



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
OF OLDER ADULTS

Omni Shoreham • Washington, DC
Tuesday and Wednesday, April 9-10, 2013

Final Agenda

The April 2013 National Summit on OTC Medication Behaviors of Older Adults will be a full-day conference in Washington, DC, focused on safe and effective use of over-the-counter (OTC) medications. Attendees from industry, academia, research, and practice will convene to evaluate current research on the OTC medication behaviors of older adults and identify gaps in the evidence base. Specific areas of focus will include OTC medication literacy, the perceptual and cognitive basis of OTC medication decision making, technologies to support optimal OTC behavior, and the interface of clinical and family care with OTC behavior. The Summit is an effort of The Gerontological Society of America (GSA) in partnership with the Consumer Healthcare Products Association (CHPA).

Objectives of the 2013 National Summit on OTC Medication Behaviors of Older Adults:

- Evaluate existing research on OTC medication behaviors among older adults.
- Identify gaps in available research and prioritize research questions to improve OTC medication behaviors of older adults.
- Determine how packaging and health literacy influence older adults' choice of OTC medications.
- Determine other influences on OTC medication use, including concerns about drug and disease interactions and clinician and family factors.
- Identify emerging technologies that support optimal OTC medication practices.
- Establish a framework and process to conduct critical research.
- Develop the science of OTC behaviors among older adults to promote safe and effective use of OTC medications.

TUESDAY, APRIL 9, 2013

6:00 PM–8:00 PM **Registration and Networking Reception**
Robert's Restaurant Private Dining Room

WEDNESDAY, APRIL 10, 2013

7:00 AM–8:00 AM **Registration and Breakfast**
Congressional Room

8:00 AM–8:30 AM **Welcome and Why We Are Here**
Barbara A. Kochanowski, PhD, Vice President, Regulatory & Scientific Affairs
Consumer Healthcare Products Association

James C. Appleby, RPh, MPH, Executive Director & CEO
The Gerontological Society of America

8:30 AM–9:00 AM **Introduction of the Workgroup, Stakeholders, and the Goals for the Day**
Steven M. Albert, PhD, *Workgroup Chairperson*
Professor and Chair, Department of Behavioral and Community Health Sciences
Graduate School of Public Health, University of Pittsburgh

9:00 AM–11:30 AM

OTC Medication Literacy and Decision Making Among Older Adults

Discussants: Margaret Dyer-Chamberlain, MALD; Laura Bix, PhD

- **Dimensions of OTC Medication Health Literacy Among Older Adults**
Michael S. Wolf, PhD, MPH
Associate Professor, Associate Division Chief
Research for General Internal Medicine, Northwestern University
- **Assessing Older Adults' Decision Making in OTC Medication Behavior**
Ruth S. Day, PhD
Director, Medical Cognition Laboratory
Senior Fellow, Duke Center for the Study on Aging
Duke University

11:30 AM–12:15 PM

Networking Lunch

12:15 PM–2:30 PM

Interventions to Promote Safe and Effective OTC Medication Use Among Older Adults

Discussants: Mary M. Bridgeman, PharmD; Steven M. Albert, PhD

- **Promoting Safe and Effective OTC Medication Behavior Through Interface With Clinical Care**
Elaine A. Leventhal, MD, PhD
Professor of Medicine
University of Medicine and Dentistry of New Jersey
The Robert Wood Johnson Medical Group
- **Promoting Safe and Effective OTC Medication Behavior Through Interface With Family Care**
Laura N. Gitlin, PhD
Professor, Department of Community Public Health, School of Nursing
Department of Psychiatry and Division of Geriatrics and Gerontology
School of Medicine
Director, Center for Innovative Care in Aging
Johns Hopkins University

2:30 PM–2:45 PM

Wiggle Break

2:45 PM–3:45 PM

Developing New Interventions to Support Safe and Effective OTC Medication Behaviors

Discussant: Patricia J. Neafsey, PhD

- **Emerging Technologies to Promote Optimal OTC Behavior**

Using Technology to Facilitate Safe OTC Medication Behaviors
Christopher B. Mayhorn, PhD
Associate Professor, Program Coordinator, Human Factors and Ergonomics Program
Department of Psychology
North Carolina State University

Assessing Incremental Risk From OTC Medications in the Therapeutic Regimens of Older Adults

Patricia Meisner, MS, MBA
Chief Executive Officer
AdhereTx Corp.

Designing Self-Management Products: Cognitive Prosthetics for Older Adults

Anthony A. Sterns, PhD
Chief Executive Officer, iRx Reminder LLC
Visiting Associate Professor, College of Nursing, Kent State University

3:45 PM–4:45 PM

Prioritize the Research Questions

Steven M. Albert, PhD, *Workgroup Chairperson*
Participants break out into small groups led by Panel Discussants and Speakers

4:45 PM

Closing Remarks: Summary of the Day and Next Steps

5:00 PM

Adjournment





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Speakers: OTC Medication Literacy and Decision Making Among Older Adults



Michael S. Wolf, PhD, MPH

Michael Wolf is an Associate Professor of Medicine, Associate Division Chief of Research, and Director of the Health Literacy and Learning Program within the Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University. Dr. Wolf is a cognitive/behavioral scientist and health services researcher with primary interests in adult literacy and learning, cognitive factors, medication adherence, and the management of chronic disease. A former Fulbright Scholar to the United Kingdom, he has received numerous national awards for his work in the field of health literacy,

medication safety, and adherence.

Dr. Wolf has written over 125 peer-reviewed publications, many of which address the problem of limited health literacy. He currently serves on many advisory committees for the U.S. Food and Drug Administration, U.S. Pharmacopeia, Agency for Healthcare Research and Quality, and National Institutes of Health. He has repeatedly provided consultation on health literacy matters to the Institute of Medicine, American College of Physicians, American Medical Association, American Pharmacists Association, and Centers for Disease Control and Prevention. He is the principal investigator on grants from the National Institute on Aging, National Cancer Institute, Agency for Healthcare Research and Quality, McNeil Pharmaceuticals, Abbott Labs, among others. Dr. Wolf also led an Institute of Medicine white paper on health literacy and medication safety, and he is the principal investigator of a trial to test enhanced drug labeling and the use of visual aids to improve patient processing and understanding of medication instructions.



Ruth S. Day, PhD

Ruth Day is Director of the Medical Cognition Laboratory at Duke University and Senior Fellow at the Duke Center for the Study of Aging. After completing her PhD in cognitive science at Stanford University, she was on the faculty at Stanford and Yale Universities before joining the faculty at Duke. She was a Visiting Scholar at Carnegie-Mellon University, on the faculty of the Linguistic Society of America Institute, and Fellow at the Center for Advanced Study in the Behavioral Sciences at Stanford. She

was a charter member of the Food and Drug Administration (FDA) Drug Safety and Risk Management Advisory Committee, serves on many other FDA Advisory Committees, is a consultant for many organizations (such as FDA, U.S. Pharmacopeia, Institute of Medicine), and has given hundreds of invited research presentations at a various professional organizations.

Dr. Day's research examines the "cognitive accessibility" of medical information – the ease with which both healthcare professionals and patients can understand, remember, and use information about drugs and devices. She has designed and tested new ways to display medical information based on established cognitive principles. The resulting enhanced displays enable people to improve their ability to understand, remember, and use the information, often dramatically. Dr. Day conducts research both in the laboratory and in the everyday world using multiple cognitive tasks to assess attention, comprehension, memory, problem solving, and decision making. Professor Day has several teaching awards, including the Trinity Distinguished Teacher Award at Duke and Ten Best Teachers at Yale. She teaches courses in basic cognition, everyday cognition, medical cognition, courtroom cognition, psycholinguistics, and great ideas across disciplines.



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Presentation Briefing

Speaker: Michael S. Wolf, PhD, MPH

Session: OTC Medication Literacy and Decision Making Among Older Adults

Individual Presentation: Dimensions of OTC Medication Health Literacy Among Older Adults

Discussant: Margaret Dyer-Chamberlain, BA, MALD

Summary:

In this session, the evidence pertaining to the associations between health literacy and older adults' understanding and use of over-the-counter (OTC) products will be reviewed. From this perspective, certain recommendations for improving labeling and information to suit older adults' needs to promote health literacy will be mentioned.

Objectives:

- Define health literacy in terms of the cognitive and social skill sets required by patients as well as how health literacy is affected by a health care system.
- Explain how age affects health literacy skills and use of OTC products.
- Identify three attributes of OTC products and labeling that contribute to medication errors and other concerns for patients' safety that are particularly salient to older adults.
- Name four ways that OTC labels could be made more understandable and actionable, supporting safe and appropriate use.

Literature Review:

As this presentation specifically focuses on the role of health literacy, the evidence reviewed for this presentation will include qualitative, quantitative, epidemiological investigations as well as efficacy or randomized trials of:

- Studies that include a measure of consumer health literacy or numeracy and look at an outcome related to OTC product understanding or use (self-selection, dosing, concomitant use, demonstrated misuse, medication dairies, adverse events, etc.).
- Studies that examine the readability or suitability of OTC-related labeling or information.
- Physician, pharmacist, or allied health professional spoken counseling with adults around OTC selection or use.

Given the specific emphasis of this research, the period of study focuses from 1990-2013 and represents a limited amount of evidence in the context of both OTC use and older adults. Research is even more limited for designing effective interventions to promote this behavior among this specific population. However, there are promising studies related to medication use (prescription products) that could apply to OTC products. Furthermore, the unique challenges to safe use among OTC products will be reviewed and specific areas for prioritization of next step research efforts identified.

Literature:

Abel C, Johnson K, Waller D, Abdalla M, Goldsmith CA. Nonprescription medication use and literacy among New Hampshire eighth graders. *J Am Pharm Assoc.* 2012;52:777-782.

Backes AC, Kuo GM. The association between functional health literacy and patient-reported recall of medications at outpatient pharmacies. *Res Social Adm Pharm.* 2012;8:349-354.

Calamusa A, Di Marzio A, Cristofani R, Arrighetti P, Santaniello V, Alfani S, Carducci A. Factors that influence Italian consumers' understanding of over-the-counter medicines and risk perception. *Patient Educ Couns.* 2012;87:395-401.

Catlin JR, Pechmann C, Brass EP. The influence of need for cognition and principal display panel factors on over-the-counter drug facts label comprehension. *Health Commun.* 2012;27:264-272.

Davis TC, Wolf MS, Bass PF, Thompson JA, Tilson HH, Neuberger M, Parker RM. Literacy and misunderstanding prescription drug labels. *Ann Intern Med.* 2006;145:887-894.

Doak CC, Doak LG, Root JH. *Assessing Suitability of Materials. Teaching Patients With Low Literacy Skills.* 2nd ed. Philadelphia, PA: JB Lippincott; 1996.

Hornsby LB, Przybylowicz J, Andrus M, Starr J. Survey of physician knowledge and counseling practices regarding acetaminophen. *J Patient Saf.* 2010;6:216-220.

King JP, Davis TC, Bailey SC, Jacobson KL, Hedlund LA, Di Francesco L, Parker RM, Wolf MS. Developing consumer-centered, nonprescription drug labeling: a study in acetaminophen. *Am J Prev Med.* 2011;40:593-598.

Lokker N, Sanders L, Perrin EM, Kumar D, Finkle J, Franco V, Choi L, Johnston PE, Rothman RL. Parental misinterpretations of over-the-counter pediatric cough and cold medication labels. *Pediatrics.* 2009;123:1464-1471.

Neafsey PJ, Strickler Z, Shellman J, Chartier V. An interactive technology approach to educate older adults about drug interactions arising from over-the-counter self-medication practices. *Public Health Nurs.* 2002;19:255-262.

Qato DM, Alexander GC, Conti RM, Johnson M, Schumm P, Lindau ST. Use of prescription and over-the-counter medications and dietary supplements among older adults in the United States. *JAMA*. 2008;300:2867-2878.

Raymond EG, Dalebout SM, Camp SI. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. *Obstet Gynecol*. 2002;100:342-349.

Raymond EG, L'Engle KL, Tolley EE, Ricciotti N, Arnold MV, Park S. Comprehension of a prototype emergency contraception package label by female adolescents. *Contraception*. 2009;79:199-205.

Serper M, McCarthy D, Curtis LM, King JA, Davis TC, Parker RM, Wolf MS. Physician, pharmacist communication with patients on medications: the role of health literacy. Under revision, *Patient Educ Couns*. 2013.

Shiffman S, Gerlach KK, Sembower MA, Rohay JM. Consumer understanding of prescription drug information: an illustration using an antidepressant medication. *Ann Pharmacother*. 2011;45:452-458.

Shone LP, King JP, Doane C, Wilson KM, Wolf MS. Misunderstanding and potential unintended misuse of acetaminophen among adolescents and young adults. *J Health Commun*. 2011;16:256-267.

Wilson EAH, Wolf MS. Working memory and the design of health materials: a cognitive factors perspective. *Patient Educ Couns*. 2009;74:318-322.

Wolf MS, Davis TC, Tilson HH, Bass PF, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. *Am J Health Syst Pharm*. 2006;63:1048-1055.

Wolf MS, King J, Jacobson K, Di Francesco L, Bailey SC, Mullen R, McCarthy D, Serper M, Davis TC, Parker RM. Risk of unintentional overdose with non-prescription acetaminophen products. *J Gen Intern Med*. 2012;27:1587-1593.

Yin HS, Parker RM, Wolf MS, Mendelsohn AL, Sanders LM, Vivar KL, Carney K, Cerra ME, Dreyer BP. Health literacy assessment of labeling of pediatric nonprescription medications: examination of characteristics that may impair parent understanding. *Acad Pediatr*. 2012;12:288-296.

Research Questions:

1. What is the prevalence of OTC misunderstanding and misuse?
 - What is the role of health literacy? Age? Other relevant patient factors?
2. In deconstructing the tasks associated with OTC use, what are the root causes of misunderstanding and misuse?

- How do older adults differ from younger adults in their selection, understanding, and use of OTC products?
- 3. What is the prevalence of health care providers' counseling and communication with patients on OTC use?
 - Does counseling occur more or less frequently among older adults or those with limited health literacy?
- 4. What are the likely solutions, in terms of OTC labeling, provider counseling, etc. that would promote health literacy for OTC use, especially among older adults?

Case Studies:

Brief cases that detail specific situations representing actual patients recruited in recent research studies will be highlighted, clarifying the epidemiology and root causes for how low health literacy is both a risk factor and target for improvement. Cases specific to non-prescription, non-opioid analgesic pain medicine will be used.

Handouts and Materials:

PowerPoint presentation



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Session: OTC Medication Literacy and Decision Making Among Older Adults

Individual Presentation: OTC Decision Making Among Older Adults

Panel Discussant: Laura Bix, PhD

Summary:

Older adults make many decisions about over-the-counter (OTC) products, such as which product to select for a given condition and how to use it. Although there is some evidence about what factors affect their decisions (both cognitive and social), there is very little evidence about how they make these decisions. This presentation provides a brief overview of representative research on OTC decision making in older adults, distinguishes research on cognitive vs. metacognitive processes, examines selected examples of research designed to understand the cognitive processes that underlie decisions rather than just the decisions themselves, and provides a roadmap for future research.

Objectives:

- Identify factors that can influence OTC decision making in older adults.
- Distinguish between studies on cognition vs. metacognition.
- Examine alternative research methods, from surveys to experiments.
- Learn ways to study how people make decisions, not just the decisions they make.
- Re-examine what it means to find age differences in OTC decision making.

Literature Review:

This presentation acknowledges what is known about OTC decision making in older adults, but focuses primarily on what is missing, both in terms of content and methods. Most of the current research relies on self-report surveys and provides a useful list of factors that can affect OTC decision making. Since other types of methods would advance this area in new ways, examples are included, especially those that use experimental designs (with systematic variation of key factors and use of established cognitive tasks).

Literature:

Amoako EP, Richardson-Campbell L, Kennedy-Malone L. Self-medication with over-the-counter drugs among elderly adults. *J Gerontol Nurs*. 2003;29:10-15.

Belcher VN, Fried TR, Agostini JV, Tinetti ME. Views of older adults on patient participation in medication-related decision making. *J Gen Intern Med*. 2006;21(4):298-303.

Conn VS. Self-management of over-the-counter medications by older adults. *Public Health Nurs*. 1992;9:29-36.

Hanna LA, Hughes CM. Public's views on making decisions about over-the-counter medication and their attitudes towards evidence of effectiveness: a cross-sectional questionnaire study. *Patient Educ Couns*. 2011;83:345-351.

Johnson MM, Drungle SC. Purchasing over-the-counter medications: the influence of age and familiarity. *Exp Aging Res*. 2000;26:245-261.

Löckenhoff CE, Carstensen LL. Aging, emotion, and health-related decision strategies: motivational manipulations can reduce age differences. *Psych Aging*. 2007;22(1):134-146.

Nichol MB, McCombs JS, Johnson KA, Spacapan S, Sclar DA. The effects of consultation on over-the-counter medication purchasing decisions. *Med Care*. 1992;30:989-1003.

Reisenwitz TH, Wimbish GJ Jr. The purchase decision process and involvement of the elderly regarding nonprescription products. *Health Mark Q*. 1997;15:49-68.

Ross MM, Carswell A, Hing M, Hollingworth G, Dalziel WB. Seniors' decision making about pain management. *J Adv Nurs*. 2001;35:442-451.

Sansgiry SS, Cady PS. How the elderly and young adults differ in the decision making process of nonprescription medication purchases. *Health Mark Q*. 1996;14:3-21.

Sclar DA, Robison LM, Skaer TL. Pharmacy consultation and over-the-counter medication purchasing outcomes. *J Clin Pharm Ther*. 1996;21:177-184.

Stephens EC, Johnson MMS. Dr. Mom and other influences on younger and older adults' OTC medication purchases. *J Appl Gerontol*. 2000;19:441-459.

Research Questions:

1. Many factors have been identified that affect OTC decisions in older adults.
 - Do these factors work independently or do some of them interact?
 - Does the number of factors needed to determine self-selection for an OTC drug create information overload and reduce the effectiveness of decisions made?
2. There are classic models of decision making that underlie behavior for a wide variety of content and contexts.
 - To what extent do they underlie OTC decisions as well?
 - Do younger and older adults rely on the same or different models?
3. Usually only one type of decision-making task is used in a given study.
 - Would the same results occur if multiple tasks were used with the same participants or are the results method-based?
4. Many of the questions asked in OTC decision-making studies are similar – what factors do people use, do the factors vary by age and other demographic variables, etc.
 - What new questions can be generated using additional research methods to open up new areas of study?
5. There is some evidence that older adults make OTC decisions in a more organized way than younger adults.
 - What is the nature of that organization?
 - To what extent is it based on thinking skills vs. prior knowledge of drug information?
 - Do older adults have a larger “toolkit” for guiding their decisions?
 - Would this organizational superiority occur across other types of OTC decision tasks?

Case Studies:

The MUST program (Medication Use Safety Training for Seniors) developed by the National Council on Patient Information and Education (NCPPIE) was designed to “give older adults and caregivers the tools and know-how to avoid medication misuse, recognize and manage common side effects, and improve medicine use knowledge, attitudes, and skills to avoid medication errors.” It includes implications for OTC decision making.

Handouts and Materials:

PowerPoint presentation



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OTC Medication Literacy and
 Decision Making Among
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CHPA CONSUMER HEALTHCARE
 PRODUCTS ASSOCIATION




THE GERONTOLOGICAL
 SOCIETY OF AMERICA



OTC Use Among the Elderly
 the role of health literacy

Michael Wolf, PhD, MPH
 Northwestern University
 Chicago, IL

Disclosure



- Abbott Labs
- Earthbound LLC
- McNeil Consumer Healthcare
- Merck Pharmaceuticals
- UnitedHealthcare
- AHRQ
- California Endowment
- California Healthcare Foundation
- Missouri Foundation for Health
- NIH
 - NCI
 - NHLBI
 - NIA
 - NICHD
 - NINR
 - OBSSR

Overview

- 'Health Literacy' (HL) as a Framework
- HL & Aging
- Deconstruct the HL Task: OTC Use
- Review of the Evidence: HL & OTC Use
- Review of the Evidence: Missed Opportunities
- Potentially Effective Solutions
- Next Steps

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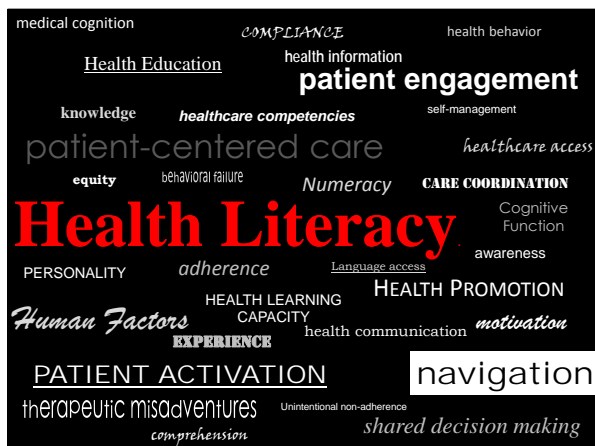
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Health Literacy Is...

“The degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”

– Institute of Medicine, USA

“The cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health.”

– World Health Organization

A \$200 Billion Problem

The business case for health literacy **HL**

- Inadequate/inaccurate knowledge of disease, treatment
- Poorer self-care skills (medication use, monitoring, device use)
- Inappropriate health services use

Translates to:

- Non-adherence
- Costly urgent services (Unscheduled visits, ED, Hospitalizations)
- Medication Errors & Adverse Events
- Poorer outcomes (HTN, Diabetes, CHF, Asthma/COPD)

Pertinent Epidemiology

- 1 in 5 adults severely lack cognitive and psychosocial skills to manage personal health

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- Greatest risk among those that are: > 60 years old, < high school educated, racial/ethnic minorities, multi-morbidity

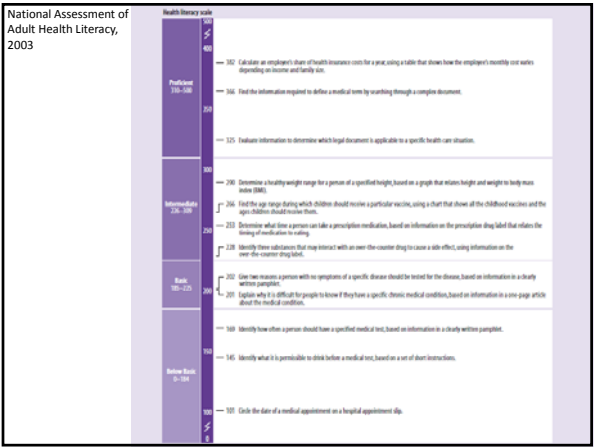
Pertinent Epidemiology

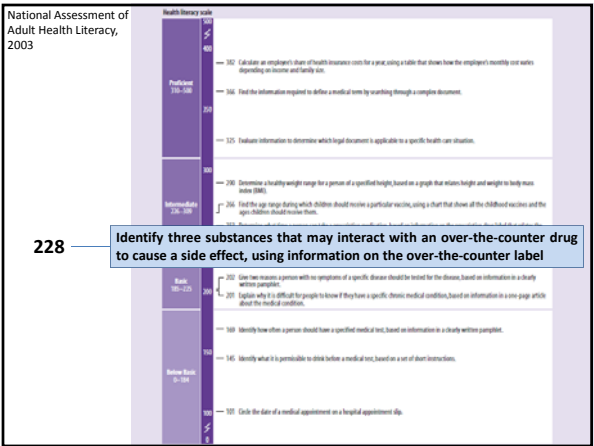
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- Prior studies suggest MDs, RNs, and PharmDs cannot easily identify at-risk patients

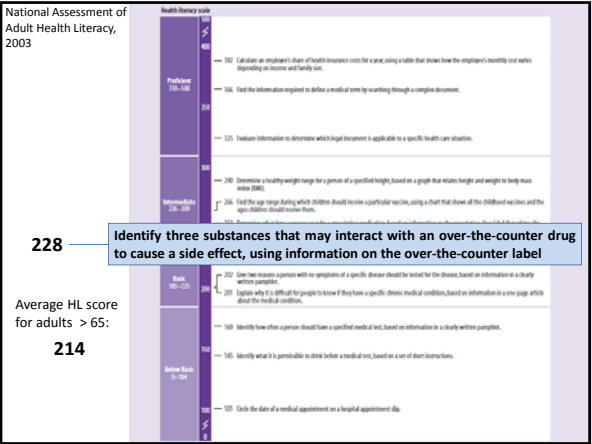
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- Prior studies suggest MDs, RNs, and PharmDs cannot easily identify at-risk patients
- Kripalani et al – low HL patients ask fewer questions; Weiss et al – don't self-identify problems

Health Literacy & Aging







Literacy, Cognitive Function, and Health: Results of the LiCog Study

Michael S. Wolf, PhD, MPH^{1,2}, Laura M. Curtis, MD¹, Elizabeth A. H. Wilson, PhD¹, William Neville, PhD³, Katherine H. Wolfe, BA^{1,4}, Samuel G. Smith, MD⁵, Sandra Wehrhahn, PhD⁶, Beth Boush, PhD⁷, David H. Rogers, PhD⁸, Denise C. Pate, PhD⁹, Jan C. Deary, PhD¹⁰, and David W. Baker, MD, MPH¹¹

Table 3. Correlations with Cognitive & Health Literacy Tests

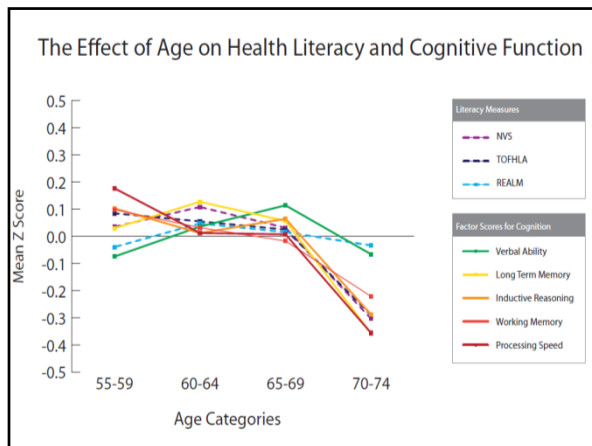
Cognitive Ability	TOFHLA	REALM	NVS
Processing Speed	0.68	0.52	0.60
Working Memory	0.65	0.43	0.59
Inductive Reasoning	0.71	0.54	0.71
Long Term Memory	0.48	0.36	0.51
Prospective Memory	0.40	0.28	0.42
Fluid Cognitive Ability	0.76	0.57	0.73
Crystallized Cognitive Ability	0.77	0.74	0.71

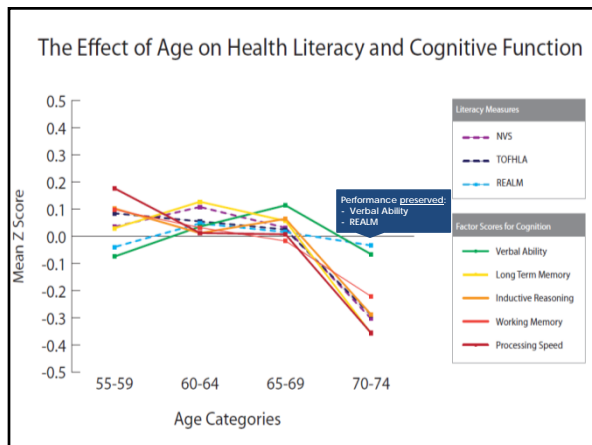
All correlations statistically significant at $p < 0.001$

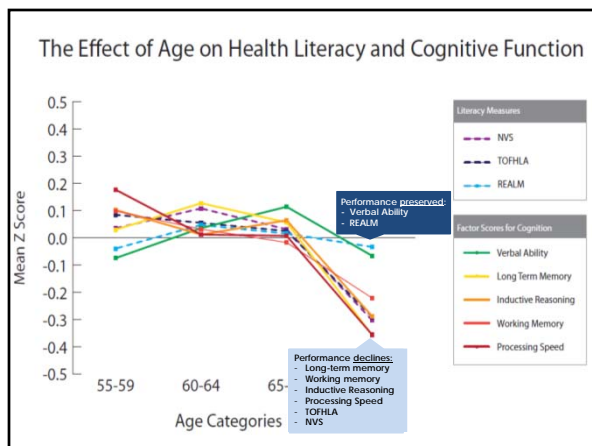
Age, HL, and Cognition

	PROCESSING SPEED	WORKING MEMORY	INDUCTIVE REASONING	LT MEMORY	VERBAL ABILITY	TOFHLA	REALM	NVS
Processing	N/A					HL to HL: 0.46 to 0.75		
Working Memory	0.64*	N/A				FA to HL: 0.37 to 0.71		
Inductive Reasoning	0.72*	0.73*	N/A			CA to HL: 0.71 to 0.74		
LT Memory	0.54*	0.49*	0.54*	N/A		Age to FA: +		
Crystal Abilities	0.66*	0.62*	0.75*	0.50*	N/A	Age to CA: -		
TOFHLA	0.68*	0.65*	0.71*	0.48*	0.77*	Age to TOFHLA: +		
REALM	0.53*	0.45*	0.54*	0.37*	0.74*	Age to REALM: -		
NVS	0.61*	0.59*	0.71*	0.51*	0.71*		0.75*	NA
Age	-0.17*	-0.12**	-0.19*	-0.11**	0.02	-0.11**	0.01	-0.09

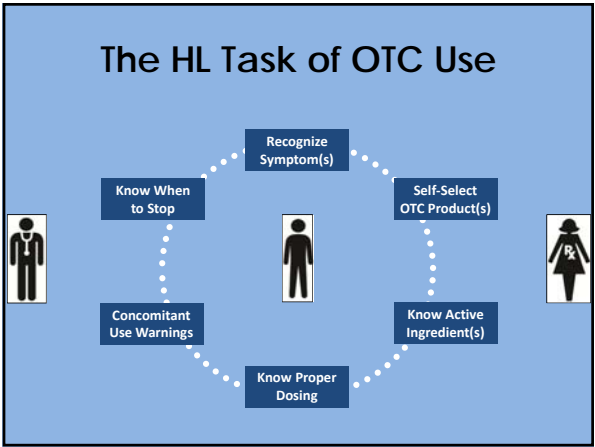
* $p < .001$ ** $p < .01$

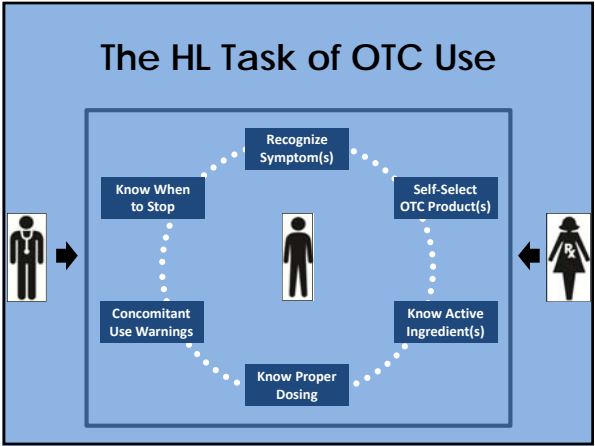






The HL Task of OTC Use





Some Unique Challenges

- # of Product Choices
 - Brand + Generic Options
 - Single & Multi-Ingredient Products
- Problematic Labeling
 - Variable, poor quality
 - Front-of-package, Drug Facts, container vs. package
 - Size of font, sequence
- No 'learned immediary'



Reviewing the Evidence

Unintentional Misuse

- 42% of older adults use OTC drugs regularly (Qato et al 2008)
- 1 in 4 (24%) adults take more than recommended max dose for one OTC product (Wolf et al 2012)
- Nearly half (46%) of adults misuse OTC products by concomitant use (Wolf et al 2012)
- Older age not consistently found to be a risk factor (NO: Taylor et al, 2012; Calamusa et al 2012; Wolf et al 2012; YES Qato et al 2008)
- What DOES matter: sex, education, HL, prior experience

What's Inside?

Drug name	% correct (n=32) ^b	Active Ingredient
Bayer®	75	Aspirin
Motrin®	47	Ibuprofen
Tylenol®	31	Acetaminophen
Aleve®	19	Naproxen sodium
Advil®	19	Ibuprofen
All correct	6	

King et al, Am J Prev Med. 2011

Functional Understanding

Wolf et al. Risk of Unintentional Overdose with Non-Prescription Acetaminophen Products. J Gen Intern Med. 2012

Dosing Individual OTC products:

- Pills per dose: **81 – 96%** correct
- Dosing interval: **61 – 86%** correct
- Max daily dose: **42 – 65%** correct

Can you take these products together?



Acetaminophen 500 mg



Acetaminophen 650 mg



Acetaminophen 500 mg
Diphenhydramine HCl 25 mg



Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg



Acetaminophen 250 mg
Aspirin 250 mg
Caffeine 25 mg

Can you take these products together?



Acetaminophen 500 mg



Acetaminophen 650 mg **41%**



Acetaminophen 500 mg
Diphenhydramine HCl 25 mg **37%**



Acetaminophen 325 mg
Chlorpheniramine maleate 2 mg
Dextromethorphan hydrobromide 10 mg
Phenylephrine hydrochloride 5 mg **40%**



Acetaminophen 250 mg
Aspirin 250 mg
Caffeine 25 mg **38%**

Table 5. Predictors of Overdose and Double-Dipping with Acetaminophen-Containing Products

Variable	Overdose			Double-Dipping		
	RR	95 % CI	P Value	RR	95 % CI	P Value
Literacy	1.00			1.00		
Adequate	1.65	1.03-2.66	0.04	1.73	0.90-3.68	0.19
Limited	1.00	0.99-1.03	0.45	1.00	0.99-1.01	0.61
Age (years)	1.02	0.72-1.43	0.90	0.64	0.49-0.83	0.001
Female	1.00			1.00		
Race						
White	0.46	0.28-0.76	0.002	1.36	0.86-2.15	0.19
Black	0.68	0.33-1.42	0.31	1.25	0.67-2.33	0.48
Other						
Household Income						
<\$50,000	1.00			1.00		
\$20,000-\$50,000	1.00	0.60-1.65	0.99	1.46	0.84-2.53	0.18
>\$20,000	0.91	0.49-1.68	0.75	1.96	1.03-3.72	0.04
Acetaminophen Use						
No use	1.00			1.00		
Moderate	0.83	0.56-1.24	0.37	1.16	0.86-1.58	0.33
Heavy	1.70	1.10-2.64	0.02	1.42	1.02-1.98	0.04
Clinic Type						
Academic	1.00			1.00		
Community	1.81	1.05-3.11	0.03	1.13	0.67-1.89	0.65

Wolf et al. Risk of Unintentional Overdose with Non-Prescription Acetaminophen Products. *J Gen Intern Med.* 2012

How Big a Problem?

- Rates of actual overdose (i.e., acetaminophen) not as high as demonstrated misuse (<10%)
- Serper et al. (in prep): Examined actual misuse among 246 ED patients
 - 2% exceeded maximum daily dose
 - 11% 'double-dipped' (concomitant use)
 - 49% were unaware of double-dipping with common OTCs
- Potential Serious Problem: Knowledge of ACTIVE INGREDIENT

Missed Opportunities



... & Simplify.

*Reduce healthcare complexity and demands
to match consumer abilities*

"Can we confuse patients less?"



Alastair J.J. Wood, MD

Unneeded Complexity



Many studies document high readability of OTC labeling
(Luk et al, 2010; Homewood et al 2009; Zite & Wallace 2009; Stevens et al 2007; Pawaskar & Sangsriy 2006)

Unneeded Complexity



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(Luk et al, 2010; Homewood et al 2009; Zite & Wallace 2009; Stevens et al 2007; Pawaskar & Sangsriy 2006)

Our study: marketing to symptom and multi-ingredients root causes of potential misuse (Wolf et al 2012)

Unneeded Complexity

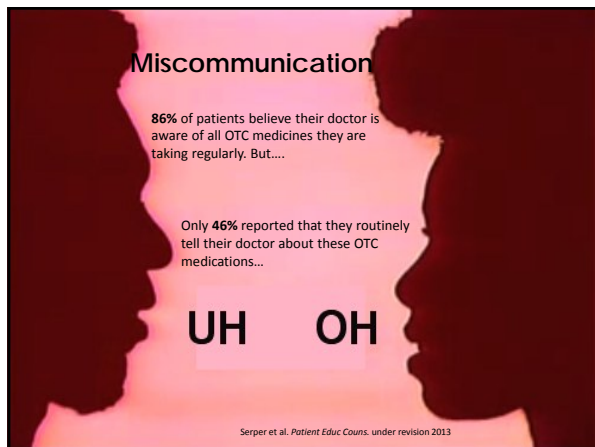


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Our study: marketing to symptom and multi-ingredients root causes of potential misuse (Wolf et al 2012)

- Few studies report prevalence of provider counseling: ~30-60%
(Serper et al 2013; LaCivita 2009; Fry et al 2007; Hensrud et al 1999)







HL Intervention Targets

- **Health Information**
 - Print
 - Multimedia (video, web, mobile, etc.)
- **Spoken Communication**
 - Face-to-face
 - Phone
- **Health Systems**
 - Access/navigation
 - Outreach
 - Follow-up

Health Information



Evidence strong for best practices:

- Plain language, written materials (Doak 1993; AHRQ 2012)
 - content, format, quantity (Seligman 2007; Wilson 2010)
 - understandability vs. actionability
- Broader evidence base to guide multimedia
 - use of imagery or icons w/ text (Morrow et al. 2012)
 - use of interactive testing for OTCs (Hedrick 2002)
 - video vs. print (Wilson et al. 2012)
 - best practices for video/web design (Wilson 2010; Sweller 2005)
- Web/mobile apps require further study (Chomutare 2011)

Redesigning labels alone may yield limited benefit

Critically Review the Standard

Content



Drug Facts	
Active ingredient (in each tablet) Chlorpheniramine maleate 2 mg	Purpose Antihistamine
Uses temporarily relieve these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat	
Warnings Ask a doctor before use if you have: ■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis ■ trouble urinating due to an enlarged prostate gland Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives When using this product: ■ You may get drowsy ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery ■ excitability may occur, especially in children If pregnant or breast-feeding, ask a health professional for advice before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions adults and children 12 years and over: take 2 tablets every 4 to 6 hours, not more than 12 tablets in 24 hours children 6 years to under 12 years: take 1 tablet every 4 to 6 hours, not more than 6 tablets in 24 hours children under 6 years: ask a doctor	
Other information store at 20°-25° C (68°-77° F) ■ protect from excessive moisture Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Justification

Sequence

Consistency

Actionability

As-Needed (PRN) Medicines

Over-the-Counter

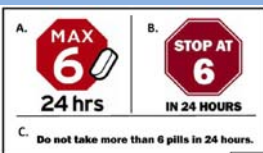


Prescription

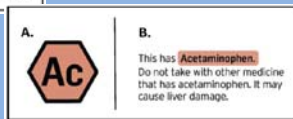
May Address Problems with
Maximum Daily Dose Only

McCarthy et al. Under Revision, *J Health Commun*, 2013

Use of Icons



C. Do not take more than 6 pills in 24 hours.



King et al. *Am J Prev Med*, 2011

Spoken Communication

Limited evidence for verbal counseling

Single Event

- 'Teach back' technique (Schlinger 2003; Kandula 2011)
- Implementation Intention (Park 2007; Armitage 2009)

Repeat Event

- Teach-to-goal (Baker et al. 2011)
- Brief Counseling (DeWalt 2009; Wallace 2009)

Moderate



3 Minutes or Less

Implementation Intention (Dress Rehearsal)

- Cognitive planning or 'mapping' a behavior
- 3 min. counseling ▲adherence (Park 2007)

- How will you take this?
- When will you take this?
- How many pills do you take at a time?
- It has to be taken with food...when do you eat meals?
- Where will you keep it so you remember?



Health Systems

Addressing practice redesign issues

- 'Hardwiring' consumer education in practice
 - the reality of limited resources (Wolf et al. 2012)
 - leveraging electronic health records (EHRs)
 - patient portals
- Multifaceted Interventions
 - necessary but difficult to implement (Kipalani 2012)
 - deconstructing what actually worked (Rothman et al. 2004)



Please Review Your Medicines			
<p>It is very important that your doctor knows all the medicines you are taking. Please show this list to your doctor at your visit today and ask them to update your chart. Follow these steps:</p> <p>Step 1. Draw a line through any medicines that you are NOT currently taking. You do not need to fill out any more information about these medicines.</p> <p>Step 2. For all other medicines, please tell us HOW MUCH of the medicine you took yesterday at morning, noon, evening and bedtime. See the example for help.</p> <p>Step 3. Place a check in the concerns column next to any concern you may have about the medicine.</p> <p>Example: If you took 2 pills of a medicine at 8:00am yesterday and 2 pills at 9:00pm and you need a refill, this is how you would fill out the form:</p>			
		<p>How much did you take yesterday?</p> <p>Morning ___2___ Evening ___ ___</p> <p>Noon ___ ___ Bedtime ___2___</p>	<p>Concerns or problems?</p> <p><input type="checkbox"/> None <input checked="" type="checkbox"/> Need Refill <input type="checkbox"/> Cost</p> <p><input type="checkbox"/> Side Effects <input type="checkbox"/> Other</p>
Medicine Name	Directions	How much did you take yesterday?	Concerns or problems?
aspirin 81 mg oral tablet	1 pill(s) by mouth Every day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
ibuprofen 600 mg oral tablet (sulfamethoxazole-trimethoprim)	1 pill(s) by mouth Daily on Mondays and Thursdays	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
Cardiogen 500 mg oral tablet (mycophenolate mofetil)	2 pill(s) by mouth Twice a day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
diclofenac sodium 100 mg oral capsule	300 mg by mouth Every day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
ferrous gluconate 324 mg oral tablet	1 pill(s) by mouth Three times a day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
furosemide 20 mg oral tablet	20 mg by mouth Every day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other
furosemide 20 mg oral tablet	20 mg by mouth Every day	Morning ___ ___ Evening ___ ___ Noon ___ ___ Bedtime ___ ___	<input type="checkbox"/> None <input type="checkbox"/> Need Refill <input type="checkbox"/> Cost <input type="checkbox"/> Side Effects <input type="checkbox"/> Other

R18HS17220, U19 HS021093, R01NR012745

DOB: [redacted] Age: [redacted] Years Sex: FEMALE MRN: [redacted]

Step 4. Add the names of any other medicines you are currently taking that are not on the list. This includes prescription drugs, (over-the-counter medicines, vitamins, herbal, nutritional, and other supplements). For each drug, please tell us how much you took yesterday and if you have any concerns about the medicine. Please don't worry if you don't have the exact spelling of your medicine.

Your Additional Medicines/Supplements Are:

Medication Name	How much did you take yesterday?	Concerns or problems?		
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	
	Morning _____ Evening _____	<input type="checkbox"/> None	<input type="checkbox"/> Need Refill	<input type="checkbox"/> Cost
	Noon _____ Bedtime _____	<input type="checkbox"/> Side Effects	<input type="checkbox"/> Other	

[illegible]

Summary

- Overall, evidence remains limited and mixed
 - both of problems and solutions
 - can infer from other areas (i.e., R_x)

Summary

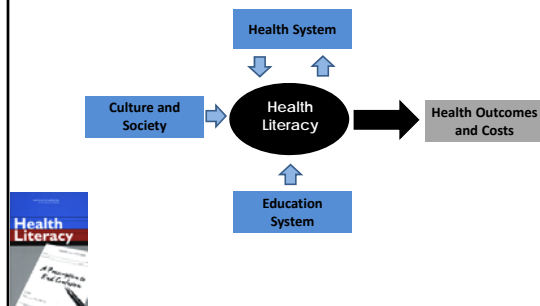
- Overall, evidence remains limited and mixed
 - both of problems and solutions
 - can infer from other areas (i.e., R_x)
- Potential risk for problems high
 - elderly at risk for low health literacy, cognitive decline, OTC misuse
 - other factors to consider: sex, prior experience, social support (?)

Summary

- Overall, evidence remains limited and mixed
 - both of problems and solutions
 - can infer from other areas (i.e., R_o)
- Potential risk for problems high
 - elderly at risk for low health literacy, cognitive decline, OTC misuse
 - other factors to consider: sex, prior experience, social support (?)
- Solutions: improve labeling, increase counseling
 - at prescribing: include in medication reconciliation activities
 - at dispensing: getting pharmacists out from behind the counter
 - both: increase awareness via public health campaigns (print, multimedia)

For the Long Term...

Adapting the HL framework...



NORTHWESTERN UNIVERSITY


HeLP

Health Literacy & Learning Program



Michael Wolf, MA, MPH, PhD
 Associate Professor, Medicine & Learning Sciences
 Associate Division Chief – Research
 General Internal Medicine & Geriatrics
mwolf@northwestern.edu

**OTC Medications:
Decision Making in Older Adults**




Ruth S. Day / Duke University

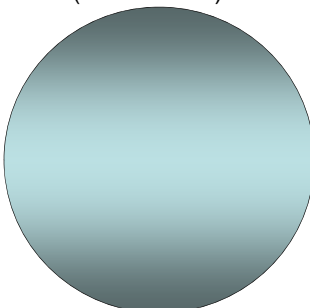
National Summit on OTC Medication Behaviors of Older Adults
April 10, 2013

What is known?

What is known



**What is NOT known
(but could be)**

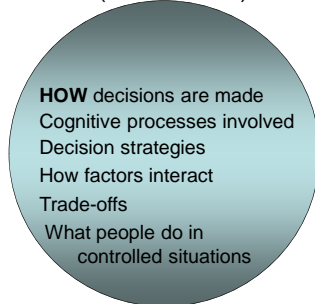


What is known



Some types of decisions
Demographic factors
Social factors
What people say they do

What is NOT known (but could be)



HOW decisions are made
Cognitive processes involved
Decision strategies
How factors interact
Trade-offs
What people do in
controlled situations

What Decisions?

Get an OTC product?
Which type of product?
Which specific product?

Self-selection?
Risks?

How much to take?
How to take it?
When to take it?
What not to do while taking it?
What to watch for?

....

What Type of Decisions?

Yes/No
Y/N/Maybe

Agree/Disagree
Categorical vs. Continuous

Choices
Factors involved
Trade-Offs?

Process steps?

What Decision Making Processes?



Sample Decision Making Processes

Select the most salient option.

Identify factors in options.

Focus on one factor, select the one that is best on it.

Focus on several factors, the ones you care about most.

Consider pros and cons for each option.

Choose the option highest on all factors.

Consider alternatives only until you find an acceptable one.

–“Satisficing” (Herb Simon)

Choose a factor; eliminate all that do not have it; repeat until done.

–“Elimination by Aspects” (Amos Tversky)

Ask someone

--experts, friends/family

Flip a coin.



Interpretation of Results

“Older adults are slower”

Why? (sensory deficit, more thoughtful,)

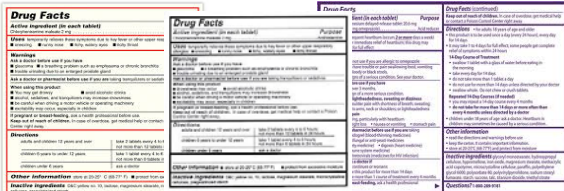
Implications? (quality of decisions,)

Interpretation of Results

“Older adults may have visual problems”

What types?
Implications? (miss words vs. overall layout?)

Reading Challenges



“Older adults may have ... trouble reading OTC labels”
Sangrity & Cady (1996); Braus (1993); Holt et al. (1990)

So do others!

Sample studies

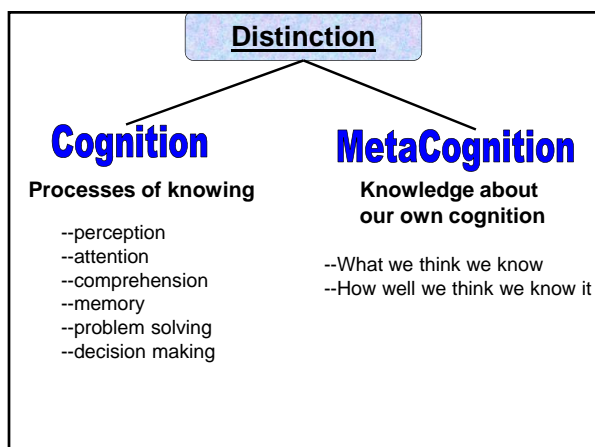
Typical Approaches	
FACTORS Age Gender Type of OTC % of label read Label info used Price Who recommends Past use Package opening	METHODS Survey --own purchases --future purchases OUTCOME MEASURES --% who choose --self-reported reasons --request help?

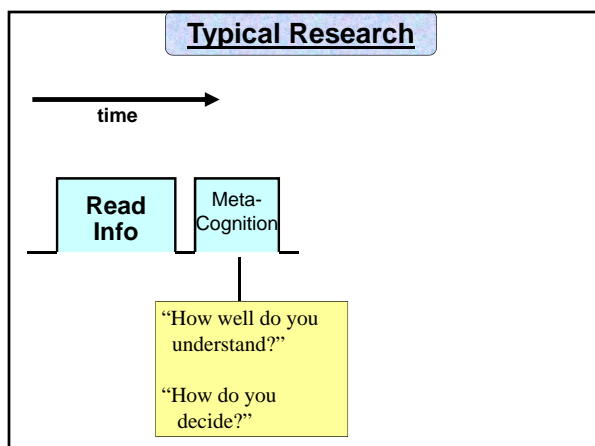
More Adventurous	
FACTORS Age Gender Type of OTC % of label read Label info used Price Who recommends Past use Package opening	METHODS Behavioral Tasks --search task --choice task (select from computerized labels) OUTCOME MEASURES --decision speed --search organization

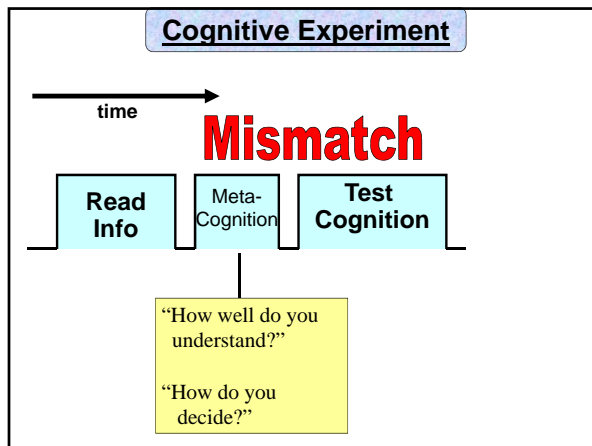
Interesting Example
Stephens & Johnson (2000) <i>The present study examined age differences in the sources of information that older and younger adults use when making decisions about purchasing over-the-counter (OTC) cold/allergy medications. Participants completed a questionnaire addressing information sources that influence OTC purchases and advertising awareness. The questionnaire was given either before or after completing a decision task in which they searched a computerized display of label information and chose one of seven brand name medications to purchase. Analyses revealed age-related differences in sources of information considered and label information used when purchasing OTC medications. Priming participants to recall specific advertising claims using the questionnaire had little effect on the information used by younger or older adults. Younger adults relied on price and product use information, whereas older adults relied on side effect and drug interaction information. This finding has implications for OTC label design and health care professionals who counsel patients about OTC medication usage.</i>
Used BOTH a questionnaire and a controlled search task. Counterbalanced the order of the two tasks.

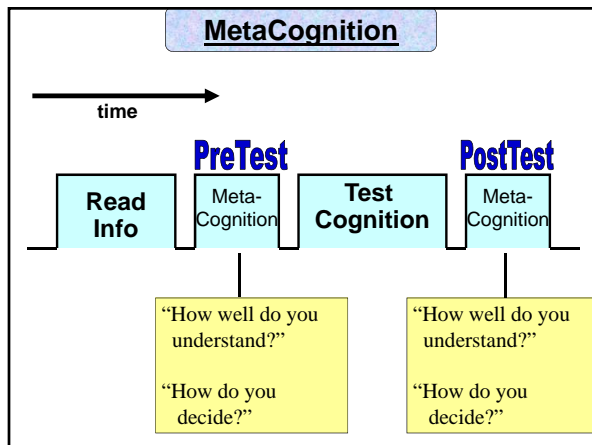
Cognition VS MetaCognition

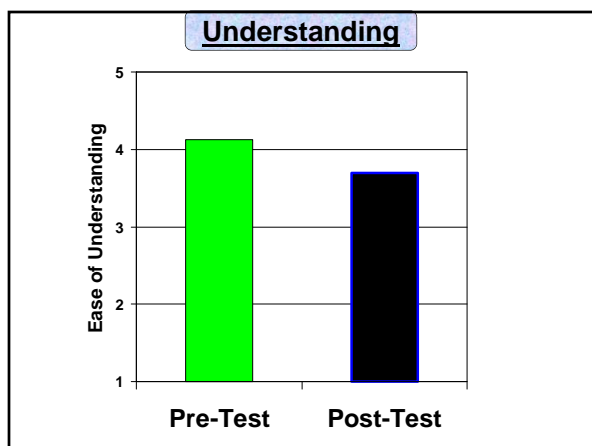
Day (in preparation)











Interpretation of Results

e.g., “[many] seniors cannot read the label”

Why? (visual perception? Comprehension?)
Implications? (larger print vs. label design?)

“MUST”

Medication Use Safety Training for Seniors

Quick Facts: Older Adults and Medicine Use

- Older adults comprise 13 percent of the population, but account for 34 percent of all prescription medicine use and 30 percent of all over-the-counter (OTC) drug use.
- Most older adults—4 out of 5—live with one or more chronic conditions.
- Many take multiple medicines at the same time. A recent survey of 17,000 Medicare beneficiaries found that 2 out of 5 patients reported taking five or more prescription medicines.
- Older adults are at increased risk of serious adverse drug events, including falls, depression, confusion, hallucinations and malnutrition, which are an important cause of illness, hospitalization and death among these patients.
- Drug-related complications have been attributed to the use of multiple medicines and associated drug interactions, age-related changes, human error and poor medical management (e.g., incorrect medicines prescribed, inappropriate doses, lack of communication and monitoring).

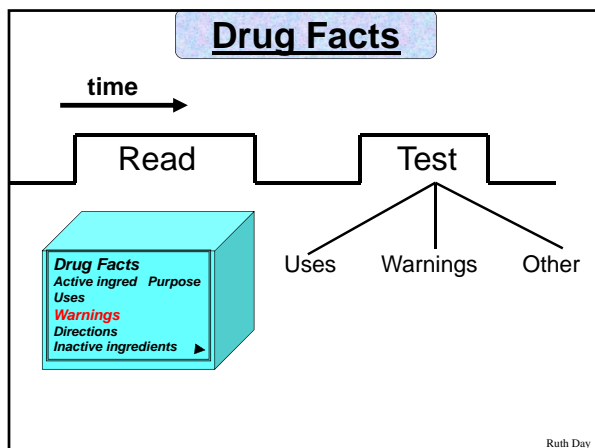
Almost 40% of seniors are unable to read prescription label.

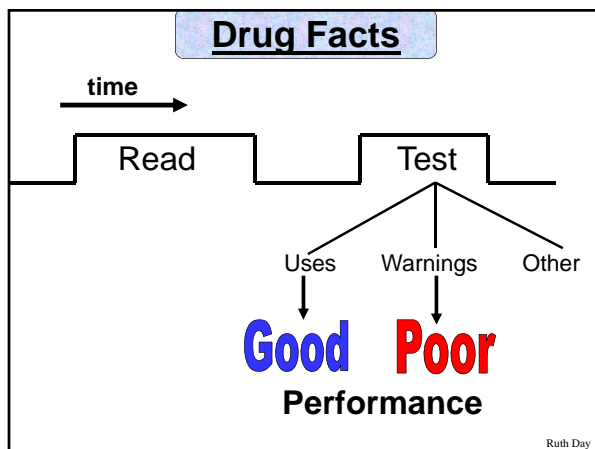
For references or additional background information, download NCPPI's Fact Sheet “Medicine Use and Older Adults,” available at www.mustforseniors.org.

Drug Facts Format

"Hidden" Warnings

Day (2002; 2009)





Aspirin

Original Version

Warnings

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives ● facial swelling ● asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

Original Version

Aspirin

Warnings

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives ● facial swelling ● asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers. Aspirin may cause stomach bleeding.

Enhanced Version

Aspirin

Warnings

Reye's syndrome: Children and teenagers should not use this medicine for chicken pox or flu symptoms before a doctor is consulted about Reye's syndrome, a rare but serious illness reported to be associated with aspirin.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives ● facial swelling ● asthma (wheezing)
- shock

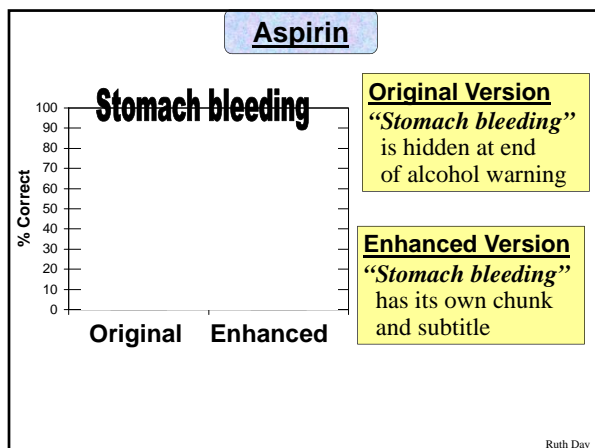
Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take aspirin or other pain relievers/fever reducers.

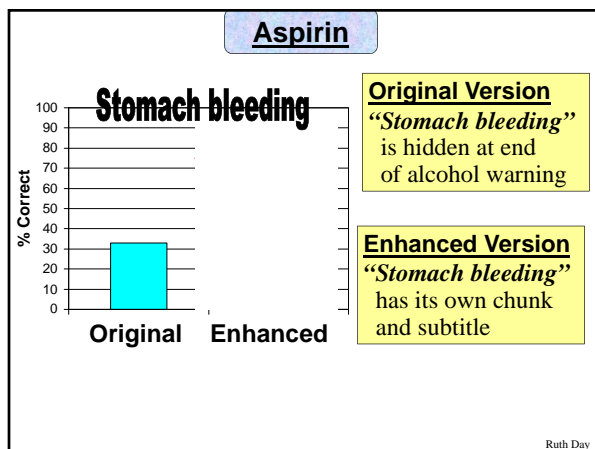
Stomach bleeding: Aspirin may cause stomach bleeding.

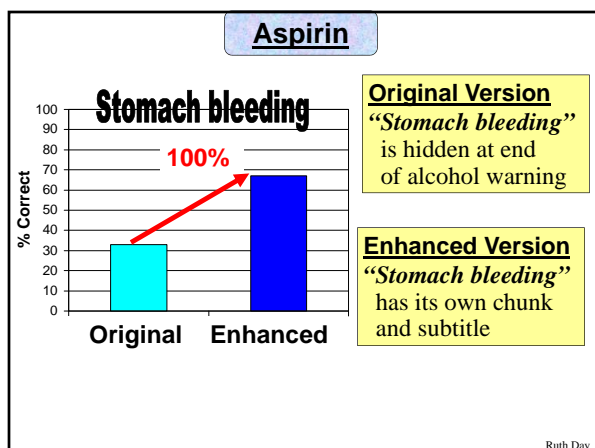
Aspirin

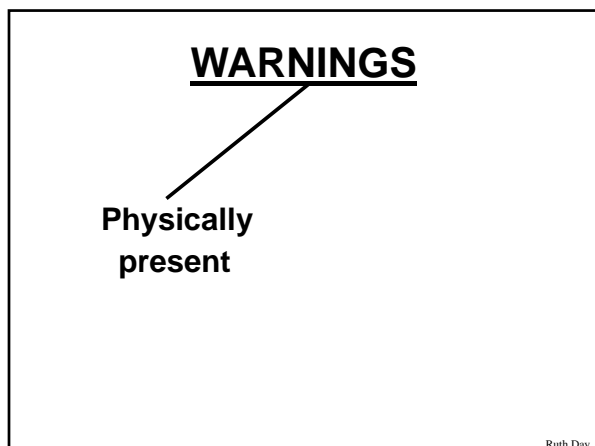
Original Version
"Stomach bleeding"
 is hidden at end
 of alcohol warning

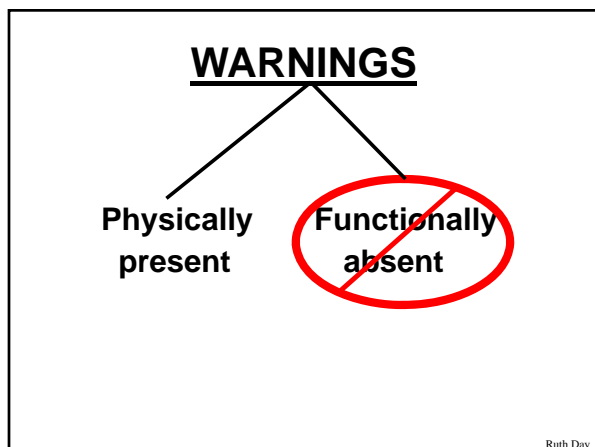
Enhanced Version
"Stomach bleeding"
 has its own chunk
 and subtitle












Many More Examples

Small things → Big differences

Big things → Even bigger differences


OTC Medications:
Decision Making in Older Adults



Good Foundation

But many: --unasked questions
--unused methods
--underused methods
--understudied processes

OTC Medications:
Decision Making in Older Adults



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ruthday@duke.edu



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
OF OLDER ADULTS

Omni Shoreham • Washington, DC
Tuesday and Wednesday, April 9-10, 2013

Speakers: Interventions to Promote Safe and Effective OTC Medication Use Among Older Adults



Elaine A. Leventhal, MD, PhD

Elaine Leventhal is a Professor of Medicine at the University of Medicine and Dentistry of New Jersey. As an internist and trained geriatrician, she actively manages and studies patients with chronic illnesses. Her particular interests are in understanding patient self-management including adherence to complex medical regimens, choosing self-management strategies and the communications between patient and care-provider. Dr. Leventhal has collaborated with investigators worldwide in areas that are critical to understanding disease outcomes, adherence, and more efficient and effective care management as well as how to use this research to inform medical education.



Laura N. Gitlin, PhD

Laura N. Gitlin, an applied research sociologist, is nationally and internationally recognized for innovative nonpharmacologic interventions to improve quality of life of persons with dementia and their family caregivers and also for research on improving daily functioning in older adults with functional disability. She has received continuous research and training grants from both federal agencies and private foundations, including the Alzheimer's Association and the National Institutes of Health for over 25 years. Her current funded research programs include testing a novel home-based intervention to enhance aging in place of older adults with disabilities, a tailored activity program to address behavioral

symptoms in persons with dementia, and a community-based partnership to address mental health disparities and reduce depressive symptoms in older African Americans. She is also involved in translating and implementing proven interventions for delivery in different practice settings. In 2011, Dr. Gitlin joined the Johns Hopkins University School of Nursing as a Professor in the Department of Community Public Health with joint appointments in the Department of Psychiatry, and Division of Geriatrics and Gerontology, School of Medicine. She is the founding director of a new inter-professional initiative, the Center for Innovative Care in Aging, which seeks to transform health care delivery and the health and well-being of older adults, families

and their communities through rigorous research, the training of health and human service professionals in evidence-based interventions and models of care, and through the translation and implementation of interventions in service delivery settings. Dr. Gitlin is the recipient of numerous awards including the 2009 Eastern Pennsylvania Geriatric Society, Charles Ewing Presidential Award for outstanding contribution to geriatric care; the 2010 United Way Champion Impact Award for Healthy Aging at Home; the 2010 National Institute of Senior Centers Award with Center in the Park; the 2010 MetLife Award for translating the Skills₂Care Program (a dementia caregiver intervention program) with Fox Rehabilitation (a home health agency); and the 2011 John Mackey Award for Excellence in Dementia Care from Johns Hopkins University. She is the author of over 180 scientific publications and has authored or co-authored four books.



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
OF OLDER ADULTS

Omni Shoreham • Washington, DC
Tuesday and Wednesday, April 9-10, 2013

Presentation Briefing

Speaker: Elaine A. Leventhal, MD, PhD

Session: Interventions to Promote Safe and Effective OTC Medication Use Among Older Adults

Individual Presentation: Promoting Safe and Effective OTC Medication Behavior Through Interface With Clinical Care

Discussant: Mary M. Bridgeman, PharmD

Summary:

As a clinician, I have too often felt the challenges of understanding patient self-management. Since the only time I have control over behavior is during a patient's hospitalization, I am fully aware that all other decisions are under patient control. Illness behavior is complex, context determined, with a large age-relevant dimension that has been nurtured in part over last 30 years in the Pandora's box of direct-to-consumer advertising, the influence of the media as well as with the advent and availability of the Internet. Thus, the urgency to understand why and what patients do regarding medication use and disease management has grown. This presentation will include the work of our research network, both in the United States and the United Kingdom on a broad model of health behavior. We have demonstrated that the Common Sense Model (CSM) of patient self-care explains the illness behaviors patients adopt and is dependent on patients' perceptions of symptoms and the best strategies to manage them. The neurological elements of the model are located in the structure and function of the brain and the psychology of self-awareness that takes place across the life span. We will discuss the research on what role drugs (whether prescription, OTC, "alternatives," or supplements) play in the illness behavior choices patients make and how physicians can best elicit and help shape patient practices in the practitioner-patient context, in the larger social milieu, or through effecting health care policy.

Objectives:

- Understand common mechanisms behind the health and illness behaviors of patients.
- Describe interventions clinicians can utilize to identify OTC medication use, be it appropriate or inappropriate.

- Recognize where, how, and what barriers—safety, access, and health literacy—can be addressed through the interface with the clinician.

Literature:

Barber N. Drugs: from prescription only to pharmacy only. *BMJ*. 1993;307:640.

Berry D, Raynor T, Knapp P. Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. *Patient Educ Couns*. 2004;53:129-134.

Bruno JJ, Ellis, JJ. Herbal use among US elderly: 2002 National Health Interview Survey. *Ann. Pharmacother*. 2005;39 (4):643-648.

Cervantes E, Heid-Grubman J, Schuerman CK. The effects of medication on older adults. *Caring*. 1996;15:58-63.

Conn VS. Self-management of over-the-counter medications by older adults. *Public Health Nurs*. 1992;9:29-36.

Curry LC, Walker C, Hogstel MO. Teaching older adults to self-manage medications: preventing adverse drug reactions. *J Gerontol Nurs*. 2005;31:33-42.

Delaney JAC, Biggs ML, Kronmal RA, et al. Demographic, medical, and behavioral characteristics associated with over the counter non-steroidal anti-inflammatory drug use in a population-based cohort: results of the Multi-Ethnic Study of Atherosclerosis. *Pharmacoepidemiol Drug Safety*. 2011;20:83-89.

Francis SA, Barnett N, Denham M. Switching of prescription drugs to over-the-counter status: is it a good thing for the elderly? *Drugs Aging*. 2005;22:361-370.

Hanlon JT, Fillenbaum GC, Ruby CM, et al. Epidemiology of over the counter drug use in community dwelling elderly: United States Perspective. *Drugs Aging*. 2001;18:123-130.

Nahin RL, Pecha M, Welmerink DB, et al. Concomitant use of prescription drugs and dietary supplements in ambulatory elderly. *J Am Geriatr Soc*. 2009;57:1197-1205.

Neafsey PJ, Strickler Z, Shellman J, et al. An interactive technology approach to educate older adults about drug interactions arising from over-the-counter self-medication practices. *Public Health Nurs*. 2002;19:255-262.

Peterson AM, Dragon CJ. Improving medication adherence in patients receiving home health. *Home Healthc Consult*. 1998;5:25-27.

Rolita L, Freedman M. Over-the-counter medication use in older adults. *J Gerontol Nurs*. 2008;34:8-17.

Roumie CL, Griffin MR. Over-the-counter analgesics in older adults: a call for improved labelling and consumer education. *Drugs Aging*. 2004;21:485-498.

Sleath B, Rubin R, Campbell W, et al. Physician-patient communication about over-the-counter medications. *Soc Sci Med*. 2002;353:357-369.

Stine JG, Sateesh P, Lewis JH. Drug-induced liver injury in the elderly. *Curr Gastroenterol Rep*. 2013;15:299.

Stoehr GP, Ganguli M, Seaberg EC, et al. Over-the-counter medication use in an older rural community: the MoVIES Project. *J Am Geriatr Soc*. 1997;45:158-165.

Stoller EP, Pollow R, Forster LE. Older people's recommendations for treating symptoms: repertoires of lay knowledge about disease. *Med Care*. 1994;32:847-862.

Tarn DM, Heritage J, Paterniti DA, et al. Physician communication when prescribing new medications. *Arch Intern Med*. 2006;166:1855-1862.

Wawruch M, Kuzelova M, Foltanova T, et al. Characteristics of elderly patients who consider over-the-counter medications safe. *Int J Clin Pharm*. 2013;35:21-128.

Research Questions:

1. Given the state of current literature in the area of geriatric OTC medication use, what kind of future studies need to be done?
2. How can we train clinicians to collect information from patients about health practices related to self-care?
3. How can patients use health information more safely?
4. What kind of national database do we need to create to inform policy decisions?

Case Studies:

Case studies and anecdotes will be incorporated throughout the lecture to highlight examples of patient illness behaviors and understanding of disease self-management.

Handouts and Materials:

PowerPoint presentation



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Presentation Briefing

Speaker: Laura N. Gitlin, PhD

Session: Interventions to Promote Safe and Effective OTC Medication Use Among Older Adults

Individual Presentation: Promoting Safe and Effective OTC Medication Behavior Through Interface With Family Care

Discussant: Steven M. Albert, PhD

Summary:

Providing care to an older family member is an activity that spans time, place, and cultures. Family members have been, are now, and will continue to be the primary caregivers for older adults. As families provide over 80% of the long-term care to older adults, they are the backbone of health care systems in the United States and worldwide. Broadly speaking, family caregivers are family members, friends, fictive kin, or neighbors who provide some form of assistance to an older adult with whom they have a relationship. Providing some form of medication assistance is part of a vast array of care tasks by families that may occur either episodically, in transition from hospital to home, or over time at home or in long-term care facilities. Family involvement in over-the-counter (OTC) medication use must be examined within the broader context of overall medication management and the complex care tasks and responsibilities families assume. Very little is known about family knowledge of OTCs and care decision making concerning these medications. A limited evidence base suggests the following: families have poor knowledge of OTC side effects and risks; family caregiver use of OTC medications may be associated with older adult OTC use; in dementia patients, being a spouse or Hispanic caregiver, and taking an inappropriate medication are associated with risk of potentially inappropriate medication use also involving OTC use. Medication management including OTCs often signals a downward trajectory in functioning of older adults and is identified by families as stressful. This presentation will provide a review of the prevalence and scope of responsibilities of family caregivers, the roles of families in the management of medication regimens of older adults, domains of concerns related to medication administration, and future research directions.

Objectives:

- Understand the magnitude of family involvement in daily care of older adults.
- Identify the knowledge base of family involvement in prescribed and OTC medication taking.
- Examine future directions for research in this area.

Literature:

Campbell NL, Boustani MA, Skopelja EN, Gao S, Unverzagt FW, Murray MD. Medication adherence in older adults with cognitive impairment: a systematic evidence-based review. *Am J Geriatr Pharmacother*. 2012;10:165-177.

Francis SA, Smith F, Gray N, Graffy J. The roles of informal carers in the management of medication for older care-recipients. *Int J Pharm Pract*. 2002;10:1-9.

Kaasalainen S, Dolovich L, Papiioannou A, Holbrook A, Lau E, Ploeg J, Levine M, Cosby J, Emily A. The process of medication management for older adults with dementia. *J Nurs Healthc Chronic Illness*. 2011;3:407-418.

Kao HF. Medication administration hassles for Mexican American family caregivers of older adults. *Nurs Health Sci*. 2011;13:133-140.

Lavretsky H. The role of family caregivers and inappropriate medication use in the community-dwelling older adults with dementia. *Aging Health*. 2012;8:457-460.

Sleath, B, Thorpe J, Landerman LR, Doyle M, Clipp E. Medication use among black and white caregivers of older male veterans with dementia. *Am J Geriatr Pharmacother*. 2004;2:133-140.

Thorpe JM, Thorpe CT, Kennelty KA, Gellad WF, Schulz R. The impact of family caregivers on potentially inappropriate medication use in noninstitutionalized older adults with dementia. *Am J Geriatr Pharmacother*. 2012;10:230-241.

Travis SS, Bethea LS, Winn P. Medication administration hassles reported by family caregivers of dependent elderly persons. *J Gerontol A Biol Sci Med Sci*. 2000;55:M412-M417.

Wolf MS, Gazmararian, JA, Baker DW. Health literacy and functional health status among older adults. *Arch Intern Med*. 2005;165:1946-1952.

Wolf MS, King J, Jacobson K, Di Francesco L, Bailey SC, Mullen R, McCarthy D, Serper M, Davis TC, Parker RM. Risk of unintentional overdose with non-prescription acetaminophen products. *J Gen Intern Med*. 2012;27:1587-1593.

Research Directions:

1. Population-based studies to:
 - Identify knowledge of family caregivers concerning OTC safety hazards (e.g., overdosing concerns), active ingredients, and label warnings.
 - Determine prevalence of potential misuse and overdose of OTC medications.
2. Intervention studies to:
 - Educate family caregivers concerning potential safety hazards of using OTC medications and potentially inappropriate medication use.
 - Support family involvement in complex medication regimens.
 - Identify effective health information approaches.
3. Workforce development studies to:
 - Educate health professionals how to assess family knowledge of OTC medications and train families in safe medication assistance.
4. Other:
 - Identification of theoretical base and mechanisms underlying decision making concerning OTC medication use and administration.



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Interventions to Promote Safe and
 Effective OTC Medication Use
 Among Older Adults



CHPA
CONSUMER HEALTHCARE
 PRODUCTS ASSOCIATION



THE
GERONTOLOGICAL
SOCIETY OF AMERICA

**National Summit on OTC
 Medication Behaviors of Older Adults**

Omni Shoreham, Washington, DC
 April 9-10, 2013

**OTC Medication Use in the Elderly:
 Promoting Safe and Effective OTC Medication
 Behavior Through Interface With Clinical Care**

Elaine A. Leventhal, MD, PhD
Professor of Medicine
 Robert Wood Johnson Medical School/UMDNJ
 New Brunswick, New Jersey

Learning Objectives

- Understand common mechanisms behind the health and illness behaviors of patients
- Describe interventions clinicians can utilize to identify over-the-counter (OTC) medication use, be it appropriate or inappropriate
- Recognize where, how, and what barriers—safety, access, and health literacy—can be addressed through the interface with the clinician

**Changes in US Health Care from the
1980s to the Present**

Direct-to-Consumer Advertising

via:

**Print Media, Television,
the Web**

Focus on “Shared Decision Making”

➡ Self-Care

**Why This Conference?
What Are the Issues for the Clinician?**

- Adverse drug reactions (ADRs)
- Drug-drug interactions
- Delayed care seeking
- Cost

**Self-Care in the Current Health Care
Environment**

- Do patients make decisions?
- If they do, how do they...
 - Decide what to do to maintain health?
 - Get better if they feel sick?

What Guides Patient Actions?

**Patients Actions Are Guided by Their
Common Sense
Perception and Beliefs About their
SELF-CONDITION AND ILLNESS**

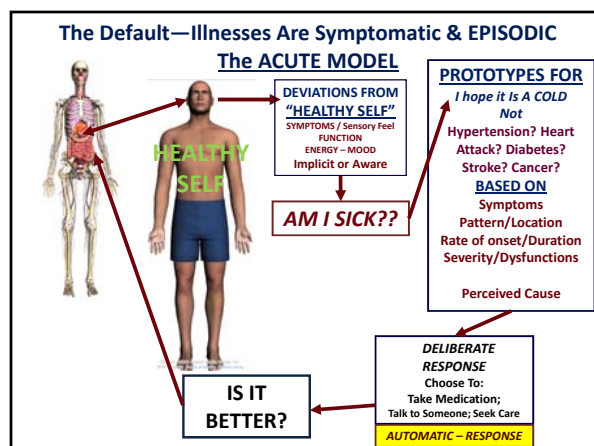
ACTIONS — Foods, over-the-counter medications,
prescription medicines, exercise, etc.
and

COHERENCE — How these parts work together

What Is Common Sense? How Does it Work in Self-Care?

The Common Sense Model (CSM)

CSM = A Model of the
Cognitive, Behavioral & Affective Processes
for Common-Sense Self-Management



Empirical Examples of CSM Health Decisions:

How People Attempt to Prevent & Manage Illness Threats in Daily Life

• EVERYDAY / MINOR ILLNESSES

- Influenza or cold/allergies
- Stomach aches or benign gastrointestinal complaints
- Headaches
- Rashes
- Others

• CHRONIC CONDITIONS

- Hypertension
- Asthma
- Myocardial infarction
- Heart failure
- Others

People Respond to Symptoms

PERCEIVED Deviations from “USUAL SELF” Triggers

Somatic sensations – SYMPTOMS – trigger care seeking

	Care Seekers N=111	Matched Controls N=111
New Symptoms YES	100%	30%
NO	-----	70%
Sought Care	100%	0%

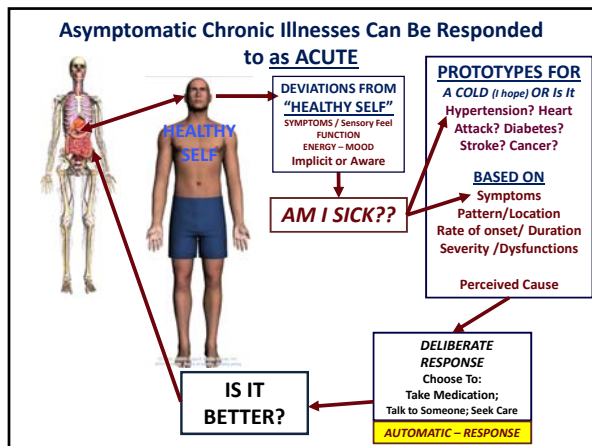
NOTE: Difference in Sx reporting by care seekers vs. controls is replicated within care seekers when ill vs. well

Cameron L, Leventhal H, Leventhal E. (1993) Health Psychology.

Common Sense and Care Seeking Properties of Symptoms Affect Seeking Care

	111 of 111 Ss At Clinic	111 controls Did NOT seek care
New Symptoms YES	100%	30% (33/111)
Sought Care	100%	0%
Number of Symptoms	7.15	6.40
Have a Disease label	68%	46%
Sx Serious	2.40	1.15
Sx Disruptive	3.27	1.39
Active Coping	85%	64%
Duration – Days	9.91	5.70
Talked to someone	92%	61%
Advised to Seek Care	50%	9%

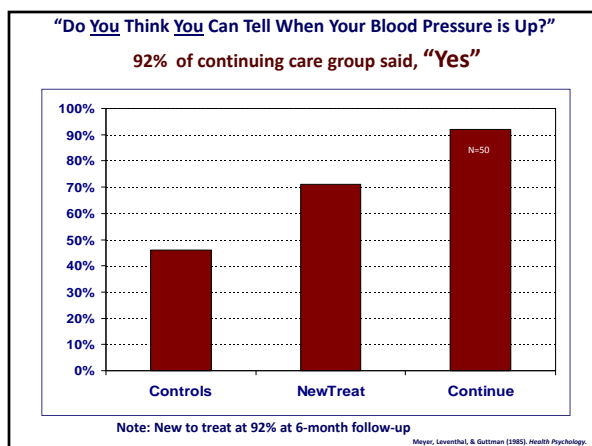
Cameron L, Leventhal H, Leventhal E. (1993) Health Psychology.

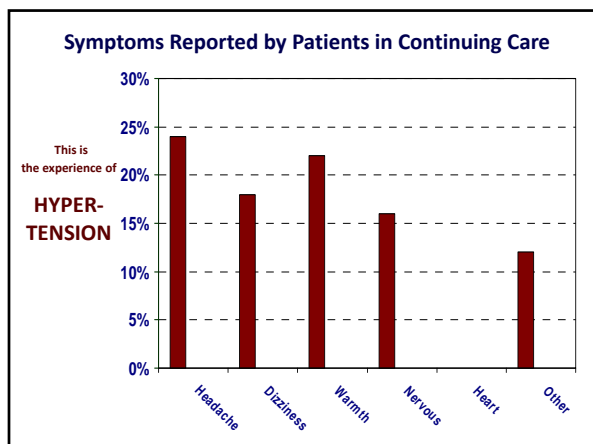


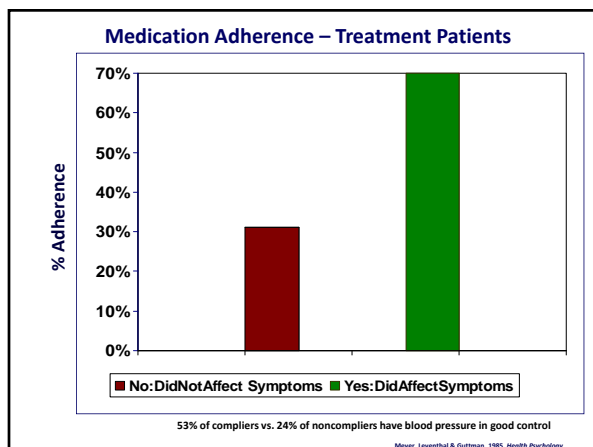
Common Sense of a Chronic Condition: Hypertension

- A group of 50 patients in continuous treatment (no history of drop outs) were asked:
 - “Do you agree that people can’t tell when their blood pressure is up?”
- 80% agreed**
- BUT** when asked...

Meyer, Leventhal, & Gutman (1985). Health Psychology







Medication Adherence Affects Blood Pressure (Continuing Treatment Patients)

53% of adherers are in control

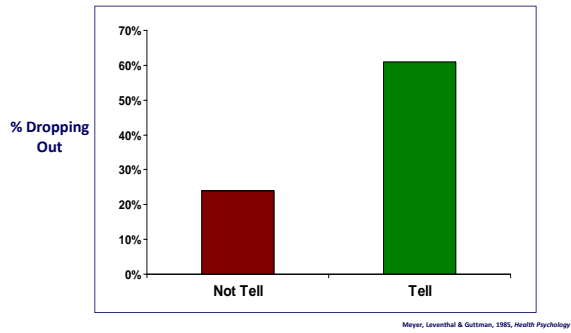
24% of nonadherers are in control

Adherence \neq control!

If Doctor Said BP Is Silent, **"You Can't Tell When BP Is High"**
and Contradicted the Patient's ACUTE, DEFAULT MODEL



Practitioners and Patients Disagree
Patients Who Told Doctor "I can monitor BP with my symptoms"
Had **DROPPED OUT** of Treatment 9 Months Later
Patients new to treatment (n=65)



"The Patient Can't Tell But

I CAN."



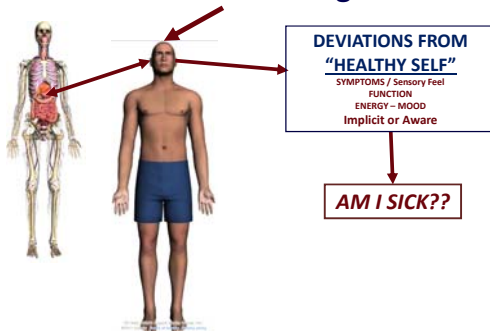
A Famous Cardiologist/Epidemiologist

The Prototype of the Healthy Self

- **HOW I FEEL & FUNCTION PHYSICALLY & COGNITIVELY**
 - Is constructed by experiences built upon pre-existing neural networks
- **PROTOTYPES OF ILLNESSES**
 - Are constructed on pre-existing neural circuits
 - Based on experiences of symptoms/pattern/location/duration/etc.

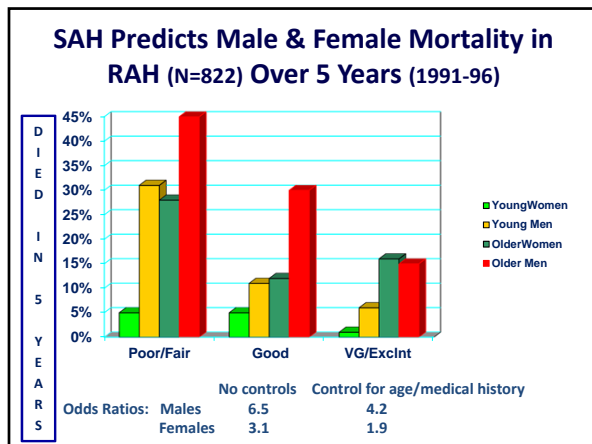
Laventhal H, Laventhal EA, Cameron L et al. (2011). Modeling health and illness behavior: The approach of the common sense model (CSM). In Baum, A., & Revenson, T.A., (Eds.). *Handbook of Health Psychology*, 2nd Edition.

Self is an Anchor for Judgments



Self-Assessments of Health (SAH)

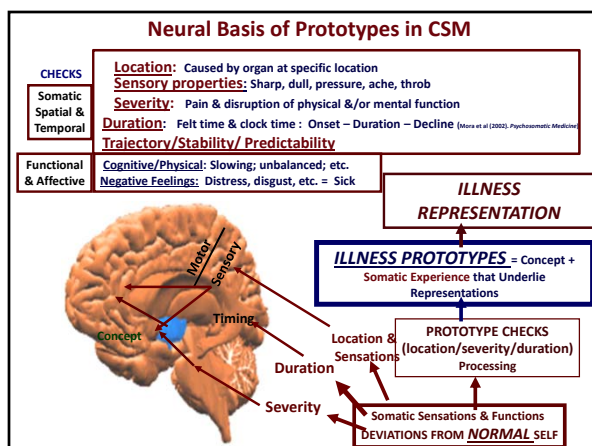
- A single question can be used for self-assessments of health (SAH)
 - In general, would you say your health is...
 - 1=Poor
 - 2=Fair
 - 3=Good
 - 4=Very Good
 - 5=Excellent
- SAH can predict important outcomes



Prototypes of Illness

Are Constructed on PRE-EXISTENT NEURAL Circuits by Experiences of:

- Symptoms/Pattern/Location/Rate of Onset
Duration/Rate of Offset/Etc.
and
- By response to intervention or treatment



Prototypes of Coronary Heart Disease (CHD)

Are Constructed on PRE-EXISTENT NEURAL Circuits Shaped by Experience
Symptoms/Pattern/Location/Rate of Onset Duration/Rate of Offset/Etc.

CONTRASTING REPRESENTATIONS of CHD

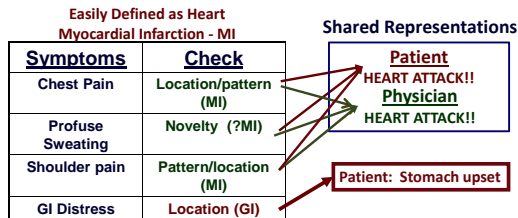
Myocardial Infarction (MI)

Representation Is Clear & Accurate

Congestive Heart Failure (CHF)

Representation Is Ambiguous &/or Invalid

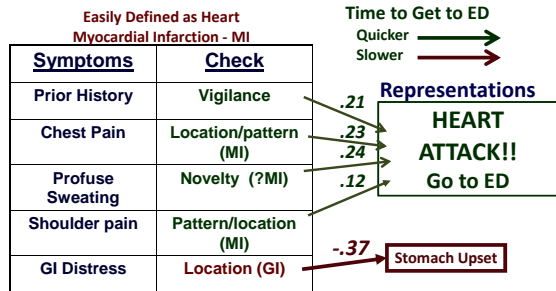
Coronary Symptoms Match Prototype for MI and Activate Representation of Heart Attack



Bunde J, Martin R. (2006) Psychosomatic Medicine.

When Symptoms Match Prototype of Heart Attack the REPRESENTATION Activates an ACTION PLAN!

Recognition Leads to Executive Decision for Action



Bunde J, Martin R. (2006) Psychosomatic Medicine.
Leventhal H. (1979) Advances in Experimental Social Psychology, 6, 119-186

Failure to Link Different Symptoms to Abstract Concept

CONGESTIVE HEART FAILURE (CHF)

Non-Recognition of Risk From Subtle & Ambiguous
Symptoms Results in Decompensation

Horowitz CR, Rein SB, Leventhal H. (2004) *Social Science & Medicine*, 58:631-648.

Misperceived as NON-Heart
In Pts. With Heart Failure (CHF)

Symptoms	Check
Frequent Dyspnea	Location - Pattern
Chronic Fatigue	Duration & Location
Feet Swollen	Location - Feet

MD/Pt. Different
Representations



Horowitz CR, Rein SB, Leventhal H. (2004) *Social Science & Medicine*, 58:631-648.

No Connection of Symptoms to Concept – CHF

Patient: *"When you hear about having heart problems ...you're supposed to feel maybe a pain in your left arm, maybe a pain in your chest, or pressure."*

"I couldn't describe what I felt as pressure but I guess it must have been that, uh because I had to struggle in order to talk..."

Patient: *"I guess it would have been more clear to me if I had chest pain and then I would have said, okay, I'll call and say I'm having chest pain but it didn't just seem to me like anything came together where I could call."*

Horowitz CR, Rein SB, Leventhal H. (2004) *Social Science & Medicine*, 58:631-648.

No Concept of CHF → No Connection Between Symptoms

Interviewer: "And how do you make that decision that it's time to go to the emergency room?"

Patient: "...well, all these things seem to happen in the middle of the night so I don't call doctors."

Interviewer: "During the week, you said you weren't feeling that great..."

→ Patient: "Maybe I was kind of tired but it just didn't seem to be anything out of the ordinary."

Interviewer: "Were there any warning signs earlier?"

Patient: "*Not that I could detect. Like I said, I didn't feel that great.*

Oh, I guess that I could have gone to the doctor after I

→ had that collapse on the hallway floor. *It might have been a good idea.*"

Horowitz CR, Rein SB, Leventhal H. (2004) Social Science & Medicine, 58:631-643.

No REPRESENTATION of HF

+

No ACTION PLAN

=

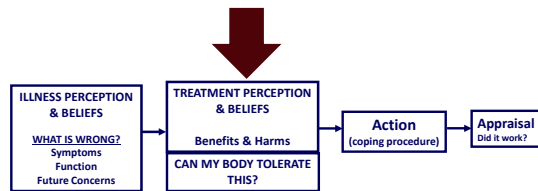
NO ACTION

Leventhal, H. (1970). Advances in Experimental Social Psychology, 5, 119-186.

Abstract Concept of Illness Such as Heart Failure

- Links diverse experiences to a common source
- Create time frames: link past, present & future
- Make "sense of actions" to manage ongoing events
- **TRANSFER OF SKILLS ACROSS EPISODES AND TIME**

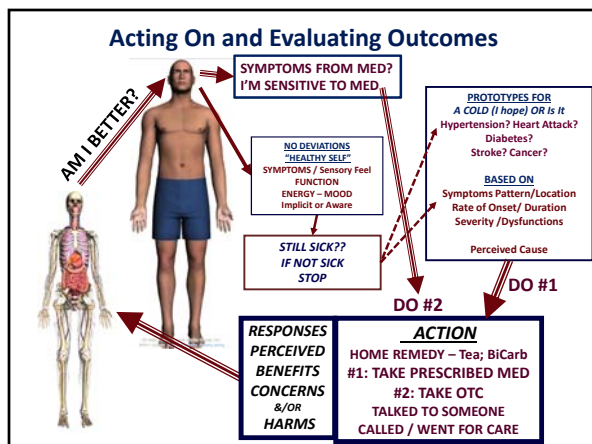
A System of Perception-Based Beliefs Is Essential for Action



Perceptual/Beliefs About Medicines/Treatments That Affect Adherence

1. MY BODY IS SENSITIVE TO MEDICINE
2. MEDICINES ARE BENEFICIAL
3. MEDICINES CAN BE HARMFUL

Acting On and Evaluating Outcomes



Sensitive SOMA / Sensitive to Medication

- My body is very sensitive to medicines
- My body overreacts to medicines
- I usually have stronger reactions to medicines than most people
- I have had a bad reaction to medicines in the past
- Even very small amounts of medicine can upset my body

Patient Case Scenario

BS: Wrong, but unfortunately also right!

Patient Case Scenario

JS: What happened to change these “self” perceptions

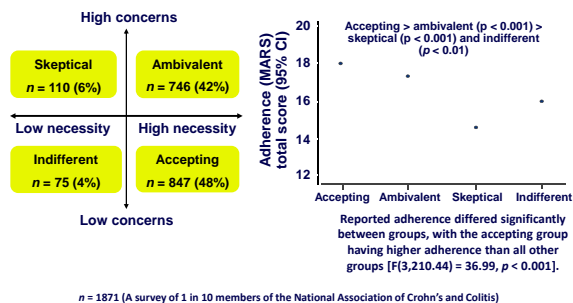
Specific Necessity/Benefit

- My life would be impossible without my medicines
- Without my medicine I would be very ill
- My health, at present, depends on my medicines
- My medicines protect me from becoming worse
- My health in the future will depend on my medicines

Specific Concerns/Harms

- I sometimes worry about the long-term effects of my medicines
- Having to take my medicines worries me
- I sometimes worry about becoming too dependent on my medicines
- My medicines disrupt my life
- My medicines are a mystery to me

Segmentation: Belief Groups & Adherence



“Common-Sense” Evaluations Trump Evidence in OTC Use

- Community pharmacy survey of 1461 people in Northern Ireland (female 81.2%; age range 20-60 years)
- Perceived efficacy and safety and brand familiarity influenced choice
- Ambivalence for need for evidence of efficacy – Previous experience more important
- Anecdotes are assumed evidence

Hanna LA, Hughes CM. (2011). Patient Educ Couns. 83(3), 345-351.

How Should We “Translate” Side Effects and Define Risks?



Patient Perceptions of MD's Use of Medicines

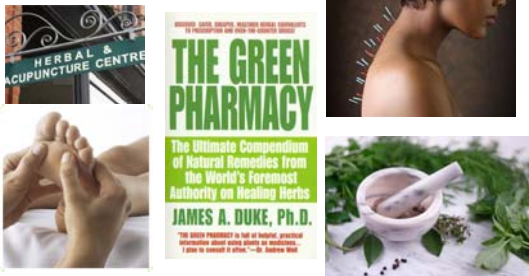
- If doctors had more time with patients, they would prescribe fewer medicines
 - Doctors use too many medicines
 - **Natural remedies are safer than medicines**

Patient Case Scenario

CO: The doting wife & natural remedies

Chemical vs. Natural

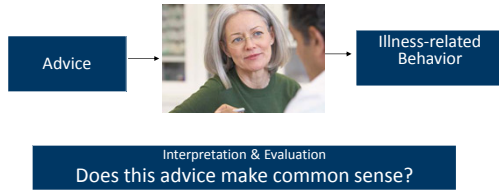
In public perceptions the harmful nature of medicines is often linked to their chemical nature, which is adversely contrasted with more "natural" and therefore 'safer' remedies
Horne R, et al. *Inflammatory Bowel Diseases* 2009;15(6):837-44.



When Medication Is the "Illness Threat"

- Patients' response to the experience of symptoms, attributed to be due to medication side effects and to concerns about potential harm (including OTC) can be explained by CSM
 - The experienced or anticipated harmful effects are operationalized as the "illness threat" entry to the cycle of representation, coping procedure and appraisal
 - The components of illness representation can therefore be applied to medication harm
- Representations of medication harm have *identity, timeline, cause, consequences* and control/cure components
- The CSM components also can be applied to understanding the common-sense evaluation of treatment *necessity*

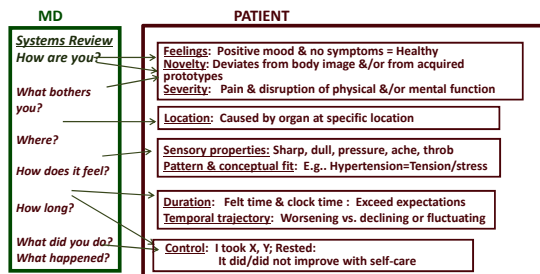
Common-Sense Regulation of Illness-Related Behaviors



Leventhal H, et al. (1997). Illness representations: Theoretical foundations. In K. J. Petrie & I. Weinman (Eds.), *Perceptions of health and illness: Current research and applications*. (pp. 19-46). London: Harwood Academic.
Leventhal H, Breland IV, Mora PA, Leventhal EA. (2010). Lay representations of illness and treatment: A framework for action. *Handbook of Behavioral Medicine: Methods and Applications*, 3, 137.

DO WE INADVERTENTLY TEACH THE ACUTE, DEFAULT MODEL IN CLINICAL SETTINGS?

Eliciting the Chief Complaint and the Review of Systems Reinforces the Acute Model for the Patient Because It Asks About Symptoms!



Leventhal H, Wollman L, Leventhal EA, Phillips LA. (2008). *Annual Review of Psychology*, 59, 477-505.

How to Change the Model

- Clinicians **NEED** to ask the questions to elicit, address, and change the acute, default model in order to enhance clinical outcomes
- The same strategies apply to eliciting patient's expectations about treatment – time frames/outcomes

Perceptions and Practicalities Approach to Facilitate Informed Engagement with Medication



Perceptual

1. Communicate a “common-sense rationale” for why the treatment is needed – taking account of the patient’s perceptions of the illness and symptom expectations
2. Elicit and address CONCERNS about potential adverse effects of the treatment? – including support with side-effect management

Practical

3. Make the regimen as convenient and easy to take as possible...

Horne R. (2011). Your treatment will not work if the patient does not take it. In *Clinical Dilemmas in Inflammatory Bowel Disease: New challenges*, Second Edition. Edited by P. Irving, C. Siegel, D. Hampton and F. Shanahan. Oxford: Blackwell Publishing

See Phillips et al 2011 for a broader application of Leventhal’s CSM to medical communication

Phillips LA, Leventhal H, Leventhal EA. (2011). *British Journal of Health Psychology*, 17(2), 244-257

The challenge for medical institutions is to educate expert physicians in the Modern Informational Age

Don't Ask, Don't Tell!



<http://healthresources.files.wordpress.com/2012/06/seniors-drugs.jpg>

THE END is just the beginning!

Drugs don't work in patients who do not take them!

— C. Everett Koop, MD, Surgeon General, 1980s

Or to Paraphrase:

Treatments don't work if patients do not do them!

There is nothing so practical as a good theory.

— Kurt Lewin, 1930s

Promoting Safe and Effective OTC Medication Behavior Through Interface With Family Care

Laura N. Gitlin, PhD

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Director, Center for Innovative Care in Aging
Johns Hopkins University

April 10, 2013

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"There are only four kinds of people in the world —

- those who have been caregivers,*
- those who currently are caregivers,*
- those who will be caregivers and*
- those who will need caregivers."*

Former First Lady Rosalynn Carter

Overview

- ◆ Magnitude of family involvement in elder care
- ◆ Profile of family caregivers
- ◆ Family involvement in medication taking
- ◆ Future research directions in family involvement in OTC use of older adults

Magnitude and Profile of Families Providing Care

Historical Perspective

- ◆ Family members historically have been and will continue to be, now and into the future, involved in the health and care of older adults
 - 80% to 90% of long-term care provided by families
- ◆ Family involvement is a global phenomenon occurring across all socioeconomic levels, within all race and ethnic groups, and in developed and developing countries
- ◆ Current societal trends place families at forefront of elder care:
 - Aging of population (1 in 5 will be 65 years old by 2030)
 - Medical advances
 - Shorter hospital and rehabilitation stays
 - Expansion of home care technologies
 - Preference to stay at home
 - New medical models depend upon families (patient-centered care, hospital at home, collaborative primary care models, hospital to home models)

Coleman, Boult, & American Geriatrics Society Health Care Systems Committee, 2003; Coleman & Pandya, 2002; National Alliance for Caregiving & AARP, 2009

Estimates of Individual Caregiving Prevalence by Age of Recipient

Type of Recipient	Prevalence	Estimated Number of Caregivers
Overall	28.5%	65.7 million
Only child recipients	1.7%	3.9 million
Only adult recipients	21.2%	48.9 million
Both adult and child recipients	5.6%	12.9 million

National Alliance for Caregiving in collaboration with AARP - November 2009

Limited Estimates of Family Members Who:

- ◆ Provide care long distance
- ◆ Accompany an older adult to health care visits
- ◆ Provide episodic care
- ◆ Provide care in specific health transitions (e.g., hospital to home)
- ◆ Monitor but do not provide hands-on care
- ◆ Are from specific race/ethnic/cultural backgrounds

Gitlin and Schulz, 2012

Who Provides Care?

- ◆ The “woman (and the man?) in the middle”
 - 66% are women
 - 59% work full-time or part-time
 - >90% graduated high school; 43% are college graduates
 - Spend >20 hours a week caring for a parent (mother)
- ◆ 1.4 million children (8 to 18 years of age) provide care to elders
- ◆ Number of male caregivers increasing
 - 40% of caregivers of people with dementia
 - 42% of older adults with other disabilities
- ◆ Average age = 49.2 years of age (older than 5 years ago)
- ◆ 66% indicate other unpaid caregivers help out
 - Older caregivers (≥65 most likely to be sole unpaid carer)
- ◆ Only 35% use paid help (aids, housekeepers, others)

National Alliance for Caregiving in collaboration with AARP - November 2009

Race and Ethnic Differences

- ◆ Hispanic caregivers may be:
 - Younger
 - Unmarried
 - Care for other children in household
 - Report greater depression/upset
- ◆ Long-distance caregivers tend to be white and affluent
- ◆ Unclear about other race/ethnic differences in profiles

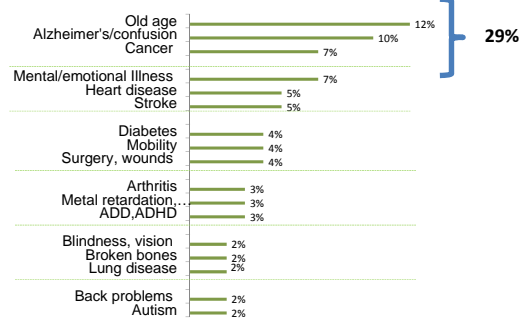
Gitlin, L. N. & Schulz, R. (2012). Family caregiving of older adults. In T.R. Prohaska, L.A. Anderson, & R.H. Binstock (eds.), *Public Health for an Aging Society*. Baltimore, MD: Johns Hopkins University Press, pp. 181-204.

Who Are Recipients of Care?

- ◆ Female (62%)
- ◆ Average age of 69.3 years (older than 5 years ago)
- ◆ Long-term physical conditions (69% of caregivers) vs short-term physical condition (35% of caregivers)

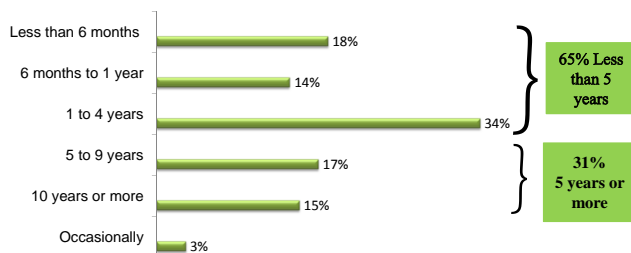
National Alliance for Caregiving in collaboration with AARP - November 2009

Main Problem or Illness of Care Recipient Identified by Caregiver



National Alliance for Caregiving in collaboration with AARP - November 2009

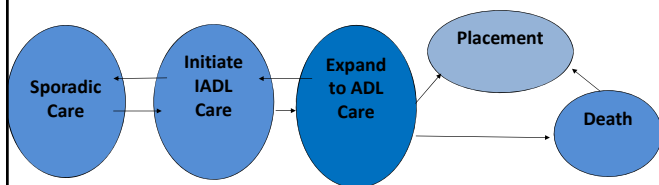
Duration of Care for Recipient



National Alliance for Caregiving in collaboration with AARP - November 2009

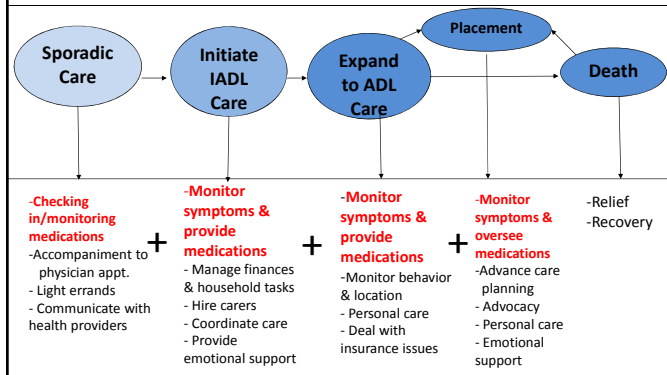
Family Involvement in Medication-Taking

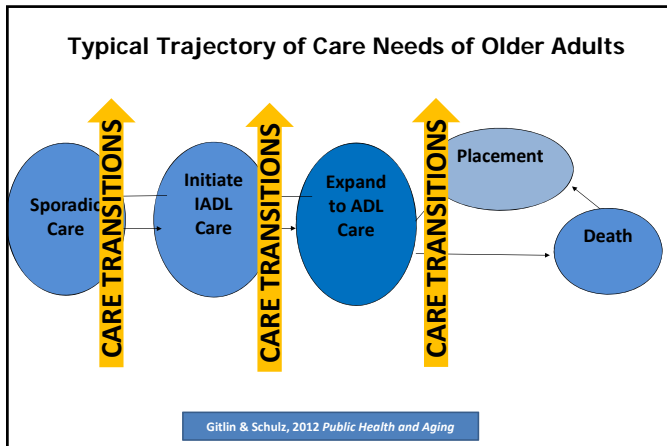
Typical Trajectory of Care Needs of Older Adults

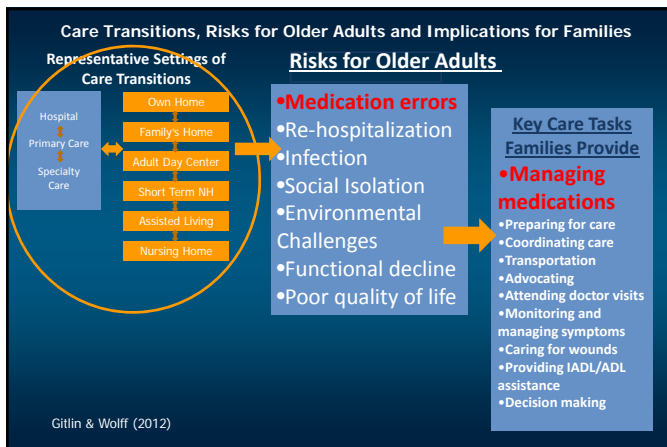


Gitlin & Schulz, 2012 *Public Health and Aging*

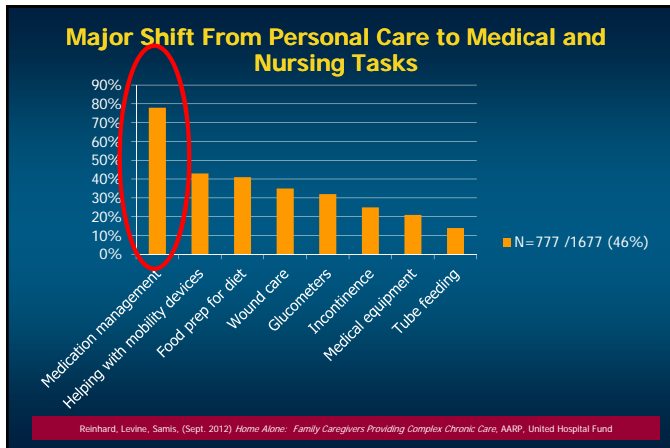
Care Tasks

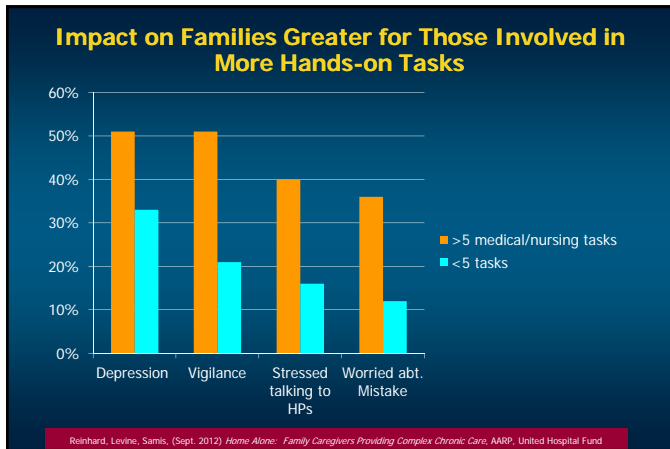


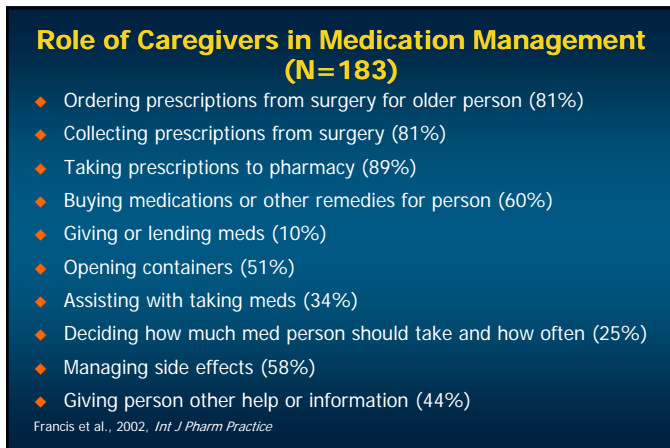




What Do We Know About Family Involvement in Medication Taking?







Caregiver "Hassles" Administering Medications

♦ 23 Families indentified 122 hassles

- Scheduling logistics (29.5%)
 - Working administration into care routines
 - Giving medications on time
 - Keeping medications filled
- Administration procedures (32.0%)
 - Giving medications to a confused/uncooperative person
 - Knowing when to hold, alter, discontinue meds
 - Knowing how to administer missed doses
- Safety issues (38.5%)
 - Recognize adverse or toxic effects
 - How to recognize an emergency
 - Knowing how to give meds safely

Travis et al., 2000, *J Gerontology*

Race and Ethnic Differences

- ♦ Fewer African Americans report OTC and total medication use than nonblacks (Hanlon et al., 1992; Sleath et al., 2004).
- ♦ National survey of 2032 caregivers of Veterans:
 - Black caregivers less likely to use any medication than white caregivers

Percentage of Caregivers Reporting Medication Use (N=2032)

Drug Class	Black	White	P
Analgesics	67.1%	84.4%	<.001
Nutritional supplements	12.3%	14.2%	.376
Vitamins	9.2%	14.4%	<.05
Antihistamines	5.4%	5.85%	.754
Mean number of drugs	3.1	4.1	<.001

Sleath et al., 2004, *Am J Geriatr Pharmacother*

Dementia Care

"My wife has a lot of headaches. I don't give her Tylenol because I know these are due to her dementia." Spouse caregiver in Gitlin et al., ACT Trial.

- ◆ 54% of caregivers actively involved in daily management of patient medications; later stages, exceeds 90% (Bradford et al., 2011)
- ◆ Caregivers actively managing their own medications (average of 4 to 6) (Sleath et al., 2002)
- ◆ Caregivers report strain in tasks related to patient medications (Smith et al., 2002)

Dementia Caregivers (REACH II N=566)

- ◆ **Potentially Inappropriate Medication (PIM) use**
 - 33% dementia patients taking 1+ PIM
 - 39% caregivers taking 1+ PIM
- ◆ **Caregiver factors associated with increased risk of patient PIM use**
 - Caregiver's own use of PIM
 - Spouse caregivers
 - Hispanic caregivers
 - Greater number of years living in US
- ◆ **Increased caregiver age associated with decreased risk of PIM patient use**

Thorpe et al., 2012, *Am J Geriatr Pharmacother*

Future Research Directions

- ◆ **Observational studies to:**
 - Identify knowledge of family caregivers concerning OTC safety hazards (e.g., overdosing concerns), active ingredients label warnings
 - Determine prevalence of potential misuse and overdose of OTC
- ◆ **Strategy:**
 - Integrate questions in existing data sets
 - National Health and Aging Trends Study
 - National Long-term Care Survey
 - National Longitudinal Caregiver Sample (US veterans with dementia)
 - Studies on OTC with older adults should include questions concerning involvement of family members

Future Research Directions

- ◆ **Intervention studies to:**
 - Educate family caregivers concerning potential safety hazards of using OTC and reviewing label warnings
 - Develop supportive strategies for the range of medication support families provide
- ◆ **Strategy:**
 - Add modules to existing supportive caregiver interventions to enhance OTC knowledge
 - Augment care transition models with specific caregiver medication support interventions

Project ACT

Nurse Medical Assessment and Caregiver Education

- ◆ Review patient's medical issues
- ◆ Provide caregiver education about:
 - Pain
 - Dehydration
 - Infection
 - Constipation
 - Medication use
- ◆ Work with caregiver to take care of themselves



Conclusions

- ◆ **Families provide >80% of long-term care to older adults**
 - Older adults on complex medication regimens involving prescription and OTC
- ◆ **Little known about family knowledge and management of medications overall and OTC specifically**
- ◆ **Considerations in family involvement in OTC**
 - Family members (e.g., spouses) are aging too
 - Health literacy may impact OTC provision
 - Knowledge/beliefs about medications/OTC
 - Race/ethnicity/acculturation and OTC decision making
- ◆ **Opportunities for research on OTC and caregivers:**
 - Leveraging existing data sets by adding questions
 - Leveraging existing intervention protocols by modules on OTC
 - New interventions needed specific to medication training



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
OF OLDER ADULTS

Omni Shoreham • Washington, DC
Tuesday and Wednesday, April 9-10, 2013

**Speakers: Developing New Interventions to Support
Safe and Effective OTC Medication Behaviors
Emerging Technologies to Promote Optimal OTC Behavior**



Christopher B. Mayhorn, PhD

Christopher Mayhorn, Associate Professor and Program Coordinator of the Human Factors and Ergonomics Psychology program, joined the faculty at North Carolina State University in 2002. He earned a BA from The Citadel (1992), an MS (1995), a Graduate Certificate in Gerontology (1995), and a PhD (1999) from the University of Georgia. He also completed a Postdoctoral Fellowship at the Georgia Institute of Technology. Dr. Mayhorn's current research interests include everyday memory, decision making, human-computer interaction, and safety and risk communication for older adult populations. Dr. Mayhorn has more than 30 peer-reviewed publications to his credit and his research has been funded by government agencies such as the National Science Foundation and the National Security Agency. Currently, he is serving on the Human Factors and Ergonomics Society (HFES) Government Relations Committee and as the Chair of the Technical Program Committee of HFES.



Patricia Meisner, MS, MBA

Patricia Meisner is CEO and Co-Founder of AdhereTx Corporation. She has 25 years of executive operating experience from both early stage and mature companies in the medical device, diagnostics, and life science companies, including Invitrogen, T Cell Sciences, and Sigma Aldrich Corporation. She has brought multiple new products to market in the areas of HIV monitoring, cancer diagnostics, and pharmaceutical drug discovery. Prior to founding AdhereTx, she founded RedTail Solutions, a Software as a Service (SaaS) company serving middle-market manufacturers in the global supply chain. While serving as its CEO (2000-2008), Ms. Meisner established a new revenue and business model in this segment and built a capital-efficient business that achieved profitability in 2007. She holds a BA in biology from Kenyon College, an MS in biochemistry, and an MBA from Case Western Reserve University.



Anthony A. Sterns, PhD

Anthony Sterns is a national expert in gerontechnology and a pioneer in the application of mobile computers and smartphones for improving the quality of life for individuals living with chronic illness. Dr. Sterns has over 20 years of experience in designing and bringing to market products and services for the silver industries marketplace. He has led National Institutes of Health grants and contracts in the development of software for medication adherence on mobile devices since 2001. His direct project experience includes serving as the principal investigator developing a post transient ischemic attack (mini-stroke) intervention and heart failure intervention both delivered using smartphones. Now serving as CEO of iRx

Reminder LLC, Faculty Statistician and Visiting Associate Professor for the Kent State University College of Nursing, and Adjunct Associate Professor for the City University of New York, School of Professional Studies, Dr. Sterns has extensive experience in research methodology, survey and instrument design, and advanced statistical analysis. He has been principal investigator and statistician for numerous completed health care, military, transportation, community agency, and corporate research projects, surveys, and technical reports. He has made over 100 presentations for national and international audiences. Dr. Sterns has previous executive start-up experience having launched six products for older adults, including the cognitive intervention therapy, The Memory Magic™ Program, which is now in over 1,500 facilities in seven countries.



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Presentation Briefing

Speaker: Christopher B. Mayhorn, PhD

Session: Developing New Interventions to Support Safe and Effective OTC Medication Behaviors: Emerging Technologies to Promote Optimal OTC Behavior

Individual Presentation: Using Technology to Facilitate Safe OTC Medication Behaviors

Discussant: Patricia J. Neafsey, PhD

Summary:

Drug interactions due to over-the-counter (OTC) self-medication practices are known adverse consequences of unsafe medication behaviors. Well-designed, usable technology offers the potential to improve the medication behaviors of older adults because it can improve information accessibility and provide cognitive support when and where it is needed. Functionalities related to behavioral monitoring, hazard alerting, and decision assistance related to error recovery and preventative action become particularly important when designing technology-based interventions. Advances in sensor technology and mobile computing offer tantalizing evidence that such interventions can be effective with older adults yet stakeholders should not lose sight of barriers such as technology adoption and privacy concerns. Discussion will focus on efforts to use design principles from human factors and ergonomics (hf/e) research to build persuasive technology. Examples of previous efforts will be presented and critiqued for the purpose of evaluating the likely effectiveness of emerging technologies.

Objectives:

- Understand how hf/e principles can improve design for technology used by older adults.
- Identify pertinent technology functionalities and describe how older adults can benefit.
- Recognize the barriers of technology use by older adults.
- Distinguish persuasive technology from other technological solutions.

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Mendat, C. C., Watson, A. M., Mayhorn, C. B., & Wogalter, M. S. (2005). Age differences in search time for two over-the-counter (OTC) drug label formats. *Proceedings of the Human Factors and Ergonomics Society 49th Annual Meeting*. Santa Monica, CA: Human Factors and Ergonomics Society.

Research Questions:

1. Can the results of intervention studies designed to assess prescription medication adherence be generalized to address OTC medication use?
2. Do technology solutions for older adults also work with other age groups? Does universal design work in this area?
3. How do trends in mobile computing and technology minimization particularly affect older adults?
4. Are older adults willing to accept and use persuasive technology?
5. How will stakeholders overcome issues with privacy related to technological innovation?

Case Studies:

Possible handouts might depict the informational format (Drug Facts) that appears on OTC medications for the purpose of evaluating readability and cognitive factors that can make regimen management difficult for older adults. Other handouts might depict screen shots from current mobile telephone applications used to manage medications.

Handouts and Materials:

PowerPoint presentation, OTC products



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Presentation Briefing

Speaker: Patricia Meisner, MS, MBA

Session: Developing New Interventions to Support Safe and Effective OTC Medication Behaviors: Emerging Technologies to Promote Optimal OTC Behavior

Individual Presentation: Assessing Incremental Risk from OTC Medications in the Therapeutic Regimens of Older Adults

Discussant: Patricia J. Neafsey, PhD

Summary:

Many older adults suffer from multiple chronic conditions, see multiple providers, and have complex therapeutic regimens as a result. The complexity can be compounded by self-medication for pain, insomnia, and other common ailments with over-the-counter (OTC) drugs, many of which are as pharmacologically active (and potentially dangerous) as prescription medications. It is difficult for the health care team to reconcile medications from various sources as their patients travel through the continuum of care. Some information may be available from electronic health records or insurance claims, but often the most important piece of information, how the patient is using his or her prescription drugs as well as any other OTC or supplements, is missing. ActualMeds™ is developing medication management and reconciliation solutions that can be used at the point of care by the health care team to assemble a patient's complete medication landscape and to identify the associated risk. This is accomplished through interoperability with other sources of medication information and the use of a structured interview to elicit important information about the patient's self-medication behavior. Once data are aggregated and validated, evidence-based rules identify risk and provide guidance to the health care team enabling them to resolve risk and tailor interventions for the patient at the point of care. This new model has potential to improve patient outcomes and reduce hospitalizations for patients with chronic conditions, such as heart failure and diabetes, that respond well to rigorous medication management in the non-acute environment.

Objectives:

- Understand how OTC medications can add considerable, hidden risk to therapeutic regimens.
- Recognize that health care teams require tools to identify risk in patient self-medication behavior at the point of care and to guide intervention.
- Recognize that adherence programs can be most effective when therapy is appropriate and optimized as the baseline.

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Research Questions:

1. What is the differential risk added by OTC medications to the already complex therapeutic regimens of older adults?
2. Can reducing the risk associated with self-medication behavior in older adults lead to better outcomes?
3. Can enabling health care teams to reconcile and optimize therapeutic regimens at the point of care make patient adherence programs more effective?

Case Studies:

Summary of several use cases that enable medication management and reconciliation in the primary care setting or at a transition of care.

Handouts and Materials:

PowerPoint presentation, Point of Care use cases summary



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Session: Developing New Interventions to Support Safe and Effective OTC Medication Behaviors: Emerging Technologies to Promote Optimal OTC Behavior

Individual Presentation: Designing Self-Management Products: Cognitive Prosthetics for Older Adults

Discussant: Patricia J. Neafsey, PhD

Summary:

US health care system presents challenges and barriers. The US health care information system is now incentivizing the use of electronic health record systems. But these systems are still paperless paper. They are generally closed systems and are universally focused on supporting the health care provider exclusively. What is needed are dynamic systems that can identify changes in a patient over time, interconnect across all providers who care for the patient, and center on self-management of the patient with mechanisms for support from health care professionals. This kind of system works within the chronic care management model proposed by Wagner [1]. **Barriers to goal attainment.** Nationally, current blood pressure (BP) control rates for hypertension are only about 34% [2]. Therapeutic inertia, or the tendency of health care providers not to intensify treatment when necessary, and patient nonadherence to antihypertensive regimens together account for a significant portion of poor BP control. For example, over half of patients have drug “holidays” consisting of several days of missed doses. “Typical” adherence is associated with nearly twice the risk of cardiovascular events compared with “ideal” adherence [3, 4]. **Mobile health (mHealth) solutions are a powerful approach.** There are six key concepts we use when developing health interventions: readiness for change, focusing on strengths, setting goals, training, giving behavior choices, and reinforcing positives [5]. Smartphone apps (i.e., mHealth) provide a practical and effective technological platform to support collaborative care [6]. Smartphone apps can provide patient education, medication reminding, and symptom tracking (e.g., BP, blood glucose [BG]). In addition, they can make medication adherence and daily measures such as BP and BG values available to support provider decisions and enable frank physician-patient discussions during office visits. Availability of smartphones is no longer an insurmountable barrier. In 2011, 35% of Americans used smartphones, and by 2012 the figure had increased to 46% [7]. With respect to access to care, smartphone technology does not discriminate; 49% of African Americans, 45% of Hispanics, and

49% of women use smartphones [8]. Our solution, the iRx Reminder software, forms a strong platform on which to design interventions. **mHealth solutions are needed.** Here we propose a smartphone-based system (i.e., “mHealth”) for patient self-management of chronic illnesses that supports collaborative care. Through funding from the National Institutes of Health, our research team has developed a flexible software platform: iRx Reminder (www.irxreminder.com). The smartphone system allows for medication reminding, surveying (e.g., BP, BG), and educating patients (e.g., podcast videos). Older adults, ages 56 to 89 years, have successfully used and reported liking the iRx Reminder system [9, 10, 11].

Objectives:

- Understand the chronic care management model.
- Recognize interventions that contain the six key elements of health behavior change.
- Understand how smartphones can provide a platform for interventions that act as a cognitive prosthetic to support independence and maintenance of healthy behaviors.

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7. Smith, A. *Smartphone update 2012*. (2012). Available from: <http://pewinternet.org/Reports/2012/Smartphone-Update-2012.aspx>.
8. Ibid.
9. Sterns, A. A. (2005). Evaluation of a curriculum design and program to train older adults to use personal digital assistants. *The Gerontologist*, 45, 828-834.
10. Mayhorn, C., & Sterns, A. (2006). Perfecting the handheld computer for older adults: From cognitive theory to practical application. *Cognitive Technology*, 12(1), 15-21.
11. Sterns, A. A., Lax, G., Sterns, H., Allen, K., & Hazelett, S. (2010). Improving chronic care management: An iPhone application for post-stroke recovery. Vancouver, BC, Canada: International Society of Gerontechnology.

Research Questions:

1. Can smart devices be used to improve adherence for the complex therapeutic regimens of older adults?
2. What are key elements and combinations of elements required to achieve high adherence in older adult patient populations?
3. Can providing smart device–based self-management monitoring tools that integrate with health care teams make long-term patient treatment more effective and efficient?

Case Studies:

Summary of smartphone-based intervention studies of patients recovering from transient ischemic attack (“mini-stroke”) and heart failure.

Handouts and Materials:

PowerPoint presentation, Point of Care use cases summary



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
OF OLDER ADULTS

Omni Shoreham • Washington, DC
Tuesday and Wednesday, April 9-10, 2013

Select Abstracts of Studies Utilizing iRx Reminder

Gerontologist. 2005 Dec;45(6):828-834.

Curriculum Design and Program to Train Older Adults to Use Personal Digital Assistants

Sterns AA. Creative Action LLC, Akron, OH 44303, USA. drtone@gmail.com

Abstract

PURPOSE: The aim of this study was to demonstrate that many older adults can share in the potential benefits of using a personal digital assistant (PDA), including using the device as a memory aid for addresses and appointments, to improve medication adherence, and as a useful organizational tool and communication device.

DESIGN AND METHODS: A curriculum, designed specifically for older adults, was developed that provided the necessary information and practice to use the technology. The degree to which the curriculum improved user skills was measured by testing participants on basic and advanced features of each of the standard PDA programs.

RESULTS: Participants were successful in using the technology and indicated satisfaction with the medication-reminder program specifically designed to accommodate the needs of older adults.

IMPLICATIONS: The PDA, supported with well-designed software and well-executed training, can provide unique benefits to older adults.

iRx Reminder Summa Health System Pilot — Improved Medication Compliance

Sterns, A. A. (2011, April). Using smartphone technology for chronic care self-management: a new strategy for health care management. Invited address of the Cellar Conference, Frances Payne Bolton School of Nursing, University Center on Aging & Health, Case Western Reserve University, Cleveland, OH.

Abstract

Recently, Sterns et al. (Grant No. 1R43AG033500, PI Sterns, A.) conducted a pilot to test improving medication compliance using smartphones for older adults (Mean Age = 65) recovering from stroke (Sterns et al., 2010). Overall, participants complied with 83% of medication events, implying 9 or more missed doses in a 2-month period. No additional interventions such as calling or behavioral reinforcements such as display of counts of successful events were provided. When asked if the individual had recorded when they took medications 77% indicated yes in the experimental group and 67% indicated they had in the control group. About 33% of the experimental group indicated they recalled missing doses and indicated that 1.3 times they had missed over the 2-month period. In the control group 44% said they recalled missing doses and indicated they missed 1.8 times over the 2-month period. These pilot outcomes show that older adults are capable of using smartphones to track medication adherence, that they are significantly better at recording taking medications with the smartphone than a diary. Also both groups missed significantly more pills than they remembered demonstrating the importance of in-the-moment data collection.

Generations. Winter 2004-2005;28(4)

Transforming the Personal Digital Assistant Into a Health-Enhancing Technology

Anthony A. Sterns¹, Scott C. Collins²

¹ Creative Action LLC, Akron, Ohio

² Ann Arbor Digital Arts, Ann Arbor, Michigan

Abstract

The challenge of connecting business and aging can focus on bringing existing products and services together in a way that meets a need of special concern to older consumers. Combining the now-ubiquitous technology of the personal digital assistant (PDA) with the high use of pharmaceuticals by older adults is a good example of such convergence. In this article, the authors discuss barriers to using the PDA, the importance of medication adherence, and approaches to bringing the technology to market.

Cognitive Technology. Spring 2007;12(1)

Perfecting the Handheld Computer for Older Adults: From Cognitive Theory to Practical Application

Christopher Mayhorn, PhD; Anthony Sterns, PhD, North Carolina State University

Abstract

The older population in the United States is increasing and the average American is getting older. These demographic changes pose a significant challenge for those interested in designing and developing technologies because the special needs of this particular group of technology users will have to be considered more fully. To illustrate how knowledge of cognition and aging can be applied through the technology design process, the purpose of this article was to describe the methodological process associated with one case study: developing personal digital assistants (PDAs) to provide cognitive support for older adults during medication adherence tasks. Findings from two separate previously published empirical studies (Mayhorn, Lanzolla, Wogalter, & Watson, 2005; Sterns, 2005) were reviewed to document how the implementation of technological interventions that are based on cognitive theory can be used in practice to improve medication adherence in older adults. Implications for training, technology design, and future directions for research were discussed.

Persuasive Pillboxes: Improving Medication Adherence With Personal Digital Assistants

Anthony A. Sterns¹, & Christopher B. Mayhorn²

¹ Creative Action LLC, University of Akron, University of Maryland, University College, 680 N. Portage Path, Akron, OH 44303, USA. drtone@gmail.com

² Department of Psychology, North Carolina State University, 640 Poe Hall, Campus Box 7801, Raleigh, NC, 27695-7801, USA. Chris_Mayhorn@ncsu.edu

Abstract

Personal digital assistants (PDAs) can be used persuasively to change attitudes regarding medication taking, thereby facilitating adherence for older adults. A pillbox that integrates onto the body of the PDA was created as a place to store mid-day pills. Results from a lab and field experiment on older adults' perceptions and use of PDAs for medication minding are reported. In both the lab and field experiment, older adults were successfully trained to use PDA standard programs and a program for medication reminding. At the conclusion of the 3-month field experiment, a physical pill count yielded increased compliance with two-thirds of the

participants missing 1 pill or less in the third month of the study. Implications for PDA training curricula, hardware design, and future research are discussed.

PRESENTATIONS

- Sterns, A. A. (2012, June) Succeeding in mHealth in the USA. A paper presentation as part of the symposium New Technologies in Health Care at the 2012 International Society of Gerontechnology meeting, Eindhoven, The Netherlands.
- Sterns, A. A., Hughes J., & Goldstein, C. (2012, June) Getting the US mHealth market to take our medicine. Gerontechnology. A paper presentation as part of the symposium Expanding e-Health Knowledge at the 2012 International Society of Gerontechnology meeting, Eindhoven, The Netherlands.
- Sterns, A. A. (2011, December 5). Smartphone-based comprehensive self-care management for chronic conditions. Part of the Chronic Disease Management symposium at the 3rd Annual mHealth Summit, Washington, DC.
- Sterns, H. L., & Sterns, A. A. (2011, November 21). An update on training, technology, and older adults. Part of a symposium presented to The Gerontological Society of America annual conference, Boston, MA.
- Sterns, A. A., & Hughes, J. (2011, November 19). Smartphone-enhanced self-management and active aging. Part of a symposium presented to The Gerontological Society of America annual conference, Boston, MA.
- Sterns, A. A. (2011, October 28). Improving clinical research performance with mHealth technologies. A presentation for research grand rounds at the Northeastern Ohio Medical (NEOMED) University, Rootstown, OH. Available from:
<http://neomediaweb.neomed.edu/mediasite/Viewer/?peid=8c1db8e93e2d41b8a101392e573fb87d1d>
- Sterns, A. A. (2011, July 14). Improving clinical research performance with mHealth technologies. A presentation to the Northeast Ohio Network of research, Northeast Ohio Universities College of Medicine, Rootstown, OH.
- Sterns, A. A. (2011, April). Using smartphone technology for chronic care self-management: a new strategy for healthcare management. Invited address of the Cellar Conference, Francis Payne Bolton School of Nursing, University Center on Aging & Health, Case Western Reserve University, Cleveland, OH.
- Sterns, A. A., & Hughes, J. (2011, March 7). Smartphone-based Comprehensive Self-care Management for Chronic Conditions. A presentation made at Driving the Future 11: Driving the Future in Today's Uncertain Healthcare Environment in Cleveland, OH.
- Sterns, A. A. (2010, October 3). Managing the development of healthcare products for seniors; Understanding the business of gerontechnology. Invited address for the University of Utrecht, Netherlands.
- Sterns, A. A., Lax, G., Sterns, H., & Allen, K., & Hazelet, S. (2010, May). Improving chronic care management: An iPhone application for post-stroke recovery. Paper delivered at the International Society of Gerontechnology conference in Vancouver, BC, Canada.
- Sterns, A. A., Lax, G., Sterns, H., Allen, K., Hazelet, S., & Fosnight, S. (2009, November). Improving Chronic Care Management: An iPhone Application for Post-Stroke Recovery. Part of a symposium on Technology presented at the 62nd annual meeting of The Gerontological Society of America, Atlanta, GA.
- Sterns, A. A. (2009, August). Innovative Research to Increase Participation of Older Adults. Invited keynote for a masterclass in Gerontechnology, The University of Luesden, Netherlands.
- Sterns, A. A., & Murphy, M. (2008, November). What are we doing and who with? Long-term activity monitoring using Smartphones. Part of the Symposium on New Tools for New Data presented at the 61st annual meeting of The Gerontological Society of America, National Harbor, MD.
- Sterns, A. A., & Sterns, H. L. (2008, June). Activity self-surveying of older adults using smartphones. A presentation for the 6th International Conference of the International Society of Gerontechnology, Pisa, Italy.

- Sterns, A. A., Collins, S. C., & Sterns, H. L. (2008, February). Long-term Older Adult Activity Surveying With PDAs. Presented at the International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Sterns, A. A., Collins, S. C., & Sterns, H. L. (2008, February). New Approaches to PDA-based Medication Reminding. Part of the symposium Older Adults and Personal Digital Assistants presented at the International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Sterns, A. A., Collins, S. C., & Sterns, H. L. (2008, February). Persuasive Pillboxes. Part of the symposium Older Adults and Personal Digital Assistants presented at the International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Mayhorn, C., & Sterns, A. A. (2008, February). Age Differences in Usability of PDA-based Medication Reminding. Part of the symposium Older Adults and Personal Digital Assistants presented at the International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Sterns, A. A., Sterns, H. L., & Sterns, R. S. (2006, November). Imagining Improved Caregiver Efficiency Through Education and Intervention Design. In R. Sterns & S.H. McFadden (Chairs), *Imagination in Interventions: Transforming Resident/Staff Expectations and Outcomes through Education in Long-Term Care*. Symposium to be conducted at the 59th Annual Scientific Meetings of the Gerontological Society of America, Dallas, TX.
- Lax, G. A., Sterns, H. L., & Sterns, A. A. (2006, November). Psychosocial Interventions: Imagining a Better Future Through Staff Education on Interventions in Long-Term Care. In R. Sterns and S.H. McFadden (Chairs), *Imagination in Interventions: Transforming Resident/Staff Expectations and Outcomes through Education in Long-Term Care*. Symposium to be conducted at the 59th Annual Scientific Meetings of the Gerontological Society of America, Dallas, TX.
- Sterns, R., Sterns, A., & Sterns, H. (2006, November 6). Therapeutic Cognitive Interventions for People with Dementia, a Poster for the Reflecting on 100 Years of Alzheimer's Conference of Case Western Reserve University at the Crown Plaza, Cleveland, OH.
- Sterns, H., Sterns, A., & Lax, G. (2006, November 6). Improving Caregiver Efficiency Through Education and Intervention Design, a Poster for the Reflecting on 100 Years of Alzheimer's Conference of Case Western Reserve University at the Crown Plaza, Cleveland, OH on November 6, 2006.
- Sterns, A., & Mayhorn, C. (2006, May 19). Invited address titled Persuasive Pillboxes: Improving Medication Adherence with Personal Digital Assistants for the First International Conference on Persuasive Technology for Human Well-Being, PERSUASIVE 2006, Eindhoven, The Netherlands.
- Sterns, A., & Sterns, H. (2006, March 1). Invited address titled Improving Medication Adherence Using Personal Digital Assistants at the 30th Anniversary celebration of the Institute for Life-span Development and Gerontology, The University of Akron, Akron OH.
- Sterns, A. (2006, February 4). Presentation titled Future PDA Applications for Older Adults presented in the track session Practical Assistive Technology Solutions. International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Sterns, A. (2006, February 3). Technology demonstration titled Training Older Adults to Use PDAs for Medication Reminding presented in the track session Products for People With Cognitive Impairment and Independent Living. International Conference on Aging, Disabilities, and Independence, St. Petersburg, FL.
- Sterns, A., & Sterns, R. (2005, May 26). A low-tech Intervention and therapy for large groups of persons with dementia. Presented at the 5th Conference on Gerontechnology, Nagoya, Japan.
- Sterns, A., Sterns, H., & Collins, S. (2005, May 25). Medication Reminding for Older Adults Using PDAs. Presented at the 5th Conference on Gerontechnology, Nagoya, Japan.
- Sterns A., Doverspike, D., Collins, S., & Sterns, H. (2005, April 16). Designing Software and Training to Support Older Adults Using PDAs. A Practitioner/Industry Collaboration Symposium presented at the 2005 Annual Conference of the Society of Industrial and Organizational Psychologist, Los Angeles, CA.

- Sterns, A., Sterns, H., & Collins, S. (2005, April 8). Training and Use of Personal Digital Assistants by Older Adults. Presented at the 29th Annual Meeting of the Ohio Association of Gerontology and Education, Aurora, OH.
- Sterns, A., Sterns, H., Sterns, R., & Collins, S. (2004, August 2). Training and Use of Personal Digital Assistants by Older Adults. Presented at the 2004 APA Annual Scientific Meeting, Honolulu, HI.
- Sterns, A. (2003, November 23). Digital Assistant Training Curriculum and Software for Older Adults. 56th Annual Scientific Meeting of The Gerontological Society of America, San Diego, CA.
- Sterns, A. (2003, March 8). Technologies to support the working and able older adult. Invited address presented at the Future Directions Symposium, the Industrial Organizational/Organizational Behavior Regional Conference, The University of Akron, Akron, OH.



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
 OF OLDER ADULTS

Developing New Interventions to Support
 Safe and Effective OTC Medication
 Behaviors: Emerging Technologies to
 Promote Optimal OTC Behavior



CHPA
 CONSUMER HEALTHCARE
 PRODUCTS ASSOCIATION



THE
GERONTOLOGICAL
 SOCIETY OF AMERICA

NC STATE UNIVERSITY

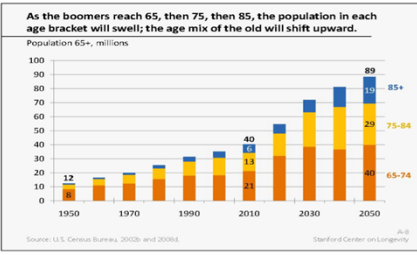
Using Technology to Facilitate Safe OTC Medication Behaviors

Christopher B. Mayhorn, Ph.D.
 North Carolina State University




NC STATE UNIVERSITY


Know Thy User: The U.S. Population Is Aging at an Unprecedented Rate



As the boomers reach 65, then 75, then 85, the population in each age bracket will swell; the age mix of the old will shift upward.

Population 65+, millions

Source: U.S. Census Bureau, 2002b and 2008d. J.A.B. Stanford Center on Longevity



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Age-Related Declines with Perceptual, Motoric, and Cognitive Variables

- Perceptual
- Motoric
- Cognition
 - Selective Attention
 - Working Memory
 - Reading Comprehension

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Increased Likelihood of Perceptual/Motor Impairments

Age Group	Arthritis (%)	Visual (%)	Hearing (%)
<45	~5	~2	~5
45-64	~25	~5	~15
65-74	~45	~8	~25
75+	~55	~12	~38

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Chronic Disease Increases with Age


Older Adults Are More Likely to Have Multiple Chronic Conditions

Age Group	One or more chronic conditions (%)	Two or more chronic conditions (%)
Ages 0-19	24%	5%
Ages 20-44	38%	13%
Ages 45-64	62%	33%
Ages 65+	84%	62%

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Drug Use and Aging

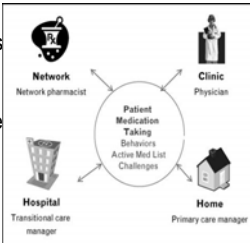
- Older adults aged 65+:
 - Are the largest users of prescription and OTC medications (Glaser & Rolita, 2009)
 - Account for 40% of OTC use in the U.S. (Maiese, 2002)
 - Are 2-7 times more likely to experience an adverse drug interaction than younger adults (Higsbee, 1994)
 - Account for 61.5% of emergency room visits associated with adverse drug reactions (SAMHSA, 2011)




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Why Do Older Adults Experience Adverse Drug Events?

- Lack of communication between patient and clinicians (Granger & Bosworth, 2011)
- Inadequate patient knowledge regarding OTC and prescription drug interactions (Neafsey et al., 2002)
- Forgetfulness (Stegemann et al. 2012)







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Functions Likely Facilitated by Technological Intervention

- For the Patient:
 - Enhanced information accessibility
 - Cognitive support
 - Hazard alerting
- For Clinicians:
 - Behavioral monitoring
 - Reconciliation solutions





NC STATE UNIVERSITY Assessing Commercially Available Technology




Observed Shortcomings

- Primary focus on prescription medications
- Reminder functionality well supported but there is a lack of decision aids
- Connectivity with mobile devices varies
- Interface design is poor
- Devices are expensive



NC STATE UNIVERSITY Focusing on OTC Interactions




Advantages:

- Portable
- Includes barcode scanner
- Connectivity to drug interaction database


Disadvantages:

- Does not support reminding
- Does not communicate with clinicians
- Complex menu system



NC STATE UNIVERSITY Potential Barriers to Adoption by Older Adults

- Privacy concerns (Wogalter & Mayhorn, 2005)
- Usability for older adults often not considered (Fisk et al., 2009)
- Design barriers might prevent older adults from using new technology (Thompson & Mayhorn, in press).
 - Trends in miniaturization (Mayhorn et al., 2005; Mayhorn & Mendat, 2006)
 - Choice of input device (McLaughlin, Rogers, & Fisk, 2009)
 - Previous experience and perceived usefulness are important factors (Mayhorn et al, 2004; Melenhorst et al., 2006)



Conclusions

- ONE SIZE DOES NOT FIT ALL!
 - Technological interventions must be tailored to meet the cognitive/perceptual needs of older adults.
- Such systems must be assessed in terms of usability (Lin et al., 2009) before they are deployed.
- Caregivers and clinical stakeholders must be educated about the needs of older adults.
- Older adults must actively choose to adopt these technologies.



(AdhereTx is becoming...).



"Assessing Incremental Risk from OTC Medications in the
Therapeutic Regimens of Older Adults "

AdhereTx Corporation
OTC Summit
April 10, 2013

Patricia S. Meisner, CEO
pmeisner@adheretx.com
508.864.9385

Company Information

ActualMeds
AdhereTx Corporation
222 Pitkin Street
East Hartford, CT 06108
Founded 2009

- Team-based solutions for medication management and reconciliation at the point of care
- Original technology developed by pharmacologists and clinical pharmacists, licensed from the University of Connecticut
- Validated in clinical trials, peer-reviewed publications

The Origin of ActualMeds: Evidence-Based Outcomes Studies

NIH Sponsored Clinical Trial: Capture and Interpret Risk of
Self-Medication Behavior in Older Adults*

Improved clinical outcomes in a hypertension model vs.
standard of care

- Greater absolute reduction of blood pressure
- Patients reached target BP more quickly
- Reduced polypharmacy and improved adherence
- ✦ **Use of NSAIDs reduced the efficacy of hypertension therapy**

Lowered cost of care in intervention group

- Fewer emergency department visits, hospitalizations and
- Savings of \$300-\$800/patient in 12 months post trial

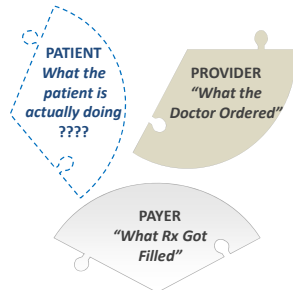
* Neasey, et. al., Aging International, Dec 2010; licensed from the University of CT, School of Nursing

\$200B in Hospitalizations Are Due to Poor Medication Management in High-Risk Patients

Medication information is incomplete and unavailable at the point of care

"Medicare beneficiaries with multiple chronic illnesses see an average of 13 different physicians, fill 50 different prescriptions per year, account for 76% of all hospital admissions - and are 100 times more likely to have a preventable hospitalization"

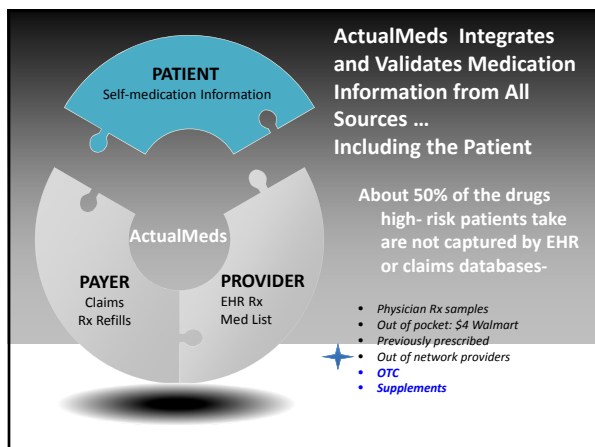
* Anderson GF. Testimony before the Special Committee on Aging. The Future of Medicare: recognizing the need for chronic care coordination. Serial No. 110-7, pp 19-20 (May 8, 2007)



ActualMeds Integrates and Validates Medication Information from All Sources ... Including the Patient

About 50% of the drugs high-risk patients take are not captured by EHR or claims databases-

- Physician Rx samples
- Out of pocket: \$4 Walmart
- Previously prescribed
- Out of network providers
- OTC
- Supplements



The Use of OTC Medications Is Pervasive

- OTC retail sales totaled \$17 billion (excluding Walmart sales) in 2010
- Currently, 35% of adult Americans use OTC medications on a regular basis
- Many are high risk for older adults
 - Analgesics and antipyretics: NSAIDs, acetaminophen w/ NSAIDs
 - Cold, cough, and allergy products: Benadryl (diphenhydramine)
 - Nighttime sleep-aids: diphenhydramine in "PM" formulations
 - Gastrointestinal products: Prilosec (omeprazole), Tagamet (cimetidine)

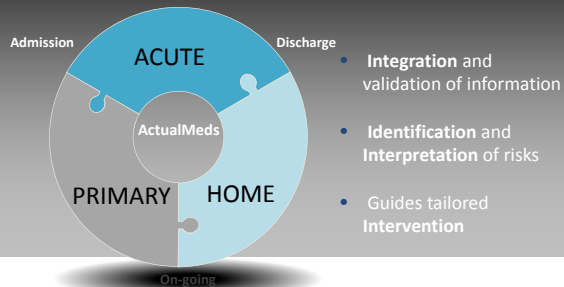
The Nielsen Company [source data on file at the Consumer Healthcare Products Association (CHPA)]. OTC retail sales—1964-2010. http://www.chpa-info.org/pressroom/Retail_Sales.aspx. Accessed July 15, 2011.

Fick DM, Cooper JW, Wade WL, Waller JL, Maclean JR, Beers MH. Updating the Beers Criteria for potentially inappropriate medication use in older adults. Results of a US Consensus Panel of Experts. Arch Intern Med. 2003;163:2716-2724.

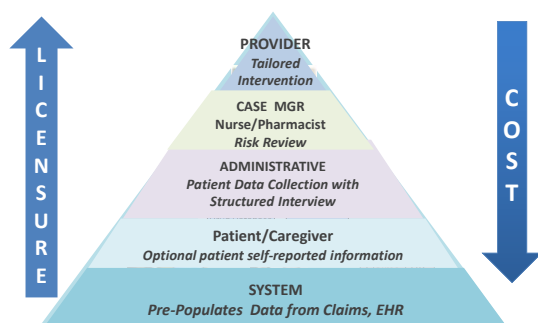
ActualMeds Supports the Role of the Care Team and Its Challenges

1. Stay abreast of the trends in OTC usage patterns as well as the risks associated with incorrect use and storage of OTC drugs.
2. Routinely document OTC use in the medical history:
 - to detect incorrect use
 - to detect potential drug-drug interactions
 - to identify therapeutic duplication
3. Discuss with patients the potential risks of the OTC medications they have disclosed during history taking.
4. Provide alternative medication choices if misuse of an OTC medication is suspected.

ActualMeds Supports Team- Based Medication Management and Reconciliation at the Point of Care



Solutions That Can Be Used by the Entire Care Team



Systematic Capture of Patient Self-Medication Behavior for Rx and OTC



Scan of medication packaging barcode facilitates entry by either "NDC" or "UPC" unique identifiers

Drug database returns name, class, route of administration and class of drug

Enter medication

Drug Name / NDC Code: Advil

Interview: Did you take...
A high blood pressure medicine?
Any aspirin (daily, low dose 325mg)?
A blood thinner - Coumadin, Plavix or Plavix?
A medication to lower cholesterol?
Any other medications for or heart pain / angina?

Advil: Ibuprofen 200 mg and tablet, extended release
Advil: Ibuprofen 200 mg and tablet, extended release
Advil: Ibuprofen 400 mg and tablet, extended release
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Advil: Ibuprofen 200 mg and tablet, extended release
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Advil: Ibuprofen 200 mg and tablet, extended release

Structured Interview: What the patient is actually doing...

Advil

Brand Name Advil
Strength Ibuprofen 200 mg
Please only take nonsteroidal anti-inflammatories

Dosage: 1 tablet (1) 2 (2) 3 (3) 4 (4) 5 (5) 6 (6) 7 (7) 8 (8) 9 (9) 10 (10) 11 (11) 12 (12)

How often Taken (times): Daily (1) Other (2) pain, as/when needed (3)

When Taken (select all hours that apply):

Selected Hours: 7am, 11pm

Date Started: 10/1/2017 Date Stopped: 10/1/2017

Prescriber: Self

Prescriber Specialty: 1 (1) 2 (2) 3 (3) 4 (4) 5 (5) 6 (6) 7 (7) 8 (8) 9 (9) 10 (10) 11 (11) 12 (12)

Date Prescribed: 10/1/2017

Prescribed Quantity: 1 (1) 2 (2) 3 (3) 4 (4) 5 (5) 6 (6) 7 (7) 8 (8) 9 (9) 10 (10) 11 (11) 12 (12)

Discharge: Discharge (1) Discharge (2) Discharge (3) Discharge (4) Discharge (5) Discharge (6) Discharge (7) Discharge (8) Discharge (9) Discharge (10) Discharge (11) Discharge (12)

Medication: Acute (1) Chronic (2)

Making OTC Risk Visible to the Health Care Team

Medications List: --					
Active History					
Drug	Dosage/Route/Strength	Prescriber	Discharge med	Episodic	Ongoing
12 Hour Cold	2 pills / oral / 6 mg-120 mg	Self	Discharge med	Episodic	Ongoing
Advil	2 pills / oral / 100 mg	Self	Discharge med	Episodic	Ongoing
Alcohol	2 drinks	Self	Discharge med	Episodic	Ongoing
Alaxan	4 pills / oral / hydrochloride 25 mg	Dr	Discharge med	Episodic	Ongoing
Alvanol	3 pills / oral / 1 mg	Dr	Discharge med	Episodic	Ongoing
Discon HCT	1 pill / oral / 12.5 mg-100 mg	Jones	Discharge med	Episodic	Ongoing

16 Adult Lateral

ACE Inhibitors may enhance the adverse/toxic effect of Nonsteroidal Anti-Inflammatory Agents. Specifically, the combination may result in a significant decrease in renal function. Nonsteroidal Anti-Inflammatory Agents may diminish the antihypertensive effect of ACE Inhibitors. More

Making Risk Actionable

Clinician Action Plan

Trigger: *Adul/Lenal*
 Risk: ACE Inhibitors may enhance the adverse/toxic effect of Nonsteroidal Anti-inflammatory Agents. Specifically, the combination may result in a significant decrease in renal function. Nonsteroidal Anti-inflammatory Agents may diminish the antihypertensive effect of ACE Inhibitors.

Originating Provider: JONES, S. S.
 Email: support@kenworthymeds.com Phone: 855-858-5553

Recommended Action: [Text Field]

Effective date: 05/24/2013

Responsible Provider: JONES, S. S.

Activity Outreach Method: ☐ Phone ☐ Fax ☐ Email ☐ Other

Action Taken: [Text Field]

Activity Date: [Text Field]

Comments: [Text Field]

Disposition: ☐ Action Accepted ☐ Action Rejected

Guidance for the Patient: SmartList™

SmartList™

Navigation: Daily Living | **OTC** | Symptoms and Conditions | Medication | **OTC**

Name: Mr. JAMES H. WILSON (Date of Birth: 12-01-1942)
 Address: 12345 Main St, Anytown, USA 12345 Phone: 555-555-5555

Medical Conditions
 High blood pressure (Hypertension) [Add]

Medical Symptoms
 [Add]

Key Health Measures
 BP last measured: 120/80 mmHg [Add] (Hours of Sleep per night (averaged) in the last 7 days) [Add]
 Expiration Date (mm/yyyy) [Add]

Current Medication Regimen

Medication	Dosage/Route/Frequency	Frequency	Prescriber	Reason Taken	Action
Aspirin 81	81 mg / 1 x daily	1 x daily	Dr. J. Smith	Heart health	[Add]
Metoprolol succinate (ER) 50 mg	50 mg / 1 x daily	1 x daily	Dr. J. Smith	High blood pressure	[Add]
Hydrochlorothiazide 25 mg	25 mg / 1 x daily	1 x daily	Dr. J. Smith	High blood pressure	[Add]

Medication from Health Claims

Medication	Dosage/Route/Frequency	Prescriber	Action
Metoprolol 50 mg	50 mg / 1 x daily	Dr. J. Smith	[Add]
Hydrochlorothiazide 25 mg	25 mg / 1 x daily	Dr. J. Smith	[Add]
Aspirin 81 mg	81 mg / 1 x daily	Dr. J. Smith	[Add]

Questions to your Healthcare Provider
 What pain relievers should I avoid?
 Is it OK to take a blood thinner if I get a cold?
 What should I do if I have trouble swallowing?


Key Areas for Further Investigation

1. What is the differential risk added by OTC medications to the already complex therapeutic regimens of older adults?
1. Can reducing the risk associated with self-medication behavior in older adults lead to better outcomes?
2. Can enabling health care teams to reconcile and optimize therapeutic regimens at the point of care make patient adherence programs more effective?

Thank You

Patricia Meisner
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Designing Self-Management Products

Cognitive Prosthetics for Older Adults

Anthony A. Sterns, PhD
 CEO, iRx Reminder LLC

Visiting Associate Professor
 College of Nursing, Kent State University

Adjunct Associate Professor
 School of Professional Studies, City University of New York

Senior Lecturer
 College of Business Administration, The University of Akron

Overview

- Challenges and Barriers
 - US Health Care Information System
 - Understanding Health Behavior Change
 - Designing for Older Adults
- iRx Reminder System
- Design
- Research





iRx Reminder
Real Time Mobile Data Capture for Clinical Trials

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 Greta Lax, MA
 Matt Carr, MA
 The University of Akron

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Sue Hazelett, RN, MS
 Summa Health System

Mary Anthony, PhD
 Barbara Drew, PhD
 Joel Hughes, PhD
 Carly Goldstein
 Kent State University





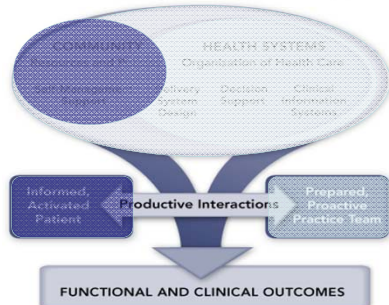

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US Health Care Information System

- Paperless Paper
- Closed
- Provider Focus
- Dynamic
- Interconnected
- Support Focus



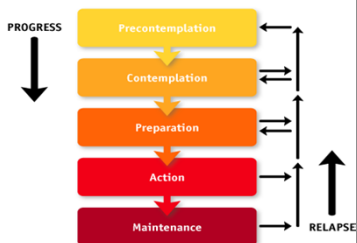
Chronic Care Management



Source: Wagner et al. 1999

Understanding Health Behavior Change

- Readiness for change



Understanding Health Behavior Change

- Readiness for change
- Focus on strengths



Understanding Health Behavior Change

- Readiness for change
- Focus on strengths
- Set goals



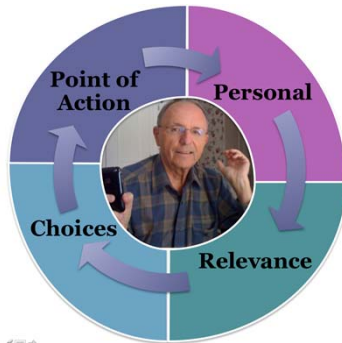
Understanding Health Behavior Change

- Readiness for change
- Focus on strengths
- Set goals
- Provide training



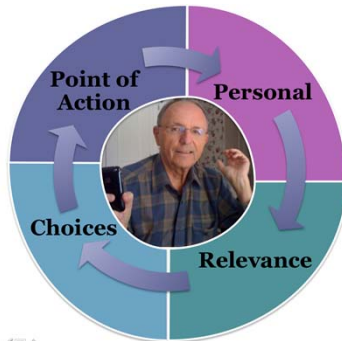
Understanding Health Behavior Change

- Readiness for change
- Focus on strengths
- Set goals
- Provide training
- Give behavior choices



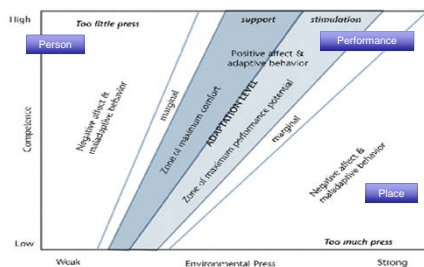
Understanding Health Behavior Change

- Readiness for change
- Focus on strengths
- Set goals
- Provide training
- Give behavior choices
- Reinforce positives



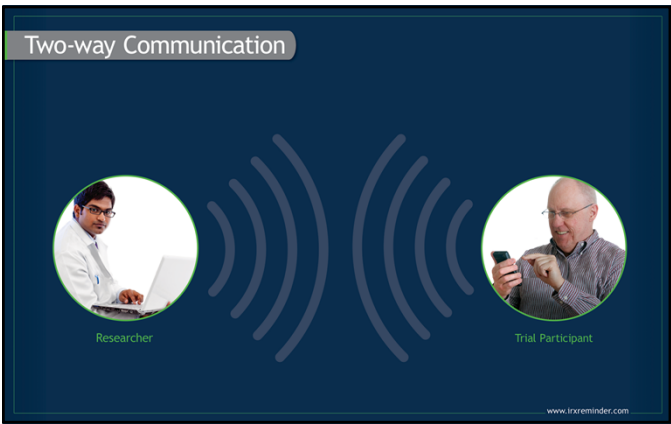
Design Challenges for Older Adults

- Heterogeneity
- User-centered
 - Capabilities
 - Limitations
- Prosthetics
 - Physical
 - Cognitive
- No effort data
- Delight



Mayhew, C., & Sterns, A. (2006). *Cognitive Technology*, 12(1), 15-21.













Telehealth vs. mHealth



Study Sessions

Session 1
Cognitive, health, and psychosocial assessments
Randomized after session

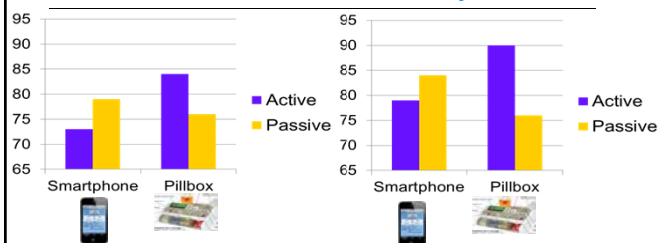
Session 2
Trained on intervention

Session 3
Intervention assessment at 28 days

Adherence (%) by Device and Condition

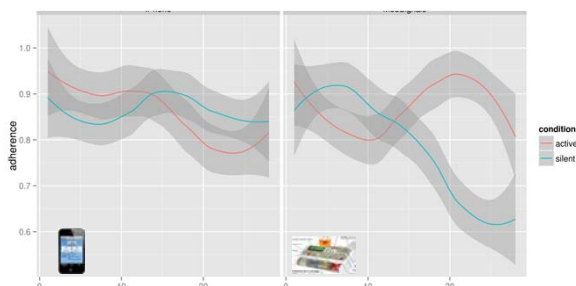
Intent to Treat

Completers

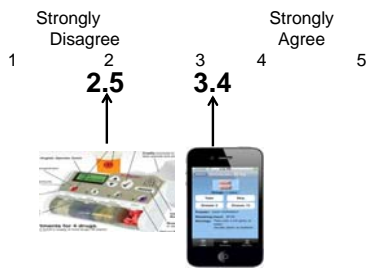


All p 's = NS

Alarm vs. Silent Compliance



Promise: Device Ratings



$F(1, 55) = 14.84, p < .001$

Beyond the Temple of Pills







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Workgroup Members



Steven M. Albert, PhD, Workgroup Chairperson

Steven Albert is a Professor in the Graduate School of Public Health in the Department of Behavioral and Community Health Science at the University of Pittsburgh. He teaches courses on aging as a field of public health, the assessment of quality of life in health and aging, social dimensions of aging, evaluation, and a public health approach to long-term care. He is also the Chair for Research and Science.

Dr. Albert's research centers on the assessment of health outcomes in aging and chronic disease, including physical and cognitive function, health service use, and the cost of care, quality of life, and clinical decision making. His recent efforts include investigation of mental health and clinical decisions at the end of life (National Institute of Mental Health) and a study of the cognitive and physical basis of independence in older people (National Institute on Aging). Dr. Albert's current projects include a study of worksite health promotion, modeling of vaccine refusal across the lifespan, and public health surveillance of the end of life. He has completed research on attitudes toward health promotion in culturally insular communities, challenges in assessing quality of life in people with cognitive impairment, and cognitive factors in medication adherence. In 2010-2014, his group is leading a statewide comparative effectiveness trial of primary prevention of falling in old age (Centers for Disease Control and Prevention) and an investigation of functional trajectories at the end of life (National Institute of Nursing Research). His ongoing studies involve medication reviews among older adults in senior housing (The Pittsburgh Foundation) and use of nasal ventilation (ALS Foundation).

During 2009-2011, Dr. Albert was the Secretary/Treasurer of the Behavioral and Social Sciences section of The Gerontological Society of America. He serves on the editorial boards for the *Journal of the American Medical Directors Association*, *Internet Journal of Mental Health*, *Preventive Medicine*, and *Journal of Aging Studies*. He is also a reviewer for the *Journal of Gerontology*, *The Gerontologist*, *American Journal of Public Health*, *Journal of the American Geriatrics Society*, *Neurology*, *Journal of Aging and Health*, *Journal of Cross-Cultural Gerontology*, *Journal of the American Medical Association*, and *Neuroepidemiology*.



Laura Bix, PhD

Laura Bix started at the School of Packaging at Michigan State University in January 2002, after receiving her PhD from the university the previous year. Specializing in medical device and pharmaceutical packaging, she teaches classes and conducts research.

In 2007, Dr. Bix was appointed as the United States delegate to ISO TC 122 WG9, a group that is creating global standards for accessible packaging design. In the United States, she has served as the Vice Chair of Committee D10.32; the Committee on Consumer, Pharmaceutical, and Medical

Packaging from 2004-2008; and has been a member of Committee F-02.

In recognition of her work, Dr. Bix was named one of the medical device industry's 100 most influential people by *Medical Devices and Diagnostics Industry* magazine in 2008. She currently serves on the editorial boards of the *Journal of Testing and Evaluation* and *Pharmaceutical and Medical Packaging News* and on the advisory boards of *Shelf Impact!* and *Medical Device Developments*. She is a member of the Include Network (RCA, UK) and of the Centers for Disease Control and Prevention's Protect and Protect Rx Initiatives.



Mary M. Bridgeman, PharmD, BCPS, CGP, FASCP

Mary Bridgeman is a Clinical Assistant Professor at the Ernest Mario School of Pharmacy at Rutgers, The State University of New Jersey, and practices as an Internal Medicine Clinical Pharmacist at Robert Wood Johnson University Hospital in New Brunswick, New Jersey. She received her PharmD from the Ernest Mario School of Pharmacy at Rutgers and completed a pharmacy residency at Robert Wood Johnson University Hospital.

Dr. Bridgeman is a Board Certified Pharmacotherapy Specialist and a Certified Geriatric Pharmacist. At Rutgers, she is responsible for the coordination of the Self-Care and Home Care course. Her research interests and community outreach activities are focused on the promotion of the safe use of medications among older adults. Dr. Bridgeman is co-author of the monthly column "OTC Case Studies" in *Pharmacy Times*.

**Laura L. Carstensen, PhD**

Laura Carstensen is the founding director of the Stanford Center on Longevity and a noted expert on socioemotional selectivity theory, a life-span theory of motivation. She is the Fairleigh S. Dickinson Jr. Professor in Public Policy and Professor of Psychology. For more than 20 years, her research has been supported by the National Institute on Aging, and in 2005 she was honored with a MERIT award from the National Institutes of Health. With her students and colleagues, she has published more than 100 articles on life-span development.

Her current empirical research focuses on ways in which motivational changes influence cognitive processing. Dr. Carstensen is a fellow in a number of professional organizations including the Association for Psychological Science, the American Psychological Association, and The Gerontological Society of America. She has chaired two studies for the National Academy of Sciences, resulting in noted reports *The Aging Mind* and *When I'm 64*. She is a member of the MacArthur Foundation's Research Network on an Aging Society.

The recipient of numerous professional awards and honors, Dr. Carstensen has been selected as a Guggenheim Fellow, received the Richard Kalish Award for Innovative Research and the Distinguished Career Award from The Gerontological Society of America, as well as Stanford University's Deans Award for Distinguished Teaching. She received her BS from the University of Rochester and her PhD in Clinical Psychology from West Virginia University.

**Margaret Dyer-Chamberlain**

Margaret Dyer-Chamberlain is Senior Research Scholar at the Stanford Center on Longevity and Managing Director since January 2009. At the Center, she plays a key role in developing research and educational programs, securing funding for programs, assisting in cultivation of donors, and overseeing staff and consultants. She is co-editor of the Center's book *Independent for Life: Homes and Neighborhoods for an Aging America*.

Previously, Ms. Dyer-Chamberlain was Senior Director of Capital Planning and Space Management at Stanford University, with responsibility for leading the capital plan process, developing space guidelines for the campus, allocating space, and designing and conducting space planning and utilization studies. With the University Budget Office, she led Stanford's space charge program. Ms. Dyer-Chamberlain was formerly at Dartmouth College from 1989-2001, where she served as Associate Provost, overseeing facilities planning, community relations, the arts, and academic support functions. She has a BA from Smith College and an MALD from the Fletcher School of Law and Diplomacy at Tufts University.



Patricia J. Neafsey, PhD

Patricia Neafsey is a Professor in the Center for Health Intervention and Prevention and the School of Nursing at the University of Connecticut. She received her BS and MS in nutritional biochemistry from Cornell University and her PhD in pharmacology and toxicology from the University of Connecticut. She completed post-doctoral work in toxicology at Tufts University.

Dr. Neafsey's current research interests involve improving health literacy and identifying and reducing adverse self-medication practices in older adults. With funding from the Donaghue Medical Foundation, she and collaborators with expertise in visual communication design, gerontology nursing, and psychometrics designed and tested an interactive learning software program to enable older adults with hypertension to avoid Rx-OTC drug interactions. In a 6-week clinical trial, older adult users of the program, Preventing Medicine Conflicts, demonstrated increased knowledge and self-efficacy concerning potential adverse self-medication practices and reported fewer adverse medication behaviors compared with older adults receiving conventional care. The International Medical Informatics Society gave the research team a "Best of Medical Informatics" citation in 2003. She was the principal investigator on a 4-year NHLBI Health Literacy study to develop and test (formal usability tests, beta trial, and a randomized controlled trial in primary care settings) the next generation Personal Education Program (PEP-NG). The PEP-NG captures patient-reported self-medication behaviors on a tablet computer, analyzes information, and delivers personalized education content (including animations and interactive questions) applicable to the patient's behaviors. Summaries of the patient's self-reported symptoms, medication use (including frequency/time data), specific drug interactions, and corrective strategies are printed for the patient and available for the clinician in advance of the primary care visit. The University of Connecticut granted an exclusive license for the PEP-NG to AdhereTx Corporation in 2009. She is a co-founder of AdhereTx and serves on the board as principal scientist.



Michael S. Wolf, PhD, MPH

Michael Wolf is an Associate Professor of Medicine, Associate Division Chief of Research, and Director of the Health Literacy and Learning Program within the Division of General Internal Medicine, Feinberg School of Medicine at Northwestern University. Dr. Wolf is a cognitive/behavioral scientist and health services researcher with primary interests in adult literacy and learning, cognitive factors, medication adherence, and the management of chronic disease. A former Fulbright Scholar to the United Kingdom, he has received numerous national awards for his work in the field of health literacy, medication safety, and adherence.

Dr. Wolf has written over 125 peer-reviewed publications, many of which address the problem of limited health literacy. He currently serves on many advisory committees for the U.S. Food and Drug Administration, U.S. Pharmacopeia, Agency for Healthcare Research and Quality, and National Institutes of Health. He has repeatedly provided consultation on health literacy matters to the Institute of Medicine, American College of Physicians, American Medical Association, American Pharmacists Association, and Centers for Disease Control and Prevention. He is the principal investigator on grants from the National Institute on Aging, National Cancer Institute, Agency for Healthcare Research and Quality, McNeil Pharmaceuticals, Abbott Labs, among others. Dr. Wolf also led an Institute of Medicine white paper on health literacy and medication safety, and he is the principal investigator of a trial to test enhanced drug labeling and the use of visual aids to improve patient processing and understanding of medication instructions.



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James C. Appleby, RPh, MPH, is Executive Director and Chief Executive Officer of The Gerontological Society of America (GSA). GSA is the nation's oldest and largest interdisciplinary organization devoted to research, education, and practice in the field of aging. The principal mission of the Society—and its 5,400+ members—is to advance the study of aging and disseminate information among scientists, decision makers, and the general public. GSA's structure also includes a policy institute, the National Academy on an Aging Society, and an educational branch, the Association of Gerontology in Higher Education. Prior to joining GSA, Mr. Appleby had a 17 year career with the American Pharmacists Association (APhA), the 60,000 member professional association representing pharmacists. He served in a variety of roles before being appointed Chief

Operating Officer and Senior Vice President of Business Strategy and Operations. In this capacity, he was responsible for managing APhA's multiple business units and served as the organization's senior executive responsible for relationships with the pharmaceutical, chain drug, and wholesaler industries. Prior to APhA, he was on faculty at the Philadelphia College of Pharmacy and Science. Mr. Appleby has worked as a hospital pharmacist at the Presbyterian—University of Pennsylvania Medical Center and Jeanes Hospital in Philadelphia. He holds a bachelor of science degree in pharmacy from the University of the Sciences in Philadelphia (formerly known as the Philadelphia College of Pharmacy and Science) and a master of public health degree from Temple University. Mr. Appleby is a member of the American Association of Colleges of Pharmacy, the American Pharmacists Association, the American Society of Consultant Pharmacists, the Drug Information Association, and the Washington DC Pharmacists Association.



Leonard M. Baum, RPh, is Vice President of Regulatory Affairs at Bayer HealthCare Consumer Care. He is a pharmacist by training with 35 years of drug development/regulatory experience. Prior to joining Bayer, he held regulatory positions with Aventis Behring, Hoechst, and Bristol Myers Squibb and was President and Chief Operating Officer of a publicly traded biotech company. During his career, Mr. Baum has been involved in a number of first-in-class approvals, including several medical imaging agents used as biomarkers. His start in industry began at Parke Davis/ Warner Lambert and he was involved in some of the early Rx-to-OTC switches including Benadryl, Benlynin, and hydrocortisone. Mr. Baum also has been active in various pharmacy and industry organizations over his career including the American Pharmacists Association, PhRMA, the US Pharmacopeia, and the Consumer Healthcare Products Association.



Marie A. Bernard, MD, is Deputy Director of the National Institute on Aging (NIA). Working closely with the NIA Director, Dr. Bernard oversees over \$1 billion in aging research conducted and supported annually by the Institute. As NIA's senior geriatrician, she is particularly interested in the translation of NIA research from the very basic laboratory to the bedside and community, and in the pipeline of future scientists. She co-chairs the Older Adults Workgroup and the Alzheimer's and Other Dementias Workgroup for Healthy People 2020. Dr. Bernard serves on the National Institutes of Health Task Force on Women in the Biomedical Workforce, co-chairing the Women of Color Subcommittee. She also serves on the Diversity Task Force and on the Bioethics Task Force. She serves as NIA's liaison to the American Federation for Aging Research, American Geriatrics Society, Department of Veterans Affairs (VA), and The Gerontological Society of America. Until October 2008, Dr. Bernard was the endowed professor and founding chairman of the Donald W. Reynolds Department of Geriatric Medicine at the University of Oklahoma College of Medicine. She concomitantly served as Associate Chief of Staff for Geriatrics and Extended Care at the Oklahoma City VA Medical Center. She has been President of the Association of Directors of Geriatric Academic Programs, President of the Association for Gerontology in Higher Education, Chair of the VA National Research Advisory Committee, and Chairman of the Clinical Medicine (now Health Sciences) Section of The Gerontological Society of America. Her research interests include nutrition and function in aging populations, with particular emphasis on ethnic minorities. She received her undergraduate degree in chemistry from Bryn Mawr College and earned her medical degree from the University of Pennsylvania. She trained in internal medicine at Temple University Hospital in Philadelphia, Pennsylvania, where she also served as chief resident. Dr. Bernard has received additional training through the AAMC Health Services Research Institute, the Geriatric Education Center of Pennsylvania, and the Wharton School Executive Development Program.



Frank Breve, PharmD, MBA, CCP, is President and Chief Executive Officer of Mid Atlantic PharmaTech Consultants LLC, a full-service consulting firm offering expertise in various clinical, regulatory, and legal aspects of multiple health care entities including, but not limited to, hospitals, long-term care facilities, dialysis centers, and surgical centers. He is also Clinical Assistant Professor at Temple University School of Pharmacy and serves as a consultant for Baxter Healthcare Renal Division (dialysis services) and Cardinal Health Medical Products and Services (home health care and hospice services) with offices in Swedesboro, New Jersey, and Baltimore, Maryland.

Carly Bushong is the Meetings and Education Manager for The Gerontological Society of America. She works with the Meetings Department to coordinate all planning aspects and on-site logistics of GSA's meetings and events including the Annual Scientific Meeting, as well as the Association for Gerontology and Higher Education's Annual Leadership Conference. A graduate of The University of Tennessee, Carly received a Bachelor of Science in Journalism and Electronic Media. She is a member of the International Association of Exhibitions and Events and Professional Convention Management Association.



Robert J. Chaponis, PharmD, FASCP, is Head of US Medical Affairs at Novartis Consumer Health. In this capacity, he leads and manages the US Medical Affairs team to support the company's commercial and scientific goals for pre-approved and marketed products. He is also responsible for overseeing the development, approval, and execution of medical communications to support medical brand strategies and tactics, the customer call center, and outcomes research initiatives. Before joining Novartis, Dr. Chaponis was Senior Director of Clinical Study Management at Pfizer Global Pharmaceuticals, where he directed the clinical study operations group for the US Medical Department. Prior to his tenure at Pfizer, he was Vice President of Research Services for The Center for Health Information, a consulting firm specializing in geriatric pharmaceutical care, research, publishing, and disease management. Previously, Dr. Chaponis was Medical Planning

Manager of Phase IV, Medical, and Scientific Affairs at Schering-Plough Corporation. He is a licensed pharmacist in the state of Pennsylvania.



Yanira Cruz, Dr PH, is the President and Chief Executive Officer of the National Hispanic Council on Aging (NHCOA). She focuses on providing the Latino perspective on public health and older adult issues to increase policy maker and public understanding of the needs impacting Latinos and disenfranchised sectors of society and to encourage the adoption of programs and policies that equitably serve everyone. To further these efforts, Dr. Cruz serves on the boards of the Consumer Health Foundation, the National Senior Citizens Law Center, and the American Society on Aging. Dr. Cruz is also an appointee serving on the Advisory Panel on Medicare Education, which advises the Secretary of the Department of Health and Human Services and the Administrator for the Centers for Medicare and Medicaid Services on opportunities to enhance the federal government's effectiveness in implementing a national Medicare education program.

She holds an adjunct faculty appointment at The George Washington University School of Public Health and Health Services. Before joining NHCOA, she served as Executive Director and Chief Operating Officer of the Hispanic-Serving Health Professions Schools (HSHPS) in Washington. She joined HSHPS after serving as Director of the Institute for Hispanic Health at the National Council of La Raza, where she led numerous public health programs to improve the health status of Latinos nationwide. Dr. Cruz received her bachelor of science in biology and holds a master of public health degree and a doctorate in public health with a specialty in global health from The George Washington University School of Public Health and Health Services.



David Dring is the Executive Director of Selfhelp Innovations at Selfhelp Community Services, a large, nonprofit social service agency in New York City. He is a social innovator in the aging services space and seeks to use technology to transform the experience of aging as well as the delivery of impactful services by professionals and family caregivers to older adults. Mr. Dring serves as a strategic advisor to governments and philanthropic organizations through his board role on the Interactive Aging Network. He is also a commissioner at Leading Age's Center for Aging Services Technology and a board member of Older Adult Technology Services, which recently launched the first technology driven senior center in New York City. Mr. Dring is a board member of the Institute for Medication Optimization, a new nonprofit venture to reduce medication-related problems especially among older adults.



Edwin Hemwall, PhD, is Vice President of Research and Development in Merck's Consumer Care Division, headquartered in Summit, New Jersey. He has devoted much of his career to studying how consumers use OTC medicines and interpret product labels as users or caregivers. He is a graduate of Pennsylvania State University (BSc) and Drexel Medical School (MS, PhD) in Philadelphia, Pennsylvania. Dr. Hemwall has worked in the pharmaceutical industry for almost 30 years, holding positions of increasing responsibility in clinical research, project management, and regulatory affairs. He is known as an expert in over-the-counter (OTC) drug regulatory affairs and switching prescription drugs to OTC status, most recently receiving Food and Drug Administration approval of OTC Oxytrol for Women to treat symptoms of overactive bladder.



Barbara A. Kochanowski, PhD, is Vice President of Regulatory and Scientific Affairs for the Consumer Healthcare Products Association (CHPA) and is responsible for activities including cooperative programs with the Food and Drug Administration, ingredient safety, and dietary supplement programs. She serves as a member of the association's senior management team. Prior to joining CHPA in 2009, Dr. Kochanowski worked for more than 23 years in research and development at Procter & Gamble Company (P&G), retiring in December 2008 as Director, Global Personal Health Care, Oral Care, and Feminine Care Product Safety and Regulatory Affairs and Corporate Microbiology. She is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, Rx-to-OTC switch, product safety, clinical research, and pharmacovigilance. While at P&G, Dr. Kochanowski was very active in CHPA activities, serving as chair of the Scientific Affairs Committee from 2007-2009, which brought with it an ex officio position on the CHPA Board of Directors for the same period. She graduated with a bachelor of science degree from Pennsylvania State University and earned a master of science and doctorate in nutritional sciences from the University of Illinois. Dr. Kochanowski is a member of the American Society of Nutrition. She also serves on the board of directors of the American Foundation for Pharmaceutical Education.



Gabriella Marie Landeros is a Communications Associate with the National Hispanic Council on Aging (NHCOA). Recently, she served as Deputy Communications Director and a Field Organizing Fellow for the Emanuel Pleitez mayoral campaign in Los Angeles. Her past experiences include reporting for the Talk Radio News Service, KUCR 88.3 FM, News at UCR: The Virtual Newspaper, and Uwire.com: The College Network. In addition, she has been a political reporter for the Independent Voter Network and a contributing writer for *Latinitas Magazine*. Ms. Landeros graduated from the University of California, Riverside with a bachelor of arts degree in media and cultural studies, concentration in film and visual media, and a minor in Spanish. She also studied at Universidad Carlos III de Madrid in Spain.

Salma Lemtouni is a Medical Officer at the Safe Use Initiative of FDA. Dr. Lemtouni worked at FDA for almost 11 years, seven of which as a reviewer at the Division of Cardiovascular and Renal Products. Before coming to FDA, Dr. Lemtouni worked in a variety of environments including device industry, academic research, and public health organizations. Dr. Lemtouni is currently working on a number of SUI projects, including the safe use of prescription and the OTC NSAIDs.



Mary Leonard leads marketing initiatives for the Consumer Healthcare Products Association (CHPA). She provides strategic direction to CHPA's overall comprehensive marketing plan and oversees the branding, design, development, copywriting, production, and distribution of materials for member-focused campaigns. Ms. Leonard's responsibilities cover the weekly and monthly member communications, promotional initiatives for CHPA's annual meetings, digital branding, and consistency for the association's web properties, and other marketing projects that enhance the visibility of CHPA programs. Ms. Leonard's expertise includes print, digital, direct, and social media marketing strategies. Prior to joining CHPA, she led the marketing initiatives for Associated Builders and Contractors and Healthcare Distribution Management Association, both trade associations in the Washington DC/Metro area. Ms. Leonard is a member of the American Marketing Association and the American Society of Association Executives.



Morris Lewis is Senior Director, Global Rx-to-OTC Switch at Pfizer Consumer Health. Morris began his career at Pfizer, Inc. in 2003, spending time leading Pfizer's Medicare Part D commercial effort from 2003 to 2008. Thereafter, until joining Pfizer Consumer Health in 2010, he led public affairs efforts across Pfizer's branded prescription medications. Prior to joining Pfizer, Morris spent 10 years consulting to the pharmaceutical industry, primarily around the topics of managed care and disease management; he also spent a number of years in other healthcare industry positions. Morris holds a Masters of Business Administration from the Wharton School of Business at the University of Pennsylvania and undergraduate degrees from Washington and Lee University.

Judie Lieu is the Senior Director of Innovation at The Gerontological Society of America (GSA). She is responsible for driving innovation across the Society including publishing, product development, and marketing activities. Ms. Lieu's previous experience includes working on patient education initiatives at the Allergy & Asthma Network, where she managed the organization's flagship newsletter and consumer magazine. Prior to GSA, Ms. Lieu managed all aspects of the development and production of high-level educational campaigns directed to health care professionals, such as the Self-Care Institute and Delivering Medication Therapy Management Services in the Community, at the American Pharmacists Association. Ms. Lieu holds bachelor of music and bachelor of arts degrees from Oberlin College and Conservatory in Ohio. She is a member of the American Management Association and the Kenyon Piano Quartet.



Beth Martin, RPh, PhD, has been on faculty at the University of Wisconsin School of Pharmacy since 1998. She earned her bachelor of science in pharmacy from the University of Wisconsin School of Pharmacy in 1990 and her master of science degree in 2003. She completed her doctoral degree with the Social & Administrative Sciences Division in 2006, with a minor in continuing and vocational education. Her research focuses on the design, assessment, and evaluation of professional education programming, with particular emphasis on the transfer of learning to practice. Dr. Martin's clinical expertise is in the areas of migraine headache, tobacco cessation, comprehensive medication reviews, and health behavior change. She uses her practice experience in community and managed care pharmacy and working with the older adult population to help shape her research initiatives and educational programs.



Commander Cathy A. Miller, RN, MPH, is a registered nurse and officer in the US Public Health Service; she has worked at the Food and Drug Administration (FDA) for the past 10 years. CDR Miller currently works as a Health Programs Coordinator in the Health Professional Liaison Programs of the Office of Health and Constituent Affairs engaging in communication outreach activities with health professional organizations, patient advocacy groups, and other stakeholders on FDA-related initiatives. She also serves on the safety team of the FDA MedWatch Program (adverse event reporting program), where she evaluates safety issues (safety communications, recalls, and safety labeling changes) for products and coordinates communications to the health professional community. Prior to her current position, CDR Miller worked for 4 years as a Safety Evaluator in the FDA Office of Surveillance and Epidemiology, Division of Medication

Error Prevention and Analysis, where she conducted pre-marketing and post-marketing safety reviews of drug labels and labeling, devices, patient labeling, proprietary name reviews, and other safety-related issues involving drug labeling. She started her career at the FDA working in the Advisors and Consultants Staff office, coordinating FDA Advisory Committee meetings, including the coordination of patient representative planning for service on the committees. Prior to entering into the U.S. Public Health Service, CDR Miller worked in the clinical setting as a critical care nurse, specializing in cardiac care. She received a bachelor of science in nursing from the University of Central Florida and a master of public health degree at George Washington University.

Danielle W. Nelson, MPH, is an Aging Services Program Specialist within the Administration on Aging at the Administration for Community Living (ACL). She holds a bachelor of science degree in human services from Virginia Tech and a master of public health degree and graduate certificate in gerontology from George Mason University. At ACL, Ms. Nelson's main area of focus is the broad array of evidence-based disease prevention and health promotion activities, ranging from behavioral health to medication management programs. Before joining ACL, she worked in long-term care for 10 years, including adult day care, Alzheimer's disease and dementia care, and program coordination within independent and assisted living. During this time she also served as a volunteer commissioner for the Fairfax County Commission on Aging.



Leslie Platt Zolov is Senior Director for US Public Affairs and Policy at Pfizer Consumer Healthcare. Her portfolio includes dietary supplements and Rx-to-OTC switches. She also oversees pain management and personal care. Ms. Platt Zolov began her career working in the Office of Congressional and Intergovernmental Affairs at the US Department of Labor. Prior to joining Pfizer Consumer Healthcare in 2012, Ms. Platt Zolov was an attorney in private practice where she provided business and strategic counsel to public health and other organizations.



Rachel Pruchno, PhD, is Director of Research, University Professor, and Endowed Professor of Gerontology at the New Jersey Institute for Successful Aging, University of Medicine and Dentistry of New Jersey (UMDNJ) School of Osteopathic Medicine. She earned her doctoral degree in human development and family studies at Pennsylvania State University in 1982; master of arts degree from Oakland University in 1979; and bachelor of arts degree from Michigan State University in 1976. Her prior positions include Director, Initiatives on Aging, Boston College; Director, Center on Aging, Bradley University; Director of Research, Menorah Park; and Associate Director of Research, Philadelphia Geriatric Center. Dr. Pruchno has been actively involved on the institutional

review boards (IRBs) of UMDNJ and Boston College (IRB Chair). She is currently editor-in-chief of *The Gerontologist*. She has served on the editorial boards of the *International Journal of Aging & Human Development* and *Journal of Gerontology: Psychological Sciences*. She has been a member of two standing National Institutes of Health (NIH) study sections (Mental Disorders of Aging, NIMH; Social Psychology, Personality, and Interpersonal Processes Study Section) and is a frequent ad hoc reviewer. She has been the Principal Investigator on NIH-funded grants totaling close to \$7 million as well as foundation grants of more than \$3 million. Dr. Pruchno has published more than 70 peer-reviewed articles and 10 book chapters. She is co-editor of the book *Challenges of an Aging Society: Ethical Dilemmas, Political Issues*.



Kristin Recchiuti, MBA, is Director of Medical Affairs, Advocacy, and National Partnerships at McNeil Consumer Healthcare. Ms. Recchiuti directs the consumer and patient education function in medical affairs and is responsible for educational initiatives intended to increase the safe use of medication and reduce preventable harm from medication misuse or errors. She has over 18 years of experience in consumer products across many disciplines including consumer sales, marketing, business development, and advocacy. She holds a bachelor of science in agricultural economics, food industry management from Cornell University and a master of business administration from Villanova University.



Marcel E. Salive, MD, MPH, joined the Division of Geriatrics and Gerontology National Institute on Aging in 2010. He oversees the research portfolio on multimorbidity treatment and prevention, polypharmacy, and comparative effectiveness. Dr. Salive has held leadership positions in the Centers for Medicare and Medicaid Services (CMS), National Heart, Lung and Blood Institute, and the Food and Drug Administration. From 2003-2010, he served as Director of the Division of Medical and Surgical Services within the Coverage and Analysis Group of CMS and was responsible for developing and maintaining national coverage decisions for Medicare beneficiaries using a rigorous and open evidence-based process. His work in developing Medicare coverage of new and innovative services was recognized with the Public Health Service Meritorious Service Medal in 2010. He has developed and led research initiatives in several areas including outcomes research, Alzheimer disease etiology, vaccine safety, and translation of clinical research into primary care practice. Dr. Salive is a Captain in the US Public Health Service Commissioned Corps, and is active in preventive medicine societies and boards. He earned chemistry and medical degrees from the University of Michigan and completed his preventive medicine residency and a master of public health degree at Johns Hopkins University.

Annette Schmidt is Senior Director of Strategic Alliances and Business Development at The Gerontological Society of America (GSA). She has over 20 years of experience in the health care/ pharmaceutical industry serving in a variety of positions that include field sales/management, training, brand and managed care marketing, national account management, advocacy, and alliance development. Her quest is to address challenging health care issues through collaboration and alignment of mutual goals across payers, patients, providers, industry, not-for-profits, and government. In her position at GSA, Ms. Schmidt is responsible for planning, developing, and implementing a comprehensive strategic alliance function focused on interdisciplinary stakeholder organizations across the broad aging enterprise. During her 10 years at Bristol Myers-Squibb, Ms. Schmidt received recognition for her teamwork, collaboration, and innovation. She developed a national training curriculum, *Understanding Medical Groups Today*, and conducted national workshops on the topic. At Sanofi-Aventis, she led internal cross functional development and implementation of the National Transitions of Care Coalition in partnership with the Case Management Society of America. In assessing unmet

health care needs of older adults, Ms. Schmidt focused on the goals of healthy aging for an aging society. Her efforts led to a unique public-private collaboration creating Community Connections to Aging Well in partnership with the National Council on Aging, The John A. Hartford Foundation, and Area Agencies on Aging. Ms. Schmidt holds a bachelor of arts degree in political science. Prior to joining the pharmaceutical industry, she was a consultant for the Chamber of Commerce of Northern California working as a business advocate on tax, housing, and environmental issues with city, county, and state government boards, agencies, and legislators.



Cate Sefton is Global Marketing Manager, Pain Management Category Team, at GlaxoSmithKline Consumer Healthcare. She is a marketing veteran with consumer and shopper marketing, sales, business analysis, and inventory management experience. Ms. Sefton has been involved in the consumer and shopper marketing of key global fast moving consumer goods, pharmacy, fashion, tourism, and alcohol brands, analyzing consumer and shopper behavior, developing key communication strategy to influence their purchase decisions for more than 18 years across numerous companies including her current position at GlaxoSmithKline as well as previously at Levi Strauss, Campbell's, and Pernod Ricard.



Jay E. Sirois, PhD, is responsible for regulatory and scientific affairs activities, including cooperative programs with the U.S. Food and Drug Administration, ingredient safety, and dietary supplement programs at the Consumer Healthcare Products Association (CHPA). Prior to joining CHPA in October 2011, Dr. Sirois was employed at Pharmaceutical Development Group as Director of Scientific Research and Clinical Studies. He is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, pharmacovigilance, Rx-to-OTC switch, product safety, and clinical research. Dr. Sirois is a member of the Regulatory Affairs Professionals Society and is an ad hoc reviewer for the journal *Neurotoxicology*.



Emily E. Skor leads the Consumer Healthcare Products Association (CHPA) Communications Department. She oversees and provides strategic direction for all external and member communications and ally development. She also oversees the CHPA Educational Foundation and serves as a member of the association's senior management team. Before joining CHPA in February 2011, Ms. Skor served as Senior Vice President at Dezenhall Resources, a nationally recognized crisis communications and issues management firm, where she counseled Fortune 500 companies and industry associations on communications issues that affect brand confidence and corporate reputation. She developed and managed comprehensive public affairs and public relations campaigns that included media, advocacy, coalition building, and consumer education. Prior to working at Dezenhall Resources, Ms. Skor worked at Cohn & Wolfe, a public affairs consultancy, and the Center for Defense Information, a nonprofit think tank. She serves on the board of directors for the National Council on Patient Information and Education and on the board of directors for the Madeline Island Music Camp.



R. William Soller, PhD, is Health Science Clinical Professor of Pharmacy at the University of California, San Francisco (UCSF) School of Pharmacy, and Executive Director of the Center for Self Care. Dr. Soller is a health policy expert and researcher who focuses on how medication therapy can better the lives of patients and consumers, in the clinic setting and at state and national policy levels. His work addresses gaps and seeks solutions on matters affecting safe and effective use of properly labeled medications, including effective health communications through drug labeling and telehealth, responsible self-care by consumers and patients, physician prescribing practices, and medication therapy management in patients with chronic diseases. Dr. Soller is published in peer-reviewed journals, and he is the principal author of over 100 submissions to government agencies, principally the Food and Drug Administration, on matters pertaining to drug safety, effectiveness and labeling, and Co-Editor in Chief of the journal *SelfCare*. His Center has funding from the National Institutes of Health, foundations, and pharmaceutical companies. Before joining the UCSF faculty, he received his doctorate in medical sciences from Cornell Medical College and was Assistant Professor of Pharmacology at the University of Pennsylvania School of Medicine, Vice President Scientific Affairs for Sterling Drug, and Senior Vice President of Science and Technology of the Consumer Healthcare Products Association.



David C. Spangler, Esq., is Senior Vice President, Policy, and General Counsel and Secretary for the Consumer Healthcare Products Association (CHPA). Mr. Spangler directs CHPA's legal affairs and international affairs, oversees association policy initiatives, and serves as a member of the association's senior management team. Mr. Spangler joined CHPA in 1984 as a legislative analyst. He subsequently served in a number of roles at CHPA in the president's office, project management, international affairs, and, after completing law school in 1995, the association's legal department. Mr. Spangler was named a Vice President in 1997 and a Senior Vice President in 2006. His responsibilities were expanded to include the legal function in 2011. Mr. Spangler serves on the board of directors of the World Self-Medication Industry. He is a member of the District of Columbia Bar as well as the American Society of Association Executives. He authored the chapter on over-the-counter medicines in *Modern Pharmaceutical Industry: A Primer* (Jacobsen and Wertheimer, eds., 2009) and is on the editorial board for The Food and Drug Law Institute's *Policy Forum*. Mr. Spangler earned his certificate in organizational management in 1991 from the US Chamber of Commerce's Institute for Organization Management.