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Amsterdam Centre for Health and Health Care Research

Guidelines for quality assurance in health and health care research:

Qualitative Research

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Guidelines for quality assurance in health and health care research:

Qualitative Research

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Guidelines for Qualitative Research[i]

Introduction

In recent years, qualitative methods have become far more commonplace in medical and health care research. Leading medical journals such as the Lancet, JAMA and the BMJ increasingly publish reports on qualitative research. This type of research addresses problems for which quantification is either not useful or (at present) not possible. Unlike quantitative research, qualitative research investigates relatively few people, the information acquisition is open and flexible, and the analysis makes use of everyday language as opposed to converting the research data into a numerical form (Maso & Smaling, 1998). Despite this clear distinction, qualitative and quantitative methods are increasingly combined in health and health care research. Both methodologies complement each other well, which can merit the quality of health and health care research.

Like quantitative research, qualitative research is systematic and verifiable and an effort is made to resolve a question in the research area concerned. In other words: scientific research is being undertaken. This means that the research aims to produce transferable results, albeit that the means of achieving this is different from that in quantitative research.

Types of question

Questions, from both the patients' and care providers' viewpoints, about the experience with and significance of diseases, diagnostics and treatment are best answered by a qualitative approach. Also questions about the backgrounds and the interrelatedness of patients' and care providers' opinions and the considerations and arguments they use, can often best be approached using qualitative methods. In recent years, a lot of qualitative research has been directed towards the communication between the patient and the care provider. Additionally, qualitative methods are suited to explore relatively uninvestigated research areas.. An example is a study at the start of the 1960s by the founding fathers of the *grounded theory* approach in medical sociology, Glaser and Strauss, into dying patients' awareness of their approaching fate (Glaser & Strauss, 1965). Another example is research into the perception of health and health care amongst ethnic minorities.

Methods

The most commonly used forms of data acquisition are: interviews (e.g. semi-structered, in depth), group interviews, observation and document analysis. These methods usually proceed on an iterative basis. In other words the initial data is provisionally analysed; on the basis of this new data is acquired, and if necessary the research question and/or the sampling strategy are modified. This process is repeated until a complete description or theory has been formed (saturation) and new data provide no additional information.

The iterative basis of qualitative research implies that the sampling does not take place randomly but on the basis of considerations related to the research question. Consequently, qualitative research usually involves no more than a few dozen patients.

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In qualitative research a lot of attention is devoted to reflexivity, so as to ensure that subjectivity in the research is sufficiently recognised. Reflexivity means that the researcher not only acquires data about the research theme, but also devotes attention to the influence that provisional hypotheses and his own presence can have on the acquisition and analysis of the data.

This memorandum

These guidelines have been specifically compiled for the quality assurance in qualitative health and health care research in AMC-UvA. This memorandum has been developed by the Qualitative Research Network AMC-UvA, a group of researchers who are involved in qualitative research.[i] To the best of our knowledge, no other guidelines for quality assurance in qualitative research exist in the Netherlands.

We have tried to make these guidelines as specific as possible to the research carried out within the AmCOGG research institute of the AMC and the specific procedures and agreements within the AMC (such as the Research Ethics Committee Procedure and the AMC Research Code). This document is intended as an aid for researchers in setting up and carrying out qualitative research according to the quality assurance guidelines in force at the AMC. Other bodies within the AMC (AmCOGG scientific advisory board, research programmes (Dutch: ODP's)) can use it in testing and assessing new and current research projects. In both cases the correct use of these guidelines will hopefully lead to the situation in which qualitative research carried out at the AMC earns the designation "high-value qualitative health and health care research".

This memorandum consists of two parts. Part I provides a quality assurance checklist for each phase of the research (research objective, design, data acquisition, data processing, data analysis and report writing). Part II is a detailed explanation of and elaboration on part I.

We hope that you will benefit from using these guidelines and look forward to receiving feedback on possible improvements.

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Part I: checklist

Overview of quality objectives and resources per research aspect

Research aspect	*Quality objective*	*Resource*
1 Research objective	Scientific research objective	♦ Overview research domain ♦ Research objective contains problem definition and research question
a Problem definition	Guarantee scientific basis	♦ Relationship with existing literature ♦ Relevance of the research
b Research question	Guarantee research question can be investigated	♦ Formulation of the research question ♦ Formulation of subsidiary questions ♦ Definition of domain, terms, variables and relationships
2 Design	Research design is appropriate to the research objective	♦ Design appropriate to the research objective ♦ Design covers: research group, research methods and research instruments ♦ Documenting the design ♦ Assessment by (external) expert ♦ Assessment Research Ethics Committee
a Research group	Selection research group and research setting which make it possible to answer the research objective	♦ Justification and arguments for choice of research group and research setting ♦ Formulation of selection criteria ♦ Estimation of feasibility ♦ Informed consent procedure
b Research methods	Methods are appropriate for the research objective	♦ Documenting choice of research design and methods ♦ Use of research protocols
c Research instruments	Explicit description of the researcher's role and other research instruments used	♦ Documenting and justifying of choice ♦ Documenting reliability and validity ♦ Reflexivity
3 Data	Quality control data	♦ Documentation procedures for data acquisition, data processing and data analysis
a Data acquisition	Quality control and timely adjustment of data acquisition	♦ Introduction in field ♦ Investigation of unreached respondents and nonresponders ♦ Notes after every period of data acquisition ♦ Structure and layout of topic list (interviews, group interviews) ♦ Preparation/practice with topic list (interviews, group interviews) ♦ Recording equipment and recording setting (interviews, group interviews) ♦ Observer in interviews ♦ Compiling a list of events, behaviour or statements (observations) to be recorded

Research aspect	*Quality objective*	*Resource*
b Data acquisition	Quality control data from third parties	♦ Agreements concerning supply of data and liability for its quality ♦ Establishing quality control performed by third parties
c Data entry	Quality control data entry	♦ Overview possible data entry systems ♦ Justification of choice ♦ Agreements and selection of transcripts ♦ Documenting content files ♦ Monitoring data entry
d Data clean-up	Creating a file for analysis	♦ Storage of primary file and transcript ♦ Agreements and documentation cleaned-up files ♦ New name for cleaned-up files
e Data storage	Securing data against loss	♦ Storage of transcript and cleaned-up files ♦ Storage of 'ready-to-analyse' data
	Protection of privacy	♦ Agreements for data storage ♦ Separating research data from private details ♦ Private details are locked away ♦ Securing data files with a password ♦ Agreements for access (possibly by third parties) ♦ Upholding a retention period
f Data analysis	Guarantee scientifically reliable analysis	♦ Data mapping ♦ Overview of analysis techniques and justification of choice ♦ Documenting codes in memos ♦ Reflection on researcher's role and research process in memos ♦ Documentation and quality control of interpretation of data and memos
	Reproduction of data analysis	♦ Documenting data storage, research plan and memos

Research aspect	*Quality objective*	*Resource*
4 Report writing	Quality control publications	♦ Documenting publication plan ♦ Agreements for interim publications ♦ Publications cover: scientific publications, presentations and non-scientific publications
a Scientific publications	Quality control	♦ Compliance with guidelines for scientific rigour and precision ♦ Definition of target audience ♦ Agreements for authorship ♦ If not in Dutch: ensure that language content is corrected ♦ Affiliations: department, research institute, AMC-UvA ♦ Anonymity of persons studied ♦ Statement of funding sources ♦ Archiving of publications
b Presentations	Quality control form and content	♦ As 4a ♦ Presentations in accordance with usual quality standards ♦ Archiving of presentation
c Non-scientific publications	Quality control of non-scientific publications and presentations	♦ As 4a ♦ Report: consideration of usability and readability for sponsors ♦ Popular-scientific: consideration of readability for lay persons
5 Other	Quality control scientific enterprise	♦ Preventing scientific misconduct ♦ Rights of ownership data ♦ Copyright of articles
	Handling the media	♦ Compliance with standards for expertise and precision ♦ Agreements for popular scientific publications ♦ Justification of choice for publicity ♦ Feedback on text before publication ♦ Involvement of Communication Department AMC

Part II: explanatory notes

1. Research objective

- *Overview research terrain*

The research objective is never an independent entity but is always embedded in a context, which should be described. At the same time, the research theme should be clearly defined. To this end, a description of the domains (application area) to which the research does and does not apply should be given.

- *The research objective contains problem definition and research question*

The research objective describes the causes and reasons for carrying out this research and as such forms the actual starting point of the research. The problem definition and the research question should explain the objective in greater detail. The problem definition is an overall description of the research theme in relation to the context considered to be relevant for the research. The research question is the precise formulation of the research theme in question form.

1a. Problem definition

- *Relationship with existing literature*

The description of the relationship with the existing literature should indicate whether the research serves to explore a subject about which little is known at present or to empirically test theories that appear to provide prior insights into the subject. The research can also serve to explore a subject for which existing theories provide insufficient insight and/or contradict each other (Giacomini & Cook, 2000).

- *Relevance of the research*

A convincing case should be made and documented for the theoretical, social and/or policy-making relevance of the research (Malterud, 2001). This can, for example, be done by describing the aim of the research, i.e. what the researcher wants to achieve by answering the research question. Different types of research can be distinguished for this (e.g. theoretical or field research: Maso & Smaling, 1998).

1b. Research question

- *Formulation of the research question*

In qualitative research the research question is often aimed at issues concerning the 'how' and 'what' of the research theme, which leads to a relatively open formulation of the research question. Furthermore, the nature of qualitative research is such that the final research question is often only formulated during the course of the research. Nevertheless, the research should start with an explicit and precisely formulated research question. This allows changes which occur during the course of the study to be continually related to the original research question, thus providing an insight as to how it developed during the study. The research question formulated should also throw some light on the practical possibilities for using empirical research to obtain an answer to the question (Maso & Smaling, 1998).

♦ *Formulation of subsidiary questions*

The central research question in the study is further elaborated on by formulating a number of subsidiary questions. Whereas the research question is often a wide-ranging, general question (concerning the 'how' or 'what'), the subsidiary questions are usually specific to the subsidiary aspects ('how much', 'when', 'who', etc.).

♦ *Definition of the terrain, terms, variables and relationships*

The research theme should be described as tangibly as possible. If possible, a description should be given of the meaning of the terms used in the research question, the terrain the research is aimed at, the variables which might play a role in this terrain and the possible relationships between the variables.

2. Research design

♦ *Design appropriate to the research objective*

Even though the research objective in qualitative research is often formulated in a relatively open manner, the research design should clearly be appropriate to the research objective. This means determining in advance which forms of data acquisition will be used to try to answer the research objective. It is also perfectly possible to combine quantitative and quantitative research methods in a single study (Devers, 1999).

♦ *Design covers: research group, research methods and research instruments*

With respect to this see 2a to 2c.

♦ *Documenting the design*

Initially, the design of the qualitative research is elaborated on in a global and open manner. Due to the iterative (repetitive) nature of qualitative research, the research design becomes more tangible during the course of the research. It is therefore important to systematically monitor and record the research process so that afterwards, methodological choices can be justified (see for example Creswell, 1990; Wester, 1991; Pope & Mays, 1995).

♦ *Assessment by (external) expert*

The research design chosen is submitted to an expert in the area of quantitative research. This can be an expert within AMC-UvA, but also an external expert.

♦ *Assessment by Research Ethics Committee*

The research design should be assessed by the Research Ethics Committee, if this is required by the Dutch Medical Research Involving Human Subjects Act (Dutch acronym: WMO). If there is uncertainty about the interpretation of the Act, the Research Ethics Committee can first of all be asked whether an assessment is necessary.

2a. Research group

- *Justification and arguments for choice of research group and research setting*

The selection of the research group and research setting depends on the objective. The research items should be chosen in such a way that once the study has been completed, it is possible to make statements which can be justified on the basis of the research group and the research setting. In qualitative research, 'systematic and purposive' sampling procedures are used (Wester, 1991; Malterud, 2001; Pope & Mays, 1999). The choice of a selection procedure and the selection criteria used within this should be documented and justified.

- *Formulation of selection criteria*

If a 'systematic or purposive' sampling procedure is chosen, the development of the selection criteria should be documented, as equally when and why the selection of research items was stopped (theoretical saturation).

- *Estimation of feasibility*

The feasibility of the chosen sampling procedure should be indicated. Estimating the feasibility is particularly important if the research question is about a sensitive subject (MacDougall & Fudge, 2001). This also applies when the study subjects are difficult to reach, for instance as with research into certain ethnic groups.

- *Informed consent procedure*

All persons and organisations participating in the study should be adequately informed about it beforehand and formally consent to participating.

2b. Research methods

- *Documenting choice of research design and methods*

All considerations about the choice of the research design and methods should be documented.

- *Use of research protocols*

A research protocol is understood to mean a systematic and detailed research design . A research protocol is used to plan, structure and systematise all research activities. The use of a protocol is necessary for the systematic carrying out of a study.

2c. Research instruments

- *Documenting and justifying choice*

The selection of the research instruments should be documented.

- *Documenting reliability and validity*

In qualitative research a variety of procedures is available to check, safeguard and increase the validity and reliability of the research results. For an overview of these quality procedures see table 1. It is advisable to use several of these procedures. The selection of one or more procedures should be documented.

♦ *Reflexivity*

An essential characteristic of qualitative research methods is that, to a greater or lesser extent, the researcher is the measuring instrument. Therefore, it is important that the qualitative researcher reflects upon his/her own research role so as to overcome, for example, the danger of 'going native' (Malterud, 2001; Giacomini & Cook, 2000; Pope & Mays, 1999). The reflection process should be explicitly described. In addition to this the influence of other staff who might participate in the study should be monitored.

Table 1. Quality procedures (Devers, 1999).

Criteria	**Strategies**
Credibility / Internal validity	♦ Triangulation: The purpose of triangulation is to make use of multiple data sources, investigators, methods or theory to the extent possible to provide corroborating evidence. ♦ Search for Disconfirming Evidence ("deviant" or "negative" cases). Instead of ignoring cases or information that "doesn't fit", the researcher actively looks for cases that do not fit the pattern and refines the theory until all cases fit, eliminating all outliers and exceptions. ♦ Subject review (also called "member checking" and "dialogue with participants"). The researcher(s) solicits research "subject", group member, or participant views of the credibility of interpretations and findings. In some cases, this strategy is also used to increase the probability that research will be used.
Transferability / External validity	♦ Detailed description of the study context, of the investigator's role in the context and a clear delineation of how the context affects the ability to answer the original research question.
Dependability / Reliability	♦ Data archiving / creating an Audit triage. The researcher(s) should ensure the completeness and accuracy of documents (e.g. interviews, observations, etc.) and be clear about the coding schemes and data analysis process. Theoretically, this would allow someone not connected with the study to review the primary documents and coding schemes to assess whether the findings, interpretations, and conclusions are supported. ♦ Sceptical Peer Review. A sceptical peer reviewer plays the role of devil's advocate, asking difficult questions about methods, meanings and interpretation of data. This process provides an external check on the research.
Confirmability / Objectivity	♦ Triangulation (see above). ♦ Sceptical Peer Review or Audits (see above). ♦ Search for Disconfirming Evidence or Negative Cases (see above). ♦ Reflective Journal Keeping by the Researcher. Because the researcher is the research-measuring instrument in qualitative research, he or she should keep journal notes on how his or her personal characteristics, feelings, and biases may be influencing the work and how he or she tries to manage them in so far this is possible.

3 Data

♦ *Documenting procedures for data acquisition, data processing and data analysis*

Due to the iterative nature of qualitative research, data acquisition, data processing and data analysis cannot always be strictly distinguished from each other. It is therefore important to ensure that these different research phases are carefully documented.

3a Data acquisition

There are various methods for qualitative data acquisition. In this checklist a distinction is made between interviews (I), group interviews (II), observations (III) and document analysis (IV). Combining two or more of

these methods of data collection ('triangulation') is a good strategy for increasing the validity (see explanation in 2c and table 1).

NB. The first three points stated below concern interviews, group interviews and observations. These are followed by a number of specific points for all four separate methods of data acquisition.

- *Introduction in field*

A good introduction should be prepared, prior to the interview, group interview or first observation. In this the following points can be considered: the researcher's role; the aim of the research; voluntary participation of the study subject(s); the length of the interview or group interview; possibly the structure of the interview; the possibility of not answering certain questions; the safeguarding of privacy; and finally the question whether everything is clear (Segers, 1983).

- *Investigation of unreached respondents or nonresponders*

Establishing why people cannot be reached or do not wish to participate is always worthwhile. With purposive sampling further efforts need to be made to find the respondents concerned. If these cannot be included, this needs to be justified in the description of the results or the development of theories. In the case of random samplings it should be ascertained whether the unresponsiveness could be associated with the subject of the study, for example, with an outspoken opinion or considerable dissatisfaction. If this is the case, respondents who risk falling outside of the study can be specifically sought. Non-response research on the basis of gender, age, ethnicity and social status is not sufficient for this purpose.

- *Make notes after every period of data acquisition*

After every period of data acquisition, the value of the data acquired should be established: are there questions which do not yield any results and which should be scrapped or reformulated? Is there a terrain which has received too little attention and therefore deserves extra questions or observation possibilities? Has the study population been selected correctly or does a new group need to be investigated? Is there bias within the study population?

I. Interview

The interview can range from semi-structured to completely open.

- *Structure and layout of topic list*

The topic list has a logical order and a clear layout with, for example, highlighted keywords and a broad margin.

- *Preparation / practice with topic list*

The interview is a product of the interaction between the interviewer and the respondent. The interviewer not only has an investigative role but also a motivating role; he or she should ensure that there is a good rapport. Communication barriers can occur due to a lack of motivation on the part of the respondent, unavailable information, language problems or because the respondent does not feel respected. However, if the interviewer's

attitude becomes too accepting and understanding so that he/she moves towards a friendly relationship then the risk of socially acceptable answers arises. In addition to this, the interviewer should listen in a non-selective manner, assess answers for their adequacy and if necessary probe further. Probing and exploration are essential skills of the interviewer. (For possible sources of error, ways of continued questioning and the relationship between the researcher and the study subject in general, see Emans 1990; Segers 1983; Maso & Smaling, 1998). If the researcher does not perform the interviews then the interviewers should be provided with a thorough training.

♦ *Good audio recording equipment and recording setting*

It is always advisable to test the equipment before use. The use of a separate microphone is preferable. Having spare batteries, an extension lead, spare tapes or mini discs ready to hand is always useful. If necessary the recording setting can be improved by sitting at a table, closing windows, and switching off computers, radios, washing machines and dishwashers. In the case of a translation, make sure that the interpreter can be understood well; if necessary give both the respondent and the interpreter a microphone. At the end of the session the respondent number and the date are recorded on the tape or the minidisk (plus box).

II. Group interview

There are different forms of group interviews such as focus group, delphi method, audit or expert meeting (Kitzinger, 1995, 1999; Jones & Hunter, 1999; Johnston et al., 2000). The explanation given below mostly relates to focus groups.

♦ *Structure and layout of topic list*

As in interviews, in group interviews it is useful to draw up a list with general starting questions and points for consideration, which can be used as a basis for a possible targeted intervention (Kitzinger, 1995).

♦ *Preparation / practice with topic list.*

That which applied to practicing interviews applies even more to group interviews: not only the interaction between the interviewer and the respondents is important but also the group interaction. Indeed, a researcher can deliberately use this interaction to stimulate people to explore and clarify their own ideas. As a result of this unexpected viewpoints can arise and the validity and reliability of the results is increased and tested.

♦ *Good audio recording equipment and recording setting*

In addition to those points stated under ‘Interview’, in group interviews it is even more important to ensure a comfortable room, the correct seating (in a circle or not) and practical matters (refreshments). Where the interviewer sits is important, for example the choice of the interviewer to sit next to a dominant person and opposite a shy person.

- *Observer in group interviews.*

In group interviews a second person should be present, who amongst other things makes notes about the group process.

III. Observation

Observations vary from non-participating, via passively participating (in which the researcher is only present) to actively participating (in which the researcher also participates in the setting to be observed). In the first two cases video recordings can be made.

- *Compiling a list of events, behaviour or statements to be recorded.*

Which events, verbal and non-verbal behaviours and statements are to be recorded, is established on the basis of the problem definition, and the literature and/or conversations with experts. Verbal behaviour is, for example, what is said and how this is said. Non-verbal behaviour covers gestures, facial expression, movements with respect to others and spatial distribution (Maso, 1989). In ethnographic studies using participating observation, this observation frequently develops from descriptive observation (what is going on here?) via focused observation to selective observation (Spradley, 1980; Maso & Smaling, 1998). The behaviour of the researcher should also be described in so far as it is thought that this could influence the study subjects or the data (see also reflexivity under 2c).

IV. Document analysis

This can concern personal documents such as letters, diaries, stories and announcements on Internet discussion lists, or impersonal documents such as reports, minutes and records (Maso, 1989). Documents can be collected in various manners: via appeals, requests to persons or organisations, archives or libraries, or they can be purchased. Obtaining access sometimes requires permission from those who manage the documents. To this end, the purpose and usefulness of the study need to be explained and agreements about the use of the documents need to be made (Maso, 1989). Sometimes documents are produced for the purpose of research (elicited documents), for example by an appeal for letters from readers or the writing of autobiographical pieces.

3b Data acquisition

- *Agreements concerning supply of data and liability for its quality*

In qualitative research the use of data by third parties rarely occurs. Yet it is not inconceivable that interviews or observations will be used by third parties, for example, audiotaped or transcribed interviews or observations recorded on tape. In this case clear agreements should be made about which data will be supplied in which form and who is responsible for the quality.

- *Establishing quality control performed by third parties*

In the case of data supplied by third parties it should be ascertained to what extent the third party has performed quality control, for example, the extent to which non-response and the selection of respondents has been recorded.

3c Data entry

NB. In this checklist the primary file refers to the notes, audio recordings or video recordings made during the data acquisition. The transcript refers to the initial processing of the primary file. The processing of the primary file can be approached in different manners, namely:

- *the transcript contains the literal, complete version of the primary file;*
- *during the transcription, so-called noise (non-research related subjects) is not elaborated on: the transcript contains a cleaned-up version of the primary file;*
- *during the transcription, a selection takes place of those parts which are not elaborated on or only partially need to be elaborated on (e.g. on the basis of initial analyses): the transcript contains a revised version of the primary file content.*

♦ *Overview possible data entry systems*

An overview of software for text input and analysis can be found in the literature, for example: Weitzman, 1999; Janssen, 1999. In general, transcription will always be done with the aid of software. In addition to word processing programs, specific software packages are available for data entry and analysis. Using this software it is also possible, next to data entry, to generate word lists and to categorise and code text segments. In addition, these programs can be used to perform analyses.

♦ *Justification of choice*

The choice of software depends, amongst other things, on the type of qualitative research being carried out and the expertise of the various users (inside and outside the AMC). Nevertheless, the choice should be clearly described. Researchers from the Network Qualitative Research AMC-UvA work with the programs Kwalitan with which considerable experience has now been gained.

♦ *Agreements for selection of transcripts*

It should be documented if and how selection will take place during the transcription (see also NB above), for example by describing if and how pauses and incomprehensible pieces will be included in the transcript. These agreements are particularly important when the transcription will be carried out by third parties.

♦ *Documenting content files*

It is necessary to briefly describe the content of files, in particular for the reproducibility of the research data by others. It is helpful if the title of a file covers the content, e.g. ‘Focus groups Turkish boys 10-10-01’. When doing this it is also wise to give the primary file (e.g. audio recording) and transcript the same name.

♦ *Monitoring data entry*

The text entered can be monitored by comparing it on a random basis with the primary file so as to ascertain whether these are the same. If the text entered is a translation, this must be back-translated by an independent translator.

3d Data clean-up

- *Storage primary file and transcript*

Both the primary file and transcript should be stored, preferably in separate places.

- *Agreements and documentation for cleaned-up files*

The manner in which a file is modified and how, for example, typing errors or obscurities that could not be clarified should be documented.

- *New name for cleaned-up files*

Cleaned-up files should be stored under a new name.

3e Data storage

- *Storage of primary files and cleaned-up files*

The primary file, the transcript and the processed files should always be stored in different places. Ideally the primary file (with a good description) should be locked away; the transcript can for example be stored on CD-ROM. In this manner the original file can always be accessed (in the event that the processed files 'disappear').

- *Storage of 'ready-to-analyse' data*

Extra copies are always made of the processed files which are 'ready-to-analyse', in other words, not only on the researcher's hard disc but also on the network (secured with password) and/or on CD-ROM.

- *Agreements for data storage*

Agreements concerning the storage of data are documented, for example, who is responsible for what and who may see the data.

- *Separating research data from private details*

The transcript and the processed files should have identifying data about people removed (these data are of course available from the primary file). If necessary, fictitious names or letters can be used.

- *Private details are locked away*

Private details are only available from the primary file, which should therefore be kept locked away.

- *Securing data files with a password*

Data files should be secured with a password.

- *Agreements for access (possibly by third parties)*

Who has access to the various files and how requests to use the data for a different study will be handled, should be recorded in writing.

♦ *Upholding a retention period*

Once the study has been completed, the data should also be kept in accordance with the retention period in force (the exact length of this can differ per study). In general a period of about five years is adhered to. This depends on the publication date. It must be possible for third parties to examine the data collected up until about two or three years after publication.

3f Data analysis

♦ *Data mapping*

Before the analysis can be started, the data need to be examined to see which data are relevant for analysis and the relationships between data. In some cases the quantification of data can provide additional insights, for example, to gain an impression of the number of occasions that a theme is mentioned.

♦ *Overview of analysis techniques and justification of choice*

An overview of possible analysis techniques can be of help in choosing a suitable analysis technique.

If themes or categories are used to analyse the data (coding) two 'completely opposite' approaches can be distinguished: inductive, where it is not known beforehand which themes or categories will be sought (for example 'grounded theory') and deductive in which use is made of categories which were already established prior to the data acquisition (for example, the 'framework approach') (Pope, Ziebland & Mays, 2000). The choice depends on the aim of the research. For example: if the aim of the research is to search for new insights/theories about a certain subject then an inductive method will probably be chosen; if the objective is more applied, the 'testing' of a certain model, then a more deductive method would be appropriate. Often an intermediate form is used, in which the study starts with a list of themes that is added to on the basis of the initial analysis.

In the analysis it should be stated whether one or more persons analysed the data. It is preferable if the analysis is performed by several people. Different variations of this are possible, ranging from the method in which every person independently analyses all of the data to a global assessment of the analysis by an expert.

If possible, existing analysis programs should be used (see also: 3c. Data entry).

The fewer the number of researchers participating in the analysis, the more important the assessment by an external expert becomes. This assessment will be easier to carry out if the material is clearly organised (see also table 1: peer review).

♦ *Documenting coding in memos*

In qualitative research the coding of the data takes place during the analysis. This coding should be systematically described in memos (see also: 3e, Data storage). Memos guide the analysis. Different types of memos can be distinguished: theoretical memos, methodological memos, concept maps and profile descriptions (of respondents). Codes are recorded with the help of concept maps (Wester, 1991).

♦ *Reflection on the researcher's role and the research process in memos*

The reflection on the researcher's role is described in a methodology memo. This reflection is necessary for interpreting the results (see reflexivity under 2c).

♦ *Documentation and quality control of interpretation of data and memos*

The interpretation of the data and memos must be clearly documented. The various memos can also help in the interpretation of the data.

Whether the quality of the data and its interpretation are satisfactory, should be checked. Different methods are available for checking the quality. Methods to check the quality of the interpretations are given in table 1.

♦ *Documenting storage of data, research plan and memos*

The reproducibility of the data analysis is important for checking the research procedure. To this end the material, the research plan, the data and the various types of memos should be available in a form that would, in principle, allow the study to be repeated. Of course a systematic storage of these materials on a computer facilitates this checking process.

4 Report writing

NB. In written reports of qualitative research, various aspects cannot always be strictly separated. For example, the method section usually contains a thorough description of the provisional theoretical framework that has guided the data acquisition technique and the selection of the study population (theoretical sampling). Furthermore, due to the interconnectedness of data acquisition and conceptualisation it is neither possible nor desirable to strictly separate the results from their interpretation (the discussion section): the description of a result, for example an interview fragment, is in many cases immediately followed by an analysis, an interpretation and conceptualisation. This leads to the presentation of further results, again followed by analysis, interpretation and conceptualisation, and so forth.

♦ *Documenting publication plan*

The publication plan contains a provisional planning with, per publication, a title or short description of the content, intended journal/book, intended author(s). This planning should preferably cover the entire study and it should be regularly evaluated and adjusted.

♦ *Agreements for interim publications*

The number and nature of interim publications which fall outside of the publication plan are also documented in the agreements.

♦ *Publications cover scientific publications, presentations and non-scientific publications*

Scientific publications are considered to be articles in scientific journals, abstracts and scientific books or contributions to scientific books. For qualitative research this often concerns medical journals and/or books in

the area of health care research; health sciences; nursing sciences; medical sociology; medical ethics; medical psychology; medical anthropology; and occasionally non-medical journals.

♦ *Compliance with guidelines for scientific rigour and precision*

Guidelines for qualitative publications have recently been published in the BMJ and the Lancet (2001; 358: 483-8). These can suffice as guidelines for AmCOGG publications. For example, the checklist from the BMJ is presented in table 2. This has been compiled for reviewers of articles in which qualitative research is reported.

Table 2: BMJ Checklist for reviewers (http://www.bmj.com/advice/33.html).

Qualitative research checklist BMJ

1. Was the research question clearly defined?
2. Overall, did the researcher make explicit in the account the theoretical framework and methods used at every stage of the research?
3. Was the context clearly described?
4. Was the sampling strategy clearly described and justified?
5. Was the sampling strategy theoretically comprehensive to ensure the generalisability of the conceptual analysis (diverse range of individuals and settings, for example)?
6. How was the fieldwork undertaken? Was it described in detail?
7. Could the evidence (fieldwork notes, interview transcripts, recordings, documentary analysis, etc) be inspected independently by others: if relevant, could the process of transcription be independently inspected?
8. Were the procedures for data analysis clearly described and theoretically justified? Did they relate to the original research questions? How were themes and concepts identified from the data?
9. Was the analysis repeated by more than one researcher to ensure reliability?
10. Did the investigator make use of quantitative evidence to test qualitative conclusions where appropriate?
11. Did the investigator give evidence of seeking out observations that might have contradicted or modified the analysis?
12. Was sufficient of the original evidence presented systematically in the written account to satisfy the sceptical reader of the relation between the interpretation and the evidence (for example, were quotations numbered and sources given)?

♦ *Definition of target audience*

Is this article being written for physicians, nurses, policy makers, patients and/or others? This choice has consequences for the form and content of the article.

♦ *Agreements for authorship*

Often, it is good to make agreements at the start of a research project with all those involved as to who will be the author/first author of the various publications. For authorship, the same rules apply as for quantitative research. These so-called Vancouver rules (see table 3) also apply to non-medical journals.

Table 3: Vancouver rules (http://www.bmj.com/advice/33.html).

Authorship

The uniform requirements for manuscripts submitted to medical journals state that authorship credit should be based only on substantial contribution to:

- conception and design, or analysis and interpretation of data
- drafting the article or reviewing it critically for important intellectual content
- final approval of the version to be published.

All these conditions must be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship.

♦ *If not in Dutch: ensure that language content is corrected*

This is always advisable, even if the first author speaks fluent English.

♦ *Anonymity of the study subjects*

In qualitative research, where the context of the phenomena studied is often important, extra attention should be devoted to protecting the identity of study subjects. Recognition can be prevented by changing irrelevant details.

♦ *Affiliations*

State own department(s), research institute and AMC-UvA

♦ *State funding sources for study*

For this, see the Research code AMC (2001).

4b Presentation

Presentations cover: lectures at congresses and workshops organised within the framework of the research, invitational conferences, symposia and congresses.

♦ *Presentations in accordance with usual quality standards*

Presentations should be given in accordance with the usual quality standards (Wubbels, 1991). Extra attention should be devoted to protecting the identity of study subjects. If recognition is unavoidable in presentations (for example, due to the use of video or audio fragments) permission should first of all be sought from the study subject(s).

4c Non-scientific publications

This includes: Reports for the sponsor(s), educational material, guidelines and material for patient care (for example leaflets).

♦ *Report: consideration of utility and readability for sponsors*

A report should be highly readable for the sponsors.

♦ *Popular-scientific: consideration of readability for lay persons*

If it concerns a popular scientific publication, particular attention should be given to the readability for non-specialists. For such publications it is worthwhile getting the readability checked by a non-specialist and/or by a scientific journalist, for example, by the Communications Department of AMC-UvA.

5. Other

For an explanation of all these points see the Research code AMC.

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Notes