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

Paul R. Jones, PhD[1], Jonas Santiago, PharmD[1], Bryon M. Pearsall, JD, RPh[1], Dan-My Chu, PhD[1], Carolyn Wolff, PhD[2] and Aaron Kearsley, MA[2]

U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993

[1]Center for Drug Evaluation and Research, Office of Medical Policy, Office of Medical Policy Initiatives, Division of Medical Policy Programs
[2]Office 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.
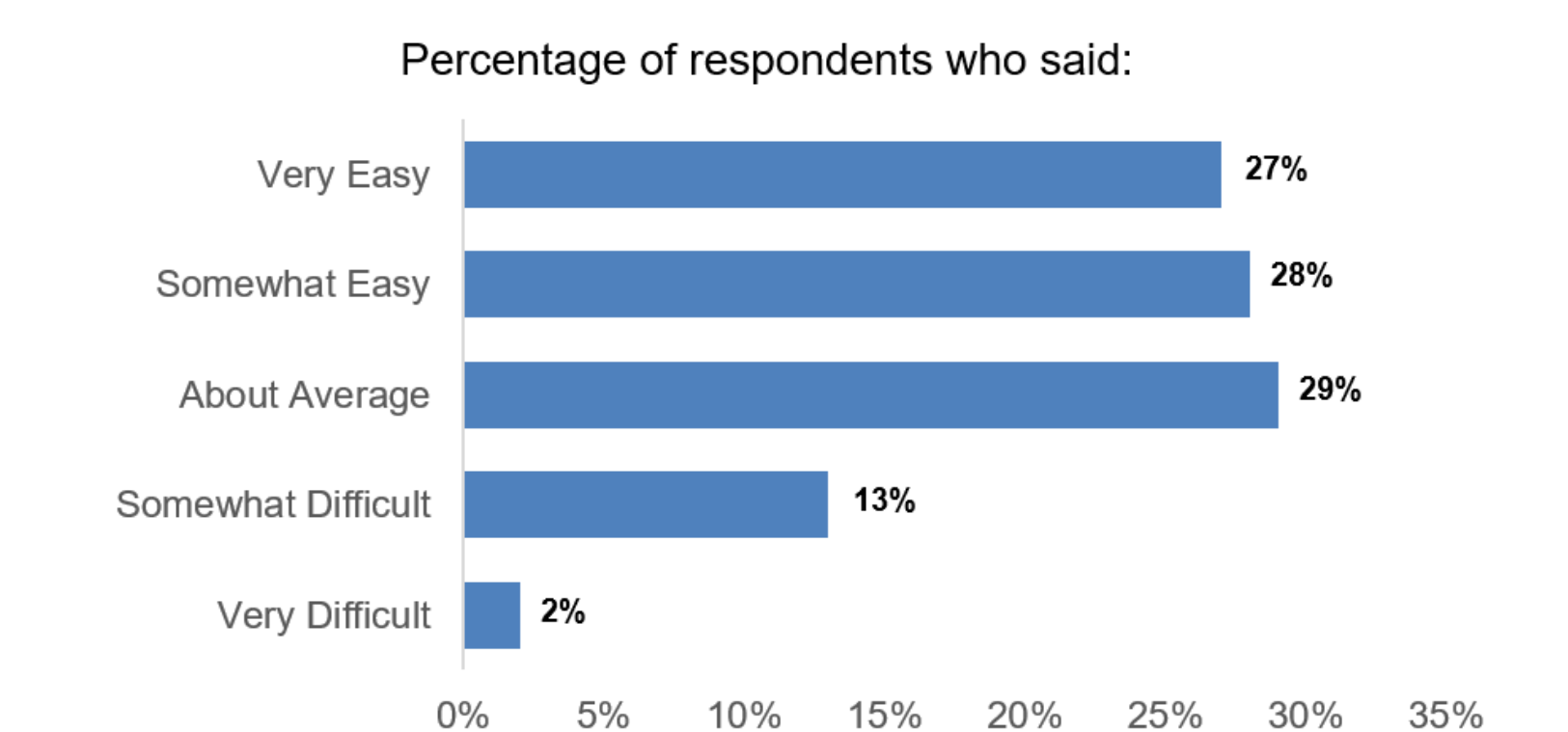
• Next, qualifying respondents completed questions 9 and 10: *How easy to [read / understand] are the MGs that you have received from a pharmacy along with your prescription medicines*? (5-pt scale: 1=*Very difficult*, 5=*Very easy*, after reverse coding responses).

• Demographic data were obtained from Ipsos 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 ≤ 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.

RESULTS

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

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

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

• Average MG reading and comprehension ease scores were higher among respondents suspected of having adequate HL than among those suspected to have inadequate HL (*p*s ≤ .0006; Table 2).

• Women, younger (18-44 years) or less educated respondents, and non-Hispanic Blacks perceived MGs as easier to read and understand (on avg.) than their respective counterparts (*p*s ≤ .0001; Table 2).
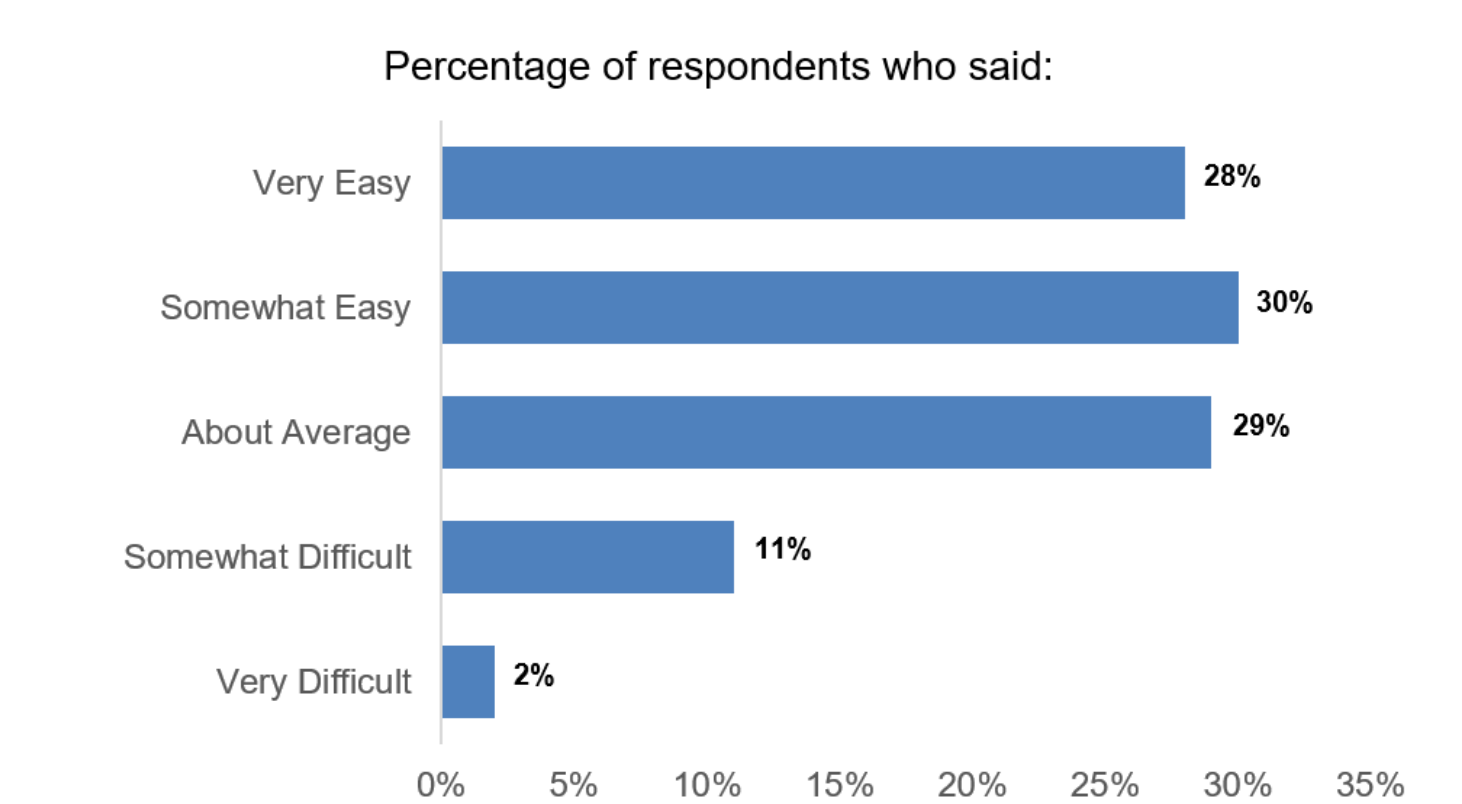
RESULTS

Figure 1a. How easy to read are the Medication Guides that you have received from a pharmacy along with your prescription medicines?

Percentage of respondents who said:
- Very Easy: 27%
- Somewhat Easy: 28%
- About Average: 29%
- Somewhat Difficult: 13%
- Very Difficult: 2%

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.

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:
- Very Easy: 28%
- Somewhat Easy: 30%
- About Average: 29%
- Somewhat Difficult: 11%
- Very Difficult: 2%

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 by a plurality of our respondents.

• 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.

• 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.

REFERENCES

1. 21 CFR 208.

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.