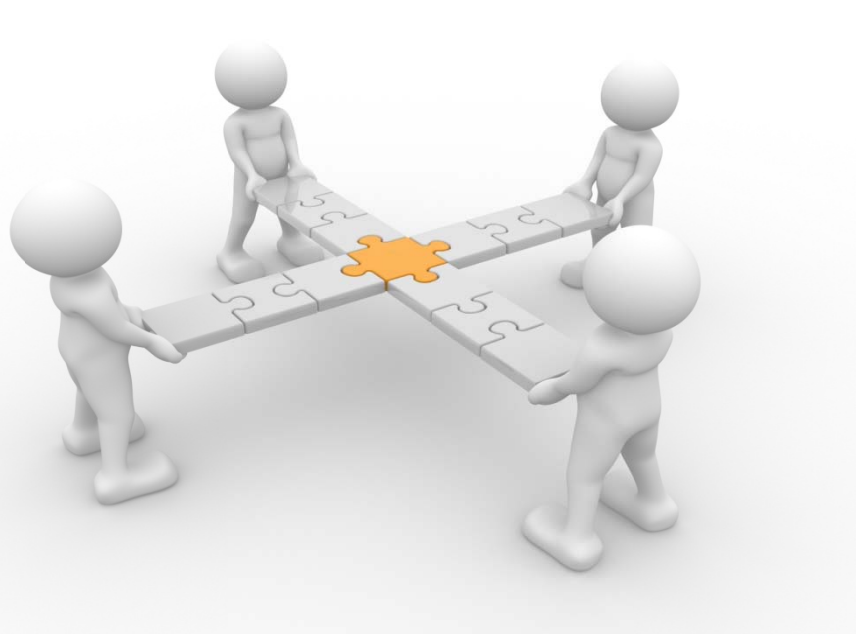
KCE REPORTS 174C

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

STAKEHOLDER INVOLVEMENT IN KCE WORKING PROCESSES



Belgian Health Care Knowledge Centre

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KCE is in charge of conducting studies that support the political decision making on health care and health insurance

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KCE REPORTS 174C
METHOD

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STAKEHOLDER INVOLVEMENT IN KCE WORKING PROCESSES

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FOREWORD

In 2009 the KCE commissioned an external audit of its impact on healthcare policy in the country. While the KCE's scientific excellence and credibility were generally recognised, the audit pointed out a number of fields in which progress could still be made. For example, the interviewed stakeholders were of the opinion that communication with the target groups could be further improved, and they also clearly expressed a call for more close involvement in the KCE study processes.

On the one hand there was the concern to have the subjects under study better attuned to the complaints in the field, by involving the stakeholders early in the projects, and in particular in the drafting of the specific research agenda. On the other hand it appeared that a good interaction with the target groups in the final phase of projects as well could contribute to a better impact of the messages and recommendations formulated in the studies.

We are now over two years further down the line. The new management plan of 2010 of course also placed the necessary emphasis on these issues. In the field of communication, a host of initiatives have already been taken, including a new editorial approach to the studies and a thorough revamping of the website. But when it comes to stakeholder involvement, we haven't been sitting around doing nothing, either. The studies on alternative medicine, on burnout among general practitioners and on the future need for residential care for the elderly, to name but a few, each had a sizeable component of intensive interaction with the groups involved in the field.

In this report we want to place this approach within a more scientific and conceptual framework. We look at the key elements of stakeholder involvement and reflect on how these can best be structured and geared to the KCE's specific duties and possibilities. The document aims to be the reference framework for a series of very practical "process notes" on the concrete terms and conditions governing specific stakeholder involvement techniques. The first of these process notes deals with qualitative methods, and is currently being prepared. Others will follow in the coming years.

But the essence of an effective involvement of the interested parties is much more than a series of methodological handbooks. What is basically involved is a vision and organisational culture that expressly defines the KCE's task on the basis of social relevance and added value. And when bringing this into practice, we cannot disregard what all those other players in the health system have to say. We therefore hope that this study provides a major impetus for this approach.

Jean-Pierre CLOSON
Assistant Managing Director

Raf MERTENS
Managing Director

SUMMARY

Stakeholder involvement, i.e. the active involvement of groups or people that are potentially or actually affected by our studies, has been fostered since the KCE was set up.

In the vast majority of the KCE projects, and in the various phases of those projects, care providers and policy-makers who have dealings with the study subject matter on a day-to-day basis will be consulted. Yet, the distinction between their contribution as an expert versus as a stakeholder is not always easy.

The involvement of other groups than the providers or policy-makers, however, has been much less systematic. Hitherto we have not carried out a comprehensive reflection on when and why best to involve the various stakeholders in our processes, neither have we developed specific, detailed methodological handbooks on how best to put this kind of involvement into practice. This report focuses primarily on the question of “when” and “why”, without going into depth on the matter of “how”. This latter point will be the subject of a series of methodological process notes.

BASIC PRINCIPLES

In the second chapter we look at stakeholder involvement from both a conceptual and empirical standpoint. In the former we based ourselves on the specialist literature in the field, and in the latter on published experiences from other sectors where stakeholder involvement proved to be meaningful and relevant. In so doing we draw not only on the experiences of other agencies and players, but also on sociological research.

We first outline the origin of stakeholder involvement in the public health research field. Next, we examine the various aspects of and approaches to stakeholder involvement in greater depth, from the initial phase through to completion of a project and dissemination of the results. This report studies:

- The possible objectives, from mere information gathering through to genuine “democratisation”, whereby the stakeholders become partners in the study who actively contribute to the results;
- How to identify and describe stakeholders;
- The importance of open communication and transparency in all phases of a project;
- The challenges and risks presented by controversial subjects;
- The skills and principles needed for successful stakeholder involvement.

FROM THE ANGLE OF THE KCE RESEARCHERS

In this methodological research project we have also looked at the place of stakeholders in past and current KCE projects, and at the obstacles, opportunities and success factors according to the KCE researchers. They based themselves here on their own experience, and their view was noted down during four discussion fora in October and November 2011. All KCE researchers took part and the meetings were chaired by an external moderator.

Among other things, the KCE experts pointed to the need for suitable training, and an adapted way of involving stakeholders according to the needs of each project. Patients were named as an important group, but one that was not always easy to approach. One oft expressed concern was that the KCE ought not to lose its independence, and that stakeholder involvement required time and could only occur in a climate of mutual respect.

HOW TO PUT STAKEHOLDER INVOLVEMENT INTO PRACTICE AT THE KCE?

On the basis of the above-mentioned insights, the last chapter of the report presents a number of approaches that could increase the KCE’s impact by ensuring a more effective involvement of various relevant stakeholders in its projects.

We identified five major strategic objectives in respect of which stakeholder involvement could be useful. By and large, they correspond to the successive phases of a research project:

1. **Make the subject tangible.** Before commencing a research project, it is useful to familiarise oneself with the subject and to make it tangible. This can be done, for example, by asking for the contribution of patients and care providers who are confronted with the study subject matter on a daily basis.
2. **Define the right scope and research questions.** If our studies aim to address the really important problems and concerns, as these are seen by the care providers, patients, the public and/or policy-makers, we must try to expose the underlying problems or controversies. This will help us to understand the more deep-seated motivations and values, and sometimes also the reasons for a possible resistance to go into certain study questions in greater depth. A careful and participative formulation of these questions can also create support for the project among the end users. It is also important to have a full understanding of the regulatory context, including its financial implications.
3. **Ensure the study structure and methods are acceptable.** See to it, insofar as is possible, that the main stakeholders accept the KCE’s approach. If necessary, add information sources or data that might be useful for obtaining a broad view.

4. **Arrive at clear-cut results and realistic answers.** Try to obtain a good view of contrasting standpoints and the main arguments, so as to be able to draft your own conclusions and recommendations in clear and explicit terms. Every recommendation should in any case be realistic, and therefore also feasible – perhaps not immediately, but at least in the long term.
5. **Find effective communication channels and spokespersons.** Try to obtain that the target groups themselves become active advocates of the reports.

These objectives can only be achieved if we bear in mind a number of values in our contacts with the stakeholders: respect, transparency, objectivity, modesty and sincere curiosity.

In practice, there is no single standard way of implementing stakeholder involvement. The question has numerous dimensions that vary according to the above-mentioned objectives, the nature of the project and the interlocutors. Consequently, we will have to develop an array of methods, corresponding to the different situations of stakeholder involvement and the results we expect it to yield.

The report ends with a list of techniques that need to be further developed into formal KCE process notes, which, ultimately, should be incorporated into the KCE's research methods.

SCIENTIFIC REPORT

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
ADAPTE	http://www.adapte.org
AGREE	Appraisal of Guidelines Research & Evaluation http://www.agreetrust.org/
AHRQ	Agency for Healthcare Research and Quality http://www.ahrq.gov/
CCOHTA	Canadian Coordinating Office for Health Technology Assessment http://www.cadth.ca/
CIHR	Canadian Institutes of Health Research http://www.cihr-irsc.gc.ca/
DACEHTA	Danish Centre for Health Technology Assessment http://www.sst.dk/English/DACEHTA.aspx
EBM	Evidence-Based Medicine
EUnetHTA	European Network for Health Technology Assessment http://www.eunethta.eu/
HAS	Haute Autorité de Santé / French National Authority for Health http://www.has-sante.fr/
HTA	Health Technology Assessment
IQWiG	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswessen / German Institute for Quality and Efficiency in Health Care https://www.iqwig.de/
KBF	King Baudouin Foundation http://www.kbs-frb.be/
NCCHPP	National Collaborating Centre for Healthy Public Policy http://www.ncchpp.ca/
NICE	National Institute for Health and Clinical Excellence http://www.nice.org.uk/
(P&)CP	(Patient &) Citizen-Patient
VIKC	Vereniging van Integrale Kankercentra

1. RATIONALE OF STAKEHOLDER INVOLVEMENT AT KCE

Although stakeholder involvement has been part of the KCE research processes since its early days, this methodological study reflects the willingness of the organization to address it in a more systematic and diversified way. The primary aim of this work is to reflect about 'why' and 'when' to involve stakeholders, with as an ultimate objective to increase the societal pertinence and the impact of the KCE reports. The latter is not only linked to the scientific quality of the research, but also to the degree the policy and practical challenges are met.

1.1. Policy challenges and objectives

The '*raison d'être'* of scientific advice institutions such as KCE is fundamentally political and pragmatic. In this sense, KCE collaborators can be seen as 'employed' by society to help and find the best ways to use the finite resources of the healthcare system for meeting the virtually infinite healthcare needs of the population. Taking up this fundamental policy challenge requires that we formulate relevant research questions, find unambiguous results and propose realistic recommendations.

Obviously, for addressing this broader perspective, we need competences in several other disciplines than medicine and health economics; we will also have to mobilize methods specific to sociology, law, and even anthropology. We must find adequate ways to deal with and value the perceptions, experiences and opinions of stakeholders, without losing our independence and objectivity.

1.2. Scientific challenges and objectives

Combining a true openness to participative approaches with the safeguard of scientific rigor and objectivity poses serious scientific challenges, such as the achievement of valid results by means of systematic and robust study processes, including qualitative research and sociological methods. This must, without any doubt, be part of the core business of KCE.

When addressing this challenge, i.e. learning to master valid ways to involve the different groups of stakeholders, we can tap into a body of knowledge available in the scientific literature and the know-how from similar institutions in other countries, but also get inspiration in the experiences from our own work.

1.3. Structure of this study report

In chapter 2, we explore the key principles of the stakeholder involvement. We address the 'who', 'why',' how' and 'when' questions of this involvement but from a theoretical and empirical point of view.

In chapter 3, we present how we involved our own stakeholders, i.e. the KCE researchers themselves, in the reflection about what the identified principles could or could not mean in practice for the KCE studies. During four group discussions, the experts have shared their experiences and their perception of the threats and the barriers but also the opportunities of involving stakeholders in their day to day work.

Finally, chapter 4 synthesizes the strategic objectives of the stakeholder's involvement at KCE, including the key values needed to make this endeavour fruitful. A number of succinct technical sheets, given in appendix, illustrate how we involved stakeholders at different stages in our study processes.

2. KEY PRINCIPLES OF STAKEHOLDER INVOLVEMENT

2.1. The rise of stakeholder thinking

Stakeholder thinking grew up **in the economic area** in the 1930s and evolved[1]:

- from stakeholders viewed as **subjects to be managed** to stakeholders as **individuals in a network**-based, relational and process-oriented view;
- from a buffered **dependency** on stakeholders towards a bridging dynamic **interdependency** between a firm and its surroundings as well as influential stakeholders.

A set of similar theoretical models has emerged **in the knowledge area**, conceived to describe whether and how research is used and to explore possibilities to increase the research impact[2].

Rational-linear models focused on dissemination of research. If policy-makers rarely used research it was because of problems of **communication** between researchers and policy makers:

- **Supply-side research initiatives** were developed to support the use of research by adapted publication formats and effective packaging[a].
- **Demand-side research initiatives** were developed to question research users about their needs and provide tailored research (rational-linear model with feedback loop)[b].

These models were abandoned in favour of more interactive models that emphasize linkages between researchers and decision makers[5].

Interactive models, recently developed, put a focus on **complex relationships** between the key variables that shape policy use of research: multiple actors, multiple exchanges, nature of the research and context of its use. These variables are no longer considered in isolation but in interaction. And the ways research is used are no more considered as rational[c]. These interactive models, in comparison to the traditional linear and rational models, incorporate the role of research users' knowledge and experience in the research use process, and ask the question of power in the postmodern critique (and the real possibility to empower partners).

Box 1: Stakeholder engagement

In 1984, Freeman pushed a stakeholder theory to the forefront of academic attention and provided boundaries of what could define a stakeholder. The core idea that underlies Freeman's theory and the subsequent ones is that management choice is a function of stakeholders' influences. These theories aim to understand the types of stakeholder influence and how firms respond to those influences with what is called **stakeholder engagement**. The World Bank Group has contributed to the diffusion of these ideas by publishing a good practice manual in 1998[6] and a good practice handbook in 2011[7].

a See the SUPPORT program description in Lavis, 2009[3]

b See the INVOLVE program description[4].

c Recently, another set of initiatives between supply and demand have begun to establish new kinds of relationship between researchers and the policy process by developing intermediary broker organizations into the policy process (Nutley 2008, p246)[2].

Figure 1: Stakeholder involvement in research-use theoretical models

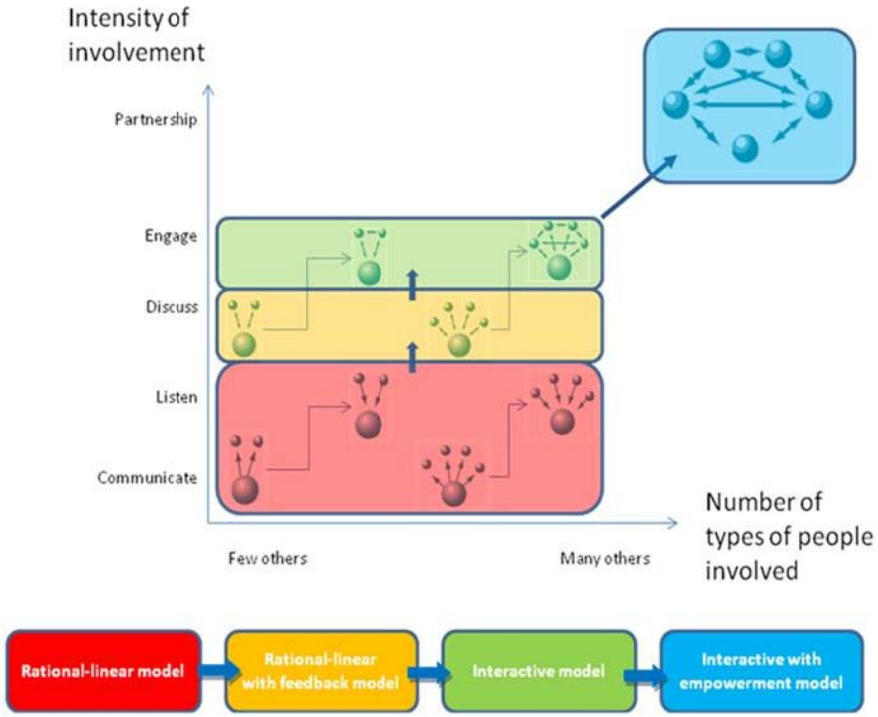


Figure inspired by "Health Canada's public involvement continuum » in Health Canada 2000, p.12[8] and "Spectrum of stakeholder engagement" in IFC 2011, p.3 [7]

Box 2: Evolution of knowledge-to-action thinking and semantics

Best and colleagues provide a framework that describes the generation of the knowledge-to-action thinking in three phases (Best et al framework cited in Nutley, 2010, p.135)[9]:

Linear models (1960s to mid-1990s)

Research is disseminated as results are handed over to others for use in various settings. Whether it gets used is a function of effective packaging. The predominant language of research use for these models is "**knowledge transfer**" and "**dissemination**".

Relationship models (mid-1990s to present)

The key processes for improving research used are the relationships that develop within networks of collaborating research producers and users. Knowledge products are defined and utilized in the context of these relationships and improving the interpersonal communication within these relationships is the key. The language of research use for these models is "**knowledge exchange**".

System models (more recently)

The way knowledge is embedded within organizations and systems is the most important factor in improving research use. For knowledge to be used it needs not only to be embedded in relationships but also interwoven with the priorities, cultures and contexts of organizations and systems. Research use is thus a dynamic process within a complex adaptive system. The language of research use for these models is "**knowledge integration**", "**translation**" and "**mobilization**".

Box 3: an epistemological shift from matter of facts to matter of concerns

The knowledge-to-action thinking has historically evolved from linear models towards more interactive models in association with "an epistemological shift which requires us to rethink our conception of research knowledge as something separate from policy knowledge. Research-policy relations become at least two-way and in some version of systems thinking, the boundaries between these two realms of knowledge become blurred"[9].

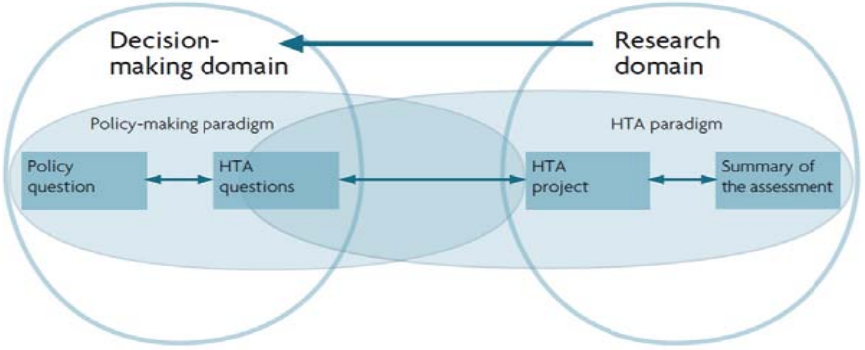
- **In the traditional linear and rational models** research was seen to provide discrete, unambiguous, factual accounts that can straightforwardly be transferred and applied to policy or practice (Nutley 2008, p.123)[2].
- **In interactive models**, we recognise that "research evidence may not arrive as uncomplicated "facts" to be weighed up in making policy decisions, but may be translated and reconstructed in the process of its use through ongoing dialogue with research producers". (Nutley 2008, p.251)[2]

EXAMPLE: The Danish Centre for Health Technology Assessment (DACEHTA)

DACEHTA published in 2008 a new handbook presenting updated and new scientific methods and approaches to HTA[10]. This handbook deals not only with elements of HTA, i.e. technology, patient, organisation, economy and ethics, but also with the steps in the HTA process.

HTA may be considered as bridging between the decision-making domain and the research domain. In order to fulfil such a purpose, the problems in focus of an HTA must be based on the need of the decision makers for a documented basis for decisions about the use of health technology.

Figure 2: Bridging between decision-making and research domains



The DACEHTA model is inspired by the rational-linear model of research use in a one-way flow representation, where the research domain targets the decision-making domain. It separates two communities, one of researchers and the other of decision-makers[d] but allows some space for interactions in the overlapping zone between the policy-making paradigm and the HTA paradigm. From (Kristensen 2008, p15)[10]

2.1.1. Who are stakeholders?

In the economic area, Freeman defined stakeholders as

> *"any group or individual who can affect or who is affected by the achievement of the firm's objectives"[e].*

The International Finance Corporation's definition adds

> *"those who may have interests in a project and/or the ability to influence its outcome, either positively or negatively. […] The "stake" that each of these different individuals or groups has in a project or investment will vary" (IFC 2011, p.10-11)[7].*

EUnetHTA recently referred to these two definitions to underline the three characteristics of stakeholders : they are **affected** by the project, **interested** in and/or potentially **influent**.

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[d] See the "two communities" thesis of Caplan[11].

[e] (Freeman 1984, p25)[12] cited in (Andriof 2002, p30)[1].

When comparing several EBM or health-related agencies' stakeholder lists, the most commonly cited stakeholders appear to be :

- industry
- policy makers and/or institutions
- patient/user representatives
- health care professionals
- health related media
- academia
- commercial enterprises

2.1.2. The circle of stakeholders

Depending on which stakeholder involvement method is chosen, the **circle** is more or less open to these seven types of stakeholders.

2.1.2.1. Wide-open consultation

Following the German Institute for Quality and Efficiency in Health Care (IQWiG) has chosen an approach in which **all interested persons**, institutions, or commercial enterprises may submit written comments on the preliminary report plans, on amendments to report plans and on preliminary reports and thereby comment on the methods or published interim results[13]. The circle of persons entitled to submit comments is **not restricted**. Private persons, as well as professional associations, institutes, and companies, may submit comments.

2.1.2.2. Closed monitoring groups

In contrast, the French National Authority for Health (HAS) has an approach in which all actors have to candidate or to be designated by stakeholders. Stakeholders may be health professionals and patient/users' representatives. **An equilibrium is searched** between types of involved health professionals, types of opinions, types of practice, places of practices. These stakeholders are involved in different groups during the entire production process of recommendations. But public agencies' representatives, health insurance companies and industries are not included in these groups ; they may be consulted on a more ad hoc basis.

EXAMPLE in the research area : EUnetHTA definition of stakeholders

When identifying stakeholders, the EUnetHTA Collaboration used a similar definition as in the economic area but restrains stakeholder involvement to a consultative role:

Stakeholders are groups or organizations which potentially will be **affected** by, or have an **interest** in and may in a consultative role **influence** on the actions or aims of an organization, project or policy directions[f].

EUnetHTA has chosen to focus on umbrella organizations operating at the European level, and on generic rather than disease specific organizations. Following groups are targeted:

- Policy makers at national/regional level
- Policy makers at hospitals/statutory health insurance/HMOs
- Patient organizations
- Healthcare professional organisations
- Industry
- Health related media

[f] Definition cited by Nielsen 2009[14].

2.1.3. The patient and the citizen

2.1.3.1. A patchwork of possibilities

There exist many forms of patient and citizen-patient (P&CP) involvement corresponding to different objectives and domains of decision. We consider that we can divide this kind of involvement into 5 domains of application: (1) the involvement of the P&CP in the research activities, (2) the involvement of the patient in its relationship with her practitioner, (3) the involvement of the patient in its relationship with the health and healthcare institutions (hospital, mutuality's, private insurance) (4) the involvement of CP in the financing options to adopt (5) the involvement of the P&CP in the determination of health priorities and choices. In each of these 5 domains, the P&CP has to be informed, to give information, to give his or her opinion, to co-decide or to decide. We limit the present section to the first domain, the research activities and more precisely the research in public health.

There exist different models to involve the citizens and the patients, ranging from mere information up to actual decision[15, 16]. For each approach, both generic and specific technical and human competencies are needed. Yet, each of these procedures that we have to conceptualize and execute should be characterized by the 'care' defined by Joan Tronto[17].

2.1.3.2. A transversal quality of the involvement: the practice of 'care'

Tronto suggests that on the most general level, caring be viewed as a human activity "that includes everything that we do to maintain, continue, and repair our 'world' so that we can live in it as well as possible. That world includes our bodies, ourselves, and our environment, all of which we seek to interweave in a complex, life-sustaining web."(Tronto, 2009, p.143)[17]. It has been suggested that this practice of care can be 'capacitating' because it could 'reveal' a certain liberty for the beneficiary. A liberty to express an opinion, an anxiety, a wish, an expectation and an hope[18-20]. This condition of 'care' seems to be quite trivial in the inter-individual relationship between the patient and the practitioner. But it is much less straightforward to concretize in other settings, such as research in public health.

2.1.3.3. Involvement of the patient in the 'research activities'

Nevertheless, we can find several examples of successful patient involvement, effectively characterized by the practice of 'care' indeed, even if this concept was not explicitly 'named' or 'used'.

A first example of such type of patient involvement is the practice guideline for normal low-risk childbirth, developed by KCE in collaboration with a group of gynaecologists and midwives[21]. On the basis of this guideline, a plain-language version has been derived, in order to be understandable by all socioeconomic categories of women. This exercise has been realized with the input from women of different education levels[22].

We also find examples of patient involvement in the work of NICE (National Institute for Health and Clinical Excellence, UK). As in the above-cited example, the information follows a 'reciprocal' pathway: the patients inform the research institution and, given this information, the research institution is able to provide better information to the patients. NICE has developed a systematic procedure to involve patients and citizens; full details can be found on the NICE website [23], which is also offering an impressive list of guidances for patients (e.g. on caesarian section[24], anxiety[25] or the Alzheimer disease[26]).

Furthermore, the information originating from the patients can also be helpful to confirm research hypotheses. This is how NICE learned that, somewhat unexpectedly, peritoneal dialysis was not the preferred option for every patient. It appeared that some of them experience this permanent presence of medical equipment in their home as a complete 'invasion' of their lives by their disease[27].

2.1.3.4. Evaluation of the patient and citizen-patient involvement

Whereas publications attest the influence of the way to involve patients for the pertinence of the research[28-31], there is also a need for evaluation of the patient involvement[32, 33]. The actual format and modalities of this evaluation remain to be defined.

2.1.4. Why stakeholder involvement?

Reasons to involve stakeholders in a research production process are numerous, and vary between agencies. Stakeholder involvement is described as useful to :

- provide legitimacy or credibility to the agency;
- promote EBM practices and EBM culture ;
- prevent disagreement or conflicts ;
- improve acceptance of results and increase impact ;
- enhance relevance of research ;
- reduce duplication.

Stakeholder involvement is seen as serving the principles of:

- Transparency
- Accountability
- Participation
- Objectivity
- Evidence-based outcome
- Patient-oriented outcome
- Scientific work.

The 'objectivity and scientific work mentioned here point to the acquisition of a richer picture and the objective rendering of all viewpoints and practices, in a so-called second-degree heuristic objectivity.

EXAMPLES of declared reasons to use stakeholder involvement in EBM and health-related agencies

EUnetHTA: because HTA agencies resemble political institutions in the sense that they are (often) public, tax-financed institutions seeking to improve the healthcare system by their activities, the question of their **legitimacy** has to be considered. Legitimacy must be understood in relation to the scientific quality of HTA products and the **fairness** and **transparency** of the production processes[14].

CCOHTA: stakeholder consultations are important as it helped in **creating an enhanced awareness and culture of best practices**.

DACEHTA: stakeholder involvement is to ensure the most efficient project course **by preventing the occurrence of disagreement and conflicts**. To improve the possible **acceptance** and **application** of the HTA results.

AHRQ: stakeholder involvement provides **credibility** to AHRQ research, helps avoid prioritizing topics that have no **relevance** to real-world issues, and reduces potential **duplication**.

CIHR: there are two primary reasons.

First, the creation of new knowledge often does not, by itself, lead to its widespread **adoption** or have an **impact** on patients' health.

Second, all of the interested parties want to see the benefits reaped by the taxpayers' dollars invested in health research by moving research into practice/action (**accountability,** Tetroe 2007, p.1)[34].

NICE: comments from stakeholders are "a vital part of the **quality assurance** and peer-review processes" (NICE 2007, p.80)[35]. In this way, stakeholders offer specialist expertise and a practical perspective to balance the science of the guideline methodology.

IQWIG: stakeholder involvement corresponds to its principle of **transparency** which is one of this agency's principles[36] : independent, objective and evidence-based, patient-oriented and scientific.

HAS: stakeholder involvement methodologies are grounded in the same principles which are : **participation** (of professionals and patients/users' representatives), **transparency** and independency.

2.1.5. Criteria of effective stakeholder involvement

2.1.5.1. Involved at an early stage of the project

DACEHTA underlines that it is important that all relevant bodies are involved from the beginning in the project. It helps to make the participants feel co-responsible for the project and creates understanding and acceptance of the different occupational backgrounds. Implicit is that good cooperative behaviour is required in stakeholder involvement with trust and high work ethics among the project participants.

2.1.5.2. Involved in transparency

IQWIG, NICE and HAS have developed specific guidelines on the involvement process to clarify confidentiality issues and publication rules, tasks to do and planning. Stakeholders have to be informed early about the amount of work needed (the number of meetings) and tasks to do.

2.1.5.3. Involved in mutual learning

The CIHR points out the importance of the knowledge exchange that occurs in the interaction between the knowledge user and the researcher, resulting in mutual learning. These interactions may vary in intensity, complexity, and level of engagement, depending on the nature of the research results and on the needs of the particular stakeholder (Tetroe 2007, p.1)[34]. Since stakeholders are involved in the research-use process, research-use is no more described in terms like “knowledge transfer” or “dissemination” but “knowledge exchange”, “knowledge integration”, “translation” or “mobilization”.

2.1.5.4. Involved with satisfaction

As influence and impact are elusive concepts, NICE recommends to pay attention to stakeholders’ satisfaction with the stakeholder involvement process and its outcome. Satisfaction relates to realistic expectations about the purpose and power of stakeholders, the usability and relevance of the outcome.

2.1.6. What are the key components of stakeholder involvement?

Stakeholder involvement encompasses a range of activities that will be developed in further sections.

- Stakeholder identification and analysis
- Communication at an early stage
- Stakeholder consultation all along the project development process
- Dialogue in case of controversies
- Management of stakeholders’ comments
- Stakeholder involvement in project monitoring
- Regular feed-back to stakeholders
- Skills to manage the process of stakeholder involvement

Figure 3: Key components of stakeholder involvement

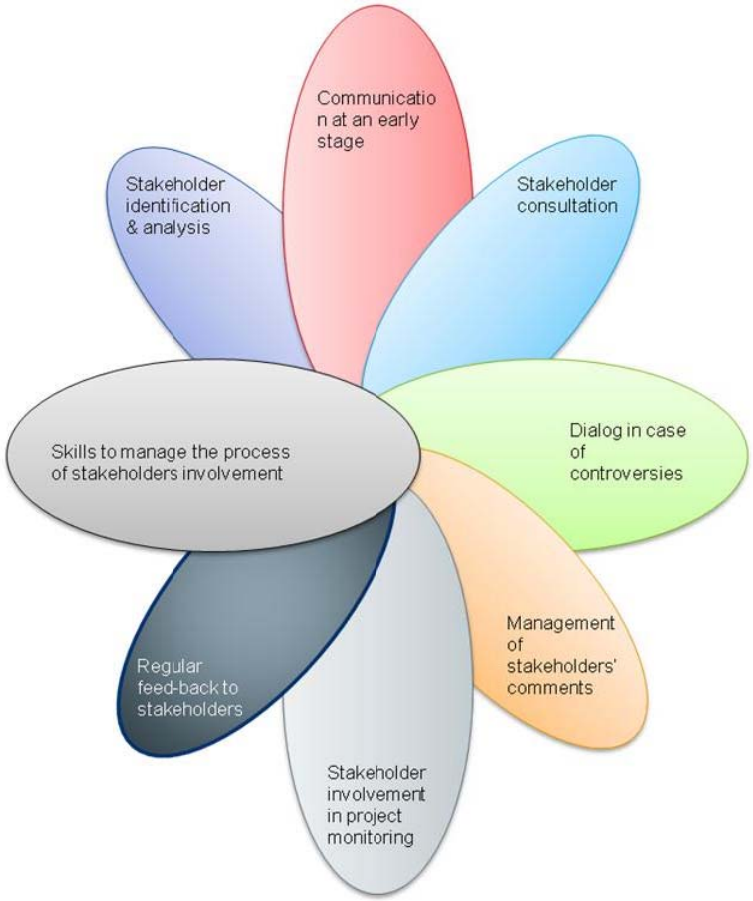


Figure inspired by Key component of stakeholders engagement in IFC 2007, p.12[7].

2.2. Stakeholder identification and analysis

Also called **environmental scan** when it is quickly performed, the stakeholder identification and analysis is the first crucial step of stakeholder involvement. To neglect or to miss identification of affected, interested or influential stakeholders may impact negatively the end outcome of your project. As mentioned by DACEHTA, this stakeholder analysis has two aims (Kristensen 2007, chapter 1)[10]:

1. to clarify who are the stakeholders;
2. to assess which stakeholders are the most important to include, and to identify which function to assign them to in the context of the project.

This task is complex as one needs to explore the social complexity of interconnections before being able to order it and to produce one's own list of stakeholders to involve.

> *"Collective situations are always intricate and the more actors are concerned, the more intricate they can get."(Venturini 2009, p.6)[37]*

Box 4: Diving in magma, the cartography of controversies

"The cartography of controversies is a set of techniques to explore and visualize issues, developed by Bruno Latour as a didactic version of Actor-Network Theory to train students in the investigation of contemporary socio-technical debate. Today it is a full research method, though, unfortunately, not a much documented one. […] Recently, the cartography of controversies has also become the object of the EU funded consortium MACOSPOL (Mapping COntroversies on Science for POLitics), which gathers eight European universities and research centers."

Source : Venturini 2010, p1[37]

2.2.1. Explore the world : from unfolding complexity to ordering complexity

> *"Social cartographers should work out their observations and descriptions at once*".(Venturini 2010, p.2)[38]

2.2.1.1. Observation : from texts to actors

> *"Following the webs of relations surrounding controversial statements, social cartographers are inevitably brought to consider connections that spread beyond the textual universe. Statements are always part of larger networks comprising human beings, technical objects, natural organisms, metaphysical entities and so on" (Venturini 2010, p.2)[38].*

Starting by reading texts about the issue under scrutiny (in grey literature, on websites, in press, in legal texts or in scientific literature) offers a first opportunity to identify potential stakeholders and connections between them. Figure 4 illustrates in a graphical way how the stakeholders in mental health services for children and adolescents can be identified from a careful scrutiny of the successive legal text on the subject.

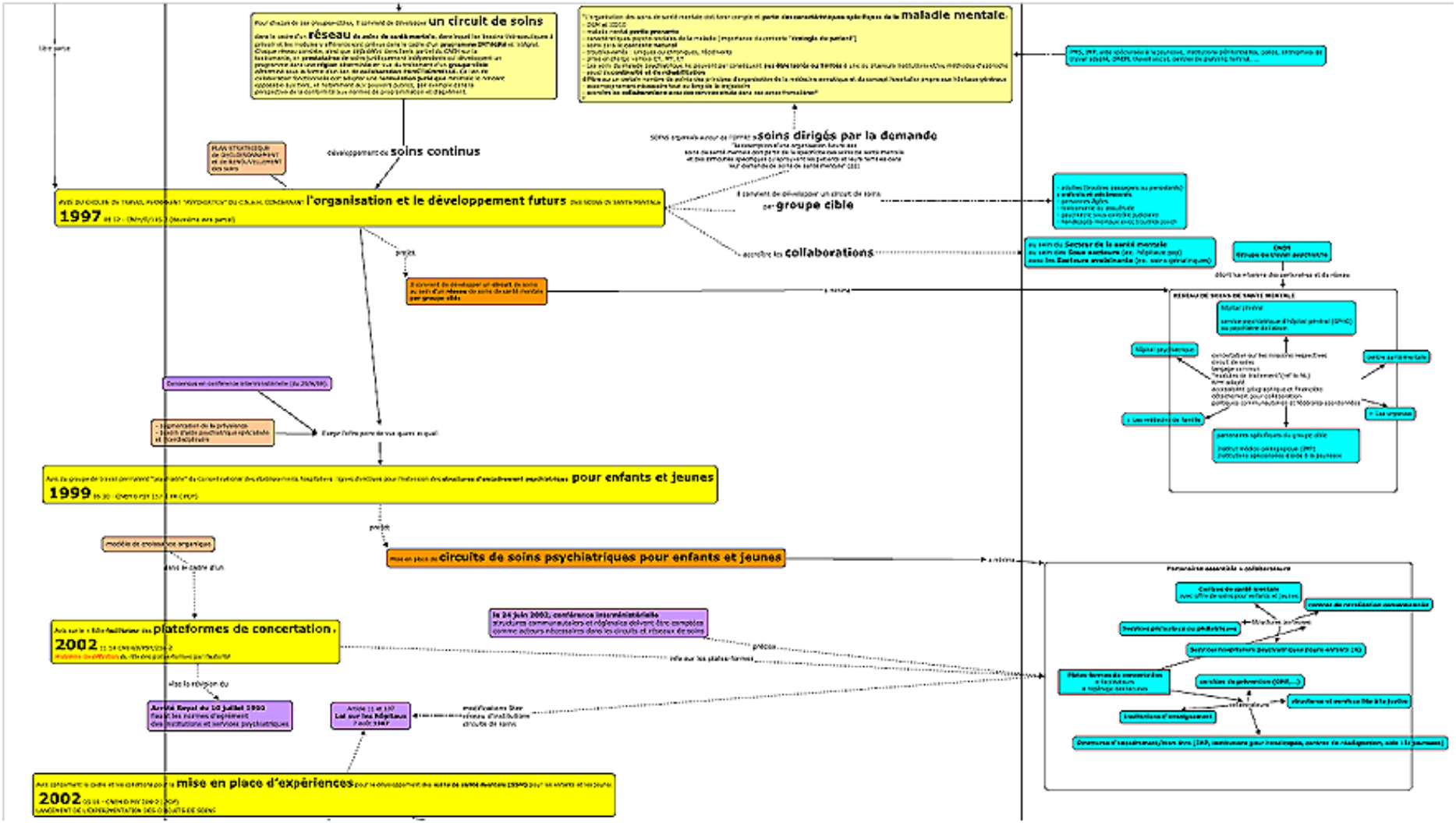
Perplexity is required in such exercise to take into account a lot of new connections. In this way, perplexity becomes a research tool, and the condition for the second-order heuristic objectivity that characterizes this approach. But, quick increase in complexity of connections has to be quickly ordered in notes and maps.

2.2.1.2. Description : from actors to texts

Notes and maps have to render the complexity legible. To give different visibility to different stakeholders we need **to be proportional** according to:

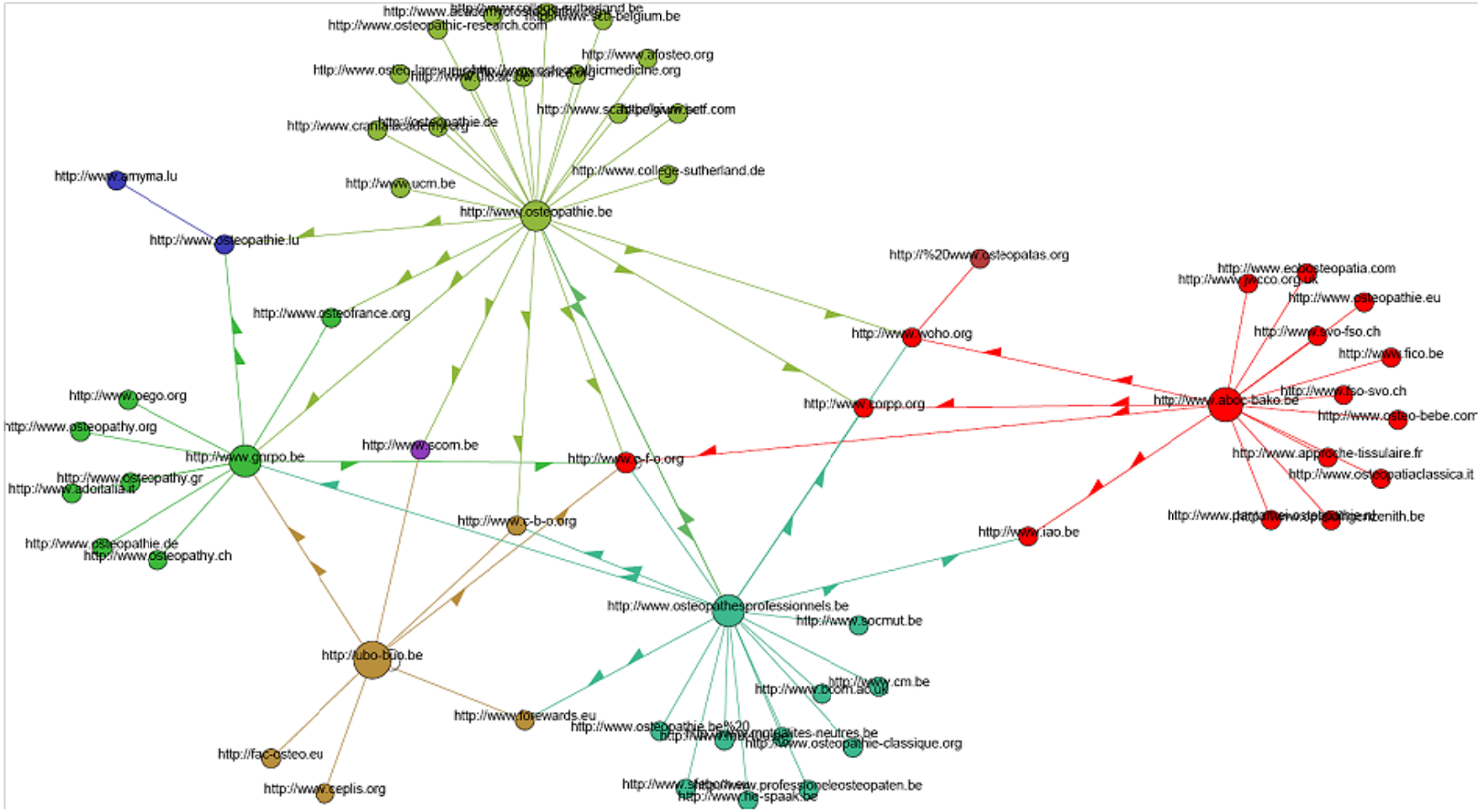
1. representativeness : how many actors subscribe to their viewpoint.
2. influence : actors on influential positions deserve special attention
3. relevance : even if stakeholders are minoritary, they might offer original perspectives and question what is given for granted.

Figure 4: Primary identification of stakeholders in legal texts



Working document from KCE Reports 170 "Organisation of child and adolescent mental health care: study of the literature and an international overview" [39]

Figure 5: Actors-networks diagram, connections between osteopathic unions in Belgium through their websites links



Mapping of the intensity (or paucity) of the connections between osteopathic unions in Belgium through their websites links. Working document from KCE reports 148 "[Ostheopathy and chiropractic: state of affairs in Belgium]" [40].

2.2.2. Be prepared before the journey

A social cartographer has to follow all these recommendations before trying to identify and analyze stakeholders' positions (Venturini 2010, p.7)[38]:

1. you shall listen to actors' voices more than to your own presumptions;
2. you shall observe from as many viewpoints as possible;
3. you shall not restrain your observation to any single theory or methodology;
4. you shall adjust your descriptions and observations recursively;
5. you shall simplify complexity respectfully;
6. you shall attribute to each actor a visibility proportional to its weight;
7. you shall provide descriptions that are adapted, redundant and flexible.

2.2.3. Organize your stakeholder identification and analysis

Using the basic framework of controversy mapping, developed in the European MACOSPOL project, several tasks may be required for relevant stakeholder identification and analysis, including the production of:

1. The glossary of non-controversial elements
2. The documentation repository
3. The analysis of scientific literature
4. The review of media and public opinions
5. The tree of disagreement
6. The scale of controversies
7. The diagram of actors-networks
8. The chronology of dispute
9. The table of interpretive frames
10. The forum (see the negotiation and partnerships chapter)

2.2.3.1. The glossary of non-controversial elements

In HTA, GCP or HSR projects, new technologies and devices, complex organizations of services or practices, may be adequately described with pictures or diagrams to underline their various components and the actors responsible of their construction or implementation. After having been identified, these actors may be involved in the study.

EXAMPLE : Sources of oxygen for home therapy

Figure used in KCE report 156C "Home oxygen therapy", page ii[41]. Source: Hulpmiddelen Kompas 2004, Zuurstofapparatuur – ISBN 90-70918-38-2

2.2.3.2. The documentation repository

From observation to description, analysis is needed to simplify the complexity of interrelationship. To assure the **reversibility** of these simplifications, field notes, interview recordings, raw data, archive documents, i.e. all traces should be kept and offered to public examination. Publication of this material must be discussed in the project team. Gate-keeping regarding information disclosure and/or publication rules must be considered carefully to guarantee trustworthy relationships between experts and stakeholders (see next chapter).

2.2.3.3. The analysis of scientific literature : bibliometric analysis

"Scientometrics can reveal the networks of scientific collaboration through the analysis of co-authorship, the relative authority actors (scientists, research centers, journals…) through citation analysis, and the diffusion of ideas through lexicographic analysis"(Venturini 2010, p.14)[38]. Scientific literature may be investigated not only to collect evidence but also to identify pools or 'schools' of scientists and stakeholders.

2.2.3.4. The review of media and public opinions

Since articles and press releases are digitally published, hand-searching is no longer necessary. Useful tools such as internet crawlers may be used to quickly scan debates and/or controversies to identify stakeholders.

See the figure 6 with connections between osteopathy websites, used in the KCE study "Osteopathy and chiropractic : state of affairs in Belgium."[40]

2.2.3.5. The tree of disagreement

> *"Cartographers should not renounce to trace how arguments are connected and structured in discourses. A position taken on a specific issue limits the positions that could be taken on other issues. This ramification can be represented in numerous ways" (Venturini 2010, p16)[38].*

2.2.3.6. The scale of controversies

> *"Cartographers are free to choose the granularity of their investigation, but they must be able to situate their object of study in the scale of disputes where it belongs" (Venturini 2010, p.16)[38].*

This scale has to be chosen to limit the number of stakeholders to potentially involve in the study. International comparisons in projects offer the opportunity to follow connections between national stakeholders and their European umbrella organization; and to describe coalitions or disputes that arise at that level of discussion.

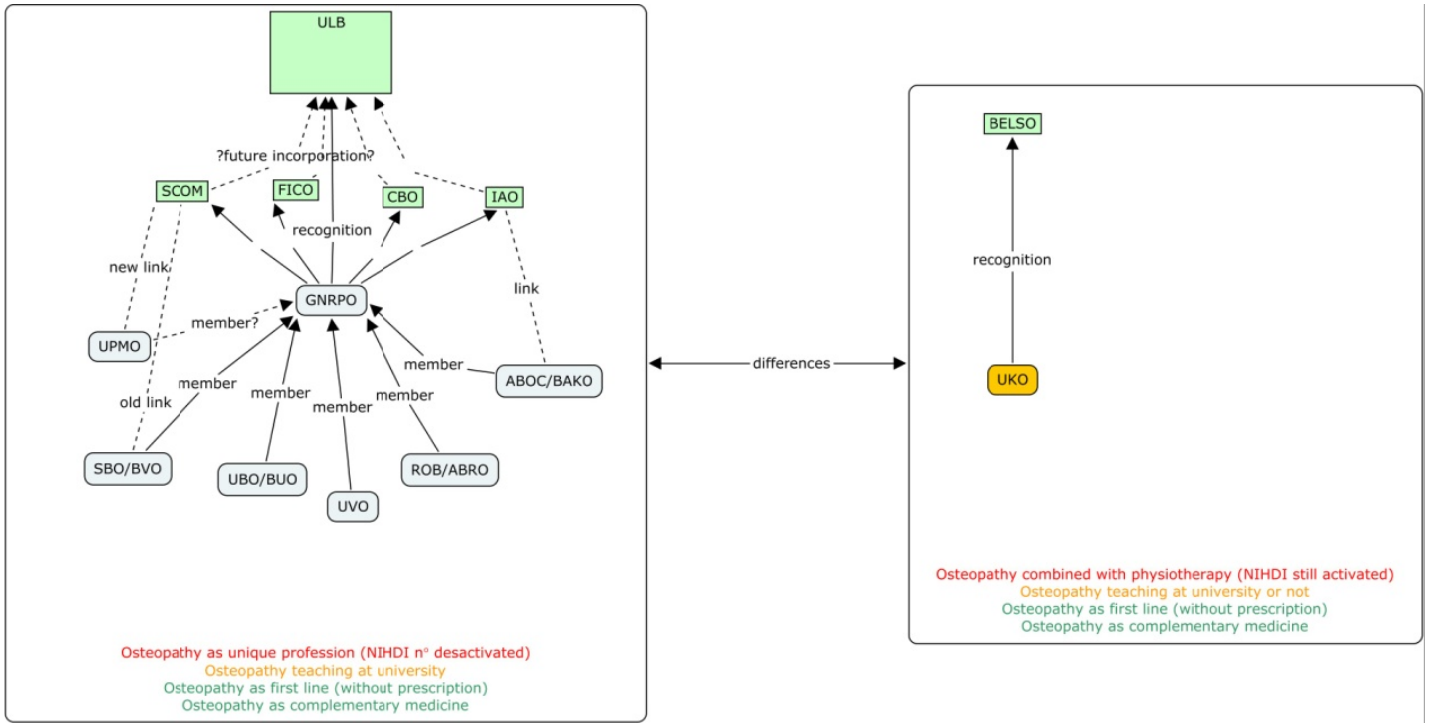
See the international confrontation of philosophies underlying the interventions for GP's burnout in "Burn-out of general practitioners : how can it be prevented and how can it be cured ?"[42]

2.2.3.7. The diagram of actors-networks : mapping burnout

> *"[…] every actor can be decomposed into a network and […] every network can be connected tightly enough to become a single actor. What used to be a single actor can suddenly dissolve in an explosion of conflicting agents and what used to be a loose constellation of agents can solidify into a unique source of action." (Venturini 2010, p.16)[38].*

During a research process, it's not rare that stakeholders' positions evolve. Some stakeholders become closer than before, others become distant. An umbrella of organizations may explode. Evolutive graphs and maps are interesting ways of representation of these magmatic movements.

Figure 6 : Actors-network diagram, representation of Belgian osteopathic unions and schools in 2010

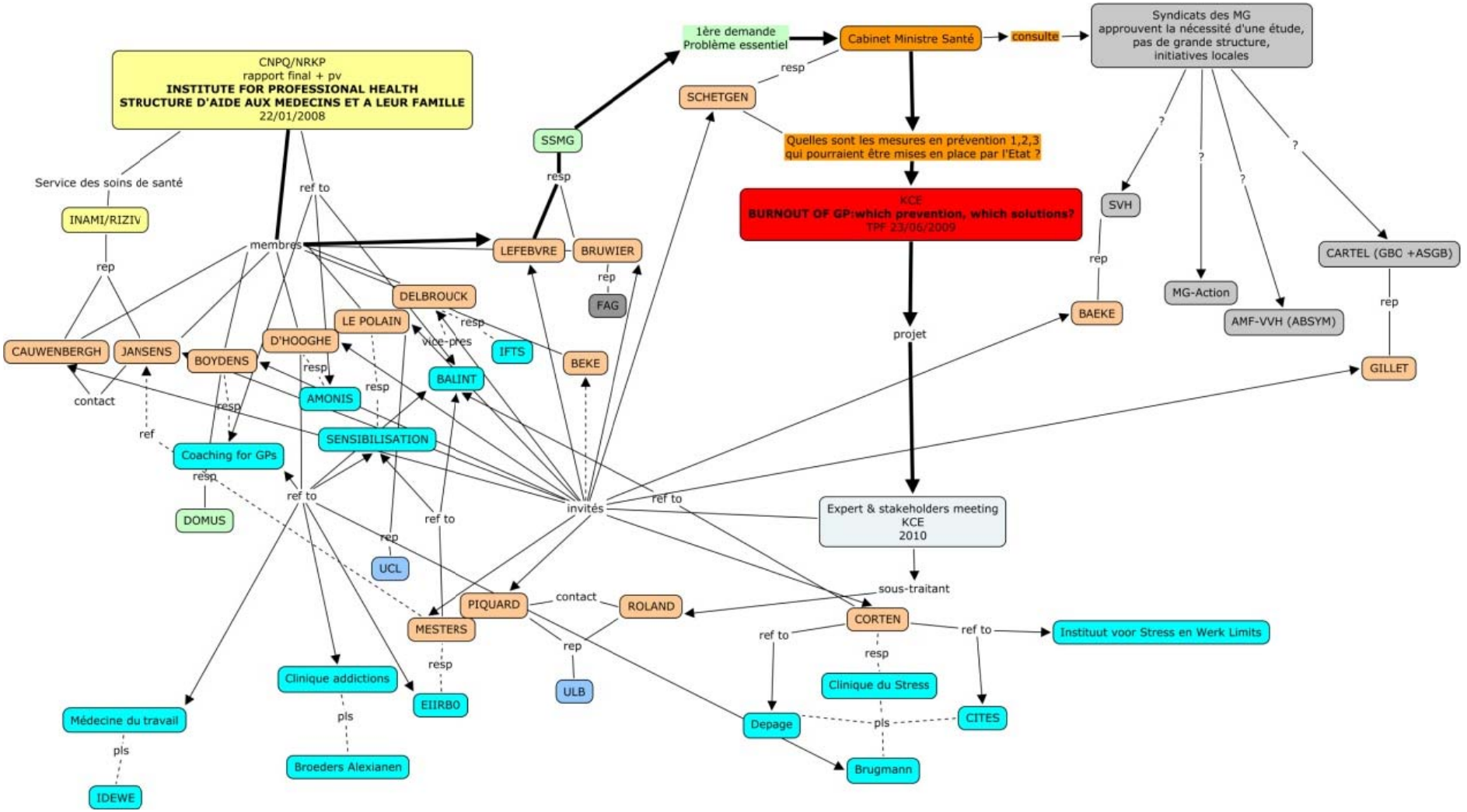


Working document from KCE Reports 148 "[Ostheopathy and chiropractic: state of affairs in Belgium]"[40].

2.2.3.8. The chronology of dispute

"Obviously, the evolution of controversies is not uniform: sometimes controversies remain dormant for years or decades and then burst in a sudden cascade of quarrels. This makes timelines difficult to draw because most events are packed in short periods separated by long empty gaps" (Venturini 2010, p.17)[38]. But these timelines offer renewed possibilities to distinguish 'permanent' stakeholders from intermittent ones. And, when KCE appears in the timeline, it's interesting to position its intervention into a flow of interactions that may have a long history.

Figure 7: Timeline of a KCE project



Working document from KCE Reports 165 "[Burnout among general practitioners: prevention and management]"[42]

2.2.3.9. The table of interpretive frames

"To handle the growing complexity of social life, all actors develop simplified interpretation grids" (Venturini 2010, p.18)[38]. The table of interpretive frames should represent all these differing point of views, showing where they diverge and where they may overlap. An interpretative frame describes for instance how actors express the problem and the solution, and how is their underlying system of values, with its corresponding worldview[43].

Figure 8 : Example of table of interpretive frames of actors involved

Actor	Judgement of solution	Problem definition	Background theories	Normative values
Ministry of Health	No evidence on effectiveness mebeverine; exclude mebeverine from health package	Increasing medicines costs	Decreasing costs of medicines is necessary to prevent other problems (waiting lists); decision model adequate for reimbursement decisions	Only effective medicines at the expense of the community; affordable health care
PAM staff	Affect prescribing practice; a study on the effectiveness useless; preferable, research on therapeutic value of mebeverine versus dietary advice	Unlikely that mebeverine can be excluded from the package	For good policy, it is important to know what is important to physicians and patients; a more social scientific approach might experience resistance, because of internal traditions	Research that is relevant and useful for policy making
Researchers	Research on the efficacy of mebeverine compared to fibers is feasible	Evidence on the efficacy of interventions for IBS patients is lacking; previous studies were methodologically flawed	Standardizing diet is complicated; if there's something in diet that is beneficial then these are fibers; valid research provides relevant information	Research that is valid and feasible
General practitioner 1	Mebeverine is effective in some patients; sometimes because the placebo effect; more attention should be paid to psychiatric or mental causes	Some IBS patients visit physicians frequently; no effective treatment strategies available; counseling and reassurance take a lot of time;	Etiology of IBS is unknown; frequently, patients are anxious for severe illness (malignancies)	A good relationship with the patient

From Moret-Hartman 2007, p.320[43].

2.2.3.10. The forum

Stakeholder identification and analysis may become more than "just observing and describing". Stakeholder meetings used to gather information for this environment scanning may transform into political arenas where relationships between stakeholders or between stakeholders and the KCE are lively and vividly performed. Controversy-websites might also provide a space to perform these public debates.

See the use of Debategraph© to perform public debate around osteopathy in Belgium (chapter Dialogue in case of controversies)

EXAMPLE : DACEHTA stakeholder identification

Stakeholders are defined by DACEHTA as groups which, to a marked degree, have influence on or are influenced by the possible changes in a given HTA. To identify stakeholders, the following questions can be asked during the stakeholder analysis (see below) (Kristensen 2007, p.24)[10] :

- Who is the initiator?
- Who are the users of the results?
- Who has to accept the results?
- Who pays for the work and the results?
- Who is affected: Who benefits/profits/has drawbacks/risks or is inconvenienced by the results?
- Who has the knowledge and resources, or contributes?

The answers to these questions will produce a list of stakeholders comprising both individuals and institutions. It is primarily the project manager who assesses which stakeholders are the most relevant to involve.

Two specific types of stakeholders are identified by DACEHTA which recommends the use of specific methods to involve them (see below).

- stakeholders with obvious opposed interests to the actual project team (we call them "opposed stakeholders");
- stakeholders who – at the completion of the project – will be close to the decision or planning processes and who can assist in implementing the results and recommendations of the HTA (we call them "end stakeholders").

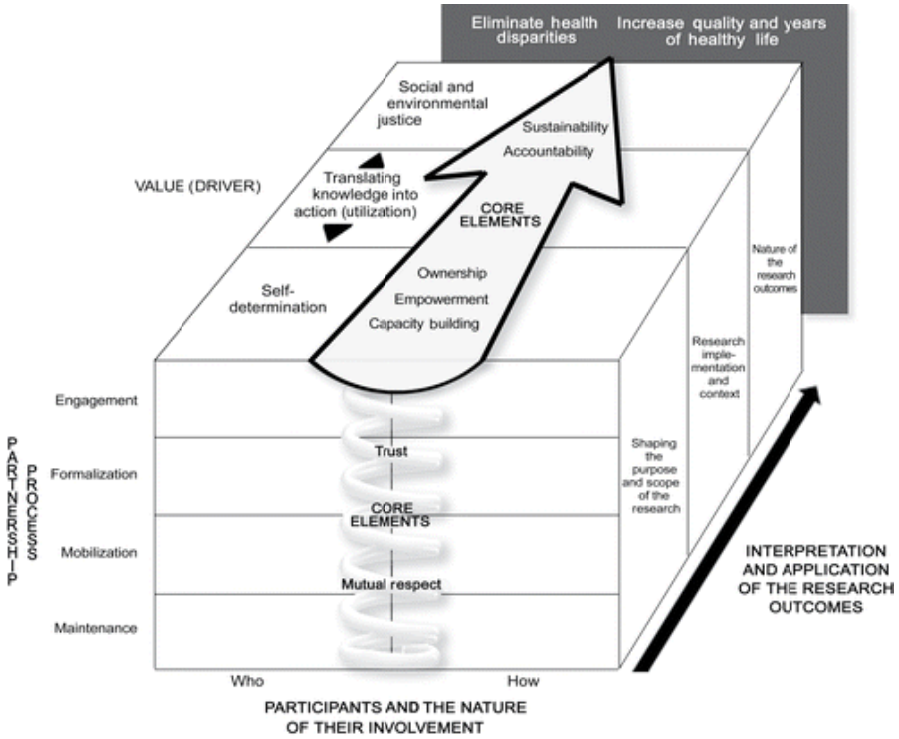
2.3. Communication at an early stage

2.3.1. Analyse the risks and benefits linked to communication

Like identification of stakeholders, communication with stakeholders is a challenge driven by principles of transparency and accountability. In the interactive model of stakeholder involvement, communication is no longer conceived as circulation of messages only, as is the case within rational linear models, but as opportunities to strengthen a network. This could be reached by putting go-betweens 'into circulation'. By go-betweens, the sociology of innovation means everything that circulates between the actors: information, things, money, people and their skills[44]. Go-betweens link up the network actors, they help to rebind and bind. In such a conception, shared knowledge is a go-between that strengthens the network.

But, while transparency and accountability are two core elements of stakeholder involvement, mutual respect and trust are two other core elements in collaborative processes (Cargo 2008, p.336)[45] (see FIGURE 9). And these are highly vulnerable to information disclosure problems, e.g. when sensitive information is disclosed (un-)intentionally by experts or by stakeholders. Literature on participatory research stresses that building mutual respect and trust takes time and patience and, even once established, can never be taken for granted.

Figure 9: Core elements of a partnership process



From Cargo 2008, p.329[45].

Secure your communication

To resolve problems of perceived betrayal linked to information disclosure, other EBM or health-related agencies are using two types of very different solutions, implemented before publication of the report.

2.3.1.1. Public communication

Scientists, industry, professional societies, doctors, and patients have the opportunity to submit comments on IQWiG's or NICE's work at different stages in the projects. In the IQWIG and NICE communication strategies, stakeholders have to give their consent to publication of their comments on these institutions' websites. As a counterpart, each comment must be acknowledged and answered as fully and as factually as possible (see chapter Management of stakeholders' comments).

Box 5: Information disclosure

"*Disclosure is a formal-sounding term for making information accessible to interested and affected parties. Communicating such information in a manner that is understandable to your stakeholders is an important first (and ongoing) step in the process of stakeholder engagement.* ***All other activities, from consultation and informed participation to negotiation and resolution of grievances, will be more constructive if stakeholders [...] have accurate and timely information about the project, its impacts, and any other aspects that may have an effect on them***"

Source: IFC 2007, p.27[7].

2.3.1.2. Confidential communication

In the HAS communication strategy, confidentiality clauses have to be signed by all stakeholders involved in guideline development groups. Information disclosure is prohibited, both before and after the report publication. Participants have the right to mention in the report if they disagree with the final version of the report[46].

In its Guide to the methods of technology appraisal, NICE describes a consultation process where evidence submitted in confidence is invited

from manufacturers and sponsors of the technology or technologies being appraised. Under exceptional circumstances, it is stated that NICE "*will accept unpublished evidence under agreement of confidentiality; for example, if the information is commercially sensitive ('commercial in confidence') or if its use might adversely affect future publication rights ('academic in confidence')*" (NICE 2008, p.22)[47].

2.3.2. Anticipate time-consuming communication activities

A 2004 evaluation of the stakeholder involvement process in NICE indicated that stakeholding activities are now integrated in business plans of all the larger organizations involved in this process. New or existing staff are re-deployed to cope with the workload, and stakeholding is included in their job descriptions (Ilott 2004, p.3)[48]. This means that communication activities may require much more time, even outside dedicated moments such as web-consultation processes or stakeholder meetings.

Personal telephone contacts, personal mail exchanges, off-record information disclosure are not unfrequent. Management of feelings and moods of interlocutors, development of convincing arguments, building of respectful and maybe trustworthy relationships are time-consuming activities. How to deal with it and how much time has to be devoted to these activities, are two questions that should be anticipated. As to "opposed stakeholders", their involvement may be more problematic than with others, as this group is expected to be very labour-intensive and focused (see various options in chapter 2.7. Stakeholder involvement in project monitoring).

> *«These days, it takes me about one hour a day (by e-mail or phone) to pass all the necessary diplomatic steps, this with various explanation. It almost seems like we 'frighten' them [the stakeholders] »*
> *(KCE expert during preparation phase of consultation process, translated from French).*

2.4. Stakeholder consultation all along the project development process

2.4.1. Refer to standards

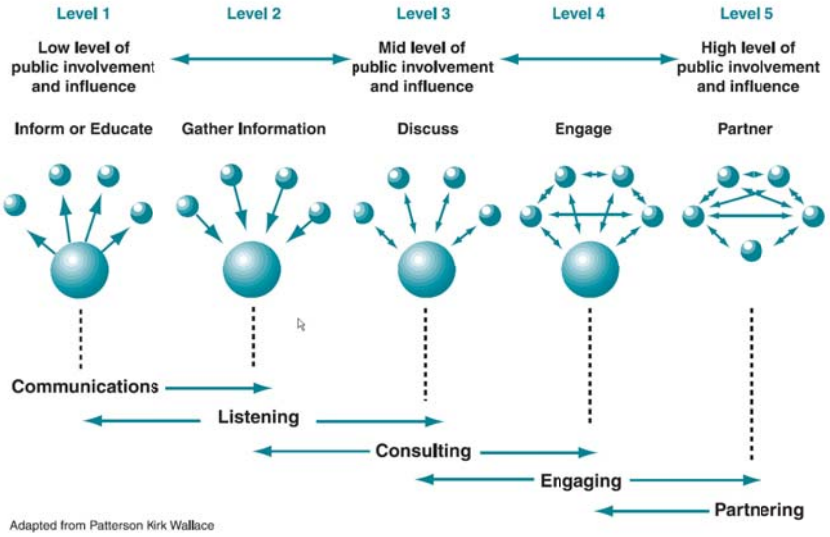
Stakeholder consultation is situated at mid-level on a continuum of decision-making activities, below the partnership level but above the information level (see FIGURE 10). At this consultation level, discussion between stakeholders and experts may occur as stakeholders are invited to do more than give or receive information. Sometimes, discussions may evolve towards a deeper engagement of stakeholders in the project.

Frameworks for assessing the quality of clinical practice guidelines now offer standards to assess the stakeholder involvement process.

In the case of a new guideline development, the AGREE instrument, for instance, is used to check whether the potential biases have been addressed adequately and whether the recommendations are both internally and externally valid, and are feasible for practice (AGREE 2003, p.2)[49]. This means that stakeholders have been correctly consulted and that the process of their involvement may meet these requirements :

- The guideline development group includes individuals from all the relevant professional groups;
- The patients' views and preferences have been sought;
- The target users of the guideline are clearly defined;
- The guideline has been piloted among target users.

Figure 10 : Health Canada's Public Involvement Continuum



From Health Canada 2000, p.12[8]

In the case of guideline adaptation, the ADAPTE instrument is used e.g. to assess acceptability and applicability of the recommendations as found in existing guidelines. This task has to be performed by a panel including key stakeholders. Necessary skills include (ADAPTE 2007, p.6)[50] :

- clinical knowledge in the topic area,
- personal experiential expertise (patient views and preferences),
- policy and administrative expertise,
- methodological expertise in guideline development and critical appraisal,
- information retrieval expertise,
- implementation expertise,
- and managerial and facilitation skills.

Box 6: The ADAPTE assessment of acceptability and applicability of recommendations

Assessing whether a recommendation is acceptable and/or applicable or not is done by discussing each recommendation in the light of the following questions:

- Does the population described for eligibility match the population to which the recommendation is targeted in the local setting (acceptable)?
- Does the intervention meet patient views and preferences in the context of use (acceptable)?
- Are the intervention and/or equipment available in the context of use (applicable)?
- Is the necessary expertise (knowledge and skills) available in the context of use (applicable)?
- Are there any constraints, organisational barriers, legislation, policies, and/or resources in the health care setting of use that would impede the implementation of the recommendation (applicable)?
- Is the recommendation compatible with the culture and values in the setting where it is to be used (acceptable and applicable)?
- Does the benefit to be gained from implementing this recommendation make it worth implementing (acceptable)?

2.4.2. Refine your process

EBM agencies pioneering in stakeholder involvement have produced their own methodological handbooks that are quite similar to standards used in guidelines development (see above). From project scoping meetings to report publication, stakeholder consultation occurs in a limited number of forms along the project development process.

2.4.3. *Choose your method*

The King Baudouin Foundation's Participatory Methods Toolkit has built a step by step procedure to identify the relevant method to choose for consultation. First of all, the following five elements must be taken into account when choosing your method (KBF 2005, p.12-15)[51]:

1. **Objectives**: Reasons for involvement and expected outcomes
2. **Topic**: The nature and scope of the issue
3. **Participants**: Who is affected, interested or can contribute to solutions
4. **Time**: Amount of time available
5. **Budget**: Availability of resources

Then, the objective of the consultation and the nature of the subject impose to answer some questions before evaluating the time and budget needed. These questions about nature and objectives of the project may be asked using a decision tree (see Figure 14). These decisions globally refer to six questions synthesized in The King Baudouin Foundation's Participatory Methods Toolkit (KBF 2005, p.13)[51] and detailed in the table below:

Table 1 : EBM agencies' stakeholder involvement' tasks and group types

Group types	Size	Timespan	Task
Project scoping group	Small, with physical presence	At the beginning	To help framing the project, scoping the research question, choosing the appropriate methodology
Inventory group[g]	Small, with physical presence	At the beginning	To identify a limited set of questions to develop in the project
Development group	Small, with physical presence	All along the project development process	To develop a project or guideline from the selection of a topic to the identification of specific questions
Rating group[46] **;**	Medium, with physical presence and web-consultation	In case of disensus	To formalize the degree of agreement needed to select proposals, guidelines, etc.
Peer-review group[h]	Very large, with web-consultation ("hearings")	Before finalization, once or several times, during 4 to 8 weeks.	To comment scope, report plan, preliminary report or set of guidelines

g See the VIKC methodology in FIGURE 13

h See the NICE and IQWIG flow charts in FIGURES 11 and 12

Table 2: Six questions to identify relevant consultation methods with stakeholder involvement

Motivation	Democratization or advising ?
Targeted output	Mapping out diversity or reaching consensus ?
Knowledge	A lot of common knowledge exists or there is little common knowledge ?
Maturity	Most people have already formed opinions on the subject or the subject is new; people are still forming their opinions ?
Complexity	The topic is highly complex or technical or not very complex nor technical ?
Controversy	The topic is highly controversial or not very controversial ?

From: KBF 2005, p.13 [51]

2.4.3.1. The objective of the consultation

What is your motivation for undertaking this stakeholder consultation?

- "*The purpose of using the method is to enable participants to employ their own knowledge to create options for tackling (policy) issues that directly concern them*" (**democratization**).
- "*The purpose of using the method is to reveal stakeholders' knowledge, values and ideas that are relevant to the process of decision-making*" (**advising**).

What is your targeted output ?

- "*The purpose is to generate a spectrum of options and information and to enable a group to disclose information (making tacit knowledge explicit) or test alternative strategies in a permissive environment*" (**mapping out diversity**).
- "*The purpose is to enable a group to reach a single informed decision on an issue*" (**reaching consensus**).

2.4.3.2. The nature of the subject

Think about the topic or nature of the subject:

- "*To what extent does the society already possess a general knowledge of the subject?*" (**knowledge**)
- "*To what extent has the society already developed opinions or even legislation on the subject ? Do strong views exist or is the issue so emergent that norms have not become established?*" (**maturity**)
- "*Is the subject highly complex, such that a great deal of (technical) information is required?*" (**complexity**)
- "*Is the issue highly controversial and has the debate become polarised, such that consensus is difficult to reach?*" (**controversy**)

2.4.3.3. The approaches

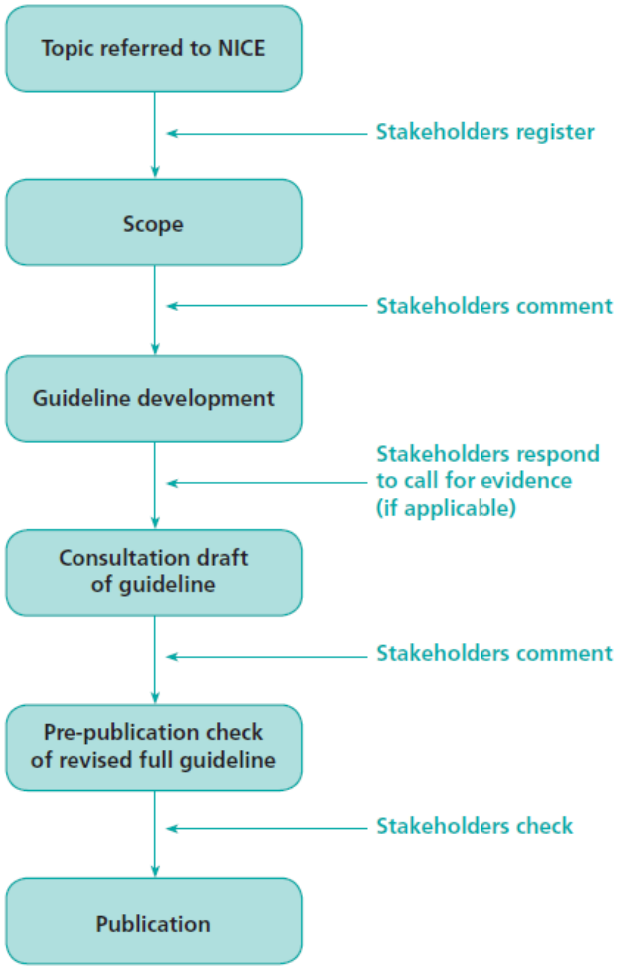
An extended set of consultation approaches with stakeholder involvement is available in the King Baudouin Foundation's Participatory Methods Toolkit [51] and in the Health Canada Policy Toolkit for Public Involvement in Decision Making [8]. Some of these approaches have already been used in KCE projects and may offer good examples.

Table 3 : Consultation approaches and application in KCE projects

APPROACHES	KCE PROJECTS
Participatory Assessment, Monitoring and Evaluation (PAME)	
Scenario Building Exercise	Child Mental Health[39]
Consensus conference	
Deliberative polling	
Search conference	
Study circles	
Study groups	
Think tanks	
Charrette	
Constituent assembly	
Delphi process	Breast cancer screening GP burnout[42]
Retreats	
Round tables	GP burnout[42]
Advisory committee, board/council or planning cell	All reports
Interactive www/e-conferencing	
Online discussion groups/list servers	Alternative Medicines : osteopathy[40]
Televoting or websurvey	Prostate cancer screening[i]
Issue conferences	
Nominal group process	
Workshops	GP burnout[42]

[i] Ongoing project : 2011-01 GCP A national clinical practice guideline on the management of localised prostate cancer

Figure 11: The NICE key stages of clinical development



From NICE 2009, p.10[52]

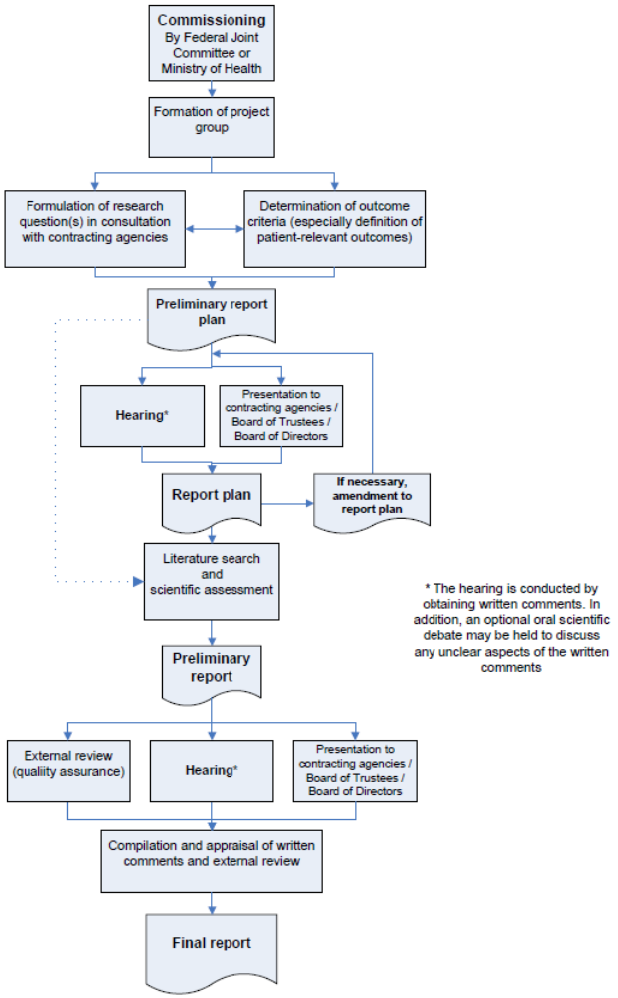
Stakeholder organizations can contribute to and comment on the clinical guideline at various stages during its development. Each stakeholder brings his/her own sectional interests. The multitude of stakeholders increases the potential for conflict. This, combined with the paucity of empirical evidence for many common interventions, adds to the complexity of stakeholder relations for NICE and to the volume of comments for the NCCs to assimilate.

The flow chart below describes the production process of the IQWIG reports and its two hearing moments inviting stakeholders to comment preliminary reports plans or reports and amendments to it. All correctly submitted comments during these hearing moments will be considered and assessed with regard to their relevance to the report. If necessary, the Institute will hold a scientific debate on unclear aspects of the comments submitted in writing. This debate is not public. The participants of the debate are invited personally[53].

In the VIKC methodology, the inventory group selects only controversial questions ("knelpunten analyse"). This inventory group then produces a comprehensive list with needs and sticking points which should be assessed. Recommendations will have to answer a limited set of these questions, selected by web-consultation.

In the KCE Ongoing Project 2011-01 GCP[j], to limit the number of recommendations to be scrutinized by KCE experts, an inventory of 19 potentially problematic recommendations was during one month presented by means of a websurvey to practitioners involved in the care for prostate cancer patients.

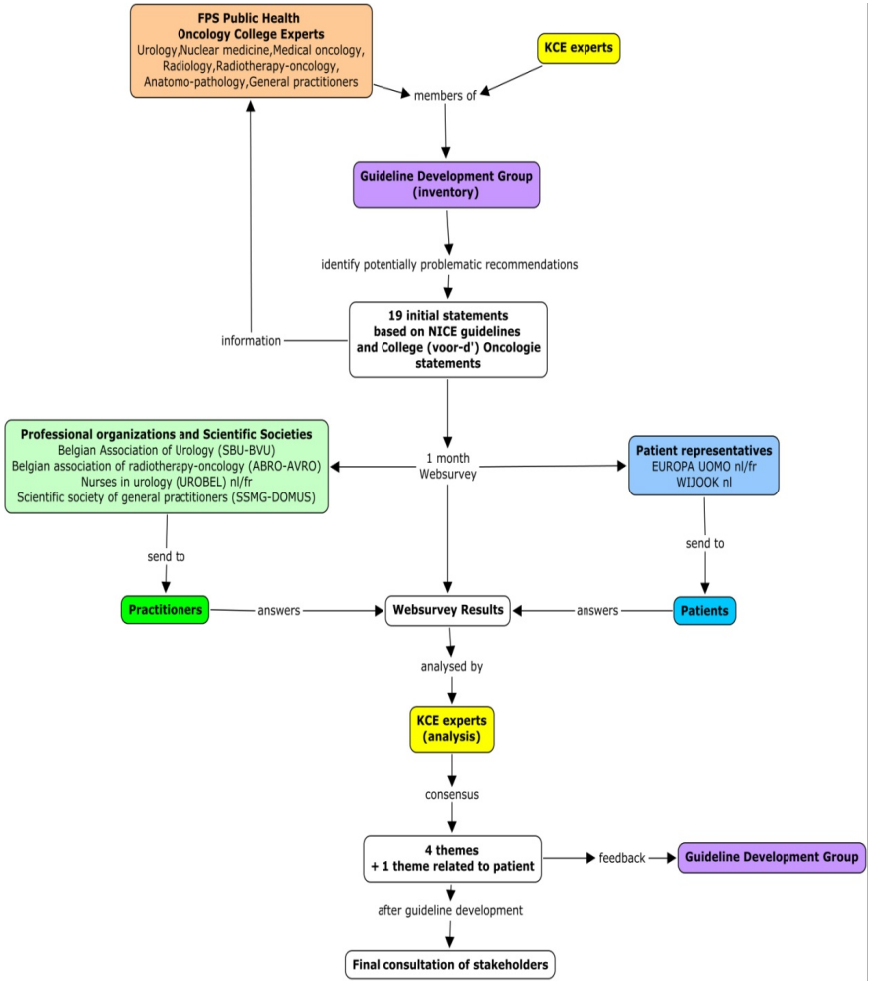
Figure 12: The IQWIG production process of reports



"Flow chart for reports", available on the IQWIG website [54]

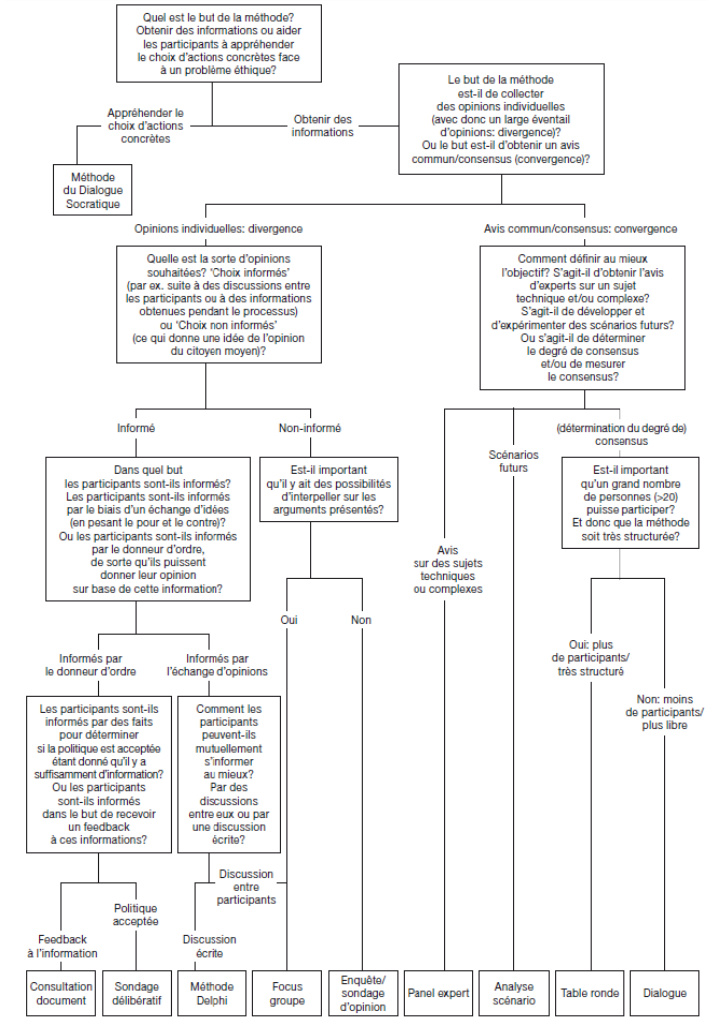
j Ongoing project : 2011-01 GCP A national clinical practice guideline on the management of localised prostate cancer

Figure 13: The VIKC key stages of guideline development used in KCE project on Prostate cancer



Flow chart based on VIKC methodology[55].

Figure 14: The Cock Burning & Honingh decision tree to identify relevant participatory methods



From KBF 2007, p.32[15]

Figure 15: Comparative chart for participatory methods

Method	Objectives	Topic*				Participants	Time		€
		Knowledge	Maturity	Complexity	Controversial		Event	Total	1-4
21st Century Town Meeting	to engage thousands of people at a time (up to 5,000 per meeting) in deliberation about complex public policy issues	+	+/-	+	+/-	Anyone	1-3 days	a year	4
Charrette	Generate consensus among diverse groups of people and form an action plan.	+/-	+/-	-	+/-	Average citizens or stakeholders. Others give input.	1-5 days	2-3 months	3
Citizens Jury	A decision that is representative of average citizens who have been well informed on the issue. Aims	+/-	+/-	+/-	+	12-24 randomly selected citizens. Experts, stake-holders & politicians give input.	3 days	4-5 months	4
Consensus Conference	Consensus and a decision on a controversial topic.	+	+/-	+	+	10-30 randomly selected citizens. Others give input.	3 weekends	7-12 months	4
Deliberative polling[6]	to get both a representative and an informed (deliberative) view of what the public thinks and feels about an important public issue	-	+/-	-	+/-	A random and representative sample of the population	1 day	8 months	4
Delphi	Expose all opinions & options regarding a complex issue.	-	-	+	+/-	Experts	Variable	Variable	1-3
Expert Panel	Synthesise a variety of inputs on a specialised topic and produce recommendations.	-	-	+	+/-	Experts	Variable	Variable	2
Focus Group	Expose different groups' opinions on an issue and why these are held (reasoning).	+/-	-	m	+/-	Stakeholders and/or citizens	2 hours – 1 day	1 month	1
PAME	Evaluating and learning	+/-	+/-	+/-	+/-	All stakeholders	Variable	Variable	Var
Planning Cells	Citizens learn about and choose between multiple options regarding an urgent & important issue. Develop action plan.	+/-	-	m	-	25 average citizens. Experts & stakeholders present positions.	5 days	5 months	4
Scenario building exercise	Planning and preparedness for uncertain future. Vision-building.	-	-	⊩	+/-	Anyone	2-5 days	6 months	1-3
Technology Festival	Provide a means for public debates about societal issues of science and technology	-	-	+/-	+/-	Anyone	1-2 days	6-12 months	4
The World Café	Generating and sharing ideas	+/-	-	-	+/-	Anyone	4 hours – 1 day	1 month	1

Legend: Explanation of chart symbols:

*Topic	+	m = medium	-
Knowledge	A lot of common knowledge exists.		There is little common knowledge.
Maturity	Most people have already formed opinions on the subject.		The subject is new; people are still forming their opinions.
Complexity	Highly complex or technical		Not very complex or technical
Controversial	Highly controversial		Not very controversial

Note: +/- means that the method can address subjects with either + or –.

€ : 1 = inexpensive; 2 = moderate; 3 = expensive; 4 = very expensive

From KBF 2005, p.27 [51]

2.5. Dialogue in controversies

> *"Social cartographers know that issues are always too complicated, subtle and ever-changing to be sliced like Gordian knots." (Venturini 2009, vol1, p.11)*[37]

Stakeholder consultation is only one preliminary step in stakeholder involvement. It helps to establish trust and credibility, to strengthen the network, to nurture a dialogue process and to foster more realistic expectations. A stakeholder dialogue organized after the consultation process will be characterized differently in the business area and in the research area:

- **In the business area**, a dialogue that follows the consultation step is characterized by negotiation (IFC 2007, p.63-68)[7].
- **In the research area**, a dialogue that can be established between experts, decision makers and other actors, aims to critically examine an issue and discuss solutions they judge suitable for addressing the problem (NCCHPP 2010, p.14-15)[56].

2.5.1. Dialogue beyond effectiveness

As stakeholders are actors involved with the objectives and/or implementation of a policy [57], dialogue with stakeholders will not only deal with the effectiveness of public policies but also with their unintended effects, their effects on equity, and mainly with issues related to their implementation (cost, feasibility, and acceptability) (Table 4).

Amongst these dimensions of public policies, acceptability is the most complex one. Moreover, acceptability is a dimension that may be scrutinized but also may be "performed", i.e. judgments and positions about acceptability may evolve during stakeholder dialogue.

Table 4 : Dimensions for analyzing public policies

Effects	**Effectiveness**	What effects does the policy under study have on the targeted problem?
	Unintended effects	What are the unintended effects of the policy?
	Equity	What are the effects on different groups?
Implementation	**Cost**	What are the financial costs of the policy?
	Feasibility	Is the policy technically feasible?
	Acceptability	Do the relevant stakeholders view the policy as acceptable?

From NCCHPP, p.4[56]

Box 7: Acceptability as the most complex dimension of the analysis

First, it involves subjective elements (the judgment of actors).

Secondly, it is influenced by all the other dimensions of the public policy being studied, among other things.

Finally, the acceptability of a policy also depends on factors that are external to it: **the position of each actor** is determined by that actor's **knowledge**, **beliefs**, **values** and **interests** (political, economic, symbolic, etc.).

Examples of Key Questions: Acceptability

- Which actors are or will be affected by the public policy being considered?
- Is the problem the policy aims to address considered to be a social issue that merits intervention?
- Is it on the discussion agenda?
- What are stakeholders' reactions to the idea of intervening to address this problem?
- What type of intervention do stakeholders propose for addressing this issue?
- What do they think of the proposed policy? Of its effectiveness, its unintended effects, its effects on equity, its costs, its feasibility? Of the degree of coercion it involves?
- What do they think of the conditions surrounding the adoption and implementation of this policy?

From NCHPP 2010, p.9-10[56]

2.5.2. Dialogue to produce knowledge synthesis

"Knowledge synthesis is a strategy for combining information from research with information from policymakers and practitioners in a systematic and transparent way in order to promote the use of knowledge" (Bos 2007, p.8)[58].

Recent development in knowledge synthesis attach much importance to these judgments because "these perceptions often carry more importance for political decision makers than objective evidence" (NCCHPP 2010, p.10)[56]. Within the context of knowledge synthesis, **deliberative processes** are set up to enrich and contextualize the data collected by other means (literature, consultation, comments management, etc.). These deliberative processes can fulfil at least three roles (NCCHPP 2010, p.14-15)[56]:

- Combining different forms of "evidence"
- Contextualizing data drawn from the literature on the subject
- Generating new knowledge

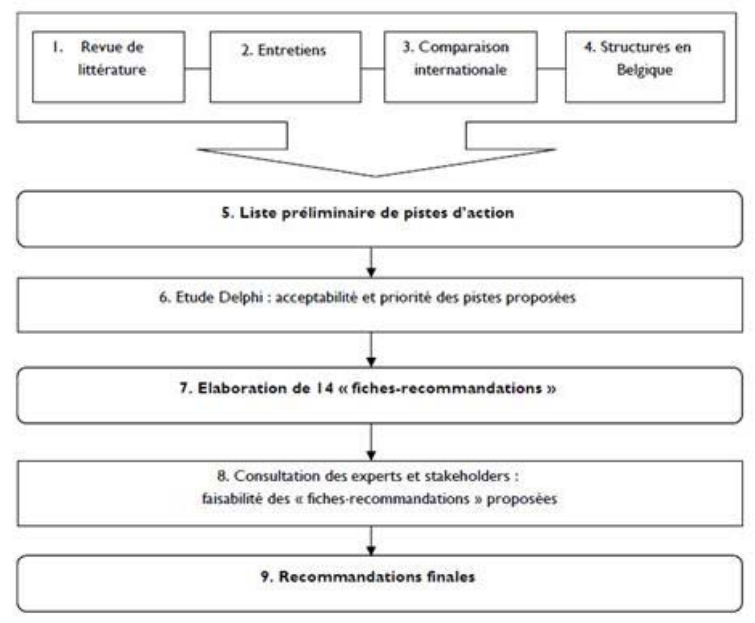
Box 8 : The Deliberative Process – A Snapshot

"*A typical deliberative process exercise involves engaging a relatively small group of participants (somewhere between 10 and 40). These processes have been used to bring together the scientific and decision maker communities but are also relied upon to bring together members of the public, patients and others. Group members, who bring diverse backgrounds, interests and values, meet face-to-face to weigh evidence on a specific issue and to debate potential options. Information pertinent to the issue is usually provided in advance, either through assigned readings before the session or through presentations by relevant experts. Participants are often given the opportunity to challenge the experts and ask further questions before beginning deliberations. In a large group or in small sub-groups, participants then debate the issues amongst themselves, with the goal of developing some formal recommendations, if not a consensus, to inform decision-making. Depending on its structure, a deliberative process exercise can range from one day to three or four days.*"

From CHRSF 2009[59]

EXAMPLE : The deliberative process in KCE project

During one day, stakeholders have deliberated about preliminary recommendations to prevent and treat burnout among the GP's in Belgium.. These preliminary recommendations were proposed by KCE experts and were based on literature review, a study of national and foreign experiences, qualitative interviews with GPs, a Delphi study in two rounds with GPs and stakeholders and expert consultations. During the final workshop with stakeholders, each recommendation was discussed, after which the stakeholders assessed its level of priority, acceptability and feasibility.



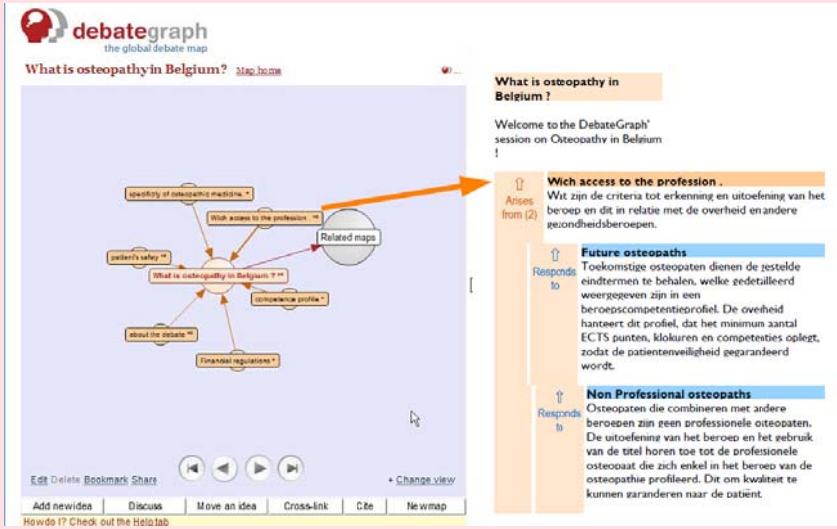
From KCE Reports 165 "[Burnout among general practitioners: prevention and management] "[41]

2.5.3. Dialogue beyond controversies

Besides observing and representing public debates, we may imagine spaces to perform them. Places –it may be digital ones (see example of Debategraph©)- where disputes are collectively elaborated and maybe arranged[k] in co-production activities.

EXAMPLE : Debategraph© used in KCE project

The Debategraph© was used to perform a debate on the web between stakeholders in osteopathic fields. This was intended to produce a two-months debate about issues like specificity of osteopathic medicine, access to profession, patient safety, competence profile and financial regulations. Participants were trained to use this tool.



From KCE Reports 148 "[Ostheopathy and chiropractic: state of affairs in Belgium][40]

[k] As the controversy-websites in the cartography of controversies described in (Venturini 2010, p.18)[38].

2.6. Management of stakeholders' comments

> *"A good process can enhance outcomes and give people satisfaction that their complaints have been heard, even if the outcome is less than optimal" (IFC 2007, p.68)*[7].

2.6.1. Acknowledge comment and respond

As stated in the NICE protocol to manage guidance consultation comments, comments received from stakeholders are a vital part of the quality-assurance and peer-review processes, and it is important that they are addressed appropriately (NICE 2007, p.123)[35]. NICE principles apply when responding to comments on the draft scope and later.

The following key points should be taken into account when responding to comments from stakeholders:

- Each comment must be acknowledged and answered as fully and as factually as possible.
- If changes are made to the guideline as a result of the comment, this must be made clear in the response.
- Responses and changes must be made with the agreement of the whole Guideline Development Group before publication.

IQWIG has also developed specific guidelines on the submission of comments during "Hearing" moments[13] (see example).

In these two guidelines and in the IFC good practice handbook, several elements in the management of stakeholders' comments have to be considered:

- transparency of the process
- publication rules
- accessibility to comment process
- response time
- good records and feed-back

EXAMPLE : The IQWIG management of stakeholders' comments

It is mentioned in IQWIG guidelines on the submission of comments that:

- the person(s) submitting comments explicitly give(s) their consent to publication on the IQWIG website;
- all authors of comments should complete a form for disclosure of potential conflicts of interest. The connections disclosed will be summarized in the documentation of comments and published.;
- the deadline is 4 weeks after publication;
- the procedure regarding the submission of comments will be described in a separate document published simultaneously with the revised report plan. Comments fulfilling the formal criteria, as well as the meeting minutes of the scientific debate, will be published. Previously unpublished documents attached to comments as evidence will also be published.

From IQWIG 2007[53]

EXAMPLE : Examples of responses to stakeholder comments received on the NICE guideline for schizophrenia

Type of comment	Example response
Compliments about the guideline	• Thank you for your comments.
Specific change was recommended and has subsequently been made.	• 4.4.5.2 sentence added. • 5.1.1 Electronics medicines compendium website added. • All corrections listed have been made.
A specific change was recommended and has subsequently been partially made.	• Noted - partially amended. • This is a NICE technology appraisal recommendation and cannot be changed. However, we have included occupational assessment in 1.1.1.1 of the short form, 2.8 in the long form.
A specific change was recommended and has subsequently NOT been made.	• The GDG is satisfied with the revised and prioritised audit criteria as they now stand, following consultation and appended to the long form. There is a balance between that which could be audited and services' capacity to do so. • We are seeking here to clarify terminology, and not to comment on mechanisms, which will not be addressed in the guideline.
Asks for something that is outside the scope of the guideline.	• Thank you for drawing attention to this. We have noted your comments, but some aspects, e.g. diagnosis, remain outside the scope of the guideline. • This is very interesting and worth pursuing. However, as physical exercise is outside the scope of this guideline we are unable to make such a research recommendation. • Outside the scope of the guideline, and is currently covered by Mental Health Act legislation and guidance.

From NICE 2007, p.81[35]

2.6.2. Use forms and forums

Web-based procedures of stakeholder comments management (as NICE or IQWIG procedures) propose **forms** to collect assessment information in a standardized way. As specified in the NICE guideline (NICE 2009, p.80)[35], all comments received by NICE are entered into a comments table in a Word file, which is sent to the National Collaborating Centre to elicit responses from the Guideline Development Group. The table contains the following information.

- Organisation – name of organisation that submitted the comments.
- Chapter/section – depending on the document that has been sent for consultation. This column can be sorted by the developers to facilitate the identification of comments by section.
- Comments – comments received from stakeholders, entered unchanged.
- Responses – blank column for the developers to complete.

In addition, literature on the efficacy of interaction approaches in research utilization highlights the importance of face-to-face contact and interaction through **forums** aimed to facilitate interpretation of research results[5]. In such a way, the ADAPTE methodology proposes a **form** when the panel has to assess acceptability and applicability of the recommendations collected in multiple existing guidelines; and a **forum** where results are fed back to the panel to be discussed. Discussion about comments is also planned in the IQWIG process after "hearing" moments where an oral scientific debate may be held to discuss any unclear aspects of the written comments.

2.7. Stakeholder involvement in project monitoring

We may talk about stakeholder involvement in project monitoring when stakeholders are involved throughout the entire process of a research project[I] :

1. shaping the purpose and scope of the research,
2. implementing the research and considering contextual factors,
3. and interpreting and applying the research outcomes.

At this level of involvement, the "bridging dynamic interdependency" used to define stakeholder involvement in the economic area (in the first chapter of this report) becomes a lively notion in the research area. As figured in theoretical models, this is the highest level of involvement which corresponds to level 5 in the Health Canada's Public Involvement Continuum (see Figure 10).

2.7.1. Consider added-values to involve stakeholders in project monitoring

At such a level of stakeholder involvement, a research project has to be compared to participatory research. "Participatory research" (PR) may be used "as an umbrella term for a school of approaches that share a core philosophy of inclusivity and of recognizing the value of engaging in the research process (rather than including them only as subjects of the research) those who are intended to be the beneficiaries, users, and stakeholders of the research" (Cargo 2008, p.326)[45].

The added value of stakeholder involvement throughout the entire process of a research project could be summarized in table 5 that is based on a critical review of the PR literature. (Cargo 2008 ,p.338-339)[45]

I Phases described in Cargo 2008, p.337[45].

Table 5: The potential added value of participatory research approaches across the three phases of the participatory research process

Level of stakeholder involvement	Potential added value
Shaping the scope and purpose of the research	• Enhanced relevance and importance of research questions to the organization, community, or public health system • Research is responsive to the community of interest • Initiation of ownership, empowerment, and capacity building through active participation in the research
Research implementation and context	Contextual advantage: • Research is less disruptive to implementing contexts • Enhanced credibility for other activities due to participation in PR projects • Linkage of study participants with needed health care resources by treating research as awareness building • Ethical agreements negotiated with academic partners address concerns of the community of interest Capacity, empowerment and ownership: • More targeted and efficient planning and problem solving • Strengthened sense of ownership through active participation in research activities • Increased capacity of non academic partners to do PR • Acquisition of specialized research knowledge, skills, and experience • Economic development through employment opportunities and local resource utilization • Acquisition of management and leadership skills • Development of decision-making skills

Level of stakeholder involvement	Potential added value
Interpretation and application of the research outcomes	Capacity, empowerment, and ownership: • Timely feedback of research results to non academic partners and the community of interest • Enhanced capacity, empowerment, and ownership from participating in research dissemination and translation • Enhanced understanding of health problems, their root causes, and solutions can galvanize people to act • Increased capacity for health promotion • Enhanced media and educational capabilities Instrumental use of scientific knowledge: • Enhanced cultural and contextual relevance of developed interventions, program planning, and action • Creation of inventories, training manuals, and handbooks to inform practice • Improved formulation of policy recommendations and policy changes Participation: • Potential for higher intervention participation rates when end users are involved in intervention development Sustaining the partnership and research products: • More effective applications for funding and leveraging of resources due to established credibility and capacity • Augmented intersectoral mobilization of leaders, volunteers, agencies, institutions, and businesses catalyzed by participation in PR • Improved linkages among community-, state-, and federal-level agencies

From Cargo 2008, p.338-339[45]

2.7.2. Consider the way to deal with controversy

"Being attentive to all viewpoints does not mean granting everyone the same status" (Venturini 2010, p.4)[38.]

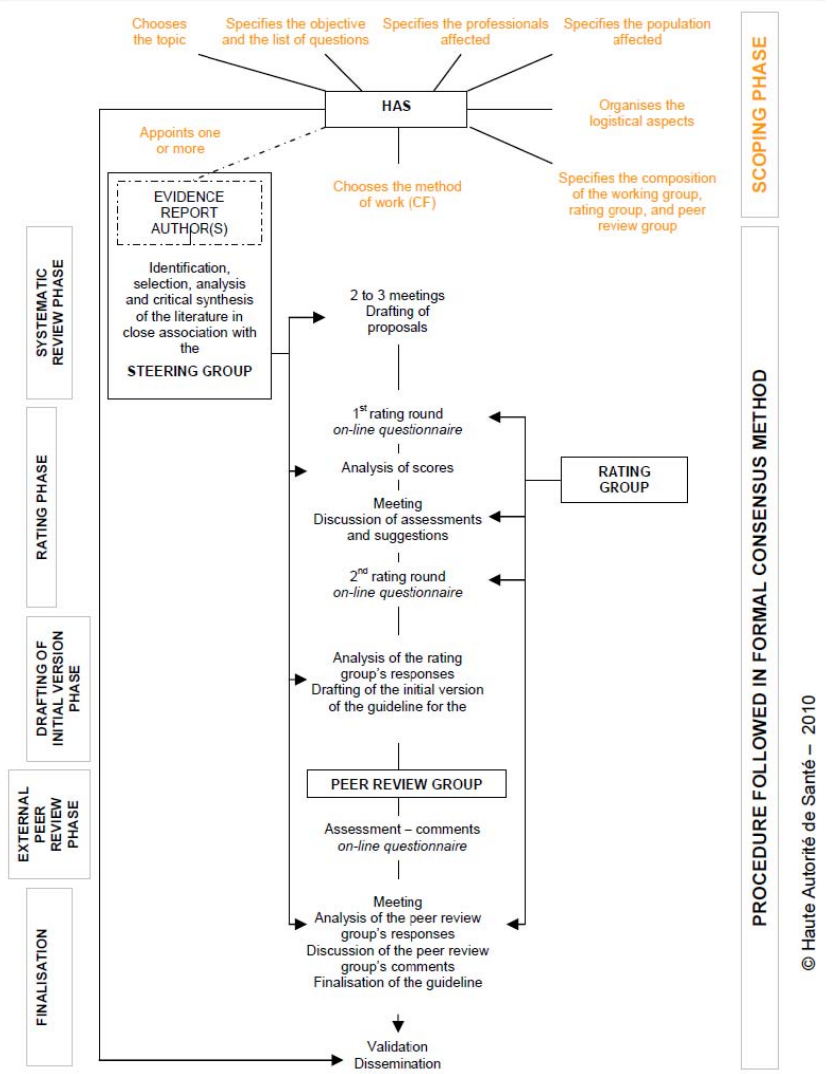
Stakeholder involvement in project monitoring has never been found in EBM agencies' processes scrutinized for this report. Although stakeholder involvement may be performed at an early stage of the project and throughout the entire process of project development (see the first chapter), involvement is usually limited to consultation, i.e. checks and comments (See the HAS figure).

Yet, the stakeholder involvement level may vary depending on the way EBM agencies have chosen to deal with controversy[m]

- either by limiting their mission to identify the matters of fact that meet everyone's agreement;
- or by extending their mission to reveal the full range of oppositions around matters of concern and by choosing to deal with these matters of concern.

Agencies pioneering in stakeholder involvement enlarge their mission to reveal matters of concern (stakeholder interests, anticipation of possible consequences, …) beyond matters of fact (literature evidences). But the way they deal with these matters of concern may differ extremely. In case of controversy, the core philosophy of inclusion that is at the heart of the highest levels of involvement may be weakened by exclusion procedures (see examples).

Figure 16: HAS procedure followed in formal consensus method



From HAS 2010, p.4[46].

m A distinction made by Bruno Latour between the positivistic 'first-degree' objectivity and the second-degree objectivity (Venturini 2010, p.3)[38]

2.8. Regular feed-back to stakeholders

A follow-through principle has to be applied in stakeholder involvement to keep **accountability** at its highest level. As already stressed in the chapter on "communication at an early stage", stakeholder involvement will be more constructive if stakeholders […] have accurate and timely information about the project, its impacts, and any other aspects that may have an effect on them.

2.8.1. Plan your communication

Determine at an early stage of the project (IFC 2007, p.88)[7]:

- what information needs to be reported,
- to which stakeholders,
- by what method,
- and how frequently.

2.8.2. Display relevant information

International standards in stakeholder engagement in the economic area recommend to brief stakeholders with relevant information. Translated into the research area, this relevant information should address (AccountAbility 2008, p.37)[60] :

- the purpose and scope of the stakeholder involvement;
- the nature of the research questions;
- how these questions are currently managed within the EBM agency;
- what policies and services are already in place;
- what the EBM agency can and wants to do about these research questions.

2.8.3. Adapt your feed-back to the level of stakeholder involvement

Information relevancy also depends on the level of stakeholder involvement:

- **for interested stakeholders**, information on the **stakeholder involvement process** as a whole has to be displayed to encourage involvement (IFC 2007, p.88)[7];
- **for consulted stakeholders**, appropriate acknowledgment and **responses** to their comment is needed to sustain involvement (see chapter Management of stakeholders' comments);
- **for main stakeholders** being represented in the project monitoring, a sufficient level of **details** is required to sustain feeling of co-responsibility;
- **for end stakeholders**, information about the **project development process** is needed to make sure that they understand that there is a need for the results, so that they expect them and will make use of them[n].

2.8.4. Use electronic media and meetings

Electronic media are widely used to collect comments and to give feedback information on the project development process to large numbers of stakeholder. EUnetHTA has put a *Stakeholder Open Forum* page on its website, to give stakeholders targeted information about developments in EUnetHTA and establish a platform for virtual communication (Nielsen 2009, p.88)[14]. NICE and IQWIG have both an information service having as a task to send to all interested parties information on new projects, current publications and new commissions advertised.

Stakeholder meetings, **one-to-one meetings**, **follow-up telephone briefings** are other means recommended to give consistent feedback to stakeholders (AccountAbility 2008, p.41)[60].

2.8.5. Give regular feed-back

Regularity of feed-back is fundamental in IQWIG, NICE and HAS report production processes (see figures). To maintain **transparency** by providing clear and ongoing communications is a clearly stated objective. It also corresponds to stakeholders' needs[o]. As underlined in the

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[n] Following the definition of DACEHTA, "end stakeholders" are those stakeholders who – at the completion of the project – will be close to the decision or planning processes and who can assist in implementing the results and recommendations (Kristensen 2007, p.25)[10].

[o] This was one result of the CCOHTA stakeholders consultations about its new program COMPUS[61].

EUNETHTA stakeholder involvement policy, “transparent processes may be the only way to “prove” that no interests were inappropriately favored” (Nielsen 2009, p.86)[14].

In participatory research, regular feedback is considered as a *maintenance* activity, the challenges of which are to maintain trust and respect to foster **sustainability** (Cargo 2008, p.334)[45]. “[…] considering sustainability in the design of participatory efforts can enhance the likelihood that the partnership will continue and that research results will be translated into action and institutionalized” (Cargo 2008, p.337)[45].

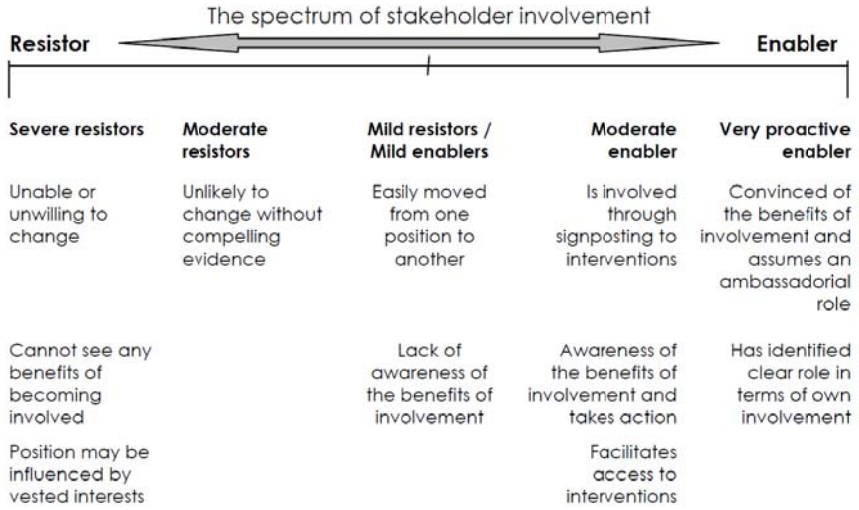
2.9. Skills to manage the process of stakeholder involvement

How to play a significant role in a stakeholder involvement process ? Positive and proactive attitudes in stakeholder involvement are not guaranteed, neither by stakeholders, nor by experts. Resistors and enablers are found both sides, due to vested interests, interest in keeping a status quo, failure to recognize the potential of stakeholder involvement and many other reasons (Griffiths 2007, p.20)[62]. The spectrum of **attitudes** towards stakeholder involvement is very large :

- from **resistors** who don’t even create opportunities for multistakeholder working
- to **enablers** who have identified a clear role for themselves in terms of involvement (see FIGURE 18).

Attitudes, behaviours and rationales may evolve with experience. Skills are needed to overcome the barrier of inability.

Figure 17: The enablers/resistors spectrum



From Griffiths 2008, p.20[62]

2.9.1. Be trustworthy and respectful

Trust and mutual respect are the core elements of any participatory research (see figure in chapter Communication at an early stage)[45]. These elements have to be established and maintained throughout the process of stakeholder involvement. This can be time-consuming, especially at the beginning of the study. “Taking the time to become familiar with and understand the context, the people, their culture, and priorities cannot be sidestepped without compromising the fragile foundations of mutual trust and respect, which, if violated, can hamper methodological quality” (Cargo 2007, p.335)[45].

DACEHTA stresses that constructive meetings and, ultimately, a good outcome require good cooperative **behaviour** with trust and high work ethics among the project participants (Kristensen 2007, p.27)[10]. Good project management skills are required (see BOX 9).

Box 9: DACEHTA recommendations to create the basis for a good and rewarding cooperation

It is important initially to agree on:

- Problem formulation and delineation – what is the main question (the policy question) and what do we want to study?
- Clarification of the alternatives to be studied
- information search strategy – what is available and how is its evidence?
- Establishment of time schedule/meeting plan for the project period
- Planning of the work phase – who does what and when?
- Planning of the completion – how, in which form and to whom are the results to be presented?
- Planning of the implementation – if changes are to take place, then, how do we do it?
- Strategy regarding follow-up and problem solving of derived questions

From Kristensen 2007, p.27[10]

2.9.2. Be involved

Why should any potential stakeholder wish to become involved ? The **rationales** for stakeholder involvement are multiple and probably mixed (see Table).

Table 6: Rationale for stakeholder involvement

Altruism	we get involved because we believe it is the right thing to do irrespective of cost
Investment	we get involved because we perceive that there will be a return on our investment
Compulsion	we get involved because we have been told we have to
Lost opportunity	we get involved because the potential benefits are so great that we cannot afford not to, or that our competitors are doing it, thus we must do the same to maintain our position

From Griffiths 2007, p.9[62]

These rationales may be found in a similar manner within expert/researcher groups. But we have to take into account specific questions, issues and challenges when talking about researcher involvement[2]:

- the degree of independence researchers can secure is a question,
- the politicization of research is an issue,
- the establishment of different relationships between research and policy is a challenge.

To answer these questions, solve these issues and win these challenges, EBM agencies pioneering in stakeholder involvement are using several means :

- clearly stated rules in standards, guides, protocols or handbooks;
- publication of good practices or lessons learned;
- research (collaboration) dedicated to stakeholder involvement (as in EUnetHTA Project WP6).

2.9.3. Be expert

To support stakeholder involvement requires more expertise. Throughout this report, specific **skills** have been overviewed for each of the key components of stakeholder involvement. These skills are summarized below :

- to recognize that research evidence may not arrive as simple “facts” to be weighed up in making policy decisions (see introductory chapter);
- to take into account a lot of new connections by maintaining openness and perplexity (see chapter Stakeholder identification and analysis);
- to overcome inherent problems of betrayal in translation process (*traditore=traditere*) (in chapter Communication at an early stage);
- to accept physical presence of stakeholders without any screen filter (in chapter Stakeholder consultation all along the project development process);
- to review one’s own judgments and positions during stakeholder dialogue (in chapter Dialogue in controversies);
- to hear, acknowledge and manage stakeholders' comments, critiques and queries (in chapter Management of stakeholder's comments);
- to maintain a good power balance, even in controversy (in chapter Stakeholder involvement in project monitoring);
- to develop an interesting study to keep stakeholders’ interest (and experts’ interest) at its highest level (in chapter Regular feed-back to stakeholder).

These skills can be improved by experience or training.

2.10. guiding principles

How can research inform public services ? To answer this practical question regarding evidence-based policy, Nutley and al. have summarized a range of guiding principles (see BOX 10). These guiding principles, that contribute to the likelihood of evidence-based practice, are the backbone of the first part of this report presenting the key components of stakeholder involvement.

Box 10: Some guiding principles to support the use of research in practice

- Research must be translated
- Ownership is key
- The need for enthusiasts
- Conduct a contextual analysis
- Ensure credibility
- Provide leadership
- Give adequate support
- Develop integration

From Nutley 2008, p.312[2]

3. CONSULTATION ROUND OF KCE EXPERTS

3.1. Rationale and objectives

Before embarking into new and more formalised stakeholder involvement procedures, the management of KCE wanted to get a better insight in the prevailing opinions and attitudes of the KCE researchers, and to offer them the opportunity to contribute ideas and suggestions on how to best integrate stakeholder involvement in the research processes. More specifically, the researchers were also polled about their resistances and fears, and asked to share their own positive and negative experiences. Incidentally, the very exercise itself was a tangible instance of stakeholder involvement, since the KCE experts will be the first ones to be affected in their daily work by whatever decision to change our stakeholder involvement policy as an organisation.

The ultimate objective of this consultation round is to make the KCE approach in matters of stakeholder involvement more effective, by tapping into the own collective knowledge and experience, by identifying the potential internal barriers and threats and by taking the appropriate measures or adapt the stakeholder involvement procedures accordingly.

3.2. Method

The format chosen for this consultation round was discussion groups to allow for each participant to express him or herself, and for a lively exchange between participants, so as to bring up in the discussion shared viewpoints and opinions, and clarify them in a dialectic way. In order to allow every single KCE researcher to optimally participate and contribute, we opted for a series of discussion groups with max 8 participants each. The meetings took place in the last half of October and the first half of November 2011.

In preparation of the discussion groups, a list of questions to be dealt with was drawn up, after several discussion sessions with the KCE management and project team. (see BOX 11).

Box 11: List of questions for the consultation round of KCE experts

Question 1 – WHO?

- What are the different types of stakeholders : Providers , Public Authorities, Payers, Private Industry, Patients-Citizens + Media and Academia?
- What is your knowledge of / experience with these different stakeholders?
- What do you think about the involvement of these different stakeholders?
- Do you have fears about the involvement of some of them? Which ones and why?
- Do you have any suggestions to improve your capacity to manage the relations and processes connected with these?

Question 2 - HOW?

- Many different types of methods are mentioned in the document. What is your knowledge of and experience with these different methods?
- Which ones seem more useful to you? Advantages and disadvantages?
- These methods require some specific skills. Which ones seem particularly problematic to you? Why?
- Who must invest in these methods? Internal specialization and/or externalization?
- Is training or support necessary? Your suggestions?

- Question 3 – WHY?
- The reports produced by KCE cover three fields - HTA, HSR, and GCP - and a large spectrum of subjects inside these fields. What's your opinion about the stakeholder's involvement for the different subjects? Is it relevant for all types of subjects or must be limited to some of them?
- Why? No added value? Too dangerous? Risk for independency? Timing? Human resources available ... Any suggestions?

Question 4 – DIMENSIONS OF INVOLVEMENT

- Different dimensions of involvement are described in the document (see chapter 4). What are your opinions/suggestions about these dimensions?

Question 5 – OTHER SUGGESTIONS AND REMARKS.

The participants were asked to read a draft version of chapter 4 of this report in preparation to the discussion.

The moderator of the discussion was an external consultant with a prior knowledge of the KCE and the 'environment' in which it operates. The role of observer and note taker was given to the KCE knowledge manager , All sessions were tape recorded, and had a duration of 2 hours.

At the beginning of the session, the objectives of the discussion group were briefly reminded to the participants, the rules of the exercise were explained and consent was asked about the tape recording. Confidentiality was guaranteed, in the sense that the reporting and publication of the results would contain no names or other recognisable details pertaining to individual participants.

After each session, there was a short debriefing of the moderator and observer. The moderator drafted detailed minutes of each session, through in depth listening to the recordings, complemented by the notes of the observer. No full transcripts were made.

Finally, the four session minutes were synthesised in a final overall report, listing all key messages coming from the discussion groups.

3.3. Results

The groups discussions resulted in several messages. The way they express them is sometimes different from group to group, but conceptually, the key points are the same. Examples are given to illustrate the messages, but only selected examples are included if the content of the messages are similar. The provided examples are as truthful as possible translations of the original messages (expressed in Dutch or French).

Messages have been grouped in 4 categories with SWOT (Strength, Weaknesses, Opportunities and Treats) approach in mind. Messages 3, 4, 7, 9, 14, 15, 16, 19 were expressed only by one group and often by one person inside this group, but without contradiction by the other members of the group. Other messages were expressed in 2 to 3 groups (5, 11, 17), or in the four groups (1, 2, 6, 8, 10, 12, 13, 18).

3.3.1. Lessons learned

Message 1. Stakeholder involvement is a long standing practice

The four groups expressed the same opinion: stakeholders' involvement is not new for KCE. KCE has already much experience of stakeholders' involvement. Several examples were provided during the discussions to illustrate methods or report some lessons learned.

A grid has been elaborated to present the different approaches in a practical way, this grid will be used in the forthcoming process note. Appendix provides grids build on the examples provided during the discussions.

Message 2. Board's involvement is not optimal

The KCE board has representatives of the main stakeholders groups, except for a direct representation of the patients. It is perceived as one way to automatically get some form of stakeholder involvement at the end phase of the projects. Yet, the interference of the board with the policy recommendations is not without stirring some disquietude.

"The most important group of stakeholders is the KCE board where all the decision makers are present. They have the opportunity to comment or to reject recommendations and to think about their implementation."

"The step between the conclusion of a study and the recommendations is not easy – This is a difficult issue."

"How to improve this? It is complex; some reports are not accepted. Some recommendations are so much reduced that they become ridiculous. Sometimes we are disappointed ourselves by the recommendations."

Message 3: Involvement of communities

Some collaborators stressed the importance to involve other levels of decision making

"The Communities and Regions are not represented in the board of directors. They should be acknowledged and involved from the beginning of the projects. They have more and more competencies."

Message 4: To be understood by

"To be understood by the other ones is crucial ..."

"Be understood by is a missing dimension in the dimensions of involvement. This is important."

Message 59: Distinction between stakeholders and experts

The experience with so-called expert meetings at KCE is that more often as not experts tend also to be stakeholders to a varying degree. This is regularly perceived as rather uncomfortable or disturbing.

"The problem is to make a distinction between stakeholders and experts. The best way should be to organize separate meetings between experts and stakeholders. But it is difficult in practice. The stakeholders are often the experts for some topics."

"The objectives of expert meetings and stakeholder meetings are different. It is important to define exactly the objectives: experience, knowledge ... and to think about the expectations generated by these meetings."

3.3.2. Requests

Message 6. Independence is a priority

The concern about the risk of losing one's independence was very frequently expressed, in a variety of different ways. The stakeholders should at least understand clearly that we are prepared to interact with them, but not to subjugate ourselves to their opinions.

"Independence must be a priority."

"We must be cautious that recommendations are not oriented by the stakeholders. The recommendations must not change if the stakeholders don't agree. The recommendations must always have a scientific background."

"We must be very clear from the beginning about the rules of the game. It is necessary to announce very clearly that we will not take their opinions as such."

"We should reinforce this perception of independence amongst all stakeholders."

"How is it possible to stay independent? And how is it possible to be perceived as independent?"

Message 7: Clear distinction to include in the report

The KCE researchers are excluding by all means that the opinions of stakeholders would be taken over in the conclusions by a 'democratic' mechanism of one sort or another. Hence, they stress the importance to clearly earmark any input from stakeholders and distinguish it from the scientific findings proper.

"It is probably necessary to make a clear distinction in the report between what's coming from the scientific literature and what's coming from other meetings or inputs. The different parts, opinions and contributions must be clearly identified. The distinction between scientific aspect and meetings is important."

Message 8 : Training is necessary

The researchers feel they lack appropriate training to engage in new forms of stakeholder involvement without adequate training.

"For smaller groups, it would be useful to be trained for specific skills: how to manage the meeting, how to give the floor, to boost

a debate (...) Sometimes we don't dare when the participants are important persons. It is missing and would be useful." "This is important, so as to avoid that some individual experts dominate the group and that the patients for instance don't dare to speak."

"To apply the right method for the right topic, training is needed."

This perceived need of training not only pertains to the technical skills for actually conducting interviews, meetings, etc…, but also to the ability to deal with the interpersonal, relational and psychological aspects characterising this type of interactions.

"Involvement generates emotions. A training to manage these emotions, to respect the other ones and to conduct the process would be important. As of yet, we are not yet ready for this. We first need to acquire new competences."

Finally, according to the KCE researchers, also the stakeholders themselves would benefit from some sort of training

"The stakeholders don't have the scientific background necessary for all the projects. If we want to involve them at all levels, we need to train them."

Message 9: Evaluation of impact is necessary

Insofar as the primary reason to invest in stakeholder involvement is to increase the impact of the KCE work, the researchers express the need to evaluate its effect.

"Evaluation of the impact is important: we should stop if the expected impact is not there."

"The target of the stakeholder's involvement is to increase the impact. This way of improving the impact will have to be compared with other methods. Is it the best approach?"

Message 10. A knowledge base of stakeholders would be useful

"It is very difficult to identify the stakeholders. It would be useful to have a tool, a database to identify the associations by topic. This database must be up-to-date."

"Not an exhaustive database but just the experiences we have, the contacts..."

Such a database could also help to "avoid that the same persons are too often solicited during the same period."

3.3.3. Possible avenues

Message 11: Motivations of Stakeholders' involvement

Although the researchers identify a range of different reasons to engage stakeholders, the discussions also reveal that they seldom acknowledge the whole span of possible objectives and motivations, but rather tend to focus on one or two goals.

"Why to involve? Is it more to install a democratic process or to formulate an advice? What do we want to reach with this stakeholder's involvement? Do we want that everybody agrees with the questions or the methodology?"

"The ultimate target of the management is to increase the impact of the KCE."

"Do we want to increase the appropriation by the citizens? If it is the case we must find new tools."

Message 12: Involvement is always important but must be adapted to each project

"It is necessary to involve the stakeholders in every single study. But we will not involve them in each step, nor with the same intensity. It will be different and specific from study to study."

"Involvement is not monolithic. The involvement at the end of the project for the recommendations is quite different from an involvement to define the research questions. The results and the perception of independence will be variable."

"Involvement will be different from project to project. We must be sure to answer to the needs. It depends of the available evidence, type of subject, type of research, type of question ..."

The researchers acknowledge that the needs may vary along the different steps of a study.

"The involvement of stakeholders is important at the beginning of the research, at the end to communicate the conclusions and in the post-publication phase."

Message 13: Involvement is possible until implementation and partnership

Involvement is perceived to be both important and possible at different levels of intensity, up to the level of co-creation and partnership

> " 'Discuss with' *is the minimum level, and then, project by project, we should analyse if we go further."*
>
> *"The scientific character of our work is priority, but we have to be pragmatic: it must be implemented. We accept to be influenced by all the stakeholders around the table ... why not to see and analyse the reaction on the floor: this would allow to include new aspects coming from the floor into our recommendations. If we want to implement new guidelines this is relevant and important."*
>
> *"We must show them that we are ready to think with them about implementation. We have to plan time to do this, but the questions must come from them. We must show that we are ready to help them."*
>
> *"This is an internal decision of the management. We have an example of a study in two parts. First part of the study: the literature gives only a few conclusions and the results from other countries are bad. Second part: the stakeholders are involved as true partners to define the reform." "This must be transparent and decided before. Only this way, they are true partners to define the reforms."*

Message 14: Key values are crucial

When stressing the importance of our key values, the researchers primarily mean that they expect to be respected in their own values of objectivity and independence. They are willing to respect the stakeholders and their viewpoints only if this respect is reciprocal.

> *"If these key values are not respected the stakeholders must be rejected. This respect of values is also important for KCE: this is a mutual respect of key values."*

Message 15: Steering committee

> *"It would be useful to set up a steering committee for each project. This steering committee would gather at the different stages. We could use this group to identify the societal trends of the society, validate the methodology, the recommendations..."*

Message 16: Involvement of EMA and citizens' panels

Some collaborators stressed the importance to also involve levels of decision making above the Belgian federal structures (EU commission, European Medicines Agency) ; and a fixed panel of five to ten citizens is suggested.

> *"We should involve people from European Medicines Agency."*
>
> *"This group could be used for all projects where the citizens' involvement is important. They can acquire a fairly good knowledge of the methodologies and the way of working. They could be paid through attendance fees."*

3.3.4. Treats

Message 17: Timing is an obstacle

There is a widespread concern that adding more thorough interactions with stakeholders will cost a substantial amount of extra time. Conversely, the researchers ask to acknowledge this extra workload in the planning of the projects.

> *"The problem with these methods is the time they take. It is not possible to use these methods if we don't have enough time, e.g. at the end of the project".*
>
> *"The choices are often dictated by the time that is available, but we must change this way of working. We must plan what's necessary and then request the necessary budget."*

Message 18: Patients' involvement is the most difficult

Although patients are invariably seen as a central stakeholder group, there is very little, if any, experience with this group at KCE, and their involvement is perceived as particularly difficult to implement for several reasons. There are issues of representativity, of perceived lack of objectivity, of feasibility…

> *"I think that the patients are the most important stakeholders. It is very difficult to involve the patients and to work scientifically with them. It is an important challenge to imply them efficiently."*

"The most difficult ones are the patients. Two options: to speak with the patients themselves or to speak with the patients' association – There are problems of availability, personal interests... "

"There are no such problems with other stakeholders – industry for instance, even if it is necessary to filter and even if they have their own agenda."

"Patients are only experts in their own treatment. There is a bias. Their opinion will not be useful for each research question."

"A distinction must be made between specialized patient associations and the general patient association cupola organisations. The specialized associations have much more knowledge than the general ones."

"The identification's phase of the patients is also difficult. There are not always patient associations and they are sometimes influenced by industry."

Furthermore, the need to distinguish between patients and the citizens is well perceived.

"A distinction must be made between patients and tax-payers/ citizens who are not ill. They tend to see things differently." "The challenge is to identify people having the capacity to discuss."

Message 19: Are we ready to give all information to the patients

In one of the discussion groups, the issue was raised of public access to sensitive data, e.g. on hospital quality indicators. If we expect openness and collaboration from patients or citizens, they may well expect similar openness from KCE in return.

"Many studies publish results on the quality of hospitals, e.g. 5y cancer survival rates. But these results are anonymous. Many patients want to know which hospitals are the best ones. We have many requests of this type :'My father has a cancer: you say that they are 5 good hospitals... where must I go?' "

"We consider that it is not our role to make rankings. But the expectations of the patients are legitimate. We have no legal barriers. What is our response?"

3.4. Conclusion

The four discussion groups organized in October and November 2011 were quite prolific and generated a real added value, thanks to the motivation, frankness and dynamism of the participants.

All relevant aspects of the messages that emerged from the discussion groups have been integrated into the KCE policy, that is detailed in chapter 4.

The actual body of experience originating from past projects with involvement of the stakeholders is given in appendix.

4. STAKEHOLDER INVOLVEMENT IN KCE PROCESSES

4.1. RATIONALE : enhancing the relevance and impact of KCE reports

The ultimate objective of KCE is to contribute in an effective way to evidence-based healthcare and healthcare policy, through the formulation of advice and guidelines, primarily aimed at policy makers and practitioners, respectively. The impact of the KCE can be measured by the degree to which this objective is reached. Clearly, performing good literature reviews and state-of-the-art data analyses and economic modeling is not sufficient.

An external audit, performed in 2009 to evaluate the impact of the KCE on the healthcare policies[63] showed the explicit demand from stakeholders to be more involved, from the very onset of the studies up to the phase of dissemination. Beyond scientific excellence, stakeholder involvement, at different stages of the projects, is a means to enhance the relevance and, consequently, the potential impact of the KCE recommendations.

From a scientific point of view, it is important to indicate clearly which elements of the study results, conclusions and recommendations are based upon stakeholder input, including a description of the methods that were applied, and their limitations and risks.

4.1.1. Impact of the KCE reports: levers and barriers

In a general manner, over and above the scientific value of the KCE reports, a series of levers potentially increasing the impact of KCE work can be identified. On the other hand, there are also potential barriers to an optimal impact.

Table 7: Levers and barriers with respect to the impact of KCE reports

Levers	Barriers
The real questions and relevant concerns are dealt with	Mismatch between values and paradigms of researchers vs. those of stakeholders
Suggested solutions are acceptable	Violation of individual/group interests
Recommendations are operational, feasible	Real-life context and constraints (financial, organisational, other…) are ignored
A priori impartiality: all groups are heard	KCE perceived as taking offending, disrespectful stance
Ownership by stakeholders	Prevailing controversies, tensions, hidden agenda's are ignored
Recognised scientific excellence; comprehensive approach	Complexity is (partly) disregarded
Public support	Perception of being accused or judged
Message (can be) adopted/relayed by credible actors	

4.1.2. *Five strategic objectives to overcome the impact barriers and operate the levers*

As a researcher or research institution, we can mobilize a number of strategies to overcome these barriers or to operate the levers. Most of these actions need the involvement of stakeholders, one way or another.

1. Make your subject tangible

KCE researchers are supposed to be specialists in matters of research methods, but more often than not, they have only limited prior knowledge of the actual healthcare subject on which they are appointed. Hence, before embarking into a research project on a given subject, it is useful to get acquainted with the subject and to make it somehow tangible. How is this specific healthcare approach organized in practice? How does it look and feel? What are the troubles with it on the field? … To have seen with one's own eyes, to have heard from the mouth of a patient, or even to have had a first-hand experience, is worth several days of reading work!

2. Get your scope and research questions right

Evidently, relevancy is an absolute prerequisite for getting any impact at all! Our studies should address the really important issues and concerns, as perceived by the providers, the patients, the public and/or the decision makers. This requires to get beyond first impressions, to identify hidden tensions, controversies or conflicts, to understand deep motivations and values… Addressing these questions in a careful, participatory manner, can also be an important step in the creation of acceptance and ownership among end-recipients.

Equally important at this stage, is to get a full understanding of the regulatory context with its financial implications. Where are the incentives (*'cui prodest'*), competing interests, barriers, complexities …?

3. Gain acceptance of your research setup and methods

People are rarely willing to readily accept conclusions or recommendations when they come out of a black box. Likewise, 'esoteric' or little understood analyses will not so easily yield very convincing answers. Researchers should be aware of the conceptual framework used by the target audience: how do they see the problems and in what terms do they spell out what they see as a solution; what are their underlying values and worldviews? When we ignore strong voices 'out there', what else can we expect than be ignored ourselves when we come with our solution? This is not to say that we should adopt other paradigms and jeopardize EBM; it means that we should not evade our duty to engage into a dialogue with other viewpoints and take a look at other sources of 'evidence'

4. Reach clear results and acceptable recommendations

This is all about the acceptability and feasibility of the recommendations that will be formulated, and, normally, this should be the natural consequence from the preceding points.

We very often produce answers that are not matching what important stakeholder groups would have expected, let alone preferred, but this is of course also our *'raison d'être'.* Even so, we should keep an acute awareness of opposing viewpoints and their most important arguments and discuss them. Showing respect for other viewpoints, by demonstrating that you have listened to them in a honest way, even if you did not follow them, can certainly help to get respect in return. Conversely, disrespectfully rejecting other viewpoints without proper arguments will only cause anger and hostility towards KCE. The acceptability could thus just pertain to the mere fact that KCE formulated conclusions and recommendation, even if they differ from those of the stakeholder. In other words, if people accept our role in the system, we have at least this asset as a ground for further discussion.

Besides being acceptable (even if only acceptable as having a different opinion), as discussed above, whatever recommendation we formulate should also be realistic in terms of feasibility – maybe not immediately, but at least in the long term.

5. Get effective communication channels and relays

The very best proof of impact is when the key target actors themselves actively disseminate and get to work with our reports. This means that this report has gone throughout the long way from awareness to understanding, acceptance and eventually adoption and ownership. For certain, the previous steps should greatly facilitate true adoption, but it may require additional efforts of translation, dissemination and advocacy.

4.2. The five key Values for fruitful stakeholder interaction

The rationale behind each of the above-cited objectives is not only to enhance the eventual impact of the work of KCE, but, by the same token, they are also the translation of a number of values underpinning our healthcare system and the role KCE is playing in this system.

1. Respect

To involve those who will be most affected by the outcome of our work is simply a matter of respect, and, in principle, should be beyond discussion. It is based on the premises that these key stakeholders have valuable input to offer and that KCE has something to learn from them. Conversely, taking an omniscient or paternalistic stance, could be seen as a form of disrespect.

When showing respect towards one's interlocutor, one is evidently entitled to expect reciprocal respect in return for our expertise in EBM methods and for the legitimacy of our research.

2. Transparency

Involving stakeholders, taking their views and opinions seriously, does not mean, nor requires that we take over these viewpoints. This should be made perfectly clear from the onset. The specific role KCE has to play in the system demands that, at a certain stage in the research, we take some distance, so as to reach valid conclusions in the view of all available evidence. Moreover, there should be a mutual understanding with whichever stakeholder being involved in the course of a study, of the role each of the actors is playing.

This goes along with a clear communication about the involvement process, and about the study progress.

3. Objectivity

Taking people's opinions and views creates the obligation to somehow render them truthfully, i.e. without subjective interpretation or filtering.

Likewise, the selection of the stakeholders to involve should not be influenced by pre-existing convictions or preferences of the researcher. It takes some judgment, though, to attribute to each stakeholder the attention and weight he or she deserves, but this judgment should be built on objective grounds whenever possible.

4. Modesty

Even if KCE is and should be keeping up its scientific rigour and objectivity, it cannot pretend to have the definitive answers to all questions, not even to have answered the right questions. The challenge is to be able to differ in opinion, while refraining from any form of disdain for one's interlocutor. Recognition and appreciation of the values and worldview behind deviant opinions, can only lead to a deeper understanding of the issues that are really at stake.

5. Curiosity

Curiosity is a valuable character trait for a scientist. But, when science is directly aimed at procuring healthcare policy advice, this curiosity should extend to the psychology, sociology and politics behind the technologies and policies under study. This form of openness should be a natural consequence of the respectful and modest attitude advocated above. Yet, when venturing out of the bastion of EBM with its statistical, epidemiological, economical certitudes, one better be prepared to step onto shifting grounds!

4.3. There are many different ways to involve stakeholders

When deciding to involve a group of key stakeholders, e.g. the professional interest lobby group of the doctors, the first approach coming to mind is a meeting with five to ten persons at the KCE premises. Yet, this is just one of the many ways one could seek to interact with stakeholders, and for each objective there might be a number of different methods that could be appropriate and effective. The actual choice will depend on the precise set of circumstances and on the expected outcomes. In a more systematic way, one can distinguish a number of **dimensions** along which each stakeholder interaction should be situated in order to be able to choose the most suitable approach.

Table 8. Dimensions of stakeholder involvement

Dimensions	Possible choices/situations
Who to involve?	Patients; General population; Media (specialised or general); Providers; Potential future providers; Industry; Other commercial actors, Foreign experts in the domain Decision makers; Administration; Insurers; Academia
Representation	Direct contact with 'the field' ↔ Via representation (representative associations)
Circle of stakeholders	Active exclusion of certain groups ↔ Closed; selected (reference) group ↔ Open, unselected (i.e. self-selected)
Level of involvement	Obtain information from ↔ Listen to ↔ Discuss with ↔ Obtain engagement ↔ Be partners
Desired output	Factual information ↔ Description (e.g. of controversies) ↔ Consensus ↔ Co-construction of solutions
Motivation	Advising ↔ Democratisation
Format	Face to face ↔ Forum ↔ Survey… Use of web tools, of social media…
Information need	Stakeholders have poor prior knowledge of the issue at stake ↔ Stakeholders are well informed
Level of controversy	Subject is highly controversial ↔ Subject is consensual Depends also on the objective of the interaction with the stakeholders
Confidentiality	Everything can be openly discussed ↔ Some elements cannot be said in public

4.4. From strategy to concrete actions

As apparent from the first part of this report, there is a wide variety of ways to involve stakeholders in the study work of advisory bodies like KCE. For each of the strategic objectives, the most appropriate method (or mix of methods) should be selected. Some choices are straightforward, others are more arbitrary and will possibly have to be revised with growing experience (see Table 10, next page).

Furthermore, each of the objectives requires interactions with stakeholders at specific moments during the project (Table 9)

Table 9. Timing of the different interactions with stakeholders

1. Make subject tangible	At the very onset of the project.
2. Get scope and research questions right	Before finalising the study protocol (projectfiche-fiche projet)
3. Gain acceptance of methods	Early in the realisation phase, possibly to be repeated once or twice
4. Reach realistic answers	Is an ongoing concern, requiring different types of interaction throughout the project; pre-finalisation phase is particularly crucial
5. Get effective communication channels	From pre-finalisation phase onwards, but facilitated by earlier interactions

Table 10: Impact enhancing strategies

Stakeholder involvement approaches	1.Make subject tangible	2.Get scope and research questions right	3.Gain acceptance of methods	4.Reach realistic answers	5.Get effective communication channels
Search of medical and lay press		+		+	
On-site visits (to healthcare institution or surgery, manufacturer, patient…),	K	+			
Individual interviews with 'typical' stakeholders	K	K	+	+	
Individual interviews with key informants (author of study proposal, engaged stakeholder, policy watcher)	+	K	+	K	
Focus groups	K	+		x	
Discussion forum (meeting with 8-20 stakeholders), for discussion of contentious points; project scoping groups; inventory groups; rating groups.		K	K	K	
Delphi methods		√	+	√	+
Scenario Building Exercise		√	+	√	
Consensus conference		√	+	√	+
Deliberative polling		√		√	
Online discussion groups/list servers		√		+	
Survey (Web, telephone, paper self-administered, ...)		K		+	
Use of social media	+	√		+	+
Workshop		+	+	K	+

K= To be applied/developed by KCE *√= Other eligible method; could be subcontracted;* *+ = Method could be of help or contribute*

A number of other participatory methods may be less relevant for KCE study processes : Search conferences, Study circles, Study groups, Think tanks, Charrette, Constituent assembly, Retreats, Round tables, Advisory committee, Board/council or planning cell, Interactive www/e-conferencing, Online discussion groups/list servers, Issue conferences, Nominal group process (see KBF 2005[51] and Health Canada 2000[8]).

4.5. Stakeholder involvement in Practice

4.5.1. Prerequisites

As a prerequisite for every stakeholder involvement exercise, there are a number of unavoidable questions to be answered by the KCE researchers. Some of them correspond to choices that have to be made in the dimensions listed in table 8:

- Who are the **key stakeholders** to involve ? *(Dimensions1, 2 and 3)*

  Given the difficulty of finding the appropriate individuals, a database of representatives of patient organizations, of professional groups, industry contacts, key persons in the administration… should gradually be built up. Even so, the help of external subcontractors might be needed in order to get the perceptions and opinions of specific patient groups, of citizens, of the healthcare workers 'on the floor'…
- What are the **significant issues** for the stakeholders ? (Will depend on the strategic objective that is pursued)
- What are the real **goals** of the involvement ? (Dimensions 4, 5 and 6)
- **SWOT** analysis (Dimensions 9 and 10)
  - What are the strengths and weaknesses of the involvement ?
  - What risks are associated with the involvement, with no involvement and with a poor involvement
  - What opportunities are associated with a complete involvement

The requirements and expectations might be quite different depending on the type of study and subject. E.g. a guideline in a non-controversial field will need other types of contacts and inputs than a HTA on a fiercely debated subject.

4.5.2. Choice of the most appropriate method(s)

Depending on the answers to the above-mentioned questions, and the specific strategic objective, one will have to choose among the methods listed in table 10 which one(s) is (are) the most appropriate. Alternatively, one might decide not to engage into stakeholder requirement, if the risks are perceived to outweigh the potential advantages, e.g. for fear of undue dominance by lobby groups. The choice will also have to take into account more practical issues like the availability of resources and competencies, and timing considerations.

4.5.3. Required competencies

Some of these competencies should be developed internally. Special attention should be paid to the psychological aspects. Interactions with patients or with sometimes exigent, suspicious or even hostile providers or other parties with vested interests may entail psychological distress in the researcher. He or she may benefit from training in conflict management, in keeping the right distance, in the management of complex group dynamics…

Thorough debriefings after completion of a research project should help in identifying the "do's and don't's" of specific approaches and contribute to the gradual building-up of an experience and knowledge base at the KCE.

For other competencies, we could make use of the services of subcontractors who have a specific experience in the field.

4.5.4. Further elaboration of methods that were considered as eligible for KCE

A number of the methods listed in table 10 that have been mentioned during the internal expert consultation organized in October-November 2011 (see Chapter 3) will in the coming months and years be further elaborated into detailed, operational KCE Process Notes.

They are briefly described in appendix, with a focus on their specific advantages and merits, as perceived by KCE researchers. The methods described explicitly target their application to stakeholder involvement; their use in other contexts is outside the scope of this report.

Insofar as KCE has still a limited experience with formal stakeholder involvement methods, key success factors and risks cannot be identified with much certainty at this stage, and the experience from other countries and institutions cannot readily be transposed either. Hence, with growing experience, this chapter will have to be updated and further elaborated during the coming few years.

5. APPENDIX: APPROACHES ILLUSTRATED DURING THE CONSULTATION ROUND OF KCE EXPERTS

APPROACH 1 – On-site visits to healthcare providers or institutions

Example(s)	KCE Reports 20 [Molecular Diagnostics in Belgium], 2005 [64] KCE Reports 46 [Home Monitoring of Infants in Prevention of Sudden Infant Death Syndrome], 2006 [65]
Objective	Make the subject tangible (with the focus on the clinical and practical aspects).
Timing	At the onset of the project.
Who to involve?	Providers/healthcare institution currently using the technology (HTA) or providing the service (HSR) under study, or caring for the condition covered by the guideline.
Selection	Not necessarily via representative organizations; rather via personal contacts; look for large-volume centres and quality-conscious providers.
Level of involvement	Information of the researchers.
Motivation	Avoiding a purely theoretical stance.
Desired output	Good grasp of the concrete (clinical) practicalities of a technology, service or diagnostic or therapeutic approach, including the regulatory/financial particularities (if debatable).
Appropriate format	Non-interfering observation of the actual clinical processes, alternated/followed by discussion with the providers and (if needed and feasible) with patients. In any case, informed consent is to be obtained from the patient. Ideally, all researchers involved in the study should participate. In practice, at least those involved in the editing of the discussion and conclusions.
Duration	½ to 1 day.
Prior information need	Stakeholders need little prior information. Researchers could benefit from prior acquaintance with the technology, medical condition, jargon, regulatory framework.
Preparatory material	None, or a set of remaining questions after preparatory reading work.
Deliverable	Brief description of the meeting (who, when , where), no other specific deliverable; an introductory chapter of the final study report, describing the problem, technology or service, may benefit from the personal observation notes of the researchers.
Follow-up	In principle not applicable.
Level of controversy	In theory, out of scope for this method; in practice, the very fact that the researches belong to the KCE may create specific perceptions among the providers, and bring out potentially controversial aspects during the visits. Hence, the nature of the visit, its objectives and the function in the project should be made very clear.
Confidentiality	All observations, and, a fortiori, all patient-related information should remain strictly confidential.
Limits	As representativity is not aimed for, the observations of the researchers cannot be considered to be formal results, and do, as such, not appear in the study report.

Risks of the method	Perception bias and preconceptions in the researcher, based upon a very limited, but potentially strong personal experience. This could require to express these potential preconceptions and test them with other actors, preferentially with opposing views.
How to evaluate?	Absence of signals that “researchers do not really know what they are talking about” or similar suggestions.

APPROACH 2 – Individual interviews with ‘typical’ stakeholders

Example(s)	KCE Reports 46 [Home Monitoring of Infants in Prevention of Sudden Infant Death Syndrome], 2006 [65]
Objective	Understand the subject also in the way it is perceived ‘in the field’.
Timing	At the onset of the project.
Who to involve?	Providers/healthcare institution currently using the technology (HTA) or providing the service (HSR) under study, or caring for the condition covered by the guideline; Patients confronted with the issue under study.
Selection	‘Normal’ providers and patients, not their political representatives; Patients could be recruited via patient organisations, social media, sickness funds, or with the help of other partners specialised in participatory work.
Level of involvement	Information of the researchers.
Motivation	Avoiding a purely theoretical stance; make sure not to miss important aspects linked to the perception of the patient and clinician when deciding on the research questions, but also in view of formulating relevant recommendations at the end of the project.
Desired output	Richer view of the different dimensions of the problem under study Good grasp of the concrete (clinical) practicalities of a technology, service or diagnostic or therapeutic approach; Relevant research questions.

Appropriate format	In depth interviews. Preferentially face-to-face (1, or max 2 KCE collaborators or subcontracting researchers), at the location of choice of the stakeholder; second choice : by telephone, after having fixed an appointment..
Duration	Approximately ¾ to 1H per interview (20 to 30 min. if by telephone).
Prior information need	Stakeholders need little prior information. Researchers could benefit from prior acquaintance with the clinical/medical aspects.
Preparatory material	Set of half-open or open questions. Interviewees should be pre-informed of the general lines of the interview.
Deliverable	Tape/video-recording of the focus groups (after consent) and notes (full transcription of the recordings is not required); synthesis and analysis
Follow-up	A synthesis of the interview (for validation, not mandatory). Active information of participants of the publication of the report
Level of controversy	In principle low.
Confidentiality	All observations and recordings should remain strictly confidential.
Limits	As representativity is not strictly aimed for, the observations of the researchers cannot be considered to be formal results, and do, as such, only appear in the study report as qualitative observations of individual persons' views. Informants may retain information (e.g. socially less desirable facts or opinions).
Risks of the method	Perception bias and preconceptions in the researcher, based upon a limited number of contacts. Team discussions should address these challenges to scientific objectivity.
How to evaluate?	No new issues appear at the later stages of the projects; main points of debate and controversy were duly identified..

APPROACH 3 – Individual interviews with key informants (author of study proposal, engaged stakeholder, policy watcher)

Example(s)	KCE Reports 27 [Quality and organization of the care for diabetes 2], 2006 [66] KCE Reports 133C Optimisation of the operational processes of the Special Solidarity Fund [67] KCE Reports 46 [Home Monitoring of Infants in Prevention of Sudden Infant Death Syndrome], 2006[65]
Objective	Understand the subject also in its more 'political' aspects (regulatory, financial, other interests).
Timing	Very early, before final choice of research questions; in the pre-final phase, to test acceptability of conclusions and recommendations
Who to involve?	The initiators of the research topic, key policy makers, key-persons in the administration; Providers/healthcare institutions currently using the technology (HTA) or providing the service (HSR) under study, or caring for the condition covered by the guideline; Foreign experts in the domain; Patients; patient organizations (if applicable). Industry
Selection	Providers and patients : via representative organizations; look for balance of viewpoints and interests; but limit to 6 à 8 in total.
Level of involvement	Information of the researchers.
Motivation	Avoiding 'to miss the point' before the final discussions on the recommendations. Identification of the key questions to be answered.
Desired output	Good grasp of the 'political' stakes, including the regulatory and financial aspects under debate and the potential controversies between interest groups. Relevant research questions; acceptable conclusions and/or recommendations.
Appropriate format	In depth interviews. Preferentially face-to-face (1, or max 2 KCE collaborators), at the location of choice of the stakeholder; second choice : by telephone or videoconferencing, after having fixed an appointment..
Duration	1H to 1.30H per interview (30 to 45 min. if by telephone).
Prior information need	Stakeholders need little prior information, except if for discussion of conclusions / recommendations : text to be sent > 1 week in advance. Researchers could benefit from prior acquaintance with the regulatory framework, financial implications, expressed viewpoints (medical and lay press).
Preparatory material	Set of half-open or open questions. Interviewees should be pre-informed of the general lines of the interview.
Deliverable	Tape/video-recording of the focus groups (after consent) and notes (full transcription of the recordings is not required); synthesis and analysis
Follow-up	A synthesis of the interview (for validation, not mandatory). Active information of all participants of the publication of the report
Level of controversy	Can be high. Even so, the nature of the visit, its objectives and the function in the project should be made very clear.

Confidentiality	All observations and recordings should remain strictly confidential.
Limits	As representativity is not strictly aimed for, the observations of the researchers cannot be considered to be formal results, and do, as such, only appear in the study report as qualitative observations of individual persons' views..
Risks of the method	Perception bias and preconceptions in the researcher, based upon a limited number of contacts. Team discussions should address these challenges to scientific objectivity.
How to evaluate?	No new issues appear at the later stages of the projects; main points of debate and controversy were duly identified..

APPROACH 4 Focus groups

Example(s)	
Objective	Understand the subject also in its more 'political' aspects (regulatory, financial, other interests) in order to formulate the research question(s) of the project.
Timing	To be planned at the beginning of the project To be conducted at the appropriate time.
Who to involve?	Patients; General population; Media (specialised or general); Providers; Potential future providers; Industry; Other commercial actors Decision makers; Administration; Insurers; Academia
Selection	Providers and patients : via representative organizations; look for balance of viewpoints and interests
Level of involvement	Listen to
Motivation	Avoiding 'to miss the point' before the final discussions on the recommendations. Identification of the key questions to be answered.
Desired output	Inventory of knowledge, perceptions, controversy and / or consensus elements of the participants regarding the topics explored by the focus groups.
Appropriate format	Several meetings (6-12 people), each focus group includes only one type of stakeholder .
Duration	Between 2. hours and 3 hours
Prior information need	Several option possible, depending on the objective of the focus groups.

Preparatory material	A script in which the topics to be addressed, are related to a general and or particular question, including an indication of the timing.
Deliverable	Tape/video-recording of the focus groups (after consent) and notes (full transcription of the recordings is not required); synthesis and analysis.
Follow-up	A synthesis of focus group (for validation, not mandatory). Active information of all participants of the publication of the report.
Level of controversy	Focus groups methodology recommend to invite people with previously identified heterogeneous opinions in separated homogenous groups in order to minimize the level of controversy on the targeted topic of discussion.
Confidentiality	All observations and recordings should remain strictly confidential.
Limits	Learnings will be limited by a de facto selection bias (availability, interest to participate, ...), are limited to the perceptions of the participants; quality of debate is strongly related to the animator skills, organisational aspects can be very limiting.
Risks of the method	Participants do not share the real information
How to evaluate?	No new issues appear at the later stages of the projects; main points of debate and controversy were duly identified..

APPROACH 5 Survey (Web survey, telephone survey ...)

Example(s)	Study 2011-10 (GCP) Clinical practice guideline for the supportive treatment for cancer patients
Objective	Select and prioritize the research question(s) of the project. Evaluate the acceptability of proposed recommendations
Timing	To be planned at the beginning of the project To be conducted at the appropriate time.
Who to involve?	Patients; General population; Media (specialised or general); Providers; Potential future providers; Industry; Other commercial actors, Foreign experts in the domain Decision makers; Administration; Insurers; Academia
Selection	Normal providers and patients, not their: political via representatives organizations; look for balance of viewpoints and interests; but limit to 6 à 8 in total Patients could be recruited via patient organisations, social media, sickness funds, or with the help of other partners specialised in participatory work.
Level of involvement	Obtain information Listen to
Motivation	Avoiding ‘to miss the point’ before the final discussions on the recommendations. Identification of the key questions to be answered.
Desired output	Get quantitative data, possibly to compare different groups of stakeholders
Appropriate format	Depending on the project : Web, Phone, paper, ...
Duration	Must be adapted regarding availability of potential respondents (think about holidays)

Prior information need	Participants must receive directive on how to complete the survey by advance..
Preparatory material	Questionnaire, directive, technical media (website, call centre, ..)
Deliverable	Quantitative data (raw data, tables, structured text,...)
Follow-up	A synthesis of results (for information and further comment, not mandatory). Active information of all participants of the publication of the report.
Level of controversy	Low
Confidentiality	All questionnaires should remain strictly confidential.
Limits	Gathered data will be limited by a de facto selection bias (availability, interest to participate, ...), and the selected media format (access to, acceptability of ...).
Risks of the method	Low participation rate, bias in representativity of the participants
How to evaluate?	No new issues appear at the later stages of the projects; main points of debate and controversy were duly identified..

APPROACH 6 Discussion forum (meeting with 8-20 stakeholders)

Example(s)	KCE Reports 167 [Residential care for older persons in Belgium: Projections 2011 – 2025] [68] Study 2011-10 (GCP) Clinical practice guideline for the supportive treatment for cancer patients
Objective	Confront draft research questions or preliminary results or recommendations to the criticism of relevant stakeholders, so as to obtain a more robust and hopefully more acceptable end product.
Timing	Depending on the points to be discussed, shortly after the start, during, or shortly before the end of the study.
Who to involve?	Representatives of patients, providers, policy maker, industry,….
Selection	For patients, providers and industry: through representative organisations.
Level of involvement	Consulting and discussion
Motivation	Make sure that the viewpoints of the principal stakeholder groups have been identified and understood.
Desired output	Identification of elements in the study that need to be reconsidered, reformulated, better argued.
Appropriate format	Face to face meeting of max 15 to 20 persons. Can be in the KCE premises.
Duration	2 hours
Prior information need	Participants received document with points to be discussed clearly identified. Required reading time should be limited to less than 1 hour.

Preparatory material	Questions/statements that will be discussed.
Deliverable	Minutes (at least 2 persons) and – if feasible and acceptable – tape recording (for verification of minutes; not to be transcribed or kept)
Follow-up	Active information of all participants of the publication of the report.
Level of controversy	Can be very high. A strong moderator is advisable.
Confidentiality	In principle not applicable.
Limits	Information obtained are 'official viewpoints', not necessarily reflecting the full image of an issue.
Risks of the method	Researchers could feel to be put under pressure; independency of KCE may need to be clearly stressed at the beginning of the meeting, i.e. the rules of the game should be clear to all participants. Participants could provide personal viewpoint instead of the official viewpoint they are excepted to transmit.
How to evaluate?	Follow-up of reactions of stakeholders after publication of report and reflection on how problems could possibly have been avoided.

APPROACH 7 : Delphi Method

Example(s)	KCE Reports 165 [Burnout among general practitioners: prevention and management], 2011 [42] KCE Reports 125 Impact of Academic Detailing on Primary Care physicians [69]
Objective	Reach a consensus about research questions, content of recommendations …
Timing	Depending on the points to be discussed, shortly after the start, during, or shortly before the end of the study
Who to involve?	Practitioners, patients, providers, policy maker, industry
Selection	"Experts" in the field
Level of involvement	Consulting and discussion
Motivation	Make the results and recommendations realistic and implementable, get effective communication channels
Desired output	Consensus
Appropriate format	Web, e-mail or postal survey
Duration	Several rounds over several weeks
Prior information need	Not necessary
Preparatory material	Questionnaire. Briefing about the expectancies and the aim of the method
Deliverable	Semi-quantitative data, priorities lists
Follow-up	Active information of all participants of the publication of the report

Level of controversy	Probably high at baseline, and low at the end of the process
Confidentiality	Responses of the participants have to remain anonymous
Limits	The results depend on the chosen experts, and of the questions asked.
Risks of the method	Instrumentalisation by some participants Artificial consensus
How to evaluate?	Number and/or content of the critics concerning this part of the report

APPROACH 8 : Workshop

Example(s)	KCE Reports 165 [Burnout among general practitioners: prevention and management], 2011 [42] Study 2010-25 (HSR) The organisation of mental health services for children and adolescents in Belgium (second phase, ongoing)
Objective	Co-creation of certain elements of the study
Timing	During the research process, possibly rather in the (pre)-final phase
Who to involve?	Stakeholder groups who will be most affected, and/or the most knowledgeable experts
Selection	Combination of 'official' representatives and personal invitations
Level of involvement	High: stakeholders are deeply engaged or real partners.
Motivation	Gain maximum relevance, acceptability, impact.
Desired output	Relevant and acceptable recommendations that have the potential to effectively boost change.
Appropriate format	Max 40 persons. Most of the work to be done in small groups of max 6 to 7 persons. Requires appropriate table configuration /meeting room(s), flip charts, number of facilitators for sub-groups, …
Duration	At least 3 ½ to 4 hours; preferentially whole day.
Prior information need	Series of information cards or sheets describing the questions or proposals on which input from the participants will be solicited should be circulated at least 1 week before the meeting.
Preparatory material	See above.

Deliverable	Written material from ‘rapporteurs’ of the subgroups; minutes (min. 2 persons) and tape recording of plenary discussions. No full transcript of tape recording needed.
Follow-up	Allow re-reading of final result of workshop by participants for validation (but avoid extensive re-editing)
Level of controversy	Can be relatively high. A strong moderator is advisable.
Confidentiality	In principle not applicable.
Limits	Product will not be ‘scientific’ in the strict sense of the word; to be clearly identified as such in the final report (explicit disclaimer…)
Risks of the method	‘Politics’ invading the study; generation of false expectations among stakeholders; researchers could feel to be put under pressure; the rules of the game should be made clear to all participants.
How to evaluate?	End product is effectively adopted, disseminated or applied by target group.

6. REFERENCES

1. Andriof J, Waddock S. Unfolding stakeholder engagement. In: Unfolding stakeholder thinking. Theory, responsibility and engagement. Sheffield: Greenleaf; 2002. p. 19-42.
2. Nutley S, Walter I, Davies H. Using evidence. How research can inform public services. Bristol: The Policy Press; 2008.
3. Lavis J, Oxman A, Lewin S, Fretheim A. SUPPORT Tools for evidence-informed health Policymaking. Health Res Policy Syst. 2009;7(Suppl 1):S1.
4. INVOLVE | INVOLVE Supporting public involvement in NHS, public health and social care research [Eastleigh: INVOLVE;2011 [cited 2012-01-11]. Available from: http://www.invo.org.uk/
5. Ginsburg L, Lewis S, Zackheim L, Casebeer A. Revisiting interaction in knowledge translation. Implementation Science. 2007;2:34.
6. Riddle M. Doing Better Business through Effective Public Consultation and Disclosure: A good practice Manual. Washington: International Finance Corporation; 1998. (0-8213-4342-4) Available from: http://www.ifc.org/ifcext/enviro.nsf/AttachmentsByTitle/p_pubconsult/$FILE/PublicConsultation.pdf
7. Sequeira D, Warner M. Stakeholder Engagement: A Good Practice Handbook for Companies Doing Business in Emerging Markets. Washington: International Finance Corporation; 2011. Available from: http://www.ifc.org/ifcext/enviro.nsf/attachmentsbytitle/p_stakeholderengagement_full/$file/ifc_stakeholderengagement.pdf
8. Corporate Consultation Secretariat, Health Policy and Communications Branch. Health Canada Policy Toolkit for Public Involvement in Decision Making. Ottawa: Health Canada; 2000. 0-662-29243-X Available from: http://www.hc-sc.gc.ca/ahc-asc/alt_formats/pacrb-dgapcr/pdf/public-consult/2000decision-eng.pdf
9. Nutley S, Morton S, Jung T, Boaz A. Evidence and policy in six European countries: diverse approaches and common challenges. Evidence&Policy. 2010;6(2):131-44.
10. Kristensen FB, Sigmund H. Health Technology Assessment Handbook. Copenhagen: Danish Centre for Health Technology Assessment, National Board of Health; 2008. (978-87-7676-649-8) Available from: http://www.sst.dk/publ/Publ2008/MTV/Metode/HTA_Handbook_net_final.pdf
11. Caplan N. The two-communities theory and knowledge utilization. American Behavioral Scientist. 1979;22(3):459-70.
12. Freeman R. Strategic management: a stakeholder approach. Boston: Pitman; 1984.
13. Submission of comments | Commenting procedure (Hearing) [Koeln: IQWIG;2011 [updated 2011-11-23; cited 2012-01-13]. Available from: https://www.iqwig.de/index.507.en.html
14. Nielsen C, Kristensen F, Bistrup M, Cecchetti A, Turk E. Involving stakeholders and developing a policy for stakeholder involvement in the European network for Health Technology Assessment, EUnetHTA. Int J Technol Assess Health Care. 2009;25(Suppl 2):84-91.
15. Leys M, Reyntens S, Gobert M. La participation des patients dans la politique des soins de santé: revue de la littérature et aperçu des initiatives internationales et belges. Bruxelles: Fondation Roi Baudouin; 2007. 978-2-87212-526-5 Available from: http://www.kbs-frb.be/uploadedFiles/KBS-FRB/05%29_Pictures,_documents_and_external_sites/09%29_Publications/FR_Participatie3.pdf
16. Becher G, Vandenbroeck P, Wouters A. Les patients, partie prenante de la politique des soins de santé: faire entendre d'autres voix. Bruxelles: Fondation Roi Baudouin; 2008. 978-2-87212-543-2 Available from: http://www.kbs-frb.be/uploadedFiles/KBS-FRB/05%29_Pictures,_documents_and_external_sites/09%29_Publications/Patients_partie_prenante%281%29.pdf
17. Tronto JC. Un monde vulnérable: pour une politique du care. Paris: La Découverte; 2009.

18. Léonard C. La responsabilisation capacitante: un nouveau paradigme pour refonder l'Etat-providence? Éthique et économique/Ethics and Economics. 2012;Accepted for publication.
19. Léonard C. Un nouveau paradigme pour les assurances sociales: la responsabilisation capacitante. In: Degavere F, Desmette D, Mangez E, Nyssens M, Reman P, editors. Transformations et innovations économiques et sociales en Europe : quelles sorties de crise ? Regards interdisciplinaires - Actes du Colloque de l'Association d'Economie Sociale: Presse Universitaires de Louvain; 2010. p. 113-31.
20. Léonard C. Fixer les priorités en soins de santé: pour une responsabilisation "capacitante" des citoyens. Prescrire. 2010;30(322):622-4.
21. Mambourg F, Gailly J, Wei-Hong Z. Recommandation de bonne pratique pour l'accouchement à bas risque. Good Clinical Practice (GCP). Bruxelles: Centre fédéral d'expertise des soins de santé (KCE); 2010. KCE Reports 139B (D/2010/10.273/63) Available from: http://kce.fgov.be/sites/default/files/page_documents/kce_139c_guideline_low_risk_birth_0.pdf
22. Albertijn M, Baeke A-M, Janssens S, Bielen F, Mambourg F, Jonckheer P. Accouchement normal : conseils scientifiques traduits en langage courant à intégrer aux documents d'information des femmes enceintes. Bruxelles: Centre fédéral d'expertise des soins de santé (KCE); 2011. KCE CLEAR (Common Language Evidence-based Advices and Recommendations) 1B Available from: http://kce.fgov.be/fr/publication/report/accouchement-normal-conseils-scientifiques-traduits-en-langage-courant-a%CC%80-inte%CC%81gr
23. Patient and public home [National Institute for Health and Clinical Excellence;2011 [cited 2012-01-11]. Available from: http://www.nice.org.uk/getinvolved/patientsandpublic/patientandpublichome.jsp
24. NICE. Caesarean section: Information about NICE clinical guideline 132. 2011. Understanding NICE guidance Available from: http://www.nice.org.uk/nicemedia/live/13620/57166/57166.pdf
25. NICE. Treating generalised anxiety disorder and panic disorder in adults: Information about NICE clinical guideline 113. 2011. Understanding NICE guidance 197 (978-1-84936-463-8) Available from: http://www.nice.org.uk/nicemedia/live/13314/52602/52602.pdf
26. NICE. Donepezil, galantamine, rivastigmine and memantine for Alzheimer's disease: Information about NICE technology apparaisal guidance 217. 2011. Understanding NICE guidance (978-1-84936-534-5) Available from: http://www.nice.org.uk/nicemedia/live/13419/53624/53624.pdf
27. Thomas V. "We were the group's conscience"- patient and public involvement at NICE. In: Proceedings of 'Patients, partenaires dans les soins de santé et la politique de santé'; 2011; Bruxelles: Fondation Roi Baudouin.
28. Caldon LJM, Marshall-Cork H, Speed G, Reed MWR, Collins KA. Consumers as researchers – innovative experiences in UK National Health Service Research. International Journal of Consumer Studies. 2010;34(5):547-50.
29. Milne RG. Reducing non-attendance at specialist clinics: an evaluation of the effectiveness and cost of patient-focussed booking and SMS reminders at a Scottish health board. International Journal of Consumer Studies. 2010;34(5):570-80.
30. Ward LJ, Rhodes CA. Embedding consumer culture in health and social care education – a university office's perspective. International Journal of Consumer Studies. 2010;34(5):596-602.
31. Barr J, Ogden K, Rooney K. Viewpoint: let's teach medical students what patient partnership in clinical practice can be, with the involvement of educationally engaged patients. International Journal of Consumer Studies. 2010;34(5):610-2.
32. Avard D, Stanton Jean M, Grégoire G, Page M. Public involvement in health genomics: the reality behind the policies. International Journal of Consumer Studies. 2010;34(5):508-24.
33. Thomas P, Wilson C, Jones P. Strengthening the voice of mental health service users and carers in Wales: a focus group study to inform future policy. International Journal of Consumer Studies. 2010;34(5):525-31.

34. Tetroe J. Knowledge Translation at the Canadian Institutes of Health Research: A Primer. Focus Technical brief. 2007;18.
35. NICE. The guidelines manual. London: NICE; 2007. Available from: http://www.nice.org.uk/media/FA1/59/GuidelinesManualChapters2007.pdf
36. IQWiG | Basic principles [Koeln: IQWIG;2011 [updated 2010-11-24; cited 2012-01-12]. Available from: https://www.iqwig.de/methods-procedures.926.en.html
37. Venturini T. Diving in magma: How to explore controversies with actor-network theory. Public Understanding of Science. 2010;19(3):258-73.
38. Venturini T. Building on faults: how to represent controversies with digital methods. Public Understanding of Science. 2010;online before print(Dec.5).
39. Mommerency G, Van Den Heede K, Verhaeghe N, Swartenbroekx N, Annemans L, Schoentjes E, et al. Organisation of child and adolescent mental health care : study of the literature and an international overview. Health Services Research (HSR). Brussels: KCE = Federaal Kenniscentrum voor de gezondheidsdzorg = Centre fédéral d'expertise des soins de santé = Belgian Health Care Knowledge Centre; 2011. KCE Reports 170C (D/2011/10.273/78) Available from: http://kce.fgov.be/sites/default/files/page_documents/KCE_170c_Children_mental_health.pdf
40. De Gendt T, Desomer A, Goossens M, Hanquet G, Léonard C, Mélard F, et al. [Ostheopathy and chiropractic: state of affairs in Belgium]. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2010. KCE Reports 148 Available from: http://kce.fgov.be/publication/report/ostheopathy-and-chiropractic-state-of-affairs-in-belgium
41. Van Meerhaeghe A, Annemans L, Haentjens P, San Miguel L, Buyse B, Benoit K, et al. Home Oxygen Therapy. Health Technology Assessment (HTA). Brussels: Belgian Health Care Knowledge Centre (KCE); 2011. KCE Reports 156C (D/2011/10.273/25) Available from: http://kce.fgov.be/publication/report/home-oxygen-therapy
42. Jonckheer P, Stordeur S, Lebeer G, Roland M, De Schampheleire J, De Troyer M, et al. [Burnout among general practitioners: prevention and management]. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2011. KCE Reports 165 Available from: http://kce.fgov.be/publication/report/burnout-among-general-practitioners-prevention-and-management
43. Moret-Hartman M, van der Wilt GJ, Grin J. Health technology assessment and ill-structured problems: a case study concerning the drug mebeverine. International Journal of Technology Assessment in Health Care. 2007;23(3):316–23.
44. Amblard H, Bernoux P, Herreros G, Livian Y-F. Une sociologie de la traduction. Les nouvelles approches sociologiques des organisations. Paris: Seuil; 1996.
45. Cargo M, Mercer SL. The value and challenges of participatory research: strenghtening its practice. Annu Rev Public Health. 2008;29:325-50.
46. HAS. Practice guidelines “Formal consensus” method. Paris: HAS; 2010. Available from: http://www.has-sante.fr/portail/upload/docs/application/pdf/2011-06/guideline_by_formal_consensus_quick_methodology_guide_110531.pdf
47. NICE. Guide to the methods of technology appraisal. London: NICE; 2008. (1-84629-741-9) Available from: http://www.nice.org.uk/media/B52/A7/TAMethodsGuideUpdatedJune2008.pdf
48. Ilott I, Mead J, Roberts J, Hammond R. Enhancing Stakeholder Involvement in NICE Guideline Development: Learning lessons from the experience of the allied health professions, health visiting, midwifery and nursing. October 2004.
49. AGREE. AGREE Instrument training manual. 2003.
50. ADAPTE. Manual for Guideline Adaptation v1.0. 2007.
51. Elliott J, Heesterbeek S, Lukensmeyer CJ, Slocum N. Participatory Methods Toolkit: a practitioner’s manual. Brussels: King Baudouin Foundation; 2005. 90-5130-506-0 Available from: http://www.kbs-

frb.be/uploadedFiles/KBS-FRB/Files/EN/PUB_1540_Participatoty_toolkit_New_edition.pdf

52. NICE. How NICE clinical guidelines are developed: an overview for stakeholders, the public and the NHS. london: NICE; 2009 January (1-84629-850-4) Available from: http://www.nice.org.uk/media/62F/36/How_NICE_clinical_guidelines_are_developed_4th_edn_FIANL_LR.pdf
53. IQWIG. Guideline on the submission of comments on preliminary reports: sample. Koeln: IQWIG; 2010. Available from: https://www.iqwig.de/download/Sample_Guidelines_on_the_submission_of_comments_on_preliminary_reports.pdf
54. IQWiG | Product preparation [Koeln: IQWIG;2011 [updated 2011-09-23; cited 2012-01-13]. Available from: https://www.iqwig.de/product-preparation.929.en.html
55. VIKC. Draaiboek richtlijnen. Onwikkelen, implementeren en evalueren van richtlijnen. Utrecht: VIKC; November 2009. Available from: http://www.oncoline.nl/uploaded/docs/AlgemeenOncolineEnPallialine/Draaiboek%20openbare%20versie%202%20november%202009%20aangepast%20voor%20drukwerk_moi.pdf
56. Morestin F, Gauvin F-P, Hogue M-C, Benoit F. Method for Synthesizing Knowledge about Public Policies. Montréal: NCCHPP; 2010. Available from: http://www.ncchpp.ca/docs/MethodPP_EN.pdf
57. Alexander JA, Hearld LR, Mittler JN, Harvey J. Patient–Physician Role Relationships and Patient Activation among Individuals with Chronic Illness. Health Services Research. 2011;Epub ahead of print(Nov. 18).
58. Bos V, Van Kammen J. Knowledge synthesis : a guide. The Hague: ZonMw; 2007.
59. CHSRF. Public engagement (part II): how do deliberative processes achieve meaningful public engagement? Ottawa: Canadian Health Services Research Foundation; 2009 Feb. Insight and action 49 Available from: http://www.chsrf.ca/Migrated/PDF/insightAction/Insight_and_Action_49_e.pdf
60. AccountAbility. AA1000 Stakeholder Engagement Standard. London: AccountAbility; 2008. Available from: http://www.accountability.org/images/content/5/4/542/AA1000SES%202010%20PRINT.pdf
61. CCOHTA. Summary Report of 2004 COMPUS Stakeholder Consultation Sessions. Ottawa: Canadian Coordinating Office for Health Technology Assessment (CCOHTA); 2004. Available from: http://64.26.163.205/media/pdf/compus_stakeholder_report_april05.pdf
62. Griffiths J, Maggs H, George E. Stakeholder Involvement: Background paper prepared for the WHO/WEF Joint Event on preventing Noncommunicable Diseases in the Workplace. Geneva: WHO; 2008. Available from: http://www.who.int/dietphysicalactivity/griffiths-stakeholder-involvement.pdf
63. E.P P, Vijfvinkel D, Vennekens A, van Hoesel P, Daue F. Study into the impact of the Belgian Health Care Knowledge Centre. Zoetermeer: 2010. Available from: http://www.kce.fgov.be/sites/default/files/page_documents/2008-55_hsr_impact_study%20kce.pdf
64. Hulstaert F, Huybrechts M, Van Den Bruel A, Cleemput I, Bonneux L, Vernelen K, et al. [Molecular Diagnostics in Belgium]. Health Technology Assessment (HTA). Brussels: Belgian Health Care knowledge Centre (KCE); 2005 22/11/2005. KCE reports 20 Available from: http://kce.fgov.be/publication/report/molecular-diagnostics-in-belgium
65. Eyssen M, Kohn L, Lambert M-L, Van Den Steen D. [Home Monitoring of Infants in Prevention of Sudden Infant Death Syndrome]. Health Technology Assessment (HTA). Brussels: Belgian Health Care Knowledge Centre (KCE); 2006 21/12/2006. KCE reports 46 Available from: http://kce.fgov.be/publication/report/home-monitoring-of-infants-in-prevention-of-sudden-infant-death-syndrome

66. Mathieu C, Nobels F, Peeters G, Van Royen P, Dirven K, Wens J, et al. [Quality and organization of the care for diabetes 2]. Good Clinical Practice (GCP). Brussels: Belgian Health Care Knowledge Centre (KCE); 2006 12/05/2006. KCE reports 27 Available from: http://kce.fgov.be/publication/report/quality-and-organization-of-the-care-for-diabetes-2

67. Guillaume P, Moldenaers I, Bulté S, Debruyne H, Devriese S, Kohn L, et al. Optimisation of the operational processes of the Special Solidarity Fund. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2010 28/07/2010. KCE reports 133C (D/2010/10.273/46) Available from: http://kce.fgov.be/publication/report/optimisation-of-the-operational-processes-of-the-special-solidarity-fund

68. Van den Bosch K, Willemé P, Geerts J, Breda J, Peeters S, Van de Sande S, et al. [Residential care for older persons in Belgium : Projections 2011 – 2025]. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2011. KCE reports 167 Available from: http://kce.fgov.be/publication/report/residential-care-for-older-persons-in-belgium-projections-2011-%E2%80%93-2025

69. Borgermans L, Dubois C, Rieppi S, Vanhaeren S, Geukens N, Fallon C, et al. Impact of academic detailing on primary care physicians. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2010 29/03/2010. KCE reports 125C (D/2010/10.273/16) Available from: http://kce.fgov.be/publication/report/impact-of-academic-detailing-on-primary-care-physicians