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SCHOOL OF POPULATION HEALTH
THE UNIVERSITY OF QUEENSLAND

ADVANCING HEALTH LITERACY THROUGH
PRIMARY HEALTH CARE SYSTEMS

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<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>ALLS</td>
<td>Health literacy component of the Adult Literacy and Skills Survey</td>
</tr>
<tr>
<td>AHR</td>
<td>Adjusted hazards ratio</td>
</tr>
<tr>
<td>AMSTAR</td>
<td>A measurement tool for the ‘assessment of multiple systematic reviews</td>
</tr>
<tr>
<td>AOR</td>
<td>Adjusted odds ratio</td>
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<tr>
<td>APHCRI</td>
<td>Australian Primary Health Care Research Institute</td>
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<tr>
<td>ARR</td>
<td>Adjusted relative risk</td>
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<tr>
<td>β</td>
<td>Beta weight in a multiple regression analysis</td>
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<tr>
<td>BMI</td>
<td>Body Mass Index</td>
</tr>
<tr>
<td>CALD</td>
<td>Culturally and linguistically diverse</td>
</tr>
<tr>
<td>CD4</td>
<td>T4 count; T-helper cells</td>
</tr>
<tr>
<td>CI</td>
<td>Confidence interval</td>
</tr>
<tr>
<td>DIS</td>
<td>Drug information sheet</td>
</tr>
<tr>
<td>GCSE</td>
<td>General Certificate of Secondary Education</td>
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<tr>
<td>GP</td>
<td>General practitioner</td>
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<tr>
<td>HALS</td>
<td>Health Activities Literacy Scale</td>
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<tr>
<td>HL</td>
<td>Health literacy</td>
</tr>
<tr>
<td>IPC</td>
<td>Interpersonal processes of care</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini Mental State Examination</td>
</tr>
<tr>
<td>N</td>
<td>Number of participants in a study</td>
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<tr>
<td>NAAL</td>
<td>National Assessment of Adult Literacy</td>
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<tr>
<td>NIH</td>
<td>National Institute of Health</td>
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<tr>
<td>Ob/gyn</td>
<td>Obstetrician gynaecologist</td>
</tr>
<tr>
<td>OR</td>
<td>Odds ratio</td>
</tr>
<tr>
<td>P</td>
<td>probability</td>
</tr>
<tr>
<td>PHC</td>
<td>Primary health care</td>
</tr>
<tr>
<td>PhD</td>
<td>Doctor of Philosophy</td>
</tr>
<tr>
<td>PtEd</td>
<td>Patient education</td>
</tr>
<tr>
<td>Quasi-RCT</td>
<td>Quasi randomized control trial</td>
</tr>
<tr>
<td>R²</td>
<td>% of variance explained in one variable by another</td>
</tr>
<tr>
<td>RACGP</td>
<td>Royal Australian College of General Practitioners</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomized control trial</td>
</tr>
<tr>
<td>REALM</td>
<td>Rapid Estimate of Adult Literacy in Medicine</td>
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<tr>
<td>SES</td>
<td>Socioeconomic status</td>
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<tr>
<td>TOFHLA</td>
<td>Test of Functional Health Literacy in Adults</td>
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<td>WHO</td>
<td>World Health Organisation</td>
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INTRODUCTION

The purpose of this systematic review is to support the advancement of health literacy through the Australian primary health care system. The review draws on best evidence internationally and considers its policy and practice relevance for Australia. While it is acknowledged that health literacy advancement is also supported through initiatives across several other sectors such as school education, the principal focus of this review is health literacy in primary health care.

The Australian Primary Health Care Research Institute defines primary health care as socially appropriate, universally accessible and scientifically sound first level care provided by a suitably trained workforce. It has integrated referral systems that give priority to those most in need, maximises community and individual self-reliance and participation and involves collaboration with other sectors. It includes the full spectrum of services from care of the sick, through to illness prevention, health promotion, advocacy and community development. The review of research evidence presented in this report is relevant to this system at both policy and practice levels. It includes evidence relevant to Commonwealth and State government strategic policy, key national professional bodies, the health professions working at the first level of care and their organisational settings such as general practices, community health centres and other health practices in public and private community based settings. It does not address health literacy advancement in wider community settings.

Cross-sectional studies in several countries demonstrate a consistent relationship between level of health literacy and a range of health outcomes including the use of health services, especially preventive services, adherence to medication, and health status. Lower health literacy is consistently associated with poorer health outcomes. Moreover, it is generally acknowledged that health systems, including primary care, have become increasingly complex and make more demands on individuals to navigate health services and self-manage their health. An individual’s health literacy is therefore thought to be increasingly important in terms of engagement with primary health care to effect better health outcomes. Arguably, a primary health care system that makes less literacy demands of its users would be more accessible and ultimately more equitable. This review therefore moves beyond a solely individual approach (i.e., health literacy as something a person has or needs) to include a health systems dimension.

HEALTH LITERACY: ITS SCOPE AND UTILITY

The original concern grew out of Canada in the 1980s and focused on the impact of low literacy on health status. The Canadian Literacy and Health Program was a model of cross-professional partnership between literacy and health experts which raised awareness, developed resources and encouraged research at the interface of low literacy and health service responsiveness. At first, their focus was general literacy skills such as reading, numeracy and comprehension abilities, negotiations skills and critical thinking. In literacy studies a further distinction is made between task-based abilities and skill-based literacy abilities (National Assessment of Adult Literacy, 2003). While task-based literacy refers to basic abilities such as reading and writing, skill-based literacy refers to the ability to apply these to practical tasks that enable full participation in social and economic life, such as using these skills to complete a job application. More recently, skill-based literacy has diversified further to account for rising complexity in knowledge-based societies. Content and context specific literacies, such as computer literacy, financial literacy, citizen literacy and so forth are being identified as essential life skills. Thus, broadly speaking, health literacy refers to content specific literacy in a health context.

Since the late 1990s, the US Institute of Medicine has fostered health literacy defining it as the capacity to acquire, understand and use health information in ways which promote and maintain good health. Their report recognises that health literacy develops over the life course, with different content being relevant to different life periods. Health literacy can also be specific to different health conditions (for example, mental health literacy) and is culturally and socially sensitive. These basic dimensions have been taken into account by a number of research
teams to develop explanatory models of health literacy. These models seek to explain how health literacy is acquired and how the level of attainment impacts on health behaviours, health orientation, such as preventive or curative perspectives, as well as ability to navigate health systems.\textsuperscript{10-13} To summarize, these explanatory models suggest personal health literacy is determined by social and cultural circumstance, education experience and health system exposure. In terms of the health system, this exposure is clearly influenced by its structural arrangements as well as personal interactions. In this formulation, health literacy is the pivotal set of individual competencies that it is desirable to acquire for achieving health outcomes in part, but not wholly, when engaging with the health care system.

Two related but distinctive approaches to health literacy advancement in health systems are evolving. The first stems from the US Institute of Medicine initiatives and has a health literacy \textit{risk management orientation}, while the second stems from a public health perspective and has an \textit{asset building orientation}.\textsuperscript{11} Both are relevant to primary health care. Risk management strategies seek to identify those with low literacy and health literacy and to take ameliorating action. The Rapid Estimate of Adult Literacy in Medicine (REALM) and the Test of Functional Health Literacy in Adults (TOFHLA) have been developed to determine level of literacy using written items on health topics.\textsuperscript{14, 15} Valuable as these may be, the risk management approach focuses attention directly on patient literacy deficits rather than on health system shortcomings. Health literacy is more than personal ability, its utility being dependant on the interaction between individual communication capabilities, the structure and operations of health care system and wider social and cultural norms.\textsuperscript{16} At the practice level, health literacy is contextualized by the adequacy of communication between health practitioner and patient, the level of intervention complexity prescribed, the way the patient is involved in the process, the way assessment and problem solving is conducted with the patient, the access to culturally appropriate services and expectations about self care and responsibility.

By contrast, an asset building approach advocates for health education that enables individuals to have greater control over their own health.\textsuperscript{11} At the core of this approach is an orientation that sets out to empower individuals in health decision making.\textsuperscript{6} The WHO adopts a definition that goes some way to accommodate this orientation: “\textit{Health Literacy represents the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information which promotes and maintains good health.}”\textsuperscript{17} The critical difference in the WHO asset approach is that it moves beyond functional abilities which enable an individual to relate better to the existing health system to one where the person has the assets to manage their own health including equitable partnering and decision making with health care providers. For primary health care this approach implies reorientation of services to promote asset building rather than intervening only when an individual is assessed as having insufficient health literacy to engage effectively with existing services and interventions.

An assets approach proposes developing health literacy capabilities beyond basic literacy skills applied in a health setting. The Health Activities Literacy Scale (HALS), which has been used in the US and the Health literacy component of the Adult Literacy and Skills survey (ALLS), which has been used in Canada and Australia, define five domains of health literacy capability.\textsuperscript{18, 19}

\begin{itemize}
  \item **Health Promotion**: Enhance and maintain health
  \item **Health Protection**: Safeguard health of individuals and communities
  \item **Disease Prevention**: Take preventive measures and engage in early detection
  \item **Health Care Maintenance**: Seek care and form partnerships with health care providers
  \item **System Navigation**: Access needed services and understand rights
\end{itemize}

Domains of health literacy have also been ascribed levels of capability.\textsuperscript{20} Health literacy can increase from functional health literacy (e.g., can take own blood pressure) to interactive health literacy (e.g., can communicate and discuss blood pressure with a GP) to critical health literacy (e.g., can make decisions about best course of action after consultation). The move from functional to critical health literacy is seen as a move from improved basic knowledge and ability to one of greater independent and personal resilience in health care self-management.
This systematic review identifies best evidence to advance health literacy through both risk management and asset building approaches.

HEALTH LITERACY IN THE AUSTRALIAN CONTEXT

Awareness and recognition of the potential of health literacy to support health outcomes has been slow to materialize in Australia when compared to Canada and the US. The extent of low health literacy in the Australian population was first quantified in a national survey in 2006. Almost two-thirds of Australians aged 15-74 had insufficient skills to manage their own health or navigate the healthcare system. Low health literacy was found to be present at all levels of educational attainment and to increase with age, especially after 60 years. This suggests that low health literacy is a population-wide issue. Improving health literacy raises policy and practice challenges that call for a system-wide response that includes Australia’s primary healthcare system.

Major policy reports, including the Health and Hospital Reform Commission findings and recommendations and the National Primary Health Care Strategy have recognized the value of a system-wide response to advancing health literacy. However, the nature of this response in both policy terms and in practice interventions has not been clearly articulated. The purpose of this systematic review is to inform policy and practice options so that these are more soundly based, and to identify gaps in current knowledge. The review addresses not only the enhancement of individual knowledge and behaviours but also how the primary health care system could be strengthened to accommodate the impact of different levels of health literacy on health outcomes.

OVERARCHING QUESTION

What are the characteristics of a primary health care system that supports and enables the development of health literacy and what are the drivers and barriers of such a system?

To help address this question in the literature it is broken down into seven key questions.

KEY RESEARCH QUESTIONS

1. What are the key components of health literacy and how do they relate to a person’s capacity for active health partnering and making informed health decisions?
2. What factors influence the development of health literacy and what strategies have been effective in developing health literacy or its key components?
3. Do these factors differ across the social gradient of health, across the life span and for specific population groups (CALD and Indigenous peoples in particular)?
4. What policy drivers and barriers exist and what opportunities are there to strategically address health literacy through primary health care systems?
5. What are the options for improving health literacy through primary care systems, settings and services and by the main primary health care professions? What are the relative costs and benefits of each of these options?
6. Who are the strategic leaders (persons and organisations) most likely to advance health literacy and what types and level of resourcing are required to impact on levels of health literacy?
7. What measures could be put in place to determine the impacts of health literacy initiatives in the Australian primary health care system?

STRUCTURE OF THE REPORT

The substance of this report begins by outlining the search strategy applied in this systematic review including the criteria for selection of articles for review. The report then considers the
results of previous published reviews of research on health literacy. A considerable volume of these published health literacy reviews are commentaries and discussions. While potentially useful, they fall outside the rigour of a systematic review. Only a small number of formal reviews of health literacy research have been previously undertaken. This report therefore begins with a meta-synthesis of the more rigorous of these previous systematic reviews. The meta-synthesis highlights what is currently known about the extent to which low health literacy is prevalent in clinical settings and general populations, its relation to health outcomes, and the effectiveness of interventions to improve health literacy.

The report then follows with a more focused review of original research literature to address our key research questions. This provides an opportunity to include research published since the previous reviews and to target research that is directly relevant to the questions addressed in this report.
METHOD

SEARCH STRATEGY

REVIEW EWS
A search for peer-reviewed systematic reviews was performed in Medline, EMBASE, CSA, Cochrane, and ERIC databases with the following search terms: health literacy and primary health care; primary health care; primary health care system; health care system.

The criteria for retention of documents retrieved were: (i) the article had to be related to health literacy; that is, the degree to which people are able to access, understand, appraise and communicate information to engage with the demands of different health contexts in order to promote and maintain good health across the life-course; and (ii) the article had to be related to the primary health care system.

GREY LITERATURE
A general web search was initially conducted on the topic of health literacy. Subsequent follow-up searches were conducted for documents in relevant web sites. Members of the reference group and other key informants provided additional reports.

ORIGINAL RESEARCH
A targeted search for health literacy research was conducted in PubMed using a modified form of the National Library of Medicine’s health literacy search strategy. Keyword searches for health literacy research were also conducted in the EMBASE, Informit, Cochrane Library, CINAHL, International Pharmaceutical Abstracts, ERIC, and CSA databases. Some of these databases (e.g., ERIC) include grey literature.

Search criteria, which were applied in all bibliographic databases, limited documents to English language research with humans in the period from 1995 to April 2009.

The search strategy for both peer-reviewed and grey literature was enhanced by the inclusion of a specialist health librarian (LE) on the research team.

PUBLICATION SELECTION
The titles of all review articles, grey literature and original research were initially evaluated for relevance. At this stage, relevance was defined as potentially reporting on health literacy research in a primary health care context.

Where publications were identified as being potentially relevant, abstracts were scanned to confirm relevance. Two reviewers evaluated each abstract and differences in evaluations were resolved by a third reviewer.

QUALITY APPRAISAL

REVIEW EWS
Review articles were appraised for quality using the AMSTAR tool (Appendix 3). Two appraisers evaluated each article (EJS, FB, IO, MB, RB or RO) and disagreements were resolved by a third (RO). AMSTAR scores for a review can range from 0-11 and evaluated reviews were classified as being of high (score 8-11), medium (score 4-7), or low (score 0-3) quality.

GREY LITERATURE
Where grey literature contained reviews of health literacy research a process identical to that used to evaluate review articles was applied. Where grey literature contained original research it was evaluated in the same manner, using the same tools, as peer-reviewed original research.
ORIGIN ALL RESEARCH

After one third of the articles were appraised by two reviewers (MB, IO, FB, RO or EJS) the appraisal process was modified to facilitate more comprehensive appraisal of higher quality research by having one reviewer (RO) exclude any articles that clearly did not contain any original research. Articles were appraised using a formal tool designed specifically for this review (Appendix 4), with evaluation questions based on Oxman and Guyatt (1993) tool. Scores on this tool can range from 0-12 and original research articles were classified as being higher (score 10-12), medium (score 8-9), or lower quality (score 6-7).

DATA EXTRACTION

Data extraction was performed on the higher quality research articles. Initially, five articles had data extracted by two reviewers and the data extraction tool and process were then evaluated for clarity and consistency across the four reviewers (MB, FB, IO, RO). Once the extraction process was functioning well, the remaining articles had data extracted by one reviewer, which was then confirmed by a second member of the research team (FB). Articles were ranked by quality (appraisal score) and by level of evidence provided (experimental/non-experimental) and data were extracted from articles in order from highest quality down beginning with highest level of evidence articles within each quality band.

RESULTS

SEARCH RESULTS

The search strategy initially identified 84 potentially relevant grey literature documents with closer inspection indicating that 21 met review criteria. Initial searches also returned 2,504 potentially relevant review articles. Title and abstract scanning identified 23 relevant reviews from the original search results. Twenty-five additional reviews were subsequently identified in the search for original research and in the bibliographies of selected grey literature and original research articles.

A summary of the review process of original research articles is shown in Figure 1. The targeted original research search returned 2,702 potentially relevant articles. Title and abstract scanning identified 534 of these as meeting our review criteria. Nine relevant articles were found in the process of appraising the original research and were hand added producing a total of 543 articles to appraise. Of these articles, 45 were excluded on the basis of their being unobtainable, PhD theses, previously identified and appraised literature review articles or duplicate articles. The remaining 498 articles were reviewed for methodological quality with 329 excluded and 169 retained for data extraction. A general review tool was used because of its applicability to the wide range of methodologies included in this review. Ultimately, the tool’s design contributed to it producing generous scores for most articles provided a reasonable level of competency was evident.
2,702 potentially relevant health literacy original research articles identified by searching eight bibliographic databases

1,459 titles excluded

1,243 abstracts assessed for relevance in more detailed evaluation

709 abstracts excluded

534 + 9 articles available for evaluation

9 articles from hand search added

498 articles appraised for methodological quality

6 duplicate articles excluded
12 articles unobtainable
15 dissertations set aside for later review
12 articles identified as reviews

329 articles excluded

169 articles available for data extraction
Data extracted from 49 highest quality articles

Figure 1. Outline of search strategy and quality appraisal results for original research articles
REVIEW ARTICLE CHARACTERISTICS

This first section synthesises findings from high quality systematic reviews. Twenty previous systematic reviews were identified. Using the quality criteria in our review assessment tool (see Appendix 3) three were identified as high quality (Paasche-Orlow et al. 2005; Clement et al. 2009; Pignone et al., 2005),27-29 four medium quality (DeWalt et al., 2004; Keller et al., 2008; Sanders et al., 2009; Schaefer, 2008)30-33 and the remainder low quality. High and medium quality reviews will be summarised here. One high quality review27 was a meta-analysis with the remaining six reviews applying narrative techniques. These reviews addressed health literacy prevalence rates, the association between literacy level and health outcomes and interventions with those who have low literacy and health literacy. Their results are now integrated under these topics.

PREVALENCE

Paasche-Orlow and colleagues estimated the prevalence of low health literacy by pooled analysis of 85 US studies conducted in health and medical settings.27 The value of this review for primary care is that the prevalence estimates relate to clinical setting attendees rather than estimates in the general population. Health literacy was identified by scores on the REALM and TOFHLA. As expected, low health literacy was associated with low educational attainment, ethnicity (Black and Hispanic in the US) with prevalence increasing with age, but not associated with gender. One quarter of the sample (26%; 95% CI 22-29 using the TOFHLA) had low health literacy and a further 20% (95% CI 16-23) were classified as having marginal health literacy from the pool of 31,129 persons. A key conclusion of the review is the need to simplify health services and to increase onsite health education to improve the impact of clinical interventions given the high proportion of clinical setting attendees with low and marginal health literacy.

Sanders and colleagues focused on health literacy among children, adolescents and young adults in a narrative review.32 The review was wide ranging with most peer-reviewed papers adopting cross-sectional designs and all using a valid measure of health literacy (REALM, TOFHLA). Based on household data extracted from 122 studies they determined that low parental and carer literacy is commonly associated with poor preventive health behaviours and low literacy levels among children and younger persons. The findings point to an intergenerational dimension potentially impacting on health outcomes.

LITERACY AND HEALTH OUTCOMES

DeWalt and colleagues reviewed 73 mainly cross-sectional studies with a valid literacy measure to determine the relationship between literacy (some measures include health related content) and the use of health care services, health outcomes and health disparities.30 Some of the studies did not account for confounding factors so it is likely that literacy level attainment may interact with or be accounted for by other variables; for example, educational attainment may at least partly explain an association between health outcomes and health service use.

The DeWalt et al. review found that better quality studies showed conflicting evidence about the relationship between literacy level and the number of physician visits. Lower literacy level was not consistently linked to more or less physician visits. However, screening and prevention services were used less by those with lower literacy levels. Those with low literacy levels were at least 50% more likely to have never used a Pap smear or mammogram service. Conversely, hospitalization was more than 50% higher for persons with lower literacy levels after adjusting for age, gender, race, health status and access to financial assistance.

In research that controlled for demographic factors DeWalt and colleagues found evidence for poor adherence among those with lower literacy (OR 3.9 CI 95% 1.1-13.4). They found mixed results for the relationship between other health behaviours and literacy levels. Study samples in this review covered a wide range of behaviours and conditions including smoking in pregnancy (no relationship); diabetes related complications such as glycemic control, retinopathy, cerebrovascular disease, likelihood of amputation, and nephropathy (all mixed relationships); hypertension (no independent relationship), HIV infection (mixed findings),...
depression (OR 2.7 CI 95% 2.2-3.4), arthritis (no relationship) and presentation for prostate cancer (higher literacy level persons present earlier).

Health literacy may act as a mediator of health disparities, but the DeWalt review found the effects to be limited once overall educational attainment; age and other social factors were taken into account.

Various measures of global health status were found to be related to literacy level with lower levels associated with poorer self-reported health status in both population and clinical samples. There was greater certainty about the contribution of lower literacy to self-reported measures of general health status than about the contribution to health outcomes and behaviours for specific medical conditions. At least part of the reason for this may be that most of the studies were undertaken in clinical settings. The results of studies reviewed by DeWalt and colleagues may therefore be confounded by variation in the quality of the service provision and the extent to which each service addresses health literacy demands among the various types of study participants. Overall, however, DeWalt and colleagues estimate low literacy is associated with a one and a half to three times greater likelihood of experiencing a poorer health outcome.30

INTERVENTIONS AMONG THOSE WITH LOW LITERACY AND HEALTH LITERACY

Intervention studies are rare in health literacy research 9, 34 and only three high or medium quality systematic reviews examining interventions to improve health outcomes among persons with low health literacy were identified through our search and appraisal process. 28, 29, 33

Outcomes concerned changes in knowledge, behaviours, disease incidence and use of preventive services. Outcome measures ranged from self-report to biometric markers, the latter showing weaker effects than self-report.

The team led by Pignone accepted 20 peer-reviewed papers to examine improvements in health outcomes.29 Interventions ranged from improvement in written materials, the addition of better interpersonal communication methods and the use of multi-media such as videos. Twelve studies, of which five were RCTs, measured knowledge gain. The five RCTs demonstrated improved knowledge specific to health conditions. It is not known whether increased knowledge translated into improvements in medical condition. Four studies measured behaviour change but only one of these was an RCT. The behaviour change outcomes concerned breast examination, smoking, dietary patterns and medication adherence. The RCT study demonstrated improved dietary knowledge and a small reduction in calorie intake in a nutrition program. Two RCTs used biomedical markers but found no significant change among low literacy African Americans in nutrition programs, one using audiotape information.

Among those with low literacy the addition of interpersonal contact may improve health outcomes. For example, the Pignone review, cited a study by Poresky and Daniels that provided a personal case manager to participants in the depression Head Start program35. This RCT study found a 25% point reduction in negative items in the case managed group compared to a 2% point reduction in the control group using the Comprehensive Adult Student Assessment Scale.

The same review team were unable to identify any RCTs designed to determine the impact of health literacy interventions on the use of preventive strategies.29 A group comparison study they cited26 examined the effect of video-based coaching, verbal recommendation alone, and verbal recommendation plus a brochure, among those with low health literacy in a mammography screening program. There was a 29% increase in attendance in the video coaching group compared to a 21% increase in the verbal recommendation group after six months.

Such findings raise a key question about whether more complex interventions beyond standard advice can improve the health of those with low literacy levels, especially when the patient is required to take on a range of self-management tasks. Clement and colleagues selected 15 RCTs and quasi-RCTs in a narrative review to address this question.26 Overall, knowledge and self-efficacy improvements were found but evidence for health behaviour change was limited.
This group of more complex interventions was wide ranging and included the use of illustration charts for mothers of newborn babies, tailored nurse telephoning with hypertension patients, improving communication of health workers working with colorectal cancer patients, personalised dietary intake interviews, verbal instruction with feedback for medication use, assigning mentors to low literacy patients, notification of low literacy patients to treating doctors, bilingual education and educator referral.

Of particular relevance to primary health care is the relationship between low health literacy, disease control and medication adherence. A review team led by Keller selected seven studies which examined disease control and four studies which examined medication adherence. All used biomedical markers as the outcome variable but all were limited to cross-sectional design without clear intervention strategies. When the biomedical markers were used no clear association was found between health literacy and a person's disease control with mixed results for medication adherence. The review underscores the limited application of well designed studies and, in particular, intervention trials in the field.

In Schaefer's review, 16 studies with any type of experimental design were used to address the question of whether health literacy interventions are helpful to self-care management and adherence to medical regimens. This review focused on making health information materials easier to comprehend in paper or computer format and improving interpersonal contact. Of the 16 studies reviewed only three demonstrated potential health benefits. One found adherence to medication regimens in the treatment of HIV/AIDS when given improved written information but the intervention also included motivational interviewing so that it is unclear which component or combination accounted for the result. A second study demonstrated intensive interpersonal contact with low literacy patients led to improved diabetes self-management when part of a diabetes education program. The final study demonstrating health benefits found that adherence to cancer screening improved when a health care provider in a colorectal cancer screening program was given information about a patient's low health literacy status, provided the health care worker was skilled in ameliorating strategies.

**SUMMARY OF REVIEW ARTICLE FINDINGS**

Our synthesis of higher quality systematic reviews finds that up to one quarter of attendees in US clinical settings have low health literacy and a further 20% have marginal health literacy, suggesting potentially significant impacts on treatment interventions, particularly those that require adherence to self-management regimens. While low health literacy is more prevalent among older people, there is also some evidence to suggest children from low literacy families are at risk of not developing sound health literacy capabilities.

Health literacy is associated with health outcomes. The best available estimate suggests those with low health literacy are between one and a half and three times more likely to have poorer health outcomes. They are also less likely to use preventive services. However, this estimate is likely to be conservative because it is based on studies which use the TOFHLA and REALM, instruments that are general measures of literacy with health content rather than specific measures of health literacy capabilities.

There are few RCTs designed to investigate the health impacts of attempts to intervene with low literacy and low health literacy. Gains have been investigated for changes in knowledge and behaviours including medication adherence, disease incidence and use of preventive services. Improvements in written material, interpersonal communication and the use of multi-media show potential for knowledge gain more than for behaviour change. Studies using self-reported benefits show stronger gains than those using biometric markers. The latter at best show mixed results.

Numerous health literacy approaches covering a wide range of applications were considered in the remaining systematic reviews. Among these are: the addition of illustrated charts and diagrams, tailored telephoning, improving communication, personalised instruction, teach back, mentoring of low literacy patients, alerting health care providers to patients’ literacy levels, the use of bilingual educators and referral to self management educators. Technology platform interventions have not featured in high quality systematic reviews to date. Broadly speaking,
this research can be categorised as interventions that improve the literacy skills of patients; that improve the materials offered to patients; and that improve processes to eliminate barriers that patients might face.

ORIGINAL RESEARCH STUDY CHARACTERSTICS

The review of previous systematic reviews provides a synthesis of the major themes in health literacy research. We now turn to a review of original research to address more directly our overarching research question and the seven subsidiary key questions. Of the 169 relevant original research articles identified in the search and appraisal process 18 were experimental or quasi-experimental studies, 14 were qualitative or mixed-method studies and 137 were non-experimental, quantitative studies. All of these studies were appraised as competently conducted research according to a modified version of the evaluation tool developed by Oxman and Guyatt.26 Forty-nine studies were appraised to be of higher quality, 95 of moderate quality and 25 of lower quality. Data were extracted from the 49 higher quality studies.

Table 1: Descriptive Characteristics of Studies Tallied by Research Type

<table>
<thead>
<tr>
<th>Types of Research</th>
<th>Experimental</th>
<th>Non-Experimental</th>
<th>Qualitative*</th>
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<td>Higher Quality Studies</td>
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Results for 49 Higher Quality Studies Below

Health Literacy Characteristics

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<th>Qualitative*</th>
<th>Total</th>
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<tr>
<td>HL as a Risk Factor</td>
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<td>43†</td>
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<tr>
<td>HL as an Asset</td>
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<td>1</td>
<td>9</td>
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<tr>
<td>Functional HL</td>
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<td>43</td>
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<tr>
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<tr>
<td>Critical HL</td>
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Sample Source

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Research Question

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<td>Q1. Key components of HL</td>
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<td>Q2. Factors that influence the HL</td>
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<td>Q3. Factors that differ across the social gradient of health; the life span; for specific population groups</td>
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<td>Q4. Policy drivers and barriers</td>
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<td>Q5. Options for improving HL</td>
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<td>Q6 Strategic leaders (persons and organisations)</td>
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<td>Q7. Measures to determine the impacts of HL initiatives</td>
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</tbody>
</table>

* Includes mixed-method study results
† Descriptive categories are not mutually exclusive and may not sum to 49
Descriptive characteristics of the 49 higher quality studies are shown in Table 1. The studies, which were mainly non-experimental in design, investigated health literacy as both a risk factor and as an asset, in both specific study samples and in broader populations. The focus tended to be on functional health literacy, rather than on higher levels of literacy, and the research primarily addressed the first and second research questions in the review. Non-experimental studies were dominated by functional health literacy research focusing on health literacy as a risk factor. A large majority (87%) of studies addressed the first review question on the components of health literacy with a smaller number of studies investigating factors influencing the development of health literacy (11%) and health literacy factors that differ across groups (24%).

Of the 49 studies selected, none directly addressed research questions 4, 6 or 7, and only one addressed research question 5. A small number of studies addressed health literacy factors that differ across groups and factors that influence the development of health literacy but research was dominated by studies of the components of health literacy. The studies reviewed, together with their main findings, are summarised in Table 2 (experimental studies) and Table 3 (non-experimental studies), which appear in Appendix 1 and 2 of this report.

EXPERIMENTAL AND QUASI-EXPERIMENTAL STUDIES

The four higher quality experimental and quasi-experimental studies (Table 1) were published since 2005. Three of the studies were disease specific RCTs conducted in primary care settings in the US; the fourth, conducted in Australia, involved a two-phase population-based survey pre- and post- the introduction of a range of community programs.

Two of the RCTs focused on prostate cancer screening and the evaluation of patient-directed educational interventions. The first of these RCTs used educational handouts appropriately designed for male patients with low health literacy and containing either detailed information or simple encouragement to talk to the doctor about prostate cancer screening. Patients who received a handout, regardless of its level of detail, reported initiating discussion about screening twice as often as those who received a handout on an unrelated health topic. A review of patients’ charts also indicated significantly more prostate specific antigen test orders for patients who received handouts, but no differences were observed in the frequency with which digital rectal examination was performed.

The second RCT used more elaborate interactive multimedia techniques including the presentation of factual medical information in an entertainment-based format. Patients were categorised as having high or low health literacy based on the sociodemographic profile of the clinic locality. All patients demonstrated improvements in knowledge but those from the low health literacy site also demonstrated reductions in decisional conflict and greater self-advocacy after receiving the entertainment-based intervention. The lower health literacy group also showed a greater acceptance of the entertainment-based intervention.

In contrast to the above studies, the third RCT involved a provider-directed intervention. The physicians of patients with diabetes who had been screened for low health literacy were randomized to receive advice about patients’ low health literacy status by way of a chart note. The study met with limited success. Despite greater use of management strategies recommended for patients with low health literacy by those physicians made aware of their patients’ status, this was not found to translate to improvements in self-efficacy scores for patients. Moreover, a notable unanticipated outcome was that physicians receiving advice about their patient’s status reported being significantly less satisfied with the consultations and marginally less effective in those consultations than those who did not receive any such advice.

In some contrast to the approach taken in the three studies above is an investigation of mental health literacy in a random population-based sample of 3015 adults in South Australia. The “intervention” in this naturalistic study was a range of broad-based community and professional education programs implemented between two data collection points in 1998 and 2004. These programs reflect determined efforts in place since 1998 to enhance public knowledge about mental health disorders and the availability of effective treatments. They have been delivered at multiple levels by government, professional, charity and industry sectors and include the
National Suicide Prevention Program; Beyond Blue; and continuing education programs such as those of the RACGP. The method used to assess mental health literacy in the study is one that has been developed and widely used by researchers in this field. It uses a vignette-based questionnaire designed to elicit respondents’ knowledge of mental health disorders and appropriate treatment seeking behaviours. The study provides some evidence for the impact of broad-based initiatives that address specific aspects of health literacy. Marked improvements in recognition of mental health disorders were observed across the two time periods. This was the case for people with no evidence of major depression as well as those experiencing depression, with or without suicidal ideation. Changes were less marked for those in the latter two groups, especially with regard to help-seeking choices. Overall, this study – and the mental health literacy field more generally – offers a rare example of a broader assets building approach to health literacy. A key conclusion is that those most in need may be least influenced by large-scale community education programs. A dual approach involving broad-based interventions and targeted support for those at risk is likely to be required.

The results of these studies - together with the scarcity of methodologically sound experimental studies - point to a lack of evidence upon which to develop interventions to advance health literacy. The small number of rigorous intervention studies suggests policy development at this time is reliant on a limited evidence base.

NON-EXPERIMENTAL STUDIES

The 44 higher quality non-experimental studies (Table 1) included 12 cohort studies and 32 cross-sectional studies. Most were conducted in the US and 30 were published in 2005 or later. With the exception of one study, which recruited young adolescents, all studies sampled adults and about one third of the studies focused on older adults. The studies otherwise are marked by a great deal of diversity with regard to the health conditions, samples and variables investigated.

The studies can be grouped into two broad categories. Thirteen of the 44 studies treated health literacy primarily as a dependent (primary outcome) variable. These studies consider a range of factors in terms of their association with health literacy. They attempt to explain differing levels of health literacy across groups and usually seek to identify risk factors for low health literacy. The studies tend to involve general community samples, including five large national random samples, rather than patient or population groups defined by specific health conditions.

Ten of the 13 studies were conducted in the US with the remaining three studies from the UK, Japan and New Zealand. Mental health literacy was the specific focus for the latter two studies, which used the abovementioned vignette method to assess knowledge of depression and treatment options in the general community.

In the remaining 31 of the 44 non-experimental studies, health literacy was the independent (treatment) variable (though in a number of these studies health literacy was also examined as an outcome variable). Essentially, these studies consider health literacy primarily as a risk factor in relation to a particular dependent (outcome) variable. The 31 studies - all conducted in the US - examined associations between health literacy and a wide range of outcomes.

The studies vary in the extent to which multivariate analyses were performed to take into account a potentially large number of confounding variables that could explain observed associations between health literacy and the various factors of interest in individual studies.

**Studies addressing risk factors for health literacy**

The 13 studies that address risk factors for health literacy (first section of Table 3) generally aim to disentangle the inter-relationships of a wide array of variables that might reasonably be expected to influence an individual’s level of health literacy. In most studies, health literacy is assessed using validated measures, frequently the TOFHLA. Sampling strategies varied across the studies but the sociodemographic characteristics tend to be similar and are also consistent with broader population-based surveys. A number of variables, including education, age, cognitive functioning, income, ethnicity and race are consistently shown to be closely associated with health literacy. Findings are mixed for other background variables, including gender,
comorbidities and urban/rural residence none of which emerge in these studies as being strongly and consistently associated with health literacy.41-44

*Education* is strongly and consistently associated with health literacy. However, it is also well demonstrated that level of education is not a proxy for health literacy. Use of the former variable (which tends to be a measure of education completed) is shown to overestimate level of health literacy (which is more likely to reflect educational attainment) for people with higher and lower education.

*Age* is also strongly and consistently associated with health literacy: levels of health literacy are lower in older age groups. Studies indicate that controlling for cognitive impairment, a factor associated with both older age and poorer health literacy, attenuates the association but age remains a significant predictor.45, 46 Under-explored is whether this reflects a cohort effect. All else being equal, health literacy might be expected to improve with greater contact with health services over the life course. However, older people encounter a health system and a set of health literacy demands that are today vastly different from those which they have experienced earlier in life.

At the other end of the age spectrum there is evidence to suggest that early adolescence may be a potentially important intervention point for the development of health literacy.47 In particular, findings based on 9-13 year-olds suggest that educational efforts commenced earlier may significantly increase both the likelihood of an interest in learning about health and a desire to follow what was taught in this age group.

**Studies that address health literacy as a risk factor**

Across the 31 studies where health literacy was identified as the treatment variable (or risk factor) for health outcomes (second section of Table 3), health literacy emerges as having a strong and consistent association with a wide range of outcome variables including: mortality and other health related outcomes, patterns of health service use, health related knowledge, understanding and behaviours, and medication adherence. One study examined health services costs as an outcome of poor health literacy (these results are considered separately in a subsequent section).48 Most of the 31 studies used validated measures of health literacy, such as the TOFHLA or REALM. These risk factor studies are therefore narrowly focused on functional health literacy.

A number of studies using sophisticated multivariate analyses show that health literacy makes an independent contribution over and above other key variables including age, sex, education, income, ethnicity, race and health status. While the magnitude of the relationship between health literacy is invariably reduced once such background variables are taken into account, only rarely does the association become non-significant.

A high quality prospective cohort study of more than 3,000 community dwelling retirees showed that health literacy predicted mortality.49, 50 After adjusting for sociodemographic variables and baseline health, both cognitive ability (measured by items from the Mini Mental Status Examination) and health literacy made significant independent contributions to the prediction of all-cause mortality up to six years post-baseline. With cognitive ability added to the model, health literacy remained a significant predictor: adjusted hazard ratio 1.27, (95% CI 1.03-1.57). A practical implication of these findings is that both literacy and cognitive demands may reduce people’s ability to manage their health and both sets of demands warrant careful consideration when delivering health services and information.

Other adverse health outcomes have been confirmed using objective clinical indicators. Among 408 patients with type 2 diabetes, inadequate health literacy was significantly associated with poor glycemic control, a lower likelihood of achieving good control and a higher prevalence of retinopathy as well as other self-reported complications of diabetes.51 Among 204 patients attending an eye clinic those with poor health literacy had greater visual field loss and significantly worse visual field parameters than patients with adequate health literacy. Other studies, including a wider community sample of 489 older people have shown health literacy to be positively associated with self-reported health status.52
Interestingly, the suggestion from one study based on 2,923 older persons is that poorer health outcomes for those with low health literacy do not arise as a result of greater health risk behaviours.\textsuperscript{53} Adjusting for relevant background variables, people with inadequate health literacy were no more likely to have smoked, to drink alcohol, to report a sedentary lifestyle, or to have a higher mean body mass index than those with adequate health literacy.

Studies examining health service usage as an outcome are consistent in showing greater use of higher end care and less use of preventive services for those with lower health literacy.\textsuperscript{48, 52, 54-56} A prospective cohort study of 958 emergency department patients found people with lower health literacy were 1.69 times more likely to be hospitalized over the two year study period (controlling at baseline for demographic variables and self-reported health status).\textsuperscript{54} This association was even stronger for people who also had been hospitalised in the year before the study: those with lower health literacy were three times more likely to be hospitalised again.

One study investigated whether access to health services differed according to health literacy levels for 2512 older men and women presenting at hospital clinics.\textsuperscript{55} People with lower health literacy were significantly less likely to have access to primary care based on a composite score reflecting whether or not the person had a regular doctor, had received an influenza vaccination, or had health insurance.

In some contrast, a study of 372 patients at a hospital clinic serving a highly socially disadvantaged group found lower health literacy to be significantly associated with greater acceptance of HIV testing when recommended by a health provider.\textsuperscript{56}

Understanding and correct use of medication has been the focus of a number of studies. While much of the work on medication adherence is based on self-report data, some studies have made use of more objective measures such as pharmacy refills and a small number have also incorporated clinical indicators.\textsuperscript{57, 58} The available evidence generally supports the finding that medication adherence is poorer among those with lower health literacy though results tend to be less conclusive when clinical markers are used.\textsuperscript{59, 60}

Poor understanding of the medications prescribed, including difficulty comprehending instructions for their correct use is likely to be a major contributing factor to suboptimal medication adherence. Davis and colleagues identify health literacy as an important patient safety issue given the clear potential for patients with limited literacy to misinterpret instructions.\textsuperscript{61-63} Such misinterpretations occurred even when efforts were made to use precise wording on prescription labels, highlighting the challenges involved in producing comprehensible written information. Further emphasising the importance of this issue is that taking a greater number of prescription medications was significantly associated with misunderstanding of instructions.\textsuperscript{61}

Not all studies demonstrate lower rates of adherence among those with low health literacy. A cohort study of 235 patients living with HIV-AIDS found higher levels of adherence and better viral load suppression among those with lower health literacy.\textsuperscript{64} Similarly, despite demonstrating poor knowledge of warfarin medication, patients with low health literacy did not have higher rates of non-adherence.\textsuperscript{65} It is possible that local service factors help to account for such findings with services developing specific strategies to meet the needs of their patient groups.

Lower health literacy is associated with poorer disease knowledge among people diagnosed with a number of studied conditions.\textsuperscript{66-68} A community based sample of older people with asthma, diabetes, congestive heart failure and/or hypertension found those with lower health literacy had more limited knowledge of their disease than those with higher levels of health literacy.\textsuperscript{67} Based on information presented in different formats, breast cancer survivors with lower health literacy were found to have greater difficulty understanding and interpreting their risk of recurrence of the disease.\textsuperscript{66} While women with higher health literacy found some formats easier to understand, the finding that women with lower health literacy did not points again to the challenges of identifying suitable methods of conveying critical health information. One study found that parents’ health literacy was not significantly associated with 48-96 hour recall of a child’s diagnosis and medication details.\textsuperscript{69}
Low health literacy may place patients at a disadvantage not only with respect to written communications. Patients assessed as having inadequate health literacy reported significantly more communication difficulties in the clinician-patient dialogue when compared with those with adequate health literacy. Shortfalls were identified in the domains of general clarity, explanation of condition and explanation of processes of care.

Overall, the findings from these studies point to health literacy as a product of key demographic, socioeconomic and cultural factors. Characteristics and demands of the health system seem rarely to have been considered as influencing health literacy though some studies have pointed to features of the patient-provider interaction in this regard. Health literacy, as defined in this body of research, seems to be a robust predictor of a range of health related outcomes across a diversity of health conditions and population groups.

QUALITATIVE STUDIES

One higher quality qualitative study examined how primary care clinic patients used their numeracy skills in health care. Fifty nine participants aged 40-74 years took part in focus group discussions on their experience of how numbers are used in their health care. Content analysis showed that patients responded to numbers both cognitively and affectively. When negative affect is associated with numbers, this may limit a person’s ability to apply basic numeracy skills that are commonly part of treatment, such as daily medication regime.

The qualitative component of one mixed-method study also informs this review. Analysis was performed on the content of incorrect responses to questions about medication label instructions. Errors were due to repetitive or unfamiliar label language, complex instructions, implicit dosage intervals, distracting content added to container by prescription provider, unfamiliar auxiliary labels, and simple respondent inattention due to rushed questionnaire answers.

The value of these two studies is that they suggest assuring comprehension involves not only clarity of written instructions but also attention to the patient’s cognitive and affective processes.

ECONOMIC EVALUATIONS

A small number of studies address the impact of literacy and low health literacy on health care costs. Of the studies identified, one was assessed as using standard econometric techniques that take into consideration the censored nature of the health care costs variable. In this US study of Medicare managed persons, those with low health literacy incurred significantly higher inpatient and emergency room costs but not significantly higher outpatient, pharmacy or overall costs. The conclusion drawn is that higher costs reflected inefficient use of a mix of health care services when compared to those with high level of health literacy.

None of the reviewed studies has undertaken rigorous economic evaluation of health literacy interventions. This is a significant gap in the evidence given that economic evaluation is recognized as a powerful tool to guide policy-making.

DISCUSSION: INTEGRATION AND POLICY RELEVANCE

This systematic review has provided a broad overview of the current state of health literacy research with a particular emphasis on research that has the potential to inform policy and practice directions in the Australian context. Population studies in the US, Canada and Australia provide some sound estimates of levels of health literacy and indicate that low health literacy is widespread. Further, a collection of mainly cross-sectional studies shows lower levels of health literacy are consistently associated with a range of adverse health outcomes. While these studies help establish the problem of health literacy, high quality research to assist policy-making is scarce. Well designed intervention studies with the purpose of improving health literacy and then demonstrating positive changes to health outcomes are rare and have not been undertaken in Australia (see Table 2, page 35). This gap in health literacy research means
that it is not possible to directly address all of the specific research questions raised for this systematic review related to the Australian context (page 9). It follows that the current state of the evidence has a bearing on the potential for integration of evidence and its policy relevance. In short, the current situation is one of a weak evidence base to inform policy on an issue that is recognized as demanding a policy response from the Australian primary health care system.

The challenge then in the final part of this report is to make a policy-relevant response in an evidence-poor environment. To achieve this end a modified version of Whitehead's framework for examining policy application is used. The first requirement for policy adoption is information on the adequacy of evidence about the problem health literacy poses for primary health care system performance. The second requirement for policy, planning and intervention is the extent to which the problem is recognized by key national organizations, governments and health professions concerned with the performance of primary health care and the level of committed action. The third requirement concerns the adequacy of the evidence for effective interventions at the practice level, for more structured programs and strategies across the primary care system and for more comprehensive strategic policy options which could support health literacy advancement.

This framework is now adopted to address the overarching question: What are the characteristics of a Primary Health Care (PHC) system that supports and enables the development of health literacy and what are the drivers and barriers of such a system?

THE ADEQUACY OF EVIDENCE FOR DEFINING THE SCOPE OF THE HEALTH LITERACY PROBLEM

Health literacy definitions vary from a focus on reading and numeracy abilities to more comprehensive health self-management abilities. A policy relevant health literacy definition will depend upon the context in which it is to be used. In this case, that context is an Australian primary health care system that aspires to be universally accessible; works from an evidence base, and engages an integrated network of medical and allied health professions. Such a system promotes more self-reliance in the management of health including a person's ability to navigate health care services. To achieve this end, it is assumed individuals need to attain adequate health literacy skills and abilities. Equally, health systems need to ensure they can support those who do not have these abilities by addressing the risks associated with low health literacy as well as build health literacy assets to support self reliance. Without doing so, the effectiveness of interventions may be diminished and so health care costs are increased. This is a basic rationale for investment in advancing health literacy in primary health care and evidence is needed to support this proposition.

Health literacies that are narrowly focused on reading and numeracy skills are likely to be necessary but not sufficient to support health advancement in a primary health care system that aims to build self-reliance. Health literacies that identify skills and abilities across health promotion and protection, disease prevention and maintenance and system navigation are more likely to contribute to this health system goal. Moreover, health literacies that move beyond accumulation of basic health knowledge to more advanced skills and abilities that include communication and critical decision making about health are more likely to support greater independence and personal resilience in health.

The 2006 Adult Literacy and Life Skills Survey (ALLS) which included health related items across these domains was applied to a representative sample of the Australian population aged between 15 and 74 years across all states and territories. Results were categorized into five levels with those reaching a skill level of 3 (1 low-5 high) being regarded by the survey developers as having the minimum required skills to meet the complex demands of everyday life. Based on this criterion, 59% of the Australian population aged 15 to 74 years achieved scores below this minimum level on a composite score for the health literacy domains; a percentage that is approximately 10 to 15% higher than the proportion that did not reach basic
literacy and numeracy levels. The proportion achieving only minimum levels of health literacy increased with age especially after 60 years. The significant proportion not achieving minimum levels suggests lower health literacy is a population-wide problem rather than one that is isolated to specific segments of the population. The review of studies presented earlier in this report also shows the widespread prevalence of lower health literacy in other countries.

Figure 2. Australia’s health literacy by age

A key issue for targeting interventions is then the way lower health literacy is distributed across the general Australian population. Levels of health literacy by educational attainment are set out in Figure 2. This shows that lower health literacy is present at all levels of education attainment: 50% of those without a post-school qualification and 45% of those with a Bachelor’s degree also failed to achieve health literacy competence (Level 3). Even so, those in the lowest quartile of the index of relative socioeconomic disadvantage score much lower on health literacy than those in the higher quartiles. Although these findings suggest low health literacy is a problem that follows the social gradient within the general population it is clearly not confined to the lower end. The context and content specific nature of health literacy appears to cross all levels of education attainment as would be expected.

Those living in the regions were slightly less likely to reach minimum level when compared to city dwellers (64% vs 58% had lower health literacy) and migrants born in a non-English speaking country were considerably less likely to reach minimum level (74% had lower health literacy). Within Australia, little more is known about the health literacy levels among specific population groups. No studies were found that investigated health literacy among Australian Aboriginal and Torres Strait Islander peoples, for example.
Figure 3. Australia’s health literacy by educational attainment

A key issue for problem definition is the relationship between the distribution of individual health literacy capability and the demands of an increasingly complex primary health care system. Risks in this relationship exist at the individual level and at the system level. Individual risk factors for lower health literacy have been investigated for social, economic and educational attainment, age and ethnicity. Being older, growing up in a household of limited literacy, being in the lower socioeconomic quartiles of the population, migrating from a non-English speaking country and having lower formal education attainment are among the well-established individual risk factors. In US studies risk is also associated with ethnic background (Black and Hispanic) but this may be confounded by socioeconomic disadvantage. Virtually no attention has been given to risks that derive from the structural complexity of the primary health care system. Descriptive studies conducted mainly in US and Canada suggest what some of these risks may be but their quantification and impacts have not been investigated in the Australian primary health care system. This is a fundamental limitation of the evidence to support problem definition. It focuses attention on what may be needed for individuals to adapt to a complex system rather than addressing complexity in the system itself.

A final issue for problem definition is the impact of low health literacy on health outcomes. Evidence for impact is derived mainly from US studies of population and clinical samples, the majority being cross-sectional studies examining associations between the use of preventive and curative services, types of service engagement (including medication adherence) and a wide range of health behaviours. Almost all these studies apply the REALM or TOFHLA test results as a measure of health literacy. The studies therefore restrict the definition of health literacy to reading and numeracy skills on items with health content rather than self-reliant health promotion, prevention, maintenance and system navigation. There is greater certainty about the association between the contribution of low health literacy to global self-reported health status (this was also found in the ALLs study conducted in Australia) than the contribution to specific conditions and health behaviours when social and economic background factors are taken into account. There is reasonable evidence that those with high health literacy are more likely to manage their health through the use of preventive strategies including the use of screening services while those with lower health literacy make more use of emergency services. Using US studies DeWalt and colleagues estimated that those with low health literacy were between one and a half and three times more likely to have adverse health outcomes compared to those with higher health literacy. However caution is advised because associations between low health literacy and health outcomes are greater for self-report measures compared with biometric markers and there are few prospective studies.
Assessments of economic impacts of low health literacy have not been attempted in Australia, are uncommon elsewhere and, with one exception, those conducted have employed limited econometric methods. The small body of available evidence suggests that improving health literacy in the population may lead to greater use of preventive services. The impact of this in terms of projected costs for individuals and the Australian health care system is yet to be evaluated.

THE EXTENT OF RECOGNITION, AWARENESS AND ACTION ABOUT THE HEALTH LITERACY PROBLEM IN PRIMARY HEALTH CARE

In Canada recognition and raised awareness of health literacy began in the 1980s with the issue being fostered by peak body partnerships like the Canadian Public Health Association and the (then) National Literacy Secretariat. Conceptual development, causal path modelling and rising institutional commitment have led to a range of research and practice projects and analysis of research gaps which include the call for policy development and cost benefit analysis of interventions. In the US the Council of Scientific Affairs of the American Medical Association has supported conceptual development, reviews of evidence and, on the basis of consensus building around research findings, has lobbied for public awareness, medical student training in health literacy, the screening of patients, patient-physician communication improvements and the need for research that identifies optimal interventions. The office of US Surgeon General has adopted health literacy as one of four public health priorities and the NIH has provided research funding specifically to advance knowledge in the field. In both countries awareness has led to commitment to a range of research and practice based initiatives. In both Canada and the US there is evidence for a strategically driven agenda by peak government and professional instrumentalities.

In Australia, most medical and allied health professions have drawn to the attention of their membership the potential importance of responding to low health literacy through reviews and commentaries in professional journals in the past two years. The recent report of the Health and Hospitals Reform Commission recommends improving health literacy to engage better with health consumers and supports incorporating health literacy into school curriculum. The Consumers Health Forum of Australia, in responding to the Commission, supported health literacy initiatives in schools but went further to encourage investment in health literacy among current health consumers. The Commission also recommended a targeted approach in such areas as mental health. It considered health literacy as one strategy to help foster a “shared responsibility” approach to health. The Report of the National Primary Health Care Strategy supports health literacy as a part of improving patient-centred practice and calls for readable consumer friendly information to be easily accessible. In South Australia an alliance of organizations to foster health literacy is in the early stage of development.

Compared with Canada and the US, Australia’s health policy and practice community appears to have recently raised awareness of health literacy but work on consensus building about the nature of the problem and a strategic agenda to drive investigation and development has not been well articulated or well fostered across peak organizations or governments to this time; either in terms of a coherent practice development agenda or an applied research agenda. There are overlaps with chronic disease self-management strategies and mental health literacy initiatives, which warrant further articulation.

INITIATIVES AT THE PRACTICE LEVEL

This review has identified a range of initiatives that have relevance and potential applicability to the primary health care setting. These interventions have focused on a wide and varied selection of health problems and patient groups. While many are directed at the patient, others are directed at health care providers. The diversity of the studies is both a strength and a weakness. As a strength, the studies offer general guidance and some principles for improving health literacy. As a weakness, isolated studies that take many different approaches and are highly context-specific mean there is little critical mass around any particular approach making it difficult to draw firm conclusions about the effectiveness of individual intervention strategies.
A small number of high quality studies help to inform health literacy practice interventions. The findings of these studies suggest reasonable evidence for increases in intermediate outcomes, such as knowledge, but mixed or limited evidence for changes in health behaviour or health outcomes. Self-reported outcomes generally show more positive results than objective biometric markers or other clinical indicators. Overall, there is reason to expect that interventions that reduce the complexity of service delivery, improve written materials, draw on alternative formats, and enhance patient-provider partnerships may be beneficial. Raising awareness among health practitioners that a large proportion of their patients will have low health literacy and that this will limit the effectiveness of the services they deliver is arguably a vital first step.

The assessment of health literacy in the practice setting

There is little or no evidence for the benefits of screening for low health literacy in clinical settings. Although calls for the introduction of screening to identify patients with low health literacy are quite common in the literature, sound evidence to support such a recommendation is difficult to find. Current tests of health literacy (TOFHLA; REALM) are primarily research tools and are largely untested for clinical application. Further, both of these tests are measures of literacy ability using health content rather than measures of healthcare management and health system navigation. Of particular concern is the potential for harm as a result of health literacy screening given the high level of stigma and shame likely to be experienced by those with poor literacy. Moreover, it is uncertain whether effective intervention strategies are readily available while information on the skill levels of health practitioners in relation to the management of low health literacy does not exist. This raises further concerns about the merit and rationale for screening to identify people with low health literacy. Based on estimates that approximately half the population have limited health literacy, universal clinical practices designed to reduce literacy burden for all may offer a more efficient, effective and equitable approach. A separate but related issue is the clear need for new measures of health literacy to assess healthcare management and system navigation.

The improvement of print-based materials

There is evidence that print-based patient handouts improve some outcomes, including adherence with treatment, attendance for screening tests and patient initiated discussion about health issues. Appropriately designed illustrations and diagrams, alone or in combination with written words, can enhance understanding. The success of print-based materials depends on their design characteristics and the use of “plain language”. Written information for patients is usually found to require a level of reading ability above that of the average consumer. Developing appropriate and effective materials involves much more than re-writing health information in simple terms to achieve a particular readability level. It is a highly skilled task for which many health practitioners are unlikely to be prepared. A well established evidence base, drawing on the field of adult education, exists to guide the development of written materials that are engaging, accessible and understandable to people across the spectrum of health literacies. Developing new, and improving existing, print-based materials requires careful attention to this growing body of work as well as to the establishment of partnerships so as to draw on the expertise of professionals in this field.

The use of multi-media

There is reasonable evidence that non-written modalities are more beneficial for people with lower literacy levels and are acceptable to those with adequate literacy. For people with low literacy, written materials may impose an immediate cognitive and affective barrier to accessing the information they contain. Multi-media such as video and technology platforms can promote more accessible communication compared with written materials, especially among those who use mediums other than the written word to stay informed and connected in everyday life. As above, careful attention needs to be given to design issues and available evidence-based
guidelines for the development of multi-media materials. Rapid developments in technology and social networking sites offer many as yet unexplored opportunities for innovation.

The inclusion and enhancement of interpersonal communication

There is sound evidence that interpersonal communication plays an important role in health literacy interventions. An interpersonal component either in combination with written and multi-media platforms or alone is shown to improve understanding especially among those with lower literacy and may help support behaviour change, attendance at preventive services and medication adherence. Verbal instruction, coaching, and strategies such as the “teach back” method have to varying degrees been shown to enhance outcomes among people with lower health literacy. Tailored telephoning and case management approaches are among other strategies in this category. The principles of plain language also apply to the delivery by spoken word of information in the health service setting.

The impact of mentors and educators

Some evidence suggests that benefits might be achieved through partnering between primary health care services and other community based resources. The appointment of personal mentors, educators and health system navigators can improve health-promoting behaviours among those with low literacy. For members of vulnerable groups, such strategies (e.g., bilingual educators) warrant closer attention. Trained community leaders and group-based approaches also hold promise. The number of studies evaluating these strategies is small and evidence for different strategies is sparse. Some existing initiatives, such as chronic disease self-management programs, might have the potential to deliver benefits but further evidence on their impacts with regard to health literacy outcomes is needed.

STRATEGIC INITIATIVES AND COMPREHENSIVE POLICY

The impacts of strategic initiatives in health literacy at the system level have not been systematically evaluated in the published literature. Recommendations for action in other countries have been suggested on the basis of epidemiological information about the extent of low health literacy, the need for professional skills training to build capacity in the health care workforce and the role of a more empowered consumer in health care.6, 77-79

The capacity for health literacy strategy building and comprehensive policy in the Australian primary health care system will require a shift from isolated awareness raising initiatives to better coordinated consensus building about the development agenda as a next step. Given the limited research evidence base at present, especially in econometric modelling, in accessible and valid health literacy practice assessment tools and in intervention trials, an applied research agenda would need to be part of this development approach. The lack of a coordinated practice and research response at the national level is a clear barrier to progress in Australia at this time.

Health literacy advancement in a primary health care system that seeks to foster a shared responsibility for health would need to build strategic initiatives around four foci:

First, a focus on the health literacy skills and abilities of consumers who use the primary health care system.

Second, a focus on primary health care services so these are easier to use and have less literacy burden for consumers.

Third, initiatives that better risk manage those with low literacy and low health literacy so there is greater equity of access and health outcomes.

Fourth, initiatives that directly build health literacy assets across specific health conditions so consumers have better opportunities to promote, prevent, maintain their health and navigate the health system.
A focus on consumer skills and abilities

The need for consumers to acquire better health literacy to engage in self-management and more equitable interaction with health care is clear and the demand for better health literacy is supported by peak Australian consumer organizations. Responsibility for the delivery of initiatives to improve health literacy and the range and level of consumer competencies sought is less well articulated.

Improving general literacy is usually the responsibility of the education sector and in particular the schools sector. It is well established that general literacy education enhances life-long learning, self and community knowledge and helps support resilience.6, 77 To the extent that health literacy is based on general literacy skills, health literacy levels are likely to improve if general literacy advances. The same principle applies to the basis of health literacy in general numeracy skills.80 For this reason, at least part of the responsibility for health literacy over the longer term rests in school-based education. However, the rapidly changing nature of both health knowledge and the primary care system strongly suggest that this is an insufficient policy response for two reasons. First, health literacy is an issue for current adult health consumers. Second, the content and context specific nature of health literacies, for example in chronic disease, during pregnancy and so forth, rests in the health domain and is often needed at specific points in the life course, for specific health conditions and is appropriately sought in combination with clinical interventions. The primary care context is a key site for the delivery of health literacy education to consumers and the content is at least in part specific to condition and intervention goals.

The development of health literacy initiatives would need to be sensitive to cultures and the needs of specific Australian populations both in content and in delivery approach. Partnering with Aboriginal and Torres Strait Islander groups and those from non-English speaking backgrounds should enhance the relevance of health literacy content and this approach has been beneficial among similar groups in Canada.6, 77

A focus on the health system

The skills and abilities required of consumers depend in large part on the demands of the health system. Increasingly complex interventions and networks of medical and allied health services in primary health care have emerged to serve health consumers better than in the past. However, emerging complexities pose challenges for enhancing consumer self-reliance and system navigation. For these reasons health literacy is not only a consumer issue but also a health system performance concern. At least two issues related to health literacy impact on health system complexity; health system navigation and the nexus between patient-centred and evidence-based practice.

Calls to streamline, simplify and standardise health systems and services stem from population and clinical survey data suggesting that most health consumers have difficulty in independently navigating the health system for their own health benefit. Quality intervention studies about system navigation were not found in this systematic review although pathway models have been suggested.13 In any case, initiatives to address structural barriers to health system access lie beyond the scope of the health literacy field. However, health literacy data suggests system changes need consideration. A key difference between the provision of simple access and system coordination (around complex chronic disease, for example) discussed in the general literature on health systems reform and the health literacy approach is the addition of perspectives that encourage consumer self reliance and decision making. There is room for an innovative development agenda in the area.

A second issue of complexity related to health literacy is the inclusion of evidence-based practice into patient-centred approaches. The links between rapid acceptance in evidence-based practice and the continued desire for a patient-centred approach poses under-investigated challenges about the role of an empowered consumer at the interface of these two dominant practice values. Consumers have had a role in the understanding of research evidence under the Cochrane Collaboration for many years but the involvement of consumers beyond the role of passive receivers of evidence-based interventions is not well developed. A
shared responsibility approach to primary care delivery suggests developments in this area could prove to be productive.

**Initiatives in risk management**

It is evident from the epidemiological data that there is a significant population with limited literacy skills and basic health literacy abilities. Further, cross sectional studies show a clear relationship between low literacy and health literacy and a range of health outcomes. Much of the better quality studies address how improvements could be made in interpersonal, written and multi-media platforms at the practice level.

A system wide concern is therefore the promotion of more productive interactions between practitioners and consumers. How to assure certainty about comprehension among consumers with low literacy and health literacy is therefore a system wide strategic issue; whether the medium for this is materials used in interventions or consumer-practitioner consultations. Quality assured materials and demonstrations of practitioner communication competencies require the development of standards and auditing processes. Quality assurance systems have been discussed as drivers for improvements in the health systems of other countries but these mechanisms do not appear to have been developed or applied to this time. Were quality assured systems to develop, the range of topics could productively cover the use of technology platforms, including video materials, as well as written materials and interpersonal communication.

**Initiatives in asset building**

An asset building focus moves beyond a remedial risk management approach to recognize that shared responsibility in primary health care needs a better informed and resilient consumer. While risk management may address comprehension assurance, asset building addresses the skill and abilities it would be desirable for every citizen to acquire so they may manage their health and engage in prevention and promotion activities. Development of such an agenda lies to some extent beyond the scope of a primary health care system. Even so, primary health care system performance is likely to depend upon the health literacy skills and abilities of the population it strives to serve.

Within primary health care systems health and disease information is commonly developed for specific conditions (diabetes, asthma, mental illness and so forth). There would appear to be considerable benefits in applying health literacy concepts to the development of these materials and processes. Such an addition may help to assure better equality of access and health outcomes.

**CONCLUSION**

This report aimed to conduct a systematic review on health literacy and to consider its policy relevance to the Australian primary care system. The limited attention to health literacy in this system is a gap in the system’s advancement. Health literacy will become increasingly significant as the system changes, grows in complexity and seeks to engage with an informed and resilient population. The systematic review in this report was restricted to studies that directly address health literacy as it has become defined in the literature. It is recognized that several related fields also inform system level performance. Among these are the literature on health practitioner communication and the literature on the impacts of health and medical practitioner training and education. Drawing synergies between these fields and health literacy will enhance further our understanding of the scope of the field.
REFERENCES


6. Rootman I, Ronson B. Literacy and health research in Canada: where have we been and where should we go? Can J Public Health. 2005 Mar-Apr;96 Suppl 2:S62-77.


**APPENDIX 1:**

**Table 2. Characteristics of Original Research and Results for Main Outcomes - Experimental and Quasi Experimental Studies**

<table>
<thead>
<tr>
<th>Reference, health issue, country of study</th>
<th>Study design, sample size</th>
<th>Population; Health Literacy</th>
<th>Intervention</th>
<th>Control</th>
<th>Primary outcome</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kripalani, Sharma, Justice et al 2007: prostate cancer screening: USA</td>
<td>RCT: N=250</td>
<td>Inner city, primarily (90.4%) African American male patients at a primary care clinic: HL assessed using REALM</td>
<td>Patient education handout (PtEd); Talk to doctor handout (Cue)</td>
<td>Control (food pyramid) handout</td>
<td>Patient-reported discussion of prostate cancer with physician; chart review to determine prostate specific antigen (PSA) test orders; performance of digital rectal examination (DRE)</td>
<td>Physician discussions significantly more common in the Cue group, and PtEd group; PSA test orders increased in the PtEd group and in the Cue group significantly more than in the control group; DRE did not change significantly</td>
</tr>
<tr>
<td>Seligman, Wang, Palacios et al 2005: Doctor-patient communication: USA</td>
<td>RCT: N=182 patients, 63 physicians</td>
<td>Diabetic patients at primary care clinic: HL assessed using TOFHLA</td>
<td>Affixed notice indicating patient level of HL to patient chart for intervention physicians</td>
<td>No notice on chart</td>
<td>Physician reported management strategies, satisfaction, perceived effectiveness, and attitudes toward HL screening: patients’ self-efficacy, feelings regarding HL screening’s usefulness, and glycemic control</td>
<td>Intervention physicians more likely to use management strategies recommended for patients with limited HL: intervention physicians felt less satisfied with their visits. No difference in intervention and control patients’ positivist self-efficacy scores.</td>
</tr>
<tr>
<td>Volk, Jibaja-Weiss, Hawley et al 2008: prostate cancer screening: USA</td>
<td>RCT: N=450</td>
<td>Older males, non-acute clinic visit: HL not assessed, assigned on basis of clinic location/clientele</td>
<td>Edutainment decision aid</td>
<td>Audiobook</td>
<td>Knowledge of prostate cancer and screening</td>
<td>Stated as significant (test results not shown); however, controls also had significant improvement</td>
</tr>
<tr>
<td>Goldney and Fisher, 2008: Mental health: Australia</td>
<td>Pre-Post: N=3015</td>
<td>sociodemographic characteristics</td>
<td>Community and professional education programs</td>
<td>none</td>
<td>Mental health literacy, i.e., problem recognition; choices of help</td>
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<tr>
<td>Random sample of population of South Australia, 1998 &amp; 2004: HL assessed using depression vignette</td>
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<td>Problem recognition significantly improved in No mental illness group, and both Depressed groups (with and without suicidal ideation), all p&lt;0.001; no improvement in choices for help in depressed with suicidal ideation group, sporadic improvements in choices for help in other two groups</td>
<td></td>
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</tbody>
</table>
## APPENDIX 2:

### Table 3. Characteristics of Original Research and Results for Main Outcomes - Non-Experimental studies

<table>
<thead>
<tr>
<th>Reference, health issue, country of study</th>
<th>Study design, sample size</th>
<th>Population, literacy</th>
<th>Treatment variables</th>
<th>Primary outcome</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td>Baker, Gazmararian, Sudano et al 2002: No specific health issue: USA</td>
<td>Cohort: N=2787</td>
<td>Medicare enrolled retirees, &gt;65 years old, mostly (84.1%) white: HL assessed using TOFHLA</td>
<td>MMSE</td>
<td>Health literacy</td>
<td>HL linearly related to MMSE total score (R^2=0.39, p&lt;0.001); HL related to each of 14 MMSE items (R = 0.09-0.38) for individual items, all (p&lt;0.001)</td>
</tr>
<tr>
<td>Baker, Gazmararian, Sudano et al 2000: No specific health issue: USA</td>
<td>Cohort: N=2774</td>
<td>Medicare enrolled retirees &gt;65 years old: HL assessed using TOFHLA</td>
<td>Age, MMSE, Reading the newspaper</td>
<td>Health literacy</td>
<td>HL linearly related to age (\beta=1.4, p&lt;0.001): Adjusting for sex, race, ethnicity, education, reading frequency, visual acuity, chronic medical conditions, health status, &amp; performance on the MMSE, HL still related to age (\beta=0.9, p&lt;0.001)</td>
</tr>
<tr>
<td>Brown, Teufel and Birch, 2007: No specific health issue: USA</td>
<td>Cross-sectional: N=1178</td>
<td>9-13 year old children taking health education classes: HL assessed using a study specific measure</td>
<td>Gender, age, personal belief, personal behaviour</td>
<td>Interest in learning about health, desire to follow what is taught</td>
<td>Age, difficulty understanding health information, belief that kids can do little to affect their future health, decreased likelihood for interest in learning about health (p&lt;0.05); same variables plus lack of interest in health significantly predicted lack of desire to follow what was taught about health (p&lt;0.05)</td>
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<tr>
<td>Gazmararian, Baker, Williams et al 1999: No specific health issue: USA</td>
<td>Cross-sectional: N=3260</td>
<td>Medicare enrolled retirees &gt;65 years old: HL assessed using TOFHLA</td>
<td>Race/language, gender, age, education, income, occupation, self-reported general health status, number of medications taken per day, presence of at least 1 target chronic condition, &amp;</td>
<td>Health literacy</td>
<td>Study location, race/language, age, years of school completed, occupation, &amp; cognitive impairment significantly, independently associated with inadequate or marginal HL (p&lt;0.001); gender, number of medications, &amp; chronic conditions not significantly related to HL</td>
</tr>
<tr>
<td>Study</td>
<td>Design</td>
<td>Sample Characteristics</td>
<td>Health Literacy Measures</td>
<td>Cognitive Abilities Mediators</td>
<td>Other Variables</td>
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<tr>
<td>Levinthal, Morrow, Tu et al 2008:</td>
<td>Cross-sectional</td>
<td>Primarily female (73%), African-American (68%), community-dwelling adults:</td>
<td>Health literacy</td>
<td>Cognitive impairment, age &amp; education, with cognitive &amp; sensory abilities as mediators</td>
<td>Gender, ethnicity, speech discrimination (p&lt;0.01), education, letter and pattern comparison, &amp; listening span (p&lt;0.001) independently predict HL; age, comorbidities, &amp; visual function not independent predictors</td>
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<tr>
<td>Hypertension: USA</td>
<td>N=492</td>
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<tr>
<td>Marie, Forsyth and Miles, 2004:</td>
<td>Cross-sectional</td>
<td>Random sample from Maori and non-Maori electoral rolls:</td>
<td>Ethnicity</td>
<td>Mental health literacy</td>
<td>No significant difference between Maori and non-Maori respondents on recognition of depression, or on perceived prognosis; both groups very highly correlated on responses to questions on: effects of depression on wellbeing, attributions of causes of depression, perceptions of treatment efficacy (all p&lt;0.001)</td>
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<tr>
<td>No specific health issue:</td>
<td>N=205</td>
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<td>New Zealand</td>
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<td>Rudd, Kirsch and Yamamoto, 2004:</td>
<td>Cross-sectional</td>
<td>Representative national sample (1992):</td>
<td>Age, gender, education, country of birth, ethnicity, wealth, health status, reading engagement, civic engagement</td>
<td>Health literacy</td>
<td>No significant difference in (unadjusted) HALS score for gender; significant differences in (unadjusted) HALS score across education level, by country of birth, ethnicity, age, wealth class, health status group, type of reading engagement, &amp; type of civic engagement (significance stated, tests not given)</td>
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<tr>
<td>No specific health issue:</td>
<td>N=26,091</td>
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<td>USA</td>
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<td>Hester, 2009:</td>
<td>Cross-sectional</td>
<td>Older (63-95 years), community dwelling volunteers:</td>
<td>Social communication</td>
<td>Health literacy</td>
<td>Item level analyses, non-significant relationships not reported; 17 significant correlations between HL test items and Social Communication (SC) test items (r ranged from 0.26-0.39, 4 significant at p&lt;0.01, remaining p&lt;0.05); 3 HL items predicted by one of 2 SC items</td>
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<td>No specific health issue:</td>
<td>N=65</td>
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<td>USA</td>
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<tr>
<td>Kaneko and Motohashi, 2007:</td>
<td>Cross-sectional</td>
<td>Community survey in two rural towns with high suicide rates:</td>
<td>Mental health literacy, i.e., problem recognition; choices of treatment, attitude to suicide</td>
<td>Sociodemographic variables including, age, gender, education, &amp; occupation; depression severity</td>
<td>Poor problem recognition was associated with being male (AOR=1.93, 95% CI 1.68-2.22), being older (AOR=2.18, 95% CI 1.58-3.00), &amp; less education (AOR=1.95, 95% CI 1.34-2.86); poor treatment choices were associated with being male (AOR=2.18, 95% CI 1.82-2.61), less education (AOR=2.34, 95% CI 1.38-3.97), and more severe depression classification (AOR=2.26, 95% CI 1.54-2.61); acceptance of</td>
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<tr>
<td>Mental health:</td>
<td>N=7202</td>
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<td>Japan</td>
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<td>Study Details</td>
<td>Design</td>
<td>Sample Size</td>
<td>Health Literacy</td>
<td>Health Literacy Variables</td>
<td>Findings</td>
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<tr>
<td>Kutner, Greenburg, Jin et al 2006:</td>
<td>Cross-sectional: N=19,714</td>
<td>Nationally representative sample (2003): HL assessed using NAAL HL</td>
<td>Gender, education, language spoken before school, ethnicity, age, wealth, self-assessed health status, health insurance, &amp; health information sources</td>
<td>Health literacy</td>
<td>suicide was associated with being male (AOR=1.33, 95% CI 1.13-1.58) and a more severe depression classification (AOR=5.77, 95% CI 4.20-7.93)</td>
</tr>
<tr>
<td>Leyva, Sharif and Ozuah, 2005:</td>
<td>Cross-sectional: N=100 parents</td>
<td>Parents of children attending a paediatric care clinic, mostly poor population: HL assessed using a study specific protocol</td>
<td>Demographic variables including age, gender, birthplace, years in US, comfort with English, &amp; education</td>
<td>Drug information sheet comprehension</td>
<td>HL significantly higher for women, at least high school education, English only spoken at home, white or Asian ethnicity, younger age, income above 175% of the poverty line, each successive level of health, &amp; employer provided health insurance (all p&lt;0.05); below basic HL least likely to use internet or written material for health information, &amp; proficient HL least likely to use television or radio for health information</td>
</tr>
<tr>
<td>von Wagner, Knight, Steptoe et al 2007:</td>
<td>Cross-sectional: N=719</td>
<td>Random population sample across UK: HL assessed using TOFHLA</td>
<td>Sociodemographic variables, including age, gender, ethnicity, English as first language, education, &amp; income; also health behaviours</td>
<td>Health literacy</td>
<td>In regression analysis with sociodemographic variables, only age (p&lt;0.001), gender (p&lt;0.05), less than GCSE education (p&lt;0.001), and low income (p&lt;0.01) predict HL; controlling for demographic variables above eating fruit and vegetables (p=0.016), not smoking (p=0.046), and self-reported health (p=0.011) significantly associated with HL; exercise not significantly related.</td>
</tr>
<tr>
<td>Zahnd, Scaife and Francis, 2009:</td>
<td>Cross-sectional: N=3,850 rural &amp; 14,260 urban</td>
<td>Nationally representative sample (2003): HL assessed using NAAL HL</td>
<td>Rural or urban residence</td>
<td>Health literacy</td>
<td>HL proficiency significantly associated with living in urban area rather than rural area, as are prose literacy proficiency, document literacy proficiency, &amp; quantitative literacy (all p&lt;0.001); controlling for age, gender, ethnicity, education, &amp; income, HL and prose literacy no longer associated with rural vs. urban residence; document literacy and quantitative literacy</td>
</tr>
</tbody>
</table>
Studies of health literacy as a risk factor

<table>
<thead>
<tr>
<th>Study Reference</th>
<th>Cohort</th>
<th>Health Literacy Measure</th>
<th>Mortality Measure</th>
<th>Risk Factor Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baker, Wolf, Feinglass et al 2008</td>
<td>Medicare enrolled retirees: N=3191</td>
<td>Health literacy, MMSE measured cognitive functioning</td>
<td>Mortality</td>
<td>All models adjusted for baseline characteristics: age, sex, race, language, income, education, physical functioning, mental health, number of chronic diseases, activities of daily living impairments, &amp; study site: Inadequate HL at significantly greater mortality risk than adequate HL (Adjusted Hazard Ratio 1.50); MMSE delayed recall &amp; ability to serial subtract numbers also associated with higher mortality (multiple significant AHRs); Analysis with both HL &amp; MMSE cognition, AHRs for cognition items remained similar, while AHR for inadequate HL decreased to 1.27 (95% CI 1.03 – 1.57) – but remained significant</td>
</tr>
<tr>
<td>Baker, Wolf, Feinglass et al 2007</td>
<td>Medicare enrolled retirees &gt;65 years old: N=3344</td>
<td>Health literacy; sociodemographic variables, including age, gender, race, income, education, physical health, mental health, activities of daily living; plus lifestyle variables, smoking, alcohol, physical activity, BMI</td>
<td>All cause and cause specific mortality</td>
<td>Crude mortality rates higher for inadequate HL (P &lt; 0.001); Adjusting for sociodemographic variables and baseline health, the hazard ratios for all-cause mortality were 1.52 and 1.13 for inadequate and marginal HL respectively, compared with adequate HL; participants with inadequate HL had higher risk-adjusted rates of cardiovascular death but not of death due to cancer</td>
</tr>
<tr>
<td>Baker, Parker, Williams et al 1998</td>
<td>Patients attending ED at large urban public hospital; mostly (93%) African American, mostly (56%) on public assistance: N=958</td>
<td>Health literacy</td>
<td>Hospitalisation</td>
<td>Inadequate HL patients twice as likely to be hospitalised in 2 year study period (p&lt;0.001); Adjusting for age, gender, ethnicity, self-reported health, socioeconomic status, and health insurance, inadequate HL patients still more likely to be hospitalised (adjusted odds ratio = 1.69, 95% CI 1.13-2.53); association</td>
</tr>
<tr>
<td>Author(s)</td>
<td>Cohort:</td>
<td>HL assessed using</td>
<td>Health literacy</td>
<td>Medical care use, &amp; health costs</td>
</tr>
</tbody>
</table>
|-----------------------------------|---------|-------------------|----------------|---------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------
| Howard, Gazmararian and Parker, 2005: | Medicare enrolled | Medicare enrolled | Health literacy | Medical care use, & health costs | USA Cohort: N=2360 Medicare enrolled retirees: HL assessed using TOFHLA Adjusting for age, gender, ethnicity, income, education, alcohol & tobacco use, & comorbidities: Inadequate HL patient (estimated) costs higher than Adequate HL for inpatient & emergency room costs (both p<0.05) but not for overall, outpatient or pharmacy costs. |
| Howard, Sentell and Gazmararian, 2006: | Medicare enrolled | Medicare enrolled | Health literacy | Medical care use, & health costs | USA Cohort: N=3260 Medicare enrolled retirees: HL assessed using TOFHLA Adjusting for ethnicity, income, age, gender, chronic health conditions, & smoking: having high school education resulted in better physical & mental health (p=0.013 and 0.004), & better self-reported health status (p<0.001) than not having high school education. Education was not associated with vaccination. Adding health literacy significantly reduced differences in self-reported health and health status by 22% to 41%. Self-reported health status & influenza and pneumococcal vaccination rates lower for African Americans (p=0.012, & p<0.001 respectively). Accounting for HL significantly reduced difference in self-reported health by 25% but did not affect differences in vaccination rates. |
| Lincoln, Paasche-Orlow, Cheng et al 2006: | Patients in a detox centre for alcohol, heroin and cocaine abuse: | Patients in a detox centre for alcohol, heroin and cocaine abuse: | Health literacy | Medical care use, & health costs | USA Cohort: N=380 Patients in a detox centre for alcohol, heroin and cocaine abuse: HL assessed using REALM Adjusting for time, gender, age, ethnicity, education, income, primary language, primary substance of choice, randomization group, mini-mental status examination, & baseline measure of outcome variable: HL not significantly related to drug or alcohol addiction severity, or to self-reported mental health functioning; but significantly worse depression over time for lower HL patients. |
| Lindau, Basu and Leitsch, 2006:     | Women patients at ambulatory primary | Women patients at ambulatory primary | Health literacy | Medical care use, & health costs | USA Cohort: N=68 Women patients at ambulatory primary Adherence to follow-up Adjusting for recommended days to follow-up age, HIV status, cancer, ethnicity, |
### Cervical cancer: USA
- Care & HIV ob/gyn clinics
- HL assessed using REALM & physician subjective assessment
- Recommendations after an abnormal Pap smear
- Unemployment, & insurance: Subjective low HL patients significantly less likely to follow up within 1 year (adjusted OR=14, 95% CI: 3 to 65). Less than high school education (hazard ratio (HR)=2.3; 95% CI: 1.2, 4.6) and low subjective HL (HR=3.4, 95% CI: 1.4, 8.2), but not REALM HL, significant predictors of duration of time to follow-up

#### Moon, Cheng, Patel et al 1998:
- No specific health issue: USA
- Cohort: N=543 families
- Parents accompanying children on acute care visits to two hospital ambulatory care centres or three suburban practices:
- HL assessed using REALM
- Health literacy
- Recall of child’s diagnosis, & medication prescribed
- Low REALM score was significantly correlated with young parental age, ethnicity, education & occupation (all p<0.0001); recall of child’s diagnosis, name, instruction for use, and purpose of medication not significantly associated with HL

#### Paasche-Orlow, Cheng, Palepu et al 2006:
- HIV, alcohol problems: USA
- Cohort: N=235
- Patients attending a number of clinics, a respite facility, answering posted flyers and referred by other participants in the Boston area:
- HL assessed using REALM
- Health literacy
- ART adherence & viral load suppression
- Unadjusted analyses, low HL participants had higher odds of adherence (odds ratio [OR] 2.23, 95% CI 1.15 to 4.30) and HIV-RNA suppression (OR 2.01, 95% CI 1.03 to 3.90) than those with higher HL: When adjusting for gender, age, education, randomization group, ethnicity, homeless status, drinking to intoxication in the past 30 days, injected drugs in the past 6 months; with or without complexity of regimen, results no longer significant

#### Sudore, Mehta, Simonsick et al 2006:
- No specific health issue: USA
- Cohort: N=2512
- Well functioning Medicare-eligible men & women aged 70-79 at two hospital clinics:
- HL assessed using REALM
- Health literacy
- Healthcare access (regular doctor, flu shot, health insurance)
- Adjusting for age, ethnicity, gender, study site, income, self-rated health, & comorbidities; healthcare access (composite score) significantly associated with low HL (OR 1.95, 95% CI 1.33-2.85), also flu shot (OR 1.70, 95% CI 1.20-2.41), & health insurance (OR 1.73, 95% CI 1.23-2.43) individually – regular doctor not significant; same results significant when also adjusting for education – e.g., composite access score OR 1.55 (95% CI 1.03-2.34)
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample Description</th>
<th>Outcomes</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cho, Lee, Arozullah et al 2008:</td>
<td>Cross-sectional: N=489</td>
<td>Medicare enrolled patients, &gt;65 years old: HL assessed using TOFHLA</td>
<td>Health literacy, disease knowledge, health behaviour, preventive care, medication compliance</td>
<td>Controlling for ethnicity, education, and gender: HL significantly correlated with all variables in the model, including control variables, covariates, and outcome variables (p&lt;0.05); HL was directly related to health status, hospitalisation and ER use (β=0.48, -0.08, -0.10; p&lt;0.05) and did not influence the outcome variables through disease knowledge, health behaviour, preventive care and medication adherence as expected; HL did have strong, independent relationships with disease knowledge (β=0.61) and preventive care (β=0.42; both p&lt;0.05)</td>
</tr>
<tr>
<td>Gazmararian, Williams, Peel et al 2003:</td>
<td>Cross-sectional: N=653</td>
<td>Medicare enrolled retirees, &gt;65 years old, with asthma, diabetes, congestive heart failure, and/or hypertension: HL assessed using TOFHLA</td>
<td>Health literacy, Knowledge of chronic disease</td>
<td>Adjusting for age, disease duration, and prior attendance at class to learn about the chronic disease HL significantly predicted chronic disease knowledge for asthma, diabetes, and hypertension (p&lt;0.001), and chronic heart failure (p=0.003)</td>
</tr>
<tr>
<td>Schillinger, Grumbach, Piette et al 2002:</td>
<td>Cross-sectional: N=408</td>
<td>Patients over 30 years of age, at 2 primary care clinics, who had type 2 diabetes: HL assessed using TOFHLA</td>
<td>Health literacy, Glycemic control</td>
<td>Controlling for age, ethnicity, gender, education, language, insurance, depression, social support, diabetes education, treatment regimen &amp; years with diabetes: HL predicts glycemic control (β=0.02, p=0.02); inadequate HL associated with less tight glycemic control (p=0.05); more poor glycemic control (p=0.02); &amp; more retinopathy (p=0.01); HL not associated with neuropathy, amputation, cerebrovascular disease or cardiovascular disease</td>
</tr>
<tr>
<td>Barragan, Hicks, Williams et al 2005:</td>
<td>Cross-sectional: N=372</td>
<td>Inner city hospital serving an indigent population: HL assessed using REALM</td>
<td>Health literacy, HIV test acceptance</td>
<td>Adjusted for age and education, HL significantly associated with HIV test acceptance (OR 2.017, 95% CI 1.19-3.42)</td>
</tr>
<tr>
<td>Brewer, Tzeng, Lillie</td>
<td>Cross-sectional:</td>
<td>Breast cancer</td>
<td>Health literacy, Meaning</td>
<td>Women with lower HL gave higher mean</td>
</tr>
</tbody>
</table>
et al 2008: Breast cancer: USA
N=163 survivors at a university breast cancer clinic: HL assessed using REALM
assigned to, and understanding of recurrence risks produced by genomic tests estimates of recurrence risk than women with higher HL (52% v. 30%, p<0.001); women with higher HL more sensitive to recurrence risk when making chemotherapy decisions than women with lower HL (interaction, F_{1,154}=5.86, p=0.02); women with lower HL did not find any risk format easier to understand than another (F_{5,150}=1.74, p=0.13); women with higher HL found some formats easier to understand (F_{5,610}=20.74, p<0.001)

Davis, Wolf, Bass et al 2006: No specific health issue: USA
Cross-sectional: N=395 3 primary care clinics serving mostly indigent populations: HL assessed using REALM
Understanding 5 medication label instructions; demonstrating a dosage instruction
Low HL patients less able to understand all 5 label instructions (p<0.001 for 3 labels, ns difference for 2 labels); in multivariate analysis, low HL the only significant independent predictor of correct demonstration of label instructions (adjusted relative risk (ARR), 3.02 [CI, 1.70 to 4.89]); controlling for potential confounding variables, low (ARR, 2.32 [95% CI, 1.26 to 4.28]) and marginal (ARR, 1.94 [CI, 1.14 to 3.27]) literacy significantly associated with misunderstanding; taking greater number of prescription medications also significantly associated with misunderstanding (ARR, 2.98 [CI, 1.40 to 6.34] for 5 medications)

Davis, Federman, Bass et al 2009: No specific health issue: USA
Cross-sectional: N=359 Adult patients at one of 3 outpatient, primary care clinics HL assessed using REALM
Misinterpreting medication label instructions
Adjusting for study site, age, gender, ethnicity, education, number of medications taken, frequency of use, & dose complexity; low and marginal HL significant independent predictors of misinterpreting instructions (low - adjusted relative risk (ARR)2.70, 95% CI 1.81–4.03; marginal -ARR 1.66, 95% CI 1.18–2.32)

Davis, Wolf, Bass et al 2006: No specific health issue: USA
Cross-sectional: N=251 Adults attending a public hospital primary care clinic: HL assessed using REALM
Interpretation of prescription medication warning labels
Controlling for age, ethnicity, gender, number of medications taken, & reading level; low HL patients less likely to interpret prescription medication warning labels correctly (AOR 3.4, 95% CI, 2.3 to 4.9)

Fang, Machtinger, Cross-sectional: Patients from an AT Prescription therapy
Health literacy
Adjusting for age, gender, ethnicity, education,
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Participants</th>
<th>Health Literacy Measures</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wang et al 2006: Anticoagulation therapy</td>
<td>Cross-sectional</td>
<td>N=179 anticoagulation clinic taking warfarin</td>
<td>Health literacy, adherence, time in therapeutic range</td>
<td>Limited HL associated with incorrect answers to questions on warfarin's mechanism (adjusted odds ratio [OR] 4.8, 95% CI 1.3 to 17.6), side-effects (OR 6.4, 95% CI 2.3 to 18.0), medication interactions (OR 2.5, 95% CI 1.1 to 5.5), and frequency of monitoring (OR 2.7, 95% CI 1.1 to 6.7); limited HL not significantly associated with non-adherence (OR 0.9, 95% CI 0.4 to 2.0) nor with the proportion of person-time in therapeutic range (OR 1.0, 95% CI 0.7 to 1.4)</td>
</tr>
<tr>
<td>Gordon and Wolf, 2009: Kidney transplant</td>
<td>Cross-sectional</td>
<td>N=124 Adults at a medical centre currently taking immunosuppressants, predominantly white:</td>
<td>Health literacy, transplant knowledge, graft function</td>
<td>Study did not assess relationship between HL and transplant knowledge – assessed each separately; controlling for age, gender, ethnicity, education, income, employment, time since transplant, donor source, &amp; number of transplants, REALM assessed HL significantly predicted graft function indicated by serum creatinine level (p=0.03), but not when HL assessed by TOFHLA; neither measure of HL predicted graft function indicated by glomerular filtration rate</td>
</tr>
<tr>
<td>Graham, Bennett, Holmes et al 2007: HIV infection</td>
<td>Cross-sectional</td>
<td>N=87 Adults at a university HIV clinic, characterised by social disadvantage:</td>
<td>Health literacy, with HIV medication beliefs as mediating variables</td>
<td>Controlling for age, race, history of drug and alcohol use, cognitive function, education, income, insurance type, social supports, current HIV viral loads, CD4 counts &amp; prior and current psychiatric diagnoses, adherence higher for participants with higher HL, $\chi^2=5.06$, df, 1, $p&lt;0.05$; no significant mediation of HL-adherence relationship (OR 2.38, CI 0.98-5.79) by medication beliefs – but relationship becomes marginally significant</td>
</tr>
<tr>
<td>Juzych, Randhawa, Shukairy et al 2008: Glaucoma</td>
<td>Cross-sectional</td>
<td>N=204 Adult patients at a university eye clinic for more than a year:</td>
<td>Health literacy</td>
<td>Poor HL patients missed significantly more appointments ($p&lt;0.001$); had significantly worse medication compliance ($p&lt;0.001$); had significantly worse glaucoma understanding (on 5 topics: all 5 $p&lt;0.001$); showed greater visual</td>
</tr>
<tr>
<td>Study Details</td>
<td>Design</td>
<td>Sample Size</td>
<td>Health Literacy Measures</td>
<td>Findings</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
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</tr>
<tr>
<td>Kalichman and Rompa, 2000: HIV infection: USA</td>
<td>Cross-sectional</td>
<td>N=339</td>
<td>Health literacy</td>
<td>Health status, disease &amp; treatment knowledge, healthcare perceptions and experiences. Lower HL associated with: lower CD4 cell counts (p&lt;0.05), higher viral loads (p&lt;0.01), lower likelihood of taking antiretroviral medications (p&lt;0.05), greater number of hospitalizations (p&lt;0.05), &amp; poorer subjective health (p&lt;0.05); after adjusting for years of formal education, lower HL associated with poorer knowledge of HIV-related health status (p&lt;0.05), poorer AIDS-related disease &amp; treatment knowledge (p&lt;0.05), &amp; more negative health care perceptions and experiences (p&lt;0.05)</td>
</tr>
<tr>
<td>Kalichman, Ramachandran and Catz, 1999: HIV infection: USA</td>
<td>Cross-sectional</td>
<td>N=182</td>
<td>Health literacy</td>
<td>Self-reported medication adherence. Controlling for age, ethnicity, education, income, HIV symptoms, substance abuse, social support, emotional distress, &amp; attitudes to primary care providers; HL significantly predicted 2-day treatment adherence (p&lt;0.05); HL does not predict adherence for people with less than 12 years education; low HL associated with missing treatment due to confusion (p&lt;0.01), depression (p&lt;0.05), and wanting to cleanse body (p&lt;0.05), but not because of side effects (p&lt;0.06)</td>
</tr>
<tr>
<td>Kalichman, Pope, White et al 2008: HIV infection: USA</td>
<td>Cross-sectional</td>
<td>N=145</td>
<td>Health literacy</td>
<td>Objective measure of medication adherence. Adjusting for age, education, years since testing HIV positive, depression, internalised stigma, social support, &amp; alcohol use; lower HL associated with poorer medication adherence (OR 3.77, CI 1.46-9.93, p&lt;0.01)</td>
</tr>
<tr>
<td>Kalichman, Benotsch, Suarez et al 2000: HIV infection: USA</td>
<td>Cross-sectional</td>
<td>N=294</td>
<td>Health literacy</td>
<td>HIV knowledge &amp; understanding. Controlling for education; lower HL persons significantly less likely to have an undetectable HIV viral load (p&lt;0.05), &amp; significantly more likely to visit doctor at least monthly (p&lt;0.01); no significant difference in AIDS diagnosis, being</td>
</tr>
<tr>
<td>Study</td>
<td>Setting</td>
<td>Design</td>
<td>Sample Size</td>
<td>Measures</td>
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<tr>
<td>Osborn, Paasche-Orlow, Davis et al 2007: HIV infection: USA</td>
<td>Patients recruited at two outpatient infectious disease clinics: HL assessed using REALM</td>
<td>Race, with HL as mediator</td>
<td>Medication adherence</td>
<td>Patients with lower HL had misperceptions that anti-HIV treatments reduce risks for sexually transmitting HIV (OR 5.8, 95% CI 2.2-15.5); &amp; beliefs that anti-HIV treatments can relax safer-sex practices (OR 6.0, 95% CI 2.6-13.6); but had little relationship to treatment optimism.</td>
</tr>
<tr>
<td>Schillinger, Bindman, Wang et al 2004: Diabetes: USA</td>
<td>Ethnically diverse, low SES patients enrolled at two primary care clinics at a public hospital: HL assessed using TOFHLA</td>
<td>Health literacy</td>
<td>Interpersonal processes of care (IPC)</td>
<td>Inadequate HL associated with poor IPC on 5 of 7 subscales (p range from &lt;0.04-&lt;0.001); controlling for age, ethnicity, gender, education, language, insurance, treatment regiment, HbA1c, depression, diabetes duration, physician’s Spanish fluency, &amp; length of time in physician’s care IPC - no longer significantly predicted by HL – now explained by language and education, but general clarity, condition explanation, &amp; process of care explanation still significantly predicted by HL (p&lt;0.01, =0.03, &amp; =0.03 respectively)</td>
</tr>
<tr>
<td>Weiss, Reed and Kligman, 1995: No specific health issue: USA</td>
<td>Older (60-94 year old) residents in assisted living housing: Literacy assessed using Instrument for Diagnosis of Reading (IDL)</td>
<td>Literacy</td>
<td>Understanding medical information, sources of information</td>
<td>Low literacy associated with better understanding of medical information ($\chi^2 = 19.9$, p=0.0002); obtaining medical information from television, newspapers, radio or magazines not associated with literacy; controlling for age, gender, education &amp; occupation; low literacy is still associated with understanding medical information (relative risk = 0.38, 95% CI 0.17-0.85)</td>
</tr>
<tr>
<td>Wolf, Gazmararian</td>
<td>Cross-sectional: Older Medicare</td>
<td>Health literacy</td>
<td>Health risk</td>
<td>In univariate analyses HL associated with...</td>
</tr>
</tbody>
</table>
and Baker, 2007: Health risk behaviours: USA

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample Size</th>
<th>Sample Description</th>
<th>Health Literacy Assessment</th>
<th>Behaviours Assessed</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=2,923 enrolees at 4 sites across the country: HL assessed using TOFHLA</td>
<td>N=2,923</td>
<td></td>
<td></td>
<td>cigarette smoking (p=0.01), alcohol use (p&lt;0.001), and physical activity (p&lt;0.001), but not BMI; adjusting for age, gender, ethnicity, income, education &amp; occupation, renders HL no longer a significant predictor of any health behaviours</td>
<td></td>
</tr>
<tr>
<td>Wolf, Davis, Shrank et al 2007</td>
<td>Mixed-methods: Descriptive qualitative, and cross-sectional: N=395</td>
<td>Low income populations visiting primary care clinics: HL assessed using REALM</td>
<td>Health literacy Understanding dosage instructions, demonstrating dosage instructions</td>
<td>Lower HL associated with greater misunderstanding of dosage instructions (p&lt;0.001), and lower capacity to demonstrate dosage instructions correctly (p&lt;0.001)</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 3:
Quality Assessment Tool for Health Literacy Review Articles

**SCREENING QUESTIONS**

I. Is the research focused on Health Literacy research?
   - Yes ☐ Continue screening
   - No ☐ STOP NOW

II. Is the publication a review of Health Literacy literature?
    - Yes ☐ Continue with article appraisal
    - No ☐ STOP NOW

**TOPIC CATEGORISATION**

This review Includes/Focuses on Health Literacy in a Primary Health Care system context.
- Yes ☐ No ☐

This review Includes/Focuses on the policy context of Health Literacy.
- Yes ☐ No ☐

The dominant Health Literacy dimension of this review is:
- Social Determinants ☐ Services in the Community ☐ Neither ☐

The dominant Primary Health Care system dimension of this review is:
- Clinical level ☐ Population Level ☐ Neither ☐

**APPRAISAL QUESTIONS**

1. Was an “a priori” design provided?
   - The research question and inclusion criteria should be established before the conduct of the review.
   - Yes ☐ No ☐ Can’t answer ☐ Not applicable

2. Was there duplicate study selection and data extraction?
   - There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.
   - Yes ☐ No ☐ Can’t answer ☐ Not applicable

3. Was a comprehensive literature search performed?
   - At least two electronic sources should be searched. The report must include years and
   - Yes ☐ No ☐
databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated, and where feasible, the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

4. Was the status of publication (i.e., grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.\(^a\)

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

6. Were the characteristics of the included studies provided?
In an aggregated form, such as a table, data from the original studies should be provided on the participants, interventions, and outcomes. The ranges of characteristics in all the studies analysed, e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

7. Was the scientific quality of the included studies assessed and documented?
“A priori” methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo-controlled studies, or allocation concealment as inclusion criteria); for other types of studies, alternative items will be relevant.

8. Was the scientific quality of the included studies used appropriately in formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity, I\(^2\)). If heterogeneity exists, a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?).

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).

11. Was the conflict of interest included?
Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

<table>
<thead>
<tr>
<th>Total Score (Tally 1 for each question answered “Yes”)</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ No</td>
</tr>
<tr>
<td>□ Can’t answer</td>
</tr>
<tr>
<td>□ Not applicable</td>
</tr>
</tbody>
</table>

“Can’t answer” is chosen when the item is relevant but not described by the authors; “not applicable” is used when the item is not relevant, such as when a meta-analysis has not been possible or was not attempted by the authors.

The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

RECOMMENDATION:  
Include □  Exclude □  Seek further information □

Comments (including reasons for exclusions):  ________________________________

(Form based on: A measurement tool to assess systematic reviews (AMSTAR) by B.J. Shea et al. Journal of Clinical Epidemiology (2009).)
### APPENDIX 4:
Quality Assessment Tool for Original Health Literacy Research Articles

<table>
<thead>
<tr>
<th>SCREENING QUESTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>III. Is the study one of the following quantitative designs?</td>
</tr>
<tr>
<td><strong>Experimental/ Quasi-Experimental. Includes treatment/intervention</strong></td>
</tr>
<tr>
<td>RCT ☐ Controlled Trial ☐ Controlled Before and After ☐ Interrupted Time Series ☐ Pre-post study ☐</td>
</tr>
<tr>
<td><strong>Non-experimental. No treatment/intervention</strong></td>
</tr>
<tr>
<td>Cohort study ☐ Case Control ☐ Case study or case series ☐ Cross-sectional survey ☐</td>
</tr>
<tr>
<td>IV. Is the study one of the following qualitative designs?</td>
</tr>
<tr>
<td>Generalisable studies ☐ Conceptual studies ☐ Descriptive studies ☐ Single case studies ☐</td>
</tr>
<tr>
<td>V. If the study does not include data collection and analysis: STOP NOW ☐</td>
</tr>
<tr>
<td>VI. Is the research exclusively conducted in a hospital inpatient setting, or does the research pertain to health and medical practice that is available locally?</td>
</tr>
<tr>
<td>YES In hospital ☐ STOP NOW</td>
</tr>
<tr>
<td>NO Locally available ☐ Continue screening</td>
</tr>
</tbody>
</table>

*If the study is an empirical study and not exclusively conducted in a hospital inpatient setting, appraise the quality of the reported research using the questions below.*
# APPRAISAL QUESTIONS

<table>
<thead>
<tr>
<th>Q No.</th>
<th>Appraisal Question</th>
<th>Yes</th>
<th>No</th>
<th>Can’t tell or Mixed response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Is the purpose of the study clear and well defined?</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Is the population well defined and properly selected?</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>Are the methods clearly described and appropriate for the type of study reported?</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>Are the results presented in a clear and understandable format?</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>Does the interpretation of the results seem consistent with the results presented?</td>
<td>2</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6</td>
<td>Are there any other explanations that could account for these results?</td>
<td>0</td>
<td>2</td>
<td>1</td>
</tr>
</tbody>
</table>

Total score: 2 (Maximum of 12)

**RECOMMENDATION:** Include [ ] Exclude [ ] Seek further information [ ]

Comments (including reasons for exclusions): ______________________________________________

(Questions derived from Oxman & Guyatt, 1994; JBI Criteria; )