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Title

Development of the Child Amblyopia Treatment Questionnaire (CAT-QoL): a disease-specific health related quality of life (HRQOL) measure for amblyopia.

Author: Jill Carlton[1], MMedSci, BMedSci

[1]University of Sheffield, Sheffield, United Kingdom

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Abstract

Purpose:

To develop a pediatric disease-specific health related quality of life (HRQOL) instrument for amblyopia.

Methods:

In a development phase, 59 children (age 45-119 months, average 6 years 3 months) with amblyopia were interviewed. Interview transcripts were analysed to identify items and levels for the descriptive system. These were used in a piloting phase which was completed by 32 children who were undergoing amblyopia treatment. Ranking exercises and cognitive debriefing were used to modify the developed descriptive system.

Results:

Following the cognitive debriefing and ranking exercise, the draft questionnaire was modified. Eleven items were identified relating to the health-related implications of amblyopia treatment. Seven versions of the Children's Amblyopia Treatment Quality of Life Questionnaire (CAT-QoL) were developed (patch; drops; glasses; patch and drops; patch and glasses; glasses and drops; glasses, patch and drops).

Conclusions:

Children were able to identify their thoughts and opinions of their own health; and to find out what impact their amblyopia treatment has had upon their daily lives. They are able to understand and articulate what it is they feel and have experienced because of their eye condition. Version 1 of the

CAT-QoL is currently being undertaken at a number of sites in England. This data will be used to assess the psychometric properties of the CAT-QOL, such as reliability and responsiveness. This measure can then be used in healthcare studies to investigate the impact of amblyopia treatment upon a child's HRQoL.

INTRODUCTION

The health related quality of life (HRQOL) implications of amblyopia are recognized(1-12;12-20), however, the way in which these have been described are largely via parent (or proxy) reporting (2;3;5;10;12;21); and the measures used to measure the HRQOL impact have been derived from clinician expert opinion.(2;3;5;10;12;21;22) Recent Food and Drug Administration (FDA) guidance on patient reported outcome measures (PROs) state that the purpose of a PRO measure is "to capture the patients experience, an instrument will not be a credible measure without evidence of its usefulness from the target population of patients".(23) They "discourage proxy-reported outcome measures" for the pediatric population.(23) Existing measures of HRQOL for amblyopia do not meet these recommendations. The purpose of this study was to develop a pediatric disease-specific HRQOL questionnaire for amblyopia. The study comprises of a number of stages; a systematic literature review(24); focus group sessions and analysis(25); development of the descriptive system; and assessment of the psychometric properties of the questionnaire. The literature review identified HRQoL implications of amblyopia and/or its treatment(24) to inform a topic guide used for three focus group sessions undertaken with clinicians. Focus group sessions were conducted to identify any additional HRQoL implications of amblyopia and/or its treatment not previously identified in the literature review(25). This paper reports upon the development of the descriptive system for the Children's Amblyopia Treatment Quality of Life Questionnaire (the CAT-QOL).

METHODS

Developing the descriptive system of the CAT-QoL

Semi-structured interviews were conducted with children who satisfied the inclusion criteria for the study. Full ethics approval and research governance had been sought prior to commencement of data collection. The interviews were conducted at two sites within Sheffield, United Kingdom (UK). All applicable institutional and governmental regulations concerning the use of human volunteers were followed during this research. The research followed the tenets of the Declaration of Helsinki. Full ethics approval and research governance was obtained prior to commencement of the study (REC Ref: 07/Q1201/5, Airedale Research Ethics Committee).

The inclusion criteria were that the child was aged over 4 years, and either had, or previously had, a clinical diagnosis of amblyopia. It was not possible to identify prior to clinical examination to identify potential participants, and therefore purposive or criteria-based sampling of the eligible study population was not possible. Instead an opportunistic recruitment (and therefore opportunistic sampling) approach was undertaken. Potential participants were informed of the study by their clinician following their scheduled consultation. Information sheets were issued to each potential participant and their parent/guardian. Written consent was obtained prior to the interview taking, by one researcher (JC). The interviews were conducted in clinic rooms.

Each interview was audio recorded, allowing the researcher to devote their full attention on the interview itself.(26) At the start of the interview, it was explained to the participant that this would be taking place. Whilst the recording device and microphones are small and unobtrusive, it was felt necessary to explain why they were there; as such equipment would not normally be seen in the clinic rooms. It was also used as an opportunity to explain that non-verbal communication would not be picked up on the microphones, and to encourage the child to vocalize their feelings instead. All interviews were undertaken by one researcher (JC).

The interviews were transcribed verbatim. The transcripts were imported into QSR NVivo 8, (QSR International, Doncaster, Australia) a computer-assisted, qualitative data analysis software package, to manage the data and to facilitate analysis. The analysis was guided by the research question; “how does amblyopia and/or its treatment affect children’s lives?” The aim was to identify dimensions of their HRQoL. Thematic content analysis was undertaken using Framework (an approach developed by the National Centre for Social Research(26)). Thematic content analysis is one approach to qualitative data analysis; where themes are identified in which both the content and context of documents are analyzed.(26) Framework is an analysis method developed by the National Centre for Social Research. It follows the principles of classifying and organizing data according to key themes, concepts and emergent categories.(26) A group of experienced and independent qualitative researchers validated the analysis. The conceptual Framework was reviewed, and samples of the transcripts were checked for coding consistency.

Qualitative Analysis of Interviews

Identifying initial themes or concepts

Each transcript was reviewed several times in order to become familiar with the data. Key phrases, sentences and words were identified that related to HRQoL and amblyopia and/or its treatment. Emergent themes were identified. The transcripts were then re-examined and coded according to the identified themes. The sentences were written verbatim, to keep the terminology and phrasing used by this patient group, and to ensure that age appropriate language and phrasing be used in the developed questionnaire.

RESULTS

In total 59 children were interviewed, although it should be noted that not all of the interviews resulted in data that could be used for analysis. Some of the interviews were terminated as the child was unresponsive (n=5). Only seven interviews were conducted with the child alone (n=7). The vast majority of participants were White (which was representative of the clinic population of Sheffield, UK). Table 1 shows a summary of the characteristics of the study population. Postcode data of each participant was used to categorize participants into socio-demographic classes. Despite the opportunistic sampling approach, a balanced demographic sample was achieved in relation to age, social class and amblyopia treatment modality (Table 1 and Table 2). The mean logMAR interocular difference in visual acuity (VA) (difference between VA in the dominant eye and VA in the amblyopic eye) was 0.21; with a range of 0.725 and 0.0 log units (median 0.15 log units). Of the 59 children interviewed, all were on some form of treatment (either glasses; patch; drops; or a combination of these).

Co-morbidities as documented in the notes were recorded. The majority of participants were in good general health. Some of the participants did have recorded co-morbidities (listed in Table 1). It is possible that other co-morbidities did exist in the study population, but that these were not severe enough to warrant hospital treatments and investigations. These participants were assumed to be in good general health.

The majority of the children coped well with the interviews. However, a number of interviews did need to be terminated, either at the request of the child, or if the child was unresponsive. Interviews varied in length from 1min 25secs to 15mins 34secs; the majority of interviews lasted in the region of 6mins. Recruitment continued until data saturation was reached; and the number of interviews conducted exceeded this point. This increased the confidence that saturation was reached.

Identified items for the draft version of the questionnaire

Eleven possible items were identified through the qualitative analysis of the interviews. A sample of some of the direct quotations from the study participants are shown in Table 3.

1. *Physical sensation of the treatment (e.g. feeling of the patch/glasses on the face, or the feeling of the drops being instilled)*

The children noted that some of the sensation of some of the treatments for amblyopia affected upon their HRQoL. These stemmed from the physical sensations experienced by having something on their face (either a patch or glasses). Other children spoke about the feelings of having the drops (atropine) instilled.

2. *Pain of treatment (e.g. removal of patch, instilling of drops)*

Some children reported that treatment for amblyopia was painful or uncomfortable. This was often associated with the wearing of a patch, and more specifically removing the patch at the end of the treatment period. Similarly, some children reported that when the drops (atropine) were instilled, these would often sting or make their eyes water. A number of children also reported that their glasses were uncomfortable.

3. *Ability to undertake school work*

This item originated from children's responses/thoughts about how their condition, or more specifically their treatment, influenced upon their ability to function at school. Some of the comments were positive in nature, although mainly it was difficulties in undertaking tasks that were highlighted. The children noted that the ability to read and write was affected to varying degrees.

4. *Ability to undertake other tasks (like playing on the computer, coloring, playing games, watching TV)*

The children also noted that their amblyopia treatment also influenced upon their ability to undertake other tasks. These were mainly hobbies and interests (such as watching television or playing on computer games.

5. Feeling sad or unhappy

Some children reported that their treatment made them feel happy, whereas others stated that having to wear their patch or have drops instilled made them feel unhappy.

6. Feeling cross

Some children stated that having to wear their patch or have drops instilled made them feel angry or cross.

7. Feeling worried

Some children reported that their amblyopia treatment made them feel nervous or worried. In some cases this related to worry about pain or discomfort (for example, from the drop being instilled); or for others about what they would look like when they had the patch on. For example:

8. Feeling frustrated

Some children reported that they felt frustrated at times due to their amblyopia treatment. This was often reported in conjunction with the ability of undertaking daily tasks, or in affected relationships with others.

9. Feelings towards family members (like parents or siblings)

This item originated from children's responses/thoughts about how their condition and/or treatment affected their relationships with others. To some this was relationships with parents and other family members. Children described that they would argue with their parents about having to have their treatment. Some went on to say that they would get cross with their parents.

10. Being able to play with other children

Some children discussed how relationships with their friends were affected because of amblyopia treatment.

11. Being laughed at or bullied by other children

Some children discussed bullying, such as name-calling and exclusion from games/friendships. To some, this was raised as something they had directly experienced; however, others mentioned that they were more worried or concerned about what their friends/peers would say if they undertook their amblyopia treatment (patching) at school.

Developing the levels for the draft questionnaire

Having identified the items for inclusion in the draft questionnaire, the levels of the items needed determining. There was an option of looking at either "frequency" (how often something occurred) or "severity" (how bad something was). The "severity" option was used. The interview transcripts were re-examined to determine the levels for the draft questionnaire. The terminology the children used informed the choice of levels. These were "a little bit"; "a bit", "quite a bit"; "quite"; "a lot"; "really"; and "very". These were used to describe by the children to describe their feelings about given items. Not every level was used for each item, and as such three categories of questions were established (Table 4).

Testing the pilot questionnaire in a clinical setting

An 11-item draft questionnaire was piloted in a clinical setting in Sheffield. The inclusion criteria were adopted from the interview-stage. Children were asked to read and complete the draft questionnaire where possible. In addition, they were asked to complete a ranking task to help determine the order of the levels of the items. Thirty-two (n=32) participants completed the pilot; 22 of these were able to complete the ranking exercise (Table 5).

Results of ranking

For the ranking exercise, a question was chosen from each of the categories (A, B and C). The questions chosen were “hurt”, “cross” and “upset with family”. Participants were asked to rank the order of severity from least to worst. When a card was ranked first, it was scored 1; when ranked second it was scored 2; and so on. Where cards were ranked as being equal, each tied ranking was given a value of the midpoint as the previous two marks (mid rank method). This approach ensures that the sum of the ranks is maintained. The results for the mean rank, standard deviation, minimum and maximum position for each question are shown in Table 6.

A small difference between the rankings indicates that the participants view the two levels to have a similar meaning. The results show that within the category B question ("cross"), "my drops made me feel really cross" and "my drops made me feel very cross" were valued as being the same (difference of -0.09). The negative value indicates that "very" can be placed above "really". In the category A question ("hurt") there is a *possibility* that participants believe "my drops hurt me a lot" and "my drops really hurt me" to be the same (as shown by a difference of 0.23). Table 7 shows the mean rank order and the difference in mean rank order between the levels.

Cognitive debriefing

Children who participated in the pilot were asked to participate in a cognitive de-briefing process. Cognitive interviewing is a process whereby participants are asked to explain their thinking, or understanding of a question. The process is used in the development of questionnaires to help identify and correct problems with survey questions.(27) Within this study, participants were asked to explain what they believed the question was asking them. The results were recorded, and clarification sought where applicable. Observations were also made as to the child's ability to read the questionnaire itself. Particular attention was made as to which words the participants struggled to read.

Modifications to draft questionnaire

Following the cognitive debriefing and ranking exercise, the draft questionnaire was modified. Based upon the ranking exercise analysis, the "really" level was removed from all category B questions. Other modifications included alterations of words easier for the child to understand or read; or reducing the number of words for a given question where possible. The purpose was to make the overall task easier for participants.

One question was omitted in it's entirety from the draft questionnaire ("feeling frustrated"). The majority of participants in the cognitive de-briefing had to have the concept of "frustration" explained to them. Even after an explanation was given, some children still did not understand what was meant by the term. The omission of this question is justified. Firstly, if a child has to have the concept explained to them, can they have experienced that emotion; secondly, if an explanation needs to be given then this limits the scope of self-completion of the questionnaire; and finally, the word itself is difficult for a child of 5-7 years to read.

The wording of one question was modified ("upset with my family") because of the de-briefing. Participants reported that they did feel upset due to their treatment, but not upset with their family. The interview transcripts were then re-examined to explore this further. Subsequent analysis demonstrated that the "upset" should be used as an item; just as "sad" is. The items are the consequence of the treatment, and not a description of why they feel that emotion.

An additional question was included in the draft questionnaire ("happy"). As part of the de-briefing process, participants were asked if they felt anything else about their patch, drops and/or glasses. A number of children reported that they felt happy. The transcripts of the interviews with children were then re-examined, and analyzed again to explore the possibility of happy as an item in the questionnaire. Seven different versions of the questionnaire are available, depending upon the treatment the child is undertaking (patch; drops; glasses; patch and drops; patch and glasses; glasses and drops; glasses, patch and drops). An example of Version 1 of the developed questionnaire is available in Supplementary Material.

DISCUSSION

The use of PROs is becoming increasingly common in the United States, United Kingdom and worldwide. They can provide information that may aid clinical decision-making. Whilst their results can inform us of the impact of the condition upon a person's quality of life, it is important to know about the instrument itself, specifically how it has been developed and validated. The instruments Amblyopia Treatment Index (ATI) and Amblyopia and Strabismus Questionnaire (A&SQ); used a top down approach in the development of the descriptive system (i.e. clinician opinion and literature based). This approach is not uncommon, and details of their development, including psychometric properties of the instruments are publicized (2;3;5;28-31); however, where a bottom-up approach (taking the views and input of patients) has been used, little detail is available on the qualitative techniques adopted.

This research has demonstrated that it is possible to interview young children in order to identify their thoughts and opinions of their own health; and to find out what impact their amblyopia treatment has had upon their daily lives. They are able to understand and articulate what it is they feel and have experienced because of their eye condition. The majority of the interviews were successfully completed; with only a small number abandoned due to non-responsiveness of the child.

A notable strength of this study is that it used the children's responses at every stage in developing the descriptive system; from identifying the items to be included; the levels for each item; and the wording of the questionnaire itself. Comments given by the children during the cognitive debriefing process were also used to alter the layout and format of the measure itself. This helps ensure the content validity (the degree to which the content of a questionnaire is an adequate reflection of the construct to be measured) (32); and face validity of the instrument. This adheres to the recommendations of the FDA who observe that issues for PRO instruments applied to children include "age-related vocabulary, language comprehension, comprehension of the health concept measured, and duration of recall".(23) Children have the capacity to reliably report upon their health between the ages of 4-6 years (33-35); the development of the descriptive system of the CAT-QoL involved participants of this age.

The research was not without limitations: the main being that the majority of interviews were conducted with the parent/guardian present. The information sheet given to parents/guardians detailing the study did state that the child would be interviewed alone however; they could be present if they wished. There are advantages and disadvantages to a child being interviewed alone. Firstly, it could be perceived that the child would be free and comfortable to express their thoughts, without a risk of upsetting their parents. Interviewing a child alone can appear quite confrontational. It could be argued that the children did not feel able to speak freely about their feelings about treatment for fear of upsetting their parent/guardian. There were times during interviews when the children would look to parents for reassurance; these were noted and taken into consideration during the analysis. Interviewing children alone can compromise the researcher when considering the possibility divulging potentially sensitive information about treatment, bullying or family dynamics. The debate surrounding the appropriateness of this form of data collection in children is complex. For the purpose of this study, all interviews were conducted in a manner to satisfy parent/guardian’s wishes. The use of focus groups may have allowed discussion of ideas between participants; however, this approach was not taken due to the potential sensitive nature of some of the issues raised.

The interviews were conducted in the Eye Clinic. There are notable advantages and disadvantages associated with this approach. Firstly, the child is familiar with this environment. They will have attended the clinic on a number of occasions prior to interview. A disadvantage could be the perceived notion that the interview has some link or association with their treatment. It is possible that the responses given by the child participants were not entirely honest or open. It may be that they believed the interviewer to be a clinician, so that they could not say that they hated their patch for example, in case they were “told off”. Every effort was made to ensure that the child participant was aware that we were interested in their thoughts and feelings; and that the interviewer was not a clinician; and that all the information they provided was confidential.

It is acknowledged that the interviews were conducted in one area of the UK, due to resource constraints. It is not certain whether the results of the items generated can be applied to the UK population as a whole. The sampling approach taken attempted to include a breadth of experiences. In qualitative methodology, the aim is not to achieve statistical representativeness, but to capture the experiences of a given population (interviewing until data saturation has been reached).(26) The piloting of the CAT-QoL is currently being undertaken at a number of sites in England. A wider breadth of socioeconomic diversity should be achieved during this stage of the study. The aim is to achieve a large sample size, due to the greater variability expected in younger children as a result of measurement error.(36) This data will be used to assess the psychometric properties of the CAT-QOL, such as reliability and responsiveness. This measure can then be used in healthcare studies to investigate the impact of amblyopia treatment upon a child’s HRQoL.

Table 1 Characteristics of the study population

Gender	
Male	36
Female	23
Ethnicity	
White	54
Mixed (white and Asian)	1
Asian – Pakistani	1
Chinese	1
Black (African)	1
Other	1
Socio-demographic group*	
1 (0-6500)	21
2 (6501-13,000)	7
3 (13,001-19,500)	14
4 (19,501-26,000)	12
5 (26,001-32,500)	5
Co-morbidities	asthma and glue ear; speech problems; mild joint hypermobility; otis

	media; juvenile arthritis and Still’s disease; Caeliac's disease, anaemia and failure to thrive; chronic lung disease and conductive hearing loss; mild eczema; Attention Deficit Hyperactivity Disorder (ADHD) and Asperger’s syndrome; history of prematurity, and delayed speech; fourth nerve palsy, rhabdomyosarcoma of bladder and prostrate; Auditory language disorder and seizures; and Familial syndrome, facial dysmorphism, short stature, and restricted joint movement
Interocular Visual Acuity (VA) difference in logMAR	Mean 0.21 log units Median 0.15 log units Min 0.0 log units Max 0.725 log units

* calculated using GeoConvert(37) to obtain a Lower Super Output Areas (LSOAs) ranking. There are over 32,000 LSOAs in England. The LSOA ranked 1, by the Index of Multiple Deprivation (IMD) 2007, is the most deprived; and that ranked 32,842 is the least deprived.(37)

Table 2 Summary Sampling Grid: Age and treatment modality

Age(years)	**Patching Now**	**Patch Ever**	**Atropine Now**	**Atropine Ever**	**Glasses Now**
3 (n=1)	1	1	0	0	0
4 (n=6)	5	1	0	0	4
5 (n=20)	16	5	3	4	18
6 (n=14)	9	6	4	2	12
7 (n=13)	7	9	2	2	13
8 (n=4)	1	3	1	1	4
9 (n=1)	0	1	0	1	1
TOTAL (n=59)	39	26	10	10	52

*Categories are not mutually exclusive

Table 3 Items identified for inclusion in draft questionnaire and supporting quotes

Item	
1. *Physical sensation of the treatment (e.g. feeling of the patch/glasses on the face, or the feeling of the drops being instilled)*	I: What does it feel like when you've got your patch on? P: Er, a bit tickly P: I just, it just itches a bit near the eye... (*patch*) P: It makes my tears; some tears come down (*atropine*) P: It tickles (*patch*) P: It feels a bit rough (*patch*) P: Erm, well it's a bit hard to blink sometimes, because your eyes can get caught on the sticky bit (*patch*) I: What don't you like about wearing the glasses...? P: When they are rubbing on my ear...
2. *Pain of treatment (e.g. removal of patch, instilling of drops)*	P: Because when I take it off it hurts (*patch*) P: It kept rubbing on my face and it hurt…. (*patch*) P: It feeled that when I took it off it hurted, and when I weared it, it tickled (*patch*) P: Yeah, and they always made a red mark around my eye (*patch*) I: It did, did it? Was it one of those patches that stuck on your face? P: Yeah. They really burnt when they took it off cos it actually took some hair off my eyebrow!

	I: ... Why don't you like wearing it? (*patch*) P: Because it hurts when I take it off P: Well it starts, stings and it wears off a bit (*drops*) P: Er, my nose starts rubbing on both sides (*glasses*) I: On both sides of your nose. And what does that make you feel? P: It just hurts
3. Ability to undertake school work	I: Do you like wearing your glasses at school as well? P: Yeah I: Yeah, why do you like wearing them at school? P: Because they're better to see stuff I: Can you still see everything that you need to see when you've got your patch on? P: Not sometimes cos it blocks one of my eyes. And say,…. I can't see writing, I can't…. I: So is the writing like, things in books, or like your homework, or? P: My homework, any kind of writing I: And when you had that patch on, could you, you know, still see everything that it was that you needed to see? P: Yeah, when I needed to look, do numeracy work… I: ... why does it bother you? P: Cause when the teacher writes on the board I can't even see. Cause I sit right at the back I: Is there anything that you can't do when you've got your patch on?

	P: Er, well, I can’t write letters right straight… I: Was there anything harder to do because you had your patch on? P: Writing I: When you were wearing your patch, you said to me that you wore it at school and at home. Which was better, wearing it at school or wearing it at home? P: Er.. home I: At home, why was it better at home rather than school? P: Because at school when I am doing the work, because the eye was covered it was harder to do things
4. *Ability to undertake other tasks (like playing on the computer, colouring, playing games, watching TV)*	I: ... Is there anything that you can’t do when you’ve got your patch on? P: I can’t play with the bricks... Because you know what, I tried I tried to make a monster but it all goes wrong I: Was there anything that you couldn’t do when you had the patch on? P: *nods head*... Painting things I: Why don’t you like it (*patch*)? P: Because when I go on Xbox360 I always get killed I: And what is it that you don’t like about them (*patches*)? P: Erm, well the way that when they get pulled off and it’s because when I am playing on the Wii, I can’t concentrate very much I: Is there anything that you can’t do when you’ve got the patch on? P: Go swimming I: Was there anything more difficult to do because you had the patch on? P: Yeah, probably going on the computer and stuff... It sort of blurred

	I: What’s more difficult to do when you’ve got your patch on? P: Like when you try, when you try like, try to see, erm, like chairs and stuff. You can’t see your way, when you’re not having it I: You know when you’ve got your patch on, is there anything that you can’t do when you’ve got your patch on? P: Erm, eating my dinner
5. Feeling sad or unhappy	I: Some people don’t mind wearing their patch. Some people are really happy about it. How do you feel about wearing it? P: Erm, sad I: So apart from it feeling funny on your face, the patch on your face, how did it make you feel? P: Unhappy I: How does it make you feel when they tell you it’s time to wear your patch? P: Erm it makes me feel sad because I want to play on the computer now but I don’t want to wear my patch when I am playing on the computer because it’s hard to see I: Do you feel happy or sad because you’ve got to wear glasses? P: Happy I: You feel happy. And why do you feel happy about it? P: Because it makes my eyes see much farer I: OK. And do you feel happy or sad about having to wear a patch? P: Sad I: How does that make you feel, that it’s only you that wears a patch?

	P:	Er... sad
	I:	It makes you feel sad. Why do you feel sad about it?
	P:	Because it,... you don’t like it on your eye. When you first like, when you first like, when the like say you have to wear a patch, and you feel like you have to have the patch on , its fun and when you start wearing it it’s not fun
	I:	Its not fun. What’s not fun about it?
	I:	Because .... because if you put an eye patch on its sticks harder, and when you try to take it off it hurts
	I:	How does it make you feel having to wear the patch?
	P:	Sad, because I didn’t want to wear them at the start
	I:	Didn’t you? Why didn’t you want to wear them at the beginning?
	P:	Because I didn’t know what they felt like
	I:	Oh, yeah. I can understand why you’d feel a bit sad then, yeah. And how do you feel about them now?
	P:	Happy
	I:	Tell me what it feels like when they told you that you have got to wear patch. How did it make you feel?
	P:	Sad
	I:	It made you feel sad. Why did it make you feel sad?
	P:	Because I didn’t want to wear them
6. Feeling cross	I:	Yeah, and what does that feel like? (*having drops in*)
	P:	Erm a bit, a bit cross
	I:	... what is it about them that you don’t like? (*patch*)
	P:	I don’t know, I just feel angry
	I:	So do you feel happy or do you feel sad when you’ve got your patch

	on? P: I feel,.. I feel a bit… I feel a bit cross I: Some of the boys and girls that I’ve spoken to, they’ve told me that sometimes they can get a bit cross with their mum or dad, or get a bit upset when they get told it’s time to put their patch on. Do you ever feel like that? P: I get grumpy I: You get grumpy do you? Why do you get grumpy about it? P: Because I hate… I hate putting the patch on I: You hate putting the patch on? Why do you hate putting the patch on? P: Just because it’s annoying P: Yeah, but with the sticky patch I get angry (SCH50)
7. Feeling worried	I: And what does it feel like when mummy puts the drop in? P: Erm…. A little bit nervous I: Now I’ve never had to wear a patch, so I don’t know what it feels like. Can you explain what it’s like to have to have a patch on? P: It feels….. *(mumbles).* Disturbing I: Why did you choose to wear it at home? (*patch*) P: Because er, I thought I might look silly at school
8. Feeling frustrated	I: Has anyone ever said anything nasty to you about your eyes or your glasses or anything like that? P: Er, yes. Sometimes, only sometimes on certain days that I’ve been a little bit frustrated at school I: And what’s made you frustrated? P: Well, maybe if they’ve kicked me out a game when it was, maybe if they’re not letting me in a game or something like that, or they’ve been

	nasty to me and said nasty words maybe, I get a bit frustrated then
9. *Feelings towards family members (like parents or siblings)*	I: Did you and mummy used to have a fight about your patch? P: Yeah I: What, every day or just some of the days? P: Some days. I: Just some of the days. Why was it that sometimes you didn't want to have it on? P: Because I was watching tele and other times I was just mucking around I: And does your sister wear any glasses or a patch? P: No I: No, so it's just you…. MUM: She's always laughing saying "oh you look funny and this…." I: So does your sister say things about having to wear a patch? P: Yeah
10. *Being able to play with other children*	I: Why did you want to take your patch off? P: Cause, cause all the time that *** said I'm too thick to play, when I'm not I: Has anyone ever said anything to you at school about wearing your glasses? About whether you know, you look good with them on, or whether that you look silly with them on or anything like that? P: Sometimes like, sometimes when I'm playing a game and they say like we're playing "High School Musical" or something like that, and people, you know you're not supposed to wear glasses. They just like say "oh you've got to take them glasses off and put them somewhere" and I say "no", so I just go away and cry I: How did you feel when they said to you that you would have to wear glasses? Did it bother you?

	P: Yes I: It did. Why did it bother you? P: Quite a lot. I thought people would think I am a nerd and stuff I: Is there anything that you couldn’t do when you had to have your patch on?... What couldn’t you do then? P: Play with my friends I: Why couldn’t you play with your friends when you had your patch on? P: Because I could see them far away. But actually they were near me but that’s why I couldn’t play with them because I,.. because then I kept on going past them
11. *Being laughed at or bullied by other children*	I: No one has ever called you any horrible names or anything? P: No ….. Except when *** calls me a geek I: Why? Because you wear glasses? P: Yeah I: Has anyone ever said anything horrible or nasty to you because you wear glasses? P: *Nods head* I: They have? What have they said? P: Specky four eyes I: Do any of your friends know that you have to wear a patch? P: No, I haven’t told them I: Why didn’t you tell them? P: It was a secret I: And why was it a secret? Why did you decide not to tell them? P: Because they would just laugh at me

Table 4 Category of questions in draft questionnaire

Question	**Category**
Physical sensation of the treatment	A
Pain of treatment (hurt)	A
Ability to undertake work at school (like reading and writing)	B
Ability to do other things (like playing on the computer, colouring, playing games, watching TV)	B
Feeling sad	B
Feeling cross	B
Feeling worried	B
Feeling frustrated	B
Feelings towards family members	C
Being able to play with other children	A
How other children have treated you (like laughing at you, or calling you names)	A

A not; a little bit; a bit; quite a bit; a lot; really

B not; a little bit; a bit; quite; really; very

C not; a little bit; a bit; quite a bit; really, very (but ordered in question differently to B)

Table 5 Study participants for pilot of draft questionnaire

	N	Sex	Number of participants Age (yrs)				
			5	6	7	8	9
Questionnaire	32	16 male 16 female	14	8	5	4	1
Ranking	22	11 male 11 female	8	4	5	4	1

Table 6 Mean rank, standard deviation, minimum and maximum position for each question

	Question category	Mean	SD	Min	Max
My drops did not hurt me	A	1.00	0.00	1	1
My drops hurt me a little bit	A	2.45	0.77	1.5	4
My drops hurt me a bit	A	3.00	0.65	1.5	4
My drops hurt me quite a bit	A	3.59	0.77	2	4
My drops hurt me a lot	A	5.36	0.52	4.5	6
My drops really hurt me	A	5.59	0.43	4.5	6
My drops did not make me feel cross	B	1.05	0.21	1	2
My drops made me feel a little bit cross	B	2.36	0.71	1	4
My drops made me feel a bit cross	B	2.89	0.55	2	3.5
My drops made me feel quite cross	B	3.70	0.63	2	4
My drops made me feel really cross	B	5.55	0.41	5	6
My drops made me feel very cross	B	5.45	0.41	5	6
My drops have not made me get upset with my family	C	1.00	0.00	1	1
My drops have made me get upset with my family a little bit	C	2.50	0.71	2	4
My drops have made be get upset with my family a bit	C	2.91	0.72	2	5
My drops have made me get upset with my family quite a bit	C	3.73	0.83	2	6
My drops have really made me get upset with my family	C	5.20	0.70	3	6
My drops have made me get very upset with my family	C	5.61	0.43	5	6

Table 7 Mean rank order and the difference in mean rank order between the levels

	Mean rank order	Difference
My drops did not hurt me	1.00	1.45
My drops hurt me a little bit	2.45	0.55
My drops hurt me a bit	3.00	0.59
My drops hurt me quite a bit	3.59	1.77
My drops hurt me a lot	5.36	0.23
My drops really hurt me	5.59	
My drops did not make me feel cross	1.05	1.32
My drops made me feel a little bit cross	2.36	0.52
My drops made me feel a bit cross	2.89	0.82
My drops made me feel quite cross	3.70	1.84
My drops made me feel really cross	5.55	-0.09
My drops made me feel very cross	5.45	
My drops have not made me get upset with my family	1.00	1.50
My drops have made me get upset with my family a little bit	2.50	0.41
My drops have made be get upset with my family a bit	2.91	0.82
My drops have made me get upset with my family quite a bit	3.73	1.48
My drops have really made me get upset with my family	5.20	0.41
My drops have made me get very upset with my family	5.61	

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