CALIFORNIA STATE
BOARD OF PHARMACY

Do you understand the directions on your Rx medicine label?

Approximately 46% of American adults do not.

A prescription label says to *"Take two tablets by mouth twice daily."* Sounds simple, doesn't it?

But patients have understood this to mean:

- Take it every 8 hours
- Take it every day
- Take one every 12 hours

Better directions might be *"Take 2 tablets by mouth at 8 in the morning, and take 2 tablets at 9 at night."*

FACT: Six out of 10 people have taken their medicines incorrectly, due to:

- confusing directions on the container label,
- poor health literacy (the ability to read, understand, and act on healthcare information), and
- inability to read and/or understand directions written in English of those whose first language is not English.

FACT: Medicine errors are among the most common medical errors, harming at least 1.5 million people every year. More than one third of these take place outside a hospital in a home setting, costing close to $1 billion annually.

FACT: Up to one-half of all medicines are taken incorrectly or mixed with other medicines that can cause dangerous reactions that can lead to injury and death.

Medicine-related errors must be reduced. One way to begin is by providing patients with easy to read and understand prescription container labeling. This can be a giant step toward increasing consumer protection and improving the health, safety, and well-being of consumers.

California recognizes the importance of improving medicine container labels. In 2007, the Legislature and Governor Schwarzenegger enacted Senate Bill 472, mandating the Board of Pharmacy to develop requirements for standardized, patient-centered, prescription drug labels on all prescription medicine dispensed to patients in California.

In 2008, the Board will hold statewide public meetings to consult with patients and health providers to improve prescription container labels. The meetings will focus on improving directions for the drug's use, using better type fonts and sizes, and placement of information that is patient-centered. The needs of senior citizens and patients with limited English reading skills also will be identified.

(916) 574-7900
WWW.PHARMACY.CA.GOV
1625 N. MARKET BLVD
SUITE N-219
SACRAMENTO, CA 95834

GRAY PANTHERS

P.O. Box 19438
Sacramento, CA 95819
916-332-5980
www.gpcal.org

March 27, 2008

Ms. Virginia Herold
California Board o f Pharmacy
1625 North Market Blvd. Ste N219
Sacramento, CA 95834

RE: Standardization of Rx Labels.

Dear Ms. Herold:

While I know that you have heard from Gray Panthers California on this issue on many occasions, I thought it important for us to be officially on record with suggestions for the standardization of Rx labels. We are aware that our partners in this endeavor, the Latino Coalition for a Healthy California, has been working with you to address the literacy issue, so I will set that aside for their advice to you. That said, it is vitally important that we make every effort to address the many different languages spoken in our State and the nuances of Rx translations that occur when non-English speakers listen or read instructions. I have confidence you will find a way, perhaps thru computer program design or other means, to address those language concerns and offer a minimum of 10 basic language options for our multi-ethnic state.

Gray Panthers would support a label with the following components which we believe are in the order of importance to the user. While you may already have them on your list, they are important to reinterate.

1. A **color** picture of the drug in addition to the **verbal description** of color, shape and codes identifying the drug within
2. Directions for use printed in a **bold, 14 pt font** and in a position of prominence
3. Name of person for whom the drug has been prescribed in 14 pt. font size.
4. Quantity in container and strength, while stated, could be in a lesser font size, say 12 pt.
5. Date of issue and expiration date of the drug dispensed.
6. Name of prescribing physician or other healthcare professional and date of prescription. 12 pt font limit
7. The dispensing pharmacy name, address and phone number or other such identifiers and logos printed in a manner so that it is subordinate to the name and use of the medication. **Recommend a 12 pt font maximum.**
8. No font size or letter width too compressed or short for large numbers of elderly to be able to read them. 14 pt is the routine size used in the disability community for easy reading.
9. **Warnings in another color than other instructions and using a small universal warning sign** (circle with a slash across it). Warnings should include "severe reactions possible, serious food or alcohol interactions, possible dangers

such as beta blockers interacting to prevent the effectiveness of emergency asthma treatments.

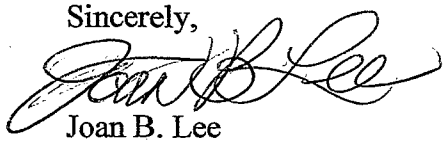
The improved directions for use is perhaps one of the most important ones in designing on a labeling standard. They, and other descriptive remarks on the label must be designed, as stated in SB 472, "so that users with a 4th grade reading level can understand it". The Internal Medicine study in 2006 stated that 70.7 percent of patients with low literacy could correctly repeat their dosing instructions and only 34.7 could demonstrate the correct number of pills to be taken in a day.

To remedy the problem of understanding dosages and appropriate use, it is vital to study each routine expression for clarity. Saying 2x daily can result in a person taking 2 at one time, perhaps not even a safe action. Thus the expression should be 2 pills, taken each day, before (or after or with) meals or "first thing in the morning" or "at bedtime". A regulation could state that the interpretation of the dosage and use must be understandable to a 4th grader.

The bottom line is that a prescription drug label is the face of the doctor to his or her patient and the pharmacist their right hand interpreter. Consults are vital, but when the patient gets home the label's accuracy, clarity and efficiency can mean the difference in wellness or sickness, in some cases even life or death.

We greatly appreciate the work you and the entire board have made toward the ultimate protection of California patients. It is of the highest value to Gray Panthers California. I will extend our thanks to all at the meeting shortly to be held in the Bay Area.

Sincerely,



Joan B. Lee
Legislative Liaison
Gray Panthers California

Cc: Board President William Powers

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

April 7, 2008

Ms. Virginia Herold, CEO
California State Board of Pharmacy
1625 North Market Boulevard, N219
Sacramento, CA 95834

Re: Testimony before the California Board of Pharmacy
Communication & Public Education Committee,
Senate Bill 472, Medical Label Subcommittee, & Prevention of Rx Errors
Public Meeting, April 12, 2008

Dear Virginia:

Enclosed please find:

1. Testimony for April 12th Medical Label and Rx Error hearing.

2. Three articles written by Kevin McCoy, USA Today, February 12-14, 2008 on reducing prescription errors. Please copy and distribute articles with my testimony.

3. I request a short summary of the fourteen California legislative bills listed under "legislation of interest, active bills" that the BOP will be looking at this week at their BOP Legislative Committee meeting. Can you please email the summaries of these bills to me along with Veronica Van Orman (vvanorman@cpha.com).

Unfortunately, I will not be able to attend the April 11th legislation hearing in Sacramento but would like to use the fourteen Board of Pharmacy bills in educating our Gray Panthers, OWL, CARA, etc. groups. I also will not be able to attend the April 12th Public Hearing on Rx errors. Please copy my testimony with the articles from the USA Today newspaper by Kevin McCoy (which are attached).

Is there a possibility that PPSI's number one priority to get a colored picture of the Rx product on the label for patients and consumers accomplished in 2008?

Thanks for your help.

Sincerely,

Fred S. Mayer, RPh, MPH
President

7. 107,000 folks are dying per year (Lucian Leape, M.D. Study from Harvard) from taking the wrong medicine, switching drugs and in general failure to counsel, etc.

8. At the November 30, 2006 Board of Pharmacy hearing and April 3, 2007 meeting, PPSI proposed twelve issues to reduce prescription drug costs. We have not seen anything come out of this November 30th hearing. We have presented much of this material again today.

9. In order for the number of prescription errors to be reduced, we must have transparency by PBMs, PDPs, HMOs & managed care organizations on how drug products are being selected for their formularies. This is especially important for the
43 million Medicare patients who are being switched from Rx to Rx, depending on kickbacks and rebates from the drug companies causing mass confusion in the marketplace.

10. Evidenced-based medicine and P & T Committees must be mandated. The California Board of Pharmacy must put new legislation into place and CPhA in order to give patients and consumers the best medicine available based on evidenced-based medicine and not what is best for the corporate bottom line.

11. There is no one in charge of oversight of the PBMs, PDPs, HMOs, & managed care groups, including CMS. SOMEONE HAS TO HAVE OVERSIGHT AND BE WATCHDOGS FOR THESE FOLKS WHO ARE RAPING THE PUBLIC.

12. PPSI has petitioned FDA and FTC regarding print size of the direct-to-consumer advertising as the print size is so small on DTC, it is referred to as "mouse print", it is illegible and unreadable.

13. Black box warnings for 80 prescription drugs must be kept out of the kiosks. Pharmacists should be mandated to warn all patients per FDA black box instructions about these medications, side effects and adverse drug issues.

14. A picture of the product in color must be on all Rx labels to prevent 49% of all wrong pills in the wrong bottle litigation and prescription drug errors.

15. Many of the causes of prescription drug errors are not being fixed because they fall under the category of "unfunded mandates". Since there is no reimbursement by managed care, HMO's, PBM's, state and federal governments, for counseling, looking at the computer screen, putting the product's picture on the label, returning outdated medications, fall under this category. THE SYSTEM IS NOT BEING CHANGED BUT CONTINUES ON. PLEASE FIX THE SYSTEM!

Finally, PPSI was instrumental in having three front page newspaper articles in February, 2008, USA Today, written by Kevin McCoy (kmccoy@usatoday.com - telephone 212 715-2084).

Thank you for allowing me to testify at the Board of Pharmacy's Communications and Public Education Committee meeting.

Sincerely,

Fred S. Mayer, R.Ph., MPH
President, PPSI

pharmacists planning service, inc.
101 Lucas Valley Road, Suite 210 • San Rafael, California 94903
Tel: (415) 479-8628 • Fax: (415) 479-8608 • e-mail: ppsi@aol.com

April 7, 2008

Ms. Virginia Herold, CEO
California State Board of Pharmacy
1625 North Market Boulevard, N219
Sacramento, CA 95834

Re: Testimony before the California Board of Pharmacy
Communication & Public Education Committee,
Senate Bill 472, Medical Label Subcommittee, & Prevention of Rx Errors
Public Meeting, April 12, 2008

Dear Ms. Herold:

Enclosed please find testimony I would like presented at the Public Hearing on April 12, 2008 in Fremont, California regarding prevention of prescription drug errors and medical labeling.

Thank you for inviting me to testify in today's SB 472 Legislation and the Baord of Pharmacy's Communication and Public Education Committee meeting.

I am Fred Mayer, R.Ph., M.P.H., President of Pharmacists Planning Service, Inc. (PPSI) a 501 C (3) nonprofit public health, consumer, pharmacy education organization. I have been a practicing pharmacist for over fifty years licensed in the State of California. I am also Past President of the California Public Health Association.

I would like to spend my time in responding to what needs to be done to fix the prescription error issue. There are four basic pieces of legislation which PPSI, the Gray Panthers, OWL, CARA, the Latino Coalition, et al. asked the California Board of Pharmacy and CPhA to consider (unfortunately only one piece of legislation made it out of Committee and was signed by the Governor). THE MOST IMPORTANT PIECE OF LEGISLATION WAS A PICTURE OF THE ACTUAL PILL OR PRODUCT DISPENSED IN COLOR ON THE LABEL, WHICH WAS DELETED IN THE PACKET. PPSI suggests for fixing the 150,000 errors and deaths which have been documented by SCR 49 (Senator Jackie Speier), Prescription Error Study, the following:

The four bills that concern the label and the labeling process are: SB 472 Corbett (label requirements), which PPSI is in favor of; AB 1276 Karnette (prescription containers and labels) which PPSI is in favor of; AB 1399 Richardson (prescription labels), which PPSI is in favor of; and AB 851 Brownley (informational inserts), which PPSI is in favor of. The other bill we should discuss is SB 966 by Simitian, which is a great idea but must be done carefully and done right. A colored picture of the prescription drug must be on the label for California patients and consumers who cannot read or comprehend.

PPSI's concerns, which were articulated to the California Board of Pharmacy in its November 30, 2006 testimony and again on April 3, 2007 to the Communcations and Public Education Committee, are as follows:

1. We've gone from 2 billion prescriptions in 2003, to 4 billion prescriptions in 2007. This is an overload on pharmacists.

2. The California Board of Pharmacy, under President Tom Nelson and Sandra Bauer, determined that pharmacists' counseling could eliminate 50% of all errors.

3. Since many PBMs, PDPs, HMOs and managed care organizations require a 30 day supply only for pharmacists, this must be changed for all maintenance drugs to a 90 day supply through legislation.

4. This would reduce the 4 billion prescriptions back to 2 billion and make time available for pharmacists to counsel, look at the computer screen and do cognitive services.

5. A few years ago, NACDS put out a White Paper on how pharmacists spend their time in the workplace. Approximately 73% of the pharmacists' time is spent on processing orders and prescriptions, 9% on managing inventory, 5% on processing pharmacy administration claims and 13% on other miscellaneous activities.

6. It has been documented there are over 700,000 prescription, OTC and herbal errors where patients need to visit hospital emergency rooms. This could be fixed by legislation to reimburse pharmacists for counseling patients.

7. 107,000 folks are dying per year (Lucian Leape, M.D. Study from Harvard) from taking the wrong medicine, switching drugs and in general failure to counsel, etc.

8. At the November 30, 2006 Board of Pharmacy hearing and April 3, 2007 meeting, PPSI proposed twelve issues to reduce prescription drug costs. We have not seen anything come out of this November 30th hearing. We have presented much of this material again today.

9. In order for the number of prescription errors to be reduced, we must have transparency by PBMs, PDPs, HMOs & managed care organizations on how drug products are being selected for their formularies. This is especially important for the
43 million Medicare patients who are being switched from Rx to Rx, depending on kickbacks and rebates from the drug companies causing mass confusion in the marketplace.

10. Evidenced-based medicine and P & T Committees must be mandated. The California Board of Pharmacy must put new legislation into place and CPhA in order to give patients and consumers the best medicine available based on evidenced-based medicine and not what is best for the corporate bottom line.

11. There is no one in charge of oversight of the PBMs, PDPs, HMOs, & managed care groups, including CMS. SOMEONE HAS TO HAVE OVERSIGHT AND BE WATCHDOGS FOR THESE FOLKS WHO ARE RAPING THE PUBLIC.

12. PPSI has petitioned FDA and FTC regarding print size of the direct-to-consumer advertising as the print size is so small on DTC, it is referred to as "mouse print", it is illegible and unreadable.

13. Black box warnings for 80 prescription drugs must be kept out of the kiosks. Pharmacists should be mandated to warn all patients per FDA black box instructions about these medications, side effects and adverse drug issues.

14. A picture of the product in color must be on all Rx labels to prevent 49% of all wrong pills in the wrong bottle litigation and prescription drug errors.

15. Many of the causes of prescription drug errors are not being fixed because they fall under the category of "unfunded mandates". Since there is no reimbursement by managed care, HMO's, PBM's, state and federal governments, for counseling, looking at the computer screen, putting the product's picture on the label, returning outdated medications, fall under this category. THE SYSTEM IS NOT BEING CHANGED BUT CONTINUES ON. PLEASE FIX THE SYSTEM!

Finally, PPSI was instrumental in having three front page newspaper articles in February, 2008, USA Today, written by Kevin McCoy (kmccoy@usatoday.com - telephone 212 715-2084).

Thank you for allowing me to testify at the Board of Pharmacy's Communications and Public Education Committee meeting.

Sincerely,

Fred S. Mayer, R.Ph., MPH
President, PPSI

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee

Senate Bill 472 Medication Label Subcommittee

Notice of Public Meeting
April 12, 2008

Wally Pond Irvington Community Center
41885 Blacow Road
Fremont, CA

10 a.m. – 2 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Call to Order **10 a.m.**

1. Invitation to Participate in the Redesign of Prescription Container Labels
   Committee Chair Ken Schell, PharmD

2. Opening Remarks
   The Honorable Ellen Corbett, California Senator, District 10

3. Presentation of SCR 49 findings, and the need for patients to understand their drug therapy as a source of reducing medication errors.
   Michael Negrete, PharmD

4. Requests for Public Comment on the Following: What works on prescription container labels? What does not? How can prescription container labels be improved to make them patient-centered?

5. Timeline for Project

6. Future Meeting Dates

Adjournment **2 p.m.**

Review and Evaluation System; Establishment, Operation, Funding, Reporting to Legislature

c. Immunization by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – B&PC Section 4052.8

2. Legislation of Interest

a. Active Bills

1. AB 501 (Swanson) Pharmaceutical Devices
2. AB 865 (Davis) State agencies: Live customer service agents
3. AB 1394 (Krekorian) Counterfeit Trademarks
4. AB 1436 (Hernandez) Nurse Practitioners
5. AB 1587 (De La Torre) Personal Information: pharmacy
6. AB 1947 (Emmerson) Pharmacy Technicians
7. AB 2516 (Mendoza) Prescriptions: electronic transmission
8. AB 2643 (Cook) Drugs and devices
9. AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency
10. SB 963 (Ridley-Thomas) Regulatory boards: operations
11. SB 1096 (Calderon) Medical Information
12. SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree
13. SB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution
14. SB 1594 (Steinberg) Bleeding Disorders Clotting Products

C. Board Approved Regulations – Awaiting Notice (Status Update)

1. Repeal of Title 16, CCR sections 1716.1 and 1716.2 and amendment to sections 1751-1751.8 and adoption of sections 1735-1735.8 (awaiting 15-day notice)
2. Title 16 CCR section 1785 – Self-Assessment of a Veterinary Food-Animal Drug retailer
3. Title 16 CCR section 1780 – Update the USP Standards Reference Material
4. Title 16 CCR 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products
5. Title 16 CCR sections 1721 and 1723.1 – Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality

D. Regulations Currently Noticed (Status Update)

Title 16 CCR 1760 – Disciplinary Guidelines

California State Board of Pharmacy
1625 North Market Blvd., N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Contact Person
Virginia Herold
(916) 574-7911

LEGISLATION AND REGULATION COMMITTEE
California State Board of Pharmacy
Department of Consumer Affairs
Notice of Public Meeting
April 11, 2008
9:30 a.m. – 1:00 p.m.

This committee meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Michelle Leech at (916) 574-7912, at least five working days prior to the meeting. All times are approximate and subject to change. Action may be taken on any item on the agenda.

Opportunities are provided to the public to address the committee on each open agenda item. A quorum of the Board members who are not on the committee may attend the meeting as observers, but may not participate or vote.

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

AGENDA

DATE: **April 11, 2008**

PLACE: Samuel Greenberg Board Meeting Room
Los Angeles International Airport – see detailed directions below
1 World Way
Los Angeles, CA 90045

A. CALL TO ORDER **9:30 a.m.**

B. Legislative and Regulatory Proposals for 2008
Discussion and Action for recommendations to the Board on legislative proposals

1. Board Sponsored Legislation for 2008
   a. SB 1307 (Ridley-Thomas) Electronic Pedigree
   b. SB 1779 (Omnibus)
      1. Section 4062 Furnishing Dangerous Drugs During an Emergency
      2. Section 4110 Temporary Permit Upon Transfer of Ownership

3. Pharmacist-in-Charge and Designated Representatives-in-Charge – Amend Business and Professions Code Sections 4022.5, 4101, 4160, 4196, 4305, 4329, 4330; Add Section 4036.5
4. Who May Order Dangerous Drugs or Devices, Exceptions – Amend Section 4059.5
5. Section 4081– Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory
6. Furnishing Dangerous Drugs by Pharmacy – Amend Section 4126.5
7. Requirements for Renewal of Pharmacist License: Clock Hours; Exemption for New Licensee – Amend Section 4231
8. Section 4362 – Entry Into Pharmacists Recovery Program (PRP)
9. Health and Safety Code Section 11165 – Controlled Substance Utilization Review and Evaluation System; Establishment; Operation; Funding; Reporting to Legislature

c. Immunization by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – B&PC Section 4052.8

2. Legislation of Interest
   a. Active Bills
      1. AB 501 (Swanson) Pharmaceutical Devices
      2. AB 865 (Davis) State agencies: Live customer service agents
      3. AB 1394 (Krekorian) Counterfeit: Trademarks
      4. AB 1436 (Hernandez) Nurse Practitioners
      5. AB 1587 (De La Torre) Personal Information: pharmacy
      6. AB 1947 (Emmerson) Pharmacy Technicians
      7. AB 2516 (Mendoza) Prescriptions: electronic transmission
      8. AB 2643 (Cook) Drugs and devices
      9. AB 2756 (Duvall) Pharmacists: furnishing drugs during an emergency
      10. SB 963 (Ridley-Thomas) Regulatory boards: operations
      11. SB 1096 (Calderon) Medical Information
      12. SB 1270 (Cedillo) Pharmacy: dangerous drug and devices pedigree
      13. SB 1504 (Ridley-Thomas) Antiepileptic drug products: substitution
      14. SB 1594 (Steinberg) Bleeding Disorders Clotting Products

C. **Board Approved Regulations – Awaiting Notice (Status Update)**
1. Repeal of Title 16, CCR sections 1716.1 and 1716.2 and amendment to sections 1751-1751.8 and adoption of sections 1735-1735.8 (awaiting 15-day notice)
2. Title 16 CCR section 1785 – Self-Assessment of a Veterinary Food-Animal Drug retailer
3. Title 16 CCR section 1780 – Update the USP Standards Reference Material
4. Title 16 CCR 1751.8 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products
5. Title 16 CCR sections 1721 and 1723.1 – Dishonest conduct during a Pharmacist's Licensure Examination/Confidentiality

D. **Regulations Currently Noticed (Status Update)**
Title 16 CCR 1760 – Disciplinary Guidelines

E. **Board-Approved – Regulation Language to be Developed**
Ethics Course for Pharmacists

F. **Public Requests for Future Legislation and Regulatory Proposals**
The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problems.

Adjournment **1:00 p.m.**

Committee materials will be available on the board's Web site by Wednesday, April 9, 2008

THE ANNALS OF PHARMACOTHERAPY

Published Online, 10 April 2007, www.theannals.com, DOI 10.1345/aph.1H582.
The Annals of Pharmacotherapy: Vol. 41, No. 5, pp. 783-801. DOI 10.1345/aph.1H582

MEDICATION SAFETY

Effect of Content and Format of Prescription Drug Labels on Readability, Understanding, and Medication Use: A Systematic Review

William Shrank, MD MSHS

Instructor, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital, Harvard Medical School, Boston, MA

Jerry Avorn, MD

Professor, Division of Pharmacoepidemiology and Pharmacoeconomics, Brigham and Women's Hospital, Harvard Medical School

Cony Rolon, BA

Research Associate, Southern California EPC-RAND, Santa Monica, CA

Paul Shekelle, MD PhD

Director, Southern California EPC-RAND; Chief, Division of General Internal Medicine, Greater Los Angeles Veterans Affairs Healthcare System, Santa Monica

Reprints: Dr. Shrank, 1620 Tremont St., Suite 3030, Boston, MA 02120, fax 617/232-8602, wshrank@partners.org

Abstract

OBJECTIVE: To evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use.

▲ Top
▪ Abstract
▼ Literature Search and Selection
▼ Extraction of Study-Level...

DATA SOURCES: We performed a systematic review of randomized controlled trials, observational studies, and systematic reviews from MEDLINE and the Cochrane Database (1990-June 2005), supplemented by reference mining and reference lists from a technical expert panel.

STUDY SELECTION: We selected studies that focused on the content of physician-patient communication about medications and the content and format of prescription drug labels.

DATA EXTRACTION: Two reviewers extracted and synthesized information about study design, populations, and outcomes.

DATA SYNTHESIS: Of 2009 articles screened, 36 that addressed the content of physician-patient communication about medications and 69 that were related to the content or format of medication labels met review criteria. Findings showed that patients request information about a drug's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists, headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. Little evidence linked label design or content to measurable health outcomes, adherence, or safety.

CONCLUSIONS: Evidence suggests that specific content and format of prescription drug labels facilitate communication with and comprehension by patients. Efforts to improve the labels should be guided by such evidence, although additional study assessing the influence of label design on medication-taking behavior and health outcomes is needed. Several policy options exist to require minimal standards to optimize medical therapy, particularly in light of the new Medicare prescription drug benefit.

Key Words: patient information, prescription drug label

Published Online, April 10, 2007. *www.theannals.com*, DOI 10.1345/aph.1H582

With the passage of the Medicare Modernization Act, the US federal government has a dramatically expanded role in the provision of prescription drugs to Americans.[1,2] This investment has led to even greater attention to the appropriate and safe use of prescription medications, and substantial concerns exist. Patients are typically adherent to only about 50% of their medication doses,[3] even for essential chronic drug therapy,[4-6] with dramatic consequences in terms of health outcomes and associated healthcare costs.[7-9] In addition, substantial shortfalls in the quality of medication therapy exist[10-14]; medication errors and adverse drug reactions occur frequently, with an estimated annual cost of $50 billion.[15-19] Efforts to improve medication adherence and safety in the Medicare prescription drug benefit are warranted and may improve the effectiveness of the federal investment in prescription drug care.

Some of these quality deficits may be due to poor comprehension by patients about their medications.[20-

[23] Several recent studies have demonstrated that patients frequently have difficulty reading and understanding medication labels.[24-27] The recent Institute of Medicine report, "Preventing Medication Errors," cited poor labeling as a central cause for medication errors in the US.[28] Although patients should receive medication counseling from their physicians and pharmacists, numerous studies have shown that discussions about drugs are often limited,[29-31] and patients frequently do not remember those conversations,[32] forcing many to rely on drug labels for information.

We sought to evaluate the evidence pertaining to the optimum content and format of patient-oriented prescription labels. We evaluated evidence pertaining to both container labels and auxiliary medication information leaflets that, when used together, might improve readability, understanding, and medication-taking behavior. To assess the optimum content of prescription drug labels, we reviewed the literature pertaining to patient preferences for the content of communication about prescription drugs. We then reviewed the literature to assess the evidence evaluating the effect of the content and format of prescription drug labels on readability, understanding, and health outcomes. Our goal was to evaluate the evidence to inform the improvement of prescription drug labels so that future efforts at redesign can be evidence-based.

Literature Search and Selection

A systematic search of the medical literature was performed to identify studies addressing prescription drug labels and patient-provider communication about prescription drugs. The initial searches were limited to articles written in English and published between January 1990 and June 2005. Sources of our search included MEDLINE and the Cochrane Database. We also reference-mined articles included from our initial search and sought input from members of a technical expert panel, drawn from diverse fields and assembled for this project. We included systematic literature reviews, observational studies, and controlled trials. All case reports and expert perspectives were excluded. Articles published before 1990 that were identified from expert recommendations or reference mining were included in this review.

Two searches were performed. Articles were included in the patient-provider communication search if they addressed patient preferences about specific content for discussions that may enhance medication-taking behavior. Articles were searched on MEDLINE, using the following search criteria: (communication or misunderstanding or miscommunication) and (patient or professional-patient relations or physician-patient relations or patient education) and (medicine or drug information services or prescriptions or drug therapy) or (risk or adverse event or adverse effect or risk factors or risk assessment). Articles from the patient-provider communication component of the search were included only if the results could be used to inform potential content of prescription drug labels. Considering that labels communicate medication information to patients, we believe that patient preferences for the communication content about medications may be assessed and used to inform optimal prescription

label creation.

In the prescription drug labeling search, articles were included if they addressed either the format or content of any type of patient-oriented labels or drug information. Several MEDLINE searches were performed and included the following criteria: drug labeling/standards or (patient education or health education) or (label or leaflet). Patient-oriented labeling has several components, all of which were included in this review. One component is the label that is directly affixed to the container. It must identify information about the medication, prescriber, and patient[33] and typically includes auxiliary stickers imprinted with directions and warnings. Package inserts are created by manufacturers, approved by the Food and Drug Administration (FDA), required for some drugs, and voluntary for others.[34] They are created primarily to educate physicians,[35] although recent improvements aim to provide summary information for patients, as well.[36]

Consumer medication information (CMI) consists of leaflets created by the private sector (pharmacies and drug information publishers).[37,38] These leaflets accompany most prescriptions dispensed at pharmacies.[39] Medication Guides, established by the FDA in 1996,[40] are standardized leaflets prepared by manufacturers for medications thought to pose a "serious and significant public health concern," and are disseminated at the pharmacy.[41] Patient-oriented information is also prepared by manufacturers for direct-to-consumer advertising (DTCA). We included all patient-oriented medication information as part of the "label" so that evidence about any type of prescription drug information may aid in future labeling developments.

Extraction of Study-Level Variables

Two reviewers (WS, PS) extracted data from the same articles, with one reviewer (WS) extracting data and the other (PS) checking the information for accuracy. Disagreements were resolved by consensus. Variables assessed included patient population (ie, age, education, location, presence of chronic conditions) and study design (ie, experimental or hypothesis testing, descriptive, or review). We assessed the relationship between the outcomes reported in the study and health outcomes in patients, ranging from patient preferences (lowest level), label readability and comprehension, medication adherence, and actual health outcomes such as blood pressure control or adverse drug events (highest level). Studies evaluating prescription label preferences, readability, and comprehension rely on an assumed relationship between readability, comprehension, and the capacity to take medications appropriately.

Data Synthesis

Articles were grouped by topics under 2 headings: patient-physician communication content about medications and medication labeling

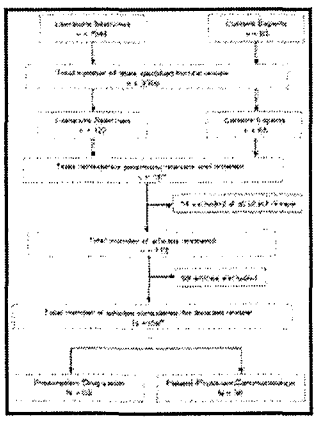
format and content. Articles addressing patient-provider communication about prescription drugs were categorized under the following topics: patient preferences for content in general, content aimed to improve adherence, administration directions, and risk communication. Topics associated with previous research on the content and format of medication labels included label organization, print, language, use of icons, and container design. Evidence tables were created for each category, and a narrative synthesis was performed.

- Extraction of Study-Level...
- Data Synthesis
- Search Results
- Patient-Requested Information
- Drug Labeling
- Discussion
- Summary
- References

Search Results

A total of 1944 articles were identified in our literature search. Additionally, expert advisors suggested articles, many from nonmedical sources, including psychology, business, marketing, and ergonomics literature; 65 of those articles were considered relevant. From all sources, 187 articles were identified as potentially relevant by a physician reviewer (WS) and confirmed by another physician reviewer (PS). Of those, 69 articles were excluded because they were either case reports or perspectives. In total, 36 articles addressing the preferred content of patient-provider communication about medications[32,42-76] and 69 articles related to the content or format of prescription drug labels[39,68,77-143] were included in our evaluation. Details of the search and yield of articles are presented in Figure 1.

- Top
- Abstract
- Literature Search and Selection
- Extraction of Study-Level...
- Data Synthesis
- Search Results
- Patient-Requested Information
- Drug Labeling
- Discussion
- Summary
- References



View larger version (20K): [in this window] [in a new window]

Figure 1. Article flow. [a]One article was used in both evidence tables.

Patient-Requested Information

A description of information that patients request about medications is shown in Table 1.[32,42-76]

View this table: **Table 1.** Evidence about Physician–Patient Communication about Drugs
[in this window]
[in a new window]

One survey of elderly patients found that only 46% recalled the drugs listed in their medical records,[63] and a second survey indicated that only 58% of elderly patients were familiar with their dosing instructions immediately after a physician visit.[32] To guide communication efforts, researchers have descriptively assessed the specific information that patients request about medication administration. In a convenience sample, 67 patients in a health maintenance organization were surveyed about medication information they request; 67% asked for information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment.[56] Another survey of 100 patients recruited at a pharmacy found that the information most commonly considered important was dosing frequency (87%), adverse effects (85%), and indication (84%).[75] This survey was also a convenience sample, with a poor response rate (11%), raising questions about the generalizability of these findings.

A survey of a convenience sample of 66 white, hypertensive patients explored the communication content that they believed would improve their adherence; 90% of those surveyed wanted to know about all possible adverse effects and 96% wanted to know about benefits of the medication.[57] In addition, 82% of patients requested more information about their disease, and concerns about duration of therapy and life-style effects were frequent. Although physicians and pharmacists express concern that discussion of adverse drug effects may adversely affect patient adherence,[52,58] 3 descriptive studies found that patients desire complete information about potential adverse effects and prefer to participate in the decision-making process.[43,54,58] All studies identified found similar results; however, none was performed in a population-based representative sample, raising concerns about generalizability.

Few studies have linked specific communication content to medication-taking behavior. One descriptive survey of 137 physicians who wrote prescriptions for antidepressant medication for 401 patients indicated that patients who were specifically advised to continue therapy for longer than 6 months were significantly more likely to adhere to those instructions (OR 3.12; 95% CI 1.21 to 8.07).[46] In addition, patients who discussed adverse effects with their physicians were less likely to discontinue therapy than

were patients who did not discuss them (OR 0.49; 95% CI 0.25 to 0.95). Two systematic reviews generally found a relationship between communication about medications and adherence, but did not specify communication content that is effective.[54,65]

Drug Labeling

Findings on the content and format of prescription drug labeling are presented in Table 2.[39,68,77-143]

View this table: [in this window] [in a new window]

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels

Organization

Three descriptive studies indicate that patients prefer that information be organized in a schematic, logical way, with information about the drug, directions for use, and its benefits followed by warnings and adverse effects.[116,132,135] A survey of 140 participants recruited from a university, a flea market, and a retirement community found that patients of all ages prefer information about indications and benefits of medications prior to information about adverse effects and warnings.[135]

In presenting risk and benefit information, patients prefer drug information to be organized into a simplified schema. Researchers in a laboratory setting asked 42 young adults and 42 elderly adults to sort medication items (eg, indication, instructions, adverse effects) to create a preferred instruction set. Young and elderly adults shared a similar schema for medication taking, preferring to read the drug's name and indication, followed by directions (schedule and duration), followed by warnings and adverse effects.[64] In addition, patients exhibited better recall of medication information compatible with this schema. The samples for the descriptive studies were either not in the US[116] or were small,[135] and the experimental design included a sample of only 84 patients in a laboratory setting,[64] raising some concerns about the generalizability of these findings.

Three studies used experimental designs to demonstrate that list formats on medication labels improve patient understanding and recall.[101,106,136] One study presented 27 elderly patients with labels in different formats.[136] The subjects preferred labels in categorized lists (lists with headers) over simple lists and simple lists over paragraph format. Elderly patients found categorized lists to be easier to read, with improved recall, answer time, and accuracy. In another experiment, older and younger patients

were presented with labels of different formats; list formats were again found to be easier to read and recall than were paragraph formats, and list formats reduced age differences in both answer time and accuracy.[101] Three studies with experimental designs have demonstrated that patients prefer leaflets that use headers to organize material[96,101,106] and white space to separate related concepts.[106] Another study with 101 elderly adults and 109 young adults indicated that patients, especially the elderly, could more easily read labels that judiciously used white space by separating related sections and grouping related material together.[87] These experiments were performed in a laboratory setting and should be evaluated in the real world setting.

Print

Font size influences readability and comprehension in both CMI and container labels. In one randomized controlled trial (RCT), 101 elderly adults and 109 young adults were presented with 12 otherwise identical over-the-counter (OTC) drug bottles with varied container labels along 3 dimensions, one of which was font size (7 vs 10 point).[87] While younger particants performed equally well in the small and large font size label groups, elderly patients had significantly reduced recall and understanding after reading the small-font labels. Both young and elderly participants preferred the larger font labels. In another experiment with 19 young and 20 elderly patients, patients of all ages preferred labels written in larger font and reported that 14 point font was easier to read than 12 point, which was easier to read than 9 point.[134] This survey also found that patients read labels with larger font more rapidly and accurately than labels with smaller font. Bernardini et al.[116] surveyed 1004 Italian patients concerning CMI; 63% of the respondents requested larger font size than is currently seen in European leaflets, and almost 80% preferred that font size be 10 point or larger. Although this survey took place in Italy, it is likely that concern about font size is less sensitive to cultural norms and that the findings are likely representative of sentiments in the US.

One experiment evaluated patients' preferences for 3 font styles for medication labels (Century Schoolbook, Helvetica, and Courier) and found that patients preferred Century Schoolbook.[134] In a descriptive survey of 60 elderly patients exposed to labels written with 5 different fonts, Scriptwriter font was considered the most difficult to read, and fonts that appeared larger were considered easier to read.[126] The survey by Bernardini et al.[116] of patient preferences concerning CMI in Italy evaluated whether the color of print affects label readability. The investigators found that approximately 66% of respondents reported that, in general, they prefer labels to be printed in black and white. Yet the same patients noted that if colors were used, certain colors are more appropriate for certain sections of the patient leaflet; warnings and adverse effects were easier to identify when printed in red type. These findings did not suggest an overall preference for the use of color and did not address concerns about color-blindness.

Language

Two descriptive studies and one RCT have found that patients have more difficulty understanding vague versus precise medication directions.[48,110,127] In a survey of medication leaflet comprehensibility for 30 commonly prescribed medications in 1060 Swedish patients, leaflets using more complex messages to communicate drug warnings and interactions were less comprehensible.[110] In one RCT, researchers presented 260 students with medication labels that varied in the use of medical jargon and risk

presentation.[77] The authors found that adherence intention was greater when the instructions were set in a negative frame (ie, the risks of nonadherence rather than the benefits of adherence) and when the language was simple and understandable, without medical terminology (ie, replacing "gastrointestinal problems" with "heartburn" on a label). The samples studied (Swedish and younger adults in the US) limit our ability to generalize the findings to a broader population.

Researchers in England performed a series of descriptive surveys to compare 2 risk communication approaches.[79] In 1998, the European Commission Pharmaceutical Guidelines required that every medicine be accompanied by a comprehensive leaflet, that a list of all known adverse effects be listed on those leaflets, and that the adverse effects be categorized into 5 verbal descriptors ranging from "very rare" to "very common." Researchers performed 4 patient surveys with a total of almost 850 participants to assess whether verbal versus numerical presentation of risk influences risk perception. In each of the surveys, patients substantially overestimated medication risks when they were presented in prose; estimation of risks was more accurate when they were presented numerically. While these studies evaluated the specific nomenclature adopted in Europe, concerns about the use of prose to communicate risk may be generalizable to other settings.

When presented with risk information, patients also request accurate benefit information. In a study of 203 patients presented with DTCA for common medications, patients were asked about their perceptions of the benefits of the medication.[137] Patients were then randomly assigned to receive the same DTCA with and without a "benefit box" that presented specific data concerning the expected benefits and risks of the drugs. Although patients had a lower perception of efficacy after reading the benefit box, approximately 93% reported that they preferred labels to include this risk and benefit information.

We found no evidence to assist with the problem of label production for patients who do not speak the languages used in the product information.

Use of Icons

Results concerning the use of icons have been mixed. One study found that a timeline icon improves patients' understanding of medication administration; however, it was helpful only when the icon was closely integrated with the text of the leaflet.[100] In children, icons were not found to improve understanding about medications.[85] In an RCT of 87 low-literacy patients in South Africa, patients given a leaflet with locally created, culturally sensitive icons were found to better understand (25% increase) and adhere to (18% increase) their medications compared with controls who received leaflets with no icons.[122] Another study in the same population found that not all icons are equally effective, and patients understood locally created icons much better than typical icons from the US.[123]

While one experimental study of 60 low-literate patients from South Africa found that the presence of icons significantly improved acquisition and comprehension of drug information,[86] another experiment with young and elderly adults in the US found that older patients have more difficulty understanding icons and icons did not improve readability in an elderly sample.[107] A more recent RCT found great variability in patients' interpretations of icons. A survey of 160 patients asked to interpret 10 icons found that patients interpreted between 7.5% and 90% correctly and that only 3 icons were understood by more

than 85% of the participants.[121] As a result, findings about icons are inconclusive, and further research is needed to explore the specific icons that most effectively communicate information to patients.

Containers

Three RCTs have evaluated the efficacy of methods to increase container label surface area. In one trial with young and elderly adults, container labels designed as tags or fold-out labels with greater surface area were easier to read and were preferred by patients.[133] When 60 older patients were exposed to a variety of OTC drug container designs, they preferred a design with a cap having an additional label that identified the drug and listed key information.[81] However, another trial evaluating the efficacy of fold-out labels found that they did not improve patient understanding about the medication.[87] The lack of consistent findings in these small studies with nonrepresentative samples makes it difficult to draw conclusions about the effect of newer container designs.

Discussion

- Top
- Abstract
- Literature Search and Selection
- Extraction of Study-Level...
- Data Synthesis
- Search Results
- Patient-Requested Information
- Drug Labeling
- Discussion
- Summary
- References

This review of the literature points to several key components of both the content and format of prescription drug labels. When optimizing content, patients prefer information about the indication for the medication, expected benefits, duration of therapy, and a thorough list of potential adverse effects, in addition to typical information identifying the drug's name, directions for use, and warnings. When optimizing label format, lists, headers, and white space enhance readability, and content should be organized to follow the schema that patients use to understand medication information. The print should be the largest size possible of fonts that are easiest to read, and language should be simple, precise, and devoid of formal medical terminology. The evidence concerning the use of icons is mixed; only well-tested, culturally appropriate icons should be used and they should be carefully tested in elderly patients. New approaches to enhance container label surface area seem promising, but more study is needed. Table 3 summarizes label features for which we judged the evidence to strongly suggest benefit.

View this table: [in this window] [in a new window]

Table 3. Summary of Findings about Content and Format of Prescription Drug Labels

Although numerous studies have evaluated patients' perceptions about readability of medication labels and comprehension, there is limited evidence linking label design to patient outcomes such as adherence or safety. Our review is limited by our assumption of a significant relationship between readability, comprehension, and appropriate medication-taking behavior. While it seems reasonable to assume that if patients cannot read and comprehend medication labels they are less likely to be adherent, the nature of

this relationship has not been well tested. Further studies evaluating the effects of label content and format should focus on their effects on medication-taking behavior (ie, adherence and error rates) and health outcomes. Additionally, many of the studies cited here were performed in a non-clinical setting; although many were randomized, they may not capture the true complexity of medication-taking in a real world setting in which patients may be taking multiple medications and have numerous competing demands. Future studies should be focused on the effects of label design in clinical settings.

Efforts to improve prescription drug labels are needed. A growing body of research has found that patients frequently misinterpret prescription drug labels. Challenges in reading and understanding labels may represent one cause for the high rates of medication errors and poor adherence. The extent to which deficits in labeling contribute to poor adherence or unsafe use of medications is unknown, but it is worth striving for improvements in these domains.

These findings come at an important time in the evolution of prescription drug labels. With the passage of the Medicare prescription drug benefit, the federal government plays an even greater role in purchasing prescription drugs. Federal payers will likely be increasingly interested in maximizing the safe and appropriate use of medications. To the extent that labeling practices can improve adherence and safety, efforts to improve prescription drug labels may have more traction. In addition, in 2007 the FDA will reevaluate whether quality and distribution guidelines for CMI are being met[38]; evidence of poor outcomes could strengthen an argument for improving CMI. Future efforts to improve prescription drug labels should focus on the need for creative design but also should be grounded in the evidence about optimal label content and format.

These findings also raise important policy issues. Previous FDA policy has relied on private industry to self-regulate CMI and state laws to regulate container labels. Our findings suggest that certain content and format components should be included on all labels, and minimum standards could be generated to enhance readability and comprehension of prescription drug information. The lack of any centralized oversight of CMI or container labels impedes the implementation of labeling improvements. Policymakers should consider developing clear standards for both the format and content of prescription drug labels to simplify patients' access to risk, benefit, and administration information about medications. Such strategies may improve the likelihood that patients will understand, safely administer, and adhere to their drug therapy.

Summary

We performed a systematic review of the published literature to evaluate the evidence regarding the optimal content and format of prescription labels that might improve readability, understanding, and medication use. The evidence suggests that patients request information about a medication's indication, expected benefits, duration of therapy, and a thorough list of potential adverse effects. The evidence about label format supports the use of larger fonts, lists,

▼ References

headers, and white space, using simple language and logical organization to improve readability and comprehension. Evidence was not sufficient to support the use of pictographic icons. There was little evidence to link label design or contents to measurable health outcomes, adherence, or safety.

Footnotes

This project was funded by a grant from the American College of Physicians Foundation. We are grateful for the support of Jean Krause, president of the Foundation.

We thank the technical expert panel assembled to advise this project. Members of the panel included Terry Davis PhD, Linda Johnston-Lloyd MEd, Sandra Leal PharmD CDE, Michael A. Moné BSP JD FAPhA, Ruth Parker MD MACP, Scott R Smith RPh PhD, W James Stackhouse MD FACP, and Alastair JJ Wood MD. We are also grateful for the expert opinions of Daniel Morrow PhD, Robert Vander Stichele MD, and Michael Wogalter PhD.

References

▲ Top
▲ Abstract
▲ Literature Search and Selection
▲ Extraction of Study-Level...
▲ Data Synthesis
▲ Search Results
▲ Patient-Requested Information
▲ Drug Labeling
▲ Discussion
▲ Summary
▪ References

1. Doherty RB. Assessing the new Medicare prescription drug law. Ann Intern Med 2004;141:391-5.[Abstract/Free Full Text]
2. Connolly C, Allen M. Medicare drug benefit may cost $1.2 trillion; estimate dwarfs Bush's original price tag. Washington Post, Feb. 9, 2005; A01.
3. Adherence to long-term therapies: evidence in action. Geneva: World Heath Organization, 2003.
4. Brown JB, Nichols GA, Glauber HS, et al. Ten-year follow-up of antidiabetic drug use, nonadherence, and mortality in a defined population with type 2 diabetes mellitus. Clin Ther 1999;21:1045-57.[CrossRef][Medline]
5. Avorn J, Monette J, Lacour A, et al. Persistence of use of lipid-lowering medications: a cross-national study. JAMA 1998;279:1458-62.[Abstract/Free Full Text]
6. Shrank WH, Hoang T, Ettner SL, et al. The implications of choice: prescribing generic or preferred formulary medications improves adherence to chronic medications. Arch Intern Med 2006;166:332-7.[Abstract/Free Full Text]
7. McDermott MM, Schmitt B, Wallner E. Impact of medication nonadherence on coronary heart disease outcomes. A critical review. Arch Intern Med 1997;157:1921-9.[Abstract]
8. Caro JJ, Salas M, Speckman JL, et al. Persistence with treatment for hypertension in actual practice. CMAJ 1999;160:31-7.[Abstract]
9. Col N, Fanale JE, Kronholm P. The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. Arch Intern Med 1990;150:841-5.[Abstract]
10. Petersen LA, Normand SL, Leape LL, et al. Comparison of use of medications after acute myocardial infarction in the Veterans Health Administration and Medicare. Circulation 2001;104:2898-904.[Abstract/Free Full Text]
11. Krumholz HM, Wang Y, Parent EM, et al. Quality of care for elderly patients hospitalized with heart failure. Arch Intern Med 1997;157:2242-7.[Abstract]

12. Shrank WH, Asch SM, Kerr EA, Adams J, Setodji C, McGlynn EA. The quality of pharmacologic care for adults in the United States. Medical Care 2006;44:936-45.[CrossRef][Medline]
13. Higashi T, Shekelle PG, Solomon DH, et al. The quality of pharmacologic care for vulnerable older patients. Ann Intern Med 2004;140:714-20.[Abstract/Free Full Text]
14. McGlynn EA, Asch SM, Adams J, et al. The quality of health care delivered to adults in the United States. N Engl J Med 2003;348:2635-45.[Abstract/Free Full Text]
15. Goulding MR. Inappropriate medication prescribing for elderly ambulatory care patients. Arch Intern Med 2004;164:305-12.[Abstract/Free Full Text]
16. Gandhi TK, Weingart SN, Borus J, et al. Adverse drug events in ambulatory care. N Engl J Med 2003;348:1556-64.[Abstract/Free Full Text]
17. Bates DW, Cullen DJ, Laird N, et al. Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. JAMA 1995;274:29-34. [Abstract]
18. Gurwitz JH, Field TS, Harrold LR, et al. Incidence and preventability of adverse drug events among older persons in the ambulatory setting. JAMA 2003;289:1107-16. [Abstract/Free Full Text]
19. Institute of Medicine. To err is human. www.nap.edu/books/0309068371/html (accessed 2005 Dec 8).
20. United States National Library of Medicine. National Institutes of Health. Current bibliographies: Health Literacy. www.nlm.nih.gov/pubs/cbm/healthliteracybarriers.html (accessed 2007 Mar 20).
21. Institute of Medicine Report. Health literacy: a prescription to end confusion. Nielsen-Bohlman L, Panzer A, Kindig DA, eds. Washington, DC: National Academy Press, 2004.
22. Kenagy JW, Stein GC. Naming, labeling, and packaging of pharmaceuticals. Am J Health Syst Pharm 2001;58:2033-41.[Abstract/Free Full Text]
23. Hoffman JM, Proulx SM. Medication errors caused by confusion of drug names. Drug Saf 2003;26:445-52.[CrossRef][Medline]
24. Wolf MS, Davis TC, Tilson HH, Bass PF 3rd, Parker RM. Misunderstanding of prescription drug warning labels among patients with low literacy. Am J Health Syst Pharm 2006;63:1048-55. [Abstract/Free Full Text]
25. Davis TC, Wolf MS, Bass PF 3rd, et al. Low literacy impairs comprehension of prescription drug warning labels. J Gen Intern Med 2006;21:847-51.[CrossRef][Medline]
26. Davis TC, Wolf MS, Bass PF 3rd, et al. Literacy and misunderstanding of prescription drug labels. Ann Intern Med 2006;145:887-94.[Abstract/Free Full Text]
27. Wolf MS, Davis TC, Shrank WH, Neuberger M, Parker RM. A critical review of FDA-approved medication guides. Patient Educ Couns 2006;62:316-22.[CrossRef][Medline]
28. Preventing medication errors: the quality chasm series. Institute of Medicine Report. Released July 20, 2006. www.iom.edu/CMS/3809/22526/35939.aspx (accessed 2006 Dec 8).
29. Scherwitz L, Hennrikus D, Yusim S, Lester J, Vallbona C. Physician communication to patients regarding medications. Patient Educ Couns 1985;7:121-36.[CrossRef][Medline]
30. Tarn DM, Heritage J, Paterniti DA, Hays RD, Kravitz RL, Wenger NS. Physician communication when prescribing new medications. Arch Intern Med 2006;166:1855-62.[Abstract/Free Full Text]
31. Sleath B, Rubin RH, Campbell W, Gwyther L, Clark T. Physician-patient communication about over-the-counter medications. Soc Sci Med 2001;53:357-69.[CrossRef][Medline]
32. Fletcher SW, Fletcher RH, Thomas DC, et al. Patients' understanding of prescribed drugs. J Commun Health 1979;4:183-9.[CrossRef][Medline]
33. Section 503(b)(2) of the Food Drug and Cosmetic Act. (21 USC §353[b] [2]).
34. 21 CFR 310. 1970. www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=310&showFR=1&subpartNode=21:5.0.1.1.2.5 (accessed 2006 May 9).
35. Food and Drug Administration. www.fda.gov/opacom/Laws/fplact.htm (accessed 2006 Jan 31).
36. Food and Drug Administration. www.fda.gov/cder/regulatory/physLabel/default.htm (accessed 2006 Jan 31).

37. 60 FR 44182. 1995.
38. Steering committee for the collaborative development of a long-range action plan for the provision of useful prescription medicine information. 1996. www.fda.gov/cder/offices/ods/keystone.pdf (accessed 2007 Jan 9).
39. Svarsted BL, Bultman DC, Mount JK, et al. Evaluation of written prescription information provided in community pharmacies: a study in eight states. J Am Pharm Assoc (Wash DC) 2003;43:383-93.[Medline]
40. Public Law 104-180. Title VI, Sec 601. Effective medication guides, 110 Stat 1593. 1996.
41. Prescription drug product labeling; medication guide requirements— FDA. Final rule. Fed Regist 1998;63:66378-400.[Medline]
42. Schneider J, Kaplan SH, Greenfield S, et al. Better physician-patient relationships are associated with higher reported adherence to antiretroviral therapy in patients with HIV infection. J Gen Intern Med 2004;19:1096-103.[CrossRef][Medline]
43. Walter FM, Emery JD, Rogers M, et al. Women's views of optimal risk communication and decision making in general practice consultations about the menopause and hormone replacement therapy. Patient Educ Couns 2004;53:121-8.[CrossRef][Medline]
44. Ogedegbe G, Harrison M, Robbins L, et al. Barriers and facilitators of medication adherence in hypertensive African Americans: a qualitative study. Ethn Dis 2004;14:3-12.[Medline]
45. Stevenson FA, Cox K, Britten N, et al. A systematic review of the research on communication between patients and health care professionals about medicines: the consequences for concordance. Health Expect 2004;7:235-45.[CrossRef][Medline]
46. Bull SA, Hu XH, Hunkeler EM, et al. Discontinuation of use and switching of antidepressants: influence of patient-physician communication. JAMA 2002;288:1403-9.[Abstract/Free Full Text]
47. Bikowski RM, Ripsin CM, Lorraine VL. Physician-patient congruence regarding medication regimens. J Am Geriatr Soc 2001;49:1353-7.[CrossRef][Medline]
48. Gramling R, Irvin JE, Nash J, et al. Numeracy and medicine: key family physician attitudes about communicating probability with patients (letter). J Am Board Fam Pract 2004;17:473.[Medline]
49. Schaafsma ES, Raynor TD, de Jong-van den Berg LT. Accessing medication information by ethnic minorities: barriers and possible solutions. Pharm World Sci 2003;25:185-90.[CrossRef][Medline]
50. Savas S, Evcik D. Do undereducated patients read and understand written education materials? A pilot study in Isparta, Turkey. Scand J Rheumatol 2001;30:99-102.[CrossRef][Medline]
51. Britten N, Stevenson FA, Barry CA, et al. Misunderstandings in prescribing decisions in general practice: qualitative study. BMJ 2000;320:484-8.[Abstract/Free Full Text]
52. McGrath JM. Physicians' perspectives on communicating prescription drug information. Qual Health Res 1999;9:731-45.[Abstract/Free Full Text]
53. Sleath B, Roter D, Chewning B, et al. Asking questions about medication: analysis of physician-patient interactions and physician perceptions. Med Care 1999;37:1169-73.[CrossRef][Medline]
54. Haynes RB, McDonald H, Garg AX, et al. Interventions for helping patients to follow prescriptions for medications. Cochrane Database Syst Rev 2002;CD000011.
55. Morris LA, Tabak ER, Gondek K. Counseling patients about prescribed medication: 12-year trends. Med Care 1997;35:996-1007.[CrossRef][Medline]
56. Gardner ME, Rulien N, McGhan WF, Mead RA. A study of patients' perceived importance of medication information provided by physicians in a health maintenance organization. Drug Intell Clin Pharm 1988;22:596-8.[Abstract]
57. Bailey BJ, Carney SL, Gillies AH, et al. Hypertension treatment compliance: what do patients want to know about their medications? Prog Cardiovasc Nurs 1997;12:23-8.[Medline]
58. Nair K, Dolovich L, Cassels A, et al. What patients want to know about their medications. Focus group study of patient and clinician perspectives. Can Fam Physician 2002;48:104-10. [Abstract/Free Full Text]
59. Scherwitz L, Hennrikus D, Yusim S, et al. Physician communication to patients regarding

medications. Patient Educ Couns 1985;7:121-36.[CrossRef][Medline]
60. Dyck A, Deschamps M, Taylor J. Pharmacists' discussions of medication side effects: a descriptive study. Patient Educ Couns 2005;56:21-7.[CrossRef][Medline]
61. Jackson C, Lawton RJ, Raynor DK, et al. Promoting adherence to antibiotics: a test of implementation intentions. Patient Educ Couns 2006;61:212-8.[CrossRef][Medline]
62. Hassell K, Noyce P, Rogers A, et al. Advice provided in British community pharmacies: what people want and what they get. J Health Serv Res Policy 1998;3:219-25.[Medline]
63. Rost K, Roter D. Predictors of recall of medication regimens and recommendations for lifestyle change in elderly patients. Gerontologist 1987;27:510-5.[Medline]
64. Morrow DG, Leirer VO, Andrassy JM, et al. Medication instruction design: younger and older adult schemas for taking medication. Hum Factors 1996;38:556-73.[CrossRef][Medline]
65. Hall JA, Roter DL, Katz NR. Meta-analysis of correlates of provider behavior in medical encounters. Med Care 1988;26:657-75.[Medline]
66. Makoul G, Arntson P, Schofield T. Health promotion in primary care: physician-patient communication and decision making about prescription medications. Soc Sci Med 1995;41:1241-54.[CrossRef][Medline]
67. Peveler R, George C, Kinmonth AL, et al. Effect of antidepressant drug counseling and information leaflets on adherence to drug treatment in primary care: randomised controlled trial. BMJ 1999;319:612-5.[Abstract/Free Full Text]
68. Schillinger D, Piette J, Grumbach K, et al. Closing the loop: physician communication with diabetic patients who have low health literacy. Arch Intern Med 2003;163:83-90. [Abstract/Free Full Text]
69. Tuldra A, Fumaz CR, Ferrer MJ, et al. Prospective randomized two-arm controlled study to determine the efficacy of a specific intervention to improve long-term adherence to highly active antiretroviral therapy. J Acquir Immune Defic Syndr 2000;25:221-8.[CrossRef][Medline]
70. Hulka BS, Cassel JC, Kupper LL, et al. Communication, compliance, and concordance between physicians and patients with prescribed medications. Am J Public Health 1976;66:847-53. [Abstract/Free Full Text]
71. Schwartz LM, Woloshin S, Welch HG. Can patients interpret health information? An assessment of the medical data interpretation test. Med Decis Making 2005;25:290-300. [Abstract/Free Full Text]
72. Smith DH, Cunningham KG, Hale WE. Communication about medicines: perceptions of the ambulatory elderly. Health Commun 1994;6:281-95.[CrossRef]
73. Raynor DK, Nicolson M, Nunney J, et al. The development and evaluation of an extended adherence support programme by community pharmacists for elderly patients at home. Int J Pharm Pract 2000; 157-64.
74. Peters E, Vastfjall D, Slovic P, Mertz CK, Mazzocco K, Dickert S. Numeracy and decision making. Psychol Sci 2006;17:407-13.[CrossRef][Medline]
75. Lyons RF, Rumore MM, Merola MR. An analysis of drug information desired by the patient (Are patients being told everything they wish to know under OBRA '90?). J Clin Pharm Ther 1996;21:221-8.[Medline]
76. Lisper L, Isacson D, Sjoden P, Bingefors K. Medicated hypertensive patients' views and experience of information and communication concerning antihypertensive drugs. Patient Educ Couns 1997;32:147-55.[CrossRef][Medline]
77. Bower AB, Taylor VA. Increasing intention to comply with pharmaceutical product instructions: an exploratory study investigating the roles of frame and plain language. J Health Commun 2003;8:145-56.[CrossRef][Medline]
78. Vuorma S, Rissanen P, Aalto AM, et al. Impact of patient information booklet on treatment decision—a randomized trial among women with heavy menstruation. Health Expect 2003;6:290-7.[CrossRef][Medline]
79. Berry DC, Raynor DK, Knapp P, et al. Patients' understanding of risk associated with medication

use: impact of European Commission guidelines and other risk scales. Drug Saf 2003;26:1-11. [CrossRef][Medline]
80. Discenza R, Ferguson JM. The instrumental role of product information: a study of warning labels for non-prescription drugs. Health Mark Q 1992;10:155-68.[Medline]
81. Wogalter MS, Magurno AB, Dietrich DA, et al. Enhancing information acquisition for over-the-counter medications by making better use of container surface space. Exp Aging Res 1999;25:27-48.[CrossRef][Medline]
82. Willy ME, Li Z. What is prescription labeling communicating to doctors about hepatotoxic drugs? A study of FDA approved product labeling. Pharmacoepidemiol Drug Saf 2004;13:201-6. [CrossRef][Medline]
83. Berry D, Raynor T, Knapp P, et al. Over the counter medicines and the need for immediate action: a further evaluation of European Commission recommended wordings for communicating risk. Patient Educ Couns 2004;53:129-34.[CrossRef][Medline]
84. Nabors LA, Lehmkuhl HD, Parkins IS, et al. Reading about over-the-counter medications. Issues Compr Pediatr Nurs 2004;27:297-305.[CrossRef][Medline]
85. Hameen-Anttila K, Kemppainen K, Enlund H, et al. Do pictograms improve children's understanding of medicine leaflet information? Patient Educ Couns 2004;55:371-8.[CrossRef] [Medline]
86. Mansoor LE, Dowse R. Effect of pictograms on readability of patient information materials. Ann Pharmacother 2003;37: 1003-9. DOI 10.1345/aph.1C449[Abstract/Free Full Text]
87. Wogalter MS, Vigilante WJ Jr. Effects of label format on knowledge acquisition and perceived readability by younger and older adults. Ergonomics 2003;46:327-44.[Medline]
88. Khurana RN, Lee PP, Challa P. Readability of ocular medication inserts. J Glaucoma 2003;12:50-3.[CrossRef][Medline]
89. Patel VL, Branch T, Arocha JF. Errors in interpreting quantities as procedures: the case of pharmaceutical labels. Int J Med Inform 2002;65:193-211.[CrossRef][Medline]
90. Raymond EG, Dalebout SM, Camp SI. Comprehension of a prototype over-the-counter label for an emergency contraceptive pill product. Obstet Gynecol 2002;100:342-9. [Abstract/Free Full Text]
91. Krass I, Svarstad BL, Bultman D. Using alternative methodologies for evaluating patient medication leaflets. Patient Educ Couns 2002;47:29-35.[CrossRef][Medline]
92. Benson JG, Forman WB. Comprehension of written health care information in an affluent geriatric retirement community: use of the Test of Functional Health Literacy. Gerontology 2002;48:93-7.[CrossRef][Medline]
93. Moisan J, Gaudet M, Gregoire JP, et al. Non-compliance with drug treatment and reading difficulties with regard to prescription labeling among seniors. Gerontology 2002;48:44-51. [CrossRef][Medline]
94. Sansgiry SS, Cady PS, Sansgiry S. Consumer involvement: effects on information processing from over-the-counter medication labels. Health Mark Q 2001;19:61-78.[CrossRef][Medline]
95. Ciociola AA, Sirgo MA, Pappa KA, et al. A study of the nonprescription drug consumer's understanding of the ranitidine product label and actual product usage patterns in the treatment of episodic heartburn. Am J Ther 2001;8:387-98.[CrossRef][Medline]
96. Dickinson D, Raynor DK, Duman M. Patient information leaflets for medicines: using consumer testing to determine the most effective design. Patient Educ Couns 2001;43:147-59.[CrossRef] [Medline]
97. Bernardini C, Ambrogi V, Perioli LC, et al. Comprehensibility of the package leaflets of all medicinal products for human use: a questionnaire survey about the use of symbols and pictograms. Pharmacol Res 2000;41:679-88.[CrossRef][Medline]
98. Estrada CA, Hryniewicz MM, Higgs VB, et al. Anticoagulant patient information material is written at high readability levels. Stroke 2000;31:2966-70.[Abstract/Free Full Text]
99. Thomas LG, Corwin EJ. The readability of printed education materials regarding hormone

replacement therapy. J Am Acad Nurse Pract 1998;10:447-52.[Medline]
100. Morrow DG, Hier CM, Menard WE, et al. Icons improve older and younger adults' comprehension of medication information. J Gerontol B Psychol Sci Soc Sci 1998;53:P240-54. [Abstract]
101. Morrow DG, Leirer VO, Andrassy JM, et al. The influence of list format and category headers on age differences in understanding medication instructions. Exp Aging Res 1998;24:231-56. [CrossRef][Medline]
102. Sansgiry SS, Cady PS, Patil S. Readability of over-the-counter medication labels. J Am Pharm Assoc (Wash) 1997;NS37:522-8.
103. Friedman CP, Romeo D, Hinton SS. Healthcare decisions and product labeling: results of a consumer comprehension study of prototype labeling for proposed over-the-counter cholestyramine. Am J Med 1997;102:50-6.[Medline]
104. Sansgiry SS, Cady PS. An investigative model evaluating how consumers process pictorial information on nonprescription medication labels. Health Mark Q 1997;14:71-90.[CrossRef] [Medline]
105. Vander Stichele RH, Van Haecht CH, Braem MD, Bogaert MG. Attitude of the public toward technical package inserts for medication information in Belgium. DICP 1991;25:1002-6. [Abstract]
106. Miselli M. What information for the patient? Large scale pilot study on experimental package inserts giving information on prescribed and over the counter drugs. BMJ 1990;301:1261-5. [Medline]
107. Morrell RW, Park DC, Poon LW. Effects of labeling techniques on memory and comprehension of prescription information in young and old adults. J Gerontol 1990;45:P166-72.[Medline]
108. Swanson JM, Forrest K, Ledbetter C, et al. Readability of commercial and generic contraceptive instructions. Image J Nurs Sch 1990;22:96-100.[Medline]
109. Steinmetz KL, Coley KC, Pollock BG. Assessment of geriatric information on the drug label for commonly prescribed drugs in older people. J Am Geriatr Soc 2005;53:891-4.[CrossRef] [Medline]
110. Gustafsson J, Kalvemark S, Nilsson G, et al. Patient information leaflets—patients' comprehension of information about interactions and contraindications. Pharm World Sci 2005;27:35-40.[CrossRef][Medline]
111. Kaphingst KA, Rudd RE, DeJong W, et al. Literacy demands of product information intended to supplement television direct-to-consumer prescription drug advertisements. Patient Educ Couns 2004;55:293-300.[CrossRef][Medline]
112. Lohiya S. The variable location, content, and legibility of expiration dates on medicine containers. J Am Board Fam Pract 2004;17:395-7.[Medline]
113. Ross BS, Potter LS, Armstrong KA. Improving patient educational literature: an understandable patient package insert for "the pill." J Obstet Gynecol Neonatal Nurs 2004;33:198-208.[CrossRef] [Medline]
114. Brinker A, Staffa J. Concurrent use of selected agents with moxifloxacin: an examination of labeling compliance within 1 year of marketing. Arch Intern Med 2002;162:2011-2. [Free Full Text]
115. Marroum PJ, Gobburu J. The product label: how pharmacokinetics and pharmacodynamics reach the prescriber. Clin Pharmacokinet 2002;41:161-9.[CrossRef][Medline]
116. Bernardini C, Ambrogi V, Fardella G, et al. How to improve the readability of the patient package leaflet: a survey on the use of colour, print size and layout. Pharmacol Res 2001;43:437-44. [CrossRef][Medline]
117. Buck ML. Providing patients with written medication information. Ann Pharmacother 1998;32:962-9. DOI10.1345/aph.17455[Abstract]
118. Kroner BA, Kelley CL, Baranowski EM. Labelling deficiencies and communication problems leading to medication misuse in the elderly. Drugs Aging 1994;5:403-10.[Medline]

119. Basara LR, Juergens JP. Patient package insert readability and design. Am Pharm 1994;NS34:48-53.
120. Luscombe DK, Jinks MJ, Duncan S. A survey of prescription label preferences among community pharmacy patrons. J Clin Pharm Ther 1992;17:241-4.[Medline]
121. Knapp P, Raynor DK, Jebar AH, Price SJ. Interpretation of medication pictograms by adults in the UK. Ann Pharmacother 2005;39: 1227-33. Epub 16 May 2005. DOI 10.1345/aph.1E483 [Abstract/Free Full Text]
122. Dowse R, Ehlers M. Medicine labels incorporating pictograms: do they influence understanding and adherence? Patient Educ Couns 2005;58:63-70.[CrossRef][Medline]
123. Dowse R, Ehlers MS. The evaluation of pharmaceutical pictograms in a low-literate South African population. Patient Educ Couns 2001;45:87-99.[CrossRef][Medline]
124. Ngoh LN, Shepherd MD. Design, development, and evaluation of visual aids for communicating prescription drug instructions to nonliterate patients in rural Cameroon. Patient Educ Couns 1997;30:257-70.[CrossRef][Medline]
125. Smalley W, Shatin D, Wysowski DK, et al. Contraindicated use of cisapride: impact of Food and Drug Administration regulatory action. JAMA 2000;284:3036-9.[Abstract/Free Full Text]
126. Zuccollo G, Liddell H. The elderly and the medication label: doing it better. Age Ageing 1985;14:371-6.[Abstract/Free Full Text]
127. Mazzullo JM 3rd, Lasagna L, Griner PF. Variations in interpretation of prescription instructions. The need for improved prescribing habits. JAMA 1974;227:929-31.[CrossRef][Medline]
128. Brass EP. Consumer behavior in the setting of over-the-counter statin availability: lessons from the consumer use study of OTC Mevacor. Am J Cardiol 2004;94:22F-9F.[Medline]
129. Melin JM, Struble WE, Tipping RW, et al. A consumer use study of over-the-counter lovastatin (CUSTOM). Am J Cardiol 2004;94:1243-8.[CrossRef][Medline]
130. Filik R, Purdy K, Gale A, et al. Drug name confusion: evaluating the effectiveness of capital ("Tall Man") letters using eye movement data. Soc Sci Med 2004;59:2597-601.[CrossRef] [Medline]
131. Gibbs S, Waters WE, George CF. Prescription information leaflets: a national survey. J R Soc Med 1990;83:292-7.[Abstract]
132. Morrow D, Leirer V, Sheikh J. Adherence and medication instructions. Review and recommendations. J Am Geriatr Soc 1988;36:1147-60.[Medline]
133. Kalsher MJ, Wogalter MS, Racicot BM. Pharmaceutical container labels: enhancing preference perceptions with alternative designs and pictorials. Int J Industrial Ergonom 1996;18:83-90. [CrossRef]
134. Smither JA, Braun CC. Readability of prescription drug labels by older and younger adults. J Clin Psychol Med Sett 1994;1:149-59.[CrossRef]
135. Vigilante WJ, Wogalter MS. The preferred order of over-the-counter (OTC) pharmaceutical label components. Drug Inf J 1997;31:973-88.
136. Morrow D, Leirer V, Altieri P. List formats improve medication instructions for older adults. Educ Gerontol 1995;21:151-66.
137. Woloshin S, Schwartz LM, Welch G. The value of benefit data in direct-to-consumer drug ads. Health Aff (Millwood) 2004;suppl Web Exclusives:W4-234-45.
138. Hallworth RB, Goldberg LA. Geriatric patients understanding of labeling of medicines: part 1. Br J Pharmaceut Pract 1984;6:6-14.
139. Morris LA, Olins NJ. Utility of drug leaflets for elderly consumers. Am J Public Health 1984;74:157-8.[Abstract/Free Full Text]
140. Morrow D, Leirer V, Altieri P, Tanke E. Elders' schema for taking medication: implications for instruction design. J Gerontol 1991;46:378-85.
141. Morrell RW, Park DC, Poon LW. Quality of instructions on prescription drug labels: effects on memory and comprehension in young and old adults. Gerontologist 1989;29:345-54.[Medline]

142. Holt GA, Dorcheus L, Hall EL, Beck D, Ellis E, Hough J. Patient interpretation of label instructions. Am Pharm 1992;NS32:58-62.
143. Whatley S, Mamdani M, Upshur RE. A randomised comparison of the effect of three patient information leaflet models on older patients' treatment intentions. Br J Gen Pract 2002;52:483-4. [Medline]

This article has been cited by other articles:

THE ANNALS OF PHARMACOTHERAPY

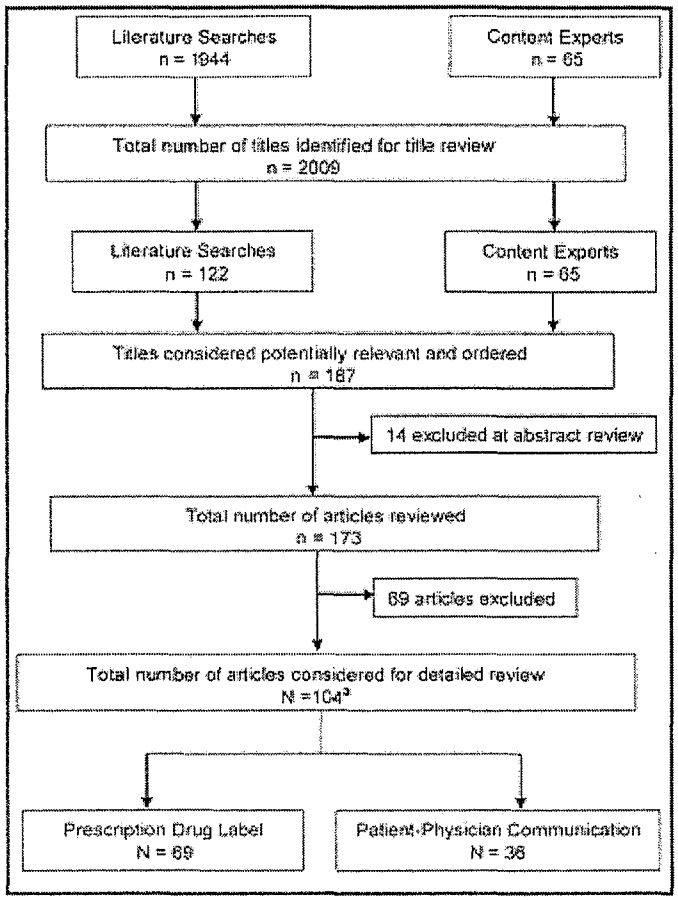


Figure 1. Article flow. [a]One article was used in both evidence tables.

Return to article

THE ANNALS OF PHARMACOTHERAPY

Table 1. Evidence about Physician–Patient Communication about Drugs

Reference	Type of Article/Design	Research Question	Population	Findings
Technical aspects[a]				
Jackson (2005)[61]	RCT; pt. report of adherence	Does communication about implementation intention improve adherence?	220 pts.	Implementation intentions specify exactly when and where pts. will perform a behavior (eg, take medications). An intervention using this technique did not significantly impact adherence to short-term antibiotics.
Bikowski (2001)[47]	descriptive; physician questionnaires and pt. observation	Do physicians and elderly pts. agree about medication doses and frequency?	50 physician–pt. pairs	In 74% of pairs, either the physician was unaware that the pt. was taking a medication or thought the pt. was taking a drug that they were not taking; 12% of pairs had dose or frequency discrepancies.
Bull (2002)[46]	descriptive; matched physician–pt. interviews	Does communication about duration of therapy and ADRs impact adherence to antidepressants?	401 pts. and 137 prescribing physicians	Discussion of therapy duration (>6 mo) led to 3 times greater odds of continuation after 6 mo. vs pts. told to take the drug for <6 mo. Discussion of ADRs was associated with 2 times greater odds of adherence.
Fletcher (1979)[32]	descriptive/; pt. interview	Do pts. understand information about	143 pts.	While 90% of pts. identified drugs

		their prescribed medication?		prescribed during the visit, only 58% knew the dosing schedules of all medications immediately after leaving their physician's office.
Gardner (1988)[56]	descriptive; pt. questionnaire	What information do pts. request about medications?	67 previsit pt. questionnaires, 70 postvisit	67% of pts. requested information about indication, 64% about instructions, 60% about precautions, and 59% about duration of treatment. One of 3 pts. was not given basic information.
Lyons (1996)[75]	descriptive; pt. questionnaire	What information do pts. desire about their medications, and how often are they provided with that information?	100 pts. responding out of 873 surveys distributed	Although >60% of pts. believed the information was important, <50% received information about storage, drug interactions, missed doses, and avoidance of ADRs; >75% received information about a drug's name, indication, dosing frequency, and duration of therapy.
Makoul (1995)[66]	descriptive; videotaped encounters, pt. interviews, written questionnaires, medical record reviews, and physician questionnaire	Do physicians and pts. in England communicate about prescription drugs in primary care, and do they agree about levels of communication?	271 pts. had full survey and videotaped data	Physicians frequently discussed product name (78%) and instructions for use (87%); pts. were passive, rarely offering their opinion or initiating discussions about medical treatment. Both groups overestimate the frequency of communication about medications.
Morris (1997)[55]	descriptive; pt. telephone survey	What are the trends over time concerning what pts. and physicians discuss about prescription drugs?	≥1000 pts. in 4 surveys conducted in 1982, 1984, 1992, and 1994	About two-thirds of physicians discuss the prescription during the encounter. About 60% discuss administration and only one-third discuss ADRs. In 1992, physicians and pts.

				discussed drugs more frequently than in the 1980s.
Rost (1987) [63]	descriptive; pt. interview and audiotaped pt.–physician encounters, medical record review	What predicts recall of medication regimens?	83 elderly pts.	On average, elderly pts. recalled 46% of the drugs in their medical records and 41% of the drugs mentioned in the clinical encounter. When physicians asked more closed-ended questions and provided more information about the medication, the pt. better recalled the medication after the visit.
Scherwitz (1985)[59]	descriptive; qualitative evaluation of tape-recorded encounters	What do physicians and pts. discuss about medications?	11 physicians making 267 physician–pt. encounters	There was little communication about drugs after the initial prescription. At the initial prescription, instructions were discussed 77% of the time, directions 31%, and indications 21%.
Sleath (1999)[53]	descriptive; qualitative analysis of taped physician–pt. communication	What do physicians and pts. talk about concerning prescription drugs?	467 physician–pt. encounters	On average, physician–pt. communication about drugs accounted for about 4 min per encounter. About half of the pts. recorded asked no questions about their prescription drugs; they most commonly asked about quantity (16%), drug identification (15%), dosage (9%), and indication (9%). Physicians asked pts. about identification (80%), effect on medical condition (56%), quantity (51%), dosing (41%), and barriers or ADRs (27%).
Adherence				
Peveler (1999)[67]	factorial; RCT testing	Do antidepressant drug counseling and	250 pts.	63% of pts. continued with therapy in the

	counseling and educational leaflets; measurement by pt. interviews and MEMS caps	information leaflets improve adherence to treatment in primary care?		counseled group vs 39% who did not receive counseling (OR = 2.7; 95% CI 1.6 to 4.8). Counseling focused on daily routine and lifestyle, understanding the disease, and treatment of ADRs and their management. Treatment leaflets had no significant effect overall.
Tuldra (2000)[69]	RCT; self-reported adherence and lab testing	Does a psychoeducative intervention to educate pts. about medications and adherence improve adherence to HAART?	116 pts.	Intervention included consultation with a psychologist who provided better education about the medication and communication follow-up about adherence. Pts. who received the intervention had >6 times the odds of adequate adherence and better viral load control than those without ($p = 0.008$ and $p = 0.026$, respectively).
Raynor (2000)[73]	intervention; pre–post design; pt. interviews	Does a pharmacist intervention to improve communication about prescription drugs improve adherence?	143 pts. in England	Intervention that allowed pts. to communicate with pharmacists about drugs led to a 24% decrease in nonadherence (from 38% to 14%; $p < 0.001$) and a 36% improvement in pts.' reporting of medical problems.
Bailey (1997)[57]	descriptive; pt. questionnaires	What information do hypertensive pts. prefer to receive about medications to improve adherence?	66 pts.	90% of pts. wanted to know about all possible ADRs, 96% wanted to know about benefits of the medication, and 82% wanted more information about their disease. Concerns about duration of therapy and lifestyle effects were frequent.
Britten (2000)[51]	descriptive; qualitative	What are physician–pt.	20 physicians and 35 pts. in	14 categories of misunderstandings were

	evaluation of recorded consultation and pt. interviews	misunderstandings about prescribing?	England	identified between physicians and pts., including physician misunderstandings about pt. beliefs and vice versa. Disagreement existed about attribution of ADRs; all misunderstandings were associated with potential or actual ADRs such as nonadherence.
Hulka (1976)[70]	descriptive; pt. interview and medical record review	Does communication influence adherence and error rates for chronic medications?	46 physicians and 357 pts. with CHF or diabetes	4 types of errors were identified: omission, commission, scheduling misconceptions, and nonadherence. Greater number of drugs and greater regimen complexity were associated with more errors. Better communication of instructions was associated with fewer errors in pts. with CHF.
Ogedegbe (2004)[44]	descriptive; pt. interview	What are barriers to adherence in hypertensive African Americans?	106 pts.	Forgetfulness and poor understanding about disease are important barriers. Reminders, knowledge of disease, better communication with physicians, having a routine for medication administration, and social support networks facilitate adherence.
Schneider (2004)[42]	descriptive; pt. questionnaires	What aspects of physician–pt. relationship lead to better adherence to HAART?	554 pts. at 22 HIV practices	Adherence dialogue, general communication, disease-specific information, trust in physician, and physician satisfaction are all related to self-reported adherence.
Schillinger (2003)[68]	descriptive; observed	Do physician communication	38 physicians and 74 diabetic	Physicians assessed recall and comprehension only

	physician–pt. interactions and evaluated pt. lab outcomes	techniques in which the physician assesses recall and comprehension impact health?	pts. with low functional health	20% of the time. Assessment of recall and comprehension was associated with improved glycemic control, even after controlling for health literacy.
Hall (1988) [65]	systematic review and meta-analysis	Is physician–pt. communication about prescription drugs associated with greater adherence?	41 studies	There was a statistically significant relationship between information-giving about medication and adherence to medical regimens ($p < 0.0005$). Giving more information was also as sociated with greater understanding and recall about medications.
Adherence				
Haynes (2002)[55]	systematic review	What interventions improve adherence?		A number of interventions have been shown to improve adherence, typically using a complex, multifaceted approach. More convenient care, information, counseling, reminders, and other interventions have been shown to be helpful.
Stevenson (2004)[45]	systematic review	What is the relationship between communication about drugs and adherence?	134 articles considered relevant, of which 116 were descriptive	There has been little research concerning whether exchange of views takes place between physicians and pts. (concordance). Physicians tend to dominate discussions. Some interventions to improve communication rates have been successful, but little guidance exists about the specific content associated with improving adherence.
Risk/benefit				

ADRs				
Dyck (2005)[60]	descriptive; qualitative evaluation of tape-recorded encounters	What do pharmacists discuss with pts. about drugs?	10 pharmacists, each encountering 2 pts.	Pharmacists discussed ADRs in all encounters, but discussed frequency of ADRs using vague terms and did not focus on potential benefits of the drugs. Using a leaflet did not substitute for communication about risk.
Gramling (2004)[48]	descriptive; physician survey	Do physicians believe it is more important to communicate quantitative or qualitative information about risk?	300 physician members of the Massachusetts Academy of Family Practice	When asked whether it is more important to communicate qualitative vs quantitative information about risk to pts., 63% of physicians felt they were of equal importance. Of the remainder of respondents, 94% rated qualitative as more important than quantitative information.
Hassell (1998)[62]	descriptive; qualitative evaluation of physician–pt. encounters and pt. questionnaires	What information do consumers hope pharmacists will provide and what do they actually provide?	2379 observed encounters and 1000 pt. interviews in England	Consumers are more interested in learning about the effectiveness of their medications, and pharmacists focus their guidance on ADRs and safety.
Lisper (1997)[76]	descriptive; qualitative evaluation of pt. interviews	From whom do pts. prefer to receive their information and what information do they need about medications?	21 Swedish pts. with hypertension	Pts. prefer to receive drug information from physicians rather than pharmacists. They prefer information at the onset of therapy and especially request information concerning possible ADRs.
McGrath (1999)[52]	descriptive; qualitative evaluation of physician interviews	What are physicians' perceptions about communicating prescription drug information?	20 physicians	Physicians think communication about drugs should be 2-way and participatory. Physicians express concern that too much information about ADRs

				may impair adherence.
Morrow (1996)[64]	descriptive; pt. interviews	Do pts. have a schema for understanding drug information?	study 1 and 2: 42 older and 42 younger adults in each study	Pts. prefer to "lump" information into packages that are easier to understand. They tend to package directions and indications together. Another group includes ADRs and emergency information.
Nair (2002) [58]	descriptive; pt., physician, and pharmacist focus groups in Canada	What do pts., physicians, and pharmacists want to discuss about medications?	88 pts., 27 physicians, 35 pharmacists, all in Canada	Physicians and pharmacists believe that pts. want less information about ADRs than they actually do and are concerned that information may impede adherence. Pts. desire both general and specific information.
Peters (2006)[74]	4 descriptive studies	How are risk frequencies best communicated when communicating risk?	1–100 students, 2–46 students, 3–46 students, 4–171 students	Framing effects were more influential in less numerate pts. More numerate pts. drew more precise affective meaning from numerical information.
Schwartz (2005)[71]	descriptive; pt. questionnaire	How well do pts. interpret health-related data?	178 pts.	There is a wide range in pts.' ability to interpret health information. Those with high numeracy scored better than those with low numeracy (71% vs 36%), high vs low quantitative literacy (65% vs 28%), and high vs low education (69% vs 42%).
Walter (2004)[43]	descriptive; focus groups	How can risk about hormone replacement be best discussed?	40 women in England	Pts. prefer open communication of risks and benefits so that they can participate in the decision-making process. Pts. also want individualized risk and benefit information.
Provider/venue/language				

choice				
Savas (2001)[50]	RCT; pt. questionnaire	Does verbal or written information improve understanding about medications in an undereducated population?	38 received written alone, 30 received verbal alone, 40 received both written and verbal information	78% read the written material. Pts. who received both verbal and written material had the best understanding about their drugs as measured by a series of 8 questions about administration and ADRs. Written information was more effective than verbal information.
Smith (1994)[72]	descriptive; pt. questionnaire	What are pts.' perceptions of the most valuable source of information about drugs and the optimal content of discussions about drugs?	110 pts.' taking OTC medications, 218 pts. taking prescription drugs	Pts. prefer to discuss prescription drugs with their physicians and would like to hear about indications, directions, ADRs, and duration of therapy. Pts. believe that they have to bring up the topic of drugs with their physicians.
Schaafsma (2003)[49]	review; MEDLINE literature review	How do pts. whose first language is not English access drug information?		There has been little research in this area. Foreign languages and cultural differences provide barriers to accessing drug information; interpreting services can help.

ADRs = adverse drug reactions; RCT = randomized controlled trial.

ADRs = adverse drug reactions; CHF = congestive heart failure; HAART = highly active antiretroviral therapy; MEMS = Medication Event Monitoring System; RCT = randomized controlled trial.

ADRs = adverse drug reactions.

ADRs = adverse drug reactions; OTC = over-the-counter; RCT = randomized controlled trial

[a] Indication, dose, administration, directions, and duration of therapy

Return to article

HOME HELP CONTACT US SUBSCRIPTIONS ARCHIVE SEARCH CURRENT ISSUE

THE ANNALS OF PHARMACOTHERAPY

Table 2. Evidence Concerning Content and Format of Prescription Drug Labels

Reference	Type of Article/Design	Type of Label	Research Question	Population	Findings
Leaflets					
Bower (2003)[77]	experiment; pt. questionnaire	CMI	What language characteristics affect intention to adhere?	260 students	Adherence intention is greater when instructions are set in a negative frame and the language is simple, understandable, and avoids medical jargon.
Dickinson (2001)[96]	RCT; pt. questionnaire	CMI	comparison of 2 CMI formats and an assessment of the proposed EU standardized format	2 groups of 20 pts.	On average, pts. correctly answered only 3 of 15 questions after reading the EU CMI and 8 of 15 from the best practice CMI. Headers and clearer language improved understanding.
Knapp (2005)[121]	RCT; pt. questionnaire	CMI	Can pts. comprehend the messages from icons? Does icon size or the frequency of presentation influence comprehension?	part 1: 160 adults part 2: 67 elderly adults in the UK	There was great variability in pts.' interpretations of icons. In the 10 icons evaluated, pts. correctly interpreted 7.5–90%; only 3 were understood by >85%. Older and

					less educated pts. were less likely to understand icons. Icons were better understood when larger ($p = 0.04$) and when presented to pts. more than once ($p < .001$).
Miselli (1990)[106]	prospective observational study; pts. exposed to 2 different leaflets and pt. questionnaire	CMI	Do different labels impact information accessibility and understandability?	6692 pts. in Italy	Experimental labels were more effective. Pts. judged an experimental label with simple language and checklists superior to a conventional label.
Morrow (1995)[136]	experimental; 3 trials evaluating pt. perceptions of label formats and impact on recall and understanding	CMI	Do list vs paragraph formats improve older pts.' understanding and recall of drug instructions?	trial 1: 27 older adults trial 2: 36 older adults trial 3: 27 older adults	List formats improved pts.' understanding, recall, and speed of accessing information vs paragraph format.
Morrow (1998)[100]	experiment with 2 trials of labels with and without icons	CMI	Does the use of icons to communicate dosing schedules improve older and younger pts.' understanding?	trial 1: 36 older and 36 younger adults trial 2: 45 older and 36 younger adults	In older and younger adults, questions about dose and time information were answered more quickly and accurately when a timeline icon was used. An icon that was less integrated to the text was ineffective.
Morrow (1998)[101]	RCT; trials using pt. questionnaires to evaluate	CMI	Does the use of list format and category headers on CMI impact	trial 1: 44 elderly and 44 young adults trial 2: 48	Lists improved pts.' ability to infer information from labels. Pts.

	understanding and recall of different label formats		understanding of medication instructions?	elderly and 32 young adults	prefer lists and headers. Lists improved understanding and recall and reduced age differences in answer time as well as accuracy. The benefit of lists was greater in older vs younger adults. Evidence of the effect of headers was inconclusive.
Ngoh (1997) [124]	RCT; pt. interview and pill count	CMI	Does CMI with icons produced by local artists and with educational organizers lead to better adherence and understanding in nonliterate pts.?	78 nonliterate pts. in Cameroon who were started on antibiotics	Both visual aids (CMI with icons) and educational organizers led to improved comprehension about drugs and adherence to antibiotic regimens.
Peveler (1999)[67]	RCT; intervention with measurement by pt. interviews and MEMS caps	CMI	Do antidepressant drug counseling and information leaflets improve adherence in primary care?	250 pts.	63% of pts. continued with therapy in the counseled group vs 39% who did not receive counseling. Treatment information leaflets had no significant effect overall.
Vuorma (2003)[78]	RCT	CMI	Does provision of a booklet with treatment information options impact treatment choices for menorrhagia?	393 pts.	Written information significantly impacted pt. behavior. Pts. who received the information chose more medical treatment, but surgical procedure rates

					did not change and fewer "new" procedures were performed.
Whatley (2002)[143]	RCT	CMI	Does the use of icons or graphs to depict risk and benefit information influence intention to take the medication?	196 pts. in Canada	Pts. randomized to the traditional, text-only CMI were less likely to consider taking the drug than were pts. randomized to receive CMI with either icons or graphs to depict risk and benefit information ($p < 0.001$).
Basara (1994)[119]	descriptive; content evaluation of 63 CMIs	CMI	Are PPIs/CMI readable?	63 CMI	Inserts written at a 9th grade reading level with small font are not very readable.
Leaflets					
Bernardini (2000)[97]	descriptive; pt. questionnaire	CMI	Can pts. understand CMI, and do they prefer the use of symbols or icons?	1004 pts. in Italy	83.5% of Italian pts. read the leaflet; 53.5% found the leaflet hard to read, 63% of those >50 y old. 47% had difficulty finding the information they sought. Although 74% of pts. preferred the use of icons, there was little agreement about which versions were most effective.
Bernardini (2001)[116]	descriptive; pt. questionnaire	CMI	How do color, print size, and layout influence readability of	1004 pts. in Italy	Pts. reported that font size must be at least 10 point to be readable,

			labels?		preferably larger. Pts. requested more detail, but in a schematic organization; they also noted that certain color print is more appropriate for certain sections (eg, warnings/ADRs should be red).
Berry (2003) [79]	descriptive; pt. interview	CMI	Do the standardized European Community guidelines for communicating risk lead pts. to understand risk?	4 studies in the UK: 1–268 students 2–112 adults 3–120 adults 4–360 adults	Using language to communicate risk led pts. to significantly overestimate the risk of ADRs vs a numerical presentation, which was much closer to the actual risk.
Estrada (2000)[98]	descriptive; SMOG evaluation of leaflets	CMI	Is warfarin CMI or handout information readable?	50 leaflets	Written at an average level of 10.7th grade, which is beyond the comprehension of most pts.
Gibbs (1990) [131]	descriptive; pt. mail survey	CMI	Do leaflets improve understanding about medications and their ADRs? Are pts. satisfied with leaflets?	3410 pts.	Pts. had better understanding of their indications for the medication, administration directions, and what to do in case of an ADR. Pts. were satisfied, overall, with leaflets and did not experience more ADRs than did those who did not receive CMI.

Gustafsson (2005)[110]	descriptive; expert evaluation of the leaflets and pt. questionnaires	CMI	Are leaflets readable and well understood by pts.?	1060 pts. who received CMI for 30 drugs in Sweden	Leaflets contained about half of the important topics desired and were deemed readable. Pts. had difficulty understanding interactions and contraindications of the drugs.
Hameen-Anttila (2004)[85]	descriptive; pt. interview	CMI	Do children understand icons in medication leaflets?	90 children in Finland	Correct interpretations of pictograms ranged from 30% to 99%, but were generally well understood. However, even well understood icons did not influence children's understanding of the leaflets.
Khurana (2003)[88]	descriptive; SMOG and other tests to measure readability	CMI	Can pts. read ocular medication inserts?	10 drug inserts	CMI for ocular medications are often too complex, average of 12th or 13th grade reading level.
Krass (2002) [91]	descriptive; leaflet evaluation	CMI	Does CMI meet the 1996 FDA Action Plan? Do consumers comprehend existing CMI and model CMI?	24 pts., 36 CMI, and 3 model CMI	Both the language and format recommendations of the Action Plan have not been widely met by the CMI evaluated. Pts. strongly preferred the model CMI to the existing ones and could understand it better.
Morris (1984)[139]	descriptive; mailed survey	CMI	Do patients who take hypertension, tranquilizer, or	1650 pts.	95% of those surveyed read the CMI, 76% keep

			arthritis drugs read CMI or keep it?		it, and 56% discuss it with another person; 42% said that the leaflet made them feel better about taking the medication.
Morrow (1991)[140]	descriptive; 2 trials requiring pt. to sort and answer questions about labels	CMI	How do elderly pts. organize medication information for best understanding? Do instructions that follow this schema increase understanding?	trial 1: 33 elderly pts. trial 2: 27 elderly pts.	Elderly patients have a schema that they use to understand drug information, and they prefer information to follow in that order: (1) medication and purpose, (2) how to take (dose, schedule, duration, warnings), (3) outcomes (ADRs, emergency information). Instructions in this order were easier to remember.
Svarsted (2003)[39]	descriptive; evaluated the CMI received by trained shoppers after filling prescriptions	CMI	How frequently do pts. receive CMI, and what is the quality of the CMI?	918 prescriptions filled at 306 randomly selected pharmacies	Shoppers received leaflets 87% of the time, but leaflet length and quality varied greatly. Only 49% of leaflets had acceptable administration directions, 28% had acceptable information about precautions, 19% had acceptable information about contraindications and what to do about them; 26%

					of pts. did not receive leaflets that were adequately readable or comprehensible.
Leaflets					
Swanson (1990)[108]	descriptive; evaluated PIs and CMI	CMI/PIs	How readable are leaflets for oral contraceptives?	93 leaflets	A great deal of variability was seen among leaflet readability levels, ranging from grade 5.5 to 13.6.
Vander Stichele (1991)[105]	descriptive; pt. survey	CMI	How do people feel about CMI?	398 respondents in Belgium	89% of respondents read the CMI and find it useful to learn about ADRs, dosage, indications, contraindications, and shelf life. Respondents were generally pleased with CMI.
Buck (1998) [117]	systematic review	CMI	Are pts. receiving highquality CMI? Are they receiving CMI at all?	NA	Leaflets are commonly dispensed. However, content is not standardized, materials are written at a high grade level, and there are poor resources for non–English-speaking pts.
Kroner (1994)[118]	review	container labels and CMI	challenges with reading labels	NA	Describes the importance of better physician–pt. communication about medications. Also

					demonstrates that labels are not very readable, but large font and particular language improve readability.
Morrow (1988)[132]	review	CMI	describes prescription drug nonadherence	NA	Medication instructions should be complete, organized in a logical way, and in list format. Precise instructions improve adherence by 10–20%.
Container labels					
Kalsher (1996)[133]	experimental; 2 pt. surveys after reading various labels	container labels	Do fold-out or tag labels improve readability? Do icons improve readability?	trial 1: 84 undergraduates trial 2: 58 older adults	Tag or fold-out labels were rated as easier to read, and pts. were more likely to read warnings, recommend label use, and prefer labels. Icons were helpful across the same domains.
Luscombe (1992)[120]	experiment; pt. survey	container labels	Do pts. have preferences for container label typology?	55 pharmacy clients in Great Britain	Pts. strongly preferred laser-printed labels compared with those printed on a dot matrix printer. In general, glossy labels were preferred over matte-finish labels.
Mansoor (2003)[86]	experiment; pt. interview	container labels and CMI	How do pictograms affect readability of pt.	60 low-literate pts. from South Africa	The presence of pictograms significantly

			information materials?		improved acquisition and comprehension of drug information; 73% vs 53% had >80% understanding when reading CMI with icons vs no icons.
Morrell (1990)[107]	RCT; pt. interview	container labels	Do icons improve younger and older adults' understanding of prescription labels?	32 older adults and 32 young adults	Younger pts. understood the labels better and more quickly. Use of icons improved younger adults' understanding but interfered with older adults' understanding of the medication directions.
Smither (1994)[134]	experiment; evaluated pts.' ability to read and comprehend labels with different formats	container labels	Do font size and font selection impact understanding and ease of reading labels?	trial 1: 19 young adults and 20 seniors trial 2: 18 young adults and 16 seniors	Larger font and certain font types are associated with ease of reading and better understanding of the labels. More errors were seen with 9 point vs 12 or 14 point font and with Courier rather than Helvetica or Century Schoolbook font.
Wogalter (2003)[87]	experimental evaluation of hypothetical container labels that varied in print size, spacing, and design	container labels	What is the effect of label format on knowledge acquisition and perceived readability of labels?	101 elderly subjects, 109 young adults	Older pts. benefit substantially from larger print. While previous studies have supported the use of extended (fold-out) labels, this study was inconclusive on that issue. Use of

					white space or chunking of information was helpful, especially in the elderly.
Wogalter (1999)[81]	experimental evaluation of hypothetical container labels that included cap labels	container labels	Can information acquisition in older adults be enhanced by using the container surface area in new ways?	trial 1: 60 subjects trial 2: 75 subjects	Trial 1: pts. preferrred labels that included a large identification label attached to the cap. Trial 2: cap labels also improved pt. knowledge about the drug. Cap labels in colors different from the container also improved pt. satisfaction and knowledge.
Container labels					
Benson (2002)[92]	descriptive; pt. interview	container labels	Can affluent seniors read container labels (as well as other health information)?	93 seniors	30% of seniors could not comprehend basic health information in prescription labels. Older seniors and those with less education performed worse.
Container labels					
Dowse (2005)[122]	descriptive; pt. Interview	container labels	Do labels with pictograms improve understanding and adherence in low-literacy pts.?	87 Xhosa pts. from South Africa	Labels were constructed in culturally appropriate ways by local artists. Patients with pictogram labels experienced 25% greater

					understanding about medications and 18% improvement in adherence.
Dowse (2001)[123]	descriptive; pt. interview	container labels	Are locally created, culturally targeted pictograms more effective than accepted pictograms for communicating with low-literate pts.?	46 Xhosa pts. from South Africa shown 23 local CMI and 23 USP CMI	Pts. exposed to locally produced, culturally appropriate icons were more likely to understand the information than were pts. exposed to USP pictograms. Almost 2 times as many pts. who received local labels understood them at ≥85% level.
Filik (2004) [130]	descriptive; pt. eye-tracking when evaluating an array of labels	container labels	Does the use of capitalized "tall man" font improve pts.' likelihood of selecting appropriate medications?	20 students and staff (non–healthcare professionals}	Pts. were almost half as likely to incorrectly identify a target drug presented in an array of drugs when using "tall man" letters, suggesting that capitalizing sections of potentially confusing drug names improves identification.
Hallworth (1984)[138]	descriptive; pt. survey	container labels	Do geriatric pts. understand the contents of container labels?	92 elderly pts.	Geriatric pts. frequently misinterpreted medication directions, and there was substantial variability in their understanding. Confusion frequently stemmed from

					timing of dosing and the relationship to meals.
Holt (1992) [142]	descriptive; pt. questionnaire	container labels	Can pts. correctly interpret dosage directions from container labels, and what characteristics of instructions improve interpretation?	321 pts.	While labels more frequently used language that vaguely instructed pts. about dosing directions (ie, "Take three times daily"), dosage instructions that specified the number of hours between doses were better understood (ie, "Take every 8 hours").
Lohiya (2004)[112]	descriptive; evaluation of container labels	container labels	Is there variability in the presentation of expiration dates on prescription drug labels?	84 drug labels	Substantial variability was seen in location, font, and legibility of expiration dates
Mazzullo (1974)[127]	descriptive; pt. interviews	container labels	How well do pts. understand prescription label instructions?	67 pts.	Pts. had substantial difficulty with instructions that were vague. Even when responding to clear instructions, the frequency of interpretive errors ranged from 8% to 64%.
Moisan (2002)[93]	descriptive; pt. interviews	container labels	Do pts. who have difficulty reading labels adhere less to their drugs?	325 seniors	No clear relationship was identified between understanding labels and adherence. However, 95% CIs are very wide

					and an important effect cannot be excluded.
Morrell (1989)[141]	descriptive; pt. questionnaires	container labels	Do age, memory load, and study time affect drug label memory and comprehension? 3 experiments varied study time, memory load, and label quality.	experiment 1: 36 elderly and 48 young adults experiments 2 and 3: 36 elderly and young adults	Older pts. had poorer recall than did younger subjects, regardless of who determined the study time. Both older and younger subjects recalled less information as more was presented. Both young and older pts. had difficulty understanding information from a community pharmacy but had better understanding when presented with a standard, high-quality label.
Zuccollo (1985)[126]	descriptive; pt. interviews and assessment of labels	container labels	How well do elderly pts. read and understand container labels?	60 British pts. and 163 medication labels	Only 40% of pts. had no difficulty reading instructions on the label. Scriptwriter typeface was least easy to read. About half of the labels were judged to have directions that were unclear.
OTC labels/DTCA					
Berry (2004)[83]	experiment; pt. questionnaire	OTC	Is risk communicated better numerically or verbally on OTC labels?	188 adults	Pts. overestimate risk in all cases, but overestimated it to a much greater extent when risk was

					presented verbally vs numerically.
Discenza (1992)[80]	RCT comparing 3 levels of warnings	OTC	How does the strength of warnings on labels affect intention to use medication?	252 volunteers attending business school	As warnings were more forceful and threatening, study participants reported they would be less likely to use the medication.
OTC labels/DTCA					
Friedman (1997)[103]	controlled trial comparing 3 prototype labels	OTC	Are cholestyramine OTC labels comprehendable?	2225 randomly selected subjects from across the US	99% of subjects understood the key message that they should call the physician before using the drug and should read the full insert. They were able to follow directions 67–92% of the time. There were no statistically significant differences among labels with text, graphics, or symbols except that high school nongraduates had significantly lower comprehension with symbols.
Sansgiry (2001)[94]	experiment assessing degree of involvement	OTC	How does consumer involvement or hypothetical symptoms impact label understanding?	256 college students	Pts. more involved in purchase of OTC drugs (those with symptoms) understood the labels better than did those who were not involved. There

					was no difference between hypothetical symptoms of a cold or headache.
Sansgiry (1997)[104]	experiment assessing 4 label designs: pictures only, verbal only, congruent picture–verbal, and noncongruent picture–verbal	OTC	Does congruence between icons and text improve understanding and intention to buy medications?	48 elderly adults and 48 young adults	Congruence between the icons and verbal information on labels leads pts. to best understand the medication directions and increases the intention to purchase the drug.
Woloshin (2004)[137]	experiment; before and after comparison	DTCA information	Do pts. prefer to have access to a "benefit box" of quantitative risks and benefits for prescription drugs that are advertised?	203 subjects in New England communities	The benefit box was widely rated as useful and readable. When added to DTCAs for rofecoxib, clopidogrel, and pravachol, pts. had a lower perception of efficacy after reading the benefit box.
Brass (2004)[128]	descriptive; pt. interview and lab tests	OTC	How well did pts. follow instructions on OTC label for cholesterol-lowering medication (the CUSTOM trial)	3316 pts. who self-selected to enroll	Only 44% of all pts. who self-selected the drug met LDL-C criteria; 24% had >20% 10 y coronary risks. Only 42% of pts. talked with their physicians before use.
Ciociola (2001)[95]	descriptive; recordings of drug use in a diary, tablet counts, and pt. interview	OTC	Do pts. understand OTC ranitidine labels?	1405 pts.	More than 84% of pts. understood contraindication of use, dose, and duration of another drug for PUD. 90%

					followed maximum daily dose instructions.
Kaphingst (2004)[111]	descriptive; expert evaluation of DTCA supplements	DTCA television ads and related Web sites	Is the information associated with DTCA readable?	23 supplements to television DTCAs	Using SMOG assessments, text DTCA supplements were written at the high school level for the body sections and college level for the summary, with specific shortfalls in layout, typology, and graphics use.
Melin (2004) [129]	descriptive; pt. questionnaires and lab tests	OTC	Do pts. understand OTC label for Mevacor?	3316 pts. who self-selected to enroll	Pts. understood labels and LDL-C improved, but 23% of pts. demonstrated behavior that created the potential for suboptimal safety.
Nabors (2004)[84]	descriptive; pt. questionnaire	OTC	Do adolescents and young adults read or understand CMI?	876 high school and college students	75% of subjects read the labels. Those with "immediate health concerns" were most likely to read them. Students were interested in dosage, ADRs, and symptoms treated. (Note: pain was not statistically significant in multivariate models.)
Patel (2002) [89]	descriptive; pt. interview	OTC	How well do pts. interpret directions that require calculations?	oral rehydration therapy: 13 subjects	77% of subjects were unable to correctly administer oral rehydration

					therapy, and performance was weakly related to cultural background and education; 56% were unable to calculate appropriate doses for their children's cough syrup. Pts. had no difficulty in understanding the appropriate dose of the tablets, but 68% planned therapy schedules that led to incorrect doses.
				OTC drops: 48 subjects OTC tabs: 31 subjects; subjects selected to have broad cultural and educational diversity	
OTC labels/DTCA					
Raymond (2002)[90]	descriptive; pt. survey	OTC	Do pts. understand an OTC label for the emergency contraceptve?	663 women	A prototype label was created; >85% of women understood 7 of 11 objectives. Worse comprehension was seen on an important safety-related topic (don't take if vaginal bleeding is present).
Sansgiry (1997)[102]	descriptive; assessed labels	OTC	Did OTC label contents meet	100 labels, 103 subjects	Poor guideline adherence: use of

	on criteria from guidelines		label readability guidelines (prior to the Drug Facts)?		small font (≤6 points on warnings and indications), all uppercase letters and use of hyphenation, lack of paragraph breaks or boldface; >40% contained advertising claims.
Thomas (1998)[99]	descriptive; evaluated using SMOG techniques	PEMs	Can pts. understand education materials about hormone replacement therapy?	27 PEMs	Pt. education materials were often hard to read and understand, ranging from grade 8 to grade 14 reading level (mean 10.8). Professional associations created the most readable PEMs.
Vigilante (1997)[135]	descriptive; pt. survey	OTC	Do pts. prefer medication information on labels to be presented in a particular order?	140 pts.: 3 stratified convenient samples that varied in age and educational status	Pts. have preferred order for items on the label: (1) indications, (2) hazards/warnings, (3) active ingredients.
PIs					
Brinker (2002)[114]	descriptive; evaluation of pharmacy claims data	PIs	Do physicians prescribe in compliance with PIs when prescribing moxifloxacin?	793 700 pts.	Physicians prescribed moxifloxacin concomitantly with a contraindicated medication (amiodarone; 0.11%). This study shows that even physicians are frequently unaware of PIs

					when prescribing.
Smalley (2000)[125]	descriptive; evaluation of pharmacy claims data	PIs	Do pts. respond to black box warnings on cisapride by taking the drug more appropriately?	24 840 pts.	In the year subsequent to FDA action requiring a black box warning for cisapride, there was only a 2% reduction in inappropriate cisapride use in each of 3 sites, with rates of inappropriate use ranging from 24% to 58%.
Stearman Ross (2004) [113]	descriptive; pt. and provider surveys	PIs	Are PIs for oral contraceptives readable?	94 pts. and 18 providers	Oral contraceptive PIs were frequently written at 10th to 12th grade levels and included substantial medical jargon. A new PI was created at the 6th grade level with simpler language.
				34 expert reviews	
Steinmetz (2005)[109]	descriptive; evaluation of PIs	PIs	What information about geriatric pts. is present on PIs?	50 PIs from the most prescribed oral medications at 1 university medical center	Approximately 50% of PIs contained precautionary statements for the elderly. Only 56% had dosing information and only 16% provided specific milligram amounts. More information is necessary about elderly dosing information on labels.

Willy (2004)[82]	descriptive; evaluation of PIs	PIs	How much variability is there in the PIs of drugs known to be hepatotoxic?	95 PIs	12% of PIs had hepatotoxic warnings in a black box, 54% in the warnings section, and 34% in the ADRs section. Mean informativeness score was 35%.
Marroum (2002)[115]	review	PIs	How is pharmacokinetic and pharmacodynamic information reported?	NA	PIs present outdated and poor-quality information about pharmacokinetic and pharmacodynamic information to physicians. Proposed a new FDA rule to improve PIs.

CMI = consumer medication information; EU = European Union; MEMS = Medication Event Monitoring System; PPI = patient package inserts; RCT = randomized controlled trial.

ADRs = adverse drug reactions; CMI = consumer medication information; FDA = Food and Drug Administration; RCT = randomized controlled trial; SMOG = Simplified Measure of Gobbledygook.

ADRs = adverse drug reactions; CMI = consumer medication information; NA = not applicable; PIs = package inserts; RCT = randomized controlled trial.

CMI = consumer medication information; DTCA = direct-to-consumer advertising; OTC = over-the-counter; RCT = randomized controlled trial; USP = United States Pharmacopoeia.

ADRs = adverse drug reactions; CMI = consumer medication information; CUSTOM = Consumer Use Study of OTC Mevacor; DTCA = direct-to-consumer advertising; LDL-C = low-density lipoprotein cholesterol; OTC = over-the-counter; PUD = peptic ulcer disease; SMOG = Simplified Measure of Gobbledygook.

ADRs = adverse drug reactions; FDA = Food and Drug Administration; NA = not applicable; OTC = over-the-counter; PEMs = patient education materials; PIs = package inserts; SMOG = Simplified Measure of Gobbledygook

Return to article

HOME HELP CONTACT US SUBSCRIPTIONS ARCHIVE SEARCH CURRENT ISSUE

THE ANNALS OF PHARMACOTHERAPY

Table 3. Summary of Findings about Content and Format of Prescription Drug Labels

Items	Study Design	Outcomes Measured
Content to be included		
clinical indication for drug	3 observational studies	pt. preferences
administration instructions	3 observational studies	pt. preferences
thorough information about potential adverse effects	3 observational studies	pt. preferences
importance of adherence	2 systematic reviews	medication adherence
duration of therapy	1 observational study	medication continuation
language describing directions should be precise	2 observational sudies and 1 RCT	pt. comprehension
information about benefits of medication	1 RCT	pt. preferences
numerical information about risk	4 observational studies	pt. comprehension
Format to be used		
lists	3 RCTs	label comprehension and recall
headers	3 RCTs	label comprehension, recall, and preferences
white space	1 RCT	pt. preferences
uniform schema that orders drug information	4 observational studies	medication recall
larger font size	2 RCTs and 1 observational study	label comprehension and recall
particular font styles	1 RCT and 1 observational study	label comprehension and recall

RCT = randomized controlled trial

Return to article

HOME HELP CONTACT US SUBSCRIPTIONS ARCHIVE SEARCH CURRENT ISSUE