CHAPTER 3

Readability and Visuals in Medical Research Information Forms for Children and Adolescents

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Science Communication, *37*(1), 89-117.

Abstract

Children are often-overlooked receivers of medical information and little research addresses their information needs. However, young children are capable of understanding medical concepts and express the desire to be informed. This study addresses the quality of medical research information forms for children in the Netherlands, by assessing text readability and the role of visuals. Children's reading books, nonfiction books and textbooks were used as comparison. Seven focus groups were conducted to identify children's preferences and needs for text and supporting visuals. We argue that the use of visuals is a powerful, but neglected, tool to improve medical information for minors.

Introduction

Children and adolescents are often-overlooked receivers of medical information and little research addresses their information needs. However, young children are already capable of understanding medical concepts (Lewis, Lewis, & Ifekwunigue, 1978; Redding, 1993). Indeed, young children express the desire to be informed and to be involved in decision-making in medical situations to some extent (Baker et al., 2013; Geller, Tambor, Bernhardt, Fraser, & Wissow, 2003; Swartling et al., 2011; Van der Pal et al., 2010).

The right for minors to be involved in decision-making is described in article 12 of the UN Convention on the Rights of the Child, which states that "children shall be provided with the opportunity to be heard in any judicial or administrative proceeding affecting the child directly" (Unicef, 1989). This statement is not specifically aimed at medical situations, but nevertheless has implications for the role of minors in medical decision-making.

As currently 45-60% of medication prescribed to children is 'off-label' (i.e. not officially approved for use in this specific group of patients or for a specific medical indication), the WHO recommends to include more children in research to identify optimal treatments and prescription doses specifically for children (WHO, 2013). This implies that in the future more children in hospitals are likely to be asked to participate in medical scientific research. Children and adolescents do not have the same rights as adults in deciding about research participation, because their decision-making capacity is still developing. However, this developing capacity to understand and oversee medical information also requires an ethical response of increasing information provision and involvement in decisions with age (John, Hope, Savulescu, Stein, & Pollard, 2008).

A number of guidelines state the right of minors to receive suitable medical information. The WHO describes that "the researcher should provide the child with information appropriate for his or her level of development to obtain the child's voluntary cooperation" (WHO, 1981). The Second Directive 2001/20/EC by the European Parliament and the Council of the European Union, states that "A clinical trial on minors may be undertaken only if (…) the minor has received information according to its capacity of understanding" (EU, 2001). In addition, the Guidelines from the Ethics Working Group of the Confederation of European Specialists in Paediatrics argue that "The information (oral and written) to be provided to the (potential) child-participant should be in conformity with the capacity of the child to understand and should be adapted to assist the child at arriving independently at a decision. In particular, the content language, and mode of communicating the

information should be adapted to the child's capacity to understanding and decision" (Gill, 2003).

In spite of these guidelines, there is little research on the quality of medical information for children and adolescents, nor evidence-based insights in how health communication can be optimally adapted for this target group. Therefore, we aim to assess the comprehensiveness of medical information material for minors, and we seek to explore how visuals could address the problem of incomprehensible medical texts for children.

Readability gap

When a patient is asked to participate in a clinical trial, a medical research information form is provided, explaining topics such as the aim, procedures, and risks & benefits of research participation. These forms are subject to legal rules stating which information should be in the document in order to obtain ethical informed consent for participation. Readability analyses of adult research information forms indicate without exception a large gap between the required reading level to understand the information and the actual reading ability of research participants (Kass et al., 2011; Souza et al., 2013; Sudore et al., 2006; Terranova et al., 2012). Poor readability of information can lead to poor understanding and uninformed consent.

Based on the poor readability of adult information material, a similar readability gap can be expected in medical information for minors. This is especially likely since children have a lower reading level than adults and require material with an even better readability in order to reach comprehension.

Various studies assessed minors' comprehension of research information, which could serve as an indicator of the appropriateness of the information process. As children's capacity to understand and process information develops over time, comprehension is strongly related with age. From the age of 9, children become capable of understanding research concepts (Berto et al., 2000; Chappuy et al., 2008; Franck & Winter, 2004; Ogloff & Otto, 1991; Ondrusek et al., 1998; Paasche-Orlow et al., 2003; Raich et al., 2001; Sanders et al., 2009; Terranova et al., 2012). However, how well children of a certain age can understand research concepts is also determined by the readability of the information material (Barnett et al., 2005). Research demonstrates that children and adolescents often do not understand essential aspects of the research that they are participating in, such as aim of the study, possible risks, and right to withdraw (Burke et al., 2005; Ondrusek et al., 1998; Swartling et al., 2011; Tait et al., 2003, 2007). Moreover, some children do not

comprehend that their participation in research is not a standard treatment (Barrett, 2005; Chappuy et al., 2008; Unguru et al., 2010). The minors in these studies indicated they did not feel informed about research or did not understand what the doctor told them. This is no surprise, as doctors sometimes deliberately choose to communicate with parents, rather than directly with the child itself (De Vries, Wit, Engberts, Kaspers, & van Leeuwen, 2010). It is thus apparent that children and adolescents are often not as informed as laws and regulations require.

Nevertheless, little evidence exists that addresses minors' information needs and preferences for medical information. A recent systematic literature review yielded only 3 studies that specifically discussed readability of research information for children (Grootens-Wiegers, De Vries, & Van den Broek, 2015). One study assessed readability of pediatric consent forms in the USA and showed an average reading level comparable to a university reading level (Tarnowski et al., 1990). A study in France compared research information for children to non-medical texts for children, such as novels (Menoni et al., 2011). The readability of research information was considerably poorer than the readability of non-medical texts. Also, the non-medical material contained a high number of supporting illustrations, whereas only 14% of the medical text did. In a third study, information material was developed together with children aged 6-12 years old, resulting in a readability twice as high as the readability of medical texts in the American study (Ford et al., 2007). This evidence seems to support the hypothesis of a readability gap in medical information for children.

Readability, comprehension and visuals

The readability score of a text is generally determined by the length of words and sentences. However, readability is not equivalent to understanding. There are other factors that also influence understanding, such as use of medical terminology, the use of complex concepts (e.g. randomization), length of the total document (Kass et al., 2011), font, lay-out of the document (e.g. use of bullet points and text boxes (Tait et al., 2007) and visual support (Mayer, 2001). Improving only the readability of medical information will thus not guarantee increased comprehension. Moreover, it has been argued that it is practically impossible to write medical information at the recommended readability levels, because of the complicated content of the information (Hochhauser, 2007). In order to improve children's comprehension of medical information, it is thus imperative to look beyond the readability itself, to reading comprehension.

Reading comprehension involves understanding the words in the text, as defined by readability and vocabulary, but also the ability to process the input and create a mental model of the information (Barnes, Raghubar, Faulkner, & Denton, 2014; Mayer, 2001). The Cognitive Theory of Multimedia Learning from Mayer (2001) describes how input is processed, divided in three assumptions. First, the dual channel assumption describes the use of dual channels for visual/pictorial and auditory/verbal information processing. The second assumption is the limited capacity assumption, indicating that both channels can only process a limited amount of input. When there is too much input in either of the channels, this cognitive overload will hinder the processing of the information (Mayer & Moreno, 2003).

Third, the active processing assumption explains how taking up and learning information requires the active selection of information, and subsequent organizing and integrating of that information into a mental model. This processing involves three activities: essential processing, incidental processing and representational holding (Mayer & Moreno, 2003). Essential processing is making sense of all relevant input, whereas incidental processing is taking up non-essential information, such as the radio in the background while reading a text. Representational holding is keeping the information in the working memory and forming a mental model (Mayer & Moreno, 2003; Pike, Barnes, & Barron, 2010). Such a mental model is created by selecting relevant information from the text, updating the model while proceeding, and suppressing irrelevant information (Pike et al., 2010). The newly encountered information is integrated with prior knowledge and experiences in the mental model (Barnes et al., 2014). The ability to update a mental model, based on inferences from the text, is essential to reading comprehension (Carlson, Seipel, & McMaster, 2014). Children are already capable of making inferences from text, but this ability improves with age (Barnes et al., 2014). In addition, the use of working memory, necessary for representational holding, improves significantly during development, leading to better reading comprehension (Pike et al., 2010). Based on this model, comprehension of complicated (e.g. medical) tests can be improved by the use of visuals. When information addresses both channels (i.e. visuals and verbal), more information can be taken up, reducing the risk for a cognitive overload and increasing comprehension (Mayer & Moreno, 2003), and better mental representations of the provided information can be made by the receiver. Visuals can help to create mental models in working memory, even if the visual does not contain any new information next to the text (Brookshire, Scharff, & Moses, 2002; Glenberg & Langston, 1992; Pike et al., 2010). Consistent with

an immature and inefficient working memory in developing children, it has been found that younger children in particular rely on visuals for reading comprehension (Pike et al., 2010). Although the effect of visuals reduces in older children, they still show an influence on their ability to make inferences and thereby create a mental model (Brookshire et al., 2002; Pike et al., 2010).

In medical information, the visual channel is often completely neglected, and information is only provided in conversations and text documents. Although almost all books for children contain many images, a study on medical texts for minors found that only 14% of the texts contained images (Menoni et al., 2011). Exploiting the visual channel could therefore be a promising approach to increase understanding when the limits of improved readability of the text itself are reached.

Abundant research has indicated the value of visuals to support written information. Patients prefer visual-based information and adding pictures to a text increases the probability that a text will actually be read (Delp & Jones, 1996; Katz, Kripalani, & Weiss, 2006; Mansoor & Dowse, 2003; Michielutte, Bahnson, Digman, & Schroeder, 1992). In an extensive overview of the influence of visuals in health communication, Houts et al. (Houts, Doak, Doak, & Loscalzo, 2006) describe the *pictorial superiority effect*: text with accompanying pictures is remembered better compared to only written or spoken text. When a patient receives verbal health information with an accompanying visual and later views the same picture, it helps the patient to remember the information, a process that is called *cued recall*. Participants also score significantly higher on comprehension when they receive a text accompanied with pictures (Austin, Matlack, Dunn, Kesler, & Brown, 1995; Mansoor & Dowse, 2003; Carney & Levin, 2002; Houts, Witmer, Egeth, Loscalzo, & Zabora, 2001). Not only can visuals improve recall, comprehension and adherence, but they also improve satisfaction with the information material (Katz et al., 2006).

Effective visuals

Not just any visual will support comprehension; the effect strongly depends on the quality and placement of the visual itself (Katz et al., 2006). Visuals need to be placed close to the text they refer to and captions should be provided to explain the picture and to indicate the most important sections of the image (Carney & Levin, 2002; Fillippatou & Pumfrey, 1996). Readance and Moore concluded that line drawings facilitated the understanding of a text more than drawings with shading or photographs, and the effect of pictures was greater when they were in color (Readance & Moore, 1981). Simple drawings are

better for comprehension than detailed pictures, as too many details can be distracting or create a cognitive overload (Houts et al., 2006; Mayer & Moreno, 2003). People prefer pictures in health information texts that refer to their own culture and that include people they can identify with (Dowse & Ehlers, 2001; Hosey & Stracqualursi, 1990). These culturally sensitive pictures influence how much, and the way in which readers perceive the information (Dowse & Ehlers, 2001; Roter, Rudd, Keogh, & Robinson, 2006). Research indicates that children prefer realistic pictures (Houts et al., 2006). So, to clearly convey a message to children with pictures, it is preferred that the pictures connect to the perception of the child (e.g. using pictures or drawings of children of the same age and ethnicity). Moll (1986) reported that medical messages for adults accompanied by cartoon drawings scored highest on comprehension. In a study among 14 year-olds, a comic book on disease information was shown to succesfully improve understanding of the material (Gillies, Stork, & Bretman, 1990).

Based on the literature, Houts et al. (2006) have proposed seven recommendations for using pictures in health education: (1) pictures should be used in health communication as literature has shown its effectiveness; (2) visuals should be simple; (3) textual information should be clear and simple; (4) guidance for picture interpretation should be provided, e.g. by captions and picture-text proximity; (5) pictures should be sensitive to the culture of the target group; (6) health professionals should be actively consulted when creating pictures; and (7) the effects of pictures need to be evaluated in research.

Aim of this study

Our aim was twofold. First, based on the readability gap between the average adult reading level and the readability of adult consent material, we hypothesized that a similar gap could be present in pediatric medical information material. We aimed to assess whether this gap is indeed present in research information forms for children and adolescents.

Second, given the extensive literature that suggests visual communication enhances the readability of text, and the evidence regarding cognitive development in children, we aimed to identify to what extent the use of visual communication enhances children's understanding of health information. In addition, the potential of visuals in medical tests was investigated, by consulting children to gain more insight in their (visual) information needs and preferences. The study is situated in the Netherlands, where children from the age of 12 are legally allowed to co-decide on research participation together with their

parents. The analyzed documents are thus of legal status and therefore it is essential that the information is adapted to the level of children and adolescents, as is stated in the various rules and regulations of the UN, WHO and others.

Methods

1. Readability analysis

A readability analysis was performed on research information forms, in order to stimulate research and discussion in this field, and to propose a preferred reading level for pediatric documents.

Collection of research information forms

Medical research information forms were collected from two Dutch academic hospitals. Together, these hospitals covered 24% of Dutch pediatric studies in 2012 (CCMO, 2012). Forms were obtained via the Institutional Review Board (IRB) of the one hospital (the most recent forms in their database) and via individual researchers from the other hospital (from active studies). All analyzed forms were approved by the IRBs.

Determination of readability

Readability was determined using four different instruments: Flesch Reading Ease (further: Flesch score), Flesch-Kincaid Grade Level, Gunning Fog Index and the Flesch-Douma Reading Ease. All instruments can be used to calculate the reading ease of a text, based on the number of words per sentence and the number of syllables per word (Douma, 1960; Flesch, 1948; Gunning, 1968). The Flesch-Douma formula is adapted from the Flesch score, accounting for the generally longer words in the Dutch language. As the different formulas can provide significantly different results, because of differences in measurements methods, it is important to use multiple formulas to supplement each other (Klingbeil et al., 1995).

The Flesch score and Flesch-Douma formula result in a number between 0 and 100 for reading ease; a score of 100 indicates a text is very easy to read, 60-70 indicates the text is good to read for the average adult, <60 varies between hard and very hard to read. Flesch-Kincaid and Gunning Fog scores indicate the years of reading education required to understand the text. Calculation with the latter formulas results in non-rounded numbers,

e.g. 8.53, which indicates one needs about 8 and a half years of reading education., In table 1 the interpretation of readability and reading level scores is indicated.
The use of these readability formulas is simplistic and limited: the formulas only measure length of words and sentences, but do not incorporate other factors influencing readability, such as whether words used are common words, length of the total document and font. However, in spite of their shortcomings, we were unable to find any studies that used a method other than these instruments to determine readability of medical information so far (Grootens-Wiegers, De Vries, & Van den Broek, 2015).
The readability analysis was performed using the online tool provided by the Language and Translation Technology Team of University College Gent (Van Oosten, Tanghe, & Hoste, 2010). Per consent form, three samples were analyzed of the first 100 words from three paragraphs in the document: goal of the study, procedures, and benefits/disadvantages of participation. If a paragraph was shorter than 100 words, the last sentences of the previous paragraph were included.

Other variables

The total length of the document (in words and pages), and number of pictures in the document were measured as well. The year of the study and age of the target group were also documented.

Material for comparison

As no golden standard for readability of pediatric consent documents exists, other texts for children were analyzed as comparison and to propose a standard for medical information. Children's novels were chosen for this comparison, since these books consist of plain text and therefore compare well to the forms. Books were selected based on bestsellers-top 10 of children's and young adults' books of bol.com, a large web shop. Three random pages were selected from each book and the first 100 words on the page were analyzed.
In order to assess the role of pictures in children's books, (non-medical) textbooks and nonfiction books were also analyzed. Five children's textbooks were collected from three local elementary schools. The textbooks were used for 12 year olds, corresponding with the 8th grade of Dutch elementary education, and covered the subjects nature, geography and history.

Table 1 Interpretation of readability and reading level scores

Flesch Reading Ease and Flesch-Douma Reading Ease	
Score	Interpretation
0-30	Very hard to read (academic journals)
30-50	Hard to read
50-60	A bit hard to read
60-70	Good to read for the average adult
70-80	Fairly easy to read
80-90	Easy to read
90-100	Very easy to read
Flesch-Kincaid Grade Level and Gunning Fog Index	
Level	Interpretation
Number of years reading education	Reading education generally starts at age 6. The score + 6 indicates the age at which children should be able to read the text
4	10 years old
5	11 years old
6	12 years old
7	13 years old
8	14 years old
9	15 years old

Six nonfiction books for children were selected by age category (i.e. from the age of 12) from a local library, and one nonfiction book was provided by a cooperating school. The books were selected to cover similar topics as the textbooks, namely nature and geography. For textbooks and nonfiction books, the first 100 words of the pages 10, 20 and 30 were analyzed (excluding captions of images). If there were less than 100 words on the page, additional words from the next page were used.

For nonfiction books that were shorter than 20 pages (indicated with an asterisk * in table 6), pages 5, 10 and 15 were analyzed. When pages had a deviant lay-out, such as assignments or only pictures, the text on the following page was analyzed.

The picture-text ratio of children's school textbooks and nonfiction books was also analyzed for pages 10/11 and 20/21. The total number of words and the number of images on the two pages were counted. Subsequently, a quantification of the number of images per 100 words of written text (excluding captions of images) was made. If the nonfiction book was shorter than 20 pages, pages 5/6 and 10/11 of the book were used. When pages had a deviant lay-out, the next pages were analyzed.

2. Qualitative Focus Groups

In-depth focus groups were performed with children in the Dutch 8th grade in 7 groups of 10-12 children. A total of 77 children (age 11-12) from three different elementary schools in the area of Haarlem (the Netherlands) participated in the focus groups.

Ten questions about the attractiveness of text and pictures in a research information form, in textbooks and in nonfiction books were discussed. Topics of the discussion were: understandability of the text, the most and least attractive book, characteristics and lay-out of a text, the pictures, the ideal nonfiction book and information form, amount and type of images, and difficult words.

A section of a representative pediatric research information form was discussed with the children. The selected sample consisted of two paragraphs about the aim and procedure of a research study on a gene variation. The section had a length of 178 words and a Flesch score of 55.43, which is fairly difficult to read for an adult. In the text, the effect of the gene on hormone secretion was discussed, as well as the procedure of coming to the hospital for drawing blood and subsequent testing.

After the children read this document, the same text- however adapted by the authors to contain images- was shown to them again. Three images were added: a photograph of drawing blood, an image of a DNA structure, and a time table for the procedure. Comprehension and preference was discussed.

The children were also asked to discuss the positive and negative aspects of text and picture use in the textbooks and nonfiction books. The last 3 focus groups also read a text from one of the nonfiction books on the topic of insects (readability Flesch score 27.94). This book was selected since even though the reading score was very low, children seemed to understand the book. Therefore, we aimed to investigate whether they found this text more or less understandable than the information form.

Results

1. Readability Analysis

Hospital 1

Eleven pediatric research information forms from the first hospital were analyzed. The forms were written between 2007 and 2012 and were directed at children and adolescents from 12-17 years old. The length of the forms varied form 628-3790 words, or 3-9 pages,

with an average of 1990 words or 5.4 pages. None of the forms contained any illustration, leading to a picture-text ratio of 0 per 100 words.
The average readability scores per document are shown in table 2. The average Flesch-Douma was 63.58, Flesch score 49.54, average Flesch-Kincaid Grade Level was 9.76 and Gunning Fox 13.16. Documents with the highest or lowest score on one scale do not necessarily have the highest or lowest score on another scale, due to the different calculation methods of the instruments.

Hospital 2
Eleven forms from between 2008 and 2013 from the second hospital were analyzed. Forms were directed at ages 12-18, and length of the forms varied from 2-11 pages, and from 512 words to 3370 words, with an average of 4.8 pages or 1503 words. Three of the forms contained illustrations: one form had a picture with every paragraph (11 in total). The average picture-text ratio was 0.11 per 100 words.
Average readability scores were Flesch-Douma 63.89, Flesch score 49.88, Flesch-Kincaid 9.96 and Gunning Fog 13.39. The scores per document can be found in table 2.

Reading books
Ten novels were analyzed for readability. The average readability was Flesch-Douma Reading Ease 83.80, Flesch score 71.75, Flesch-Kincaid Grade Level 6.54 and Gunning Fog 9.06. The scores and age target groups per book can be found in table 3.

Textbooks
Five children's school textbooks from the 8th grade were analyzed. Average readability scores were Flesch-Douma Reading Ease 80.76, Flesch score 68.37, Flesch-Kincaid Grade Level 5.87 and Gunning Fog 8.51. The picture-text ratio was 2.83 per 100 words. The scores of the books and their editors can be found in table 4.

Nonfiction books
Seven children's nonfiction books suited for children aged 12 and over were analyzed for readability. Average Flesch-Douma Reading Ease was 63.51, Flesch score 49.45, Flesch-Kincaid Grade Level 9.15 and Gunning Fog 11.82. The picture-text ratio was 1.83 per 100 words. The scores of the books can be found in table 5.

Table 2 Readability of medical research information forms from Hospital 1 and Hospital 2

Hospital 1							
Year	**Pages**	**Words**	**Pictures**	**Flesch-Douma**	**Flesch**	**F-K**	**Gunning Fog**
2013	8	3790	0	64.34	50.37	9.36	12.60
2012	4	1460	0	49.31	33.88	12.56	16.61
2012	8	2829	0	57.89	43.31	11.15	15.16
2012	9	3226	0	57.16	42.49	10.72	14.68
2012	4	1325	0	59.04	44.56	10.90	13.69
2012	3	628	0	56.80	42.11	11.43	14.03
2012	6	2406	0	64.96	51.06	8.87	11.26
2009	3	1374	0	77.72	65.08	7.90	11.23
2009	4	1305	0	78.52	65.90	5.73	9.24
2009	4	1067	0	80.06	67.63	6.56	9.47
2007	6	2476	0	53.60	38.60	12.19	16.83
Average	5.4	1990	0	63.58	49.54	9.76	13.16
Hospital 2							
2013	2	512	0	70.79	57.43	7.40	10.84
2013	4	1034	0	66.09	52.30	9.66	13.11
2012	4	1601	0	69.26	55.78	8.99	12.78
2012	2	644	0	59.35	44.91	11.04	15.51
2012	4	1215	0	71.20	57.90	8.56	11.48
2010	4	1376	11	67.33	53.67	9.49	12.83
2010	11	3058	3	41.81	25.64	13.56	16.54
2010	6	1883	6	80.77	68.41	6.45	10.31
2008	9	3370	0	44.48	28.60	14.24	17.34
2008	3	597	0	80.79	68.45	6.97	9.97
2008	4	1245	0	50.87	35.62	13.19	16.57
Average	4.8	1503	1.82	63.89	49.88	9.96	13.39

Table 3 Readability of reading books

Title	Author	Age target group	Flesch-Douma	Flesch	F-K	Gunning Fog
Hoe overleef ik mijn vader? (en hij mij!) *How do I survive my dad? (and he me)*	Oomen, F.	10-12	92.90	81.72	4.19	7.59
Sproetenliefde *Freckle love*	Stoffels, M.	10-12	91.91	80.65	4.80	6.90
De Hongerspelen *The Hunger Games*	Collins, S.	13-15	78.88	66.36	7.93	10.35
Hasta la Vista	Visser, J.	15-18	80.75	68.42	7.41	10.11
Het leven van een loser / 7 *Diary of a Wimpy Kid*	Kinney, J.	10-12	80.35	68.00	8.18	11.11
Broederband / 3 De Jagers *Brotherband / 3 The Hunters*	Flanagan, J.	10-12	80.15	67.74	7.29	9.25
Spijt! *Regret!*	Slee, C.	13-15	95.34	84.41	4.15	6.31
Gone – licht *Gone - light*	Grant, M.	15-18	76.63	63.87	7.37	9.43
Promille	Vreeswijk, H.	15-18	73.71	60.66	7.95	10.69
Inwijding *Divergent 1*	Roth, V.	15-18	87.34	75.64	6.15	8.91
Average			83.80	71.75	6.54	9.06

Table 4 Readability and picture-text ratio of nonfiction books

Title	Author	Age target group	Flesch-Douma	Flesch	F-K	Gunning Fog	Picture-text ratio
Ooggetuigen – Weer** *Eyewitnesses - Weather*	Cosgrove, B.	≥ 12	55.19	40.32	11.19	14.46	1.76
Ooggetuigen – Dieren** *Eyewitnesses - Animals*	Jackson, T.	≥ 12	62.15	47.96	9.43	12.65	1.18
Insiders – Insecten en spinnen** *Insects and spiders*	Tait, N.	≥ 12	51.60	36.36	11.07	13.63	1.34
Insiders – Extreem weer** *Extreme weather*	Mogil, H.M.	≥ 12	53.41	38.34	10.53	12.86	1.90
Doc – De toendra* *The tundra*	Kolfschoten, M. van	11-12	79.55	67.05	6.08	7.85	0.43
Doc – Ziek in je hoofd* *Ill in the head*	Jansen, W.	11-12	79.12	66.60	6.81	9.43	0.26
Animal planet – Super zintuigen** *Super senses*	Burdon, A	11-12	63.55	49.49	8.94	11.86	5.96
Average			63.51	49.45	9.15	11.82	1.83

* Books with less than 20 pages.
** Translated into Dutch from the original (English) version.

Table 5 Readability analysis and picture-text ratio of textbooks

Title	Publisher	Age target group	Flesch-Douma	Flesch	F-K	Gunning Fog	Picture-text ratio
Wijzer door de tijd, Geschiedenis *History*	Wolters Noordhoff	11-12	87.20	75.46	4.77	6.65	2.38
Naut, Natuur en Techniek *Nature & Technics*	Malmberg	11-12	79.45	66.95	6.29	8.56	2.26
Hier en daar, Aardrijkskunde *Geography*	Malmberg	11-12	82.78	70.60	5.73	8.03	4.22
De blauwe planeet, Aardrijkskunde *Geography*	ThiemeMeulenhoff	11-12	76.54	63.74	6.49	10.28	4.03
Leefwereld, Natuur en Techniek *Nature & Technics*	Wolters Noordhoff	11-12	77.81	65.12	6.05	9.03	1.25
Average			80.76	68.37	5.87	8.51	2.83

Comparison

Scores of the forms for both hospitals taken together indicated an average Flesch score of 49.71, Flesch-Douma Reading Ease 63.73, Flesch-Kincaid Grade Level 9.86 and Gunning Fog 13.28. Average readability and reading level scores for each of the texts are indicated in boxplots in figure 1. Note that the Flesch-Douma is adapted from the Flesch Reading Ease with a constant, and therefore shows an equal spread.

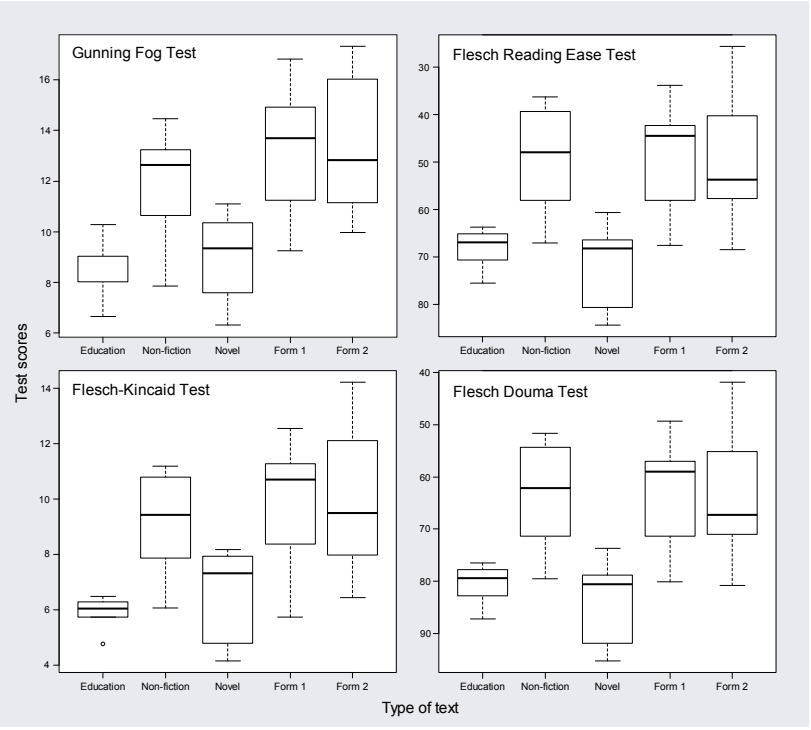


Figure 1. Boxplots indicating the reading level (left boxes) and readability (right boxes) of education and nonfiction books, novels and research information forms for children. Reading level values indicate number of reading years required to read the text; readability values under 65 are difficult to read for the average adult. Research information forms are harder to read than education books and novels, but not nonfiction books.

Prerequisites for ANOVA were tested with a Fligner-Killeen and a Bartlett test for homogeneity of variances. An ANOVA was performed using the software R ("R", 2011) for each of the readability scores to compare the five types of texts. The ANOVA indicated a significant difference between the groups ($P<0.01$).

A post-hoc test was performed with Tukey's HSD test, to identify significant differences between certain text types, the results are indicated in the figure 2. The forms scored significantly lower on readability than novels ($p<0.05$ for Flesch-Kincaid, $p<0.01$ for Flesch, Flesch-Douma and Gunning Fog) and textbooks ($p<0.05$ for all readability scales). Novels had a significantly better readability than nonfiction books according to the Flesch Reading Ease ($p<0.01$) and the Flesch-Douma tests ($p<0.01$), but not according to the Flesch-Kincaid Grade Level and the Gunning Fog tests ($p>0.1$). Nonfiction books show a trend of poorer readability than textbooks; however these differences were not significant. Novels and textbooks had a similar readability; also information forms and nonfiction books were comparable.

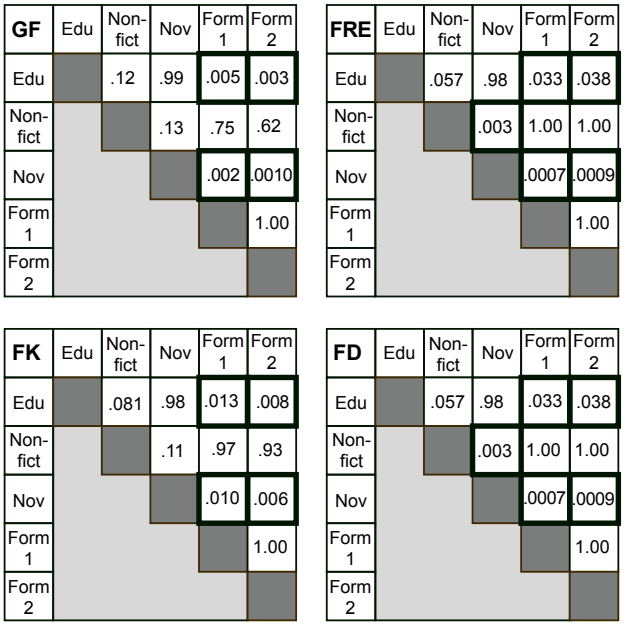


Figure 2. P-values of the Tukey test indicated per readability instrument (GF = Gunning Fog; FRE = Flesch Reading Ease; FK = Flesch-Kincaid Grade Level; FD = Flesch-Douma Reading Ease). P-values below 0.05 indicate a significant difference in readability between two types of text. These figures confirm the difference in reading level between research information forms and novels and education materials for all four instruments. In addition, readability scores but not reading levels are significantly different between forms and nonfiction books.

2. Qualitative Focus Groups.

Children's opinions on the research information forms in relation to the textbooks and nonfiction books

Children thought the text from the research information form was hard to read and boring: '*You are distracted easily when the text is so boring.*' They indicated the abbreviated gene name was especially difficult. None of the children could give us the definition of a gene. One child thought it was '*something in your blood*' and another thought it was a disease. Upon asking what would happen if you had a deviant form of the gene, one boy answered: '*I think you die.*' Another boy mentioned he found the text to be *'negative'* and '*sinister*'. Only three children knew how to interpret the general intention of the research described: '*They found something in your DNA and they are going to investigate it.*' *S*ome children were confused: *'I don't understand this, because they think that with some people such a deviant gene can change the hormones in the body. But, does the heart change into a lung then, for example*?'

All children could understand the method: taking a blood test. In all focus groups, children mentioned they would prefer a better explanation of the meaning of a gene. '*You can see this was written by an adult.'; 'If this is supposed to be for children, I would make it easier.'*

When asked, the children in the focus group said they would not want to participate in the research, because they needed a better explanation. After we told them that a research information form is usually a few pages long, instead of the 9-sentence sample, they thought no one would read it.

'I think four pages, a child that's going to read that will never finish it. That's more for the parents.'

When presented with the adapted form with accompanying pictures, some children indicated they could understand it better, but still quite a few did not fully understand the text. Some children indeed showed an improved understanding but there were still errors in their explanations, such as: '*Well, that's your DNA and the genes come into your blood or something.*'

In general, almost all children thought the text looked better with pictures ('*more attractive*'), although two children preferred a text without visuals. Children in different focus groups independently stated that they would prefer a drawing of the blood test over a photograph, because it was '*less scary*'; '*You want to know if you're going to be okay. That if they take a blood test, you will be healthy again*'

They had a strong opinion on the pictures used and a lot of suggestions: '*More pictures!'; 'More color!'; 'Arrows or lines to the pictures with explanations.'; 'I'd like it to be a cartoon.'; 'I'd like the font of the text to be bigger.'*

One of the children suggested the information form should be written by a child. We asked whether they would like an example of another child participating in the research, and they were enthusiastic: *'When I went to surgery there was a booklet about that too. In it was written what was going to happen to you. I really liked that.'*

The text from a nonfiction book about insects, which had a remarkably low readability (Flesch score 27.94, comparable to academic journals), was considered by all participants easier to read than the form: '*It's not very hard to read.'; 'A lot of words in it we have learned already.'* The text from the nonfiction book looked more attractive, according to the children: '*You see the pictures and the text and you feel eager to read it because you know what the picture is about.'; 'It's more exciting because there are more things to see.'; 'And then you'd like to know more about it.'*

Children's opinions on the lay-out of textbooks and nonfiction books

We showed the children all the textbooks and nonfiction books, and the majority preferred an nonfiction book about the weather with spectacular computer-generated 3D images, and a nonfiction book about animals, from Animal Planet. Upon asking them why they liked those particular books, they answered: '*A lot of pictures.'; 'And not so much text.'; 'There's a lot to see even before you read the text.'; 'The whole page looks colorful!'; 'It looks really cool.'; 'You just want to read it now.'*

Other books were least favorite, because the pictures were too small and looked '*old-fashioned'* and *' gross!'* and the colors were boring. '*These are just pictures of clouds. I can look outside if I want to see clouds!'; 'Those pictures have nothing to do with the text!'*

Many children expressed a preference for photographs over drawings, because they are more realistic. Still, some of them also said that the image of the blood test should be a drawing, to make it less real and less scary. Also, computer-generated 3D images evoked enthusiastic reactions from the children, because they were '*exciting'* and '*it looks like you're actually there because the picture is so big!'* In one focus group, the children specifically stated they liked exciting pictures. Many children mentioned they wanted a text to have an element of fun, or a joke and children liked it when cartoons were used in the books.

The majority of the children preferred the text to be divided into smaller sections, or boxes, spread onto the page, because '*it makes the text look shorter*'. Only a few stated a preference for a continuous text, because it was '*less distracting*'. Almost all children wanted difficult words to be explained, preferably on the same page. Upon asking what they did when they encountered a difficult word, they replied they would either skip it, read it again, ask someone ('*my mum*') or look it up on the internet or in a dictionary.

We asked the children whether they would prefer difficult words to be explained by a picture, they responded: '*Depends on the picture.'; 'But still with a little bit of explanation, because a picture alone is just… Look, if that text is not there… then you still don't know what it is exactly. You need to explain it.'*

In all focus groups children expressed they still needed a written explanation of the picture in order to help them understand what it was they were looking at.

We asked what the children would think of a page containing a lot of pictures. Almost all children answered they would find that distracting. '*Normally you look once and you're done, and now you'll have to look a hundred times!'; 'You want to read it but instead you only look at the pictures.'; 'And then I don't know where I left off reading! Then you don't know which picture belongs to which piece of text.'*

Some children -of whom one indicated to 'hating' reading-, would rather see lots of pictures. When asked whether they would prefer images in color or black and white, all children preferred color. One child also told that black and white pictures would still be better than no pictures at all.

Some children expressed to be especially disappointed if a text would not contain any pictures: '*If you see the cover of such a large book, it's very colorful. Then it looks nice. And then when you look inside there's no color!'; 'Or no pictures at all!';'That's why I always look inside the book before reading.'*

Discussion

In this study, the current quality of medical research information forms for children and adolescents was analyzed. In addition, children were consulted about their preferences and needs for text and visuals in medical information. To our knowledge, this is one of the first studies in which the quality of medical research information forms is examined and discussed in consultation with children.

Readability analyses

The information forms were very lengthy, with a maximum of 11 pages or 3790 words. Some studies have shown that if a document is longer than 1000 words, people will merely skim the text (Rugege-Hakiza et al., 2003; Sharp, 2004). In our sample, 18 of the 22 documents exceeded a length of 1000 words, which leads to the likelihood that children would not read the full document. This will affect their understanding and ability to consent or dissent to a study.

Only five of the 22 documents had a Flesch score higher than 58, which is the minimum level of readability for adult forms, as indicated by the Dutch Central Committee on Research involving Human Subjects (CCMO, 2008b). The Flesch-Kincaid Grade Level average was 9.86 and Gunning Fog 13.28 years of reading education required to read the documents. Even the most forgiving instrument, the Flesch-Kincaid, indicates that documents require much more reading experience than can be expected from 12 year-olds, the age at which in the Netherlands children are formally asked to consent to research (in addition to parental consent).

A significant difference between the readability of information forms and novels and textbooks was found. Although the Tukey HSD test is not very powerful (i.e. does not generate significant differences as easily as other tests), we still detected significant differences with $p<0.001$ between the forms and novels, indicating large differences between the two. The novels were significantly easier to read than nonfiction books, and a non-significant trend was found for a lower readability of nonfiction books as compared to textbooks.

The nonfiction books were of the same readability as the forms, even though they contained similar topics as the (easier to read) textbooks. Remarkably, there is little spreading in the data for textbooks, even though the sample size is small (n=5). Information forms and nonfiction books show a lot of spreading, while these had a higher sample size than

the textbooks. A possible explanation for this difference is that school textbooks are bound to regulations more so than nonfiction books, and possibly are revised more extensively by writers as well as teachers. The lack of specific regulations for nonfiction books and research information forms leaves room for interpretation of the reader's capacities by the writer.

Visuals and comprehension

Only three information forms out of 22 used visuals to clarify the information in the document. In one form, medical scanning procedures were explained next to photographs of the patient's position on the apparatus. In another, a visual vaccination schedule was supplied to illustrate the study procedure. The third document had a picture next to each new paragraph, and an illustrated overleaf, as in a brochure. All of the other documents consisted of plain text, and the resulting overall average picture-text ratio of the forms was very low.

All children except for 2 (=97%) voiced a preference for visuals in books and texts, to create an image of what they were reading. The children considered the nonfiction books easier to read than the forms, even though both had a comparable readability. We hypothesize that this difference is explained by the presence of visuals in the nonfiction books, decreasing the cognitive load of the text and supporting the creation of mental models required for reading comprehension (Mayer, 2001). Indeed, when visuals were added to the information form it was better understood by most children than the original only-text sample. Children rated nonfiction books with a high picture-text ratio more positively than books with a low picture-text ratio. It is noteworthy that children themselves suggested that there should be just as much images as text or more. Possibly, children unconsciously estimate the picture-text ratio of a text before they start reading.

In the book that was designated the most favorite by the majority of the children, the images contained a lot of information, portraying processes, structured by arrows and captions. The amount of text on the page was low, which resulted in a high picture-text ratio.

A combination of an attractive lay-out, pictures and explanations might make the text look understandable for a child. If children feel that they are unable to understand a text, they might become discouraged and, as a consequence, indeed understand less of the text. But when a text lay-out gives the reader the feeling that it is readable, regardless of

its actual readability, it might have a positive influence of the comprehension level, and stimulate children to read and make an effort to understand the information.

Children's preferences for visuals

Children made it clear that visuals should be informative, rather than only decorative. Almost all children expressed a need for guidance by captions next to illustrations. In addition, there was a need for clear and concise explanations of terms and difficult words, within the text itself, or in a small box on the same page. It is important to children that visuals are attractive in color, size, and content. The children generally preferred realistic images, such as photographs or 3D images. Some children preferred drawings, while others thought drawings were childish. Surprisingly, almost all children liked funny cartoons, which are essentially drawings as well. The funny aspect of cartoons was appealing to them, because they would prefer a text not to be too serious. Naturally, research information is of a serious nature and the use of funny cartoons and 'exciting' pictures might not be appropriate. However, the idea to use cartoons to explain medical information is not new and can be very effective, if they are used in a considerate way (M. J. Green & Myers, 2010).

The children indicated they would consider reading a text of which they found the topic not very interesting, if it had attractive features. On the other hand, if a text would not contain any visuals, they would likely not read it.

Children were very enthusiastic about improving the information forms with their own ideas. After consulting the children about the form, one boy actually said: '*I'm just thinking by myself right now that I would like to know more about DNA and stuff, it seems quite interesting to me.*'

Children aged 12 are likely capable of coping with difficult words or processes if only these are explained to them well. An effective explanation raises interest, such as in the quotation above, which helps a child to be motivated to keep reading the rest of the text.

Limitations

In addition to readability and format of information forms, other factors also play a role in the quality of these forms, such as selection of the content, or use of fonts and colors. In addition, emotions towards the information content might differ between medical information and books and might influence understanding. These aspects were not included in our analysis.

The context of the focus groups was different from the situation were a child in the hospital receives medical research information, in that the children only read an excerpt of the form and that they had no personal relation or emotional connection to the information. Further research should address these factors.

The instruments used for readability measure length of words and sentences, but differences might exist in length of words between languages. In addition, length of words or sentences is not the only factor influencing readability, as long every-day words might be much easier to read than short medical terms. Thus, the readability analysis should not be considered to give an absolute judgment on readability, but rather a rough indication of the current standard of pediatric consent forms.

In addition, a possible bias might have occurred in the selection of the forms. Forms were obtained via the IRB and via individual researchers. Selection therefore was partly dependent on the willingness of researchers to offer their forms for analysis.

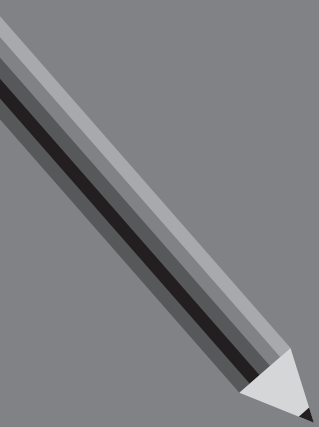
Conclusion and Recommendations

As children and adolescents have a growing influence in the consent process, they need to understand the information provided. Our readability analysis on 22 pediatric forms from 2 out of the 6 large Medical Centers in the Netherlands demonstrates a very low readability for the majority of the forms. Some of the analyzed forms were very long and only 3 forms did contain visuals, which could greatly support understanding of the information (Mayer, 2001).

To improve reading comprehension, information material and consent documents should be written with the average reading level of the target group in mind, using plain language (J. B. Green, Duncan, Barnes, & Oberklaid, 2003; Houts et al., 2006; Lorenzen, Melby, & Earles, 2008; Terranova et al., 2012). Guidelines on writing research information and other medical information material are necessary. In the Netherlands, where the current study was performed, the Central Committee on Research involving Human Subjects (CCMO, 2008b) provided a writing guide for consent documents. However, these guidelines only mention the preferred Flesch Reading Ease for adults (58-65), but do not mention pediatric documents. The same is true for the 'Second Evaluation of Research Involving Human Subjects Act', which contains advice to write clear texts for adults, but no word is spent on the pediatric situation (Stukart et al., 2012).

Therefore, we suggest that pediatric material should be written at a grade level 6 or 7 or a corresponding Flesch Reading Ease of 80. This level indicates that texts are readable for someone who has received 6 or 7 years of reading education, which applies to children of 12 or 13 years old.

We are aware that changing length of words and syllables as measured by these indexes is not the only factor to improve understanding. Also, at times it can be impossible to approach this high readability when explaining medical information. And even when a suitable readability is met, the medical terminology might discourage the reader and reduce comprehension. Therefore, we strongly encourage the use of visuals in research information forms. There is a strong theoretical framework for the supporting effect of visuals in reading comprehension, even more so in younger children with a relatively inefficient working memory capacity and higher risk for cognitive overload (Glenberg & Langston, 1992; Mayer 2001; Pike et al., 2010). Our study has demonstrated that even text with a readability that is theoretically too low, can be understood by children when sufficient visual support is provided. Visuals can motivate children to pick up a text and keep reading to the end, and are a powerful tool to increase their comprehension of the medical information. The forms studied were directed at the age range of 12-18, in which children develop into adolescents and preferences change. Therefore, further studies are needed to investigate visual use and preferences among adolescents ages 13-17. Future research should address the effectiveness of visuals in medical information (both research and treatment) in a non-simulated setting, with the entire form instead of an excerpt, tested in the hospital with prospective research or treatment participants.



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