

Additional file 1. Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Journal: *The Patient – Patient-Centered Outcomes Research*

Manuscript: Development of a novel tool to assess the impact of itching in pediatric cholestasis

Authors: Binita M Kamath, Linda Abetz-Webb, Ciara Kennedy, Bonnie Hepburn, Martha Gauthier, Nathan Johnson, Sharon Medendorp, Alejandro Dorenbaum, Lora Todorova, Benjamin L Shneider

Corresponding author details: Binita M Kamath, Hospital for Sick Children and the University of Toronto, Toronto, ON, Canada; e-mail address: binita.kamath@sickkids.ca

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist

Developed from:

Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

No. Item	Guide questions/description	Response
Domain 1: Research team and reflexivity		
Personal Characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	Martha Gauthier (MG), Nathan Johnson (NJ)
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	MG: MA, NJ: MPH
3. Occupation	What was their occupation at the time of the study?	MG, NG: Research associates
4. Gender	Was the researcher male or female?	MG: Female, NJ: Male

5. Experience and training	What experience or training did the researcher have?	Interviewers had expertise in qualitative interviewing in the context of patient-reported outcomes and followed IRB-approved study procedures and documentation, including a semi-structured interview guide. They also completed National Institutes of Health Human Participant Protection training, as well as data protection and interview training. See methods.
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	No
7. Participant knowledge of the interviewer	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	The participants were introduced to the researchers and informed about the study purpose and design via the information and consent form (ICF).
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	Not reported. Interviewers were employees of Adephe Values and had no specific interest in the research topic. However when possible, organizers of the events where interviews were conducted would provide a brief description regarding the purpose of the research and introduce the interviewers.
Domain 2: study design		
Theoretical framework		
9. Methodological orientation and Theory	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	Interview responses were analyzed based on grounded theory methods. See methods for further details.
Participant selection		
10. Sampling	How were participants selected? e.g. purposive, convenience, consecutive, snowball	Any patient with ALGS or PFIC1 who had experienced itching at least 3 of the 7 days before the eligibility assessment was eligible as long as they had not undergone liver transplant or surgical interruption of enterohepatic circulation. Other than these criteria, there was no selection – all patients with these rare diseases (or caregivers of patients) who met these criteria and provided consent to participate were included. See methods for details.
11. Method of approach	How were participants approached? e.g. face-to-face, telephone, mail, email	Face-to-face through Alagille Syndrome Alliance-sponsored community events throughout the USA, and via online forums and support groups for ALGS or PFIC. See methods for details.
12. Sample size	How many participants	12 patients with ALGS and 24 caregivers

	were in the study?	of patients with ALGS. See results for details.
13. Non-participation	How many people refused to participate or dropped out? Reasons?	None refused to participate. None dropped out, but the results of four interviews were excluded from analyses owing to study protocol violations. See results for details.
Setting		
14. Setting of data collection	Where was the data collected? e.g. home, clinic, workplace	Interviews were conducted either face-to-face or using Skype. See methods.
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	The minimum age for participation in the interviews was 5 years. Participants were interviewed separately; if required, caregivers could remain in the room during patient interviews. See methods.
16. Description of sample	What are the important characteristics of the sample? e.g. demographic data, date	Dates of data collection (July 2012 through December 2012) are provided in the methods. Detailed demographic data were collected for patients (age, itching severity, treatments being taken for itching) and caregivers of patients (age, relationship to patient, education and employment status). Details are provided in the results.
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	For concept elicitation, interviewers followed a semi-structured interview guide. Interviewers asked open-ended questions to identify clinical features relevant to patients with ALGS or PFIC1 and their caregivers. If required, interviewers could ask follow-up questions. Patients were prompted to comment on itching if this concept was not reported spontaneously. The interview guide was not pilot tested per se, but amended as needed after feedback from the first set of interviews. See methods for further details.
18. Repeat interviews	Were repeat interview carried out? If yes, how many?	No
19. Audio/visual recording	Did the research use audio or visual recording to collect the data?	Yes, audio recordings. See methods for further details.
20. Field notes	Were field notes made during and/or after the interview or focus group?	Interviewers took notes throughout the interview and used these notes as a reference during analysis. Audio recordings of interviews were transcribed. See methods for further details.
21. Duration	What was the duration of the interviews or focus group?	60 minutes. See methods.
22. Data saturation	Was data saturation discussed?	Yes, Information obtained during concept elicitation was summarized in a saturation grid. See methods for further details.
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	No
Domain 3: analysis and findings		
Data analysis		

24. Number of data coders	How many data coders coded the data?	Two, MG and NJ.
25. Description of the coding tree	Did authors provide a description of the coding tree?	A coding tree was not used, however a detailed code list was developed based upon the content of the interview guide, the first transcript reviewed, as well as from coding meetings attended by MG and NJ.
26. Derivation of themes	Were themes identified in advance or derived from the data?	Themes were derived from the data per grounded theory methods used. See manuscript in the method section for more information.
27. Software	What software, if applicable, was used to manage the data?	ATLAS.ti version 7.0 software; ATLAS.ti Scientific Software Development GmbH, Berlin, Germany. See methods.
28. Participant checking	Did participants provide feedback on the findings?	No.
<i>Reporting</i>		
29. Quotations presented	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	Quotations are presented and participant numbers are provided. See Online Resource 2
30. Data and findings consistent	Was there consistency between the data presented and the findings?	Yes. See discussion.
31. Clarity of major themes	Were major themes clearly presented in the findings?	Yes. See results.
32. Clarity of minor themes	Is there a description of diverse cases or discussion of minor themes?	Yes. See results.