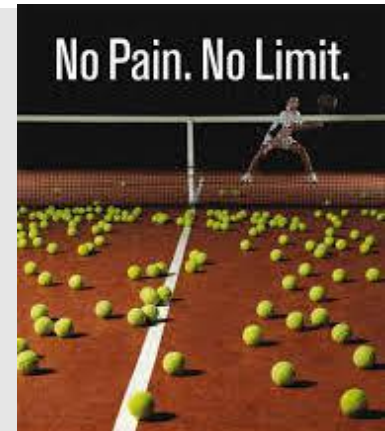




# Reducing Preventable Harm From Non-Steroidal Anti- Inflammatory Drugs



**NOW, WE'VE GOT YOUR BACK.**  
(AND YOUR KNEES, SHOULDERS,  
NECK, HIPS AND MUSCLES.)

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  - Grant funding: FDA
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  - Member, Kidney Health Initiative, Prioritizing End-stage Renal Disease Symptoms for Intervention



# NSAIDs: Wolves in Sheep's Clothing

- Prescription and OTC non-steroidal anti-inflammatory drugs (NSAIDs) are widely used
- Community-acquired acute kidney injury (CA-AKI) leads to poor outcomes but is common and preventable
- Patient knowledge of kidney risks with NSAIDs is poor and materials to educate are limited
  - 78% of people have taken an OTC pain medication, only 34% can name the active ingredient
  - NSAID avoidance education in community pharmacies
    - Pre and post patient knowledge questions (PKQ) administered (n=152). PKQ scores increased significantly after the education program (mean  $\pm$  SD,  $3.3 \pm 1.4$  vs.  $4.6 \pm 0.9$ , respectively,  $p=0.0019$ )
    - 48% reported current NSAID use and 67% reported that the program encouraged them to limit use of these agents

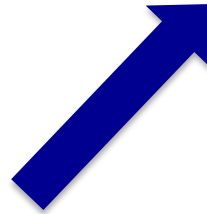
[http://www.bemedwise.org/survey/summary\\_survey\\_findings.pdf](http://www.bemedwise.org/survey/summary_survey_findings.pdf) Jang SM et al. NSAID-avoidance education in community pharmacies for patients at high risk for acute kidney injury, upstate New York, 2011. Prev Chronic Dis. 2014 Dec 18;11:E220



## Reducing Preventable Harm from NSAIDs: A Multi-Pronged Approach

- Evaluate adverse kidney risks of Rx and OTC NSAIDs in a large cohort
- Implement a data driven, innovative community based-education program (CBEP) in the medical neighborhood

Epidemiologic study using large primary care data set (DARTNet)



Community Based  
Education Program  
**Patient-Primary Care**  
**Provider-Pharmacy**  
Medication label literacy  
New Education Materials

- Mobile application
- Plain language print material
- Shelf talkers on product shelving
- Tear pads for pharmacists



# MedLit-NSAID Medication Label Literacy Tool

- Focused on literacy around medication labeling
- Based on a previously developed and validated tool for dialysis patients (MedLit-D)
- MedLit-NSAID evaluates several aspects of literacy (locating, calculating, generating, integrating)
- Two specific questions on the MedLit NSAID tool query participants regarding kidney risks using the FDA medication guide (for Rx) and the OTC label to answer the questions
- Newest vital sign literacy tool also evaluated for comparison
- A priori analysis by three strata; gender, age (< or > 65) and estimated glomerular filtration rate (eGFR < or > 60 mL/min/1.73m<sup>2</sup>)





# Prescription NSAIDs: FDA Medication Guide

**Before taking NSAIDs, tell your healthcare provider about all of your medical conditions, including if you:**

- have liver or kidney problems

**What are the possible side effects of NSAIDs?**

**NSAIDs can cause serious side effects, including:**

**See “What is the most important information I should know about medicines called Nonsteroidal Anti-inflammatory Drugs (NSAIDs)?”**

- new or worse high blood pressure
- heart failure
- liver problems including liver failure
- kidney problems including kidney failure

- kidney problems including kidney failure

- bleeding and ulcers in the stomach and intestine
- low red blood cells (anemia)
- life-threatening skin reactions
- life-threatening allergic reactions
- liver problems including liver failure
- asthma attacks in people who have asthma

- nausea
- vomiting
- dizziness





# Integrating Literacy Question (Rx)

Jamie has early kidney problems. Based on the medication guide provided what should be done about using this medication?

- A. The drug is definitely safe to use.
- B. Jamie should ask the provider about using the medication.
- C. Jamie not use this medication at all.
- D. Jamie should take over-the-counter ibuprofen instead.



# The Patient Interface: OTC NSAID Label

rash ■ blisters

If and allergic reaction occurs stop use and seek help right away.

**Stomach bleeding warning:** This product contains an NSAID which may cause severe stomach bleeding. The chances are higher if you:

■are age 60 or older ■have had stomach ulcers or bleeding problems ■take a blood thinning (anticoagulant) or steroid drug ■take other drugs containing prescription and non-prescription NSAIDs (aspirin, ibuprofen, naproxen, others) ■have 3 or more alcoholic drinks per day while using this product ■take more or for a longer time than directed

**Do not use** ■if you have ever had an allergic reaction to any other pain reliever/fever reducer ■right before or after open heart surgery

**Ask a doctor before use if** ■you have problems or serious side effects from taking pain relievers or fever reducers ■the stomach warning applies to you ■you have a history of stomach problems such as heartburn ■you have high blood pressure, heart disease, liver cirrhosis, or **kidney disease** ■you have asthma ■**you are taking a diuretic**

**Ask a doctor or pharmacist before use if you are** ■taking aspirin to prevent heart attack or stroke because ibuprofen may decrease this benefit of aspirin ■under a doctor's care for any serious condition ■taking any other drug

**When using this product** ■take with food or milk if stomach upset occurs ■the risk of heart attack and stroke may increase if you use more than directed for longer than directed

**Stop use and ask a doctor if** ■you experience any of the following signs of stomach bleeding: ■feel faint ■vomit blood ■have bloody or black stools ■have stomach pain that does not get better ■pain gets worse or lasts more than 10 days ■fever gets worse or lasts more than 3 days ■redness or swelling is present in the painful area ■any new symptoms occur

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use ibuprofen in the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery

**Keep out of reach of children:** in case of overdose get medical help or

Jamie is a person who has kidney problems, and wants to use this medicine now. What should Jamie do?

## Choose One Answer

- A. Take 1 tablet now.
- B. Take 1 tablet now and call the doctor or pharmacist.
- C. Call the doctor before taking the medicine.

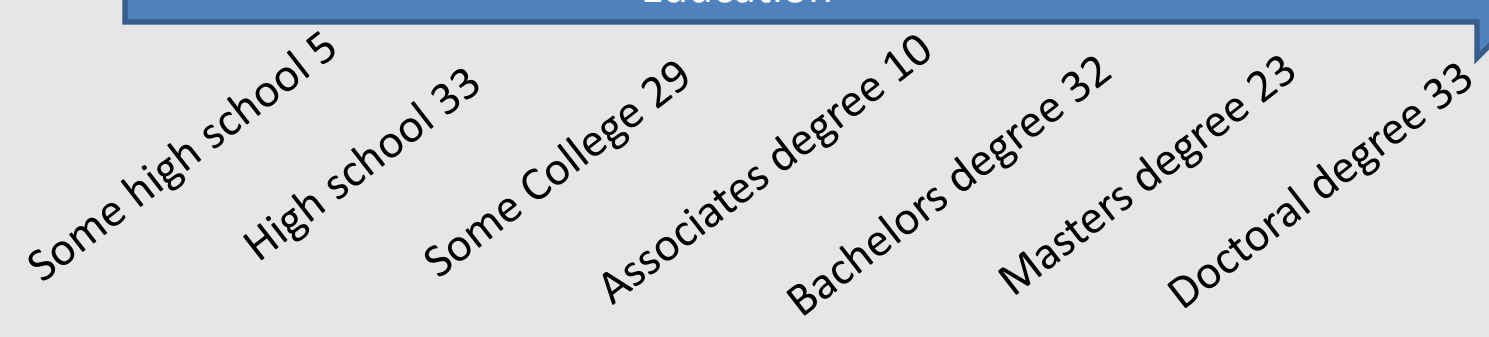


# Demographics

- 145 participants enrolled
- Mean age  $56 \pm 15$  years
- Predominantly white, English primary language
- Majority report they self-manage their own medications









## Education





# Literacy Tool Scores

Pre-Defined Strata	Newest Vital Sign Score	MedLit-NSAID Score	Comments
<b>Gender</b> Males vs. Females		 $p < 0.05$	No difference in number of integrating questions correct
<b>Age</b> < 65 vs $\geq 65$ years	 $P < 0.05$		No difference in number of integrating questions correct
<b>Kidney Function</b> eGFR < 60 vs > 60 mL/min/1.73m <sup>2</sup>		 $P < 0.01$	Responses were similar for Rx question 61% of people with eGFR < 60 answered the OTC question incorrectly vs 11% with eGFR > 60



# Summary

- Education materials required to be provided with NSAID prescriptions *are not heavily focused on kidney risks* and do not contain patient action plans regarding kidney risks.
- OTC NSAID labeling *may not be sufficient for patients* to make informed judgements about their kidney risks.
- *Innovative approaches should be studied* to improve both patient and provider awareness of kidney risks with NSAIDs to reduce episodes of CA-AKI.