



GSA and CHPA National Summit
OTC MEDICATION BEHAVIORS
 OF OLDER ADULTS

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Over-the-Counter Medication Behaviors of Older Adults:

Research Is Needed to Better Understand and Promote Safe and Effective Use

Summary and Recommendations from The Gerontological Society of America and Consumer Healthcare Products Association National Summit on Over-the-Counter Medication Behaviors of Older Adults

CONVENED APRIL 10, 2013, IN WASHINGTON, DC



Introduction

Every day, 10,000 Americans celebrate their 65th birthday. The 2010 Census determined that 40.3 million people in the United States are 65 years of age and older, representing an increase from 35 million in 2000 and 31.2 million in 1990. Projections for 2020 show that the population aged 65 years and older will reach 55 million and by 2050 climb to 88.5 million.¹

While older adults comprise 13% of the U.S. population, they account for 34% of prescription drug use and 30% of nonprescription or over-the-counter (OTC) medication use.² Complicating the high rate of OTC medication use is the knowledge that older adults are at increased risk of serious adverse drug events associated with age-related physiological changes, polypharmacy, drug interactions, and inappropriate prescribing and monitoring of drug

therapy.² Furthermore, health literacy in the population of older adults is lower than in other adult age groups, which detrimentally affects health and health outcomes.^{3,4}

As life expectancy lengthens and the baby boomer population ages, concern about the use of OTC medications among older adults is escalating. These demographic trends underlie the need for more research to learn how older adults currently select and use OTC medications and for the development of education about the appropriate use of these products along with interventions that will safeguard the health of older adults.

The Gerontological Society of America (GSA), in partnership with the Consumer Healthcare Products Association (CHPA), called together experts from academia, industry, government, and medical practice to participate in the National Summit on OTC Medication Behaviors of Older Adults in Washington, DC, on



in partnership with



April 10, 2013. The goals of the Summit included a review of existing research regarding OTC medication use by older adults for the purpose of identifying gaps and prioritizing research needs to create solutions that ensure the safe and effective use by older adults. Areas of focus included OTC medication literacy, the perceptual and cognitive basis of OTC medication decision making, the interface between clinical and family care in OTC medication use, and technologies to support optimal OTC medication use.

Summit Objectives

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

The experts convened for the GSA and CHPA National Summit on OTC Medication Behaviors of Older Adults included academicians, clinicians, geriatrics specialists, psychologists, and entrepreneurs. Participants included experts in the fields of cognitive/behavioral science, health services research, nursing, packaging, preventive medicine, social science, pharmacy and pharmacology as well as professionals from pharmaceutical companies and the U.S. Food and Drug Administration (FDA). Following the

speakers' presentations, the participants assembled into working groups to identify and prioritize key questions and research needs based on issues raised in the presentations: health literacy, decision making, clinical care interface, family care interface, and technology. A listing of Summit participants, GSA and CHPA team members, and the workgroup that organized the agenda and facilitated the Summit is included in the Appendix.

The scope of concern regarding OTC medication use is underscored by the realities that adults aged 65 years and older:

- Use more prescription and OTC medications than any other demographic group.⁵
- Account for 30% of OTC medication use in the United States.²
- Are significantly more likely to experience an adverse drug reaction than younger adults.^{5,6}
- Account for 61.5% of emergency department visits associated with adverse drug reactions.⁷
- Are at high risk for adverse reactions from many common OTC products for pain, cough and cold, allergies, sleep, and gastrointestinal disorders.⁸
- Are 100 times more likely than younger adults to have a preventable hospitalization.⁹
- Are hospitalized three times more often than people of all ages—at a rate of nearly 34% for those 65 years and older compared with approximately 11.5% for all others.¹⁰
- Have difficulty understanding and acting on health information.²

Older Adults' Use of OTC Medications

Despite the striking statistics, there is surprisingly little information in the peer-reviewed literature about how older adults choose and use nonprescription medications. Gaps in knowledge include: How does OTC medication use differ from prescription medication use? How do attitudes surrounding choice and use of OTC medicines change as a person ages? How do different expectations for OTC and prescription medication use affect the behavior of consumers and providers?

Compared with prescription medications, is it easier or more difficult to ensure safe and effective use of OTC products?

The 2008 National Social Life, Health, and Aging Project examined the prevalence of both OTC and prescription medication use among adults aged 57 to 85 years old. Results of the survey showed that 81% of the respondents took at least one prescription medication (29% took five or more prescription medications concurrently); 42% used at least one OTC medication; and 49% used a dietary supplement. Of those taking a prescription medication, 46% also took an OTC medication.⁶

Age-related changes can impact a drug's safety and efficacy. Among these changes are reductions in liver and kidney function, which affect a drug's absorption and elimination; memory impairments, hearing loss, and visual difficulties that can make it difficult to understand and remember medication instructions; declines in weight, loss of body fluid, and increased percentage of body fat, which can alter the way drugs are distributed and concentrated in the body.²

Health Literacy and Decision Making Among Older Adults

Summit Speakers

Michael S. Wolf, PhD, MPH

Associate Professor of Medicine, Associate Division Chief of Research, Director of the Health Literacy and Learning Program in the Division of General Internal Medicine, Feinberg School of Medicine, Northwestern University

Ruth S. Day, PhD

Director of the Medical Cognition Laboratory at Duke University, Senior Fellow at the Duke Center for the Study of Aging

The Effect of Health Literacy on OTC Medication Use

The use of OTC medications is affected by multiple factors, including social, psychological, and economic issues as well as family support, caregiving scenarios, and other variables. Dr. Wolf reported that his review of research articles on these topics revealed a clear need to apply

state-of-the-art methods in behavioral social science, cognitive psychology, and neuroscience to determine which factors significantly impact the decision-making process and the multiple stages of medication usage (i.e., from selection to adherence).

The Institute of Medicine (IOM) defines health literacy as “the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.”¹¹ Without those abilities, individuals are likely to be less adherent to their medication schedules and more likely to require costly services such as visits to the emergency department or hospitalization. Low health literacy is also associated with medical errors and adverse events, which are responsible for poorer outcomes—especially in people with chronic conditions.¹¹ Besides reading skills, health literacy includes writing, listening, speaking, arithmetic skills for calculating dosing, and conceptual knowledge.¹¹

The 2003 National Assessment of Adult Literacy (NAAL) was the first large-scale study in the United States to measure health literacy. The study examined individuals’ ability to use literacy skills to read and understand written health-related information encountered in everyday life. The survey reported that adults in the oldest age group—aged 65 years and older—had lower average health literacy scores than adults in the younger age groups.³

NAAL categorized findings into four levels (Table). Whereas 36% of adults surveyed were deemed to have basic or below basic health literacy, 59% of individuals in the group over 65 years old scored at those low literacy levels. Correspondingly, a greater proportion of younger individuals were at the intermediate or proficient level—65% to 71% versus 41% of older adults.³

Dr. Wolf noted that lack of health literacy has been considered a communication problem and there is an ongoing need to present information in ways that enable individuals to make correct health-related decisions. Consequently, it is essential

Table. Health Literacy Levels of U.S. Adults

Health Literacy Level	Definition	Percentage of Adults in Level	
		All Adults	Adults ≤ 65 Years
Below basic	Has no more than the most simple and concrete literacy skills, such as locating identifiable information in short, uncomplicated prose	14%	29%
Basic	Can perform simple and everyday literacy activities, such as reading and understanding information in simple documents	22%	30%
Intermediate	Can perform moderately challenging literacy activities, such as locating information in dense, complex documents and using it to solve problems	53%	38%
Proficient	Can perform complex and challenging literacy activities such as integrating, synthesizing, and analyzing multiple pieces of information in complex documents	12%	3%

Adapted from Reference 3.

to know how individuals process the information available to them.

Epidemiological research has shown that one in five adults lack the cognitive and psychosocial skills to manage their personal health and conduct everyday tasks, including use of medications. The greatest risks occur in people over 60 years old, those with less than a high school education, racial/ethnic minorities, and those with multiple morbidities.³

A report on health literacy from the IOM stated that people with low health literacy understand health information less well, get less preventive health care such as cancer screenings, and use expensive health services such as hospital and emergency department care more frequently.¹¹

A 2011 meta-analysis of 96 peer-reviewed papers on health literacy found that low health literacy was consistently associated with more hospitalizations, greater use of emergency care, lower receipt of mammography screenings and influenza vaccine, poorer ability to demonstrate taking medications appropriately, and poorer ability to

interpret labels and health messages. The authors also reported that low health literacy among elderly persons was associated with poorer overall health status and higher mortality rates.¹²

Dr. Wolf reported that the measures used to define health literacy are highly correlated with cognitive function and he described results from his ongoing Literacy, Cognitive Function, and Health (LitCog) study suggesting that active learning abilities decline as people age.¹³ He also reported that similar findings related to active learning or cognitive traits were observed in research conducted by Denise Park, PhD, at the University of Texas. Despite these age-related declines in cognitive abilities, Dr. Wolf noted that older adults are still capable of learning.

The LitCog project has identified six tasks related to taking OTC medications:¹³

- Symptom recognition: do patients understand their conditions?
- Self-selection: why have patients decided to seek relief for their symptoms on their own?
- Active ingredient: do patients know the active ingredients of the many

OTC medications available for a particular condition (e.g., pain)?

- Dosing: do patients distinguish between prescription regimens and “use-as-needed” instructions for OTC products?
- Concomitant use warnings: do patients know the ingredients they need to heed because of warnings (e.g., acetaminophen users)?
- When to stop: do patients heed the maximum daily dose or duration of use warnings?

Unintentional medication misuse has been documented as occurring in different ways. In a study of OTC products containing acetaminophen, 24% of adults were found to take more than the recommended maximum dose. Approximately one third of self-treating people struggled with dosing timing, such as taking another dose too soon. In addition, 46% of study participants used more than one product with the same active ingredients.¹⁴ A small study found that many individuals do not routinely examine product label information—and in some cases, more than 50% of consumers are unaware of the active ingredient in the OTC pain reliever they are taking.¹⁵

Although a number of studies have documented the high readability of OTC medication labeling, the LitCog study suggests that marketing products for symptom relief and the availability of multi-ingredient products are root causes of potential misuse.^{13,15,16} When looking at available products, people focus on symptom relief, which is an appropriate part of selecting a product. However, when they see one product for cough and cold and another for congestion, they may use both without realizing that these products may contain the same ingredient, thereby increasing their risk of an overdose.

Lack of counseling as well as miscommunication with physicians also contribute to confusion for patients. While 86% of patients believe their physicians are aware of all the OTC medications they take regularly, only 46% report their OTC medication use to their doctors.¹⁶ Research about interventions to encourage

OTC medication counseling is needed to determine what it takes to prompt physicians, pharmacists, and other health care providers to talk to consumers about appropriate use of these products.

Dr. Wolf suggested three main target areas for interventions that can impact low health literacy: (1) improve health information, (2) improve spoken communication, and (3) redesign packaging. Research is needed to evaluate current interventions and to develop and test new ones.

The Health Literacy working group articulated the following key question and next steps to help better understand OTC medication use among older adults.

KEY QUESTION:

When communicating to consumers about the benefits and risks of OTC medications, is it better to continue to focus on symptoms or should the emphasis be on active ingredients? Changing the emphasis would require different marketing by retailers and different educational strategies.

NEEDS:

1. Ascertain the profile of OTC medication use among older adults, beginning with age.
2. Improve the messaging about OTC products.
3. Provide education and training for everyone involved (e.g., physicians, pharmacists, family caregivers) in the care of older adults.
4. Develop robust medical record systems that can reliably obtain and track all medications (prescription and OTC) that patients are taking.

The Decision-Making Process in Older Adults

Although previous research has provided some information about the factors that affect older adults’ decisions when selecting an OTC medication, there is limited evidence available in the public domain. Yet, according to Dr. Day,

Decisions for Using OTC Medications

- Should I get an OTC product?
- If so, which type of product?
- Which specific product?
- Should I select it myself?
- What are the risks?
- How much should I take?
- How should I take it?
- When should I take it?
- What shouldn’t I do while taking it?
- What should I watch for?

pharmaceutical companies have developed a significant amount of this information for submission to FDA when attempting to convert a prescription medication to one that is available as a nonprescription product (known as the “Rx-to-OTC switch”). She pointed out while there may be exceptions, this type of information is not typically published in the peer-reviewed literature. Dr. Day called on industry representatives to make their research findings and conclusions available to assist in helping older adults use OTC medications safely and effectively.

Dr. Day pointed out that decision making is complex. It is not just about cognition; it is also about perceptions and experiences. Presently, the responsibility for OTC medication decisions rests with the patient. OTC medications are safe and effective when used as directed. She noted that research should be designed to determine whether additional information and guidance can further improve the safe and effective use of OTC medications by older adults.

As Dr. Day described, there is some information available about certain aspects of decision making, such as demographic and social factors; however much more remains to be learned on a range of issues that affect older adults’ approach to medication use (Figure).

In reviewing the literature on medication decision making, Dr. Day learned that many existing research reports do not address the specific process that people use when making a decision to purchase an OTC medication—the steps they go through, whether they consider all of

the pertinent options, whether cost is a concern, and how much weight is given to each factor. She suggested that new research into the decision-making process needs to be more robust to provide actionable results. For example, she found that much of the existing literature states that older adults are slower. But, she asked, what does that mean? Is it a sensory deficit? Can't they adequately see the small print on the label? Is it because they do not comprehend what they are reading? Or, is it because they are being more thoughtful about their decision, going through more steps, or recalling prior experience?

A 2000 study examining the influence of age on the decision-making process found that older adults, in general, were slower than younger adults to review the information on the product label, were more likely to have used OTC medications, and were more organized in their searches for information.¹⁷

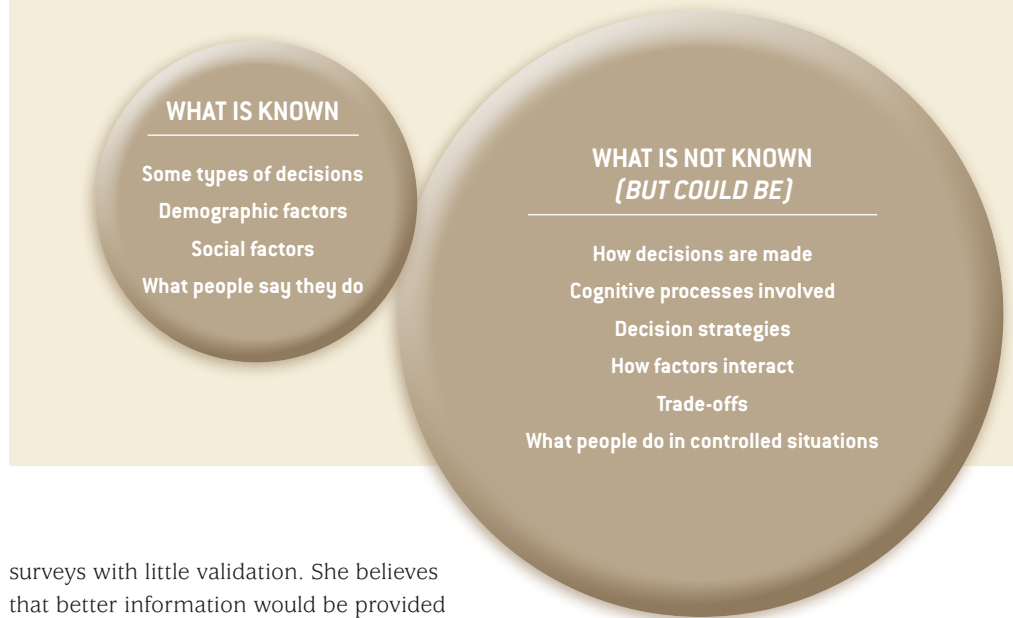
Another study comparing decision making between older and younger adults revealed that older adults took more time to search information yet looked at less information. They felt that side effect information was most important, while younger adults reported price as being important. Older adults said that health care providers and drug labels—particularly drug interactions and warnings—influence their decisions about OTC medications; younger adults were more likely to be influenced by friends and family.¹⁸

An earlier study reported that older adults preferred easier-to-open packages, wanted counseling by a pharmacist, and were concerned about side effects. Older adults did not like child-resistant packaging, while younger adults preferred it. Safety, strength, and price were rated very important by both groups.¹⁹

Revising the Drug Facts label is an ongoing process; while some improvements have been made, questions remain about the clarity of the information presented in terms of both readability and complexity. Furthermore, there are calls to improve the prominence of some of the information, such as the active ingredient, maximum daily dose, and warnings.^{15,17,20}

Dr. Day found that many of the earlier research studies relied on self-report and

Figure. Available Evidence on the OTC Decision-Making Process in Older Adults



surveys with little validation. She believes that better information would be provided if more sophisticated methods were used (e.g., search tasks, choice tasks), where the decision-making process can be observed and measured. Although some elements are known about OTC decision making, there remain unasked questions, underused methods, and processes that are not adequately understood.

At the Duke University Medical Cognition Laboratory, Dr. Day's research involves the difference between cognition and metacognition in relation to how people use medical information. Cognition describes the processes of knowing: perception, attention, comprehension, memory, problem solving, and decision making. Metacognition is knowledge about one's own cognition: what we think we know. Her studies reveal that there is a mismatch between cognition and metacognition. People overestimate what they think they know versus what they actually know. She said that more studies are needed on how cognitive decline is experienced by older adults, how cognitive decline affects OTC medication use, and what types of cognitive decline are linked to decision making.

Interventions on cognitive behavior and decision making must be designed and tested in a rigorous manner to demonstrate the impact they have on

health outcomes—specifically, whether they help to achieve the ultimate goals of reducing medication errors, decreasing adverse drug events, and improving disease or symptom outcomes.

The Decision Making working group articulated the following key question and next steps to help better understand OTC medication use among older adults.

KEY QUESTION:
OTC medication use, like prescription medication use, is complex. How can we present needed information more clearly and comprehensibly?

NEEDS:

1. Develop fundamental insight into decision making to clearly understand which factors drive decisions in order to design and optimize systems that deliver information effectively.
2. Determine the factors that influence sound decision making and ascertain how to build a system to implement the process.
3. Synthesize information from the public domain and from pharmaceutical companies' Rx-to-OTC

switch product documents concerning factors used in OTC medication decision making, particularly with regard to self-selection.

The Role of Professional and Lay Caregivers in OTC Medication Use Behavior

Summit Speakers

Elaine A. Leventhal, MD, PhD

Professor of Medicine, Robert Wood Johnson Medical School

Laura N. Gitlin, PhD

Professor, Department of Community Public Health, School of Nursing; Professor, Department of Psychiatry and Division of Geriatrics and Gerontology, School of Medicine; Director, Center for Innovative Care in Aging, Johns Hopkins University

Whereas younger people are more likely to rely on their friends or family for information about OTC medications, older adults are more likely to seek a learned intermediary such as a pharmacist or other health care provider. When examining the influence of others on OTC medication use and decision making, it is important to differentiate the perspectives of professional clinicians from those of family caregivers.

Interface With Clinical Care

Consumers' health care decisions have become more complex in recent decades due to the amount of information available to them, including direct-to-consumer marketing and the expansion of health information available on the Internet. Thus, the urgency to understand how

Common Sense Model of Decision Making²¹

Patients' actions are guided by their:

Perception and beliefs about their general health and their illness

and

Knowledge of what actions they can take.

patients approach medication use and self-care has intensified.

Dr. Leventhal suggested that clinicians can play a major role in helping older adults in their decision making regarding many health-related behaviors, including use of OTC medications. However, health care providers require a better understanding of that process to effectively assist their patients. Providers need to understand the common mechanisms behind the health and illness behaviors of patients, and they must be aware of the thinking of older adults who engage in self-care selection and treatment.

Research has shown that patients base their decisions on common sense. The prototype of the healthy self—specifically, how one feels and functions physically and cognitively—is constructed by experiences built upon pre-existing neural networks. It is “hard wired” into the brain.

Dr. Leventhal, who participated in the development of the Common Sense Model of the cognitive, behavioral, and affective processes for common sense self-management, noted that the model explains the illness behaviors that patients adopt based on their perceptions of symptoms and the best strategies to manage those symptoms. The role that drugs (including prescription and OTC medications as well as dietary supplements) play in patients' symptom management and selection choices needs definition.

The Common Sense Model can be applied to chronic conditions as well as minor acute illnesses such as colds, allergies, stomach aches, headaches, and rashes. These are the ailments for which self-management and choice of action often occur. When symptoms arise that are outside an individual's perception of the healthy self, the person must determine how to manage those symptoms. The person must consider whether it is serious and whether he or she has had the same symptoms previously. An individual's decision to use an OTC medication may well be influenced by prior experience.

Studies of patients with chronic conditions, such as heart disease and hypertension, have revealed that patients' understanding of their condition is often

erroneous. For example, a large number of patients being treated for hypertension believe they could tell when their blood pressure rises, when in fact there are no symptoms of elevated blood pressure.²²

Attitudes toward medications influence both prescription medication use and OTC medication choices. These attitudes range from recognition of the value of a medication to worries about long-term effects to fear of dependence to skepticism. Not surprisingly, adherence to treatment regimens is highest among those who truly believe the treatment is necessary.²³

The common sense approach is based on people's perceptions of what works and what does not work for them. Clinicians need to understand the patient's personal inclinations. The challenge is determining how to educate physicians and pharmacists to find out what their patients are doing.

Clinicians must ask questions that will elicit, address, and change patients' misperceptions. This can be done through both perceptual and practical approaches:²⁴

- Communicate a common sense rationale regarding the need for treatment, taking into account the patient's perceptions and expectations.
- Elicit and address concerns about potential adverse effects, including ways to manage them.
- Make the regimen as convenient and easy to follow as possible.

While there are interventions to assist clinicians in improving the safe and effective use of medications, these are focused primarily on prescription drugs. Dr. Leventhal concluded her presentation by calling for research that can determine the effectiveness of interventions for use of prescription medications and identify which of those interventions can be used for OTC medications. Additionally, training solutions are needed to remind health care providers to ask about their patients' use of OTC medications and then to record that information in the patient's chart or, ideally, in the electronic health record. Ultimately, policy solutions may be needed

Consumers' health care decisions have become more complex in recent decades due to the amount of information available to them, including direct-to-consumer marketing and the expansion of health information available on the Internet. Thus, the urgency to understand how patients approach medication use and self-care has intensified.



to require the addition of OTC medications to the health record.

The Clinical Care Interface working group articulated the following key question and next steps to help better understand OTC medication use among older adults.

KEY QUESTION:

What are the best ways to get OTC medication use information into the patient's electronic health record?

NEEDS:

1. Evaluate the effectiveness of mechanisms for delivery of information and stimulate research on which mechanisms work best for patient education.
2. Compare the effectiveness of physician education versus pharmacist education and evaluate the effects of those different mechanisms for delivery of health information across the continuum or transition of care.
3. Target specific product classes for older adults rather than trying to evaluate the entire OTC medication use issue (e.g., focus on pain, sleep aids, and treatment of gastrointestinal disorders).
4. Delineate education for clinicians on the key issues regarding older adults' use of OTC medications.

5. Investigate the importance of policy solutions and policy change; clinician behavior will not change unless there is a driving force behind the impetus for change. Consider whether regulatory changes or potential reimbursement drive behavior change in clinicians.

Interface With Family Care

Dr. Gitlin opened her presentation by noting that 80% to 90% of the long-term care for older adults is provided by family caregivers.²⁵ This group includes not only relatives, but also friends or neighbors who provide some form of assistance to an older adult with whom they have a relationship. Family caregiving is a global phenomenon that spans all racial and socioeconomic levels.

The use of family caregivers is expanding as the population ages. Moreover, our current health care system is based on the premise that there will be someone to help patients at home after they are discharged from hospitals. A 2009 study from the National Alliance for Caregiving and AARP estimates that 66 million people are acting as caregivers. Care recipients range across the spectrum of chronic conditions and mental illness; 22% of care recipients need assistance due to old age and Alzheimer's disease or cognitive decline.²⁵

Some form of assistance with medications is part of the vast array of family care tasks; it may occur episodically, in transition from

hospital to home, over time at home, or in transition to a long-term care facility. Medication-related care tasks range from sporadic monitoring of medications to increasingly intensive monitoring of symptoms and providing medications.²⁶ Family caregivers are involved in coordinating care, transporting to and from the medical center, attending doctor visits, communicating with professional health care providers, and advocating for the patient as well as guiding or making decisions about medications. They also are involved in collecting prescriptions from the hospital or pharmacy, purchasing OTC medications, deciding the dosage and timing for taking the medications, assisting in administering the medications (including opening the containers), and managing adverse events.²⁷

According to Dr. Gitlin, very few empirical studies address OTC medication management by lay caregivers. What little is known tells us that families have minimal knowledge about medication use, and caregivers report greater stress as medication management needs expand. Among caregivers of people with dementia, 54% are actively involved in the daily management of medications; in later stages of the disease, that number rises to more than 90%.²⁸

Similarly, Dr. Gitlin noted that very little is known about family knowledge of OTC medications and decision making concerning use of these products. A limited evidence base suggests that

families have poor knowledge of OTC medication adverse effects and risks. One recent study examined potentially inappropriate prescription and OTC medication use by patients with Alzheimer's disease. Results showed that 33% of patients were taking at least one inappropriate medication, and 39% of the caregivers were personally taking one or more inappropriate medications.²⁹

Family involvement in OTC medication use must be examined within the broader context of overall medication management and the complex care tasks and responsibilities that families assume. Dr. Gitlin presented research needs that can improve the safe and effective use of OTC medications by older adults with family caregivers:

- Population-based studies to identify knowledge of family caregivers concerning OTC safety hazards (e.g., overdosing concerns), active ingredients, and label warnings, and to determine the prevalence of potential misuse and overdose of OTC medications.
- Intervention studies to support family involvement in complex medication regimens and identify effective health information approaches.
- Development and testing of ways to educate family caregivers concerning potential safety hazards of using OTC medications and potentially inappropriate medication use.
- Workforce development studies to educate health professionals how to assess family knowledge of OTC medications and train families to safely assist with medications.

The Family Care Interface working group articulated the following key question and next steps to help better understand OTC medication use among older adults.

KEY QUESTION:

How should the OTC medication therapy review differ between the older adult and that person's caregiver?

NEEDS:

1. Collect OTC medication data in

national surveys and incorporate the information in educational modules that address medication use (prescription and OTC).

2. **Analyze which interventions work best; focus on transitions of care situations, where people are leaving the hospital and families are involved.**
3. **Incorporate OTC medication use into the patient health record, and provide ways for family caregivers to access the patient's health record.**

Technologies to Support Safe and Effective OTC Medication Use

Summit Speakers

Christopher B. Mayhorn, PhD

Associate Professor, Program Coordinator, Human Factors and Ergonomics Program, Department of Psychology, North Carolina State University

Patricia Meisner, MBA

Chief Executive Officer, ActualMeds Corp.

Anthony A. Sterns, PhD

Chief Executive Officer, iRx Reminder LLC; Visiting Associate Professor, College of Nursing, Kent State University

How Can Technology Improve Older Adults' OTC Medication Use?

Opening this segment of the Summit, Dr. Mayhorn asserted that well-designed, usable technology offers the potential to improve the medication behaviors of older adults. Emerging technologies bring opportunities to promote optimal OTC medication use behavior among all patients, including older adults. Technological interventions such as smartphone applications can enhance accessibility to relevant information for the user when and where it is needed, provide reminders when medication is due, and alert patients to hazards. They offer clinicians ways to monitor medication-taking behavior and to implement medication reconciliation solutions.

Dr. Mayhorn acknowledged that current commercially available technology has shortcomings: it primarily focuses on prescription drug use; connectivity with

mobile devices varies; the interface design is poor; and the devices are expensive. Furthermore, trends in miniaturization make the screens more difficult to read and the buttons/touchscreens more challenging for older adults to use.

It is generally known that aging brings some degree of visual disorders, hearing loss, cognitive impairment, and forgetfulness. It is not so well known that older adults have trouble discriminating between colors, are affected by glare, and experience changes in tactile ability. Motor function may become impaired. Many of these age-related changes affect older adults' ability to understand and effectively use technology. Older adults also are subject to distraction and may be confounded by complicated situations such as complex medication regimens.³⁰⁻³²

Dr. Mayhorn noted that newly developing technology products must overcome these issues. Furthermore, it is essential to recognize that "one size does not fit all." Technology must be developed in conjunction with human factors. Developers must consider their projected users' needs, and tailor interventions allowing users to have an experience that delivers relevant information applicable to them. New systems must be tested in terms of usability by older adults before such systems are deployed.³³ Finally, there must be assurance that older adults will actively choose to use the new technologies.³⁴

The group discussed two major technologies to pursue as solutions for promoting optimal OTC medication use in older adults: enhanced health records and smartphone applications.

Solution 1: Enhanced Health Records

Many older adults are on complex therapeutic regimens to treat multiple acute or chronic conditions. Appropriate use of these prescription medications can become even more complicated when people self-medicate with OTC products for pain, insomnia, or other common ailments. Likewise, 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

Technological interventions such as smartphone applications can enhance accessibility to relevant information for the user when and where it is needed, provide reminders when medication is due, and alert patients to hazards. They offer clinicians ways to monitor medication-taking behavior and to implement medication reconciliation solutions.

electronic health records or insurance claims, but often the most important piece of information—how the patient is using his or her prescription medications as well as any OTC medications or supplements—is missing.

Ms. Meisner suggested that one possible way to complete the missing information regarding both the medication regimen and patient adherence to the regimen is the integration of technology from multiple sources. Technological solutions can validate available information about each patient as well as identify and rank potential risks and thus present actionable information for use in medication reconciliation and development of a cogent action plan for the patient.

In her presentation, Ms. Meisner described a solution being developed by ActualMeds that is based on the findings of a National Institutes of Health (NIH) trial of a tailored intervention that reduced adverse self-medication behaviors and improved blood pressure control in older adults.³⁵ The system aims to enable medication management and reconciliation solutions to be used at the point of care by the health care team to assemble a patient's complete medication landscape and identify the associated risks. To accomplish these goals, data are combined from various sources of medication information and a structured interview is used 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, thereby enabling them to resolve risk and tailor

interventions for the patient at the point of care.³⁵

In designing medication management and reconciliation programs, Ms. Meisner noted that developers need to understand the differential risk added by OTC medications to the already complex therapeutic regimens of older adults. More research must be done to determine whether reducing the risk associated with self-medication behavior in older adults leads to better outcomes. Other studies must analyze whether enabling health care teams to reconcile and optimize therapeutic regimens at the point of care can increase the effectiveness of patient adherence programs.

Solution 2: Smartphone Applications

Although the U.S. health care information system is now incentivizing the use of electronic health record systems, these systems are still little more than paperless paper. They are generally closed systems and are focused on supporting the health care provider exclusively. In his presentation, Dr. Sterns explained that dynamic patient-centric systems are needed to identify changes in a patient over time, interconnect across all providers who care for the patient, and focus on self-management of the patient with mechanisms for support from health care professionals.

Dr. Sterns described the approach of iRx Reminder as a smartphone-based system designed to aid patient self-management of chronic illnesses. With NIH funding, the company developed a flexible software platform that allows for medication reminding, monitoring

(e.g., blood pressure, blood glucose), and educating patients (e.g., podcast videos). Older adults, ages 56 to 89 years old, have successfully used these applications and reported favorable responses to the technology.^{31,36,37}

According to Dr. Sterns, before technology solutions become widely adopted, continued research must document whether smart devices can be used to improve adherence for the complex therapeutic regimens of older adults. He noted that it is critical to identify key elements—and combinations of elements—that are necessary to achieve adherence in older adult patient populations. On a macro level, research must be done to validate the concept that smart device self-management monitoring tools that integrate with health care teams can make long-term patient treatment more effective and efficient.

The Technology working group articulated the following key question and next steps to help better understand OTC medication use among older adults.

KEY QUESTION: How can technologies be used in care transitions?

NEEDS:

1. Define the most effective points of intervention, especially when educating consumers and health care providers.
2. Evaluate which kind of technology is most suitable at the point of care.
3. Compare the accuracy of episodic risk assessment with longitudinal validation.

Risks and Costs Will Continue to Rise

No discussion of OTC medication use would be complete without information about the associated costs. According to a 2012 report on the value of OTC medications, use of these products saves the U.S. health care system more than \$102 billion annually—half by employer-based health insurance, one quarter by the Medicare and Medicaid health programs, and one quarter by individual patients.³⁸ Approximately \$30 billion of those

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savings are due to OTC medication use by older adults. Even when drug costs are transferred to patients, they save money because OTC medications generally cost less than prescription medications.^{38,39} The report also projects that without the availability of OTC medications, additional emergency department visits would drive up health care system costs by nearly \$4 billion each year.³⁸

Since 1976, more than 700 OTC products, involving 107 ingredients, indications, or dosage strengths have made the switch from prescription to nonprescription status. This transition has allowed increased availability of medications and lower overall health care costs.³⁹ Rx-to-OTC switches have led to significant cost savings for consumers (\$13 billion) and managed care organizations (\$20 million).⁴⁰

Further, an estimated \$200 billion in unnecessary emergency department visits and hospitalizations have been attributed to events in high-risk and older patients who lacked information and guidance regarding medications.⁹ If there are not advancements in older adult education and practice regarding OTC and prescription medication safety and adherence, the occurrence of medication errors and adverse events will continue to raise costs to the health care system through increased utilization of emergency care and hospitalizations.⁹

In addition to failing to resolve patients' symptoms, poor medication management for older adults is associated with increased risks of medication errors and adverse events. Older adults are at increased risk

of serious adverse drug events, including depression, confusion, hallucinations, malnutrition, and falls that are important causes of illness, hospitalization, and death among these patients.^{2,40} Drug-related complications have been attributed to the use of multiple medications and associated drug interactions, age-related changes, human error, and poor medical management (e.g., incorrect medications prescribed, inappropriate doses, lack of health care provider communication and monitoring).^{2,41} If patients cannot comprehend needed health information, attempts to improve the quality of care and reduce health care costs and disparities may fail.¹¹

Research Priorities and Needs

These practical solutions emerged from the GSA and CHPA National Summit on OTC Medication Behaviors of Older Adults as suggested next steps:

1. Work with NIH to identify funding announcements on OTC medication behavior in older adults; develop an NIH Request for Applications.
2. Ask gerontology journals to develop special issues and calls for papers on OTC medication use.
3. Improve documentation in national surveys of older adults or in the Centers for Disease Control and Prevention Behavioral Risk Factor Surveillance System.
4. Attempt to optimize standardized labeling of OTC medications so information is presented in a format that is easily accessible to the aging population.

Concluding the Summit, James Appleby, RPh, MPH, Executive Director and CEO of GSA, noted that this was the first meeting to bring together a diverse group of professionals from academia, industry, government, and medical practice to examine issues affecting how older adults use OTC medications. While there are some data available, much more needs to be generated to fully understand the issues and motivations regarding decision making. He challenged the individuals present to help their organizations prepare for the demographic shifts that are upon us. The challenge to all, he said, is to work

collectively to update some of the policies and clinical practice activities discussed. The priority is to change the research agenda to provide the answers that will help older adults use OTC medications safely and effectively.

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Appendix. Roster of Persons Attending the 2013 GSA and CHPA National Summit on OTC Medication Behaviors of Older Adults

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