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MN

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Federal Trade Commission
Office of the Secretary
Room 159-H
600 Pennsylvania Avenue NW
Washington, DC 20580

To whom it may concern:

Comments: Interagency Proposal to Consider Alternative Forms of Privacy Notices Under the Gramm-Leach-Bliley Act

Biography

I'm a readability consultant. In 2001 I reviewed 60 GLB financial privacy notices (attached) and participated in the December "Get Noticed" Conference. I've also consulted with the Department of Health and Human Services on language issue in HIPAA Privacy Notices, and I've written extensively about consent forms in clinical trials, managed care report cards, employee benefits documents—all projects that reviewed how complicated information was presented to consumers in response to Federal regulatory requirements.

Compliance vs communication is the major problem

Above all, because financial institutions want to be in compliance with GLB regulations, they use language taken directly from the Federal Register. But such regulatory language is often inconsistent with basic communication principles. As long as compliance is the major (or only goal), GLB notices will not be written in consumer-friendly language. (See enclosed article on "Compliance v Communication")

The need for testing and readability standards for GLB Notices

Often a junior high reading level is recommended because policy makers assume that anyone with eight years of education will understand. But that isn't always so. Readability doesn't taken into account document design, reader interest, etc. Plus, writing at a junior high level is very hard; most of the complicated documents I review are written at about a grade 14-17 reading level. Because rewritten versions come down one or two grade levels, getting GLB privacy notices to an 8th grade level will be very difficult—perhaps impossible. Plus, the most widely used readability formula, the Flesch-Kincaid in Microsoft Word is flawed: It does not report scores higher than grade 12.

There is a need for consumer testing of financial privacy notices. Financial institutions or associations should give focus groups of consumers several different forms and let the consumers tell them what they like, what they don't like, what they understand, and what they don't understand.

Draft versions can be evaluated in several ways. Qualitatively, notices can be evaluating using one-on-one interviews, or focus groups. Quantitatively, readability formulas can provide some basic information about how hard or easy the document is to read, or cloze testing can be used to measure comprehension more precisely.

Plain language principles to guide the draft

Of course privacy notices should be written using plain language techniques. But note that the HIPAA regulations stated: "A covered entity can satisfy the plain language requirement if it makes a reasonable effort to: organize materials to serve the needs of the reader; write short sentences in the active voice, using "you" and other pronouns; use common everyday words in sentences; and divide materials into short sections."

But, "We do not require particular formatting specifications, such as easy-to-read design features (e.g., lists, tables, graphics, contrasting colors and white space), type face, and font size." As a result, some organizations reduced the size on their copiers to get everything to fit on one sheet of paper. Such HIPAA forms might be readable, but not legible!

Moreover, although HIPAA notices were "required" to be written in plain language, I have yet to see a single plain language HIPAA notice. That plain language requirement was not met, and there are no penalties for writing notices that are incomprehensible. "Requiring" plain language GLB notices will probably have no effect on the way the notices are actually written.

Privacy notice writers would benefit from having several templates as examples from which to choose. Some compromises would have to be made; financial institutions probably wouldn't use large type (which is more readable) if it requires too many sheets of paper and adds too much to postage costs.

Consumer testing as the key part of privacy notice development

Consider GLB privacy notices as a "product" that financial institutions are tying to sell to their customers. If consumers opt-out, they decided not to "buy" the privacy product; If they allow information sharing, they decided to "buy" the privacy product. Viewing privacy notices as products means that they can (and should) go through the same kind of consumer testing and market research as more traditional products.

From this perspective, consumer testing is the most important part of privacy notice development. Include typical consumers in the writing and editing process, and give them the opportunity to evaluate different privacy notice designs and content.

Standardization might help

Standardized formats might help by allowing consumers to more easily recognize privacy notices. But standardized language has to be done with some opportunity for language flexibility. Will a one-size-fits-all notice work? Ask consumers by giving them several versions to evaluate.

Yours truly,

Mark Hochhauser

Lost in the Fine Print: Readability of Financial Privacy Notices

By Mark Hochhauser, Ph.D.
Readability Consulting

Posted on the Privacy Rights Clearinghouse Website, July 2001
www.privacyrights.org

Note: This document replaces "Lost in the Fine Print I" and II, which were posted on the PRC Website in April 2001 and May 2001.

Summary:

Readability analyses of 60 financial privacy notices found that they are written at a 3rd-4th year college reading level, instead of the junior high school level that is recommended for materials written for the general public. Consumers will have a hard time understanding the notices because the writing style uses too many complicated sentences and too many uncommon words.

Beginning this year, banks and other financial institutions have begun to inform their customers about their privacy rights. The federal Financial Services Modernization Act, also known as Gramm-Leach-Bliley (GLB), requires customers to be given the choice to opt-out of their bank's sharing of personal information with third parties. "Privacy notices" are being mailed to consumers in their bank statements, credit card statements, investment reports, mortgage statements, insurance mailings and so on.

How readable are the "Privacy Notices?"

I reviewed 60 privacy notices using several software programs including Prose, WStyle 1.6, Grammatik 6.0, Reader 1.2, and Correct Grammar 2.0. These programs calculated the Flesch Reading Ease Score, writing style, sentence and vocabulary complexity and word commonness.

Instead of being written in plain English, the 60 privacy policies average a 3rd-4th year college (grade 15.6) reading level, making them "difficult" to read on the Flesch Reading Ease Score. Note that readability software programs don't score higher than grade 17--first year graduate school. It's possible that some of the policies written at a graduate school reading level may be more complicated than a grade 17. In short, average readers will find these notices hard to understand, especially the elderly and those whose primary language is not English.

Recent Census data shows that about 85% of adults have a high school degree. About 25% have one or more college degrees. Despite these levels of educational attainment, research shows that many people read three-to-five grades lower than their highest level of educational attainment. Thus, it's not unusual for someone with a high school diploma to be reading at a 7th to 9th grade reading level. Because of that gap, literacy experts recommend that materials written for the "general public" be at about a junior high reading level.

One of the factors involved in readability is the number of words per sentence. Research suggests that to be easily understood, documents should average about 15-20 words per sentence. When sentences

get too long (over 40 words), readers may forget the beginning of the sentence by the time they get to the end.

The following table shows the results of my readability analyses of 60 GLB privacy policies. These policies are ranked from "best" to "worst" in terms of Reading Ease. None of the notices, however, scored any better than "difficult," since the scores ranged from 24 to 47. Rudolf Flesch calculated Reading Ease based on the following scoring system:

Flesch Reading Ease Score

0 - 29 = Very Difficult
30 - 49 = Difficult
50 - 59 = Fairly Difficult
60 - 69 = Standard
70 - 79 = Fairly Easy
80 - 89 = Easy
90 - 100 = Very Easy

Financial Privacy Notice	Flesch Reading Ease (60 recommended)	Grade Level (8 recommended)	Writing Style
River Valley Credit Union	Difficult/47	13	Weak
Manufacturer & Traders Trust	Difficult/47	13	Weak
Northern Trust	Difficult/46	14	Weak
Seattle Savings Bank	Difficult/44	13-14	Poor
Anchor Bank	Difficult/43	14	Poor
Washington Mutual	Difficult/42	14	Weak
FDS	Difficult/42	14	Weak
Discover Card	Difficult/42	14-15	Poor
ePacific	Difficult/41	14	Poor
Deseret First Credit Union	Difficult/40	14-15	Weak
Postal Credit Union	Difficult/39	14-15	Weak
Key	Difficult/38	15	Poor
Patelco Credit Union	Difficult/38	15	Poor
Missoula Federal Credit Union	Difficult/38	15	Poor
May National Bank	Difficult/38	15	Weak
Providian Bank	Difficult/38	15	Poor
Bank of America	Difficult/37	15	Poor
UNCLE Credit Union	Difficult/37	15-16	Poor
Synovus	Difficult/37	15-16	Poor
FirstStarBank	Difficult/36	15-16	Poor
Sears	Difficult/36	16	Poor
Target (Retailers National Bank)	Difficult/36	15	Poor
Wescom Credit Union	Difficult/35	15-16	Weak
Advanta National Bank	Difficult/35	15	Poor
Boeing Credit Union	Difficult/35	15	Poor
Capital One	Difficult/35	16	Poor
State Farm	Difficult/35	15-16	Poor
National City Bank	Difficult/35	15	Poor
Provident Financial Group	Difficult/35	15-16	Poor
Mellon Financial Services	Difficult/35	15-16	Poor
USbancorp	Difficult/35	15-16	Poor

Wescom Credit Union	Difficult/36	15-16	Weak
Macy's	Difficult/34	16	Poor
Bank One	Difficult/34	15-16	Poor
Cascade Bank	Difficult/34	15-16	Poor
Greater Nevada Credit Union	Difficult/34	15-16	Poor
Unitrust Financial Services	Difficult/33	16	Poor
Fleet Boston Financial	Difficult/33	16	Poor
Household Bank	Difficult/33	16	Poor
Wells Fargo	Difficult/33	16	Poor
Sterling Financial Services	Difficult/31	16	Poor
Exxon Credit Card	Difficult/31	16	Poor
People's Bank	Difficult/31	16-17	Poor
California Federal Bank	Very Difficult/30	16	Poor
Chase	Very Difficult/30	16-17	Poor
Cambridge Savings Bank	Very Difficult/29	Graduate School	Very Poor
MBNA	Very Difficult/29	Graduate School	Poor
Union Bank of CA	Very Difficult/29	16	Poor
USAA	Very Difficult/28	16	Poor
Conseco	Very Difficult/28	Graduate School	Poor
PNC Bank	Very Difficult/28	Graduate School	Poor
Forum Credit Union	Very Difficult/28	Graduate School	Poor
Members 1st Credit Union	Very Difficult/27	16	Poor
Marquette Bank	Very Difficult/27	Graduate School	Poor
American Express	Very Difficult/27	Graduate School	Poor
Wachovia	Very Difficult/25	16	Poor
Evergreen National Bank	Very Difficult/25	Graduate School	Very Poor
Honeywell Federal Credit Union	Very Difficult/25	Graduate school	Poor
Zions First National Bank	Very Difficult/25	Graduate School	Poor
Webster Bank	Very Difficult/25	Graduate School	Poor
Countrywide Loans	Very Difficult/24	Graduate School	Poor
Average	**Difficult/34**	**15.6**	**Poor**

How do the Notices compare to state readability requirements?

Many states have readability requirements for insurance policies sold within the state. For example, Arkansas, Indiana, Kentucky and Ohio require a minimum score of 40 on the Flesch Reading Ease. Only 10 of the 60 notices reviewed would have met that requirement. Connecticut and Florida require a minimum of 45 on the Flesch; three of the notices met those state requirements. Maine requires a 50; none of the notices met that requirement.

Why elderly consumers will have a hard time understanding the Notice.

Across all age groups, people 65 and older have the lowest literacy scores, with an average educational attainment between 11th and 12th grade. Seventy year-old bank customers (born in 1931) with an average 11th - 12th grade education completed their education in the late 1940s. The following table shows the education levels of the populace versus individuals age 65 and over.

Educational attainment (1998)	Total Persons	65 and over
Not a high school graduate	17%	33%
High school graduate	34%	35%
Some college (no degree)	17%	13%
Associate degree	8%	4%
Bachelor's degree	16%	9%
Advanced degree	8%	6%

How "Clear and conspicuous" are the privacy notices?

According to the law, these new financial privacy notices are supposed to be written in a "clear and conspicuous" style. This means that the language used should be "reasonably understandable," a term which is not defined. But based on the readability statistics, none of these 60 notices was even close to meeting that criterion. WStyle, which analyzes writing style, classified 10 notices as having a "weak" writing style; 48 have a "poor" writing style, and 2 have a "very poor" writing style.

The GLB regulations offer six strategies for ensuring that the notice is written in a "clear and conspicuous" manner.

1) Presenting information in a clear and concise way. The readability analysis shows that the notices were not written in a clear and concise writing style. Being concise isn't the same as being clear.

Most notices say that "We maintain physical, electronic and procedural safeguards to protect customer information." (12 words) That's concise, but what does it mean?

The longer version (27 words) doesn't help much: "We also take other steps to safeguard customer information by maintaining physical, electronic, and procedural safeguards that comply with federal standards to guard your non-public personal information."

And the really long version (63 words) only confuses things more: "As further described below, we maintain administrative, technical and physical safeguards designed to (1) insure the security and confidentiality of customer records and information, (2) protect against anticipated threats or hazards to the security or integrity of such information and records, and (3) protect against unauthorized access to or use of such records or information which could result in substantial harm or inconvenience to our customers."

2) Using short explanatory sentences or bullet lists. Although all of the notices used bullet lists to some extent, some of the notices included too many bullet points with too much information. A bullet point doesn't help much if it's followed by two paragraphs of text (150 words). By the time you finish reading the bullet point you've forgotten what the bullet point is supposed to summarize. The 60 notices averaged about 48 sentences per notice: Grammatik software estimated that about 17% of those sentences were "short."

Grammatik 6.0 also measures "Sentence Complexity," based on the number of words and clauses in the notice--with a maximum "very complex" score of 100. The 60 privacy notices averaged 70, with a range of 38 to 92.

3) Using concrete everyday words. One way to measure this is to analyze word "commonness" of the privacy notices. Based on Reader software, a normal score is 1,450: a lower score means that the

notice has many common words, and a higher score means that the notice has many uncommon words. The average score for the 60 notices was 1,993, which means that most notices are full of uncommon words. Nineteen of the notices scored below 1,450; forty-one scored above 1,450 -- with a range from 1,075 to 4,217.

Grammatik 6.0 measures "vocabulary complexity" based on the number of syllables in a document and a comparison to words in a list of unusual or difficult words -- with a maximum "very complex" score of 100. These 60 privacy notices averaged a vocabulary complexity score of 62, with a range of 42 to 75.

4) Using the active voice. WStyle Writing Style Analyzer software recommends that about 60% of sentences should be in the active voice. These notices averaged about 65% in the active voice, with a range of 43% to 83%. For example, a passive voice sentence is: "Every product or service we offer is designed to reflect the ways our customers actually use their accounts." The active voice version is: "We design every product or service to reflect the ways our customers actually use their accounts."

5) Avoiding multiple negatives. Most people have a hard time understanding sentences that have double negatives in them. On the one hand, federal guidelines state one way to make notices reasonably understandable is to avoid multiple negatives. On the other hand, those same guidelines offer a sample clause that will meet the opt-out requirements:

"If you prefer that we not disclose nonpublic personal information about you to nonaffiliated third parties, you may opt out of those disclosures, that is, you may direct us not to make those disclosures (other than disclosures permitted by law.)"

Here are a few other examples:

- "If you choose not to receive such solicitations from unaffiliated third parties, you may instruct Cal Fed not to disclose your non-public personal information (see below)." (California Federal Bank)
- "If you choose not to exercise your opt-out of sharing, no action is required." (Webster Bank)
- "We do not provide nonpublic information about you to any non-Fleet company whose products and services are being marketed unless you authorize us to do so." (Fleet Boston Financial)
- "We have opted out all of our customers from sharing with non-affiliated parties, meaning you do not have to formally notify us not to disclose your nonpublic personal information to non-affiliated parties." (Provident)
- "If you prefer that we not disclose nonpublic personal information about you to nonaffiliated third parties, you may opt out of those disclosures, that is, you may direct us not to make those disclosures (other than disclosures permitted by law.)" (Advanta) This is the approved clause in the federal regulations.

6) Avoiding imprecise explanations that may be interpreted differently.

Some examples of sentences open to interpretation:

Clarity

Number 50 November 2003

Journal of the international movement to simplify legal language

Editor in chief:
Michèle Asprey

Guest editor for this issue:
Professor Peter Butt

In this issue

Compliance vs Communication

Mark Hochhauser

Psychologist; consultant on document readability and writing style

2003 HIPAA privacy notices

In April 2003, patients in the US began receiving Health Insurance Portability and Accountability Act (HIPAA) privacy notices from their doctors, hospitals, clinics, pharmacies, and other "covered entities" that use their personal health information. HIPAA privacy notices were designed to inform patients of their privacy rights regarding their personal health information, and what they could do to limit the "use and disclosure" of that information.

As part of the HIPAA regulatory guidelines (Section 164.52(b)—Content of Notice), privacy notices were to be written in "plain language" (Final Privacy Rule Preamble. II. Section-By-Section Description of Rule Provisions, http://www.hhs.gov/ocr/part2.html).

They are not. The regulations tell writers that "A covered entity can satisfy the plain language requirement if it makes a reasonable effort to: organize materials to serve the needs of the reader; write short sentences in the active voice, using "you" and other pronouns; use common, everyday words in sentences; and divide materials into short sections." (p. 137, Final Privacy Rule Preamble). These modest requirements proved insufficient to get HIPAA writers to use plain language. The requirements were essentially ignored.

As part of my consulting work with the US Department of Health and Human Services, I downloaded and analyzed six privacy notices and 31 online privacy notices (www.privacyrights.org/ar/HIPAA-Readability.htm). I found them to be written at an average 2nd-4th year college-reading levels. Patients will have a very hard time understanding the notices. The typical writing style used too many words per sentence, too many complicated sentences, and too many uncommon words.

While federal guidelines require HIPAA notices to be written in plain language and offer some suggested guidelines about plain-language writing strategies, there are no penalties if organizations do not write their notices in plain language. Also, the regulations did not include any examples of materials actually written in plain language.

In the aftermath of HIPAA, companies are issuing bizarre press releases, touting that they are "HIPAA compliant"—even though their notices are virtually incomprehensible to the average reader. For these companies, being compliant means that they have appropriate measures in place to protect patients' health information, not that they've written plain-language privacy notices. So they are "compliant" and "non-compliant" at the same time.

The legal need to "comply"

An employee of a state agency dealing with HIPAA emailed me: "However, the language required by the law and regulation make it near impossible to comply with regulations and make this a readable document." To that, a colleague in a federal agency dealing with HIPAA replied: "What a cop out"—seeing that argument simply as a rationale for not writing notices in plain-language.

The only language required verbatim in the notices is the all-capitalized header that must accompany all privacy notices:

> THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

"Comply with regulations" is the key phrase. When HIPAA rules first came out, various health associations had law firms write sample notices that the associations made available to their members. From the very beginning, notices were written to comply with federal regulations, not to communicate privacy rights to patients. Many of the notices looked or sounded alike, probably because the health-care organizations simply used (sometimes with only minor changes) the examples that their professional associations had developed.

But this was not the goal of HIPAA regulations. Each health-care organization was supposed to develop its own unique notices. That they did not is testimony to the complexity of HIPAA regulations. For example, they cover 187 single-spaced pages in the Federal Register: Standards for Privacy of Individually Identifiable Health Information; Final Rule (http://www.hhs.gov/ocr/hipaa/privruletxt.txt), and a further168 pages in the Final Privacy Rule Preamble II: Section-by-section description of rule provisions (http://www.hhs.gov/ocr/part2.html). In addition, these 355 pages were only a small part of all HIPAA regulations which were developed in the Clinton Administration and changed by the Bush Administration. Health-care organizations clearly believed that to reduce the likelihood of being non-compliant and getting into trouble with the federal government, the safest thing to do was to use the language of their health-association law firms. If law firms approved the language, then it must be all right, even if it wasn't "plain language."

Lawyers try to protect their clients from legal problems. It's not surprising, then, that the HIPAA notices, which are written with much legal input, tend to reflect legal language rather than patient language. Unfortunately, it may be almost impossible for most HIPAA privacy notice writers to communicate in language that is both legally compliant and understandable to patients. I've had several HIPAA privacy notice writers tell me that "The lawyers made us use this language." So legal input (and legal language) trumps plain language. It is interesting how much influence lawyers have over the content of materials written for consumers. Lawyers seem to be the final judge of what's acceptable or unacceptable, and no other employee in the organization seems to be able to override those judgments.

But this perspective of legal language over plain language is not unique to HIPAA. About two years ago, I also reviewed 61 Gramm-Leach-Bliley financial privacy notices that were supposed to inform consumers of their financial privacy rights. These notices were written at about a 3rd-4th year college reading level. They had too many complicated sentences and too many uncommon words (www.privacyrights.org/ar/GLB-Reading.htm). And so I was not surprised that both HIPAA notices and the financial privacy notices were unreadable, because the same emphasis of compliance over communication was at work in both settings. In fact, I do not believe that federal regulators can pass any law requiring consumer privacy notices to be written in ways that consumers can understand.

Reading vs understanding

In the spring of 2002, a US Food and Drug Administration speaker at a clinical trials conference said that the FDA was requiring clinical-trial consent forms (which may include HIPAA privacy information) to be written at a sixth-grade reading level, but was not able to offer any rationale for that requirement. Let me make some comments on that. First, I doubt that anyone in the federal bureaucracy can write a consent form at a sixth-grade reading level; anyone who recommends that kind of writing should be required to provide an example. Second, on the basis of Rudolf Flesch's Reading Ease Score, a consent form written at a sixth-grade level would have to average about 14 words per sentence and 139 syllables per 100 words. Since consent forms are a combination of both legal and medical jargon, writing to meet that criterion is virtually impossible. While some medical terms can be made simpler, they probably can't be made simple enough to reach a statistical sixth-grade reading level.

Behind such "write to the formula" recommendations is the assumption that if you write at a lower grade level more people will understand. However, this assumption has not been borne out by the research studies.[1-8] These studies assessed the impact of re-writing consent forms, patient education materials and jury instructions from higher grade levels to lower grade levels. The results are mixed. Sometimes comprehension is better, sometimes it isn't. But subjects in many of these studies tended to be college-educated, among whom the impact of plain language might be less evident.

Writing at a sixth-grade level does not mean that materials can be understood by anyone with sixth-grade education—that's a common misconception. It does not take into account changes in psychological development and how thinking skills change from concrete to abstract during adolescence. Not everyone develops into an adult with good abstract thinking skills, so readers at any age may be concrete thinkers who simply will not be able to understand abstract information in HIPAA privacy notices, financial privacy notices, informed-consent forms, patient-rights documents, etc—regardless of the grade level at which they are written. Readability and understanding are not the same.

Less information = more understanding

Readability formulas do not measure information overload. (However, I find the total number of words, sentences, and syllables/word provided by some readability software to be very helpful in estimating the amount of information readers have to process.) With changes in technology since readability formulas were developed, many writers have suggested that our technologically advanced culture can give people more information than their brains can process and understand. Different writers use different terms—"information overload" (Alvin Toffler), "information fatigue syndrome" (David Lewis), "data smog" (David Shenk), "information anxiety" (Richard Wurman). These terms try to capture what happens when readers are confronted with more information than they can easily process.

Informed-consent forms are "cognitively complex." The FDA regulates clinical trials, and requires each consent form to contain eight basic elements of informed consent (purpose, risks, benefits, etc) and six "when appropriate" elements.[9] Add to that five HIPAA elements, and recipients have to read and understand a consent form that includes 13-19 pieces of information (See Table #1 on next page).

Table #1: FDA Required Elements of Informed Consent

Eight basic elements

- A statement that the study involves research, an explanation of the research purposes and expected duration of the subject's participation, a description of procedures to be followed, and identification of experimental procedures.
- A description of any reasonably foreseeable risks or discomforts to the subject.
- A description of any benefits to the subject or to others which may reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained and noting the possibility that the FDA may inspect the records.
- For research involving more than minimal risk, an explanation as to whether any compensation and any medical treatment are available if injury occurs and, if so, what they consist of, or where further information may be obtained.
- An explanation of who to contact for answers to pertinent questions about the research and research subjects' rights, and who to contact in the event of a research-related injury to the subject.
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Six additional elements of informed consent to be used when appropriate:

- A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforseeable.
- Anticipated circumstances under which the investigator may terminate the subject's participation without the subject's consent.
- Any additional costs to the subject that may result from participation in the research.
- The consequences of a subject's decision to withdraw from the research, and procedures for orderly termination of participation by the subject.
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject.
- The approximate number of subjects involved in the study.

HIPAA-related elements of informed consent (still evolving)

- Use and disclosure of personal health information for research.
- Use and disclosure of research information for treatment, payment, and facility administration.
- Access to information relating to your participation in the study.
- Right to decline/withdraw authorization.
- Expiration of authorization

At this point, reading-grade levels are almost irrelevant. Instead of helping people make an informed decision, too much information often leads to increased stress, confusion, impaired judgment, helplessness, and paralysis through analysis.

Informed-consent forms and HIPAA—some suggested improvements

Because medical information about human subjects in clinical trials can be shared with drug companies, federal regulatory agencies, contract research organizations, insurance companies, and the like, clinical trial consent forms will have to include a HIPAA notice as part of the informed consent process. Moreover, because consent forms suffer from the same language problems as HIPAA notices, a summary might help readers understand these incredibly complicated materials.

Table #2 is an example an informed-consent summary that could give prospective subjects an overview of a clinical trial[10]. I have been told by some in the clinical trial industry that it's too simple and doesn't include enough information. My response is that it's supposed to be simple. Would you rather have a subject read the summary or sign the consent form without reading it at all?

Too much information is an especially serious problem for older readers. President Clinton asked medical researchers to include more elderly subjects in clinical trials. But research shows some age-related declines in cognitive skills. These include short-term memory, long-term memory and reasoning—all beginning at about age 60-65. At the very time researchers are trying to recruit older subjects, those potential subjects will be starting to experience cognitive declines that may make it more difficult for them to understand the research-consent process!

And so it is with HIPAA. A large percentage of hospital patients are Medicare patients aged 65 and older. Many will be completely overwhelmed by the cognitive demands of trying to read and understand typical HIPAA privacy notices, especially those printed in tiny type.

Table #2: Informed Consent Summary

Questions	Answers
What's the purpose of this study?	This is an experiment to compare two cancer drugs for your bone cancer.
What's the procedure?	You'll get an experimental drug or standard treatment, blood tests, physical exams for 6 months.
What are the risks of being in this study?	Side effects—fever, weakness, loss of appetite. Your cancer might not get better.
What are the benefits of being in this study?	You probably won't benefit. But your involvement may help others with bone cancer.
Can I choose alternative treatments with existing cancer drugs?	Yes. You can choose standard medical treatment instead.
Is information about me kept confidential?	Yes. Your name will not appear in any publications. We may share information with government agencies.
Who should I contact if I have any questions?	Dr. Smith at 555-123-4567 or Dr. Jones at 555-987-6543 for questions about your rights as a subject.
Is my participation voluntary?	Yes. You may leave the study at any time without losing any benefits.

When HIPAA rules were being developed, an early strategy required patients to sign that they understood their HIPAA privacy rights. By the time the final rules came out, that requirement was changed to having patients sign only that they had been given their HIPAA notice—not that they understood it. Had the "sign here that you understand" requirement been kept, millions of Americans would have signed HIPAA notices that were actually incomprehensible. They had to sign; without that signature they could not be medically treated. But aside from collecting and counting signatures, and concluding that everyone understood their HIPAA rights because they said they did, what's the point of asking people to sign a document they don't understand? That would be compliance without communication.

What rights do patients have if they don't understand those rights?

This conflict of "compliance versus communication" pervades other areas of health care as well. In my home state of Minnesota, HIPAA privacy notices are given to patients along with other written materials (see my HIPAA report at privacyrights.org). For example, clinic and hospital patients receive a 10-page, 4,221 word "Minnesota Patient Bill of Rights" booklet describing patient rights under Minnesota and federal law. The Minnesota rights section is written at about fourth-year college level; the federal rights section is written at graduate-school reading level. However, when combined with HIPAA notices (which are handed out separately, because patients have to sign that they received a HIPAA notice), these three patient-rights documents total about 6,500 words (the equivalent of about 26 double-spaced pages of text)—about 30 minutes of reading time for average readers.

Re-writing such documents in plain language is almost impossible. The Minnesota Association of Patient Representatives tried to have the patient "Bill of Rights" written in plain language. Because it had to be done through the legislative process, they were told that patient representatives could give patients a more understandable document without giving them the original legislative version. But the Association could not get help to rewrite it in a way that would assure accuracy—as determined by the legislature. Even if they could, patients would have to be given both original and revised versions. If both Minnesota and federal laws were rewritten, would patients read all four documents? If HIPAA notices were rewritten, would patients read all six documents? And so in Minnesota, hospitals and clinics comply with state law by giving patients copies of their "Patient Bill of Rights"—even if patients can't understand those rights.

Typing versus document design

Although federal HIPAA regulations required plain language, they also stated: "We do not require particular formatting specifications, such as easy-to-read design features (e.g., lists, tables, graphics, contrasting colors, and white space), type face, and font size" (p 137 of the Final Privacy Rule Preamble). I was not surprised, therefore, to hear that one health-care organization shrank their HIPAA notice down to about 3 pages by simply reducing the font size! Nothing like making readers squint to read about their privacy rights.

Document-design features—such as the amount of white space in margins and between paragraphs, font size, the number of fonts, the use of illustrations, highlighted text or text in boxes, etc—can make a big difference in a document's appeal to the reader. Without any formatting specifications, most HIPAA privacy notices were simply typed, not designed.

The layered design

Federal guidelines suggested a "layered notice," as long as the key elements were included in the HIPAA notice given to patients. In this way, HIPAA requirements could be met by giving patients both a short notice that briefly summarized their rights, and a longer notice that contained all the required elements. Some support for this suggestion came from financial privacy notice research, where consumers said they didn't want to read six single-spaced detailed pages; couldn't the writers give them a shorter summary? But this recommendation was optional, not required, and I have seen only one HIPAA privacy notice (Kodak) using a layered design.

In a layered design, the first layer of the privacy notice would be something like my one-page bullet point example below (Table #3). For readers interested in more details, the next few pages would be the typical HIPAA notice (the 2nd layer). Federal regulations require that the header "THIS NOTICE DESCRIBES..." be in all-capital letters; plain-language guidelines did not apply.

It would be wonderful if HIPAA privacy notice writers could develop a one-page summary of HIPAA. But there's such an emphasis on compliance that many health care organizations simply are afraid that a one-page summary doesn't give enough information, and that they might be sued for being "non-compliant." I've been told that my one-page summary isn't feasible because it doesn't provide enough information! That's why it's a one-page summary, not a six-page single-spaced document. Others have developed one-page privacy notice summaries—they include the Atlanta Law Firm of Hunton and Williams (http://www.hunton.com/news_events/press/HIPAA_template.html) and Eastman Kodak. Has any organization been sued because their information was too easy to understand? In 2001, a federal agency employee told me—in relation to financial privacy notices—"You can't be sued for telling the truth."

The importance of consumer psychology

Is it fair to say that nobody can comply with the notice requirements and still communicate clearly? If so, is it because the ideas are too complex or there are too many pieces of information? The answers to these questions are "yes" and "no."

It's probably impossible to develop a privacy notice that can be understood by 100% of the population. Admitting that, a goal for policy makers and federal regulatory agencies is to consider what percentage of the population they'd like to be able to read and understand a privacy notice—100%? 75%? 50%? 25%? 5%?

Table #3: Summary Notice of HIPAA Privacy Practices

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Summary of your Privacy Rights

We may share your health information to:

- treat you
- get paid
- run the hospital
- tell you about other health benefits & services
- raise funds
- include you in the hospital directory
- tell family and friends about you
- do research

We may use your health information for:

- health and safety reasons
- organ and tissue donation requests
- military purposes
- worker's compensation requests
- lawsuits
- law-enforcement requests
- national-security reasons
- coroner, medical-examiner or funeral-director use

You have the right to:

- get a copy of your medical record
- change your medical record if you think it's wrong
- get a list of whom we share your health information with
- ask us to limit the information we share
- ask for a copy of our privacy notice
- complain in writing to the hospital if you believe your privacy rights have been violated

When I talked with someone at a federal regulatory agency about testing the 2001 financial privacy notices, the response was: "We never thought of that." All the effort went into developing the notices, and none into measuring the their outcome.

Policy makers are thinkers and writers, not researchers and evaluators. From a political standpoint, decisions are often made for reasons that have nothing to do with measures of success or failure.

But if you're an evaluator, an evaluation strategy is a key part of project development and implementation from the very beginning. If you're not an evaluator, you may try to figure out how well a program works after it's been in place for a while. Many times that just can't be done. I've worked with too many clients who bring me in at the end of a project and want me to help them figure out if it worked or not; usually there's no way to answer that question adequately, because the program wasn't developed with evaluation in mind.

Privacy concepts are complicated with many pieces of information. But research would show how much privacy information people actually understood. I'm not aware of any research on that topic. The federal agencies seem naively to assume that if it's written in plain language, everyone will understand it. That's nonsense. You can't write anything that everyone will understand. Intuitively, you'd think that plain language would make it more understandable; but you need evidence to support that belief. The federal agencies appear unaware of the potential problem of information-overload in privacy notices, and how the amount of information may be more important than the (plain) language in which those notices are written.

In short, federal agencies are recommending only one strategy, with no specific evidence to support it. But is plain language enough? What about document design issues? What do consumers want? No one has asked the public what kind of privacy notices they'd prefer to read, or done studies on the kind of privacy notices they really do read. Without consumer testing, plain language recommendations will not prove very effective.

Privacy-notice writers should be working with marketing experts in their organization, to conduct research into privacy notices the way they conduct market research on other corporate products and services. For example, consumer-testing could evaluate several different privacy notice formats. What do consumers understand? What don't they understand? Is there a "best" format that all financial and health-care institutions could use as a template? Without any evidence-based standard, how can companies develop privacy notices that consumers can read and understand? The only way to do that is to involve consumers as a key part of the privacy notice design and writing process.

Is it ethical to give people information they can't understand?

There are ethical implications in giving people information they cannot understand and act on, particularly when the presumed goal of that information is to enable people to make informed choices based on what they believe is best for them. On the one hand, policy makers and regulators argue that patients need more and more information so they can make better decisions. On the other hand, if information = empowerment, what are the ethical consequences of giving people incomprehensible information and then expecting them somehow to make better choices based on information they can't understand?

Unreadable information is unethical because it takes away the ability of patients to make a truly "informed" choice. At best, patients make choices that are uninformed or misinformed—not informed. How can they make informed decisions if they can't understand the information upon which those decisions are supposed to be based? Patients can't be expected to make good decisions based on bad information.

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Further Reading

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