

The Write Stuff



Patient information leaflets: Writing for children and adolescents

by Virginia Watson

Children and young people recruited into clinical trials need to be provided with information about the study and, if deemed old enough, will be required to assent to participation. Indeed, parents and physicians should not exclude children and adolescents from decision-making; all people involved in children's healthcare should listen to children [1].

The ICH E11 Guideline states that fully informed consent should be obtained from the parent or legal guardian but also states that "participants should be informed to the fullest extent possible about the study, in language and terms that they are able to understand". In 1995, the American Academy of Paediatrics issued a policy statement that "a patient's reluctance or refusal to assent should also carry considerable weight when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk". The Declaration of Helsinki also includes a statement on the need for the "minor's consent to be obtained in addition to that of the minor's legal guardian".

According to the ICH E11 age categories, children are aged 2 to 11 years and adolescents are aged 12 to 17 years. The age for assent is usually determined by the IRB/Ethics committee and local legal requirements, but in practice, for the purposes of providing written medical information to children for assent to a trial procedure, we are probably looking at those children aged six and upwards. This is a very broad age band and range of intellectual development. Often one Patient Information Sheet (PIS) is produced for children aged 6 to 11 years and one for the 12- to 16- or 18-year-olds. Nevertheless, if you think about it, what is written for a six-year-old is unlikely to be suitable for the average 11-year-old. Having said that, I have been told that when informed consent forms are written for both children and adults, many adults read and absorb the information from the children's PIS!

Children's understanding of illness and hospital is different from adults'

Are children old enough to give assent? Several surveys suggest that a young child will do what Mummy and Daddy think best; a 9-year-old will want to have a say but will leave the final decision to their parents; and young people of 12 and upwards want to have some degree of control and input into the decision.

So what should we as medical writers consider when producing patient information for children and adolescents? First and foremost it is important to think about the needs of the children we are writing for. What does the reader need to know and how should we present it?

Children's understanding of illness and hospital is very different from that of adults. In

1 article 12 of the UN Convention on the Rights of the Child

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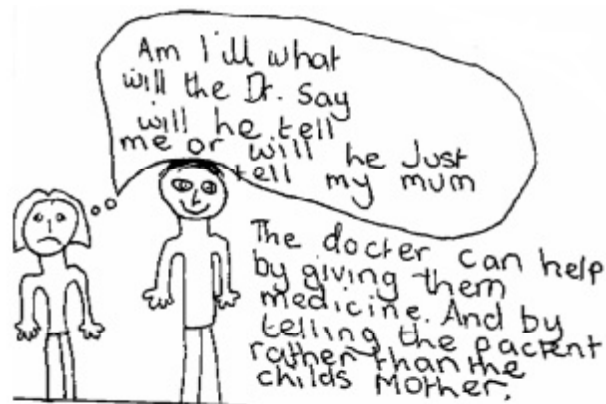
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1995, a project in 254 children was conducted in the UK by Action for Sick Children, a charity to improve the standards and quality of child healthcare. It emerged from this survey that the main concerns in children were

- What will they do to me and will it hurt?
- Will I get better?
- How long will it take?
- What will the doctor or nurse be like?
- Will the doctor talk to my mother/father – why not tell me what is going on?
- What am I missing: school, holidays, friends?
- Will it embarrass me?
- Will it help to cure others?

There is also a tendency for children to feel that it is their fault that they are ill: that, somehow, they are to blame.

The adult PIS contains all the GCP elements and so not all these points need to be covered in the children's assent information. Before starting to write, decide the age range for each of the information sheets you are writing.



Maybe you will decide on one for the 6- to 8-year-olds, one for those aged 9 to 11 years, another for 11 to 14 years and one for the 15- to 18-year-olds. Next, think about the information you need to impart and how to address the children's concerns, remembering also that some of the older participants may be smoking, drinking, abusing drugs and may be sexually active. Also, it is important to realise that a child's perception of time is different from that of an adult, so try to relate study visits to periods of time that mean something to them such as the school term, holidays, after school, etc.

Then, I would suggest you look at examples of material written for children/adolescents of that particular age group – comics, books, etc. Look at language used in TV programmes, videos and on websites. Use clear language. Think about the number of sentences per paragraph and page – these will vary according to the age you are writing for. For young children use short and simple words, for adolescents try to use words to which they can relate.

You don't have to use A4 paper; A5 is a better size for children to handle. Think also about the presentation style – don't use font size 12, go for 18 or 20 and Arial or Comic sans are more suitable font types. There is nothing to stop you using colour print. Although illustrations, cartoon characters and comic strip presentation may be an effective means of communicating medical information to children, I would not regard these as appropriate in the context of the PIS for a clinical trial. As with adults, consider any

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cultural issues that you may need to cover and, most importantly, avoid information overload. Also, don't be patronising or talk down to them, whatever the age of the child.

Writing for children does mean adapting your style of writing and thinking very carefully about your reader. It certainly requires the ability to use Plain English. It does, however, add an interesting dimension to our work as medical writers.

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Note: The child's drawing pictured in this article is republished with permission from the book 'Pictures of Healthcare – a Child's Eye View' published in 1998 by Action for Sick Children. More information about this charity, which seeks your support, can be found at www.buy.at/a4sc.

CALL FOR WORKSHOP LEADERS

Would you like to contribute to EMWA by developing and running a workshop?

The EMWA Professional Development Committee (EPDC) would like to expand the range of workshops offered at the Annual Conference and November Meetings and are inviting proposals for foundation, advanced and short workshops.

All topics are welcome but we are also looking for workshop leaders for the following:

- Developing Research Materials into Articles
- Grant Writing
- Scriptwriting for Multimedia
- The Investigational Medicinal Product Dossier (IMPD)
- Writing About Health and Medicine for Magazines
- Writing Abstracts

If you would like to submit a proposal for a workshop, or are thinking about it, but would like to know more, please contact me or any member of the EPDC (www.emwa.org).

The Workshop Leaders' Handbook contains information on workshop format, workshop approval, templates, train-the-trainer training, expenses and other matters of interest to workshop leaders. A member of the EPDC will act as a mentor and provide support during the development of your workshop.

New ideas for workshops are welcome at any time, even if you do not wish to be a workshop leader yourself – you might also wish to suggest a leader.

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