



Does Variation in the Physical Characteristics of Generic Drugs Affect Patients' Experiences?

Results from a National Survey of Pharmacists and Patients

Ameet Sarpatwari, J.D., Ph.D.

Instructor in Medicine, Harvard Medical School

Assistant Director, Program On Regulation, Therapeutics, And Law (PORTAL),
Division of Pharmacoepidemiology and Pharmacoeconomics,
Department of Medicine, Brigham and Women's Hospital

Disclosure

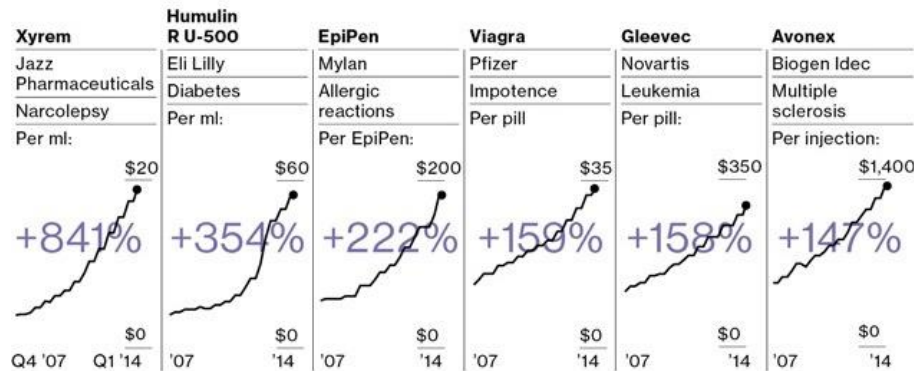
- I have no actual or potential conflicts of interest in relation to this presentation.

Medication Non-Adherence

- Burden: \$105 billion in avoidable health care costs annually
-IMS Institute for Healthcare Informatics (2013).

- Primary driver: cost

- 2008 -14: Price increase of most common brand-name drugs: 127%
-Express Scripts (2015).



-Bloomberg (2014).

- Cost-related non-adherence: patients and their families
 - Not filled a prescription in the past year: 24%
 - Cut pills in half or skipped doses in the past year: 19%
-Kaiser Family Foundation (2015).

- Initiation on a brand-name vs. generic drug: 13% lower adherence
-Shrank et al., Arch Intern Med (2006).

Pill Appearance Changes: Prior Studies

- ❑ Antiepileptic drugs
 - ❑ Nested case-control: non-persistence vs. persistence
 - ❑ Population: initiators of treatment
 - ❑ Odds of discordance: 2 refills before non-persistence
 - ❑ Color: OR=1.27 (95% CI, 1.04-1.55)
 - ❑ Shape: OR=1.47 (95% CI, 0.85-2.54)
-Kesselheim et al. JAMA Intern Med (2013).

- ❑ Cardiovascular drugs
 - ❑ Nested case-control: non-persistence vs. persistence
 - ❑ Population: initiators of treatment after discharge from hospitalization for MI
 - ❑ Odds of discordance: 2 refills before non-persistence
 - ❑ Color: OR=1.34 (95% CI, 1.12-1.59)
 - ❑ Shape: OR=1.66 (95% CI, 1.43-1.94)
-Kesselheim et al. Ann Intern Med (2013).

Objectives

- ❑ To compare pharmacists' and patients' preferences for, perceptions of, and responses to changes in pill appearance

Methods: Pharmacists

- ❑ Target population: 2,161 licensed pharmacists
 - ❑ Practice setting: independent, franchise, and chain
- ❑ Data source: SK&A Master File
- ❑ Token honorarium: \$5
- ❑ Instrument
 - ❑ Questions
 - ❑ Pill appearance preferences
 - ❑ Perceptions of pill appearance changes
 - ❑ Actions in response to pill appearance changes
 - ❑ Mode of administration: paper invitation, paper or online completion
- ❑ Date: January-April 2016

Methods: Patients

- ❑ Target: 16,243 household phone numbers (mobile and landlines)
 - ❑ Age: 50 years or older
 - ❑ Medication: generic drugs for epilepsy, diabetes, hypertension, hyperlipidemia, depression, or HIV
- ❑ Data source: Survey Sampling International
- ❑ Instrument
 - ❑ Questions
 - ❑ Pill appearance preferences
 - ❑ Perceptions of pill appearance changes
 - ❑ Actions in response to pill appearance changes
 - ❑ Mode of administration: telephone
- ❑ Date: February-April 2016

Pharmacist Response Rate and Demographics

N=719 (33% Response Rate)

Characteristic

N (%)

Female 327 (47)

Race

Caucasian 557 (80)

Non-Caucasian 136 (20)

Year Practiced

<10 148 (22)

10-19 166 (24)

20-29 140 (20)

30-35 107 (16)

>35 126 (18)

Pharmacy Type

Independent 261 (38)

Regional chain 118 (17)

National chain 242 (35)

Franchise 5 (1)

Other 69 (10)

Characteristic

N (%)

Title

Chief Pharmacist 135 (19)

Owner Pharmacist 151 (22)

Staff pharmacist 390 (56)

Other 22 (3)

Number of Prescriptions Per Day

<100 63 (9)

100-200 269 (39)

201-300 165 (24)

>300 199 (29)

Drug Information Source

Continuing education 659 (94)

Pharmaceutical representative 275 (39)

Payor formulary committee 50 (7)

Professional journals 538 (77)

Package inserts 464 (66)

Text or reference books 321 (46)

Pharmacist colleagues 314 (45)



Patient Response Rate and Demographics

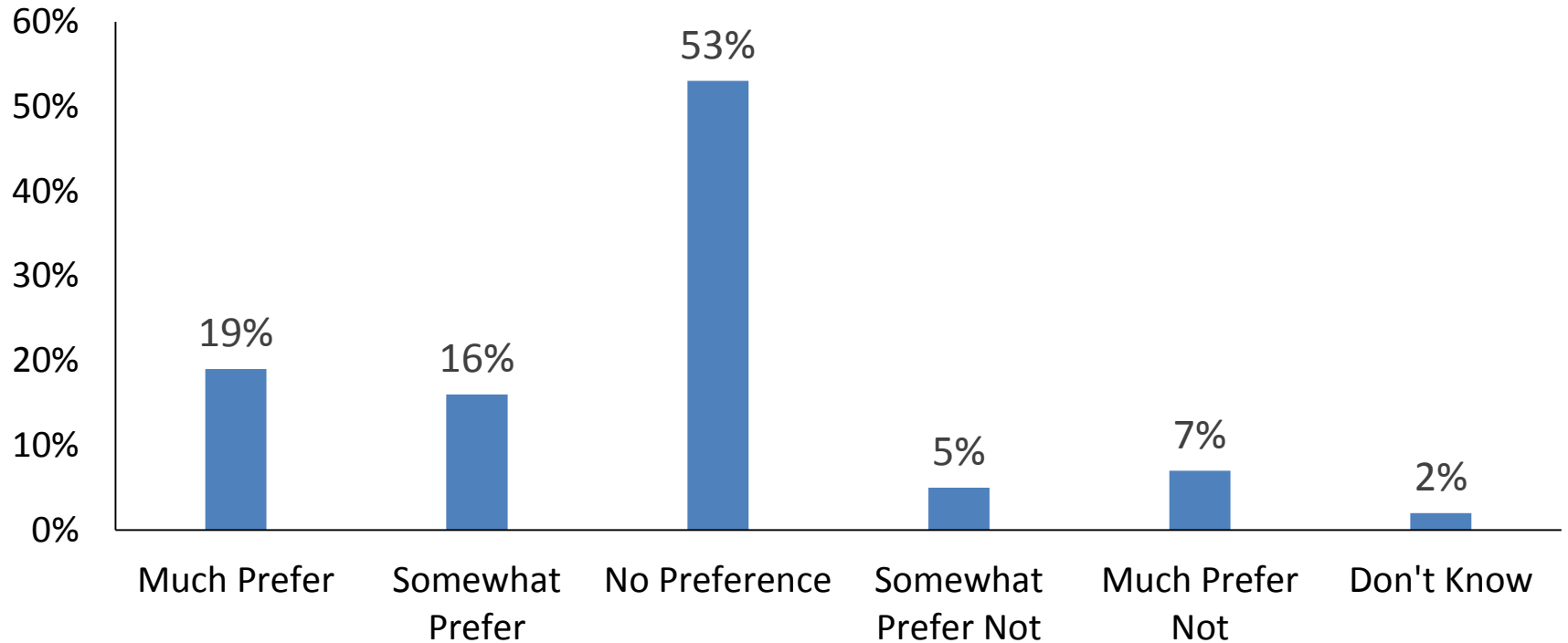
N=1,006 (30% Response Rate)

Characteristic	N (%)
Gender	
Female	615 (62)
Age	
50-57	161 (16)
58-65	273 (27)
>66	572 (57)
Education Level	
Less than high school	33 (3)
High School/GED	275 (27)
Some college or 2 year college degree	300 (30)
4 year college degree	193 (19)
Master's degree	142 (14)
Advanced health-related degree	29 (3)
Advanced non-health-related degree	21 (2)
Decline to answer	13
Income Category	
<\$15,000	80 (8)
\$15,000-\$35,000	171 (17)
\$35,000-\$50,000	160 (16)
\$50,000-\$75,000	175 (17)
\$75,000-\$100,000	98 (10)
>\$100,000	138 (14)
Not sure	27 (3)
Decline to answer	157 (16)

Characteristic	N (%)
Spanish or Hispanic	
Yes	48 (5)
No	947 (94)
Decline to answer	11 (1)
Ethnicity	
Caucasian	825 (82)
African American	82 (8)
Asian or Pacific Islander	9 (1)
Native American	15 (2)
Mixed racial background	20 (2)
Other	32 (3)
Decline to answer	23 (2)
Census Region	
East	177 (18)
South	389 (39)
Midwest	265 (26)
West	168 (17)
Decline to answer	7 (1)

Pharmacist Preferences

Dispensing Generics with Same Appearance as Brand-Name Drugs



Years in practice	N (%)			
	<10	10-19	20-29	>30
Prefer dispensing the same (much or somewhat)	35 (24)	40 (24)	54 (39)	103 (44)
No preference/not sure	96 (65)	100 (61)	74 (53)	105 (45)
Prefer not dispense the same (much or somewhat)	17 (12)	25 (15)	12 (9)	24 (10)

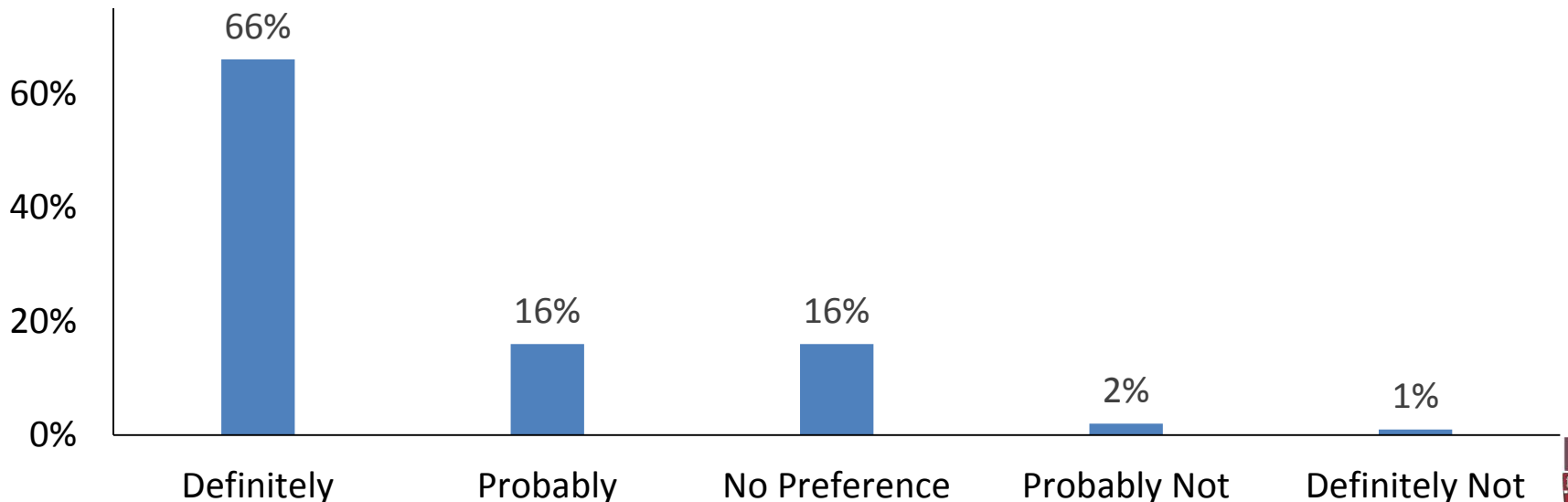
One-way ANOVA: $F=12.46$, $p<0.0001$

Patient Preferences

How much would you prefer for the pills in the refill to have the same...?

	Response, N (%)				
	Definitely	Probably	No Preference	Probably Not	Definitely Not
Color	409 (41)	229 (23)	330 (33)	13 (1)	21 (2)
Shape	401 (40)	231 (23)	334 (33)	15 (1)	22 (2)
Size	430 (43)	253 (25)	288 (29)	14 (1)	17 (2)
Markings	374 (37)	175 (17)	402 (40)	15 (2)	25 (3)

Desire to be Notified of Change

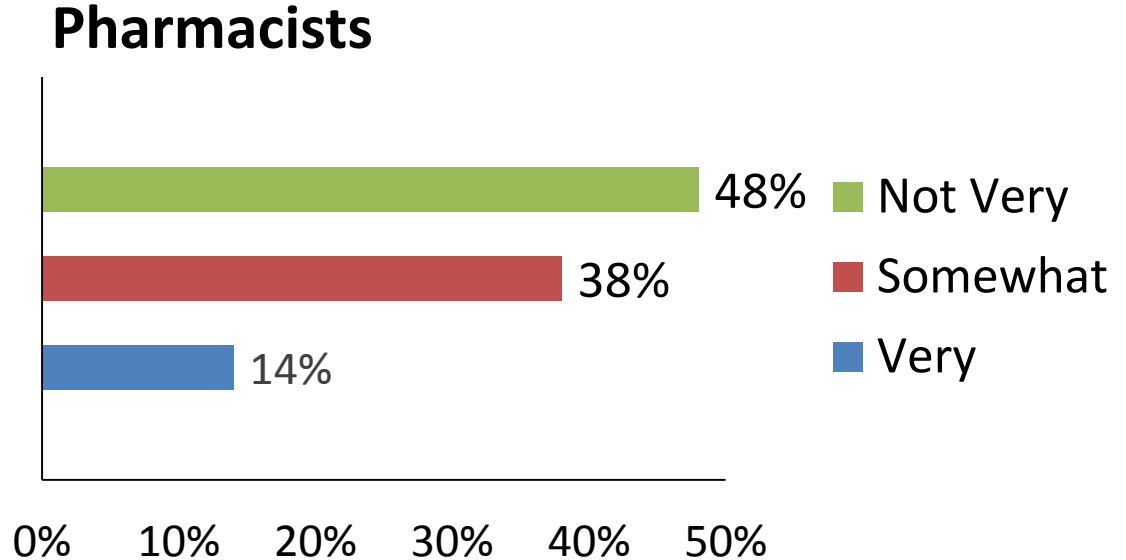


Patient Willingness to Pay

	Responses, N (%)		
	Yes	No	Don't Know
<u>Assume that generic pill A costs you \$5 per month</u>			
Would you pay \$6 per month for generic pill A to ensure that your pill has the same size, shape, and color at each refill?	369 (37)	606 (60)	28 (3)
<u>Assume that generic pill B costs you \$10 per month</u>			
Would you pay \$15 per month for generic pill B to ensure that your pill has the same size, shape, and color at each refill?	94 (9)	893 (89)	17 (2)
<u>Assume that generic pill C costs you \$15 per month</u>			
Would you pay \$25 per month for generic pill C to ensure that your pill has the same size, shape, and color at each refill?	43 (4)	947 (94)	11 (1)

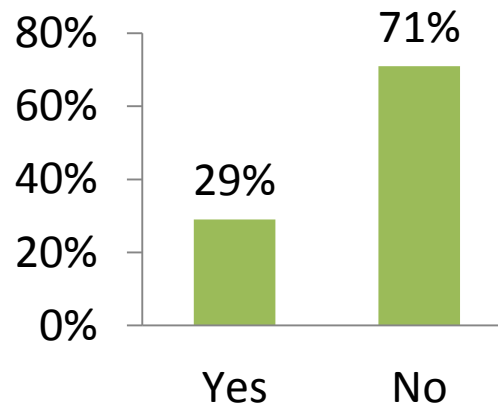
Pill Appearance Change Concerns

How likely is it that similarities in appearance among different manufacturers' versions of the same pill will cause pharmacists to make a dispensing error?

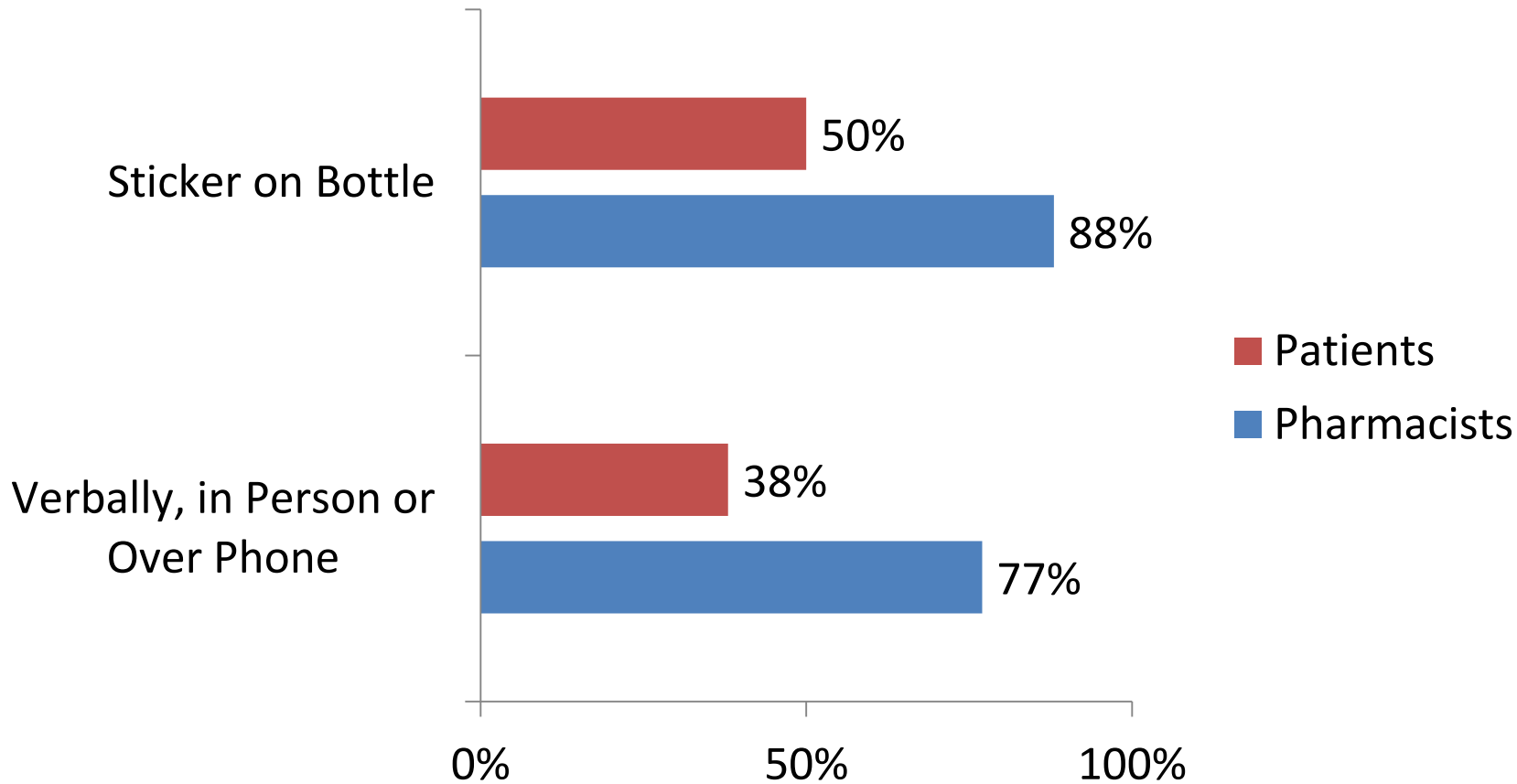


Patients

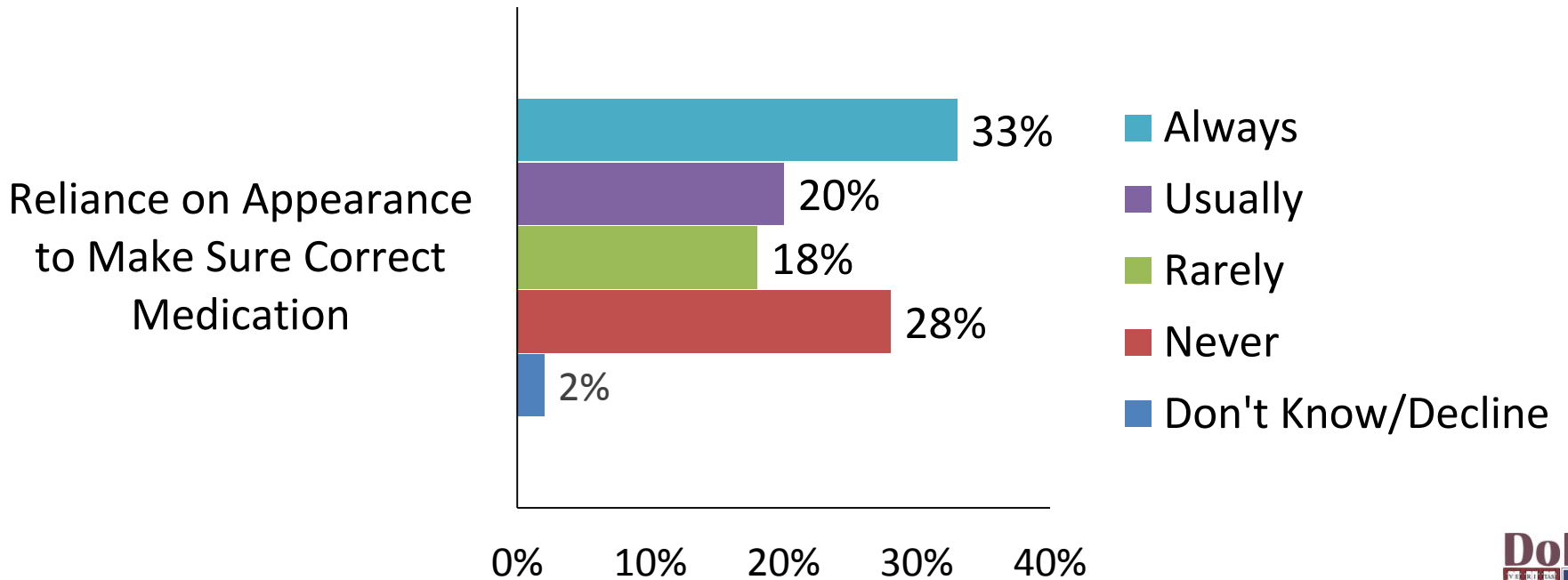
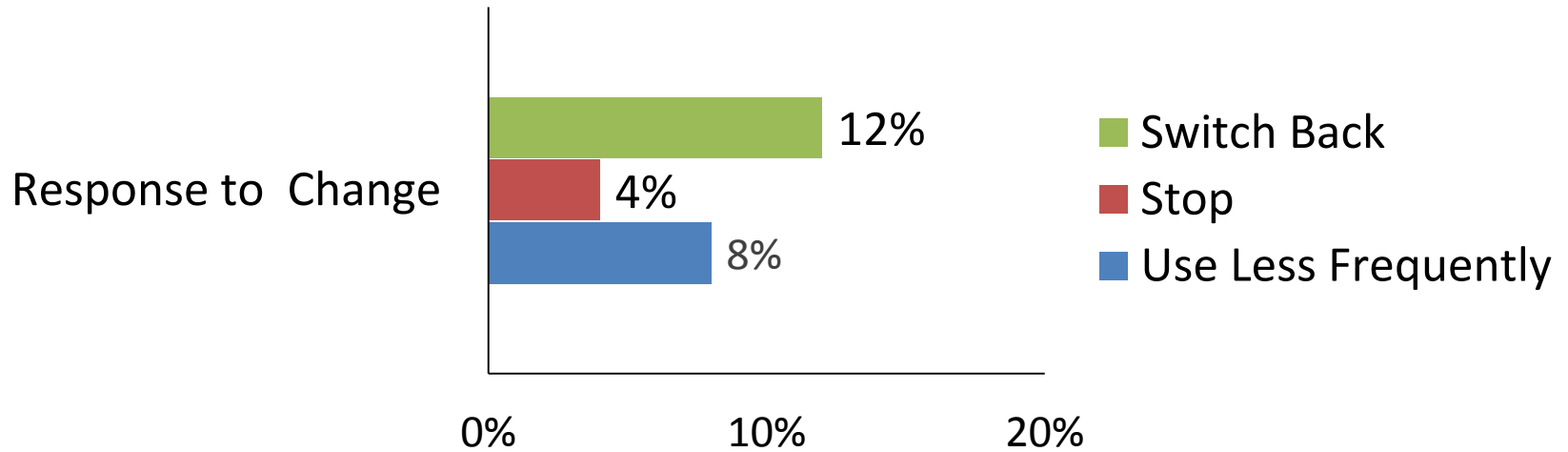
Thought: Received Wong Pill



Pharmacist Notification of Appearance Change



Patient Actions



Conclusions

- ❑ Concerning discrepancies
 - ❑ Preferences as to pill appearance consistency
 - ❑ Recollection of notification practices
- ❑ Potentially large impact
 - ❑ ~50% rely on pill appearance to ensure medications are correct
 - ❑ ~10% use medication less frequently if it changes in appearance
- ❑ Possible measures
 - ❑ Standardizing pharmacy notification practices
 - ❑ Requiring uniform generic appearance

Acknowledgements

- Aaron S. Kesselheim, M.D., J.D., M.P.H.
 - Associate Professor of Medicine, Harvard Medical School
- Joshua J. Gagne, Pharm.D., Sc.D.
 - Assistant Professor of Medicine, Harvard Medical School
- Moa A. Lee, Pharm.D., M.P.H.
 - Research Specialist, Brigham and Women's Hospital
- Macarius Donneyong, Ph.D., M.P.H.
 - Research Specialist, Brigham and Women's Hospital