Information for patients: should we reconsider our assumptions?

Informação para pacientes: devemos reconsiderar nossos pressupostos?

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visual design, information about medicines, evidence, performance

In order to take medicines correctly, it is essential that people receive suitable information. Without information it is difficult to consider, take, store, and discard medicines. At the moment, many people have difficulties to find, read, understand, and apply information about medicines. In the European Union, most information about medicines is presented in a text format. Very few visuals are used. Furthermore, information about medicines does not make much use of the digital opportunities. The logical next steps are to improve the design of visual information about medicines, and to embrace digital opportunities. However, the regulatory frameworks that govern information about medicines need to be modified. The regulations need to focus on usability, understanding, findability, and relevance. Experiments and prototypes are essential to find out what kinds of information and formats are effective. This requires a shift towards a 'digital design strategy based on healthcare outcomes.'

design visual, informação sobre medicamentos, evidência, desempenho

Para usar medicamentos corretamente, é fundamental que as pessoas recebam informações adequadas. Sem informação, é difícil considerar, usar, armazenar e descartar medicamentos. No momento, muitas pessoas têm dificuldades em encontrar, ler, compreender e aplicar informações sobre medicamentos. Na União Europeia, a maior parte da informação sobre medicamentos é apresentada em formato de texto. Muito poucos recursos visuais são usados. Além disso, a informação sobre medicamentos não aproveita muito as oportunidades digitais. Os próximos passos lógicos são melhorar o design da informação visual sobre medicamentos e aproveitar as oportunidades digitais. Contudo, as regulamentações que regem a informação sobre medicamentos precisam ser modificadas. Os regulamentos precisam se concentrar na usabilidade, compreensão, localização e relevância. Experimentos e protótipos são essenciais para descobrir que tipos de informação e formatos são eficazes. Isso requer uma mudança em direção a uma 'estratégia de design digital baseada em resultados de saúde.'

1 Situation: Why should we provide information about medicines for patients?

1.1 Why do patients need information about medicines?

The literature mentions the following reasons to provide information about medicines:

- to help people to make their own decisions;
- to motivate people to actively participate in their treatment;
- for correct use (correct time, correct amount, correct way, effective, safe);
- to know what to do when unwanted effects occur (side effects, allergies, overdose, underdose);
- to know what a medicine is for, and what the benefits and risks are of both 'taking' and 'not taking';
- it's a human right to know what you put into your body.

These six reasons show that information about medicines is essential.

1.2 Medicine use will increase

It is likely that the use of medicines will keep increasing over the next decades. The global and national figures for medicine use are vast. Both the actual numbers as well as the financial figures are staggering in every country. And this is partly caused by the assumption that all ailments can be treated with a medicine. Many consultations between a prescribing doctor and a patient result in the prescription of medicines. Furthermore, patients expect that medicines are always effective in all contexts and situations. These assumptions are questioned at the moment. However, it is unlikely that the balance between 'this medicine is essential' and 'this ailment can be resolved in other ways' will change. The consequence is that medicine use will continue to surge.

1.3 Package leaflets

Most of the visual information about medicines is provided in a 'package leaflet'. This type of document has many different names, but it basically is a printed sheet of paper that tells people what the medicine is for, it gives warnings and instructions, it lists possible side effects, and provides storage instructions.

Walter Modell wrote in 1967, when he was the editor of *Clinical Pharmacology and Therapeutics*: *'The stuffers are generally printed in Lilliputian type on Bible paper, and are hard to handle and very difficult to read'*. He concluded that good stuffers were sorely needed (Modell, 1967). The independent *Dutch Medicine Bulletin* concluded in a detailed review

fifty years later that: *'Progress in readability and comprehensibility is hampered because the guidelines and templates of the registration authorities are still far from sufficient and stand in the way of an understandable package leaflet'* (Geneesmiddelenbulletin, 2017).

A systematic review of publications about the European package leaflet (van der Waarde, in progress) shows that very few of the approximately 400 studies mention any positive effects of these package leaflets in Europe.

Until now, information about medicines in Europe has been poor. A combination of legal requirements, commercial interests, legal protection, and rigorous medical accuracy has led to texts on paper that are largely irrelevant, long, hard to scan and search, difficult to understand, and hard to use. It seems that little progress has been made in the last thirty years since the introduction of these package leaflets in Europe in 1992. Digital information about medicines is still in its infancy and discussions how to start providing people with screen-based information about medicines are ongoing.

1.4 Artificial Intelligence-software?

If we look a few years ahead, it is likely that an Artificial Intelligence system might provide information about medicines to patients. It is possible because a lot of information about medicines follows standards. AI generated information is likely to be 'easier to find' and 'easier to understand', especially because it is possible to ask questions like 'tell it to me in simpler words' or 'can you illustrate this?'.

However, artificial intelligence software could not provide us with relevant, and usable instructions for four reasons. In the first place is artificial intelligence information based on existing information, and that information is not very good. The second reason is that information needs to relate to an individual patient, task, and context. Without personalised details, it is likely that information is partly inappropriate. The third reason is that AI could not tell us yet 'who is excluded' by providing information. There will always be groups of patients that expect and need alternative information. And the fourth reason is that the difference between 'information that is approved by the regulatory authorities' and 'other information' will blur. Until these four issues are dealt with, it is essential to provide patients with information that has been approved and checked by humans to make sure it is relevant, reliable, and usable.

1.5 Concluding part 1

The current situation is awkward. Patient must receive reliable and understandable information and the information that is supplied in 2023 does not achieve this. For the foreseeable future, it is necessary to provide visual information on both paper and in digital formats. The writing and

designing will be aided by artificial intelligence software, but it (still) needs to be validated by humans.

This article looks at the relations between people (categorising characteristics?), the visual presentation of information about medicines (a visual design strategy?), and design processes (evidence?). It aims to figure out what the role of visual design in the provision of information about medicines could be.

2 Patients are people

2.1 Profiling patients?

It is common to describe people who take medicines as 'patients'. This is correct for a large number of medicines, but it does not encompass everyone. Medicines are also used to prevent illness or pregnancy, and medicines are used to detect ailments. These are given to 'healthy people'. And some medicines for minor inconveniences can be bought without a prescription by 'consumers'. Furthermore, professional healthcare providers need information about medicines, and so do family and informal carers. The word 'patient' therefore only covers a segment of the readers of information about medicines.

2.2 Different groups?

There is a tendency to characterise people who have difficulties reading information about medicines into a sub-category. These groups are tagged as 'those with low health literacy', or 'vulnerable people'. Literacy seems to be an umbrella-concept which is related to 'health literacy, visual literacy, nutrition literacy, digital literacy, media literacy, and technology literacy, to name but a few. Vulnerable is often related to the frail and elderly, but high-risk athletes and professionals executing dangerous tasks are just as vulnerable if accidents occur.

Three assumptions wrong about these denominations of vulnerable and low literacy seem to be wrong. In the first place do these tags distinguish between a 'a group who knows', and a 'group who does not know'. This division makes the start of a possible dialogue about treatments and medicines more difficult. It also suggests that the group who does not know needs to inform themselves first before a fruitful dialogue can start. The knowledge and experience of this group – which is a fundamental part of the conversation – is seen as less important.

The second assumption is that these descriptions refer to groups that are characterised by a single shared attribute, namely 'having difficulties reading' or 'vulnerability'. The variety within these groups is likely to be substantial. A young, highly educated, and well earning professional is likely to have a very low literacy level in an unfamiliar language.

The third assumption is that it is somehow possible to 'establish' or 'measure' the 'literacy level' or 'vulnerability' of a person. These indicators are simply irrelevant when a healthcare provider and a person need to have a conversation about treatments and medicines. Delaying a conversation by asking to fill in a form first seems counterproductive. It blames one party for not understanding information even before the conversation has started?

Although it is convenient to group people as a single category 'patients', and to subdivide this category further according to literacy and vulnerability levels, this approach is unhelpful.

2.3 Communication requires co-operation

These assumptions about conversations with people about medicines are directly applicable to visual information.

Visual information needs to start from the needs and expectations of several different groups of people who require information about medicines. It's not about everything that could be told about a medicine, but it's about what people want and need to know.

Information about medicines needs to take into account that people often have difficulties understanding and using this information. This applies to everyone, because reading is affected by the reader, the context, and the reading materials. People who must read information about medicines are often ill, might have a migraine or suffer from sleep deprivation, could be in stressful environments, and might have individual characteristics that make reading more difficult. Expecting that everyone would be able to read everything is incorrect.

And lastly, it is a fallacy that it is possible or useful to establish a level of literacy or vulnerability before information is read. It is degrading for people to be classified according to a fairly arbitrary scale. Instead, information needs to be designed to be suitable for the largest segments. Alternatives must be provided for people who require different formats. And it might need to be recognised that it is not possible to reach everyone with visual materials. For these smallest groups, individual approaches to inform might be required.

2.4 Concluding part 2

In order to communicate with people about medicines, it is important to stop blaming people for their characteristics or their situation. Developing and providing information about medicines is part of a two-way communication process. It must be based on 'people' who 'need to do things' in 'specific contexts'.

3 Text only, using pictograms, or something else?

At the moment, nearly all information about medicines in Europe is provided in a text-only format. Visuals are rarely used. It is likely that this is a consequence of the legal framework. The European legislation only mentions 'pictograms and symbols' and does not mention any other type of visual (European Commission, 2023, article 73). It is unclear why the legislation expresses such a restricted view of the design of visual information.

3.1 Assumptions about pictograms

In both Europe and the USA, the regulations about information about medicines are being reconsidered in 2023 (European Commission, 2023; U.S. Food and Drug Administration [FDA], 2023). Both mention 'pictograms, symbols, and icons', but both show very different perspectives.

On the one hand, there is a severe doubt that pictograms are beneficial. The FDA proposal states: '*We are proposing that pictograms and icons not be used in Patient Medication Information (PMI) for several reasons. For example, research indicates that different cultures may have different interpretation of pictograms and icons.*' (FDA, 2023). And a European guideline states: '*If there is any doubt about the meaning of a particular pictogram it will be considered inappropriate.*' (Readability Guideline, 2009, p. 10). These are clear indications that there are issues with the interpretation of pictograms.

On the other hand, pictograms are believed to be effective. The European regulations state that information '*may include symbols or pictograms designed to clarify certain information ... that is useful for the patient*' (Directive 2001/83/EC, article 62). This phrase would not have been included if it was clear that pictograms are ineffective. Another example of this belief is provided by the Dutch Authorities. The Dutch Medicines Evaluation Board recently approved a set of eight newly designed pictograms to be used in information about medicines, but only when they are accompanied by standardised texts (CBG, 2021). They state '*With a pictogram, a message can be conveyed in a compact way, which is easy to recognize and also accessible to everyone. A pictogram helps people to better understand instructions and in many cases also makes people more accepting of instructions. Finally, a pictogram can help to follow these instructions.*'[1] (CBG, 2021).

In other words, the legislation in Europe and the USA are at least inconsistent in their views on the use and effects of pictograms for information about medicines.

3.2 Two practical examples

The consequence of this inconsequent status for the use of pictograms can be seen in practice. Two examples might make clear that 'pictograms'

1 Original Dutch text: "Met een pictogram kan een boodschap worden overgebracht op een compacte manier, die gemakkelijk te herkennen is en die ook toegankelijk is voor iedereen. Een pictogram helpt mensen om instructies beter te begrijpen en zorgt er in veel gevallen ook voor dat mensen instructies meer accepteren. Tenslotte kan een pictogram bijdragen aan het opvolgen van deze instructies."

are not an effective solution to provide people with information about medicines.

Figure 1 shows the outer packaging of a COVID-19 Antigen Detection kit. It includes nine pictograms on its front. It is likely that this kit is used at home to check if a person carries the COVID-virus. The kit will be used before meeting other people or before a journey.

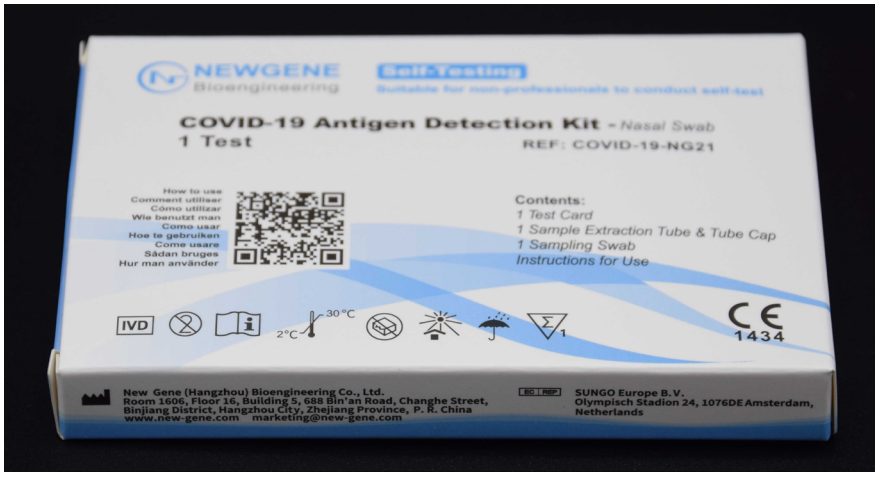

Figure 1 A box for a Covid-19 antigen-test. It shows nine pictograms on the front without accompanying text. These standardised symbols are supposed to be 'clearly comprehensible'.

The CE-mark with number 1434 in the right bottom corner indicates that a Polish certification organisation has checked that this kit, its packaging, and its instructions conform to European legislation. The nine pictograms are therefore deemed to be 'easily legible and clearly comprehensible' (Regulation (EU) 2017/745, article 10).

One of the pictograms is a circle, with a slash through a 2. This is an official ISO symbol (ISO 7000: 1051) and means 'Do not re-use', or 'only use once'. Placing this symbol on the outside of the box indicates that the manufacturer of this COVID-19 test fears that people would use this test more than once. The symbol is added, instead of designing the test in such a way that re-use is impossible. This approach shifts the responsibility of 'do not re-use this test' to the consumer.

Figure 2 The international symbol for 'do not re-use'. (ISO 7000: 1051).

A second example shows an obligatory warning on the outside of a medicine package for sodium valproate tablets (Figure 3). Sodium valproate is an effective anti-seizure medicine in the treatment of epilepsy,

bipolar disorder, and migraine. If it is taken during pregnancy, there is a severe risk of malformation and developmental disorder of the unborn child. In practice, it is difficult to balance 'seizure-control' and 'risks to the unborn child'. This decision should be made in a dialogue between a female and a prescribing doctor, and it should be based on the goals of a patient. However, the text and pictogram suggest that all women who take valproate against seizures might consider to become pregnant, and all need to consult a doctor before making this decision (Arkell, 2023). In reality, it is likely that most female patients will be able to make well considered and balanced decisions about the risks of seizures and a possible pregnancy. The pictogram over-emphasizes the risk without showing the benefits and belittles the personal considerations and knowledge of people who must take sodium valproate.

Figure 3 The 'pregnancy pictogram' was made obligatory for sodium valproate packaging in 2017.

3.3 Are pictograms effective?

Both situations are very different. One is a home-test for COVID-19, the other a medicine against seizures. What they share is a belief that pictograms are effective in informing and warning people about substantial risks.

It's clear that patients need to be informed about their treatments, their medicines, and their medical devices. It is also very clear that 'just adding a pictogram' is unlikely to lead to a positive outcome. The ISO-pictogram in Figure 2 does not prevent consumers to use a COVID test more than once. The pregnancy pictogram in Figure 3 does not help female patients who suffer from seizures to make balanced decisions.

However, adding a pictogram moves the responsibility for decisions to the user of the product. Both pictograms are now mainly risk-avoidance measures to reduce liability by showing 'We've warned you, so it's your decision if you get into trouble.'

In both examples, the reality of using these products is more complex, and requires a balanced examination of the situation. What people

really need is support to take decisions. And that requires very different approaches in both situations.

3.4 The need for a visual strategy: a structured argument to enable people

In both situations, pictograms on their own do do not provide enough information to make balanced decisions. A pictogram, or a visual explanation in combination with text, needs to be part of a considered visual information strategy.

For the covid-19 test kit, this strategy should prevent people from using the test more than once. For example, by designing the test in such a way that it is impossible to re-use it. The risks of sodium valproate should be made clear from the moment it is prescribed for the first time, and continuously be restated during the treatment. However, most people who suffer from seizures cannot or do not consider to get pregnant. A visual information strategy would only focus on those people that might be affected, and the strategy must be based on their personal considerations and knowledge.

It is very likely that a combination of analogue and digital information is the most effective way of informing people about their medicines and treatments. A visual information strategy will combine the benefits of both.

3.5 Concluding part 3

A focus on text, with a minimal use of pictograms has proven to be an ineffective approach to enable people to use medicines. The idea that all pictograms are really effective in all circumstances and for all actions is incorrect. The visual approach needs to be broader. Visual information needs to part of a complete visual information strategy that includes both paper-based as well as screen-based information.

4 Evidence based design?

The first part of this article showed that visual information about medicines remains indispensable. The second part showed that this information must be based on 'people' who 'need to do things' in 'specific contexts' regardless of their literacy – or vulnerability-levels. The third part indicated that a visual information strategy is required to enable people to make decisions about their health and care. The question that needs to be answered in this last part is how visual designers could get more involved and develop information about medicines that really enables people.

There are at least two things that visual communication designers could add: insights into design processes, and providing reliable evidence.

4.1 Design processes: Visual design is more than optimizing visual elements

Design studies has developed over the last fifty years. And although 'visual communication' has often been seen as 'pretty and witty without much depth', it has developed into disciplines such as information design (Black et al., 2016), interaction design (Rogers et al., 2023), service design (Pfannstiel, 2023), and human-centered design (ISO 9241-210, 2019; Marchese, 2021).

What these various design disciplines share is that they start from people, context, and tasks. The ISO definition of usability is a useful reference. It states that usability is the '*extent to which a system, product or service can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use*' (ISO 9241-11, 2018). This would be a good aim for information about medicines.

We need to focus on 'performance within a specified context of use'. Jörg Fuchs correctly concludes (Fuchs, 2020, p. 374): '*A design science-based approach includes a user-centred design process, generation and application of evidence-based design features as quality criteria standard, and testing with the participation of representatives of intended users.*'

A second shared principle is that 'design' is not the optimalisation of a list of separate elements. Designing visual materials always requires a balance between the visual elements, in combination with the rhetorical aims of information, and a consideration of the longer-term relations between the person who reads and the author/designer.

It is impossible to summarize the processes and considerations of several design-disciplines in a few paragraphs. However, the abovementioned principles are very useful to approach the development of information about medicines.

4.2 Visual design needs to supply evidence that it is effective, efficient, and satisfying

The design processes in different design disciplines have evolved into effective ways to develop visual information. Unfortunately, this has not led to an increase in our knowledge about the actual effects that designed information can bring about. There still is a severe lack of reliable evidence that designed information really performs in specific contexts of use.

In order to be accepted to collaborate within the medical disciplines, visual design needs to provide evidence that their work is effective and beneficial, and does no harm. The answer of designers that 'it's easy to see that it works' is not acceptable. The design profession needs to provide real data. This requires a shift in professional design practice.

The example in Figure 4 is a classic and seemingly convincing story about illiterate mineworkers in South Africa. It is effective in warning against Euro-centric assumptions in an educational environment, but it is unlikely to be correct. It seems obvious that no mineworker would risk

Figure 4 A instruction for South African mineworkers in three images. The original caption states: 'Because many South African mineworkers are unable to read, this cartoon was devised to persuade them to leave the rails free of stones. However, it did not work – increasing numbers of stones were found on the rails. The cause, it was discovered, was that the miners tended to read the message from right to left, and so they helpfully complied and took the stones out of the wagons!' (Mijksenaar & Unger, 1974).

their own safety and the safety of their colleagues by putting stones on rails. Mineworkers are paid to take materials out of mines. Depositing stones inside a mine is counterproductive. Could it more have to do with an intelligent 'hostile reading' of this cartoon from right to left to justify sabotage? To find out which interpretation is correct, some evidence is required.

Furthermore, designers are trained to make mistakes and learn from them. Healthcare professionals are trained to avoid mistakes at all costs. Although healthcare professionals undoubtedly will learn from mistakes too, they have an obligation to record and report these so that others will not repeat mistakes. Such a system does not exist in visual design disciplines.

The lack of evidence about the real performance of designed visual information causes suspicions in the medical profession. And this points to the underlying reason that 'visual design' is not seen as relevant for the provision of information about medicines for patients. There is not enough convincing evidence from a medical perspective that visual communication really is effective, efficient, and satisfactory to achieve specific goals.

4.3 Concluding part 4

Designers know how to make information that suits the needs of readers, supports tasks, and is suitable within a larger context. Design processes deliver effective, efficient, and attractive information that enables people to find, understand, and apply information. Through the involvement of people in design processes, it is clear that information can be used.

But that is not enough. It does not provide the evidence that is required. It does not provide data that could be used to compare the actual performance in different situations. And that evidence is required to show that visual design can really be beneficial in the process of

developing information about medicines for people. Without this evidence, the current visual information about medicines must be accepted as satisfactory.

5 Conclusions

If we want to make sure that patients are involved in their treatments and understand when and why to do things, we need to design materials that enable that. These materials need to fit into structures that support patients. Both are real challenges because the current information about medicines is based on questionable assumptions. Just telling patients what to do, instead of providing what they want to know and need to know, turned out to be a wrong starting point. And we've designed structures that decentralise patients and focus on efficiency and profits instead of care.

The following four conclusions can be drawn:

1. We're in a awkward situation. Until now, visual information about medicines has been poor. Patient must receive reliable and understandable information and the way this information is supplied at the moment does not achieve this. A combination of legal requirements, commercial interests, legal protection, and medical accuracy has led to texts on paper that are to a high extent irrelevant, hard to find, difficult to understand, and hard to use.
2. We need to stop blaming patients by categorizing them in terms of 'low-health-literate' or 'vulnerable'. Those labels are not appropriate and don't help to communicate more effectively. We need to focus on 'people' who 'need to do things' in 'specific contexts'.
3. A focus on text, with a minimal use of pictograms or symbols is not a suitable approach. The belief that 'pictograms can easily be understood by all' has proven to be incorrect. Furthermore, focusing on pictograms only is the wrong kind of discussion. The discussion needs to be broader and focus on a complete visual information strategy.

   Information about medicines needs to be more visual and provided in digital ways. Patients simply expect this. Highly standardised information that ignores differences between patients, medicines, treatments, contexts, and languages has proven to be ineffective. It's not about what could be told about medicines, but it's about what patients want and need to know.
4. We need to focus on 'performance in practice'. This requires that designers must show evidence for their decisions and results. One of the ways to do that is to involve patients in design processes.

For medicines, medical devices, and treatments, we know what the problem is, but we are not much closer to providing suitable information that is relevant, findable, understandable, and usable. The main way forward is to start from the needs and expectations of patients.

These differ according to the type of medicine, the treatment, the context, and the tasks.

In the last fifty years, we thought that we could start just by making information available and hope that patients would respond in the anticipated correct manner. That assumption has proven to be incorrect. It needs to be replaced by an assumption that has proven to be effective: 'just start by listening to patients'.

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