Optimizing Patient and Lay Audience Materials

Using Health Literacy & Patient Activation Principles

Annlouise Assaf; Michael Wolf; Stacy Bailey; Asia Lem; Candida Halton

Disclosures

- **Annlouise Assaf** receives salary and stock from Pfizer, Inc. where she is an employee.
- **Michael Wolf** has received funding via his institution and personal fees from Pfizer. Dr. Wolf also reports grants from the NIH, Merck, Eli Lilly, Amgen and the Gordon and Betty Moore Foundation and personal fees from Sanofi and Luto.
- **Stacy Bailey** has received funding via her institution and personal fees from Pfizer. Dr. Bailey also reports grants from the NIH, Merck, Eli Lilly and the Gordon and Betty Moore Foundation and personal fees from Sanofi and Luto.
- **Asia Lem** receives salary and stock from Pfizer, Inc. where she is an employee.
- **Candida Halton** is a director at Studio Health, which has received consultancy fees from Pfizer, Roche, Takeda, MSD and AstraZeneca.

What we'll cover today

1	Introduction and context	Annlouise Assaf
2	Evidence-based principles for materials optimization; benefits to patient comprehension & decision making	Michael Wolf
3	PRODUCT X Case Study	Stacy Bailey with Asia Lem
4	Optimizing patient facing scientific materials	Candida Halton
5	Q&A	Facilitated by Annlouise Assaf

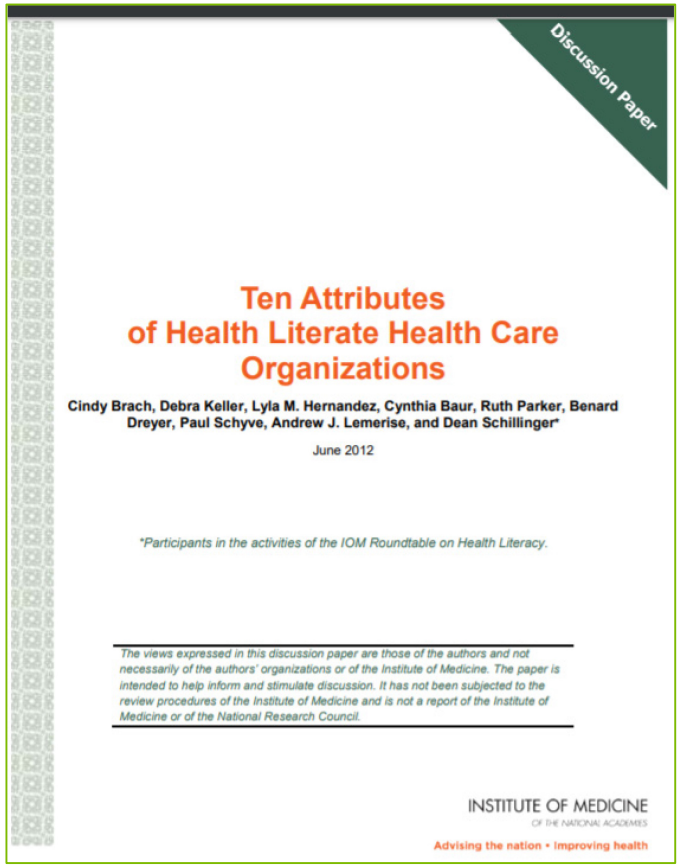
Disclaimer

The information and opinions presented in these materials are the express opinion of the author and may not represent the opinions or views of Pfizer Inc. and Pfizer Limited.

The materials presented are informational only and do not represent a guarantee by the author based on the use or misuse of such information.

Addressing health literacy is critical to delivering person-centered health care

Institute of Medicine, 2012



Cindy Brach, Debra Keller, Lyla M. Hernandez, Cynthia Baur, Ruth Parker, Benard Dreyer, Paul Schyve, Andrew J. Lemerise, and Dean Schillinger. Ten Attributes of Health Literate Health Care Organizations. IOM Round Table on Health Literacy. June 2012

Activating Patient Health

Better information accelerates health outcomes by empowering patients, caregivers & providers.[1-3]

- **Optimize patient and prescriber content** for relevance, quality & impact
- **Demonstrate meaningful impact of content** on understanding, motivation, activation & clinical outcomes
- **Accelerate quality improvement** in health content best practice at the levels of direct care, healthcare system and policy change

1 von Wagner et al. (2009) https://doi.org/10.1177/1090198108322819 2 Carman et al. (2017) https://doi.org/10.1016/j.pec.2016.07.009
3 Barello et al. (2014) https://www.researchgate.net/publication/263088534

Health Literacy and Activation

Spotlight on Optimizing Patient Content for Quality, Understandability and Actionability. Partnership with Northwestern University Center for Applied Health Research on Aging (CAHRA)

Increasing interest by regulators and healthcare industry in optimizing and evaluating patient facing information to improve quality, understandability and actionability

Promoting a consistent, harmonized approach to health literacy and patient activation

- **Risk Evaluation and Mitgation Strategies (REMS) Submissions**
- **Post-Authorization Safety Study**
- **Benefit Risk Trade-Off Studies (BRTO) Patient Preference Studies (PPS)**
- **Instructions for Use (IFU) Optimization**
- **Website for Clinical Trial Participation**
- **Plain Language Summaries (PLS)**

Optimizing Patient and Lay Audience Materials

Using Health Literacy & Patient Activation Principles

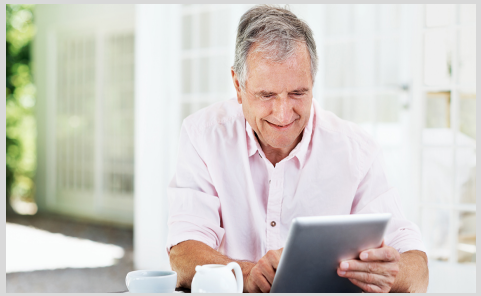
Annlouise Assaf; **Michael Wolf**; Stacy Bailey; Asia Lem; Candida Halton

Your New Prescription Medication

Seemingly Simple…Often Unclear

The Importance of Understandable, Actionable R_x Information

PMI = Patient (or Prescriber) Medication Information




Walgr

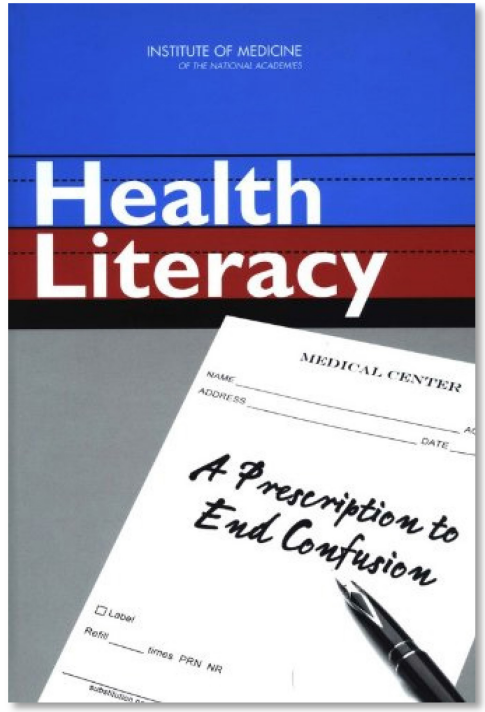
The Problem

- Patients often do not read R_x information
  - estimates suggest only 10-30% may review and keep PMI
- When they do read it, patients may not understand it
  - studies consistently find >50% of patients misunderstand R_x information, instructions
- Inadequate understanding is linked to R_x errors, ADEs, poor adherence
- R_x errors, ADEs, and poor adherence linked to hospitalization, worse outcomes

Root Cause
- PMI length
- Format

Root Cause
- Content
- Patient centered?

…And the Story Deepens



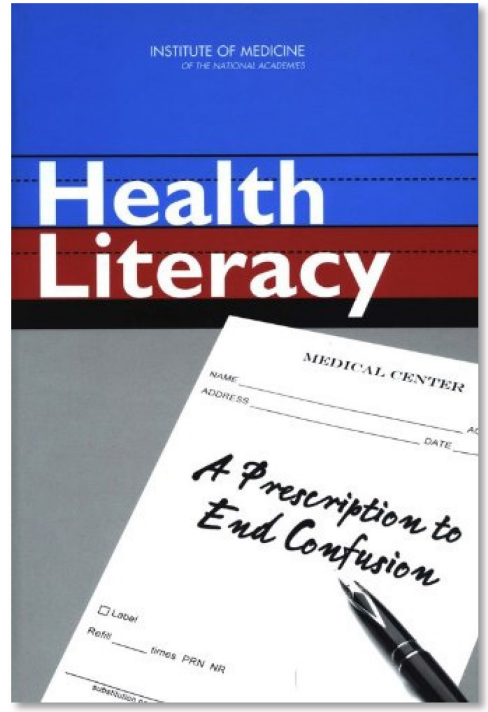
- Adults with limited '**health literacy**' are at greatest risk for
  - misunderstanding R_x information
  - unintentional medication errors
  - demonstrating inadequate adherence
  - poorer clinical outcomes

CAHRA
Center for Applied Health Research on Aging

NORTHWESTERN UNIVERSITY
HeLP
Health Literacy & Learning Program

Northwestern Medicine®
Feinberg School of Medicine

…And the Story Deepens



- Adults with limited '**health literacy**' are at greatest risk for
  - misunderstanding R_x information
  - unintentional medication errors
  - demonstrating inadequate adherence
  - poorer clinical outcomes
- 40-50% of U.S. adults have limited health literacy; 20% **low health literacy**
  - prevalence higher among older adults, lower SES, those with chronic conditions
  - not easily identified in healthcare; these patients ask fewer questions
  - ! **must take 'universal precautions' – design health materials for diverse audiences**

Addressing Missed Opportunities

- Inadequate information & communication channels with prescribers & pharmacists likely root cause for…
  - low rates of provider-patient counseling
  - poor quality and/or incomplete counseling
- Optimizing prescriber information could improve frequency & quality of counseling

Patient Education and Counseling 99 (2016) 1489–1495

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

An efficacy trial of an electronic health record-based strategy to inform patients on safe medication use: The role of written and spoken communication

Laura M. Curtis[a,*], Rebecca J. Mullen[a], Allison Russell[a], Aimee Fata[a], Stacy C. Bailey[b], Gregory Makoul[c], Michael S. Wolf[a]

NIH Public Access
Author Manuscript
Patient Educ Couns. Author manuscript; available in PMC 2014 November 01.

Published in final edited form as:
Patient Educ Couns. 2013 November ; 93(2): 306–311. doi:10.1016/j.pec.2013.06.030.

What patients think doctors know: Beliefs about provider knowledge as barriers to safe medication use

Marina Serper[a,b,*], Danielle M. McCarthy[c], Rachel E. Patzer[d], Jennifer P. King[a], Stacy C. Bailey[e], Samuel G. Smith[f], Ruth M. Parker[g], Terry C. Davis[h], Daniela P. Ladner[b], and Michael S. Wolf[a,b,i]

Root Cause: Cognitive Load of R_x Information

- Readability (e.g. reading grade level)
- Incomplete or vague information & instructions
- Amount of content
- Format, organization
- Conflicting sources, nature of source
- Modality (spoken, print, multimedia)/opportunity for re-review
- Lack of coordinated 'system' of information
- Factual vs. procedural content
- Distraction (e.g. extraneous information, discordant imagery, environment)
- Communication speed (audio, visual)

Contents lists available at ScienceDirect

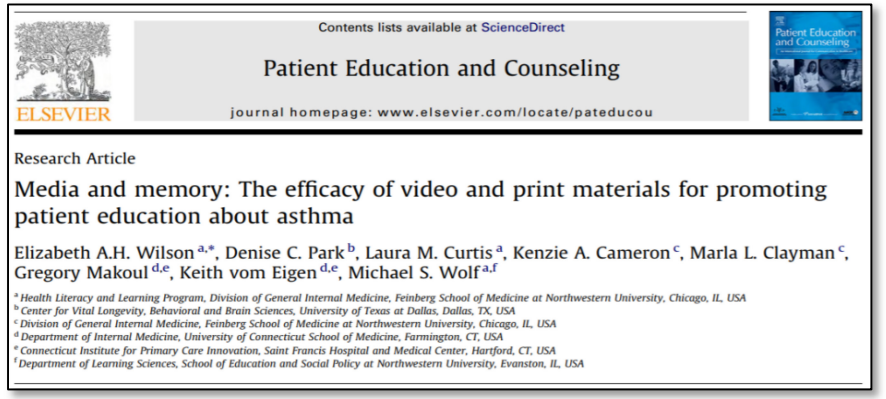
Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Working memory and the design of health materials:
A cognitive factors perspective

Elizabeth A.H. Wilson [a,b,*], Michael S. Wolf [a,c]

[a] Health Literacy and Learning Program, Center for Communication in Healthcare, Institute for Healthcare Studies, Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University, Chicago, IL, USA
[b] The Beckman Institute, University of Illinois at Urbana-Champaign, Urbana, IL, USA
[c] Department of Learning Sciences, School of Education and Social Policy, Northwestern University, Evanston, IL, USA



Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Research Article

Media and memory: The efficacy of video and print materials for promoting patient education about asthma

Elizabeth A.H. Wilson [a,*], Denise C. Park [b], Laura M. Curtis [a], Kenzie A. Cameron [c], Marla L. Clayman [c], Gregory Makoul [d,e], Keith vom Eigen [d,e], Michael S. Wolf [a,f]

[a] Health Literacy and Learning Program, Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University, Chicago, IL, USA
[b] Center for Vital Longevity, Behavioral and Brain Sciences, University of Texas at Dallas, Dallas, TX, USA
[c] Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University, Chicago, IL, USA
[d] Department of Internal Medicine, University of Connecticut School of Medicine, Farmington, CT, USA
[e] Connecticut Institute for Primary Care Innovation, Saint Francis Hospital and Medical Center, Hartford, CT, USA
[f] Department of Learning Sciences, School of Education and Social Policy at Northwestern University, Evanston, IL, USA

CAHRA
Center for Applied Health Research on Aging

NORTHWESTERN UNIVERSITY HeLP Health Literacy & Learning Program

Northwestern Medicine® Feinberg School of Medicine

Evidence-Based Practices Available

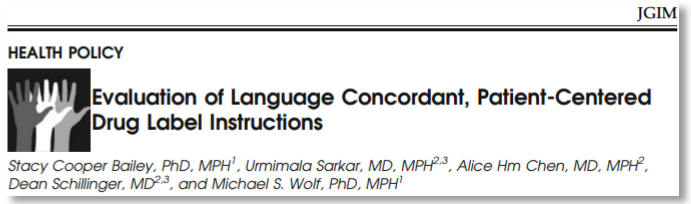
3 decades of health literacy research - informed by cognitive science, human factors, educational and health services research - drive health materials optimization

Received: 25 October 2017 | Revised: 5 April 2018 | Accepted: 11 June 2018
DOI: 10.1002/pds.4614

ORIGINAL REPORT — WILEY

What is the quality of drug safety information for patients: An analysis of REMS educational materials

Hilda W. Chan[1] | Andrea M. Russell[1,2] | Meredith Y. Smith[1]



JGIM

HEALTH POLICY

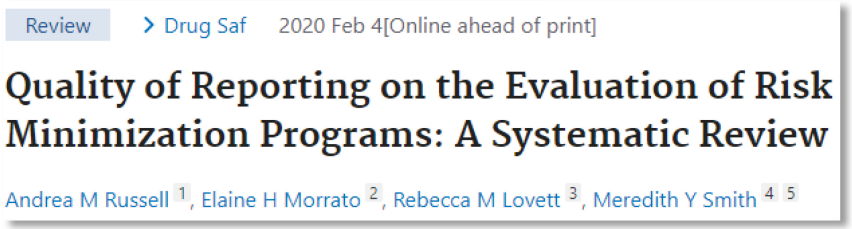
Evaluation of Language Concordant, Patient-Centered Drug Label Instructions

Stacy Cooper Bailey, PhD, MPH[1], Urmimala Sarkar, MD, MPH[2,3], Alice Hm Chen, MD, MPH[2], Dean Schillinger, MD[2,3], and Michael S. Wolf, PhD, MPH[1]

ORIGINAL INVESTIGATION

Improving Prescription Drug Warnings to Promote Patient Comprehension

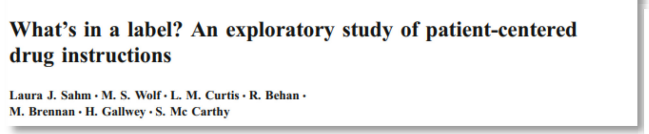
Michael S. Wolf, PhD, MPH; Terry C. Davis, PhD; Patrick F. Bass, MD, MPH; Laura M. Curtis, MS; Lee A. Lindquist, MD, MPH; Jennifer A. Webb, MA; Mary V. Bocchini, BS; Stacy Cooper Bailey, MPH; Ruth M. Parker, MD



Review › Drug Saf 2020 Feb 4[Online ahead of print]

Quality of Reporting on the Evaluation of Risk Minimization Programs: A Systematic Review

Andrea M Russell [1], Elaine H Morrato [2], Rebecca M Lovett [3], Meredith Y Smith [4 5]



PHARMACOEPIDEMIOLOGY AND PRESCRIPTION

What's in a label? An exploratory study of patient-centered drug instructions

Laura J. Sahm · M. S. Wolf · L. M. Curtis · R. Behan · M. Brennan · H. Gallwey · S. Mc Carthy

ELSEVIER

Patient Education and Counseling 62 (2006) 316–322

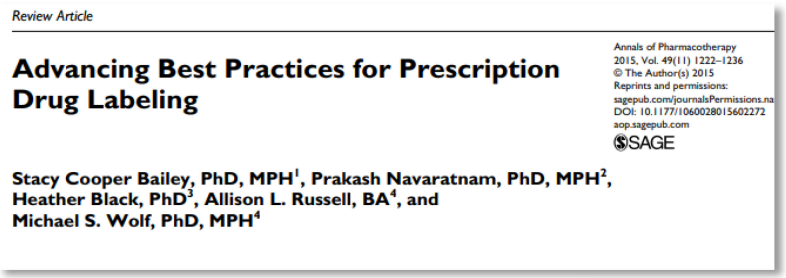
Patient Education and Counseling

www.elsevier.com/locate/pateducou

A critical review of FDA-approved Medication Guides

Michael S. Wolf[a,*], Terry C. Davis[b], William H. Shrank[c], Marolee Neuberger[d], Ruth M. Parker[e]

[a] Institute for Healthcare Studies, Division of General Internal Medicine, and Robert H. Lurie Comprehensive Cancer Center, Feinberg School of Medicine at Northwestern University, 676 N. St. Clair Street, Suite 200, Chicago, IL 60611, United States
[b] Departments of Medicine and Pediatrics, Louisiana State University Health Sciences Center, Shreveport, LA, United States
[c] Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital, Boston, MA, United States
[d] Western Michigan Area Health Education Center, Grand Rapids, MI, United States
[e] Emory University School of Medicine, Atlanta, GA, United States



Review Article

Advancing Best Practices for Prescription Drug Labeling

Annals of Pharmacotherapy 2015, Vol. 49(11) 1222–1236 © The Author(s) 2015 Reprints and permissions: sagepub.com/journalsPermissions.na DOI: 10.1177/1060028015602272 aop.sagepub.com SAGE

Stacy Cooper Bailey, PhD, MPH[1], Prakash Navaratnam, PhD, MPH[2], Heather Black, PhD[3], Allison L. Russell, BA[4], and Michael S. Wolf, PhD, MPH[4]

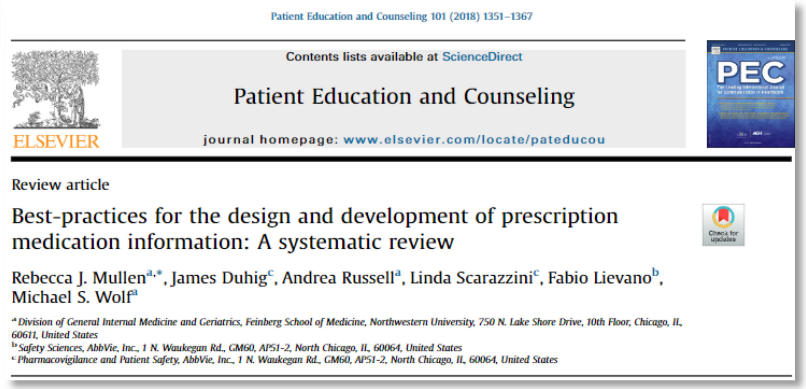
ORIGINAL ARTICLE

Comparative Effectiveness of Patient-centered Strategies to Improve FDA Medication Guides

Michael S. Wolf, PhD, MPH,*† Stacy C. Bailey, PhD, MPH,‡ Marina Serper, MD,* Meredith Smith, PhD,§ Terry C. Davis, PhD,‖ Allison L. Russell, BA,* Beenish S. Manzoor, BA,¶ Lisa Belter, MPH,* Ruth M. Parker, MD,# and Bruce Lambert, PhD¶

A Patient-Centered Prescription Drug Label to Promote Appropriate Medication Use and Adherence

Michael S. Wolf, PhD MPH[1,2], Terry C. Davis, PhD[3], Laura M. Curtis, MS[1], Stacy Cooper Bailey, PhD MPH[4], JoAnn Pearson Knox, MSW[5], Ashley Bergeron, MPH[1], Mercedes Abbet, BA[5], William H. Shrank, MSHS MD[6], Ruth M. Parker, MD[7], and Alastair J. J. Wood, MD[8]



Patient Education and Counseling 101 (2018) 1351–1367

Contents lists available at ScienceDirect

Patient Education and Counseling

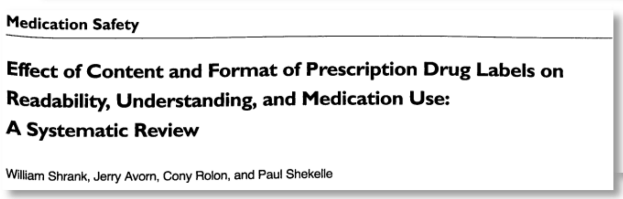
journal homepage: www.elsevier.com/locate/pateducou

Review article

Best-practices for the design and development of prescription medication information: A systematic review

Rebecca J. Mullen[a,*], James Duhig[c], Andrea Russell[a], Linda Scarazzini[c], Fabio Lievano[b], Michael S. Wolf[a]

[a] Division of General Internal Medicine and Geriatrics, Feinberg School of Medicine, Northwestern University, 750 N. Lake Shore Drive, 10th Floor, Chicago, IL, 60611, United States
[b] Safety Sciences, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States
[c] Pharmacovigilance and Patient Safety, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States



Medication Safety

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review

William Shrank, Jerry Avorn, Cony Rolon, and Paul Shekelle

Effect of Standardized, Patient-Centered Label Instructions to Improve Comprehension of Prescription Drug Use

Michael S. Wolf, MA, MPH, PhD,*†‡ Terry C. Davis, PhD,§¶ Laura M. Curtis, MS,† Jennifer A. Webb, MA,*† Stacy Cooper Bailey, MPH,*† William H. Shrank, MD, MSHS,‖ Lee Lindquist, MD, MPH,*† Bernice Ruo, MD,*† Mary V. Bocchini, BA,§¶ Ruth M. Parker, MD,** and Alastair J. J. Wood, MD†‡‡

The Process of Optimization

- Make R_x information **understandable** + **actionable**

- Objective, evidence-based, structured assessment

  - Patient Education Materials Assessment Tool ‘PEMAT’ (the SCIENCE)

  Re-review, in context of material’s purpose, use, context (the ART)

- Involve Patients (target population + naïve), Key Informants (e.g. prescribers)

  - ‘think aloud’ cognitive interview, mixed methods protocols

- Repeat as necessary (an iterative approach)

Patient Education Materials Assessment Tool (PEMAT)

Assess Understandability

Content
- purpose evident?
- distracting content?

Word Choice/Style
- use common language?
- medical terms avoided or clarified if used?

Numbers
- numbers easy to understand?
- does not require user to make calculations?

Organization
- uses informative headers?
- content laid forth in logical sequence?
- provides summary?

Layout/Design
- Uses visual cues for key points?
- text easy to read?

Visual Aids
- illustrations or other visuals used if aids understanding?
- if used, visuals reinforce and not distract from content?
- if used, have clear titles or captions?
- if used, uncluttered?

Assess Actionability

Identifies as least 1 action user can take

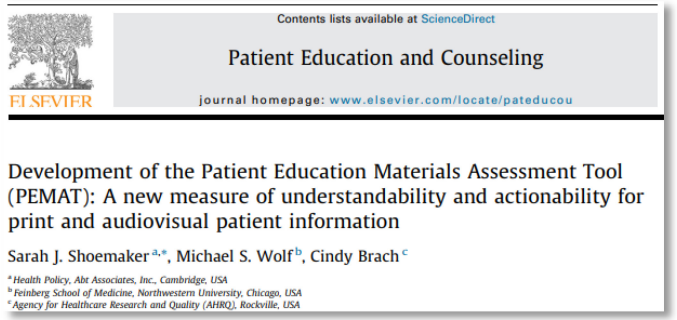
Addresses user directly when describing actions

Breaks down any action into manageable steps

Provides tangible tools when possible to make actions explicit

Provides simple instructions or examples

Uses visual aids when available to aid instructions



The Process of Optimization

- Make R_x information **understandable** + **actionable**

  Objective, evidence-based, structured assessment

  - Patient Education Materials Assessment Tool ‘PEMAT’ (the SCIENCE)

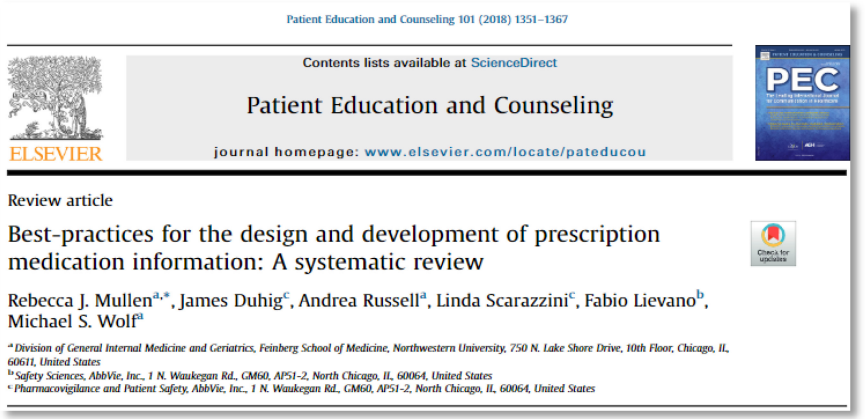
  Re-review, in context of material’s purpose, use, context (the ART)

- Involve Patients (target population + naïve), Key Informants (e.g. prescribers)

  - ‘think aloud’ cognitive interview, mixed methods protocols

- Repeat as necessary (an iterative approach)

2018 Systematic Review



Patient Education and Counseling 101 (2018) 1351–1367

Contents lists available at ScienceDirect

Patient Education and Counseling

journal homepage: www.elsevier.com/locate/pateducou

Review article

Best-practices for the design and development of prescription medication information: A systematic review

Rebecca J. Mullen[a,*], James Duhig[c], Andrea Russell[a], Linda Scarazzini[c], Fabio Lievano[b], Michael S. Wolf[a]

[a] Division of General Internal Medicine and Geriatrics, Feinberg School of Medicine, Northwestern University, 750 N. Lake Shore Drive, 10th Floor, Chicago, IL, 60611, United States
[b] Safety Sciences, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States
[c] Pharmacovigilance and Patient Safety, AbbVie, Inc., 1 N. Waukegan Rd., GM60, AP51-2, North Chicago, IL, 60064, United States

Strong evidence

- Typographic cues (e.g. bolding, bullet points, headings, >12 point font size)
- Information chunking
- Plain, behavior-oriented language
- Lower reading level (≤ 5th grade)
- Standardized formatting

Moderate evidence

- Pictograms/icons with paired text
- Use of color
- Graphics and illustrations
- Web-based modalities
- Shorter length
- Reading level tailored to literacy or education
- Quantitative information in percentage/frequencies

Limited evidence

- Q & A headings
- Pictograms/icons without paired text
- Quantitative information in narrative form

87% of interventions that included patients in the design of R_x materials reported positive findings vs. 67% that did not

Evidence of Benefit: It Works!

- Multiple studies, most conducted with larger samples (>200), have repeatedly found PMI designed using health literacy best practices, compared to those that did not…

  - are more efficiently reviewed (e.g. eye tracking studies)

  - improve patient comprehension (by 20-40%), treatment decision making, demonstrated use

  - higher adherence rates

  - patients who are older, with less education, lower health literacy, and with more complex regimens see greatest benefit of patient-centered instructions

  - 'closing the gap' - >50% reduction in disparities in comprehension between limited vs. adequate health literacy

Optimizing Patient and Lay Audience Materials

Using Health Literacy & Patient Activation Principles

Annlouise Assaf; Michael Wolf; **Stacy Bailey**; Asia Lem; Candida Halton

Case Study: PRODUCT X

- To optimize and assess performance of the PRODUCT X Risk Evaluation and Mitigation Strategy (REMS):
  - Patient Guide
  - Patient Wallet Card
  - Healthcare Setting Guide
  - Provider Knowledge Assessment

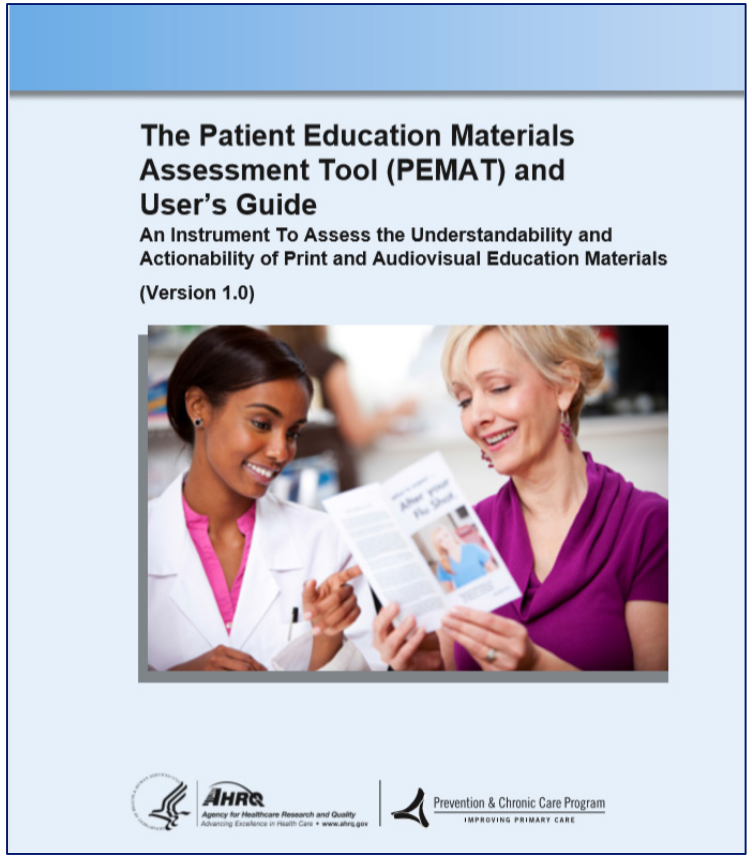
Study Steps

- Improve materials using health literacy ‘best practices’
- Seek feedback from patients/caregivers and providers to guide further revisions
- Assess the performance of optimized materials and identify any areas needing further improvement

Methods – Incorporating Health Literacy Practices

- Northwestern investigators reviewed each material to:
  - Assess readability (Lexile, Gunning Fog, Flesch-Kincaid)
  - Apply the Patient Education Materials Assessment Tool (PEMAT)
  - Consider evidence from health literacy research

- Revisions to simplify wording, layout, and sequencing of information to enhance readability and actionability



CAHRA
Center for Applied Health Research on Aging

Northwestern Medicine®
Feinberg School of Medicine

Methods – Incorporating Target Audience Feedback

- Northwestern investigators involved members of target audience in review and revisions (2 patient/caregivers, 2 providers)
- Individuals were shown materials about “Product X” and asked to interpret text, identify barriers to comprehension
- Involvement was iterative, review was qualitative in nature
- Industry partner reviewed suggested revisions and determined final content for subsequent user testing

Methods – User Testing

- Semi-structured interviews conducted with patients (N=30) and physicians (N=15) to assess comprehension, satisfaction with materials
- Participants recruited from prior studies, online advertisements, personal/professional networks
- Northwestern staff contacted participants to verify eligibility, obtain consent, schedule an interview, mail hard copies of materials
- Mixed methods approach with interviews conducted via videoconferencing software and data captured in REDCap

Results – User Testing

- High levels of comprehension achieved for all materials
  - Patients: **>80%** comprehension of 14 out of 15 key messages
  - Providers: average score of **95%** on knowledge assessment
- Qualitative and quantitative feedback revealed high levels of satisfaction with amount of content, appearance, quality
- Root cause analysis of provider performance on knowledge assessment identified 4 items (out of 22) needing further optimization

Suggested Revisions

- For Patient Materials:
  - Bolding and re-ordering information in one section to enhance patient understanding
  - Adding language and context to two sections to address patient information needs
  - Exploring alternate modalities, use of links to external websites
- For Provider Materials:
  - Removing or rewording assessment items that were a source of confusion
  - Ensuring ‘need to know’ information is consistently included throughout all sections
  - Highlighting the need for respondents to answer all questions correctly for certification

Conclusions

- High levels of comprehension achieved for patient and provider REMS materials
- Additional, minor revisions may increase comprehension and utility of Guides and improve knowledge assessment performance
- Limitations include small sample size, convenience sampling, introduced to project later than ideal
- Overall, goal is to provide guidance on optimizing materials from patient and provider perspectives to support understanding and use

Optimizing Patient and Lay Audience Materials

Using Health Literacy & Patient Activation Principles

Annlouise Assaf; Michael Wolf; Stacy Bailey; **Asia Lem**; Candida Halton

Product X REMS materials optimization: perspectives

- The quality of the REMS materials were significantly improved through the optimization efforts by Northwestern.
- The qualitative testing part of the project revealed additional useful suggestions for improvement of comprehension, utility and knowledge assessment performance.
- When this type of research is done prior to submission it can be used to inform the initial submission; if it is performed during a regulatory review cycle it can be leveraged during negotiations with Regulatory Agencies.
- The feedback provided principles for the design of the materials, that can be considered in any updates made in response to regulatory feedback

Optimizing Patient and Lay Audience Materials

Using Health Literacy & Patient Activation Principles

Annlouise Assaf; Michael Wolf; Stacy Bailey; Asia Lem; **Candida Halton**

Introduction

- Providing an overview of a business workflow to improve existing Plain Language Summary Results in terms of Quality, Readability, Understandability, Actionability.

1. **Audience Profile and Insights**
2. **Content Scope and Structure**
3. **Formatting and Language**
4. **Testing**

Demonstrate	Optimize	Accelerate
meaningful impact of content on understanding, motivation, activation, adherence and clinical outcomes	patient and prescriber content for relevance, quality and impact	quality improvement in health content best practice at the levels of direct care, healthcare system and policy change

1 Audience Profile and Insights

Audience Profile and Insight

- Understand audience information needs, so that these can be met[4]
  - Understanding is the first step for changing behaviour and ‘activating’ patients
- Understand audience profile and preferences, so that these can be integrated into design and content planning
- Research confirms materials designed for people with lower health literacy are not off-putting for those with higher health literacy[4]

Data on health literacy shows:

- Higher levels of health literacy positively impacts patient outcomes
- Lower levels of health literacy negatively impacts access and use of healthcare services, self-care behaviors and use of medicines
- The majority of people in most countries have difficulty understanding basic health information[5-7]

1
What is the purpose of the patient material?

2
Who is the audience?

3
What are their information needs?

Audience Profile and Insight

How you can ensure patient materials are suitable for all levels of health literacy?

1. Involve patients with content scope, structure and development
2. Ensure that a wide range of literacy abilities are included in material development
3. Use available tools to assess health literacy and patient activation levels[a-f]
4. Recruit lower HL-level patients, in addition to patient advocates or expert patients for this stage
5. Understand patients' beliefs about their illness[g], attitudes to their medicines and adherence

Tools

a. Newest Vital Sign
b. Rapid Estimate Adult Literacy in Medicine
c. Test of Functional HL in Adults
d. Comprehensive Health Activities Scale
e. Patient Activation Measure
f. Consumer Health Activation Index (CHAI)
g. Brief Illness Perceptions Questionnaire. Broadbent *et al.* 2006

2 Content Scope and Structure

Content Scope and Structure

- Clearly set out purpose and intended audience
  - If appropriate include author[4]
- If reporting study results to lay or patient audience[11]
  - Provide information on study population
  - Prioritize primary endpoints
- Use brand name if more easily recognized[11] (subject to legal guidance)
- Signpost reader to other (non-commercial/ non-promotional) resources where appropriate[11]

Tips

- Use **plain language** to explain the purpose
- **Involve** the reader
- Make the **content easy to read**
- Make it **look easy to read**
- Only include **visuals that clarify** and motivate[4]
- Explain how to read tables and graphs and clearly label

Content Scope and Structure

Guidance on ensuring content quality

Content should be:

- Factual and scientifically accurate
- Unbiased in scope and tone
- Specific to the topic of the question, study or article
- Comprehensive (but focused)
- Reflect current evidence and follow a hierarchy of evidence
- Aligned to relevant guidelines

Numerical Information

- Numbers are more challenging for people to understand[9]
- Use frequency and percentage
  - 10 patients in 100 (10%)[10]
- Describe risk and benefit by framing both ways
  - 9 in 10 and 1 in 10

3 Formatting and Language

Formatting and Language

Do use[4,11-18]

- A simple template
- Reduced background visuals to leave open, white space
- 1.15 space lines
- Normal (or wide) margins
- Font size 12 with larger font for headings
- A simple font
- Shading and numbering to denote section headings
- Bullet points (with keywords used early)
- Chunk information
- Lay titles for sections (in a PLS)
- An active voice throughout
- Short, clear sentences (<16 words, and aim for <30 syllables per sentence)
- 4-6th grade reading level

Avoid using[4,11-18]

- CAPITALIZATION, *italicisation* and <u>underlining</u>
  - To highlight use **bold**
- Jargon, technical language or complex terms
  - Or give definitions in the text
  - Use (brackets) or “quotation marks” after the plain language term
  - Consider using audio phonetics to help with pronunciation
- Footnotes (or use with caution as people often do not read them)

4 Testing

Testing

Literature confirms that testing draft materials with patients is a critical step to optimizing content.[17-22]

- Increasingly, regulatory agencies require this step for certain materials. For example Plain Language Study Results Summary (PLSRS) or Plain Language Summary (PLS)

We recommend three common, validated measures for testing materials:

1 Testing for readability
Is the material easy to read?

We recommend the **readable.io** online tool

- a simple online tool to measure readability
- uses the most common scales, including Flesch-Kincaid

2 Testing for understandability
Is the material easy to understand?

3 Testing for activation
Will the reader take action?

We recommend the validated Patient Education Materials Assessment Tool (PEMAT) and the **Suitability Assessment of Materials (SAM) process**[21]

Testing Materials with Patients

- Successfully testing materials with patients requires thoughtful selection of research cohort as well as methods[17-22]
  - Recruit patients with a range of health literacies to participate
  - Select measures to reflect understanding and activation that go beyond readability
  - Try to incorporate testing into regular practice
- Prior to testing with patients test with individuals who are not knowledgeable about the disease, or product, e.g. colleagues from other departments

There are several routes to engaging patients in asset development to discuss and evaluate:

1. Work directly with a Patient Advocacy Group
2. GMIA has established a MSA with North-Western University, leaders in developing and testing patient-facing materials
3. Pfizer has an established Health Literacy Community of Practice

Where to find out more information

Bibliography

1. von Wagner, C., Steptoe, A., Wolf, M. S., & Wardle, J. (2009). Health literacy and health actions: A review and a framework from health psychology. Health Education & Behavior, 36, 860–877 (pp. 862-3). https://doi.org/10.1177/1090198108322819
2. Carman, KL., Workman, TA., Engaging patients and consumers in research evidence: Applying the conceptual model of patient and family engagement. Patient Education and Counseling 100 (2017) 25–29. https://doi.org/10.1016/j.pec.2016.07.009
3. Barello S, Graffigna G, Vegni E, Bosio AC. The challenges of conceptualizing patient engagement in health care: a lexicographic literature review. J Participat Med. 2014 Jun 11; 6:e9. https://www.researchgate.net/publication/263088534
4. Centers for Disease Control and Prevention. Simply put: a guide for creating easy-to understand materials. https://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf. 3d edition April 2009. Accessed April 28, 2020
5. Sørensen, K., Pelikan, J. M., Röthlin, F., Ganahl, K., Slonska, Z., Doyle, G., Fullam, J., Kondilis, B., Agrafiotis, D., Uiters, E., Falcon, M., Mensing, M., Tchamov, K., van den Broucke, S. & Brand, H. (2015). Health literacy in Europe: comparative results of the European health literacy survey (HLS-EU). European Journal of Public Health, 25(6), 1053-1058 (p. 1055, Figure 1) https://doi.org/10.1093/eurpub/ckv043
6. Kutner, M., Greenberg, E., Jim, Y. & Paulsen, C. (2006). The health literacy of America's adults: Results from the 2003 national assessment of adult literacy (NCES-2006-483). Washington, DC: U.S. Department of Education https://nces.ed.gov/pubs2006/2006483.pdf
7. Australian Bureau of Statistics. (2006). Health Literacy, Australia. Canberra: Australian Bureau of Statistics https://www.abs.gov.au/AUSSTATS/abs@.nsf/Latestproducts/4233.0Main%20Features22006
8. Michie, S. van Stralen, M.M., West, R. The behaviour change wheel: A new method for characterising and designing behaviour change interventions. Implement Sci. 2011; 6:42 https://implementationscience.biomedcentral.com/articles/10.1186/1748-5908-6-42
9. Rowlands, G., Protheroe, J., Winkley, J., Richardson, M., Seed, P. T., & Rudd, R. (2015). A mismatch between population health literacy and the complexity of health information: an observational study. The British Journal of General Practice, 65(635), e379-86. https://doi.org/10.3399/bjgp15X685285
10. Zikmund-Fisher, B.J., Witterman, H.O., Dickson, M., Fuhrel-Forbis, A., Kahn, V.C., Exe, N.L., Valerio, M., Holtzman, L.G., Scherer, L.D., Fagerlin, A. Blocks, Ovals or People? Icon Type Affects Risk Perceptions and Recall of Pictographs. Medical Decision Making 34.4 (2014):443-453 https://doi.org/10.1177/0272989X13511706
11. Raynor, DK. Dickinson, D. Key principles to guide development of consumer medicine information -content analysis of information design texts. Ann Pharmacother. 2009 Apr;43(4):700-6 https://doi.org/10.1345/aph.1L522
12. Doak C, Doak LG, Root JH. Assessing suitability of materials. In: Belcher M, editor. Teaching Patients With Low Literacy Skills. Philadelphia: J. B. Lippincott Company; 1996 https://journals.lww.com/ajnonline/Fulltext/1996/12000/Teaching_Patients_with_Low_Literacy_Skills.22.aspx
13. NCI. Clear & Simple: Developing E□ ffective Print Materials for Low-Literacy Audiences. https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/clear-communication/clear-simple Accessed April 28, 2020
14. Shoemaker, S.J., Wolf, M.S., Brach, C. Development of the Patient Education Materials Assessment Tool (PEMAT): A new measure of understandability and actionability for print and audiovisual patient information. Patient Educ Couns. 2014; 96(3):395-403 https://doi.org/10.1016/j.pec.2014.05.027
15. Hill-Briggs, F., Smith, A.S., Evaluation of Diabetes and Cardiovascular Disease Print Patient Education Materials for Use With Low–Health Literate Populations. Diabetes Care 31:667–671, 2008. https://doi.org/10.2337/dc07-1365
16. Coleman, C., Hudson, S., Pederson, B. (2017). Prioritized Health Literacy and Clear Communication Practices For Health Care Professionals. Health Literacy Research and Practice, 1(3), e90-99. https://doi.org/10.3928/24748307-20170503-01
17. Stossel, LM., Segar, N., Gliatto, P., Fallar, R., Karani, R. (2012). Readability of Patient Education Materials Available at the Point of Care. J Gen Intern Med 27(9):1165–70. https://doi.org/10.1007/s11606-012-2046-0
18. Wang et al. Assessing readability formula differences with written health information materials: Application, results, and recommendations. Research in Social and Administrative Pharmacy 2013; 9,503–516 https://doi.org/10.1016/j.sapharm.2012.05.009
19. Beyer DR, Lauer MS, Davis S. Readability of informed-consent forms. N Engl J Med. 2003;348(22):2262–3 https://doi.org/10.1056/NEJMc030704
20. Kaphingst KA, Kreuter MW, Casey C, Leme L, Thompson T, Cheng M-R, et al. Health Literacy INDEX: development, reliability, and validity of a new tool for evaluating the health literacy demands of health information materials. J Health Commun 2012;17(Suppl. 3):203–21 https://doi.org/10.1080/10810730.2012.712612
21. Smith S. SAM: suitability assessment of materials for evaluation of health-related information for adults (2012). http://aspiruslibrary.org/literacy/SAM.pdf.
22. Raynor, D.K., Myers, L., Blackwell, K., Kress, B., Dubost, B.A., Joos, A. Clinical Trial Results Summary for Laypersons: A User Testing Study. Therapeutic Innovation & Regulatory Science 2018, Vol. 52(5) 606-628 https://doi.org/10.1177/2168479017753129
23. Cochrane. Standards for the reporting of Plain Language Summaries in new Cochrane Intervention Reviews (PLEACS) version 3.0. https://consumers.cochrane.org/sites/consumers.cochrane.org/files/public/uploads/pleacs_2019.pdf Published February 28, 2013. Accessed April 28, 2020.


Q&A