Paediatric health related quality of life : a European perspective : instrument development, validation, and use in clinical practice

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3

A child focus group methodology: experiences from the European DISABKIDS project

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> Without including children in the main stage of HRQoL research, we believe that children's fundamental beliefs, feelings and understanding of their disorders and their interface with society might not be revealed (G.M. Ronen, 2001).

Abstract

A cross-national patient-derived methodology was applied during the development of the European DISABKIDS health related quality of life (HRQoL) instrument to identify relevant HRQoL statements. Focus groups were used in the DISABKIDS project to include the child and adolescent's own concepts, language and culture, and to acknowledge the patient as the expert in their own lives. Participants included children and adolescents with a chronic medical condition, their parents and health care professionals. Focus groups were monitored by two moderators and facilitated by a series of semi-structured questions and probes. HRQoL statements were identified from the literal transcripts for the development of the European DISABKIDS instrument. The DISABKIDS manual served as a guide to assure that a similar method was used in all countries. The focus groups and interviews were conducted in eight institutions in seven European countries. Participants included 154 children and adolescents with a chronic medical condition, 142 family members and 26 health care professionals. Focus group progress was related to the developmental abilities of the child. A total amount of 3515 HRQoL statements were collected. These statements have subsequently been used for the development of the DISABKIDS instrument. This patient-derived procedure made it possible to reflect on aspects that are important to the patient group and phrase items in their own words. However, a number of issues need to be considered when adapting the focus group methodology for use in children and adolescents, which include the developmental abilities of the participants.

Introduction

In the past children and adolescents have often been treated as passive receivers of medical services and health care. Even paediatric health related quality of life (HRQoL) was often assessed by the parent instead of the child [1-3]. As proxy measures are not necessarily representative of how the child or adolescent feels the focus is currently directed towards the child and adolescent [4-7].

Including the young patient's opinion is now recognised as important, not only for the assessment of their HRQoL but also during the questionnaire's developmental process [8-12]. As HRQoL is inherently an attribute of the patient, the questionnaire should reflect the concerns and opinions that are important to the patient. Using only expert opinions for the development of a questionnaire is thought to lead to investigator bias and poor face and content validity [13]. Therefore the patients should be involved in the development of a questionnaire [13,14]. As a consequence patient-derived methods are being used as an aid in the development of HRQoL questionnaires. The focus group methodology is such a patient-derived method, which is regularly used in de development of paediatric HRQoL questionnaires [10,11,15].

Focus groups have been defined as "a research technique that collects data through group interaction on a topic determined by the researcher" [16]. It is a qualitative research method, which helps to understand beliefs, views, knowledge, ideas, attitudes and experiences in a certain group in relation to a certain topic. It gets its advantage from group interaction, which can deepen and clarify topics within a group [17-19]. The communication and interaction between the participants can generate useful data and allows the investigator to learn about the participants' perspectives. Focus groups were first used as a marketing research tool but are now more widely used for health care research and services. Within a focus group, one can address clinical questions, identify problems or learn how patients experience illness or health care services. Focus groups are also found to be useful in a preliminary phase of a study to identify important research issues or develop suitable items for a new questionnaire [8,14,18,19].

There is however little information available on the methodological adaptations that are necessary to run focus groups with children and adolescents [8,17]. One can assume that there is a need to consider issues related to the child and adolescent's developmental level. Such issues include the child and adolescent's verbal comprehension, their ability to report back on a specific time period, and the age appropriateness and changing importance of HRQoL issues [20]. When conducting focus groups or interviews with children and adolescents one especially needs to consider that their communication and social skills depend on their age and attained cognitive level [17,20,21]. Although their skills and developmental level may form a challenge in focus group research, the developmental variability of the child and adolescent is also an advantage. Focus groups can provide investigators with the child and adolescents own ideas, supplied in their language and including their view of health, which can help to adapt the questionnaire to their level of understanding.

This paper describes the cross-national patient-derived method that was applied in the European DISABKIDS project. Focus groups and interviews were conducted with children and adolescents with chronic medical conditions, their parents and health care professionals to capture their view on HRQoL. A description will be given of the methodology used in this large cross-national project. Positive and negative aspects will be discussed, which will help in the application of the focus group methodology with children and adolescents in the future.

Method

The DISABKIDS project

The DISABKIDS project is a European collaboration, which consists of eight partner institutions in seven countries (Austria, France, Germany, Greece, the Netherlands, Sweden and the United Kingdom). The aim was to cross-nationally develop a new European HRQoL instrument for children and adolescents with a chronic medical condition in several countries simultaneously [22]. Chronic medical conditions included in the project are asthma, juvenile idiopathic arthritis (JIA), atopic dermatitis, cerebral palsy (CP), cystic fibrosis (CF), diabetes and epilepsy. The DISABKIDS project intends to provide for the growing need of multilingual cross-nationally validated paediatric HRQoL instruments for use in (international) clinical trials and clinical practice [23]. The final instrument has a modular build-up, with a chronic generic module that is applicable to all children with a chronic medical condition, and seven condition-specific modules.

The items for the DISABKIDS instrument were collected through a patient-derived (bottom-up) procedure based on focus groups and interviews with children and adolescents with a chronic medical condition. This child focused research method was applied in each of the DISABKIDS centres and provided the opportunity to capture the child's perspective on HRQoL. The identified HRQoL statements comprised the data pool from which the final instrument items were constructed. Focus group discussions and interviews were also conducted with parents and health care professionals in order to incorporate their views into the DISABKIDS instrument.

The DISABKIDS focus group methodology

To assure that a similar method was used in all countries a manual was developed which included the outline of the focus groups and the semi-structured questions. In view of time and resource constraint and if participants were unable to attend a planned focus group there was the option of participating in an individual interview. Each centre was responsible for training the moderators and recruiting participants for the focus groups and interviews.

Each of the eight DISABKIDS partners aimed to run focus groups for at least two to three chronic conditions. Separate focus groups were conducted for each chronic condition and were divided by age (4-7, 8-12 and 13-16). Each focus group did include a mixture of disease severity and gender. The general aim was to have between 4 and 8 participants in a focus group [17]. Parents and health care professionals participated in separate focus groups or interviews.

Two moderators ran the focus group discussions. Both moderators were familiar with group discussions as well as working with children. While the first moderator led the discussions the task of the second moderator included the technical aspects of tape-recording, observing the group and writing down content and non-verbal behaviour during the session.

At the start of each focus group the aim, duration and confidentiality was explained to the participants. Permission for the audio-taping was also asked. The moderators used the semi-structured focus group questions supplied in the manual (Box 1). The discussion was led in a non-directive fashion. The questions were chosen in order to lead the participants from a general discussion to more specific information about their quality of life. If necessary probe questions were used to stimulate conversation.

Semi-structured questions:
What do you like about your life?
What do you like best about your life?
What makes you happy?
What bothers you most in your life?
What kind of things keeps you healthy? (coping styles / activities)
If you could make a wish, what would you wish for in order to be happier or more satisfied?
Tell me about condition. (e.g. epilepsy / diabetes / asthma etc.)
Apart from yourself, do you know any other children with this condition?
How does their condition affect them at school / home?
How does your condition affect you at school / home?
What would you like people to say at school / home / hospital to help?
What would you like people to do at school / home / hospital to help?

More specific questions:
What do you think of your condition?
What do you think of your medication / treatment / hospital / the doctors.
What are the disadvantages of having your condition? Are there advantages?
Do you know what other kids think of you having this condition?
Are you different compared to children without this condition?

Box 1. Prepared semi-structured questions included in the focus group and interview manual.

The focus groups were organised into two parts (Table 1). Part one was intended to discuss various health and illness related topics. Part two allowed the children and adolescents to write down questions that would give a clinician a good impression of their HRQoL. They also listed which questions they found most important and possible question formats and response categories were discussed.

The focus groups and interviews were tape-recorded and transcribed verbatim to conserve the exact expressions used by participants. Statements related to HRQoL were identified from the literal transcripts to form a pool from which the final items were constructed.

Phase		Time frame	Purpose
Part 1	Introduction	5 min	Warm up
	Discussion	35 min	Discussing perceived HRQoL issues
	Break	10 min	
Part 2	Question construction	30 min	Writing individual questionnaire items
	Debriefing	10 min	Group evaluation and any missing topics

Table 1. Focus group structure.

Participants

The participants (children, adolescents and their parents) were chosen via the hospital register or patient associations and had a confirmed diagnosis of one of the seven chronic medical conditions included in the project protocol (asthma, JIA, atopic dermatitis, CP, CF, diabetes or epilepsy). All potential participants were contacted by letter with an explanation of the project and details of what they would be asked to do. Families willing to participate returned a form agreeing to the study and were contacted via telephone in order to co-ordinate a date suitable for all focus group participants to meet. All participants had inclusion criteria to comply to (Box 2). There was no requirement that the participants should be unknown to each other. The participants completed a standardised consent form prior to entering the focus groups and interviews. Where possible the location of the groups was outside the hospital premises. The focus groups were divided by chronic condition and stratified by age (4-7, 8-12 and 13-16 years). Each focus group consisted of a mixture of disease severity and gender. Parents were invited to participate in separate focus groups (grouped according to the chronic condition and age of their child). If participants were unable to attend a planned focus group they could take part in a personal interview. Health care professionals were contacted directly by the investigators and were often affiliated to the research centres. The European commission approved the study as well as each of the Medical Ethics Committees in each study centre.

Inclusion criteria:

- Consent to participate in the study
- Between 4 and 16 years of age
- Have one of the seven chronic conditions
- No other chronic medical condition
- Sufficient knowledge of language and able to express themselves

Box 2. Inclusion criteria for the child and adolescent.

Results

Focus groups and interviews were conducted in each of the DISABKIDS centres: the University of Vienna in Austria, the University Hospital of Marseille in France, the University Hospital of Hamburg in Germany, the Medical University of Lüebeck in Germany, Thessaloniki University Paediatric Clinic in Greece, Leiden University Medical Center in the Netherlands, the University Hospital of Lund in Sweden and the Royal Hospital for Sick Children in Edinburgh the United Kingdom. The University of Verona in Italy participated in the focus group research as an affiliated centre. Moderators were members of the research teams. Each centre included one to three chronic conditions (Table 2), which included separate focus groups for the different age ranges and parent groups.

Country	Condition A	Condition B	Condition C
Austria	Diabetes mellitus		
France	Epilepsy		
Germany (H*)	Atopic dermatitis		
Germany (L†)	Juvenile idiopathic arthritis	Cerebral Palsy	
Greece	Cystic Fibrosis	Asthma	
Italy	Asthma		
Netherlands	Asthma	Juvenile idiopathic arthritis	
Sweden	Diabetes Mellitus	Epilepsy	Asthma
United Kingdom	Cerebral Palsy	Epilepsy	

Table 2. Number of chronic conditions included in the focus groups and interviews per DISABKIDS centre.
*Hamburg / †Lüebeck

A total number of 322 participants contributed to the DISABKIDS focus groups and interviews. Of these 154 were children and adolescents, 142 were family members and 26 health care professionals. The data output consisted of the focus group and interview tape-recordings, notes from the moderators and cards or flipchart pages with suggested questions written by the children and adolescents. The group size ranged from three to six persons in each country and the time to complete the focus groups was between 60 and 90 minutes.

The Greek centre used videos as 'warming-up' activity at the start of the focus groups. This helped to relax the children. Others applied a general introduction round. The moderator's task was to stimulate new topics and guide the discussion, which was sometimes experienced as difficult, especially with the youngest age group. Young children were not always able to express their opinion or feelings in more than a few words. Answers were short and it was hard to stimulate group discussions. From the age of 6 there was a noticeable increase in their ability to express themselves. Interaction with group members was apparent from the age of 10 years. In some instances one speaker dominated the discussion while another child hardly spoke. The large age variation in the adolescent groups presented a few problems, for example the life experience of a 13 yr old boy can be very different to that of a 16 yr old girl. The amount of time children could focus on the topic increased by age and reached a maximum of 90 minutes in the adolescent groups. Parents, on the other hand, were reluctant to stop at the end of the sessions. In the parent and health care professional groups the discussions developed automatically. There was group interaction with participants discussing topics with each other and not just answering the moderator's questions. On the whole all the participants indicated that they welcomed this opportunity to talk to others in a similar situation, felt they where acknowledged as experts and would volunteer to participate in similar exercises in the future.

The tape-recordings were written or typed out literally, and included the notes and observations from the second moderator. This process was time consuming and took between 6 to 10 hours. Each country selected relevant HRQoL statements from their national focus group or interview transcripts. This resulted in a total amount of 3515 statements. Collected statements showed various similarities between countries. Medical aspects such as treatment and symptoms were discussed in all countries. Other recurring topics included experienced limitations, school, relationships with peers, and emotional reactions to having a chronic medical condition. The parents often discussed the health care system extensively. The collected statements, clustered by condition, were divided into three modules (generic, chronic generic and condition-specific). All the statements that were not directly related to health or a chronic medical condition (n=488) were merged to form a generic module. The statements that were applicable to any chronic medical condition (n=1647) were merged to form the chronic-generic module. The statements that were specific to each of the medical conditions (between 340 and 66 statements) formed the seven condition-specific modules (Table 3).

This division was the basis of the three-modular structure; the generic, chronic generic and condition-specific modules. From this point onwards the statements in each module underwent a reduction process for the development of the pilot instrument. These results are reported elsewhere [24].

Module		Collected statements
Generic		488
Chronic generic		1647
Condition-specific	Asthma	304
	JIA	340
	Atopic dermatitis	66
	CP	183
	CF	167
	Diabetes	141
	Epilepsy	179

Table 3. Number of collected statements per module.

Discussion

The focus groups and interviews enabled a bottom-up procedure for the development of the DISABKIDS instrument. Although focus groups and interviews have been used previously for the development of paediatric HRQoL questionnaires this has not been done simultaneously in several countries and for several chronic medical conditions. The applied patient-derived method has proven to be effective for data collection in the DISABKIDS project. All centres reported that there were many spontaneous responses, which suggests that participants were using their own way of expression and ideas.

There are some issues specifically related to running focus groups and interviews with children and adolescents that should be discussed. The methodology must be adopted to create the right kind of environment where the child can be open and motivated to participate. Being successful at child focus groups depends on the skills of the moderator and requires attention to several factors [16,25]. It cannot be emphasised enough that the moderators must be trained and aware of the cognitive and social capacities of children of different ages, and must be aware of their communication ability and attention span. The experienced age dependent change in ability to express themselves, interact with the group and stay focussed coincided with earlier described changes in childhood development [8,17,26,27]. As the quality of the supplied data is tied to the skills of the moderator we emphasise the importance of (international) training in this skill, especially for future cross-national studies.

Other problem areas concern group processes: the discussion may lack spontaneity, one participant can dominate the group and some participants may not join in the discussions or show disrespect. There are several guidelines to apply in such situations of which most were provided in the DISABKIDS manual (Box 3)[17]. We were also confronted with various developmental levels and different gender priorities in the adolescent groups [8,17,21]. For this reason we would choose to divide the adolescent group by gender and into two age groups in the future. Overall, one needs to keep in mind that focus groups are a time consuming method that needs careful planning and adaptation to the group of participants. It can also be difficult to recruit participants due to practical (previous appointments, summer time, travel distance) or personal reasons (shy, refusing to talk about medical condition).

There are limitations related to collecting data through focus groups and interviews. The generalisation of the collected data can be questioned as only a limited number of children, adolescents, parents and health care professionals participated (154, 142 and 26 respectively). Selection bias is also a limitation and creates the risk that the participants do not represent the general population of interest. It was also not possible to check that all relevant HRQoL aspects were discussed. Participants may have found it difficult to talk about certain (sensitive) issues, or topics were not thought of at the time. Other studies have continued conducting focus groups till no new data were presented [28,29]. However, this was not possible in the DISABKIDS project due to time constraints. Reassuring is that overall the number of participants was relatively large for focus group research and that a considerable amount of HRQoL statements were collected. The simultaneous setup in different countries supported the cross-national developmental process and demonstrated that various issues were relevant in all countries.

- Supply a good introduction and an opportunity to get to know the group
- Introduce some general rules on confidentiality and respect
- Let the children know that they are the experts and the investigator needs their input
- Consider the developmental age of the child and their ability to take part in the discussion
- Allow the children some control over the discussion
- Let them express themselves as freely as possible, listen attentively and don't interrupt
- Gather the information as objectively as possible
- Encourage descriptions of events by getting them to tell a story of their day or anecdotes
- Be relaxed during the interviews as this will relax the children as well
- Be sensitive to the mood of the group
- Do not insist on discussing painful themes
- Avoid making participants feel that they have failed if they can't answer the questions
- If you think the participants are telling lies then DO NOT press them for the truth
- Always end a focus group with a debriefing

Box 3. Aspects a moderator should apply during focus group work with children and adolescents.

Other issues concern the construction of the statement pool and what data to use from the focus groups and interviews. Qualitative patient-derived methods, like the focus group or interview, do not provide statistical data [29]. There is no statistical or standardised method to apply to the selection of HRQoL statements from the national focus group and interview transcripts. As the statement selection was a subjective process, based on general content analysis, it can be influenced by personal interpretations, interests and subjective factors [30]. Previous investigators have used the computer to facilitate this step, however as the qualitative data were in several different languages this was not applicable to the DISABKIDS project [31,32].

Conclusion

The applied child-focused patient-derived methodology aided in the collection of HRQoL statements for the development of the European DISABKIDS HRQoL instrument. The focus group and interviews were successful in embracing the child and adolescent's own point of view, concepts, culture and have acknowledged the child as the expert in their own lives. The described cross-national focus group and interview methodology made it possible to reflect on aspects that were important to the patient group, compare cross-national data and provided HRQoL statements for use in the DISABKIDS instrument. Being successful at focus group research does require attention to several factors (Box 4). In addition, sufficient consideration needs to be given to the organisational aspects related to focus group research, the developmental level of the participants and the method of processing qualitative data.

Preparations	Determine your goal and target population Agree on an available budget and timeline Get approval of the ethical committee Recruit at least two moderators Focus group manual with guidelines and questions Find suitable locations (avoid a hospital setting when possible) Send letters to potential participants
Inclusion criteria	Consent to participate in the study Fit the age requirements of the study Fit the group description (e.g. chronic medical condition) Sufficient language skills
Materials	Focus group manual Tape recorder and tapes with labels Pencils and paper or flipcharts Refreshments Token of appreciation
Moderator qualities	Familiar with group discussions Experience with children's cognitive and social capacities Aware of children’s communication abilities and attention span Non-authoritarian and patient
Basic data	Participants' names Age and gender Type of school / grade Health Status Medication
Output	Literal transcription from tapes (takes 8-12 hours) General outline from tape (takes 4-8 hours) Data from notes (2-3 hours) Data from memory (1 hour)
Moderator debriefing	Did the moderator keep to the rules and suggested interview structure? Did the children understand the instructions? Did the discussion flow smoothly? Where there problems? What was the general atmosphere of the session? How did the session end?

Box 4. General guidelines for focus group research.

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