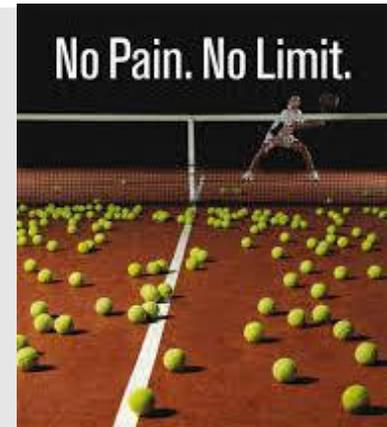




Reducing Preventable Harm From Non-Steroidal Anti- Inflammatory Drugs



NO PAIN. NO LIMIT.
NOW, WE'VE GOT YOUR BACK.
(AND YOUR KNEES, SHOULDERS,
NECK, HIPS AND MUSCLES.)

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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

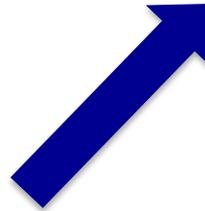
http://www.bemedwise.org/survey/summary_survey_findings.pdf Jang SM et al. NSAID-avoidance education in community pharmacies for patients at high risk for acute kidney injury, upstate New York, 2011. *Prev Chronic Dis.* 2014 Dec 18;11:E220

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/1.73m²)



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
- | | |
|--|---|
| <ul style="list-style-type: none">• 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 | <ul style="list-style-type: none">• 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

<p>rash ■ blisters</p> <p>If and allergic reaction occurs stop use and seek help right away.</p> <p>Stomach bleeding warning: This product contains an NSAID which may cause severe stomach bleeding. The chances are higher if you:</p> <p>■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</p>
<p>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</p>
<p>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</p>
<p>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</p>
<p>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</p>
<p>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</p>
<p>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</p> <p>Keep out of reach of children: in case of overdose get medical help or</p>

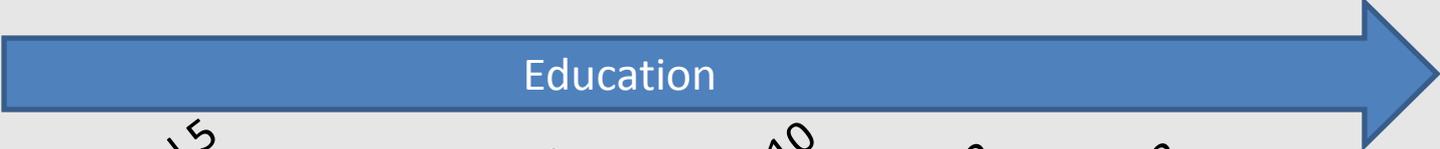
Jamie is a person who has kidney problems, and wants to use this medicine now. What should Jamie do?

Choose One Answer

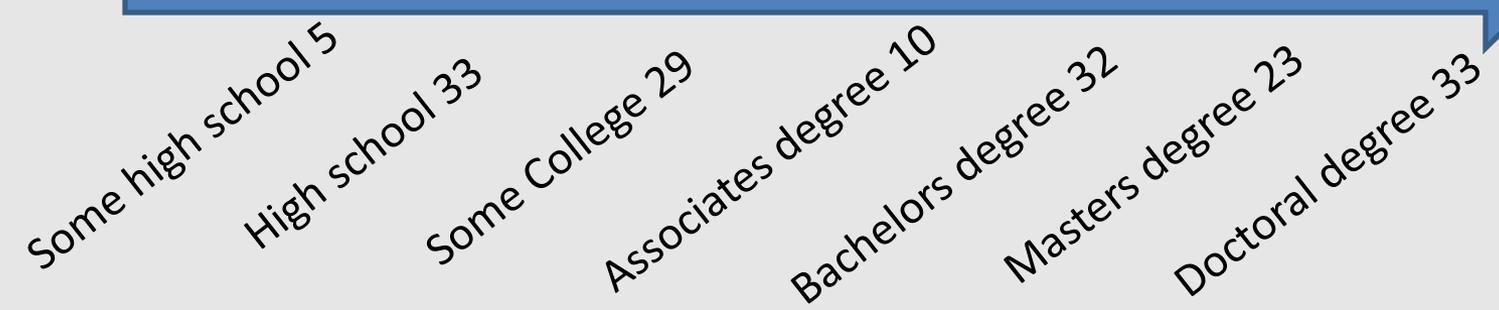
- A. Take 1 tablet now.
- B. Take 1 tablet now and call the doctor or pharmacist.
- C. Call the doctor before taking the medicine.

Demographics

- 145 participants enrolled
- Mean age 56 ± 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
Gender Males vs. Females		 p < 0.05	No difference in number of integrating questions correct
Age < 65 vs ≥ 65 years	 P < 0.05		No difference in number of integrating questions correct
Kidney Function eGFR < 60 vs > 60 mL/min/1.73m ²		 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.