FDA U.S. FOOD & DRUG **ADMINISTRATION**

Paul R. Jones, PhD¹, Jonas Santiago, PharmD¹, Bryon M. Pearsall, JD, RPh¹, Dan-My Chu, PhD¹, Carolyn Wolff, PhD² and Aaron Kearsley, MA² U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

¹Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiatives, Division of Medical Policy Programs ²Office of the Commissioner, Office of Policy, Legislation, and International Affairs, Office of Economics and Analysis

BACKGROUND

- Medication guides (MGs) are FDA-approved handouts, created by drug manufacturers, to be distributed to patients with certain prescription drug products, including biological products, that FDA determines pose a serious and significant public health concern.¹
- Several studies examining whether patients can read or understand MGs produced varying results (e.g., ^{2,3})
- However, it is unclear whether any of these results generalize to adults residing in the U.S., aged 18 years or older (18+).

 We also lack well-established, population-level estimates of how easy to read and understand U.S. adults perceive MGs to be and data on how these perceptions differ by demographic factors.

OBJECTIVES

- Conduct a two-part, nationally-representative survey on prescription drug information (part 1) and perceptions of MG reading and comprehension ease among U.S. residents, aged 18+ (part 2). This study focuses on part 2 of the survey.
- Estimate how easy to read and understand U.S. adults perceive MGs to be.
- Examine differences in perceived MG reading and comprehension ease by suspected health literacy (HL) level and whether reported MG reading and comprehension ease vary among different demographics.

METHODS

- Nov. 22 Dec. 2, 2019, 8,333 U.S. adults were invited to complete a 10-item, online survey.
- Respondents were part of Ipsos's KnowledgePanel[®], a probability-based panel representative of U.S. households, and received a \$1 incentive.
- We focused on the 3,852 respondents who completed part 2 by answering "yes" to question 8: Have you ever received a[n] MG with any of your prescription medicine? (3-pt scale: 1=Yes, 2=No, 3=I don't know).

• To improve recall, we paired our part 2 instructions with a sample MG for the fictitious drug *Rheutopia*, indicated to treat rheumatoid arthritis.

A nationally-representative survey on perceived medication guide reading and comprehension ease among U.S. residents, 18 years or older

METHODS

• Next, qualifying respondents completed questions 9 and 10: How easy to [read / understand] are the MGs that you have received from a pharmacy along with your prescription medicines? (5-pt scale: 1=Very difficult, 5=Very easy, after reverse coding responses).

 Demographic data were obtained from lpsos and we measured HL with item 2 from the Brief Health Literacy Screening Tool (BRIEF)⁴: How confident are you in filling out medical forms by yourself? (5-pt scale: 1=Not at all, 5=Extremely, after reverse coding).

 HL scores were used to categorize respondents into 3 HL groups: Inadequate (score \leq 3); *Marginal* (score of 4); and *Adequate* (score of 5).

 Individual units in our sample were weighted to reflect the population of U.S. adults and all tests were computed in SAS[®] 9.4 and JMP[®] with α =.005.

RES

 Table 1 shows demographic data for 74% of respondents (n = 3,852)reported receiving an MG with prescription drugs.

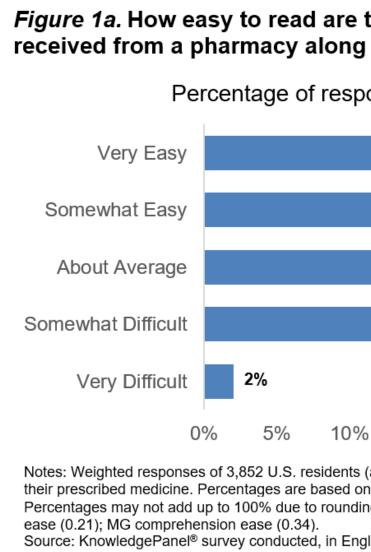
Nearly 85% of these respond perceived MGs as either "very e "somewhat easy," or "about average read (Figure 1a).

 Our perceived MG understanding yielded comparable results (Figure 1b)

 Average MG reading and compreher higher ar scores were ease respondents suspected of having adec HL than among those suspected to inadequate HL ($ps \le .0006$; Table 2).

• Women, younger (18-44 years) or less educated respondents, and non-Hispar Blacks perceived MGs as easier to read understand (on avg.) than their respect counterparts ($ps \le .0001$; Table 2).

haracteristics of U.S. re						
_		ving a Medication Guide		Reported not R	eceiving a Medication Gu M(95% CI)	uide $(n = 557)$ ±SI
Respondent Characteristics	n (%)	M(95% CI)	±SD	n (%)	M (95% CI)	±91
$\begin{array}{l} \text{Characteristics} \\ \text{Age, in years } (y)^a \\ \text{Overall} \\ 18-44 \ y \\ 45-64 \ y \\ \geq 65 \ y \end{array}$	3,852 (100.0) 1,205 (31.3) 1,494 (38.8) 1,153 (29.9)	53.54 (53.01–54.08)	17.01	557 (100.0) 308 (55.3) 162 (29.1) 87 (15.6)	44.21 (42.79–45.63)	17.
<u>Gender</u> Male Female	2,029 (52.7) 1,823 (47.3)			333 (59.8) 224 (40.2)		
Health Literacy ^a Dverall Inadequate Marginal Adequate	3,847 (99.9) 754 (19.6) 1,267 (32.9) 1,826 (47.4)	4.20 (4.17–4.23)	0.95	556 (99.8) 170 (30.5) 178 (32.0) 208 (37.3)	3.91 (3.82–4.01)	1.1
<u>Education</u> ≤ High school Some college ≥ College Graduate	1,230 (31.9) 1,121 (29.1) 1,501 (39.0)			216 (38.8) 146 (26.2) 195 (35.0)		
Race/Ethnicity Black, Non-Hispanic White, Non-Hispanic Other ^b Household Income	369 (9.6) 2,775 (72.0) 708 (18.4)			80 (14.4) 333 (59.8) 144 (25.9)		
≤ \$49,999 \$50,000-\$99,999	1,147 (29.8)			194 (34.8)		
$ \frac{>}{2} \frac{$100,000}{$100,000} \frac{>}{999} \frac{>}{2} \frac{$100,000}{$100,000} \frac{>}{999} \frac{>}{100,000} \frac{>}{999} \frac{>}{100,000} \frac{>}{999} \frac{>}{999} \frac{>}{100,000} \frac{>}{999} \frac$	either reported receiving y of U.S. residents, age 1 n a continuous scale. "Hispanic" (11.1); "Othe spondents (15.3%) who ion medicine? When com	or not receiving an MG: 0.1 3+ conducted Nov. 22-Dec. 7 r, Non-Hispanic" (3.7); and ither reported "I don't know bined with respondents who	% and 0.2%, respect 2, 2019. "2+ Races, Non-His " (15.0%) or failed t reported not receiving health literacy]	ively. Race and ethnicity in panic" (3.5). o answer (0.3%) screener q ng an MG with their prescri	formation is combined into a s uestion 8: <i>Have you ever recei</i> ption drugs (n = 557), the com	single variable ved a Medicat ibined n = 1,35 J.S. reside
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$\geq \$100,000$ bbreviation: MG, medication g ariable among respondents who kace/Ethnicity). ource: KnowledgePanel® surver These variables are measured of "Other" category includes (%): Table excludes data from 795 re- builde with any of your prescript Table 2 Mean self-reported MCC ged 18+ years <u>Variables</u> <u>Health Literacy</u> Inadequate Marginal Adequate <u>Gender^{1,2}</u> Male Female <u>Education</u> \leq High school Some college \geq College Graduate <u>Race/Ethnicity</u> Black, Non-Hispanic White, Non-Hispanic White, Non-Hispanic Other ³	1,469 (38.1) ide. Notes: These are un either reported receiving y of U.S. residents, age 1 in a continuous scale. "Hispanic" (11.1); "Othe spondents (15.3%) who ion medicine? When com Perc Question: "Hy you have rece your prescrip Observations 772 1,210 1,721 1,697 2,010 1,359 1,060 1,289 433 2,401	or not receiving an MG; 0.1 8+ conducted Nov. 22-Dec. 2 r, Non-Hispanic" (3.7); and ither reported "I don't know bined with respondents who prehension ease by h eived MG Reading ow easy to read are to eived from a pharma tion medicines?" Weighted <u>M</u> 3.42a,b 3.58b,c 3.82a,c 3.57e 3.73e 3.80g 3.68h 3.49g,h 3.97j,k 3.60j	% and 0.2%, respect 2, 2019. "2+ Races, Non-His, " (15.0%) or failed t reported not receiving the alth literacy 1 Ease the MGs that cy along with $\pm SD$ 1.08 1.01 1.05 1.02 1.09 1.11 1.06 1.00 1.07 1.00	194 (34.8) rounding and/or missing da ively. Race and ethnicity in panic" (3.5). o answer (0.3%) screener q ng an MG with their prescri evel and demograp! Perceived M Question: "How e that you have rece with your prescrip Observations 771 1,205 1,721 1,694 2,009 1,286 1,059 1,358 434 2,399	formation is combined into a s puestion 8: Have you ever recet ption drugs (n = 557), the combined hic variables among U G Comprehension E asy to understand are ived from a pharmacy ition medicines?" Weighted M 3.39d 3.62 3.91d 3.62f 3.78f 3.79i 3.72 3.61i 4.00Lm 3.65i	single variable wed a Medicat. ubined $n = 1,35$ J.S. reside the MGs y along $\pm SD$ 1.04 0.98 1.01 0.99 1.05 1.08 1.04 0.95 1.05 0.97
$\geq \$100,000$ bbreviation: MG, medication g ariable among respondents who Cace/Ethnicity). ource: KnowledgePanel® survery These variables are measured of "Other" category includes (%): Table excludes data from 795 re- uide with any of your prescript Table 2 Mean self-reported MCC ged 18+ years <u>Variables</u> <u>Health Literacy</u> Inadequate Marginal Adequate <u>Gender^{1,2}</u> Male Female <u>Education</u> \leq High school Some college \geq College Graduate <u>Race/Ethnicity</u> Black, Non-Hispanic Other ³ <u>Age, in years (y)</u> 18-44 y $\geq 65 y$	1,469 (38.1) aide. Notes: These are un either reported receiving y of U.S. residents, age 1 n a continuous scale. "Hispanic" (11.1); "Othe spondents (15.3%) who of ion medicine? When com e reading and com Perce Question: "H you have received your prescrip Observations 772 1,210 1,721 1,697 2,010 1,359 1,060 1,289 433 2,401 873 1,473	or not receiving an MG: 0.1 8+ conducted Nov. 22-Dec. 2 r, Non-Hispanic" (3.7); and ither reported "I don't know bined with respondents who prehension ease by h eived MG Reading ow easy to read are 1 eived from a pharma tion medicines?" Weighted M 3.42a,b 3.58b,c 3.82a,c 3.57e 3.73e 3.80g 3.68h 3.49g,h 3.97j,k 3.60j 3.67k 3.77n,o	% and 0.2%, respect 2, 2019. "2+ Races, Non-His " (15.0%) or failed t reported not receivin Health literacy I Ease the MGs that cy along with $\pm SD$ 1.08 1.01 1.05 1.02 1.09 1.11 1.06 1.00 1.22 1.16	194 (34.8) rounding and/or missing da ively. Race and ethnicity in panic" (3.5). o answer (0.3%) screener q ng an MG with their prescri evel and demograp. Perceived MI Question: "How e that you have rece with your prescrip Observations 771 1,205 1,721 1,694 2,009 1,286 1,059 1,358 434 2,399 870 1,470	formation is combined into a s nestion 8: Have you ever receil ption drugs (n = 557), the com- hic variables among U G Comprehension E asy to understand are vived from a pharmacy tion medicines?" Weighted M 3.39d 3.62 3.91d 3.62f 3.78f 3.79i 3.72 3.61i 4.00lm 3.65i 3.71m 3.78p	single variable ved a Medicat ibined $n = 1,35$ J.S. reside Sase the MGs y along <u>±SD</u> 1.04 0.98 1.01 0.99 1.05 1.08 1.04 0.95 1.05 0.97 1.18 1.13
$\geq \$100,000$ bbreviation: MG, medication g ariable among respondents who kace/Ethnicity). ource: KnowledgePanel® surver These variables are measured of "Other" category includes (%): Table excludes data from 795 re- builde with any of your prescript Table 2 Mean self-reported MCC ged 18+ years $\frac{Variables}{Health Literacy}$ Inadequate Marginal Adequate Gender ^{1,2} Male Female Education $\leq High school$ Some college $\geq College Graduate$ Race/Ethnicity Black, Non-Hispanic Other ³ Age, in years (y) 18-44 y 45-64 y	1,469 (38.1) aide. Notes: These are un either reported receiving y of U.S. residents, age 1 n a continuous scale. "Hispanic" (11.1); "Othe spondents (15.3%) who diver ion medicine? When com Perce Question: "H you have received your prescrip Observations 772 1,210 1,721 1,697 2,010 1,359 1,060 1,289 433 2,401 873 1,473 1,345	or not receiving an MG: 0.1 8+ conducted Nov. 22-Dec. 2 r, Non-Hispanic" (3.7); and ither reported "I don't know bined with respondents who prehension ease by P eived MG Reading ow easy to read are t eived from a pharma tion medicines?" Weighted M 3.42a,b 3.58b,c 3.82a,c 3.57e 3.73e 3.80g 3.68h 3.49g,h 3.97j,k 3.60j 3.67k 3.77n,o 3.63o	% and 0.2%, respect 2, 2019. "2+ Races, Non-His " (15.0%) or failed t reported not receivin Health literacy I Ease the MGs that cy along with $\pm SD$ 1.08 1.01 1.05 1.02 1.09 1.11 1.06 1.00 1.07 1.00 1.22 1.16 1.01	194 (34.8) rounding and/or missing da ively. Race and ethnicity in panic" (3.5). o answer (0.3%) screener q ng an MG with their prescri evel and demograp. Perceived MI Question: "How e that you have rece with your prescrip Observations 771 1,205 1,721 1,694 2,009 1,286 1,059 1,358 434 2,399 870 1,470 1,346	formation is combined into a s nestion 8: Have you ever receil ption drugs (n = 557), the com- hic variables among U G Comprehension E asy to understand are vived from a pharmacy tion medicines?" Weighted M 3.39d 3.62 3.91d 3.62f 3.78f 3.79i 3.72 3.61i 4.00Lm 3.65i 3.71m 3.78p 3.69	single variable ved a Medicat bined $n = 1,35$ U.S. reside Ease the MGs y along $\pm SD$ 1.04 0.98 1.01 0.99 1.05 1.08 1.04 0.95 1.05 0.97 1.18 1.13 0.99
$\geq \$100,000$ bbreviation: MG, medication g ariable among respondents who Cace/Ethnicity). ource: KnowledgePanel® survery These variables are measured of "Other" category includes (%): Table excludes data from 795 re- uide with any of your prescript Table 2 Mean self-reported MGG ged 18+ years <u>Variables</u> <u>Health Literacy</u> Inadequate Marginal Adequate <u>Gender^{1,2}</u> Male Female <u>Education</u> \leq High school Some college \geq College Graduate <u>Race/Ethnicity</u> Black, Non-Hispanic White, Non-Hispanic Other ³ <u>Age, in years (y)</u> 18-44 y 45-64 y ≥ 65 y <u>Household Income</u>	1,469 (38.1) aide. Notes: These are un either reported receiving y of U.S. residents, age 1 n a continuous scale. "Hispanic" (11.1); "Othe spondents (15.3%) who do ion medicine? When com Perce Question: "H you have rece your prescrip Observations 772 1,210 1,721 1,697 2,010 1,359 1,060 1,289 433 2,401 873 1,473 1,345 889	or not receiving an MG: 0.1 8+ conducted Nov. 22-Dec. 2 r, Non-Hispanic" (3.7); and ither reported "I don't know bined with respondents who prehension ease by h eived MG Reading ow easy to read are t eived from a pharma tion medicines?" Weighted M 3.42a,b 3.58b,c 3.82a,c 3.57e 3.73e 3.80g 3.68h 3.49g,h 3.97j,k 3.60j 3.67k 3.77n,o 3.63o 3.51n	% and 0.2%, respect 2, 2019. "2+ Races, Non-His " (15.0%) or failed t reported not receiving the alth literacy I Ease the MGs that cy along with $\pm SD$ 1.08 1.01 1.05 1.02 1.09 1.11 1.06 1.00 1.07 1.00 1.22 1.16 1.01 0.99	194 (34.8) rounding and/or missing da ively. Race and ethnicity in panic" (3.5). o answer (0.3%) screener q ng an MG with their prescri Perceived MI Question: "How e that you have rece with your prescrip Observations 771 1,205 1,721 1,694 2,009 1,286 1,059 1,358 434 2,399 870 1,470 1,346 887	formation is combined into a s uestion 8: Have you ever receil ption drugs (n = 557), the com- hic variables among U G Comprehension E asy to understand are- vived from a pharmacy tion medicines?" Weighted M 3.39d 3.62 3.91d 3.62f 3.78f 3.79i 3.72 3.61i 4.00l,m 3.65i 3.71m 3.78p 3.69 3.61p	single variable ved a Medicat ubined $n = 1,35$ J.S. reside Ease the MGs y along ±SD 1.04 0.98 1.01 0.99 1.05 1.08 1.04 0.95 1.05 0.97 1.18 1.13 0.95



by a plurality of our respondents.

 Although no survey is perfect and more research is needed, our data suggest most U.S. residents (18+) who received pharmacy-dispensed MGs perceived them to be "about average" to "very easy" to read and understand.

- 1. 21 CFR 208.

RESULTS						
KESULIS						
the Medication Guides that you have with your prescription medicines?	Figure 1b. How easy to understand are the Medication Guides that you have received from a pharmacy along with your prescription medicines? Percentage of respondents who said:					
ondents who said:						
27%	Very Easy 28%					
28%	Somewhat Easy 30%					
29%	About Average 29%					
13%	Somewhat Difficult 11%					
15% 20% 25% 30% 35%	Very Difficult 2%					
(age 18+) who said they received a medication guide with any of n weighted data and rounded to the nearest whole number. ng and/or missing data. Missing data by variable (%): MG reading lish, Nov. 22-Dec. 2, 2019.	0% 5% 10% 15% 20% 25% 30% 35% Notes: Weighted responses of 3,852 U.S. residents (age 18+) who said they received a medication guide with any of their prescribed medicine. Percentages are based on weighted data and rounded to the nearest whole number. Percentages may not add up to 100% due to rounding and/or missing data. Missing data by variable (%): MG reading ease (0.21); MG comprehension ease (0.34). Source: KnowledgePanel® survey conducted, in English, Nov. 22-Dec. 2, 2019.					

DISCUSSION & CONCLUSION

MGs were not viewed as "somewhat difficult" or "very difficult" to understand

• With few exceptions, our HL results were on par with prior studies.⁵

 Average MG reading and comprehension scores ranged between "about average" and "somewhat easy" for every demographic subgroup we analyzed.

REFERENCES

2. Enger et al. The effectiveness of varenicline medication guide for conveying safety information to patients: A REMS assessment survey. Pharmacoepidemiol Drug Saf. 2013;22: 705-715.

3. Wolf MS, King J, Wilson EAH, et al. Usability of FDA-approved medication guides. J Gen Intern Med, 2012; 27(12), 1714-1720.

4. Haun et al. Testing a Health Literacy Screening Tool: Implications for Utilization of a BRIEF Health Literacy Indicator. *Fed Pract.* 2009; 26:24–31.

5. Kutner et al. The Health Literacy of America's Adults: Results From the 2003 National Assessment of Adult Literacy. U.S. Department of Education. Washington, DC: National Center for Education Statistics; 2006.