

Making leaflets clearer for patients

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Abstract

This article examines the clarity of several health information leaflets issued to the public in Europe. It finds that some of the language is quirky, ambiguous, and confusing. In one leaflet, the size of type is too small for easy reading, even by people with good eyesight. The article briefly discusses euphemism in health information. It also offers some principles for plain-language writing and sources of further guidance.

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According to the Old Testament, God smote the Philistines of Ashdod – who had made the serious tactical error of stealing his Ark – with ‘emerods in their secret parts’. The Good Book is silent, though, about what ointment the victims applied to their bleeding behinds, or whether it came with the kind of leaflet that (in the 1980s) accompanied tubes of Nupercaine and described that popular emerod/haemorrhoid treatment like this:

*A non-greasy, water-miscible cream with a marked anti-pruritic and analgesic action. The special base achieves intimate contact with moist surfaces, has a drying effect on exudative skin conditions and is particularly suitable for application to exposed surfaces.*¹

For me, this is pitched at too high a level for a mass audience. As a rough and unscientific guide, the website Readability-Score.com gives it a required UK reading age of about 19 years. The (UK) National Literacy Trust’s website implies that the average adult has a reading age of about 13 years (I simplify a little).² So there is a wide gap here, with words like *miscible*, *pruritic*, *analgesic*, and *exudative* being unknown to most. This evidences the difficulty familiar to authors trying to communicate technical matters to a lay audience – how do they

write clear, interesting, defensible, concise, and accurate material without losing vital details or writing in a nursery-book tone?

Some leaflets assessed

Regulatory pressure and calls for plain language have led many companies to clarify their patient information in the years since the Nupercaine leaflet came out. Having not seen a really bad example for some time, I did a little digging among packets of pills and potions lurking in my relatives’ bathroom cabinets. After all, what else are family visits for?

Any optimism I may have felt about the plain-language movement’s success was lessened by a 2013 leaflet from Mölnlycke Health Care AB of Sweden for Mepilex Lite, an absorbent silicone dressing. The leaflet uses many unusual terms such as *minimizing maceration*, *peel forces*, *moist wound environment*, *compromised skin*, *exudate*, *skin stripping*, *adherent side*, *excoriation*, *fixate Mepilex with a bandage or other fixation*, and *dressing regimen*. ‘Peel forces’ is an interesting example of compression as it means, I guess, the forces applied when the dressing is peeled off.

A devil’s advocate may plead that context often helps explain unusual vocabulary for proficient readers. Which may be true, but weaker readers tend to have poor guessing skills. How much would the context for two of the most difficult words, italicised here, help?:

- ‘Mepilex Lite is thin and highly *conformable*, making it easy to keep the dressing in contact with the wound surface...’.
- ‘As Mepilex Lite maintains a moist wound environment, supporting *debridement*, there might be an initial increase in the wound size’.

Too little, I fear. Readers may consult a dictionary, but I think they’re more likely to skip what they don’t understand or just cast the leaflet aside. ‘The

Living Word Vocabulary’,³ which lists what words will be understood by people with particular US-grade-level attainment, includes neither word, so they are probably rarities. Among readers without a medical background, perhaps only one reader in 500 will understand them. *The New Oxford Dictionary of English*⁴ says conformable means similar in form or nature; and debridement does not mean, as you may think, the ejection of a bride from her wedding ceremony, but the removal of damaged tissue or foreign objects from a wound.

Manufacturers must provide the information needed to use dressings and other devices safely and properly, taking into account the knowledge of potential users, according to Medical Devices Directive 93/42/EC⁵ issued by the European Commission (EC). The UK Medicines and Healthcare Products Regulatory Agency (MHRA) told me: ‘[...] where the device is intended for a professional user it would be acceptable to use technical terms and where it is used by patients themselves we would expect the language to be simpler for general understanding’.⁶

So if the wording is unclear for its main audience, how legible is it? The text type is tiny, about 5.5 pt – only just big enough for people with good eyesight to read. It’s well below the size stated in EC guidance on the legibility of patient information leaflets (also known as patient package inserts or PPIs), which says: ‘[...] a type size of 8 points, as measured in font ‘Times New Roman’, not narrowed [...] should be acceptable as absolute minimum’.⁷ This leaflet is not a PPI, because Mepilex Lite is classed as a device not a medicine, but why does the type have to be so small? After all, the 64-page multilingual booklet has 24 blank pages, so space is available. The MHRA said: ‘The size the information is presented in is not specified in the Directive but is nonetheless relevant in that it cannot be said to enable the device to be used safely if it is too small to be read and understood’.⁶ Mölnlycke did not respond to my requests for a comment.

PPIs to be issued to European users of medicines must pass a face-to-face clarity test with real people. This is more rigorous than a mere desk-based check using readability formulas of the kind shown at Readability-Score.com, useful though these can sometimes be as a rough yardstick.² Official guidance on the EC test says: ‘A satisfactory test outcome [...] is when the information requested within the package leaflet can be found by 90% of test participants, of whom 90% can show they understand it. That means to have 16 out of 20 participants able to find the information and answer

each question correctly and act appropriately’.⁷ It goes on: ‘In approving package leaflets the competent authorities will look for evidence that people who are likely to rely on the package leaflet can understand it and act appropriately’.

The PPI for Bendroflumethiazide from Bristol Laboratories Ltd, a UK company, is full of technical terms but these are generally well explained, e.g. ‘dispyramide (used to control an irregular heart-beat)’ and ‘gout (high levels of uric acid in the blood), causing crystals to deposit in [the] joints of hands or feet causing pain (hyperuricaemia)’. The leaflet helpfully uses bold type to emphasise important points. There are some oddities, though. Symptoms of an overdose are said to include ‘decreased volume within blood vessels’ (how would a lay person know?), while you are supposed to tell your doctor if you notice you have ‘low blood magnesium and sodium levels’ (again, how would you know?). Better is the fact that the leaflet is willing to equip highly literate people with unusual terms they may wish to know, e.g. ‘dizziness on standing due to low blood pressure (postural hypotension)’ and ‘skin that is red, flaky and peeling (exfoliative dermatitis)’. Writing extra-clearly for people who can’t read very well need not mean disadvantaging those who can.

There are several verbose and clunky sentences. For example, concerning a visit to the doctor, the leaflet says, ‘Take your medicine in its original packaging with you in order to enable the doctor to identify your medication easily’. This could be more crisply put as ‘Carry your medicine with you in its original packaging so the doctor knows exactly what it is’.

The explanations sometimes seem vague, for example, ‘It is recommended not to take alcohol with Bendroflumethiazide tablets as it may aggravate dizziness on standing due to low blood pressure’. This seems a strange word order and is unclear, having at least three possible meanings:

1. I will always get dizzy on standing if I have low blood pressure, and if I take the tablets and alcohol at or near the same time this may make the dizziness worse.
2. My blood pressure will be lower because I am on these tablets. This may make me feel a bit dizzy when I stand up. So I should not drink any alcohol within X hours of taking the tablets.
3. I should not drink any alcohol during the whole time I am on these tablets because it could worsen any dizziness I feel when I stand up.

Similarly, I am puzzled by: ‘Bendroflumethiazide tablets can cause dizziness, make sure you are not affected before driving or operating machinery’. Even ignoring the horrible comma (should be a stop), is this the best expression? Perhaps it could say: ‘Bendroflumethiazide can cause dizziness. If you feel dizzy, do not drive or operate machinery’.

The leaflet for Betahistine dihydrochloride from Accord Healthcare Ltd (UK) seems generally clear, with a decent layout and a heading system that follows the standard (and good) pattern, namely: What the medicine is and what it is used for; What you need to know before you take it; How to take it; Possible side-effects; How to store it; and Contents of the pack. Regrettably there is a proof-reading howler early in the text: ‘If any of the side-effects, talk to your doctor’. The word ‘efficacy’, which in a long and varied reading life from Thomas the Tank Engine to Turgenev I have never before encountered, is not explained. And ‘exacerbated’ is unusual, too. The ‘Living Word Vocabulary’³ rates it as a US grade 13 word (British reading age 18 years). Perhaps we could use ‘worsened’ or ‘made worse’. A handy source on how to decide which words are easy to understand, based on the ‘Living Word Vocabulary’, is the ‘Plain English Lexicon’.⁸

The leaflet about paracetamol from Bristol Laboratories Ltd has many good explanations, e.g. ‘Paracetamol is an analgesic and an antipyretic which means it relieves pain and reduce[s] high temperature and fever’. But it tells readers to inform their doctor if they notice ‘a severe reduction in the number of white blood cells’. Time to get out the home testing kit again! One of the most important sentences is, oddly, written in the impersonal passive: ‘Immediate medical advice should be sought in the event of an overdose’. (Prefer: ‘Get immediate medical advice if...’.) And it ends by dropping a dreadful (but thankfully non-clinical) clanger when it says: ‘Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These medicines will help to protect the environment’. (For ‘These medicines’, read ‘This’).

Occasionally, the PPIs I examined lapsed into a mixture of business and marketing speak, like the first few sentences of the leaflet for Gengigel HMW Hyaluranon, a gel for treating gingivitis (Ricerfarma SRL, Italy):

What is Hyaluranon? Gengigel products contain naturally-derived high quality, high molecular weight (HMW) Hyaluranon, a substance found

naturally in your soft tissues but in especially high concentrations in your gums (gingivae). It is an important component having both a structural and regulatory role.

Users may wonder what ‘naturally-derived’ and ‘high molecular weight’ mean and why these terms might be relevant to them – the all-important ‘So what?’ question. Some will not understand ‘high concentrations’ or, indeed, ‘soft tissues’ outside the box-of-Kleenex context – an explanation of ‘soft tissues’ arrives about 90 words later. The final sentence above, about Hyaluranon’s ‘structural and regulatory role’, requires high-level literacy and abstract-thinking skills because even if readers know the words ‘structural’ and ‘regulatory’, they may find them hard to relate to their gums.

This brief snapshot of patient information leaflets suggests that there is a long way to go before they satisfy the description of ‘plain language’ due to be adopted by the Plain Language Association InterNational: ‘A communication is in plain language if its wording, structure, and design are so clear that the intended readers can easily find what they need, understand what they find, and use that information’.⁹

Avoiding the dirty habit of euphemism

On a hospital ward I once heard a nurse asking a newly admitted young woman, ‘Have you opened your bowels today, dear?’, to which she replied apologetically, ‘I’m sorry, nurse, I haven’t brought them with me’.

I’ve never understood why some medics talk to patients about ‘stools’ and ‘back passages’, as if they are in a hardware store. To avoid the confusion that can arise from both taboo and high-register language, I’ve occasionally persuaded health trusts to use words like ‘poo’ and ‘pee’ in their leaflets, and these are becoming more widespread. Of course, there’s a difficult line to tread between being clear and causing offence, but I feel it’s better to err on the side of clarity. These days, ‘What colour is your poo?’ is likely to be well understood by most people without any embarrassment. Few people understand ‘faeces’, and even fewer can pronounce it.

Ridicule was heaped on National Health Service (NHS) Tayside physiotherapists in 2006 for their leaflet ‘Good Defaecation Dynamics’. Yet, for them to explain better bowel habits was both brave and worthwhile – it was just their title that was fabulously absurd. Had they ditched the jargon and

called it ‘How to crap well’, they would doubtless have offended a few precious souls but struck a blow for clear, basic English.

When the Canadian blogger Mark Rabnett had to provide a poo sample, he was nonplussed by the apparently Dracula-themed title of the kit that arrived from Helena Laboratories, Beaumont, Texas, namely ‘ColoScreen: a test for fecal occult blood’. The weird and medicalised 600-word instructions – which included ‘Do not ingest high doses of aspirin’ and ‘Specimen Handling: It is very important that the stool specimen be applied as a very thin smear to the Occult Blood Slides’ – culminated in the instruction ‘Flush tissue with stool’. This remarkable phrase actually meant ‘Flush the used tissue and the rest of your poo down the toilet’.

Rabnett wryly remarks: ‘[This episode] has convinced me that the literate need to learn how to write as badly as the illiterate need to learn how to read’.¹⁰ The UK’s NHS now sends everyone who reaches the age of 60 a birthday present, namely a poo-sample collection kit to test for bowel cancer. My pleasure in the clarity of the instructions – they really were pretty good – greatly exalted this dismal task.

Some principles on writing plain language for a mass audience

The usual advice on writing clearly for a mass audience will, I’m sure, be familiar to journal readers: keep sentences to 15–20 words on average; use words your parents/grandparents are likely to understand; favour the active voice unless the doer is unknown or obvious or you want to focus on the person or thing being acted upon; personalise your writing with ‘you’ and ‘we’ when that’s suitable; eschew footnotes and acronyms whenever possible; use well-labelled pictures and diagrams; organise the material in a reader-centred and easy-to-use way (what will most people want to know first, second, and third?); and involve typical readers as much as possible in the writing and testing process.² It helps a lot if authors use ‘The dog ate the biscuit’ word order and prefer concrete to abstract language. And it does no harm to politely challenge the producers of over-complex writing, whoever they may be. I’m helping someone make a personal injury claim against an optometrist, and the opposing insurer has just hit me with this 75-word sentence:

We would also mention that cataract surgery is undertaken with local anaesthetic in the vast majority of cases and the very remote possibility

that another medical condition would arise, which would be a contra-indication to this and require an operation under general anaesthetic, which in turn would be contra-indicated due to further medical complications, would not have been in contemplation when considering whether or not a cataract operation would have been appropriate six years ago.

Suspecting an ulterior motive when intelligent people do not explain themselves clearly, I have asked for a restatement in plain English.

Verby not nouny writing is good, too. Consider this example from a UK Department of Health report¹¹, which I first saw reproduced verbatim in a health authority’s leaflet for parents – not its original purpose, of course – as if it were the last word on how to feed their under-fives:

The provision of adequate dietary energy to ensure normal growth and development should be a principal determinant of the diets of children under five years of age.

This is nouny in a way that only academic style can be, the main nouns being *provision, energy, growth, development, determinant, and diets*. What if we want to get the same ideas across to a mass audience? Terms like ‘principal determinant’ and ‘dietary energy’ will be puzzling. According to the Department of Health, the latter just means ‘calories’, a technical term whose ubiquity will probably make it well understood. The sentence holds an important message for parents of under-fives, namely, ‘Give your children plenty of calories, otherwise they could die of malnutrition’ – which has happened occasionally. A sprinkling of verbs will make it more concrete. For example, we could say:

To ensure that children under five grow and develop normally, one of the main things they need is calorie-rich food.

We could then say what else they need, as if we are speaking to a parent face to face:

While Helen is under five, she needs food that has plenty of calories. This means things like a, b, and c. These foods will help her to grow and develop normally. She also needs some x, y, and z for taste and variety.

So while the original is good English, it needs rewriting if its purpose and audience change. This

is not dumbing down – a criticism often levelled at those who advocate plain language – but clearing up.

What are regarded as common words may sometimes be misunderstood. A study on the meaning of ‘unconscious’ among 700 people visiting an accident and emergency department with a head injury¹² found that 16% thought they could still talk when unconscious, 16% said they could stand up, and 41% believed their eyes could not remain open after losing consciousness. The study has implications for the design of public health information, including the scripts that emergency services use when responding to phone calls. In a leaflet, the signs of unconsciousness would have to be stated; in a call script, questions designed to test for unconsciousness would have to be included.

At Liverpool’s Alder Hey Children’s Hospital during the 1980s and 1990s, parents signed consent forms saying, ‘I hereby consent to a post mortem examination and to the removal of tissue (other than for the purpose of transplantation) at the time of this examination [...]’. They were unaware that this allowed doctors to harvest and store body parts and whole organ systems. Using similar consents, various hospitals are thought to have stored 150 000 organs. The word ‘tissue’, taken direct from the Human Tissue Act, wasn’t apparently difficult. But its legal meaning differed from its everyday meaning and should have been explained. The grief of those parents whose children’s organs had been stored without their knowledge led to a government inquiry and fierce legal disputes.²

We can also break up complex information into lists. A piece of text about antiretroviral therapy explains why osteonecrosis (death of bone tissue) might occur. It uses a complicated sentence where the main verb is long delayed:

The length of combination antiretroviral therapy, corticosteroid use, alcohol consumption, severe immunosuppression, higher body mass index, among others, may be some of the risk factors for developing this disease.

As an exercise, researchers rewrote this in a list as:

‘People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight’.

In a small-scale test, most of the 10 respondents had some difficulty in clearly identifying the risk factors for the condition when using the original version. None had any difficulty in using the rewrite and all preferred it.¹³ The European Medicines Agency accepted the revised text.

Some sources of guidance

For guidance on plain language generally, *the Oxford Guide to Plain English*² (reviewed on page 36 in this issue of the journal) is a good source – and if it isn’t, I am wholly to blame. You can also subscribe to Plain Language Commission’s free newsletter, Pikestaff, through <http://www.clearest.co.uk>. Sarah Carr, a former NHS manager, has written an excellent book called, self-explanatorily, *Tackling NHS Jargon*.¹⁴ The best source of information on melding the disciplines of writing, design, and testing in things like medical labelling and patient leaflets seems to be the website of the Communications Research Institute of Australia, communication.org.au/. The NHS England website gives details of its certification programme for health and social care organisations, the Information Standard, at <http://www.england.nhs.uk/tis>. As a commercial service, Plain Language Commission gives editorial advice and accreditation of individual documents and websites under the Clear English Standard scheme (<http://www.clear-est.co.uk>).

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From the land of mixed metaphors

Sometimes you wonder what people are thinking. While researching the epidemiology of dengue virus, a colleague came across this amusing title:

*Lessons raised by the major 2010 dengue epidemics in the French West Indies*¹

This had us wondering what questions were learned...

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