APPENDIX B

Initial experiences with invasive meningococcal disease: Insights from survivors and their caregivers

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Appendix B. Qualitative analysis methods

A combined inductive and deductive approach was used to identify symptoms (acute), sequelae and impacts (short-term and long-term) described by survivors and their caregivers during the interviews.

Detailed qualitative expressions of experiences and/or emerging trends provided by participants during the interviews were analyzed thematically and summarized. The quotes included descriptions of symptoms (at the time of disease onset i.e., acute), short-term impacts, sequelae, and long-term impacts, their dimensions (i.e., frequency, number), anecdotes, and coping methods/aids. The analyses were conducted separately for caregivers and survivors.

Data Coding

The goal of coding was to identify themes and concepts in the text that could be used to address the study's objectives. Transcripts which were generated verbatim from the recorded interviews were analyzed in US English. Data were coded using a qualitative analysis software (MAXQDA™).

Before coding began, the study team designed a coding framework that evolved as new concepts emerged from the interviews. The codes were organized within a coding framework based on the preliminary conceptual model structure and the content of the interview guide. The coding framework was entered into MAXQDA™ prior to the qualitative analysis. Using this coding framework, text was deductively coded as "spontaneous" if the participant reported that they experienced a symptom, sequelae, or impact without being prompted by the moderator. For example, if the moderator asked, "Do you experience any long-term consequences due to your *<term used for IMD by the survivor>*?" and if the participant responded with "Yes, hearing loss", this was coded as a spontaneous code. If the moderator asked, "Do you experience long-term consequences such as hearing loss due to meningococcal disease?", this was coded as being prompted (or probed) by the moderator. Symptoms, sequelae and impacts in the preliminary conceptual model were probed after participants had been given the opportunity to provide their experiences spontaneously. In addition to this deductive coding approach, inductive coding, a technique where codes were derived from the data as concepts and ideas naturally appear during coding, was also applied. As such, the coding framework was continuously updated throughout the coding process and regularly reviewed by study team members. Separate codebooks were developed for survivors and caregivers.

Two qualitative scientists (coders) from the study team were involved in coding the transcripts, with oversight by a senior researcher who conducted the interviews. Prior to undertaking independent coding, 20% (n=2) of the transcripts were double coded to ensure the coders' comprehension of the codebook and the accurate application of codes. Coders reviewed each transcript to identify text that included concept expressions and tagged selected text with a code. Any new codes were retroactively applied to already coded transcripts. Periodic alignment meetings between the coders were interspersed during the coding process to ensure that coding was consistent between coders and remained up to date. Any differences in coding were discussed and resolved. Once the coding process was completed, the qualitative analysis software output listing the number of occurrences of each code was generated and served as the basis for results included in the summary tables. Data were analyzed using a variety of capabilities within MAXQDA™ as well as via outputs exported directly from MAXQDA™.

Concept saturation

As per the US Food and Drug Administration (FDA) PRO Guidance,[1] concept saturation is defined as "the point when no new relevant or important information emerges and collecting additional data will not likely add to the understanding of how patients perceive the concept of interest". In the current study, concept saturation was evaluated for symptoms and impacts reported by survivors. Saturation was not assessed for sequelae due to the heterogeneity of reports made by survivors. Saturation was not assessed for the caregivers' group as well due to a small sample size.

To assess saturation, the following steps were followed:

(1) Transcripts were split into 3 waves (or sets) based on the order in which the interviews were conducted. Wave 1 and Wave 2 each included 4 transcripts, and Wave 3 included 3 transcripts for a total of 11 survivor transcripts.

(2) The symptom/impact codes that were derived from Wave 2 of the interviews were compared with symptom/impact codes from Wave 1. This was done to determine if any new information at the concept level was present in Wave 2. If new codes appeared in the transcripts from Wave 2, saturation was deemed to not have been achieved, and further comparisons were made between Wave 2 and Wave 3. Concept saturation was achieved if no new concepts appeared in the third (final) wave of interviews.

[1] US Food and Drug Administration [Internet]. Guidance for Industry Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims 2009 [cited 2024 June 05]. Available from: https://www.fda.gov/media/77832/download.