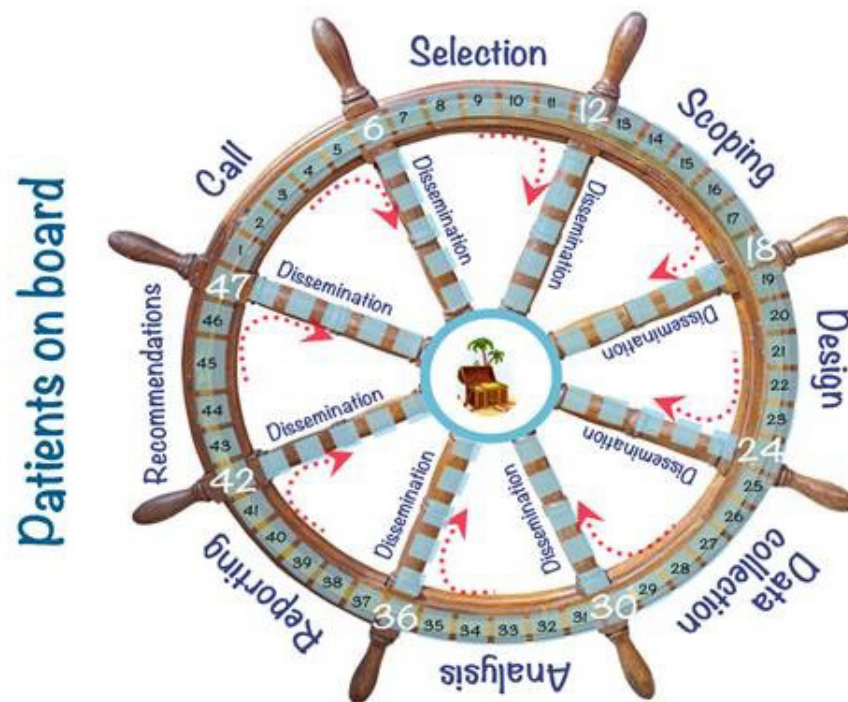


SHORT REPORT

POSITION OF KCE ON PATIENT INVOLVEMENT IN HEALTH CARE POLICY RESEARCH



SHORT REPORT

POSITION OF KCE ON PATIENT INVOLVEMENT IN HEALTH CARE POLICY RESEARCH

IRINA CLEEMPUT, MARIE DAUVRIN, LAURENCE KOHN, PATRIEK MISTIAEN, WENDY CHRISTIAENS, CHRISTIAN LÉONARD



■ SHORT REPORT

TABLE OF CONTENTS

■	SHORT REPORT	1
1.	BACKGROUND	4
2.	WHAT IS PATIENT INVOLVEMENT	5
2.1.	DEFINITION	5
2.2.	INVOLVEMENT IN ALL OR SOME RESEARCH PHASES	5
2.3.	DIFFERENT LEVELS OF INVOLVEMENT	5
3.	WHO IS “THE PATIENT”?	6
4.	WHAT IS THE RATIONALE FOR INVOLVING PATIENTS IN POLICY RESEARCH?	7
4.1.	FUNDAMENTAL ETHICAL RATIONALES	7
4.2.	PROCEDURAL AND INSTRUMENTAL RATIONALES	7
5.	WHAT ARE THE EFFECTS OF PATIENT INVOLVEMENT IN HEALTH POLICY RESEARCH	9
5.1.	POSITIVE EFFECTS.....	9
5.2.	BARRIERS, RISKS AND CHALLENGES	10
6.	REQUIREMENTS FOR MEANINGFUL PATIENT INVOLVEMENT IN RESEARCH	11
6.1.	WHEN DOES PATIENT INVOLVEMENT MAKE SENSE?.....	11
6.2.	STANDARDS FOR PATIENT INVOLVEMENT.....	12
7.	IS KCE READY FOR PATIENT INVOLVEMENT?	13
7.1.	KCE CULTURE	13
7.2.	MORE ARGUMENTS PRO THAN CONTRA PATIENT INVOLVEMENT.....	14
8.	WHO, WHEN AND FOR WHAT?	15
8.1.	INCREASING ROLE OF PATIENTS AT KCE.....	15
8.2.	WHO TO INVOLVE AND WHEN?	15



8.3.	EMBEDDED CONSULTATION	16
8.4.	... UNDER SPECIFIC CONDITIONS.....	16
8.5.	COMMITMENT TOWARDS THE PATIENTS INVOLVED	16
9.	KCE'S POSITION STATEMENTS REGARDING PATIENT INVOLVEMENT IN HEALTH POLICY RESEARCH	17
■	REFERENCES	19



LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
BS – MB	Belgisch Staatsblad – Moniteur Belge
CADTH	Canadian Agency for Drugs and Technologies in Health
CBPR	Community-based practice research
GCP	Good Clinical Practice
HIV	Human Immunodeficiency Virus
HSR	Health Services Research
HTA	Health Technology Assessment
NICE	National Institute for Health and Care Excellence
NIHDI	National Institute for Health and Disability Insurance
NIHR	National Institute for Health Research
PREMs	Patient-reported experience measures
PROMs	Patient-reported outcome measures
SMC	Scottish Medicines Consortium
SPOR	Strategy for Patient Oriented Research



1. BACKGROUND

KCE was established by a programme law on 24 December 2002 (BS/MB 31-12-2002). Its remit is to perform and publish scientific research, to support a high quality, sustainable and accessible health care system in Belgium. To meet this aim, KCE performs several research activities, ranging from literature reviews, economic evaluations, data analyses and qualitative or quantitative data collection. The role of patients in these activities, as active participants in the research, has not been defined nor mentioned, but not excluded either, in the program law.

In the last five to ten years, we have seen an international evolution towards more patient involvement in policy research projects.¹ Several prominent organisations such as the National Institute for Health Research (NIHR, UK), the National Institute for Health and Care Excellence (NICE, UK), ZonMw (the Netherlands), the Scottish Medicines Consortium (SMC), the Canadian Agency for Drugs and Technologies in Health (CADTH) and others consider it no longer acceptable to not address patient involvement in health policy research. Several agencies, including KCE, have established seats at important advisory commissions or –as in the case of KCE- their Board of Directors, but not always with voting rights.

In the early years of KCE, huge emphasis has been put on quantitative “hard data”, i.e. data coming from randomized controlled trials, data registries, etc., imposing high quality criteria. Quality of life was from the very beginning considered to be an important outcome and included in assessments, at least if studies of sufficiently high quality were published in the literature, preferably in peer-reviewed journals. Patients were sporadically consulted, but rarely involved directly in the research projects, e.g. to define the scope, make methodological choices, interpret the results, formulate recommendations or help in the dissemination of the results.

Throughout the years, KCE has increasingly involved stakeholders, including patients, in its research processes. It even devoted a specific report on this process of stakeholder involvement ([KCE-report 174](#)).² Until now, KCE has considered and treated patients as one of the stakeholders. However, it should be acknowledged that they are in a different position than other stakeholders, especially when they are suffering or affected by the

disease under consideration. To be physically, emotionally and/or financially affected by a condition gives them a different perspective to a problem, compared to stakeholders that are professionally or economically affected by the issue or have no direct experience with the disease under consideration. Patients or their representatives have experiential knowledge that could help to improve research decision making. Therefore, involving patients or their representatives in research requires specific approaches which might differ from the classic stakeholder involvement approaches.

For this reason, KCE wants to think more thoroughly about the way in which it wants to involve patients structurally and coherently in its studies, and check whether it is ready to commit itself to this.

The objective of this position paper is to address a number of more fundamental questions: “What is KCE’s perspective on patient involvement in policy research? Does KCE support patient involvement? Why? To what extent? What are or should be the (limits to the) implications of patient involvement in terms of commitment towards patients, accountability, weight given to their input in the formulation of conclusions and recommendations?”

To develop a KCE position on patient involvement in policy research, we considered different rationales for patient involvement in policy research as described in the literature and policy statements of agencies similar to KCE in other countries, dug into the ethical and philosophical rationales for patient involvement, measured the current patient involvement culture at KCE and experience up to now, and interviewed several Belgian experts with experience in patient involvement in research. The draft position statements were presented and voted upon by the entire KCE team, involving all staff members, from management to the secretariat and supporting staff.

Operational questions, such as “In which research phase should patients be involved?”, “How should they be involved?”, “Who should be involved to represent the patient?”, etc. will be addressed in an operational guide that is yet to be developed.



2. WHAT IS PATIENT INVOLVEMENT

2.1. Definition

INVOLVE, the national advisory group on public involvement in health and care research, funded by the National Institute for Health Research (NIHR) in the UK, defined patient and public involvement in research as 'doing research **with** or **by** people who use services rather than **to**, **about** or **for** them'.^a While this definition encompasses public involvement in research and our focus is only on patient involvement in research, the definition still applies.

2.2. Involvement in all or some research phases

Patients can be involved in all or some of the different research phases, i.e. in

- the identification of research topics
- the prioritization of topics
- the scoping of a study project
- the design of a study
- the execution of the research (data collection, analysis and interpretation)
- the reporting of the study results
- the dissemination of the findings of the research projects.³

2.3. Different levels of involvement

To be able to speak about patient involvement in research, there must be a partnership between researchers and patients.³ Within this partnership, patients can have more or less control over the decisions made during the research process. The intensity of patient involvement can vary, from consultation, over collaboration to full patient control.^{4, 5} Further specifications are possible. We use the levels as proposed by Hughes and Duffy.⁶

Involving patients in key decisions throughout the research project life cycle does not automatically imply joint decision making, but could also imply targeted consultation or embedded consultation. In case of **targeted consultation**, patients are consulted on specific aspects of the research study on an *ad hoc* basis. They may not receive much information regarding progress, outputs or impact of the study. **Embedded consultation** is a type of involvement where patients are *regularly* consulted throughout the research process.⁶

Besides consultation, patients can also be involved as collaborators or co-producers of research. **Collaboration and co-production** implies involving patients in the research team, either as researchers/co-authors or as contributors to key decisions regarding research processes and findings.⁶

A final level of involvement intensity is **user-led involvement**, whereby patients, academics and practitioners work together systematically across all areas of the research cycle, from scoping to dissemination. Patients take the lead in directing the nature and direction of a study.⁶ The research is actively controlled, directed and managed by patients and/or patient organizations.

^a <https://www.invo.org.uk/resource-centre/jargon-buster/?letter=P>

INVOLVE systematically uses the term '*patient and public involvement*', because their scope encompasses all 'users of services'. Other terms

frequently used in literature are citizen involvement, consumer involvement, health service user involvement, etc. Our position statement relates to the more narrow focus of patient involvement.



3. WHO IS “THE PATIENT”?

In this position paper, we use the term ‘patient’ to encompass different groups of people that can provide patient-relevant input in the research process:

- **Experts by experience**, i.e. individuals with a specific condition or having recovered from a specific condition, or having experience with the healthcare system (e.g. through pregnancy and delivery)
- **Relatives or informal caregivers**, i.e. people close to the patients, if the patients are unable to express themselves
- **Patient-experts**, i.e. experts by experiences with knowledge about scientific approaches (trained or acquired through frequent involvement in research projects).
- **Patient representatives**, i.e. representatives of a patient organisation or patient population, not necessarily affected by the condition under consideration. Patient representatives are considered to be advocates defending specific interests of a specific patient group (e.g. patients with lung cancer) or a broader group of patients (e.g. cancer survivors). They have a broader perspective on the problems and experiences of the population than the individual expert by experience.
- Representatives of the **umbrella organisations** of patient associations, defending the interests of patients in general or supporting their member organisations in their activities. They generally take a different position in advisory committees than the advocates of a specific patient population. If they support a patient representative in an advisory committee, they help this representative to formulate his/her perspective, without influencing their viewpoint.
- Representatives of **sickness funds**, considered to speak on behalf of healthcare service users, which can be patients suffering from a health condition but also general public using and paying for healthcare services.

Even though we acknowledge that carers and families of patients could also be involved on their own behalf as relevant stakeholders, because caregivers might also be directly affected by policy research or the policy decisions informed by it, we do not include them as separate actors because the focus of the position paper is on involvement of patients with the objective of bringing in the *patient perspective* in policy research.

For some specific topics, e.g. prevention of a particular contagious disease, or general topics, e.g. criteria for priority setting in healthcare, ‘patients’ can include people without (targeted) experience with the healthcare system. In these cases, we are interested in their perspective as potential patient or **healthcare user**.

The focus of this position paper is on the involvement of *patients* in research, rather than the involvement of citizens or the general public. The objective of **KCE** is to improve the inclusion and assessment of patient-related issues in its research by involving patients in this research. More specifically, it **wants to know how the quality of its research on patient-related issues (e.g. impact of a treatment on quality of life, patient priorities, etc.) can be improved by involving patients in decisions about the scope, design and execution of research projects**. Citizens can be involved to learn about the aspects that are relevant for the society as a whole, but this is a different kind of perspective which might require a different approach to involvement.



4. WHAT IS THE RATIONALE FOR INVOLVING PATIENTS IN POLICY RESEARCH?

Several rationales for patient involvement in research are described in literature. We can make a distinction between fundamental ethical, philosophical or moral rationales and procedural, instrumental rationales.

4.1. Fundamental ethical rationales

Fundamental ethical rationales may answer questions like: “Should we do this, for what reason and if not, what are the ethical arguments for not doing it?”⁷ One fundamental ethical rationale refers to the *moral right* of patients to be involved in research that concerns them directly or indirectly and is funded with public money. This relates to fairness and legitimacy through democratic participation.

Another fundamental ethical rationale relates to our humble recognition that as researchers we do not necessarily know what are the important features for the patient. Patients have a conception of what the human being is, what good health is or should be, what health improvement means and whether such an improvement is necessary, and what autonomy and responsibility for own health is, can or should be. These concepts, as perceived by patients, are essential for the relevance for the community of our research work.

These fundamental ethical rationales for patient involvement seem to be more common in projects based on community-based participatory research (CBPR) and, to a lesser extent, in qualitative study designs. CBPR is rooted into social justice theory and often concerns very specific groups or situations, e.g. patients with HIV. The aim of CBPR is to ensure that everyone who may be affected by research is fairly involved in the research process, recognising everyone's unique strengths.⁸

From the interviews with Belgian researchers who involved patients, we learnt that these arguments are rarely the main rationale for involving patients, as opposed to instrumental or procedural arguments. A few exceptions exist, such as the King Baudouin Foundation, which has a strong foundation in democratic principles.

KCE endorses the involvement of patients on the basis of 'democratic participation for the sake of justice'. It means that the different partners in the research listen to each other's perspectives and arguments, and are prepared to reach a consensus on this. However, it should be acknowledged that not all decisions made during a research project (e.g. regarding the study design, the data collection methods, the analyses) require deliberation and that not all project-related choices resulting from a deliberation are acceptable.⁹ Results of a deliberative process still need to be put against the central values of the healthcare system: to develop and maintain a sustainable and fair health system, providing high quality of care.

4.2. Procedural and instrumental rationales

Procedural and instrumental rationales include (1) increasing the relevance of a research project to health care goals of society and health care needs of patients, taking patients' values and norms into account; (2) procedural legitimacy leading to more confidence in the results; (3) content-related legitimacy leading to adherence to decisions, and (4) capacity building via patient empowerment.¹⁰⁻¹²

Patients are considered 'instrumental' to scientific policy research because they contribute to research from a unique perspective that differs from those of the researchers, healthcare professionals or other experts.

They can contribute valuably to different research phases, from the identification and prioritization of research topics to the dissemination of research results and recommendations. For example, they can help to ensure that the selected research topics match patient needs, that the right research questions are posed and the most important outcomes are selected for the study, that data collection methods are appropriate and feasible, that the statistical analyses are performed in the right context (e.g. defining a meaningful effect size), results are reported in an appropriate way.



Patients can also help in the dissemination of findings and recommendations through their informal networks.

In addition, involving patients in the process of drawing conclusions from the research and formulating recommendations, improves procedural legitimacy. It has been argued that patients might understand conclusions and recommendations better if they have been involved in the research process.¹³ This argument actually applies to all types of stakeholders. KCE supports this rationale, as demonstrated by the implementation of its stakeholder involvement process. It is clear, though, that stakeholders might have different opinions which cannot always be taken into account up to the same level in the project and by extension, the recommendations. Hence, the level of acceptance of the recommendations will still differ amongst stakeholders.

Finally, by involving patients in policy research, their capacity to contribute effectively to research will be strengthened (capacity building via empowerment).¹²

KCE recognizes the procedural and instrumental rationales for patient involvement in policy research, but considers the level of involvement to be contingent on the topic and phase in the research process. Careful consideration of the relevance of patient involvement in research projects and the required intensity of involvement is required in a very early phase. It may be useful to involve patients in this reflection process.

Note on patient-based quantitative and qualitative evidence

Health policy research aims to provide or contribute to the justification of decisions, by collecting relevant data and evidence, analysing these and weighing the different pieces of collected evidence to formulate recommendations. Different types of evidence, quantitative and qualitative, on different aspects of healthcare (e.g. safety, effectiveness, organisation) are usually automatically considered in policy research, and this should continue to be the case, but also patient-based evidence should get the necessary attention. Patient-based evidence refers to evidence about the broader implications of an issue for patients (or their families), generated in a scientifically sound manner. The scientific approach to the collection of data from patients makes evidence distinct from the outcomes of an informal

consultation. Patient-based evidence is often published in peer reviewed journals and should be treated in the same way as clinical or economic evidence in the evidence synthesis.

For example, defining the relevant outcomes that need to be studied or the relevant patient-related aspects of a health policy problem could be derived from published patient-based evidence.⁹ This might reduce the issue of possible disagreements between patients of the same patient population regarding the relevant aspects to be included in the research design or objectives.

Patient involvement in research projects is complementary to reviews of published evidence on patient perspectives and experiences, not a substitute for scientific evidence. If such evidence is lacking, primary data might need to be collected in patients. Patient involvement in research can help to define the best ways to collect data in patients on patient-related issues.

To avoid that patient involvement is dismissed as being purely subjective and unscientific, diluting the scientific nature of the health policy research performed at KCE, **it is important to make the right choices about who to involve, in what role, in which phase of the research project and for what purpose.** This applies also to other stakeholders involved in the research process. KCE conducts research with a social interest. The research topics often have implications for both the individual patients and the society as a whole. Therefore, individual patient preferences and perspectives should be balanced against other relevant parameters, which might be less important for patients from their individual or group perspective but which are relevant from a societal point of view. KCE considers the collection and reporting of published patient-based evidence, where relevant, as an essential component of policy research. If such evidence is lacking, data might need to be collected in patients.



5. WHAT ARE THE EFFECTS OF PATIENT INVOLVEMENT IN HEALTH POLICY RESEARCH

Several systematic reviews look at the effects and impact of patient involvement in health policy research.^{4, 5, 13-35} The reviews show that, in general, patient involvement has effects on patients, on researchers and on the research process and research outcomes. The review process was often hampered by lack of coherence in the terminology and definitions used regarding patient involvement across primary studies. Also the methods of patient involvement varied between studies, as well as the phase of the research process the patients were involved in.

All reviews found that there were only few studies that applied comparative methods to demonstrate effects and added value of patient involvement: most of the reported effects seem to be opinion based and much of the evidence concerning impact remains rather weak. Very few studies use qualitative research techniques to study the impact of patient involvement on research processes.

The overall impression is that patient involvement may lead to positive effects, but also numerous challenges exist.

5.1. Positive effects

In general, patient involvement in health policy research may have the following positive effects:

- for patients:
 - Patient involvement enhance the relevance and importance of the research for patients' needs and circumstances.
 - Patients report feeling empowered and valued, gaining confidence and life skills.
- for researchers:
 - Researchers develop a greater understanding and insight into their research area, gaining respect and a better connection with the community
- for the research process and outcomes:
 - Impacts were reported for all research phases, including the development of user-relevant research questions, development of user-friendly information, questionnaires and interview schedules, more appropriate recruitment strategies, user-focused interpretation of data and enhanced implementation and dissemination of study results:
 - Patient involvement can enrich researchers' understanding of the needs, priorities, and health concerns of communities, organizations, and the public health system and lead to refined and new research questions.
 - Patient involvement can improve research quality by increasing recruitment and retention rates, reducing reporting bias, and reducing measurement error from survey and interview questions that are not culturally aligned.
 - Integrating patient perspectives with research results can lead to research products that are tailored to meet the needs of implementing systems, implementers, and end users



- Perceived outcomes of patient involvement include the facilitation of the research process and the application of the results, and the empowerment of stakeholders.

Subjectively, it is felt by researchers and patients engaging in patient involvement activities that the level of benefit derived for patient involvement is proportional to the level of resources made available and investment in obtaining and facilitating that involvement.³⁶

5.2. Barriers, risks and challenges

Possible barriers to meaningful involvement of patients in research encompass:

- Additional time and resources needed for patient involvement,^{13, 17} for example to identify patients, invite them to participate in meetings or consultation rounds, guide them through the process, possibly educate them, compensate them for incurred costs, but also to coordinate, follow up and evaluate the activities of patient involvement within the organisation.
- Emotional burden put on patients and researchers: for some patients, having to recall or talk about their own experiences and listen to those of others is emotionally very difficult¹⁷. For their part, researchers may feel uncomfortable when patients' ideas do not match their expert vision, particularly when it concerns different visions of what constitutes good research.³² Lack of preparation and training led some patients to feel unable to contribute to the research.¹⁷
- Frustrations in patients when they feel that they are not taken seriously or receive no feedback from researchers.³²
- Lack of motivation and scepticism on the part of researchers or lack of interest on the part of patients to participate. In addition, participating patients may also be reluctant to express their opinions or have difficulty listening to others.
- Operational issues. For example, lengthy processes that involve training, transportation, attendance to meetings, inaccessible meeting rooms, etc.^{13, 17, 33, 37}

Risks include:

- Tokenism: patients are only involved because researchers 'have to' according to the organization's procedures.
- Selection bias: only the most vocal patients, representatives of patient groups with high profile diseases (e.g. breast cancer), patients with higher socio-economic profiles and patients with a specific cultural background are selected as patient partners in health policy projects. Other profiles of patients, like rare conditions, lower socio-economic profiles, poor health literacy, ethnic or cultural minorities, risk to be included less frequently.³⁸ Insufficient awareness of this may undermine the organisation's patient involvement efforts, especially if the fundamental reason for involving patients is fairness, equity and legitimacy. This must therefore be a point of attention from the very beginning of the study.
- Conflicting interests: may occur when patients with a large decision-making power in the study have an interest in a particular outcome, or are strongly influenced by clinicians or the pharmaceutical industry. As for any other stakeholder, this can cause bias.⁷

Several other challenges have been described in literature (see chapter 7 of the scientific report). The overall challenge is to find the right balance between allowing patients to have their say in the course of the research, on the one hand, and maintaining scientific rigour and validity, on the other. Besides being evidence-based and value-based, good research also has to be experience-based.

Involving patients also comes with an important organisational challenge that might have strong ethical implications. The involvement of specific patient groups will be extremely difficult. For instance, patients with severe rare diseases, marginalised patients, patients with some acute diseases, homeless people, people without social networks, hard to reach patients, patients with communication difficulties and patients with mental disorders. Lack of awareness of these challenges might reduce the value of the patient involvement endeavour, especially if the fundamental rationale for involving patients is fairness, equity and legitimacy.



6. REQUIREMENTS FOR MEANINGFUL PATIENT INVOLVEMENT IN RESEARCH

6.1. When does patient involvement make sense?

We have learnt from our research that there is no single effective approach but a range of methods for patient involvement. The patient involvement approach, encompassing the level of involvement, the people to involve and their role, needs to be chosen based on the objectives of the patient involvement, the topic, the expected barriers and the resources available. The *process* of patient involvement is equally important as the *outcomes* of the patient involvement.³⁹

There are personal as well as contextual factors that will determine the patient involvement quality.³⁹

Personal factors include, for instance, the extent to which patients feel valued and acknowledged, feel able to achieve their own goals by being involved in the work of research institutions, feel able to make a contribution to research, and feel able to take on new research challenges. These relate mainly to patients' confidence and feeling of empowerment. Some level of *education* or *training* might foster these factors. However, depending on the reason for the involvement, patient training might be more or less needed or even desired.

Contextual factors that might influence the quality of the patient involvement encompass two dimensions: factors related to the research context and factors related to the organizational context.

The **research context** refers for instance to the *reasons* for involving patients in the research, the *clarity with respect to the role, responsibilities and required skills/experience* of patients, and clarity about the ethical and legal *rules* for the research (e.g confidentiality).

Factors related to the **organizational context** include first and foremost the patient involvement culture in the research organization. It has been described in the literature that one of the key conditions that fosters successful patient involvement in research is an organization-wide policy that acknowledges patients as key stakeholders, with mutual respect to one another's different knowledge and experience.⁴⁰

When the organizational culture is supportive of patient involvement, **resources** will more easily be allocated to patient involvement activities, expertise and skills in supporting patients in their activities and connecting and communicating with patients can more easily be developed. *Funding* for patient involvement activities is crucial to create a solid **structure** to support patients and researchers engaging in patient involvement activities in research, to create an environment that takes into account the ways of working that suit the patients at locations that are easily accessible, to *coordinate* patient involvement activities (avoid patient exhaustion), ensure real partnerships (avoid tokenism!), and *manage expectations* of both patients and researchers.

Strategies and actions that enable patient involvement in a research process include, for example, developing strategic partnerships with patient organizations, make patient involvement mandatory in grant applications (as in the KCE trials programme and several Innoviris^b programmes), make sure patient contributions influence the research and communicate to patients how their contributions influenced the research. Availability of resources, and formal and informal support networks that facilitate and coordinate the patient involvement activities is also one important condition for successful patient involvement identified in literature.⁴⁰

Different organisational models have been described in literature or applied in practice:

- Incidental involvement: this model corresponds to a **targeted consultative approach** to patient involvement. Different methods for consultation can be applied: individual interviews, focus groups,

^b *Innoviris: Brussels Instituut voor Onderzoek en Innovatie /Institut Bruxellois de Recherche et d'Innovation*



nominal groups, surveys, research days, etc. KCE applied this approach in several research projects, e.g. about the treatment of low back pain, the organisation of enteral and parenteral nutrition, the treatment of prostate cancer, breast reconstruction after mastectomy for breast cancer, etc.

- Patient advisory committee: this model fits best with the **embedded consultative approach** to patient involvement.
- Patients as full members of the project steering group that takes the decisions about the design and execution of the research project: this model is appropriate when the approach chosen for patient involvement is **collaboration/co-production** or **user-led** decision making. Successful examples of such structures, embedded in existing research organizations include INVOLVE (UK), the James Lind Alliance (UK), SPOR (Canada). From the interviews with representatives of Belgian initiatives, we identified one example of a research project initiated by patients: they commissioned a research center to investigate the needs of their community.

6.2. Standards for patient involvement

For defining the KCE standards for patient involvement, we rely on the work of INVOLVE in the UK, which published a framework with standards and indicators for public involvement in research.⁴¹ We re-formulated the indicators as success factors for meaningful patient involvement and adapted them slightly to our purposes.

The values and success factors included in the table below should be considered as part of KCE's position statement regarding patient involvement in research.

Standards for patient involvement in KCE research (adapted from INVOLVE⁴¹)

Standard	Patient involvement is more likely to be meaningful if ...
Inclusive opportunities	<ul style="list-style-type: none"> • patients are involved at an early stage • barriers for patients to getting involved in research are identified and addressed • information about opportunities for patient involvement in research are made available using different methods so that relevant and interested people are reached • processes for patient involvement in research are fair and transparent • choice and flexibility in ways to get involved in research are offered
Working together	<ul style="list-style-type: none"> • the purpose of the patient involvement activity is jointly defined • patient involvement plans and activities are developed together • there is shared understanding of roles, responsibilities and expectations, which may evolve over time • individual ideas and contributions are recognized and decisions are upheld together
Support learning and	<ul style="list-style-type: none"> • resources to ensure and support effective patient involvement are designated and monitored • support is offered to researchers and patients to address identified needs • there is an identified point of contact for information and support • the team builds on what was learned in other projects
Communications	<ul style="list-style-type: none"> • inclusive and flexible in communication methods are used to meet the needs of different people • feedback is gathered, offered, shared and acted upon
Impact	<ul style="list-style-type: none"> • patients are involved in the assessment of patient involvement in research



-
- the purpose for patient involvement and its intended outcomes are agreed upon
 - information that will help assess the impact of patient involvement in research is collected
 - the extent to which the intended purpose and predicted outcomes are met are reflected upon, learnt from and reported

Governance

- patient voices are heard, valued and included in decision making
- patient involvement strategies and/or plans are in place and regularly monitored, reviewed and reported upon
- responsibility for patient involvement is visible and accountable throughout the management structure
- money and other resources are allocated for public involvement

Adapted from INVOLVE (2019)⁴¹

7. IS KCE READY FOR PATIENT INVOLVEMENT?

7.1. KCE culture

Based on a survey amongst KCE employees, we found that patients have already sporadically been involved in former KCE projects. The current position paper aims to define a patient involvement policy that is supported by the entire organization. Therefore, we wanted to explore to what extent experts and other employees at KCE are open to patient involvement in their research and prepared involve patients. We also wanted to assess whether the KCE staff is ready to endorse the position statements.

First, we measured the prevailing culture at KCE with respect to patient involvement in health policy research by means of a brainstorming session, operationalised as a board game. All employees, from general management, to researchers and supporting staff, were involved in the activity. Arguments in favour or against patient involvement in different research phases, as well as conditions for patient involvement were collected and analysed using qualitative research techniques.

In a second phase, we presented 19 position statements to the entire group and asked them to vote on each of the statements. The position statements were based on the literature review, interviews with representatives of Belgian initiatives and patient (umbrella) organisations, and the overview of international initiatives and patient involvement activities at international agencies. The rationale for each statement was briefly explained. Based on the results of the votes, a distinction was made between statements for which consensus was reached in favour of a statement (more than 75% agreed, and less than 10% disagreed with the statement, n=14) or against a statement (more than 75% disagreed and less than 10% agreed, n=1), and statements for which no consensus was reached amongst KCE employees (n=4). The latter were discussed in a plenary session and re-voted upon. Afterwards, everyone was given the opportunity to comment on all the statements via an online survey. Based on the discussion during the meeting and the written comments, the wording of some of the statements was changed. There was no new vote on the statements. The final decision



whether or not to keep a statement was taken by the management. Rejected statements were about (1) the consultation of patients in the selection of methods for the research projects (statement for which consensus on disagreement was reached amongst KCE employees), (2) the consultation of patients in the interpretation of the results and (3) the review of the synthesis by patients before publication. One statement which had initially not reached consensus, was nevertheless retained after reformulation based on the comments of the KCE employees. The statement related to the involvement of patients in the scoping phase to help define the elements that need to be addressed in the research project. While the initial statement suggested co-production of these elements by means of a joint decision making process, the reformulated version suggests consultation. This was the level of involvement most employees would be able to agree with, according to the comments received. Finally, one statement that did not reach consensus amongst KCE employees was nevertheless retained. It related to the consultation of patients in the selection and testing of data collection instruments on patient issues.

A summary of all comments is included in the scientific report.

7.2. More arguments pro than contra patient involvement

We observed variability between experts, both within and between research domains (HTA, HSR, GCP and Trials), but in general, across all KCE employees (including management and staff) and across all research phases, more arguments in favor of patient involvement were given than against. These corresponded to a large extent with findings from the literature.

People were least enthusiastic about involving patients in the design phase of the project, and most about patient involvement in the dissemination phase. The ability of patients to identify the unmet needs and highest priorities in their disease area was especially appreciated for the 'call for proposals' phase by several groups.

People's main concern was the impact of patient involvement on time, personnel and resources. It was also stressed that researchers and patients should clearly communicate their expectations at the start of the project, so that they can be adjusted if necessary. In this way, frustrations and

disappointments are avoided as much as possible. Although some concerns were raised about potential conflicting interests and the scientific credibility if patients are involved as project partners, the general culture at KCE seems to be favourable towards patient involvement in research.

The final position statements (see below) are fully supported by the KCE management. The management is prepared to allocate the necessary resources and to adjust the planning, within the framework within which the KCE has to fulfil its mission. The concrete operationalisation of patient involvement in the KCE research projects (e.g. which 'type' of patient representatives to involve in specific research phases) will be developed in a KCE process book that is yet to be developed.



8. WHO, WHEN AND FOR WHAT?

8.1. Increasing role of patients at KCE

For KCE, a national research agency strongly embedded in a democratic society and aiming at supporting legitimate decision making in healthcare, patients do indeed have a moral right to be involved in policy research. Since its conception, KCE has contributed to the fundamental reflections about legitimacy in decision making, as demonstrated by several of its published reports. In 2012 it published a report about "Stakeholder Involvement" in KCE work processes ([KCE-rapport 174](#)).² One year later, KCE published a report about the acceptability and feasibility of patient and citizen involvement in health policy to different stakeholders ([KCE-rapport 195](#), 2013).^{42, 43} In 2014, KCE defined the relevant criteria for the appraisal of therapeutic and societal need and we consulted the Belgian general public, by means of a large survey using a quantitative approach, about the relative importance of these criteria for the appraisal of therapeutic and societal need and the added therapeutic value ([KCE-rapport 234](#)).⁴⁴ An accountability for reasonableness framework for reimbursement decisions was established, recommending the use of these criteria weights. In 2016, the criteria and their weights were used in a multi-criteria decision analysis model for the appraisal of therapeutic and societal needs, that was piloted in collaboration with the unmet needs commission of the NIHDI for the appraisal and ranking therapeutic and societal needs in healthcare ([KCE-rapport 272](#)).⁴⁵ The central role given to patients in KCEs work, is also demonstrated by the projects about patient-reported outcome measures (PROMs) and patient-reported experience measures (PREMs) to assess and improve the quality of care, be it at the national, institutional or individual patient level ([KCE-rapport 303](#), 2018).⁴⁶

In addition to these reports, representatives of four umbrella organizations of patient associations in Belgium (Flemish, French-speaking and German-speaking and RaDiOrg, the Belgian rare diseases organisation) are members of the KCE Board of directors since 2015. KCE also applies a patient-centered strategy in its publicly funded trials programme: a patient representative is part of the Trials Board, and patient involvement in the design of the pragmatic trials submitted for funding is a requirement.

8.2. Who to involve and when?

We need to take a position as to who to involve, in which role, when in the research process, for what purpose and how.

In terms of who to involve, there are different options (chapter 2): individual patients, patient-experts, patient organisations, umbrella organisations of patient associations and sickness funds. Our position is that the goal of patient involvement in a policy research project will determine to a large extent the actors to be involved, their role and the involvement approach. It is important to carefully consider the appropriate approach for the specific goal of the involvement, as goals may conflict and give rise to bias depending on how patients are involved in the research process.⁷ Bias occurs if patients with a vested interest in the outcome of the research, or heavily influenced by the information they received from clinicians or industry, have strong decision power on specific aspects of the study. Researchers and patients might not always be aware of the impact on patients' views of these influences.⁷ Because of these considerations, which are mainly contextual, the question of who to involve will be tackled in the process book. In this position paper, we apply the high-level term 'patient' to encompass the different possible representatives mentioned before.

In terms of the 'when', we learnt that the quality of the patient involvement will depend on patients' having the opportunity to bring in own ideas. Therefore, it is important to involve of patients in the early phases of a research project. This also creates realistic expectations about what can be achieved, and can help to define ways of working that align with patients' needs. This becomes harder when the study is already ongoing.³⁹



8.3. Embedded consultation ...

The 'how' question is at this stage answered by means of using the high-level approaches described in paragraph 2.3, being consultation, collaboration or user-led decision making.

KCE supports the idea of embedded consultation, i.e. patients are regularly involved in all research phases. The "patient" involved in each stage of the research process might change throughout the process. For example, while in the 'selection of topics', it could be decided to involve the umbrella organisations and sickness funds but not individual patients (as is the case now). Individual patients return in the process in the scoping and design phase.

8.4. ... under specific conditions

KCE aims at involving patients in all research phases, *if* this is relevant and appropriate for the project. The KCE will take patients' views into account, but this does not mean that all decisions made in the research process (e.g. on the choice of outcome parameters to be studied, the tools to be used to collect data from patients, the conclusions to draw from the literature on patient preferences) will solely be based on the input of patients. The extent to which the advice of patients can be followed will depend on any other relevant parameters for the study, which may be less important for the patients concerned, but are important for society as a whole and should therefore be included in the study because of the remit of KCE. Sometimes choices will have to be made to keep the research process feasible and at the same time make it fit within the remit and mission of KCE.

8.5. Commitment towards the patients involved

Involving patients in research processes implies a commitment towards these patients. A fundamental question we need to address in this position paper is therefore "what is the level of commitment we should take towards the patients involved and what are the limits to this commitment?"

KCE's support of the democratic rationale for patient involvement in research has implications for the level of commitment that each partner in the research process takes with regards to the choices made for the

research project, e.g. with respect to the design, outcomes, analyses etc. Deliberative democracy requires that the different partners in the process listen to each other's perspectives and arguments and are willing to discuss these in order to reach a consensus.

Concretely, a possible level of commitment could be that patients are heard and involved but not held responsible for or committed to endorse the choices made during the research process, or the conclusions and recommendations of the study. On the one hand, this may allow them to speak more freely and genuinely play their role as patients. They contribute from their perspective to allow better-informed decisions during the research process. On the other hand it allows the researchers to take responsibility for choices made during the research process that do not completely follow the advice of patients but must be taken to comply with the broader mission of KCE to support policy decisions that take aspects of sustainability, equity and quality of the healthcare system into account. Patients should not feel limited in their contributions by these broader goals of health policy, even though most patients are not naïve with respect to the decisions to be made by the policy makers in healthcare. However, it should be mentioned when the conclusions of a study are contradictory with to the patient's voice.

From a pragmatic point of view, we could state that the level of commitment towards actors representing the patients in research processes is directly linked to the high-level involvement approach. In case of targeted consultation, we have a commitment to seriously consider the contribution of patients in the decision making process. The decision itself is not made with the patients. In case of embedded consultation, the decision is made in discussion with the patients who contributed to the consultation, but the 'control' and hence responsibility remains with the research group. In case of collaboration/co-production, the patients or representatives take co-responsibility for the decisions they were involved in. Their responsibility is absolute in case of user-led decision making during research. Note that in one project, different levels of involvement can co-exist. Hence, it might be that patients do take the responsibility for one aspect of the research decisions, but not for others.



9. KCE'S POSITION STATEMENTS REGARDING PATIENT INVOLVEMENT IN HEALTH POLICY RESEARCH

KCE wants to involve patients as much as possible in its research projects, in order to support choices to be made during the research process about the (best) ways to evaluate patient-related aspects. This will improve the quality of its research about patient-related issues. Below are KCE's position statements on how it intends to do this. These are inextricably linked, and must therefore be considered as a whole.

KCE always has to find the balance between its commitments towards the patients and its legal remit. The management of KCE will try to maintain this balance in the most efficient way when making its choices.

A next step is the development of a process book with practical guidance for patient involvement in health policy research. This will cover several aspects, such as who to involve in which research phase, how to select the patient (representative) to be involved and which method to use to guarantee meaningful patient involvement.

1. KCE perceives the fundamental ethical, as well as the instrumental and procedural rationales for patient involvement decisive enough to take a positive position towards patient involvement in health policy research. Patients have the democratic right to be involved in research about them, and they can contribute a unique perspective to the research from their personal experience, competences and knowledge.
2. KCE aims to involve patients in all research phases if this is relevant and appropriate for the project. Patients should not necessarily be involved in all policy research projects. The relevance and need for patient involvement in research projects should be assessed project by project.
3. Patient involvement in health policy research is complementary to the review of scientific evidence and primary data collection, not a substitute for it.
4. Sufficient resources (human, financial, time) should be made available to ensure and support effective patient involvement in health policy research. KCE aims to assure this availability.
5. The planning and processes of the projects have to be adapted to implement patient involvement in an optimal way.
6. Researchers and patients or patient organisations should be trained to effectively involve patients or be involved in health policy research.
7. Patient involvement activities in health policy research should be regularly evaluated and procedures revised when appropriate.
8. Patient contributions and their potential impact on the research process should be reported in the research report.
9. Patients and KCE researchers should give feedback to each other about the collaboration, to potentially improve future collaboration.
10. Everybody, hence also patients, can already today submit topic proposals to KCE. This possibility should be maintained.



- 11. Patients should be consulted in the scoping of the KCE projects to allow researchers to better describe the context of the research topic, taking patient issues into account.**
- 12. Patients should be consulted in the scoping phase to define the patient-related elements that need to be addressed in the research project.**
- 13. Patients should be consulted in the selection of the patient-relevant outcomes to be included in the study.**
- 14. Patients could contribute to the decision about the recruitment of study participants if primary data collection in patients or healthcare users is needed.**
- 15. Patients should be consulted in the selection and for the testing of the data collection instrument(s) to be used in patients or healthcare users.**
- 16. Patients should be consulted to define the minimal important difference in patient-relevant outcomes.**
- 17. Patients should be consulted to get input about the formulation of the policy recommendations. This is currently already the case, thanks to the presence of the Belgian umbrella organisations of patient associations in the Board of KCE. This possibility should be maintained.**
- 18. Patients should be invited to collaborate on the dissemination of the results of the KCE project.**



■ REFERENCES

1. Hoddinott P, Pollock A, O’Cathain A, Boyer I, Taylor J, MacDonald C, et al. How to incorporate patient and public perspectives into the design and conduct of research. *F1000Research*. 2018;7(752).
2. Piérart J, Léonard C, Chalon PX, Daue F, Mertens R. Stakeholder Involvement in KCE working processes. *Method*. Brussels: Belgian Health Care Knowledge Centre (KCE); 2012 20120402. KCE Reports 174 (D/2012/10.273/11) Available from: https://kce.fgov.be/sites/default/files/page_documents/KCE_174C_stakeholder%20involvement_in_KCE_working_processes.pdf
3. NIHR I.2019 [cited 4/07/2019]. Available from: <https://www.invo.org.uk/>
4. Boote J, Baird W, Beecroft C. Public involvement at the design stage of primary health research: a narrative review of case examples. *Health Policy*. 2010;95(1):10-23.
5. Boote J, Baird W, Sutton A. Public involvement in the systematic review process in health and social care: a narrative review of case examples. *Health Policy*. 2011;102(2-3):105-16.
6. Hughes M, Duffy C. Public involvement in health and social sciences research: A concept analysis. *Health Expectations*. 2018;21(6).
7. Facey K, Ploug Hansen H, Single A. *Patient Involvement in Health Technology Assessment*. Verlag S, editor. Singapore: ADIS; 2017.
8. Faridi Z, Grunbaum JA, Gray BS, Franks A, Simoes E. Community-based participatory research: necessary next steps. *Prev Chronic Dis*. 2007;4(3):A70.
9. Sandman L, Bond K, Hofmann B. Exploring Ethical Rationales. In: Facey K, Ploug Hansen H, Single A, editors. *Patient Involvement in Health Technology Assessment*. Singapore: Adis; 2017. p. 17-29.
10. Toledo-Chávarri A, Perestelo-Pérez L, Álvarez-Pérez Y, Abt-Sacks A, Santoro Domingo P, Villalón D, et al. Participación de los pacientes en la Evaluación de Tecnologías Sanitarias: manual metodológico. Ministerio de Sanidad, Servicios Sociales e Igualdad. Servicio de



- Evaluación del Servicio Canario de la Salud; 2016. Informes de Evaluación de Tecnologías Sanitarias.
11. ZonMw. Handboek patiëntenparticipatie in wetenschappelijk onderzoek. 2006.
 12. Abma TA, Broerse JE. Patient participation as dialogue: setting research agendas. *Health Expect*. 2010;13(2):160-73.
 13. Domecq JP, Prutsky G, Elraiyah T, Wang Z, Nabhan M, Shippee N, et al. Patient engagement in research: a systematic review. *BMC Health Serv Res*. 2014;14:89.
 14. Bailey S, Boddy K, Briscoe S, Morris C. Involving disabled children and young people as partners in research: a systematic review. *Child Care Health Dev*. 2015;41(4):505-14.
 15. Blackburn S, McLachlan S, Jowett S, Kinghorn P, Gill P, Higginbottom A, et al. The extent, quality and impact of patient and public involvement in primary care research: a mixed methods study. *Res Involv Engagem*. 2018;4:16.
 16. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. Mapping the impact of patient and public involvement on health and social care research: a systematic review. *Health Expect*. 2014;17(5):637-50.
 17. Brett J, Staniszewska S, Mockford C, Herron-Marx S, Hughes J, Tysall C, et al. A systematic review of the impact of patient and public involvement on service users, researchers and communities. *Patient*. 2014;7(4):387-95.
 18. Brett J, Staniszewska S, Mockford C, Seers K, Herron-Marx S, Bayliss H. The PIRICOM Study: A systematic review of the conceptualisation, measurement, impact and outcomes of patients and public involvement in health and social care research. Royal College of Nursing; 2010.
 19. Camden C, Shikako-Thomas K, Nguyen T, Graham E, Thomas A, Sprung J, et al. Engaging stakeholders in rehabilitation research: a scoping review of strategies used in partnerships and evaluation of impacts. *Disabil Rehabil*. 2015;37(15):1390-400.
 20. Cargo M, Mercer SL. The value and challenges of participatory research: strengthening its practice. *Annu Rev Public Health*. 2008;29:325-50.
 21. Chen PG, Diaz N, Lucas G, Rosenthal MS. Dissemination of results in community-based participatory research. *Am J Prev Med*. 2010;39(4):372-8.
 22. Concannon TW, Fuster M, Saunders T, Patel K, Wong JB, Leslie LK, et al. A systematic review of stakeholder engagement in comparative effectiveness and patient-centered outcomes research. *J Gen Intern Med*. 2014;29(12):1692-701.
 23. Conklin A, Morris Z, Nolte E. What is the evidence base for public involvement in health-care policy?: results of a systematic scoping review. *Health Expectations*. 2012;18(2):153-65.
 24. Cook WK. Integrating research and action: a systematic review of community-based participatory research to address health disparities in environmental and occupational health in the USA. *J Epidemiol Community Health*. 2008;62(8):668-76.
 25. De las Nueces D, Hacker K, DiGirolamo A, Hicks LS. A systematic review of community-based participatory research to enhance clinical trials in racial and ethnic minority groups. *Health Serv Res*. 2012;47(3 Pt 2):1363-86.
 26. Deja E. A multi-sited ethnography of patient and public involvement in epilepsy research. Liverpool: University of Liverpool; 2014.
 27. Drahota A, Meza RD, Brikho B, Naaf M, Estabillo JA, Gomez ED, et al. Community-Academic Partnerships: A Systematic Review of the State of the Literature and Recommendations for Future Research. *Milbank Q*. 2016;94(1):163-214.
 28. Duffett L. Patient engagement: What partnering with patient in research is all about. *Thromb Res*. 2017;150:113-20.
 29. Forsythe LP, Szydlowski V, Murad MH, Ip S, Wang Z, Elraiyah TA, et al. A systematic review of approaches for engaging patients for research on rare diseases. *J Gen Intern Med*. 2014;29 Suppl 3:S788-800.



30. Frankena TK, Naaldenberg J, Cardol M, Linehan C, van Schrojenstein Lantman-de Valk H. Active involvement of people with intellectual disabilities in health research - A structured literature review. *Res Dev Disabil.* 2015;45-46:271-83.
31. Gagnon MP, Desmartis M, Lepage-Savary D, Gagnon J, St-Pierre M, Rhainds M, et al. Introducing patients' and the public's perspectives to health technology assessment: A systematic review of international experiences. *Int J Technol Assess Health Care.* 2011;27(1):31-42.
32. Puts MTE, Sattar S, Ghodraty-Jabloo V, Hsu T, Fitch M, Szumacher E, et al. Patient engagement in research with older adults with cancer. *J Geriatr Oncol.* 2017;8(6):391-6.
33. Shen S, Doyle-Thomas KAR, Beesley L, Karmali A, Williams L, Tanel N, et al. How and why should we engage parents as co-researchers in health research? A scoping review of current practices. *Health Expect.* 2017;20(4):543-54.
34. Staley K. 'Is it worth doing?' Measuring the impact of patient and public involvement in research. *Res Involv Engagem.* 2015;1:6.
35. Tierney E, McEvoy R, O'Reilly-de Brún M, Brún, Okonkwo E, Rooney M, et al. A critical analysis of the implementation of service user involvement in primary care research and health service development using normalization process theory. *Health Expectations.* 2016;19(3):501-15.
36. Morley RF, Norman G, Golder S, Griffith P. A systematic scoping review of the evidence for consumer involvement in organisations undertaking systematic reviews: focus on Cochrane. *Res Involv Engagem.* 2016;2:36.
37. Shalowitz MU, Isacco A, Barquin N, Clark-Kauffman E, Delger P, Nelson D, et al. Community-based participatory research: a review of the literature with strategies for community engagement. *J Dev Behav Pediatr.* 2009;30(4):350-61.
38. Perestelo-Perez L, Rivero-Santana A, Abt-Sacks A, Toledo-Chavarri A, Brito N, Alvarez-Perez Y, et al. Patient Empowerment and Involvement in Research. *Adv Exp Med Biol.* 2017;1031:249-64.
39. Morrow E, Ross F, Grocott P, Bennett J. A model and measure for quality service user involvement in health research. *International Journal of Consumer Studies.* 2010;34(5):532-9.
40. Miller CL, Mott K, Cousins M, Miller S, Johnson A, Lawson T, et al. Integrating consumer engagement in health and medical research - an Australian framework. *Health Res Policy Syst.* 2017;15(1):9.
41. National Institute for Health Research. National Standards for Public Involvement in Research. 2018.
42. Christiaens W, Kohn L, Léonard C, Denis A, Daue F, Cleemput I. Models for citizen and patient involvement in health care policy - Part I: exploration of their feasibility and acceptability. Brussels: Belgian Health Care Knowledge Centre (KCE); 2012.
43. Cleemput I, Christiaens W, Kohn L, Leonard C, Daue F, Denis A. Acceptability and Perceived Benefits and Risks of Public and Patient Involvement in Health Care Policy: A Delphi Survey in Belgian Stakeholders. *Value Health.* 2015;18(4):477-83.
44. Cleemput I, Devriese S, Kohn L, Devos C, van Til J, Groothuis-Oudshoorn K, et al. Incorporating societal preferences in reimbursement decisions - Relative importance of decision criteria according to Belgian citizens Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2014 22/12/2014. KCE Reports 234 Available from: http://kce.fgov.be/sites/default/files/page_documents/KCE_234_reimbursement_decisions_Report.pdf
45. Cleemput I, Devriese S, Christiaens W, Kohn L. Multi-criteria decision analysis for the appraisal of medical needs: a pilot study. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE); 2016 28/06/2016. KCE Reports 272 Available from: http://kce.fgov.be/sites/default/files/page_documents/KCE_272_Unmet_needs_Report2.pdf
46. Desomer A, Van den Heede K, Triemstra M, Paget J, De Boer D, Kohn L, et al. Use of patient-reported outcome and experience measures in patient care and policy. Health Services Research (HSR). Brussels: Belgian Health Care Knowledge Centre (KCE);



2018 07/2018. KCE Reports 303 Available from:
https://kce.fgov.be/sites/default/files/atoms/files/KCE_303_Patient_reported_outcomes_Report_2.pdf



COLOPHON

Title:	Position of KCE on patient involvement in health care policy research – Short report
Authors:	Irina Cleemput (KCE), Marie Dauvrin (KCE), Laurence Kohn (KCE), Patriek Mistiaen (KCE), Wendy Christiaens (KCE), Christian Léonard (KCE)
Project coordinator:	Nathalie Swartenbroekx (KCE)
Senior supervisor:	Irina Cleemput (KCE)
Reviewers:	Jef Adriaensens (KCE), Wendy Christiaens (KCE), Marijke Eyssen (KCE)
External Experts:	Ingrid Adriaensen (Thomas More Hogeschool), Hervé Avalosse (Mutualité Chrétienne – Christelijke Mutualiteit), Sofie Bekaert (Biobanking and Biomolecular resources Research Infrastructure Belgium (BBMRI.be)), Alain Bourda (Union Nationale des Mutualités Socialistes – Landsbond van de Socialistische Mutualiteiten), Leen Broeckx (Thomas More Hogeschool), Jean-Pierre Bronckaers (Union des Mutualités Libérales – Landsbond van Liberale Mutualiteiten), Nathan Charlier (Université de Liège), Corinne Courtois (Groupe Hospitalier Jolimont), Nour de San (Common Health Design), Saskia Decuman (INAMI – RIZIV - Institut National d'Assurance Maladie Invalidité – Rijksinstituut voor Ziekte-en Invaliditeitsverzekering), Queenie Degruytere (Vlaams Patiëntenplatform - VPP), Anouk Delameillieure (KULeuven), Martine Delchambre (LUSS – Ligue des usagers des services de santé), Fabienne Dobbels (KULeuven), Micky Fierens (LUSS), Siska Germonpré (Union Nationale des Mutualités Socialistes – Landsbond van de Socialistische Mutualiteiten), Bénédicte Gombault (Fondation Roi Baudouin – Koning Boudewijnstichting), Alain Goolaerts (FRS – FNRS - Fonds National de la Recherche Scientifique), Anne Hendrickx (Union Nationale des Mutualités Socialistes – Landsbond van de Socialistische Mutualiteiten), Evelyne Hens (Union Nationale des Mutualités Socialistes – Landsbond van de Socialistische Mutualiteiten), Xavier Hulloven (Institut Bruxellois pour la Recherche et l'Innovation Sociale – Instituut Ter Bevordering van het Wetenschappelijk Onderzoek en de Innovatie Van Brussel INNOVIRIS), Laure Istas (Plateforme pour l'Amélioration continue de la Qualité des soins et de la Sécurité des patients PAQS), Isabelle Kniebs (Patienten Rat & Treff), Sophie Lanoy (LUSS), Dan Lecocq (Université Libre de Bruxelles), Anneleen Lintermans (VPP), Mandana Mehta (UCLouvain), Patrick Miqueu (Institut Jules Bordet), Karen Mullie (Mutualité Chrétienne – Christelijke Mutualiteit), André Néron (Université Libre de Bruxelles), Isabelle N'Guyen (Fondation Roi Baudouin – Koning Boudewijnstichting), Christiana Noestlinger (Institute of Tropical Medicine), Mathieu Noirhomme (Common Health Design), Grâce Ntunzwenimana (Ancien membre Action+/ GRECOS), Benoit Pétré (Université de Liège), Charlotte Pezeril (Observatoire du SIDA et des sexualités), Mitchell Silva (European Patients' Academy EUPATI), Annemie T'Seyen (Fondation Roi Baudouin – Koning Boudewijnstichting), Frederik Van Acker (FWO - Fonds Wetenschappelijk Onderzoek Vlaanderen), Chris Van Hul (Mutualités Libres – Onafhankelijke Mutualiteiten), Sigrid Vancorenland (Mutualité Chrétienne – Christelijke Mutualiteit), Hilde Vanderhoudt (Thomas



More Hogeschool), Sofie Verhaege (UGent), Kelly Verheyen (Thomas More Hogeschool), Ilse Weeghmans (VPP), Stéphanie Wermeester (Patienten Rat & Treff)

Acknowledgements:

The research team would like to thank their colleagues – members of staff, experts and management - for their support and participation during the development of the KCE position, especially Christophe Janssens and Els Van Bruystegem. The research team also thank all the participants to the interviews for the valuable contributions.

Reported interests:

All experts and stakeholders consulted within this report were selected because of their involvement in the topic of Patient involvement in research. Therefore, by definition, each of them might have a certain degree of conflict of interest to the main topic of this report

Participation in scientific or experimental research as an initiator, principal investigator or researcher: Marie Dauvrin (senior researcher in the Participate project funded by INNOVIRIS).

Layout:

Ine Verhulst, Joyce Grijseels

Disclaimer:

- **The external experts were interviewed as part of the (qualitative) data collection for this study. They did not co-author the scientific report and do not necessarily agree with its content.**
- **This report has been approved by common assent by the Executive Board (see <http://kce.fgov.be/content/the-board>).**
- **Only the KCE is responsible for errors or omissions that could persist.**

Publication date:

18 December 2019 (2nd print; 1st print: 06 November 2019)

Domain:

Method

MeSH:

“Patient Participation”, “Methods”, “Policy”, “Research”

NLM Classification:

W84.3 Health Services Research (General)

Language:

English

Format:

Adobe® PDF™ (A4)

Legal depot:

D/2019/10.273/56

ISSN:

2466-6459

Copyright:

KCE reports are published under a “by/nc/nd” Creative Commons Licence
<http://kce.fgov.be/content/about-copyrights-for-kce-publications>.



How to refer to this document?

Cleemput I, Dauvrin M, Kohn L, Mistiaen P, Christiaens W, Léonard C. Position of KCE on patient involvement in health care policy research – Short report. Method Brussels: Belgian Health Care Knowledge Centre (KCE). 2019. KCE Reports 320Cs. D/2019/10.273/56.

This document is available on the website of the Belgian Health Care Knowledge Centre.