Optimal Aging Through Research

OTC Medication Behaviors of Older Adults

GSA Annual Scientific Meeting
New Orleans, LA
CHPA Mission

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

serving the self-medication industry since 1981

Self-Treatment Saves Time and Money

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

CHPA Efforts

CHPA Educational Foundation

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Your E-mail

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GSA 2013 Annual Scientific Meeting
New Orleans, LA
Specific Summit Goals

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

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
### 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

<table>
<thead>
<tr>
<th>Organ System/Therapeutic Category/Drug(s)</th>
<th>Recommendation</th>
<th>Quality of Evidence (QE) &amp; Strength of Recommendation (SR)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anticholinergics (includes TCA)</td>
<td>Avoid.</td>
<td>QE: High (Hydromazin and Promethazine), Moderate (All others); SR: Strong</td>
</tr>
<tr>
<td>First generation antihistamines (as single agent or as part of combination products)</td>
<td>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. Use of diphenhydramine in special situations such as acute treatment of severe allergic reactions may be appropriate.</td>
<td></td>
</tr>
<tr>
<td>Brompheniramine</td>
<td></td>
<td></td>
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<tr>
<td>Carboxamine</td>
<td></td>
<td></td>
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<tr>
<td>Cetirizine</td>
<td></td>
<td></td>
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<tr>
<td>Clemastine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cypriolizine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Desloratadine (oral)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dextromethorphan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diphenhydramine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Doxylamine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydramine</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### FDA Safe Use Initiative

1. **(1)** Establish guidelines
   - (a) Create national guidelines present inpatient and outpatients
   - (b) Implement guidelines
   - (c) Establish guidelines
   - (d) Cross-functional training
   - (e) Whole-system training
   - (f) Training in medical school

2. **(2)** Prevent physician interaction
   - (a) Eliminate requirements
   - (b) Requiring across the spectrum
   - (c) Directing the training
   - (d) Cross-functional training
   - (e) Whole-system training
   - (f) Training in medical school

3. **(3)** Promotion of existing and new technologies
   - (a) Promotion of existing and new technologies
   - (b) Promotion of existing and new technologies

4. **(4)** Create a flexible decision support tool
   - (a) Individualized, user, higher-powered model
   - (b) Patient medical history decides
   - (c) Specific for NWAS age
   - (d) Incorporates activities of daily living

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Taylor et al., Curr Gerontol Geriatr Res. 2012
• GSA-CHPA National Summit on OTC Medication Behaviors of Older Adults
• Omni Shoreham, Washington, DC, April 10, 2013

Summit Participants and Focus

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.
Goals of the Summit—Overall

• 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

• 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

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

Summit Dissemination

- Conference Calls
  - July-Aug 2013
- Webinar
  - Sept 2013
- White Paper:
  - OTC Medication Behaviors of Older Adults: Research Is Needed to Better Understand and Promote Safe and Effective Use
  - June 2013
- GSA Annual Scientific Meeting Symposium:
  - OTC Medication Behaviors of Older Adults: Results from a GSA Workgroup
  - November 2013
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., smartphones) with older adults? SES differences?

Appraisal

• “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.”
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
Adapted from:

National Assessment of Adult Literacy

<table>
<thead>
<tr>
<th>Health Literacy Level</th>
<th>Definition</th>
<th>Percentage of Adults in the level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Below Basic</td>
<td>No more than the most simple, concrete literacy skills (locating identifiable information in short, uncomplicated prose)</td>
<td>14% 29%</td>
</tr>
<tr>
<td>Basic Simple</td>
<td>Simple everyday literacy activities (reading and understanding information in simple documents)</td>
<td>22% 30%</td>
</tr>
<tr>
<td>Intermediate</td>
<td>Moderately challenging literacy activities (locating information in dense, complex documents and using it to problem solve)</td>
<td>53% 38%</td>
</tr>
<tr>
<td>Proficient</td>
<td>Complex and challenging activities (integrating, synthesizing and analyzing multiple pieces of information in complex documents)</td>
<td>12% 3%</td>
</tr>
</tbody>
</table>
• 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

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

Complexity in Decision Making

Adapted from:


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

• 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:

We Do Know

• 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

We Do Know

WHAT IS KNOWN?

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

We need to know more
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

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

M Bridgeman, SM Albert

The Health Literacy Task of OTC Use

- Recognize Symptom(s)
- Self-Select OTC Product(s)
- Concomitant Use Warnings
- Know Proper Dosing
- Know When to Stop
- Know Active Ingredient(s)
The Health Literacy Task of OTC Use

Greater Complexity: Family Care, Multiple Prescribers

Recognize Symptom(s)

Know When to Stop

Self-Select OTC Product(s)

Know Active Ingredient(s)

Concomitant Use Warnings

Know Proper Dosing

Self-Select OTC Product(s)

Greater Complexity:
Family Care, Multiple Prescribers

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?
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?

Chronic Responded to as if ACUTE

DEVIATIONS FROM “HEALTHY SELF”
- SYMPTOMS / Sensory Feel
- FUNCTION
- ENERGY – MOOD
- Implicit or Aware

PROTOTYPES FOR
- A COLD (I hope) OR Is It
- Hypertension? Heart Attack? Diabetes?
- Stroke? Cancer?

BASED ON
- Symptoms
- Pattern/Location
- Rate of Onset/Duration
- Severity/Dysfunctions
- Perceived Cause

DELIBERATE RESPONSE
- Choose To:
  - Take Medication;
  - Talk to Someone; Seek Care

AUTOMATIC – RESPONSE

IS IT BETTER?
OTC Medication Behaviors

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

Adherence is lower

Medication Adherence—Treatment

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

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

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...

Key Message—1

• 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
Key Message—2

- 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
The Health Literacy Task of OTC Use

Greater Complexity: Family Care, Multiple Prescribers

Recognize Symptom(s)

Know When to Stop

Self-Select OTC Product(s)

Know Active Ingredient(s)

Know Proper Dosing

Concomitant Use Warnings

Prevalence of Family Caregiving

<table>
<thead>
<tr>
<th>Type of Recipient</th>
<th>Prevalence</th>
<th>Estimated Number of Caregivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>28.5%</td>
<td>65.7 million</td>
</tr>
<tr>
<td>Only child recipients</td>
<td>1.7%</td>
<td>3.9 million</td>
</tr>
<tr>
<td>Only adult recipients</td>
<td>21.2%</td>
<td>48.9 million</td>
</tr>
<tr>
<td>Both adult and child recipients</td>
<td>5.6%</td>
<td>12.9 million</td>
</tr>
</tbody>
</table>

National Alliance for Caregiving in collaboration with AARP -
Dynamics of Care Tasks

- Sporadic Care
  - Check in and monitoring
  - Monitor symptoms, meds
  - Monitor symptoms and provide medications
  - Monitor symptoms, oversee medications
- Initiate IADL Care
  - Accompany to physician
  - Manage finances
  - Coordinate care
  - Advance care planning
  - Advocate
- Expand to ADL Care
  - Light errands
  - Household tasks
  - Personal care
  - Monitor behavior
- Placement
  - Monitor symptoms
  - Personal care
  - Death

Major Shift from Personal Care to Medical and Nursing Tasks

- N=777 / 1677 (46%)

Reinhard et al. (Sept. 2012) Home Alone: Family Caregivers Providing Complex Chronic Care, AARP, United Hospital Fund
Challenges

“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)
Developing New Interventions to Support Safe and Effective OTC Medication Behaviors

PJ Neafsey, SM Albert

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
Emerging Technologies

• 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

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

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

Aging Int
DOI: 10.1007/s12126-010-9085-9
Challenges with Age

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

Challenges with Technologies

- Connectivity
- Interface design
- Miniaturization
- Expense
- Privacy
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

Conclusions—Next Steps

- Key problems and solutions identified
**OTC Behavior in Old Age—1**

- **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**

- **Key Problem:** Label complexity and sequencing; use vs. warnings

- **Potential Remedy:** Simplification; “chunking” of information
OTC Behavior in Old Age—3

- **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

- **Key Problem:** Lay caregivers are OTC gatekeepers without adequate guidance

- **Potential Remedy:** Caregiver interventions to enhance OTC knowledge
Some Progress But More Work Ahead

- 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

www.geron.org/otc
- Webinar Power Point
- Webinar Recording
- Summit White Paper