide range of outcomes. Health information including PtDAs needs to be designed so that it is appropriate for the health literacy levels of the majority of consumers for whom it is prepared. A person’s ability to effectively use a PtDA will be determined both by their health literacy skills and the quality and suitability of the PtDA.

What is the evidence to support including or excluding this quality dimension?

We reviewed several sets of evidence related to this dimension: 1) evidence on the effects of health literacy on decision making outcomes, including knowledge, values clarity, and patient involvement; 2) evidence on the effects of interventions designed to mitigate the effect of low health literacy on decision making outcomes; and 3) evidence on whether decision aids address low health literacy and are tested in low literacy populations.

In an existing systematic review, we found evidence from 14 out of 16 trials that lower health literacy is associated with lower patient health knowledge. In a review that we conducted, no studies reported on values clarity *per se*, but two reasonable-quality studies showed that low health literacy is related to higher decisional uncertainty and regret. Three studies showed that lower health literacy was associated with lower desire for involvement in decision making, 2 showed it was related to lower question asking, and 3 with adjusted analyses found that it was related to a lower patient centered communication process. The effects of low health literacy on other measures of patient involvement (e.g., perceptions of interaction and receipt of information) were mixed.

In an existing review, fourteen studies reported practical design strategies to improve knowledge for lower health literacy patients. These strategies include presenting essential information only or first, presenting information in tables or pictographs rather than text, presenting numerical information so that the higher number is better, using the same

denominators to present treatment benefit information, presenting numerical information as frequencies for conditional probabilities, and adding video to verbal narrative to improve the salience of information. In a review we conducted, a single pre-post study also found that video that improved the salience of information also reduced decisional uncertainty. No studies of interventions addressed outcomes related to patient involvement.

In our review of the 97 trials of PtDAs, we found only 3 PtDAs which addressed the needs of lower literacy or education audiences. In 90% of trials neither the readability of the PtDA or health literacy of the audience were reported. However, in the studies where literacy or education were addressed, results were encouraging, suggesting increases in knowledge and informed choice.

To ensure equity in access to decision aids, developers need to ensure that tools are appropriate for lower as well as higher health literacy consumers. In doing so, developers need to attend not only to issues of comprehension (functional health literacy); they also need to foster insight into one's attitudes towards the pros and cons of different health care options (values clarification), as well as foster the processes (communicative and critical literacy) involved in the decision making encounter itself, in order to support shared decision making.

SECTION 3: DEFINITION (CONCEPTUAL/OPERATIONAL) OF THIS QUALITY DIMENSION

a) Original Definition

No explicit definition of “health literacy” was provided in the original chapter, which focused on “plain language”.

b) Updated Definition

Literacy

Literacy is a complex concept with two distinctive elements – those that are task-based (e.g., reading and writing basic text) and those that are skills-based (the knowledge and skills required to perform key literacy tasks, ranging from word recognition to drawing inference from text) (1). Literacy can be measured in absolute terms by distinguishing between those who can read and write and those who cannot, and in relative terms by assessing the skill differences between adults who are able to perform relatively challenging literacy tasks and those who are not. Even the most basic functional literacy skills enable people to better develop their knowledge and improve their potential to achieve goals.

Health Literacy

Health literacy can be considered as a “domain” of literacy. Health literacy is commonly defined as *‘the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions’* (2, 3).

Broader definitions encompass a wider range of cognitive and social skills that enable people to feel empowered to take control and improve their health (4, 5). According to Nutbeam (6, 7), health literacy comprises three levels:

1. Functional health literacy – basic reading comprehension and writing skills to understand health information/messages, together with knowledge of health conditions, services, and systems.
2. Interactive health literacy – higher level communicative and social skills required to extract and discuss information with others.
3. Critical health literacy skills – advanced literacy, cognitive, and social skills to analyze information and make informed decisions.

One could argue that these levels correspond with the skills required to effectively use patients' decision aids (PtDAs) and to engage in shared decision making.

Furthermore, health literacy is both context- and content-specific; different health care contexts require specific content knowledge and skills (7). This means that even those with higher literacy skills may have difficulties in novel health care environments (7).

c) **Emerging Issues/Research Areas in Definition**

See Section 6.

**SECTION 4:
THEORETICAL RATIONALE FOR INCLUDING THIS QUALITY DIMENSION**

a) **Original Theoretical Rationale**

No explicit theoretical rationale about “addressing health literacy” was provided in the original chapter, which focused on “using plain language”.

b) **Updated Theoretical Rationale**

Background

A large proportion of people living in developed nations have difficulties performing everyday literacy tasks. National adult literacy surveys conducted across Organization for Economic Co-operation and Development (OECD) countries indicate that between 16% and 48% of the general population (depending on the definitions and measures used) have inadequate functional *literacy* skills (8-11).

Furthermore, although methods of assessment vary, data indicate that inadequate *health literacy* is common, particularly among elderly, ethnic minority, and socially disadvantaged populations. These same populations generally experience higher rates of preventable disease and poorly managed chronic disease. In the US, approximately 80 million adults (36%) were described as having “basic” or “below basic” health literacy (1); in Australia, 9 million adults (60%) were found to lack basic health literacy skills (8). This is problematic, since there is now moderate to strong evidence that lower health literacy is independently associated with a range of outcomes, including increased mortality, reduced overall health status, and a poorer ability to take medication appropriately and interpret health messages (12, 13).

In addition, numeracy skills (“the ability to understand and use numbers in daily life”), which are sometimes conceptualized a sub-component of health literacy, also influence how well people can read and interpret health information and make informed health decisions (14). Up to 50% of adults have been shown to possess basic or below numeracy skills and would therefore experience difficulties performing tasks, such as reading nutrition information, measuring medication dosages, and understanding risk information about benefits and harms of medical treatments (9, 10, 15).

Health Literacy and the Design of Patients’ Decision Aids

Taken together, the results of these surveys provide a sharp reminder of the need to provide health information in a form that is appropriate for the literacy and numeracy levels of the majority of adults for whom it is prepared.

Therefore, since a person’s ability to effectively use a PtDA will be determined by both their health literacy skills *and* the quality and suitability of the PtDA (16), designers of PtDAs need to ensure that these tools can be accessed and understood by adults across all health literacy levels, including those with lower health literacy, and can support decisions that are informed and behaviorally implemented. This background chapter examines existing reviews and theoretical literature in order to extract basic principles that could guide PtDA developers towards this objective.

c) Emerging Issues/Research Areas in Rationale

See Section 6.

SECTION 5: EVIDENCE BASE UNDERLYING THIS QUALITY DIMENSION

a) Summary of the Original Evidence Base

The original chapter focused on the evidence base relevant to “plain language”, rather than the evidence about “health literacy”.

b) Updated Evidence Base

The overall aim of our literature review was two-fold:

- I. To review evidence for the effects of health literacy and numeracy on decision making outcomes including knowledge, values clarity, and patient involvement and communication.
- II. To review the trials of PtDAs to date, with respect to their attention to a) accounting for health literacy, and b) testing with low literacy populations.

I. Decision Making Among Consumers With Lower Health Literacy, Literacy, or Numeracy: Review of Evidence

Background

This first aspect of our review was guided by two questions: 1) What is known about how health literacy affects decision-making outcomes? and 2) What is known about interventions' ability to mitigate the effects of lower health literacy on decision making outcomes?

Source

To answer our questions, we took two approaches. First, we searched 2004 and 2011 systematic reviews on Health Literacy Interventions and Outcomes (13, 17) for answers and, if available, summarized their results. Second, when questions were not answered, we performed our own systematic review and data synthesis.

Methods

Full details of our systematic review methods are available elsewhere (18). In brief, to identify relevant articles on health literacy and decision making, we searched articles included in 2004 and 2011 systematic reviews performed for the U.S. Agency for Healthcare Research and Quality (AHRQ). These reviews examined health literacy (including numeracy) interventions and outcomes. We also searched the titles and abstracts of articles that were excluded from the AHRQ 2011 review to identify articles reporting on decision making outcomes and interventions. These articles had been excluded from the 2011 review either because 1) they did not use a quantitative measure of health literacy or 2) they used a quantitative measure of health literacy, but reported only on decision making outcomes (such as values clarity, decisional confidence or uncertainty, decision satisfaction or regret, patient desire for involvement, actual patient involvement, and communication quality) (17). To ensure that we had identified all relevant literature, we also reviewed the bibliographies of narrative reviews on health literacy and shared decision making(19) and communication(20), systematic reviews on PtDAs (21), question asking (22), and patient centred care (23), and we queried experts for missing studies.

Inclusion criteria for this review mirrored the AHRQ criteria; however, these criteria were extended to include articles that included individual-level self-reported assessments of health literacy. We additionally required intervention studies to either stratify results by health literacy level or be performed in a lower literacy-only population. We followed standard systematic review procedures to identify articles, to abstract evidence, and to rate the quality of included articles. We included all fair- or good-quality studies in our review.

Results

The results of this aspect of our literature review are structured according to the following general functional goals of PtDAs (21):

1. **PtDA Goal 1:** To support users to understand health information relevant to their decision.
To achieve this goal, PtDAs provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities and scientific uncertainties.
2. **PtDA Goal 2:** To support users to clarify their values.
To achieve this goal, PtDAs help patients to recognize the values-sensitive nature of the decision, and to clarify--either implicitly or explicitly--the value they place on the options' benefits, harms, and scientific uncertainties.
3. **PtDA Goal 3:** To support users to be actively involved in decision making and to communicate with others.
To achieve this goal, PtDAs provide structured guidance in the steps of decision making and communication of their informed values with others involved in the decision (e.g., clinician, family, friends).

PtDA Goal 1:

To support users to understand health information relevant to their decision.

Relationship between Health Literacy and Knowledge, Comprehension, and Accuracy of Risk Perception

A 2004 systematic review conducted for the AHRQ found that low health literacy (measured predominantly by the Rapid Estimate of Adult Literacy in Medicine (REALM) or Test of Functional Health Literacy in Adults (TOFHLA)) was related to patient knowledge in 14 of 16 studies dating from 1980 through 2003 (13). Of the two studies that did not show a relationship, one was clearly underpowered. Therefore, investigators concluded that the relationship was so clear that additional examination of this relationship was not necessary during a 2011 update.

In 2011, AHRQ-funded investigators assessed the effect of numeracy on knowledge and accuracy of risk perception from 1966 to February 2011 (17). In four studies with a quantitative measure of numeracy, investigators found mixed effects of numeracy on general and disease specific knowledge. Additionally, in five studies with a quantitative measure of numeracy, investigators found mixed effects of numeracy on the accuracy of perception of risk and treatment benefit, with notable variation by task and measured outcomes (i.e. disparities in accuracy were even greater for participants when stating verbatim versus gist risk).

Effect of Health Literacy Interventions on Knowledge, Comprehension, or Accuracy of Risk Perception

A paper published from the 2011 AHRQ review that included an updated search (24) identified 38 studies published between 1966 and February 2011 that met the following criteria: they examined the effect of single or multiple literacy-directed strategies on knowledge or comprehension; they quantitatively assessed participants' health literacy or numeracy; and they stratified analyses by health literacy level.

Fourteen of these studies (13 RCTs and 1 non-randomized controlled trial) specifically examined the effects of single strategies that might be useful in PtDA design. Among these 14 studies (which were reported in 12 articles) (25-32), investigators found multiple discrete design features that improved comprehension for low health literacy individuals in at least one study. These are summarized in Table 1 below.

Of the remaining 24 studies that reported on interventions using a mixture of literacy-directed strategies, only one reported on a PtDA intervention (33). While this pre-post study of a prostate cancer PtDA reported improved knowledge among individuals in all health literacy subgroups (adequate health literacy: + 1.27 points of 10 point scale, adjusted $p < 0.01$; inadequate health literacy +2.05 points, adjusted $p < 0.01$; p for interaction not reported), it did not report its literacy-directed strategies in sufficient detail to allow literacy-directed recommendations to be derived.

Table 1. Design Features that Improved Comprehension for Lower Literacy Individuals in at Least One Study

Design Features
<ul style="list-style-type: none"> • Presenting essential information by itself or first (29) • Presenting numerical information in tables or pictographs rather than text (26, 30) • Presenting numerical information so that the higher number is better (i.e. “nurses per patient”(more is better) rather than “patients per nurse” (less is better)) (29) • Presenting numerical information with the same denominator(26) • Using natural frequencies to help individuals understand the probability of disease following testing (26) • Adding video to verbal narratives to improve the salience of information (31)

PtDA Goal 2:
To support users to clarify their values.

We addressed the effect of health literacy and numeracy on values clarity outcomes and interventions through our own systematic review. (See Table 2).

The Relationship between Health Literacy and Values Clarity

We found no studies that examined the relationship between health literacy and values clarity *per se*. However, four cross-sectional studies (34-37) investigated the relationships between health literacy and decision uncertainty, decisional regret, and decision confidence. In the two studies that performed adjusted analyses, lower health literacy increased both decision uncertainty (34) and decision regret (36). The effect of health literacy on decision confidence is less clear, with two unadjusted analyses showing mixed results (38, 39).

Interventions Designed to Help Low Literacy Individuals Clarify Values

In the single intervention study in this group (37), Volandes et al. found that a PtDA using video images to help elucidate the salience of various health states reduced decision uncertainty among all patients, with the greatest reduction found among patients with lower health literacy.

PtDA Goal 3:
**To support users to be actively involved in decision making
and to communicate with others.**

The Relationship Between Health Literacy And Patient Involvement And Communication

Thirteen studies reviewed the relationship between health literacy level and various aspects of the decision making encounter, such as: patient activation and desire for participation; question asking; broader participation; and communication quality (see Table 2). Three studies, including two that adjusted for confounders, reported that adults with lower health literacy were less likely to want to be involved in decision making compared to those with higher literacy (40-42). A fourth showed that patient activation was associated with numeracy, but not health literacy in unadjusted correlational analysis (29).

Two papers addressed the relationship between literacy and question asking (43, 44). One (43) found that both level and type of health literacy (functional, communicative, or critical) influenced question asking, with lower levels of communicative health literacy associated with less question asking. The other (44) found that lower literacy patients were less likely to ask questions overall (although this just failed to reach statistical significance). Of the questions asked, lower literacy patients asked significantly fewer medical and lifestyle questions and more clarification questions suggesting lack of understanding.

Two papers addressed patient involvement more broadly. One study reported (43) patients with lower “communicative” health literacy perceived they had less involvement in clinical consultations (although this just failed to achieve statistical significance likely due to the small

sample size). Arthur et al. (45) reported a trend toward less “mutuality” among US diabetes patients with limited health literacy.

Of the eight studies examining communication quality, three large well done studies with adjusted analyses reported lower patient-centered communication across several communication outcomes among those with lower health literacy. Communication was not specific to decision making and the effect varied by outcome (46-48). A fourth study found that ratings of patient-centered communication varied by measurement of numeracy. Patients with low objective numeracy reported more favorable communication and those with low subjective numeracy reported less favorable communication (49). One unadjusted analysis found no difference between lower and higher health literacy patients’ perceptions that doctors facilitated their involvement in diabetes care (40).

Results of the remaining studies varied by outcome. One study found that parents with lower health literacy reported more favorable interactions with their child’s healthcare provider (50). Another found poorer decision satisfaction about breast cancer treatment among those with lower health literacy (34). Finally, one study (43) found that those with low critical health literacy were more likely to report adequate information when more information was given (whereas those with high literacy did not), offering a potential explanation for the contrasting findings above.

Interventions Designed to Help in The Communication Encounter

We identified no papers that tested interventions, although one reported baseline data from a cluster randomized trial (51).

Table 2. Summary of Findings for PtDA Goals 1 and 2: Supporting Values Clarification, Patient Involvement and Communication Among Lower Literacy Consumers

PtDA Goal	Outcome	No of Studies	Summary of findings
2	Decisional uncertainty	2 (34, 36)	Lower HL associated with higher uncertainty and decisional regret.
	Decisional regret		
	Confidence in DM	2 (38, 39)	Effect unclear.
	Intervention studies: to assist values clarification	1 (37)	Video images to increase the salience of health states reduced decisional uncertainty with strongest effect in lower HL patients.
3	Preferences for participation in DM / patient activation	3 (40-42)	Lower preference for involvement among lower HL patients.
		(29)	Patient activation associated with lower numeracy not HL.
	Question asking	2 (43, 44)	Less question asking among those with lower communicative HL. More clarification questions asked (indicating lack of understanding)
	Level of involvement	2 (43, 45)	Patients with lower ‘communicative’ HL reported less involvement. Less ‘mutuality’ observed between Drs and lower HL patient
	Communication quality / Patient centred care (PCC)	5 (40, 47, 49, 50, 52)	Less PCC among lower HL patients in 3 studies with adjusted analyses. 1 study reported effects varied by how numeracy is measured.
		3 (34, 43, 50)	Effects varied
	Intervention studies:	None	N/A

HL - health literacy DM - decision making

Discussion

Limitations

There are some limitations to this aspect of our review. A single reviewer reviewed articles to exclude those unrelated to the topic of our review. Although the articles closest in subject to our review’s purposes were assessed by two reviewers, it is possible that some relevant studies were missed. Other limitations are the inherent potential for publication bias, the diversity of measures used for similar outcomes, and the small number of physicians (despite adequate numbers of patients) that were included in studies of health literacy and communication. Although not a

specific limitation of our reviews, one additional issue is that we excluded studies stratifying analyses by education. We made this choice because our search was not designed to pick up education as a proxy for literacy and we likely would have missed many relevant studies. It should be noted, however, that important information may be learned from such studies (53, 54).

Interpretations

Overall, this aspect of our review suggests that consumers' health literacy levels are likely to influence aspects of PtDAs and the shared decision making process: knowledge and understanding of the disease/condition, treatment options and outcomes; values clarification with respect to feelings of uncertainty and decisional regret; and the desire and ability to participate in decision making (communicate with and ask questions of health professionals). Patients with lower health literacy in general had poorer outcomes across most of the measures examined (e.g., lower knowledge, higher uncertainty, poorer communication, and less patient centered-care). If PtDAs are to be helpful in structuring and guiding decision making, they must address health literacy issues related to these critical processes. Intervention research relating to values clarification and the decision-making encounter (goals 2 and 3) are extremely limited with almost no intervention studies available to guide PtDA developers. More research here is especially needed to understand potential differential effects of interventions by literacy level. However, there is evidence to support improving the design and content of PtDAs—as summarized in Table 1—to facilitate comprehension among lower health literacy patients. The use of these strategies is recommended for the development of PtDAs for lower health literacy consumers.

II. Attention Paid to Health Literacy in PtDA Trials: Review of Evidence

Background

This second aspect of our review was guided by the question: What level of attention is paid to literacy in trials of PtDAs to date?

Source

The latest available Cochrane Collaboration's systematic review of randomized controlled trials of PtDAs (21), updated (using the same search strategy) to identify new trials published in 2010.

Methods

For full details, see (18). In brief, the evaluative criteria for this review were based on the published 2006 IPDAS health literacy criteria (55), which recommend that PtDAs should be:

1. Written at a level that can be understood by those in the target group;
2. Written at a grade 8 equivalent or lower on a readability score such as SMOG or FRY;
3. Presented using media other than reading (audio, video, in-person).

These three published criteria constituted the core criteria that astute DA developers should meet (55).

Five additional criteria were used in this review, in order to assess internet-based PtDAs and the basic adequacy of the trial design for evaluating PtDA effectiveness in low literacy populations.

The five new criteria addressed whether the PtDA study:

4. Provided PtDAs by internet;
5. Stratified by health literacy / literacy;
6. Stratified by education as a proxy for health literacy;
7. Had adequate power to analyze lower literacy samples;
8. Addressed health literacy in the conclusions.

Each study was graded using these eight evaluation criteria. Criteria were coded as present/absent/unknown. Lack of indication of IPDAS criteria and lack of mention of literacy at all were coded as “absent”. If articles made a global reference to the IPDAS criteria, but made no specific mention of the criteria addressed, they were scored as “unknown”.

Results

The total number of PtDA trials in the latest Cochrane Collaboration’s update was 87. Ten more trials were identified in the updated search up to and including 2010, so that the total set of PtDA trials evaluated was 97 (21). Table 3 below lists the percentages and absolute numbers of individual studies that were evaluated according to our literacy criteria.

Table 3: Attention Paid to Health Literacy in PtDA Trials: Percentages (and Absolute Numbers)

	Criteria Used to Evaluate PtDA Trial							
	Literacy Level Stated[†]	≤ Grade 8 Reading Age	Media other than Text^{††}	Web-Based	Stratified by Literacy	Stratified by Education	Adequate Power	Literacy Addressed in Conclusion
Present	4 (4)	5 (5)	68 (67)	6 (6)	2 (2)	0 (0)	2 (2)	3 (3)
Absent	93 (91)	92 (89)	30 (29)	90 (87)	98 (95)	100 (97)	98 (95)	96 (94)
Unknown	1 (2)	3 (3)	1 (1)	1 (1)	0 (0)	0 (0)	0 (0)	0 (0)
On Web	NA	NA	NA	3 (3)	NA	NA	NA	NA
Total Trials	100% (97)	100% (97)	100% (97)	100% (97)	100% (97)	100% (97)	100% (97)	100% (97)

[†] Most trials did not identify the literacy level of the intended audience. We operationalized this criterion to code ‘present’ if the research sample group’s literacy requirements were stated.

***If the PtDA was text based, but included graphics of frequencies and other numeric data, these were considered to be text. This criterion was meant to provide for alternative media for non-readers such as pictures, video explanations of data, voice-over narration, etc.*

Five percent of all RCTs (56-60) reported the PtDA reading level as grade 8 or below. Two trial reports (61, 62) stated that IPDAS criteria were followed but made no reference to which specific criteria. Many PtDAs used media other than pure text, including interactive video and audio tape, although it was not clear whether these modalities were used specifically to address issues of literacy. There were eight web-based PtDAs (63-70), though in many the presence or absence of content other than straight text could not be determined.

The following studies recruited patients presumed to have lower health literacy based on their educational status and reported conclusions about health literacy (54, 57, 61, 71, 72-74). Three randomized trials compared lower health literacy or education groups to higher health literacy groups. Two Australian studies developed PtDAs for bowel cancer screening, one specifically designed for a lower health literacy audience (61, 74). One US study additionally addressed prostate cancer screening through a comparison 'edutainment' PtDA and a paper PtDA (54). All three of these PtDAs appear to have adhered to the IPDAS criteria and included quantitative outcome data and explaining technical terms. One PtDA was paper-based (74); the remaining two focused on either audio or multi-media.

Two of three studies showed that PtDAs increased knowledge in samples presumed to have lower health literacy based on their educational status. Trevena et al (74) found a significant increase in knowledge in both low and highly educated participants in the DA arm. Smith et al. (75) reported a 38% increase in knowledge and a 22% increase in informed choice (adequate knowledge and consistent attitudes and behaviour) in low education adults who received the literacy-sensitive PtDA compared with those who received standard information. The third study on prostate cancer screening, which also used education as a proxy for health literacy, found no difference in knowledge between the 'edutainment' and an audio-booklet presentation containing the same information (54). However, the entertainment-based aid was associated with lower decisional conflict and greater self-advocacy when compared to "low health literacy" patients given the audio booklet. No differences between aids were observed for "high health literacy" patients.

Discussion

Limitations

The small number of PtDA RCTs that addressed health literacy suggests neglect of this important area in the field. Health literacy was not directly measured in any study. Proxy measures were used in three studies that reported having recruited individuals with unspecified deficits in education and health literacy. A limitation of our review of the attention paid to literacy in DAs is that we have not included the background articles that describe the development of PtDAs (e.g., (61)) tested in the trials. Adding these may provide greater insight into how literacy was addressed. It does not, however, address the lack of attention to literacy in the trials and in identification of research questions. A related limitation is that we included only

RCTs. Other studies of PtDAs that used different research designs may have included PtDAs that addressed low health literacy. We also note that there is now mixed evidence regarding the benefit of alternate media on improving outcomes for lower literacy patients (24), thus criteria may need to be revised for future reviews.

Interpretations

Overall, very little attention was paid to literacy concerns in the PtDA RCTs reviewed. Only 3 out of 97 PtDA trials included adults with low education or literacy or used PtDAs designed explicitly to address low literacy audiences. In 90% or more of the trials, the reading needs of the participants and the reading level of the PtDAs were not reported. A clear bottom line is that PtDAs are rarely developed with low literacy populations in mind, despite the observations that: in many developed countries only half the population has more than basic reading skills (1); and health information developed for adults at a grade 9 reading level is widely accepted by more educated as well as less educated users (76, 77). However, importantly in PtDA studies in which education and literacy were addressed, results across literacy groups are encouraging in that increases in knowledge and in informed choice have been reported.

SECTION 6: EVIDENCE-BASED PRINCIPLES AND EMERGING ISSUES

Overall Conclusions

Lower health literacy groups tend to have the lowest levels of knowledge and involvement in health care, and some of the poorest health outcomes. The consistent observation that patients with lower health literacy desire less involvement in decision making may be a consequence of a lack of awareness that they can be involved (61) and a lack of confidence in sharing the decision process with health care providers. In patients with higher health literacy, desire for involvement has been found to increase when patients are shown the PtDA tools that are available (78). Accordingly, in order to ensure equity in access to PtDA resources and shared decision making, developers of PtDAs need to ensure that these tools are accessible to lower as well as higher health literacy consumers, and that lower health literacy groups are better equipped and supported to utilize PtDAs.

Some principles for PtDAs can be derived from our current review-based and expert-opinion-based evidence about the health literacy needs of consumers. There are also large areas in which there is scant research about important health literacy issues in the field of PtDAs. Below, we highlight some of those relatively established principles and relatively unexplored issues.

Principles for the Design, Development, Testing, and Implementation of PtDAs for Lower Health Literacy Consumers

Review-Based Principles

The reviewed literature reports the results of direct tests of ways to enhance understanding of PtDA-provided information among lower health literacy consumers. Here, we summarize that literature's "take home" messages for PtDA developers:

1. Present essential information by itself or first. *See Chapter B: Presenting Information about Options for further guidance on the presentation of information.*
2. Present numerical information in tables and/or pictographs rather than in text only.
3. Present numerical information so that the higher number is "better". For instance, present "nurses per patient" (higher number better) rather than "patient per nurse" (lower number better).
4. Use a consistent denominator for numerical information (e.g. 1 out of 1000, 500 out of 1000). *See Chapter C: Presenting Probabilities for further guidance on the presentation of numerical/probabilistic information.*
5. If possible, add video to verbal narratives to improve the salience of information about unfamiliar health states. *See Chapter E: Using Personal Stories for further guidance on the use of narratives.*

We emphasize that these principles are based on the available literature to date, which derives from a small number of studies. Further direct tests of ways to enhance understanding of PtDA-provided information are needed in the field of health literacy; such studies may generate different results in different populations.

Expert Opinion-Based Principles Emerging from The Broader Literature

Based on systematic reviews of the broader health literacy literature, the authors of this chapter believe that particular principles can be tentatively applied to the design, development, testing, and implementation of PtDAs for lower health literacy consumers. (For example, the AHRQ systematic review (24)-- although not specific to PtDAs -- identified a number of features that appear to improve the effectiveness of interventions for lower health literacy populations.)

- Use high intensity interventions. In the broader health literacy literature, successful interventions combine multiple literacy-directed strategies. Thus, designing decision aids that support knowledge acquisition and understanding (through plain language, simple numbers, and a range of visual and linguistic techniques) generally would be expected to produce better outcomes. Multiple reinforcing contacts following delivery of the decision aid would also generally be expected to support active decision making.

- Use theory-based interventions when appropriate. In the broader health literacy literature, successful interventions are theory-based. Thus, theory might be used to maximize the impact of decision aids. For instance, there are well-established behavioral and communication theories that might be applied in decision aids to motivate engagement with the decision aid or, if appropriate, engagement in specific behaviors (e.g., colon cancer screening).
- Pilot testing before full implementation. In the broader health literacy literature, successful interventions have been pilot-tested prior to implementation. Patient decision aids that have worked successfully with higher literacy populations cannot be assumed to be useful with lower literacy groups. Pilot testing is needed to examine the information needs and communication preferences of lower literacy populations and should examine the *whole* process of decision making among lower health literacy consumers. This means checking not only understanding of the language and content but also whether the PtDA helps users to clarify values, communicate with health professionals, and implement a decision.
- Increased emphasis on skill building among lower health literacy consumers. In the broader health literacy literature, successful low literacy interventions help with skill building. This suggests that demonstrating and modeling values clarification and physician interactions in decision aids may improve outcomes among low literacy users of decision aids.
- Delivery of the intervention to lower health literacy consumers by a health professional (e.g., pharmacist, health educator, nurse practitioner, physician). In the broader low health literacy literature, the most successful low literacy interventions are delivered by a health professional rather than by non-clinicians. This suggests that delivery of decision aids in the context of clinical care might result in the best outcomes.

Research Gaps in the Design, Development, Testing, and Implementation of PtDAs for Lower Health Literacy Consumers

Research addressing health literacy in PtDAs is in its infancy. To date, not enough attention has been paid to the needs of lower literacy consumers in PtDA research. There are important deficits in the extent to which attention has been paid to health literacy in PtDA development and evaluation. (For example, the application of the IPDAS 2006 (79) health literacy criteria to the development of PtDAs has not been systematically investigated). And much work is still needed to develop and test strategies to help adults with lower health literacy to gain key literacy skills, to engage in the values clarification process, and to be involved in doctor-patient communication.

These research gaps could be closed if PtDA developers used systematic study methods and reporting strategies such as:

1. Assessing literacy/health literacy and/or numeracy levels in study samples by:
 - a) directly measuring functional health literacy and/ or numeracy among a representative sample of the target sample of consumers, using a recognized measure such as TOFHLA, REALM, or Newest Vital Signs (NVS); and

- b) using a self-report health literacy and/or numeracy measure to assess perceived skills (e.g., (80, 81) – bearing in mind that there are well-recognized limitations to self-reported health literacy/numeracy measures.
2. Selecting a measurable strategy to ensure that the language of the PtDA is written at a level that is understood by the majority of the target audience (e.g., Flesch-Kincaid, Simple Measure Of Gobbledegook (SMOG), Fry Readability Formula (or Fry Readability Graph), or other accepted approaches; see <http://www.nlm.nih.gov/medlineplus/etr.html>), Suitability Assessment of Materials (SAM) or Systemic Functional Linguistics [74].
3. Stating how the PtDA accommodated health literacy or numeracy requirements identified in the population.
4. Stating that good health literacy principles were followed in the PtDA development (e.g., 83, 84-88).
5. Recruiting, where possible, adequate numbers of low health literacy/numeracy individuals to evaluate effectiveness specifically in this population through stratified analysis. If full inclusion is not possible, reporting results of pilot studies among lower health literacy consumers.

Other research gaps include the need to identify the characteristics of PtDAs that are universally acceptable and helpful, and those characteristics that are particularly effective at enhancing shared decision making among people with lower health literacy/numeracy. Ultimately, this future research will contribute in important ways towards understanding the effects of PtDAs on health inequalities and towards ensuring that lower literacy/numeracy groups are not disadvantaged.

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APPENDIX
Original Chapter J: Using Plain Language

Margaret Holmes-Rovner (lead)	Michigan State University	USA
Angie Fagerlin	University of Michigan	USA
Kirsten McCaffery	University of Sydney	Australia
Lisa Schwartz	Dartmouth Medical School, Dartmouth College, New Hampshire	USA
Stacey Sheridan	University of North Carolina	USA
Sue Stableford	University of New England	USA

Original Rationale/Theory

Patient decision aids are designed to present medical evidence that assists patients to identify screening, diagnostic testing, and treatment options, to determine their values associated with the potential harms and benefits of these options, and to participate in medical decisions. It is therefore, crucial that the text and graphics used to present this information are written in language that is easily understood. Ideally, patient decision aids should be comprehensible to everyone in the target audience, regardless of literacy level. However, medical detail required to describe harms and benefits is, by definition, technical language that is more challenging for readers to understand and particularly difficult for readers with limited literacy skills. These types of resources can be improved by applying the principles of plain language to a document's design, and by measuring readability.

Plain Language

There is no gold standard for what constitutes plain language, although there is wide agreement about many attributes, based on research evidence, about reading, cognitive psychology, social marketing, usability, and document design. The 3 major categories of attributes are: 1) the use of everyday language and other clear writing styles; 2) well-structured, logically sequenced, and focused information; and 3) effective document design. When these attributes are used, even good readers have demonstrated improvements in speed and accuracy of reading. As well, in medical situations many adults lack the context necessary to understand and apply the information which further impairs the use of new information. Finally, patients faced with health decisions frequently experience heightened emotional stress which interferes with cognitive abilities. Therefore, developing patient decision aids using attributes of plain language is important for patients of all literacy levels.

Readability

The most valid and reliable measure of the level of a text's comprehension difficulty is its readability. Patient decision aids need to be as transparent as possible in describing the literacy

level required to read or listen to the information provided. The majority (50% or more) of “the target population” should be able to understand the patient decision aid.

Therefore, in general, the readability of patient decision aids should be at the level equivalent to grade 7 or 8 in the US. However, when patient decision aids are specifically targeted to lower literacy populations, the readability level should be adjusted accordingly. Finally, the method used to assess readability should be reported with the readability levels.

Original Evidence

Literacy Rates

According to the 1992 National Adult Literacy survey, about half of US adults read at or below the 7-8th grade level. The issue of literacy is of ongoing concern across many countries that include Australia, Canada, Germany, New Zealand, Sweden, the United Kingdom, and the US.

Plain Language

There is some evidence that increasing reading ease improves comprehension, and emerging evidence of the effect on health outcomes. Poor literacy has been found to be related to lack of preventive health behaviors (e.g., cervical and breast cancer screening, influenza and pneumococcal immunization), increased risk of hospitalization, decreased ability to follow medical instructions (e.g., use of inhaler), and less control of chronic illness (e.g., glycemic control). However, several studies have shown that health outcomes can be responsive to interventions designed to improve the readability of materials. While the evidence is weak, and it is unclear whether interventions directed at improving readability will lead to better health outcomes, low literacy may be part of a complex of problems relating to poor health outcomes. A recent review identified 24 studies that examined interventions to improve health for persons with low literacy. These studies found mixed results about the interventions’ ability to affect knowledge, intermediate markers of disease, disease prevalence and incidence, health behaviors, and use of health services. Few studies examined each type of literacy intervention (text, videotape, computer, oral presentation), therefore it is not clear which types of tools are most effective. Additional limitations included variability in the study designs, the interventions tested, and the outcomes assessed.

Readability Measurement

There are well-validated tools for readability (e.g. SMOG, Fry). However, the easily accessible readability measures in word processing software are not very accurate or acceptable. Readability measures focus on the text, while more recent work on health literacy has focused on the abilities of the persons reading the text. Despite their limitations, these existing tools are helpful to good document design and should be used; in the meantime, investigators should re-validate them with various populations and develop more sensitive and specific tools to predict informed decision-making and health outcomes.

Inventory of Available Patient Decision Aids

There is no evidence found on the assessment of readability of patient decision aids and their suitability for particular audiences. Most of the 131 patient decision aids, in the Cochrane review inventory, were developed for general audiences (O'Connor et al., 2003). Further research should focus on: a) demonstrating which characteristics of patient decision aids enhance readability and improve comprehension resulting in better health outcomes; b) examining the use of patient decision aids in both low and high literacy groups to determine whether the intervention ameliorates differences according to literacy status; and c) determining whether interventions work directly to improve patients' knowledge and understanding or indirectly through other mechanisms.

Current Initiatives

The research agenda in health literacy should be enhanced by the work of the Institute of Medicine in this field. The Institute of Medicine's report *Health Literacy: A Prescription to End Confusion*, released in April 2004, highlights the scope of the problem and outlines a research and policy agenda with key recommendations.

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Importance of Health Literacy Generally

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Computerized readability software. Available at www.micropowerandlight.com

Doak C, Doak L, Root J. *Teaching Patients with Low Literacy Skills* (2nd ed). Philadelphia: Lippincott, 1996.

SMOG scoring directions: Harvard School of Public Health website. Available at: www.hsph.harvard.edu/healthliteracy

Literacy Status of Populations

National Assessment of Adult Literacy 2003 (NAAL) project will produce several published reports that address the status of literacy among adults in the U.S. and literacy trends over time. The working title of the principal NAAL 2003 national and state reports is: *Literacy Skills of America's Adults in Workplace, Family, and Community Settings*. Available at: <http://nces.ed.gov/naal/>

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National Needs and Impact Survey of Literacy, Numeracy and ICT Skills, October 2003. Department for Education and Skills, DfES Research Report 490. HMSO.

Original Appendices

Measuring Readability

Using a readability formula is a good first evaluation of any patient decision aid. The result, usually expressed in a grade level, gives an estimate of the level of reading difficulty. The formulas (e.g., SMOG, Fry) are generally valid within 1-2 grade levels and have good inter-formula correlation. Variation is largely due to different assumptions about level of reader comprehension. All formulas, however, are just indicators of reading ease or difficulty and should be used within a larger context of using plain language writing and design techniques.

Directions for using the SMOG are at this Harvard School of Public Health website: www.hsph.harvard.edu/healthliteracy. Directions for using the Fry are in “Doak, Doak, and Root (1996). Teaching Patients with Low Literacy Skills”.

If developers of patient decision aids want to use their computers to assess readability, they need to purchase software designed especially for this purpose (see references). The assessment software built into MS Word is not accurate and the Flesch-Kincaid formula as programmed in the software does not report a grade level above grade 12.

If using a computer program, the document must be “cleaned up” prior to running the readability analysis program. This includes deleting all titles and subtitles, extraneous periods (for example, after “Dr..”), and all bulleted lists. There may be other software instructions to follow as well.

Resources For Plain Language Writing

The following are several governmental and not-for-profit organizations’ guidelines for plain language that would be helpful to patient decision aid developers:

- www.plainlanguagenetwork.org
- www.plainlanugage.gov
- www.cdc.gov/publications.htm (publication at end of list titled .“Simply Put.” for CDC standards)
- http://oc.nci.nih.gov/services/Clear_and_Simple/HOME.HTM (These are NIH guidelines)
- www.usability.gov/guidelines/usability/guidelines.pdf (federal standards for website usability)
- www.discern.org.uk
- www.clear.nald.ca