KCE REPORT 187B

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

L'UTILISATION DES MÉTHODES QUALITATIVES DANS LES ÉTUDES DU KCE

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KCE REPORT 187B
METHOD

Federaal Kenniscentrum voor de Gezondheidszorg
Centre Fédéral d'Expertise des Soins de Santé
Belgian Health Care Knowledge Centre

L'UTILISATION DES MÉTHODES QUALITATIVES DANS LES ÉTUDES DU KCE

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PRÉFACE

En janvier de cette année, nous avions publié un rapport méthodologique relatif à l'implication des parties prenantes (stakeholder involvement), et sur la manière de mieux intégrer cette approche dans nos procédures de recherche KCE. Dans les dernières pages de ce rapport, nous avions donné un premier aperçu de méthodes appropriées pour cet objectif. Nous avions promis de les développer plus en détail dans un futur proche. Le présent rapport est une première concrétisation de cette promesse.

Certes, les méthodes de recherche quantitatives, qui sont la pierre angulaire de l'approche de la médecine fondée sur les preuves dans la recherche biomédicale, ont toujours eu et conservent une place centrale dans l'«ADN» du KCE.

Mais par ailleurs, pour de nombreuses questions politiques très pertinentes, les preuves solides, reliées au contexte, ne sont tout simplement pas disponibles. Et même en présence de résultats quantitatifs clairs, l'étape de la formulation des recommandations pertinentes pour les politiques n'est pas toujours simple.

Dans le domaine des soins de santé, toute décision est influencée par des valeurs, des convictions et des perceptions. De la décision clinique individuelle relative à une procédure de diagnostic ou à un traitement, aux décisions relatives à des remboursements et l'allocation de budgets, il n'est jamais uniquement question de risques relatifs ou ratios coût-efficacité. Les décisions ne sont dès lors tout à fait compréhensibles que lorsque tous ces facteurs sont pris en compte explicitement. C'est là que les méthodes qualitatives se révèlent particulièrement utiles.

Ce rapport est avant tout un outil pratique pour les chercheurs du KCE et les sous-traitants. Mais, compte tenu d'une familiarisation insuffisante à l'égard de ces méthodes, il offre également un aperçu de ce domaine méthodologique et de ses avantages potentiels pour la recherche similaire à celle effectuée au KCE.

Nous espérons que cela nous aidera à toujours mieux répondre aux besoins réels des patients, dans le respect des aspirations légitimes des prestataires de soins.

Raf MERTENS

Directeur Général

RÉSUMÉ

INTRODUCTION

Le KCE produit régulièrement des notes détaillées de ses processus pour ses propres chercheurs et sous-traitants, et ce afin de les aider à produire des rapports de recherche scientifique de qualité, basés sur les meilleures données disponibles. Cependant, parfois, soit aucune preuve n'est encore disponible soit les preuves disponibles ne sont pas transférables au contexte des soins de santé belge ou de la population. Par conséquent, la recherche “basée sur les données probantes” ne donne pas toujours des réponses adéquates à nos questions de recherche. En outre, elle prend peu en compte l’apport du patient et ses préférences[2]. Dans le contexte “evidence-based”, les recherches qualitatives sont considérées comme ayant peu de valeur[2].

Clarifier ce qu’est la recherche qualitative, insister sur la plus-value des résultats qualitatifs et se préoccuper de la qualité des études qualitatives sont autant de moyens pour assurer que les résultats des recherches qualitatives soient reconnus comme des «preuves»[2].

Les Méthodes de Recherches Qualitatives (MRQ) couvrent une série de techniques de collecte et d’analyse de données[5]. Elles visent à comprendre les expériences personnelles et à expliquer certains (aspects de) phénomènes sociaux tels que la santé et la maladie. Les MRQ peuvent renforcer la capacité du KCE à bien comprendre les besoins des usagers et prestataires en soins de santé et à les intégrer lors de la formulation des recommandations adressées aux gestionnaires du système

Cependant, puisque les MRQ sont traditionnellement utilisées en sciences sociales, les professionnels de la santé et chercheurs qui disposent d’une formation de type biomédicale, en sciences naturelles ou économiques, comme c’est le cas pour la majorité des chercheurs du KCE, peuvent être peu familiers avec ces dernières.

OBJECTIF ET CONTENU

Ce document est divisé en deux parties :

1. La première partie décrit le contexte au sein duquel les MRQ peuvent être appliquées au KCE. Elle décrit ce qu'est la recherche qualitative et de quelle manière celle-ci peut contribuer à comprendre des concepts tels que la "santé", la "maladie" et les "soins de santé efficaces". Les barrières relatives à l'utilisation des MRQ et les fausses croyances qu'elles suscitent sont discutées.
2. La seconde partie est plus pratique. Elle fournit des guides pratiques et critères d'utilisation des MRQ dans le contexte des projets de recherche du KCE. Ces "notes de processus" ciblent les méthodes les plus utilisées au KCE, à savoir les entretiens individuels semi-structurés, les focus groups, l'observation directe et la méthode Delphi.

Ce rapport n'a pas l'ambition d'être un manuel en recherche qualitative, mais est développé spécifiquement pour le public des chercheurs du KCE et en fonction des besoins du KCE.

MÉTHODOLOGIE

Afin d'ajuster ce document aux besoins des chercheurs du KCE, nous avons adopté 3 stratégies :

1. Une analyse d'un échantillon de 60 rapports réalisés par le KCE, afin d'évaluer l'utilisation des MRQ par le passé et afin d'identifier le rôle potentiel que la recherche qualitative pourrait jouer à l'avenir.
2. Des interviews par focus group de 2 groupes de chercheurs du KCE (ayant une expérience ou non avec les MRQ) et d'un groupe constitué par les 4 membres de la direction dans le but d'appréhender leurs positionnement et attentes à l'égard des méthodes de recherche qualitatives, mais aussi afin de connaître leurs expériences et leurs besoins futurs.
3. Une consultation de la littérature sur l'usage des méthodes qualitatives dans la recherche en soins de santé.

RÉSULTAT

PARTIE 1: Place des méthodes qualitatives dans la recherche au KCE

Dans les premières années du KCE, le processus de travail et les procédures étaient essentiellement basées sur une approche Evidence-Based Medicine (EBM, médecine basée sur les preuves) au sein de laquelle les MRQ n'avaient aucun rôle à jouer. Progressivement, nous avons assisté à un changement de paradigme.

Aujourd'hui au KCE, les MRQ sont de plus en plus considérées comme un outil utile pour mieux comprendre le contexte des questions de recherche et afin d'impliquer les stakeholders aux différentes étapes des projets de recherche. Cependant, les chercheurs ont toujours tendance à considérer les méthodes de recherches quantitatives comme une référence et un standard lorsqu'ils évaluent les MRQ. Ceci amène à une série de malentendus comme par exemple l'atteste une supposée hiérarchie des preuves, au sommet de laquelle on trouverait les essais contrôlés randomisés et au bas de laquelle se retrouveraient les résultats issus de la recherche qualitative. La recherche qualitative est aussi souvent associée à des problématiques moins quantifiables et à un danger de subjectivité, tant au moment de la collecte des données que durant les analyses.

En passant au crible les rapports du KCE, nous avons constaté que, par le passé, les MRQ ont déjà été utilisées avec succès au KCE, principalement dans le domaine de la recherche relative à l'organisation des services de santé (HSR), pour comprendre la perception des patients (par exemple, leur opinion sur un traitement) ou des prestataires de soins, cela en ayant principalement recours à des entretiens individuels semi-structurés ou à des focus groups.

La conclusion principale des focus groups menés avec les chercheurs du KCE est que ceux-ci considèrent les MRQ comme particulièrement adéquates pour générer des hypothèses. Les MRQ sont également utiles, d'après eux, pour approfondir ou expliquer des résultats d'études quantitatives, et particulièrement pour comprendre des résultats étranges ou inattendus. La capacité de gagner en profondeur d'analyse a également été soulignée.

Au KCE semble vivre la croyance que “le stakeholder involvement est une MRQ”. Or, le stakeholder involvement est un but en soi, alors que les méthodes de recherche qualitative ne sont qu’un moyen parmi d’autres d’atteindre cet objectif.

La décision d’intégrer ou non une partie qualitative dans une recherche du KCE n’est pas toujours aisée : les MRQ sont-elles indispensables pour répondre de manière adéquate aux questions de recherche ou offrent-elles simplement des idées supplémentaires qu’il serait bon d’avoir ?

PARTIE 2: Comment faire de la recherché qualitative? Process notes pour les projets KCE.

Dans cette partie, nous décrivons comment élaborer un projet de recherche qualitative en insistant sur les raisons pour lesquelles le choix peut se porter sur une MRQ et sur la manière d’évaluer sa qualité en ayant recours à des critères généraux ou des check-lists.

Ensuite, nous avons essayé d’apporter une aide lors du choix de la méthode appropriée parmi celles qui ont été développées dans ce rapport : les entretiens individuels semi-structurés, les focus groups, l’observation et l’enquête Delphi.

Enfin, chacune de ces méthodes est décrite en termes de :

- définition
- pertinence d’utilisation
- forces et faiblesses
- planning
- modalité de collecte de données
- outils de collecte de données
- échantillon
- ressources humaines nécessaires
- aspects pratiques
- analyse
- rapportage des résultats
- critères de qualité
- exemples de rapports kce utilisant cette méthode

CONCLUSION

Ce rapport ne doit pas seulement permettre aux chercheurs du KCE de se familiariser avec les méthodes qualitatives, il doit aussi les convaincre qu’elles sont crédibles et parfois indispensables en tant que telles ou en complément à des méthodes plus quantitatives. Ce rapport pourra in fine les guider concrètement lors de l’utilisation de ces méthodes.

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
CA	Conseil d'Administration
CAQDAS	Computer-Assisted Qualitative Data Analysis Software
DSW	Delphi Survey Web
EBM	Evidence-Based Medicine
EBP	Evidence-Based Practice
EPB	Equity and Patients Behavior
FG	Focus group
GCP	Good Clinical Practice
HSR	Health Service Research
HTA	Health Technology Assessment
QALY	Quality-Adjusted Life Year
QoLS	Quality of Life Scale
QRM	Qualitative Research Method
RvB	Raad van Bestuur
SI	Stakeholder Involvement

SCIENTIFIC REPORT

INTRODUCTION

"*Behind every quantity there must lie a quality*".

(Selznick, G.J.[1])

The KCE is the Belgian Health Care Knowledge Centre providing public authorities with scientific studies to found decisions about health care and health insurance. The KCE research covers three domains:

1. the analysis of clinical practices and the development of recommendations of Good Clinical Practice (GCP)
2. the evaluation of new medical technologies (Health Technology Assessment: HTA)
3. the organization and financing of health care (Health Service Research: HSR)

KCE offers to their researchers and subcontractors detailed process notes to help them deliver good quality scientific research based on the best evidence available. However, sometimes there is not yet any evidence available, or is the available evidence not transferable to the Belgian health care context or population. By consequence the evidence-based working practice does not always allow KCE researchers, nor subcontractors to provide adequate answers to the research questions they are confronted with. Especially since evidence-based practice gives small consideration to patient input and preferences[2]. Yet within the context of evidence-based practice qualitative research findings are considered to have little value[2]. Clarifying what qualitative research is, stressing the utility of qualitative findings and addressing quality in qualitative studies are a means of assuring a place for qualitative research as "evidence"[2]. Qualitative Research Methods (QRM) have a lot to offer to those studying health care and health services[3], furnishing in-depth information about patient's and health care provider's needs, wishes, experiences, and fears regarding health care[4]. QRM could help researchers such as KCE researchers to strengthen the KCE capacity to formulate recommendations tailored to the needs of care seekers and providers, within a context of increasing demands and limited budgets.

Qualitative research method is a research strategy covering a range of several qualitative data collection and analysis techniques[5], aiming at understanding personal experiences and to explain social (aspects of) phenomena, such as health and illness.

However, because QRM are traditionally used in social science, health care professionals and researchers with a biomedical, natural science or economical background, like the majority of KCE researchers, may be unfamiliar with them.

At the KCE several issues related to qualitative research methods are regularly raised, for example what is QRM, what is the added value, when and how to use it.

In a response to these questions this report will introduce the main qualitative methods available for the study of health and health care. In addition it will show how qualitative research methods can be appropriately employed in the domain of health care and health services use. The KCE needs and early experiences with QRM were taken as a starting point for this report, and it was partly based on a preliminary intern process note on focus group interviews, written by Leys & Kohn in 2009 (not published).

We tried to make this report more than a list of technical procedures. We follow Barbour (2001) when she states that "*checklists can be useful improving qualitative research methods, but overzealous and uncritical use can be counterproductive*"[6]. We also would like to show that doing qualitative research is more than a rigorous application of rules and guidelines. It is a way of looking at social reality. Rather than looking for the right answers, qualitative research is also concerned by formulating the right questions.

In this report the main qualitative research methods useful for the study of health and health care are introduced and described in function of their use in KCE studies.

AIMS

This document describes basic guidelines and aspects that have to be reflected upon and documented in a KCE research report in which qualitative methods are used. It is limited to "instrumental" methodological aspects for qualitative research strategies that are useful for KCE studies.

This report is different from handbooks of qualitative research, since it is developed for a KCE researchers audience and in regard of KCE needs. Although every researcher implicitly or explicitly brings a theory, hypotheses, or assumptions to the start of a research project, we will not address the theoretical perspectives or paradigms in qualitative research[a]. The main aims of the report are:

- To inform researchers who are unfamiliar with qualitative research as to what qualitative research is and how it can contribute to our understanding of health, illness and effective health care.
- To remove barriers and false beliefs which impede the use of QRM at the KCE.
- To provide hands-on guidelines and criteria for the use of QRM.
- To broaden the knowledge base about QRM at the KCE.

[a] Those who want to read more about these aspects, we refer to handbooks such as 'The SAGE Handbook of Qualitative Research' by Denzin and Lincoln (2005)[7] or 'The Landscape of Qualitative Research' by the same authors 2007)[8], 'The SAGE Handbook of Qualitative Research in Health Research' by Bourgeault et al. (2010)[9]. In Dutch we consider the 'Handboek Kwalitatieve Onderzoeksmethoden' by Mortelmans (2007)[10] to be a good reference. In French, the electronic methodological review 'Recherches Qualitatives' could be useful http://www.recherche-qualitative.qc.ca/revue.html.

METHODOLOGY

General design

In order to tailor this document to the needs of KCE researchers, we used three strategies:

1. An analysis of a sample of KCE reports in order to evaluate the use of qualitative research methods in the past and identify the potential role of qualitative research in the future.
2. Focus group interviews with KCE researchers and managers to learn about their attitudes and beliefs regarding qualitative research, their past experiences and future needs.
3. A reading of the literature on the use of qualitative research methods in health care research.

Based on these sources (part one of this report), "process notes" were developed and completed by elements based on the authors' experience and knowledge in the field (part two of this report). The process notes are related to the methods most used at the KCE, i.e. individual semi-structured interviews, focus group interviews, direct observation, and the Delphi method. Notes on others methods, such as meta-synthesis, meta-narrative approaches, nominal group or mixed-methods, will probably be developed in the future.

Analysis of published KCE reports

Objectives

Two samples of KCE reports were screened in order to:

4. Identify "qualitative questions" that could be answered in KCE projects;
5. Identify "qualitative methods" useful for KCE projects.

Sampling

One member of the managers and one KCE researcher identified the two samples:

- A sample of 30 reports in which qualitative research methods (QRM) have been used or were assumed to have been used. This list is partly based on a first analysis of the 100 first KCE reports[11] and was completed with more recent published KCE reports.A sample of 30 reports whith a high potential for QRMs to be used, i.e. incorporating some research questions which lend themselves to a qualitative approach, but which have not been addressed in that way.

Selection criteria were research domain (HSR and HTA) and relevance of patient or health care providers issues.

Analysis

All the reports were screened on whether QRMs were used or could have been used to answer the stated research questions. Note that we restricted ourselves to the research questions as formulated in the report. We did not imagine new research questions on the topic of the report.

A table identifying the main question(s), the presence of qualitative data in the report, the QRMs used and the utilization of QRM findings in the recommendations was elaborated and filled in by 2 reviewers trained in QRM.

Focus groups with KCE researchers and managers

Objectives

Focus groups were organized at the KCE in order to:

- Describe the place of QRM at the KCE.
- Benefit from KCE researchers' earlier experiences with qualitative methods (both positive and negative).
- Identify what researchers need to know and what they expect to find in a process note on QRMs.

Participants

In order to build homogeneous groups of participants, all the eligible KCE researchers were 'classified' in a grid according to their level of expertise in QRM and their type of job at the KCE. The managers formed a separate group. To be eligible for the participation in the focus groups, researchers had to work at least 1 year at the KCE.

Table 1 – Distribution of the KCE researchers regarding their expertise in QRM and their job at KCE

Job	Experienced in QRM	Novice in QRM
Physicians	5	5
Economists		
HTA	1	5
HSR	1	2
Jurist	1	0
HSR	2	1
Statistician/data manager	1	3

Three focus groups were formed:

1. A focus group with the 4 managers of the KCE (FG managers),
2. A focus group with KCE researchers novice' in QRM (8-10 researchers) (FG novices),
3. A focus group with KCE researchers 'experienced' in QRM (8-10 researchers) (FG experienced).

To maintain the same spread of the 'types' of KCE researchers, as far as possible 4 physicians, 3 economists (1 HTA and 2 HSR), 1 HSR researcher, 1 jurist and 1 statistician/data manager were included in each focus group.

If there were too many researchers in a category, participants were chosen at random.

Course of the data collection

All of the focus groups have been carried out in KCE meeting rooms by 3 persons:

- A moderator who lead and synthesized discussions,
- An observer who took notes on the non-verbal communication in the group and helped the moderator to encourage participants to talk,
- A reporter who took notes on the discussion using a mindmapping technique.

Before beginning the focus group interview, the objectives, the selection procedure, the speech distribution rules and the roles of the moderator, observer and reporter were explained, confidentiality of the discussion was assured and permission to audio-record the discussion was requested.

Each researcher expressed him/her-self in his/her mother-tongue.

All the focus groups were audio-recorded using 2 numeric Dictaphones. Recording were transcribed by two KCE secretaries.

Data collection tools

For each focus group a specific interview guide was developed (see Appendix 1). Some of the questions were common to all groups.

Themes addressed were:

- Definition of QRM (including differences with quantitative approaches)
- Experience with QRM
- Evolution of QRM at KCE
- Positive and negative aspects of QRM (perceived as well as own-experience)
- Needs of KCE researchers regarding QRM
- Link between QRM and stakeholder involvement

Analysis

The transcripts of the 3 focus groups have been coded in QSR Nvivo 9[12] independently by two KCE researchers qualified in qualitative research (LK and WC, the authors of this report). The node structures built by both researchers were compared, discussed and merged into one agreed upon node structure. In a next step, the node structure was divided into parts and each researcher wrote down the description and interpretation of his part of the nodes content. Next, the researchers reviewed each other's text. Comments were discussed. When a final text was agreed upon, it was inserted at the appropriate places in this report.

We reported some quotes (in the mother-tongue of the researcher) in the text to illustrate our findings.

Consultation of the literature

Rather than a systematic search of the literature, an iterative process akin to Bates' (1989) 'berrypicking' model, was used. Berrypicking is a model of searching that is closer to the real behavior of information searchers than the traditional model of information retrieval. In real-life, for example internet users begin with one feature of a broader topic and move through various sources. Each new piece of information gives the user new ideas and directions and thus a new conception of his/her query. This is not simply a change in search terms. Rather the query or information need itself (and the search terms used) is continually evolving[13]. At each stage the user identifies useful information and references. In other words, the query is satisfied not by a single final retrieved set, but by a series of selections of individual references and bits of information at each stage of the ever-modifying search.

All the papers related to QRM known by the authors of the report as well as all publications available at the KCE library were used. We complemented our sources of information by searching for books related to QRM in general, QRM in health care or every particular methodology in a university library and on the Internet (via Google scholars and amazon.com).

PART ONE: QUALITATIVE RESEARCH METHODS AT THE KCE

1 PLACE OF QUALITATIVE METHODS IN KCE RESEARCH

In this section, we describe the evolution of the place of QRM at the KCE, based on the analysis of screened KCE reports and the focus group interviews with KCE researchers and managers. In addition, a brief discussion of the KCE researchers' believes regarding QRM is presented.

1.1 Evolution of QRMs at the KCE

When the KCE was created, the work process and procedures were essentially based on Evidence-based medicine (EBM). At that time QRM had no role to play. Progressively, a paradigm shift took place and more and more qualitative research methods were used. The KCE managers and researchers felt the need for 'something else'. Although the positivist approach[b] undoubtedly contributed to the knowledge base of medicine, in some ways it failed to provide a holistic view of the complexity of human behavior and experience. This position is also present in the literature on the role of QRM in EBM (e.g. Morgan and Drury, 2003[15]; Nelson, 2008[2]).

At the KCE we found that in some research projects evidence in function of specific research questions or contexts (e.g. Belgian field of geriatrics or psychiatry) was lacking. The recommendations formulated at the end of each KCE report were sometimes too straightforward and undifferentiated. By consequence some reports were not well received by the stakeholders. A participant of the focus groups reminded us of the report on the treatment of Alzheimer's disease:

> *« …dans le rapport sur les médicaments anti Alzheimer, il y avait le verdict assez sec, qui était très mal reçu par les gériatres (…). Un peu de qualitatif aurait permis de mieux nuancer ce verdict, il ne devrait pas le changer pour autant … » (Focus group managers)*

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b Positivism is a philosophy of science assuming that there is an objective reality "out there" which can be uncovered by the use of scientific methods (see e.g. Cohen and Crabtree, 2008[14], p. 333).

Progressively the idea grew that there was a need for QRM in KCE research projects in order to give adequate and complete answers to particular research questions, but this was not imaginable at the start of the institution.

In sum, today KCE managers are preoccupied by how to increase the impact of the KCE reports. Identified solutions were:

- To increasingly take into account the context of the research questions,
- To increasingly involve the stakeholders at different steps of the research projects[16], e.g. to consider their opinion on the subject during exploration of the field.

For both strategies, the KCE managers think of QRM as a useful tool to contribute to their realization. Next (and linked) to this strategic plan of the managers, the arrival of a new general director has been mentioned as a key element in the more frequent use of QRM and its potential sustainability at KCE. From the KCE researchers point of view, the evolution results also from the human resources available. Since more researchers know and use QRM, more qualitative oriented questions appear in the projects and are answered by means of qualitative research methods than. Nevertheless, still some KCE researchers, Belgian stakeholders and more quantitatively oriented scientists are not yet convinced that QRM can bring an added value to KCE projects.

> *"Ik zou wel graag overtuigd worden van voorbeelden waaruit blijkt dat het onderzoek inderdaad belangrijk is, zodanig dat we de nood voelen om ze te gebruiken, als het verschil gemaakt heeft?" (Focus group novices)*

Although the need is felt to use QRM at KCE, its implementation is not self-evident neither for the managers nor for the KCE researchers. EBM processes are perceived as clear, well-described and agreed upon, robust, objective, scientific, and therefore easier or more comfortable to rely on. QRMs are perceived as more difficult to work with, are still less known, less uniformly described, and perceived as more subjective, and hence less 'scientific'. The contraposition between "the need for something more" at one hand, and the lack of knowledge of and experience with QRM at the other hand, results in frustration. The process notes further in this report on QRM were developed to relieve this discomfort, to encourage the use of QRM, and to be more systematic in carrying out the qualitative part(s) of a research.

Finally once it is decided that a research question implies the need for qualitative research, as with other kinds of questions, an exploration of the qualitative research literature in function of the specific research question, is appropriate. As with other types of systematic reviews, there are methods available to review qualitative material, e.g. meta-synthesis.

1.2 KCE researchers' and managers' (mis)beliefs about QRM

During the focus group interviews, the following questions were raised by KCE researchers:

- What is qualitative research? How does it differ from quantitative research?
- Knowledge about QRMs and when it is appropriate to use which method.
- What is the added value of QRMs?
- How to convince all KCE researchers of its added value?
- What happens during the validation of a report which is partly based on qualitative research? How to defend when the approach is questioned by validators or the Board (RvB/CA)?
- What are the criteria to decide on the quality of qualitative research?
- How to integrate studies reporting on qualitative research in literature reviews and recommendations?

Some of these questions reflect existing (mis)beliefs towards QRM. We identified the following four main characterizations:

- "There is a lot of subjectivity in QRM."
- "QRM serve less quantifiable issues."
- "QRM are inferior to quantitative research techniques."
- "QRM is only a last option."

- These (mis)beliefs may cause qualitative research to be labeled unscientific, subjective, or anecdotic[3]. Most KCE researchers are familiar with research methods associated with a quantitative approach. By consequence they use quantitative research methods as a benchmark to build their ideas about QRM. In section 1.2.1 we elaborate on quality criteria for qualitative research. For each characterization we added the position QRM literature takes.

1.2.1 Is there a lot of subjectivity in QRM?

1.2.1.1 What is the current KCE conception?

During the focus group interviews, KCE researchers made clear that they associate qualitative research methods with (the danger of) subjectivity, both in the stage of data collection and during the analysis of the data.

- In the data collection: the interviewer – in the way he formulates the questions – might influence (unconsciously) the answers of the respondent in function of his own opinion or feelings.

  «Il y a certainement le rôle de la personne qui pose les questions qui pourra même influencer les réponses. Il faut être prudent vis-à-vis ça dans le qualitatif » (Focus group experts)

- In the analysis of the data: qualitative data leaves more room for interpretation for the researcher. In the worst case the researcher searches for elements in the data that confirm his own ideas, while the deviating issues are neglected.

  « Ik had soms het gevoel dat de onderzoeker zijn visie had en in de interviews zijn elementen ging halen om zijn visie te staven en dat er geen rigoureuze methode was gebruikt om alle elementen aan te halen, zelfs die niet stroken met zijn visie. Dan werd er een tekst geproduceerd waarvan ik dacht met dezelfde interviews kan ik totaal het tegenovergestelde beweren.» (Focus group experienced)

  «Bij kwalitatief onderzoek heb ik het gevoel er zit een enorme subjectieve factor in en als iemand anders dat analyseert dan kan die tot heel andere conclusies komen dan als de eerste analyseert. » (Focus group experienced)

1.2.1.2 What is the conception in the literature on QRM?

In quantitative research it is assumed that phenomena can be explained by objective and factual measures, free from researcher bias[17]. In this positivist modernist tradition subjectivity is a danger introducing bias and threatening the scientific character of an inquiry. This point of view was encountered in the focus group interviews with KCE researchers and managers.

Qualitative researchers however recognize that the subjectivity of the researcher is intimately involved in scientific research (not only qualitative research). Subjectivity guides the choice of the subject of the research, the formulation of hypotheses, the selection of methodologies and the interpretation of the data. Researchers should reflect on the values and objectives they bring to their research and how these affect the research project[17]. Qualitative researchers make subjectivity their strength, rather than their weakness. Interpretative approaches (e.g. ethnography, phenomenology, symbolic interactionism) "*attempt to understand the nature of social reality through people's narrated accounts of their subjectively constructed processes and meanings, as opposed to the measurement of quantity, frequency and distribution across a given population*" (Morgan and Drury, 2003[15], p. 4). Some scholars talk about intersubjectivity. This is "*a concept that denotes the act of according meaning between two or more subjects and establishing the objectivity of a claim made in research*"[18] (p. 3).

Qualitative research methods deal with subjective matters in an objective and systematic way. Objective knowledge about social reality requires active, subjective processes, and conversely, subjective processes can enhance objective comprehension of the world[17].

1.2.2 Does QRM serve less quantifiable issues?

1.2.2.1 What is the current KCE conception?

KCE-researchers associate QRM with less quantifiable issues.

> *« Oui, je dirais aussi que ça consiste à collecter de l'information dont l'objectif n'est pas d'arriver à un résultat chiffré … Mais plutôt aller dans l'analyse du texte, du contenu de ce qui était exprimé et essayer de mettre cet avantage en évidence … que d'arriver à des moyennes, médianes, etc. » (Focus group experienced)*

1.2.2.2 What is the conception in the literature on QRM?

Indeed the qualitative researcher is not interested in the frequency of an occurrence, but wants to understand meanings, how they develop[10] and vary between contexts. Also QRMs aim at identifying the issues salient to the people involved. In addition, *"Qualitative researchers study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them"* (Denzin and Lincoln, 2008[8], p. 4*)*. However, it is difficult to define "less quantifiable issues". Most issues can be studied both in a quantitative or a qualitative way, depending on the research question. The example of quality of life was given during the focus group interviews, but even quality of life can be addressed with standardized measurement instruments such as the Quality of Life Scale (QoLS)[19], which is a quantitative approach. In qualitative research quality of life will be studied in the natural daily living of the respondent, searching for deeper lying meanings related to the research question. In a standardized quantitative approach on the contrary, the respondent's quality of life is measured to look for causal or associative relations with other variables such as subjective health and to capture it in statistics such as means and standard deviations to generalize to a certain population.

1.2.3 Are QRMs inferior to quantitative research techniques?

1.2.3.1 What is the current KCE conception?

KCE researchers see quantitative and qualitative approaches in opposition to each other, and use quantitative research techniques they are familiar with as a point of reference to build their ideas about QRM.

> *«Ik denk dat als uw onderzoeksvraag kwantitatief onderzoek toelaat moet je bijna kwantitatief onderzoek gaan doen omdat dat volgens mij hoger op de ladder staat en meer reproduceerbaar is dan kwalitatief onderzoek. » (Focus group novices)*

Nevertheless, during the focus group interviews it was concluded that the comparison between qualitative and quantitative research techniques is inadequate.

1.2.3.2 What is the conception in the literature on QRM?

From QRM literature in general, it is also clear that QRM is indeed often defined in opposition to quantitative research techniques. The difference between both approaches is often reduced to a difference in sample size. However, a low number of respondents does not make a research qualitative. Small sample size is not a decisive criterion, other elements such as the interpretative approach, the natural setting, the in-depth information are more distinctive of qualitative research

In section 1.1.2, we elaborate more on the distinction between qualitative and quantitative research methods.

1.2.4 Is QRM only a last option?

1.2.4.1 What is the current KCE conception?

Several KCE-researchers perceive the use of QRM as a last option: if a research question can be addressed by means of quantitative research methods, in their logic this is what should be done, because it is more objective and reproducible. In other words, a hierarchy is presented with RCT's at the top and QRMs at the bottom, which is in accordance with the logic of Evidence-Based Practice (EBP) (see e.g. Nelson, 2008[2]). The origin of EBP in health care can be traced back to Evidence-based medicine (EBM) which was introduced in the early nineties. EBM encourages doctors to interpret clinical information using the best evidence available from quantitatively based randomized clinical trials and the meta-analysis of these studies, rather than past experiences, instincts or an understanding of the basic mechanisms of disease. Thus, a hierarchical system of evidence is inherent in EBM. Also qualitative research findings are considered to be of low value and small consideration is given to patient input and preferences. Moreover empirical research evidence is preferred over clinical expertise or the so-called "tacit" knowledge of the practitioner, in clinical decision making[2].

> *"Als uw onderzoeksvraag een kwantitatieve methode toelaat, dan vind ik persoonlijk dat je kwantitatief onderzoek moet doen. Tenzij dat je achteraf nog wat meer context wilt en dat kan je doen met kwalitatief onderzoek, maar omwille van reproduceerbaarheid moet je kwantitatief onderzoek gebruiken, want dat staat volgens mij hoger op de ladder." (Focus group novices)*

1.2.4.2 What is the conception in the literature on QRM?

This idea of hierarchy in research evidence, and by extension, research methods, foregoes the fact that quantitative and qualitative research methods are complementary and their use depends on the research question. It is seldom that both research perspectives are equally useful to address one and the same research question. "*Qualitative research is a prerequisite of good quantitative research, particularly in areas that have received little previous investigation*"[20] (See also in part 2, section 1.1 on 'why to use QRM'?).

The standpoints defended above are in line with a critical realist approach as is described below (see part 2, section 1.2.1). This is supportive of a mixed method approach, hence supports the viewpoint that qualitative and quantitative research methods are complementary, should be used in function of the research question and can be integrated in one research project.

Key messages

- **When the KCE was created, the work process and procedures were essentially based on Evidence-based medicine (EBM). At that time QRM had no role to play. Progressively, a paradigm shift took place.**
- **Today at KCE QRM is thought of as a useful tool to:**
  - **increasingly take into account the context of the research questions**
  - **increasingly involve the stakeholders at different steps of the research projects, e.g. to consider their opinion on the subject during exploration of the field.**
- **At the KCE mostly quantitative research methods are still used as a benchmark to built ideas about QRM, which leads to a number of misbeliefs regarding QRM, e.g. there is a hierarchy of evidence, with qualitative research findings at the bottom and RCT's at the top. Qualitative research is associated with less quantifiable issues and the danger of subjectivity, both in the stage of data collection and during analysis.**

2 USE OF QUALITATIVE METHODS IN KCE PROJECTS

2.1 Which qualitative research methods (QRM) have been formerly used in KCE projects?

In the screened KCE reports, until now mainly three QRMs have been used, i.e. focus groups, individual semi-structured interviews and Delphi-methods. Other methods, such as site visits, workshops and round tables were occasionally applied, but in those cases there was no rigorous methodological description in the report.

In addition, researchers and/or stakeholders meetings are common practice at the KCE. They are embedded in KCE working procedures. They are as such not always described in the reports, because they are not considered as a QRM methodology, but rather as a self-evident part of KCE working practice (see before, chapter on the place of QRM at KCE).

2.2 For which domains have QRM been used in KCE projects?

Among the 60 selected reports for screening (see methodology), 27 belong to the Health Service Research (HSR) domain, 13 to the Good Clinical Practice (GCP) domain, 18 are Health Technology Assessment (HTA) reports and 2 are Equity and Patients Behavior (EPB) related reports.

Table 2 gives an overview of the methods used in each research domain in the sample of 30 reports containing a QRM.

Table 2 – Overview of methods used in KCE reports per domain

Applied research methods	HSR	GCP	HTA	EPB	Total
Focus group	4	1	0	0	5
Individual semi-structured interview	12	0	3	1	16
Delphi	2	0	0	0	2
Observation/site visit	1	1	1	0	3
Content/narrative analysis of documents – meta-synthesis	2	2	0	0	4
Workshop	2	0	0	0	2
Group discussion/round table	1	0	1	0	2
Telephone interview	0	0	1	0	1
Total number of reports	21	4	5	1	30

In the screened reports a qualitative research method of one kind or another was used 30 times in total. The majority (n=21) was used in HSR reports. The most popular methods for data collection are individual semi-structured interviews, especially used in HSR, followed by focus groups.

In order to analyze the potential QRM use in the screened reports, we have classified them into three categories in relation to the proposed research question(s):

- The use of QRMs could have been useful,
- The use of QRMs would not have created an added value,
- It is unclear whether the use of QRMs would have been useful,

The classification was made in function of whether the use of QRMs was useful to answer the research questions of the report. More specifically

questions about clinical or cost effectiviness, prevalence assessement or clinical quidelines were estimated as not appropriate for QRM.

Table 3 – Potential added value of QRM in screened KCE reports

	QRM would have been useful			No qualitative research question			Unclear		
Frequency	17			10			3		
Domains	HSR	HTA	GCP	HSR	HTA	GCP	HSR	HTA	GCP
Frequency	7	6	4	2	5	3	2	1	0

In 17 out of 30 reports (more) qualitative research methods could have been useful for finding an answer to one or more research questions: 7 in HSR, 4 in GCP, 6 in HTA.

2.3 For what type of research questions have QRM been used or could QRM be used in KCE projects?

From the analysis of the published KCE reports and the research questions that were addressed, it appears that meanings are very central to qualitative research in the KCE . *"[…] qualitative researchers study things in their natural sittings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them"* (Denzin and Lincoln, 2008[8], p. 4) Table 4 gives an overview of the various types of research questions for which QRM has been used.

Table 4 – What type of research questions were addressed in screened KCE reports?

Type of question	Method used to answer this type of question	Number of projects
What are the EXPERIENCES with the use of a certain technology or system?	Interviews, focus groups, Delphi	6
Which INFORMATION is needed?	Focus groups	1
Is it FEASIBLE in practice?	Focus groups	1
What are the MOTIVATIONS to…?	Interviews	2
What are expert OPINIONS about…?	Interviews, focus groups, Delphi	2
EVALUATIONS of a system, practice, legislation or technology	Interviews	3
The DESIGN OF METHODOLOGY	Focus groups, interviews, Delphi	1
To assess the PERCEIVED EFFICACITY of a technology	Interviews, Delphi	3
To EXPLORE THE FIELD	Observations (site visit)	1
To understand MEANINGS attached to a certain experience	Interviews	1

In Table 5 we present research questions which have not been addressed by means of QRMs, although it would have been meaningful to do so. The entire list is included in Appendix 3. Mostly these research questions are addressed by means of a literature review, while individual or group interviews could have been useful to learn about patients' and health professionals' experiences with the Belgian health care system.

Table 5 – Examples of research questions to which QRM could have contributed

Domain	Research question	Employed method	Missed opportunity
GCP	Consequences of chronic low back pain for active population	Literature review	In addition to the literature review, patients could have been interviewed about their experiences and how chronic low back pain impacts their daily life.
HTA	What essential patient/caregiver and organizational aspects are to be considered in the context of pharmaceutical and non-pharmaceutical interventions for Alzheimer's Disease?	Literature review	Patient and caregiver issues, together with organizational aspects could have been addressed by means of individual or focus group interviews. This would have allowed an in-depth understanding of these issues within a Belgian health care context.
HSR	To explore the expectations for the future and identify the future needs related to genetic testing; and confront these with the present situation.	International comparison	Individual or focus group interviews with health care professionals could have been useful to discuss future needs and identify the strengths and weaknesses of the current situation.

In KCE researchers' opinion, several types of research questions could be answered using QRM in KCE reports. The general aims mentioned in the focus group interviews with KCE researchers correspond to what is described in QRM textbooks: QRMs are especially suited *to generate hypotheses*. QRMs are useful *to deepen or explain* the results of a quantitative study, especially to understand odd or unexpected figures or results.

> *"Ik denk dat het niet systematisch moet gebeuren, ik denk dat het misschien beter gebeurd als je in je cijfers iets vreemd ziet waar je denkt dat je meer uitleg voor nodig hebt (…) We krijgen dus voor borstkanker QALY-cijfers, op een gegeven moment vind je dus voor borstkanker, als je die studies moet geloven maakt het weinig uit of een vrouw een borst wordt afgezet of niet. Het zou dus interessant zijn met kwalitatief onderzoek een beetje dieper …." (Focus group experienced)*

The capacity to gain in-depth knowledge or insight was stressed.

> *"C'est étudier en profondeur et pas uniquement de manière superficielle un grand nombre de questions ; donc c'est plutôt moins de questions mais vraiment aller en profondeur » (Focus group experienced)*

More specifically, for the KCE domains of research (HTA, HSR, GCP), QRMs are especially appropriate when one wants to *understand the perception* of patients (i.e. their opinion on a treatment) or health care practitioners. This aspect is especially salient to the KCE's role of 'policy advisor'. Without qualitative research methods it is nearly impossible to get a clear understanding of motivations, perceptions or attitudes. All these goals emphasize the search for more in-depth information that surpasses the meanings of a figure or statistic, and are in line with the aims resulting from the screening of a sample of KCE reports.

> *"Je kan het nog veel radicaler zien en zeggen dat vanuit uw rol als adviesorgaan voor de overheid rond de gezondheidszorg, dat het uw plicht is om de betekenissen die voor de bevolking belangrijk zijn en voor de zorgverstrekkers erg belangrijk zijn in de beslissingen van de gezondheidszorg, dat het uw plicht is om die actief te gaan zoeken en te incorporeren in uw onderzoek." (Focus group managers)*

> *"Ik denk dat bepaalde onderzoeksvragen alleen maar op een deftige, wetenschappelijke manier te beantwoorden zijn in het kwalitatief onderzoek." (Focus group experienced)*

> *"Vooral voor een arts, het is heel moeilijk te weten hoe hij eigenlijk redeneert met een kwantitatieve studie. Je moet er heel veel over weten en deze info coderen, maar eigenlijk moet je al kwalitatief onderzoek gedaan hebben voor je maar zelfs een vragenlijst kan opstellen. Anders kan je nooit te weten komen waarom doet hij dat, wat was zijn redenering, wat denkt hij erover en wat voelt hij hierbij. Bijv. Bij borstkankerscreening waarom bieden ze dat aan terwijl men weet dat het soms meer kwaad kan doen dan goed?" (Focus group experienced)*

In addition, KCE researchers mentioned also the following aims of QRM in the KCE context:

- To prepare questionnaires, make them adequate, with the right language and the suitable items, modalities of response, etc.
- To produce another kind of evidence to integrate in the recommendations of the final KCE report.

Finally, KCE researchers find it difficult to decide whether a qualitative research part should be added to a project or not, because it goes back to the question what is necessary to answer the research questions versus just nice to learn or research.

> *"Soms is dat evident zoals in dat onderzoek van dialyse maar in andere onderwerpen kun je zeggen: ik kan dat hier nu doen kwalitatief onderzoek, dat is altijd heel interessant, nooit oninteressant daar gaat het niet over maar is dat nuttig." (Focus group experienced)*

2.4 A particular case: QRM and stakeholder involvement

As we have mentioned already, in order to increase the impact of KCE reports, it was decided to involve stakeholders more frequently and efficiently during the research process. A separate report is devoted to this subject[16]. The report mentions several methods that could be used to involve stakeholders, depending on the aim and the intensity of the involvement targeted. Among these methods, we can find several qualitative approaches.

It appears that in KCE researchers' and in some managers' minds the distinction between 'stakeholder involvement' and 'QRM' is unclear. At the KCE lives the idea that "stakeholder involvement is a QRM". However, stakeholder involvement is an end in itself, while qualitative research is a means to reach this end, although not the only one. First, we have to define the way we want to involve stakeholders and consequently, decide which method is the most appropriate to do so.

> *" Dus ik denk dat we ons voor elk rapport de vraag moeten stellen: hoe gaan we de stakeholders betrekken en moeten we dan ook bijgevolg een tool ter beschikking hebben om na te denken, hoe gaan we dat dan doen en ik denk toch dat kwalitatieve methodes dan bij de meeste mensen als eerste mogelijkheid naar voor komen en waar ze dan ook een richting aanwijzer invullen terwijl je niet kan zeggen dat je voor elk rapport d'office ook kwalitatieve methodes gaat nodig hebben voor de verdere onderzoeksvragen". (Focus group managers)*

> *"(…) willen we een helderder beeld krijgen van een problematiek dan zitten we bij doelstelling 1, willen we de scoping juist krijgen, doelstelling 2 en welke methoden zijn daar dan voor en dat is dan de articulatie tussen het werk wat je bezig bent met het ontwikkelen van die steekkaarten naar process notes maar dat op een hoger conceptueel niveau mee laten doordringen in de geesten van de mensen dat daar tools voor zijn en dat daar voor elke doelstelling wel verschillende tools mogelijk zijn maar niet voor alle doelstellingen altijd dezelfde tools." (Focus group managers)*

Talking with people, such as practitioners, surgeons, etc. to become familiar with the subject in the beginning of a project does not necessarily require a 'method':

> *"(…) Je kan stakeholder involvement doen zonder strikte methodologie of door u open te stellen voor stakeholders en met mensen te gaan praten en dat niet op een methodologische, reproduceerbare manier te gaan vastleggen en aanreiken maar u wel een "mind set" eigen maken of tenminste u openstellen voor andere percepties dan uw eigen, om met een bredere view aan een onderzoek te kunnen beginnen. Dus dat is een zeer persoonlijke doelstelling die niet resulteert in wetenschappelijke resultaten (…)" (Focus group managers)*

Key messages

From the screening of KCE projects we concluded that:

- **QRMs have already been successfully used. More specifically QRM is especially appropriate when one wants to *understand the perception* of patients (i.e. their opinion on a treatment) or health care practitioners.**
- **At the KCE the most popular QRMs are individual semi-structured interviews, especially used in HSR, followed by focus groups.**

From the focus group interviews we mainly concluded that:

- **QRMs are especially suited to generate hypotheses. QRMs are useful to deepen or explain the results of a quantitative study, especially to understand odd or unexpected figures or results. Also the capacity to gain in-depth knowledge was stressed.**
- **At the KCE lives the idea that "stakeholder involvement is a QRM". However, stakeholder involvement is an end in itself, while qualitative research is a means to reach this end, although not the only one.**
- **Often it is difficult to decide whether a qualitative research part should be integrated in a project, because it is about what is necessary to answer the research questions versus what is just nice to learn or research.**

PART TWO: HOW TO DO QUALITATIVE RESEARCH: PROCESS NOTES FOR KCE PROJECTS

1 HOW TO SET UP A QUALITATIVE RESEARCH PROJECT?

Following the discussions we have heard in the different focus groups, not every KCE researcher expressed the need to use or understand QRM. Nevertheless, for those interested in QRM, we try to respond to the different researchers' needs through this report and the notes that will be published in the KCE process book based on the present report[c].

1.1 Why opt for a qualitative approach?

"The goal of qualitative research is the development of concepts which help us to understand social phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences, and views of all the participants"[20] (p. 43). This quotation gives a nice summary of the specificities of qualitative research methods, which are discussed below.

1.1.1 Specificities of qualitative research methods

First, qualitative research encompasses all forms of field research performed with qualitative data. "Qualitative" refers to *data in nonnumeric form*, such as words and narratives. There are different sources for qualitative data, such as observations, document analysis, interviews, pictures or video's, etc. Each of these data-gathering techniques has its particular strengths and weaknesses that have to be reflected upon when choosing for a qualitative research technique. In the social sciences, the use of qualitative data is also closely related to different paradigms trying to develop insight in social reality. Elaboration on these paradigms is however outside the scope of this report[d].

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c For further reading: Silverman (2011)[21]

d For those interested we refer to Denzin and Lincoln, 2008[8, 22], Bourgeault et al., 2012[9] or in Dutch, Mortelmans, 2009[10]

Second, the aim of qualitative research is developing a "thick description[e]" and "grounded or *in-depth understanding*" of the focus of inquiry. The benefits of well developed qualitative data-collection are precisely richness of data and deeper insight into the problem studied. They do not only target to describe but help also to get more meaningful explanations on a phenomenon. They are also useful in generating hypotheses[1]. Types of research questions typically answered by qualitative research are "What is going on? What are the dimensions of the concept? What variations exist? Why is this happening?"[24]. Qualitative research techniques are primarily used to trace "*meanings* that people give to social phenomena" and "interaction processes", including the interpretation of these interactions[25]. "*They allow people to speak in their own voice, rather than conforming to categories and terms imposed on them by others.*" (Sofaer, 1999[1] p. 1105). This kind of research is also appropriate to investigate social phenomena related to health[24].

Third, one of the key strengths of qualitative research is that it studies people in their *natural settings* rather than in artificial or experimental ones. Since health related experiences and beliefs are closely linked to daily life situations it is less meaningful to research them in an artificial context such as an experiment. Therefore data is collected by interacting with people in their own language and observing them in their own territory[26] or a place of their own choice. This is also referred to as naturalism. Therefore the term naturalistic methods is sometimes used to denote some, but not all, qualitative research[3]. Also this characteristic is not always relevant to the use of QRM at the KCE. For example focus group interviews are usually not performed in the natural setting of the participants, but rather in the setting of a meeting room.

A fourth feature of qualitative research in health care is that it often employs *several different qualitative methods* to answer one and the same research question[3]. This relates partly to what is called triangulation (see part 2, section 1.2.2).

Finally, qualitative research is always iterative starting with assumptions, hypotheses, mind sets or general theories which change and develop throughout the successive steps of the research process. It is desirable to make these initial assumptions explicit at the beginning of the process and document the acquired new insights or knowledge at each step.

1.1.2 Qualitative versus quantitative approaches

Although it is meaningful to do qualitative research in itself, qualitative research is often defined by reference to quantitative research. Often it is assumed that because qualitative research does not seek to quantify or enumerate, it does not 'measure'. Qualitative research generally deals with words or discourses rather than numbers, and measurement in qualitative research is usually concerned with taxonomies or classifications. "*Qualitative research answers questions such as, 'what is X, and how does X vary in different circumstances, and why', rather than 'how big is X or how many X's are there?*"(Pope, 2006[3] p3).

By emphasizing the differences the qualitative and quantitative approach are presented as opposites. However, qualitative and quantitative approaches are complementary and are often integrated in one and the same research project. For example in mixed methods research the strengths of quantitative and qualitative research are combined for the purpose of obtaining a richer and deeper understanding[27]. Also qualitative data could be analyzed in a quantitative way by for example counting the occurrence of certain words.

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[e] A "thick description" of a human practice or behavior include not only the focus of the study, but its context as well, such it becomes meaningful to an outsider. The term was introduced in the social science literature by the anthropologist C. Geertz[23] in his essay in 1973.

Often health services researchers draw on multiple sources of data and multiple strategies of inquiry in order to explore the complex processes, structures and outcomes of health care. It is common that quantitative and qualitative methods answer different questions to provide a well-integrated picture of the situation under study[28]. Especially in the field of health services research qualitative and quantitative methods are increasingly being used together in mixed method approaches. The ways QRMs could be used combined or not, are:

- Qualitative research only:
  - To know the variation in experiences related to health or illness.
  - To build typologies regarding health services use, patient attitudes, health beliefs, etc.
- Qualitative preliminarly to quantitative:
  - To explore new area, new concepts, new behaviour, etc.[25] before to start with measurement.
  - To build quantitative data collection tools (questionnaires): using appropriate wording[25], variables to submit, to develop reliable and valid survey instruments[1], etc.
  - To pre-test survey instruments[1].
- In supplement to quantitative work:
  - As a part of a triangulation process that consist in confronting results coming from several data sources[25].
  - To reach a different level of knowledge[25]: "*If we focus research only on what we already know how to quantify, indeed only on that which can ultimately be reliably quantified, we risk ignoring factors that are more significant in explaining important realities and relationships.*" (Sofaer, 1999[1], p. 1102).
- In complement to quantitative work by exploring complex phenomena or areas that are not reachable with quantitative approaches[25].
- Sofaer[1] provides us the insight that in many cases, inquiry can move from being unstructured, largely qualitative in nature, to being structured and largely quantitative in nature. This is how she describes the continuum: *"(…) there is uncertainty not only about answers, but about what the right questions might be; about how they should be framed to get meaningful answers; and about where and to whom questions should be addressed. As understanding increases, some of the right questions emerge, but uncertainty remains about whether all of the right questions have been identified. Further along, confidence grows that almost all of the important questions have been identified and perhaps framed in more specific terms, but uncertainty still exists about the range of possible answers to those questions. Eventually, a high level of certainty is reached about the range of almost all of the possible answers."*(p. 1103).
- In sum, over time investigations related to a certain area, start with qualitative research to explore the field, find the right questions, prepare for more focused questions and discover theories and hypotheses. Next, quantitative research is in place to test hypotheses and finally, qualitative research can be used to deepen the findings or to search for explanations quantitative research techniques cannot provide.

1.2 How to evaluate QRM?

In this section we want to address quality criteria for the use and evaluation of qualitative research. At the one hand it should guide those who want to apply QRM in their research project(s), at the other hand KCE researchers asked for criteria that allow them to evaluate existing qualitative studies or publications resulting from qualitative studies, for example in function of a systematic review.

1.2.1 Usefulness of quality criteria to evaluate qualitative research

"*Whatever the method, it needs to be well-defined, well-argued, and well-executed*"

(Snijders, 2007[29])

The increasing demand for qualitative research within health and health services research has emerged alongside an increasing demand for the demonstration of methodological rigor and justification of research findings[30]. Not only is qualitative research challenged by the current evidence-based practice (EPB) movement in healthcare, also the emergence of meta-analyses (e.g. meta-synthesis) of qualitative research findings urges for quality criteria. Although in quantitative health sciences research, there exist widely-recognized guidelines, no comparable standardized guidelines exist for qualitative research. This can be explained by a lack of consensus related to how to best evaluate "rigor" in qualitative research[2]. Every qualitative paradigm has its own implications regarding the definition of good quality research. First, we introduce the reader briefly in the debate about quality criteria, second, we present the framework of Walsh and Downe[31] as the most complete and comprehensible list of quality criteria to appraise qualitative research studies, and the framework of Côté and Turgeon as a shorter and practical alternative. For other checklists we refer to Appendix 1.

Among qualitative researchers there is a debate going on between those demanding for explicit criteria, for example in order to serve systematic reviewing and evidence-based practice, and those who argue that such criteria are neither necessary nor desirable[32]. The quest for quality criteria assumes that qualitative research is a unified field, but this image does not fit reality. In fact, apart from a variety of other positions (e.g. symbolic interactionism, hermeneutics, phenomenology, ethnography) three main paradigms can be discerned in relation to this discussion:

- The **interpretativist paradigm** assumes that social realities are multiple, fluid and constructed. This framework values research that illuminates subjective meanings and multiple ways of seeing a phenomenon. These researchers question the need for and the utility of quality criteria for qualitative research or apply specific criteria for qualitative research, such as clear delineation of the research process, evidence of immersion and self-reflection, demonstration of the researcher's way of knowing (e.g. tacit knowledge)[33].
- The **positivist approach** stands at the other end of the continuum and assumes that there is a single objective reality that is knowable. Positivists apply traditional quantitative criteria, such as validity and reliability to qualitative work.
- The **realist perspective** is positioned in between. It maintains a belief in an objective reality, but knowledge of reality is always imperfect[33]. Realists use techniques such as triangulation, member validation of findings, peer review of findings, deviant or negative case analysis and multiple coders of data, to promote to verify findings. The realist perspective adopts a philosophy of science that is in line with positivism, but at the same time embracing the complexity of social life and recognizing the importance of social meanings. "*By maintaining a belief in an objective reality and positing truth as an ideal qualitative researchers should strive for, realists have succeeded at positioning the qualitative research enterprise as one that can produce research which is valid, reliable, and generalizable, and therefore, of value and import equal to quantitative biomedical research"* (Cohen, 2008)[33] p. 336).

The position one takes in the debate about quality criteria is heavily influenced by the paradigm one feels most attracted to, or identifies with.

1.2.2 General quality criteria

Most of the quality criteria are applicable to all research, both quantitative and qualitative. For example in 2008, Cohen and Crabtree[33] reviewed and synthesized published criteria for good qualitative research. They identified the following general evaluative criteria: 1) ethical research, 2) importance of the research, 3) clarity and coherence of the research report, 4) use of appropriate and rigorous methods, 5) importance of reflexivity or attending to researcher bias, 6) importance of establishing validity or credibility, 7) Importance of verification or reliability. Researcher bias, validity, and reliability are most heavily influenced by quantitative approaches. Table 6 bridges quantitative and qualitative research by illustrating the parallels

between criteria for conventional quantitative inquiries and qualitative research.

Table 6 – Lincoln and Guba's translation of terms

Quantitative research	Qualitative research	Methods to ensure quality
Internal validity	Credibility: Are the findings credible?	Member checks[f]; prolonged engagement in the field; data triangulation
External validity	Transferability: Are the findings applicable in other contexts?	Thick description[g] of setting and/or participants
Reliability	Dependability: Are the findings consistent and could they be repeated?	Audit – researcher's documentation of data, methods and decisions; researcher triangulation
Objectivity	Confirmability: To which extend are the findings shaped by the respondents and not researcher bias, motivation or interests?	Audit and reflexivity – e.g. awareness of position as a researcher and its influence on the data and findings

Source: Adapted from Finley[36]

In what follows we pay attention to some keywords appearing in Table 6.

[f] Informants may be asked to read transcripts of dialogues in which they have participated to check whether their words match with what they actually intended[34], or they may be asked to check the accuracy of early findings[35].

[g] Thick description refers to rich qualitative data allowing not only the description of social behaviour, but also to connect it to the broader context in which it occurred[10].

Reflexivity

"Reflexivity is an awareness of the self in the situation of action and of the role of the self in constructing that situation." (Bloor and Wood, 2006[35]*, p. 145)*

Because in qualitative research, the researcher could not be 'blinded', he/she has to take into account subjectivity in an explicit way. To demonstrate this reflexive awareness during the research process, the following 'good practices' can be used (Green, 2009[37], p. 195):

- Methodological openness: report steps taken in data production and analysis, the decisions made, and the alternatives not pursued.
- Theoretical openess: theoretical starting points and assumptions should be adressed.
- Awareness of the social setting of the research itself: be aware of the interactivity between the researcher and the researched.
- Awareness of the wider social context, including historical and policy contexts and social values.

Triangulation

"*Qualitative research is inherently multimethod in focus (Flick, 2002, p.226-227). However, the use of multiple methods, or triangulation, reflects an attempt to secure an in-depth understanding of the phenomenon in question. Objective reality can never be captured. We know a thing only through its representations. Triangulation is not a tool or a strategy of validation, but an alternative to validation (Flick, 2002, p. 227). The combination of multiple methodological practices, empirical materials, perspectives, and observers in a single study is best understood, then, as a strategy that adds rigor, breadth, complexity, richness, and depth to any inquiry (See Flick, 2002, p. 229)"* (Denzin and Lincoln, 2008[8], p. 7).

Triangulation is the use of several scientific methods, both qualitative and quantitative, to answer the same research question[35]. Often triangulation is understood as producing the same results by means of several methods, sources or analysts. However, different methods or types of inquiry are sensitive to different nuances, so that they may lead to somewhat different results. In fact, triangulation is more about finding inconsistencies to gain deeper insight into the relationship between the inquiry approach and the subject under study. Thus, finding inconsistencies do not weaken the credibility of the results, but rather strengthen it[28].

Five kinds of triangulation can contribute to the quality and consistency of qualitative data analysis:

1. Methods triangulation:
   Information obtained through several methods is compared. These methods can be qualitative, or quantitative or both. Often qualitative and quantitative data can be fruitfully combined as they mostly elucidate complementary aspects of the same phenomenon[28].
2. Triangulation of sources:
   Information derived at different times and by different means is compared, e.g. comparing observational data with interview data, but also comparing what people say in public with what they say in private[28].
3. Analyst triangulation:
   Several observers, interviewers, researchers or analysts are used. By this way the potential bias that comes from a single person doing all the data collection and/or data analysis is reduced. In addition to several researchers or data analysts, analytical triangulation may also be to have those who were studied review the findings[28].
4. Theory/perspective triangulation:
   It involves the use of different theoretical perspectives to look at the same data. Also, for example, data can be examined from the perspective of various stakeholder positions[28].
5. Member validation:
   It is a popular kind of triangulation that consists of “checking the accuracy of early findings with research respondents” (Bloor and Wood, 2006[35], p. 170).

These kinds of triangulation protect the researcher against the accusation that findings are an artifact of a single method, or source or investigator’s biases[28].

Transferability

Earlier in this report we argued that qualitative research is context sensitive and it is not aimed at making generalizations to the wider population. This may appear to contradict with the notion of transferability which is just about the extent to which findings of one study can be applied to other situations (external validity)[38].
Transferability refers to the responsibility of the researcher to provide sufficient contextual information about the fieldwork to enable the reader to determine how far he can be confident in transferring the findings to other situations[39]. However, the situation might be complicated by the possibility that factors considered by the researcher to be unimportant, and consequently unaddressed in the research report, may be critical in the eyes of a reader[39].

1.2.3 Checklists

We have found four papers[30,31,33,40] reviewing the literature on quality criteria or guidelines for qualitative research. One of them[31] provides us with a synthesis of eight existing checklists and summary frameworks (see Table 7). This checklist is quite detailed and is designed in function of meta-synthesis, which is a kind of systematic review of qualitative research papers.

The list of criteria was built in order to rigorously appraise studies first before submitting them to the meta-synthesis technique. Agreement on criteria to judge rigor was necessary in order to decide which studies to include in the meta-synthesis. Walsh and Downe[31] tabulated the characteristics mentioned in each of the papers in their review. Then they mapped together the characteristics given in all the included papers, sorting them by the number of checklists in which they appeared. In the next step both authors independently attempted a synthesis before coming together to discuss. Redundant criteria were excluded if both authors agreed that the exclusion would not change the final judgment on the meaningfulness and applicability of a piece of qualitative research. Finally the table below was constructed, structured into three columns, namely stages, essential criteria and specific prompts. Although some criteria may seem self-evident, others are less obviously fundamental[31]. This list of criteria is very detailed. In some studies, especially those with short time frame, a shorter and more pragmatic hands-on list could be practical. Therefore we also added the grid of Côté and Turgeon[40] [h] (Table 8) which is shorter, adapted to the specific context of heath care and easier to use for researchers who are less familiar with qualitative research. Other checklists are described in Appendix 1.

The use of a checklist may improve qualitative research, however they should be used critically: not every criterion is appropriate to every research context[6]. For example the list of Coté and Turgeon mentions interpretation of results in an innovative way as a quality criterion (point 10, Table 8), while this is not necessarily the case. Most important is a systematic approach during research process. For example the credibility of data analysis could encompass the use of software (Table 7), triangulation and/or member checking (point 7, Table 8), whereas a systematic approach with a detailed description of each step in the research process could have been sufficient.

[h] A French-speaking version is also available[41]

Table 7 – Summary criteria for appraising qualitative research studies

Stages	Essential criteria	Specific prompts
Scope and purpose	Clear statement of, and rationale for, research question / aims / purposes	• Clarity of focus demonstrated • Explicit purpose given, such as descriptive/explanatory intent, theory building, hypothesis testing • Link between research and existing knowledge demonstrated
	Study thoroughly contextualized by existing literature	• Evidence of systematic approach to literature review, location of literature to contextualise the findings, or both
Design	Method/design apparent, and consistent with research intent	• Rationale given for use of qualitative design • Discussion of epistemological/ontological grounding • Rationale explored for specific qualitative method (e.g. ethnography, grounded theory, phenomenology) • Discussion of why particular method chosen is most appropriate/sensitive/relevant for research question/aims • Setting appropriate
	Data collection strategy apparent and appropriate	• Were data collection methods appropriate for type of data required and for specific qualitative method? • Were they likely to capture the complexity/diversity of expereince and illuminate context in sufficient detail? • Was triangulation of data sources used if appropriate?
Sampling strategy	Sample and sampling method appropriate	• Selection criteria detailed, and description of how sampling was undertaken • Justification for sampling strategy given • Thickness of description likely to be achieved from sampling • Any disparity between planned and actual sample explained

Stages	Essential criteria	Specific prompts
Analysis	Analytic approach appropriate	• Approach made explicit (e.g. thematic distillation, constant comparative method, grounded theory) • Was it appropriate for the qualitative method chosen? • Was data managed by software package of by hand and why? • Discussion of how coding systems/conceptual frameworks evolved • How was context of data retained during analysis • Evidence that the subjective meanings of participants were portrayed • Evidence of more than one researcher involved in stages if appropriate to epistemological/theoretical stance • Did research participants have any involvement in analysis (e.g. member checking) • Evidence provided that data reached saturation or discussion/rationale if it did not • Evidence that deviant data was sought, or discussion/rationale if it was not
Interpretation	Context described and taken account of in interpretation	• Description of social/physical and interpersonal contexts of data collection • Evidence that researcher spent time 'dwelling with the data', interrogating it for competing/alternative explanations of phenomena
	Clear audit trail given	• Sufficient discussion of research processes such that others can follow 'decision trail'
	Data used to support interpretation	• Extensive use of field notes entries/verbatim interview quotes in discussion of findings • Clear exposition of how interpretation led to conclusions
Reflexivity	Researcher reflexivity demonstrated	• Discussion of relationship between researcher and participants during fieldwork • Demonstration of researcher's influence on stages of research process • Evidence of self-awareness/insight • Documentation of effects of the research on researcher • Evidence of how problems/complications met were dealt with

Stages	Essential criteria	Specific prompts
Ethical dimensions	Demonstration of sensitivity to ethical concerns	• Ethical committee approval granted • Clear commitment to integrity, honesty, transparency, equality and mutual respect in relationships with participants • Evidence of fair dealing with all research participants • Recording of dilemmas met and how resolved in relation to ethical issues • Documentation of how autonomy, consent, confidentiality, anonymity were managed
Relevance and transferability	Relevance and transferability evident	• Sufficient evidence for typicality specificity to be assessed • Analysis interwoven with existing theories and other relevant explanatory literature drawn from similar settings and studies • Discussion of how explanatory propositions/emergent theory may fit other contexts • Limitations/weaknesses of study clearly outlined • Clearly resonates with other knowledge and experience • Results/conclusions obviously supported by evidence • Interpretation plausible and 'makes sense' • Provides new insights and increases understanding • Significance for current policy and practice outlined • Assessment of value/empowerment for participants • Outlines further directions for investigation • Comment on whether aims/purposes of research were achieved

Source: Walsh and Downe, 2006[31]

Table 8 – Grid for the critical appraisal of qualitative research articles in medicine and medical education

	Yes	+/-	No
Introduction			
1. The issue is described clearly and corresponds to the current state of knowledge.			
2. The research question and objectives are clearly stated and are relevant to qualitative research (e.g. the process of clinical or pedagogical decision-making).			
Methods			
3. The context of the study and the researchers' roles are clearly described (e.g. setting in which the study takes place, bias).			
4. The method is appropriate for the research question (e.g. phenomenology, grounded theory, ethnography).			
5. The selection of participants is appropriate to the research question and to the method selected (e.g. key participants, deviant cases).			
6. The process for collecting data is clear and relevant (e.g. interview, focus group, data saturation).			
7. Data analysis is credible (e.g. triangulation, member checking).			
Results			
8. The main results are presented clearly.			
9. The quotations make it easier to understand the results.			
Discussion			
10. The results are interpreted in credible and innovative ways.			
11. The limitations of the study are presented (e.g. transferability).			
Conclusion			
12. The conclusion presents a synthesis of the study and proposes avenues for further research.			

Source: Côté et Turgeon, 2005[40]

1.2.4 Conclusion

To conclude this chapter on quality criteria we wish to warn against a rigid use of checklists and quality criteria in qualitative research and to argue instead for flexible use. Moreover this also applies to quantitative research.

Barbour criticizes the widespread use and description of assumed quality indicators like theoretical sampling, grounded theory, multiple coding, and triangulation in scientific articles, as an unequivocal guarantee of robustness. These dimensions of qualitative research should be embedded within a broader understanding of the qualitative research design and not "*stuck on as a badge of merit*" (Barbour, 2001[6] p. 1115).

We agree with Walsh and Downe[31] that a checklist is indicative of good quality research, but not a guarantee.

Key messages

- **Although in quantitative health sciences research, there exist widely-recognised guidelines, no comparable standardised guidelines exist for qualitative research.**
- **Among qualitative researchers there is a debate going on between those demanding for explicit criteria, for example in order to serve systematic reviewing and Evidence-Based Practice, and those who argue that such criteria are neither necessary nor desirable.**
- **The framework of Walsh and Downe as an comprehensible example of quality criteria checklist to appraise qualitative research studies. The grid of Côté and Turgeon is more simple and could be recommended as tool for evaluation in KCE reports.**

2 QUALITATIVE RESEARCH METHODS USEFUL FOR KCE PROJECTS

Although there is no unified definition of qualitative research, most authors agree about its main characteristics (see above, section 1.1.1). Creswell formulated it like this: "*Writers agree that one undertakes qualitative research in a natural setting where the researcher is an instrument of data collection who gathers words or pictures, analyzes them inductively, focuses on the meaning of participants, and describes a process that is expressive and persuasive in language*" (p. 14)[42]. The gathering of qualitative data takes many forms, but interviewing and observing are among the most frequently used, no matter the theoretical tradition of the researcher.

2.1 How to chose a qualitative method?

We so far identified 4 types of QRM suitable for the KCE research projects useful to describe in a first report: interviewing (individually or in focus groups), observing and structuring discussions among experts with a Delphi survey. Others should be developed in the future.

Before entering in the practical aspect of each method, we will briefly describe them in order to give some guidance to choose the most appropriate one.

Semi-structured individual interview aims at searching for data through questioning the respondent using conversational techniques, *"…being shaped partly by the interviewer's pre-existing topic guide and partly by concerns that are emergent in the interview."* (Bloor and Wood, 2006[35], p. 104). "*It gives the opportunity to the respondents to tell their own stories in they own words"* (Bowling, 1997[43], p. 336).

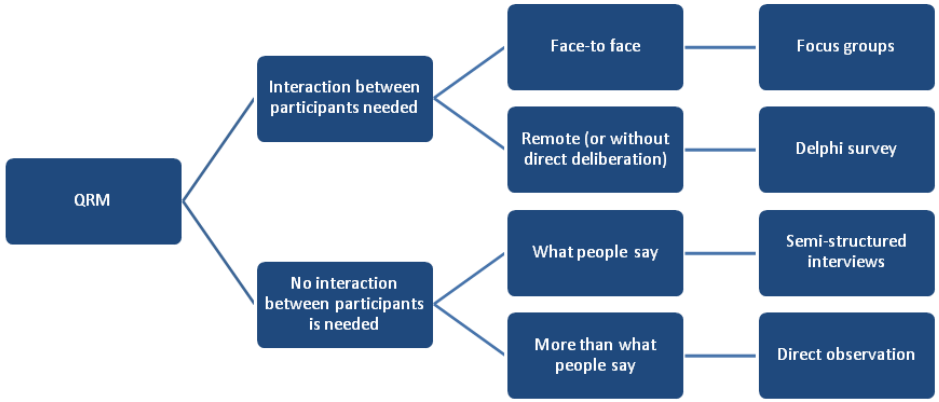
The use of such a method in the KCE context is appropriate when the aim is to identify different point of views, beliefs, attitudes, experience of people such patients, practitioners, stakeholders, etc. when no interaction between the respondents is required or appropriate (according to the topic for example). It could also be chosen because of practical reasons, e.g. when participants are not easily 'displaceable', or lack time.

Focus groups is a form of semi-structured interview. It consists on "*a series of group discussions held with differently composed groups of individuals and facilitated by a researcher, were the aim is to provide data (via the capture of intra-group interaction) on groups beliefs and group norms in respect of a particular topic or set of issues*" (Bloor and Wood, 2006[35], p. 88). This is useful *"where we need interactivity to enhance brainstorming among the participants, gain insights and generate ideas in order to pursue a topic in greater depth"* (Bowling, 1997[43], p 352). Focus groups *'"worked well and provide the richest data in relation to public's view of priorities for health services and (…) were less inhibiting for respondent that one-to-one interviews*" (Bowling, 1997[43], p. 354).

Observation is useful to understand more than people say about (complex) situations[43]. In the KCE context, it will be useful for site visits, when preparing a report on a hospital or a health service, a procedure, etc.

The **Delphi survey** aims to achieve consensus or define positions among experts panelists, through iterations of anonymous opinions and of proposed compromise statements from the group moderator[35]. For KCE reports, this method could be useful for setting priorities, clarify acceptability of a new technology or system or innovations.

Figure 1 – Decision tree to chose between the methods proposed in this report



2.2 Data collection by interviewing people (individually or in groups)

There are many ways to interview people, e.g. individually or in focus groups. However, they share some general principles and techniques. Therefore in what follows we address the general principles. After that we present a chapter on individual semi-structured interviews and a chapter on focus groups.

2.2.1 General principles

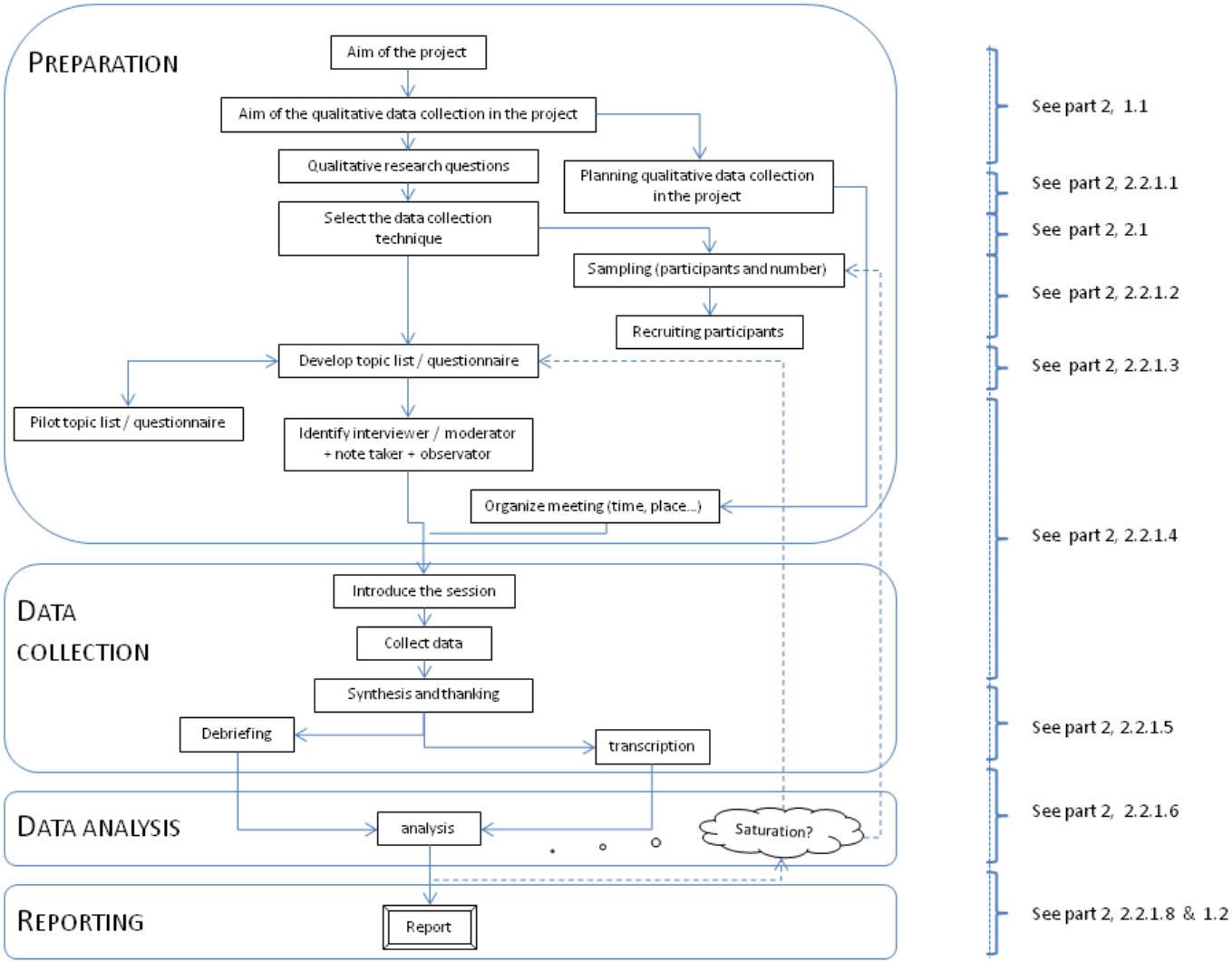
General principles addressed in this chapter are (1) planning, (2) sampling issues, (3) the development of a topic list or interview guide, (4) running the data collection, (5) preparation of the data, (6) data analysis, (7) the validation of findings, (8) how to report and (9) common pitfalls.

2.2.1.1 How to plan the research design?

As with any data collection, interviewing (individually or in focus groups) has to be planned within the overall research approach taking into account the particular aims of the qualitative data collection.

The planning of data collection has to be prepared early in the process of the overall research. Qualitative research is time consuming, on the level of data-collection, data-analysis and reporting. All the steps are presented in the next figure.

Figure 2 – Flowchart: interviewing people



2.2.1.2 Sampling issues in qualitative research: who and how many?

Selection of participants

In qualitative research we select people who are likely to provide the most relevant information[24]. In order to design the sample and cover all variability around the research issue, the researchers must have an idea about the different perspectives that should be represented in the sample. This is called "field mapping" of the key players who have a certain interest in the problem under study. The role of this explicit "field mapping" is often underestimated but essential in order to build a purposive sample. It is possible that this "field map" evolves during the data collection. The notion of "representativeness" here is not understood in the statistical way. The idea of representation is seen as a "representation of perspectives, meanings, opinions and ideas" of different stakeholders in relation to the problem researched and their interest. In order to select the participants for interviews or focus groups, one should ask "do we expect that this person can talk about (represent) the perspectives (meanings given to the situation) of this stakeholder group". The aim is to maximize the opportunity of producing enough data to answer the research question[44].

Ideally there should be a mixture of different "population characteristics" to ensure that arguments and ideas of the participants represent the opinions and attitudes of the relevant population. Also the unit of analysis should be taken into account. This could be for example "individuals for their personal opinions/experience/expertise" or "individuals because they represent organizational perspectives".

Moreover in order to make comparisons within and between types of participants, the sample design should take this already into account. In Table 9, two criteria for comparison, for example age and socio-economic status, are already included to allow comparative analysis between age or status groups.

Sampling approaches

There is a wide range of sampling approaches (e.g. Miles and Huberman, 1994[45], Patton, 2002[46], Strauss and Corbin, 2008[47]). It is not uncommon in qualitative research that the research team continues to make sampling decisions during the process of collecting and analysing data. However, a clear documentation of the sampling criteria is needed when doing qualitative research. These criteria should cover all relevant aspects of the research topic. The researcher should identify the central criteria and translate them in observable sample criteria. In addition, the chosen criteria should leave enough variation to explore the research topic[10]. For example, in a research about factors influencing the decision to have or refrain from having a refractive eye surgery in the two last years, sampling criteria were:

1. To have experienced or to have considered a refractive surgery. We want to explore both the pro and cons.
2. To be older than 20 and younger than 70. Refractive eye surgery is not an option for those younger than 20 or older than 70.

In what follows we describe a number of sampling strategies. All the sampling strategies are non-probabilistic. A randomized sample is not useful in qualitative research, since generalizability to the general population is not the aim. Moreover with a random sample the researcher would run the risk of selecting people who have no link with the research subject and thus nothing to tell about it[10]. In purposive sampling the point of departure are the sampling criteria as described above. There are different forms of purposive sampling:

- Stratified purposive sampling[46]:
  Purposive samples can be stratified (or nested) by selecting particular persons that vary according to a key dimension/characteristic (e.g. a sample of people from large hospitals, and a different sample with people from small hospitals) and the selection ideally represents the different positions within the 'system' or phenomenon under investigation. The stratification criteria are the equivalent of independent variables in quantitative research. The researcher should think ahead about independent variables which could provide new information regarding the research topic. For example, in the research project on refractive eye surgery we expected that reasons to chose or

refrain from chosing for refractive eye surgery vary with age, with financial resources and can be different in the Dutch- and French-speaking part of the country. Therefore we added age, socio-economic status and region as criteria introducing heterogeneity. This results in the following matrix:

- Homogeneous sampling:
  In the case of homogeneous sampling variation between respondents is minimised. Participants are chosen because they are alike, in order to focus on one particular process or situation they have in common[10]. However the homogenous character does not exclude comparisons between types of participants, because for example unanticipated dimensions might emerge from the data. It is also useful to take into account hierarchy, hence not to put for example nurses and specialists working in the same hospital together in a focus group, as this might create bias in the responses.This sampling strategy is used when the goal of the research is to develop an in-depth understanding and description of a particular group with similar characteristics or people on equal foot. For example for the KCE research project on alternative medicines[48-50] only regular users were sampled.

Table 9 – Example of stratified purposive sample

	Already had eye surgery or surgery planned									Considered eye surgery but refrained from having it								
Age	20-30			31-40			>40			20-30			31-40			>40		
Socio-economic status	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c	a	b	c
Number of respondents	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2	2

- Heterogeneous or maximum variation sampling :
  In the case of heterogeneous sampling variation between repondents is maximised, relevant to the research question.
- Extreme or deviant cases sampling:
  For some purposes it can be useful to search for outliers or highly unusual persons or representatives of opinions. A selection of persons that, emerging from an analysis, appear to be the 'exception to the rule' could be considered to get a better understanding of these outliers or “negative cases”. The process of identifying extreme or deviant cases occurs after of the data collection and analysis have been partially completed. Therefore it is a sampling strategy which is always conducted as complementary to other sampling strategies.
- Typical case:
  Cases are selected from which it is expected that they will provide information about a typical situation. This strategy is used in case of a new research area. If knowledge about a research topic is completely absent, a typical case can provide the basic knowledge necessary to construct theoretical explanations, preparatory to the search for more variation in cases. The typical case is one that occurs frequently[10].
- Critical case sampling:
  This sampling is especially used in case studies, a research strategy “*to understand social phenomena within a single or small number of naturally occurring settings. The purpose may be to provide description through a detailed example (…)*” (Bloor and Wood, 2006[35], p. 27). It can be used when time or resource constraints limit the possibilities to recruit participants. A small number of important cases is selected to "*yield the most information and have the greatest impact on the development of knowledge*" (Patton, 2002[46], p. 236). It is crucial that the research team identifies the dimensions that make the participants “critical”. Snowball sampling can be used to identify critical informants who can provide a great deal of information about a phenomenon.
- Theory-based or theoretical sampling:
  Theoretical sampling refers to the process of selecting "incidents, slices of life, time periods, or people on the basis of their potential manifestation or representation of important theoretical constructs" (Patton, 1999[28], p. 238).

- Confirming and disconfirming cases:
  Identification of confirming and disconfirming case occurs after data collection and analysis has partially been completed. Cases are sought to lend further support to an initial analysis or theory (confirming cases), or to disconfirm the theory and provide rival explanations (disconfirming cases). Researchers seek out confirming and disconfirming cases in order to develop a richer, more in-depth understanding of a phenomenon and to lend credibility to one's research account.

Recruitment strategies

In order to achieve the expected sample, several ways to find and recruit participants could be suggested:

- Convenience sampling:
  It is a pragmatic solution, i.e. selecting respondents based on ease, speed, and low cost, without any in-depth considerations on the selection of the participants. This strategy should ideally be avoided[33], but in some cases it is the only feasible option due to practical reasons (such as time, costs, etc.). A good description of the sample is especially important with convenience sampling, so that the reader can know how the results came about.
- Snowball sampling:
  This strategy is especially used when the researcher has no clear idea about where to search for respondents or who could provide him with the information he envisions. Hence the researcher searches for one or a few respondents and asks them who else they know could provide information. These individuals are contacted and in their turn asked whether they know other potential respondents. Once indivuals the same names are mentioned, the sample has reached his maximum size[10].
- At random, but still purposive:
  As already mentioned above a random selection as such is not useful in qualitative research. However, there is one exception: random selection can be used when the researcher by using one of the sampling strategies mentioned above, gets more cases than he can interview or observe with his available time and resources. In that situation randomness can be an additional selection criterion[10].

Sample size

"Determining adequate sample size in qualitative research is ultimately a matter of judgement and experience in evaluating the quality of the information collected against the uses to which it will be put, the particular research method and purposeful sampling strategy employed, and the research product intended" (Sandelowski, 1995[51], p. 199).

Typically, in qualitative research one should continue sampling until **saturation** is reached– this is the point at which no new information or themes are emerging from the data[35]. Therefore sampling goes hand in hand with data analysis and cannot be planned totally in advance. In reality in every research institution, the sample size is also determined in function of the budget, the time and human resources available. This means often practical aspects of the research project may constrain the size of the sample before theoretical saturation is reached. This is also true for KCE working practice, since budgets and time schedules are limited and fixed.

Beware that saturation can be reached prematurely if one's sampling frame is too narrow, if one's analytical perspective is biased or limited; if the data collection method is not resulting in rich, in-depth information or when the researcher is unable to get beyond the surface.

First contact with a respondent

- The first contact with a respondent is often made by telephone. It is very important as it will set the tone for the rest of the interviewing. During this telephone conversation the researcher must convince the respondent of the importance of the research and his participation. To convince the researcher could search for arguments that are important in the eyes of the respondent, rather than arguments in function of the importance of the research. Not too much information should be provided during this first contact. Additional information can be provided by means of an information letter. Box 1 presents information that can be provided during the invitation to participate.

Box 1: Information to be given during first contact

Background information

- Goal of the interview
- Person responsible for the research
- Reason why the respondent is invited to participate
- How the respondent was recruited
- Reason why the respondent is called at that specific moment in time
- The recording of the interview

Arguments pro praticipation

- How the results of the research will be reported, including (non)anonymity issues (e.g. in quotations)
- Influence of the results on policy making

Costs of the participation

- The kind of information the respondent is expected to provide
- The duration of the interview
- (Non) anonymity of the provided information
- How the recording of the interview will be treated after the interview

Source: Adapted from Emans, 1986[52] cited by Mortelmans, 2009[10]

It is important that people understand that participation in interviews or focus groups is completely voluntary, and that they may choose to leave at any time during the discussion. In addition, it is imperative that participants are aware that they will receive no tangible benefit for participation. That is why the question on offering incentives is often rather contentious[37]. Nevertheless their traveling costs could be reimbursed or they can receive a slight compensation or a small gift.

Also it is recommended to leave the choice of place (where the interview will take place) up to the respondent, in order to facilitate his participation. The context in which the interview takes place determines partly the interactions during the interview. For example a patient at home or in the waiting room of a hospital will disclose other kinds of information, not only because he/she feels more or less comfortable, but also because the setting triggers other associations and thoughts. The interviewer/researcher should be well aware of and anticipate the impact the interview location is likely to have on the data generated.

The same accounts for the characteristics of the interviewer. In the qualitative interview the researcher empathizes with his or her respondents and views their situation from their own points of view[53]. In general this empathic stance as well as gaining trust from the respondent, is facilitated if the interviewer resembles the respondent in terms of race or other characteristics relevant to the research topic. Gender however is an exception to this rule. There is a debate in the literature about whether same sex or opposite sex is preferable in order to achieve rapport during interviews. Some argue that men are more comfortable in talking with women (especially about intimate topics) that they are with other men[53].

2.2.1.3 How to develop an interview guide?

An interview guide should be adapted to the language and vocabulary of the participant(s) and is generally built out of three components:

1. A reminder of the goal of the research.
2. The main topics or questions, the interviewer wants to address during the interview.
3. Relaunching questions. They are an essential part of the interview. It may happen that the interviewee does not give an answer to the question or gives an unexpected answer. In that case the interviewer can probe in order to delve deeper. In case a respondent does mention an aspect you thought of in advance or you are particularly interested in, you can repose the question focused on that specific issue. For example the initial question could be: "Which difficulties you experienced after your surgery?". The respondent mentions all kinds of worries and inconveniences, but you are particularly interested in the organization of after care. Hence you could ask: "How did you experience the organization of after care?".

How to construct a topic list or semi-structured questionnaire?

A topic list covers all the topics the interviewer should ask during the interview. It enables the interviewer to guide the interview while allowing the discussion to flow naturally. The sequence of topics generally moves from the general to the specific. The sequencing of topics can be introduced in a flexible way, and within a general framework of topics, the focus of the discussion can be reset. A topic list is also used in preparation of the semi-structured questionnaire

In a questionnaire semi-structured questions are formulated in speaking language and are posed as such during the interview. The same questions with the same formulation, sometimes in the same sequence, are posed in each interview. The disadvantage however is that it can threaten the natural flow of the conversation.

Both for the topic list and the semi-structured questionnaire, questions/topics should evidently be selected in function of the research objectives. An open ended-formulation of the questions is important in order to enable the interviewee to talk freely without predispositions of the interviewer influencing the narrative. For example, rather than asking "Did you worry about the surgery?", one could ask "How did you feel about the surgery?".

A topic list or questionnaire may be adapted or improved in the course of the research, in line with the iterative nature of QRM (see 1.1.1). The more interviews you have done, the more you know and the more specific or detailed your questions can be[10]. However, continuity should be guarded. The topics of the first interview should also be represented in the following interviews, although the latter can also contain much more detailed questions.

For an example of a topic list and a semi-structured questionnaire, see Appendix 6 and Appendix 7 respectively.

What types of questions can be posed?[i]

The interview starts with an **easy opening question** which is mostly to set the interviewee at ease, break the ice and get to know each other. With this question the researcher does not expect to get a lot of useful information, the main function is to start up the conversation.

After that the conversation is started with a **first general and easy to answer question addressing the content of the research**. It can be an attitude question to enable the respondents to roll into the conversation. An example could be: "If you hear breast cancer screening, what are your first thoughts?".

Next, **transition questions** involve the respondents in the research subject, for example through asking questions about personal experiences or specific behavior regarding the topic. Attitudinal questions are more difficult to answer and should therefore be addressed later in the interview. An example is "How did you experience your eye surgery?".

Subsequently the **key questions** are addressed. These questions are the reason why the interview is done. The interviewer can make clear that the interviewee can take some time to answer these questions. An interview can count up to five key questions each taking up to fifteen minutes to answer them.

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[i] based on Mortelmans, 2009[10]

Finally, the interview is terminated by means of a **concluding question and thanking** the interviewee for his participation. Three types of concluding questions can be distinguished:

1. Summary questions provide the interviewee with a summary of what he has told the interviewer,
2. Final questions can address elements that have not been mentioned during the interview, for example: "Do you want to add something to this interview?". Make sure you allow enough time for the concluding questions.

It is useful to conduct a pilot (focus group) interview in order to test, assess and validate the format and the appropriateness of the topic guide or questionnaire.

2.2.1.4 How to run the data collection?

Preparations for the interview

- Preparations for the interview encompass the recruitment of participants and the making of appointments, becoming knowledgeable about the research topic, including learning the interview guide by heart, anticipating questions of participants regarding the research project, access to a physical space where the interviews can take place and preparation of the recording equipment[54]. Well functioning of the recorders is crucial, so batteries, tapes and microphones should be carefully checked. It could be practical to foresee a second recorder as back-up. Finally also a notebook, a pen, and of course the topic list or interview guide you prepared for the interview should not be forgotten.

Box 2: What to take to the interview?

Equipment

- 1 digital tape recorder (plus 1 extra, if available)
- Spare batteries
- Field notebook and pens

Interview packet

- 1 interview guide (in the appropriate language)
- informed consent forms (2 per participants: 1 for interviewer, 1 for each participant, in the appropriate language)
- Participant reimbursement (if applicable)

Source: Adapted from Mack, 2005[54]

Running the interview

Informed consent should be obtained from each participant before starting the interview. Also permission should be asked to record the interview. Also it should be explained how the tapes will be used and stored.

The research aims should be briefly repeated. Probably the research aims were already explained during the first contact with the respondent in order to convince him of participating. Next, all the topics or questions on the checklist or questionnaire need to be addressed. Participants are probed for elaboration of their responses in order to learn everything they want to share about the research topic[54]. Mobile phones should be switched off during the interview so as not to imply that the participant's testimony is of secondary importance.

During the interview back-up notes could be taken, the interviewee's behaviors and contextual aspects of the interview should be observed and documented as part of the field notes. Field notes are expanded as soon as possible after each interview, preferably within 24 hours, while the memory is still fresh[54].

To get deeper or redirect the discussion, probing techniques can be used:

- Repeat the question but in a different wording.
- Summarise the anwer the relevant aspects of the interviewee's answer, in an interrogative way. For example: "In sum, you say that…?"
- Probe explicitly, for example: "What do you mean?" or "Could you give me a second example?"
- Purposive probing, for example: "Why was it that you?" or "What happened then?"
- Repeat the last couple of words in an interrogative way. For example: "R: (…) I think it is dangerous and I don't trust doctors". I: "You don't trust doctors?"
- Introduce a short silence.
- Verbalise emotions, for example: "I can see that thinking of that discussion makes you very angry."

The interview is closed by thanking the participant(s).

2.2.1.5 How to prepare the data for analysis?

Transcribing is the procedure for producing a written version of the interview. Ideally, the information recorded during the interview will need to be transcribed in order to enable accurate data analysis. A transcript is a full written literal text of the interview. It often produces a lot of written text.

Good quality transcribing is not simply transferring words from the tape to the page. The wording communicates only a small proportion of the message. A lot of additional information is to be found in the way people speak. Tone and inflection, timing of reactions are important indicators too. With experienced observers and note-takers, a thematic analysis of the notes taken during the interviews could be used as a basis for analysis of the "non-verbal" aspects.

Transcribing is a time consuming and costly part of the study. The research team should consider in advance the question "who should do the transcribing"? Resources may be needed to pay an audio typist, a strategy usually more cost effective than a researcher. Be aware that "typists" are often unfamiliar with the terminology or language used in the interviews which can lead to mistakes and/or prolong the transcribing time.

It may not be essential to transcribe every interview. It is possible to use a technique known as tape and notebook analysis, which means taking notes from a playback of the tape recorded interview and triangulating them with the notes taken by the observers and note-takers. However, bias can occur if inexperienced qualitative researchers attempt tape and notebook analysis. It is certainly preferable to produce full transcripts of the first few interviews. Once the researcher becomes familiar with the key messages emerging from the data tape analysis may be possible. Transcripts are especially valuable when several researchers work with the same data.

2.2.1.6 How to analyse the data?

As in any research method, analysing collected data is a necessary step in order to draw conclusions. Analysing qualitative data is not a simple nor a quick task. Done properly, it is systematic and rigorous, and therefore labor-intensive and time-consuming *"[…] good qualitative analysis is able to document its claim to reflect some of the truth of a phenomenon by reference to systematically gathered data"*[55], in contrast *"poor qualitative analysis is anecdotal, unreflective, descriptive without being focused on a coherent line of inquiry*."[55]"(Pope, 2000[56] p. 116). Qualitative analysis is a matter of deconstructing the data, in order to construct an analysis or theory[10].

The ways and techniques to analyse qualitative data are not easy to describe as it requires a lot of "*fingerspitzengefühl"* and it is unrealistic to expect a kind of recipe book which can be followed in order to produce a good analysis. Therefore what we present here is a number of hands-on guidelines, which have proven useful to others.

The difficulty of qualitative analysis lies in the lack of standardization and the absence of an universal set of clear-cut procedures which fit every type of data and could be almost automatically applied. Also there are several approaches for taking the analysis forward: for example thematic analysis, the general inductive approach, grounded theory or the framework approach. These approaches move from inductive to more deductive, but in practice the researchers often moves back- and forwards between the data and the emerging interpretations. Hence induction and deduction are often used in the same analysis. Also elements from different approaches may be combined in one analysis[3].

The approach chosen depends largely on the design and the aims of the research. Some designs and/or research questions require an inductive, others a deductive approach. Inductive means that themes emerge from the data, while deductive implies a pre-existing theory or framework which is applied to the data. Different aims may also require differing depths of analysis. The analysis of an interview-based study will probably be more detailed than the analysis of a small number of interviews carried out as an exploratory part of a mixed method study encompassing several components. "*The analysis may seek simply to describe people's views or behaviors, or move beyond this to provide explanation that can take the form of classifications, typologies, patterns, models and theories (Pope and Mays, 2006[3], p. 67).*" The two levels of analysis can be described as following:

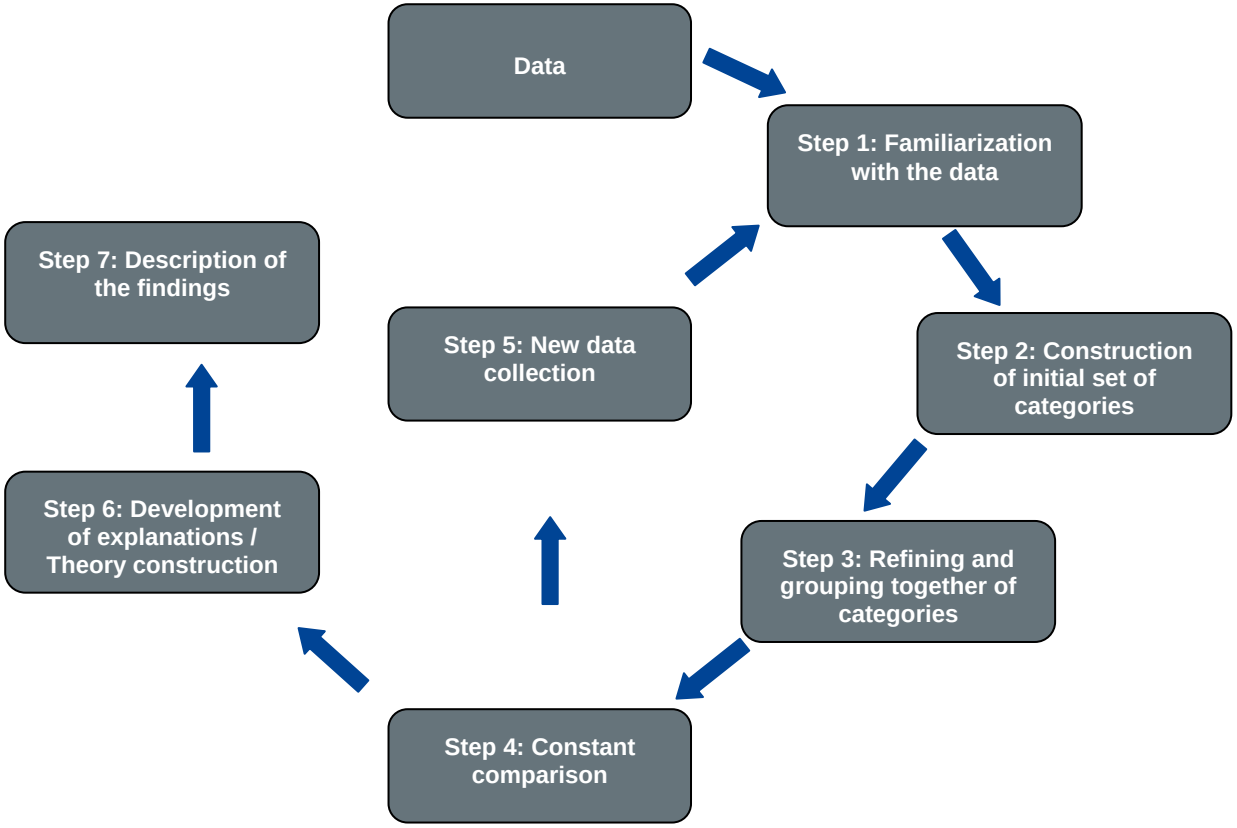
- The basic level is a descriptive account of what was said (by whom) related to particular topics and questions. Some texts refer to this as the "manifest level" or type of analysis.
- The higher level of analysis is interpretative: this is the level of identifying the "meanings" of the responses. It is sometimes called the latent level of analysis. This second level of analysis can to a large degree be inspired by theories.

The steps in the analysis

1. Independent of the approach of analysis, a qualitative analysis always starts with the **preparation of the gathered data** and a first reading of the interview transcripts and/or field notes **to get familiar with the data**.
2. The following step is very laborious (especially with large amounts of data) and consists of reading and re-reading the data in order to develop an profound knowledge of the data. This way **an initial set of themes or categories is identified**. This means pieces of text are coded, this means given a label or a name. In fact meanings are isolated in function of answering the research question. One piece of text may belong to more than one category or label. Hence there is likely to be overlap between categories. Non-relevant data is omitted. Opposing or non-consensual visions related to themes or items discussed have to be documented/reported. Major attention should be paid when "rival explanations" or interpretations about the data can be made.
3. In a third step **the categories are further refined and reduced by being grouped together**. Word processors or software for qualitative data analysis will prove to be very helpful at this stage. During the analysis the researcher might (as a third step) constantly compare the constructed categories with new data, and the new categories with already analysed data. This results in a kind of inductive cycle of **constant comparison** to fine tune categories and concepts arising from the data. New data collection could also be necessary to verify new point of views or insights emerging from the analysis.

This general a-theoretic procedure reflects what in the literature is called the **general inductive approach** for analysing qualitative data. It does not aim at the construction of theories, but the mere description of emerging themes. It provides a simple, straightforward approach for deriving findings in the context of focused research questions without having to learn an underlying philosophy or technical language associated with other qualitative analysis approaches[57].

Figure 3 – Conceptual representation of iterative process of qualitative analysis with an inductive approach



Theoretical approaches

The process described above is inductive and is in line with the principles of e.g. grounded theory and the general inductive approach.

Grounded theory is more than a way to analyse data, it is a complete methodology, a way of conceptualizing a qualitative research project. Key to grounded theory is the emphasis on theory as the final output of research[58]. Other approaches may stop at the level of description or interpretation of the data."The appeal of grounded theory analysis is the structured and detailed procedures for the generation of theory from data"[59]. The steps in the procedure are:

- Open coding, or the identification of an initial set of themes or categories (called codes) (see step 2 in the analysis)
- Axial coding, or the identification of relationships between themes or categories. This is a way of refining the initial codes (see step 3 in the analysis)
- Selective coding, or the movement towards "*the development of analytical categories by incorporating more abstract and theoretically based elements*" (Pope and Mays, 2006[3], p. 71).

Data analysis is generally expected to be an iterative process**.** Especially in the grounded theory approach constant comparative analysis is emphasized. This means that overall data collection and data-analysis are not organized in a strict sequential way. Constant comparative analysis is a process whereby data collection and data analysis occur on an ongoing basis. The interview is transcribed and analysed as soon as possible, preferably before the next interview takes place. Any interesting finding is documented and incorporated into the next interview. The process is repeated with each interview until saturation is reached. As a result it could be possible that the initial interviews in a research project differ a lot from the later interviews as the interview schedule is continuously adapted and revised. For this reason researchers have to clarify and document on how structured or unstructured their data-collection method is and keep memo's of the process. Notes and observations made at the time of the interview are re-examined, challenged, amended, and/or confirmed using transcribed audio or video tapes. One expects that all members of the research team participate in a review of the final interpretation, in which data and analysis are again re-examined, analysed, evaluated, and confirmed. The use of more than one analyst can improve the consistency or reliability of analyses.

The term 'grounded theory' has often been used in research papers, without any mention of the elements described above[3]. The grounded theory approach is popular, although this kind of analysis is unpredictable to some extent: "*it is seldom possible to specify precisely the dimensions or direction of the research at the outset*" (Pope and Mays, 2006[60], p. 71). This characteristic is often problematic for research funders, program managers and ethical committees in general, and at the KCE in particular.

Within the KCE context in particular and applied and policy research in general a more deductive approach could be useful. Often several forms of data gathering and analysis are used within one research project, hence qualitative research is often only one component within a broader whole. The other parts often provide input and may lead to the development of a preliminary framework which may guide the qualitative data analysis.

Framework analysis has been developed specifically for applied or policy relevant qualitative research, and is used in deductive research strategies. In a framework analysis the objectives of the investigation are set in advance. The thematic framework for the content analysis is identified before the research or the qualitative research part in the project commences.

The decision on using frameworks when analysing data is closely related to the question for what purpose the qualitative material will be used in the overall research strategy. "Frameworks" are generally deducted from hypotheses of theoretical frameworks: e.g. if the aim of a focus group is trying to get a picture of stakeholders interests and potential conflicting perspectives on a health care issue, and the focus group tries to grasp on how stakeholders develop power plays or influence strategies to set agenda's, a conceptual framework of decision-making processes and power play will serve as a useful tool to orient data-collection and data-analysis.

Applying framework analysis concretely means that the themes emerging from the data are placed in the framework defined a priori. The framework is systematically applied to all the data. Although a analytical framework can be very useful, it is not suited, if the aim is to discover new ideas, since a framework or grid could be blinding[61].

Software to analyse qualitative data

Analysis may either be done manually or by using qualitative analysis software, for example Nvivo©[j], Atlas ti©[k], Maxqda©[l], etc.

These Computer-Assisted Qualitative Data Analysis Software (CAQDAS) offer a support to the analyst with the storage, coding and systematic retrieval of qualitative data[35]. They are able to manage different types of qualitative materials, such as transcripts, texts, videos, images, etc. their utility for the analysis depends on the size of the corpus of analysis (number of interviews, plurality of the data sources) and has not to be automatic. They also could be useful for collaborative purposes when several researchers are analysing the same data. They not guarantee the scientific nature of the results[62]. Indeed, quality of the results does not depend on the tool used, but on the scientific rigor and the systematic analysis of the data.

2.2.1.7 How to validate qualitative research findings?

External validation, also called transferability of the analysis, refers to whether you can apply the findings to other settings. It is largely determined by the sampling strategy and the setting. (see also 1.2.2 General quality criteria in part 2).

Quality criteria and validation techniques for qualitative research methods are described more extensively in section 1.2.1 (part 2).

2.2.1.8 How to report qualitative research findings?

Interviews can be presented in a number of ways, there is no specific format to follow. However, alike other research methods, justification and methodology of the study should be provided. The research process should be fully transparent so that any researcher can reproduce it. In addition, it should be comprehensible to the reader.

A possible structure could be:

1. Introduction and Justification
2. Methodology
   - 2.1 How were respondents recruited?
   - 2.2 Description of the sample
   - 2.3 Description of selection biases if any
   - 2.4 What instruments were used to collect the data?
     You may want to include the topic list or questionnaire in an appendix
   - 2.5 Over which period of time was the data collected?
3. Results : What are the key findings?
4. Discussion
   - 4.1 What were the strengths and limitations of the information?
   - 4.2 Are the results similar or dissimilar to other findings
     (if other studies have been done)?
5. Conclusion and Recommendations
6. Appendices (including the interview guide(s)/ topic guide)

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j http://www.qsrinternational.com/products_nvivo.aspx

k http://www.atlasti.com/index.html

l http://www.maxqda.com/

When writing up findings qualitative researchers often use quotes from respondents. Quotes are useful in order to[63]:

- Illustrate the themes emerging from the analysis.
- Provide evidence for interpretations, comparable to the use of tables of statistical data appearing in reports based on quantitative findings.
- Strengthen credibility of the findings (despites critics argue that researchers can always find at least one quote to support any point they might with to make).
- Deepen understanding. The actual words of a respondent could sometimes be a better representation of the depth of feeling.
- Enable voice to research participants. This enables participants to speak for themselves and is especially relevant in a participatory paradigm.
- Enhance readability by providing some vividness and sometimes humour: Braking up long passages of text by inserting spoken words, could help to keep the reader focused, but there could be a danger in moving too far towards a journalistic approach.

Ideally, quotes are anonymous and are accompanied by a pseudonym or description of the respondents. For example, in a research about normal birth, this could be: (Midwife, 36 years). There are however exceptions the rule of anonymity, e.g. stakeholder interviews, in which the identity of the respondent is important for the interpretation of the findings. In that case the respondent should self-evidently be informed and his agreement is needed in order to proceed.

Also in terms of lay out quotations should be different from the rest of the text, for example by using indents, italic fond or quotation marks. Quotes are used to strengthen the argument, but should be used sparingly and in function of the findings. Try to choose citations in a way that all respondents are represented. Be aware that readers might give more weight to themes illustrated with a quotation.

When the research is conducted in another language than the language of the report in which the findings are presented, quotes are most often translated. "*As translation is also an interpretive act, meaning may get lost in the translation process* (Van Nes et al, 2010[64], p. 313)". It is recommended to stay in the original language as long and as much as possible and delay the use of translations to the stage of writing up the findings[64].

KCE practice is to translate quotes only for publications in international scientific journals, but not for KCE reports. Although KCE reports are written in English, inserted quotes are in Dutch or French to stay close to the original meaning. The authors should pay attention to the readability of the text and make sure that the text without quotes is comprehensive to English speaking readers.

2.2.1.9 What are the common pitfalls?

In the following paragraph we mention a number of common pitfalls typical for interviews. They are based on the work of Mortelmans[10] and the Qualitative Research Guidelines Project[33].

- The methodology needs to be transparent. Each step of the sampling, data collection and analysis should be described in sufficient detail, this means that it must enable other researchers to replicate the same study.
- The sample should be well constructed and described.
- Avoid dichotomous questions which elicit a yes or a no. In an interview we are especially interested in rich descriptions and we want the interviewee to talk a lot and elaborate on the topic of the question.
- Avoid double questions, for example: "Once you decided to have a screening, what was the next step? How did you proceed? How did it change the way you thought about potential risks?" The interviewee can not respond to all the questions at once and thus picks out one. This means the other questions are lost.
- Avoid the expression of value judgements or your own opinion, for example: "What do you think about the endless waiting times?" The word "endless" suggests irritation.
- Avoid to be suggestive, for instance by giving examples: "Which kind of difficulties did you encounter, like long waiting times, full waiting rooms etc?" This kind of examples provide the interviewee with a frame, which he will possibly not transcend. This way you loose what he would have answered spontaneously.

- Avoid a reverse of roles. The interviewee should not be asking you questions. An example could be: I: "What does it mean to you to be a patient?", R: "I don't know. What does it mean to you?". If this happens you can say that you are willing to answer that question after the interview, but that you can not answer it during the interview in order not to influence the answers of the interviewee. A reverse of roles can be avoided if the interviewer introduces himself in a neutral way, for example as a researcher, but not as, for example a physician or an expert in an issue related to the topic/goal of the interview, in order for the respondent not to ask you too many questions on a particular condition or issue.
- Avoid letting the interviewee deviate to far from the topic or elaborates on irrelevant matters by returning to the question posed.
- Avoid being too jargony, but use a familiar terminology which does not need explications or definitions.
- The analysis should not be superficial but really in-depth. However it may not transcend the data. The data must always support the results.

2.2.2 Individual semi-structured interviews[m]

2.2.2.1 What are individual semi-structured interviews?

Interviews are used in many contexts (journalism, human resource managers, etc.) and for many purposes (entertainment, recruitment of personnel, etc.), hence scientific data collection is only one very specific application, which should not be confused with other applications. The interview is easily trivialized as it is common practice in the media landscape which surrounds us. Fontana and Frey even speak about "the interview society"[65] according to Atkinson and Silverman[66]. Practicing health professionals routinely interview patients during their clinical work, and they may wonder whether simply talking to people constitutes a legitimate form of research[67]. In qualitative research, however, interviewing is a well established research technique and two types can be distinguished: semi-structured and unstructured. Structured interviews are out of scope here, because they consist of administering structured questionnaires producing quantitative data.

Unstructured interviews are more or less equivalent to guided conversations[67]. Originally they were part of ethnographers' field work, consisting of participant observation and interviewing key informants on an ongoing basis to elicit information about the meaning of observed behaviors, interactions, or artifacts[67]. There is no list of questions, nor an interview guide, the questions asked are based on the responses of the interviewee, as in the natural flow of a conversation[68].

Semi-structured interviews are often the sole data source in a qualitative research project. A set of predetermined open-ended questions is used to guide the interview, but other questions emerging from the dialogue can be added[68]. Also the iterative nature of the research process in which preliminary data analysis coincides with data collection, results in altering questions as the research process proceeds. Even so, questions that are not effective in eliciting the necessary information can be dropped or replaced by new ones[68].

Essentially an interview consists of someone who asks questions (interviewer), someone who answers these questions (interviewee) and the registration of those answers in some way[10].

The interview as qualitative research method differentiates from other forms of interviewing used in varied domains. Mortelmans[10] pays attention to four characteristics:

- Flexibility; with flexibility internal and external flexibility is meant: external refers to the iterative use of interviewing and data analysis. Structure and content of the subsequent interview may be changed in function of the analysis of the previous one. Internal flexibility points to the fact that the sequence of the prepared interview questions and themes should stands in function of the interviewee in order to guard the natural flow of the conversation.
- The interviewee leads so to speak the conversation. The interviewer only guards the scope of the conversation and makes sure that all the topics are covered.

[m] In this chapter, we will focus on face-to-face interviews.

- Non-directiveness; the interviewee steers the interview and the interviewer only makes sure that the conversation does not stray too far by means of non-directive interview techniques.
- Direct face-to-face contact is important to built trust and get in-depth information, but this depends on the topic and should be considered case by case.

2.2.2.2 When to use individual semi-structured interviews?

Individual semi-structured interviews are useful to:

- Collect data on individuals' personal histories, perspectives, and experiences, particularly when sensitive topics are being explored[54].
- Elicit a vivid picture of the participant's perspective[54].
- Provide context to other data, offering a more complete picture[69].
- Learn about the perspectives of individuals, as opposed to, for example, group norms of a community, for which focus groups are more appropriate[54].
- Get people to talk about their personal feelings, opinions, and experiences[54].
- Gain insight into how people interpret and order the world on the research topic[54].
- Address sensitive topics that people might be reluctant to discuss in a group setting[54].
- Elicit information from key informants[1].
- Examine people's experiences, attitudes and beliefs[24].

2.2.2.3 Strengths and weaknesses of the method

Strengths:

- They provide much more detailed information than what is available through other data collection methods, such as surveys[69].
- Questions can be prepared ahead of time. This allows the interviewer to be prepared and appear competent during the interview[33].
- Semi-structured interviews also allow informants the freedom to express their views in their own terms[33].
- Semi-structured interviews can provide reliable, comparable qualitative data[33].

Weaknesses:

- Interviews can be time-intensive because of the time it takes to recruit participants, conduct interviews, transcribe them, and analyse the results. In planning your data collection effort, care must be taken to include time for transcription and analysis of this detailed data[69].
- Interviewers must be appropriately trained in interviewing techniques. To provide the most detailed and rich data from an interviewee, the interviewer must make that person comfortable and appear interested in what they are saying. They must also be sure to use effective interview techniques, such as avoiding yes/no and leading questions, using appropriate body language, and keeping their personal opinions in check[69].
- Data from individual semi-structured interviews are not generalizable in a statistical way, but they are theoretically transferrable, because small samples are chosen and no random sampling methods are used. Individual semi-structured interviews however, provide valuable information, particularly when supplementing other methods of data collection. It should be noted that the general rule on sample size for interviews is that when the same stories, themes, issues, and topics are emerging from the interviewees, then a sufficient sample size has been reached[69].

2.2.2.4 How to plan the research design?

See part 2, 2.2.1.1 "How to plan the research design?"

2.2.2.5 Modalities of data collection

Individual semi-structured interviews are usually conducted face-to-face and involve one interviewer and one participant. Phone conversations and interviews with more than one participant also qualify as semi-structured interviews, but, in this chapter, we focus on individual, face-to-face interviews[54].

2.2.2.6 Data collection tools

The data collection tools to carry out interviews are topic lists, questionnaires and field notes. Topic lists and questionnaires are described in part 2, section 2.2.1.3.

Researchers use field notes to record observations and fragments of speech. Field notes should be written up as soon as possible after the events to which they refer. If possible, short "aide-mémoire" or pocket dictaphones may be used in fieldwork settings, to facilitate later expansion of the notes into proper fieldnotes[35]. In the chapter on observational techniques field notes are addressed in more detail (section 2.3.6.2 in part 2).

2.2.2.7 Sampling

For general issues on sampling, see 2.2.1.2 "Sampling issues in qualitative research: who and how many?" in part 2.

2.2.2.8 Human resources necessary

In the ideal scenario researchers plan, organize, carry out and transcribe the interviews themselves, to be completely immersed in the data, but in practice the interviews are often carried out by subcontractors and the transcriptions are often done by professional typists.

2.2.2.9 Practical aspects

Preparations for the interview See 2.2.1.4 "How to run the data collection" in part 2.

Physical organisation of an interview. Take the following rules into account:

1. Interviewee and interviewer should not sit opposite each other, but rather at an angle of 90° or less.
2. The interview should take place in a quiet place where the interviewee feels at ease.
3. Avoid the presence of third parties.

2.2.2.10 Analysis and reporting of findings

See 2.2.1.6: "How to analyse the data?" and 2.2.1.8 "How to report qualitative research findings?" in part 2.

2.2.2.11 Examples of KCE reports using the method

- Home monitoring of infants in prevention of sudden infant death syndrome[70]
- Making general practice attractive: encouraging GP attraction and retention[71]
- Osteopathy and chiropractic: state of affairs in Belgium[49]
- Acupuncture: state of affairs in Belgium[50]
- Homeopathy: state of affairs in Belgium[48]
- Burnout among general practitioners: prevention and management[72]
- Evaluation of a fixed personal fee on the use of emergency services[73]

2.2.3 Focus groups

2.2.3.1 What are focus groups ?

A focus group is a particular technique in qualitative research. In order to do a focus group interview a group of individuals is gathered in function of their specific profile or characteristics to explore a limited number of "focused questions"[1]. Groups are generally homogenous on a or several criteria relevant to the focus of the discussion.

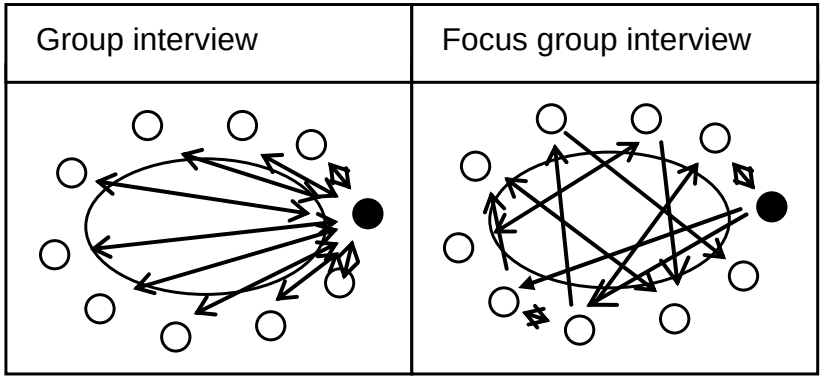
"*In essence, a focus group is a small (usually 6-12 people) group brought together to discuss a particular issue (..) under the direction of a facilitator who has a list of topics to discuss*" (Green and Thorogood, 2009[37], p. 111).

Focus groups are ***group*** semi-structured interviews used for the purpose of collecting information ***focused*** on a specific subject or area of concern, for exploration and discovery, in-depth understanding of a problem as it is experienced in context, to assess needs, preferences, attitudes and interests related (in the context of KCE research) to health and health care issues.

It differs from individual semi-structured interviews, as the interaction component is used to bring out insights and understandings in ways which questionnaire items or individual questions may not be able to do. The interaction between the moderator and the group, as well as the interaction between group members, may result in more in-depth information, and to elicit differing perspectives related to carefully designed questions. Focus groups are thus not to be considered as a pragmatic time saving substitute for individual semi-structured interviews (e.g. if for any reason the planning does not allow for individual interviews), as the methodological groundings of both techniques differ.

A focus group is not synonymous to 'group interview': For a focus group, people are recruited specifically to participate in a research protocol, using a certain method. It is a group interview in the sense that it gathers data simultaneously from different participants[37]. However it differs from a group interview in the importance that is attached to the interaction among participants. Participants might change their perspective during the focus group interview because of this interaction. In a group interview the interaction between participants is limited, and occurs mainly between interviewer and interviewees.

Figure 4 – Interaction patterns in a group interview versus focus group interview



Depending on sampling strategy and aims, group interviews can take several forms, e.g. consensus panel, focus group, natural group or community interview (Coreil 2005 cited by Green and Thorogood, 2009[37]).

Focus groups can be used as a single research strategy, as well as in combination with other methods in a multi-method research strategy.

2.2.3.2 Specific questions suitable for the method

Specific questions suitable for interviews in general were elaborated in section 1.1. (part 2).

The principal feature of focus group interviews is interaction between participants. Kitzinger (Kitzinger, 2006[74], p. 22) highlights that this particularity could be used to:

- "Highlight the respondents' attitudes, priorities, language and framework of understanding.
- Encourage participants to generate and explore their own questions, and to develop their own analysis of common experiences.
- Encourage a variety of communication from participants – tapping into a wide range and different forms of discourse.
- Help to identify group norms/cultural values.
- Provide insight into the operation of group social processes in the articulation of knowledge (e.g. through the examination of what information is sensitive within the group.
- Encourage open conversation about embarrassing subject and to permit the expression of criticism.
- Facilitate the expression of ideas and experiences that might be left underdeveloped in an interview, and to illuminate the research patient's perspectives through the debate with the group."
- Allow topics which participants have given little thought in advance to emerge from the discussion[75].

2.2.3.3 *Strengths and weaknesses of the method*

The **benefits** from focus groups highlighted are:

- Interaction between participants[37].
- Ability to produce a large amount of data on a topic in a short time[14].
- Access to topics that might be otherwise unobservable[14].
- Access to explore sensitive topics, such as dissatifaction with a service: it can be easier for an interviewee if negative ideas are reported as coming from a group than from one single person[37].
- Ability to insure that data directly targets researcher's topic[14].
- Access to comparisons that focus group participants make between their experiences. This can be very valuable and provide access to consensus/diversity of experiences on a topic[33].

The **limitations** of focus groups are related to the limitations of group interviews:

- Inappropriate to uncover marginal or deviant opinions[37].
- Importance of social norms: participants are influencing each other, creating a certain kind of implicit norm[76], or consensus.
- Otherwise, group dynamics may contribute to cristallization of opinions.
- Not easy to organize: several selected people have to be gathered in the same place during a couple of hours .

2.2.3.4 *How to plan the research design?*

Since focus group interviews are a collective data collection technique requiring direct person-to-person contact (several people have to come together at the same moment and in the same place) a careful planning of all activities and related tasks is necessary.

2.2.3.5 *Modalities of data collection*

The data collection by focus group could vary according to[33]:

- The level of standardization of the questions (see part 2, 2.2.3.6).
- The number of focus groups (see part 2, 2.2.3.7).
- The number of participants in each groups(see part 2, 2.2.3.7).
- The level of implication of the moderator (see part 2, 2.2.3.8).

2.2.3.6 *Data collection tools*

During the preparation of the focus group interviews a set of topics or questions is developed and takes the form of a topic list or questionnaire. For the general principles, see part 2, 2.2.1.3”

A focus group interview is in most cases a structured group process structured by means of an agenda to keep the group focused and on track. A focus-group should be experienced as free-flowing and relatively unstructured, but in reality, the moderator must follow a pre-planned script of specific issues and set goals for the type of information to be gathered. An introduction of up to 15 minutes should be carefully planned, as well as a good opening question. In order to keep the time schedule, as several people are going to participate and answer to the questions, it is important to foresee a maximum duration for each question.

The use of a well designed guide is helpful to compare information from one group to another as it is expected to have more than one focus group for a given topic.

Examples of topic lists used in focus groups can be found in appendices or in KCE reports in which this technique have been used (see part 2, 2.2.3.13).

2.2.3.7 Sampling

For general issues on sampling, see part 2, 2.2.1.2 "Sampling issues in qualitative research: who and how many?"

Identification of units of analysis

The starting point for selecting participants for focus groups is to identify the unit of analysis. Is the unit of analysis "individuals for their personal opinions/experience/expertise", or is it "individuals because they represent organizational perspectives"? It has a major impact on the people invited to the focus group interview and therefore it should be clearly described.

The sample of focus groups will consist of groups of people, instead of individuals. People who are invited to take part need to have an interest in the subject.

Composition of the groups

Ideally groups have to be internally homogenous on criteria relevant to the topic but externally heterogeneous between groups. Homogeneity in the group capitalizes on people's shared experiences[74].

It is best to select people who do not know one another, but have *similar* relationships with the topic being investigated (although it could in practice be difficult for particular topics). Selecting participants who are similar may help them to share ideas more freely and develop an in-depth analysis of a topic (homogeneous groups).

Sometimes, heterogeneous groups can be used after the primary analysis of homogeneous focus groups has started. Heterogeneous groups are used to "confront" diverging opinions. In general terms, heterogeneous groups are composed of representatives of all relevant stakeholders.
In this case, the researcher has to pay attention to potential power differences or inequalities between participants. This may prevent some people from talking freely during the discussion and by consequence prevent the collection of rich data[74].

In the Belgian context, focus group interviews can be carried out with French-speaking or Dutch-speaking and even German-speaking, participants. It is advisable to conduct unilingual groups: it is easier and richer for facilitators and participants. For heterogeneous groups, like stakeholders samples, it could be difficult to separate people in groups according to their mother tongue. In this particular case, it is important that participants express themselves in their mother tongue and to be sure that every participant understands the other language. The moderator has to be thus perfectly bilingual.

Number of participants per group

A group of six to twelve people is sufficient for a focus group. The ideal size for a focus group is eight to ten respondents. In general, the smaller the group, the more manageable it is. From experience, a group of 6-8 participants allows enough time for discussion and is easier to manage. Where the purpose is to generate in-depth expression from participants, a smaller group size may be preferable in combination with carrying out more focus groups to attain saturation.

In order to make sure that a group counts enough participants, it is advisable to recruit 25% more people than required[37]. If too few participants turn up, one should foresee an additional focus group to substitute for the low attendance.

Number of groups

The number of focus group interviews needed depends on the aims and available resources . It is almost impossible to give clear standardized guidelines on the number of focus groups needed.

It is methodologically important for both approaches to conduct *at least* two focus groups by 'type of people'. Using only one focus group to arrive at conclusions is risky since the opinions expressed may have had more to do with the group dynamics (i.e. persuasive skills of one or two members) than a true sampling of the opinions of the population that the group represents. Even the preset number of two focus groups is generally too limited to make in-depth analyses, especially if the topics discussed are rather "broad" or general (see also paragraph analysis on continuous comparative method). Having two homogeneous groups that provide different results suggests that more information is necessary (data saturation is not reached). One rule of thumb is to conduct focus groups until they no longer provide any new information on the topic discussed.

2.2.3.8 Human resources necessary

Three people (from the research team) could chair the focus group interview:

1. **The moderator** (also called 'facilitator') plays a crucial role in the success of a focus group interview and can have a major impact on the outcomes of the data collection. He should lay down some 'rules', explain the duration of the focus group interview, plan a break in between, make everybody welcome before hand, do the paperwork (e.g. informed consent) before actually starting the interview. Before the opening question, is it important to ask everybody to introduce themselves briefly.
   He has "to establish a relaxed atmosphere, enable participants to tell their stories, and listen actively" (Green, 2009[37], p 126.). Facilitating or moderating focus group interviews requires particular competencies: interpersonal skills (including non-verbal communication skills) are needed as well as a non-biased attitude towards the issues discussed. A focus group moderator should be able to keep the discussion on track and make sure every participant is heard. He/she has to be able to summarize what has been said, to structure the discussion. However he/she should not take position, avoid to make quick assumptions or conclusions, avoid to develop answers for the participants or give advice. Focus groups are intended to make in-depth studies of the perceptions, attitude and opinions of the participants, not of the research team (or moderator).

   The moderator makes it socially acceptable for participants to have another point of view.

   If participants get off track or get ahead of the issue being discussed the moderator must pull the group back together.

   He/she does not need to be an expert in the domain of the research.

   The moderator needs to use "probing techniques" when necessary: probing is essentially a means of further investigating a topic that has already been introduced. Probing can be used to clarify, to obtain more detail and to assure completeness. For this purpose, see also part 2, 2.2.1.4. In the particular case of focus group interviews, the moderator could use disagreements in the group to force participants to develop and elucidate their point of view.
   An experienced interviewer could decide whether or not to follow the lead of the interview or to return to the sequence of the interview guide[1]

   In the particular case of bilingual groups, the moderator has to master both languages.

2. The **note-taker** will take notes during the discussion while the moderator is introducing questions. The note-taker could sit next to the moderator. Nevertheless, pay attention that if he/she is typewriting on a laptop directly, the sound of the typing on the keyboard is not disturbing.

   Moderator and note-taker can take turns in asking questions and taking notes (this requires a well functioning team that clearly understands its roles and can adapt to the situation). It should be discussed and reported whether different or the same persons facilitate the respective focus group interviews.

3. The **observer** is a third facilitator who could be useful to observe the focus group participants (non-verbal language) and to help the moderator in identifying not very talkative participants and in keeping time.

As focus group have to be transcribed afterwards. It is also useful to engage the services of an audio **typist**.

2.2.3.9 Running of data collection

For general principles see part 2, 2.2.1.4 "How to run the data collection?".

In the case of focus groups, once the group of respondents is gathered for the discussion, the moderator should give a brief introduction to set everybody at ease[n]. More concretely, the moderator should:

- Explain the purpose of the discussion, how the information collected will be used and reported.
- Introduce note-taker and observer who will remain in the room during the discussion.
- Explain that the discussion is for scientific purposes and that information will solely be used with the context of the research.
- Ensure participants that the rules of confidentiality apply to everyone in the room, including the note-takers, observers.
- Explain how names will be used (real names or pseudonyms).
- Explain the group rules (speak one at a time, avoid interrupting or monopolizing, etc.).
- If the discussion is to be tape-or video-recorded, obtain permission from the respondents first, and explain how the tapes will be used, stored and eventually destroyed. – Tip to increase the quality of the recording: use 2 recorders, preferably stereo recording, one at each side of the table: it is useful to understand everybody and prevent the loss of data in case of disfunctioning of the recorder.

The Moderator will then begin the focus group interview by asking an 'icebreaker question' to facilitate the discussion in the group. Afterwards, he/she will come to the focus of the discussion.

Immediately after the focus group a **debriefing** has to be foreseen with the moderators/facilitators. The debriefing part is an essential step for the analysis. The debriefing exercise is best supported by a template of dimensions, upon which the moderator/facilitator team needs to comment (example in Appendix 9).

The facilitators should review the notes taken during the focus group and have a first assessment of clarity and understanding.

They should discuss, compare and record observations or impressions about the group not readily apparent from the notes.

Discuss and record any insights or ideas emerging during the interviews while they are still fresh in the mind.

2.2.3.10 Practical aspects

Preparations for the interview

See also part 2, 2.2.1.4 "How to run the data collection?**".**

Location & timing

- The location where the focus groups will be held should be carefully selected.
- Accessibility and transport issues (and mobility needs of participants) should be considered.
- Avoid noisy areas where it will be difficult for participants and the moderator to hear each other.
- The setting should be comfortable, non-threatening for the respondents. Refreshments should be provided.
- The focus group table can be organized before hand and this allows the researcher to place name tags in the way he wants.
- Seating should be arranged to encourage participation and interaction, preferably in a circle, with or without name tags. It can be discussed whether tables are needed. Moderators/facilitators (and note takers) should be integrated as much as possible within the discussion setting.
- The timing of the focus group interview need to be acceptable for all potential respondents in order to avoid selective "non-response" as much as possible (take into account the socio-demographic profiles of the targeted participants such as working times, daily activities, family life, etc.).

[n] We propose a example of a 'standard introductive text' in appendix.

Duration

The length of the focus group should be between 1 and 3 hours.

Allow sufficient time at the beginning to welcome participants, give them an introduction and let them introduce themselves. This part should not take excessive time (about 10 minutes).

Material

Data are collected through different sources: audio or video-taping can be considered. When focus group interviews are recorded, the equipment should be of good quality and easy to use (check batteries and microphone). For larger groups, it may be necessary to use two tape recorders or multi-channel equipment, strategically placed to maximize the probability of recording contributions from all participants.

"Field notes" are an essential part during data collection. They capture all of the essential "non-verbal" information during the focus group interview.

Information has to be collected in an unbiased manner (avoid to filter out information as pre-interpreting it as unimportant, especially in the first focus groups).

The context of statements made during focus groups should be documented (important for giving meaning to the statements in the phase of analysis).

Try to capture nonverbal behavior of group participants (nonverbal reactions of other participants after a participant statement may indicate consensus or disagreement).

2.2.3.11 Analysis and reporting of findings

For general issues on **analysis**, see part 2, 2.2.1.6 "How to analyse the data?".

In the particular case of focus groups, separate analyses have to be performed on data gathered "within-focus group" and continuously compared "between focus group". This is also an iterative process.

It is important that statements be understood in the context which they were made. Nonverbal communication observed during the interview can also be very informative.

For **reporting**, see part 2, 2.2.1.8 "How to report qualitative research findings".

Note that findings are reported by focus group as unit of analysis and not by person.

2.2.3.12 Quality criteria

See section part 2, 2.2.1.7 "How to validate qualitative research findings?"

Vermeire et al propose a checklist specific to critical appraise the quality of focus groups in health care research articles in primary healthcare[77].

2.2.3.13 Examples of KCE reports using the method

- Evaluation of the Belgian reference reimbursement system[78].
- Evidence-based content of the written information provided by the pharmaceutical industry to the general practitioner[79].
- Quality development in general practice in Belgium: status quo or quo vadis ?[80].
- Mental health care reforms: evaluation research of 'therapeutic projects'[81].
- Emergency psychiatric care for children and adolescents[82].

2.3 Data collection by observation

"The purpose of participant observation is partly to confirm what you already know (or think you know) but is mostly to discover unanticipated truths. It is an exercise of discovery"

(Mack, 2005[54], p. 23)

In this chapter we explicitly try to focus on direct observation, instead of participant observation. However, two remarks are in place. One, there is nearly always some participation involved in observing, unless the researcher is covered behind for example a one-way mirror. In all other cases the researcher is present in a setting, hence inevitably becomes part of the setting. Second, in the KCE context participant observation is unlikely to be applied because it is very time consuming, intensive and hence is not compatible with KCE working procedures. However, that does not mean that observational techniques are irrelevant to a KCE researcher. They can be very useful, for example in case of site visits. In the following chapter although participating is not the main goal, it often enters the logics and quotes used.

2.3.1 What is (naturalistic) observation?

Observing is more than looking around, it is actively registering information along a number of dimensions, namely places (physical place or setting), persons (the actors involved) and activities (a series of acts)[83]. Observing means having attention for (1) the detail of the observation, (2) visual as well as auditory information, (3) the time dimension, (4) the interaction between people, and (5) making links with mental categories[10].

Observing includes roughly three steps:

1. A descriptive step; the researcher enters the research setting and gets a general overview of the social setting.
2. A focused step; more focused observations are a step closer to the research question. The aim is to search for relationships or connections between several elements in his research question, for example X is a characteristic of Y, or X is the result of Y. More concrete, suppose a researcher wants to study the way emergency care is organized in Belgium, he would do some descriptive observations in the emergency department of hospitals to get an idea of the general structures and processes characteristic for emergency care. In a next step he turns to his research question which is about how cost-effectiveness of emergency care could be attained. Hence the focus of his observation will relate to all possible costs and which could be avoided.
3. A selective step[83]; In this last phase, after the researcher may have analysed his data (field notes), he may have identified a lack of information of one specific category of costs, e.g. cleaning and housekeeping costs, and may therefore decide to do extra observations in function of this specific aspect.

2.3.2 When to use observations?

- *To collect* data on naturally occurring behaviors in their usual contexts[54]. Observation also captures the whole social setting in which people function by recording the context in which they live[84].
- Unstructured observation illustrates the whole picture, captures context/process and informs about the influence of the physical environment[84].
- To check whether what people say they do is the same as what they actually do[84]. Both what people perceive that they do and what they actually do are however valid in their own right and just represent different perspectives on the data[84].
- Observation is also an ongoing dynamic activity that is more likely than interviews to provide evidence for processes, things that are continually moving and evolving[84].
- To study the working of organisations and peoples' roles and functioning within organisations[20].
- To uncover behaviours or routines of which the observed themselves are not aware of[20]. What the researcher considers an important finding may belong to the self-evident nature of daily life from the participants' point of view.
- To understand data collected through other methods (e.g. interviews) and also to design the right questions for those methods[54].

2.3.3 What are the strengths and weaknesses of observations?

2.3.3.1 Strengths

A number of strenghts have already been described under "When to use observations?". We could add that:

- Observation has the advantage of capturing data in more natural circumstances[84].
- The Hawthorne effect[o] is an obvious drawback but once the initial stages of entering the field are past most professionals are too busy to maintain behaviour that is radically different from normal[84].

2.3.3.2 Weaknesses

- It can be very difficult to get **access to the setting**. An observer is often experienced as a threat, especially if the setting is not asking for the research to take place. Observation (and especially participant observation) might lead to knowledge of informal procedures or rules, which people do not want to be uncovered. Also the researcher can be experienced or perceived as a barrier for the normal daily routine in the setting[10]. In direct observation, the researcher does not participate in the setting, hence is known as a stranger and gets only access to the public or formal layer of the social reality. He does not become an insider and will miss inside information because he is too distant from the actors he is observing[10]. "*Access, then, is not a straightforward process of speaking to the person in charge and obtaining the approval of the ethics committee. It usually involves considerable time and effort and a constant endeavour to strive for 'cultural acceptability' with the gatekeepers and participants in research sites*" (p. 310)[84].
- Once inside the setting there is the **problem of avoiding "going native"**: This means "*becoming so immersed in the group culture that the research agenda is lost or that it becomes extremely difficult or emotionally draining to exit the field and conclude the data collection*" (p. 183)[20].
- Observational data, are more than interview data, subject to interpretation by the researcher. Observers have a great degree of freedom and autonomy regarding what they choose to observe and how they filter the information[84].
- Observations are time-consuming and hard work at every possible hour of the day.
- An observer can get emotionally involved in what he observes, and by consequence lose his neutrality.
- It is impossible to write down everything that is important while observing (and participating). The researcher must rely on his memory and have the discipline to write down and expand the field notes soon and as completely as possible[54].

2.3.4 How to plan the research design?

Often observations are carried out at the beginning of the data collection phase, but the method can also be used later on during the research process to address questions suggested by data collected though other methods[54]. Before starting the observations, the researcher should try to find out as much as possible about the site where he will be observing.

At the KCE, site visits are common to allow the researchers to become familiar with the research topic and setting. This is often combined with interviews or less formalized talks to key persons on the site. After a number of site visits the scope of the research project is determined and precise research questions are formulated.

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[o] The Hawthorne effect is the process where human subjects of an experiment change their behavior, simply because they are being studied http://www.experiment-resources.com/hawthorne-effect.html.

2.3.5 Modalities of data collection

2.3.5.1 Participant versus direct observation

The role to adopt during observation and the extent to which participants are fully informed are somewhat intertwined[84]. Typically researchers refer to Gold's typology of research roles[85]:

- The complete observer, who maintains some distance, does not interact and whose role is concealed;
- The observer as participant, who undertakes intermittent observation alongside interviewing, but whose role is known;
- The participant as observer, who undertakes prolonged observation, is involved in all the central activities of the organization and whose role is known;
- The complete participant, who interacts within the social situation, but again whose role is concealed.

Mack et al.[54] describe observing as remaining an "outsider" and simply observing and documenting events or behaviors being studied, while participating is taking part in the activity while also documenting it. Pure observing, without participating is a situations that in fact seldom occurs, because once you are present, you are visible, you influence the activities around you, you participate in some degree. There are two reasons for this participation, or to better understand the local perspective, or in order not to call attention to yourself[54].

2.3.5.2 Structured versus unstructured observation

- Structured observations are associated with the positivist paradigm and aim at recording physical and verbal behavior by means of a list of predetermined behaviours[84].
- Unstructured observations are not 'unstructured' in the sense of unsystematic or messy, "instead, observers using unstructured methods usually enter 'the field' with no predetermined notions as to the discrete behaviours that they might observe. They may have some ideas as to what to observe, but these may change over time as they gather data and gain experience in the particular setting. Moreover, in unstructured observation the researcher may adopt a number of roles from complete participant to complete observer, whereas in structured observation the intention is always to 'stand apart' from that which is being observed" (p307)[84].

2.3.5.3 Overt versus covert observation

Covert observation corresponds to two roles in Gold's typology[85], i.e. complete observer and complete participant (see above). Most authors agree that covert observation is only legitimate in very specific circumstances and should be avoided. Mack et al.[54] formulate the following ethical guideline regarding observations: "*When conducting participant observation, you should be discreet enough about who you are and what you are doing that you do not disrupt normal activity, yet open enough that the people you observe and interact with do not feel that your presence compromises their privacy.*"(p. 16) As with all qualitative research methods, researchers must also protect the identities of the people they observe or with whom they interact, even if informally. "*Maintaining confidentiality means ensuring that particual individuals can never be linked to the data they provide*"[54].

2.3.6 Data collection tools

2.3.6.1 Checklists

Before you enter the setting and start observing, it might be a good idea to have some questions in mind. It may be helpful to carry a checklist in your pocket to help you remember what you are meant to observe[54].

2.3.6.2 Fieldnotes

"Fieldnotes are used by researchers to record observations and fragments of remembered speech. Although researchers may use other means of recording (such as video) and other form s of data (such as interview transcripts), fieldnotes remain one of the primary analytic materials used in ethnography." (p. 82) [35].

Depending on the research questions, the researcher is interested in other aspects of social reality. Mulhalls' schema[84] includes the following **types of field notes**, each covering an aspect of social reality:

- Structural and organizational features – what the actual buildings and environment look like and how they are used

- People – how they behave, interact, dress, move.
- The daily process of activities.
- Special events – in a hospital ward this might be the consultant's round or the multidisciplinary team meeting.
- Dialogue.
- An everyday diary of events as they occur chronologically – both in the field and before entering the field.
- A personal/reflective diary – this includes both my thoughts about going into the field and being there, and reflections on my own life experiences that might influence the way in which I filter what I observe.

It is particularly important to detail any contradictory or negative cases. Unusual things often reveal most about the setting or situation[20].

Documenting observations consists of the following steps[54,86]:

- Quick notes during the observation.
- Once the researcher left the setting, he expands his notes into fieldnotes. This means he reads them through and adds other things he can remember, but has not yet written down. Note taking in the setting is not self-evident and it is impossible to write down everything you see. Therefore good note taking should trigger the memory by means of key words, symbols, drawings, etc.
- After expansion, the researcher "translates" his shorthand into sentences.
- Together with the translation phase, a descriptive narrative can be composed. The researcher writes down a description of what happened and what he has learned about the setting. In this step the researcher should distinguish between describing what happened and interpreting.

The researcher should be well aware of the **difference between describing what he observes versus interpreting what he observed**. It should be avoided to report interpretations rather than an objective account of the observations[54]. For example, an interpretive description of a patient could be "he was in terrible pain". An objective description would be "he was screaming and his face turned pale while grimacing". "*To interpret is to impose your own judgment on what you see*" (Mack, 2005[54], p23). The danger is that interpretations can turn out to be wrong. Therefore the researcher should ask her/himself "what is my evidence for this claim?"[54]. One way of separating descriptions and interpretations is by separating them visually on paper or screen.

2.3.6.3 Draw a map of the setting or settings you observe.

Maps might support your memory and are a tool to reconstruct interactions and movements of people in a room.

2.3.6.4 Audio or video

Audio or video recordings of observations are generally not permissible unless all ethical requirements are fulfilled and informed consent has been obtained.

2.3.7 Sampling

As outlined in the general principles of the chapter on interviewing (part 2, 2.2.2), sampling in qualitative research is seldom statistically based. Also samples of settings or groups to observe are purposive.

Specifically for observation the sampling units are places, locations, and blocks of time, but usually not individuals. The aim is to select 'information-rich' cases, but in practice site selection is often a pragmatic decision based on existing networks and accessibility. Ideally however, sites are chosen because they typify some larger population of sites (such as clinics) or perhaps because they are exceptional in some way. Observation methods may be used across multiple sites and one could select the ones representing a range of typical settings[37].

2.3.8 Human resources necessary

Observations can be the work of one researcher, a pair of researcher, or a whole team. Which arrangement is most appropriate depends on the research questions and the features of the setting. Also members of a team can disperse to different locations individually, or in pairs or groups, in order to construct a more complete picture of the issues being studied.

One of the advantages of team work is that field notes can be compared and that team members can question each other about assertions being made. "*Taking another perspective on validity Graneheim et al. (2001) used multiple data collectors with different perspectives (insider or outsider) to observe the same situation. This may not accord with the idea that every researcher may produce a unique account of a situation that is valid in its own right. But with extensive mutual reflection, as undertaken by Graneheim and colleagues, these combined observations may have consensual validity. However, from a practical standpoint few projects are afforded the luxury of multiple data collectors*." (Mulhall, 2003[84], p. 309).

2.3.9 Practical aspects

- Try to be "invisible" as an observator. Adapt to the setting in which you will do the observations, in terms of dress code, the way of behaving, and what is expected from you by the other actors in the setting.
- Start with short observations to explore the field and to get yourself used to your role as observer.
- First you should get an idea of "the normal" way of life in a setting, before you are able to identify unusual or abnormal situations.
- Circumstances may make it difficult or unacceptable to make fieldnotes, hence the researcher has to write down his observations afterwards. This can lead to a memory bias.
- Field notes should not contain interpretations, but merely descriptions.
- There is also the practical problem of how, especially in large and busy social settings, like an emergency department, to inform and obtain consent from everyone who might 'enter' the field of observation[84].
- Note that once inside the setting it might be **difficult to get out again**: Ending the fieldwork should not happen abruptly. The researcher must take time to "ease out". In the 'easing out' phase the researcher is more and more absent from the setting. This means more time to analyse the data. When present in the setting, the researcher can confront his preliminary analysis with new observations in the setting[10]. In the literature the advice is to keep in contact with the setting until the final report is written[87].

2.3.10 Analysis

Field notes contain a lot of detail and are highly descriptive. In order to find explanations or answers to the research questions, the researcher should develop categories and test them against hypotheses, and refine them. This is an iterative process that starts during the data collection phase.

2.3.11 Reporting of findings

As with other qualitative research methods it is important that evidence from the data is presented to support the conclusions of the researcher, by means of examples or quotations. The main principles have already been mentioned in (see part 2, 2.2.1.8 "How to report qualitative research findings").

2.3.12 Quality criteria

The quality of observational studies depends largely on the quality of the descriptions of data collection and analysis provided by the researcher. Details about how the research was conducted are crucial and should be well documented. For example, how much time was spent in the field, how typical were the events recorded, description of the attempts to verify the observations made, etc.
The general criteria to assess the quality of qualitative research are described in part 2, section 1.2.1 and also apply to observational methods.

2.3.13 Examples of KCE reports using the method

So far no observational studies have been carried out at the KCE.

2.4 The Delphi method

Consensus reaching methods generally used in health care are Delphi panel, nominal group or consensus conference. They are useful to organize "*qualitative judgments and, which is concerned to understand the meanings that people use when making decisions about health care.*" (Black, 2006[88], page 132). They are not as such qualitative methods because they may use quantitative data collection tools (questionnaires, scales), and quantitative element in the analysis (statistics).

All the consensus methods cited here are characterized by the provision of information prior to the discussion, privacy (participants express their opinion in private), opportunity for participants to change their view and explicit and transparent derivation of the group decision, based on (statistical) analysis[88].

2.4.1 Description of the method

The **Delphi method** (named so because of the Delphi Oracle) was initiated by the RAND corporation, a nonprofit institution that helps improve policy and decision making through research and analysis[p]. The original definition given in the 50[s] was that it "*entails a group of experts who anonymously reply to questionnaires and subsequently receive feedback in the form of a statistical representation of the "group response*," after which the process repeats itself. The goal is to reduce the range of responses and arrive at something closer to expert consensus."[89] Today, the method has evolved and Delphi surveys could aim at different goals or have several designs[q]. It could be define more as *"a method for structuring a group communication process"* and not as a method to produce consensus[90]. The method could also be defined as a systematic collection and aggregation tool of informed judgment from a group of experts on specific questions and issues" (Hasson, 2011[91], p. 1696).

Delphi surveys are used in several domains (politics, psychology, agriculture, etc.) and could vary in different ways. Several types of Delphi often used in health research (non exhaustive) are presented in Table 10.

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p http://www.rand.org

q See the special issue 78 of the review 'Technological Forecasting & Social change" (2011) available at http://www.journals.elsevier.com/technological-forecasting-and-social-change/.

Table 10 – Types of Delphi designs

Design Type	Aim	Target panellists	Administration	Number of rounds	Round 1 design
Classical	To elicit opinion and gain consensus	Experts selected based on aims of research	Traditionally postal	Employs three or more rounds[r]	Open qualitative first round, to allow panelists to record responses
Modified	Aim varies according to project design, from predicting future events to achieving consensus	Experts selected based on aims of research	Varies, postal, online, etc.	May employ fewer than 3 rounds	Panelists provided with pre-selected items, drawn from various sources, within which they are asked to consider their responses
Decision	To structure decision-making and create the future in reality rather than predicting it	Decision makers, selected according to hierarchical position and level of expertise	Varies	Varies	Can adopt similar process to classical Delphi
Policy	To generate opposing views on policy and potential resolutions	Policy makers selected to obtain divergent opinions	Can adopt a number of formats including bringing participants together in a group meeting	Varies: It theoretically needs 5 rounds but could be done in 3 or 4 rounds	Can adopt similar process to classical Delphi or 1- preformulating the obvious issues by the research team; 2- seeding the list with an initial range of options but allowing for the respondents to add to the lists[92,93]
Real time/consensus conference	To elicit opinion and gain consensus on real time	Experts selected based on aims of research	Use of computer technology that panelists use in the same room to achieve consensus in real time rather than post or via Internet[94]	Varies	Can adopt similar process

Adapted from Hasson, 2011[91], p. 1697 and Keeney, 2011[95]

[r] Note that the number of rounds should ideally be based on the saturation of the responses and is difficult to fix in advance

2.4.2 Specific questions suitable for the method

The following questions could be answered by using a consensus reaching method such as the Delphi panel:

- To help the decision making process.
- When personal contact is not necessary[96].
- To choose the most appropriate method or tool (e.g. data collection technique, scales, questionnaires, etc.).
- To identify the best choice of treatment (when no other evidence is available or to complete it).
- To identify the form of a programme.
- To clarify professional roles[97].
- To develop clinical guidelines[98].

2.4.3 Strengths and weaknesses of the method

2.4.3.1 Strengths

- Lower production cost[99].
- Relatively rapid results[99].
- Participant can express their opinion anonymously[96], without external (perceived) pressure while the process allows to catch the view of the entire group[96].
- Avoid domination by individuals or professional interests[97];

2.4.3.2 Weaknesses

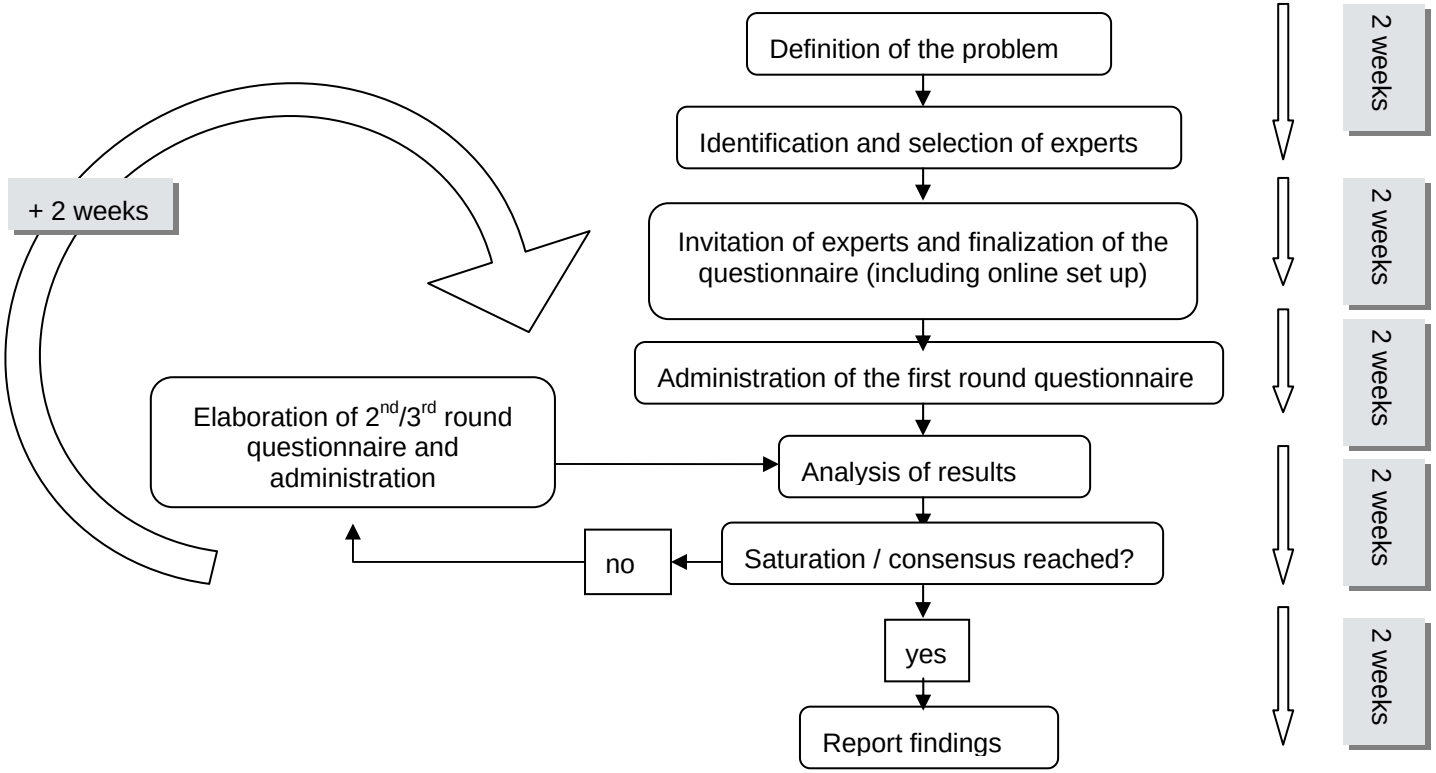
- Success depends on the qualities of the participants.
- Reliability increases with the number of participants (and the number of rounds). In addition, it is difficult to keep everybody in successive rounds[96].
- Coordination is difficult[96].
- The existence of a consensus does not necessary mean that it reflects an appropriate or “correct” answer[97].

2.4.4 How to plan the research design

A Delphi survey takes several weeks, even if the number of participants is small.

It has to be planned in the beginning of the project or, if the necessity to conduct such a study appears late in the course of the project, it is important to realize that the whole process takes several weeks, depending on the number of rounds needed. The next figure illustrates the whole process and the time needed.

Figure 5 – The Delphi process



Adapted from Slocum et al.[93]

2.4.5 Modalities of data collection

Delphi could be administrated 'paper-and-pencil' by mail or e-mail.

Online Delphi's are more and more carried out. Software is available to support the data collection and the analysis (Delphi_Survey_Web (DSW)[100], Mesydel©[101])

The number of rounds is not necessarily defined a priori (often because of budgetary, time or human resources limitations): data collection must stop when the saturation or the consensus is reached.

2.4.6 Data collection tools

The Delphi method uses iterative (e-)mailed questionnaires in successive rounds. Because there is no interaction between the respondent and the researcher, the formulation of the questions has to be clear, and definitions should be given where necessary.

The questionnaire of the first round encompasses open-ended questions, to identify items to include in the second round.

Next rounds could be exclusively qualitative or composed of closed questions with scales (from totally agree to totally disagree, i.e. from 1 to 9), or combining both qualitative and quantitative questions. They present a synthesis of the results issued from the previous round.

In the case of closed questions, agreement is usually summarized by using the median and consensus assessed by presenting interquartile ranges for continuous numerical scales[97]. Graphical presentations of the results are welcomed.

In KCE reports the questionnaires used in each round are presented in appendices.

2.4.7 Sampling

Participants have to be carefully chosen because of their expertise, experience or knowledge in the field of the research question. In addition, the variety of positions in the field or opinions regarding the subject, should be covered. In that way, lay people could be added to increase the variety of viewpoints[102].

They could be identified through publically available bibliographic information[102]. Snowballing recruitment could be useful to secure easy agreement to panelist invitation and strengthen panelist retention[102].

There is no practical limit to the number of participants in a Delphi survey[89].

2.4.8 Human resources necessary

The administrator of the survey develops the questionnaires, identifies, mobilizes and recruits participants, analyses findings and reports them. He/she is responsible for keeping a low attrition rate and insure the coherence between the different steps of the method.

Administrative support could be needed to (e-)mail the questionnaires and manage reminders and answers.

2.4.9 Practical aspects

- It is important to clearly explain the goal of the questionnaire and the way it will be analysed. The redaction of the invitation/introduction letter is thus crucial. "Stressing the practical policy application of the Delphi yield to experts panelists to aid their retention" (Rowe, 2011[102], p. 1489).
- The research team should have managers skills to follow up the returned questionnaires and mailing.
- The utilization of online tools could be very useful as well for the research team (rapid results) as for the participants.
- While anonymity in the process of the Delphi is required, "using social rewards for recognition in participation, such as subsequently publishing panel membership listings" (Rowe, 2001[102], p. 1489) could improve panelists recruitment and retention.

2.4.10 Analysis

Each step of the Delphi requires a specific analysis.

In a classical Delphi, open-ended questions from round 1 should be content analysed 'in order to group statements generated by the experts panel into similar areas'[95].

Round that uses closed questions should be statistically analysed. Summary statistics are used to decide whether or not consensus is reached. The level of the consensus has to be defined in advance (i.e. 70% of agreement).

There is no agreement on the threshold indicating a consensus, nor how to choose this threshold[95]. Each researcher has to reflect on it, case by case.

The proposals that have reached consensus should be eliminated from the next round.

2.4.11 Reporting of findings

Intermediary results are reported directly in the successive questionnaires.

All the consensus and dissensus items are listed and discussed at the end of the process.

2.4.12 Quality criteria

It seems that no consensus exists with regards to the standard of methodological rigor to apply. And that *"no definitive evidence exists which demonstrates the reliability or validity of the technique"* (Keeney, 2011[95], p. 104). This is partly due to the variety of the Delphi surveys and the constant evolutions in this field[91].

We have not identified any checklists to assess the quality of a Delphi survey.

However, the following aspects of the survey could be assessed (adapted from Jillson[103] and Hasson[91]):

- Applicability of the method to the specific research problem
- The quality of the composition of the Delphi panel. Participants have to be carefully chosen in function of their expertise and position in the group.
- Design and administration of the questionnaire
- Feedback

A Delphi survey should be reviewed in terms of reliability, validity and trustworthiness to judge its worth[91].

2.4.13 Examples of KCE reports using the method

- Impact of academic detailing on primary care physicians[104]
- Burnout among general practitioners: prevention and management[72]
- Methods for including public preference values in reimbursement decision making processes for health interventions. Exploration of the feasibility of different models in Belgium (ongoing project, publication foreseen end 2012)

2.4.14 Basis references

For practical tips see the report of the King Baudouin Foundation available in French, Dutch and English[93].

APPENDICES

APPENDIX 1. INTERVIEW GUIDES FOR THE FOCUS GROUPS WITH KCE RESEARCHERS AND MANAGERS

Appendix 1.1. Interview guide focus group with managers

	Question	Relance	Timing
Introduction	Suivre slide show		10
Question 1	Quelle a été votre première réaction quand vous avez reçu l'invitation à participer à ce « mini focus group » ?		5
Question 2	Quelle est votre définition de ce qu'est la recherche qualitative ?		15
Question 3	Quelle expérience personnelle éventuelle avez-vous des méthodes de recherche qualitatives ?		15
Question 4	Comment décririez-vous l'évolution de l'utilisation des méthodes qualitatives au KCE, depuis la naissance du centre à ce jour ?	Quels éléments clés, s'il en est, identifiez-vous pour expliquer cette évolution ? /Comment expliquez-vous cette ouverture progressive ? D'après vous , en théorie, quel type de plus-value ces méthodes devraient-elles apporter à un rapport KCE ?	15
Question 5	Concrètement, il y a déjà eu plusieurs expériences de recours à une méthodologie qualitative au KCE. Que pouvez-vous nous dire par rapport à ces expériences ?	Dans la conduite de projets Au moment de la validation Par rapport à l'impact des rapports	20
Question 6	Quelle est votre opinion sur l'intérêt de la littérature qualitative dans les revues de littérature du KCE ?		10

Question 7	Comment voyez-vous l'articulation entre « méthodes de recherche qualitatives » et « stakeholders involvement » ?	Peut-on envisager que certaines méthodes qualitatives ne soient pas du SI ? Peut-on imaginer du SI sans méthode qualitative ? Peut-on imaginer du SI au moyen d'autres méthodes systématiques qui ne sont pas des méthodes qualitatives? Peut-on imaginer du SI sans méthode tout court ?	20
Question 8	Avez-vous des choses à ajouter par rapport à ce qui a été dit au cours de ces 2 heures ?		8
Clôture	Nous vous remercions pour votre participation. A l'issue des 3 focus groups, nous rédigerons un draft que nous vous proposerons de discuter ensemble.		2

Appendix 1.2. Interview guide focus group with novices

	Question	Relance	Timing
Introduction	Suivre slide show		10
Question 1	Quand vous entendez parler de méthodes qualitatives, qu'est-ce que cela vous évoque ?		20
Question 2	D'après vous, quelles sont les différences entre les approches qualitatives et quantitatives ?		10
Notre definition			2
Question 3	D'après vous, quel peut être l'apport des méthodes de recherche qualitative dans un rapport de recherche ?		15
Question 4	D'après vous, quels sont les aspects négatifs des méthodes de recherche qualitatives ?	Critiques à émettre à leurs encontre Difficultés d'implémentation Coût / temps…	15

Question 5	Quels sont vos besoins en méthodologie qualitative en tant qu'experts du KCE ?		10
Question 6	Comment voyez-vous l'articulation entre « méthodes de recherche qualitatives » et « stakeholders involvement » (SI) ?	Peut-on envisager que certaines méthodes qualitatives ne soient pas du SI ? Peut-on imaginer du SI sans méthode qualitative ? Peut-on imaginer du SI au moyen d'autres méthodes systématiques qui ne sont pas des méthodes qualitatives? Peut-on imaginer du SI sans méthode tout court ?	15
Question 7	Si nous organisons un workshop sur les méthodologies qualitatives, quelles seraient vos attentes spécifiques ?		10
Question 8	Comment voyez- vous votre utilisation des méthodes qualitatives dans un avenir à court ou moyen terme (d'ici fin 2012) ?		20
Question 9	Avez-vous des choses à ajouter par rapport à ce qui a été dit au cours de cette discussion ?		15
Clôture	Nous vous remercions pour votre participation. Comme je vous l'ai dit en début de session, les résultats seront traités afin d'être répercutés dans le rapport final prévu pour le CA de juin.		2

Appendix 1.3. Interview guide focus group with researchers

	Question	Relance	Timing
Introduction	Suivre slide show		10
Question 1	Quand vous entendez parler de méthodes qualitatives, qu'est ce que cela vous évoque ?		10
Question 2	Quelle est votre définition de ce qu'est la recherche qualitative ?		10
Notre definition			2
Question 3	Comment décririez –vous l'évolution de l'utilisation des méthodes qualitatives au KCE, depuis la naissance du centre à ce jour ?	Quels éléments clés, s'il en est, identifiez-vous pour expliquer cette évolution ? Comment expliquez-vous cette ouverture progressive ? D'après vous , en théorie, quel type de plus-value ces méthodes devraient-elles apporter à un rapport KCE?	10
Question 4	Quelle expérience personnelle éventuelle avez-vous des méthodes de recherche qualitatives ?		20
Question 5	Quelles difficultés avez-vous rencontré dans l'utilisation des méthodologies qualitatives, quelles soient personnelles ou dans le suivi des équipes ?	Au niveau du protocole (dont triangulation et mix-methods) Au niveau de la collecte Au niveau de l'analyse Au niveau du reporting	20
Question 6	Quelle plus value éventuelles vous ont apporté le recours à des méthodologies qualitatives (pour vous ou pour vos projets) ?		15
Question 7	D'après vous, quels sont les critères d'une 'bonne' recherche qualitative ?		15
Question 8	Ces critères s'appliquent-ils à toutes les méthodologies qualitatives ? quelles spécificités éventuelles voyez-vous pour certaines méthodologies ?		10

	Question	Relance	Timing
Question 9	Comment voyez-vous l'articulation entre « méthodes de recherche qualitatives » et « stakeholders involvement » (SI) ?	Peut-on envisager que certaines méthodes qualitatives ne soient pas du SI ? Peut-on imaginer du SI sans méthode qualitative ? Peut-on imaginer du SI au moyen d'autres méthodes systématiques qui ne sont pas des méthodes qualitatives? Peut-on imaginer du SI sans méthode tout court ?	15
Question 10	Si nous organisons un workshop sur les méthodologies qualitatives, quelles seraient vos attentes spécifiques ?		10
Question 11	Avez-vous des choses à ajouter par rapport à ce qui a été dit au cours de cette discussion ?		15
Clôture	Nous vous remercions pour votre participation. Comme je vous l'ai dit en début de session, les résultats seront traités afin d'être répercutés dans le rapport final prévu pour le CA de juin.		2

APPENDIX 2. NODE TREE RESULTING FROM THE ANALYSIS OF FOCUS GROUP DATA

Two themes emerged from the data resulting from focus group meetings with (1) the KCE directors, (2) the KCE researchers with experience in QRM, and (3) the KCE inexperienced researchers:

- The knowledge about and attitudes concerning QRMs and their use at the KCE
- The expectations and experiences of KCE researchers regarding the use of QRMs at the KCE

For each of these themes a node tree was constructed illustrating the subthemes occurring within each of the themes mentioned above.

Figure 6 – Node tree of researchers' knowledge and attitudes concerning QRMs

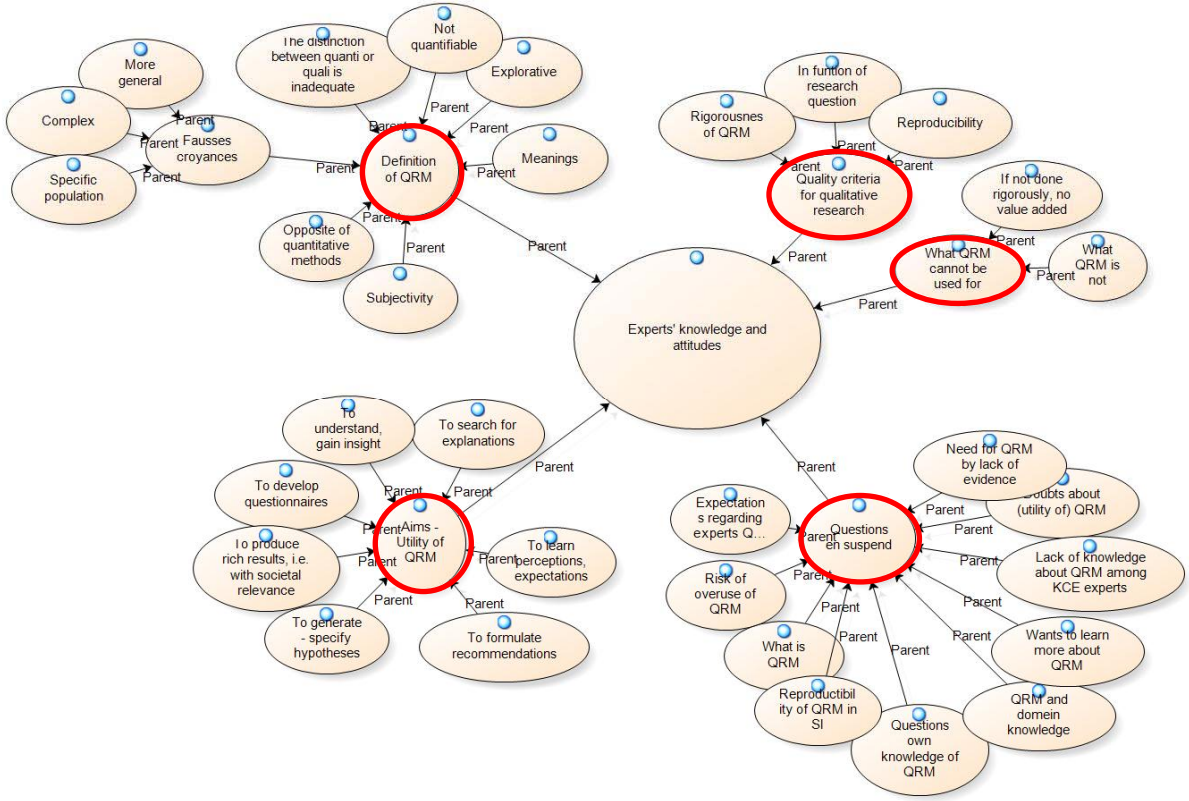
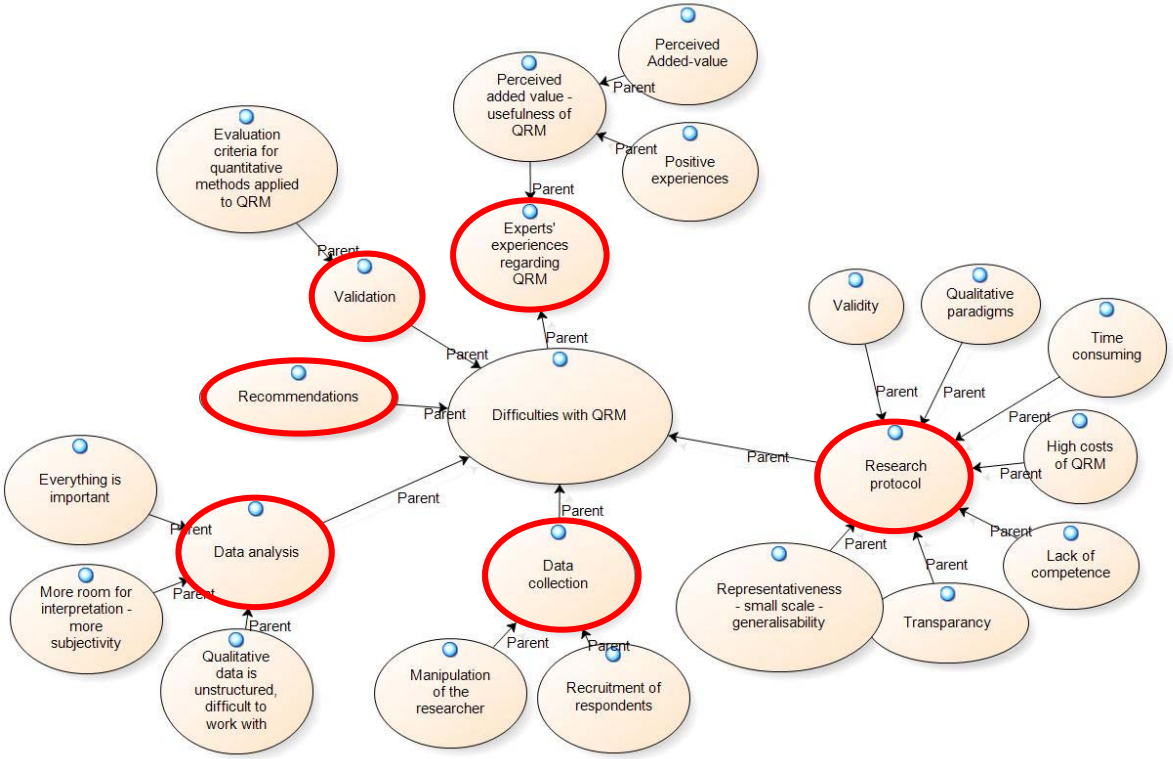


Figure 7 – Node tree of researchers' experiences regarding QRMs



APPENDIX 3. MISSED OPPORTUNITIES

Domain	Research question	Employed method	Missed opportunity
GCP	What are the advantages and disadvantages of breast cancer screening?	Literature review	In addition to the literature review, women and/or health care providers could have been interviewed about what they define as pro and cons for screening.
GCP	Consequences of chronic low back pain for active population	Literature review	In addition to the literature review, patients could have been interviewed about their experiences and how chronic low back pain impacts their daily life.
GCP	Evaluation of the available strategies to screen for osteoporosis and treatment.	Literature review	In addition to the literature review, an expert meeting or Delphi panel could have been a way to evaluate the available strategies to screen for osteoporosis in a Belgian context.
HSR	Does the evidence show that any particular intervention or combination of interventions is effective in treatment, management or rehabilitation of adults and children with a diagnosis of CFS?	Literature review	To address patients issues, in addition to clinical evidence, QRM would have been of a considerable surplus value: Belgian patients would have been able to tell about experiences with the Belgian health care system.
HTA	To document the effectiveness of cervical cancer screening and in particular the role of Human Papillomavirus (HPV) testing.	Literature review	Patients issues are addressed through a literature search, but here women could have been interviewed to learn about their experiences in a Belgian context.
HTA	What essential patient/caregiver and organisational aspects are to be considered in the context of pharmaceutical and non-pharmaceutical interventions for Alzheimer's Disease?	Literature review	Patient and caregiver issues, together with organisational aspects could have been addressed by means of individual or focus group interviews. This would have allowed an in-depth understanding of these issues within a Belgian health care context.
HTA	To describe patient-related issues in different dialysis modalities	Questionnaire to patient organisations and literature review	Open or semi-structured methods could have been a way to address the experiences with different dialysis modalities both from a patient and caregiver perspective. Also informal caregivers could have contributed (Often they assist in the daily organisation, e.g. transport to the hospital).
	To draw conclusions for the organization and financing of dialysis in Belgium.		
HTA	How is the PSA test in prostate cancer screening currently used in Belgium?	Secondary data analysis + Primary data collection	Focus groups or in-depth interviews, even the Delphi technique could have been used to discuss the current use both with health

Domain	Research question	Employed method	Missed opportunity
		by means of panel discussion and structured questionnaire	care professionals as with patients. This would have been especially valuable to identify motivations and unmet needs.
	What ethical issues are involved in prostate cancer screening?	Literature review	
HTA	The use of impantable cardioverter defibrillator is considered from a patient and a public health care perspective.	literature review and telephone interviews with patient organisations	Interviews with patients could have learned about how this device impacts daily living and one identity.
HSR	To explore the expectations for the future and identify the future needs related to genetic testing; and confront these with the present situation.	International comparison	Individual or focus group interviews with health care professionals could have been useful to discuss future needs and identify the strengths and weaknesses of the current situation.

APPENDIX 4. CHECKLIST FOR THE PREPARATION OF FOCUS GROUP INTERVIEWS

Research questions of the focus groups	
Population	
Segmentation of the participants	Criteria: FG1: FG2: FG3: FG4: …
Recruiting mode (comfort, snowballing, …)	decision
Type of interview (directed, half-directed)	decision
Interview guideline	- principal question - specific questions - time per question
Test of the guideline	
Material	Tape recorder/ numeric recorder Batteries (tape)
Organization of the meetings	Decide where Decide when Contact people (presentation of the studies, time needed, practical information, …

APPENDIX 5. OTHER CHECKLISTS AND QUALITY CRITERIA FOR QUALITATIVE RESEARCH

In what follows we will elaborate on two other checklists enabling qualitative researchers to guard the quality of their work.

Henwood and Pidgeon[105] identified seven attributes which characterise good qualitative research. Their schema, which links criteria with methods of achieving sound research, offers a helpful guide for novice researchers. They argue for:

- **The importance of fit** - The themes or analytical categories offered by the researcher should fit the data. The researcher demonstrates this by writing clear, explicit accounts of how these categories were evolved.
- **Integration of theory** - The researcher needs to discuss the relationship between units of analysis and the degree to which they can be integrated or generalised (for instance, exploring how themes might be combined moving towards a theory).
- **Reflexivity** – The role of the researcher needs to be acknowledged and accounted for in the documentation of the research.
- **Documentation** – The researcher needs to provide an audit trail: a comprehensive account of what was done and why.
- **Theoretical sampling and negative case analysis** – The researcher needs to continuously develop and modify any emerging theory, exploring cases that do not fit as well as those which might generate new knowledge.
- **Sensitivity to negotiated realities** – While participant validation may be necessary, the researcher needs to demonstrate awareness of the research context, power differentials and participant reactions to the research. It is particularly important to explain any differences between the researcher's interpretations and those of the participant(s).
- **Transferability** - The researcher should suggest how the research may have applicability beyond the particular research context.

Malterud[106] provides the following checklist:

- Aim
  - Is the research question a relevant issue?
  - Is the aim sufficiently focused, and stated clearly?
- Reflexivity
  - Are the researcher's motives, background, perspectives, and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?
- Method and design
  - Are qualitative research methods suitable for exploration of the research question?
  - Has the best method been chosen with respect to the research question?
- Data collection and sampling
  - Is the strategy for data collection clearly stated (usually purposive or theoretical, usually not random or representative)?
  - Are the reasons for this choice stated?
  - Has the best approach been chosen, in view of the research question?
  - Are the consequences of the chosen strategy discussed and compared with other options?
  - Are the characteristics of the sample presented in enough depth to understand the study site and context?
- Theoretical Framework
  - Are the perspectives and ideas used for data interpretation presented?
  - Is the framework adequate, in view of the aim of the study?
  - Does the author account for the role given to the theoretical framework during analysis?

- Analysis
  - Are the principles and procedures for data organization and analysis fully described, allowing the reader to understand what happened to the raw material to arrive at the results?
  - Were the various categories identified from theory or preconceptions in advance, or were they developed from the data?
  - Which principles were followed to organize the presentation of findings?
  - Are strategies used to validate results presented, such as cross-checks for rivalling explanations, member checks, or triangulation? If such strategies are not described in this section, they should appear as validity discussion later in the report.
- Findings
  - Are the findings relevant with respect to the aim of the study?
  - Do they provide new insight?
  - Is the presentation of the findings well organized and best suited to ensure that findings are drawn from systematic analysis of material, rather than from preconceptions?
  - Are quotes used adequately to support and enrich the researcher's synopsis of the patterns identified by systematic analysis?
- Discussion
  - Are questions about internal validity (what the study is actually about), external validity (to what other settings the findings or notions can be applied), and reflexivity (the effects of the researcher on processes, interpretations, findings, and conclusions) addressed?
  - Has the design been scrutinized?
  - Are the shortcomings accounted for and discussed, without denying the responsibility for choices taken?
  - Have the findings been compared with appropriate theoretical and empirical references?
  - Are a few clear consequences of the study proposed?
- Presentation
  - Is the report easy to understand and clearly contextualized?
  - Is it possible to distinguish between the voices of the informants and those of the researcher?
- References
  - Are important and specific sources in the field covered, and have they been appropriately presented and applied in the text?

APPENDIX 6. AN EXAMPLE OF A TOPIC LIST

The example presented below is fictitious. It could have been used in the KCE research project on refractive eye surgery (in progress), but instead a questionnaire was used.

- Discovery of eye problems
  - When?
  - How?
  - Which solution?
  - Reaction?
- Satisfaction with solution. Change to new solution, which one?
- Encounter with eye surgery
  - When?
  - How?
- Consideration of the eye surgery
  - Motivations?
  - How far in the process
  - Final decision/decision so far
- Planning of the eye surgery
- Experience of the eye surgery and after care
  - Emotions – fears
  - Practicalities
  - Informed consent
- Evaluation of the eye surgery
  - Quality of sight
  - Pain
  - Adverse effects
- Reimbursement of glasses, contact lenses, refractive eye surgery

APPENDIX 7. AN EXAMPLE OF A QUESTIONNAIRE

Questionnaire used in the KCE research project on citizen and patient participation in reimbursement decision-making (to be published in 2013).

PART 1 – Prior experience and purpose

- Has citizen-patient participation with regard to reimbursement decisions already been discussed in one or several groups?
- At what occasion? When was that? Why was this? Which decision / organ was involved? What type of citizen-patient was involved?
- What were the arguments pro and/or con?
- What was the motivation/background for/of these arguments? Which targets were researched?
- What type of participation was considered? and what type was not considered ? (who, method, decision, …)
- What were or are the conclusions regarding citizen-patient participation?
- Is participation important for the future of our healthcare system or no?
- If no why?
- If yes why? Is it feasible now? What is the high-level goal that could be achieved now and in the future? What are the main obstacles?
- What do you want to attain by including public preferences in health care decision making?

PART 2 – HOW TO INVOLVE

Explanation by interviewer of levels of participation: inform – consult – debate – co-decision – decision

- What level(s) of participation would be most desirable and why?
- What would influence this choice: the subject/type of decision? The moment in the decision-making process?
- For each of these desired levels of intensity, what would be advantages / disadvantages?
- From your knowledge of the different stakeholders, what is feasible now? What is feasible in the Belgian context?
- How should such participation be organised?
- Who could be involved :
- Citizen? Taxpayer? Consumer? Patient? Expert?
- From your experience, what's the opinion of the stakeholders about the citizen-patient to involve or not to involve ?
- Who would represent the citizen-patient ?
- What would be your ideal scenario to involve the citizen-patient in reimbursement decisions.

PART 3 – EXAMPLES OF PARTICIPATION

- From your experience, can you give examples of participation linked to reimbursement decisions that you know about of have witnessed? If none, is there an example you have been thinking of yourself?
- What was positive or negative about these examples?

  [Probe for more than one example. If they are giving foreign examples, we ask them how this could work in Belgium. What would be the same, what would be different.]

  Systematic probing questions for all examples the respondent gives:
  - what would be better compared to a situation without participation
  - what would be negative ?
  - how would it work / be organized
  - who would be involved (who would represent the citizen-patient)
  - what barriers do you see

PART 4 – WRAPPING UP

Based on the choice made, probe again with regard to:

- Type of motivation for participation: democracy, equity, efficiency, …
- Which role do citizen-patient have to take within the decision making process? The user of health services perspective (more particular) or the public policy perspective (more diffuse).

Understand the priorities :

- what would be the most interesting to achieve at mid term? at long term?
- what would be the easiest to get going: the way of lesser resistance?

Closing question when thanking:

- Anything else you would like to say or stress?

APPENDIX 8. AN EXAMPLE OF AN INTRODUCTORY TEXT

Bonjour,

Je me présente, je m'appelle [Prénom Nom], je travaille pour [institution] en tant que [décrire sa fonction en essayant de ne pas se positionner comme 'supérieur' au(x) répondant(s)], C'est moi qui distribuerai la parole ce soir et modérerai la discussion.

Comme vous le savez, nous réalisons en ce moment un projet relatif au [sujet de l'étude].

Dans ce cadre, nous souhaiterions connaitre les opinion, expériences, sentiments de [description de la population d'étude] quant à [description du sujet de l'étude].

Ce projet est financé/demandé par [bailleur de fonds] avec pour objectif de [objectif de l'étude].

Nous vous avons contacté parce que vous [reprendre les caractéristiques du segment de l'échantillon attendu]. Vous avez été identifié(s) via [source de recrutement].

Notre discussion durera approximativement [fourchette de durée de l'interview/focus group].

Le contenu des discussions et les propos échangées resteront confidentiels. Autrement dit, si certaines phrases seront reprises dans notre rapport final, aucune citation ne reprendra le nom de la personne qui l'a formulée.

(Pour les focus groups) Avant de commencer, je voudrais également vous présenter [Prénom Nom de l'observateur] qui va observer ce groupe afin de voir comment se déroulent les discussions et m'aider éventuellement à distribuer équitablement la parole et garder le temps en vue.

Je vous présente également et [Prénom et Nom du rapporteur] qui prendra note des discussions.

(Pour tous) Je souhaiterais par ailleurs vous demander l'autorisation d'enregistrer l'entretien/les discussions : cela nous permettra de revenir sur vos propos exacts lors de l'analyse de l'ensemble des entretiens, de ne pas déformer vos propos en cas de citation pour illustrer nos résultats et ne pas prendre de notes trop précise pendant l'entretien, ce qui facilitera nos échanges. Si vous/personne n'y voit d'inconvénients, je laisse le dictaphone enregistrer. (celui-ci ayant été enclenché dès le début de l'entretien)

Quelques règles de base : il n'y a pas de bonne ou mauvaise réponse. Les discussions se font dans le respect mutuel de chacun.

(Pour les focus groups) Nous vous remercions de bien vouloir ne pas rapporter ce qui se sera dit ici à l'extérieur du groupe.

Pour ce qui est de la prise de parole, ne parlez pas entre vous, en aparté, mais faites profiter le groupe de vos réflexions. En plus, s'il y a plusieurs conversations en même temps, l'enregistrement en pâtira. Si vous souhaitez prendre la parole, faites-moi un petit signe.

(Pour tous) Vous êtes libre de quitter le groupe/arrêter l'interview à tout moment.

(Pour les focus groups) Avant de passer à la première question, je vous propose de commencer par un tour de table afin de vous présenter en donnant votre prénom et [1 ou 2 caractéristiques en fonction de la question de recherche]. Si vous préférez vous pouvez donner un pseudonyme.

APPENDIX 9. AN EXAMPLE OF A DEBRIEFING TEMPLATE

- Comment le groupe a fonctionné ?
- Contexte environnemental
- Tensions éventuelles
- Problèmes éventuelles avec certaines questions/topic
- Points à approfondir au cours des interviews suivantes
- Premier résultats frappants

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