

Good Medicine for Seniors:

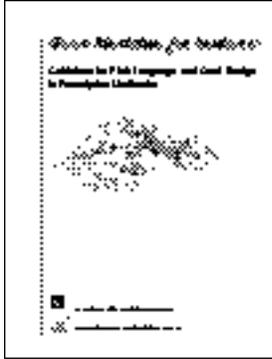
Guidelines for Plain Language and Good Design
in Prescription Medication



Canadian Public Health Association



National Literacy and Health Program



Good Medicine for Seniors:

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ISBN: 1-894324-23-4

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Canadian Public Health Association

The Canadian Public Health Association (CPHA) is a national, independent, not-for-profit voluntary association representing public health in Canada with links to the international public health community. CPHA's mission is to constitute a special national resource in Canada that advocates for the improvement and maintenance of personal and community health according to the public health principles of disease prevention, health promotion and protection, and healthy public policy.

National Literacy and Health Program

The National Literacy and Health Program (NLHP) is a partnership of 28 national health associations working together to raise awareness among Canadian health professionals about the links between literacy and health. The NLHP provides health professionals with resources to help them serve people with low literacy skills more effectively. The NLHP's Plain Language Service offers plain language assessments, revisions and workshops to the public, private and voluntary sectors.

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Foreword and Acknowledgements

The aging of the Canadian population has received much attention in recent years, particularly as seniors are living much longer lives and the Baby Boom generation is approaching retirement. While the wisdom of age and good health can make growing older a positive one, the reality is that older people often experience illness, infirmity, isolation, loss and grief, deteriorating eyesight, and so on.

With aging often comes the need to take medication to manage chronic conditions, acute illness or trauma, and sometimes all of these. Managing a drug regimen can be complex and sometimes potentially dangerous, particularly for those who have difficulty reading. The low literacy rates among Canadian seniors led the Canadian Public Health Association (CPHA) to undertake this project to examine the issues and problems related to low literacy and medication management, and come up with solutions.

These Guidelines should help those involved with providing patient information to use plain language and clear verbal communication – pharmaceutical manufacturers, physicians, pharmacists and other health care providers. The document was developed with funding from the National Literacy Secretariat (Human Resources Development Canada) and Health Canada. The project was guided by a multi-stakeholder Steering Committee and benefited from the advice and input of the partners in CPHA's National Literacy and Health Program. I would like to thank all those involved.

Graphics were generously provided by Pharmasystems® Inc., and Literacy Volunteers of America.

It is CPHA's belief that patient information in plain language will help seniors maintain good health and independence through the proper use of their medications.

Dianne Kinnon, Steering Committee Chair

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Lois took the medicine bottle out of her purse, hoping for quick relief from her stress. What was it the doctor had said? Lois tried to remember. Was it one pill three times a day? Three pills once a day? When she tried to read the label, the words didn't seem to make sense.

The numbers on the label were one and three, so she was pretty sure that taking three pills a day was okay. Since it was almost supper time, she decided to take all three right away. It would make her feel better faster!

Lois woke up in the hospital several hours later. Luckily, her husband had called an ambulance when he couldn't wake her up. Lois had taken too much medicine at one time because she couldn't remember what the doctor had said, and couldn't read the medicine label.



INTRODUCTION:

About These Guidelines and How to Use Them

Patients need to understand their medication regimens and comply accordingly to ensure they get the greatest benefit from these drugs.

This document has been written to assist those who develop and provide information for patients who use prescription medication. This includes manufacturers of pharmaceutical products and those whom they employ to create information materials, physicians, pharmacists, and software manufacturers who produce electronic information that is printed for patients at the time a medication is dispensed. The Guidelines will help in preparing written patient information materials in plain language and incorporating clear design features. The heart of the publication is a Compendium of Plain Language Terminology for commonly used instructions to patients who are taking prescription medication (see Chapter II).

As we will learn in Chapter I, a disproportionate number of Canadian seniors (defined herein as age 65 and older) have literacy skills that fall below the level of everyday reading demands. Because seniors also consume most of the medications prescribed in Canada, it is essential that they be able to understand and follow the instructions given to them verbally by care

providers as well as written patient information that comes from a variety of sources.

Written information can be provided on a medication package label or on a patient package insert in the case of original package dispensing. However, the vast majority of prescription drugs in Canada are repackaged and dispensed by the pharmacist; in this case, written information appears on a label affixed to the repackaged container and frequently on a computer-generated information sheet provided at the time of dispensing.

Those who cannot understand verbal or written medication information due to low literacy skills are at risk. Indeed, several Canadian research studies show that roughly one-quarter of hospital admissions of seniors are related to problems with medication mismanagement. The resulting costs to the health care system and to the personal well-being of older patients are staggering.

This document encourages the use of plain language so that most patients understand the instructions on their medications. When preparing or rewriting text in plain language, a Grade 6 reading level is a generally

accepted target to reach most people. However, there are segments of the population who fall below this level in terms of reading comprehension ability, don't understand either of Canada's official languages, or are blind. No amount of plain language will be of use to these people; thus, they will need assistance from others such as family members or home care workers, who will also benefit from plain language information.

Although this document is intended primarily for those who write patient information materials (i.e., manufacturers of pharmaceutical products and software manufacturers of pharmacy-generated patient information), the Guidelines will be of interest to other members of the "medication management team" who work together to ensure good patient care. In addition to manufacturers, team members include:

- health professionals involved in prescribing and administering medication;
- pharmacists;
- formal and informal caregivers who administer medications; and
- patients themselves.

Each member of the team has a role to play in ensuring the safe and effective use of medication, and collaboration is a key part of the process.

The text in this document is organized into three main chapters:

- *Chapter I:* background information on seniors and literacy, as well as the drug regulatory context;
- *Chapter II:* plain language and good design in patient information, and the Compendium of Plain Language Terminology; and
- *Chapter III:* techniques for enhancing compliance.

In addition, an Appendix contains definitions of literacy from the International Adult Literacy Survey.

This document is part of a series of publications by the Canadian Public Health Association (CPHA) and its National Literacy and Health Program (NLHP). CPHA and the 27 national partners in the NLHP focus on plain language health information and clear verbal communication in health professional practice. The program has produced the following materials, aimed primarily at health professionals, which provide plain language and clear verbal communication tools and techniques. These materials are available from CPHA's Health Resources Centre.

- *Easy Does It!* is a training package for health care professionals, providing information, tips and techniques to improve the way they communicate with their patients. The package includes a manual, a training video and a CD-ROM game called (plain•word)TM.
- *Working with Low-literacy Seniors* is a resource which focuses specifically on

the senior segment of the population, giving practical strategies for health providers serving these Canadians, and a bibliography of resources.

- *Creating Plain Language Forms for Seniors* is a guide for the public, private and not-for-profit sectors on the design and plain-language wording of forms intended to be used or completed by seniors.

Good Medicine for Seniors was developed under the guidance of a Steering Committee of stakeholder representatives and with the advice and input of industry, seniors, pharmacists and regulatory bodies. These stakeholders then reviewed the Guidelines and assisted in the dissemination of the document. CPHA is grateful to the many organizations and individuals who contributed to the project.





CHAPTER I:

Seniors, Literacy, and Patient Information

The United Nations designated 1990 as International Literacy Year, to draw attention to the scope and nature of literacy (and illiteracy) around the world as well as to examine its social, economic and political implications. The Year generated considerable activity in some countries, including Canada.

Prior to the Year itself, Statistics Canada conducted its first major national survey on the subject, Literacy Skills Used in Daily Activities, and produced an analytical report. In 1994, Statistics Canada and the Organisation for Economic Co-operation and Development (OECD) carried out a joint study, the International Adult Literacy Survey (IALS).

...we now have a rich source of data and analysis to help us understand the many aspects of literacy...

Together with other pioneering studies and demographic data, we now have a rich source of data and analysis to help us understand the many aspects of literacy, including the particular needs and characteristics of older persons with low literacy levels. The following section presents pertinent facts about Canada's aging population and IALS statistics to establish a rationale for the use of plain language in medication information for patients.

A Snapshot of Canadian Seniors

Thanks to extensive research and analysis, particularly over the past two decades, we have learned much about older Canadians and the phenomena associated with the aging of the population as a whole. The following points highlight some of the more significant facts about Canada's seniors.¹

- Seniors are the fastest-growing segment of the Canadian population. In 1998, there were 3.7 million Canadians aged 65 and over (12.3% of the population). Projections indicate that by the year 2031, this figure will almost double to 21.7%. Seniors aged 85 and older represent one in ten of all seniors, up from one in twenty earlier in the 20th century.
- Women live longer than men in Canada, making up 57.4% of all seniors and 69.8% of seniors aged 85 and over.

¹ Source: *Canada's Seniors*, prepared by Statistics Canada for the Division of Aging and Seniors, Health Canada, 1999. For the purposes of these figures, the age of 65 was used to define "senior".

- The vast majority of seniors live at home. Of the 93% who do, 29% live alone (mostly women, who tend to outlive their spouse); 7% live with members of their extended family (such as a daughter, son or sibling); and 2% live with non-relatives. Seniors living with a spouse or common-law partner account for 58% of those living in private households.
- Only 8% of seniors held a university degree in 1996, compared with 17% of Canadians aged between 25 and 64. Six out of ten did not complete high school, and 37% had less than a grade 9 education.
- In 1996, 4% of all people aged 65 and over could not speak either official language, as opposed to 1% of those aged 15-64. This difference reflects, in part, the fact that many seniors are immigrants.
- The average income for households headed by a senior was just over \$20,000 in 1997, compared with well over \$30,000 among those aged 35-54. Senior men had an average income of \$26,150, while women in this age range had an average income of \$16,070. Of unattached seniors, 45% were considered to have low incomes.
- Seniors rely on others for help with housework, shopping, etc. In 1996, 84% received some form of support, including 11.9% for personal care.
- Similarly, many seniors provided support to others (family and friends): 35.3% helped by checking up on others, 27.3% gave emotional support, and 4.2% provided personal care.
- Causes of death among seniors in 1996 included 30% attributed to heart disease, 26% from cancer, 11% from respiratory diseases, and 24% from other diseases and conditions.
- Many seniors suffer from chronic health conditions: in 1997, 42.4% lived with the pain of arthritis, while 32.6% had high blood pressure.
- Also in 1997, one in four Canadian seniors living at home had a long-term disability. The proportion rises sharply with age, with 45% of those aged 85 and over suffering from a handicap.
- One-quarter of seniors experience chronic pain, compared with only 12% of those aged 25-54.
- In 1997, 84% of all seniors living at home took some form of prescription or over-the-counter medication, with 56% using two or more medications. Pain relievers were taken by 62% of all seniors; 33% took medication for high blood pressure, 19% for other heart problems. Other medications included stomach remedies (11%), diuretics (11%), and cough or cold medication (10%).

What is a senior?

The arbitrary age of 65 is the most commonly used (and easily understood) definition of the beginning of one's senior years. It has traditionally been the age of eligibility for pension benefits, both public and private, and for other benefits such as government drug plans and tax rebates.

In recent years, the over-65 population has been broken into three sub-categories: "young-old", aged 65-74; "middle-old", aged 75-84; and "old-old", those aged 85 and over. Although some people find these distinctions offensive, the categories have proven useful in research, statistical analysis, and policy and program development.

The increasing trend to early retirement has also led researchers to examine more closely the cohort aged 55-64. Those in this group are often referred to as "early retirees", "pre-retirees" or "older workers", depending on their status and the issue(s) under study.

These days, a healthy 78-year-old could have better health status and a more active lifestyle than someone 20 years younger. Both could be taking the same medication. Which is the "senior"?

Many have dealt with the issue by using the term "older Canadians".

These figures reveal a segment of the Canadian population that is rapidly becoming the largest age cohort in this country. As the Baby Boom generation (those born between 1945 and 1965) ages, this diverse population will come to dominate many aspects of Canadian life – economic, social and political. Seniors are and will be a focal point in policy and programs affecting their lives, particularly in health care and, pertinent to this document, medication issues. Even though the Baby Boom generation may be among the most educated in history, a significant portion of this population – like those of generations before it, and the ones that will follow it – has low literacy skills for enduring reasons such as poverty, rapidly changing information and communication technologies, etc.

The fact that so many seniors take medication – whether prescription, non-prescription, natural health products, herbal medicines, homeopathic medicines – cannot be overlooked by companies serving this market. In Canada, \$15 billion a year is spent on drugs; approximately 290 million prescriptions are written every year. Because more than half of seniors take more than one medication – many take more than ten a day – they must understand their drug regimen in order to avoid negative interactions. The Guidelines presented in this document should help those developing and/or distributing pharmaceutical products and services aimed at older Canadians to provide them with the best possible written information which will help ensure that they take their medication safely and correctly.

The next section looks at the levels of literacy found among older Canadians, and discusses the implications for patient information materials about prescription medication.



The Facts on Literacy in Canada

As mentioned above, Canada has been a world leader in the measurement of literacy. The International Adult Literacy Survey, undertaken by Statistics Canada in partnership with the Organisation for Economic Co-operation and Development (OECD), assessed literacy levels in several countries in 1994 and published their findings the following year in a report entitled *Literacy, Economy and Society*.²

A major component of the study was the development of clear definitions of literacy as well as a methodology to measure effectively the literacy levels among the sample populations. The IALS adopted the following **basic definition of literacy**: *using printed and written information to function in society, to achieve one's goals, and to develop one's knowledge and potential.*

Further refining this definition, IALS identified three distinct types of literacy, defined as follows.

- **Prose literacy**: the knowledge and skills needed to understand and use information from texts including editorials, news stories, poems and fiction.
- **Document literacy**: the knowledge and skills required to locate and use information contained in various formats, including job applications, payroll forms, transportation schedules, maps, tables and graphics.
- **Quantitative literacy**: the knowledge and skills required to apply arithmetic operations, either alone or sequentially, to numbers embedded in printed materials, such as balancing a chequebook, figuring out a tip, completing an order form or determining the amount of interest on a loan from an advertisement.

These three domains were then broken down into five levels in order to understand the broad and diverse nature of literacy and its meaning, extent and distribution. Level 1 was identified as the poorest and Level 5 the highest; individuals in Level 5 were defined as being capable of handling most everyday reading demands. (The levels are more fully described in the Appendix.) Testing took place in a face-to-face environment, where subjects were asked to complete a series of tasks such as reading a text and then answering questions about the content, filling in forms, finding pieces of information, performing arithmetical calculations, etc.

² Statistics Canada and the Organisation for Economic Co-operation and Development, *Literacy, Economy and Society*, 1995.

The following table shows the results of the IALS testing for Canada. The sample size was 4500 and included English, French and immigrant Canadians aged 16-65.

<i>Literacy levels by age, Canada, 1994</i>				
Age group	Level 1	Level 2	Level 3	Level 4/5 (aggregated)
	%	%	%	%
16-25	10.4	22.3	36.4	31.0
26-35	13.5	25.3	33.8	27.5
36-45	13.8	22.0	36.8	27.4
46-55	23.0	31.0	23.6	22.4
56-65	43.8	23.7	23.8	8.7

Source: Statistics Canada, OECD

Legend
Level 1 – lowest
Level 5 – highest

It is worth noting that, even combining the numbers for Levels 4 and 5, the oldest age group performed significantly worse than did the other age cohorts, with only 8.7% achieving a level where individuals could handle most everyday reading tasks. The fact that 43.8% fell into the lowest category (Level 1) has serious implications for providing written information to this age group and to those who are older (whose skills are likely to be even poorer).

These low levels of literacy among older Canadians prompt us to ask: Why? What factors caused (or are causing) seniors in this country to have trouble with printed materials?

Contributing Factors

In addition to historical factors, such as the Great Depression, World War II and generally lower education levels, other variables contribute to low literacy. What becomes of literacy skills over time? Like many skills, they can become rusty without regular use. For some, reading is simply not an enjoyable activity; for others, it is an admission of inability. The resulting avoidance over the years can lead to loss of whatever skills they may have had.

The changing nature of our society also has an impact on reading skills. A

reading level which may have been satisfactory 40 years ago will not suffice in today's technological, computerized world, when higher levels of education in the general population have raised the norm. New vocabulary, new concepts, new attitudes demand constant upgrading of literacy skills to keep pace with our culture. Literacy is relative to time and society: it is dynamic, not static.

The normal physical changes that come with aging can also have a bearing on older people's reading ability, particularly vision. As eyesight declines, it becomes more difficult to see small print or read from a distance. High contrast is needed to separate letters from background, and some colours or colour combinations can hamper readability.

Many of these factors will be explored more fully in subsequent chapters.

The Health Impact of Low Literacy on Seniors

Although advances in medicine, health promotion and technology have improved the health status of Canadians dramatically, it is still a fundamental reality of aging that disease and chronic conditions increase as people get older. As noted above, the incidence of heart disease, cancer, arthritis and other problems are high in the older population. Those who have low literacy skills are more vulnerable in several ways.

Health information, by its very nature, is complex. In order to be accurate and

complete, written materials are often equally complex, using technical terms and a style of writing aimed more at high-level readers, such as health professionals, than at the general public. This makes the information inaccessible to many, particularly those with low literacy skills.

The fact that seniors often experience multiple illnesses and/or conditions, and may therefore be taking several medications, means that they are likely to require information from several sources about several medications. As shown above (and in more detail in the Appendix), the capacity to make high-level inferences from several documents is a Level 4 or 5 skill. If the language in these information materials is already at a high reading level, the person with low literacy skills will likely not be able to understand or manage the complexities of a multi-medication regimen.

The reality of medical conditions and corresponding drug therapies is that they are complicated. However, it is not always necessary for patients to receive all of the information all of the time. Key facts – presented in clear language and reinforced by physicians, pharmacists and caregivers – are often sufficient to assist patients in understanding their medication. When these “multiple interventions” are further reinforced by print materials written in plain language, patients with low literacy skills are much more likely to be able to understand their medical status and take their medication properly. Seniors will enjoy a higher level of health and well-being as a result.

Seniors as Caregivers

Studies have shown that many seniors provide care to, or receive care from, family and friends. It has been estimated that more than 90% of elder care in Canada is provided informally; it ranges from personal care (including managing and administering medication), to housework, transportation and emotional support.

Increasingly, seniors are growing older in their homes as community care replaces hospital and institutional care. However, seniors need more help and support in the home, for example, when it comes time to take their medication, than they do in an institutional setting. If we want seniors to remain as independent as possible in a safe, supportive and healthy environment, it is important that medication instruction be clear and practical and in plain language.

For those patients who, for whatever reason, no longer have the capacity to manage their own medication at all, it is essential that informal caregivers they rely on be able to understand the medication therapy they are administering. Thus, it is not only the patient but the caregiver as well who may require plain-language information.

Seniors typically provide care for other seniors – spouses, siblings, friends, and even aging parents. It is increasingly common for a young senior to be caring for a very elderly parent.

Seniors often find themselves caring for grown children who are ill or disabled or in some way needing care. The growing incidence of HIV/AIDS has also affected many seniors who may be caring for a family member stricken with the disease, and drug regimens for this condition are usually very complex. Understanding how and when to administer medications becomes a critical factor in maintaining the health of these patients, or caring for them during the process of dying. Plain-language information can make this task easier and safer, especially if the patient is in an isolated or rural area where supports – such as home care services or additional informal caregivers – are limited.

How Do Patients Get Medication Information?

Where do people get information on medication? The initial source is, of course, the **prescribing physician** (or dentist). The time of issuing a prescription is the opportunity for the

physician to provide a verbal explanation of the drug, its purpose, how to take it, precautions and side effects. If the physician has a copy of the patient package insert, it can be reviewed. A demonstration may also be useful if there is a device involved, such as an inhaler or a syringe. At this time,

the physician may also provide supplementary patient information produced by the manufacturer, brochures on the nature of the illness or condition requiring the medication, and other appropriate materials. Although the amount of counselling by physicians varies from one to the next, generally some patient information is provided, either verbal or written (or both).

This information is later reinforced by the **pharmacist** when the medication is dispensed. Pharmacists are now required to provide a counselling service, especially the first time a prescription is filled. At this time they ensure that the patient understands what the physician has explained, and reinforce the verbal and written information that he/she has received. Pharmacists also may give additional written information about the medication to the patient as a computer print-out. Hospital pharmacists frequently provide counselling and information as necessary when a patient is discharged from an institutional care setting.

Health personnel – such as nurses, therapists, dietitians, and social workers – may be involved in supporting the patient or an informal caregiver in understanding and managing medication.

Many patients like to supplement the information received from care providers through their own research. Several **publications** are on the market which list thousands of drugs and provide information and instructions on their use. The level of writing in these references is inconsistent, some being fairly technical in nature and others

using a level of language more accessible to the average reader. Most are produced in the United States, and may not provide the Canadian brand or trade name, which often is different from the U.S. name. This can make it very difficult to look up a particular drug using the index.

Similar problems occur in drug information available on the **Internet**. Some sites have an opening page inviting the visitor to choose one of two portals: one for physicians, pharmacists and other professionals; the other for consumers. The language and terminology is then provided at a suitable level. The professional section usually requires registration and a password for access. A growing number of physicians are using these sites.

A danger of Internet sites is that the distinction between providing information versus marketing products is not always evident. Some sites are in the business of selling a wide range of pharmaceutical products (dubbed “online drugstores”). Others are sites maintained by pharmaceutical manufacturers who use the opportunity of a visit to promote their products. A system known as Health on the Net (abbreviated HON), in which companies agree to abide by a set of established principles, is a helpful designation indicating that the information is not only accurate but also unbiased. Consumers should be aware of this and check for the HON logo on the opening website page.

Media stories – both print and electronic – can also be a source of information on medication. Whether in

the form of a news story or an in-depth story, article or documentary, this can be a useful source of information (assuming it is accurate) and is usually written in an accessible style for the average reader or listener.

In Canada, **pharmaceutical manufacturers** are not permitted to promote products requiring a prescription through the media except under strict Health Canada guidelines. Some argue that such media advertising, known as direct-to-consumer advertising (DTCA), can cause more visits to physicians, increase the use of medication and result in higher costs for the health care system and for public and private drug plans. Others claim that it is an important method for patient education. DTCA is currently permitted in the United States, and Canada's proximity means a spill-over into the Canadian media environment is impossible to prevent. Health Canada continues to monitor the situation.

Regulation in Canada and Abroad

Information provided with prescription medications – both in Canada and in other countries – is strictly regulated.

Canadian Regulations

Pharmaceutical manufacturers, physicians, and pharmacists know that medications in Canada are controlled by Health Canada, through its Therapeutic Products Directorate (TPD) and Natural Health Products Directorate (NHPD). Drugs for human use which are submitted to TPD for approval are required to conform to the federal *Food*

and Drugs Act and the associated Regulations. The *Food and Drugs Act* is part of the *Criminal Code of Canada*, and only infractions that can be considered of a criminal nature can be prohibited by the legislation.

Drug or pharmaceutical products in Canada are regulated under several legal statutes administered by Health Canada's Health Products and Foods Branch. The main statute – the *Food and Drugs Act* and Regulations – requires that all pharmaceutical products offered for sale be authorized by Health Canada prior to marketing. As part of the evaluation process undertaken by Health Canada to determine if a product meets the requirements of the legislation, the labelling material proposed to be used by the sponsor of the product is subject to review.

A TPD guideline on labelling requirements, produced in 1989, is available to manufacturers. This guideline, used in conjunction with the Act and Regulations, contains definitions of terms and current interpretations of labelling requirements. These interpretations are based on legal precedents and advisory opinions established over a number of years.

The purpose of the Health Canada guideline is to help manufacturers develop labelling material that fully informs the health professions and the general public about the use of particular medicines. It applies to over-the-counter medicines as well as prescribed and parenteral drugs (those taken into the body otherwise than by way of the digestive tract).

Definition of a Label

Under the legislation, the term “labelling” for a drug product is considered to be all-inclusive. In addition to the actual labels, it includes extensions of the labels such as package inserts, product monographs, information on prescribing, and file cards whether included in the packaging or available on request.

When a submission or request for approval of labelling materials is made, all such pertinent documents are required to be submitted.

Elements of a Label

Several elements of a label are mandatory, and the Health Canada guideline lists these very specifically. They include such information as the proper or common name of the product, the Drug Identification Number (DIN), declaration of medicinal ingredients, and dosage form. This information is necessary for the health professional as well as the laboratory analyst to properly identify the medication, and to determine if the product meets quality requirements. Consumers are also served by consistency in nomenclature as they may need to recognize differences between products as well as similarities in situations where an ingredient may need to be avoided.

Wording of a Label

The Health Canada guideline makes a clear distinction between *information* that is directed to the professions and *instructions* for use aimed at the public, i.e., the consumer. Although technical terminology may be important for physicians and pharmacists, the guideline recognizes that such jargon has little meaning to the lay public. It states:

For example, the pharmacological classification of a medicine as an anti-emetic would not be sufficient on an OTC [over-the-counter] label; an additional indication, such as “motion sickness”, would be necessary.³

Health Canada’s guideline does not specify the actual wording of directions for use, warnings, etc., aimed at the consumer of the medicine. The manufacturer is required to provide certain required information, but may phrase these elements in lay terms, provided the intent of each element of these directions is conveyed. Indeed, looking at the example above, the use of lay terms or plain language may be necessary, not optional, in order to satisfy the requirement of the legislation to provide “adequate directions for use”.

³ Health Canada, *Labelling of Drugs for Human Use*, 1989, p. 29.

The purpose of the CPHA guidelines in this document is to provide plain language terminology for use by pharmaceutical manufacturers to meet this requirement.

International Regulations

During the research phase of this project, CPHA reviewed legislation and regulations on labelling and packaging of prescription medications in several other countries.



European Union

In 1999, the European Commission (EC) adopted *A Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use*. Several directives require that label text “shall be easily legible, clearly comprehensible and indelible”, and “be written in clear and understandable terms for the patient” (Council Directive 92/27/EEC). As with the Health Canada guideline, the EC document is for use by pharmaceutical manufacturers seeking approval (termed “marketing authorisation”).

The EC guideline draws a similar distinction between required wording and elements which may be written in plain language. Similar to these CPHA guidelines, it provides suggested plain language terminology, as well as design tips and a section on testing for readability. Every effort has been made in the CPHA guidelines to achieve consistency with the European guideline in order to make product information transferable among countries, for the

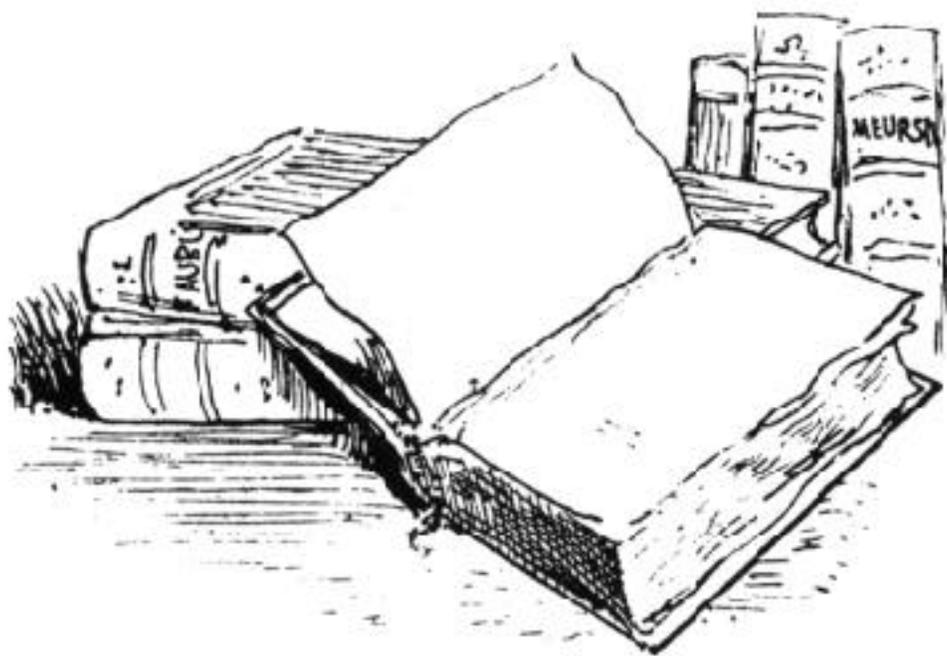
benefit of both patients and manufacturers who may produce pharmaceuticals in several countries.



United States of America

The United States has also been moving in the direction of plain language in patient information, particularly since the release of a Presidential Memorandum on Plain Language in 1998 which mandates federal employees to write or rewrite federal documents to make them easy for the public to understand and use. The U.S. Food and Drug Administration (FDA) announced a new regulation for over-the-counter drugs in March 1999 requiring easy-to-understand labelling on these products.

A public workshop held by the FDA in March 2000 on prescription drug information for patients developed consensus that comprehensibility and legibility were key criteria. The agency agreed to move in the direction of this consensus. The FDA is also evaluating the impact of a private-sector, industry-based action plan implemented in 1997, the goal of which is to provide patients with better and easy-to-read information about prescription drugs. No regulation has yet been adopted. An FDA director noted at the workshop that “a century or more of a professional model that didn’t trust patients with information has created much inertia to overcome.”



CHAPTER II:

Plain Language and Good Design

The National Pharmaceutical Council in the United States recently released some sobering statistics:

- Nine of every ten outpatients are believed to be taking prescribed medications **improperly or not at all**.
- An estimated three to five out of every ten prescriptions fail to produce desired results **because they are used improperly**.¹

Having established the link between literacy and health earlier in this document, it can safely be assumed that these disturbing figures are largely due to patients having difficulties understanding their medication information. With this in mind, Chapter II provides information on the use of plain language and good design in the preparation of medication information and packaging.

The section begins with an overview of **plain language writing techniques** which are widely accepted by writers and editors who specialize in the development of written materials for readers who may have low literacy skills. They are also used by literacy practitioners in preparing texts for their students. These techniques can be adapted to virtually any subject matter, even when the content and concepts are complex. When used in the development

of patient information materials, these basic techniques can bring clarity to the management of what can sometimes be a difficult drug regimen. This is essential, for people with low literacy skills.

The second part of this chapter is a **Compendium of Plain Language Terminology** for use in patient information materials. The wordings are consistent with similar terminology approved for use in Australia as well as the countries forming the European Union.

A third part contains advice on the use of **clear design, layout and graphics** to help the reader make sense of the information. Also included are design ideas to ensure that people with poor eyesight can make out the text.

A review of **techniques to test the readability of materials** follows, with tools to analyze the text and methods of testing a document with test subjects.

The chapter concludes with a look at the **physical design of packaging** and how it can help patients, such as seniors who may have arthritis or other problems, manipulate the package safely and effectively.

¹ Facts of Life: Issue Briefings for Health Reporters. *Pills that aren't taken can't work*. National Pharmaceutical Council, 1997

Introduction

As demonstrated in the previous chapter, using plain language and clear verbal communication is essential so that people with low literacy skills understand how to take their medication properly. Failure to understand and follow medication instructions can have a direct effect on an individual's health and well-being. Plain language and clear communication can enhance physician-patient and pharmacist-patient relationships when medication is prescribed and dispensed.

Seniors are at particular risk for the following reasons:

- their higher use of medications;
- the vulnerabilities that can accompany typical physical and cognitive changes related to aging, such as poor vision, confusion or forgetfulness; and
- lower literacy levels.

Other reasons may include the fact that some seniors:

- live alone and are unable/unwilling to self-medicate properly;
- don't trust doctors and so don't take their prescribed medications;
- are over-medicated (they may have more than one physician prescribing medication) and need an assessment to determine if the number of medications can be reduced;
- accumulate their medication and save it for a time when they feel they will

“really need it”, or use medication prescribed for someone else;

- use over-the-counter (non-prescription) medications, herbal preparations or other remedies but don't inform their doctors;
- may have trouble communicating verbally (as well as in written form); and
- see doctors as authority figures and find it difficult to ask questions.

Seniors from ethnocultural communities also have particular reasons for being at risk. These are outlined in *Use and Misuse of Drugs by Seniors: A Cross-Cultural Educational Model*, a publication produced by the Canadian Ethnocultural Council in January 2000. Some of the findings reveal that language issues are significant, and that many ethnic seniors do not go to the pharmacy themselves and thereby do not receive counselling, or rely on someone else (usually a family member) to convey the information received from the pharmacist.

Individual responses to the aging process vary depending on several variables, such as physiology, genetics, socio-economic status, and environmental factors. Literacy levels also vary widely.

The resulting heterogeneity of older people as a group adds to the challenges of communicating important information about managing a medication regimen. Clearly, older patients must be able to both understand and carry out the required

steps to ensure they take the right dose of medication at the right time, in the right way.

Presenting written and verbal communications in an easy-to-understand style will do much to enable seniors to take charge of their care. This, in turn, will allow them to maintain their autonomy, health and well-being.

An involved and informed patient is more likely to adhere to prescribed medication therapy. Indeed, lack of compliance may often be no more than the inability to read or to understand complex verbal instructions.

Patients who don't understand written or verbal instructions about their medications should ask their doctor, nurse, pharmacist or health care worker for more information.

The Basics of Plain Language

Plain language is a way of organizing and presenting information so that it makes sense in terms of organization and flow and is easy to read for the intended audience. When writing for the general public, material should be written at a Grade 6 level so that the greatest number of people will get the message. Tools for assessing readability by grade level are provided later in this chapter.

To help clarify the writing task as you begin, you should answer the following questions:

- Why are you writing this document?
- What do you want to say?

- Who is your audience?
- How will your reader use the document?
- How should you organize the information?
- How should you present the information?

Basic plain-language techniques will help make your writing clearer and easier to understand. The following are taken from CPHA's *Easy Does It!*, a plain language and clear verbal communication training manual for health professionals.¹

Techniques

1. **Use the active (rather than the passive) voice.**

Instead of:

This medication is to be taken before every meal.

Use:

Take this medication before every meal.

2. **Use common words rather than technical jargon.**

Instead of:

Neuralgia which accompanies fractures of the fibula indicates the advisability of administering an analgesic.

Use:

Giving pain relievers to patients with broken legs helps make them more comfortable.

¹ Canadian Public Health Association. *Easy Does It! Plain Language and Clear Verbal Communication*. Ottawa, 1998.

3. Use a positive tone wherever possible.

Instead of:

Do not fail to notify your family doctor in case of illness.

Use:

Notify your family doctor when you are sick.

Sometimes, however, a negative tone gives a clearer message.

Instead of:

This medicine is suitable for children over 12 years of age.

Use:

Do not give this medicine to children under 12 years of age.

4. Write directly to your reader (using the “you” voice) to make your document more personal.

Instead of:

Patients are asked to register at the reception desk before each appointment.

Use:

Please register at the reception desk before your appointment.

5. Use short words and short sentences.

Instead of:

Patients’ responsibilities for home convalescence will be enumerated by the attending physician before departure from the clinic.

Use:

Speak with your doctor before you leave the clinic. He or she will explain how to take good care of yourself when you get home.

6. Write instructions in the order that you want them carried out.

Instead of:

Before you leave the clinic, make an appointment for a follow-up visit at the reception desk.

Use:

Before you leave the clinic, make an appointment at the reception desk for a follow-up visit.

7. List important points separate from the text.

Instead of:

Feb. 7-8, 2002, Hotel Grand, Toronto, Better Breathing '02, Ontario Thoracic Society, 201-573 King St. E., Toronto, ON M5A 4L3; tel. (416) 864-9911; fax (416) 864-9916

Use:

Better Breathing '02

When: Feb. 7-8, 2002

Where: Hotel Grand, Toronto, Ontario

Tel: (416) 864-9911

Fax: (416) 864-9916

For more information, contact:

Ontario Thoracic Society

201-573 King St. E.

Toronto, ON M5A 4L3

8. Don't change verbs into nouns.

Instead of:

All decisions pertaining to the payment of medical claims which exceed \$500 are the prerogative of your insurance company.

Use:

Your insurance company will decide if it will pay medical claims which are more than \$500.

9. List items in a parallel (the same grammatical) form.

Instead of:

Three healthy habits are:

- Getting eight hours of sleep each night.
- You should eat three balanced meals every day.
- It is important to exercise regularly.

Use:

Three healthy habits are:

- Getting eight hours of sleep each night.
- Eating three balanced meals every day.
- Exercising regularly.

General Stylistic Tips

- Don't use long sentences (i.e., more than 20 words) unless absolutely necessary.
- Keep words that are three syllables or longer to a minimum.
- Avoid run-on sentences and subordinate clauses.

- Use punctuation – commas, periods, dashes, and bulleted points – sparingly.
- Introduce a group of bulleted or numbered points with a colon.
- Place a period at the end of the group of bullet points.
- Begin a list of bulleted or numbered points with the uncommon and specific case and end with the common or general case, unless this is inappropriate for the product. For example:

Be sure to tell your doctor if you have:

1. pulmonary tuberculosis
2. any allergies that affect your lungs
3. any chronic lung condition.

- Use a minimum number of words in the bulleted points and never more than one sentence.
- Do not use more than nine items where the bulleted points are simple, and no more than five when they are complex.
- Avoid abbreviations and acronyms if possible; however, when they are necessary, always show the abbreviation or acronym at the beginning of the text, immediately following the first use of the full word or phrase, as in this example:

The Canadian Public Health Association (CPHA) is a national, not-for-profit organization...

Compendium of Plain Language Terminology

for Use in Prescription Medication Patient Information

What's in this Compendium

This Compendium contains:

- A brief background section outlining the importance of plain language in patient information;
- A framework for organizing patient information, typically for a patient package insert (PPI), also referred to as a “leaflet”, or other forms of information such as a package label or computer-generated leaflet. Note that the wordings provided are derived from existing materials or are adapted from product monographs. It is essential that the accuracy of information be maintained, but that the terminology be as clear and simple as possible to ensure the user can understand it.
- Plain language terminology for a range of prescription medications, among them:
 - Pills, tablets, capsules, caplets and the like;
 - Syrups, suspensions and other solutions that are swallowed or used as a rinse;
 - Powders that are dissolved or otherwise prepared by the patient and swallowed or used as a rinse;

- Inhalers and sprays;
- Drops (for the eyes, ears or nose);
- Suppositories, vaginal medications, etc.;
- Creams, lotions, gels, soaking solutions, shampoos and soaps.

It should be noted that parenteral drugs are not included in this Compendium; neither are potentially hazardous drugs or complex preparations (such as an AIDS ‘cocktail’). Medications such as these require counselling from physicians and pharmacists and it is not the purpose of these Guidelines to replace such professional guidance and training.

1. Background

Other sections of the Guidelines provide considerable detail on seniors, literacy, why and how to write in plain language, and issues related to patient compliance. This Compendium offers practical advice on the organization of information as well as wording which will ensure that your instructions are understandable by a maximum number of patients.

Not everyone wants to receive the information in a patient information leaflet, or is going to read it. However, this information should be given to the patient regardless, and it should be presented in a way that the majority of patients can understand it easily.

Some health professionals and manufacturers express the view that

information that is written in plain language is oversimplified for the patient. Indeed, many health professionals find that their clients or patients want more information, rather than less. The guiding principle to keep in mind in this instance is that patients who have moderate to high education levels have the skills and means to obtain additional information if they want it.

In the case of patients with low literacy skills or vision problems, the label or patient package insert may be their only source of information. In addition to not being able to read or comprehend well, many patients with low literacy skills do not have the skills or facilities to go to the Internet for further information, or to consult printed sources such as drug reference publications and other documents.

Some are so embarrassed by their inadequate reading skills that they will not ask questions, for fear that the person they are talking to might discover this fact. They typically have low self-esteem due to their circumstances and/or do not have the motivation to seek out further information.

These are the patients who need material written in plain language. Some will be able to read and understand it on their own. Others will find someone to read it for them.

Information that is accurate, complete and written in plain language benefits all of these people: those on medication, those caring for them (family members,

friends and neighbours, and low-skilled home-care providers) and professionally trained caregivers.

It is essential that writers and designers of patient information materials understand these different audiences and their behaviours, and take them into account at all stages of development.

Some key points for presenting patient information

- Pronunciation of drug names is difficult for most people, regardless of literacy level. Always include an easy-to-understand phonetic pronunciation, for example: Nilandron – nigh-LAND-ron. Note that the syllables are presented as common words, with the stress indicated by upper case. It is not normally necessary to provide a pronunciation for the generic name of the drug.
- The information about the medicine should be presented in a logical sequence. For example, important warnings and contraindications about who should not take the medicine should be placed near the beginning of the leaflet, in case the patient is not able or willing to read the rest of the leaflet. At least he or she will be able to read that section and perhaps determine that this medicine is not suitable to take. More information on logical sequencing is presented in other parts of this Chapter; the next section shows an outline for a leaflet that will be easy for people to follow.

- Avoid placing marketing messages in patient information. Low-literacy readers may not be able to tell the difference between important information and a sales pitch, resulting in confusion or misunderstanding. A patient could be persuaded to consume medication that is inappropriate and either exacerbate a condition or conflict with an existing medication regime.
- Any graphics that are used in the leaflet should be clearly laid out. There should not be too much detail and writing in the graphics, but too little information is also a problem. See the section of this Chapter entitled Clear Design, Layout and Graphics.
- People who have reading problems take words (and letters) literally. They skip over words (or numbers or letters) they do not understand and thus often miss the context of the information. Therefore, they could look at a number and see it as a letter. This may lead to confusion, which may discourage the patient, who could then decide not to continue reading the rest of the text.
- Generally speaking, people with low literacy skills cannot read tables, often used to present dosing information. This is especially true if there is a lot of information in the table. If it is necessary to present a lot of information, such as in the case of a medicine that has to be divided up into different doses for infants, children, youth and adults, it is easier to present it in bullet points with the age and/or the weight of the child at the beginning of the bulleted point.
- People with low literacy skills often find it easier to read numbers in numerical form than written out in words, such as “18” instead of “eighteen”. However, care must be taken to choose a font that does not make the number “1” appear as a lower-case “L” or an upper-case “I”.
- Another area of difficulty for patients with poor numeracy skills is the use of metric units of measurement. They, like many seniors who grew up with the Fahrenheit standard for temperature, do not know exactly what “store between 15-30 degrees Celsius” means. They also would have problems understanding that 5 ml is approximately one teaspoon or that 2.5 centimeters is about an inch. Provide Imperial equivalents.
- Other examples where numeracy could be a problem occur:
 - When it is necessary to specify a fraction of a pill. For example, “give 1/8 of a malarial prophylactic pill to a two-year old child”. Reading this fractionated number could be difficult for some people with poor literacy skills, and for those whose first language is not English. Instead, suggest “For a child who is two years old, cut the pill into eight pieces and give one piece to the child each day.”
 - When describing the chances of getting a particular side effect. For

example, “5% of people who take this medicine have this side effect.” In this case, it is better to give the chances as a proportion rather than as a percentage. “1 out of 20 people who take this medicine have this side effect.” Related to this issue are estimates of efficacy, such as when comparing several drug options.

- When a complicated word is used when a simple term would suffice. For example, instead of “This is an octagonal, crimson pill..” use “This is an eight-sided, dark-red pill...”
- Finally, make the leaflet attractive and inviting to read. Use as positive a tone as possible. Minimize the scare factor and patients will make the effort to read and understand what you need to communicate to them. Use design to focus the reader’s attention on the most important information.

2. A Structure for the Patient Information Leaflet

The most logical way to order information is to use the sequence of actions and events that the patient will go through when taking the medication.

Identifying information should always appear at the beginning of the leaflet. It should be large enough for easy reference and contain important and required information about the drug:

- Brand name
- Pronunciation of brand name

- Generic name and form
- Manufacturer or supplier
- Active and inactive ingredients
- Dosage amount and quantity contained in the package
- Drug Information Number (DIN)
- Physical description

A graphic element such as a simple line can be used to separate this information from the instructional sections that follow.

The following main headings demonstrate ordering of information by sequential actions and can be presented in two styles: simple headings and question-style headings. (The name of the medicine would replace the “XXX”).

About this leaflet
What XXX is used for
Before you use XXX (including warnings)
How to use XXX
While you are using XXX
Side effects
After using XXX
What else to know about XXX

What is this leaflet for?
What should I know before I use this medicine?
How do I use XXX?
What should I know while I am taking XXX?
What side effects are possible?
What do I do after taking XXX?
What else should I know about XXX?

The following sections provide brief explanations of the content of each heading in the structure and give examples.

Identifying information

Brand name. The brand or “trade” name should appear in a large, bold font. Assuming the patient will keep the leaflet, this will permit easy retrieval from among other leaflets.

Pronunciation. This should be placed beside or immediately beneath the brand name, in brackets or preceded by the word “Pronounced:”. It should appear in a similar or slightly smaller font to prevent the reader from thinking this is another part of the brand name. Try to use recognizable words or very simple phonetics, as in these examples:

Cardioquin – CAR-dee-oh-kwin
Elocon – ELL-oh-con
Naphcon-A – NAFF-con, ay
Rynatan – RYE-nuh-tan

Note that the syllables are linked by hyphens or commas unless there are separate words or an additional letter, such as the “A” in the third example. The stressed syllable is identified by capital letters or could be bolded or italicized.

This section should also contain a **description of the medicine**. This information should be placed near the beginning of the leaflet. It allows a patient who is taking several different kinds of pills to be able to figure out which pill to take at which time. It can be very confusing for a patient with low literacy skills to remember the names and administration schedules for several different medicines. This description also makes it easier for a caregiver, or perhaps a relative who is called in at a

time of emergency, to identify the particular medicines and to prepare a list of these medicines, if this is needed for another doctor or for the hospital.

A description of a drug could include any of the following details:

- colour
- shape
- size
- form or consistency of medicine
- markings or text on pill
- smell
- details about related devices, such as inhaler

About this leaflet

This section should tell the patient the following:

- Read all the information in this leaflet, or ask someone to read it for you or explain what it says. Be sure you understand everything about your medicine.
- If you are worried or unsure about any information in this leaflet, talk to your doctor or pharmacist.
- Keep this leaflet in a safe place because you might need to read it again, or a caregiver might need to read it.
- If you are taking several medications, keep all the leaflets in the same place. A file folder is handy for this.
- When you go to see a doctor or visit a clinic or hospital, take this file with you.

- This section should also feature the date the leaflet was prepared (month and year).

What this drug is used for

Explain in terms as simple as possible how the medication treats a certain illness. It may be necessary to use medical or scientific words, such as “hypertension”, but these should always be paired with a plain-language equivalent, in this case “high blood pressure”.

For some medications, it may be necessary to explain that the drug helps to control a condition but will not cure it.

Avoid long, complicated explanations of the way the drug works in the body. Keep in mind the distinction between “need to know” and “nice to know”. Too much detail can confuse poor readers and lead to concerns that they don’t understand enough about the medication and possibly result in non-compliance.

Before you use this drug

This section contains details about people who should not take this medicine. It is sequenced early in the patient information leaflet due to the importance of the information. Patients who have difficulties with reading often become frustrated and give up reading after a short time. Therefore, it is important to place essential information such as this first, and information that is not so crucial later in the leaflet.

Include in this section some of the most important standard warnings that the

patient should be aware of, such as interactions with other medications, food or alcohol.

Make reference to any special features of the package, if appropriate, such as whether there is a tamper-evident seal or child-resistant closure (or not).

How to use this drug

In this section, the manufacturer would provide instructions, in simple language, which explain how to take the medicine or administer it to someone else, such as a child. Dosage and timing details would appear here, with a reminder to follow the instructions faithfully. Include information specific to the drug such as “take with food” or “do not lie down for 45 minutes after taking this medicine”.

If the medication must be prepared by the patient, such as dissolving a powder or mixing two or more ingredients, provide detailed instructions.

If a device is involved, such as a squeeze-bottle of eye drops, explain the sequence of steps to use it. Similarly, explain how to insert a suppository, how and where to apply a patch, how to use a cream, shampoo or mouth rinse, etc.

Warn patients that “more is not necessarily better” to discourage them from taking extra doses. Note if the patient is to take all the medication provided in the prescription, such as in the case of an antibiotic. Provide details on length of treatment.

Special warnings, such as “do not consume grapefruit or grapefruit juice

while taking this medication” would appear here.

Specific or special instructions should be included that relate only to the medicine or class of medicine. These instructions should follow immediately after the instructions about how to take the medicine.

While you are using this medicine

Important information and warnings not mentioned previously should appear in this section, such as the effect of the medicine on the ability to drive vehicles or to operate equipment. Include as well instructions on storage – temperature, moisture, etc. – and remind the patient to keep the medicine out of the reach of children.

Special warnings, such as the effects on sensitivity to exposure to the sun, would be placed here. Indicate that patients should not share their medications.

Explain here what to do and what not to do in the event that a dose is missed, and what to do if too much of the medication is taken.

Discuss the impact of the drug in terms of long term usage, length of time for the effect to be felt, and the possibility of addiction, if relevant. Advise patients not to stop taking the medicine if they start to feel better.

Provide special warnings, such as what to do if the patient suspects she is pregnant.

Always encourage the patient to consult with a doctor or pharmacist on any

aspect of the drug treatment.

Recommend that patients should inform all doctors, dentists and pharmacists treating them that they are taking this medication.

Side effects

The side effects should be broken down into four separate categories.

- Immediate and serious side effects, and what to do if these occur
- Common side effects
- Rare side effects
- Long term side effects

It is important not to scare patients into non-compliance when describing side effects. Suggest ways of minimizing side effects, such as standing up more slowly if dizziness occurs.

After using this drug

Describe what to do if symptoms persist or return once the course of treatment has ended. Provide special instructions on how to stop treatment, particularly if there may be withdrawal or other adverse affects.

Provide details of disposal, if appropriate, of empty packages or medication that has not been used or has expired.

Recommend taking leftover medication to a pharmacy for proper disposal.

What else to know about this drug

Use this section to provide additional, non-critical information, or helpful advice on other things that can be done to enhance the effect of the medication, such as dietary changes, starting an exercise program, etc.

3. Plain Language Terminology

The following is a list of common terms, grouped under the headings shown in the structure section above.

While the list not exhaustive, the terms are good examples of the level of wording that should be used. As mentioned previously, very complex terms and instructions are beyond the scope of this document.

Identifying information

Most of the information in this section is required and standardized. Here are some plain-language terms, phrases and sentences that would be useful in this section.

Quantity

This package contains (quantity, in numbers, except “1”) (product form). Note that when the product cannot be counted individually, the measurement units should be included, with metric first followed by Imperial in brackets.

- For example: This package contains 30 pills.
- For example: This package contains one inhaler.
- For example: This package contains 500 ml (17 ounces) of liquid.

Package information

These pills are (or are not) in a child-resistant package. (note: Do not use the term “child-proof”.)

Do not use this product if the package was opened before you bought it. Take it back to the pharmacy. (This phrase explains that the package has a tamper-evident feature.)

Form

(Product name) is a (form).

- For example: Nyquil is a syrup.
- For example: Losec is a coated pill.

Description of product

This section goes into more detail to describe the product.

This (product) is (light) (dark) (basic colour). Avoid complicated or unfamiliar colours, no matter how accurate they may be.

- For example: This pill is light green. (Instead of “chartreuse”.)
- For example: This syrup is dark red.

It has a (shiny) (dull) coating.

The name of the (drug company) (drug) is marked on the (product).

- For example: The name of the drug is marked on the capsule.
- For example: The tablet has the letters “APA” stamped on it.

The pill has (number) sides.

This medicine smells like bananas.

Here is a composite example:

- Q.** What does this medicine look like?
- A.** The medicine envelope may be orange and white in colour, or yellow and white. When you tear the paper envelope open, you will see tin foil inside the package. The medicine is a powder made up of large grains of fibre that are brown, orange and white in colour. When you open the package, the medicine may smell a little like oranges.
- Q.** What does the suppository look like?
- A.** The suppository is a long slim capsule made of a waxy substance. It is creamy white in colour. The medicine is contained inside the waxy material of the suppository.

About this leaflet

This leaflet will give you answers to some of your questions about the medicine that your doctor has prescribed for you. If you are worried or concerned about any of the information in this leaflet, please contact your doctor or pharmacist.

Be sure to:

- read and understand all of the information in this leaflet, or
- ask someone to read it for you and explain what it means.

Please keep this leaflet in a safe place. You may need to read it again, or you can show it to someone who is helping you with your medications. It may be important to read it again if your condition changes, or if your doctor prescribes another medicine for you.

If you are taking several medications, keep the leaflets for all of them in the same place. A file folder is handy for this.

When you go to see a doctor or visit a clinic or hospital, take this file with you.

Direct Patient Information

The information in the following section is present in Question and Answer (Q&A) format. These phrases could also be re-organized into other formats while maintaining the plain language nature of the text.

Patient information for several specific product types appears in this section, as examples. Not every product or product category is represented. Demonstrating how the plain language “style” can be adapted virtually any product is the purpose of this section.

What this drug is used for

The following example relates to one specific group of medicines and shows how a fairly complex drug and disease interaction can be explained in plain language.

- Q.** What is an anti-inflammatory or non-steroidal anti-inflammatory drug (NSAID)?
- A.** An anti-inflammatory medicine is one that reduces the pain and inflammation that comes with arthritis (pain in the joints). This anti-inflammatory medicine is one of a group of medicines called Non-Steroidal Anti-Inflammatory Drugs. This means that they do not contain steroids. NSAIDs reduce the amount of the chemical in your body that causes the inflammation

and pain in your joints. NSAIDs cannot cure arthritis, but they can help to make your joints less painful as long as you continue to take the medication.

Before you take this drug

This section is also presented in Q&A format, but could easily be adapted to short sentences and point-form lists. Include in this section information about this package, such as whether it is child-resistant and/or tamper evident.

- Q.** Are there any reasons why I should not use this medicine?
- A.** Do not use this hormone pill if you have any of the following:
- You are pregnant, suspect you may be pregnant, or are trying to become pregnant;
 - You have ever had cancer or problems with your breasts or uterus (or womb);
 - You have vaginal bleeding;
 - You have blood clotting problems or a history of stroke;
 - You have a history of migraine headaches;
 - You have severe liver disease.
- Q.** Is there anything I should talk to the doctor about before taking this drug?
- A.** Talk with your doctor if you’ve had any of the following:
- High blood pressure or hypertension;
 - Heart or kidney disease;
 - Asthma;
 - Epilepsy or seizures;
 - Migraine headaches;
 - Sugar diabetes or high blood sugar;
 - Depression; or
 - Endometriosis.
- Q.** Are there any people who should not take this medicine?
- A.** Yes, there are a few people who should not take this drug:

- Women who are pregnant, breast-feeding or planning to become pregnant;
 - People who are allergic to sulfonamides and pyrimethamine;
 - People with kidney disease;
 - People with liver disease;
 - People with blood disease;
 - People with porphyria or anemia; and
 - Children under 2 months old.
- Q.** Who can use this medicine?
- A.** This medicine is meant for males between the ages of 18 and 65 who want to treat their baldness.
- Q.** Is there anybody who shouldn't use this medicine?
- A.** This medicine should not be used by:
- Women;
 - Those who are allergic to minoxidil (used to treat high blood pressure or hypertension), alcohol or propylene glycol; or
 - Those with heart problems or heart disease.
- Q.** Is there anything I should discuss with my doctor before taking this medicine?
- A.** Yes, before taking this medicine, talk to your doctor if you have any of the following conditions:
- You have had an allergic reaction to any ingredient in this medicine;
 - You are pregnant, breast-feeding or think you might be pregnant;
 - You have serious kidney or liver disease;
 - You have unusual bleeding or vomiting;
 - You are taking or have taken any other medicine in the past; or
 - You are taking any dietary supplements such as vitamins or herbal remedies.
- Q.** Is there anything I should know before my child takes this medicine?
- A.** You should discuss with your doctor whether your child has had any of the following before using this medicine:
- Allergies;
 - High blood pressure;
 - Heart disorders;
 - Thyroid disorders,
 - Glaucoma (or high blood pressure in the eye);
 - Epilepsy or seizures;
 - Agitation or nervousness;
 - Tension or stress;
 - Motor tics, twitches or uncontrollable movements of muscles;
 - A family history or diagnosis of Tourette's syndrome (a disease where the person cannot control tics, grunts, verbal outbursts, repetition of words, or imitating others);
 - Depression or feeling very sad;
 - Psychosis or mental disorders where the person does not know what is real and what is imagined;
 - Anxiety (a condition where the person has many deep fears);
 - Drug or alcohol abuse; or
 - Other medical problems.
- Q.** Is there anything I should know before I take this medicine?
- A.** There are a few things you should know before taking this medicine:
- If you have diabetes or high blood sugar, your dose of insulin or oral anti-diabetic agent may need to be altered. You should monitor your blood glucose level carefully.
 - If you are taking an anticoagulant, such as coumadin or warfarin, to thin your blood, your dose may need to be changed. Check with your doctor about this.
 - You may lose some of your hair during the first few months of treatment but this is usually temporary.

Q. Are there any medicines I shouldn't take while taking this drug?

- A.** Yes, there are medicines that cannot be taken with this drug:
- sulfonamides (these are sulfur drugs prescribed for bacterial infections);
 - pyrimethamine (these are medicines given to prevent malaria); or
 - trimethoprim (these are medicines prescribed for bacterial infections).

Q. Who should not use this suppository for pain and fever?

- A.** You should talk to a doctor or a pharmacist if you have any of the following conditions:
- You are allergic to acetaminophen.
 - You have been drinking more than 2 alcoholic beverages a day for a long time. This includes wine, beer or liquor.
 - You have kidney disease.
 - You have liver disease.
 - You are taking other medicines that contain acetaminophen or salicylates.

How to use this drug

Q. How should I take this medicine?

- A.** The following are guidelines on how to take this drug but your doctor may adjust it for you:
- Take this medicine exactly as ordered.
 - Take a single dose with supper or a half a dose at breakfast and half a dose at supper.
 - Do not take a double dose of this medicine.
 - Follow your doctor's advice on diet and exercise.
 - Do not change the dosage or stop taking the medicine without telling your doctor.
 - See your doctor regularly.
 - Avoid large quantities of alcohol.
 - Do not start taking any other

medicine without first seeing your doctor.

- Let your doctor know if you suffer a severe injury or infection.
- Let your doctor know about any dental surgery (or other surgery) that you are planning to have.
- Tell your dentist you are taking this medicine.

Q. How should I take this tablet?

A. Follow this advice to take your medicine:

- Take this tablet with a small amount of water.
- The tablets must always be swallowed whole and never chewed nor crushed.
- Do not take the tablet with food.
- Take it 1 hour before you eat one hour before or 2 hours after you eat.
- This will allow you to absorb as much of the medicine as possible into your body.

Q. How should I take this tablet?

A. Follow your doctor's advice about taking the tablet. Read the label on the package with care. Take the medicine in the following way:

- The usual dose for children over 12 is 20 mg 2 times a day.
- You should swallow the tablet whole without chewing it.
- Take it with a full glass of water.
- Take the tablet 2 hours after eating food, or one hour before eating food.
- Try to take the tablet at the same time each day.

Q. How should I take this pill?

A. Follow your doctor's advice about taking the pill and read the instructions carefully because they may change the next time you get your prescription filled. As well:

- Take the tablet with food or right after food.

- If you forget to take a dose, you can take it later in the day.
 - Do not take more tablets in one day than your doctor advised you to take.
- Q.** How often should I take it?
- A.** You should take the tablet 2 times a day, once in the morning and again the evening. It lasts for up to 12 hours.
- Q.** When should I take the pill for my asthma?
- A.** You should take the pill every day as your doctor has prescribed it to control the symptoms of your asthma during the day and the night.
- Q.** What is a calendar pack?
- A.** A calendar pack is a convenient way to remember when to take your tablets. The pills are in a blister card with labels showing the days of the week, and there are usually 2 slots for each day of the week. Take the pills as explained below:
- Make sure you note down the day of the week that you are starting to take the tablet.
 - Find where on the pack it is labeled “start”, and punch out that pill and take it.
 - Take the next tablet about 12 hours later.
 - Find the label that shows that correct time and day, and punch out that pill.
 - Keep following the system, and taking a pill on the correct day and either from the morning or the evening slot. This will help you to remember to take the tablet 2 times a day.
 - When you finish a card of pills, note down the day and the time that you took the last pill. Then take the next pill from the new card of pills.
 - Call your pharmacist for a refill before you use the last 4 tablets.
- Q.** What should I do if I miss a pill from the calendar pack?
- A.** If you miss a dose, take another tablet as soon as you remember it. If it is almost time for the next dose of medicine:
- Take the tablet right away.
 - Do not take a double dose of the medicine.
 - Go on taking the medicine 2 times a day.
 - Make a note of what day and time you missed the tablet as this will mix up the days and time shown on the calendar packs.
- Q.** How do I take a suppository?
- A.** To use a suppository tablet follow these steps:
- If you have to empty your bowel (or have a bowel movement), do that first.
 - Wash your hand with soap and water.
 - Remove the plastic wrapper that is around the suppository.
 - Wet the outside of the suppository lightly, with cool water so that it can slide in easily.
 - Lie on your bed on your left or right side. Your bottom leg should be straight. Bend the leg, which is on top, and bring your knee towards your chest.
 - While keeping this position, insert the narrow tip of the moist suppository into your rectum, the opening where you push out your bowel movements or stools. Use your finger and push the suppository tablet as high up into the rectum as possible. This will make sure that it stays in place.
 - Do not go to the bathroom right after inserting the suppository.
 - Wash your hands again with soap and water.
- Q.** What is the correct dose of suppository to take?
- A.** The correct dose to take is one suppository tablet every 4 to 6 hours, as needed for pain and fever.

- Q.** How often should I take the suppository?
- A.** You can take a suppository up to six times a day for pain and fever if you need it.
- Q.** How should I mix the acne lotion?
- A.** To mix the acne lotion, follow these steps:
- Add the liquid in the bottle with the white cap to the powder in the bottle with the black cap.
 - Shake the bottle until both ingredients are well mixed.
 - The lotion will last for 21 days and should be thrown out after it has expired.
 - Mark down the day the lotion was mixed so that you will know when 21 days have passed and you can throw out the expired lotion.
 - A new bottle should be mixed after you have thrown out the old one.
- Q.** How should I use this acne lotion?
- A.** Follow your doctor's instructions about how to use this acne lotion. To apply the lotion:
- Wash the infected area thoroughly with water and mild soap. Pat it dry with a towel.
 - Shake the bottle well before applying the lotion to the area using a cotton ball or a gauze pad.
 - Apply it at night before going to bed and again in the morning.
 - Wash the lotion off before going about your daily activities.
 - Continue applying 2 times a day for 4 days.
 - After the 4th day, apply it once a day at night for the rest of your treatment.
 - Continue applying the lotion for 3 nights after the spots have disappeared.
 - The entire treatment should last about 4 to 6 weeks.
- Q.** How should I take these eye drops?
- A.** The eye drops comes in a white plastic bottle with a dropper tip. Follow the instructions shown below:
- Wash your hands.
 - Press your middle finger on the inside corner of your eye. Keep your middle finger pressed on the inside corner of your eye (while you put in the drops) and for 1 to 2 minutes after the drops have been put in your eye.
 - Tilt your head back and use your index finger (finger next to thumb) of the same hand to pull the lower lid of the eye out to form a little pouch or pocket.
 - Drop the eye drops into the pouch or pocket and close your eye gently.
 - Keep your eyes closed to allow the drops to be absorbed. Do not blink your eyes.
 - After you apply the eye drops, wash your hands again.
 - Be careful to not touch the tip of the eyedropper to your eye, or any other surface. This will keep the tip of the eyedropper free of germs, or sterile.
 - Keep the bottle of eye drops closed tightly.
 - If you are using the 2-ml sample, make sure that the bottle has not been used before you get it. Twist off the cap.
 - Do not reuse the sample bottle. Throw out the remainder.
 - The eye drops also come in small vials with enough medicine to apply one time to your eye.
 - As this bottle does not contain any chemical to kill the germs, it is important to use it once and then throw out the rest of the bottle after you have used it.
- Q.** How do I know how much asthma inhaler medicine to take?
- A.** The label on your inhaler can / will tell you how many puffs to take and how

often to take them.

- If you do not understand this information, you should consult your doctor or pharmacist.
 - Do not take more than 8 puffs a day and children should not take more than 4 puffs a day.
 - If you feel that this amount is not helping or that your breathing is getting worse, call your doctor.
- Q.** How long should one puff of asthma inhaler last?
- A.** One puff usually lasts 4 to 6 hours.
- Q.** Can I take other medicines along with this asthma inhaler?
- A.** Yes, other asthma medicine that has been prescribed by your doctor can be taken with this asthma inhaler.
- Q.** How should I take this stool softener or laxative?
- A.** When you take this stool softener or laxative, you should also drink more fluids. These could include water or juice.
- Q.** What kind of package does the cream come in?
- A.** The cream comes in packets containing 250 mg each. There are 12 packets in each box.
- Q.** How often should I use cream?
- A.** The cream should be applied to the warts 3 times a week, waiting 1 day between treatments. For example, you could apply it on Monday, Wednesday and Friday, or Tuesday, Thursday and Saturday.
- Q.** How should I apply the cream?
- A.** The cream should be applied like this:
- Wash your hands before applying the cream.
 - Open a new packet of cream and squeeze some onto your finger.
 - Apply a thin layer of cream to the wart area at night before going to bed.
 - Rub the cream in until it can no longer be seen.
- Do not use excessive amounts of cream - just enough to cover the wart area. (Note that the actual area may change during treatment.)
 - Throw the packet away and wash your hands.
 - The treated area should not be bandaged or covered, so that air can reach it.
 - Do not bathe the area for the 6 to 10 hours that the cream is on.
 - When you awake in the morning (6 to 10 hours later) remove the cream by washing the area with mild soap and water.
- Q.** How long will it take the cream to work?
- A.** After a few weeks, there should be some visible changes to your warts. The average treatment takes anywhere from 4 to 16 weeks. New warts may develop during the course of the treatment because the cream is not a cure.
- Q.** How should I apply the gel?
- A.** Follow these guidelines to apply the gel:
- Apply the gel after washing (either at night or in the morning but at the same time each day).
 - Clean your hands before applying the gel.
 - Remove the pump cover.
 - When you open a new pump, press on the pump once or twice in order to prime or start the pump. Discard the gel that comes out during the first 1 or 2 times you press the pump.
 - Press firmly on the pump once and collect about 1.25 g of the gel in your hand.
 - Apply the gel to one arm covering an area about 4 times the size of your hand.
 - Apply the gel to the other arm.
 - Other possible areas to apply the gel are the insides of the thighs or the abdomen.

- Do not apply the gel to your breasts.
- Allow the gel to dry for 2 minutes before you cover the skin with clothing.

Q. How do I use this cream rinse?

A. Follow these steps to use this medicine properly:

- Wash the hair with a conditioner-free shampoo. Do not use a conditioner. Rinse with water and towel dry the hair thoroughly.
- Shake the medicine bottle well.
- Apply enough of the cream to thoroughly soak the hair and scalp (usually 1/2 to 1 bottle's worth). Be careful to apply the cream behind the ears and at the base of the neck.
- Leave the cream on the hair for 10 minutes.
- Rinse off the cream using water.
- Towel dry hair and comb to remove tangles.
- Remove the nits.

Q. How do I remove the nits?

A. Here are the steps to follow to remove the nits:

- Part hair into sections.
- Start as close to the scalp as possible. Remove the nits using a fine toothed nit comb or fingers.
- Be sure to comb to the end of the hair shaft to remove all the nits.
- The nit comb should be disinfected by soaking in hot water after each use.
- Inspect entire head of hair well for any stray nits that might be hiding.
- Repeat this entire nit-removing process every day for 7 days following treatment.

Q. How many times should I apply this cream?

A. Usually, one use of the cream is enough because the active ingredients continue to kill nits for up to 10 days if you do not put any conditioner on your hair. If

you continue to see live lice and nits after the 7 days, use the cream again as directed above.

Q. How do I use this drug?

A. Follow these steps to use this drug properly:

- Wash your hair daily using a mild shampoo.
- Make sure your hair, scalp and hands are thoroughly dry before applying this medicine.
- Apply 1 ml of the drug to your scalp 2 times a day, twelve hours apart. For example, you could apply it at 7:00 in the morning and again at 7:00 in the evening.
- Spread the solution around to cover the entire bald area. Avoid eyes, ears and other sensitive areas.
- Don't use a blow dryer to make the solution dry faster. This decreases the effectiveness of the medicine.
- Wash your hand after applying the medicine.
- Don't use more than 2 ml a day, unless instructed by your doctor.
- Don't use any other medicines on the scalp, while using this drug.

Side Effects

This section provides examples of wordings for:

1. Immediate and serious side effects
2. Common side effects
3. Rare side effects
4. Long-term side effects

1. Immediate and serious side effects

Q. What should I do if I become pregnant while taking this acne pill?

A. If you become pregnant while taking it, contact your doctor immediately. Your doctor will discuss with you the chances of your baby being deformed. The doctor will give you information, which will help you decide whether you should continue with the pregnancy.

- Q.** What are some of the serious side effects of the anti-inflammatory drug?
- A.** You should see your doctor as soon as you can if you see or feel any of the following:
- You may have bloody or black tarry stools or bowel movements;
 - You may feel short of breath, wheeze or feel tightness in the chest;
 - You may notice skin rash, swelling, hives or itching;
 - You may have an upset stomach that does not go away;
 - Your skin or eyes may become yellow;
 - You may feel tired, sick or do not feel like eating;
 - You may notice some changes in your urine;
 - You may notice that your feet or lower legs become swollen;
 - You may notice that your vision becomes blurred, or that you have other problems with your eyes;
 - You may feel confused, depressed or dizzy;
 - You may have problems with hearing;
 - You may have pain while peeing or emptying your bladder;
 - You may have other side effects that you think may have been caused by the drug.

You should contact your doctor right away if you have any of these side effects

- Q.** What are some of the possible serious short-term effects of this medicine?
- A.** This medicine contains strong harsh or toxic chemicals, which can cause serious side effects in your body. Some of these side effects are:
- Bone-marrow suppression. Bone marrow produces red blood cells. If this is suppressed or stopped, you would have fewer red blood cells and may feel more tired.

- Hypersensitivity reactions. You may have an allergic reaction such as hives or a rash to the medicine.
- Gastrointestinal toxicity. Due to the toxic or strong chemical in the medicine, you may have abdominal cramps, diarrhea, flatulence or gas.
- Pulmonary toxicity. You may have coughing or wheezing. The lungs could produce mucus as a result of the toxic side effect of the medicine. So you may find that you are coughing up more mucus.

If you notice that you are experiencing any of these serious side effects, see your doctor right away.

- Q.** What are some of the warning signs of this medicine?
- A.** Contact your doctor immediately if you experience:
- Skin rash (patches of red skin);
 - Vasculitis (inflammation or swelling of the lining of small blood vessels). You may notice that the skin becomes red, warm to touch or swollen. This could be a sign of vasculitis.
 - Bleeding;
 - Fever;
 - Persistent or continual cough.

If you notice any of these or other unusual symptoms, see your doctor as soon as possible.

- Q.** What should I do if I have disturbing thoughts or unusual behaviour while taking this drug?
- A.** If you have any unusual or scary thoughts or if you find you are acting differently while taking this medicine, talk to your doctor immediately. Some of these behaviours may include:
- Aggression – becoming angry, arguing with others, interrupting conversations;
 - Extroversion – talking to others more than usual, talking continually;
 - Confusion – forgetting where you

are or what you were doing;

- Strange behaviour – any behaviour which is not normal for you;
- Restlessness – feeling as if you have to be moving constantly, unable to sit still or concentrate;
- Hallucinations – seeing or hearing things that aren't real;
- Feeling like you are not yourself;
- Depression – feeling sad or unable to do your normal activities;
- Suicidal thinking – thinking about killing yourself.

Report any of these symptoms to your doctor right away.

2. Common side effects

Q. What are the possible side effects of this suppository?

A. In a few cases, you may be allergic or more sensitive to acetaminophen. In this case, you may get a rash or hives. You should talk to your doctor about the rash or hives.

Q. What are the possible side effects of this asthma pill?

A. The possible side effects are:

- Headache or stomach indigestion. If you have these, they will likely be mild and you can keep on using the asthma pill.

Q. What is happening? I've been taking the pill for acne and my acne is getting worse!

A. For the first two weeks your acne may seem to get worse. It will get better after one or 2 months of treatments.

Q. What are some possible side effects of taking this acne pill?

A. Possible side effects you may have are:

- You may feel that your lips, the inside of the nose, mouth and your skin in general feel dry.
- You may have rashes on the face or body.
- You may have flaking, itching and

peeling of the skin, especially on the palms and soles.

- You may notice that you have become more sensitive to the sun.
- You may notice that your lips or gums swell, or that your gums or nose bleed.
- You may have aches or pains in your joints.
- You may find that your skin is easily injured or bruised.
- You may feel more tired or fatigued.
- You may find that you are not able to see well at night. You may also find that your eyes itch and water. This may cause problems for contact lens wearers.
- You may find that your hair is becoming thinner.

If you have any of these symptoms and they concern you, contact your doctor for advice.

Q. What are the possible side effects of using acne lotion?

A. When you first begin to use this acne lotion, the following may occur:

- Your skin may become red.
- Your skin may feel warm.

Q. What are some of the possible side effects of using a decongestant?

A. Some side effects only occur if the dose given is too high. The side effects could include:

- The person may become too excited, especially if he or she is a child.
- The person may feel drowsy.

Q. What are some of the possible side effects of taking eye drops after surgery on my eyes?

A. Some of the side effects of taking eye drops after surgery on your eyes are:

- Burning, redness, itching and/or swelling of the eyes. This could be caused by either the eye drops, or the surgery, or by both.

- Your vision may be blurred after putting the drops in your eyes.

Q. What are the side effects from taking too much laxative medicine?

A. You may become dependent on the laxative if you use it too much. This means that, when you stop using it, it will be difficult to have a bowel movement (or to expel stools from the bowel).

Q. What are the most common side effects of the pain reliever?

A. The most common side effects are stomach problems. These could include any of the following:

- Heartburn;
- Nausea;
- Vomiting;
- Stomach pain;
- Diarrhea; or
- Indigestion.

Q. What are the side effects of the cream?

A. Some of the effects in the treated area can be:

- redness in the genital area;
- wearing away of the skin, in the area where you have been applying the ointment;
- the skin may seem to come off in flakes; or
- the tissue may swell.

Inform your doctor if these side effects are very severe. If you wear cotton underwear, this may also help reduce any of these reactions to the cream.

Q. What are some of the most common side effects of this pill?

A. Some of the side effects are:

- Having a headache;
- Finding it difficult to fall asleep;
- Feeling nervous;
- Feeling you are going to vomit;
- Having a dry mouth; or
- Feeling dizzy.

These side effects usually disappear after a few days or if the doctor tells you to

reduce the dose. The side effects are also lessened if you start off slowly and reach the maximum dosage after a few days.

Q. What are the most common side effects of this pill?

A. Some of the side effects are:

- Feeling drowsy;
- Feeling dizzy;
- Feeling lightheaded;
- Having difficulty in coordinating your movements, such as walking, performing actions;
- After stopping this medicine you may have anxiety and trouble sleeping for a few days.

Q. What are some of the possible side effects of this medicine?

A. Some of the possible side effects are:

- The lining of the uterus may grow too thick.
- You may have irregular menstrual periods.
- You may feel nauseous.
- Your breasts may feel more tender, sore, or swollen.
- You may retain more fluid and find your clothes or rings are tighter than usual.
- You may feel depressed or more depressed than before.
- If you suffer from migraine headaches or other headaches, you may find that they are worse.
- You may feel nervous.
- You may feel dizzy.
- You may feel tired.
- You may feel irritated.
- Your skin may feel irritated, sensitive or tender.
- You may notice bleeding from the vagina.

Contact your doctor if any of these side effects become troublesome.

Q. What are the most common side effects of this drug?

A. The most common side effects of this drug are:

- upset stomach;
- nausea;
- headache; or
- your skin may become more sensitive to sunlight.

Q. What are the most common side effects of this medicine?

A. The most common side effects include:

- itchiness;
- redness;
- swelling of the skin on the scalp;
- stinging/burning;
- numbness; or
- discomfort.

Q. What are the most common side effects of this pill?

A. The most common side effects of this pill are:

- headaches;
- weakness;
- constipation, or being unable to have a bowel movement easily;
- diarrhea; or
- abdominal pain.

Q. What are some of the most common side effects of this medicine?

A. The most common side effects of this pill are:

- stomach discomfort;
- nausea, or feeling that you may throw up or vomit;
- feeling that you are not hungry, or that you do not want to eat;
- being unable to sleep.

These problems will go away with time.

Q. What if my side effects don't clear up after I stop taking the medicine?

A. If your side effects are still there after a few weeks, see your doctor right away.

Q. What are the side effects of the cream?

A. Some of the effects in the treated area can be:

- Redness in the genital area;
- Wearing away of the skin, in the area where you have been applying the ointment;
- The skin may seem to come off in flakes; or
- The tissue may swell.

Inform your doctor if these side effects are very severe. If you wear cotton underwear, this may also help reduce any of these reactions to the cream.

Q. What are some of the side effects of this drug?

A. Some of the common side effects are:

- aching muscles;
- muscle cramps;
- tiredness or weakness;
- fever; or
- blurred vision.

Let your doctor know as soon as possible if you have any of these symptoms.

3. Rare side effects

Q. What are some of the rare or infrequent side effects of this medicine?

A. This is a list of the rare or infrequent side effects. If you have any of them, stop using this medicine and contact your doctor as soon as possible.

- Feeling that your heart is beating at a rapid rate or irregular heart beat.
- Gaining weight (2.5 kg or more) quickly. This means weight gain that is not due to a change you have made in eating, or exercising.
- Having swelling or puffiness of hands, face, ankles or stomach.
- Feeling dizzy or lightheaded, or fainting.
- Seeing objects in a blurred way.
- Having a severe pain in chest, shoulder, or arm.

- If you already have pain in the chest, shoulder or arm, noticing that the pain is more severe or happens more often.
- Having severe indigestion, or pain in the stomach.
- Having severe discomfort or pain in lower chest or abdomen.
- Feeling nausea or vomiting; or
- Feeling that your scalp is very irritated.

Q. What are the rare or infrequent side effects of this pill?

A. A few people who take this medicine may find that their lips, face or tongue swell. If you experience any swelling in these areas, stop taking the medicine and contact your doctor right away.

Q. What are the rare or infrequent side effects of this pill?

A. The rare or infrequent side effects of this pill are:

- You may feel short of breath.
- You may have a drop in your blood pressure. If this happens, you may feel weak, unable to stand, feel dizzy or faint.
- You may notice small bumps or hives on your skin. The bumps or hives may be red or itchy.

If you see or feel any of these symptoms, stop taking the medicine and contact your doctor right away.

Q. What are the rare or infrequent side effects of this medicine?

A. A few people who take this medicine may have serious side effects which are:

- You suddenly get a high fever.
- Your heart starts beating quickly.
- You cannot breathe in a normal way.
- You may have chest pain.
- You may start sweating.
- You may vomit.
- You may see bruises on your body, but they are not due to a bump or fall.

- You may notice that your muscles twitch or that you have a tic.
- You may have a sore throat.
- You may feel confused or not know what you are doing or where you are.
- You may hallucinate, or see or hear things that aren't real.
- You may have convulsions. This means that your muscles twitch or jerk rapidly in a way that you can't control. You may become unconscious.

Contact your doctor immediately if you have any of these symptoms.

Q. What are the possible side effects of this asthma pill?

A. The possible rare side effects are:

- You may get a rash when using the pill.
- You may also get other symptoms of allergic reaction to it, such as itching.

If these side effects become severe, contact your doctor.

Q. What are the possible side effects of using acne lotion?

A. You may feel more severe side effects:

- You may get a skin rash.
- Your skin may itch.
- Your skin may feel irritated or tender.

You should see a doctor if you are concerned about any of the side effects.

Q. What are some of the possible side effects of taking this decongestant?

A. Some side effects only occur if the dose given is too high. At high doses, side effects may include:

- Feeling nervous or anxious;
- Feeling dizzy; or
- Being unable to sleep.

If you have any of these side effects and they continue for more than 5 days, you should see your doctor right away.

Q. What are some of the possible side effects of the asthma inhaler?

A. Some of the side effects of the asthma inhaler include:

- Feeling palpitations, or irregular heart beats;
- Feeling that there is a pain in your chest;
- Feeling that your heart is beating rapidly;
- Feeling tremors in your muscles; or
- Feeling nervous.

Do not stop taking the drug because of this. Instead, keep taking the drug and consult with your doctor. These side effects should stop after your body adjusts to the medicine.

Q. Are there any more serious side effects from this asthma medicine?

A. In a few cases, the medicine may affect the liver and you may feel some of the following symptoms:

- You feel sick, or tired.
- You may feel like you have the flu.
- You may feel itchy.
- You may have a pain in the right side of your stomach, just below the ribs.
- You may get a yellow colour in your skin or eyes. This is called jaundice.

If you have any of these signs and symptoms, tell your doctor right away.

Q. What should I do if my symptoms change while taking this asthma inhaler?

A. You should contact your doctor right away if you notice the following:

- You are having more attacks of wheezing.
- You are finding it difficult to catch your breath.
- You have a tight feeling in the chest.
- You are using more of your fast-acting relief medicine to treat your asthma.
- You wake up at night with tightness in the chest, you cannot get your breath, or you are wheezing.

Q. Are there any symptoms that I should tell my doctor about while taking this tablet for acne?

A. Consult your doctor immediately if you:

- Have aches in your joints and have trouble moving around;
- Feel depressed or sad;
- Have headaches, nausea, vomiting, vision problems, especially blurred vision;
- Have severe stomach pain, diarrhea, or bleeding from the rectum, the opening at the end of the bowel;
- Have dry and itchy eyes over a long period of time;
- Notice your skin is turning yellow, or if your urine has turned dark; or
- Have any other signs or symptoms that you feel may be caused by the acne tablet.

Q. Are there any symptoms I should be looking for when I use the acne lotion?

A. If you notice any of the following signs or symptoms, you should see your doctor right away:

- sore throat;
- fever;
- fatigue; or
- mouth sores.

Q. What will this pill do to my memory?

A. This type of sleeping pill has been known to produce amnesia (memory loss) of a few hours if you wake up before the drug has left your body. For this reason, this pill should not be taken while you are traveling.

Q. What are some of the rare or infrequent side effects of this drug?

A. Some of the rare or infrequent side effects are:

- Constipation – you may be unable to have a bowel movement or pass stools out of the bowel;
- Diarrhea;
- Gas;
- Stomach upset;
- Nausea or a feeling that you're going to vomit;

- Pain in the abdomen;
- Headache;
- You may feel dizzy or lightheaded;
- You may notice one or more patches of red skin.

Let your doctor know if you experience any of these signs or side effects.

- Q.** What are some of the rare or infrequent side effects of this medicine?
- A.** Severe depression is a rare side effect of this medicine. The severe depression may include the following symptoms:
- You may feel very sad.
 - You may be unable to make any decisions, or feel whatever you do is not correct or acceptable.
 - You may notice a change in your appetite. This means that you may not feel hungry or you may eat more than usual.
 - You may not be able to do your usual activities or work.
 - You may feel very tired and have no energy.

Report this side effect to your doctor.

- Q.** What are some of the rare or infrequent side effects of this medicine?
- A.** Some of the rare or infrequent side effects are:
- Kidney stones – you may feel pain in the back below the waist or in the lower abdomen if you have kidney stones.
 - Kidney disease or failure – you may have pain in the back below the waist. You may also notice that your lower legs and feet are swollen.
 - Increased bleeding in hemophiliacs.
 - Liver failure – you may feel pain in the right side of your body.
 - Rapid decrease in red blood cells – you may feel tired.
 - Diabetes, or an increase in blood sugar.
- Q.** What are some of the rare or infrequent side effects of this drug?

- A.** Some of the rare or infrequent, but severe side effects are:
- Your tongue may feel sore, sting and/or swell.
 - You may notice severe skin rashes on the body.
 - You may feel itchy.
 - You may have a fever.
 - You may have a sore throat.
 - Your skin may become pale.
 - Your joints may ache.
 - You may notice bruises that appear without any reason, such as after a bump or a fall.
 - You may see that your urine or pee is darker in colour than usual.
 - You may notice that your skin or the white parts of the eyes are becoming yellow.
 - You may get a severe bacterial or fungal infection.

Some of these symptoms may be caused by an allergic reaction. It is best to see a doctor as soon as possible if you have any of these reactions.

4. Long-term side effects

- Q.** Are there any serious side effects that I may get when I use acne lotion?
- A.** One of the ingredients in this acne lotion, chloramphenicol, may cause a serious blood disorder called aplastic anemia, if it is taken into the mouth or the body. Aplastic anemia can make you very sick or can cause death. It is important that you use the lotion very carefully, and that you do not put the lotion near your mouth or your eyes. You should not use this lotion for a long time.
- Q.** What are some of the possible serious long-term effects of this medicine?
- A.** Some of the long-term serious effects are:
- Infertility – if you have this side effect, you will be unable to have children.

- Cancer.

If you notice any unusual symptoms, see your doctor right away. You should discuss the chances of your getting these side effects with your doctor.

After using this drug

- Q.** What should I do with leftover pills?
- A.** If you do not need the pills any more, you should return them to the pharmacist. He or she will dispose of them safely.
- Q.** What should I do if the pills have expired?
- A.** If it is past the expiry date on your pills, return them to the pharmacist.

What You Should NOT Do:

- Q.** Can I throw leftover pills in the garbage?
- A.** Do not throw leftover pills in the garbage. Return them to a pharmacist for disposal.
- Q.** Can I flush leftover pills down the toilet?
- A.** Do not flush leftover pills down the toilet. Return them to a pharmacist for disposal.
- Q.** Can I still take my medicine if the expiry date on the package has passed?
- A.** If the expiry date on the package of pills has passed, do not use the pills. Take the medicine to your pharmacist for safe disposal.

Conclusion

This section of the guidelines included examples of how the patient information leaflet should be presented, a sample leaflet structure, and examples of terms grouped by the headings given in the pamphlet structure.

The above examples give the person preparing patient information some ideas about how to express complex medical information in a simpler way.

These examples are not meant to be exhaustive — but to provide ideas about how to put the necessary information into plain language. Writers of patient information should consult the plain language section of the guidelines for specific advice on how to present material in plain language.

Overall, these examples provide helpful information on what information to provide to patient with low literacy skills and, more importantly, how to provide it. Many patients with low literacy skills, but not all, will welcome the chance to read about their medicine in a way that does not cause frustration. This will help patient to take their medicine in a responsible way, which in turn, will lead to better health. This is a goal that we all want to achieve.

Clear Design, Layout, and Graphics

The following information is based on guidelines developed by the Nonprescription Drug Manufacturers Association of Canada. Suggestions contained in CPHA's own publication, *Creating Plain Language Forms for Seniors* have also been integrated in this section of the document.

Design and layout of text can go beyond merely creating an eye-pleasing document; it can also accomplish much in aiding the reader's comprehension. For example, "chunking" information, i.e., breaking it into small sections, will help readers distinguish discrete ideas and reduce reading fatigue. Adding graphics or design elements such as lines or boxes can help to reinforce the text content and help readers follow the flow of the information.

All parties – drug manufacturers, designers, etc. – must be aware of design issues and be involved in the design process to ensure that the principles and goals of plain language are implemented visually.

The following layout and design recommendations can help produce patient information materials that successfully convey the important information about medication to consumers at all literacy levels.

White Space

White space is the blank space between and around text and graphics. The reader needs white space in order to rest the eyes and stay oriented in the text.

To keep your text from looking crowded, incorporate some white space:

- in margins and between paragraphs;
- between words and letters;
- between lines; and
- at the end of lines.

A page that incorporates white space not only "feels" more spacious, but offers an opportunity for writing in special notes or reminders.

Type (font) Size, Style, and Leading

When designing a package label or insert, choose a **type (font) size** that is sufficiently large to allow easy reading. For side panels on drug packaging, use the largest point size possible while respecting regulatory requirements and packaging constraints. Type size is extremely important for low-literacy seniors who may have poor eyesight compounding their poor reading skills.

Most readers identify words and letters by shape. The most shapely **type styles** are called "serif types", serifs being the short lines extending from the main strokes of a letter, such as the "feet" on the letter "A". Serif type (such as Times Roman) is appropriate for the body copy of a package insert in a type size of 10 points or more.

At small type sizes less than 10 points, it is best to use a "sans serif" type (without serifs). These type styles (such as

Helvetica, Univers or Arial) are less ornamented and will stay crisper in the sizes needed for packaging panels. They appear larger than a serif type.

Following are examples of serif and sans serif type styles, both in 12-point size:

This is an example of a serif type style (Times).

This is an example of a sans serif type style (Arial).

Leading is the white space between lines of print, which is related to font size as a percentage (usually 10% above the type and 10% below).

When text type is very small, designers need to compensate by adjusting the leading so that the space between lines increases by another few percentage points.

Type Alignment

Use **left-justified** text alignment, with ragged right edges as used in this document.

This prevents the forced gaps between words created by **fully justified** text, and reduces the need for hyphenation.

Hyphenation is not recommended. Breaking a word interrupts the reader's concentration and the flow of meaning; some readers may have trouble connecting the two parts of the word to understand it.

Centre-justified text creates a problem for less-skilled readers because they tend to lose the flow of text. Their eyes have to jump different distances for each line. There is no rhythm to reading centered text, leaving readers frustrated and lost in the text.

Line Length

Readability research is divided on the question of the ideal line length, which is usually measured in number of characters per line (including spaces and punctuation). Some say 39 characters is the maximum; others recommend 60 to 65; and others prefer 52 (the equivalent of two alphabets).

Note that too short a line length can be tiring to the eyes. Readers are unable to make efficient use of their peripheral vision and the normal pattern of eye movements is disrupted.

Text on a long side panel should be broken into two columns to prevent excessive line lengths.

Headings

Headings are visual markers that lead the reader quickly to key information. They also serve to break text into logical chunks. Headings should be used to separate the key information.

Leave more space above a heading than below it to separate it from the preceding information and to link it with the text which follows. Never break a

column immediately below a heading, as this separates the text from its identifier.

Sans serif type fonts make good headings, because their straight lines lead the reader's eye down into the text that follows. Always put headings in bold face.

Emphasis

Bold is the best way to emphasize text in drug packaging, provided it is not used in continuous text, where it can create after-images for the reader. Avoid extensive use of *italics*, underlining, ALL UPPER CASE, reverse (white or light type on a solid, dark background) and shadow types. These can increase reading strain when used in small type sizes or for long sections of text.

Colour and Contrast

Colour alone should never be used to cue the reader to important information. Use it in combination with bold face, graphics or symbols.

High contrast – dark lettering on a light surface – is best for readability. Avoid colour-saturated backgrounds and grey or coloured screens which reduce contrast and cause eyestrain, especially with small type sizes. Designers sensitive to these issues recommend that a background screen should be no more than 65% of the solid colour used for the text, for example, 100% black text against a 65% or less screen background. Some readers find anything over 40% contrast is difficult to decipher.

Colours have their own inherent colour density, which must be taken into

account. For example, solid pale blue against a 50% green screen would be difficult to read. Solid black on solid red is widely used, but is notoriously poor in contrast. Colour blindness can also be a factor when two colours are used.

Brightness and high contrast help readability; glossy or reflecting surfaces do not, because the glare interferes with reading, particularly for older eyes that have trouble adjusting to extremes of light. The weight of the paper stock used on an insert should also figure into this equation (opacity), as text printed on both sides of a thin sheet can show through and make reading difficult.

Layout

The organization of text begins with the writer, but continues with the designer and layout artist. As noted, chunking information can help the reader focus on logical sections of text and understand that each paragraph, which may or may not have a heading, deals with a single subject.

Ordering the text in a familiar reading pattern on the page is important as well. For example, newspaper-style columns are familiar to most readers. A hairline to separate columns can be a helpful device.

Using a box to emphasize text is effective if there is sufficient white space available to set off the box from the text around it. Several boxes on a side panel, however, may reduce the impact and produce crowding and clutter; in such cases, hairline separators may be a better alternative.

Numbers placed at the beginning of major sections of text can be used to help guide poorer readers through a document. Format them in a large, bold font to make the roadmap easier to follow. However, avoid using numbers in lists, such as adverse reactions to a medication which are equally common, as some readers may think they are listed in priority. If they are, say so; otherwise, use bullets instead of numbers to reduce the reader's impression of ranking.

Graphics and Illustrations

Whether you use simple line drawings, full-colour illustrations or photographs, graphics should always serve to help your audience understand the text. There is good reason for their use.

Visual presentations have been shown to be 43 percent more persuasive than unaided presentations. The research on visuals and graphics shows that the memory systems in the brain favour visual storage, so that when a message is visualized we remember it better than if we just read or hear it.²

Visuals have a number of advantages over words. They can be:

- identified more accurately when seen at a glance;
- understood by people with low literacy skills;
- used to represent information in condensed form (thereby reducing the amount of written material); and

- designed to be multidimensional, incorporating colour, shape and size as well as combinations of these.

Graphics should not interrupt the reader's journey through the text, but, rather, facilitate it. Placement of illustrations should follow a logical flow just as the written content should. For example, a column of drawings placed beside a column of text they illustrate is an arrangement that would be intuitive and transparent to the reader. The same can be applied to horizontal rows.

As with text, noted above, it is useful to number clearly the frames of a step-by-step illustration – such as how to use an inhaler or nasal spray – to lead readers properly through the procedure. This avoids confusing readers who may not know whether to follow the steps across or down in, say, a four-step process set up as a two-by-two grid.

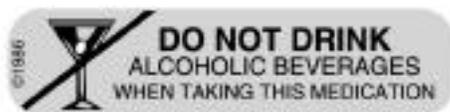
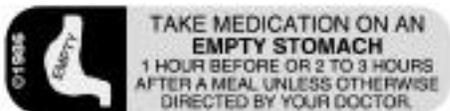
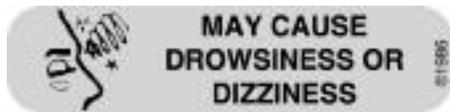
Visuals can have problems that prevent or diminish their value and effectiveness. Here are some common problems associated with visuals:

- too small;
- too complex, or totally incomprehensible;
- illegible, badly drawn or coloured, poor contrast;
- too much information; and
- missing information.

² Cecilia C. Doak, Leonard G. Doak, and Jane H. Root, *Teaching Patients with Low Literacy Skills*, 2nd edition, Philadelphia, PA. J.B. Lippincott Company, 1996.

Graphics work best when they demonstrate actions. This is sometimes difficult in a static drawing, but lessons can be learned from the art of cartoonists and action photographers. Actions also need to be divided into understandable steps. Focus in on the essential actions; and avoid unnecessary clutter in illustrations.

One of the most familiar examples of the use of visuals with medication is the small rectangular strip (with rounded corners) affixed to pill vials by the pharmacist. These consist of a short message, written in plain language (e.g., TAKE WITH FOOD!) and a simple symbol such as the following examples.



These labels contain a simple message reinforced by an illustration. They are easiest to read when affixed vertically.

Other examples of visuals to reinforce patient information are shown in Chapter III.

Testing for Readability

Canadian pharmaceutical manufacturers provide patient information on prescription medications, either required under the regulations or supplied at the manufacturer's discretion. Typical examples are:

- the label on the container of the medicine and/or the package enclosing the container;
- the patient package insert or leaflet;
- supplementary information distributed by physicians and/or pharmacists; and
- the patient information section of the product monograph.

To reach the maximum audience, a Grade 6 reading level is the commonly accepted standard.

How can a manufacturer be sure that patient information is communicating important messages effectively? There are two main techniques for testing the readability of written materials, and these should form an integral part of the development of the materials and guide the writing, revision, design and layout prior to final approval and production.

The two techniques can be used simultaneously or at different stages in the development process. They are:

Standardized readability assessment tools. These tests involve analyzing the text using formulas and calculations to come up with an indicator, usually grade level, to measure the readability of the

information. They are applied directly to the text and do not involve readers.

Focus testing. This process involves the use of test subjects who, either individually or in a group, are presented with the materials and invited to respond to a series of interview questions to determine whether they understood the information presented. Test subjects may be representative of specific user groups or selected at random.

Examples and descriptions of several commonly used tests are presented below.

Standardized Readability Assessment Tools

The literature reports approximately 40 readability tests, most of which are based on the idea that big words and long sentences are harder to understand than simple terms and shorter sentences. They typically involve selecting sections of the test document, counting long words and long sentences, and performing a calculation to yield a reading level. Some are available as computer programs to analyze text electronically, but many of these can be unreliable. For example, a program that counts sentences by using the period as a marker would count “Mr.” as a sentence.

Although these tests are quick and easy to perform, they lack sophistication. For example, they do not take into account words that may be short but are used in an unusual context, or complex conceptual structures or assumptions that lie behind an apparently simple text. As well, grade level is not consistent from one educational jurisdiction to another; nor does it take into account linguistic

and cultural differences common to ethnic sub-groups. (Note: Readability formulas are available for several languages other than English or French.)

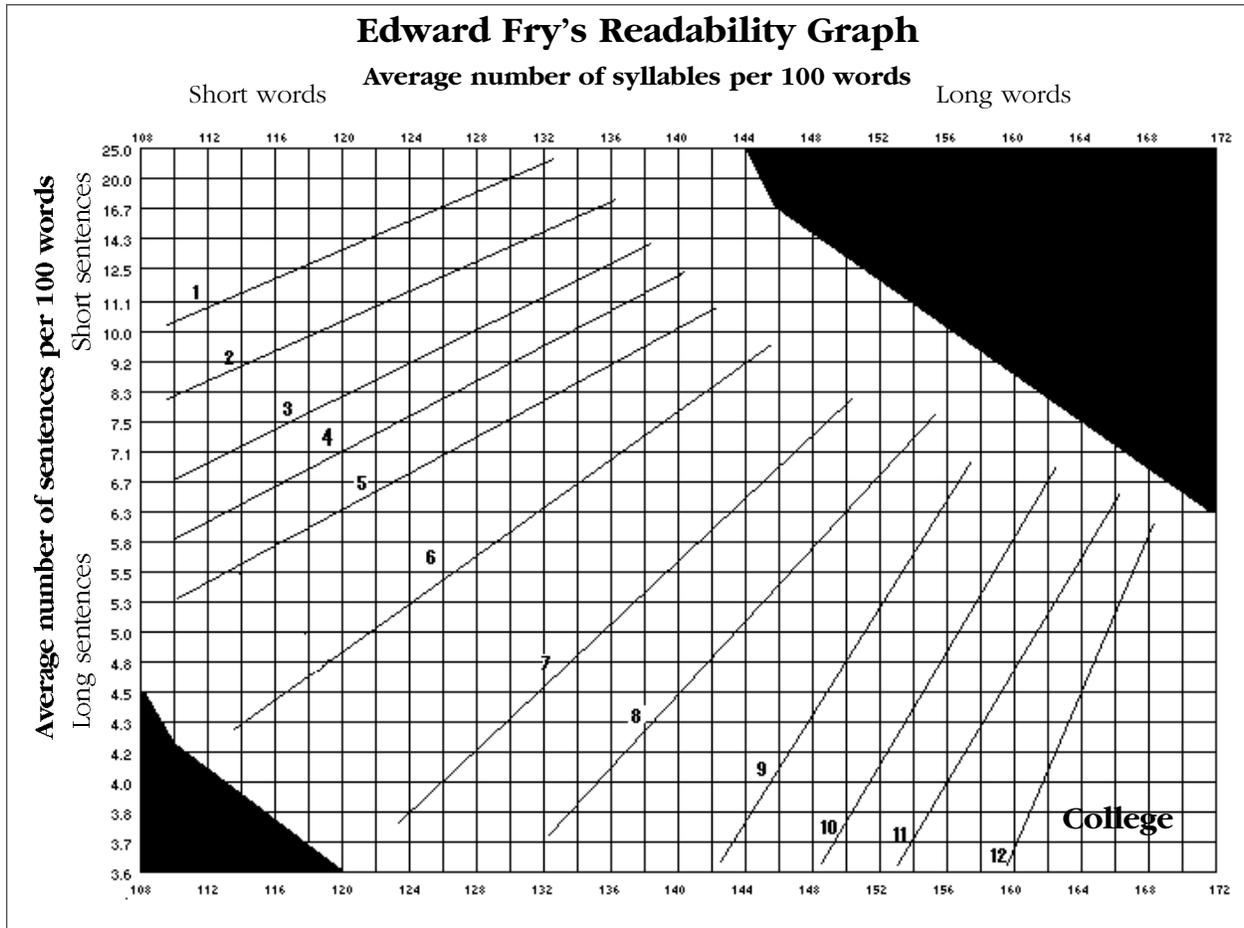
Presented here are three summary examples of readability assessment tools that do not require the use of test subjects.

The Fry Readability Graph

This graph is an interpretive device which takes the scores from word and sentence counts and yields a grade level for readability. Developed by Edward Fry, it is among the most commonly used assessment tools and is widely available on the internet.

To perform the test, follow these steps:

1. Select one or more 100-word passages from the text, depending on the total length of the document.
2. Count the number of sentences in each passage.
3. Count the number of syllables in each passage.
4. If you are using more than one passage, calculate the average for each figure.
5. Place the scores on the graph below:
 - find the number of sentences on the left-hand axis;
 - find the number of syllables across the top and bottom of the graph;
 - follow each line across or down to a point of intersection.



- The point of intersection falls within an area that establishes an approximate grade level for the test.

The S.M.O.G. (Simple Measure of Gobbledygook) Readability Test

Like the Fry readability formula, this test can help establish the grade level of a document by applying a simple calculation to the number of polysyllabic words in the text. Developed by G.H. McLaughlin in 1969, the test is widely used.

If the text has 30 or more sentences:

- Select 30 sentences within the document: 10 consecutive sentences at the beginning, 10 in the middle, and

another 10 near the end of the text. Do not include titles and headings.

- Mark all polysyllabic words in the 30-sentence sample.
- Count the total number of polysyllabic words.
- Find the squared number that is closest to this total and calculate its square root. For example, if the total number of polysyllabic words is 29, the nearest squared number is 25. The square root of 25 is 5.
- Add a constant of three to the square root. This gives you the reading level a person must have to understand the text. In the example given above, the reading level would be Grade 8 (square root of 25 + constant of 3).

If the text has fewer than 30 sentences:

1. Count all polysyllabic words in the text.
2. Count the number of sentences in the text.
3. Find the average number of polysyllabic words per sentence:

average = Total # of polysyllabic words divided by...

Total # of sentences

4. Subtract the total number of sentences from 30 and multiply the remainder by the average number of polysyllabic words per sentence.
5. Add this figure to the total number of polysyllabic words.
6. Find the square root (as described in step 4 in the previous set of steps for text with 30 or more sentences) and add the constant of 3. This gives you the reading level a person must have to understand the text.

Additional guidelines for using the S.M.O.G.:

- Hyphenated words are considered one word.
- Numbers in numeric form should be pronounced to determine if they are polysyllabic. (Example: 337 has 8 syllables.)
- Proper nouns, if polysyllabic, also should be counted.

- Abbreviations should be read as unabbreviated to determine if they are polysyllabic. (Example: ON, for Ontario, has four syllables.)
- Include all repetitions of the same word, no matter how often it is used.
- The grade level is accurate to +/- 1.5 grades.

Suitability Assessment of Materials (SAM)

This tool was developed by C.C. Doak, L.G. Doak and J.H. Root, and is contained in their seminal publication, *Teaching Patients with Low Literacy Skills*³. This book is essential reading for anyone involved in the development and/or assessment of patient information materials.

The SAM is unique among readability tests because it consists of six areas to be assessed, with subsections within each. As with the previous example, sections of the text are selected according to the length of the document and evaluated against the criteria listed on the score sheet.

Once this assessment is complete, the figures are totalled and a percentage calculated based on a 44-point perfect score. A score over 70% indicates superior material; 40-69% is adequate; and 0-39% means the material is not suitable.

It is worth noting that the SAM can be applied, with minor changes, to audio and video materials as well as printed text.

³ Ibid.

Assessing Suitability of Materials: SAM Scoring Sheet

- 2 points for superior rating
- 1 point for adequate rating
- 0 points for not suitable rating
- NA if the factor does not apply to this material

Factor to be Rated	Score	Comments
1. Content		
a) Purpose is evident	_____	_____
b) Content about behaviors	_____	_____
c) Scope is limited	_____	_____
d) Summary or review included	_____	_____
2. Literacy Demand		
(a) Reading grade level	_____	_____
(b) Writing style, active voice	_____	_____
(c) Vocabulary uses common words	_____	_____
(d) Context is given first	_____	_____
(e) Learning aids via “road signs”	_____	_____
3. Graphics		
(a) Cover graphic shows purpose	_____	_____
(b) Type of graphics	_____	_____
(c) Relevance of illustrations	_____	_____
(d) List, tables, etc. explained	_____	_____
(e) Captions used for graphics	_____	_____
4. Layout and Typography		
(a) Layout factors	_____	_____
(b) Typography	_____	_____
(c) Subheads (“chunking”) used	_____	_____
5. Learning Stimulation, Motivation		
(a) Interaction used	_____	_____
(b) Behaviors are modeled and specific	_____	_____
(c) Motivation—self-efficacy	_____	_____
6. Cultural Appropriateness		
(a) Match in logic, language, experience	_____	_____
(b) Cultural image and examples	_____	_____

Total SAM score: _____

Total possible score: _____ Percent score : _____ %

Focus Testing

The use of test subjects to review information materials in various stages of development can be a useful, if not always reliable, technique for assessing readability. As noted, test subjects may be drawn from a specific target group (or several groups) or selected randomly, depending on the nature of the medication and user profiles.

Consumers respond to written information in ways that may be unpredictable. Choosing test subjects who come from a range of backgrounds and circumstances will help demonstrate how various users of the product react to the patient information materials.

There are conflicting views on the design of the focus testing exercise, primarily related to the use of group versus individual interviews. It could be wise to use a combination of both options in designing a focus test.

Group interviews: This option can have the advantage of a dynamic exchange of viewpoints, information and advice. However, even with a skilled facilitator, some participants may emerge as “leaders” and shape the opinions of those who may be shy or reluctant to participate fully in the group, thus skewing the discussion and the results.

Individual interviews: This method relies very heavily on the design of the interview and the technique of the person conducting it, but the value of personal contact and a non-competitive environment can add to the quality of the input.

Two examples of focus testing using subjects are the Cloze Procedure and Diagnostic Testing, both of which can be used in a group test or with individual interviews.

Cloze Procedure

Cloze procedure, developed in the early 1950s by a psychologist, is a technique in which words are deleted from a passage according to a word-count formula, such as every fifth word, or various other criteria. In schools or reading programs, the passage is presented to students who, as they read, insert words to complete and construct meaning from the text. This procedure can be used as a diagnostic reading assessment technique, or to help assess the readability of text for readers with varying levels of literacy.

○ Purpose

The purpose of using Cloze procedure as a teaching tool is usually to determine which cueing systems are effectively used by readers to construct meaning from print. It is also used to assess the extent of readers’ vocabularies and knowledge of a subject, and to encourage students to think critically and analytically about text and content.

As a test for readability, the procedure reveals whether the text is conceptually sound, follows a logical sequence, uses properly constructed sentences, and contains or implies vocabulary that is understandable to the test subjects.

○ Procedure

The person(s) running the procedure should clearly explain Cloze to the test subjects, and should administer in advance a sample exercise, prepared using the following methods, to ensure they are familiar with the procedure. Then, following the same procedure, they should administer the text that is to be tested.

1. Select a self-contained passage of a length appropriate for the grade or reading level of the test subjects being assessed.
2. Leave the first and last sentences intact as well as all punctuation in the text.
3. Carefully select the words for omission using a word-count formula, such as every fifth word or other criteria. To assess subjects' abilities to use semantic cues, delete content words which carry meaning, such as nouns, main verbs, adjectives and adverbs. To assess their use of syntactic cues, delete some conjunctions, prepositions and auxiliary words.
4. When preparing the final draft of the test passage, make all blanks of equal length to avoid including visual clues about the lengths of omitted words.
5. Have the subjects read the entire test passage before they fill in the blanks.
6. Encourage subjects to fill in all of the blanks if possible.

7. Although there should be no time limit for this exercise, the time necessary for completion should be noted.
8. Suggest that subjects reread their completed passage.

○ Scoring the Procedure and Interpreting the Results

There are two ways of scoring these procedures.

- *Exact replacement.* Only those words that are exactly the same as the deleted words are scored as correct. If exact replacement is necessary, a score of 40% or less indicates the reader is unable to read the passage effectively or has reached a frustration level. A higher score indicates that the material is appropriate for both guided and independent reading experiences.
- *Synonymous replacement.* Words are scored as correct if they are the same as the deleted words or if they are synonyms or words which preserve the meaning of the sentence in which the blank occurs. If the procedure is scored using this method, a score of 70% or lower indicates that the material is inappropriate and frustrating for the reader.

Scores and completion times can then be used to determine the suitability of reading material for the individual and/or group of test subjects.

Diagnostic Testing

Diagnostic testing, as developed by the Communications Research Institute of Australia, helps assess a document by observing and analyzing subjects' behaviour in using the document. It consists of:

- asking users to carry out the tasks they might carry out when using the information in a normal, non-test environment;
- observing and recording in detail what they do;
- recording anything they say, either about the particular tasks they are undertaking or about the document in general; and
- probing to find out whether they can appropriately interpret and use the information they have read.

○ The Testing Process

The Communications Research Institute of Australia (CRIA), in its publication *Writing about Medicines for People*,⁴ recommends that the testing be carried out by the person who wrote the document, to allow for firsthand observation of the test subjects' response to the information. This can help considerably when the testing is iterative, i.e., performed at several stages of the document's development. As an added benefit, the knowledge gained by the writer through this process is easily transferred to the writing of new documents.

⁴ Communications Research Institute of Australia. Sless, David and Wiseman, Rob. *Writing about Medicines for people*. 2nd ed. 1997

Test subjects may be selected from the populations at risk – those people who are likely to have problems using the medicine – or, in the case of rare or complex ailments, from actual sufferers who would be more likely to have the patient knowledge to assess the document effectively. CRIA's process is based on individual interviews.

The document should be tested in the layout and on the same paper stock as it will be presented to consumers. This will ensure a genuine response. As well, different ways of presenting the information can be tested, provided you avoid giving both options to the same subjects, as the information gleaned from the first document may assist them in interpreting the second.

○ Developing Test Questions

Because the aim of this process is to determine how consumers go about using the document, test questions should be developed by first considering what specific patient actions are required. For example, if you are probing about how to store the medication, the subject may have to first locate information from several parts of the document; then interpret these correctly; and explain each step or relevant information in a comprehensive way that demonstrates that the document has succeeded (or not) as intended. Questions should be open-ended (such as: "What would you do if you took too much of this medication?") and not simply call for a "yes or no" answer.

CRIA suggests that about 15 key questions is a good number, so as not to tire the subjects. Many participants will

start to noticeably tire after about 30-35 minutes. Questions should be clear and to the point, avoiding a formal style or technical jargon. Do not answer the question in the question itself (such as: “Would you rather see the dosage information in a table format?”). Start with easy, general questions and proceed logically through the document. Do not be afraid to conclude with general questions so that participants can raise points not triggered already (such as: “How can we improve this leaflet?”).

The questions should be tested in advance and modified if they are not eliciting an adequate response.

○ **Conducting the Test**

Conduct test sessions in a relaxed and informal manner to put participants at ease. Offer refreshments to break the ice. Remind subjects that they are making an important contribution to the success of the document and that the purpose of the test is to assess the document, not them.

Following the test session, make thorough notes. It may help to tape-record sessions, provided participants agree. Summarize the results to determine their implications for changing the document or to identify sections that were particularly successful.

If diagnostic testing is part of an iterative process, in which the document is tested, modified and re-tested, recruit new participants for each round of testing. A test subject who is already familiar with the document will use prior knowledge during the second

round, which will give a false indication of the success of the revised version.

The Importance of Testing

Any or all of the methods above can be used as part of the development of patient information materials; some are more powerful than others. When preparing information about medication that often has a considerable impact on a patient’s health and well-being, particular attention should be devoted to the capacity of potential users to understand and act on the instructions. If the document is not tested, it may fail to convey important information in a usable way.

The Physical Design of Packaging

Introduction

In the world of medications, the physical design of packaging is not merely a matter of aesthetics; rather, it is important for conveying critical information to consumers and conforming to government and industry regulations. In addition, the package needs to accomplish the following:

- ensure the stability, sterility, safe transport and proper storage of the medication;
- meet the needs of pharmacists in dispensing the medication;
- meet environmental standards concerning the amount of packaging; and

- provide optimum usability to the consumer, particularly:
 - opening the package;
 - using the medication appropriately and safely;
 - closing the package;
 - storing the package appropriately and safely;
 - disposing the package after use.

This section focuses on physical design as it pertains to prescription medications but, according to the Nonprescription Drug Manufacturers Association of Canada, over-the-counter medications typically follow similar guidelines for packaging.

This document has demonstrated that seniors have special needs when it comes to medication packaging that should be taken into consideration during the design process. For example, a number of seniors have problems with arthritis, strength and shakiness; these all have implications for the manual dexterity required to handle and open certain types of packaging. Vision difficulties should be considered when selecting type size and font style used in package labelling. Finally, seniors with poor hearing can have problems when the doctor or pharmacist is explaining the package's directions for the medication and how to take it.

Package design can help compensate for diminished capacities. A good example was a new container for a well-known over-the-counter analgesic featuring a cap which:

- was large enough to be gripped comfortably;
- had knurled edges to improve grip;
- required only a quarter turn to open and re-secure; and
- was not child-resistant, but was coloured bright red.

For consumers with arthritic hands, who are typical users of this product, the new design was a success. However, the new package was not child-resistant; some users had difficulty removing the tamper-evident plastic; and the product was more expensive in this form of packaging. Nevertheless, the example shows how package design can be sensitive to the needs of consumers.

Packaging can also enhance compliance, reduce errors, and improve the quality of life and health for consumers. Of course, there are trade-offs in terms of the cost to produce such packaging as well as the effect on the environment. Other sections of this document provide detail on issues such as layout, design and compliance.

Prescription medications are typically dispensed in one of two ways: in the original package provided by the manufacturer; or in a package provided by the pharmacist, such as pill vials or bottles for liquids.

Original Package Dispensing

Manufacturers of prescription medication design and print their individual-use packaging (or purchase it from a packaging manufacturer), fill it with

medication, and distribute it to pharmacists. “Original package dispensing” (OPD), as it is known, constitutes about 10-25% of all prescription medication in Canada, the remainder being repackaged at the pharmacy.

When a medication is intended for OPD, the manufacturer often prepares a “patient package insert” (PPI) or leaflet containing detailed information about the medication. This paper insert is usually included in the package which is designed for individual use.

Compliance packaging, often in the form of the blister pack, is an OPD option designed to increase the correct taking of the medication by prompting the consumer in various ways. These types of packaging are discussed in more detail in Chapter III of this document.

Despite these important advantages to OPD, there are also drawbacks:

- The dispensing pharmacist is required to put a label on the package with certain elements which are regulated by provincial pharmacy authorities. This label may (and often does) obscure a portion of the information on the original package. Some manufacturers have met this challenge by designing a package with a blank space for the pharmacist’s label so that valuable information is not covered.
- The size of the package may preclude the provision of adequate information. For example, a small and irregularly shaped container of eyedrops is often too small for the label which may be wrapped

completely around the container, obscuring all information provided by the manufacturer. The pharmacy label may even overlap itself, covering up important information (such as the expiration date). In addition, the font may be too small to be read easily and the container itself may be difficult to handle (the manipulability factor) by seniors and others. The obvious solution to this problem is to package the small container in a larger box, to accommodate the pharmacist’s label and also permit the inclusion of a PPI. However, there are trade-offs, including increased packaging material finding its way into the environment and higher costs for the manufacturer.

How a package opens and closes can also be important. Pharmaceutical and packaging manufacturers worked together to develop **child-resistant closures** (CRCs) to make it difficult for children to open a package containing medication and possibly ingest the contents. Although some patients request non-CRC packaging, it is important not to lose sight of the importance of child safety. Patients who remove child-resistant caps to make access easier should ensure child safety by keeping medications out of the reach of visiting grandchildren, for example.

Tamper-evident packaging was developed following the well-publicized tampering of some over-the-counter medications. If such packaging has been opened (or possibly tampered with) prior to purchase, it is physically evident and easy to see. These measures offer degrees of security; however, they have negative implications for ease of use,

especially for seniors who may find tamper-evident seals difficult to open.

Manufacturers have developed several solutions:

- visible perforations in the seal which can be separated to remove it, either by pulling on the perforated section with a fingernail or by twisting the cap to snap the perforation;
- a cardboard box to contain the medication which is glued shut, preferably with one side perforated for easy opening by the consumer;
- inner bottle seals which are lightly glued and are easy to remove; and
- inner bottle seals that require stronger adhesion due to the nature of the contents (e.g. liquids) but have a tab or ring for easy removal (grocery-product manufacturers and packagers have been innovators in this field).

Other issues present problems and solutions. As noted, manufacturers must ensure the integrity, stability (from the deleterious effects of heat, light and moisture) and sterility of the product. These requirements are prime considerations in the design process for a new package. Meeting these requirements can make it difficult for some consumers to manipulate the package.

Another problem arises when manufacturers want a similar “look” to their lines of medications. However, when packaging has such a homogeneous look, there is a distinct possibility that a pharmacist can inadvertently choose the wrong (and

potentially very harmful) product or strength. Manufacturers must ensure that their products are clearly marked and easily distinguishable.

Drug manufacturers must face all of these issues and more when designing and producing original package design for their products. Related issues are found with repackaged drugs.

Repackaging

As mentioned above, manufacturers produce original package designs for their products (for individual use). However, the vast majority of drugs (an estimated 75-90% in Canada) are delivered in bulk form and are then repackaged into smaller containers by the pharmacist for the individual consumer.

Most repackaged medications, particularly tablets, capsules, etc., are dispensed in vials supplied by the pharmacist. This is most common among products which come in large bulk containers and are then counted out to fill each prescription.

If a patient package insert is available for such products, the pharmacist may provide it to patients at the time of dispensing, although this option is problematic in practical terms, as many pharmacies lack storage space for such material or are simply too busy to provide it. Often, a computer-generated patient information sheet is provided at the time of dispensing.

Seniors and others receiving medication in vials from their pharmacist can request a closure that is not child-resistant but is easier to open (e.g., a “flip-cap”). This

request is then usually stored on the patient's file for future reference. Unfortunately, not all patients who need this option are aware of it. Education on this point is required to ensure that seniors who prefer this type of packaging can take advantage of it. Otherwise, it has been reported that patients leave the CRC package open or transfer the contents to another, easier-to-open container, losing the important label information and possibly causing deterioration of the product. Some seniors report injuring themselves using a tool such as a kitchen knife or screwdriver to open a CRC package. Although flip-caps are generally easier to handle, some seniors may wish to request CRC packaging, to ensure that children don't get into the medication when they come to visit.

Most vials or caps are manufactured in ultraviolet light-resistant colours to maintain the integrity and stability of the contents. These coloured vials may make it difficult for seniors and others with poor sight to see the size and shape of the drugs inside. Seniors often identify pills by shape and/or colour without opening the container or reading the label. Coloured vials which distort the shape and colour of the pills can be especially problematic for those with low literacy and/or vision problems who may have trouble reading the labels. One solution would be to standardize the colour of vials but use a colour that least distorts the contents. In addition, these coloured vials have associated costs.

As described earlier in this chapter, pharmacists often use small stick-on labels (affixed to the vial) to highlight important information for consumers. For example, the "TAKE WITH FOOD" label is a common one familiar to

many people. The labels may consist of words only or may be words plus a simple illustration. These become an integral part of the package when applied, as the simple graphics help to reinforce instructions.

Some pharmacists are repackaging medications in their own blister packs. These provide a convenient and easy-to-handle way of storing medications and include compliance mechanisms. You can find more on this form of packaging in Chapter III.

Conclusion

This chapter has reviewed the following:

- plain-language writing techniques;
- proposals for the presentation of patient information and medication labelling (the Compendium of Plain Language Terminology);
- the design and layout of information, the reinforcement provided by good graphics and illustration;
- the need for adequately testing the information; and
- the physical design of the package and/or container.

These elements are complex in themselves, and need to interact in a way that ensures good understanding by patients of how to properly take their medicine. Manufacturers who are sensitive to the special needs of Canadian seniors and those with low literacy skills can make a significant contribution to their safety, health, and well-being.



CHAPTER III:

Techniques for Enhancing Patient Compliance

Introduction

To get the most benefit from a drug, the patient has to take the medication as prescribed by the doctor – in the correct amount, at the proper times, and for the complete duration. Compliance (i.e., correctly following the instructions for use) not only helps improve the individual's health, it saves money for both the patient and society through savings to the health care system. This chapter outlines techniques that can involve all members of the medication management team – manufacturers, physicians, pharmacists, health personnel, informal caregivers and patients.

The importance of medication compliance, especially among low-literacy seniors, may not be fully appreciated by practitioners and the public. For the professional audience, this topic should be included in conferences, seminars, workshops and journals. Some health associations have undertaken programs and advertising campaigns that focus on educating target groups (such as doctors, nurses and pharmacists) about medication compliance issues. For example, the Canadian Pharmacists Association has developed a set of materials called

Just Checking offering pharmacists guidance in counselling their clientele; and Canada's Research-Based Pharmaceutical Companies (Rx&D) has a *Knowledge is the Best Medicine* kit for community workshops.

Links among industry, non-governmental organizations and government are needed to develop and spread the word. Literacy associations, consumer groups, community associations and caregiver groups should all be partners in the goal of medication compliance. In particular, educating their constituencies can be of tremendous value.

It is also widely recognized that individuals have a responsibility for their own health care. The patient is responsible for following the advice and directions given by the health care practitioner. Patients who are seniors typically want to retain their independence and autonomy. Carrying an updated medication record booklet (such as that provided in the *Knowledge is the Best Medicine* kit) to visits to health care professionals is one way to do that. The booklet can be filled in to include a complete list of prescription medications, over-the-counter drugs, alternative medicines, herbal preparations, vitamins, etc., being taken by the patient.

Using compliance-enhancing interventions, strategies and tools empowers seniors, enabling them to manage their care. This empowerment can improve quality of life, and the therapeutic gains from compliance can contribute to their well-being.

Senior citizens who are patients may not adhere to medication regimens for a variety of reasons:

- low literacy;
- isolation;
- cognitive impairment;
- general forgetfulness;
- diminishing physical abilities, chronic diseases, etc.;
- lack of feeling in control of their lives which leads them to give up; and
- lack of social supports which can lead to poor personal care and hygiene.

Identifying the relevant reasons for individual patients is important in order to determine the most appropriate and effective techniques to overcome them. Clearly written plain language information materials can help to compensate for low literacy levels. Home care and other services can help reduce isolation and allow family members and friends to spend quality time with the patient and avoid burnout. Educational and counselling strategies and memory aids can compensate for forgetfulness. Physical compliance “tools”, including innovative packaging,

can influence behaviour. An appropriate, supportive emotional framework set by good physician-patient and pharmacist-patient communication can gain patient trust, nurture a positive attitude, and motivate the patient to adhere to a medication regimen.

No one strategy will result in patients taking their medication properly. A combination of techniques, counselling and innovative packaging – tailored to the individual’s unique needs – is needed to improve compliance. Just as behaviour and people are dynamic, ongoing monitoring and flexibility are essential to ensure that changing needs are met. This can mean researching, being aware of, and taking advantage of new strategies and devices as they are developed and become available.

Techniques for Involving the Patient

Whenever possible, patients should be involved in setting up the drug regimen so they have a sense of control and responsibility for their medication-taking and well-being. Both the physician and the pharmacist play an active role in counselling patients and explaining the purpose of the medication, how to take it, precautions and possible side effects. The patient information materials provided by the manufacturer can be a key element in this process. Everyone involved must view the patient as an

active participant unless illness has caused an incapacity to self-manage a drug regimen.

Personal Communication and Education

All members of the medication management team have a role to play in communication and education.

Drug manufacturers operate at the beginning of the process and can set the stage for doctors, pharmacists and patients. By realizing that low literacy may be one of the factors in patient profiles, manufacturers can work with health professionals to ensure clarity in their education material. The patient package insert – which is put directly into the medication box or container – offers an important opportunity to reach low-literacy patients. Drug manufacturers can help to increase the correct taking of medication by ensuring that the information and instructions are written in plain language, are easy to read, and in a readable font size. One idea for increasing compliance is the use of graphics (in addition to words) to convey information. Another is to add a daily or weekly calendar (see examples below) to the patient package insert; the pharmacist can explain to the patient how to use it as a reminder device and to record the taking of medication.

Product sponsors cannot be expected to prepare packaging/labelling material that will meet the needs of all segments of the population, no matter how small this segment may be. For example, only the two official languages are required on drug products directly accessible to the

public (one official language on prescription medication), and Braille print is not mandatory. Patients or consumers who may not be able to read or understand medication instructions are advised to seek assistance.

Doctors who prescribe medications are at the next stage of the process. Giving simple and clear information verbally, especially to seniors who may have low literacy, is essential. One method for increasing patients' recall of the information is to organize what is to be said into an "agenda" and following a logical sequence.

Such a conversation begins by telling a patient what the agenda contains: 'I'm going to tell you':

1. What I think is wrong with you.
2. What tests we need to carry out to be sure.
3. What I think will happen to you.
4. What treatment you will need.
5. What you can do to help yourself.¹

Developing a good rapport with the patient is the foundation of good communication and relationship-building. The patient must feel safe, accepted, valued and respected. Nurturing trust and confidence requires developing an open, empathetic, caring, non-judgemental demeanour.

¹ Cecilia C. Doak, Leonard G. Doak and Jane H. Root, *Teaching Patients with Low Literacy Skills*, 2nd edition, Philadelphia, PA: J.B. Lippincott Company, 1995, p. 163.

Doctors need to tell patients in a very clear manner what they need to do, and how and when to do it. Seniors need to hear and understand why it is important to take medications, in the dose prescribed and at stated times, for the medicines to work properly. Practitioners need to explain possible unwanted side-effects, and what patients should do if side effects occur.

Pharmacists are playing an increasingly important role in patient care, particularly with mandatory patient counselling. By realizing that seniors may have low literacy skills, pharmacists understand the importance of demonstrating and verbally reinforcing instructions given by the doctor. In today's world, patients are relying more on pharmacists for information and advice. As a result, pharmacists have the opportunity and the obligation to speak with patients and give them verbal advice and written materials that can increase compliance. Pharmacists can play a coordinating role for patients who deal with different medication regimens; this is needed because the patient package insert is product-specific.

Formal and informal caregivers continue to care for patient needs in many ways, especially with shorter hospital stays. Because the care is given in a home setting, the patient tends to be comfortable with formal caregivers such as home care workers and private or non-profit services. Informal care given by family members and friends is also very trusted. All of these caregivers can convey instructions to and from the patients and the doctor and pharmacist. They may also remind patients when it

is time to take their medication. (Note: certain caregivers, such as some home care workers, are not permitted to administer medication or fill medication organizing boxes.)

Educational Support Groups

These groups – often organized by health associations, hospitals and community groups – are a useful tool for patients with special conditions such as heart disease, asthma or diabetes. Information is conveyed verbally by guest speakers who can provide valuable ongoing learning while group members can share practical information tips. Patients with low literacy can thus get information verbally in a supportive environment.

Regular Patient Contact and Monitoring

Health care practitioners need to do ongoing review and reinforcement with the patient to explain the purpose of the therapy and the instructions for use. Similarly, periodic reassessment of the patient's cognitive and physical abilities will help to ensure that the materials and tools are at an appropriate level. Modifications such as larger print labels or additional memory cues may be required as the individual ages. Ongoing monitoring allows for adjustments in scheduling and compliance tools to meet the patient's changing needs. Services such as home care as well as family and friends can be involved in this process.

At the same time, seniors need to be able to access health care professionals

on a timely basis in order to make informed decisions or to clarify medication use. Such access can contribute significantly to reducing the misuse of medication by seniors.

Written Patient Information

Doctors and pharmacists should review patient information with the patient. This can be supplemented with demonstrations (as appropriate) and plain language materials such as pamphlets and information sheets.

Patients must understand the materials; if low-literacy patients cannot read and understand them, they may not take the medication properly. Chapter II, which discusses plain language and clear communication, gives advice on how to prepare these documents. Pamphlets serve as a reference for the patient to review and reinforce counselling from the physician and pharmacist. Most people find it reassuring to have something to refer to when questions or concerns arise and to take personal charge by knowing all they can about their medication.

Triggers and Links

One of the most effective ways to improve compliance among low-literacy seniors is to tailor the regimen to the patient in ways that do not necessarily rely on written materials. Identifying patient routines, such as mealtimes, that coincide with dosing intervals can be helpful, acting as a trigger to reinforce adherence. The schedule has to be practical for the senior and fit in with his or her life.

The health care practitioner should discuss the patient's daily routine and find something to "hang" taking medications on. For example, if a certain medication should be taken in the morning and that's the usual time to walk the dog, the patient can mentally link the two activities to remember to take the medication.

Depending on the individual and the dosage frequency, patients often find morning and bedtime routines as well as meal times to be helpful reminder aids. Routines may vary on weekends and holidays, and patients must be informed of tolerable time limits and what to do if they miss a dose.

Some seniors have poor eating habits and tend to skip meals or eat at inconsistent times. This can cause problems when taking a medication is expected to be triggered by a mealtime; it can also cause problems with absorption, etc., if the medication needs to be taken with food.

As well, irregular sleeping patterns are common among older persons, and it may be unrealistic to hope for a routine bedtime and wake-up time as a trigger.

It is useful to advise patients to keep their medication in a handy, highly visible area such as on the kitchen table, by the television, at a routine work or recreational station, or right at the front of the refrigerator. However, safety

precautions must be taken to prevent accidental ingestion by children or others and ensure that the medicine will not deteriorate.

Demonstration and Practice

Special medical devices such as inhalers must be demonstrated, and the patient needs the opportunity to practise the technique with the pharmacist or other practitioners. Clearly written instructions and simple illustrations will reinforce the demonstrations.

Did you hear the one about...

An elderly woman, recently diagnosed as diabetic, took a class in an out-patient clinic to learn how to self-inject her insulin. The nurse provided sample syringes and an orange to each participant and taught the techniques step by step.

Several days later the woman arrived at emergency. At home, she had taken her insulin syringe, injected an orange and eaten the orange.

This is not really a funny story, but it does illustrate the necessity of clear verbal communication. In this case, the nurse should have asked each participant to repeat the steps back, and the error could then have been detected and corrected.

Audiotapes and Videotapes

Educational reinforcement using audiotapes and videotapes has been proven effective in some clinical settings, and may be adapted to reinforce compliance at home. For low-literacy seniors, the visual and auditory reinforcement can be particularly effective. Health care practitioners should carefully screen patients to ensure that this technique is suitable.

Telephone Reminders

It is helpful to have someone who can “remind” the patient to take their medications. This can be done by phone or in person by a caregiver (volunteer or paid) or family member. Recorded medication messages can be programmed if it is not feasible to have a personal call. A family member or other familiar voice should record the message. A call tracking system should be used to follow-up and report unanswered calls. Paging services can also be used for this purpose.

Electronic Cues and Memory Aids

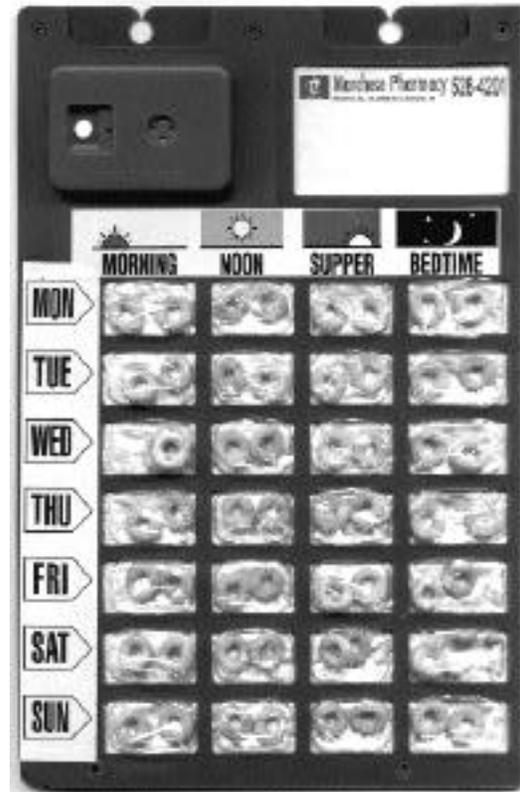
A basic alarm clock or programmable watch with an alarm function can provide the patient with an audio cue to take their medication at the right time. For patients with hearing impairments, visual cues can be provided by devices such as a programmable flashing light or a vibrating bracelet.

More sophisticated devices are on the market using technology to provide cues and reminders. Although the cost of these devices is high now, the price will

continue to drop as the cost of technology decreases. These products are options for people who are on their own or very busy and need a regular, external cue that does not require personal contact.

Some of these reminder devices also record and monitor the taking of the medication. However, they all need to be programmed which may be difficult for low-literacy seniors. In these cases, patients may need someone else, such as a paid or volunteer caregiver, to teach them how to program the device or to actually program it for them.

The cutting edge of reminder devices comes in the form of technology which dispenses drugs to patients in blister cards integrated with inexpensive microchip technology. The cards are programmed to “beep” at dosing intervals, monitoring and recording the times the drug was actually taken so the information can be downloaded for assessment by the pharmacist and physician. This allows early detection of problems and may indicate the use of other, perhaps more successful, interventions.



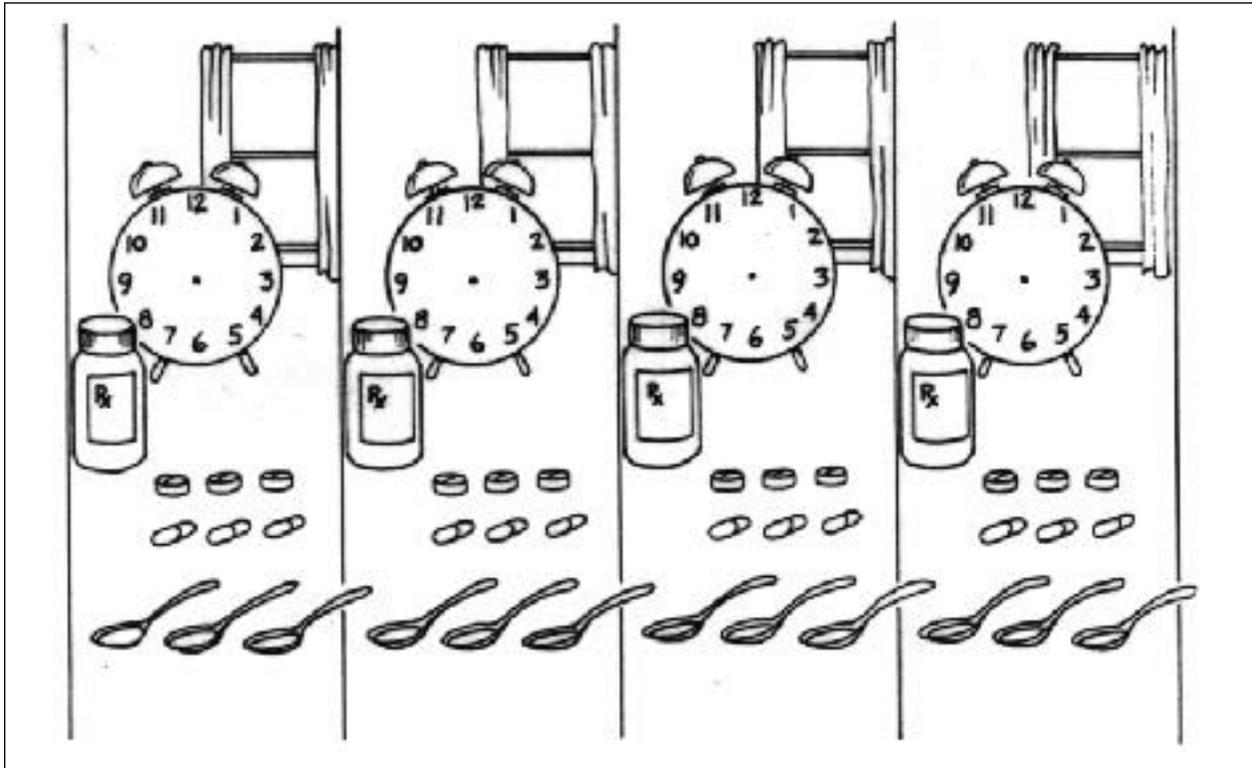
This product combines (a) a custom blister pack made up by the pharmacist with (b) microchip technology to create a reminder and recording device.

Calendar Tracking and Scheduling Charts

Tracking medication administration on a calendar or diary can be a helpful reinforcement to people on either

<i>Daily schedule</i>					
Drug Name & Strength	Directions	7 a.m. breakfast	12:00 noon lunch	5:00 p.m. supper	10:00 p.m. bedtime
Drug A					
Drug B					
Drug C					

<i>Weekly Schedule</i>							
Day & Strength	Drug Name	Time	Time	Time	Time	Time	Time
Mon.							
Tue.							
Wed.							
Thurs.							
Fri.							
Sat.							
Sun.							



Reminder sheet for medications that the patient marks and takes home. (Source: This information is taken from: Do You Understand? developed by the Hospital Awareness Committees of LVA Nassau County and LVA Rochester, NY, Inc. © 1989.)

simple or complex drug regimens. Personalized schedules must be tailored to reflect the patient's needs and lifestyle to support the regimen.

A medication calendar or chart, identifying the time and dose required in a grid, allows the patient to simply cross off doses as taken. This can be very useful in both reminding and recording, especially for low-literacy seniors who rely on the visual aspects of a chart. Caregivers can easily review the chart to detect and remedy problems early. Two samples are shown here.

Other Visual Aids

Pharmacists and others can use various visual aids to enhance compliance in individuals who have low literacy skills. For example, the pharmacist can sit down with a patient and use the pictorial representation of a clock to illustrate how, when and how much medication should be taken. The patient can draw in the hands at scheduled dosage administration times and pictorially depict the dosage form (and quantity).

Visual devices can be useful by:

- helping the patient to concentrate on the main message;
- reducing the amount to be read;
- providing visual cues and interaction; and
- providing motivation.



Suitable features for poor readers are:

- Clear line drawing of commonly used medicines
- Patient can point to the medicine being taken

Figure displays and communicates information helpful in a medical history. (Source: This information is taken from: Do You Understand? developed by the Hospital Awareness Committees of LVA Nassau County and LVA Rochester, NY, Inc.© 1989.)

Counter caps that fit on prescription bottles are available. These have built-in counters that “count down” the number of pills/capsules so that patients can keep track of how much medication they have taken. This visual indication is useful for low-literacy seniors.

A scratch-off label, similar to a “scratch and win” or lottery card, can help patients keep track of medication. In this system, the patient scratches off the appropriate scheduled dose when the dose is taken. Although the visual nature of the system is useful for low-literacy seniors, this system requires a degree of manual dexterity.

Organizing and Packaging Medication

Pre-packaged containers organize and package medication to enhance compliance. These containers allow separation and identification of each dose to facilitate patient handling and accurate self-medication. Three examples of such container packaging are:

- medication organizers;
- blister or bubble packaging; and
- original package dispensing.

Medication organizers, which are commonly available in pharmacies, are re-usable plastic containers that organize doses of medication. The most widely used is known as the DOSETT®. The boxes are divided into sections for different times throughout the day (usually morning, afternoon, evening and bedtime). Medication organizers come in different sizes, and can hold a day's or a week's worth of medication. The patient's medications are placed in each compartment according to when they are to be taken. This provides a visual reminder to patients to take (or that they have taken) their medications. As

well, if a patient sees pills in the organizer box at a point in the day after the medication should have been taken, this can provide a visual reminder to check more often to ensure that medications are taken at the proper time. Patients can fill the organizers themselves, or a home care provider or pharmacist can do it.

Blister or bubble packing of medication in-store is sometimes done by pharmacists for individual patients. Blister packs help organize the doses of medication in the same way as commercial organizers do. Blister packs are sealed on cards with clear plastic bubbles that hold the doses for each scheduled administration, and the card can be custom-printed at the pharmacy. When it's time to take the dose, the patient pushes the medication out through the back of the card. The bubbles are usually divided into four columns labelled morning, noon, evening and night, with a different row for each day of the week. More than one card may be required to fit all medications. Some medications, such as creams and drops, are not suitable for this type of packaging.

Original package dispensing is one of the two ways that medications are typically dispensed in Canada; the

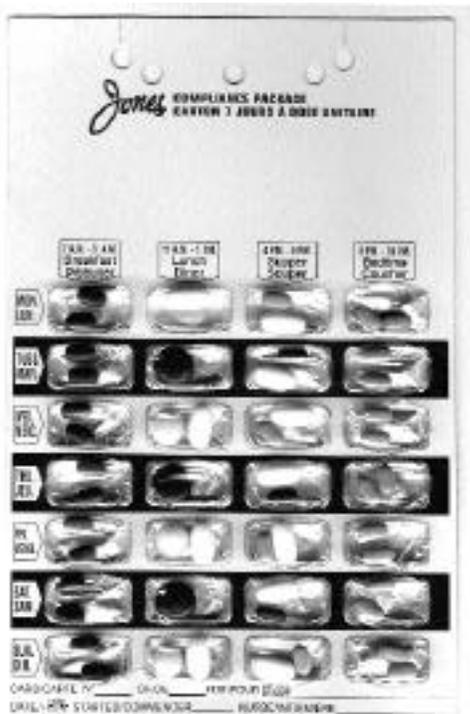
Vial dispensing: In this traditional dispensing method, medications are packaged in bulk and delivered to the pharmacist in this form. The pharmacist then fills individual prescriptions by putting the necessary quantity in a plastic vial or other container and labels it for the patient. This method is cost-effective but provides no reminder mechanism as part of the package. In Canada, between 75-90% of medications are dispensed in vials.



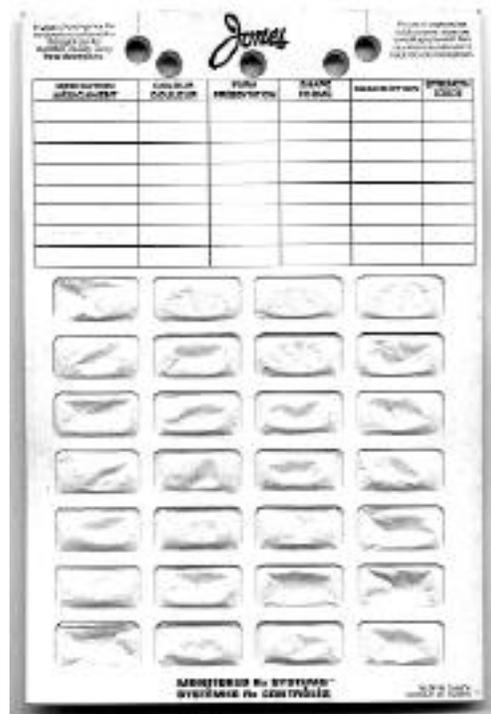
This organizer holds a week's worth of medication, with four compartments for each day. Labels are in English, French and Braille. The DOSETT® is available in two sizes and comes with an optional locking device.



The advantage of this organizer is that each day's section can be removed, a handy option when the patient will not be at home when the medication is to be taken.



This customized, disposable and inexpensive blister pack is made up by the pharmacist. There is space at the top for the pharmacist's label, and on the back a place to describe each medication's colour, shape, etc. This is especially useful when several different people are involved in administering the medication.



other method is the vial dispensing method (see sidebar). As discussed in more detail in Chapter II, the medication arrives at the pharmacy already pre-packaged for patients, frequently in the form of blister packaging as discussed above. Patients usually receive complete product information and instructions. The unit-dose, blister type packaging itself provides a visual cue and allows the patient or caregiver to see if a required dose has been taken. Original package dispensing, which is more costly than vial dispensing, is still relatively rare in Canada. The drugs available this way tend to be the newer, costlier therapeutic agents or where the manufacturer wishes to distinguish the product from earlier generations. Concerns about patients' ease of use of this type of packaging were reflected in a 1993 survey carried out by the Packaging Association of Canada. The National Survey on Packaging Experiences found that 40% of respondents over age 75 found it inconvenient or difficult to open some forms of blister packaging.

Putting It All Together

Strategies and devices are useful tools for:

- giving senior patients the appropriate information, expressed and/or written in plain language;
- motivating them to take their medications properly; and
- providing “simple tools” to help them monitor and facilitate medication-taking.

However, used alone, none of these strategies and tools is the magic bullet. The complexity of compliance requires a multi-faceted approach that integrates counselling, instructional materials and innovative packaging with a combination of tools and techniques to help the individual by organizing, providing cues, and tracking the appropriate taking of medication. These physical and cognitive techniques require collaboration and partnership between the drug manufacturer, practitioner, pharmacist, patient and caregiver to ensure success.



APPENDIX Literacy Definitions and Levels Used in the International Adult Literacy Survey

Prose Literacy

Level 1

Most of the tasks at this level require the reader to locate one piece of information in the text that is identical or synonymous to the information given in the directive. If a plausible incorrect answer is present in the text, it tends not to be near the correct information.

Level 2

Tasks at this level tend to require the reader to locate one or more pieces of information in the text, but several distractors may be present, or low-level inferences may be required. Tasks at this level also begin to ask readers to integrate two or more pieces of information, or to compare and contrast information.

Level 3

Tasks at this level tend to direct readers to search texts to match information that require low-level inferences or that meet specified conditions. Sometimes the reader is required to identify several pieces of information that are located in different sentences or paragraphs rather than in a single sentence. Readers may also be asked to integrate or to compare and contrast information across paragraphs or sections of text.

Level 4

These tasks require readers to perform multiple-feature matching or to provide several responses where the requested information must be identified through text-based inferences. Tasks at this level may also require the reader to integrate or contrast pieces of information, sometimes presented in relatively lengthy texts. Typically, these texts contain more distracting information and the information that is requested is more abstract.

Level 5

Some tasks at this level require the reader to search for information in dense text that contains a number of plausible distractors. Some require readers to make high-level inferences or use specialized knowledge.

Document Literacy

Level 1

Most of the tasks at this level require the reader to locate a piece of information based on a literal match. Distracting information, if present, is typically located away from the correct answer. Some tasks may direct the reader to enter personal information onto a form.

Level 2

Document tasks at this level are a bit more varied. While some still require the reader to match on a single feature, more distracting information may be present or the match may require a low-level inference. Some tasks at this level may require the reader to enter information onto a form or to cycle through information in a document.

Level 3

Tasks at this level appear to be most varied. Some require the reader to make literal or synonymous matches, but usually the matches require the reader to take conditional information into account or to match on multiple features of information. Some tasks at this level require the reader to integrate information from one or more displays of information. Other tasks ask the reader to cycle through a document to provide multiple responses.

Level 4

Tasks at this level, like those in the previous levels, ask the reader to match on multiple features of information, to cycle through documents, and to integrate information; frequently however, these tasks require the reader to make higher order inferences to arrive at the correct answer. Sometimes, conditional information is present in the document, which must be taken into account by the reader.

Level 5

Tasks at this level require the reader to search through complex displays of information that contain multiple distractors, to make high-level inferences, process conditional information, or use specialized knowledge.

Quantitative Literacy

Level 1

Although no quantitative tasks used in the IALS fall below the score value of 225, experience suggests that such tasks would require the reader to perform a single, relatively simple operation (usually addition) for which either the numbers are already entered onto the given document and the operation is stipulated, or the numbers are provided and the operation does not require the reader to borrow.

Level 2

Tasks in this level typically require readers to perform a single arithmetic operation (frequently addition or subtraction) using numbers that are easily located in the text or document. The operation to be performed may be easily inferred from the wording of the question or the format of the material (for example, a bank deposit form or an order form).

Level 3

Tasks found in this level typically require the reader to perform a single operation. However, the operations become more varied – some multiplication and division tasks are found in this level. Sometimes two or more numbers are needed to solve the problem and the numbers are frequently embedded in more complex displays. While semantic relation terms such as “how many” or “calculate the difference” are often used, some of the tasks require the reader to make higher order inferences to determine the appropriate operation.

Level 4

With one exception, the tasks at this level require the reader to perform a single arithmetic operation where typically either the quantities or the operation are not easily determined. That is, for most of the tasks at this level, the question or directive does not provide a semantic relation term such as “how many” or “calculate the difference” to help the reader.

Level 5

These tasks require readers to perform multiple operations sequentially, and they must dis-embed the features of the problem from the material provided or rely on background knowledge to determine the quantities or operations needed.