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595. Animated instructions for medicines: Who can assess the quality and effects?

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ABSTRACT Information for patients about medicines is a global problem. Texts are incomprehensible, hard to read, difficult to apply, and very hard to relate to other information. The Regulatory Authorities (Food & Drug Administration, European Medicines Agency) are aware of this and keep suggesting improvements. Despite many efforts patients do not receive information about medicines in a format that they can use. The pharmaceutical industry, pharmacists, hospitals, and insurance companies are developing additional information sources on websites, on smart phones, and as ‘patient education materials’. These documents are still tightly regulated, but provide alternative information sources for patients. The quality and benefits of all visual information sources need to be evaluated. During the development of animations about treatments and medicines, it became clear that there are at least six different groups of people who can assess the information about medicines. These are:

- a. the writers/designers: applying linguistic and visual criteria*
- b. the client: applying commercial and strategic criteria*
- c. the regulatory authorities: applying legal criteria*
- d. professional disciplines (writers/designers/doctors/pharmacists/nurses): applying disciplinary criteria*
- e. patients: applying health criteria (finding, understanding, applying information to maintain or improve health)*
- f. society: applying civil criteria (sustainability, cost/benefits, public concern)*

In order to establish if a simple animation is acceptable, it was necessary to apply the often mutually exclusive criteria of all six groups. A focus on the needs of patients is an essential starting point, but the other perspectives must be considered too. Balancing these remains a major issue and makes compromises unavoidable. Toulmin’s argument layout offers a useful approach to discuss the relevance of the six perspectives for the design of information for patients.

Keywords: information for patients, information about medicines, animation, visual, quality assessment, Toulmin’s argument layout.

Introduction: well designed information for patients?

Providing patients with information about their medicines is an essential part of a therapy. Without information it is very difficult to find out when and how to take medicines, what their purpose is, and which potential risks they might cause. Professional healthcare providers (doctors, pharmacists, nurses), industry, carers (family), and different media (television, internet, newspapers) contribute information at different points in a therapeutical process. For individual patients, this information is not given in a coordinated manner, and it is not provided in formats that are easily accessible, understandable, and applicable in specific situations.

Medicines information is strictly regulated and aims for neutral and objective instructions. At the moment, most of the regulated information is on paper, although the same information can be downloaded as pdf-files or can be seen as a webpage. The visual qualities of the design of this information is often of a poor standard and leads to confusion, errors, time-wasting, and frustration (van der Waarde 2017). This issue is recognized in Europe by both the European Commission (2017) and the European Medicines Agency (2017) who have set out strategies to remedy some of these problems.

The pharmaceutical industry, pharmacists, doctors, patient organisations, and hospitals all develop alternative formats to satisfy the needs and expectations of patients. All are based on the regulated information, and all add their own perspectives and priorities. Figures 1, 2, and 3 show examples of stills of animations that are funded by the pharmaceutical industry, patient organisations, and hospitals.

Developing alternative forms of information

Based on the experience with patient information leaflets, in combination with research results, the approach to provide information about medicines for patients is changing. There are at least six major shifts:

- focus on a specific medicine (not a standardized 'one-size-fits-all' for all medicines)
- focus on correct use in actual context (not on an 'imagined use' in an 'imagined context')
- combine text and images (text on its own is not enough)
- combine information on paper and digital information (paper on its own is not enough)
- shift from a medical/legal genre towards a healthcare and patient-focused genre
- cooperate with patients, doctors, and other healthcare professionals (the development of information cannot be done independently).

Although there are some indications that these shifts have led to more effective information about medicines, convincing evidence is still missing. Figures 1, 2, and 3 give examples of the questions that need to be answered. But before empirical studies can be designed to answer these questions, it is first necessary to list what kinds of evidence might be most useful.

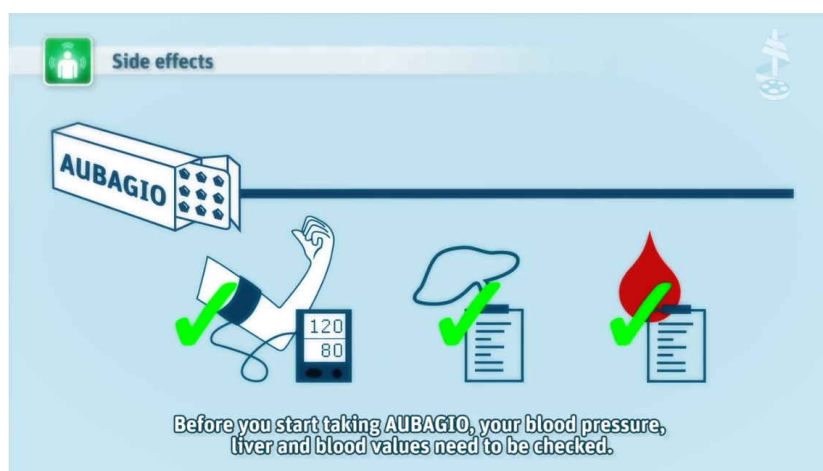


Figure 1: Which value systems can be applied to assess the quality and effects of this animated instruction?

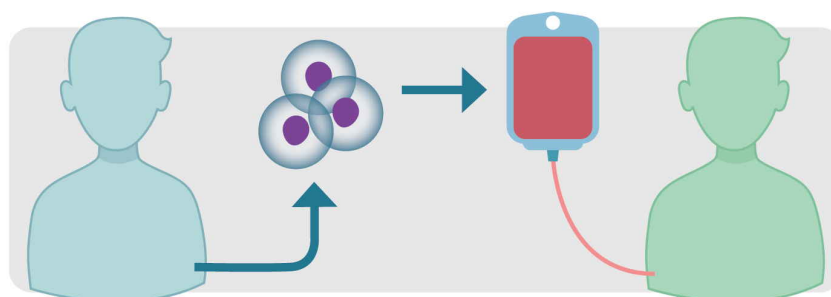


Figure 2: What kinds of knowledge tests could provide an indication if low literacy, low health literate patients understand explanations?

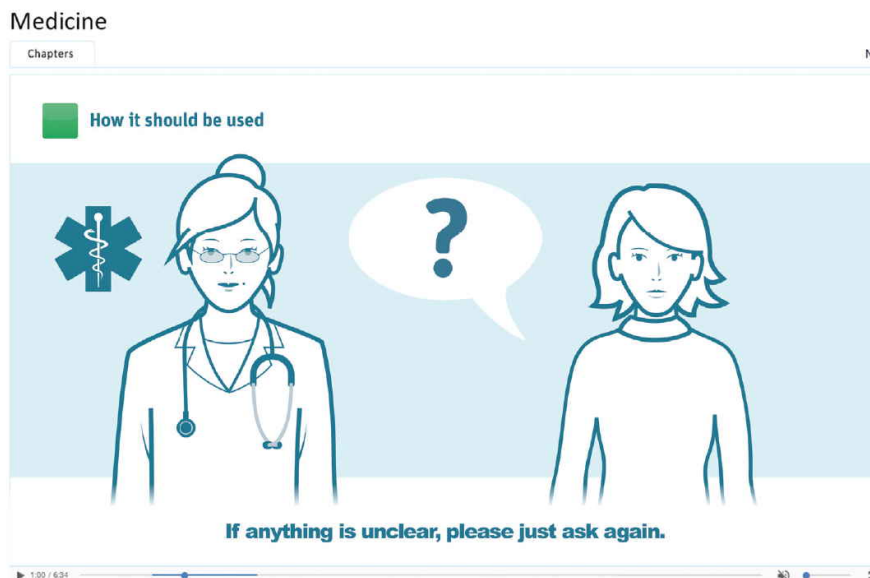


Figure 3: Who benefits from animated visuals?

Quality assessments?

During the development (writing, designing, testing) of the animations in a commercial design practice, it turned out that there are at least six groups that could provide a relevant assessment of the quality of the design of these animations.

These groups are:

- **The designers.** This group consists of writers, designers, usability-testers, and programmers. This group applies linguistic, visual, and design criteria.
- **The client.** Commercial or governmental organizations focus on financial and strategic criteria.
- **Regulatory authorities.** This group applies legal criteria, and considers standards and guidelines.
- **Professional disciplines.** Most professions (writers/ designers/ doctors/ pharmacists/ nurses) are represented by disciplinary bodies. These bodies develop and apply disciplinary criteria and professional protocols.
- **Patients.** Patients – and their carers - apply criteria related to health. They need to find information, understand information, and apply information to maintain or improve health.
- **Society.** A society applies civil criteria such as sustainability, cost/benefits, and public concerns.

One of the major challenges to develop information for patients about medicines is that these six different groups need to be considered simultaneously. The difficulty is that the criteria of each of these six groups cannot be easily related to each other. Some of them are even in direct conflict. For example, information might be designed well, for an acceptable price, very usable according to professional standards, and societally acceptable, but if it is not adhering to the legislation, it still will not be accepted. At the moment, the assessment of package leaflets – the ‘stuffers’ as they are found in every medicine pack in Europe – is heavily inclined towards the criteria of the regulatory authorities.

Discussion: a theoretical approach?

How can these different perspectives of these six groups be resolved into a consensus that is acceptable for all? What kinds of evidence is convincing for these groups, and would a group accept evidence that is not related to its own focus? One possible approach to relate the different arguments for different situations is to apply a standard description of an argument. Stephen Toulmin (1958) published an analysis of the different parts of an argument and their configuration. Figure 4 shows the general layout of an argument.

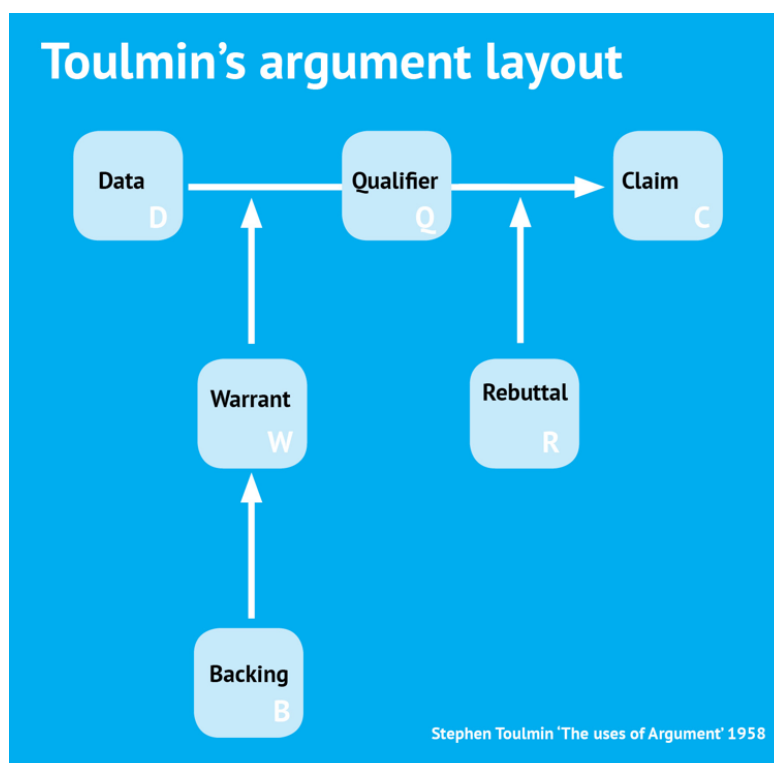


Figure 4: Toulmin's argument layout (*'The uses of Argument'*, 1958) suggests the necessity to explicitly describe the warrants and backing in order to make a valid claim.

A very brief description of Toulmin's diagram is as follows. If we want to make a convincing claim (C) then we need to provide data (D) to support that claim. We also need to qualify (Q)

this claim because it is unlikely to be applicable everywhere at any time. We need to justify the relation between the data and the claim - a warrant (W) - by referring to general rules and principles. And we might need to provide reasons why these general rules are relevant by referring to an authority: the backing (B). And lastly, we need to consider the conditions of exceptions in which the claim cannot be correct. This is the rebuttal (R) or refutation. The argument layout has been discussed for over 60 years, and continues to attract academic attention (Jackson and Schneider, 2018).

It seems that the provision of information about medicines to patients can be seen as an argument. It is a series of statements to persuade a patient to take medicines correctly and effectively. Toulmin's diagram shows which parts of an argument need to be considered to support this claim. The animated instructions of figures 1, 2, and 3 are used as examples to relate the design of visual information to Toulmin's diagram.

The claim (C) that designers make is that '*well designed information enables patients to act appropriately*'. In order to make this claim, designers need to provide evidence and data (D) and qualify this claim. The qualifications (Q) for the animations are that they are specifically made for low-literate and poor health-literate patients in the Netherlands. Some empirical evidence is provided by the results of usability tests and comprehension tests. Results of academic studies further support this claim by providing evidence that current patient package inserts are problematic, patients struggle with medical terminology, and adherence to medical regimens is poor. All together, this provides facts and evidence that the animations perform better in practice than the original regulated package leaflets. At least patients can understand the information, remember it, and find it when they need it.

The warrant (W) – or the justification that this evidence is relevant for the claim – is provided by the idea that people can understand and remember 'combined media' better than 'text only'. The animations use a combination of moving visuals, static visuals, text in captions, text in pictures, spoken words, and music. It is inferred that the general rule can be applied to information about medicines. The backing (B), the 'kind of authority' this approach relies on, is both practice based ('it seems effective in the real world'), and its findings in fields like cognitive psychology and applied linguistics are related to memory and understanding. The rebuttals (R), for the designer's claims, look at the exceptions and refutations. For the animations, these rebuttals relate to the visually impaired, the hearing impaired, and digitally challenged patients who have difficulties watching the animation.

Toulmin's model nicely indicates why this 'design argument', with its evidence, qualifiers, warrants, and backing, is not persuasive enough for the other five groups who can assess the qualities of the animations about medicines. For example, clients have difficulties in relating this argument to the financial and strategic criteria that are relevant to their activities. Questions like 'what are the financial consequences if patients understand and remember information about their medicines?', and 'how easy is it to modify this information if changes need to be incorporated?' are outside the design realm and are rarely dealt with by designers. Regulatory authorities struggle with these animations too because there are no guidelines or legislation that could help to assess them. Patients mainly focus on their health,

and the design arguments don't really address this. The real health benefits for patients of well understood and applicable information remains uncertain.

In general, based on Toulmin's diagram, the warrants and backing of the different groups are very hard to combine. The evidence that designers provide to support their claim needs to address the financial, legal, disciplinary, usability, and societal criteria too. It is not simply a matter of 'producing a considered argument' from a design perspective. All other perspectives, which might be internally subdivided even further, need to be addressed.

Toulmin's model, and especially the warrant and backing provides a clear theoretical description of the fundamental cause of the poor information that patients receive when they need to take medicines. At the moment, the emphasis is mainly on the regulatory and economical perspectives. Information for patients about medicines follows the legislation, and is produced for the lowest possible price. The other perspectives, such as the health perspective of patients do not receive as much attention. In order to develop information that would really enable patients to act appropriately, it seems necessary to address the arguments from the perspectives of the other groups too. This means that it is necessary to find relevant evidence in areas that until now have received insufficient attention from designers.

Conclusion

Providing patients with relevant information about their medicines is still problematic. There are at least six different groups who can provide an evaluation of the quality of this information. In practice, these six groups have very little in common, and assess information based on different criteria that are related to different value systems. A designer needs to consider design, finances, legislation, disciplinary habits, health, and societal preferences simultaneously, and try to find a balance between all of them.

Toulmin's argument layout provides a visual representation of this fundamental conflict of interests. Each design makes a claim that it is an improvement in comparison to the existing situation. The evidence to back up this claim needs to convince at least six different groups. This requires different kinds of evidence to allow for different kinds of warrants and different kinds of backing systems.

It is now possible to set up specific experiments that investigate the consequences of the animations for these six different groups. Although it is likely that some experimental results will be rejected as irrelevant by some groups, these results will add to strengthen the relevance of design in the provision of information about medicines for patients.

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