

# Drug Facts Label Communication: Successes and Challenges

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# DFL as a Communication Tool

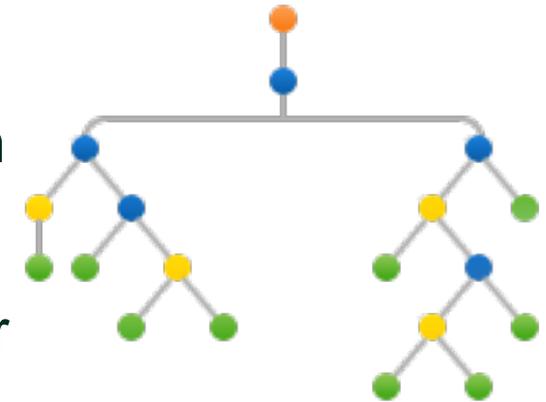
- DFL → substantial improvement with many benefits
  - Standardization
  - Plain language
  - Bullet points, sections, readability

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>    <b>Purpose</b></p> <p>Famotidine 10 mg.....Acid reducer</p> <p><b>Uses</b></p> <ul style="list-style-type: none"> <li>■ relieves heartburn associated with acid indigestion and sour stomach</li> <li>■ prevents heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to famotidine or other acid reducers</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>■ if you have trouble or pain swallowing food, vomiting with blood, or bloody or black stools. These may be signs of a serious condition. See your doctor.</li> <li>■ with other acid reducers</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating, or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent <b>chest pain</b></li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting    ■ stomach pain</li> </ul>	<p><b>Drug Facts (continued)</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b></p> <p>■ adults and children 12 years and over:</p> <ul style="list-style-type: none"> <li>■ to <b>relieve</b> symptoms, swallow 1 tablet with a glass of water. Do not chew.</li> <li>■ to <b>prevent</b> symptoms, swallow 1 tablet with a glass of water <b>60 minutes before</b> eating food or drinking beverages that cause heartburn</li> <li>■ do not use more than 2 tablets in 24 hours</li> <li>■ children under 12 years: ask a doctor</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions and warnings before use</li> <li>■ keep the carton. It contains important information.</li> <li>■ store at 20°-25°C (68°-77°F)</li> <li>■ protect from moisture and light</li> </ul> <p><b>Inactive ingredients</b> carnauba wax, hypromellose, iron oxide red, iron oxide yellow, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, pregelatinized starch, talc, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b> 1-800-719-9260</p>
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- Still, DFL remains a static, non-customizable, text-based communication tool

# Barriers to Communication

- **Complex, multi-attribute criteria for decision-making**
  - Struggle to integrate multiple pieces of information from DFL
  - E.g., Simultaneous need to factor in medical history, age, and/or other risk factors
- **Example: Omeprazole Studies**
  - High level of comprehension on individual statements on DFL ( $\geq 90\%$ ) (Bierer 2002)
  - Lower ability to correctly self-select or comply with dosage directions when need to simultaneously consider multiple components of the DFL ( $\leq 21\%$ ) (Fendrick et al. 2004)



# Barriers to Communication



- Individual consumer characteristics and ability levels interfere with DFL accessibility/communication
  - Health literacy, visual ability, language barriers, and cognitive limitations are all associated with lower DFL comprehension (see Catlin & Brass 2018 for summary)
- Non-adaptive nature of print DFL prohibits customization for individual needs
  - Text-based format, space limitations prevent additional language options, etc.



# Additional Barriers: Knowledge, Attitudes, Beliefs

- Some consumers do not read the DFL or discard packaging contents during or before use (e.g., Soller & Shaheen 2011)

## Survey of Histamine2-Receptor Antagonist Purchasers

*Asked how much package labeling influenced their purchase decision:*

**68% stated “not at all”**

Shi, C.-W., Gralnek, I. M., Dulai, G. S., Towfigh, A., & Asch, S. (2004). Consumer usage patterns of nonprescription histamine2-receptor antagonists. *American Journal of Gastroenterology*, 99(4), 606–610.



# Barriers: Knowledge, Attitudes, Beliefs

- Some consumers only read part(s) of the DFL
  - Eye-tracking shows more attention to brand vs. other aspects of DFL (Bix et al. 2009)
  - Use of cognitive shortcuts, such as brand name (Catlin, Pechmann, & Brass 2012)

## Study of *Brand vs. Generic* PDP Effects on DFL Attention/Comprehension

Among participants with lower need for cognition:

Less time spent reviewing DFL  
AND

Lower comprehension of DFL

when principle display panel featured a brand vs. generic name

Catlin, J. R., Pechmann, C., & Brass, E. P. (2012). The Influence of Need for Cognition and Principal Display Panel Factors on Over-the-Counter Drug Facts Label Comprehension. *Health Communication*, 27(3), 264–272.



# Barriers: Knowledge, Attitudes, Beliefs

- **Even if read, some consumers ignore/disregard the need to follow DFL instructions**
  - **Some believe they can choose their own dose**  
(Kaufman et al. 2012; 2018)
  - **Misconceptions about OTC drug risks** (Catlin, Pechmann, & Brass 2015)

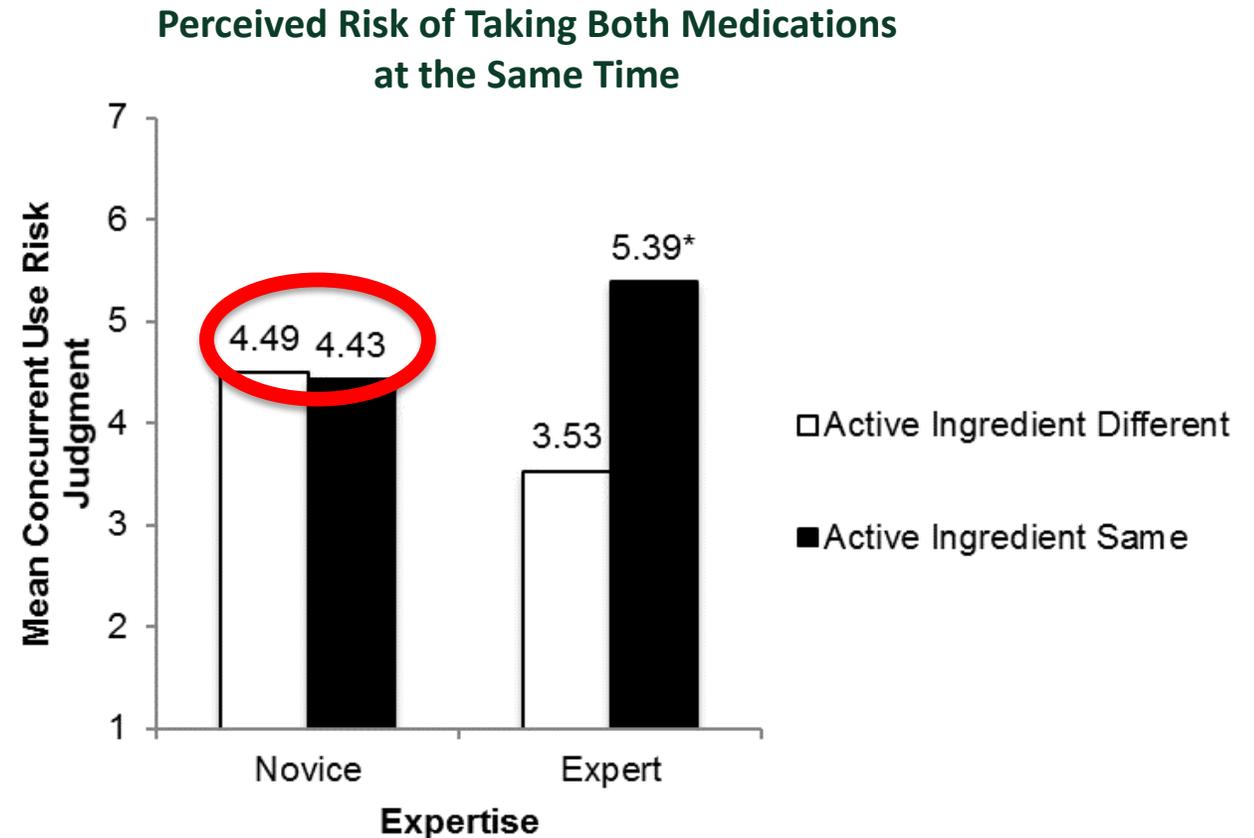


# Barriers: Knowledge, Attitudes, Beliefs

## Study of Participants with Medical Training (“Experts”) vs. Regular Consumers (“Novices”)

*Among participants without medical training, evaluating two OTC drugs for concurrent use:*

“Double dosing” was not perceived to be any riskier than taking two meds with different ingredients.



# DFL Modifications: Icons and Warnings

- Considerations to improve DFL communication:

- Icons
- Warnings
- Highlighting specific information

<b>Drug Facts</b>	
<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>
Acetaminophen USP, 650 mg	Pain reliever/ fever reducer
<b>Uses</b> ■ temporarily relieves minor aches and pains due to: ■ muscular aches ■ backache ■ minor pain of arthritis ■ toothache ■ premenstrual and menstrual cramps ■ headache ■ the common cold ■ temporarily reduces fever	
<b>Warnings</b> Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 caplets in →	

- May be effective in isolation, but usually leads to *adding* information to an already dense communication format
  - Potential for “**Information Overload**” → **looking for “shortcuts”**



# DFL Modifications: Visuals / Diagrams

- Label comprehension study for naloxone using step-by-step diagram

**Better performance** on primary endpoints measuring understanding of *single steps* ( $\geq 90\%$  correct)

**Lower performance** on composite measures including *multiple steps*:

- 3 steps combined (81.1% correct)
- 5 steps combined (74.6% correct)

- But...relatively small gap between single and multi-step comprehension suggests utility of a more “flexible” approach to communication via DFL

Drug Facts	
Active ingredient (in each XX) Naloxone hydrochloride X mg	Purpose Emergency treatment of opioid overdose
Uses • To “revive” someone during an overdose from many prescription pain medications or street drugs such as heroin • This medicine can save a life	
Directions	
 <b>1 CHECK</b> WAKE UP!	<b>Step 1: CHECK</b> <ul style="list-style-type: none"><li>• <b>CHECK</b> for a suspected overdose: the person will not wake up or is very sleepy or not breathing well</li><li>• yell, “Wake up!”</li><li>• shake the person gently</li><li>• if the person is not awake, go to Step 2</li></ul>
 <b>2 GIVE</b>	<b>Step 2: GIVE 1<sup>st</sup> dose</b> <ul style="list-style-type: none"><li>• <b>GIVE</b> the 1<sup>st</sup> dose of this medicine</li><li>• Place the injector on the LEG above the knee and press down</li></ul>
 <b>3 CALL</b>	<b>Step 3: CALL</b> <ul style="list-style-type: none"><li>• <b>CALL 911</b> immediately after giving the 1<sup>st</sup> dose</li></ul>
 <b>4 WATCH/GIVE</b> 2-3 Min	<b>Step 4: WATCH &amp; GIVE</b> <ul style="list-style-type: none"><li>• <b>WAIT</b> 2-3 minutes after the 1<sup>st</sup> dose to give the medicine time to work</li><li>• if the person wakes up: Go to Step 5</li><li>• if the person does not wake up:<ul style="list-style-type: none"><li>• <b>CONTINUE TO GIVE</b> doses every 2-3 minutes until the person wakes up</li><li>• it is safe to keep giving doses</li></ul></li></ul>
 <b>5 STAY</b>	<b>Step 5: STAY</b> <ul style="list-style-type: none"><li>• <b>STAY</b> until ambulance arrives: even if the person wakes up</li><li>• <b>GIVE</b> another dose if the person becomes very sleepy again</li><li>• You may need to give all the doses in the pack</li></ul>
Warnings When using this product some people may experience symptoms when they wake up, such as shaking, sweating, nausea, or feeling angry. This is to be expected.	
Other information • store at room temperature • [advise insert tamper evident statement here]	
Inactive Ingredients	
Questions? (phone number, website)	

# Summary

- DFL was a major step forward, but research shows clear barriers to communication via DFL, including:
  1. Communication of complex, multi-attribute criteria
  2. Responding to individual differences and ability levels
    - Health literacy, visual ability, language barriers, cognitive limitations
  3. Pre-existing knowledge, attitudes, and beliefs limit DFL attention and adherence
- Mitigation of these challenges is difficult due to the DFL's format as a *static, text-based, non-customizable* format
  - Consider possibilities of “**DFL+**”
    - Solutions could come from “outside the label” via adjunctive technology or other mechanisms
      - Increased customization/relevance could mean increased attention/adherence



# Thank You!

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