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Qualitative Research in Epidemiology

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1. Introduction

By using integrated knowledge from natural sciences with insights from population sciences and the humanities and social sciences, qualitative research has been gaining a greater influence both in the development of epidemiology (Daly et al., 2007; Lloyd, 2000; Long & Eskin, 1995) and in the organization and delivery of healthcare (Shuval et al., 2011). In spite of the growing acceptance of qualitative methods in health sciences, most biomedical scientists have tended to devalue the contributions of interpretative research methods (Albert et al., 2008).

Traditional epidemiology is dominated by a positivist perspective, which means that social reality is seen as stable and therefore the best way to analyze it is through the rigorous application of a limited range of quantitative techniques (Popay, 2003). By contrast, qualitative research and interpretative methods have been dismissed as subjective, soft and unscientific (Green & Britten, 1998) or second class science (Shuval et al., 2011), and their findings have been deemed thin, trite, and banal (Lambert & McKeivitt, 2002).

The following quotation from a reviewer's comment on an original qualitative paper submitted for publication in 2010 by Susana Silva and colleagues illustrates the perception of this methodology as an "entertaining" and "enjoyable" mode of inquiry. The reviewer, who recognized his/her "ignorance" in the field of qualitative methods, reported that "this article [is] very entertaining to read. (...) I do not feel competent to assess the scientific strengths and weaknesses of the study presented in the article. (...) There may be aspects of the study design, and the representativeness of the findings that could be addressed, which I cannot comment on due to my ignorance in these disciplines. Nevertheless, the readers (...) might as well enjoy reading this paper". While this sympathetic response from a reviewer can be drawn on the emotive quality of quotations included in the article, the excerpts are not self-validating and require analysis (Daly et al., 2007: 44).

This thought partly reflects the training and academic background of epidemiologists, where some dichotomies still characterize the methodological debate, such as medical science versus social science and positivism versus interactionism/constructionism (Baum, 1995). Black (1994) argued that epidemiologists were unaware of qualitative methods and some took pride in their ignorance in the nineties, but nowadays epidemiologists are starting to recognize the potential of qualitative research and they are becoming more familiar with these methods. The *Journal of Clinical Epidemiology*, for example, published a

comment on the strength of evidence in qualitative research, arguing that qualitative studies are able to illuminate the “black box” of complex interventions (Jones, 2007), as was demonstrated by Campbell and colleagues (2000) in the analysis of the design and execution of randomized trials. In fact, the use of an iterative phased approach that harnesses qualitative and quantitative methods should lead to improvement in study design, execution and generalizability of results (Campbell et al., 2000).

The findings of the Economic and Social Research Council International Benchmarking Review of the field of health and medical research within United Kingdom sociology, published in 2010, identified the separation between a quantitative (epidemiological) and qualitative (interpretive) work as important reason contributing to its weaknesses. According to this report, there is an increasing demand for the qualitative skills of health and medical sociologists, but sometimes they have to accept marginal roles in large health and medical research teams, as the lack of strong quantitative skills renders them unable to take principal investigator roles, making it harder for them to obtain opportunities to collaborate on international projects (Economic and Social Research Council, 2010: 14). Furthermore, the decreased likelihood of funding opportunities for qualitative research remains a potential obstacle to its growth, although contributing to qualitative research has historically been at the forefront of new research agendas (Muntaner and Gómez, 2003).

Such a framework impacts on scientific journals at two interrelated levels. First, in some cases editors’ and reviewers’ skills are inadequate to appraise qualitative studies, and this might result either in their rejection or in the publication of papers of poor quality (Daly et al., 2007). Second, while leading medical and healthcare journals apply for qualitative research papers and develop criteria for their evaluation, the proportion of original qualitative research articles in medical journals is low (Shuval et al., 2011).

Journals’ policies impact on the publication of qualitative research, through the appearance of specific guidelines for authors and editorials/methodological papers on the subject, irrespective of the journals’ impact factor (Shuval et al., 2011). Since 1997 the *British Medical Journal* (BMJ) has been establishing guidelines for qualitative articles (Greenhalgh & Taylor, 1997), and in 2001 the *Lancet* published criteria for qualitative inquiry (Malterud, 2001). The *British Medical Journal* (BMJ) and the *Journal of the American Medical Association* (JAMA) have accepted qualitative research papers since 1990, and the *Lancet* published the first qualitative articles in the second half of the nineties (Yamazaki et al., 2009). In *The New England Journal of Medicine* it became possible to find articles based on a qualitative and interpretative perspective only after 2010 (Kesselheim et al., 2010). Currently we have found more than 60000 publications in Medline using qualitative methods.

In the last 20 years, the publishing of original qualitative research papers by leading medical and healthcare journals, as well as the foundation of journals like *Qualitative Health Research* (1991) and the *International Journal of Qualitative Studies on Health and Well-Being* (2006), specially devoted to the discussion of theoretical and empirical issues on qualitative research in health, have been contributing to shape the way biomedical scientists and practitioners look at qualitative methods. At the same time, flexible research methods and socio-environmental approaches have been used by public health researchers in order to answer complex questions embedded in social, political and economic factors (Baum, 1995).

Popay (2003) synthesized the contributions of qualitative research to epidemiology in two contrasting models:

- The enhancement model, which perceives qualitative research as adding a little extra to the knowledge provided by traditional epidemiological research through explaining unexpected results, generating hypotheses to be tested by quantitative epidemiological research, and helping to develop measures of social phenomena.
- The epistemological model, which presupposes an equal relationship between qualitative and quantitative approaches, recognizing the possibility of challenge and tension between them, expressed on the following specific contributions of qualitative methods to epidemiological research: addressing different kinds of questions; shifting the balance between the researcher and the researched; and adding conceptual and theoretical depth to knowledge.

The first perspective – the enhancement model – is most common when conceiving the relationship between qualitative research and epidemiology. However, the publication of explicit criteria to construct a hierarchy of evidence-for-practice for assessing qualitative empirical studies in the *Journal of Clinical Epidemiology* may serve as a basis to strengthen the epistemological model, in the sense that these criteria, based on the study type and its features and limitations, would both assist in transparency in peer review and help practitioners identify the research which provides the strongest basis for action (Daly et al., 2007).

The objective of this chapter is to discuss the contributions of qualitative methods to the development of epidemiological research, arguing that qualitative and quantitative methodologies are complementary approaches to answer different research questions. This discussion is informed by the authors' research experience in the context of reproductive and genetic technologies and the social determinants of health in adolescents. Our aim is to focus on the following four main topics related to the role and scope of qualitative methods used in epidemiology:

- To address the main techniques of data collection and analysis, and to critically appraise their appropriateness to study designs.
- To discuss the representativeness of the findings and their internal validity (the study investigates what it is meant to investigate) and external validity (in what contexts the findings can be applied).
- To examine how mixed-method research, using qualitative and quantitative approaches, can contribute to deepen traditional epidemiological research.
- To explore the challenges and embodied practices that emerge from undertaking qualitative research.

2. Data collection and analysis

More than describing the principles and approaches of the main techniques used to collect and to analyse qualitative data (see Green & Thorogood, 2009, Part I), this section aims to show how qualitative research makes sense in the epidemiological way of doing and thinking. Qualitative data provide answers to specific research questions in epidemiological studies, by focusing on the understanding of meanings, beliefs, and attitudes from the point

of view of the social actors (Lloyd, 2000; Mays & Pope, 1995), allowing in depth analysis of human behaviour. Qualitative methods are useful for studies with the following broad objectives (Alderson, 2001: 5-6):

- To explore and map out a little known field and to give voice to habitually silenced and excluded groups.
- To provide detailed findings on people's views and experiences and to understand how they make sense of their beliefs, values, rules and behaviours with a flexibility which standardized quantitative enquiries cannot cater for.
- To discuss new questions and emerging theories or conclusions through data collection, working reflexively.
- To reveal and analyse complexity, difference, ambiguity, contradiction and gradual changes which are hard to capture in more static quantitative measures.

2.1 Qualitative interviews

The interview is the most commonly used technique for producing data in qualitative health research. While the interview is generally seen as an informal and spontaneous dialogue, there are two main differences between them: first, the interviewees are the protagonists and the interviewers must listen very carefully and encourage him/her to speak; second, the guide of the interview aims to obtain data to answer the research questions.

Qualitative interviews have been categorised as structured, unstructured, semi-structured, and in-depth:

- In a structured interview, the interviewer follows a previously defined set of questions in a specific order. The interview often produces data to be submitted to quantitative analysis.
- Unstructured interviews are more or less equivalent to guided open conversations about the field in which the interviewer is gathering information. It is usually conducted in conjunction with the collection of observational data in the context of ethnographic studies.
- The semi-structured interview lies between the above mentioned categories. There is an interview guide with a set of predetermined open-ended questions, but several questions may emerge during the interview. It is the most commonly used strategy to obtain data for qualitative health research, and it requires from the interviewer a great knowledge of the subject that is being studied.
- An in-depth interview generally starts with open and thematically oriented questions. A few specific and effective questions for eliciting the necessary information may be asked, even if they differ from the planned itinerary, as they follow the interviewee's knowledge and interest.

The qualitative interviews, especially in-depth interviews, require several skills from the interviewer, who must be trained, both in the objectives of the research, and in the social and technical norms of interviewing, namely regarding the following aspects:

- Methods for recording interview data, such as audiotape recording, videotape recording and note taking. To maintain high quality in the audiotape recording, the most frequently used method, the interviewer should take into account the following

factors: the avoidance of excessive background noise; checking the batteries; placing the recorder in a suitable position; testing the recorder before using it; having a back-up recorder ready to be used; asking for specific consent for tape-recording prior to an interview. Recorded data need to be carefully guarded and eventually destroyed after completion of the transcription or analyses.

- Processes for transcribing data. Although this process remains relatively unexplored, the accuracy of transcribed data is difficult to appraise, because transcribers must make judgments when capturing the spoken word in text form. Thus, to ensure accuracy during interpretation, most experienced researchers listen to the audiotape while reading the transcriptions (DiCicco-Bloom & Crabtree, 2006).
- Strategies and procedures for working with interpreters on cross-language qualitative interviews, and their influence on the data generation process and on the validity of the data, in a context where an “interpreter-facilitated” approach seems to be an effective alternative to more commonly used and more laborious and expensive translation practices (Williamson et al., 2011).

Researchers face two main issues concerning sampling procedures when conducting qualitative interviews - the method of sampling and the number of participants:

- The strategies used to recruit the participants depend on the objectives of the study. In some situations, like a small number of potential participants or in exceptional cases, sampling decisions have to be made opportunistically (opportunistic or convenience sampling). However, most qualitative investigations rely on purposive (or purposeful) and theoretical sampling, which means that they select participants who are likely to generate appropriate and useful data to address the research question, grounded on an iterative process in order to maximise the depth and richness of the information. While purposive sampling selects participants with different characteristics which are relevant to the study to cover as wide a range as possible, theoretical sampling aims to fill in gaps discovered at earlier stages or to expand the range of participants linked to an issue which has come to be seen as important in order to illustrate and test emerging theories.
- The sample size is generally determined by data saturation, which means that recruitment continues until no new categories or themes emerge from the interview data. Awareness of the saturation point requires a reflexive attitude and experience of at least two researchers. In sum, qualitative studies aim to obtain a theoretical representative sample, regardless of its size.

In epidemiology, qualitative interviews have been used to collect data that quantitative methods are unable to discover. For instance, smoking is becoming more frequent among adolescents (Fraga et al., 2006) despite the many prevention campaigns which targeted them. These results were obtained from the baseline of an epidemiological cohort of adolescents and led us to conclude that tobacco epidemics did not seem to be under control. These adolescents were the target of many campaigns in schools and through the media at the time of the interview. Therefore the authors wanted to understand how the information about tobacco and smoking was absorbed by adolescents. With the purpose of understanding this trend, Fraga and colleagues conducted 30 semi-structured qualitative interviews with adolescents in order to assess how they perceived smoking behaviour, concluding that adolescents were aware of the serious health implications of smoking, but

they only referred to it as a long-term effect in adulthood and no consequences during adolescence were reported (Fraga et al., 2011a).

As Baum stated, “while the causal link between tobacco and lung cancer may be explained by experimental and quasi-experimental methods, the power of tobacco companies and their advertising strategies, the reasons people continue to smoke despite strong evidence about the health risks it entails and the social meanings of smoking (...) require qualitative research inquiry” (Baum, 1995: 464). However, the collaboration between epidemiology and qualitative research in the substance use field is a difficult one, partly because qualitative research often adds issues of context and meaning that challenges the traditional epidemiological data of interest (Reisinger, 2004).

Silva and Machado (2010) explored similar issues in the case of unsuccessful in vitro fertilization programmes. Eleven semi-structured qualitative interviews (four heterosexual couples and seven women) were conducted with Portuguese in vitro fertilization patients in order to analyse the social meanings of the failure of these treatments and the strategies deployed by the patients in the reconstruction of expectations toward them despite evidence about the limitations, risks and uncertainties they entail. The authors concluded that the uncertainties and risks of in vitro fertilization procedures and their implications in the mobilization and in the actions of different social and/or professional groups should be central topics in debates on medicine and bioethics in a broader sense and in the local ethics of clinical research and doctor-patients relationships. Furthermore, these debates should incorporate the experiences of women and men who try to have a biological child by using these techniques and should produce reflection about the social, cultural, technical and medical changes that are necessary to make these technologies increasingly successful. These are important considerations underlying patient-friendly medicine because they could minimize the negative feelings that many patients might have, especially women - for example, that they themselves are to blame for an unsuccessful in vitro fertilization treatment cycle.

Another example of the contributions of qualitative research might be the findings in a paper about the public perceptions of genome-based knowledge and bio-information technologies. Semi-structured qualitative interviews performed with 31 inmates in three prisons for male adults in the north of Portugal between May and September 2009 were useful in the understanding of Portuguese prisoners’ awareness of the new gold standard for individual identification - DNA profiling or DNA fingerprinting. Individuals currently imprisoned seemed to grasp the advantage of keeping a convicted person's DNA profile on the national forensic DNA database as a protective measure to prevent being “rounded up” by the police when a crime has occurred and the released prisoner fits the (non-DNA based) search criteria for suspects. Moreover, the prisoners argued in favour of a universal DNA database - something that civil liberty advocates would strongly disagree with (Machado et al., 2011).

While single interviews allow the researcher to deeply explore social and personal issues, interviewing couples may offer a potentially strong basis to understand the processes by which the social relationships and gender identities are deployed to construct meanings and to provide significance to personal experiences in health, illness, and medicine. For example, the emergence of a new type of “hermaphrodite patient” (Ploeg, 2001) - the couple - in the case of in vitro fertilization treatments challenges epidemiology to analyse issues related with this new unit of analysis (Kenny et al., 2006).

With the purpose of understanding how ovarian stimulation makes sense within the context of heterosexual couples' relationships, for example, Silva and Machado conducted 15 semi-structured interviews with Portuguese patients who have undergone in vitro fertilization programmes performed with eggs collected in stimulated cycles. The authors concluded that the cultural assumptions underlying women's duties regarding maternity reinforce a moral framework in which the pain and the complications associated with ovarian stimulation were naturalized, normalized and accepted. Furthermore, this paper shown how men can be incorporated into roles that are supportive of women's social well-being and reproductive health by means of two essential devices: increasing cross-gender interactions, emotions, co-operation and men's involvement in the injection of hormones into his partner's body; the re-construction and the challenging of the discourses and practices surrounding the vulnerable and 'inappropriate' women and strong men, so that women do not blame themselves for the reproductive failings of heterosexual couples (Silva & Machado, 2011b).

There are also group interviews, where the interviewer simultaneously gathers data from several participants. Besides assessing individual participant's perspectives about a certain issue, the researcher obtains information on strategies of interaction between participants, allowing the understanding of how knowledge is produced in daily life. However, the public nature of the process prevents a deep exploration of individual matters. Some examples of group interviews include consensus panel, focus group, natural group or community interview.

The focus group is the most commonly used strategy in qualitative health research. The choice of this technique is related both with the researcher's working preferences and study objectives. A focus group is a small group of 6 to 12 people who are invited to jointly discuss a particular theme, under the guidance of a moderator. Sometimes there is a co-moderator or note-taker that assists the moderator. The co-moderator takes some written notes about the emerging themes and participants' interactions during the session and ensures that tape recorders are working. Moderators must be very familiar with the interview guide and the objectives of the study and must have a strong background in the issue that is under discussion. The role of a moderator is to establish a relaxed atmosphere, to enable all participants to tell their stories and to listen very carefully. The physical setting is particularly important for the success of this technique. It should be quiet and comfortable, without any disturbance.

2.2 Documental analysis

Documental analysis refers to the use of a wide range of existing written and/or visual sources related to a topic. In qualitative health research, the main documentary sources are mass media outputs, such as newspapers or magazines, public documents, research articles, personal and work diaries, and photographs or video recordings (Green & Thorogood, 2009: 173 ss.).

While existing documents are one of the most accessible and widely available sources that can be used in epidemiological studies, health researchers cannot take them for granted as reliable sources of information. All formal procedures must be described very carefully in

order to answer a research question. The use of standardized and well documented procedures as in a systematic literature review contributes to increase reproducibility and transparency of the qualitative findings from documental analysis.

The analysis of the portfolio of risks presented in the Portuguese law of assisted reproductive technologies (Law n.º 32/2006, July 26th) and in consent forms that must be signed by the beneficiaries of these techniques is an illustration of documental analysis (Silva & Machado, 2011a). This study aimed to understand how medical practitioners and legal framers attribute meanings to the benefits and risks involved in assisted reproductive technologies. The authors concluded that these assessments reproduce existing relations and practices, particularly the social power of medicine and technology, the dominant perceptions about women's and men's bodies and the geneticization of genealogy. However, they also generate new ways of thinking and talking about individual and institutional management of expectations, risks and responsibilities imbued with hope and trust, whereby some citizens' rights may be weakened. New rights based on genetic information, such as the right to genetic identity, the right to genetic inheritance, the right to know one's genetic history, and the right not to inherit genetic problems that can be scientifically detected and eliminated, demand both a "healthier" genetic society and changes in the social definition of identity, affiliation and citizenship. At the same time, individual and institutional responsibilities are now based on co-production of medicine, law and social order to guarantee the success and acceptability of assisted reproductive technologies, benefiting from the creation of new social actors and new scientific fields to regulate them, such as biolaw, bioethics, and The National Council of Medically Assisted Reproduction.

Another example that demonstrates the utility of this technique is related to the use and storage of genetic information in forensic DNA databases (Machado & Silva, 2009). The authors aimed to explore the practices of informed consent in the context of DNA sample collection for forensic processing in Portugal, and they concluded that these practices need to incorporate responses to risks and also uncertainties posed by collecting DNA samples and DNA profiling.

Drawing on three different documentary sources - the Portuguese law of assisted reproductive technologies (Law n.º 32/2006, July 26th) and the Portuguese law concerning the DNA profile database for civil and criminal identification purposes (Law n.º 5/2008, February 12th); information available on the websites of two non-public centres for reproductive medicine that recruit egg donors and/or semen donors in Portugal; and news articles published in the press about the intentions to create the first public egg and sperm bank in this country - Silva and Machado (2009a) analyzed the discourses on donation of biological material in two distinct contexts: the medical context of gamete (eggs and sperm) donation; and volunteers for donation of DNA material for the forensic national DNA database. Framing these narratives in rhetorical devices of gift, altruism, informed consent and social responsibility, the authors concluded that several parallelisms between donor characteristics (e.g., gender, age, professional status, clinical and gynaecological history, and altruistic motivations) and the dominant social, cultural and political order were established, creating multiple inequalities in terms of citizens' interactions with biotechnology. The fulfilment of the apparent possibility that any citizen could become a biological material donor depends on the existence of some requirements, grounded on biological and genetic factors, but overall socio-cultural, economic, moral and emotional

criteria. The inequalities and genetic (in)security are naturalised through two discursive patterns: the reduction or suppression of risks associated to biotechnology by emphasising the rhetoric of gamete quality and the safety of genetic databases and by reaffirming the dominant conception of DNA as an objective measure of individual identity; and purification, a discursive mechanism which stresses individual responsibility in the donation of biological material in order to achieve collective well-being – procreation and security, a task assisted by biotechnology.

2.3 Observation

In qualitative health research observational methods provide direct access to what people do, as well as to what they say and think. Observation has been categorised as participant and non-participant, depending on the involvement of the researcher with the activities and people under scrutiny. Participant observation refers to the cases when the researcher takes part in the activities and directly interacts with participants. Thus, it requires reflexivity from the researcher, as well as the use of “epidemiological imagination” (Ashton, 1994), that is, the ability to make links based on new strategies to collect and analyse data. Ethnographic observation is commonly used to study health beliefs of groups or communities and to understand health care organization. It is especially effective in the analysis of the meanings and functions of physical places and the study of social interactions.

Béhague and Gonçalves (2008), for example, show how ethnographic analyses reveal multiple pathways of influence and causality when interpreting epidemiological results on the determinants of mental morbidity and age of sexual initiation, obtained in the 1982 birth cohort from Pelotas, Southern Brazil. The authors concluded that the following set of mediating factors generally related to particular experiences of specific subgroups account for the epidemiological results: the awareness and experience of inequities; the role of violence in everyday life; traumatic life events; social isolation and emotional introversion; and approaches towards psychological maturation. These factors “are likely to vary depending on the specificity of socio-political and economic contexts. As such, to be adequately tailored to each setting, public health strategies need to be based on a more detailed, in-depth and context-specific understanding of the *reasons* accounting for the salience of statistical associations” (Béhague and Gonçalves, 2008: 8).

The authors of this chapter will use ethnographic observation within an on-going project aiming to address the negotiation of expectations, rights and duties of parents of very preterm babies in the context of Neonatal Intensive Care Units (project “Parenting roles and knowledge in neonatal intensive care units”, PTDC/CS-ECS/120750/2010). This technique will be used to describe the configuration of the physical spaces; to analyse the organization of care; and to understand the interactions between mothers and fathers, parents and babies, and parents and staff. In this study, the researcher will not be in a familiar setting, which facilitates the achievement of an analytic distance. The analysis of the co-constitution of parenting (both mothering and fathering) and medical technologies, and biomedical and embodied knowledge in the context of Neonatal Intensive Care Units has been grounded on qualitative studies of the experiences and views of parents of children born prematurely on the following main domains: informed consent practices and perceptions of risk (Alderson et al., 2006); information and communication needs (De Rouck & Leys, 2009); meanings of acceptable quality of future life (of offspring) and legitimacy of end-of-life decisions (Vermeulen, 2004); and breastfeeding (Renfrew et al., 2010).

2.4 Analysis and interpretation

To organize, classify and compare data is the first step in the process of analyzing qualitative material. Computer-assisted qualitative data analysis software, such as NVivo Research Software®, NUD*IST, ATLAS.ti or Ethnograph, are available to assist in data management and they can draft content analysis through coding and systematic retrieval of data. Although these tools have seen an overall improvement since 2000 (Yamazaki et al., 2009), they neither spontaneously classify nor compare data.

Qualitative data analysis ideally occurs concurrently with data collection. During this iterative process, the investigators generate an emerging understanding about research questions with two main objectives: first, this preliminary analysis leads to the identification of issues where data need to be further enriched; second, it informs the sampling process, in the sense that researchers are aware of the point in the data collection in which no new categories/themes emerge – data saturation –, signaling that data collection is complete.

Undertaking analysis of qualitative material includes art (Denzin & Lincoln, 2005) and imagination (Popay, 2003), involving a very time consuming learning process that only can be achieved by doing and by thinking about interpretation. It requires the ability to make links and a particular focus on issues of diversity and data saturation. Thus, excellence in qualitative research analysis depends on the experience and expertise of researchers.

The epidemiological imagination (Ashton, 1994), like the sociological imagination (Mills, 1959), is the capacity to shift from one perspective to another and requires the application of imaginative thought and new theoretical and practical knowledge to ask and answer unfamiliar and alternative research questions, taking into account the ways in which the wider social context (e.g. country, time period and social class), actors (e.g. norms, motives and values) and social actions shape outcomes, and how they interact and influence each other. As Popay argues in his paper *Qualitative research and the epidemiological imagination: A vital relationship*: “If epidemiology is to fully develop its imaginative potential then the intellectual frame that guides it and the methods it deploys must encompass both empirical observation and interpretation – measurement, meanings and context – and together these will provide both explanation and understanding” (Popay, 2003: 59).

Three main broader analytic strategies have been widely used to analyze and interpret qualitative data: an “editing approach”, when researchers review, identify and interpret text segments like an editor; a “template approach”, when investigators apply categories based on a code-book that results from prior research and theoretical perspectives; and an “immersion/crystallization approach”, a less structured approach which involves several reflective cycles until interpretations intuitively crystallize (DiCicco-Bloom & Crabtree, 2006).

Content analysis is the most commonly used technique for qualitative data analysis. It involves the categorization and indexation of recurrent data or common major themes, allowing the identification of salient issues for particular groups or typical responses of all participants. Key issues and themes emerge as the researchers look in detail at transcripts, a task which may be developed through several processes:

- Systematic sorting of transcripts, line by line, to sift, chart, and sort material.
- Intensive scrutiny of notes and transcripts.

- Regular checking and re-checking of all the data, to evaluate the relevance of selected categories and their connection with data.
- Comparison of each segment in turn to appraise its relevance to categories and to map the range and variation of each category.
- Counting all references to certain issues or use of certain words.

When working in teams, data should be coding separately by two independent researchers and, as the analysis evolves, themes should be discussed between them. Sometimes a third expert solves potential disagreements. This process grounds the identification of theories and topics that should guide subsequent stages of data collection. Researchers start reading one transcript or the notes of one case, looking for one particular theme or question of the study or looking for stages in a sequence of events, and after a while subdivisions will emerge; for example:

“When people are talking about considering consent to brain surgery they may talk about feelings – hope, fear, disgust, dread. Each feeling can be marked with a different colour. Fear may begin to subdivide into what people fear, how afraid they say they are, and how despairing dread may gradually change towards anxious hope. After checking through one transcript several times, move on to the next. Does it fit the tentative subheadings-colours you have begun to use? Do you need to subdivide them further, or can you combine some? (...) The data begin to seem to form into groups as the analysis grows organically and the researcher can gain confidence that the analysis and theory generating are well grounded in the evidence” (Alderson, 2001: 24).

Thus, findings from qualitative research do not merely describe participants’ narratives and experiences. They are based on a reflexive process, and researchers should be very knowledgeable about the subject under study.

3. Generalizability and validity

Lack of representativeness of qualitative studies is often criticized by traditional epidemiologists, although there are experiments in the natural sciences that are not based on random samples and large sample size, with findings contributing to a general theory of a certain phenomenon. In epidemiology generalizability or external validity refers to the extent to which findings from a study apply to a wider population or to different contexts. Qualitative studies rarely use random sampling, and the logic of generalizability is quite different from that of a sample survey. The qualitative findings are not supposed to be valid for population groups at large as they are descriptions, notions, or theories applicable within a specific setting but always within a wider context.

In qualitative research the generalizability of the findings is defined in relation to relevant literature, which enables researchers to show how far the research data and conclusions can be applied in other settings or to other groups. Thus, analytic generalization is associated with the generalization of a theory that explain the phenomenon being studied, or a theory that may have much wider applicability than the particular case studied.

Sampling procedures and determination of the sample size are relevant issues discussed in qualitative methodology, representing an active process of reflection. It involves thinking about the kind of relationship the study findings have to other populations and settings, and

accurately extracting inferences that can be drawn from the data analysis. In this context, the concept of generalizability gives rise to the concept of transferability. Transferability refers to the degree to which the findings of qualitative research can be generalized or transferred to other contexts or settings, a responsibility of the researcher who is doing the generalization. The qualitative researcher can enhance transferability by doing a thorough job of describing the research context and its central assumptions. The person who wishes to "transfer" the findings to a different context is then responsible for making the judgment of how sensible the transfer is.

The scientific community has been discussing the value and legitimacy of a specific set of standards and guidelines for evaluating qualitative research. Popay (2003: 62) identified the following common "technical" quality assessment criteria:

- Appropriateness of the method to research question.
- Explicit link to theory.
- Clearly stated aims and objectives.
- Clear description of context, of sample and of fieldwork methods.
- Some validation of data analysis.
- Inclusion of sufficient data to support interpretation.

Many quantitative researchers see such criteria merely as a relabeling of the very successful quantitative criteria, a strategy aiming to accrue greater legitimacy for qualitative research. They suggest that a correct reading of the criteria for evaluating quantitative papers would show that these are also appropriate to appraise qualitative studies. According to this view, alternative criteria represent a different philosophical perspective that is subjectivist in nature, because scientific research presupposes some reality that is being observed and can be observed with more or less accuracy or validity, otherwise it is not scientific research.

Qualitative researchers commonly relate the well known principles of truth, respect, justice and avoiding harm with overlapping criteria for assessing research – validity, reliability and replicability, representativeness, and generalizability – taking into account bias as part of the methods and the findings. The following strategies have been used to guard against potentially adverse effects (Alderson, 2001: 10):

- Asking a balanced range of questions.
- Checking through all the data for how typical or exceptional each kind of response is.
- Examining the important unusual cases as to how and why they might be unusual, and the relevant examples that seem to challenge or disapprove a tentative general theory.
- Being aware of researchers' own prejudices and how they might affect the way the data are collected and interpreted.
- Selecting a broad sample of different types.

In sum, the following set of good practice guidelines will add credibility to the analysis and assure the validity of qualitative findings (Green & Thorogood, 2009; Popay et al., 1998):

- Transparency - The methods should be clearly stated and described in-depth to the audience, allowing other researchers to follow the same steps. An honest account of how the sample was chosen, how analysis was performed, and how the coding categories were developed should be provided.

- Maximizing validity – Validity means the truth of an interpretation, not in the sense of a positivist idea of a fixed truth, but a truth that is socially situated. Interpretations should be grounded both on theoretical approaches and empirical data, with relevant quotes to illustrate the typicality. The following strategies can contribute to maximize validity in qualitative studies: first, a simple count of answers can increase the audience's faith in validity, but it is not always appropriate; second, providing in-depth descriptions of the context with the purpose of facilitating the understanding of the interpretation, including, for example, the characteristics of the interviewers, the research setting and technical procedures.
- Maximizing reliability – Reliability relates to the repeatability of interpretation, that is, when the same methodological procedures are followed within a context with similar characteristics, the finding should be analogous. A strategy for improving reliability can include having more than one researcher coding and analyzing the data. At the same time, the line of thought behind codes and themes should be clearly recognized. However, qualitative research about personal experiences of health and illness are still harder to replicate, because people's knowledge and feelings may be complex, ambiguous and may depend on time, place and whom they are talking to. Thus, reliability also depends on giving a faithful report of peoples' changing accounts (Alderson, 2001: 9).
- Comparative – Qualitative researchers should compare all the narratives in order to find regularities in the data, and they should compare their findings with other findings attained in the same context or field or those that relate theoretically to the issue.
- Reflexivity – Taking into account that a qualitative researcher is part of the process of producing data and their meanings, reflexivity must guide his/her conducts. A reflexive awareness of the research process, the researcher's role, even the social setting or social context, would increase the rigor of analysis. Qualitative researchers should examine not only what people say and do, but also "why they might be saying these words and how the interview setting, the questions and themes, and the relationship between interviewee and interviewer might influence how each person reacts, as together they construct and re-construct their conversations" (Alderson, 2001: 14).

4. Mixed-methods research

The mixed-methods research approach, using qualitative and quantitative methods, has become unexceptional in recent years, and it has come to be seen by some writers as a distinctive research approach that warrants comparison with both quantitative and qualitative research (Creswell, 2008). However, the combination of quantitative and qualitative research in health studies remains scarce (Yamazaki et al., 2009). Indeed, bringing quantitative and qualitative research together in epidemiology is no easy task, because "too often the preoccupation of both sides (...) with the 'righteousness' of their cause – of their way of 'knowing' the world – deflects them from appreciating the value and power of research from the other tradition" (Popay, 2003: 59).

There are different types of mixed-methods research, depending on the following factors (see Bryman, 2006: 98):

- The quantitative and qualitative data may be collected simultaneously or sequentially.

- Priority may be given to quantitative or to qualitative data, depending on the study' design and objectives.
- The function of the integration may be, for example, triangulation, explanation or exploration.
- The mixed-methods research may occur at different stages in the research process, namely: question formulation; data collection; data analysis; or data interpretation.
- The number of research methods and hence sources of data.

Bryman (2006) devised a detailed scheme with the justifications that are found in both methodological writings and social science research articles for employing a mixed-method research approach, which arose from the following rationales: enhancement or building upon quantitative/qualitative findings; sampling; completeness; triangulation or greater validity; diversity of views; instrument development; different research questions; explanation; confirm and discover; context; offset; process; illustration; utility or improving the usefulness of findings; credibility; and unexpected results. The author concluded that the reasons given for using the mixed-methods research approach are not always aligned with their uses, thus calling for further theoretical and methodological thought on these rationales.

We are of the opinion that epidemiologists could add an important contribution to the discussion about the grounds on which mixed-methods research is conducted through the examination of concrete examples of research (e.g. Kessel et al., 2009; Krein et al. 2006). Fraga and colleagues, for example, combined quantitative and qualitative research when studying the case of alcohol use among adolescents, because the authors realized that both data were complementary and contributed to a better understanding of the problem (Fraga et al., 2011b). A cross-sectional study was carried out with 2036 adolescents where a structured questionnaire was administered; this made it possible to obtain the prevalence of alcohol use. Qualitative interviews with 30 of these adolescents were therefore conducted. The authors concluded that a high proportion of adolescents had experimented alcohol at 13 years of age, showing the importance of starting prevention at early life stages. While quantitative data showed that adolescents recognised that drinking alcohol is harmful, classifying alcohol as an addiction which is difficult to treat, qualitative interviews reveal some underlying misconceptions - adolescents were unable to identify serious consequences of alcohol use. In fact, they only reported minor temporary consequences of drinking alcohol, usually related to very high and acute consumption. Therefore, drinking behaviours of these adolescents are partly explained by social images that tended to devalue the major health consequences of alcohol use.

Qualitative research will be combined with a quantitative approach in an on-going research by Susana Silva and colleagues on the similarities and differences between the views and values of those in vitro fertilisation couples who agree to donate embryos for research and those who refuse to do so. A hospital-based survey has been performed after couples sign their informed consent sheet in order to indicate broad patterns of social, demographic, psychological, medical and treatment characteristics of in vitro fertilization couples. It will highlight the determinants of the acceptability of embryo research. All couples who are being asked to participate in the hospital-based survey will be contacted four months after receiving their pregnancy result, to request their participation in an in depth interview. The researchers will sample for maximum variation of views and experiences -heterogeneity

sampling -, with the aim of recruiting sufficient participants to allow thematic saturation to be reached. The purpose of these in depth interviews is to address in vitro fertilization couples' negotiation of the personal and social dilemmas raised by the decision about the fates of their embryos, particularly the rights of prospective parents and children, notions of healthy embryos and child welfare, and expectations and concerns regarding the quality, safety, and efficacy of embryonic stem cell research. While this decision was made in advance, unanticipated consequences of combining quantitative and qualitative research may emerge when gathering the data due to surprising findings or unrealized potential in the data (Bryman, 2006).

5. Embodied experiences

The regulatory frameworks, legislation provisions and guidelines for ethical scientific procedures and guidance have been constructed worldwide over the last four decades (Montgomery & Oliver, 2009). In line with legal and professional ethical guidelines, qualitative researchers should state their engagement in informative and mutually respectful interactions and explain the benefits to those individuals participating in the study when submitting research proposals (Sandelowski & Barroso, 2003).

In fact, the process of establishing rapport, which involves a safe and comfortable environment, trust and a respect both for the participant and the information he/she shares, is essential to develop positive relationships during traditional ethnography, observation and qualitative interviews. As qualitative data is personal, context specific and likely to be identifiable, there can be three levels of informed consent: first, consent to take part in the research; second, consent the publication of the data; third, consent to secondary analysis (Alderson, 2001: 17-18).

DiCicco-Bloom and Crabtree (2006: 319) identified four main ethical issues related to the interview process:

- The risk of unanticipated harm should be reduced. Researchers must be prepared to provide psychological support, if it is needed.
- The interviewee's information must be protected through the maintenance of anonymity. However, qualitative researchers may be aware that "absolute confidentiality, that no-one would ever be written about in a way recognizable to their family, colleagues, doctor - or themselves - is rarely possible" (Alderson, 2001: 18).
- Ensuring adequate communication and effectively informing interviewees about the nature of the study and of the intent of the investigation. By asking for consent to participate several times in on-going interviews might reinforce participants' right to disengage from a research at any time.
- The risk of exploitation of the interviewees should be reduced, and their contributions to the success of the research process must be acknowledged.

Those ethical considerations tend to focus on the researcher-researched dyad (Aldred, 2008) and refer primarily to one side of the dialogue in developing guidelines for human subjects' protection - researched protection and risk management concerns (Connolly & Reid, 2007). At the same time, standard ethical practices that guide qualitative research represent work in progress, and "researchers need to consider the implications of their own research and

use their experiences as a guide to enhance their own ethical standards” (DiCicco-Bloom & Crabtree, 2006: 319).

Conducting qualitative research is an embodied experience where researchers knowledgeable emotions and feelings. The discussion of methodological issues such as disclosure and reciprocity, listening to untold stories, reflexivity and management of emotions, as well as complex and shifting social and political relations with a focus on gender, power and organizations, is recent in qualitative health research (Aldred, 2008; Dickson-Swift et al., 2007, 2009). How to deal with these emotional costs and dilemmas associated with qualitative research experiences also needs to be discussed by epidemiologists.

One main issue concerns the gender of the participants in the study. In the context of studying infertility, for example, should the unit of analysis be woman, man or the couple? And should the interviewer be a woman or a man? In two studies conducted by Machado and Silva (2010), most of the men who participated were interviewed together with their wives (nineteen heterosexual couples, twenty-five women and one man) and the interviewers were females. While this interview context might have restricted the male participants’ speeches and emotional repertoires, if we take into consideration that men tend to be socialized to silence their emotions and anxieties, in particular in the presence of women, it supports the understanding of the processes by which the social relationships and gender identities are deployed to construct meanings and to provide significance to personal experiences in the context of infertility.

Another subject is related with the presence of social inequalities in access and use of medical care in the field of in vitro fertilization treatments in Portugal, as well as the couples’ narratives about cryopreservation of embryos (Silva & Machado, 2009b), which are usually accompanied by strong emotions. Silva still remembers an acute feeling of exhaustion at the end of an individual qualitative interview with a woman who was crying uncontrollably during the first five minutes of the interview. This female interviewee became so upset that Silva switched the tape recorder off and give the interviewee her hand. Like many others qualitative researchers, we think that it is very important to respond to the interviewees as human beings, touching them and offering support (Dickson-Swift et al., 2007: 336), grounded on mutual understanding and availability to look at and listen to them.

When feeling the weight of sharing human experiences characterized by social injustices, physical and psychological suffering and stigmatization, Silva felt the social responsibility to propose measures that can help to achieve social justice and equal citizenship (Sampson et al., 2008; Silva and Barros, 2011). While producing recommendations is not always seen by epidemiologists as scientific work, to understand the mediating factors accounting for the salience of statistical associations is essential, and these include the awareness and experience of inequities and emotional introversion as a response to life’s difficulties (Behague & Goncalves, 2008).

Furthermore, while Silva studied other people’s fertility, her own was equally questionable. For most qualitative health researchers, it can be perceived as a context that ensures reciprocity in the research relationship (Liamputtong & Ezzy, 2005). However, Silva said to a female interviewee that “all went well” with the birth of her first child, although the ultra-

sound of the second trimester pregnancy exam revealed that her child's kidneys were dilated with what appeared to be multicystic dysplasia. The doctors detected bilateral hydronephrosis when the child was 3 days old and he underwent a surgical procedure at 10 days of age.

This particular research relationship caused some suffering, for two main reasons. First, she was asking to the interviewees to talk about their personal experiences, but she didn't want to share her own experience. Second, some writers advocate researchers' self-disclosure as good research practice (Dickson-Swift et al., 2007: 332-334; Oakley, 1981). While Silva is now available to talk about this personal aspect of her life, when she conducted this qualitative interview, she intensely hated the stigmatized nature of how others projected meanings onto her unhealthy baby. Furthermore, she thought that her own research participant did not want to hear it.

In this particular decision-making process, Silva applied an embodied interpretation that touches both 'head' and 'heart' aspects of emotion work (Dickson-Swift et al., 2009), and formal methodological procedures and ethical guidelines seem of limited help to sustain or not sustain Silva's decision. We think that an embodied research approach in epidemiology should be promoted, including the analysis of the research relationships and researchers' emotions and feelings into reflections about research experiences, namely at the following levels: disclosure and reciprocity; reflexivity and management of emotions; rights and protection of both researchers and participants.

6. Conclusion

This chapter deals with how the underlying strategies and principles for data collection and textual interpretation are much the same as those of epidemiological research, with different procedures, because of the different type of data used and questions to be answered. Qualitative research is a science which depends upon conceptual analysis (Lambert & McKevitt, 2002) that aims to understand the basis of social action within wider heterogeneous social and material contexts. It is not just a limited set of specific methods always used in small scale studies and nor is it an easy option which contrasts with quantitative research (Popay, 2003).

There are multiple pathways of influence and causality that should underlie debate concerning the soundness of qualitative and quantitative methods. Qualitative methods contribute to the understanding of the complexities of human behavior which are sometimes dismissed by quantitative approaches. Thus, qualitative and quantitative methods are complementary tools that look for answers to different research questions in order to further epidemiological knowledge, aiming to describe, explain and understand the contexts we live in and to contribute to health improvement and to enhance social justice.

By highlighting the contributions that interpretative action can make in the wider body of published epidemiological research, epidemiology can reinforce the trustworthiness of qualitative research and its legitimacy, as well as the receptiveness of biomedical scientists towards social sciences. In doing so, epidemiology researchers produce evidence to improve the health of the population and reduce health inequalities.

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