

NC IOM TASK FORCE ON HEALTH LITERACY
DECEMBER 12, 2006
NC HOSPITAL ASSOCIATION

MEETING SUMMARY

WELCOME

Thomas J. Bacon, DrPH

Co-Chair

Executive Associate Dean & Director

NC Area Health Education Centers Program

J. Allen Dobson, MD

Co-Chair

Assistant Secretary for Health

NC Department of Health and Human Services

Dr. Bacon welcomed everyone to the meeting. The day's agenda focused on written and verbal communications that accompany medications and strategies the pharmaceutical industry can take to improve compliance with prescriptions. The speakers discussed prescription labeling, pharmacy regulation, and community pharmacists. There also was a presentation on resources that are available through the AHEC Digital Library and NC Health Info.

PRESCRIPTION DRUG LABELS: A CRITICAL REVIEW

William H. Shrank, MD, MSHS

Instructor in Medicine

Harvard Medical School and Division of Pharmacoepidemiology and
Pharmacoeconomics

We currently have a highly fragmented system of prescription drug labeling. The rationale for investing in high quality labeling is that better labels will improve adherence to medications by reducing confusion about medication regimens, enhancing understanding about disease and indications, and improving understanding about side effects. Better labels also could improve quality of care and decrease medication errors by helping patients follow instructions and identify inappropriate prescriptions.

The prescription drug label has four components: 1) the container label; 2) the consumer medication information (CMI), which is an auxiliary leaflet that consumers get at the pharmacy and is frequently stapled to the bag; 3) the package insert, which is the official product label that consumers sometimes pick up at the pharmacy and is a more technical document with a summary table; and 4) the medication guide, which the Food and Drug Administration (FDA) requires for medications that cause a significant health threat.

Consumers have to wade through all of this information to figure out what is relevant to them.

The system for creating and regulating these labels is quite fragmented. The content of container labels is governed by state law and the FDA; the format of container labels is controlled by software vendors and pharmacies. The content of CMI is controlled by data management companies and the format of CMI is controlled by software vendors and pharmacies. The content and format of package inserts and medication guides are controlled by the FDA and pharmaceutical manufacturers.

Dr. Shrank et al. conducted a literature review of 104 articles on prescription drug labels and doctor-patient communication about prescription drugs. The following CMI formats were associated with readability and understanding: list format, headers, bullets, white space, topics ordered logically, sans serif typeface, larger than 10-point font, 6th grade level language, short and simple sentences, less jargon, numbers as compared to prose. It was unclear if icons were helpful. There was no data linking CMI format to outcomes.

The following container label formats were associated with readability and understanding: headers and sections, lists, white space, large font size, and sans serif typeface. New bottle shapes may also improve readability and understanding. There was no data linking container label format to patient outcomes. On labels, patients prefer that the directions avoid vague terminology. They want the label to include information on: the benefits of the medication (i.e., the indication), warnings and possible side effects, suggested responses to side effects (e.g., when to call the doctor or to stop taking the medication), and the duration of the therapy.

To measure container label variability, Dr. Shrank et al. filled identically written prescriptions for Atorvastatin (Lipitor), Alendronate (Fosamax), TMP (Trimethoprim-Sulfamethoxazole), and ibuprofen at six pharmacies. They collected 85 prescription labels for evaluation. In terms of font size, the pharmacy name or logo was larger than the medication instructions, drug name, and warning stickers on most labels. In terms of items emphasized, only items used by pharmacists or identifying the pharmacy were in color, bold font, or highlighted. There was a lot of variability in the warning stickers on labels for the same medication. For ibuprofen, no warnings were present 33% of the time and none of the prescriptions were accompanied by a medication guide as required by the FDA. The literature review suggested that there is a lot of variability in the content of warnings and instructions and that prescription labels are not patient-oriented. On a positive note, some data exists to direct us in improving label formatting. Several factors may make this the right time to push for standardized label formatting: the Institute of Medicine report on medication errors; recent standardization successes of container labels (i.e., Nutrition Facts for food, Drug Facts for over-the-counter drugs; and Medication Guides); and the Medicare Modernization Act.

Comments/Questions

The discussion that followed began with questions about research into what information consumers are most likely to read. A handful of studies suggest that consumers read

CMI, but just when they receive the medication. The concern about distributing some low literacy parallel to CMI is that consumers will feel overloaded with information and pharmacists may be less likely to verbally counsel consumers. The discussion then turned to what an ideal label would look like. We need to use a common sense and patient-centered approach rather than a business approach to labels. First, we need to figure out what really needs to be on the label and get rid of everything else. The key items for patients (e.g., drug name, patient name, instructions, and warnings) need to be very visible. The stickering system does not make a lot of sense. The order and appearance of the information should be standardized. If consumers do not mind, we should add the indication of the medication on the label. Target has improved their prescription bottles by turning the bottle on its head and creating a larger and flatter surface area for information. The bottles have color rings to indicate which drugs belong to which family member, and there is a pocket for CMI.

HEALTH LITERACY ISSUES AND THE PHARMACIST

Jay Campbell, JD

Executive Director, NC Board of Pharmacy

Even patients who can read may have trouble understanding directions on prescription medications. Many patients, of course, cannot read at all. Even patients who do read well may lack an understanding of their drug therapy, its place in their treatment regimen, and the potential risks and side effects of prescription drug therapy. Governmental bodies—particularly the federal government—have responded to concerns about patient understanding of their drug therapy by mandating that more and more written material be provided with prescription medications (e.g., Medication Guides, Patient Package Inserts). The solution to health literacy is not more literature. The answer is not more information but smarter information, tailored to the needs of the particular patient.

There are several drawbacks to written information: more written information does not help patients who are illiterate or mal-literate, written information does little for non-English speakers, and the amount of written information can be overwhelming even for patients who read. Pictograms may be a better way to communicate with consumers. Some studies have shown that pictogram labels can substantially improve understanding of, and adherence to, prescription drug therapy. However, there are several barriers to using pictograms: there is a lack of standardized pictograms, it would be difficult to incorporate pictograms into the embedded systems, and it would be difficult to determine which patients would benefit from pictogram labeling.

The best way to communicate with consumers is most likely through pharmacy counseling. Pharmacists in every state are required by law to offer to counsel patients on their medications. According to 21 N.A.C. 46.2504, “patient counseling” shall mean the effective communication of information to the patient or representative to improve therapeutic outcomes. An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative.

Active counseling can achieve several literacy-related benefits. Counseling can identify patients with reading or reading comprehension problems. Through counseling, pharmacists can communicate critical drug therapy information in clear, easy-to-understand language tailored to the individual patient. Counseling also can prevent information overload brought on by excessive, poorly-tailored hand-outs. However, there are a number of barriers to effective patient counseling. Pharmacists may be resistant to counseling because they are too busy, they are uncomfortable with close patient contact, or they lack training in counseling techniques. Prescribers may be resistant to pharmacists counseling patients because physicians might complain that patient counseling interferes with patient-provider relationships. Another barrier to effective counseling is that the Board of Pharmacy's enforcement of the counseling requirement has been inconsistent over the years. In addition, third-party payers have been unwilling to recognize the health benefits of patient counseling and to provide monetary incentives for such activities.

There are special challenges when trying to counsel non-English speakers. Rule .2504 states that "counseling may be conducted by the provision of printed information in a foreign language if requested by the patient or representative." The burgeoning Hispanic population in North Carolina is probably being underserved on patient counseling. There have been efforts to improve pharmacy services to non-English speakers. Pharmacists are encouraged to learn Spanish: there are Spanish courses aimed specifically at pharmacists; pharmacists receive continuing education credit for language classes; and pharmacy school curricula have become increasingly sensitive to the issue. In addition, pharmacies advertise their language capabilities and reach out to leaders in non-English speaking communities. Polyglot Systems, Inc. is developing a multi-language computer-based tool for providing written and spoken drug therapy directions and counseling to patients.

Comments/Questions

The discussion that followed began with questions about what label improvements can be made without lots of resistance from retail merchants. The group talked about font size, deemphasizing certain information, and emphasizing other information as possible improvements. There is not going to be any change that is easy but that does not mean it should not be done. The discussion then turned to bringing stakeholders to the table earlier in the process of reform. At this point, it is easier to focus on changes at the state level than at the federal level. North Carolina could be a pilot test for national reform. Then, the group talked about the need for pharmacists to join together and challenge poor working conditions. The group discussed physical environment as a barrier to effective patient counseling. Finally, the group discussed the services that could be provided by pharmacy technicians and the regulation of pharmacy technicians.

COMMUNITY PHARMACISTS COUNSELING: HELPING PATIENTS UNDERSTAND THEIR PRESCRIPTIONS

Gina Upchurch, RPh, MPH

Executive Director, Senior PHARMA*ssist*

There are major public health concerns about seniors' medication use. Seniors make up roughly 13% of the total population and receive 34% of medications. There is underuse due to cost and under-treatment, and there is overuse due to polypharmacy and uncoordinated care. When a senior reports noncompliance, 30% of the time the prescriber changed the directions without writing a new prescription.

Seniors are at a greater risk for chronic illnesses, social isolation, and cognitive impairment. They are more likely to suffer from vision and/or hearing loss than other populations. Health literacy is a big challenge to serving older populations. Half of Durham residents 65 and over do not have a high school education compared to 16% of residents between ages 18 and 64 (NC Division of Aging, 1995).

Pharmaceutical care is complicated because many assumptions are made: medications have been prescribed correctly, medications have been dispensed correctly, medications have been administered correctly, and medications are being monitored routinely. Medication errors are prevalent because multiple prescribers means less gatekeeping, a shortage of pharmacists means more dispensing errors, and prescribers, pharmacists, and nurses receive little formal training in geriatrics. Pharmaceutical care is defined as the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life. It helps individuals obtain and correctly administer the medicines they need and avoid the ones they do not need. Pharmaceutical care requires education and coordination involving consumers, caregivers, and healthcare providers. There are two critical elements of pharmaceutical care: 1) creating community-based intake units that can help seniors sort through all of their options for prescription benefits and 2) identifying the most at risk seniors and providing comprehensive community-based medication therapy management and disease state management with trained pharmacists.

Interventions aimed at seniors need to include many strategies. A health literacy intervention in 1997 suggested that pharmacists should employ the following strategies: state the most important points first, use lay terms or teach vocabulary, leave out background and extraneous information, demonstrate techniques, use recall, use tailoring, simplify medication regimens, and make patients comfortable. One-on-one personal interaction is critical. It is important that health providers act as a team and share information across systems.

Senior PHARMA*ssist* provides medication therapy management, assistance with paying for medications, tailored community referral, and participant activation. Senior Pharm*Assist* has adopted several strategies to improve health literacy in the senior population. Counselors see patients every six months. They provide seniors with a

Medication Record to keep track of all their medications. They teach seniors to tell their provider, “Wait a minute, I have a few questions.” The program encourages providers to have patients explain information back to them to improve retention. Senior PharmAssist recommends that pharmacists not overload patients with information; instead, pharmacists should note comments in patients’ charts for their next visits.

Comments/Questions

The discussion that followed focused on the importance of supporting good relationships between medical providers and pharmacists. Doctors and pharmacists have to work together to make sure patients are getting appropriate medications. The discussion then turned to possible tools that might assist seniors in communicating with providers. It was determined that direct communication is the best way to improve patients’ understanding and compliance.

HEALTH SCIENCES LIBRARY: HELPING ADDRESS HEALTH LITERACY PROBLEMS

Diana McDuffee, MLS

Network Director AHEC Information and Library Systems

Christie Silbajoris, MSLS

Director, NC Health Info

Research shows that people are already using the internet to find health information. The PEW Internet and American Life Project reported that 60% of high school students and 91% of college graduates have access to the internet. E-NC found that in 2004 54% of North Carolina homes had internet access and 82% of those had access to hi-speed internet. The proportion of rural homes with internet access has doubled between 2000 and 2004. Currently, over three-quarters of North Carolina’s population have access to the internet. Eight out of ten internet users look for health information online. Even people with low health literacy are using the internet: 20% of individuals with below basic health literacy, 42% of individuals with basic health literacy, and 67% of individuals with intermediate health literacy.

The problem is that search engines return the most popular but not necessarily the most accurate or appropriate links. Nearly 70% of people believe that the health information they find online is correct. While many people are comforted by the information they find online, 22% report being overwhelmed and 18% report being confused.

The UNC Health Sciences Library selects and evaluates information resources based on the currency, scope, authority, and quality of sources. The library provides direct service to consumers and providers and supports UNC, AHEC, and other libraries and universities.

NC Health Info is directly linked to Medline Plus, which has information available in English and Spanish. Health literacy was a priority in the design phase and the site has been evaluated by an academic expert in health literacy and an adult learner. The site

receives 35,000 visits per month, has 4,000 health services sites, and has been modeled by 23 other sites in various states.

A new web-based consumer information portal is underway and is a cooperative program with academic and public libraries throughout the state. It will expand the health information that is available to the consumer. It will contain sites targeted to specific populations.

The AHEC Digital Library offers its 15,000 members access to multiple resources through a guest log-in. There are links to information for providers to give to patients. Low-literacy resources are flagged throughout the site. There are links to multiple well-researched and reputable sites. It is currently functioning as a portal to house resources for providers.

DISCUSSION AND PRELIMINARY REVIEW OF RECOMMENDATIONS

- Community colleges should be added to the first recommendation
- Pharmacy
 - Standardize training for pharmacy techs
 - Support another work group that is looking into this
 - Fund pilot projects that would change the pharmacy work environment so that pharmacy techs can provide better education of patients
 - Add wording about the pharmacist as a counselor
 - Fund as an action research project
- Grade Level
 - Focus on fostering communication rather than on restricting written materials
 - Rather than setting a grade level documents have to meet, simply require that all materials are tested for grade-level so organizations have an idea of how difficult their materials are
 - Make sure difficult or long terms are defined
 - Do target audience testing to measure understandability rather than relying on readability tests
- All the materials developed by the Center should be put on the internet (i.e., ADL, NC Health Info, etc.)