



Optimal Aging  
Through Research

New Orleans • Louisiana

**GSA Annual  
Scientific Meeting**

NOVEMBER 20-24, 2013  
Sheraton New Orleans • New Orleans Marriott

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Optimal Aging  
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**OTC Medication Behaviors of  
Older Adults**

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## CHPA Mission




**Committed to promoting the role of OTC and Dietary Supplement products through Science, Education and Advocacy**

*serving the self-medication industry since 1881*






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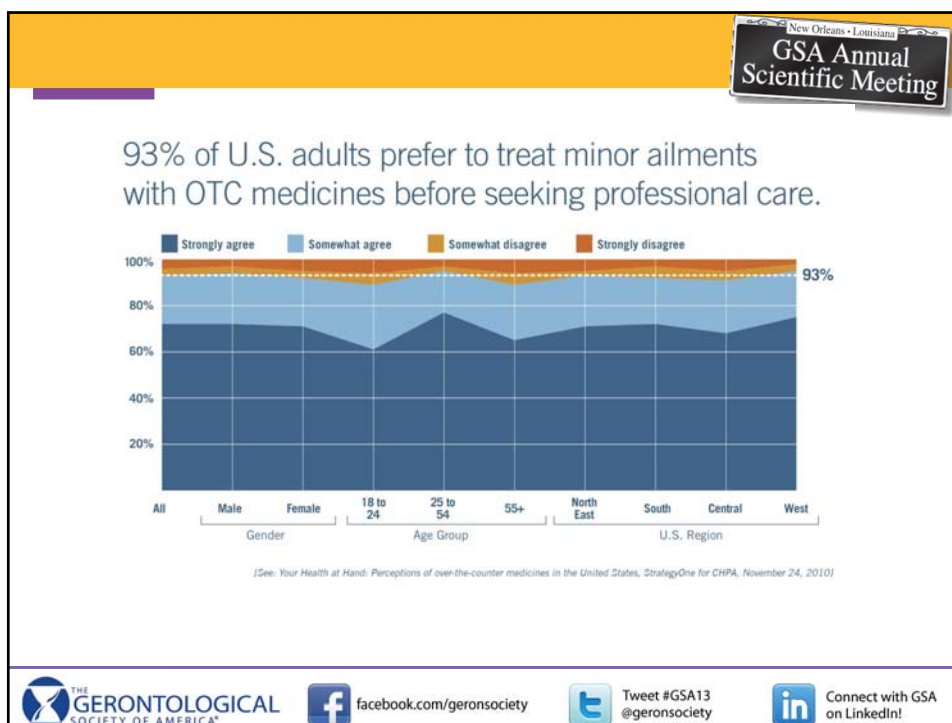
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## Self-Treatment Saves Time and Money



**...but consumers need to know how to use OTCs safely and appropriately**


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## Consumer Behaviors: Unintentional Misuse

1. Failure to read/follow the label
2. Not familiar with ingredients in the medicines they take
3. Take too much at one time
4. Take another dose too soon
5. Take multiple medicines with the same active ingredient
6. Failure to follow age-appropriate dosing/give adult medicines to kids


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## CHPA Educational Initiatives to Address Unintentional Misuse



**CHPA EDUCATIONAL FOUNDATION**


**OTCsafety.org**


**KnowYourDose.org**  
 Acetaminophen Awareness Coalition


 Put your medicines  
**up AND away**  
 and out of sight


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## CHPA Efforts


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Stay in Touch with OTCsafety







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# OTCsafety.org

**OTCsafety.org**  
Your Resource for Over-The-Counter Medicine Safety

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Your Resource for Over-The-Counter Medicine Safety

**OTC Treatments** **Active Ingredients** **Medicine Safety** **From the Experts**

**OTC Treatments**

- Allergy Medicines
- Asthma Medicines
- Cough Expectorants
- Cough Suppressants
- Multi-Symptom Cold Medicines
- Nasal Decongestants
- Pain Relievers and Fever Reducers
- Topical Pain Relievers

[view all treatments](#)

**Active Ingredients**

- Acetaminophen
- Aluminum Hydroxide
- Aspirin
- Benzocaine
- Bismuth Subsalicylate
- Cetirizine
- Chlorpheniramine
- Cimetidine

[view all ingredients](#)

**Treat**  
Parents: When do?

[Read more](#)

**Reading OTC Labels**

There is never guesswork about correct dosing with over-the-counter (OTC) medicines because every OTC medication has dosing instructions right on its label. The OTC label, known as the Drug Facts label, has specific instructions for safe use and should be followed precisely. Approved by the U.S. Food and Drug Administration (FDA), the directions tell you what amount of medicine to take, how to take it, when to take it, and when not to take it. If a label does not list dosing amounts for the person taking the medicine, call a doctor for advice on the best treatment options.

OTCsafety.org offers an interactive Drug Facts label to help you better understand and follow the directions on the label. [Scroll over the different sections to learn more about the various sections on the label.](#)

Drug Facts	
Active ingredient (in each tablet)	Purpose
Acetaminophen (325 mg)	Pain reliever
Aspirin (325 mg)	Pain reliever, fever reducer
Chlorpheniramine (4 mg)	Antihistamine
Diphenhydramine (25 mg)	Sleeping aid, allergy medicine
Doxylamine (12.5 mg)	Sleeping aid, allergy medicine
Ephedrine (24 mg)	Decongestant
Phenylephrine (10 mg)	Decongestant
Pseudoephedrine (30 mg)	Decongestant
Sedating antihistamine (1 mg)	Sleeping aid, allergy medicine
Non-sedating antihistamine (1 mg)	Allergy medicine
First Aid Antacid (1 mg)	Heartburn medicine
Second Aid Antacid (1 mg)	Heartburn medicine
Third Aid Antacid (1 mg)	Heartburn medicine
Fourth Aid Antacid (1 mg)	Heartburn medicine
Fifth Aid Antacid (1 mg)	Heartburn medicine
Sixth Aid Antacid (1 mg)	Heartburn medicine
Seventh Aid Antacid (1 mg)	Heartburn medicine
Eighth Aid Antacid (1 mg)	Heartburn medicine
Ninth Aid Antacid (1 mg)	Heartburn medicine
Tenth Aid Antacid (1 mg)	Heartburn medicine

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# Know Your Dose

**Cold And Flu Season Is Here**  
DOUBLE CHECK YOUR MEDICINE LABELS. DON'T DOUBLE UP ON ACETAMINOPHEN.

Americans catch **1 BILLION** colds per year

**7 in 10** Americans use over-the-counter medicines to treat cold and flu symptoms each year

**MORE THAN 600** over-the-counter and prescription medicines contain acetaminophen, including many for cold and flu symptoms

**NEVER TAKE 2** medicines that contain acetaminophen at the same time

CHOOSE ONE

TAKING MORE ACETAMINOPHEN THAN DIRECTED IS AN OVERDOSE AND CAN LEAD TO LIVER DAMAGE.

**Acetaminophen**  
is in more medicines than you might think

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## Specific Summit Goals

- Identify gaps in research
- Assess factors that influence choice of meds
- Examine contexts of OTC use
- Identify emerging technologies



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### Drug Facts

**Active ingredient (in each tablet)** Chlorpheniramine maleate 2 mg

**Purpose** Antihistamine

**Uses** temporarily relieves 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 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



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**Use of Prescription and Over-the-counter Medications and Dietary Supplements Among Older Adults in the United States**


**Dima M. Qato, PharmD, MPH, G. Caleb Alexander, MD, MS, Rena M. Conti, PhD, Michael Johnson, BA, Phil Schumm, MA, and Stacy Tessler Lindau, MD, MAPP**


**1 in 25 individuals potentially at risk  
for a major drug-drug interaction (JAMA, 2008)**



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**OTC med users significantly more likely to be  
adherent to Rx med regimen**


**Correlation between the use of “over-the-counter” medicines  
and adherence in elderly patients on multiple medications**  
*Int J Clin Pharm Oct 2013*



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## AGS BEERS CRITERIA FOR POTENTIALLY INAPPROPRIATE MEDICATION USE IN OLDER ADULTS

FROM THE AMERICAN GERIATRICS SOCIETY

**TABLE 1: 2012 AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults**

Organ System/ Therapeutic Category/Drug(s)	Recommendation, Rationale, Quality of Evidence (QE) & Strength of Recommendation (SR)
<b>Anticholinergics (excludes TCAs)</b>	
First-generation antihistamines (as single agent or as part of combination products)	<b>Avoid.</b>
<ul style="list-style-type: none"> <li>■ Brompheniramine</li> <li>■ Carbinoxamine</li> <li>■ Chlorpheniramine</li> <li>■ Clemastine</li> <li>■ Cyproheptadine</li> <li>■ Dexbrompheniramine</li> <li>■ Dexchlorpheniramine</li> <li>■ Diphenhydramine (oral)</li> <li>■ Doxylamine</li> <li>■ Hydroxyzine</li> </ul>	<p>Highly anticholinergic; clearance reduced with advanced age, and tolerance develops when used as hypnotic; increased risk of confusion, dry mouth, constipation, and other anticholinergic effects/toxicity.</p> <p>Use of diphenhydramine in special situations such as acute treatment of severe allergic reaction may be appropriate.</p> <p>QE = High (Hydroxyzine and Promethazine), Moderate (All others); SR = Strong</p>




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## FDA Safe Use Initiative



Taylor et al., *Curr Gerontol Geriatr Res.* 2012

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- GSA-CHPA National Summit on OTC Medication Behaviors of Older Adults
- Omni Shoreham, Washington, DC, April 10, 2013

  
**CHPA**  
CONSUMER HEALTHCARE  
PRODUCTS ASSOCIATION

  
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Summit Participants and Focus


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**46** attendees from **industry, academia, and practice** convened to evaluate current research on OTC medication behaviors in older adults and identify gaps in the evidence base

  
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## Goals of the Summit—Overall

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- Develop the science of OTC behaviors among older adults to promote safe and effective use of OTC medications
  - Recruit cadre of behavioral scientists with appropriate expertise to work in this critical and relatively neglected area



## Goals of the Summit—Specific

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- Identify **gaps in research** required to improve OTC medication behaviors of older adults
- Assess **factors that influence older adults' choice of OTC medications**, e.g., health literacy, vision, cognitive strategies, packaging
- Examine **contexts of OTC use**: role of clinicians and lay caregivers
- Identify **emerging technologies** that may support optimal OTC medication practices



Program

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## Presenters

- OTC Medication Patient Behaviors
  - Health Literacy (Michael Wolf, PhD, MPH)
  - Decision Making (Ruth Day, PhD)
- Contexts of OTC Knowledge and Use
  - Clinical Care (Elaine Leventhal, MD, PhD)
  - Lay Caregivers (Laura Gitlin, PhD)
- Technologies to Support Safe and Effective Use
  - Products (Chris Mayhorn, PhD; Patricia Meisner, MS, MBA; Anthony Sterns, PhD)
- Comment: M Dyer-Chamberlain, L Bix, M Bridgeman, S Albert, P Neafsey

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Summit Dissemination

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## Questions from Webinar

- Would making wording prominent by using bolding and colors be a good immediate solution to helping the OTC user identify risks?
- Any diagnostic yield to ordering acetaminophen levels on seniors who present with unexplained elevation of liver function tests?
- Any plans to collaborate with companies to allow pharmacists more time to interact with patients?
- What about low use of technology (e.g., smart phones) with older adults? SES differences?

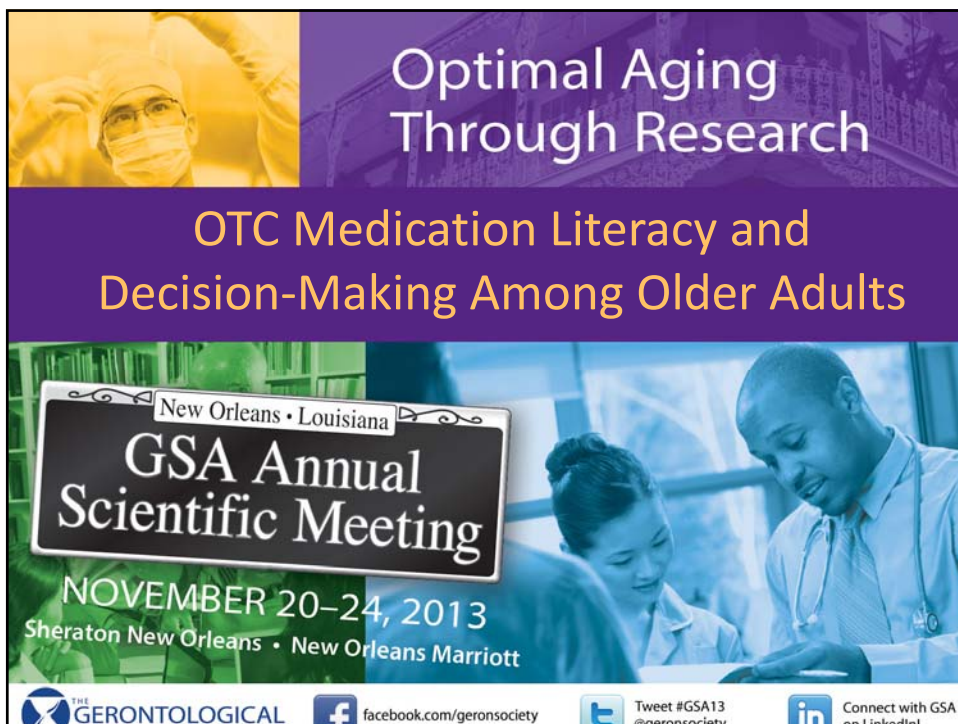


## Appraisal

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- “The Summit exceeded my expectations! From the collegial atmosphere, to the well-facilitated sessions, to actually feeling like we accomplished the goals set before us! Great work!”
- “The Summit was a great start, but there are major factors that were not addressed. The issue will need more than one day to address. It could be a semester course on its own at a university.”





# Optimal Aging Through Research

## OTC Medication Literacy and Decision-Making Among Older Adults

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# Health Literacy

“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

[http://www.nap.edu/download.php?record\\_id=10883](http://www.nap.edu/download.php?record_id=10883)

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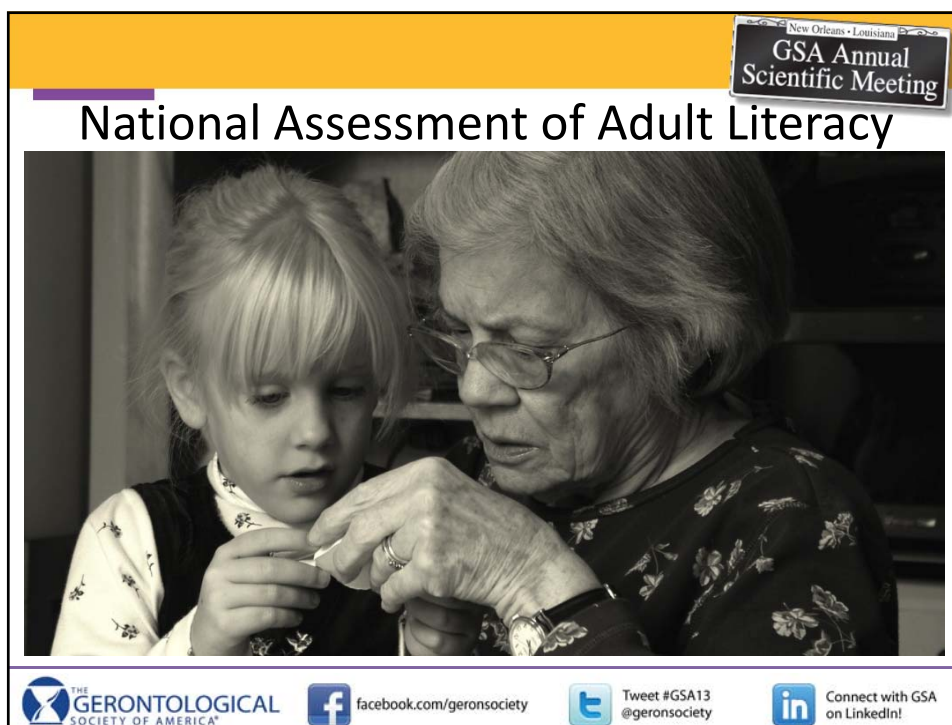
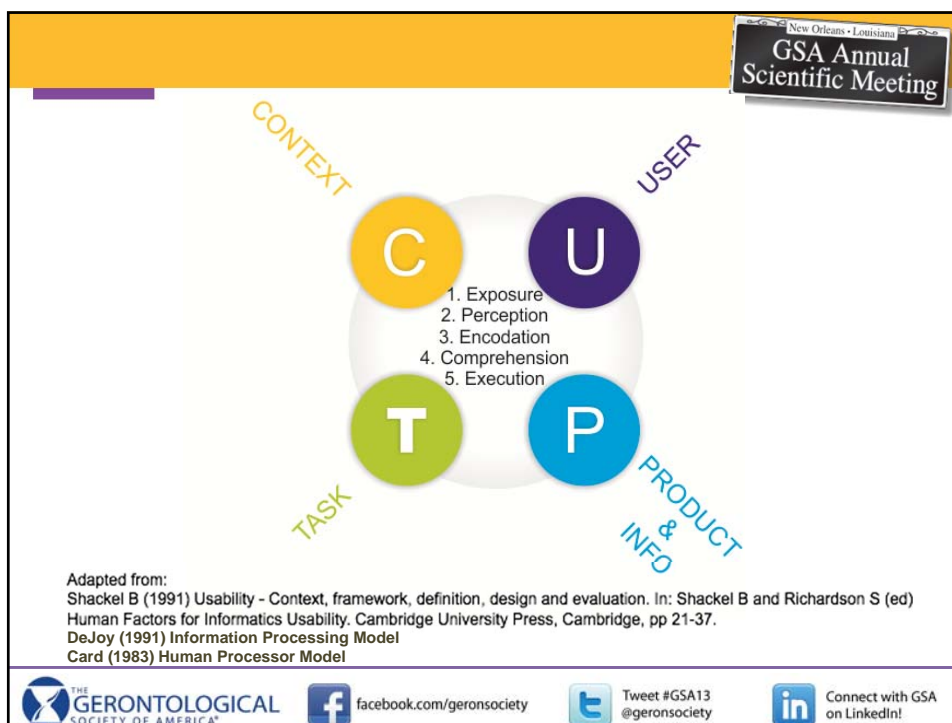
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- Meta-analysis 96 papers
  - Low health literacy
    - More hospitalizations
    - Greater use of emergency care
    - Lower receipt of preventive care (vaccination, mammography)
    - Poorer compliance with medication
      - Poorer ability to read and interpret labels
  - Lower health literacy among elderly persons to be associated with poorer health status and higher mortality rates



Berkman, ND; Sheridan, SL; Donahue, KE et al. (2011). Low health literacy and health outcomes: an updated systematic review. *Annals of Internal Medicine*. 155 (2). 97-107


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## Six Tasks Related to Taking an OTC

- Symptom recognition
- Self-selection
- Active ingredient
- Dosing
- Concomitant warnings
- When to stop?

Wolf, MS; King, J; Jacobson, K et al. (2012) Literacy, cognitive function and health results of the LitCog Study. *Journal of General Internal Medicine*. 2012, 27(12):1587-1593.


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## Complexity in Decision Making

Adapted from:  
**DeJoy D.** A Revised Model of the Warnings Process Derived from Value-Expectancy Theory. Human Factors Society 22nd Annual Meeting, Santa Monica, CA Human Factors Society; 1991: 1043-1047.

Shackel B (1991) Usability - Context, framework, definition, design and evaluation. In: Shackel B and Richardson S (ed) *Human Factors for Informatics Usability*. Cambridge University Press, Cambridge, pp 21-37.

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## Significant gaps in understanding with regard to information processing, decision making, OTC drugs and older consumers

de la Fuente, J. and Bix, L. (April, 2011). "A Tool for Designing and Evaluating Packaging for Healthcare Products." *Journal of Patient Compliance*. 1(1). Pp. 48-52.

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## We Do Know

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- Older adults are at increased risk for serious adverse drug events
  - Physiological changes
  - Polypharmacy
  - Increased potential for drug interactions
  - Inappropriate monitoring and prescribing of drugs in these populations



National Council on Patient Information and Education. Fact Sheet: Medicine Use and Older Adults. October 2010. Available at: <http://www.mustforseniors.org/facts.jsp> Accessed 11/6/13



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## We Do Know


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- Many consumers self-medicate improperly
  - 24% of adults took more than the recommended maximum dosage
  - 1/3 struggled with dose timing
  - 46% of participants used multiple products with the same active ingredient
- Many are under informed
  - Many do not examine the product labeling of OTCs
  - Unaware of the active ingredient in the pain reliever that they take


Wolf, MS; Jacobson, K, et al. (2012). "Risk of unintentional overdose with non-prescription acetaminophen products." *Journal of General Internal Medicine*. 27(12): 1587-1593.  
King, JP; Davis, TC; Bailey, SC; et al. (2011). "Developing consumer-centered, nonprescription drug labeling: A study in acetaminophen." *American Journal of Preventive Medicine*. 40(6): 593-596.




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## We Do Know

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WHAT IS KNOWN?


---

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


WHAT IS NOT KNOWN?  
(BUT COULD BE)

---


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




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## We Do Know

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# We need to know more



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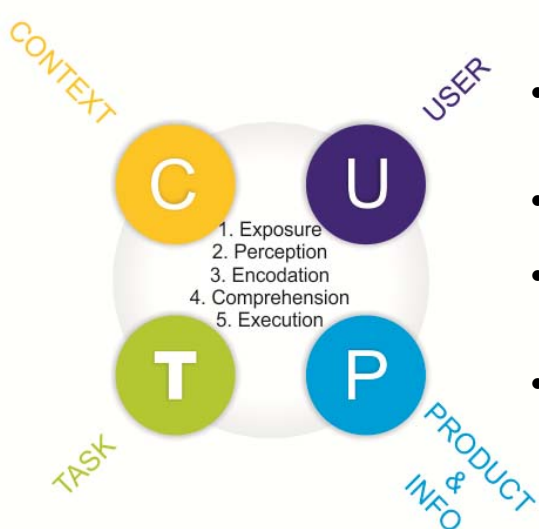


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## Needs



- Ascertain the profile of OTC medication use among older adults
- Improve the messaging regarding OTC products
- Provide education and training to all involved in the care of older adults
- Develop robust medical record system that can reliably obtain and track all medical records


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“While information alone will not ensure a secure patient, the corollary is more difficult to refute.... It is essential that individuals understand the nature of OTC medications, the consequences and benefits of compliance.”

Lumpkin, et al., 1990

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## Interventions to Promote Safe and Effective OTC Medication Use among Older Adults: Clinicians and Family Caregivers

M Bridgeman, SM Albert



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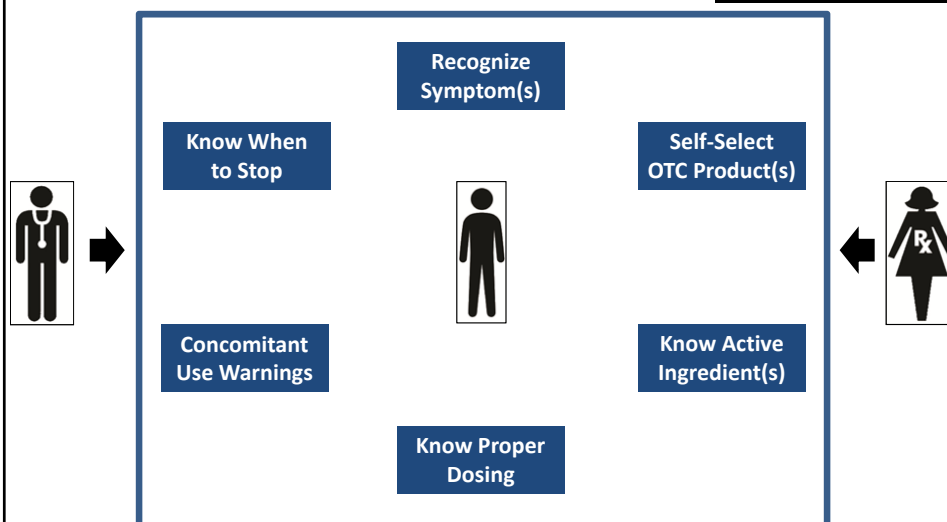
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### The Health Literacy Task of OTC Use

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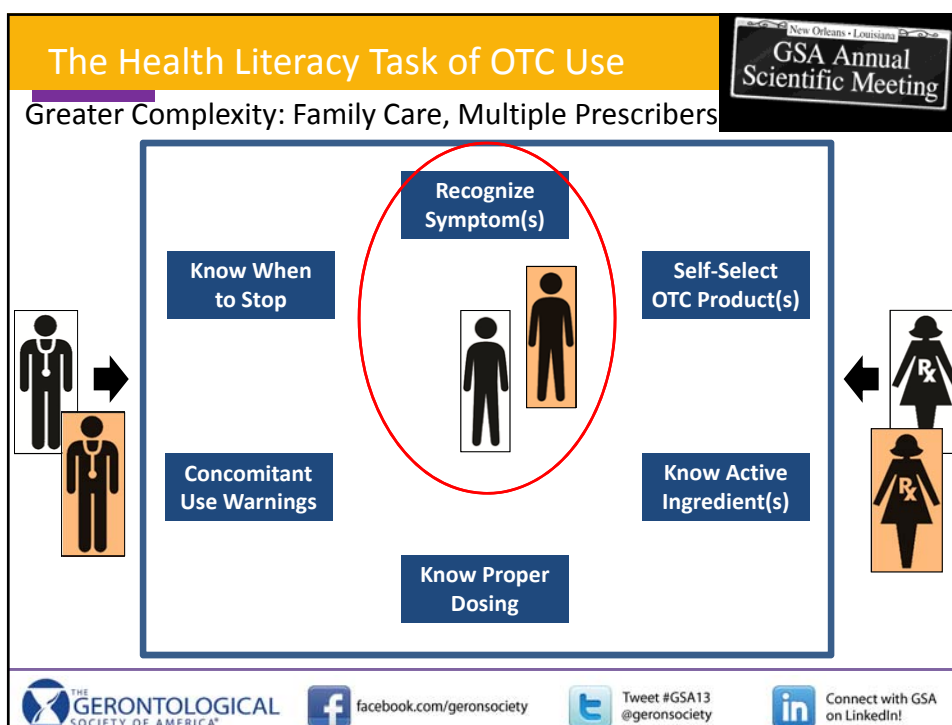
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## Differences—Older and Younger Adults

- Sources of information
  - Younger: more likely to rely on friends or family for information about OTC
  - Older: more likely to seek advice from pharmacist or other health care provider
- Response to direct-to-consumer marketing?
- Linking symptoms to courses of action and choice of OTC products?

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## Patients (and Caregivers) Rely on (Acute) Common Sense Model

- What is wrong?
- Am I sick? How bad is it?
- How can I alleviate symptoms?
- What worked in the past?
- Should I seek clinical care or handle myself?
- **NOT: Is it chronic condition or acute?**

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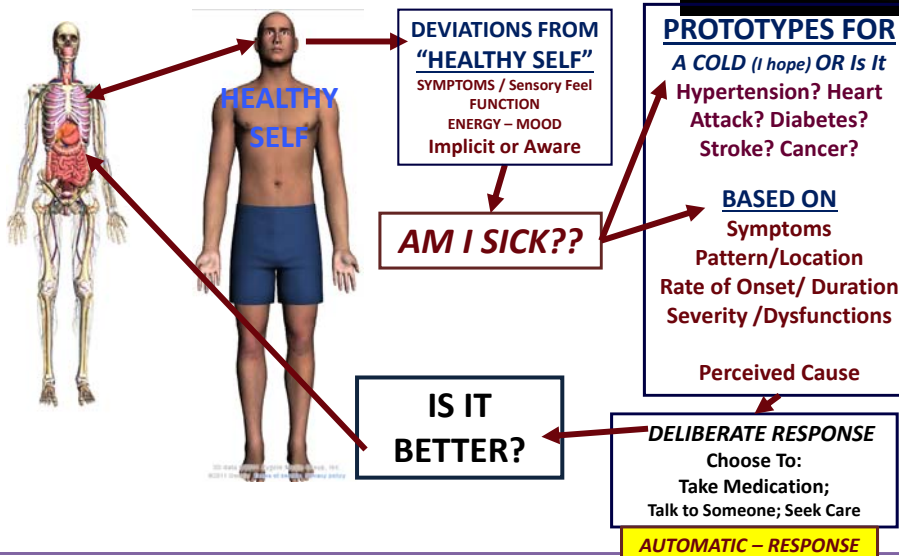
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## Chronic Responded to as if ACUTE

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## OTC Medication Behaviors

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If doctor says BP is silent (“you can’t tell when BP is high”), contradicting patient’s ACUTE, DEFAULT MODEL...

Adherence is lower



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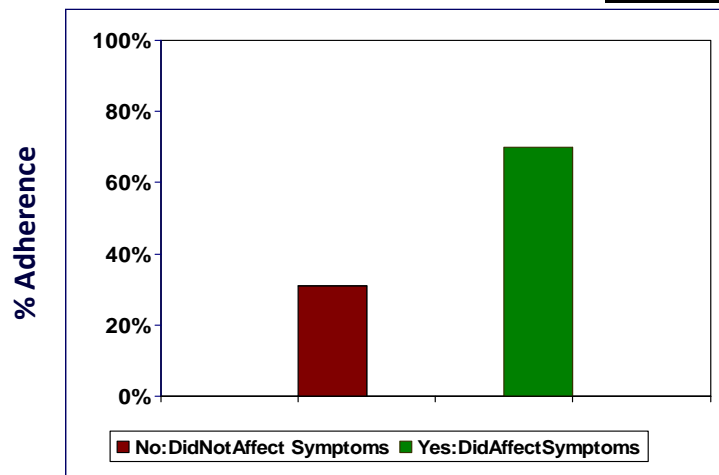
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## Medication Adherence—Treatment

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53% of compliers vs. 24% of noncompliers have blood pressure in good control

*Meyer, Leventhal, and Guttman, 1985, Health Psychology*



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## Miscommunication

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86% of patients believe their doctor is aware of all OTC medications they are taking regularly. But...

Only 46% reported that they routinely tell their doctor about these OTC medications...

UH OH

Serper et al. *Patient Educ Couns.* 2013

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## Key Message—1

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- Clinicians must ask questions about OTC use that will elicit, address, and change patients' misperceptions about medication use and illness
  - Communicate a rationale regarding need for treatment
  - Elicit and address concerns
  - Ensure regimen is as convenient and easy to follow as possible

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## Key Message—2

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- Clinicians need training solutions to elicit patients' use of OTC medications and record information in the patient health record
- Policy solutions may be needed to require addition of OTC medications to electronic medical records

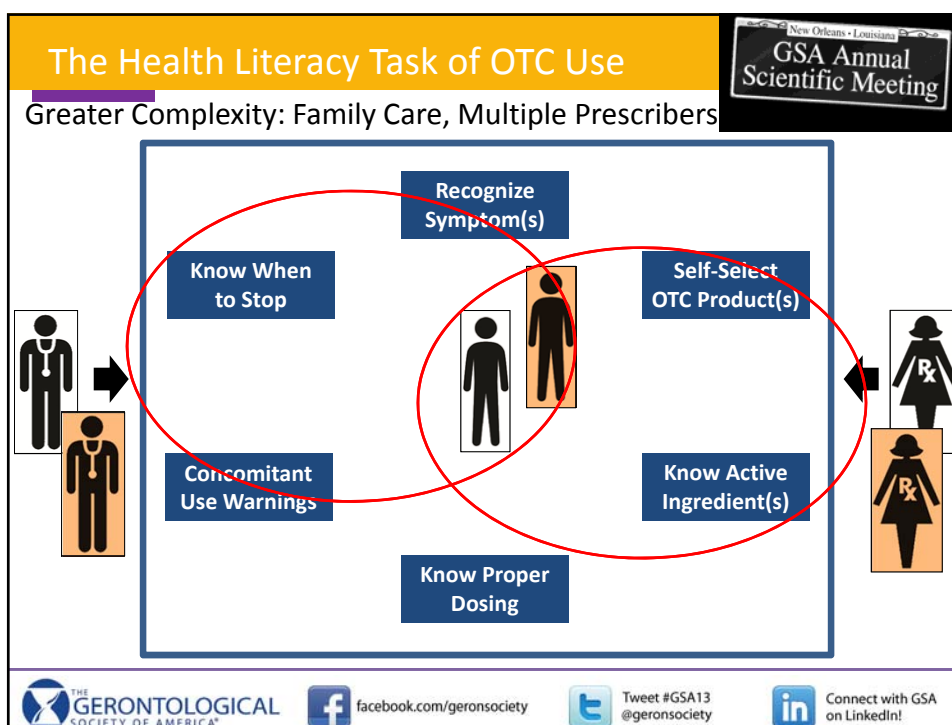


## Promoting Safe and Effective OTC Medication Behavior Through Interface With Family

LN Gitlin

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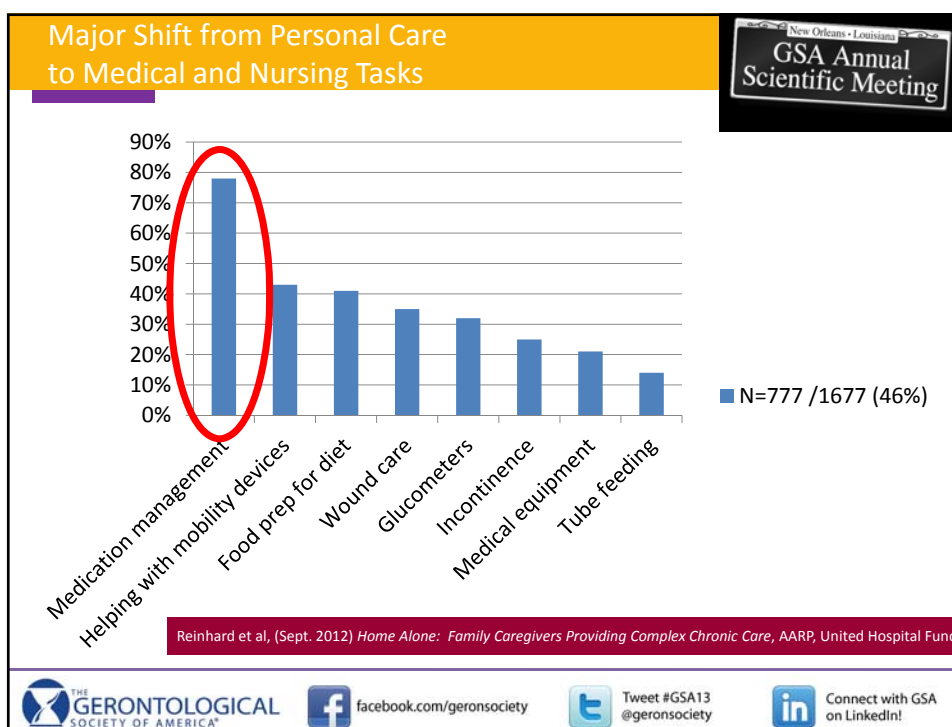
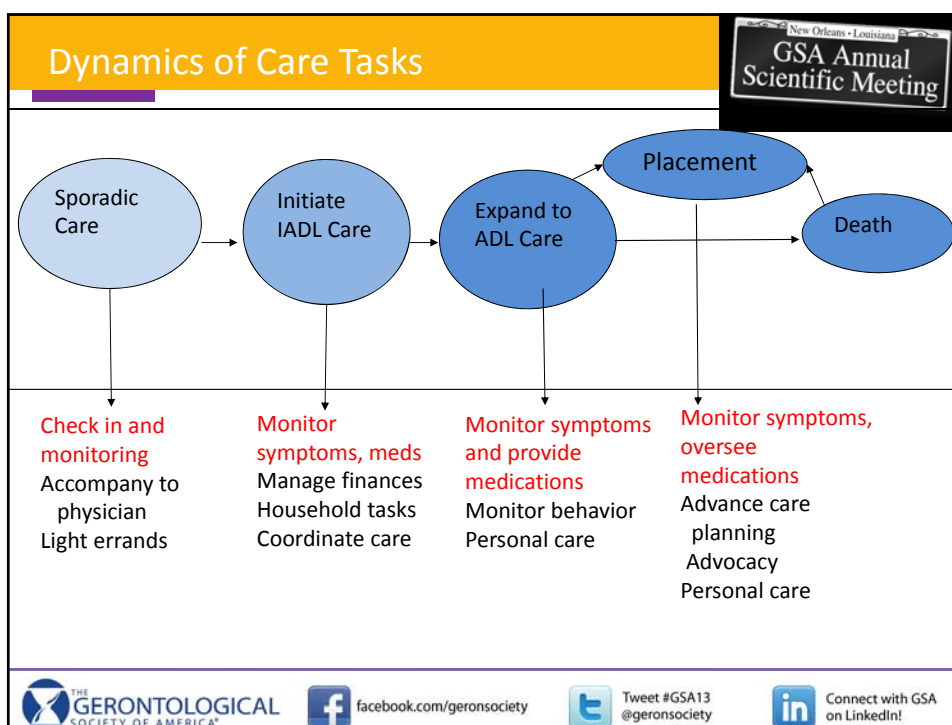


### Prevalence of Family Caregiving

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 -

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## Challenges

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The image displays three overlapping OTC drug labels for dextromethorphan. The labels contain various sections such as 'Drug Facts', 'Warnings', 'Directions', and 'Other Information'. The text is dense and uses different font sizes and bolding to highlight important information, which can be difficult for older adults to navigate and understand.

"Older adults may have ... trouble reading OTC labels"

Sansgiry and Cady, (1996); Braus, (1993); Holt et al, (1990)

Family caregivers may face similar challenges



## Dementia Care and OTCs

- 54% of caregivers actively involved in daily management of medications; in later stages 90% (Bradford)
- One third of patients take at least one inappropriate medication; 39% of caregivers also take one or more inappropriate medications (Thorpe)



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## **Developing New Interventions to Support Safe and Effective OTC Medication Behaviors**





PJ Neafsey, SM Albert

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### **Emerging Technologies**

- Smartphone apps
  - Point of purchase information
  - Personal health information
- SMS text messaging
  - Reminder systems
- Integrated databases
  - Integration of OTC meds with electronic health record

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## Emerging Technologies

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- Enhance accessibility to relevant information when and where it is needed
- Provide reminders when medication is due
- Alert patients to hazards
- Offer clinicians ways to monitor drug-taking behavior and reconcile medications in care transitions



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Ageing Int  
DOI 10.1007/s12126-010-9085-9

### Reducing Adverse Self-Medication Behaviors in Older Adults with Hypertension: Results of an *e*-health Clinical Efficacy Trial

Patricia J. Neafsey • Cyr E. M'lan • Miaomiao Ge •  
Stephen J. Walsh • Carolyn A. Lin •  
Elizabeth Anderson



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## Technologies

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### Challenges with Age

- Visual disorders (including color discrimination, glare, contrast sensitivity)
- Hearing loss
- Cognitive impairment
- Changes in tactile ability
- Willingness to use?



## Technologies

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### Challenges with Technologies

- Connectivity
- Interface design
- Miniaturization
- Expense
- Privacy



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## Integrated Databases

- Link data for medication management and reconciliation at the point of care
- Evidence-based rules identify risk and provide guidance to the health care team



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## Conclusions—Next Steps

- Key problems and solutions identified



## OTC Behavior in Old Age—1

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- **Key Problem:** Unintentional misuse
- **Potential Remedy:** Increase knowledge of active ingredient; move away from marketing to symptom; increase access to intermediaries (pharmacist)



## OTC Behavior in Old Age—2

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- **Key Problem:** Label complexity and sequencing; use vs. warnings
- **Potential Remedy:** Simplification; “chunking” of information



### OTC Behavior in Old Age—3

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- **Key Problem:** Common Sense models of health complicate chronic care; challenge to adherence
- **Potential Remedy:** Clinician elicitation of OTC medications as part of patient record; make patient partner for effective use of OTC



### OTC Behavior in Old Age—4

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- **Key Problem:** Lay caregivers are OTC gatekeepers without adequate guidance
- **Potential Remedy:** Caregiver interventions to enhance OTC knowledge



## Some Progress But More Work Ahead

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- What is optimal labeling for OTC medications?
- How do older and younger people differ in use of OTC medications?
- How to ensure optimal personalized OTC medication use for older adult?
- How to integrate OTC medications into medical management?
- How can lay caregivers support safe and effective OTC medication use?



## Thank You/Q&A

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[www.geron.org/otc](http://www.geron.org/otc)

- Webinar Power Point
- Webinar Recording
- Summit White Paper







The banner features a collage of images: a scientist in a lab coat and mask on the top left, and two healthcare professionals (a man and a woman) looking at a tablet on the bottom right. The background is a mix of purple and blue tones.


# Optimal Aging Through Research


## Questions


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