

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

Reference; Health issue; Country of study	Design; Sample size; Population; Literacy assessment	Intervention	Control	Primary outcome	Results
Gazmararian, Jacobson et al. (2010); No specific health issue; USA	Controlled Before and After; N=275; Indigent, minority population, predominantly low literacy; (PILL Study) REALM	3-part; (1) automated telephone refill reminders, (2) pictorial prescription representation; (3) training for pharmacists on clear communication and the use of pictorial prescriptions	Control site continuing with usual prescription filling practices	Medication adherence as measured by Cumulative Medication Gap (CMG)	There was no significant difference in pre- and post-intervention CMG between the control and experimental groups
Muir, Ventura et al. (2011); Glaucoma; USA	RCT; N=127; Military veterans, all but one are male; TOFHLA	Educational intervention showing an informational video where the language of the video varied according to subject HL	Usual care	Days without medication (DWM)	There was no significant difference in DWM between the interventions and the control groups, although the effect of the intervention was larger for lower literacy participants than for those with higher health literacy

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

Reference; Health issue; Country of study	Design; Sample size; Population; Literacy assessment	Treatment variables	Primary outcome	Results
<i>Descriptive features of Health Literacy</i>				
Praska, Kripalani et al . (2005); No specific health issue; USA	Descriptive study; N=30 pharmacies; Pharmacies in urban Atlanta – average education level <12 years; Respondent’s own understanding of health literacy	None	Pharmacy health literacy practices	3 (10%) pharmacies noted a lack of concern regarding health literacy because they were located in a middle-class neighbourhood and did not serve many Medicaid recipients; 2 (7%) pharmacies attempted to identify the health literacy needs of patients; 22 (73%) provided written or verbal counselling; 8 (27%) provided packaging or organisational aids such as pill bottles; 5 (17%) provided a refill service; and 4 (13%) provide graphical or multimedia aids for patients
O'Reilly, Bell et al. (2010); Mental health; Australia	Cross-sectional; 391; Registered pharmacists (19% response rate); Jorm mental health vignette protocol	None	Mental health literacy	92% of pharmacists could identify depression and 79% could identify schizophrenia from the symptoms in the vignette
Webb, Davis et al. (2008); No specific health issue; USA	Cross-sectional; N=85; Primary care patients (45) and members of adult education classes (40); REALM	None	Percentage of people able to match a warning label with its corresponding icon	Five of 10 common prescription drug warning labels were understood by greater than 80% of the sample (Range: 82-96%)

Risk Factors for Health Literacy

Bradley-Baker, Mullins et al. (2011); No specific health issue; USA	Cross-sectional; N=113; Pharmacists in direct contact with patients; AHRQ Pharmacy Health Literacy Assessment Tool	Demographic variables including age, gender, race, years since graduation, average script volume, and time at current practice; Formal Health Literacy Training; Pharmacy practice setting; chain, independent, or hospital	Health Literacy	Only occasional marginally significant relationships found for demographic variables; print and verbal health literacy practices as well as health literacy sensitivity were significantly correlated with formal health literacy training (r=0.34, 0.24, and 0.39; p=0.009, p=0.025, and p<0.0001 respectively); print and verbal health literacy practices as well as health literacy sensitivity also significantly correlated with practice setting (r=0.42, 0.31, and 0.53; p<0.001, p=0.002, and p<0.0001 respectively)
Wolf, Shekelle et al. (2009); No specific health issue; USA	Cross-sectional; N=96 prescriptions (from 24 community pharmacies); Chain, grocery store and independent pharmacies across the United States; No specific health literacy measure	Type of pharmacy	Medication label features that demonstrate health literacy principles	6% of prescriptions omitted dose frequency; 2% gave precise timing of administration; and 38% had indications for use transcribed on to the label; The provision of indication for use differed by type of pharmacy being provided by 56%, 20% and 28% of Chain, Grocery store, and Independent pharmacies respectively (chi-square statistic not provided, p<0.05)
Wong, Lam et al. (2011); Mental health;	Cross-sectional; N=200; Chinese population of	Gender	Health Literacy	25% of men and 75% of women correctly identified depression; 24% of men and 76% of women correctly identified schizophrenia in the

Australia	Melbourne; Jorm mental health vignette protocol			vignettes. These differences were not statistically tested
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Health Literacy as a Risk Factor

Backes and Kuo (2011); No specific health issue; USA	Cross-sectional; N=79; University hospital outpatients; S-TOFHLA	Health Literacy	Medication knowledge	Patients with adequate health literacy correctly reported the names of their medications more often than those with inadequate health literacy (84% vs 60%, p<0.001); correctly reported medication dosage more often (83% vs 71%, p=0.03); and correctly reported the frequency of their medications more often (85% vs 62%, p<0.001); there was no difference between the health literacy proficiency groups in the correct reporting of medication indication
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Cameron, Ross et al. (2010); No specific health issue; USA	Cross-sectional; N=267; Primary care patients; REALM	Health Literacy	Medication use self efficacy (MUSE score)	Health literacy predicted medication use self-efficacy. Mean MUSE scores were 28.7 (4.3); 28.5 (3.7); and 29.1 (3.7) respectively for Inadequate, Marginal, and Adequate health literacy (p<0.001)
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Davis, Wolf et al. (2006); No specific health issue; USA	Cross-sectional; N=395; Indigent and clinically underserved populations; REALM	Health Literacy	Errors in medication label understanding; Misunderstanding medication labels	More participants in the Low health literacy group made 1 or more errors in their understanding of medication labels than participants in the Marginal or Adequate health literacy groups (62.7%, 51.3%, and 37.7% respectively; p<0.001); Adjusting for demographic variables and number of medications, Low health literacy patients were more likely to misunderstand medication labels (ARR 2.32: CI 1.26-4.28) than Adequate health
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<p>Davis, Federman et al. (2009); No specific health issue; USA;</p>	<p>Cross-sectional; N=359; Indigent and clinically underserved populations; REALM</p>	<p>Health Literacy</p>	<p>Incorrect interpretation of medication label instructions</p>	<p>literacy patients. This was also true for Marginal health literacy patients (ARR 1.94: CI 1.14-3.27)</p> <p>Low and Marginal health literacy respondents were more likely to misinterpret one or more label instructions, adjusting for demographic factors, number of medications, frequency of use and dose complexity (ARR Low HL: 1.66, CI 1.18-2.32; Marginal HL: 2.70, CI 1,81-4.03); Instructions that gave time periods (e.g., morning, evening) or specific times (e.g., 8:00am, 5:00pm) were less likely to be misinterpreted than instructions that indicated how often in a day medications should be taken (ARR Time period: 0.42, CI 0.34-0.52; Specific times: 0.60, CI 0.49-0.74)</p>
<p>Gatti, Jacobson et al. (2009); No specific health issue; USA</p>	<p>Cross-sectional; N=275; Indigent, minority population, predominantly low literacy (PILL Study) REALM</p>	<p>Health Literacy</p>	<p>Morisky 8-item Medication Adherence Scale (MMAS-8)</p>	<p>Health literacy did not significantly predict medication adherence as measured by the MMAS-8</p>
<p>Johnson, Jacobson et al. (2010); No specific health issue; USA</p>	<p>Cross-sectional; N=275; Indigent, minority population, predominantly low literacy (PILL Study) REALM</p>	<p>Health Literacy</p>	<p>Morisky 8-item Medication Adherence Scale (MMAS-8)</p>	<p>This report investigated the relationship between MMAS and HL using Chi-square analysis but as with Gatti et al. (2009) found that health literacy was not related to MMAS-8 scores; Analysis of social support found that greater social support is associated with better medication adherence but only for people with</p>

				adequate health literacy
Kripalani, Henderson et al. (2006); Coronary heart disease; USA	Cross-sectional; N=152; Indigent, minority population, predominantly low literacy; REALM	Health Literacy	Medication management capacity as assessed by the Drug Regimen Unassisted Grading Scale (DRUGS)	Overall ability to manage medication was significantly associated with low health literacy (chi-square test result not provided, $p < 0.001$); this result is largely due to low health literacy's association with patient's scores on the <i>Ability to identify medications</i> sub-scale of the DRUGS measure (test statistic not provided, $p < 0.001$); this result held in multivariate analysis adjusting for demographic factors and cognitive function (AOR 10.93, CI 2.09-51.54)
Marks, Schectman et al. (2010); No specific health issue; USA	Cross-sectional; N=100; Socio-economically disadvantaged group; REALM	Health Literacy	Medication knowledge	Health literacy was associated with knowledge of Medication name ($Rho=0.69$, $p < 0.001$); Dosage ($Rho=0.22$, $p=0.02$); Purpose ($Rho=0.42$, $p < 0.001$); and Potential side-effect ($Rho=0.31$, $p < 0.001$); In multivariate analysis, health literacy provided an additional 8% explanation of medication knowledge over and above that provided by demographic variables ($p < 0.001$)
Shrank, Patrick et al. (2009); No specific health issue; USA	Cohort study; N=127,153; Blue Cross Blue Shield administrative claims database; No specific measure of health literacy	Medication labels designed for Target pharmacies based on health literacy principles	Health service utilization	New users of the redesigned Target medication labels did not differ significantly from a matched sample of patients using standard (non-Target) labels in outpatient visit rates or inpatient visits and emergency department visits
Wolf, Davis et al.	Cross-sectional;	Modified drug	Attention to	Low health literacy patients were more likely to

(2010); No specific health issue; USA	N=500; Predominantly minority patients REALM	warning labels using simplified text and icons	warning labels	attend to simplified text labels than standard labels (AOR 1.60, CI 1.09-2.33); Low and Marginal health literacy patients were more likely to attend to simplified text plus icons than simplified text only labels (AOR Low HL 3.22, CI 1.39-7.50; AOR Marginal HL 2.59, CI 1.24-5.44)
Wolf, Curtis et al. (2011); No specific health issue; USA	Cross-sectional; N=464; Older patients; NVS	Health Literacy	Patient reports of how often throughout a day they would take a standard set of medications	Low health literacy was the only independent predictor of taking medications more often – given a standardised setting (Beta=0.67, p=0.02); patients with low health literacy and no chronic conditions dosed more than any other combination of literacy and chronic condition (test statistic not provided, p=0.005)
Wolf, Davis et al. (2011); No specific health issue; USA	Cross-sectional; N=500; Predominantly minority patients REALM	Health Literacy	Correct interpretation of prescription medication label instructions	Health literacy was not significantly related to correct label interpretation across different types of labels; Low health literacy patients correctly interpreted the patient-centred label more often than the standard label (RR 1.39. CI 1.14-1.68);

CI: 95% confidence interval; RR: Risk Ratio; ARR: Adjusted Risk Ratio; AOR: Adjusted odds ratio