

Drug Facts Label Communication: Successes and Challenges

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DFL as a Communication Tool

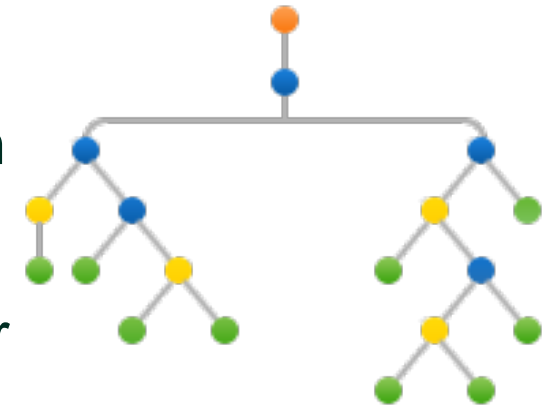
- DFL → substantial improvement with many benefits
 - Standardization
 - Plain language
 - Bullet points, sections, readability

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

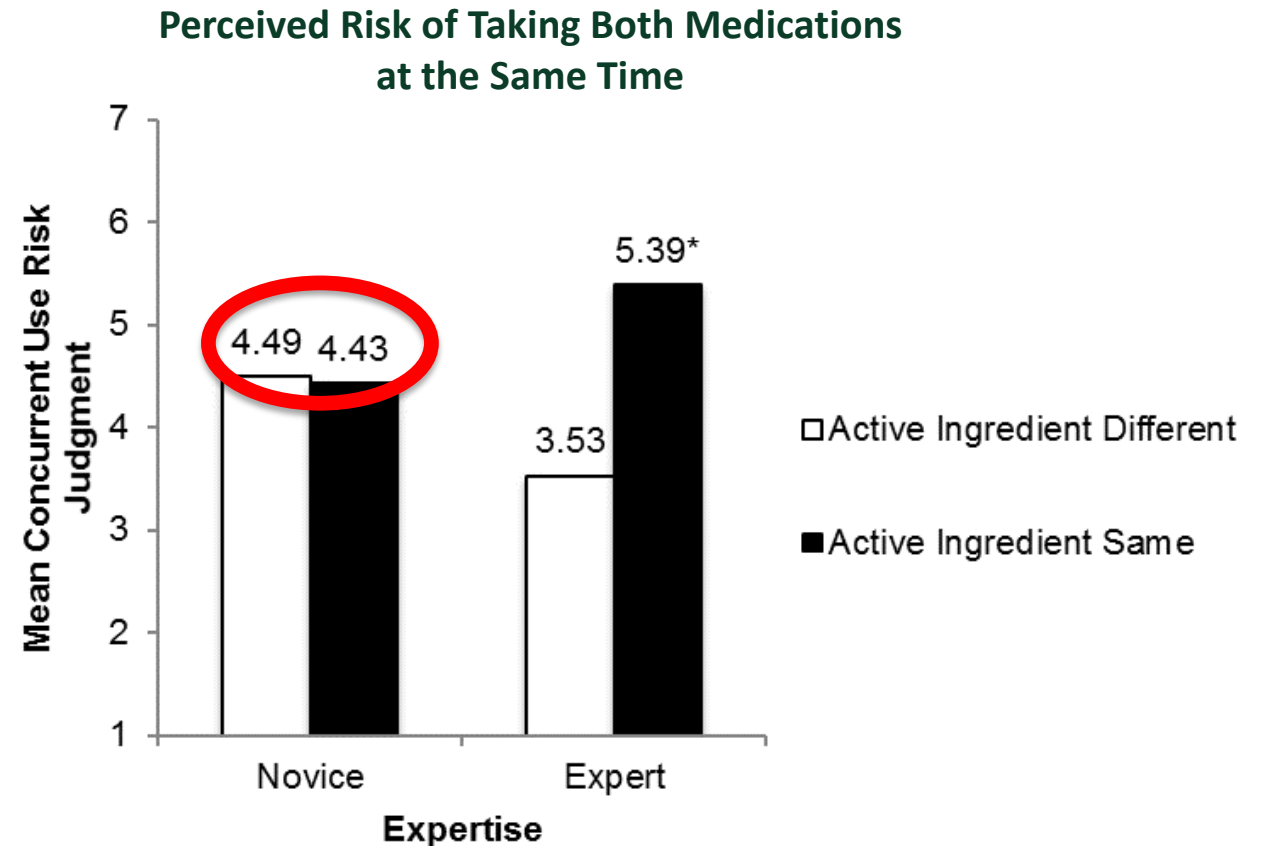


Barriers: Knowledge, Attitudes, Beliefs

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

Drug Facts	
Active ingredient (in each caplet)	Purpose
Acetaminophen USP, 650 mg	Pain reliever/ fever reducer
Uses ■ 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	
Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 caplets in	

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	
 <p>1 CHECK WAKE UP!</p>	<p>Step 1: CHECK</p> <ul style="list-style-type: none"> • CHECK for a suspected overdose: the person will not wake up or is very sleepy or not breathing well • yell, “Wake up!” • shake the person gently • if the person is not awake, go to Step 2
 <p>2 GIVE</p>	<p>Step 2: GIVE 1st dose</p> <ul style="list-style-type: none"> • GIVE the 1st dose of this medicine • Place the injector on the LEG above the knee and press down
 <p>3 CALL</p>	<p>Step 3: CALL</p> <ul style="list-style-type: none"> • CALL 911 immediately after giving the 1st dose
 <p>4 WATCH/GIVE 2-3 Min</p>	<p>Step 4: WATCH & GIVE</p> <ul style="list-style-type: none"> • WAIT 2-3 minutes after the 1st dose to give the medicine time to work • if the person wakes up: Go to Step 5 • if the person does not wake up: <ul style="list-style-type: none"> • CONTINUE TO GIVE doses every 2-3 minutes until the person wakes up • it is safe to keep giving doses
 <p>5 STAY</p>	<p>Step 5: STAY</p> <ul style="list-style-type: none"> • STAY until ambulance arrives: even if the person wakes up • GIVE another dose if the person becomes very sleepy again • You may need to give all the doses in the pack
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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