Improving Patient’s Awareness of Acetaminophen in Over-the Counter (OTC) and Prescription (Rx) Medicines: “APAP” OFF and Icon ON

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Draft - Confidential
Acetaminophen: Important Ingredient in OTC and Rx Medicines

- One of the most widely used and most important medicines in the United States.
- When used according to the label directions has well-established record of safety and efficacy.
- Although very rare in the context of its broad usage, overdose can be toxic and lead to acute liver failure.

Situation: Gaps in Acetaminophen Awareness

- Patients may not recognize that acetaminophen:
  - is the active ingredient
  - is common to many OTC and Rx medicines
  - use from multiple acetaminophen-containing products places them at risk for overdose
- Patients may not be able to identify acetaminophen in Rx medicines labeled as “APAP”
- Limited awareness has been identified as a root cause of acetaminophen overdose
- Increasing patient understanding of acetaminophen and its proper use is key to minimizing risk
Increasing Acetaminophen Ingredient Awareness Needs to Involve Multiple Stakeholders

IMS Health, MIDAS May 2009; 24 billion Dosage Units of Acetaminophen Containing Medicines Sold (2008)
Variable Awareness of Analgesic / Antipyretic Ingredients in OTC and Rx Products

Does this product contain acetaminophen? – “Yes”


Many Patients Are Unaware that Rx Medicines Labeled as “APAP” Contain Acetaminophen
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Hill, Tray 05/28/09
TAKE ONE TABLET BY MOUTH EVERY FOUR HOURS AS NEEDED FOR PAIN.

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NO REFILLS 28 TAB Drug Exp 5/28/2010

Hill, Tray 05/28/09
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Hill, Tray 05/28/09
TAKE ONE TABLET BY MOUTH EVERY FOUR HOURS

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NO REFILLS 28 TAB Drug Exp 5/28/2010

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WEST-WARD GENERIC DISPENSED
NO REFILLS 28 TAB Drug Exp 5/28/2010
Many Patients Are Unaware that Rx Medicines Labeled as “APAP” Contain Acetaminophen

- Space limitations in drug name fields in pharmacy computer systems and on the pharmacy label, often prevent the use of complete generic names\(^1\)
  - If only a Rx brand name is used the label may not list acetaminophen or “APAP” at all\(^1\)
  - Acetaminophen portion of the name is commonly abbreviated as “APAP” which patients may not recognize as acetaminophen\(^1,2\)

- Patients don’t recognize APAP as abbreviation for acetaminophen\(^3\)

Actions to Help Patients Recognize Acetaminophen as an Ingredient

- Standardize how acetaminophen appears on OTC\(^1\) labels and pharmacy-generated labels \(^2\)
  - “Don’t Hide the Acetaminophen”\(^2\)
- Avoid all abbreviations for medication names.\(^3\)
- Don’t use drug name abbreviations, such as APAP for acetaminophen, to avoid consumer confusion.\(^4\)
  - Replace “APAP” with “acetaminophen”
- Add acetaminophen ingredient icon to all OTC & Rx acetaminophen-containing medicines\(^5\)
  - Develop and implement icon

Icon Development and Testing Plan

- Premise: A graphical icon can help consumers recognize acetaminophen in multiple products, and help minimize simultaneous use
- Goals:
  - Primary: Improve awareness and identification of acetaminophen as an active ingredient
  - Secondary: Avoid use of multiple products containing acetaminophen at the same time
- Advisory Board Formed (Q42009)
- Research Underway (Q42009)
- Engagement for implementation on all OTC and Rx acetaminophen containing medicines
Health Literacy / Icon Expert Consultants

- Dr. Eric Brass
  - Prof. of Medicine, UCLA David Geffen School of Medicine; NDAC Chair 98-01
- Dr. Terry Davis
  - Professor of Medicine and Pediatrics at LSUHSC, LA
- Dr. Dan Formosa
  - Consultant in product design and design research
- Dr. Ruth Parker
  - Professor of Medicine at the Emory University School of Medicine
- Dr. Carol Pollack-Nelson
- Dr. Saul Shiffman,
  - Research Professor of Psychology (Clinical and Health Psychology) at University of Pittsburgh, and Senior Scientific Advisor to Pinney Associates
- Dr. Mike Wolf,
  - Assoc. Professor of Medicine, Assoc Division Chief of Research, and Director of the Center for Communication in Healthcare, Feinberg School of Medicine at Northwestern University
Overview of Icon Development & Research Program

- Developed multiple graphical / design approaches & candidates
- Conducted qualitative testing (3 rounds, 3 cities, n=147) to assess consumer and patient responses
- Iterative development and evolution of icon
  - Enhanced visibility and prominence
  - Minimized incorrect or distracting meanings
  - Improved effective communication of key message
  - Assessed compatibility with label language
- Planning quantitative test of final candidates to assess improved recognition of acetaminophen as an ingredient
## Icons Tested in Different Context: Iterative Research for In-Process Icon Refinement

<table>
<thead>
<tr>
<th>Qualitative Round 1:</th>
<th>Qualitative Round 2:</th>
<th>Qualitative Round 3:</th>
<th>Lead Options:</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘A associated with other medications and products (aspirin, etc.)’</td>
<td>begin exploration of other options in context. APAP generally not understood</td>
<td>ensure icons do not connect with other medications or products in a positive or negative way</td>
<td>narrowing direction based upon consumer feedback of importance and connection with acetaminophen</td>
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</tbody>
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![Diagram showing icons and their connections](image-url)
“APAP” as an Ingredient Icon Did Not Qualitatively Test Well

- 27/30 (90%) responses negative feedback
  - “APAP” – confused about – have no idea what it means. Don’t know what it is.
  - Don’t know what “APAP” means – but doctor/pharmacist would understand. But I know what acetaminophen means
Lessons Learned and Next Steps

Lessons Learned:

- Icon with text is more effective than an icon alone
- Acetaminophen-icon supports identifying the ingredient and warnings on OTC and Rx products
- Healthcare providers agree:
  - acetaminophen-icon is needed on both Rx and OTC products
  - education is necessary to maximize impact

Next Steps:

- Additional qualitative testing
- Quantitative testing
Increase Acetaminophen Ingredient Awareness: Example of Icon across multiple adult acetaminophen containing products

Note: for demonstration purposes only. Manufacturers beyond McNeil have not been consulted
Timely Actions and Stakeholder Commitment Needed:
“APAP” OFF + Icon ON

° Timely actions:
  • Remove ‘APAP’ from all Rx labels - spell out acetaminophen
  • Add icon to all OTC and Rx acetaminophen-containing medicines

° Stakeholder commitment:
  • All acetaminophen manufacturers
  • FDA
  • All State Boards of Pharmacy
  • Pharmacists
  • Retailers
  • Pharmacy Rx label system providers
  • Others?
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