Title

A systematic review of the prevalence and associations of limited health literacy in chronic kidney disease

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Word counts: Abstract: 341; Body text: 3472

Running Title: Health Literacy in CKD Systematic Review

Key Words: Health Literacy, Chronic Kidney Disease, Dialysis, Transplantation.

Abstract

Background and objectives: The self-management and decision-making skills required to manage chronic kidney disease (CKD) successfully may be diminished in those with low health literacy. A 2012 review identified five papers reporting the prevalence of limited health literacy in CKD, largely from US dialysis populations. The literature has expanded considerably since.

Design, setting and participants: Systematic review, pooled prevalence analysis, meta-regression, exploration of heterogeneity in studies of patients with CKD (all stages).

Results: From 433 studies, 15 new studies met the inclusion criteria and were analyzed together with five studies from the 2012 review. These included 13 cross-sectional surveys, five cohort studies (using baseline data) and two using baseline clinical trial data. Most (19/20) were from the USA. In total, 12,324 patients were studied (3,529 non-dialysis CKD; 5,289 dialysis; 2,560 transplant; 946 with unspecified CKD), median 198.5 (IQR: 128.5 to 260) per study. Median prevalence of limited health literacy within studies was 23% (IQR: 16% to 33%), pooled prevalence 25% (95% CI: 20 to 30%) with significant between-study heterogeneity (I^2 =97%). Pooled prevalence of limited health literacy was 25% (95% CI: 16 to 33%; I^2: 97%) among non-dialysis CKD patients, 27% (95% CI: 19 to 35%; I^2: 96%) among dialysis patients and 14% (95% CI: 7 to 21%; I^2: 97%) among transplant patients. A higher proportion of non-white participants was associated with increased limited health literacy prevalence (p=0.044) but participant age was not (p=0.4). Within studies, non-white ethnicity and low socioeconomic status were consistently and independently associated with limited health literacy. Studies were of low or moderate quality. Within-study participant selection criteria had potential to introduce bias.

Conclusions: Limited health literacy is common in CKD, especially among individuals with low socioeconomic status and non-white ethnicity. This has implications for the design of self-management and decision making initiatives to promote equity of care and improve quality. Lower prevalence among transplant patients may reflect selection of patients with higher health literacy for transplantation, either because of less comorbidity in this group or as a direct effect of health literacy on access to transplantation.

Introduction

Chronic kidney disease (CKD) affects 12% of US adults and is associated with significant morbidity and mortality, predominantly through increased cardiovascular risk (1). CKD progression further increases cardiovascular risk (2) and the risk of requiring renal replacement therapy (RRT) (3). CKD management aims to reduce these risks, and prepare people with advanced CKD for dialysis, transplantation or conservative care (4). Increasingly, CKD management involves shared decision-making and self-care activities, which are actively promoted in healthcare policy (5, 6). However, these activities require patients to learn, understand, appraise and apply knowledge of a complex disease process and its treatment. As CKD progresses, the burden of self-management activities increases, while patients' capacity (7, 8) to perform these activities may reduce because of disease-related reduction in function (9). Further, CKD is associated with low socioeconomic status (SES) (10), so people with CKD may lack the social resources needed for successful CKD management (8). Effective self-management may therefore depend on individual skills in managing health such as health literacy (11).

Health literacy is a personal attribute that 'entails people's knowledge, motivation and competences to access, understand, appraise and apply health information' (12). As a potentially modifiable factor influencing individual health, it is the focus of an expanding field of research. Multiple tools have been developed to measure health literacy or to screen for low or 'limited' health literacy (13). In general populations, limited health literacy is associated with poorer health (14), less efficient use of healthcare services (15), and higher mortality (16). However, investigation of limited health literacy in CKD has been relatively limited: a 2012 systematic review identified four studies of hemodialysis patients, one study of transplant patients, and one including patients with early CKD (17). Only 1,405 patients were studied in total. Limited health literacy was associated with lower SES (18-21), and increased comorbidity (20). One study showed increased mortality among dialysis patients with limited health literacy (22). The review identified a need for studies measuring health literacy among patients with CKD stages 1-4 and for studies from outside the USA.

Since this review, investigation of limited health literacy as a barrier to effective clinician-patient communication has been identified as a research priority in CKD (23). Health literacy measures specific to CKD have been developed and validated (24, 25). A Cochrane review of health literacy-focused interventions in CKD is underway (26). We

recognized that health literacy research in CKD had increased significantly. This study aimed to re-explore the prevalence and socio-demographic associations of limited health literacy among patients with CKD, compare patients with non-dialysis CKD, on dialysis and with a kidney transplant and identify causes of heterogeneity in reported results.

Materials and Methods

The review protocol was registered with the international prospective register of systematic reviews. (http://www.crd.york.ac.uk/PROSPERO; registration number D42016036742).

English-language references from between December 2010 and July 2016 were identified from Medline, Embase, Ovidfulltext (including Psycharticles), Health Management Information Consortium, CINAHL and Psychinfo. The search strategy (see supplementary material) was developed from the 2012 review, from a Cochrane systematic review protocol for health literacy interventions in CKD (26) and from review articles of health literacy measurement tools (24, 27-32). In addition to database searches, reference lists from articles included in this review and from other review articles were hand-searched.

Two reviewers (DT and SF) independently assessed journal articles for inclusion by three criteria:

1. At least 50 adults over 18 with CKD were included (aiming to identify studies with a predominantly quantitative rather than qualitative focus)
2. The study used a validated measure to quantitatively describe health literacy
3. The study reported the prevalence of limited health literacy, or data from which this could be derived.

Full texts of journal articles were reviewed if the first criterion and either of the other two were met. Authors were contacted if required to establish if a study should be included, or to request additional data. Articles which met the inclusion criteria were analyzed along with the five articles included in the 2012 review. In a sensitivity analysis, searches were widened to include unpublished studies available as abstracts from nephrology and health literacy conferences (see Supplementary Material).

Study quality was scored independently by DT and SF, guided by a review of tools for assessing the quality of observational studies (33). Studies were assigned scores for sample size, setting, recruitment methods, and potential for unrecognized confounding of results. Scores were combined to indicate study quality and used to inform grading of studies as 'low', 'moderate' or 'high' quality. However, this scoring acted as a guide only and grading of studies was decided by discussion between the two reviewers.

For each study, the prevalence of limited health literacy, number of unique participants, study methods and demographics of participants were recorded. Meta-analysis was performed with subgroup analysis by CKD treatment stage (Non-dialysis CKD; Dialysis; Transplant) and by health literacy measure. Results were presented as Forest plots, with 95% confidence intervals for each prevalence value and for the pooled prevalence of limited health literacy. I^2 statistics were calculated to measure the degree of heterogeneity between studies and subgroups. A random-effects model was used because we expected to find significant heterogeneity in the prevalence of limited health literacy based on the results of the 2012 review (9). Univariate meta-regression was performed for continuous variables, which included the proportion of patients with non-white ethnicity and the age of participants (mean or median). If data on treatment stage, age or ethnicity were unavailable, studies were excluded from each analysis.

For studies where more than one validated health literacy measure was used, scores from STOFHLA (Short Test of Functional Health Literacy in Adults) are presented here because of its use as a reference measure to validate health literacy screening tools (24, 25, 34). Analyses were then repeated using scores from other measures to establish if this altered the overall results. Socio-demographic characteristics significantly associated with limited health literacy were summarized, with covariates included in multivariate models, to identify independent associations. Statistical significance within studies was defined by individual study methods. A p-value of <0.05 was selected *a priori* to define statistical significance for meta-analysis and meta-regression. Analyses were performed using the user-written commands 'metaprop' and 'metareg' in Stata 12 (StataCorp LP, USA).

Results

Figure 1 shows the study selection process, which identified 433 unique studies, 15 of which met the inclusion criteria (24, 25, 35-47), with full agreement between the two reviewers. Table 1 summarises the 15 new studies in

addition to five studies included in the 2012 review (19-22, 48). All 20 studies are included in the following description and analysis.

Of 20 studies, 13 were cross-sectional surveys, five used baseline data from cohort studies and two used baseline data from clinical trials. One study presented UK data (45), all others reported from the USA. Study quality was graded as 'low' for 15 studies and 'moderate' for five studies (19, 22, 43-45).

In total, 12,324 patients were studied, including 1,327 patients included in the 2012 review. This included 3,529 patients with non-dialysis CKD from seven studies, 5,289 dialysis patients from ten studies, and 2,560 transplant patients from five studies. Five studies included patients from multiple treatment stages. The prevalence of limited health literacy by treatment stage was not available for 946 patients from two studies (41, 42), even after communication with authors. Studies included a median of 198.5 patients (IQR: 128.5 to 260).

One study included live kidney donors (37), and one included recipients of solid organ transplants of different types (42) in addition to patients with CKD; subgroup information was available from published data. One study (41) measured health literacy in 46,000 emergency department attendees, including 851 with CKD (41). The authors provided data on this subgroup by personal communication.

Table 2 summarises the health literacy measures and definitions of limited health literacy used.

One study included all emergency department attendees (41) and one aimed to approach all eligible patients UK-wide (45). Two studies surveyed patients from clinical trials whose primary objective was unrelated to health literacy (20, 35). All others recruited from clinical environments without efforts to obtain a sample representative of a target CKD population. Two studies surveyed CKD patients at transplant assessment clinics (38, 42), while one excluded patients listed for transplant (20). Three studies reported offering a monetary gift to participants (46-48). At least 11 studies excluded patients with cognitive impairment. One study included patients deemed suitable for an educational intervention (22). Six studies specified an upper limit for age, ranging from 74 to 80 years (21, 24, 36, 43-45).

Ethnicity data were unavailable for one study (total 95 patients) (42), and age data for two studies (total 322 patients) (25, 42). From the remaining data, the median proportion of participants of non-white ethnicity was 48%

(IQR: 23 to 64%) and mean or median age ranged from 47 to 72 years. In some US studies, the majority of study participants had Black ethnicity (21, 24, 40). One study excluded patients with Hispanic ethnicity (43). Twelve studies included only English speakers. Three studies included Spanish speakers, and used health literacy measures translated into Spanish (25, 40, 44).

The median prevalence of limited health literacy by study was 23% (IQR: 16 to 33%). The overall pooled prevalence of limited health literacy was 25% (95% CI: 20 to 30%). A high degree of heterogeneity was present between studies (I^2 =97.4%).

Figure 2 shows a Forest plot of the prevalence of limited health literacy in all 20 studies with subgroup analysis by health literacy measure. Studies using the Newest Vital Sign (NVS) and Single-Item Literacy Screener (SILS) reported significantly different prevalence values, but only one study used each measure (39, 45). These prevalence values contributed to the significant overall heterogeneity in limited health literacy prevalence between studies using different measures (p<0.001). However, when studies using REALM (Rapid Estimate of Adult Literacy in Medicine), STOFHLA and BHLS (Brief Health Literacy Screen) were compared alone, no significant between-group heterogeneity was detected (p=0.8).

Figure 3 shows sub-group analysis by CKD treatment stage, excluding two studies where subgroup information was unavailable (41, 42). The pooled prevalence of limited health literacy was 25% (95% CI: 16 to 33%) among patients with non-dialysis CKD, 27% (95% CI: 19 to 35%) among dialysis patients, and 14% (95% CI: 7 to 21%) among transplant patients. Overall, there was significant between-group heterogeneity (p=0.03), although this appears to be related to the lower prevalence of limited health literacy in transplant patients: when patients with non-dialysis CKD and dialysis patients were compared separately, no significant between-group heterogeneity was present (p=0.8).

Univariate meta-regression analysis showed a significant association between the proportion of non-white participants in a study and the prevalence of limited health literacy (ß:0.35; 95% CI: 0.001 to 0.69; p=0.044). This equates to a 3.5% increase in the prevalence of limited health literacy for every 10% increase in the proportion of non-white participants. Average age of study participants was not significantly associated with the prevalence of limited health literacy (ß: 1.05; 95% CI: -0.5 to 2.6; p=0.4).

Two studies used multiple health literacy measures, reporting three limited health literacy prevalence values each (24, 25). In the above analyses, results defined by STOFHLA were used for both studies. Repeated analyses using each of nine possible combinations of limited health literacy prevalence values did not lead to a change in the significance of the above results, except for meta-regression by proportion of non-white participants. In four of nine combinations, this association was no longer statistically significant. A further sensitivity analysis included 11 conference abstracts in addition to the 20 published papers included here. Analysis of results from all 31 studies showed a pooled prevalence of limited health literacy of 25%, and no change in the pattern of results as presented above. However, when abstracts were included, the significance of the association between proportion of non-white participants and limited health literacy prevalence increased (p=0.005).

Table 3 summarizes significant associations with limited health literacy and covariates included in multivariate models. A large variety of variables was tested. In ten studies which undertook multivariate analysis, the only demographic factors consistently and independently associated with limited health literacy were ethnicity (20, 22, 35), and markers of lower SES including income (19, 21, 35) and lower educational level (19-22, 37, 45). Independent associations were also reported between limited health literacy and older age (21), male gender (22), lower English fluency (45), individual comorbidities (39, 43) and higher comorbidity score (45).

In patients with non-dialysis CKD, two studies reported independent associations between limited health literacy and lower eGFR (39, 43). Limited health literacy was associated with deceased-donor transplantation (compared to live-donor) and transplantation after dialysis start (compared to pre-emptive) (45). One study reported an independent association between limited health literacy and mortality (22).

Discussion

This systematic review of literature published until mid-2016 demonstrates the significant expansion of health literacy research in CKD. Fifteen studies published since 2012 were identified, and 12,324 patients have now been studied, compared to 1,405 in the 2012 review by Fraser et al (17). Geographical variation of studies remains limited: only one was from outside the USA. The pooled prevalence of limited health literacy in the present analysis was 25%, similar to 23% in the 2012 review. The six new studies of patients with non-dialysis CKD and four new studies of

transplant patients allowed meta-analysis by patient group, confirming the reduced prevalence of limited health literacy among transplant patients, which has been reported in individual studies (45). Four new studies used the BHLS, and comparison with studies using REALM and STOFHLA showed no significant difference in limited health literacy prevalence, increasing the confidence with which results can be compared between studies of CKD patients using these health literacy measures.

The lower prevalence of limited health literacy among kidney transplant patients has several possible explanations. Firstly, limited health literacy may directly impede effective clinician-patient communication, reducing the likelihood of clinically-suitable patients understanding the benefits of transplantation and pursuing it as a treatment option. Because of associations with low SES, limited health literacy has been implicated as a possible mediating factor in reducing access to transplantation. However, mechanisms by which low SES associates with reduced access to transplantation (49) are complex (and in the USA, include reduced access to immunosuppressant drugs (50). The associations of both limited health literacy (45) and SES (51) with increased comorbidity add further complexity: patients with limited health literacy and low SES may in fact be less suitable for transplantation for clinical reasons. These complex associations warrant further investigation.

A higher proportion of individuals with non-white ethnicity was significantly correlated with a higher prevalence of limited health literacy. As 19 out of 20 studies were from the USA, non-white ethnicity represents patients with Black American or Hispanic ethnicity. Non-white ethnicity in the USA has established, complex associations with low SES (52) and poorer health outcomes (53), so this may represent confounding by SES and comorbidity. Although all three studies that reported independent associations between ethnicity and limited health literacy adjusted for SES (20, 22, 35), only one adjusted for comorbidity (as presence or absence of diabetes) (22). Age of study participants did not appear to influence the prevalence of limited health literacy.

Even after adjustment for treatment stage, health literacy measure, age or ethnicity, there was significant residual heterogeneity in the prevalence of limited health literacy between studies. Study methodology had potential to contribute to this heterogeneity. Sample size was mostly small (median 189). The majority of studies recruited patients by convenience in clinical environments, which may result in participation bias. Studies which included only patients who had been referred for transplantation (or excluded those who had been referred) are likely to produce biased estimates of limited health literacy prevalence (20, 47, 48). Patients with cognitive impairment or language

difficulties may demonstrate a reduction in understanding and be falsely classified as having limited health literacy. Many studies excluded those with cognitive impairment for this reason, but some did not, and no associations between cognitive impairment and health literacy were tested. The approach to patients whose first language is not English could also bias results. Some studies excluded non English-speakers, who would be more likely to have limited health literacy because of its association with non-white ethnicity and lower SES. Others used translated versions of health literacy measures to allow inclusion of non-English speakers. However, non-English versions of health literacy measures have not been validated extensively, and comparison of results between English and non-English versions is problematic because of inherent differences between English-speaking and non English-speaking populations (54). Other studies used English health literacy measures for all participants, which could result in patients being falsely classified as having low health literacy because of poor understanding related to language.

The different health literacy measures used vary in their method of assessment and in the skills which are assessed. This limits comparability of results between studies. REALM and STOFHLA are direct assessments of pronunciation and reading comprehension, whereas the screening tools BHLS and SILS focus on patient's perception of their level of understanding. It is reassuring that the BHLS produced similar prevalence estimates to REALM and STOFHLA in our meta-analysis, although health literacy screening tools have been shown in validation studies of CKD and other populations to lack sensitivity and specificity in detecting limited health literacy defined by REALM or STOFHLA (24, 25, 34, 55). Screening tools benefit from short administration times, so are more practical for use in large-scale cohort studies or for screening in clinical practice. The NVS (56) is the only measure used here that assesses poor numeracy: a common characteristic of patients with CKD (57) and other chronic diseases (58) which may impair patients' ability to dose medications, follow dietary advice and keep appointments (59).

Systematic reviews of health literacy prevalence in other populations report similar findings. A 2005 review of US studies reported a pooled prevalence of 26% 'low' health literacy, associated with lower educational level, Black ethnicity and older age (60). A review of health literacy in patients with musculoskeletal diseases found between 7% and 42% low health literacy, associated with lower SES (61).

This review benefits from a comprehensive search strategy using updated search terms. Eligibility criteria were clearly defined. We sought and received valuable communication from many authors, enhancing the quality of the review. A sensitivity analysis, which included data from conference abstracts, identified no major differences in

results. There are several limitations. Firstly, studies were of low or moderate quality because of small sample size, single center samples and non-representative sampling methods. Second, studies using newer measures that measure multiple aspects of health literacy on separate scales (13), but do not define limited health literacy could not be included. Third, most studies used cross-sectional data and the association of limited health literacy with increased mortality (22) could result in survivorship bias and an underestimate of limited health literacy prevalence in cross-sectional studies. Fourth, meta-regression to account for age and ethnicity differences between studies was especially limited by missing data, and multivariate meta-regression was not possible. However, a positive association was still shown between non-white ethnicity and limited health literacy prevalence, despite this lack of power. Fifth, ages of study participants were available as mean *or* median, limiting the reliability of meta-regression analysis by age. Lastly, one study showed a lower prevalence of limited health literacy among those listed for transplantation compared to incident dialysis patients (45), but this association could not be investigated here because of the absence of consistent data on wait-listing status.

Clinicians should recognize that a quarter or more of CKD patients have reduced health literacy skills. Standard shared decision-making and self-management initiatives may not be suitable (11, 62). Further, those with limited health literacy have an increased burden of disease and treatment due to comorbidity, and may lack social resources required to manage disease because of low SES (7, 8). In the face of these challenges, health literacy-sensitive communication methods, educational tools and decision-aids may be key to improving clinical outcomes and may have a role in reducing inequity in access to transplantation.

The expansion of health literacy research in CKD since the last review is welcome, but further work is required to use this knowledge to promote improved clinical outcomes. All health literacy research will be facilitated by evidence-based consensus on the optimal tools to measure health literacy. Prospective studies are required to examine the impact of limited health literacy on healthcare service use, CKD management and RRT modality choice (including non-dialysis care). Interactions between health literacy and other patient attributes such as capacity (8) and patient activation (63) warrant investigation. Knowledge of the mechanisms by which limited health literacy could impair navigation of the CKD care pathway will inform enhanced communication methods, and modified approaches to shared decision-making and self-management. By improving patients' understanding, these initiatives would aim to reduce inequity of care and improve the health of the CKD population.

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Disclosures

Dominic M Taylor	None
Simon Fraser	None
John A Bradley	None
Clare Bradley	CB received consulting fees (relating to diabetes, unrelated to this work) for one advisory board meeting and some consultancy fees, 2014-2016. She is the majority shareholder in Health Psychology Research Ltd. Her other research (not including this work) is funded by four grants from GSK/ViiV. She receives royalties for the use of her patient-reported outcome measures, none of which are referenced in this manuscript (and none of which relate to health literacy).
Heather Draper	None
Wendy Metcalfe	None
Gabriel Oniscu	GO received royalties from book authorship (Wiley), unrelated to this manuscript
Charles Tomson	None
Rommel Ravanan	None
Paul Roderick	PR received grant support from Pfizer 2012-2014 for an MRSA study, unrelated to this manuscript.

Acknowledgements

This article presents independent research funded by the National Institute for Health Research (NIHR) under the Programme Grants for Applied Research scheme (RP-PG-0109-10116). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

The funding body did not have any role in deciding study design, data collection, analysis, interpretation of data, writing the report or the decision to submit for publication.

Table 1: Characteristics of studies included in the review.

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Prevalence of limited health literacy (%)
Adeseun (35)	2012	USA	72	[52]	68	Incident Dialysis (HD or PD)	Examine relationship between health literacy and cardiovascular disease risk factors	Cohort (baseline data)	Adults from transplant evaluation clinics taking part in the Dialysis Heart and Bone Study.	100% with limited health literacy were Black, compared to 50% of those with adequate health literacy	Previous coronary revascularization, cardiac devices or weight >350lbs	STOFHLA	BP, lipid profile, waist-to-hip ratio, BMI, Tobacco use	21
Boulware (36)	2013	USA	130	60	40	Non-dialysis CKD 3-5	Compare the effectiveness of educational interventions on pre-emptive living donor kidney transplantation	Cohort (baseline data)	Nephrology clinics	46% White 47% Black <1% Hispanic	<18, >70, Non-English speaking, previous transplant, cancer heart failure, severe liver disease, PVD, HIV, unstable coronary artery disease.	REALM	-	25
Brice (25)	2014	USA	227	-	-	Prevalent HD	Validate TILS and SILS against STOFHLA	Cross-sectional	Adults from 7 HD centers	English (96%) and Spanish speakers (4%)	<18, Unable to speak English or Spanish. 'Mental impairment' defined by dialysis staff. Poor vision.	STOFHLA, SILS and TILS (English or Spanish)	-	45 (STOFHLA) 22 (SILS)
Cavanaugh 1 *(22)	2010	USA	480	62	56	Incident HD	Measure the prevalence and associations of limited health literacy and risk of all-cause mortality	Cohort	Adults 'eligible for a patient education program' from 77 Dialysis units. Health literacy measured if low literacy was suspected by case manager.	52% White 50% Diabetic	<18; Non-permanent dialysis patients, Known cognitive impairment, Non-English speakers, Nursing-home residents.	REALM	Mortality	32
Cavanaugh 2 (24)	2015	USA	143	[52]	51	Prevalent HD	Validate BHLS against REALM and STOFHLA	Cross-sectional	Adults from 4 dialysis units	73% Black.	<18. >80. Dialysis initiation <1 month. Non-English speakers. Cognitive impairment	BHLS (0-15) REALM and STOFHLA	-	23 (BHLS) 27 (REALM) 8 (STOFHLA)
Dageforde 1 (37)	2014	USA	255	[48]	64	Incident Transplant	Compare health literacy between live- and deceased-donor kidney transplant recipients and live kidney donors	Retrospective chart review	Transplant recipients and donors at single transplant center surveyed for health literacy preoperatively	65% White LDR (n=103) DDR (n=152)	<18; No recorded answer to BHLS	BHLS (0-15)	Donor type, Education and demographics	12 (LDRs: 9%; DDRs: 14%)

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Prevalence of limited health literacy (%)
Dageforde 2 (38)	2015	USA	104	[53]	61	Dialysis (n=14) and non-dialysis CKD (n=90)	Characteristics of attenders vs absentees for kidney transplant evaluation appointments	Cross-sectional	Convenience sample of patients scheduled for initial evaluation for kidney transplant at a single center	46% White	<18, Non-English speakers, cognitive impairment.	BHLS (0-15)	Attendance vs non-attendance	23 (14% dialysis; 24% CKD)
Devraj (39)	2015	USA	150	45% over 60	47	Non-dialysis CKD1-4	Relationship between health literacy and eGFR	Cross-sectional	Adults attending follow-up nephrology outpatients appointments at a single center. Given a $20 merchandise card to participate	40% White 41% Hispanic	<21, Non-English speaking, AKI, cognitive impairment defined by medical notes, or if <4 on cognition screening test, Poor visual acuity	NVS	eGFR (MDRD formula)	63
Foster (40)	2011	USA	238	[58]	54	Prevalent Dialysis (HD or PD)	Assess disaster preparedness in dialysis patients	Cross-sectional	Adults approached during dialysis at 6 dialysis units	57% Black 6% Spanish-speaking, 94% English Speaking	<18, unable to understand consent process	STOFHLA (English or Spanish)	Disaster preparedness	49.5
Gordon* (19)	2011	USA	124	[47]	57	Transplant	Relationship between health literacy, transplant knowledge and graft function	Cross-sectional	Sequential transplant recipients from a single center recruited at post-transplant clinic visit for 30-minute interview.		<18, Non-English-speaking; Visually impaired, Too unwell to participate	STOFHLA and REALM-T	Demographics and graft function	9
Green* (20)	2011	USA	260	64	57	Prevalent HD	Describe prevalence and associations of limited health literacy	Cohort (baseline data)	Patients from 9 dialysis units included in an RCT of strategies for managing pain, sexual dysfunction and depression	40% Black	<18, less than thrice-weekly dialysis, non-English Speakers, Cognitive impairment, considering switch to PD or transplantation	REALM	Demographics, SES, Comorbidity	16
Grubbs* (21)	2009	USA	62	[52]	66	Prevalent HD	Association of poor health literacy with access to transplantation	Cross-sectional	Adults approached during dialysis session in 5 dialysis units.	73% Black	<18, >75, ethnicity other than Black or White, <9 months on dialysis, previous transplant, cognitive impairment	STOFHLA	Referral for transplant evaluation, wait-listing or transplantation	32
McNaughton (41)	2014	USA	851[α]	55	57	CKD3-5, including dialysis or transplant if eGFR<60ml/min/1.73m^2	Relationship between limited health literacy and BP at ED presentation	Cross-sectional	Adults attending ED at a large quaternary hospital screened for health literacy as part of admission nursing assessment.	Study included 31902 patients, of whom 851 (3%) had kidney disease. 60% White	<18; Nursing assessment or health literacy measure not completed, Admitted with pre-eclampsia or alcohol withdrawal.	BHLS (0-15)	BP at hospital presentation (in all ED attenders)	26[α]

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Prevalence of limited health literacy (%)
Miller-Matero (42)	2015	USA	95	-	-	Referred for transplantation (dialysis or advanced CKD)	Assess health literacy of patients referred for solid-organ transplantation	Cross-sectional	Patients considered for solid organ transplantation at a single center.	-	-	REALM	Demographics, cognitive impairment, reading ability, numeracy (in all organ transplant recipients)	37.8
Ricardo (43)	2014	USA	2340	[58]	54	Non-dialysis CKD1-4	Association of limited health literacy with kidney function and CV risk factors	Cross-sectional	Adults with CKD recruited from 7 clinical centers.	52% White 48% Black	<21 or >74 years; Polycystic Kidney (43)Disease; Hispanic Ethnicity	STOFHLA	eGFR (MDRD formula), BP, LDL cholesterol <100mg/dL, HbA1c <7%, self-reported CV disease	16 (Black 28%; White 5%)
Robinson (44)	2015	USA	170	[50]	59	Prevalent Transplant	Validate a sun-protection education program	RCT (baseline data)	Adults from 2 transplant programs	35% Black; 28% Hispanic; 36% White	<2 or >24 months after transplant; Non- Spanish speakers; <18 or >70; poor vision; ethnicity other than Black, White or Hispanic	STOFHLA (English or Spanish)	-	36 (Black 58%; Hispanic 54%; White 0%)
Taylor (45)	2015	UK	5520	54	62	Incident Dialysis (HD or PD), Incident Transplant and Transplant wait-listed (Prevalent dialysis- and non-dialysis CKD)	Describe prevalence and associations of limited health literacy	Cohort (baseline data)	Adults approached for notes review and survey from all 71 UK renal units	Representative nationwide sample. 79% White. Non-dialysis CKD patients were all pre-emptively wait-listed for transplant	<18 or >75 years or unable to provide informed consent.	SILS	Demographics, SES, Comorbidity	16 (Dialysis 18%; CKD Wait-listed 9%; Incident Transplant 12%)
Weng (46)	2013	USA	252	[55]	60	Prevalent Transplant	Prevalence and correlates of medication non-adherence	Cross-sectional	Adults approached during a transplant clinic visit at a single center. Offered $15	58% White 27% Black Median 2.9 years post-transplant	<6 months post-transplant, <18, Non-English speakers, Unable to consent. Dual organ transplant.	STOFHLA	Medication non-adherence	2.4

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Prevalence of limited health literacy (%)
Wright* (48)	2011	USA	401	58	53	Non-dialysis CKD1-5	Measure awareness and knowledge of CKD to develop a CKD knowledge survey	Cross-sectional	Adults attending a follow-up nephrology clinic appointment at a single center. Offered $10	83% White	<18, Non-English speakers, kidney transplant or dialysis, vision or cognitive impairment	REALM	Kidney disease knowledge	18
Wright-Nunes (47)	2013	USA	154 (after excluding 401 from Wright)	58	54	Non-dialysis CKD1-5	Assess feasibility and impact of a physician-delivered education tool to increase CKD knowledge	Clinical trial, (baseline data)	Adults at single center asked to complete a survey (written or read aloud). Offered monetary compensation.	77% white, 78% CKD3-5.	<18, Non-English speakers, kidney transplant or dialysis, vision or cognitive impairment	REALM	-	22

Outcome variables are listed only if statistical models included health literacy as an exposure variable. * Studies included in Fraser 2012 review. α Frequencies from personal communication with the authors.

CKD- Chronic Kidney Disease; HL-Health Literacy; HD- Hemodialysis; PD- Peritoneal Dialysis; BP-Blood Pressure; BMI- Body Mass Index; PVD- Peripheral Vascular Disease; LDR-Live-donor recipient; DDR- deceased-donor recipient; AKI- Acute Kidney Injury; MDRD: Modification of Diet in Renal Disease; ED- Emergency Department; LDL- Low density lipoprotein; SES-Socioeconomic status

Table 2: Health literacy measures used in studies included in this review.

Health literacy measure	Number of studies using measure (%)	Form	Approximate time taken	Health literacy categorization
Short Test of Functional Health Literacy in Adults (STOFHLA)	9 (45) (3 studies used both English and Spanish versions)	36 reading comprehension items- select from four choices to replace missing words in text (modified Cloze procedure)	12 minutes	0-22 Limited 23-36: Adequate
Rapid Estimate of Adult Literacy in Medicine (REALM)	6 (30)	125 health-related words (66 in more commonly used form) tested for pronunciation accuracy	3 minutes	0-44 Inadequate 45-60: Marginal 61-66: Adequate (Limited= Inadequate + marginal)
REALM-T (Transplant-specific version of REALM)	1 (5)	69 kidney transplant-related terms tested for pronunciation accuracy	3 minutes	Not clearly defined
Brief Health Literacy Screen (BHLS)	4 (20)	Three questions: How confident are you filling out forms by yourself? How often do you have someone help you read hospital materials? How often do you have problems learning about your medical condition because of difficulty reading hospital materials? All graded 1-5, scores range 3-15 (or 0-12 in one study(64)	<1 minute	3-8 (or 0-5): Lower 9-14 (or 6-12): Moderate/Higher (<10/15 or <6/12 indicates limited health literacy)
Newest Vital Sign (NVS)	1 (5)	Six-item assessment of reading comprehension from an ice-cream nutrition label	6 minutes maximum (average 2.9 minutes)(56)	0-1: High likelihood marginal/inadequate 2-3: Possible marginal/inadequate 4-6: Adequate (Score <4 indicates limited health literacy(39))
Single-Item Literacy Screener (SILS)	2 (10) (1 used English and Spanish versions)	'How often do you need to have someone help you when you read instructions, pamphlets or other written material from your doctor or pharmacy', answered on a 5-point Likert scale from '1-Never to '5-Always'	<1 minute	<3: Adequate ≥3: Limited
Two-Item Literacy Screener (TILS)	1 (5) (English or Spanish)	Two questions: What was the last (educational) grade you completed? Can you estimate your reading ability with one of the following: 'I frequently read complete books', 'I read the newspaper', 'I occasionally need help with the newspaper', or 'I frequently need help with the newspaper' Scored from -4 to +5	<1 minute	Sensitivity/specificity of different cut-off points was tested. Use of TILS>1 to indicate limited health literacy is suggested.

Table 3: Summary of univariate and multivariate associations with limited health literacy

		Demographics							Socioeconomic							Comorbidity										Biochemistry				Drugs			Dialysis				Transplant				Knowledge/education					
Univariate Associations		Older age	Male	Ethnicity	English Fluency	Veteran	Support person	Renal unit	Non-Employment	Lower income	Lower educational level	Non car ownership	Non-married	More children	Insurance	Other SES measure	Lower Physical Activity	Kidney disease duration	Higher comorbidity index	CV disease	Diabetes	BMI	Hypertension	Higher Blood Pressure	Hyperlipidaemia	Psychosis	Smoking	Lower eGFR	Proteinuria	Albumin	HbA1c	ACE/ARB	Insulin use	Aspirin	Dialysis initiation	Dialysis adequacy (Kt/V)	Fistula (compared to catheter)	Age at dialysis start	Dry Weight	Deceased-donor (vs live)	Non pre-emptive transplant	Time since transplant	Previous transplant	Lower objective knowledge	Lower percieved health	Kidney education resource use	Nephrologist care	Aware of diagnosis	Know someone with CKD	Increased mortality
Adenseun				• *						•	•																																				
Cavanaugh 1				• †							•		•																•								•									•
Dageforde 1																																						•									
Devraj				• ‡						•	•				•																																
Gordon										•	•		•																																		
Green				• *		•				•	•								•																	•											
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Ricardo		•		• †						•	•						•			•	•		•					•	•			•										•				
Taylor		•		• §	•				•		•		•	•					•							•													•	•							
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Ricardo	1																			•								•																	
	2																			•																										
Taylor					•				•		•	•							•							•																			
Wright																																														

Markers indicate statistically significant associations with limited health literacy. Shaded boxes indicate covariates included in multivariate models. *African-American, † Non-white; ‡ Hispanic § South Asian, Chinese.

Figure legends

Figure 1: Study selection process.

CKD: Chronic Kidney Disease; HL: Health literacy.

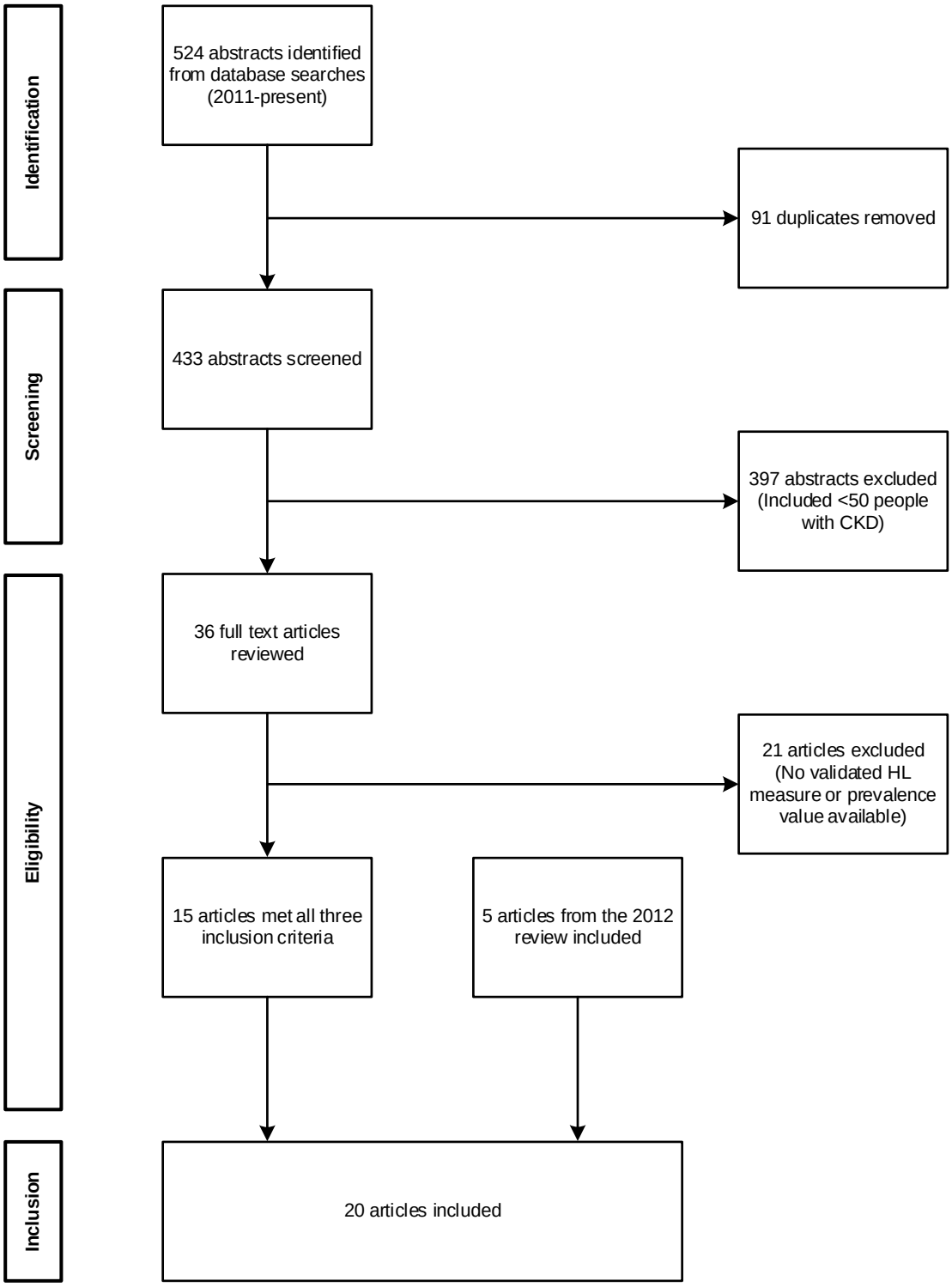


Figure 2: Forest plot showing the pooled prevalence of limited health literacy, grouped by the health literacy measure used. Dashed reference line indicates pooled prevalence value.

HL: Health literacy; CI: Confidence Interval; CKD: Chronic Kidney disease; BHLS: Brief Health Literacy Screener; REALM: Rapid Evaluation of Adult Literacy in Medicine; SILS: Single-Item Literacy Screener; STOFHLA: Short Test of Functional Health Literacy in Adults.

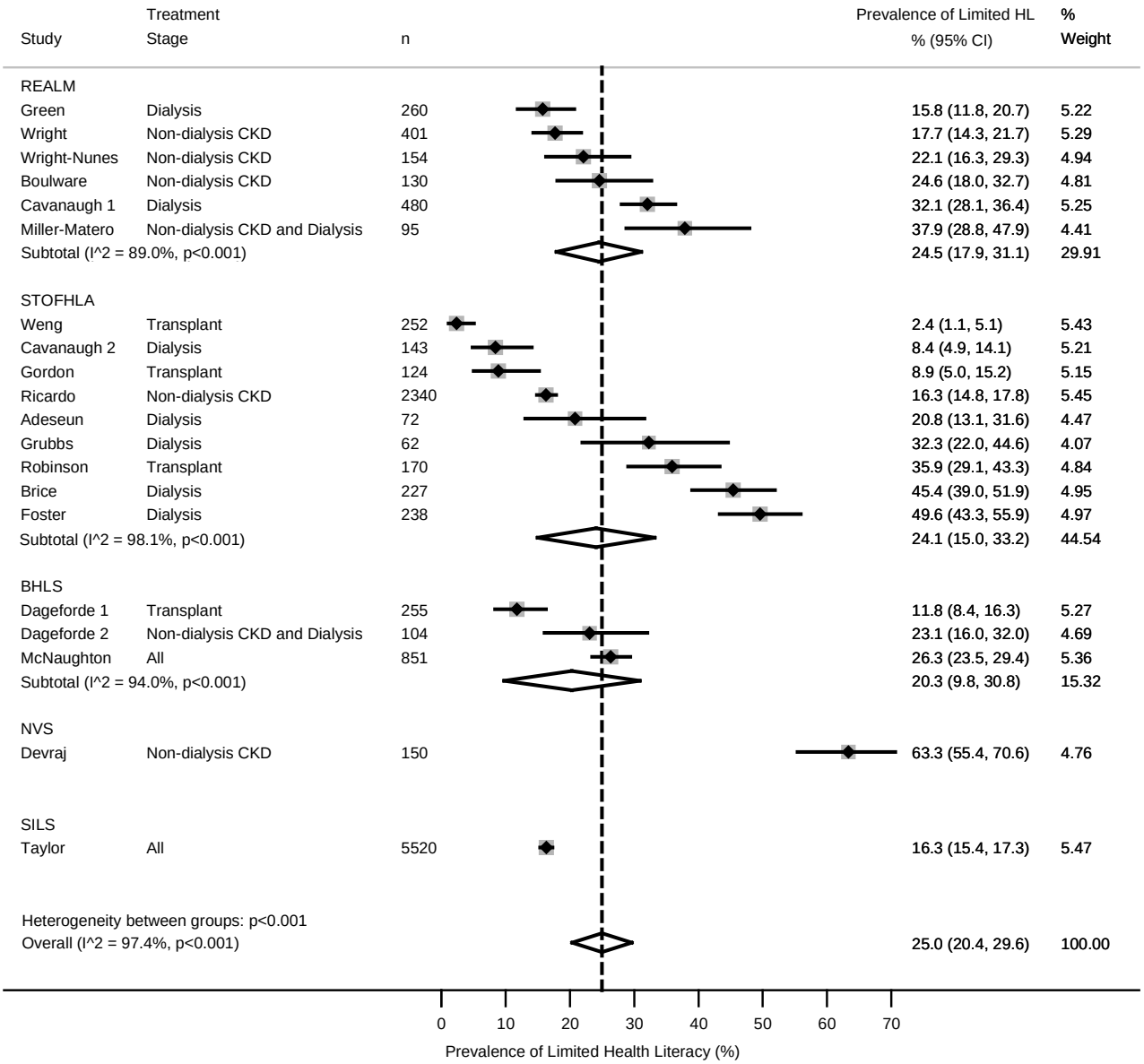
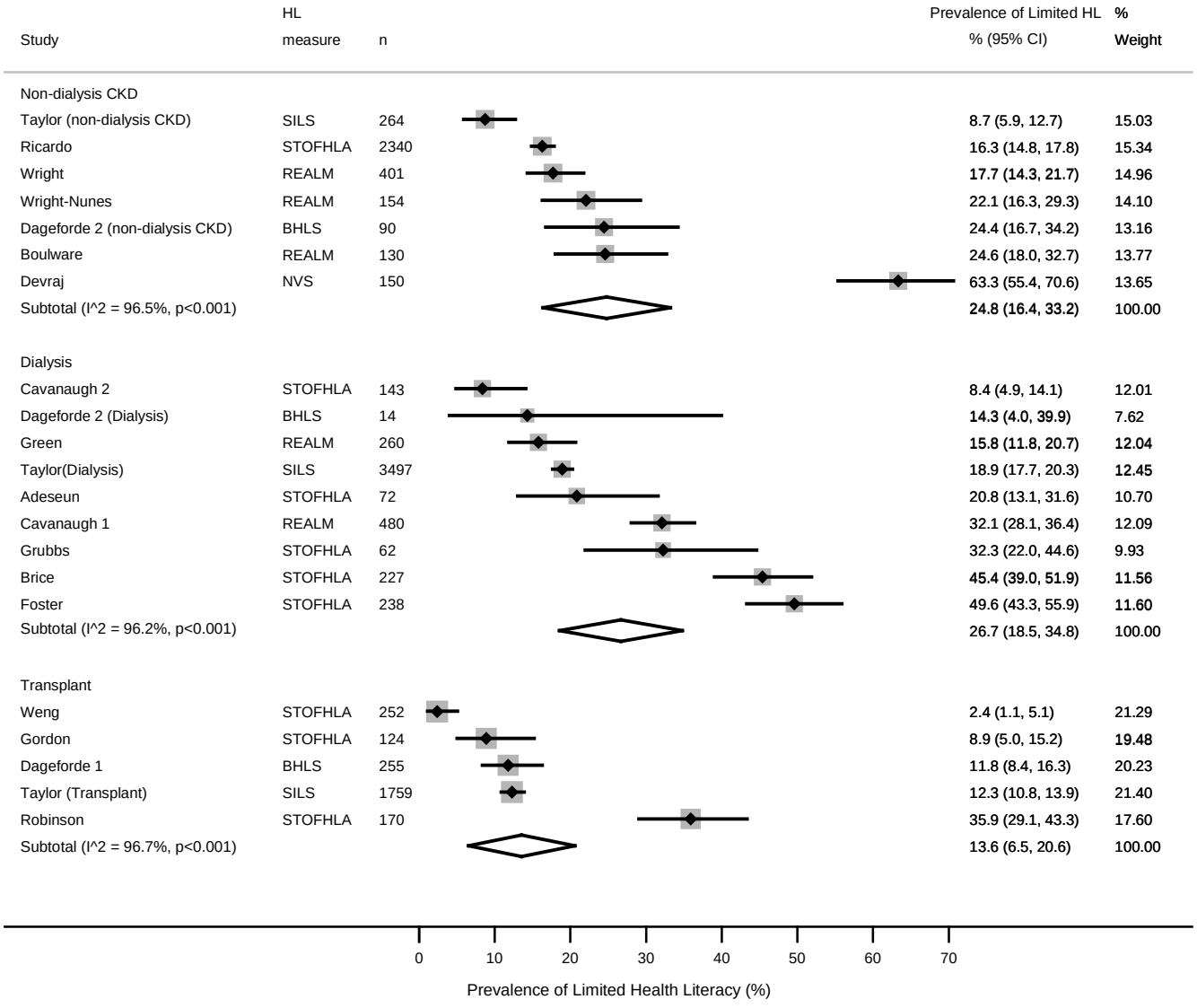


Figure 3: Forest plot showing the pooled prevalence of limited health literacy, grouped by CKD treatment stage. Two studies where treatment stage was not defined are not shown.

HL: Health literacy; CI: Confidence Interval.



Supplementary Material

Search terms

The search terms used in electronic database searches are shown in Figure S1.

Sensitivity analysis: inclusion of conference abstracts

In a sensitivity analysis, searches were widened to include conference abstracts. Abstracts from the American Transplant Congress, World Transplantation Congress, International Congress of the Transplantation Society, National Kidney Federation, Australia and New Zealand Society of Nephrology and American Society of Transplant Surgeons were identified by the original database searches. Abstracts archives 2011-2016 from the UK Renal Association, European Renal Association/European Dialysis and Transplant Association, International Society of Nephrology and American Society of Nephrology were searched separately for the terms 'health liter*' and 'literacy'. The UK Health Literacy Network (32) and Health Literacy Research Conferences (33) 2011-2016 were searched for CKD-related terms.

Sixty conference abstracts were identified by these searches. These included 14 studies of more than 50 patients with CKD. Eleven of these used a validated health literacy measure and provided a prevalence value for limited health literacy, so were included in this sensitivity analysis and summarised in Table S1.

Conference abstracts were analysed along with the 20 studies included in the primary analysis. Of 31 studies, 19 were cross-sectional surveys, eight used baseline data from cohort studies, three used baseline data from clinical trials and one was a review of patient notes where health literacy was measured during routine care. One study presented UK data, one from multiple countries (see Table S1 caption), one from New Zealand and 28 from the USA. Study quality was low for 24 studies and moderate for seven studies.

In total, 25,532 patients were studied, including 1,405 patients included in the 2012 review. This included 4,903 patients with non-dialysis CKD from 13 studies, 17,125 dialysis patients from 15 studies, and 2,560 transplant patients from 5 studies. Five studies included patients from multiple treatment stages. Limited health literacy prevalence by treatment stage was not available for 946 patients from two studies, (1, 2) (47, 48) even after communication with authors. Studies included a median of 170 patients (IQR: 107-330.5).

The median prevalence of limited health literacy by study was 23% (IQR: 16-35%). The overall pooled prevalence of limited health literacy was 25.2% (95% CI: 21.7-28.6%). A high degree of heterogeneity was present between studies (I^2 =97.5%). Pooled prevalence of limited health literacy was 25.1% (95% CI: 19.0-31.3) among patients with non-dialysis CKD, 24.9% (95% CI: 20.5-29.2) among dialysis patients, and 13.6% (95% CI: 6.5-20.6) among transplant patients. Overall, there was significant between-group heterogeneity (p=0.02), although this appears to be related to the lower prevalence of limited health literacy in transplant patients: when patients with non-dialysis CKD and dialysis patients were compared separately, no significant between-group heterogeneity was present (p=0.95).

Univariate meta-regression analysis by proportion of non-White patients and mean or median patient age showed that higher proportion of non-White participants was associated with higher limited health literacy prevalence (ß:0.31; 95% CI: 0.1-0.5; p=0.005), although significant residual between-study heterogeneity was present. Age of study participants was not significantly associated with the prevalence of limited health literacy (ß:0.38; 95% CI: -0.6-1.4; p=0.4).

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12. Singla A, Parikh R, Kreimerman J, Cavanaugh KL, Melamed ML: Associations of poor health literacy and CKD outcomes in the Bronx. *Am J Kidney Dis,* 67 (5)**:** A102, 2016
13. Weng F, Brown D, Holland B, Peipert J, Waterman A: A cluster randomized trial of an educational intervention to increase knowledge of living donor kidney transplant among potential transplant candidates. *Transplantation,* 98**:** 493, 2014

Search Strategy for Medline, Embase and Ovidfulltext (including Psycharticles) [via Ovid SP]

1. (Health adj3 litera*).tw.
2. (literacy or literate).tw.
3. HL.tw
4. Health Education/
5. Consumer Health Information/
6. educational status/
7. Patient Education as Topic/
8. Health Knowledge, Attitudes, Practice/
9. comprehension/
10. Patient Education.tw.
11. or/3-10
12. and/2,11
13. numeracy.tw.
14. Wide Range Achievement Test.tw.
15. Rapid Estimate of Adult Literacy in Medicine.tw.
16. Peabody Individual Achievement Test.tw.
17. Slosson oral reading test.tw.
18. National Adult Reading Test.tw.
19. (Woodcock-Johnson and test).tw.
20. (medical terminology and achievement).tw.
21. literacy assessment for diabetes.tw.
22. adult basic education test.tw.
23. Newest Vital Sign.tw.
24. Short Assessment of Health Literacy.tw.
25. Health literacy Screening Question Methodologies.tw.
26. Single-Item Literacy Screener.tw.
27. Health Literacy Skills Instrument.tw.
28. Medical Term Recognition Test.tw.
29. Short Literacy Survey.tw.
30. Brief Health literacy Screen.tw.
31. or/14-30
32. (SORT and read).tw.
33. (REALM and read).tw.
34. (MART and read).tw.
35. TOFHLA.tw.
36. STOFHLA.tw.
37. WRAT.tw.
38. PIAT.tw.
39. NART.tw.
40. AMNART.tw.
41. NVS.tw.
42. SAHLSA.tw.
43. HLSQM.tw.
44. SILS.tw.
45. HLSI.tw.
46. HLSI-SF.tw.
47. METER.tw.
48. SAHL-S&E.tw.
49. SLS.tw.
50. BHLS.tw.
51. or/32-50
52. and/2,51
53. 1 or 12 or 13 or 31 or 52
54. Kidney diseases/
55. exp Renal replacement therapy/
56. renal insufficiency/
57. exp renal insufficiency, chronic/
58. renal replacement therapy/
59. dialysis.tw.
60. (hemodialysis or haemodialysis).tw.
61. (hemofiltration or haemofiltration).tw.
62. (hemodiafiltration or haemodiafiltration).tw.
63. peritoneal dialysis/
64. (peritoneal and dialysis).tw.
65. (kidney disease* or renal disease* or kidney failure or renal failure).tw.
66. (ESRF or ESKF or ESRD or ESKD).tw.
67. (CKF or CKD or CRF or CRD).tw.
68. (CAPD or CCPD or APD).tw.
69. (predialysis or pre-dialysis).tw.
70. Kidney transplantation/
71. (renal transplant* or kidney transplant*).tw.
72. or/54-71
73. and/53,72

Search Strategy for Health Management Information Consortium , Cinahl, Psychinfo [via NICE Healthcare databases]

1. (Health adj3 litera*).tw
2. (literacy OR literate).tw
3. HL.tw
4. HEALTH EDUCATION/
5. CONSUMER HEALTH INFORMATION/
6. EDUCATIONAL STATUS/
7. PATIENT EDUCATION/
8. ATTITUDES/ OR KNOWLEDGE/
9. COMPREHENSION/
10. Patient AND Education.tw
11. 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10
12. 2 AND 11
13. numeracy.tw
14. Wide AND Range AND Achievement AND Test.tw
15. Rapid AND Estimate AND of AND Adult AND Literacy AND in AND Medicine.tw
16. Peabody AND Individual AND Achievement AND Test.tw
17. Slosson AND oral AND reading AND test.tw
18. National AND Adult AND Reading AND Test.tw
19. (Woodcock-Johnson AND test).tw
20. (medical AND terminology AND achievement).tw
21. literacy AND assessment AND for AND diabetes.tw
22. adult AND basic AND education AND test.tw
23. Newest AND Vital AND Sign.tw
24. Short AND Assessment AND of AND Health AND Literacy.tw
25. Health AND literacy AND Screening AND Question AND Methodologies.tw
26. Single-Item AND Literacy AND Screener.tw
27. Health AND Literacy AND Skills AND Instrument.tw
28. Medical AND Term AND Recognition AND Test.tw
29. Short AND Literacy AND Survey.tw
30. Brief AND Health AND literacy AND Screen.tw
31. 14 OR 15 OR 16 OR 17 OR 18 OR 19 OR 20 OR 21 OR 22 OR 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30
32. (SORT AND read).tw
33. (REALM AND read).tw
34. (MART AND read).tw
35. TOFHLA.tw
36. STOFHLA.tw
37. WRAT.tw
38. PIAT.tw
39. NART.tw
40. AMNART.tw
41. NVS.tw
42. SAHLSA.tw
43. HLSQM.tw
44. SILS.tw
45. HLSI.tw
46. HLSI-SF.tw
47. METER.tw
48. SAHL-SandE.tw
49. SLS.tw
50. BHLS.tw
51. 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50
52. 2 AND 51
53. 1 OR 12 OR 13 OR 31 OR 52
54. KIDNEY DISEASES/
55. ((renal replacement therapy)).af
56. dialysis.tw
57. (hemodialysis OR haemodialysis).tw
58. (hemofiltration OR haemofiltration).tw
59. (hemodiafiltration OR haemodiafiltration).tw
60. PERITONEAL DIALYSIS/
61. (peritoneal AND dialysis).tw
62. (kidney AND disease* OR renal AND disease* OR kidney AND failure OR renal AND failure).tw
63. (ESRF OR ESKF OR ESRD OR ESKD).tw
64. (CKF OR CKD OR CRF OR CRD).tw
65. (CAPD OR CCPD OR APD).tw
66. (predialysis OR pre-dialysis).tw
67. KIDNEY TRANSPLANTS/
68. (renal AND transplant* OR kidney AND transplant*).tw
69. exp KIDNEY DISEASES/
70. exp RENAL SERVICES/ OR exp KIDNEY DISEASES/ OR exp KIDNEY TRANSPLANTS/ OR exp HAEMODIALYSIS/
71. 54 OR 55 OR 56 OR 57 OR 58 OR 59 OR 60 OR 61 OR 62 OR 63 OR 64 OR 65 OR 66 OR 67 OR 68 OR 69 OR 70
72. 53 AND 71

Figure S1: Search terms used for electronic databases.

Table S1: Characteristics of conference abstracts meeting the inclusion criteria.

Outcome variables are listed only if statistical models included health literacy as an exposure variable. * Studies included in Fraser 2012 review. α Frequencies from personal communication with the authors β- Australia, New Zealand, Canada, UK, USA, Belgium, France, Countries of the former Gulf Cooperation Council', Germany, Italy, Japan, Russia, Span, Sweden, and Turkey.

CKD- Chronic Kidney Disease; HD- Haemodialysis; PD- Peritoneal Dialysis; CV- Cardiovascular; CVD: Cardiovascular disease; BP-Blood Pressure; BMI- Body Mass Index; MAP- Mean Arterial Pressure; DBP- Diastolic Blood Pressure; PVD- Peripheral Vascular Disease; LDR-Live-donor recipient; DDR- deceased-donor recipient; AKI- Acute Kidney Injury; MDRD: Modification of Diet in Renal Disease; CPR: Cardiopulmonary resuscitation; ED- Emergency Department; LDL- Low density lipoprotein; SES- Socioeconomic status

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Limited health literacy prevalence (%)
Blandon (3)(37)	2011	USA	225	-	49	Non-dialysis CKD 2-4	Health literacy and BP control in Hispanic Americans	Cross-sectional	Adults from nephrology outpatients clinic	91% Hispanic 73% low income 61% diabetic	None stated	STOFHLA (English /Spanish)	BP control	46
Cavanaugh 3* (4)	2010	USA	50	[51]	48	Prevalent HD	Association of health literacy and type of dialysis access used	Cross-sectional	Adults from a single dialysis unit	74% Black 33% dialysis catheter	Not stated	REALM	Dialysis catheter use	32
Cavanaugh 4 (5)(39)	2015	Multiple countries	11476	-	-	Prevalent HD	Assess International variation in health literacy and association with mortality	Cohort	International sample from the DOPPS4 and DOPPS5 cohorts-randomly selected patients from dialysis units in participating countries β	-		BHLS (0-12)	Mortality	25
Eneanya (6)(43)	2015	USA	152	[68]	60	Non-dialysis CKD 4-5	Investigate health literacy as a mediator of racial disparities in CPR knowledge	Cross-sectional	Adults at a single center	56% White 44% Black	<45, Non-English-speaking, Ethnicity other than Black or White, Listed for transplant, Dementia	REALM	CPR Knowledge	34 (Black 62%; White 14%)
Jang (7)(45)	2014	USA	110	>65 (exact figure not known)	58	Prevalent HD	Compare medication label understanding to REALM-SF	Cross-sectional	Adults from 3 dialysis centers	83% White. 11% hadn't completed high school	<18. Non-English speaking, 'unable to reasonably manage medications'	REALM-SF	Medication label understanding	23
Marshall (8)(46)	2015	NZ	99 α	[56]	63	Prevalent dialysis (PD and HD)	Validate BHLS in multi-ethnic NZ population	Cohort (baseline data)	Random sample from single dialysis center, stratified to include equal groups by ethnicity (NZ Māori/Pacific Peoples/Other) and	35% NZ Māori; 35% Pacific Peoples; 30% White or other	<17. Logistic or safety risk to interviewers, severe mental illness, severe communication difficulty, unable to give informed consent	BHLS	-	42

Study	Year	Location	n	Median age (years) [mean]	Male (%)	CKD stage	Aim	Design	Setting & recruitment method	Participants	Exclusion criteria	Health literacy measure	Outcome variables tested	Limited health literacy prevalence (%)
									dialysis location (home/center)					
Nelson (9)(49)	2015	USA	208	[72]	56	Non-dialysis CKD3b-5	Relationship between health literacy, medicines management capacity and treatment adherence	Cross-sectional	Adults under regular nephrology care in a single unit		-	REALM	Medicines management capacity and self-reported medication adherence	23
Puher (10)(50)	2014	USA	512	[66]	50	Non-dialysis CKD3-5	Assess relationship between health literacy and patient understanding	Cross-sectional	Nephrology outpatients surveyed on understanding of kidney tests via an online portal	97% White	<2 clinic attendances. Patients who don't use online portal.	BHLS (0-15)	Self-reported understanding of test results	17
Singh (11)(53)	2012	USA	101	-	49	Prevalent HD	Association of health literacy with dialysis quality measures	Cross-sectional	Adults in a single dialysis center	-	None stated	STOFHLA	Lab values, infections, hospitalization, dialysis access	8
Singla (12)(54)	2016	USA	74	[58]	57	Non-dialysis CKD 3-4	Identify prevalence and associations of low health literacy	Cohort	Participants already recruited to a clinical trial.	38% Black; 8% White; 48% Hispanic	None stated	REALM	Demographics, hospitalization, dialysis initiation at 2 years	30
Weng 2 (13)	2014	USA	499	[54]	65	Non-dialysis CKD (n=203) and Prevalent dialysis (n=296)	RCT of an educational intervention to increase knowledge of live donor kidney transplantation	Clinical trial (baseline data)	Single transplant center.	Potential transplant candidates referred for evaluation	None stated	NVS	-	9 (Non-dialysis CKD 5%; Dialysis 11%)