# Assessment of literacy and numeracy skills related to non-steroidal anti-inflammatory drug labels

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#### Abstract

**Background:** Non-steroidal anti-inflammatory drugs are widely used and have a potential for over-the-counter misuse. Limited health literacy is associated with poor health outcomes. Identification of new strategies to assess literacy and numeracy could be useful in targeting effective education initiatives.

**Objective:** To characterize numeracy and literacy skills related to non-steroidal anti-inflammatory drug labels in primary care patients.

**Methods:** Patients were recruited and consented over an 8-month period after their regular primary care visit. Demographic information was collected and two instruments were administered to assess literacy and numeracy skills: (1) a medication label literacy instrument focused on non-steroidal anti-inflammatory drugs (MedLit-NSAID) and (2) a general healthy literacy-screening tool, the Newest Vital Sign. Two questions on the MedLit-NSAID instrument evaluated understanding of the Food and Drug Administration medication guide for non-steroidal anti-inflammatory drugs and the Food and Drug Administration approved over-the-counter label.

**Results:** A total of 145 patients were enrolled. Mean MedLit-NSAID and Newest Vital Sign scores were 6.8 (scale range 0–8) and 4.2 (scale range 0–6), respectively. Higher education level was associated with higher scores for both tools ( $p \le 0.05$ ). Total MedLit-NSAID scores on average were higher in females compared with males (6.5 vs 6, p = 0.05). Patients with decreased kidney function (n = 18) had significantly lower MedLit-NSAID scores ( $p \le 0.05$ ). Test–retest scores were not significantly different for MedLit-NSAID (p = 0.32). The correlation between the tools was 0.54 and internal consistency MedLit-NSAID was 0.61.

**Conclusion:** A medication information focused instrument provided specific information to assess health literacy related to non-steroidal anti-inflammatory drug labels. This information could be utilized to develop patient education initiatives for medication label comprehension.

# Keywords

Health literacy, primary care, drugs, non-prescription, non-steroidal anti-inflammatory agents

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# Introduction

Prescription and over-the-counter (OTC) non-steroidal antiinflammatory drugs (NSAIDs) are widely used.<sup>1,2</sup> NSAIDs are often inappropriately prescribed to older patients and recent data suggest there are high rates of OTC NSAID misuse.<sup>2,3</sup> Although NSAIDs may seem innocuous to patients, they can carry a significant risk of disrupting blood flow to the kidneys and thus precipitating community-acquired acute kidney injury (CA-AKI) in high-risk patients.<sup>4</sup> Episodes of CA-AKI have been shown to lead to costly hospitalizations and long-term consequences such as new onset or more rapid progression of chronic kidney disease (CKD).<sup>4,5</sup> NSAID use is associated with increased risk of CA-AKI and that risk increases with concomitant use of renin-angiotensin-aldosterone inhibitors and diuretics with

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the highest risk profiles among patients older than 65 and those with pre-existing CKD.<sup>6,7</sup> Many cases of NSAIDinduced AKI could be avoided by recognizing high-risk patients such as those taking renin-angiotensin-aldosterone inhibitors and/or diuretics and providing effective education to advise them on the kidney risks and appropriate use of NSAIDS. Most patient education material, including the Food and Drug Administration (FDA) NSAID medication guide and OTC labeling, are focused on bleeding risks with NSAIDs and offer limited information regarding risks of kidney injury. Both sources of information advise patients to contact their provider if they have kidney disease. However, they do not provide information for patients to determine their individual risk of kidney injury from NSAIDs if they do not have kidney disease, but are high risk or they are not aware they have kidney disease. This is important information to convey to patients to reduce preventable harm from NSAIDs-associated kidney injury.7 A study by Wolf et al.8 evaluated 185 FDA medication guides for reading difficulty and appropriateness using Lexile analysis and the suitability assessment of materials (SAM) tools. Structured interviews were also conducted to assess literacy and consumer use of FDA medication guides in 449 patients with ages ranging from 18 to 85. The analyses demonstrated that the FDA medication guides average reading level was 10-11th grade and most were lengthy with an average of 1923 words. None of the medication guides evaluated provided summaries to assist the patient in self-tailoring information specific to them in the additional content. In previous studies, the NSAID medication guide was shown to have a reading difficulty of 12th grade.9 However, there are currently no data evaluating patient comprehension of existing NSAID labeling regarding kidney risks in the context of lit-

Approximately one-third of US adults have limited health literacy which is associated with poor health outcomes.<sup>10</sup> It has also been shown that numeracy skills in health domains are significantly worse than financial or pure math domains.<sup>11</sup> In a study conducted by Wright Nunes et al.<sup>12</sup> in 399 CKD patients assessing perceived and objective knowledge, 72% of patients felt they had little or no knowledge of medications that could help the kidney and 62% felt they had little or no knowledge about medications that could harm the kidney. Because the widespread use of NSAIDs and recognizing the potential for widespread OTC misuse, identification of new strategies to assess literacy and numeracy regarding prescription medication information provided at dispensing (i.e. the FDA medication guide) as well as OTC labeling could be useful in targeting effective education initiatives. The primary objective of this pilot study was to characterize responses to literacy and numeracy questions related to NSAID labeling and a secondary objective was to compare these responses to a general health literacy tool.

eracy and numeracy skills.

# **Methods**

## Participants and setting

This was a prospective, cross-sectional pilot study to evaluate health literacy relevant to medication labels in primary care patients recruited from a large private medical practice. Patients who were at least 18 years of age and who had no significant vision, hearing, or cognitive impairment were included. Patients who resided in long-term care or assistedliving facilities were excluded. Patients were recruited from a large primary care practice in upstate New York from November 2015 to June 2016. The study protocol was approved by the Institutional Review Board (IRB) approved of Albany College of Pharmacy and Health Sciences and all participants provided written informed consent.

Design. The site was selected due to the large number of total patients (7256) and the range with which providers prescribed NSAIDs (3–39%). Potential participants received an IRB approved informational handout at their visit check-in and were made aware that research assistants were available in a private area of the clinic post-visit. Enrollment was conducted post-visit from 9 to 5pm Monday through Friday. Interested participants were then consented and received the instruments and demographic questions. Two instruments were administered: (1) a novel medication label literacy instrument (MedLit-NSAID in Supplemental Material) and (2) the Newest Vital Sign (NVS).13 The MedLit-NSAID instrument was developed by the principal investigator Amy Barton Pai (ABP). It is comprised of eight questions that evaluate literacy and numeracy in multiple domains including calculating, integrating, generating, and locating relevant to prescription and OTC NSAID labels which is similar in format and scoring to the NVS. Questions were designed to be easily readable by patients and were developed in consultation with health literacy experts. The advice and contribution of these experts during development of the screening measure established content and face validity for the tool.<sup>14</sup> The MedLit NSAID is scored by the number of correctly answered questions. A subset of 30 patients were randomly selected from the original sample in this study and requested to repeat the instruments within 3 months of the original completion to determine re-test reliability of the instrument. The NVS is a screening tool developed for use in primary care that determines risk for limited health literacy.13 Patients are given a copy of a nutrition label and asked six questions about how they would interpret and act on the information. Scores are classified as high likelihood (0-1), possibility of limited literacy (2-3), and adequate literacy (4-6).<sup>13</sup> The NVS was selected for comparison because this instrument assesses reading comprehension and was representative of the domains (e.g. calculating, integrating) assessed by the MedLit-NSAID instrument.<sup>14</sup> Basic demographic information was collected from patients, including age, gender, and

education level. Kidney function was determined by the most recent laboratory reported estimated glomerular filtration rate (eGFR) obtained from the primary care clinic's electronic medical record and categorized as > or  $\le 60 \text{ mL/min}/1.73 \text{ m}^2$ . CKD was defined as eGFR  $\le 60 \text{ mL/min}/1.73 \text{ m}^2$ .<sup>15</sup>

Outcome. The main objectives of this initial study were to characterize MedLit-NSAID scores and compare those scores with the NVS in a cross section of general primary care patients. NVS and MedLit-NSAID scores were calculated and descriptive statistics including mean ± standard deviation (SD) and percentage correct for individual items and item-scale correlations were calculated. Bivariate analysis of the association between domain scores and other demographic factors were used to provide additional evidence of construct validity. The paired sample t-test and chisquare test were used for continuous and categorical data, respectively. Internal consistency reliability of both tools was preliminarily determined using Cronbach's alpha and test-retest reliability using the intra-class correlation coefficient (ICC). The paired sample t-test was used to determine the difference between the mean score of the initial test and re-test to assess the MedLit-NSAID tool's reliability. All hypothesis tests were two-sided with alpha-level of 0.05. All statistical analyses were conducted using SAS, version 9.2 (SAS Institute, Cary NC, USA).

# Results

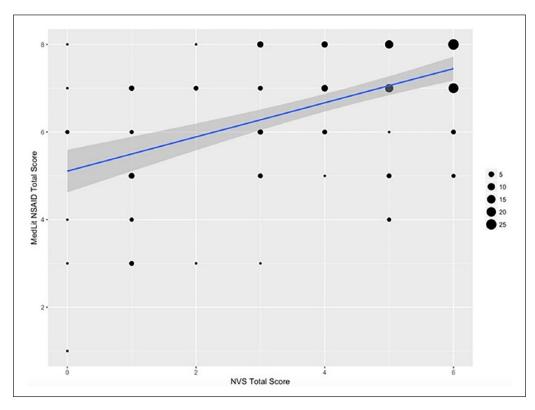
The majority of the 145 study participants were White (86%), self-managed their medications (99%), and were taking less than five medications (72%). One third of patients were over 65 years old (average age 56 ± 15 years) and there was even gender distribution (Table 1). The correlation between NVS and MedLit-NSAID total scores was 0.54 (Figure 1). Twenty six of 30 patients contacted completed a MedLit re-test and preliminary analysis of internal consistency reliability for both NVS and MedLit-NSAID were acceptable ( $\alpha$ =0.8 and  $\alpha$ =0.61, respectively) (Tables 2 and 3).

The average score for NVS was  $4.2 \pm 1.9$  (70%  $\pm 32\%$ ) and for MedLit-NSAID was  $6.8 \pm 1.4$  (85%  $\pm 18\%$ ). Mean scores were not statistically significantly different between initial test scores and re-test scores for NVS (p=0.06) and MedLit-NSAID (p=0.32). Correlation coefficients between different types of questions in the MedLit-NSAID and NVS were determined (Supplemental Table 1). The strongest correlation (r=0.47) was found between the calculating questions of the MedLit-NSAID and the NVS (Figure 2). Patients who had higher education levels (completed bachelor degree or above) performed better on both the NVS (p=<0.05) and MedLit-NSAID (p=<0.05). The number of patients who scored above the cohort average was higher for both the NVS and MedLit-NSAID in patients with higher education Table 1. Patient demographics.

Characteristic % (n)	(n=145)
Age (n)	
Less than 65	68% (98)
65 or older	32% (47)
Gender	
Male	48% (69)
Female	52% (76)
Estimated Glomerular Filtration Rate (eGFR)	
>60 mL/min/1.73 m <sup>2</sup>	88% (127)
$\leq$ 60 mL/min/1.73 m <sup>2</sup>	12% (18)
Education level	
Some high school	3% (5)
High school/GED	23% (34)
Some college	21% (30)
Associate degree	8% (11)
Bachelor's degree	23% (34)
Master's degree	17% (25)
Doctoral degree	3% (5)
Ethnicity	
Caucasian	86% (125)
Self-manage medications	
Yes	99% (143)
Number of medications	
Less than 5 medications	72% (105)
5–10 medications	25% (36)
II-I5 medications	1% (2)
15 or more medications	1% (1)

GED: General Education Diploma.

(Supplemental Table 2). Variability in MedLit-NSAID scores decreased as education level increased (Figure 3). For the NVS, there was no significant difference among males and females  $4.1 \pm 1.9$  versus  $4.3 \pm 1.8$ , respectively (p=0.3); however, on average, females scored higher than males  $6.9 \pm 1.1$  versus  $6.5 \pm 1.7$ , respectively (p=0.05), on the MedLit-NSAID. The mean  $\pm$  SD scores for NVS were higher in patients <65 years  $(4.6 \pm 1.7)$  compared with patients  $\geq 65$  years (3.5  $\pm$  2.1; p < 0.05). However, the mean  $\pm$  SD scores of the MedLit-NSAID were similar in participants <65 years  $(6.8 \pm 1.3)$  and those >65 years  $(6.6 \pm 1.6, p=0.58)$ . A total of 18 participants (12%) had kidney disease (eGFR  $\leq 60 \text{ mL/min}/1.73 \text{ m}^2$ ). Their mean scores were significantly lower compared with the patients with normal renal function for both NVS  $(3.1 \pm 2.1 \text{ vs } 4.4 \pm 1.8,$ p=0.02) and MedLit-NSAID (5.8 ± 1.8 vs 6.7 ± 1.3, p=0.02). A total of 60% of patients with kidney disease answered the OTC integrating question (Question 8 in Supplemental Material) incorrectly compared with 12% of patients with normal renal function (p=0.04). There was no significant difference in the proportion of patients with that answered the prescription label integrating question incorrectly (Question 5 in Supplemental Material) among patients with and without kidney disease.



**Figure 1.** The total scores of the Newest Vital Sign and MedLit-NSAID. The size of the dot on the figure represents the relative number of patients. This figure shows the relationship between total scores of the Newest Vital Sign (NVS) and MedLit-NSAID (r=0.54).

Table 2. Analysis of the correlation of different types of question for the Newest Vital Sign (NVS) and the MedLit-NSAID.

	Locating questions in the MedLit-NSAID	Calculating questions in the MedLit-NSAID	Integrating questions in the MedLit-NSAID
Calculating questions in the NVS	0.404	0.456	0.236
Integrating questions in the NVS	0.272	0.299	0.261

 Table 3. The number of patients who scored above the overall average with education levels above or below a bachelor degree for the Newest Vital Sign and the MedLit-NSAID.

	NVS tool		MedLit-NSAID tool	
	Below bachelor	Above bachelor	Below bachelor	Above bachelor
Above average	38	44	46	58
Below average	42	20	34	6

NVS: Newest Vital Sign.

# Discussion

We characterized results of an instrument developed to assess specific skills related to NSAID medication label literacy. There was good correlation between NVS and MedLit-NSAID (r=0.54) that was consistent with other comparisons of newly developed tools with standard validated tools.<sup>13</sup> The correlation between the Test of Functional Health Literacy in Adults (TOFHLA) with the NVS when originally developed was 0.49.<sup>16</sup> The internal consistency coefficient for MedLit-NSAID tool was 0.61, which is considered acceptable even though it is lower than the internal consistency coefficient suggested by Nunnally and Bernstein<sup>17</sup> ( $\alpha$ =0.7). Nonetheless, our findings are consistent with other medication health literacy tools focused on tacrolimus and metformin that were formatted similar to the NVS.<sup>18</sup> Their internal consistency coefficients for those instruments

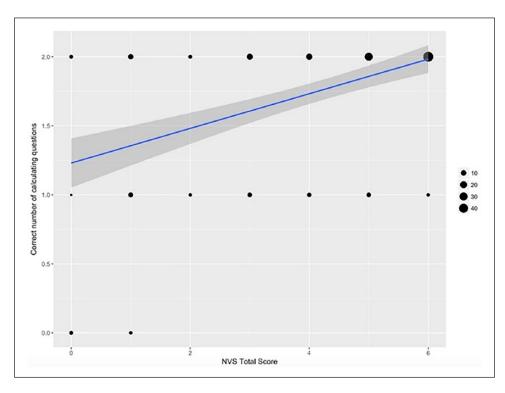


Figure 2. The NVS total score versus calculating questions for MedLit-NSAID.

The size of the dot on the figure represents the number of patients. This figure shows the relationship between total scores of the Newest Vital Sign (NVS) and score for calculating MedLit-NSAID questions (r=0.47).

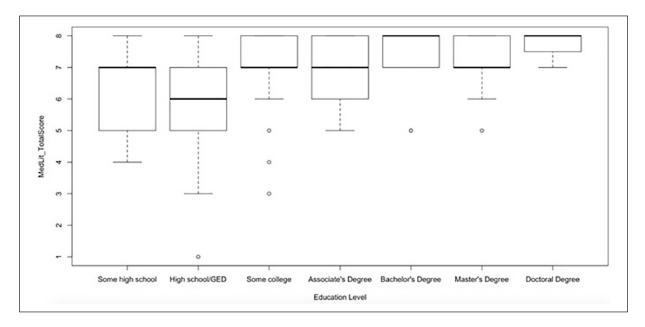


Figure 3. Boxplot for MedLit-NSAID scores for different education levels.

This boxplot shows the MedLit-NSAID total scores in different education levels. An empty dot represents outliers, a thick line represents median score in each education group, and the box represents interquartile range.

ranged from  $\alpha = 0.4$  to  $\alpha = 0.69$ . Test–retest is commonly performed to determine instrument reliability.<sup>19,20</sup> For the MedLit-NSAID, test–retest scores among the 26 patients who completed the survey a second time were not significantly different (p-value 0.32) indicating appropriate instrument reliability. We also found good correlation (r=0.47) between questions that assess numeracy within the two tools but poor correlation with more complicated integrating questions that were specific to the standard medication information provided to participants. These data suggest

that more difficult literacy tasks such as those that require the reader to pull together pieces of information from a text or document may need to be topic specific to inform development of education material.<sup>21</sup> An advantage of the NVS is that it facilitates health literacy comparisons cross-sectionally across different populations but does not provide specific content information to inform development of literacy appropriate education materials.<sup>22</sup> In contrast, the MedLit-NSAID assesses numeracy similarly to NVS but may also provide additional useful information to guide educational material development.<sup>7</sup>

Our data also show that education level is an important predictor for medication label literacy. In our study, patients with higher education scored significantly higher on both the NVS and MedLit-NSAID instruments. This is consistent with a study by Davis et al.<sup>23</sup> that examined patients' ability (n=395) to understand and demonstrate instructions on common prescription labels and correlated them with their health literacy using Rapid Estimate of Adult Literacy in Medicine (REALM). They found low literacy was associated with less education (p=0.001) and these patients also displayed misunderstanding of the instructions on prescription medication labels. Paasche-Orlow et al.<sup>24</sup> reviewed 85 studies (n=31,129patients) and also reported that lower educational achievement was consistently associated with limited health literacy (p = < 0.05). This may suggest obvious targeting of education materials to patients with less education but also may indicate it is necessary to redesign current medication education materials that meet plain language and literacy frameworks as outlined by the Agency for Healthcare Research and Quality.25

There was no gender difference observed with total NVS scores, however, females scored significantly higher on the MedLit-NSAID in this study. It is possible that women are more familiar with NSAID medication labels. It has been shown previously that NSAID prescriptions for musculo-skeletal disorders are higher among women.<sup>26,27</sup> The observation of lower MedLit-NSAID scores in men represents an opportunity to target education because it has been reported that men (especially those between 18 and 44 years) also commonly use NSAIDs.<sup>3</sup>

Older age has been associated with a decline in cognitive function and worse health literacy.<sup>28–30</sup> Total NVS scores in patients <65 years old were significantly higher compared with patients  $\geq 65$  years. Although the overall mean scores for the NVS scores in the study showed adequate literacy, the mean scores for  $\geq 65$  years old showed limited literacy. Conversely, for the MedLit-NSAID instrument, no significant difference in age strata were observed. This may be potentially explained by the fact that older patients may be familiar with the medication labeling due to increased medication use.<sup>31</sup> Data suggest that about 30% of  $\geq 65$  years old patients > 65 years old reported NSAID use at least once a week.<sup>31</sup>

Although a small proportion of study subjects had decreased kidney function (eGFR  $\leq 60 \,\text{mL/min}/1.73 \,\text{m}^2$ ), they scored lower than the average for both instruments. A higher proportion of patients with kidney disease associated with incorrect answer to the OTC label integrating question. This is consistent with the current literature on significant relationship between health literacy and renal function. Devraj et al.<sup>32</sup> used the NVS tool to examine the association between health literacy and eGFR in CKD patients. They found every unit NVS score increase was associated with a 1.9% higher eGFR. Limited health numeracy is also strongly associated with poor health outcomes of patients with kidney disease.<sup>33</sup> Wright et al asked open-ended questions to African American patients receiving dialysis to identify barriers to health numeracy.34 Patients mentioned lack of time spent with clinicians explaining numeric information such as medication dosages or laboratory values, and its relevance was one of barriers to understanding numeric information. Although it remains unclear what factors drive poor health literacy in among CKD patients, this population should be prioritized as a population in need of literacy appropriate education materials.

Adverse events: None.

Limitations. This study should be considered in the context of several limitations. The study population was recruited from a predominantly White, affluent suburb in upstate New York. Although the MedLit-NSAID was developed in collaboration with content experts, establishing face validity,<sup>14</sup> further studies of reliability are being conducted. Ethnicity is a known predictor for health literacy. African Americans, for example, have been shown to have high prevalence rates of low literacy.24,30 Further evaluation of the MedLit-NSAID in more diverse populations is necessary. Our study shows that literacy and numeracy scores focused on medication questions were similar between participants aged less than or greater than 65 years. These data imply that medication literacy may differ from general health literacy and should be further studied. The MedLit-NSAID tool assesses both prescription and OTC label literacy and numeracy skills. Because the prescription label is presented first, this poses a risk of contaminating the answers for the subsequent OTC label. In fact, we did find that patients with kidney disease were more likely to answer the OTC integrating question than patients with intact kidney function. A study of the MedLit-NSAID tools exclusively in patients with CKD seen by a nephrologist is ongoing.35 Oral literacy skills such as listening and speaking are also essential for patient-provider interactions and public health communication. This study was only designed to evaluate reading comprehension, and oral literacy was not assessed.

## Conclusion and relevance

The MedLit NSAID instrument correlated with a general health literacy tool. Although the MedLit-NSAID tool

provides more specific health literacy information than a general tool, prescription and OTC questions are combined and cannot be assessed independently. Lower education, male gender, and poor kidney function were found to be associated with lower comprehension of relevant NSAID medication labeling domains. These data suggest additional information may be able to be gleaned from medication label-focused instruments and could be used to more strategically inform development of NSAID avoidance education in targeted populations.

### **Declaration of conflicting interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

#### **Ethical approval**

Ethical approval for this study was obtained from Albany College of Pharmacy and Health Sciences (protocol number 15-018).

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#### Informed consent

Written informed consent was obtained from all subjects before the study.

#### Supplemental material

Supplemental material for this article is available online.

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