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Identifying Items for the Child Amblyopia Treatment Questionnaire

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Identifying Items for the Child Amblyopia Treatment Questionnaire

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Number of Tables: 2

Date of Submission: 12th December 2012
ABSTRACT

Purpose:
Patient reported outcome (PRO) instruments are increasingly common in both clinical practice and research. The data obtained from these instruments can be used to help inform decision-making and policy-making decisions. The methodological approaches undertaken in developing PROs is not frequently reported. Literature on the development of the descriptive systems for PROs is sparse in comparison to the assessment of the psychometric properties of such instruments. The purpose of this study is to describe the methodological approach taken in identifying potential items for the Child Amblyopia Treatment Questionnaire (CAT-QoL); a paediatric disease-specific health related quality of life instrument for amblyopia designed for children aged 4 to 7 years.

Methods
Semi-structured interviews were undertaken with 59 children (age 3 yrs 9 months – 9 years 11 months; average 6 years 3 months) with amblyopia. Interview transcripts were analysed to identify potential items to be included in the descriptive system.

Results:
Eleven potential items were identified for inclusion in the Children’s Amblyopia Treatment Questionnaire (CAT-QoL) instrument.

Conclusions:
Children are able to identify their thoughts and opinions of their own health; and to describe 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. Items for the draft descriptive system for a paediatric self-reported amblyopia HRQoL have been identified.

Keywords:
1. Amblyopia
2. Health related quality of life (HRQoL)
3. Child
4. Questionnaire
5. Patient reported outcome (PRO)
The health related quality of life (HRQOL) implications of amblyopia are recognised however, the way in which these have been described are largely via parent (or proxy) reporting and the instruments used to measure the HRQOL impact have been derived from clinician expert opinion. Recent Food and Drug Administration (FDA) guidance on patient reported outcome measures (PROs) state that the purpose of a PRO instrument 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”. They “discourage proxy-reported outcome measures” for the paediatric population. Existing HRQOL instruments for amblyopia do not meet these recommendations.

The overall purpose of this study was to develop a paediatric disease-specific HRQOL questionnaire for amblyopia that could be used in research or routine clinical practice. The study comprises of a number of stages; a systematic literature review; focus group sessions and analysis; 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 to inform a topic guide used for 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. This paper reports upon the identification of potential items for inclusion in the Child Amblyopia Treatment Questionnaire (CAT-QOL).

METHODS

Interview Procedure

The study was approved by the NHS Research Ethics Committee (REC Ref: 07/Q1201/5), and followed the tenets of the Declaration of Helsinki. Semi-structured interviews were conducted with children attending Eye Clinics in Sheffield, United Kingdom (UK). The inclusion criteria were that the child was aged over 4 years, and either had, or previously had, a clinical diagnosis of amblyopia. Potential participants were identified following their scheduled consultation with the clinician.

A topic guide was used for the interviews. The topic guide contained themes to be discussed with the children, and not specific questions. The aim was to use the child’s responses to develop the instrument. If specific questions were to be used to interview the children, adults would have developed such questions (via clinicians’ input and informed by the literature reviews). This would be imposing adult perspectives on a child’s response; and would go against the purpose of interviewing children to develop an instrument for
children, by children. Therefore, the interviews were only guided by the themes detailed in the topic guide. The aim of the interviews was to identify how amblyopia and/or its treatment affect children’s lives, from the child’s perspective. Children were encouraged to talk about their amblyopia treatment via open-ended questions. Such as “tell me about your patch” and “what does your patch feel like”? The child’s responses were probed to try to identify what aspects of the treatment impacted upon their daily lives. Each interview was recorded, allowing the researcher to devote their full attention on the interview.\(^\text{18}\)

**Qualitative analysis**

The interviews were transcribed verbatim and imported into QSR NVivo 8\(^\text{©}\), (QSR International, Doncaster, Australia). The analysis was guided by the research question; “how does amblyopia and/or its treatment affect children’s lives?” The aim of the analysis was to identify possible items (questions) to be included in the instrument. Thematic content analysis (where themes are identified in which both the content and context of documents are analysed\(^\text{18}\)) was undertaken using Framework. Framework follows the principles of classifying and organizing data according to key themes, concepts and emergent categories.\(^\text{18}\) Each transcript was reviewed several times in order to become familiar with the data. Key phrases, sentences and words, and emergent themes were identified. Transcripts were then re-examined and coded according to the identified themes. Care was taken to keep the terminology and phrasing used by the children. Once the transcripts were coded into themes, the data was organised into items for the draft instrument. Lewis and Ritchie state that within qualitative research, internal validity issues such as sample coverage; sample of the phenomena; labelling; interpretation; and display of the data should all be considered.\(^\text{19}\) In doing so, the validity and subsequent generalisability of the data adds credibility to the research findings. Following analysis of the interview data, three experienced and independent qualitative researchers validated the analysis approach taken. This involved an independent assessment of the analysis approach adopted, and also an assessment of the accuracy of the approach itself. In the first instance, the conceptual Framework was reviewed. Then samples of the transcripts were checked for coding consistency.

**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, the majority of children were interviewed with their parent/guardian present. The vast
majority of participants were white (which was representative of the clinic population). 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. This was calculated using GeoConvert\textsuperscript{20} 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.\textsuperscript{20}

A balanced demographic sample was achieved in relation to age, social class and amblyopia treatment modality (Tables 1 and 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). Participants were rated in terms of their amblyopia severity at both the start of treatment, and at the time of the pilot. This grading system adopted was that of the PEDIG model of amblyopia classification.\textsuperscript{21-28} Mild amblyopia was categorised as $0 \geq 0.3$ logMAR; moderate amblyopia $0.31 \geq 0.60$ logMAR; and severe amblyopia $> 0.61$ logMAR. Co-morbidities as documented in the hospital records were noted. The majority of participants were in good general health. Some of the participants ($n=15$) did have recorded co-morbidities. These are listed.

1. asthma and glue ear
2. speech problems
3. mild joint hypermobility
4. otitis media
5. Speech therapy
6. juvenile arthritis and Still's disease
7. Coeliac disease, anaemia and failure to thrive
8. chronic lung disease and conductive hearing loss
9. mild eczema
10. constipation
11. Attention Deficit Hyperactivity Disorder (ADHD) and Asperger's syndrome;
12. history of prematurity, and delayed speech
13. fourth nerve palsy, rhabdomyosarcoma of bladder and prostrate;
14. Auditory language disorder and seizures
15. Familial syndrome, facial dysmorphism, short stature, and restricted joint movement

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. Of the 59 children
interviewed, all were on some form of treatment (either glasses; patch; drops; or a combination of these). This is shown in Table 2.

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, with an average interview length of 6min 15secs. Recruitment continued until data saturation was reached; and the number of interviews conducted exceeded this point. Confidence that data saturation was achieved was high, as all interviews were conducted by one researcher.

**Item identification for possible inclusion in the CAT-QoL instrument**

Qualitative analysis of the interview data identified eleven possible items to be included in the draft questionnaire. A conceptual Framework was derived purely from the qualitative data; this was not informed by existing literature before the qualitative data was collected. The aim was to analyse the data with an aim to identify possible items for the draft questionnaire, using a “bottom up” methodological approach.29

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 their HRQoL. These stemmed from the physical sensations experienced by having something on their face (either a patch or glasses). For example, “a bit tickly” (patch); “it just itches a bit near the eye....” (patch); “it tickles” (patch); “it feels a bit rough” (patch); “well it’s a bit hard to blink sometimes, because your eyes can get caught on the sticky bit” (patch); “rubbing on my ear...” (glasses). Other children spoke about the feelings of having the drops (atropine) instilled (“it makes my tears; some tears come down”).

2. **Pain of treatment (hurt)**

   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. For example, “It kept rubbing on my face and it hurt....” (patch); “when I take it off it hurts” (patch); “it feeled that when I took it off it hurted, and when I weared it, it tickled” (patch) ; “it hurts when I take it off” (patch); “they really burnt when they took it off cos it actually took some hair off my eyebrow!” (patch).

   Similarly, some children reported that when the drops (atropine) were instilled, these would often sting or make their eyes water. For example, “Well it starts, stings and it wears off a
3. Being able to play with other children
Some children discussed how relationships with their friends were affected because of amblyopia treatment. For example, “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”; “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”; and “Cause, cause all the time that *** said I’m too thick to play, when I’m not”.

4. How other children have treated them (like laughing or name-calling)
Some children discussed bullying, such as name-calling and exclusion from games/friendships. To some, this was raised as something they had directly experienced (“when *** calls me a geek” and “Specky four eyes” (due to wearing glasses); 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. For example, “I haven’t told them ... It was a secret ... Because they would just laugh at me” (having to wear a patch).

5. Ability to undertake work at school
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 (“they’re better to see stuff”, glasses), although mainly it was difficulties in undertaking tasks that were highlighted. For example, “I can’t see writing”; “the teacher writes on the board I can’t even see”; “at school when I am doing the work, because the eye was covered it was harder to do things”. The children noted that the ability to read and write was affected to varying degrees (“I can’t write letters right straight”).

6. Ability to undertake other tasks (like playing on the computer, colouring, playing games, watching TV)
The children also noted that their amblyopia treatment also influenced their ability to undertake other tasks. These were mainly hobbies and interests, such as watching television or playing on computer games. For example, “I can’t play with the bricks”; “when I go on Xbox360 I always get killed”; “when I am playing on the Wii, I can’t concentrate very
“much”, “on the computer and stuff... It sort of blurred”. Some children noted that when they were having their treatment they were unable to participate in particular tasks (“go swimming”; or “eating my dinner”). Another noted that when they wore their patch walking around was more difficult (“when you try like, try to see, erm, like chairs and stuff. You can’t see your way”).

7. **Feeling sad or unhappy**
Some children reported that their treatment made them feel happy (“happy ..... because it makes my eyes see much farer” (glasses), whereas others stated that having to wear their patch or have drops instilled made them feel unhappy or sad. For example, “it makes me feel sad because I want to play on the computer now but I don’t want to wear my patch”; “sad, because I didn’t want to wear them at the start… because I didn’t know what they felt like” (patch); “sad... because it,... you don’t like it on your eye. When you first 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”.

8. **Feeling cross**
Some children stated that having to wear their patch or have drops instilled made them feel angry or cross. For example, “I just feel angry”; “I feel a bit cross”; “I get grumpy… because I hate… I hate putting the patch on”; “with the sticky patch I get angry”.

9. **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 having the drop being instilled (“a little bit nervous”). Others were worried about what they would look like when they had the patch on. For example, “I thought I might look silly at school”.

10. **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 affecting relationships with others. (“on certain days that I’ve been a little bit frustrated at school,… 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”).

11. **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 (“She’s always laughing saying “oh you look funny and this…..”). 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.

**DISCUSSION**

The use of PROs is becoming increasingly common and it is important to know how these have been developed and validated. The FDA encourages instrument developers to make their instruments and related development history available and accessible publically.\(^{15}\) However, the literature on the development of the descriptive systems for PROs is sparse. This study describes the development of the descriptive system for the CAT-QoL instrument, prior to any further refinement of the instrument.

Matza et al have identified a number of considerations to be made when designing a paediatric HRQoL instrument.\(^{30}\) The first is the age at which children can report their own HRQoL. Children do seem to have the capacity to reliably report upon their health between the ages of 4-6 years.\(^{31-33}\) The findings of this study confirms this. It was possible to interview young children in order to identify their thoughts and opinions of their own health; and to find out what impact amblyopia treatment has had upon their daily lives. Children are able to understand and articulate what it is they feel and experience due to their eye condition.

Children were able to discuss and explore how their amblyopia treatment impacted upon their daily lives. The interview questions were intentionally “open-ended”, and every effort was made not to prompt participants. That said, some issues were probed; an attempt was made to find out exactly how they felt or experienced problems as a result of their amblyopia and/or treatment. It could be argued that this is a different complexity of task (cognitively speaking) compared to responding to questions on a self-complete questionnaire.

Analysis of the interview data identified potential items for inclusion in the CAT-QoL instrument. A theoretical HRQoL framework, was not utilized for a number of reasons. Firstly, there is no universally agreed definition of the concept of “HRQoL”. If a theoretical framework were to be applied, then the choice of definition (and therefore content of the framework itself) could be argued. The definition of “paediatric HRQoL” is also far from agreed. In a review of paediatric QoL instruments, Davis et al reported upon the range of
definitions, theories, domains and items used in the conceptual framework of child HRQoL. The use of a theoretical framework in this study was counterintuitive. The overall aim of the research was to produce an instrument for children, by children, using a bottom-up methodological approach.

The number of interviews conducted to develop descriptive systems for PRO instruments is not always reported. In qualitative studies, the aim is not to achieve statistical significance but to capture views of a given population. The number of interviews conducted in this study (n=59), is slightly lower than that carried out during the development phase of the generic Child Health Utility 9D (CHU9D) instrument (n=74). The length of the interviews short, but not dissimilar to those reported in the development of the CHU9D questionnaire. This is unsurprising, as in this study the children were only asked to consider one aspect of their health, as opposed to their general health. The age group was younger, and therefore not as likely to describe things in as much depth compared to older children.

The research is 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 also be perceived as being 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 of the interview data. Interviewing children alone can compromise the researcher when considering the possibility of divulging potentially sensitive information about treatment, bullying or family dynamics. It is acknowledged that interviewing children in the presence of a parent/guardian may have changed the dynamic of the relationship between the child and the interviewer (and as such, may have altered the content of the interview itself). This is an important consideration particularly when reflecting on the “bottom up” methodological approach adopted in this research. 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 of this approach is that some participants may have felt obligated to take part in the study.\textsuperscript{36}

Another 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 only one area of the UK, due to resource constraints. Nonetheless, the sample of the child interview participants was balanced in relation to age, social class and treatment modality. 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).\textsuperscript{18} This was achieved in this study. However, it should be noted that there are low numbers of child participants from differing ethnic backgrounds. Further research is needed to identify if there are any additional HRQoL issues for given ethnic groups.

Items for the draft descriptive system for a paediatric self-reported amblyopia HRQoL have been identified. A draft version of the CAT-QoL instrument has been developed using the methods outlined in this paper. Further research is required to refine and assess the psychometric properties of the instrument.

**Acknowledgements:**
This work is produced by Jill Carlton under the terms of Personal Development Award research training fellowship issued by the NIHR. The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, The National Institute for Health Research or the Department of Health.
Table 1   Characteristics of the study population (n=59)

<table>
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<th>Study Population</th>
<th>Total</th>
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<tbody>
<tr>
<td>36 male; 23 female</td>
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<tr>
<th>Ethnicity</th>
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<tr>
<td>White</td>
<td>54</td>
</tr>
<tr>
<td>Mixed (white and Asian)</td>
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<tr>
<td>Asian – Pakistani</td>
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<tr>
<td>Chinese</td>
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<tr>
<td>Black (African)</td>
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<td>Other</td>
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<th>Socio-demographic group using LSOA scores (worst deprived – least deprived)</th>
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<tr>
<td>0-6500</td>
<td>21</td>
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<tr>
<td>6501-13,000</td>
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<tr>
<td>13,001-19,500</td>
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<tr>
<td>19,501-26,000</td>
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<td>26,001-32,500</td>
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<table>
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<tr>
<th>Number of participants with co-morbidities present</th>
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<tr>
<td></td>
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<tr>
<th>Interocular Visual Acuity (VA) difference in logMAR</th>
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<tbody>
<tr>
<td>Mean 0.21 log units</td>
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<tr>
<td>Median 0.15 log units</td>
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<tr>
<td>Min 0.0 log units</td>
<td></td>
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<tr>
<td>Max 0.725 log units</td>
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<th>Interocular difference at time of interview</th>
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<tbody>
<tr>
<td>Mild</td>
<td>46</td>
</tr>
<tr>
<td>Moderate</td>
<td>9</td>
</tr>
<tr>
<td>Severe</td>
<td>4</td>
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<th>Amblyopia level from “normal” at time of interview</th>
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<tr>
<td>Mild</td>
<td>41</td>
</tr>
<tr>
<td>Moderate</td>
<td>11</td>
</tr>
<tr>
<td>Severe</td>
<td>7</td>
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Mild amblyopia 0 ≥ 0.3 logMAR;
Moderate amblyopia 0.31 ≥ 0.60 logMAR;
Severe amblyopia > 0.61 logMAR.
Table 2  Summary sampling grid: Age and treatment modality

<table>
<thead>
<tr>
<th>Age(years)</th>
<th>Patch</th>
<th>Patch</th>
<th>Drops</th>
<th>Drops</th>
<th>Glasses</th>
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<tbody>
<tr>
<td></td>
<td>Now</td>
<td>Ever</td>
<td>Now</td>
<td>Ever</td>
<td>Now</td>
</tr>
<tr>
<td>3 (n=1)</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>4 (n=6)</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>4</td>
</tr>
<tr>
<td>5 (n=20)</td>
<td>16</td>
<td>5</td>
<td>3</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td>6 (n=14)</td>
<td>9</td>
<td>6</td>
<td>4</td>
<td>2</td>
<td>12</td>
</tr>
<tr>
<td>7 (n=13)</td>
<td>7</td>
<td>9</td>
<td>2</td>
<td>2</td>
<td>13</td>
</tr>
<tr>
<td>8 (n=4)</td>
<td>1</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>9 (n=1)</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>TOTAL (n=59)</td>
<td>39</td>
<td>26</td>
<td>10</td>
<td>10</td>
<td>52</td>
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*Categories are not mutually exclusive*
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