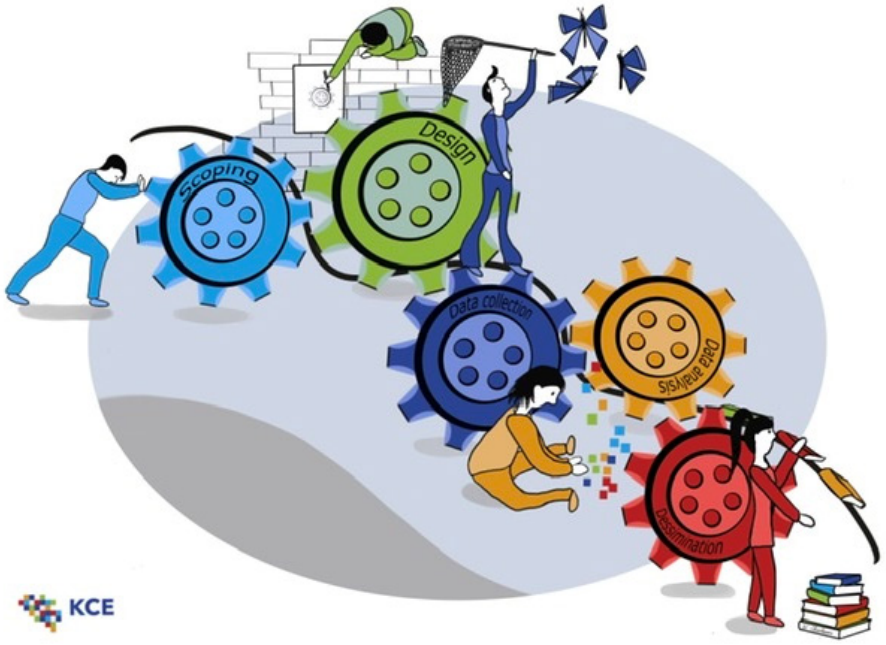
KCE REPORT 340

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

PROCESS NOTE: PATIENT INVOLVEMENT IN KCE RESEARCH



KCE REPORT 340
METHOD

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PROCESS NOTE: PATIENT INVOLVEMENT IN KCE RESEARCH

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COLOPHON

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VOORWOORD

In 2019 sprak het KCE zich expliciet uit over zijn engagement om vaker patiënten als partners te willen betrekken bij zijn onderzoek. We hebben intussen de eerste stappen naar een meer systematische patiëntenbetrokkenheid gezet. Deze eerste ervaringen hebben ons geleerd dat een praktische gids over hoe patiënten betrokken kunnen worden zinvol is voor onderzoekers en patiënten. Dit is het doel van deze procesnota.

Hoewel het niet meer dan normaal lijkt om patiënten te betrekken bij onderzoek dat hen rechtstreeks aanbelangt, is dit niet altijd vanzelfsprekend voor beleidsvoorbereidend onderzoek. Het KCE heeft als missie om het gezondheidsbeleid te ondersteunen met wetenschappelijk onderzoek, rekening houdend met de brede maatschappelijke doelstellingen van het gezondheidsbeleid (betaalbaarheid, billijkheid, kwaliteit). Deze ruimere maatschappelijke context overstijgt vaak het individuele belang van patiënten.

Maar dit is geen argument om patiënten niet te betrekken bij het onderzoek. Het individuele belang van patiënten kan immers ook maatschappelijke implicaties hebben. Denk bijvoorbeeld aan de evaluatie van nieuwe interventies (HTA): zijn patiënten zelf vragende partij voor deze interventies of is de vraag eerder gestuurd vanuit de aanbieders? Of, in het geval van studies over de organisatie van gezondheidszorg (HSR): hoe staan patiënten tegenover veranderingen in de organisatie van zorg, wat zijn voorwaarden voor het slagen van een reorganisatie? Zonder patiënten heeft geen enkele aanpassing in het gezondheidszorgsysteem immers enige waarde.

De uitwerking van deze procesnota heeft ons geleerd dat de weg naar het betrekken van patiënten bezaaid is met hindernissen en praktische bezwaren. Zo vergt het betrekken van patiënten extra tijd en zijn patiënten potentieel kwetsbaar en dus niet altijd in staat om deel te nemen zoals ze zelf zouden willen. Maar uitdagingen zijn er om aangegaan te worden. Met deze procesnota, worden mogelijke obstakels aangepakt en worden concrete voorstellen gedaan over hoe onderzoekers patiënten actief kunnen betrekken bij hun onderzoek. Deze nota is een levend document. Naarmate we meer ervaring opbouwen met het betrekken van patiënten in ons onderzoek, zullen we ook nieuwe inzichten verwerven om de nota te verfijnen en verbeteren.

Het KCE heeft voor de ontwikkeling van deze procesnota dankbaar beroep kunnen doen op de input van vele patiënten, patiëntenvertegenwoordigers en onderzoekers. Er is al heel wat beschreven in de literatuur over hoe patiënten kunnen worden betrokken, maar de vertaalslag naar de Belgische context zou onmogelijk zijn geweest zonder de waardevolle input van al deze mensen. Wij wensen hen allen van harte te bedanken hiervoor!

Christophe JANSSENS	Irina CLEEMPUT	Marijke EYSSEN
Adjunct Algemeen Directeur a.i.	Directeur Wetenschappelijk Programma a.i.	Algemeen Directeur a.i.

PRÉFACE

En 2019, le KCE s'est explicitement engagé à impliquer les patients de façon plus systématique comme partenaires dans ses recherches. Depuis lors, quelques premiers pas concrets ont été faits en ce sens. Ces premières expériences nous ont fait comprendre qu'il serait utile, à la fois pour les chercheurs et pour les patients, de disposer d'un guide pratique sur la manière de procéder. C'est l'objet de la présente *process note*.

Bien qu'il semble tout à fait normal d'impliquer les patients dans les recherches qui les concernent directement, cette démarche ne va pas toujours de soi lorsqu'il s'agit de recherches destinées à préparer de nouvelles politiques. La mission du KCE est précisément de fournir des arguments scientifiques solides pour étayer les politiques de santé en prenant en compte leurs grands objectifs sociaux d'accessibilité, d'équité et de qualité. Or ce contexte sociétal élargi transcende souvent les intérêts individuels des patients.

Ceci ne constitue toutefois pas un argument pour ne pas impliquer les patients dans la recherche. Après tout, les intérêts individuels des patients peuvent aussi avoir des implications sociales. Prenons par exemple les études de *Health Technology Assessment* (évaluation des technologies de santé) : les patients eux-mêmes sont-ils demandeurs de ces nouvelles interventions ou la demande est-elle plutôt dictée par l'offre ? Ou, dans les études de *Health System Research* (organisation et financement des soins de santé) : quelle est l'opinion des patients à l'égard des changements proposés ? Quelles sont à leurs yeux les conditions pour que la réorganisation soit une réussite ? Après tout, aucune modification du système de santé n'a de valeur si les patients ne suivent pas.

L'élaboration de cette *process note* nous a appris que l'implication des patients suit un chemin semé d'obstacles et de difficultés pratiques. Cela nécessite notamment un supplément de temps ; en outre, comme ils sont potentiellement vulnérables, les patients ne sont pas toujours en mesure de participer aussi pleinement qu'ils le souhaiteraient aux processus de recherche. Mais les défis sont faits pour être relevés. Cette *process note* aborde les obstacles potentiels et formule des propositions concrètes pour aider les chercheurs à impliquer activement les patients à leurs travaux. Il s'agit d'un document vivant : il s'enrichira et se nuancera au fil de la construction de notre expérience.

Au cours de ce travail, nous avons pu compter sur les apports et éclairages de nombreux patients, représentants de patients et chercheurs. Beaucoup a déjà été écrit sur l'implication des patients dans la littérature scientifique, mais sans ces contributions précieuses, la transposition de ce savoir au contexte belge aurait été impossible. Nous tenons donc à les remercier tous très chaleureusement !

Christophe JANSSENS	Irina CLEEMPUT	Marijke EYSSEN
Directeur Général Adjoint a.i.	Directeur Programme Scientifique a.i.	Directeur Général a.i.

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LIST OF ABBREVIATIONS

ABBREVIATION	DEFINITION
CA	Conseil d'Administration (Board of administrators)
EC	Ethical committee
EUPATI	European Patients' Academy on Therapeutic Innovation
GDPR	General Data Protection Regulation
G-I-N	Guidelines International Network
HSR	Health Services Research
HTA	Health Technology Assessment
KCE	Centre fédéral d'Expertise des Soins de Santé – Federaal Kenniscentrum voor de Gezondheidszorg – Belgian Healthcare Knowledge Centre
LUSS	Ligue des Usagers des Services de Santé
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
PEC	Patient Expertise Centre
RedETS	Spanish Network of Agencies for Assessing National Health System Technologies and Performance / Red Española de Agencias de Evaluación de Tecnologías Sanitarias y Prestaciones del Sistema Nacional de Salud
RvB	Raad van Bestuur (Board of administrators)
ULB	Université Libre de Bruxelles
VPP	Vlaams Patiëntenplatform

SCIENTIFIC REPORT

1 INTRODUCTION

At the end of 2019, KCE published its position statement on patient involvement in health policy research (Report 320 [1]) (https://kce.fgov.be/sites/default/files/atoms/files/KCE_320_Patient_involvement_health_care_policy_research_Report_2.pdf). The main starting position was that:

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.

Recommendation of the KCE position paper [1]

This position paper already included a series of recommendations but the concrete steps to bring them into practice had to be developed. A KCE process note with practical guidance for patient involvement in health policy research, and particularly in KCE projects, was then needed.

Everybody, hence also patients, can already today submit topic proposals to KCE. This possibility should be maintained.

Recommendation of the KCE position paper [1]

Currently, patients are already involved in the earliest research phase of a project, i.e. the submission of topics proposals to KCE.

Patients are also involved in the validation of the recommendations of every KCE report by participating in the KCE Board through representatives of umbrella organisation of patient associations.

For the other research phases of the project, no formal involvement was foreseen until now. Sometimes, patient representatives were consulted or

invited together with other stakeholders; however, no structured or formal approach to consideration of patient involvement in these other research phases of the research process existed.

The current process note covers several aspects, such as what are the **prerequisites** to involve patients, **who to involve** (patient representatives), in which research **research phase**, how to **select the patient** (representative) to be involved and **which method** to use to guarantee meaningful patient involvement.[2]

Patient involvement in health policy research is complementary to the review of scientific evidence and primary data collection, not a substitute for it.

Recommendation of the KCE position paper [1]

Patients expect KCE, as a public research institution, to set a good example for researchers wanting to develop patient involvement in research.

The current report describes how we built the process note and the process note itself. This will be published as part of the KCE process book, which also covers other processes for KCE projects. The process book is publically available on the KCE website.

In a next step we will produce a 'patient guide' in order to present the role of the patients in the KCE research process in a patient-friendly way. This guide will be available in French and Dutch.

2 METHODS

In order to build a practical and effective process note, reflecting the needs and points of attention of all involved participants, we combined different information sources: the literature, results of workshops with the umbrellas of patient associations, results of workshops with patients and patient representatives, results of a Delphi survey and our experience with a pilot project. The detailed results of each part are presented in the appendices.

The final process note was presented during a stakeholder meeting before submission to the KCE board.

2.1 Literature

For this process note, we reused the useful elements of the pragmatic literature review performed for the position paper. More information is available in the KCE report 320[1] We added more recent sources identified in the grey literature during the redaction of the report by snowballing. We did not perform a systematic literature search.

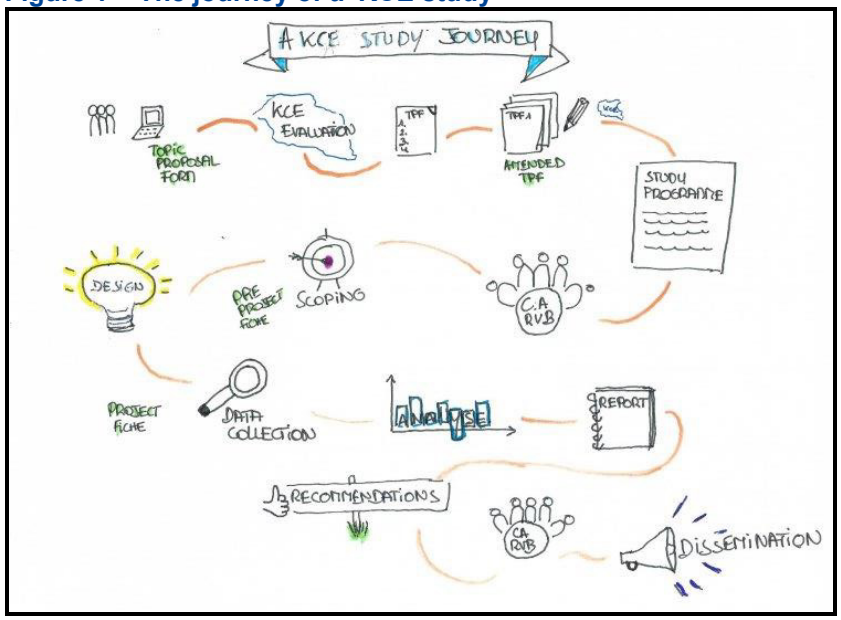
2.2 Workshops

2.2.1 Workshops with the umbrella organisations of patient associations and sickness funds

Two 3-hours workshops were organized: one face-to-face with 2 out of 3 umbrella organisations of patient associations and one through videoconference (because of COVID-19-related sanitary restrictions) with the sickness funds.

The aim was to brainstorm on how they could be involved or support KCE with patient involvement in KCE projects. We organized the discussion around a classic journey of a KCE research project.

Figure 1 – The journey of a 'KCE study'



CA – RvB: Conseil d'Administration – Raad van Bestuur (Board)

Concrete questions for each research phase of a project were:

- What are potential roles for the umbrella organisations / sickness funds in a KCE project?
- What resources do they need (human, time and financial)?
- Which other points does KCE have to pay attention to?

These questions were proposed using a visual template (see Appendix 1).

A summary of the discussion useful for this process note was sent to participants and to people that were unable to participate in the workshops. They were invited to add their comments and perspectives on the summary.

Results nourished the current process note. A summary of the discussions is presented in the Appendix 1.

2.2.2 Workshops with patients[a]

2.2.2.1 Aim of the workshops

The workshops with patients aimed at gathering information from patients and/or their representatives which could serve as input for the process note.

More specifically, the workshops were designed to gain insight into how patients feel about different ways of identifying and recruiting patients to become involved in a KCE study and about different methods of involving patients in research. In Appendix 1, a narrative overview of the results of these workshops are presented.

2.2.2.2 Target group and participants

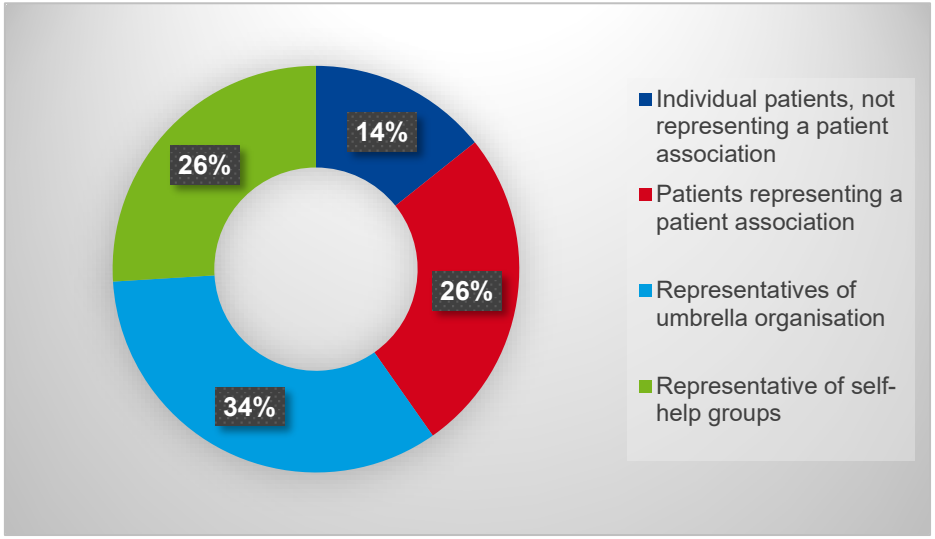
The target group consisted of patients, representatives of patients (i.e. from patient organizations and umbrella organizations of patient associations). The number of participants in the workshops was limited to a maximum of 6 to allow for sufficient interaction between the participants as recommended when conducing online discussion.[3]

Patients were recruited by KCE through publication of the invitation in social media and targeted mailing to the umbrella organizations of the patient associations (Vlaams Patiëntenplatform (VPP) and La Ligue des Usagers des Services de Santé (LUSS)), Patienten Rat und Treff (for the German patients) and sickness funds. Patients could register by sending an e-mail to the KCE secretariat.

[a] Authors: Dethier Marleen, Carton Catherine, Van Overloop Maaike, Steyaert Stef

In total, 38 participants registered for either a French or Dutch workshop. Figure 2 shows the background of the participants in the workshops, covering both the Dutch and French one.
A German-language session was planned, but had to be cancelled due to the absence of registrations.

Figure 2 – Background of the participants to the workshops with patients



2.2.2.3 Design

Initially, KCE wanted to organize a face-to-face symposium on May 7, 2020, followed by several workshops on "Patient involvement in health care policy research".

Due to the COVID-19 pandemic and lock-down from March 2020, people were no longer allowed to come together physically. KCE and WhoCares?!, the subcontractor who would moderate and report on the workshops, considered different alternatives and finally opted for 6 (3 French and 3 Dutch) online workshops of 3 hours each by Zoom. A short break of 15 minutes was provided to maintain the participant's engagement during the entire workshop.

To help patients who were less or not familiar with Zoom, a manual on how to use Zoom was sent together with the invitation. Each session was recorded to have a fall-back in case the written reporting was unclear. Each participant signed an informed consent in advance of the workshop. The recordings were destroyed after the final reporting. Each report provided by WhoCares?! to KCE was anonymised, and at no time a link could be made between the statements and the participants.

A moderator and a reporter from WhoCares?! were present at each session. The moderator first explained the context of the study and objectives to the participants. Secondly, the moderator asked questions one by one and stimulated the discussion. In order to avoid steering towards certain answers, additional suggestions were only made when the participants in the sessions themselves no longer gave any answers. The moderator made sure that everyone was heard. The reporter did not take part in the discussion, but made notes of the participants' input.

A team member of KCE was also present in 1 Dutch and all the French sessions, to help interpret and clarify questions related to the remit, organization and procedures of KCE.

2.2.2.4 Material

In collaboration, KCE and WhoCares?! developed an interview guide for the workshops, both in French and in Dutch (see Appendix 4). Based on the idea of 'patients on board', a boat theme was chosen as a symbolism. Main questions of the interview guide were included in a slideshow to facilitate the online discussion.

Each workshop was divided into different parts:

- An **introductory round of the participants**, as well as an explanation of the most important features of Zoom (chat, raise hand, mute/unmute).

- A **presentation of the context of the study and objectives of the research**. The slides referred to the position statement of KCE on “Patient Involvement” and explained why KCE specifically wanted to involve patients in the process of developing the guidelines for the patient involvement process note. After this part, the presentation was closed and the participants were asked if the set-up was clear. If needed, further clarification was given.
- An **interactive discussion based on patient-friendly questions**. The questions were dealt with one by one and were briefly visualised on a slide. The presentation was then closed so that the participants’ faces were visible to everyone during the interactive conversation.
    - First, the discussion went deeper into their general vision on involving patients in policy preparatory research. Questions included were:
        - What do you, as patients, users of the health system, think about the general idea that patients will be more involved in policy-preparing health research?
        - The degree of involvement is defined as "consulting patients". What do you understand when you are told that you will be consulted for a research project?
        - "Patients are asked for their opinion, but this is not binding for the research team". What do you think of this role proposed by KCE?
        - How can KCE announce to the patient/patient association that a study is starting, and that they want to recruit patients for getting involved?
        - How can patients/patient associations let KCE known that they wish to be involved in a specific research project?
        - Once a patient/patient association has decided to contribute, how can they best be involved in the study?
    - Second, possible ways to involve patients in a meaningful, effective and feasible way in three phases of a research project were discussed: (1) scoping, (2) design (defining the approach of the research project (e.g. methods, data collection tools)) and (3) interpreting results related to patient-related aspects. The following questions were asked :
        - What needs to be concretely foreseen in order to be able to consult you?
        - What are essential conditions for your participation?
        - What do you need to make you feel at ease in this phase?
        - Are there practical points to take into account?
        - To what extent do patients want to be involved in all facets of the research discussed in this phase? i.e. including the aspects not related to patient-related issues.”?

Each workshop ended with the question of whether everything was clear and participants had additional comments. At the end of the session, the participants were asked how they appreciated the session.

Results were used to build the current process note and are detailed in Appendix 1

2.3 Rapid Delphi-survey

Because of the difficulties when defining criteria to decide if patient involvement is relevant for a specific KCE project, we performed a rapid Delphi survey in KCE experts and stakeholders, i.e. patients who have participated in the workshops, representatives of the sickness funds, umbrellas of patient associations and members of the conservatorium of chronic diseases of the RIZIV/INAMI.

A first round questionnaire was launched the 27th of January 2021 and ran until the 3rd of February 2021 with 2 questions:

1. In your opinion, what criteria determine whether involving patients as research partners in one or more phases of a KCE study is relevant and feasible? Please explain these criteria and, if possible, justify them.
2. In your opinion, what criteria should be used to decide NOT to involve patients as research partners in one or more phases of a KCE study? Please explain these criteria and, if possible, justify them.

Based on the results of the first round, we built a second questionnaire presenting the criteria proposed by the Delphi panel in order to assess their relevance. Criteria mentioned during the first round but not related to the selection of the KCE projects for which patient involvement is possibly desirable, such as prerequisites, conditions of implementation or criteria to decide which patient to involve, were integrated in the process note where relevant and useful, but were not included in the second Delphi round.

Respondents were also asked to identify the 5 more important criteria to be taken into account. The second round started the 5th of February 2021 and was closed early in the morning of the 15th of February 2021.

Criteria that were judged to be 'fully relevant' and 'quite relevant' by more than 75% of the respondents *and* were not considered 'not at all relevant' by more than 5% of the respondents were chosen as useful for reflection and to be considered when deciding for which projects KCE should consider to involve patients.

The second questionnaire and the final results are available in Appendix 4

2.4 Pilot study

2.4.1 Aim

Following the recommendation of the Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS)[4] to build up experience with patient involvement through pilot studies, we decided to pilot-test the collaboration between a patient association and KCE during the KCE project "Psychosomatic Care". The project "Psychosomatic Care" aims at understanding why the somatic care for the severely mentally ill patient is sub-optimal and how this can be improved. One step of this project consists of gathering data from the patients themselves. To improve the quality of data collection and ensure patient participation in the data collection, KCE teamed up with a patient association – Psytoyens. The results of the project Psychosomatic Care are reported elsewhere (see Report 338).

2.4.2 Design

The method consisted of the administration of a semi-directive online questionnaire at 3 key phases of the research project and a final transversal evaluation at the end of the project through semi-directive interviews.

2.4.3 Instrument for data collection

Four questionnaires were developed. Each questionnaire contained a common set of questions, to allow for comparison over time, and specific questions to allow capturing the experience related to specific tasks (see Appendix 1).

Common set of questions involved:

- the perceived degree of involvement,
- the experiences regarding specific aspects of the research phases,
- the state of mind during the research phase,
- the strengths and weaknesses of the research phase,

- the do's and dont's for the next research phase.

We built a progressive questionnaire to be completed separately by the patients association, the umbrella and the KCE researchers aiming to identify what went wrong / difficulties, and what went well /strengths. The questionnaires were developed in French and put online via LimeSurvey. The three first questionnaires were tested by a volunteer citizen for the technical and literacy aspects. All questionnaires were reviewed by KCE researchers belonging to the qualitative cell for the content and the overall structure.

The final questionnaire aimed at assessing the overall process and was designed to be administered through a semi-directive interview. This questionnaire included the core results of the three previous evaluation questionnaires – presented anonymously. It also collected points of attention and advice for future projects.

2.4.4 Participants

All actors involved in the different phases of the research project were invited to complete the evaluation questionnaire. Participants were:

- members of the patient association Psytoyens;
- representative of the umbrella organisation « Ligue des Usagers des Services de Santé »;
- the KCE researchers;
- the KCE project facilitator;
- the KCE communication expert.

As the communication expert was only invited in the last phase of the research process, she only participated in the last evaluation round.

2.4.5 Data collection

At the end of each phase of the project (see Table 1), each participant received a personal link to the online survey.

Table 1 – Assessed periods and phases of the "Psychosomatic care" project

Period assessed	Activities conducted during the period	Number of expected participants
December 2019- August 2020	• Launch of the collaboration between KCE & Psytoyens • Role definition of the LUSS • Discussions around expectations of participants • Definition of work methods: meetings, planning, communication mode… • Redaction of the collaboration charter • Development of the recruitment strategy	10
September 2020-December 2020	• Recruitment of participants for data collection • Data collection • Development of the data analysis plan	10
January-February 2021	• Reviewing of the draft chapter and the synthesis	9
End of February 2021	• Transversal evaluation of the process • His/her perception and if it has to be done again, how should I do, as researcher or as patient representative?	10

To prevent any difficulty related to numeric literacy, participants could also directly contact the researcher for a face-to-face semi-directive interview. However, none of the participants contacted the researcher for a face-to-face interview.

Participants had 2 weeks to complete the questionnaire. A reminder was sent by e-mail 5 days before deadline.

2.4.6 Ethical and deontological considerations

In order to increase objectivity and trust, data were gathered and analysed by a KCE researcher external to the collaborating teams but familiar with patient involvement. Responses were anonymised: only the researcher in charge of the evaluation had access to the raw data.

3 PROCESS NOTE ON 'PATIENT INVOLVEMENT'

The planning and processes of the projects have to be adapted to implement patient involvement in an optimal way.

Recommendation of the KCE position paper [1]

This section is the process note that will be published in the KCE process book as a tool to be used by everyone wanting to involve patients in a KCE project.

3.1 What is patient involvement?b

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'.[c] While this definition encompasses public involvement in research and our focus is only on patient involvement in research, the definition still applies.

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.[5]

Patient Involvement in a research differs from data collection in patient. Patients can be involved as PARTNERS in research at different times. The aim is to involve them in the implementation of the research (e.g. to choose or help develop tools for collecting data from patients) and not as 'subject/object of data collection' (i.e. not as participants in a survey or focus group, for example).

3.2 KCE standards for patient involvement[d]

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.[6] 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.

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b This section is extracted from the KCE short report[2]

c 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.

d This section is extracted from the KCE short report[2]

Table 2 – Standards for patient involvement in KCE research (adapted from INVOLVE[6])

Standard	Patient involvement is more likely to be meaningful if …
Inclusive opportunities	• 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	• 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 and learning	• 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	• inclusive and flexible communication methods are used to meet the needs of different people • feedback is gathered, offered, shared and acted upon
Impact	• 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)[6]

3.3 Prerequisites and conditions for implementation of patient involvement at the organisational level

From our position paper we already learned that in order to establish a successful researcher-patient partnership, it is important to pay attention to several aspects. We combined and adapted these principles with what we have learned from the patients, the patient representatives and associations, the patient umbrella organisations and what is recommended by several agencies and authors, in particular:

- ZonMW, who published a checklist for researchers and patients to improve the effectiveness of patient involvement in research, dealing with the different challengese
- Witteman et al. who made 12 concrete suggestions to researchers, to deal with three challenges of patient involvement7:
- the RedETS – who proposes actions[4]: we mainly focus on short terms actions.

In order **to clarify the perspectives of what involvement implies before initiating the project**[2], we propose a series of conditions or prerequisites to be met both before, during and after the patient involvement process.

For reminder, different types of patient representatives could be engaged in the process. How to define which type is more appropriate will be described later. Nevertheless, it is important to distinguish professional patient representatives, i.e. from the umbrella organisations of patients associations or from the sickness funds, from non-professional patient representatives, i.e. from patients associations relying solely on volunteers or individual patients. These latter will require more attention because of their potentially vulnerable status.

3.3.1 Remind that patient involvement is an institutional choice made by KCE

According to RedETS, short terms actions to enable patient involvement include: "*Make a public statement of the interest of the agency in the involvement of patients in health policy research.*" and "*Agree on a normative framework for the involvement of patients in health policy research.*"[4]

With the position paper, KCE has inscribed the patient involvement in its institutional strategy. This is an important enabler as it gives legitimacy to the process of patient involvement.

3.3.2 KCE should make itself better known to the general population

Because KCE's mission is to advice decision makers, the agency is not really known by the patients. Making KCE more visible and better known in the general population could increase the interest of patients to participate in KCE studies.

3.3.3 Prepare the researchers

Researchers should be prepared to work with patients and determine the framework in which this involvement will take place, which boundaries are necessary/desirable and which adaptations they are ready to make to ensure involvement (i.e. working outside regular hours).[1]

The whole research team should be positive about the patient involvement and be fully engaged with it.

"An important lesson from the projects of ZonMW on patient involvement in palliative care research, is that researchers should be careful about a priori's. Thinking that patients are too ill to participate or will probably not be interested is a threat. Moreover academic and practice researchers must be

[e] www.participatiematrix.nl

open to relinquishing and sharing control to facilitate new ways of working." (Cleemput[1], p.56)

Researchers should be clear about their duties and responsibilities as researchers.

3.3.4 Foresee resources

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.

Recommendation of the KCE position paper [1]

According to the type of patient representative that will be involved, the type of collaboration and the research phases in the projects, several resources will be needed, i.e. human, time and money. Details on resource requirements will be given in the course of this process note. Nevertheless it is important to anticipate the needs before engaging in the process.

3.3.4.1 Human resources

A fully bilingual researcher (French/Dutch) or a researcher of each language devoted to the patient involvement tasks should be foreseen at start. They will be responsible for the communication with the patients.

3.3.4.2 Sufficient time

Patient involvement requires time to prepare the collaboration and during the process. To allow for an ethical involvement, time resources have to be foreseen implying a realistic planning.[8]

3.3.4.3 Financial resources

Training of the patients' representatives may be necessary to enhance qualitative involvement. Reimbursement of the patients' expenses of patients is a condition to involve them ethically.[9]

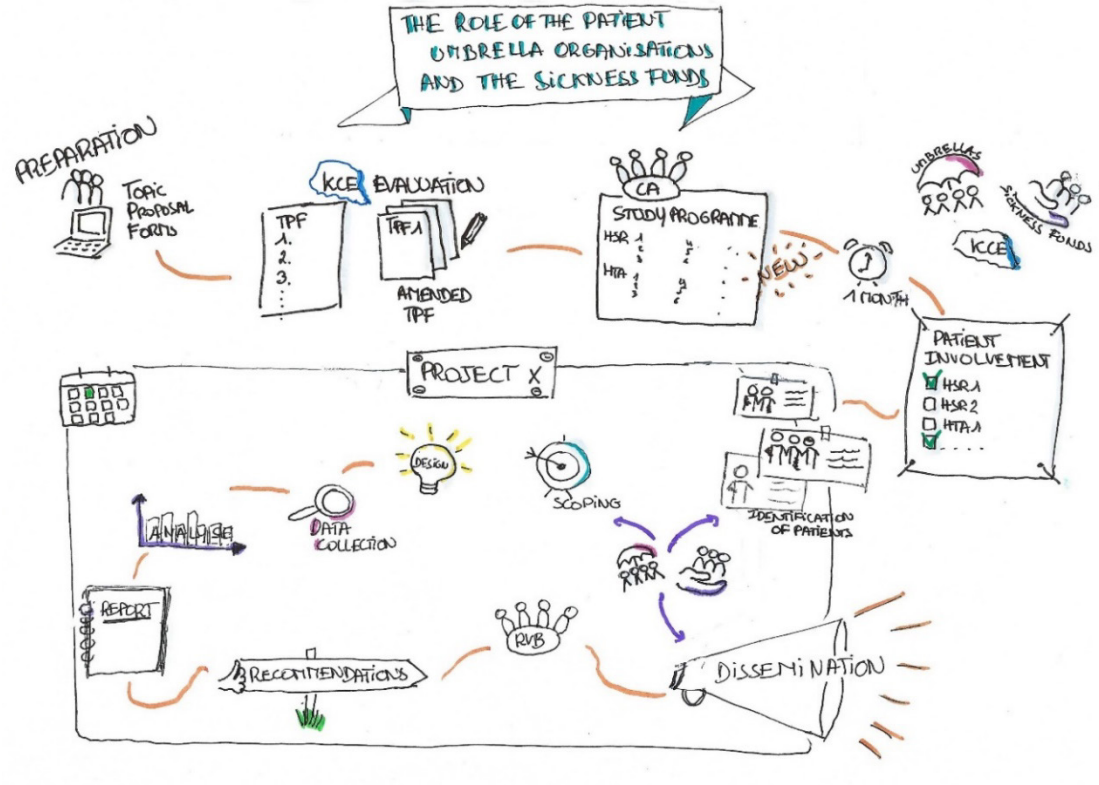
3.3.5 Identify the studies for which patient involvement is desirable

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.

Recommendation of the KCE position paper [1]

In order to ensure that patient involvement makes sense to the research and to the patients [1], once a year, after the validation of the yearly research programme by the Board, KCE will organise a meeting with the umbrella organisations of patient associations and the sickness funds. The umbrella organisations receive a two-page summary of each new project on the annual research programme in advance of the meeting to allow them to prepare the meeting within their organisation. The content of the documents and the discussion remain strictly confidential.

Figure 3 – The role of sickness funds and patient umbrella organisations in the 'KCE patient involvement processes'



HSR: Health Services Research; HTA: Health Technology Assessment; CA - RvB: Conseil d'Administration – Raad van Bestuur

Based on the list of criteria in Box 1, the participants will define a shortlist of projects where patient involvement could be valuable and feasible. These criteria were consensually considered by the stakeholders of the Delphi panel as meaningful to support the discussion. No criteria for *not* involving patients have been retained from the Delphi panel.

Box 1 – Criteria to support the discussion of whether patient involvement is valuable and feasible in KCE projects*

- **There will be a clear added value to patient involvement.**
- **The research project aims to study an intervention, treatment, drug, care service or health technology**
  - **used or to be used by the patient**
  - **whose mode of administration/use involves an active role for the patient**
  - **with possible side-effects**
- **The research project aims**
  - **to study (among other things) the quality of life or well-being of patients.**
  - **to study the relationship between health care providers and patients.**
- **Research results are likely to have an impact on**
  - **patients' quality of life**
  - **patients' expenditures**
  - **the relationship between providers and patients**
  - **patient satisfaction**
  - **the perception of citizens**
- **Patients' vision cannot be obtained by other means.**
- **The research is likely to involve data collection from patients.**

**Results from the rapid Delphi survey (see section 2.3)*

During the meeting, when appropriate, potential patient associations concerned by the projects, if any, will be identified through the respective networks of the participants. A first rapid reflexion on specific attention points to allow an optimal patient involvement regarding the population of interest and necessary requirements according to their condition will be also discussed.

The result of the meeting will be transmitted to the Observatory of Chronic Diseases and Radiorg to inform them about projects where their involvement could be valuable and to communicate the planned schedule. In case of interest, they will be invited to designate a representative to participate in the meetings around the project and be communicated in which parts of the project they will be involved.

3.4 Guidance for researchers on how to involve patients

Once it is decided to involve patients in a study, the involvement of the patients - and other relevant actors - should begin as soon as possible in the research process.[1]

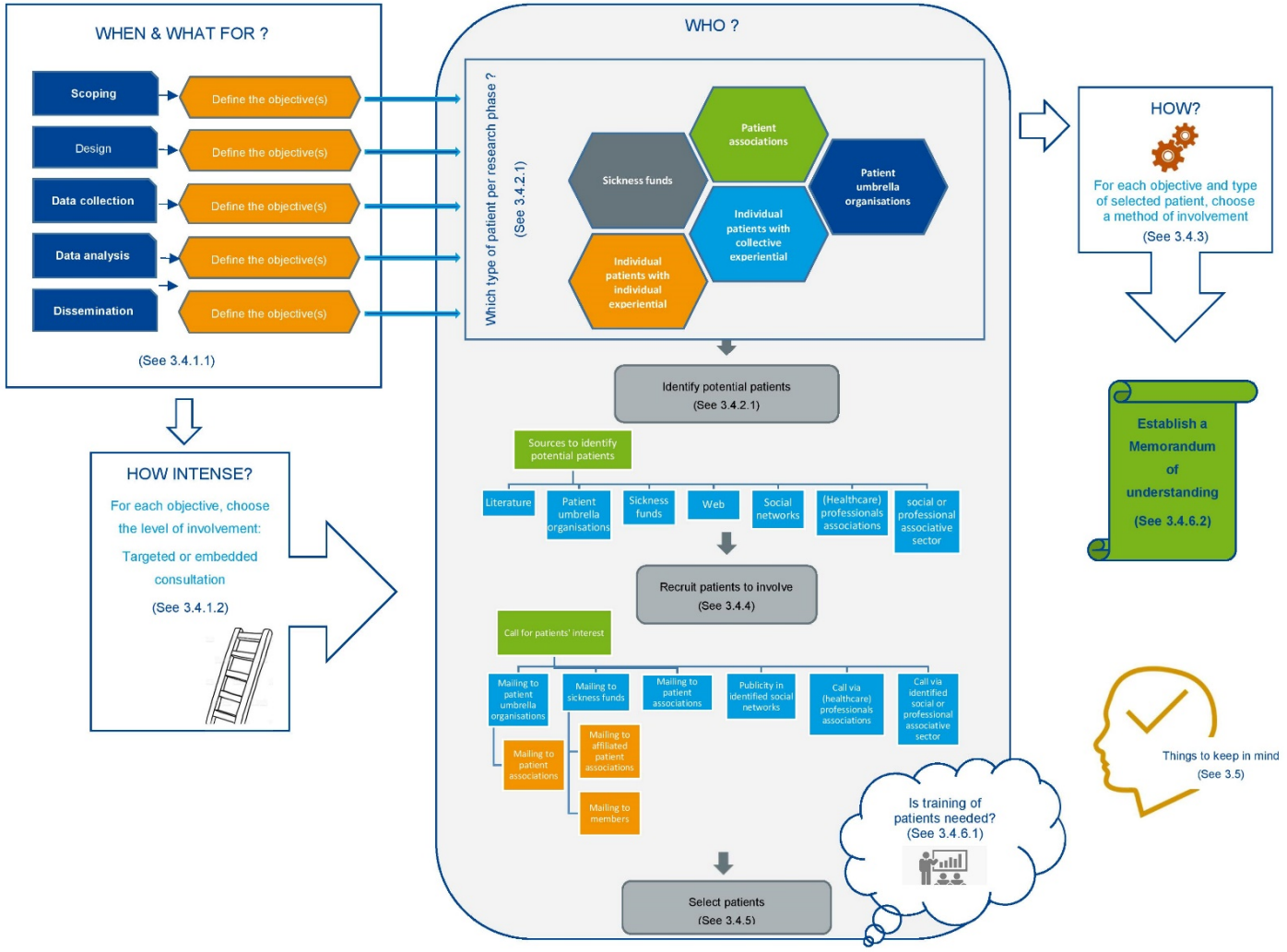
In order to decide who to involve, the research team could count on the results of the brainstorming of the management, after concertation with the patient umbrella organisations and the sickness funds around the yearly KCE research program (see section 3.3.5). The network and expertise of the researchers of the team is obviously also useful in this reflexion.

3.4.1 Identify, for each research phase, the opportunity to involve patients and the intensity of involvement

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.[1] It is not a requirement to involve patients in all aspects of the research though, to ensure a meaningful involvement. For example, in the case of a study on tele-monitoring of cardiac patients, patients could be involved to better understand and describe the impact of tele-monitoring on the patients' life, expectations and beliefs; they should not necessarily be involved in the assessment of the clinical effectiveness of tele-monitoring.

Once it is decided that patients will be involved in a project, a process has to be followed. Figure 4 schematically presents a summary of this process.

Figure 4 – Process to involve patients in a specific research project



3.4.1.1 *The research phases of a KCE project and the related objectives*

The objectives of patient involvement by research phase presented in Table 3 are issued from the recommendations of the KCE position paper and enriched by the discussions during the workshops and comments of the Delphi panel. This list is, however, not exhaustive and has to be considered as a non-binding checklist.

Table 3 – The research phases and steps of a KCE project with their related objectives

Research phase	Research step	Objectives
Development of the research protocol	Scoping	To allow researchers to better describe the context of the research topic, taking patient issues into account
		To define the patient-related elements that need to be addressed in the research project
	Design	To select the patient-relevant outcomes to be included in the study.
		To decide about the recruitment strategy of study participants if primary data collection in patients or healthcare users is needed.
		To select the data collection instrument(s) to be used in patients or healthcare users.
		To build the patient-related data collection tools
		To assess the feasibility of the protocol for the patients (e.g. whether the assessments are feasible for the patients and are not too burdensome)
Data Collection	Data collection	To test the data collection instrument(s) to be used in patients or healthcare users.
		To recruit participants
		To observe data collection in patients (in case of face-to-face data collection approaches)
		To disseminate the publicity for the data collection among patients
Reporting and synthesis	Data analysis	To define the minimal important difference in patient-relevant outcomes
		To validate the analysis plan for the patients issues
		To help in the interpretation of the patient-related results
		To review the draft report
	Recommendations	To get input about the formulation of the patient-related policy recommendations.
	Dissemination	To collaborate on the dissemination of the results of the KCE project.
		To prepare a summary of the report addressed to patients.

Patients could be involved at all phases of the research process, as long as it makes sense and is well prepared. Nevertheless, for each step and each objective of the research, the research team first has to answer the question: "***Is patient involvement relevant and useful for this research step?***"

Involving the sickness funds as patient representatives (see 3.4.2.1) could be very helpful in several steps of the research, in particular for the development of the data collection tools and the recruitment of participants in data collection. For example, KCE wants to conduct a study in which patients need to be contacted in order to complete a questionnaire. In that case the sickness funds can contribute by elaborating the content of the questionnaire and volunteers in their members can test the questionnaire for readability.

For the recruitment of pre-testers or participants, the sickness funds can draw up a sample of members they can contact via their communication channels via e-mail with the aim of completing the questionnaire online. Even for studies relying on qualitative methods, the sickness funds can participate in the recruitment of participants in focus groups, interviews... Nevertheless they have their own studies ongoing and it will therefore not always be possible for them to help KCE.

3.4.1.2 Decision on the intensity of the involvement

The next decision that has to be made is **"what intensity of involvement is desirable and feasible?"**

The intensity of the patient involvement could range from targeted consultation to user-led research. In the KCE short report 320[2], the intensity of involvement was described as follows:

"In one single 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 other. 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.[10]"

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.[10] The patients or representatives take co-responsibility for the decisions they were involved in.

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.[10] They carry full responsibility for all choices made during the research process. The research is in this case actively controlled, directed and managed by patients and/or patient organizations.

For KCE studies, 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 for 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.

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 by or 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. "

The intensity of involvement recommended for KCE studies are presented in Box 2.

Box 2 – Recommended levels of involvement for KCE reports

Targeted consultation:

Patients are consulted on specific aspects of the research study on an ad hoc basis. The researchers defines the course of events, but seeks the patient's opinion".

"The patients advise and the researchers decide".

Embedded consultation:

Patients are regularly consulted throughout the entire research process or research phase. The proposals and ideas of patients are taken into account by the reserchers. However, in case of conflicting views, the researchers make the final decisions, based on what they consider to be the most appropriate.

From the workshops with patients, we learnt that patients have a strong opinion about consultation as a level of involvement. They believe that consultation should not be seen as a kind of informal approach to involvement, because this may lead to disappointment among the patients involved.

The concept of consultation should be clarified by KCE, as it does not have one clear meaning for patients. KCE researchers must communicate clearly about what they understand by "non-binding" advice, so that it does not seem as if the patients' voice can be ignored.

In the process of designing a study, patients ask that researchers at least make a first proposal of the high-level structure and design features. In a second phase, patients can be involved to refine the design. Patients agree that the expertise of researchers will play a leading role with regard to the design phase.

3.4.2 Define and identify for each step WHICH 'patient' will be involved

3.4.2.1 What are the types of patients

Patients can have different hats: patients as citizens, patients as experts and patients as representatives. Depending on the group, a specific role and related activities could be defined.[1]

We refer to the definitions in Table 4 for the good understanding of this process note.

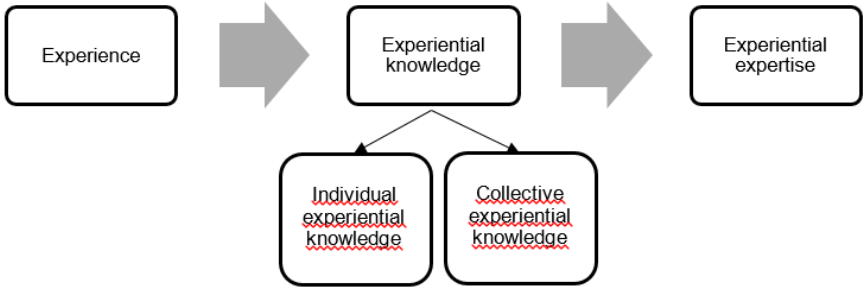
Table 4 – Types of patient representatives

Type of patient representative	Definition
Individual patients with individual experiential knowledge	Patients recruited for their personal experience, belonging or not belonging to or representing a patient association or other organised form of patient representation – random selection
Individual patients with collective experiential knowledge	Patients with collective knowledge based on contacts with other patients, either through a patient association or through an informal gathering of patients (e.g. as moderator of a Facebook group or spokesperson of a group of people). These patients do not formally represent a patient association – purposive selection
Patient associations	Formal gathering of patients (and professionals) aiming at advocating, supporting and promoting patient issues and rights. The size, the degree of formalisation, the presence of health care professionals and the objectives –among others– vary from association to association. Patient associations usually concern a specific disease, health condition or symptom.
Sickness funds	Sickness funds represent patients as health care consumers under the term of national health insurance. They represent all the patients registered to their funds and are – in a certain sense – influenced by a specific "ideological" perspective (socialist, liberal, Christian, independent) although differences are more historic than really influencing the current practices.
Patient umbrella organisations	Patient umbrella organisations regroup numerous patient associations and aim at advocating for patient rights from a general perspective – without referring to a specific disease, health condition or symptom. Patient umbrella organisations can also represent patients for whom no association exist. It should be noted that not all patient associations are members of patient umbrella organisations.

When considering the individual patient involvement, according to the results of our workshops with patients, to obtain the most complete input, the patients' voice should be a mix of group and personal experiences. Patients who are too ill to contribute should be replaced by caregivers or by others who have relevant knowledge or experience (i.e. employee or volunteer with a patient organization).[11]

In line with the recommendations of the Guidelines International Network (GIN) and a policy note of the *Vlaams Patiëntenplatform*[12], patient associations are preferred to individual patients because of their capacity to act or talk for the group and bring in experiential expertise, as opposed to individual experiences (see Figure 5). Experiential expertise can be provided by people/patients who have collective knowledge through their own experiences and exchanges with multiple other patients with similar experiences, and who gained additional competences through training and education. Training and education might help to communicate easier with researchers and contribute to the research process, but care should be taken that it does lead to 'distancing' from the patient group the patient expert is representing (see section 3.4.5.1).

Figure 5 – From individual experience to experiential expertise[12]



Source: Castro, 2018[13] cited by Bruneel, 2020[12]

The contribution of collective experiential knowledge and experiential expertise from patient associations provides insight into the collective disease-specific problems.[12]

If it is only possible to involve individual patients, it is important to be aware that on the one hand they can contribute something about their personal perception and experience but on the other hand not all patients are willing or able to share this experience. It will then be useful to foresee brief training to individual patients to allow them to convey their individual experiential knowledge in a more general manner (i.e. independent from their own story) (see 3.4.6.1).

KCE researchers received also the advice from a participant in the Delphi survey to constantly remain aware that some patients do not have this ability to distance themselves from their personal experiences which completely absorb them. This might create a bias in the feedback or input received during a consultation phase. This could be compensated for in various ways: involving multiple individual patients, extracting the dimension of general and collective interest, cross-referencing, synthesising, etc. while taking care to show empathy towards these patients and respect for what they are going through, for the way in which they understand it.

3.4.2.2 How to identify patients that could be involved in the research?

The identified patient associations during the joint meeting of the management of KCE, patient umbrella organisations and sickness funds (see 3.3.5) could be completed by a search in the (grey) literature, on the Internet or by exploring and searching through social networks (Fora, Facebook groups, etc.).

Healthcare professionals associations could also be useful sources to identify patients or patient associations that are not members of an umbrella organisation or a sickness fund.

The Patient Expert Centre (PEC)[f] trains patients to become patient experts (i.e. patients with experiential expertise). They could be solicited to identify patients in their address book.

When it is necessary to reach patients with features not depending on their health(care) status, e.g. deprived people, other kinds of associations could be solicited, such as NGOs, the CPAS/OCMW, sociocultural associations, sport clubs…. Online repositories such as "Bruxelles-Social-Sociaal Brussel" or the "Sociale Kaart" are useful resources to identify these alternative contact points. The experts by experience of the FPP Social Integration[gh] and the Intercultural Mediation Cell of the FPS Public Health[i] could also help reaching various groups.

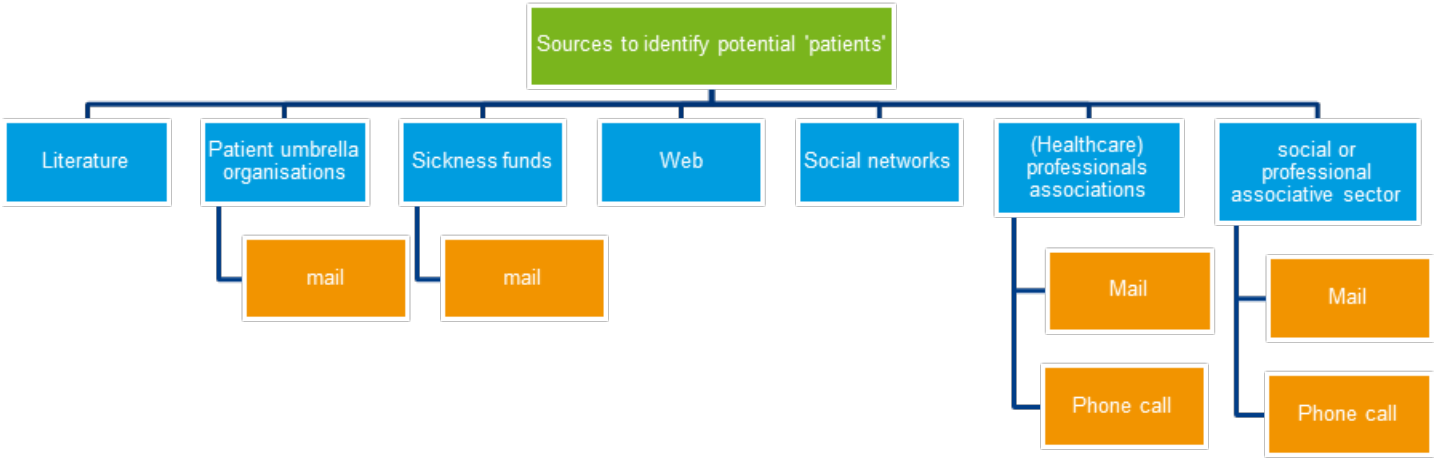
[f] http://www.patientexpertcenter.be

[g] To know more: https://www.mi-is.be/fr/themes/experts-du-vecu/methodologie

[h] Experts by experience could be found in numerous public institutions. https://www.mi-is.be/fr/themes/experts-du-vecu/organisations-partenaires

[i] To know more: https://www.health.belgium.be/fr/sante/organisation-des-soins-de-sante/qualite-des-soins/mediation-interculturelle-dans-les-soins-de

Figure 6 – Sources to identify patients



3.4.3 Define for each step HOW patients will be involved

Once you have decided who to involve for which step, **you have to choose a method to involve** the patient.

The processes and methods should be rigorous. It is necessary to differentiate between qualitative research methods and patient involvement activities, even if the distinction is not always clear-cut and some methods can be used for both purposes.

There is a plethora of possible methods, each one with their advantages and limitations. This process note proposes a short list of the more classical ones that are, a priori, more or less feasible in the KCE research context. Nevertheless, it is always advisable to make in addition a rapid search in the scientific and the grey literature to check if one of these methods is preferable and, perhaps if other methods could be more suitable according to the topic of the research and the target patient population.

Each method pursues a specific objective as described in Table 5 and is more or less suitable according to the desired level of involvement (Table 6).

Table 5 – Methods to involve patients and their objectives

Methods	Objectives
Delphi process[j]	To systematically investigate a complex problem to reach a consensus among experts
Steering committee	To oversee and support a project from a management level, alongside other stakeholders[14]
Open forum	To produce informal interactions in order to generate shared reflexions on a topic
Questionnaires & surveys[a]	To gather information on a defined topic or to validate emerging findings
Nominal group	To formulate ideas and to clarify a topic to support implementation or further reflexions
Work meetings	To work and discuss on a predefined theme or problem heading towards an outcome or target.

Based on the inventory or Table 5, you should select a suitable method regarding

- The level of involvement (Table 6)
- The research research phase (Table 7), and the purpose of the patient involvement in this research phase
- The available resources (time, potential number of participants, budget…)
- The possibilities of the patients given their condition

Table 6 – Methods to involve patients according to the level of involvement

Method	Targeted consultation	Embedded consultation
Delphi process		X
Steering committee		X
Open forum	X	X
Questionnaires & surveys	X	
Nominal group	X	X
Work meeting	X	X

If you would like to check if the method has already been used in a KCE project, and in which one, please go to [link to a table on the S to be added].

Once you determined for each step whether patients will be involved, at what level, who will be involved and how according to your objective and the target group, you should weigh the advantages and challenges of each method to involve patients (Table 8) and/or practical aspects (Table 9).

j See also the specific process note on Delphi process on the KCE process book

Table 7 – Methods to involve patients according to the different research phases

Method	Scoping	Design	Data collection	Data analysis	Recommendations	Dissemination
Delphi process	X				X	
Steering committee	X	X	X	X	X	X
Open forum	X			X		
Questionnaires & surveys	X			X	X	
Nominal group	X				X	X
Work meeting	X	X	X	X	X	X

Table 8 – Advantages and challenges of patient involvement methods

Method	Advantages	Challenges
Delphi process	Combine sharing expertise and opinions without the bias of influence found in face-to-face techniques	Keeping the participants involved (at least 3 rounds are usually needed), not enough details retrieved from the exchanges
Steering committee	Allow for decision making and "real" involvement Distribution of power among stakeholders	Need balance between stakeholders Managing power issues
Open forum	Suitable for simple or complex topics, room for creativity, self-organisation, favourable to learning and initiatives, suitable for large groups, orientation of results is quickly known	Need distinct rooms for each group, unpredictable results, no having a leader may impede the process, need neutral secretaries in each group
Questionnaires & surveys	Easy to use, could be spread to a large number of participants, suitable for defined topics, allow for integrated validated instruments for measuring the topic of interest (ex: quality of life, mental health factors, etc.), anonymity can be guaranteed	Do not capture complexity, data management issues, no interactions between participants
Nominal group	Allow for individual and collective reflection, suitable for ranking and prioritizing ideas and solutions	Need experienced moderator, time should be devoted to individual reflection to prevent contamination, need to be adapted for patients with problems for writing
Work meeting	Easy to use and organise, most common working mode, may be combines with animation techniques to facilitate the discussion	Risk of social desirability bias Large group prevents discussion

Table 9 – Practical considerations for the application of patient involvement methods

Method	Suitable for virtual	Face to face	Costs	Specific material needed	Number of participants	Number of researchers needed	Duration
Delphi process	X	X	€€€	online platform	10 (min. 4)	1 to 2	Min. 1 month excl. preparation
Steering committee	X	X	€	preparatory documents	+/- 7	Team	Max 2 hours/ meeting
Open forum	X	X	€€	only defining the topic	No limitations	Depends on the number of participants (min. 2)	1-2 days
Questionnaires & surveys	X	X	€€€	questionnaire	undefined	1	No more than 30 min.
Nominal group	X	X	€€	discussion guide	8 to 12	2 to 3	Min 4h /
Work meeting[15-18]	X	X	€	Agenda to be defined beforehand	7-15	2 to 3	2h[k]. minutes

It is always advisable to submit the proposed choice of the patient involvement method to the selected patients (once they are recruited) to check if they are comfortable with it.

You can use the following table to have a global picture of the patient involvement in your specific project.

[k] It seems however that the average concentration time is 37.5 minutes, pleading for short meetings. Besides Cohen (2011) insists that meetings staring and end on time are perceived more favourably than those not respecting planning, independently of the length or number of breaks[18]. See also Phillips & Crocco for practical tips.[15, 17]

Table 10 – Checklist for identifying, for each research phase and objective, IF patients will be involved, the INTENSITY of involvement, which TYPE OF PATIENT to involve and the METHOD of involvement

Phase	Objective	Involve?	Intensity?	Type of patients	Method for involvement
Scoping	To allow researchers to better describe the context of the research topic, taking patient issues into account	❒ Yes ❒ No	❒ **Targeted consultation*** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To define the patient-related elements that need to be addressed in the research project	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
Design	To select the patient-relevant outcomes to be included in the study.	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To decide about the recruitment strategy of study participants if primary data collection in patients or healthcare users is needed.	❒ Yes ❒ No	❒ Targeted consultation ❒ **Embedded consultation**	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not)	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____

Phase	Objective	Involve?	Intensity?	Type of patients	Method for involvement
				❒ Individual patients with individual experiential knowledge	
Design	To select the data collection instrument(s) to be used in patients or healthcare users.	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To build the data collection tools	❒ Yes ❒ No	❒ Targeted consultation ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To assess the feasibility of the protocol (e.g. whether the assessments are feasible for the patients and are not too burdensome)	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
Data collection	To test the data collection instrument(s) to be used in patients or healthcare users.	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not)	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____

Phase	Objective	Involve?	Intensity?	Type of patients	Method for involvement
				❒ Individual patients with individual experiential knowledge	
	To recruit participants	❒ Yes ❒ No	❒ Targeted consultation ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To disseminate the publicity of the data collection	❒ Yes ❒ No	❒ Targeted consultation ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
Data analysis	To define the minimal important difference in patient-relevant outcomes	❒ Yes ❒ No	❒ **Targeted consultation** ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
	To validate the analysis plan	❒ Yes ❒ No	❒ Targeted consultation ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not)	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____

Phase	Objective	Involve?	Intensity?	Type of patients	Method for involvement
				❒ Individual patients with individual experiential knowledge	
	To help in the interpretation of the results	❒ Yes ❒ No	❒ Targeted consultation ❒ Embedded consultation	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____
Recommendations	To get input about the formulation of the policy recommendations.	**Yes****	**Embedded consultation**	**Umbrella organisations**	**Steering committee**
Dissemination	To collaborate on the dissemination of the results of the KCE project.	❒ Yes ❒ No	❒ Targeted consultation ❒ **Embedded consultation**	❒ Patient umbrella associations ❒ Sickness funds ❒ Patients with experiential expertise (usually from patient associations; with training) ❒ Patients with collective experiential knowledge (from a patient association or not) ❒ Individual patients with individual experiential knowledge	❒ Delphi process ❒ Steering committee ❒ Open forum ❒ Questionnaire/survey ❒ Nominal group ❒ Work meeting ❒ Other: _____

**__In bold__ what was recommended in the 'position paper'*
***This is currently already the case, thanks to the presence of the Belgian patient umbrella organizations of patient associations in the Board of KCE. This possibility should be maintained.*

✉ **If you have had a interesting experience, e.g. using a specific method for patient involvement in your project, that could be useful to update the process note, please don't hesitate to share it with us. Your experience is extremely valuable!**

3.4.4 Launch a call for interest

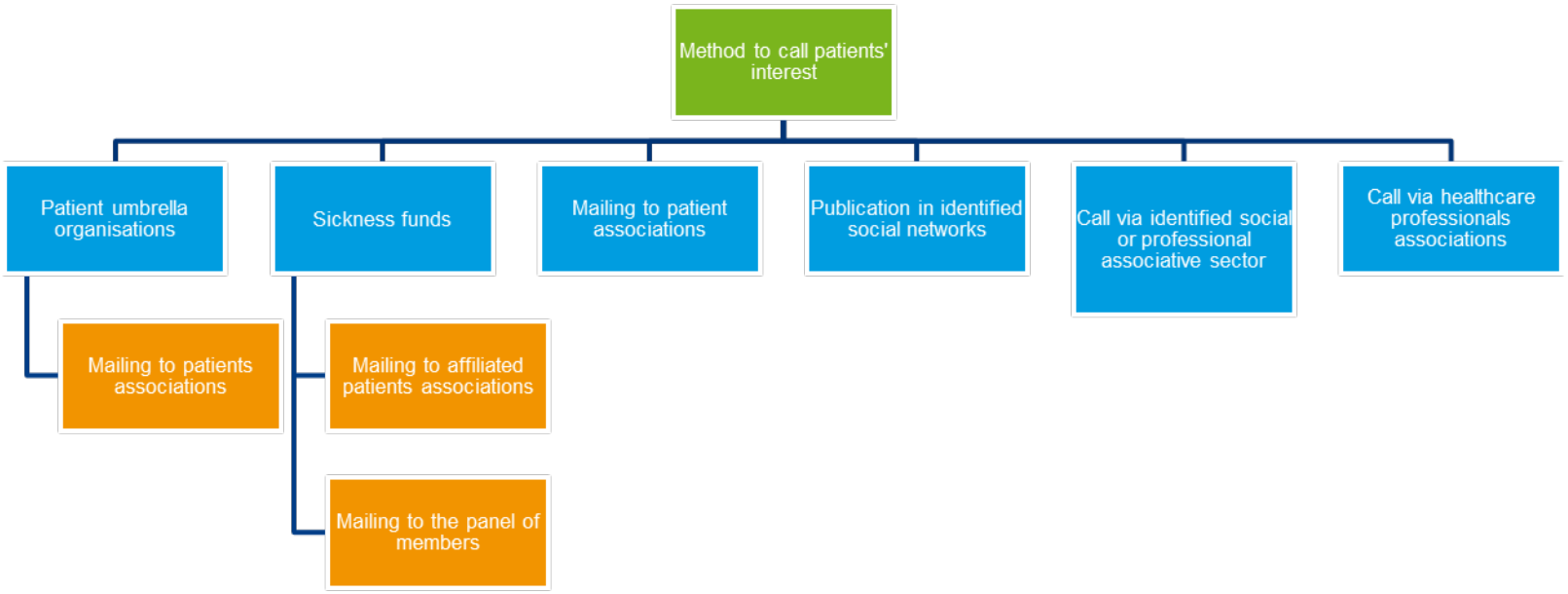
It is time now to launch a call for interest to find candidates to involve in the research.

The announcement should be made public, but targeted to the type of patients you want to involve.

Umbrella organisations and sickness funds can directly be contacted by mail. If you target patient associations you can ask the umbrella organisations and sickness funds to contact their affiliated patients associations. You can also directly contact the patients associations you identified by other means.

While patient associations are strong channel to reach their affiliated members, it was highlighted during the workshops that some patients do not feel the need to join an association. These patients should a priori not be excluded if you aim at involving individual patients for their individual experiential knowledge. If you target 'individual patients' with experiential expertise it is preferable to combine online and offline approaches. Online approaches include publication of the call in social media; offline approaches encompass direct publicity of the call through (healthcare) professionals or through the associative sector; i.e. leaflet or posters.

Figure 7 – Methods to call patient's interest in a study



The registration process should be simple and user-friendly, using clear language. Possibilities to register should be possible both online (e.g. via a specific form on the KCE website) and offline (e.g. via a phone call).

It is important to inform the patients about their possibilities in terms of doing voluntary work as a patient, with an explanation of all the conditions (fiscal, legal, etc.) and possible consequences. This information is available at the sickness funds.

Another point of attention is related to the GDPR. Make sure to comply with the established KCE processes with respect to data collection and storage when collecting personal data.

The registration form should inform the research team on the 'appropriateness' of the candidate for the expected activities in the project, to allow for an informed selection (see 3.4.5)

3.4.5 Select the candidates

3.4.5.1 Check the ''appropriateness' of the candidates

Inspired by what is done at NICE[19] we advise to check if selected patients present the following experience, knowledge and skills:

- Relevant experience of the condition, and the issues that matter to people with that condition
- The willingness to reflect the experiences of a wide group of people with a condition, for example, contact with people through patient organisations, forums or self-helpgroups. Indeed, the patients involved in the study should be able to distance themselves from their particular case, but rather draw from it an experience that can help others.
- The time and commitment to attend the meetings,and if necessary, do background reading and comment on draft documents
- Good communication and teamwork skills
- The ability to maintain confidentiality

In addition it is a plus if patients already trained in research could be selected (see 3.4.6.1).

A prerequisite is that patients have basic computer skills to facilitate the work. Patients will be contacted by email, might be invited for online meeting, or receive questions through an online platform etc. Without basic computer skills on the part of the patients, the work of the research team is seriously hampered. However, for specific projects, it might be needed to involve people without these skills. In these cases, agreements on how to communicate should be made with the patients involved. It might be necessary to adapt our standard working procedures to the requirements and needs of the patients involved.

To avoid that patients act in the interest of other purposes (e.g. industry) it is necessary to obtain declarations of interest from them, including identification of sources of funding or in-kind support for patient associations.[11] If there is a conflict of interest, the risk should be assessed. The team might decide to avoid the collaboration.

3.4.5.2 Define the number of patient representatives

"*Wherever possible, more than one member should be recruited to help provide different perspectives and social support for other patient and public members. (…) It also helps each patient have the confidence to speak out, as they are less likely to feel like an isolated individual if there are other non-health professionals in the group.*" (G-I-N, 2015 [11] p.41)

3.4.5.3 Contact patients representatives

After the selection, both selected and not-selected candidates should be contacted. For the latter, you should justify your decision.

Invite selected participants for a first meeting in order to discuss and organize the concrete involvement.

3.4.6 Launch the collaboration

3.4.6.1 Preparing the non-professional patient representatives

Preparing the collaboration with non-professional patient representatives is needed both before the start of the collaboration, by offering training to patients when it is required, and during the collaboration, by giving all they need to effectively participate in the discussions.

The minimal preparation should be a clear explanation about the objectives of the research project.[1]

Offer training to patients

Researchers and patients or patient organisations should be trained to effectively involve patients or be involved in health policy research.

Recommendation of the KCE position paper [1]

It is essential to provide some prior training to the patient. Indeed, not all patients are familiar with the terminology and procedure of a scientific study.

This preparatory step should preferentially be done before the formalisation of the project to ensure that the patients have all the elements necessary to understand the research process. Training needs are to be discussed at start.[1, 9]}

Witteman et al. propose to talk about "*orientation rather than training, to avoid the connotation of implicit power imbalance inherent in the term. Orientation intends to make all team members familiar with a specific terminology*." [7] p.559)

In the G-I-N toolkit[11](p.42) it is proposed that the training could consist of:

- *in technical areas such as how to understand the terminology around medical research*
- *how to take part in the group effectively (for example, assertiveness).*

It is not necessary that KCE endorses this training. The patient umbrellas or some patient associations organise such training as well. Nevertheless, it is the research team's responsibility to make sure that people feel safe to give their input (e.g. by means of choosing the right techniques).

"*Training can be in-house, provided out-of-house, or self-directed (for example, online training)*." (G-I-N, 2015[11] p.49) For out-of-house training, an option, proposed by patients during the workshops, could be to refer patients to training centres. Multiple initiatives exist already to train patients, e.g. VPP, LUSS, EUPATI, PEC…Belgian University and other academic research centres also develop training aiming at supporting patient involvement in research (see, i.e. the certificate Patient Partenaire at the ULB). Abroad, numerous initiatives also exist as – to name one the Université des Patients in France[l] - aiming at promoting patient involvement.

The in-house training could consist in, among other, developing materials to inform and educate patients about research processes[4], and how to contribute to its different phases but also material explaining the work and missions of KCE.

Offer preparatory material

To be efficient and comfortable during a meeting or a collaboration moment *"Wherever possible, provide opportunities for patient and public members to prepare for the meeting. This can include offering pre-meetings, supportive phone calls, or asking patient and public members if they would like to exchange contact details with other patient and public members, from this group or previous ones, so that they can share concerns and experiences."* (G-I-N 2015[11] p.42)

3.4.6.2 Establish a memorandum of understanding with the patient representatives

The KCE position paper already highlighted that to involve patients adequately, it is necessary to define a clear objective, with a work framework agreed upon by all actors and clarify the expectations of each party to prevent frustrations and misunderstandings.[1]. Communicating clearly from the outset around the objectives of the patient involvement manages the expectations of all partners.[8]

There is no legal framework that defines the way patients are allowed to be involved in KCE research. Consequently the opportunities as well as the boundaries of patient involvement are not specified or enforceable. Therefore, it is important to develop, for each project where patients are involved, an agreement or charter that clarifies the respective expectations and commitments of the researchers and the patients and enhances the engagement of both in the patient involvement process. A "memorandum of understanding", with is something in-between a formal legally-binding contract and an informal agreement, could be established to define the terms of collaboration. It may avoid uncomfortable situations where for instance a document is sent to patient representatives last minute with the

l https://universitedespatients-sorbonne.fr/

request to review it by next week; or where patient representatives block the finalization of a report because the recommendations do not fit completely with their interests." During the workshops, patients also emphasized that it should be clear to those involved that the policy makers will ultimately decide what to do with the recommendations of KCE.

The memorandum of understanding should be established between the patients and KCE as a first step of the process.

According to experiences abroad and what was suggested in our position paper, the document has to address the following topics:

Box 3 – Content of a "memorandum of understanding" between KCE and patients involved in a research project

- **Introduction on KCE: what is KCE, its remit and processes**
- **General description of the project**
- **Description of the different parts of the study and the one(s) where patient involvement is foreseen**
- **Confidentiality policy**

  Define the confidentiality requirements, both related to the involvement activities and to the project. This is of particular importance to ensure the safety and the respect of each participant, health care professionals and researchers included.
- **Type of collaboration**

  Explain that the final scientific report stays the full responsibility of KCE. Therefore, discussion may take place with patients about how to present the results but the final responsibility of the scientific work remains with the researchers.
- **Partners**

  Identify all partners in the research project:

  At KCE side, including defining a contact person for patients

  At patients side: if multiple patients are involved, it is important to appoint a single contact person who makes the link between the patients and the research team
- **Description of each partner's role in each step of the project**

  Describe "who does what by when" for each step
- **Facilitation**

  It could be useful to get the help of an external facilitator to enhance the communication, mutual understandability and collaboration. This could, for instance, be endorsed by the patient umbrella organisations. (see also sections 3.5.1, 3.5.2 and 3.5.4)
- **Proofreading delays**

  Patients are not necessarily employed by a patient association, or do not necessarily have much time to participate in research. They should be given adequate time for consultation of documents and possible rereading to avoid a sense of tokenism. The delays should be decided in agreement, paying attention to the delays related to the implication of others actors such as the communication cell, translation, and layout.
- **Provisional schedule**

  Make a planning with clear decision points, define how the decision will be informed and who will take the final decision.
- **Financial aspects:**

  Foresee reimbursement of the patients' expenses.

- **Authorship**

  The patient's voice should be acknowledged. Decision about the way to publicly do it, e.g. by authorship, by acknowledgement, etc. should be decided. It should also be clarified whether these mentions will be nominal at a personal level (names of patients involved), association(s) level or general level (e.g. as "the patients who contributed to the research as research partners").

- **Ownership of results and future publications**

  Patients should be formally acknowledged for their contribution: they could participate with researchers to conferences or specific events, or be associated to the redaction of vulgarized documents.

3.5 General recommendations to researchers during the collaboration

3.5.1 Facilitating good communication

Researchers have to be aware of communication issues they can face: they have to think carefully about labels, as labels may convey implicit values. They also have to beware of jargon and acronyms when communication with patient representatives.

In order to **establish and maintain a culture and expectation of mutual respect**, Witteman et al.[7] recommended to:

- Have a face-to-face meeting with the full team as early as possible
- Introduce yourselves with stories, not titles
- State individual and project goals explicitly: ask all team members to state explicitly what they hope to bring to the project, what they hope to get out of it and what they hope the project contributes to healthcare

In addition, we suggest:

- To check and decide at the start on the use of the national languages and/or English in the meetings and/or correspondence
- To agree on the way to invite the patients to meetings: is an outlook invitation acceptable or not?
- To ensure having informal contacts with patients (before or after the meetings) to gain their trust

In order to **actively involve all team members during the collaborative moments**, Witteman et al.[7] suggest to:

- Recognize different kinds of contributions and efforts
- Invite people to contribute and take up roles
- Privately check with people who are quiet: some people may prefer to comment individually, by email or in a subsequent meeting after reviewing notes and summary documents.

Finally, the information that has to be mobilized during the collaboration has to be tailored to the patients[9].Patients we met in our workshops suggested for example that KCE researchers provide a simple and compact dossier to the patients.

3.5.2 Pay attention to the relational aspects

"Patients and researchers should feel respected and legitimated in their respective expertise. A climate of trust and exchange should be ensured and efforts should be made to create a "win-win" situation." (Cleemput, 2019[1] p.125) Both researchers and patients should have the willingness to work together.

"An asset to projects involving patients is having a neutral and experienced facilitator."(Cleemput, 2019[1] p.120)

The use of a “coach” for the patients, so that they could share their experience of participation with a “trust person” or relying on a (professional) facilitator, with a neutral position, able to “feel the tension of the room” and to ensure the balance of power between participants could be useful.

This role could be endorsed by the LUSS or the VPP for example.

3.5.3 Pay attention to all day-to-day details and needs of patients

Pay attention to the very practical aspects to ensure that everybody feels comfortable physically and mentally[1].

To be comfortable it is important to consider needs of the patients: avoiding long meetings, considering dietary needs, transportation issues (e.g. meetings in Brussels with public transport can be a barrier for some patients), hours of the meeting, day-care for children, patients needing constant supervision from relatives, or language used (i.e. German-speaking Belgian patients are often wrongly considered as fluent in French).

For research on very severe conditions, diseases in advanced stages or conditions that cause a lot of physical problems it is recommended that KCE researchers travel to the patients and not the other way around. Alternatively, digital solutions (videoconferencing) could be considered.

To consider possible vulnerabilities, researchers could be helped in such preparatory work by the patients themselves, by representatives of patients or by experts in multi-stakeholder discussions.

For some patients it is important to guarantee the accessibility of the research material, for instance to be able to involve people with functional difficulties (visually impaired, hearing impaired, etc.) and enable them to take active part in the research.

3.5.4 Maintain communication during the project

At the organizational level, it is important to communicate regularly on the calendar and in any case to send a reminder 1 day before a planned meeting or a deadline.

At the ‘content’ level, patients strongly indicate that feedback on what happens with their input is indispensable.

Contacts between the patient representatives and the patients they represent should also be stimulated to make sure they remain well aligned with them.

It is useful to write the minutes of the meetings and share them within the entire team, including the patients.

3.5.5 Use animation techniques to facilitate involvement

Animation techniques are useful to make the collaboration more effective and comfortable. While for researchers and health professionals it is common practice to perform work meetings and share their perspectives, it might be intimidating for patients to have to share their opinions in a ‘classical’ work meeting where everyone sits at a table and is faced to all other collaborators. By using animation techniques, you could also “break the ice” and help each participant to feel at ease. It helps people to get to know each other, which is particularly critical when the patient involvement is planned to take several months or years. Moreover, such techniques may help to overcome the loss of concentration. The animation techniques presented here (Table 11) can be used in every collaboration context at KCE (not only with patients but also with non-professionals). Other techniques exist and may always be adapted to the KCE context. We would therefore advise the researchers to test the technique beforehand to ensure the smoothness of its use during the discussion.

Table 11 – Animation techniques

Technique	Objectives	Useful for	Description	Details and supports
Brainstorming	To collect a wide range of ideas: brainstorming allows for submitting "wild" ideas, stimulating creativity, evidencing divergences...	Connecting participants	The moderator gives the theme of the discussion. Participants can either write down ideas (e.g. on sticky notes) and display it on a board, or speak out loud. In some cases, the use of a "Speech Staff" could be useful to ensure the circulation of the parole.	
Mind mapping	To visually display information related to an issue in a non-linear way that allows for eliciting connexions and relationships between components & subcomponents To help to provide a preliminary framework of analysis	Developing a shared language	A mindmap is a quick method to gather ideas at the pace they come to the mind, without paying attention to their order, and then to visually structure them to facilitate analysis. This serves for the intuitive organisation of ideas, tasks, words or concepts related to a central issue.	Examples of templates: https://www.mindmapping.com/mind-map
Problem tree	To create a structural (and visual) analysis of the causes and effects of an issue or problem To help identifying priorities	Developing a shared language	Problem tree analysis (also called Situational analysis or just Problem analysis) helps to find solutions by mapping out the anatomy of cause and effect around an issue in a similar way to a Mind map, but with more structure	Brouwer & Brouwers[20], 2017 pp 39-40 (including template)
Problem definition worksheet	To analyse the problem you are working on	Connecting participants	This tool can help to clarify and frame the issue at stake in a study. Often what seems to be the problem is only a symptom of a deeper problem. This tool helps to understand the dimensions of the problem, by looking at it from different angles. You can apply it individually, but also do this with a group of stakeholders as a way to bring ideas towards a similar direction.	Brouwer & Brouwers[20], 2017pp 23-24 (including template)
Futures wheel	To structure reflexions and questions about a future situation	Connecting participants	The Futures wheel is a form of structured brainstorming. The issue is written down at the centre of a paper sheet. Lines coming from centre are drawn. Primary impacts of the issue are written at the extremity of the line. Impacts of the primary impacts constitute the second ring of the wheel. This wave effect is continued until obtaining a useful view of the impact of the issue discussed.	Slocum[21], 2003 p 156 Examples of templates: https://www.mindtools.com/pages/article/futures-wheel.htm

Technique	Objectives	Useful for	Description	Details and supports
Make-a-wish	To clarify demand by opting a positive perspective : problems are transformed into wishes (=possible solutions)	Developing a shared language	Make-a-wish consists of a 3-steps process : 1) open discussion about personal experiences leading to XX key points; 2) focus group discussion on the XX key points to transform it into wishes; 3) wishes are transformed into actions.	PAQS ASBL[22],2018 p33
Visualisation tools * (e. g. rich picture)	To help participants understand the complexity of an entire situation.	Connecting participants	A rich picture is a drawing of a situation that illustrates the main elements and relationships that need to be considered in trying to intervene in order to create some improvement. It consists of pictures, text, symbols and icons, which are all used to illustrate graphically the situation. It is called a rich picture because it illustrates the richness and complexity of a situation.	Brouwer & Brouwers[20], 2017 pp 11-12 (including pictures)
Photoscan	To collect experiences by using visual support, making it more tangible	Sharing a common language	Photoscan consists of a 3-step process: 1) participants are invited to take or bring pictures illustrating their experiences; 2) participants justify their choice during an individual interview; 3) a group discussion is organised to discuss pictures and related issues, with participants having taken / not having taken pictures.	PAQS ASBL[22],2018 p13
Patient journey / user journey	To visualise all steps a patient encounters in a defined situation in order to uncover interactions, to learn from these interactions and to better understand what happens in the process	Sharing a common language	The patient journey consists of the in-depth description of a patient experience of a defined type of situation. Based on a "persona", participants have to identify the beginning of the journey. They then identify the high levels / key stages and add context to the journey. When the journey is completed, participants select the most crucial phases in the journey and try working out a solution around that phase.	Rosenbaum et al.[23] Examples of templates: https://creately.com/usage/patient-journey-mapping-templates/
Stakeholder identification	To help make an 'initial sweep' of stakeholders and their characteristics, and to identify roles of stakeholders.	Connecting participants	This tool allows you to quickly visualise actors concerned by a defined issue and their interrelations. It can be done on a whiteboard or wallpaper with the help of yellow notes and markers.	Brouwer & Brouwers[20], 2017pp 15-16 (including pictures)

Technique	Objectives	Useful for	Description	Details and supports
Netmapping	To help people understand, visualize, discuss, and improve situations in which many different actors influence outcomes.	Developing a shared language	This tool helps stakeholders to determine which actors are involved in a given network, how they are linked, how influential they are, and what their goals are. Using a participatory approach, both interviewees and interviewers draw a network map of the actors involved in the policy arena and characterize the different links between the actors. They then add “influence towers,” made of checkers pieces, to transfer abstract concepts of power and influence into a three-dimensional form. Finally, the interviewee assesses the goal orientation of the different actors.	Brouwer & Brouwers[20], 2017pp 30-32 (including pictures) Practical illustration (with question guide): https://netmap.wordpress.com/about/
Stakeholder analysis	To capture the degree of influence and level of interest of each stakeholder over the relevant issues or possible objectives on an issue	Developing a shared language	Making an Importance versus Influence Matrix helps to map out stakeholders and their relation to the issue in the project. It generates insights on the importance and influence of each stakeholder. With this information, it becomes possible to develop a specific approach and strategy for the identified stakeholders (e.g. recruitment, specific data collection, dissemination…).	Brouwer & Brouwers[20], 2017pp 33-35 (including visual support + examples of questions)

We present in Table 12 with which method animation techniques can be used.

Table 12 – Animation techniques according to the method selected to involve patients

	Delphi process	Steering committee	Open forum	Questionnaires & surveys	Nominal group	Work meetings
Brainstorming	(1st round)	X	X			X
Mind mapping		X	X		X	X
Problem tree			X		X	X
Problem definition worksheet	X	X	X	X	X	X
Futures wheel			X		X	X
Make a wish		X	X			X
Rich picture		X			X	X
Photoscan	(1st round)					X
Patient / user journey	X	X	X	X	X	X
Stakeholder identification	X	X	X	X	X	X
Netmapping		X	X		X	X
Stakeholder analysis	X	X	X	X	X	X

3.6 Reporting patient involvement

Patient contributions and their potential impact on the research process should be reported in the research report.

Recommendation of the KCE position paper [1]

Besides the necessity to report the patients' contributions and their potential impact on the research, patients stated during the workshops that the decision whether or not to include the patients' input should preferably be explained and justified where needed. This is seen as a form of respect for the patients' commitment. The patients also want to recognize the patients' voice in the recommendations.

Nevertheless the researchers must guarantee and check that any personal data reported is anonymized to maintain patient confidence and ensure confidentiality.

3.7 Evaluation of the patient involvement

- **Patients and KCE researchers should give feedback to each other about the collaboration, to potentially improve future collaboration.**
- **Patient involvement activities in health policy research should be regularly evaluated and procedures revised when appropriate.**

Recommendation of the KCE position paper [1]

ZonMW[24] advises to

- "develop a strong and rigorous methodology – including the evaluation of the impact of patient involvement;" (p.46)
- "plan and organise (a) feedback and (a) debriefing moment(s) with the patients" (p.57)

This process note is a living document. We will develop the way to evaluate the patient involvement later.

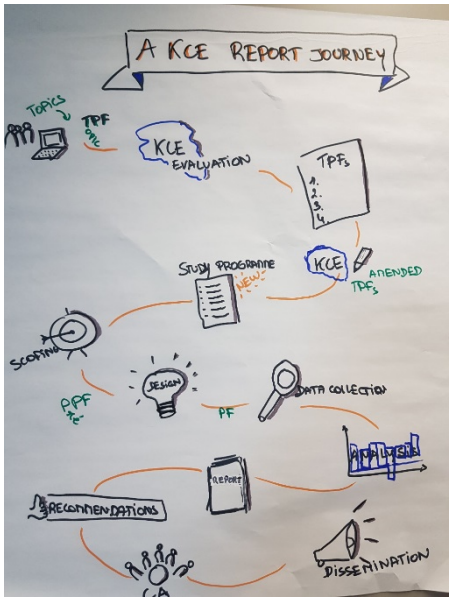
APPENDICES

APPENDIX 1. WORKSHOP WITH PATIENT'S ASSOCIATIONS UMBRELLAS

Material

We met the LUSS during a 3 hours face-to-face workshop in order to brainstorm on how they could be involved or support KCE with patient involvement in KCE projects.

We organized the discussion around a classic journey of a KCE report (see picture below) and used a visual canvas.

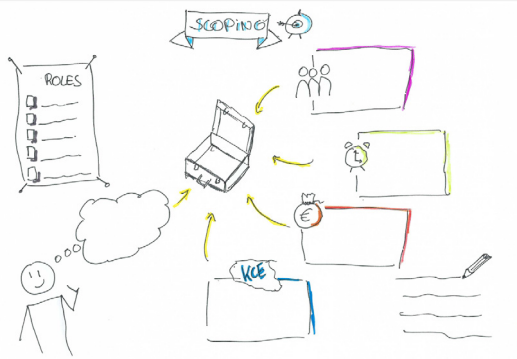


Concrete questions for each step of a project were:

- What are potential roles for the patient umbrella organizations in a KCE project?

- What resources do they need (human, time and financial)?
- Which other points does KCE have to pay attention to?

These questions were proposed using a visual template.



Results

Phase 1: Selection of studies for which patient involvement is desirable

Once KCE has prepared the study programme that has been approved by the Board, a meeting could be organized with all umbrella organizations and the KCE management. Preparatory material for the meeting, i.e. the amended TPFs, are shared with the umbrella organisations but remains confidential (the umbrella organizations do not share these with their members).

The aims of the meeting are

- to identify which studies it would be appropriate to involve patients,
- to identify (a) patient association(s) to invite to participate, if any, and
- to identify specific conditions for implementation of patient involvement, related to the features of the patient population.

When the KCE management has decided, based on the outcome of the joint meeting with KCE and umbrella organizations, that patient involvement is relevant and feasible, KCE researchers and the umbrella organizations contact the patient association(s) (considering the provisional planning of the projects).

Before the scoping of a particular study, the umbrella organization will contact the patient associations to explain the study and assess their willingness to participate. If there is no patient representatives identified for a topic, they could act as patient representative themselves.

Phase 2: Scoping and design of a specific study

A **first introductory meeting** with KCE and the patient representative(s) should be organized to get to know each other and decide on the modalities of the collaboration. The umbrella organizations could accompany the patient representative(s) in this meeting as well as in the next steps if necessary. The writing of a (collaboration) charter (explaining the aims of the collaboration, each actor's role, the subject of the collaboration etc.) could then be addressed. This document will be finalized once the design will be clearer. Timing of a final charter is important to define before 1st intervention of the patient organization. If the design research phase includes the development of Informed Consents documents and that patient involvement is suitable for that research phase (reviewing before submission to EC), then the charter should be final before the design research phase

Patients associations and/or umbrella organizations will always be invited in the scoping phase of an individual study.

The **scoping/design research phase** should lead to the identification of the project research phases where the patient's perspective should be included. These aspects will be discussed with the patient representative(s).

The consultation of the patients could be done via email, online meeting or face-to-face meetings, according to the specific needs of the patients. Umbrella organizations could help the patient representative(s) in the process, as facilitator. Umbrella organizations could participate on the demand of the teams and should care to manage expectations of both teams (KCE researchers and patient representatives). For instance, it has to be

clear that the involvement will mainly consist in consultation, the researchers will not search for consensus and the KCE team takes, and is responsible for, the final decision.

Preparatory material, if any, needs to be foreseen in the language of the participants. Patients should be given sufficient time to prepare their intervention.

A project schedule has to be established and the collaboration document finalized.

The methods used to involve patients in general should be clearly thought through in order to avoid unrealistic timings and expectations.

Phase 3: Data collection, analysis and reporting

The umbrella organizations do not see a role for them in the **data collection**, except to disseminate the information if there is a need to recruit participants.

They neither see any role in the **analyses**, nor the **reporting** of the data.

Phase 4: Recommendations

Recommendations are under the responsibility of the KCE research team but are validated by the KCE Board. Because umbrellas are represented in the KCE Board, they already have an official voice about the final recommendations. Nevertheless the umbrellas could consult patient organizations in recommendations development prior to the KCE Board meeting.

Phase 5: Dissemination

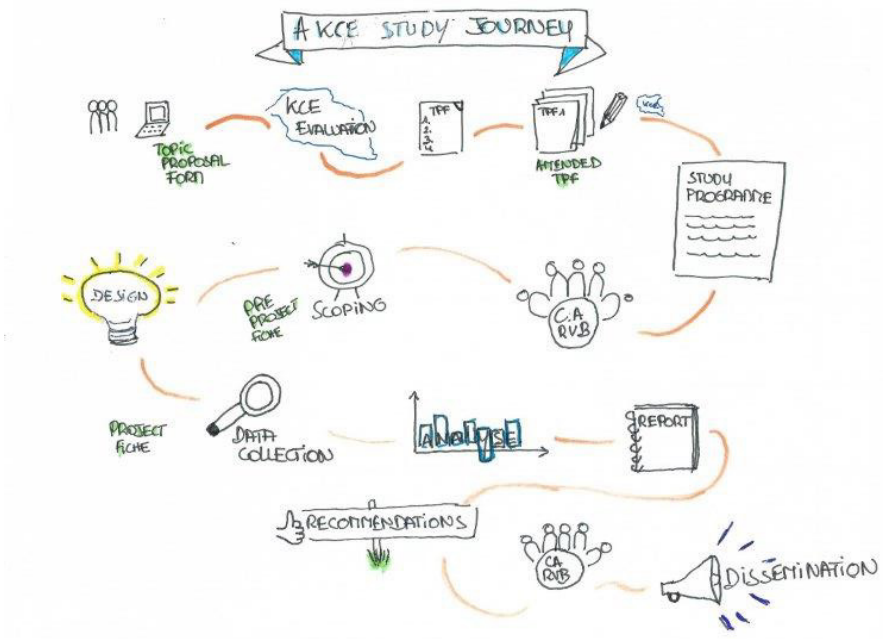
Umbrella organizations could help to **disseminate** the final publications related to the studies among the patient associations. Nevertheless, innovative methods need to be developed to touch a wider public.

APPENDIX 2. WORKSHOP WITH SICKNESS FUNDS

Material

We met 3 sickness funds during a 2 hours workshop to brainstorm on how they could be involved or support KCE with patient involvement in KCE projects. The discussion took place via ZOOM.

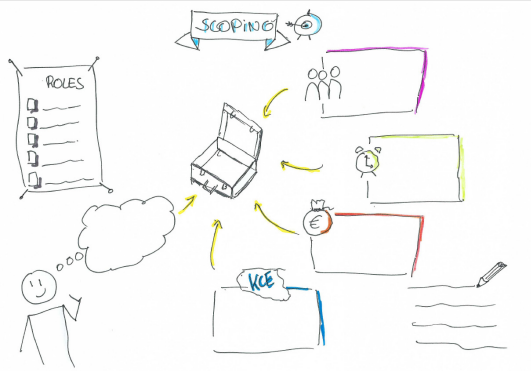
We organized the discussion around a classic journey of a KCE report (see picture below) and used a visual canvas.



Concrete questions for each research phase of a project were:

- What role could sickness funds play as representative of the healthcare consumer –i.e. beyond their role as stakeholder in the broader healthcare system- in a KCE project?
- What resources do they need (human, time and financial)?
- Which other points does KCE have to pay attention to?

These questions were proposed using a visual template.



Results of the workshop

General considerations

The sickness fund as relay to patients

When KCE wish to contact patients for specific studies, sickness funds can be a resource to identify and contact specific groups such as patients associations or other associations or groups where citizens are participating, e.g. single mothers or patients with social problems, that are in their network.

Disclaimer

Contributions of the sickness funds will always depend on the available time, human resources, internal organization and internal planning. Demand should always be balanced with the sickness funds' possibilities.

Phase 1: Selection of studies for which patient involvement is desirable

Once KCE has prepared the study program that has been approved by the KCE Board, a meeting could be organized with all umbrella organizations, the sickness funds and the KCE management. Preparatory material for the meeting, i.e. the amended TPFs or a summary thereof, is shared with the participants to the meeting but remains confidential.

The aims of the meeting are:

- to identify in which studies it would be appropriate to involve patients,
- to identify (a) patient association(s) to invite to participate, if any

In general, transparency of the patient representative(s) that have been involved in different research phases of the study is crucial. Expectations of both teams (KCE researchers and patient representatives) need to be clear from the onset of the study. For instance, it has to be clear that the involvement will mainly consist in consultation, the researchers will not search for consensus and the KCE team takes, and is responsible for, the final decision.

Phase 2: Scoping and design of a specific study

The **scoping / design phase** should lead to the identification of the relevant questions for the patients/healthcare users and the resources available at the sickness funds to contribute to the assessment of the research topics: available data in sickness funds' databases, possible candidates to pretest data collection tools, potential participants for primary data collection…

It is important to specify what is expected of the sickness funds, either as separate entities or as part of IMA-AIM (inter sickness funds agency).

The way to consult the sickness funds could vary according the needs and the timing: email, online meetings or face-to face meetings should be used in a flexible manner. It could be discussed during the kick-off meeting what

the modalities for the collaboration will be. This may depend on the topic and the preferences of the people.

Sickness funds are invited to propose a way of working with KCE after internal discussion (who is the point of contact, for what type of questions, etc.).

The design research phase is also a key moment to define what is feasible in the timeframe of a KCE study and according the resources (human, time) of the sickness funds.

It is always important to invite the sickness fund as patient representative but there is no obligation for them to engage in the process.

Phase 3: Data collection

Regarding the **data collection research phase**, sickness fund are willing to help.

Firstly they can help in the building of the data collection tools. For example, KCE wants to conduct a study in which patients need to be contacted in order to complete a questionnaire. In that case the sickness funds can contribute by elaborating the content of the questionnaire and volunteers in their members can test the questionnaire for readability.

For the recruitment of pre-testers or participants, the sickness funds can draw up a sample of members they can contact via their communication channels via e-mail with the aim of completing the questionnaire online. Even for studies relying on qualitative methods, the sickness funds can participate in the recruitment of participants in focus groups, interviews... Nevertheless they have their own studies ongoing and it will therefore not always be possible for them to help KCE.

Phase 4: Data analysis and reporting

If the sickness funds are involved in the reflection around the scoping and the design, there is no need to involve them in the **analyses and reporting phase otherwise** than in their participation in the final 'classic' stakeholders meeting.

Phase 4: Recommendations

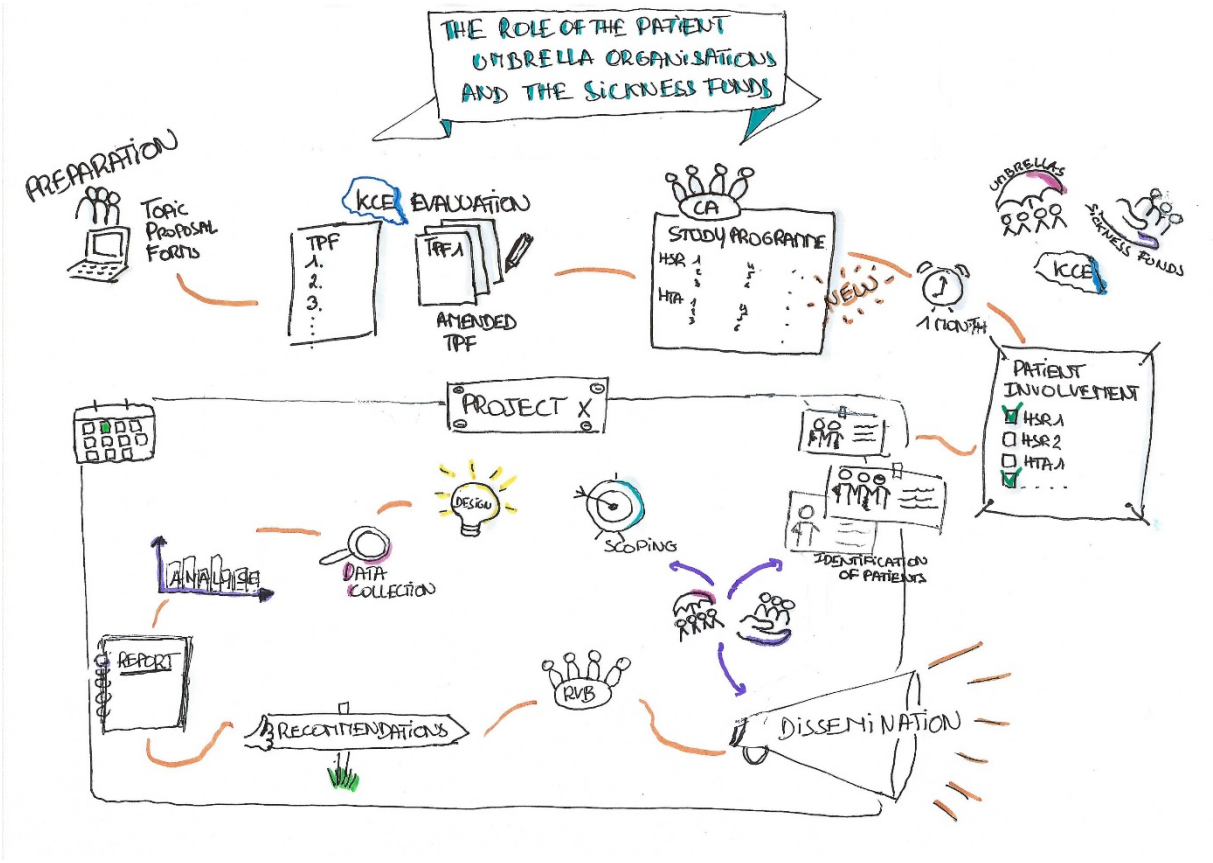
The **recommendations** are the responsibility of the KCE research team but are validated by the KCE Board. Because the sickness funds are represented in the KCE Board, they already have an official voice about the final recommendations.

Phase 5: Dissemination

Sickness fund could help to **disseminate** the final publications related to the studies among their members. They reported during the meeting that this research phase deserves a more proactive approach from their side to translate KCE reports in common language and spread them among their members. They can use the press release published by KCE but, in some cases, more extensive or more restricted reporting can be envisaged by the sickness funds. In that case, KCE could help to verify the correctness of the more extensive of restricted version before publication. A collaboration between KCE and the sickness funds could be set up for this in these cases.

ADDENDUM

We visually summarized the discussions carried with the LUSS and the sickness funds in order to have a complete picture of the possible process.



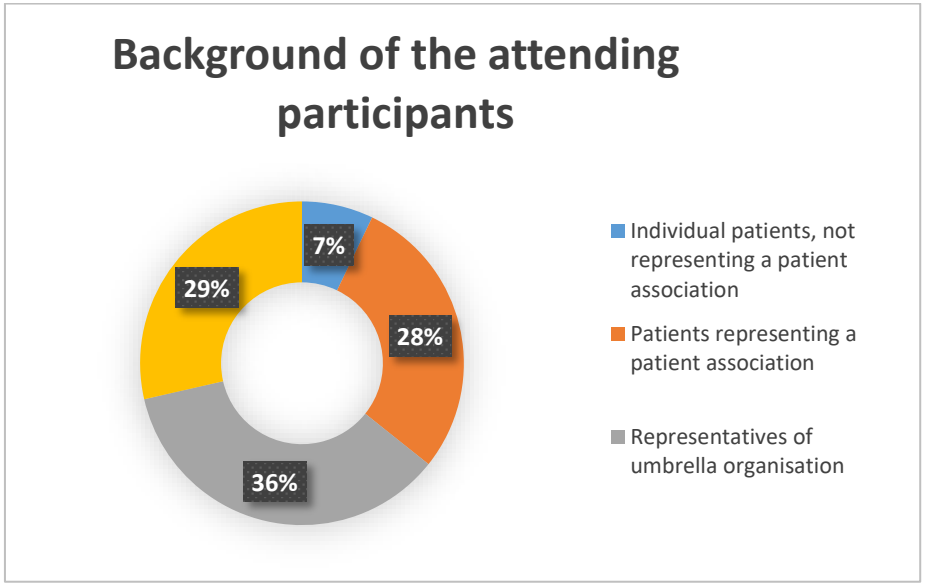
APPENDIX 3. WORKSHOPS WITH PATIENTS

Authors: Dethier Marleen – Carton Catherine – Van Overloop Maaike – Steyaert Stef[m]

Participants to the workshops

Of the registered people, 28 effectively participated in the workshops: 14 were French-speaking and 14 Dutch-speaking. They were divided over 3 French-speaking and 3 Dutch-speaking workshop sessions:

Date	Language	Registered	Participated
20 October 2020	French	6	6
23 October 2020	Dutch	5	5
26 October 2020	French	6	2
26 October 2020	Dutch	8	4
28 October 2020	French	7	6
30 October 2020	Dutch	6	5
TOTAL		38	28



In the comparison between the two graphs, it is noticeable that, despite registration, the group of individual patients more often does not turn up for the actual workshops. We did not contact the participants to investigate the reasons of non-attendance.

[m] The original report has been edited by KCE for style consistency thorough the process note.

Results of the workshops

Part 1: General vision of patients on "patient involvement in health care policy research"

Patients' general idea on being more involved in health care policy research

"Nothing about us without us" is the motto that unanimously emerges from the participants' general vision. It is abundantly clear that patients want to be involved in policy-preparing research. On the one hand there is an intrinsic motivation to help others, on the other hand they are convinced that they can determine patient-specific emphases and priorities in order to steer the research.

Participants believe that only patients know what it really means to experience a disease. Where healthcare providers often strive to improve health, for participants, patients put quality of life first. In doing so, they have an eye for the unspoken or "invisible" aspects of being ill. They can also voice the (unmet) needs and the organisational conditions that make experiencing the side effects of treatments more bearable. Participants hope that these aspects will not be forgotten in the research, but will also be addressed through their input.

By involving patients in research, according to the participants, researchers get them out of the patronizing atmosphere. Participants prefer to see themselves participating as an equal partner. Depending on their experiences, participants feel that they are currently not being consulted, not sufficiently consulted or being lately consulted, which makes them feel they have to 'undergo' rather than co-manage.

However, participants also make a number of comments about their inputs. It must be clear who is meant by 'the patient': someone who has been ill or someone who is ill? In any case, it is not easy to involve or stimulate patients to participate for several reasons: people who are in the middle of their illness are often too sick, even though they can provide an important input. In that case, the informal carer can be called upon in equal measure. Chronic patients often experience inconveniences that make long-term involvement or relocation difficult. Patients who are over the peak of their illness are the easiest to contribute but they are volunteers and are often over-questioned. Participants find it a pity that there is so little structural support from the government. For the participants, patients themselves need to understand that there is also a personal gain in participating into (KCE) research projects: efforts should be made to make it clearer for them.

Participants also indicate that "THE" patient does not exist. There exist expert pools that are made up of patients who have received training so that their input could be considered as broad and valuable. In that respect, there is also a suggestion to involve the "Patient Expert Center" (PEC). The aim of the PEC is to train patients together with patient organisations to become patient experts. Training as a patient expert includes a generic component and a disease-specific component (from www.patientexpertcenter.be). In the training of these patient-experts, it is important to find a balance between on the one hand not influencing patients by discussing approach and content, and on the other hand providing them with sufficient support to allow them to contribute in a neutral and unbiased way. In addition, it remains a challenge to bring not only the strongest patients (educated, easy to reach, articulate, assertive, available, with experience in research...) but also the underprivileged or weaker patients (with low educational level, hard to reach, timid, less able to speak, docile, less available, no experience in research, etc.).

There is no unanimous belief that paid employees from patient associations can provide the same lived experience and that they can simply replace the presence of the patient. However, they can support the patient as a sounding board, by being present in pairs, as a coach, to help translate the patient's message, as a trusted presence to help overcome the patients' uncertainty…and participate together.

Finally, participants would like to advise KCE to think carefully about what exactly is required of patients in the study, at whatever stage, in order to fit the right profile. The profiles of patients are diverse: some are willing to participate in a working group, others prefer individual consultation, some want to think strategically, others prefer to deliver very concrete data, some want to help translate scientific language into patient language... This will

have to be examined on a project-by-project basis to find out what the needs are exactly as well as the right choice of target group and disease that fits within the project.

The expected contribution must be clearly explained and communicated. It is mainly a question of clarifying that involvement does not mean participation in testimonials. Participants also recommend considering the criterion of literacy: this requires the scientific community to speak a language that is accessible to patients.

POINTS OF ATTENTION ON GENERAL VISION

- Patients need to be seen as essential and equal partners who define patient-specific emphases and priorities.
- For the patients, the question "what's in it for me" is also important and the advantages of being involved in a study should be made clear.
- The KCE researchers should clearly define what they mean with ‘a patient’, in the context of the study: do they wish to involve patients still experiencing the health problem or the disease, patients who are no longer ill… .
- Patients advise the KCE researchers to think carefully about what exactly is required of patients in the study, at every stage, in order to fit the right profile.
- Patients who are too ill to contribute should be replaced with their caregivers.
- Researchers should take into account the physical limitations of the patients.
- KCE can collaborate with expert pools from the “Patient Expert Center” or have patients assisted by permanent employees of patient associations.
- Researchers must use understandable language throughout the research and in all collaborative contacts with the patients.

What do patients understand by “consulting patients”?

Participants differently perceive "being consulted in a research project" differently, depending on whether and to what extent they already have this kind of experience in the past.

For many participants, their experience in scientific research is limited to cooperating in data collection from the experience of their illness. They therefore translate "being consulted" mainly as participating in questionnaires. Thinking along at a higher, strategic level is usually still unknown to them. During the different workshops, participants have difficulty understanding the broader meaning of “consultation”, despite explanations and the provision of examples.

Others participants have a more strategic approach to the term “consulting” itself. They translate it like "My opinion is asked for and is taken into account as much as possible". The majority of participants to the workshops finds “consulting” too non-committal.

This could lead to disappointment for the patients if their contributions to research are given a different weight than the ones they want it to have. Participants feel that the term "involve" should be used instead of "consult", as it is felt to have a stronger and more binding meaning. They also indicate that consultation must take place throughout the entire process of the study and that there must be feedback on what has happened with the input of the patients.

There is a consensus that consultation should not be limited to questioning an opinion. Rather, one sees the consultation as a "consult", as a consultation with a well-considered voice. One prefers to be asked for advice rather than an opinion. In that sense, for participants, the terms as “consult” should be correctly defined and used.

Finally, participants present a crucial statement: "**I don't want you to ask what MY idea is. I want you to ask me what I think applies to OTHERS**". For the participants, it is important to ensure that the inputs are the voice of a supported patient-community, and not the opinions of one single patient and his/her personal experience. Participants suggest consulting self-help groups, patient associations or trained expert patients in order to get less

individual opinions and not only consult the individual patients. However, participants also recall the need to bring along personal and specific experiences, admittedly in an anonymous manner. For the participants, both the group and the individual experiences should be brought along to get the most complete input for the research.

POINTS OF ATTENTION ON CONSULTING PATIENTS

- Patients strongly believe that consultation should not be seen as a kind of informal approach to involvement in order to avoid disappointment among patients.
- KCE should clarify the concept of consultation as it does not have a clear and common meaning for patients.
- Patients strongly indicate that feedback on what happens with their input is indispensable.
- The patients' voice should be a mix of group and personal experiences to obtain the most complete input.
- Personal data should be anonymized to maintain patient trust.

Patients' views on the definition of consulting by KCE: "Patients are asked for their opinion but this is not binding for the research team"

Participants first react negatively to the 'non-binding' dimension of the consultation process at KCE. If the patient does not find anything about his/her input in the final report, for the participants, it gives the impression that the patient is not being heard and this can be demotivating. One wonders whether the patient's opinion is then taken into account. For the participants, this description does not seem to be a good starting point. Some participants offer alternatives such as 'taking into account' or 'co-creating'.

According to the participants, this description implies that the voice of the scientist/health practitioner weights more than that of the patients. Despite experiencing the disease themselves, they feel they are the third recognized source of knowledge. In that respect they plead for an equal status.

More in-depth questions show that the resistance is not so much about being the term "non-binding", but that participants fear that their input might not be found in the final scientific report. What matters is that the patient's opinion is included somewhere in the study, even if it is a minority opinion. In that case, it is considered possible and acceptable that the inputs from the patients are not processed at the condition that an explanation/motivation of the non-inclusion is crucial. For participants, mentioning the patient's input is a form of respect for the patient's involvement. This means that the advice does not necessarily have to be binding.

In any case, participants advise for transparent information beforehand about what the objectives of the consultation.

POINTS OF ATTENTION ON THE DEFINITION OF "CONSULTATION" BY KCE

- KCE must clearly define what it is intented by "non-binding" advice to prevent patients feeling not being really heard. Patients suggest rephrasing "non-binding" by 'has to be taken into account".
- Patients consider extremely important to have their inputs included in the final report, irrespective of whether the research team decided to work with that input. Partients see it as a form of respect fot the patients' commitment.
- Patients state that the decision whether or not to include the patients' input should preferably be argued and explained.
- Patients plead for an equal status of all stakeholders contributing to the research.

Patients' suggestions on patient-recruitment methods

There is not one way to reach patients: it should always be a mix of contact possibilities in order to reach the wider audience possible. A distinction can be made between **the channel** through which patients are reached *(where to find them*) and **the tool** through which this is best done *(how to find them*).

To reach clearly identified patient groups

- When talking about clearly defined disorders and the channel through which contact is best made, there is unanimity that the **patient association** or self-help groups' organizations are the most suitable for this. In order to reach as many people as possible in this way, patients suggest ithat health care professionals should better encourage patients to join patient associations. The "Sociale Kaart" can also make this more public. The "Sociale Kaart" is an online application that provides an overview of the services, organisations and facilities of the welfare and health sector in Flanders and Brussels. Patient associations are also listed here. However, patients point out that some patient associations are already overwhelmed by request to join research and other questions. For these patient associations, it is difficult tendorse a dispatching role.
- **KCE** can also improve its visibility as research center and the visibility of its projects. KCE can also create a permanent database of volunteers. Patients and citizens could register and indicate their availability and expertise. The KCE researchers can then now who they can consult and when. This register could also help to distinguish different degrees of involvement. For example, this register can help to identify patients willing to be invited only for data collection or, on the contrary, patients who are trained as experts and are willing to be involved in the whole research process.
- Patients also suggest **hospitals as gateways**. Doctors can discuss the study directly with the patients. Patients also suggest that the reception desk at the hospitals could be asked to propose participation in a study to patients who present themselves to the hospital, by asking them whether researchers may contact them for this purpose. In this way, a database can be created. Patient involvement is already a common practice at hospital level, as accreditation is only granted if patients participate. This approach gives an additional opportunity to talk to patients about participation into research.
- Patient suggest working with **centers of expertise** for very specific groups, like orphan diseases.
- P**atient committees already exist**, like 'Zelfhulpvriendelijk Ziekenhuis', "patiëntenraden" that can be called upon, or other **patient partnerships**, sometimes with a third trusted party. For example, the eHealth platform acts as a Trusted Third Party (TTP or independent third party) for certain bodies listed in the law within the framework of a request for the provision of personal data relating to health.
- Patients also suggest that, for those whose health condition prevents participating into research, informal **caregiver associations** should be brought in so that the caregiver can participate on behalf of the patient.

To reach underrepresented or broader patient groups

Some issues need the involvement of underrepresented patient groups or patients sharing a social issue or health care consumption habits, leading to a broader group of patients. Participants make some suggestions to reach them.

- Through **primary care** with a wide range of care and social workers, because they are in contact with various people from different target groups
- Through the **sickness funds**: some participants see a possible role of the sickness funds via the Observatory for Chronic Diseases, as they did previously for the federal integrated chronic care projects[n]. Sickness

[n] See more information on the website of Integreo www.integreo.be

funds support these pilot integrated care projects and actively participate in them at various levels, for example by providing patient data. However, other participants declare that sickness fundss are too strongly of the opinion that they have more knowledge of patients than the patients themselves. These participants believe that sickenss funds have to limit their involvement to the financial and administrative support of patients. Participants previously contacted by sickness funds found it very confronting because they were identified by drawing up lists based on health data. GDPR however imposes limits on this and privacy must be respected.

- **Through community health centers, social services, diverse residential settings, like nursing homes or centres for the disabled, and nurses**. These intermediaries can be directly contacted to reach target groups who are less familiar or unfamiliar with digital applications. **Volunteer associations** can also help reaching vulnerable target groups.

Patient recruitment tools

Because of the diversity of patient profiles, e.g. whether or not they are familiar or have digital tools at their disposal, it is important to use different tools alongside each other.

- Verbal explanation (e.g. at patients' association meeting or trainings)
- Mail
- Newsletter
- Social media
- Posters
- Leaflets
- Online platform: technologically, one online database of existing studies would be very interesting because the information related to ongoing studies is very fragmented. Participants suggest an overview of existing studies at either the Belgian or Flemish/Walloon level, or even by disease.

In other countries, central platforms already exist. It might be interesting to provide such a central platform in Dutch and French. Some participants suggest developping a booklet containing all ongoing and recent studies by pathology and distribute it via health services or pharmacies (for non-digitally skilled patients).

POINTS OF ATTENTION ON RECRUITING PATIENTS FOR PATIENT INVOLVEMENT

- Recruitement of patients for patient involvement should always include online and offline approaches.
- Participants recommend to use broad information channels to reach as many people as possible, in addition to targeted gateways for certain target groups.
- The patient association is a strong channel to reach their affiliated members. It is a simple and uniform way to reach patients. However, some participants indicate that they felt little need to join a patient association.
- Sickness funds could also help to identify relevant recruitment channels or use their own communication channels with their membership to help in recruiting patients for involvement.
- GDPR is a possible difficulty when it comes to the transmission of personal data.

Patients' suggestions on ways to register and enrol for involvement in a KCE study

Just as patients need to be able to learn about a call for involvement in a study both online and offline, there must also be the possibility to sign up online and offline.

Channels

- Through **patient associations,** even if they cannot serve as intermediary for all researchers
- The **patients** can take action, especially as not all patients are members of a patient association
- Through **KCE**. In the invitation that is sent, in addition to brief information, there may be a link that can be clicked on to permit to the candidates to register directly. It is important to keep the process simple. It is necessary that KCE makes itself sufficiently known to the population: it is not yet known everywhere.
- Through **healthcare professionals** after they have made the project known to the patients.

Tools

- Mail
- Phone
- Letter or reply strip
- Social media
- Through a centralized platform where calls are collected
- Contact form or a form on a website

POINTS OF ATTENTION ON THE REGISTRATION OF PATIENTS FOR INVOLVEMENT

- Registration should be possible both online and offline.
- KCE should make itself better known to the population.
- KCE should make the registration process simple and user-friendly, using clear language.

Patients' suggestions on involvement and data collection methods

Participants have difficulties to distinguish methods for being involved from methods for data collection with patients: this confusion reflects the difficult distinction between being a participant in a study and being consulted for the study. Methods for involvement should be custom-made. They therefore need to be **chosen first according to the research question**; second to the characteristics of the targeted patients (competences, choice of interaction, availability...).

Patients mention the growing number of **patient experts or experts by experience**. They speak from a wide range of backgrounds, are trained to endorse their role as experts and are able to transcend their own story. Nevertheless, some participants believe that the individual story can make an extra contribution. In any case, close contact with the peers is crucial.

For some participants, a distinction can be made between **involvement of an individual patient and the involvement of a patient association**. One the one hand, the patient association can represent the voice of the patients on the condition that the patients are actually heard and thus that the association regularly involve its members in consultative activities. On the other hand, it is indicated that it can be useful to find out through the associations which method is most suitable for the target group one wants to reach. For example, for chronic pain patients, it is even possible to make a home visit if moving is too strenuous. Sitting for hours is not easy and regular breaks are certainly recommended.

Some participants also distinguish the **involvement of an individual patient and the involvement of a group of patients.** The involvement of a group of patients can happen in two ways. The group of patients can work directly with the KCE researchers, without intermediary. The group of patients can hold a discussion, i.e. in their association, without the researchers, and then transfer their conclusions to the research team. This can be done thanks to the moderation of an employee of the patient association or an umbrella, who then transfer the results to the KCE researchers.

Participants diverge about being involved via a patient association or directly. Similarly, some patients prefer being involved individually, others prefer being in a group and do not fear being outspoken. Involvement as an individual should, according to some participants, be avoided because the patient group must be largely represented. Group work makes it possible to confirm each other's story, even if sharing sensitive information in a group is sometimes difficult. Hearing each other is an enrichment, especially in conversations with fellow patients. It is important to make sure that everyone has their say. Nevertheless, the majority believes that the possibility of individual interviews should always be offered. Besides, participants say that, when collecting data, the more inputs, the more complete the answers to the research questions. Several participants mentioned the combination of individual face-to-face interviews with group discussions as a best practice when involving patients.

Participants made several suggestions both how to involve patients and how to improve data collection with patients:

- Relying on (patient) experts and/or personal contacts – online or face-to-face-support patient involvement.
- The more the research question concerns a sensitive, emotional and intim issue, the more patients recommend investing in a small number of participants to get an in-depth comprehension of the issue at stake. Relying on interviews can then be interesting.
- A written exchange or from one person to another is considered a method to enrich answers.
- (Online) workshops, guided by a moderator, allow for investigating deeper some questions.
- Patients recommend a gradual involvement of participants, especially when patients are reluctant to collectively share their experiences. After a first individual meeting, a group session could be organised if there are bottlenecks that need to be resolved.
- Similarly, patients recommend a gradual involvement of those who are vulnerable when it comes to expressing their opinions.
- Focus groups or group interviews are good methods for supporting patient involvement, although it is not easy for everyone to free themselves at the moment of a focus discussion.
- Involvement can take place in pair: a patient expert from an association and a employee from the patient association together in the research group. The employee could then help the patients to frame their expectations or questions.
- It could be meaningful to create different discussion groups in which patients are separated from health care professionels, especially physicians, because patients often see them as "specialists", which can influence their input. Other patients believe on the contrary that the patients and health care professionals should cooperate in the research team at all times.
- Patients also suggest that the patient association can rely on one of its employees to act as an intermediary between the patients and the research team. The patient association collect inputs from patients throughout the research on specific steps and give feedback to the research team.
- Patients also suggest establishing a form of 'patient statute' setting out the framework and the rules for involvement in research.

POINTS OF ATTENTION ON METHODS OF INVOLVEMENT

- Patients recommend preferring face-to-face contacts to supporte patients involvement , as not everyone has access to online tools. This applies not only proper data collection but also for supporting involvement as such, as the face-to-face contacts allow for informal interactions and a better apprehension of non-verbal signals.
- All deterrent factors should be avoided. Contributions to the research should not cost the patient any money. Transportation costs should be reimbursed.

- Patients advise not to limit project work to working hours but, for example, also consider activities in the evening.
- It would be useful to foresee a kind of partnership agreement between KCE and patients that stipulates methods, rights and preconditions.
- Patients should be informed by their sickness fund about their possibilities in terms of doing voluntary work as a patient, with an explanation of all the conditions (fiscal, legal, etc.) and possible consequences.
- Patients recommend having a third party who makes the link between the patients and the research team. Whether or not that person should be a permanent member of the research group depends on the type of research. In some studies, being part of the team can certainly be useful, e.g. in rare diseases.

Part 2: Patients' perspectives on the three phases of a research project (scope, design, results)

Although definitions of scoping, design and results were explained during the presentation, and also illustrated these phases with concrete examples, in both the Dutch and in the French workshops, these phases remained abstract and vague for the participants. Many participants still understand cooperating in a study in particular as filling in a questionnaire as a design method. The broad involvement in the research, from scoping through design to drawing up and distributing guidelines, is much less in the knowledge and experiences of the participants.

Participants who themselves are active in research, and often work in patient organisations, better understand the overview and purpose of these phases.

Patients' ideas on involvement in the scoping phase of the research

Scoping aims, among others, at answering two questions: firstly, what are the priority research questions for the patient, and secondly, how do you involve patients in formulating a research question?

For the first question, participants suggest bringing together patients who formulate questions/problems within their illness. These patients can think about which themes they would like to be addressed by the research team. Participants make clear that **patients also prefer to be involved in the choice of the research topic, before being contact for the scoping phase**. Once the scope of the research topic has been chosen, the KCE researchers can then formulate the research questions, taking into account the patient perspectives. For the participants, the patients do not have to formulate research questions.

During the scoping, the patients need to know clearly why the research is being carried out and what the expected added-value is. Participants find not always easy to assess the scope of a question and understand its value without additional explanation. The KCE research team can organise preparatory meetings with the patients on what to do and inform them about what is expected of them in the scoping phase. The question needs to be asked very specifically. Some participants point out that patients may need

a great deal of explanation, insisting on the need to take time to prepare appropriate support. The participants recommend then that the KCE researchers **provide a simple and compact project description to facilitate the discussion during the scoping phase.**

Participants also report that, because of the "professional terminology", the questions are often at **too high-level for the patient**. For participants, the language of the lived experience needs to be distinguished from the scientific university based language. The scoping questions must be comprehensible and accessible for the patient. Training may be necessary for patients to understand the information. Some organisations already offer this type of training: participants cite the Patient Expert Centre or Eupati of Eurordis[o].

Participants feel that **quality of life and well-being** should be given more consideration into research questions. They notice that research questions from the health care professionals are (often) about treatment and cure while, for patients, there is a need for questions aiming at providing patient-related problems, with a focus on practical and specific questions about support in daily life, quality of life and well-being. Some participants illustrate this lack of attention to well-being by relating that they often feel abandoned once they get their diagnosis.

Patients express a lack of responsiveness of (KCE) researchers to address research questions or topics that are (directly) relevant to patients. **They strongly suggest to always try including at least 1 research question that address the patient needs and perspectives.**

Participants highlight the need for deepening the scope of the project, not especially broadening the research question**.** For them, researchers should systematically include patient's perspective. KCE itself can launch a call on topics that are relevant to patients because patients are often deeply and concretely immersed in the subject and can then raise the attention to research needs.

The presence of the patient within the research team is important. Allowing patients to participate in the research team guarantees continuity and involvement in the entire process. Participants also recall to bring in the carers for patients who are too ill to participate themselves. They advise avoiding putting 5 researchers next to 1 patient because this can be intimidating. Because **equivalence is important,** researchers should be identified by surname, first name and photo; not by titles.

Regarding practical involvement, patients expect KCE to set a good example in involving the patient. A public structure must be able to compensate financially for patients' time investment. A travel allowance is obvious, or, if necessary, provide a taxi. For patient groups having transportation problems, researchers should consider to go to them instead of the other way round.

POINTS OF ATTENTION ON INVOLVEMENT IN THE SCOPING PHASE

- Scoping is about identifying the most important research questions for the patients. Involving patients can help to formulate the appropriate patient-related research questions.
- Researchers can facilitate the consultation process by providing a simple and compact project description to the patients.
- The scoping questions must be comprehensible and accessible for the patient. A distinction must be made between the scientific language and the language of the lived experience.
- The participants recommend more attention to support for daily life, quality of life and well-being into research (questions).
- Patients strongly recommend to always try to include at least 1 research question that reflects the patients' needs and perspectives.

[o] https://www.eurordis.org/content/eupati-0

- The presence of patients within the research group is important and is equally important.
- Patients expect that KCE, as a public research institution, serve an inspiration for researchers wanting to develop patient involvement, including practical involvement.

Patients' ideas on involvement in the design phase of the research

With regard to the design phase, different contributions from the patient are possible. On **choosing the proper design method,** there are different opinions in the workshops:

- Some participants feel that choosing the design method really needs a scientific approach in which the patient has little input, because this is outside the patient's expertise. There is plenty of literature available and patients do not need to reinvent anything there. For these patients, there is no need for methodological training. This is a scientific matter: the patient is not qualified, could be not willing to do so or have medical impairments preventing them to do it properly. These participants believe that patients should be able to rely on the expertise of the research team with regard to the design phase. However, there is a possibility to work on design methods with patients. Some associations (such as MUCO) have a community advisory board at European level where there are reflexions and discussions on research methods after extensive information sessions.
- Others participants believe that the researchers can first develop a design proposal before presenting and discussing with the patients. The KCE researchers can present the different research options, explain the different possible methods/tools that can be used and then ask the patients what may be relevant.
- Regarding data collection in itself, participants declare that questionnaires can be done on paper, by phone or online. The questions should always be asked clearly and the number of questions should be limited.

The patients can also help by **translating** the scientific questions into a clear understandable language for the other patients. Patients can also help in drawing up a survey and making the questions clear to patients.

For the participants, the patients can give a number of practical tips for supporting the data collection among patients. They also point that it is important that the patients are clearly informed about the burden that the research may place on the patients. **In the design step, the role of the patients is more in considering the prerequisites and conditions for feasible and appropriate patient studies.**

Reimbursement is not necessary in the design phase but an expense allowance is a minimum (transport, a sandwich/lunch) and, again, the patient should not face any additional costs.

POINTS OF ATTENTION ON PATIENT INVOLVEMENT IN THE DESIGN PHASE

- Patients agree that the expertise of researchers will play a leading role with regard to the design phase.
- Researchers should make a first research proposal before presenting and discussing it with the patients
- Patients can help with translating the research questions into a clear understandable language for the patient.
- The role of the patients is more in considering the prerequisites and conditions for feasible and appropriate patient studies.
- Patients feel that at least their expenses should be reimbursed when they participate in this phase.

Patients' ideas on involvement in interpretation of the data, recommendations and dissemination

When interpreting the results, it is important to check with the patients whether this is what they meant. Participants recommend to invest in the human relationship and provide regular feedback to all the patients involved in the research project. **It is important to discuss with patients how the research results can be translated into practical and feasible recommendations.**

It is crucial to **talk to patients before formulating recommendations**, so that conclusions can be drawn partly on the basis of their inputs. To this end, patients must also be able to read the study results. If there are any discrepancies, these should be stated in the report. Patients should be able to adjust recommendations corrections from a patients' view. It is not necessary to take part in the editing process but patients must be able to access the report and read it before publication.

For **proofreading,** other patients who have not participated from the start of the study may be used. This can also be done in a focus group.

It is key to **adapt the language of the report to the target group**. For patients, this means an adapted version translated language tailored to the patient. A lay abstract containing the main conclusions is enough. Offering the report in a language other than the patient native language should be avoided. In terms of language use, reports should aim for people who have completed secondary education. KCE reports seem to have been written for people who have completed higher studies, even the Dutch synthesis reports. A glossary can be useful to define certain terms/abbreviations in order to better understand the report of the study. Clear and simple images (graphs) are important to convey a clear message. A short flyer summarising the results may be interesting to develop. Patients suggest to proofread the flyer on legibility and understandable language before it is published.

The patient should recognise the patient's voice in the recommendations made in the report and check that it has not been snowed under by the greater weight of other interests. Patients insist that when they are asked to cooperate in drawing up recommendations, they need to see and feel that their contributions were meaningful. Patients should feel proud of their contribution and have the opportunity to contribute to the dissemination of the recommendations, for example, during a press conference.

Participants stressed that patients should understand that **the policymakers will ultimately decide what to do with the KCE recommendations**. Getting feedback after finalisation of the projects is important (e.g. when a recommendation has been put into a legal text).

Participants explain that patients should also understand the limits and constraints for the implementation of the recommendations (e.g. budget, time...). Participants therefore insist that, if the policy goes against the (KCE) recommendations,) patients need to understand why. Some patients regrettably feel that the (KCE) recommendations are still often non-committal for the health care professionals. The implementation of the recommendations is then let at the discretion of the professionals and the policymakers. A participant gave the example of specialist doctors not following the reimbursement criteria.

Patients believe they can help identify **the patient associations and groups should receive the results of the report.** When it comes to **distributing the report,** patient associations can place the results on their website deliver the results individually. If you ask fellow-sufferers to disseminate the results, the patients' advice would be to make it feasible for the volunteers and make a financial contribution in return. Some participants feel it is not the patient's responsibility to provide research information/recommendations or to disseminate decisions to patients. In fact, they feel it is up to the policy to ensure that there is a good flow of information- involving patients and patient associations, not giving the responsibility to them.

Participants point the **lack of a good database** where recommendations can be found.

POINTS OF ATTENTION ON PATIENT INVOLVEMENT IN THE INTERPRETATION, AND DISSEMINATION OF RESULTS

- KCE should organise a meeting with the patients before formulating recommendations to assess whether specific patient-related recommendations should be included. This is also a moment where the inputs from patients should be presented.
- The KCE research team should discuss with patients about how the research results can be translated into practical and realist recommendations.
- Patients strongly recommend to adapt the language of the reports to the target group.
- Patients who have not been involved from the start of the study may be invited for proofreading. This can also be done in a focus group.
- The patients should recognise the patients' voice in the recommendations.
- It should be explained to patients that the policy makers will ultimately decide what to do with the recommendations.
- Patients may have a role in advising KCE who they should target in their communication of the results and recommendations.

Other elements introduced by participants

There needs to be an important mind shift among the researchers, namely that patients have a positive input and that more can be achieved together. The participants advise that the researchers ask: “What is going on in the life of the patients and what do they need?” Patients call on the researchers to really collaborate with and listen to them. Some participants stress that one of the conditions for obtaining European research funding for research on mental health is the representation of the patient in the research. In other words: make it compulsory. However, that does not mean that patients should only be involved in order to obtain funding but also and priority for their added-value.

The Covid19 pandemic also has a strong impact on patients’ daily operations. Working digitally is not an option for many patients. Patients hope that **KCE will not rely 100% on digital contact, so that no input will be missed**.

Workshop sessions often last a long time for patients living with chronic pain. It is always best to provide 1 minute break every 20 minutes of work for digital meetings.

There are many common questions and concerns between the patient associations. However, patients associations work in a very fragmented way. **A common forum of exchanges** could partly solve this problem.

Patients strongly insist that there is a need for a structure that guarantee that the knowledge and recommendations provided from researchers are **also implemented into practice.**

Some bigger problems need to be addressed. For instance there must be more **focus on prevention and health promotion**. The lack of health**care literacy** is also pointed as a general social problem that need more attention.

When involving patients, the researchers must also pay attention to groups of patients who have a rare disease or who are hard to reach.

In every study, there should always be a discussion whether other patients also benefit from the questions/results. Participants pointed that some conditions already receive much more attention than others (e.g. breast cancer) and this is perceived as “not correct” and “unfair”. Participants also urge not to forget family and carers.

Additional questions for the patients

The following section presents additional topics discussed in some of the workshops. Not all groups were able to discuss as the time was up.

Patients' ideas on when to involve the patient

> *"Is it best for patients to get on board for the whole journey, or only at certain stages?"*

The answer to this question is not so simple. Some patients feel it is interesting to be on board from the beginning to help set it in the right direction along instead of realizing that it is too late. In the ideal scenario, the patients want to join in from the start but that is difficult to achieve. This is more feasible for employees of the patient associations. Some participants report that having a permanent patient representative on board should be a valuable alternative. This solution is, however, not always feasible for practical reasons, which is regretted by participants. They feel they can only be involved in relevant questions. In some associations, the decision of being involved in a research project is taken by the Board. Patients rely on KCE to contact them at the right time.

Both systems have advantages and disadvantages to both systems: participants advise for a good mix. Getting patients involved is a difficult consideration: it requires time, manpower and resources.

Patients' ideas on the need for patient involvement per research phases

> *"Is the involvement of patients more necessary in some research phases than in others?"*

For patients, the ideal situation is getting as much input as possible from the patient perspective in the 3 phases. If they have to choose, patients find both the input phase (phase 1) and the output phase (phase 3) to be more important. If patients are not involved in phase 1, the project starts off on the wrong foot. Providing insights in phase 2 is sufficient.

Evaluation of the workshop

Positive comments

The majority of participants found the workshop valuable and interesting. Some participants found it fascinating to receive confirmation on how important it is to involve patients and they were very pleased with everyone's openness. Participants were glad that KCE considers important to work on patient involvement. Some participants also mentioned that they learned a lot, especially for those who had little experience in (KCE) research.

Points of attention

Some participants found the questions too complicated and suggested making them easier. Due to the switching in the Zoom session between showing the presentation with questions and removing the presentation for discussion, there was sometimes too little time to properly capture the questions. A suggestion was made to leave the slide longer visible.

Practical suggestions

The participants were curious about the conclusions and the outcomes of the discussions in the other groups. They certainly would like to receive the presentation and the report. Some regretted that only a small number of patients were included and therefor suggest to make more advertising for these workshops. Final suggestion was to send a reminder the day before the workshop.

> *« C'était super de nous consulter pour savoir comment nous consulter. Je trouve ça bien que la KCE s'empare de ce sujet. Ce serait bien que vous puissiez arriver à une méthodologie afin de nous impliquer au mieux. C'est intéressant d'avoir le point de vue du KCE. »*

> *« Ce petit atelier était une pré-information très intéressante qui décortique le fonctionnement. Je suis satisfait d'y avoir participé. »*

> *« Ik vond het boeiend om de bevestiging te krijgen hoe belangrijk het is om patiënten te betrekken. Ik krijg graag feedback via de presentatie en het verslag. »*

« Het was een waardevol en interessant gesprek. We hebben een aantal pijnpunten aangehaald. Stapje voor stapje gaat dat wel lukken met KCE, maar het is een lange weg. »

The synthetic report of the group discussions and the presentation were send afterwards.

Conclusion

Participants appreciated the workshops and supported KCE in the idea of involving patients in the research. The workshops reinforce the idea that there is no 'one size fits all' solutions as the process of patient involvement is complex. Patients therefore identified key messages for the KCE researchers and management.

APPENDIX 4. DELPHI PANEL TO IDENTIFY SELECTION CRITERIA

Questionnaires of the second round

French-speaking questionnaire

Critères pour impliquer les patients dans les projets du KCE - 2ème volet

Merci de répondre à ce nouveau questionnaire basé sur les réponses obtenues, et ce avant le 15 février à 10h

Il y a 7 questions dans ce questionnaire.

Madame, Monsieur,

Nous vous remercions d'avoir participé à la première étape de notre questionnaire.
Nous avons reçu 53 réponses très riches et diverses. Merci à toutes et tous !

Nous avons regroupé les idées relatives aux critères à prendre en considération dans la réflexion sur l'opportunité et la faisabilité d'impliquer les patients dans des projets spécifiques du KCE.
Nous aimerions maintenant vous demander votre position par rapport à ces critères.

A noter que, parmi les réponses que nous avons obtenues, nous avons également lu beaucoup d'éléments permettant de nourrir la réflexion sur l'utilité d'impliquer les patients dans une recherche KCE, sur les conditions nécessaires à une implication efficace des patients et les risques que cela pouvait comporter tant pour la recherche que pour les patients. Ces aspects sont extrêmement intéressants. Toutefois, ils n'apparaitront pas dans cette partie de l'enquête qui se focalise sur l'évaluation des projets du programme annuel du KCE pour lesquels la participation des patients peut être opportune et réalisable. Mais croyez bien qu'ils seront abordés dans la process note !

Vous répondez à ce questionnaire en tant que (plusieurs réponses possibles) *

Cochez la ou les réponses
Veuillez choisir toutes les réponses qui conviennent :

- [ ] Représentant d'une coupole d'associations de patients
- [ ] Représentant d'une mutualité
- [ ] Représentant de patient/patient
- [ ] Membre de l'observatoire des maladies chroniques
- [ ] Direction élargie du KCE
- [ ] Expert KCE
- [ ] Autre:

Voici la liste des critères qui se dégagent des réponses reçues via le 1er questionnaire.

Dans quelle mesure pensez-vous que chacun d'entre eux devrait faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités, pour envisager d'impliquer des patients dans un projet de recherche spécifique ?

Pour rappel il s'agit bien d'impliquer les patients dans le processus de recherche et pas comme participants à une collecte de donnée (entretien, enquête, etc.)

*

Choisissez la réponse appropriée pour chaque élément :

	Tout à fait pertinent	Assez pertinent	Peu pertinent	Pas du tout pertinent	Je ne comprends pas ce critère
Le sujet a été introduit par un représentant de patient ou un patient	○	○	○	○	○
Il s'agit d'une recherche qui touche à la perception des citoyens	○	○	○	○	○
Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé utilisé(e) ou qui sera utilisé(e) par le patient	○	○	○	○	○
Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé dont le mode d'administration/utilisation implique un rôle actif du patient	○	○	○	○	○
Le projet de recherche vise à étudier (entre autre) la qualité de vie ou le bien-être des patients	○	○	○	○	○
Le projet de recherche vise à étudier une intervention, un traitement, médicament, technologie de santé... qui peut avoir des effets secondaires	○	○	○	○	○
Le projet de recherche vise à étudier la relation entre les prestataires de soins et les patients	○	○	○	○	○
La pathologie concernée pas la recherche n'est pas aiguë	○	○	○	○	○
Il est possible d'identifier des patients en lien avec le sujet de la recherche	○	○	○	○	○
Il existe une association de patients en lien avec le sujet de la recherche	○	○	○	○	○
Les résultats de la recherche sont susceptibles d'avoir un impact sur la qualité de vie des patients	○	○	○	○	○
Les résultats de la recherche sont susceptibles d'avoir une implication financière pour les patients	○	○	○	○	○

	Tout à fait pertinent	Assez pertinent	Peu pertinent	Pas du tout pertinent	Je ne comprends pas ce critère
La recherche comportera probablement une collecte de données auprès de patients	○	○	○	○	○
Les résultats de la recherche sont susceptibles d'avoir un impact quant à la satisfaction des patients	○	○	○	○	○
Les résultats de la recherche sont susceptibles d'avoir un impact sur la relation entre les prestataires de soins et les patients	○	○	○	○	○
Il y aura clairement une valeur ajoutée à l'implication des patients	○	○	○	○	○
On sait par avance que les patients seront réticents à participer à une collecte de données	○	○	○	○	○
La vision des patients ne peut être obtenue par d'autres biais	○	○	○	○	○
Il faut toujours impliquer les patients dans des études du KCE	○	○	○	○	○

Voici la liste des critères que vous retiendriez pour faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager d'impliquer des patients dans un projet de recherche spécifique.

Quels sont pour vous les critères les plus importants à prendre en compte? (max 5)

*

Cochez la ou les réponses
Veuillez sélectionner 5 réponses maximum
Veuillez choisir toutes les réponses qui conviennent :

- ☐ Le sujet a été introduit par un représentant de patient ou un patient
- ☐ Il s'agit d'une recherche qui touche à la perception des citoyens
- ☐ Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé utilisé(e) ou qui sera utilisé(e) par le patient
- ☐ Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé dont le mode d'administration/utilisation implique un rôle actif du patient
- ☐ Le projet de recherche vise à étudier (entre autre) la qualité de vie ou le bien-être des patients
- ☐ Le projet de recherche vise à étudier une intervention, un traitement, médicament, technologie de santé…qui peut avoir des effets secondaires
- ☐ Le projet de recherche vise à étudier la relation entre les prestataires de soins et les patients
- ☐ La pathologie concernée pas la recherche n'est pas aiguë
- ☐ Il est possible d'identifier des patients en lien avec le sujet de la recherche
- ☐ Il existe une association de patients en lien avec le sujet de la recherche
- ☐ Les résultats de la recherche sont susceptibles d'avoir un impact sur la qualité de vie des patients
- ☐ Les résultats de la recherche sont susceptibles d'avoir une implication financière pour les patients
- ☐ La recherche comportera probablement une collecte de données auprès de patients
- ☐ Les résultats de la recherche sont susceptibles d'avoir un impact quant à la satisfaction des patients
- ☐ Les résultats de la recherche sont susceptibles d'avoir un impact sur la relation entre les prestataires de soins et les patients
- ☐ Il y aura clairement une valeur ajoutée à l'implication des patients
- ☐ On sait par avance que les patients seront réticents à participer à une collecte de données
- ☐ La vision des patients ne peut être obtenue par d'autres biais
- ☐ Il faut toujours impliquer les patients dans des études du KCE

Voici la liste des critères qui se dégagent des réponses reçues via le 1er questionnaire pour envisager de **ne pas** impliquer les patients.
Dans quelle mesure pensez-vous que chacun d'entre eux devrait faire partie de de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager **de ne pas** impliquer des patients dans un projet de recherche spécifique ?

*

Choisissez la réponse appropriée pour chaque élément :

	Tout à fait pertinent	Assez pertinent	Peu pertinent	Pas du tout pertinent	Je ne comprends pas ce critère
Il s'agit d'un projet méthodologique	○	○	○	○	○
Il s'agit du développement d'un modèle économique	○	○	○	○	○
Il s'agit d'une étude recourant uniquement à une approche quantitative	○	○	○	○	○
Le projet consiste uniquement en une revue de la littérature scientifique	○	○	○	○	○
La question de recherche est plus orientée vers les prestataires	○	○	○	○	○
La question de recherche concerne une maladie très grave	○	○	○	○	○
La question de recherche peut impliquer un risque émotionnel pour le patient impliqué dans la recherche	○	○	○	○	○
La question de recherche soulève des aspects éthiques complexes	○	○	○	○	○
La question de recherche est trop abstraite	○	○	○	○	○
La question de recherche est trop théorique	○	○	○	○	○
Le sujet est trop douloureux pour le patient	○	○	○	○	○
Il s'agit d'un sujet controversé	○	○	○	○	○
Les résultats de l'étude sont attendus rapidement	○	○	○	○	○
Les ressources humaines disponibles sont trop limitées	○	○	○	○	○
Il sera trop difficile d'identifier des patients à impliquer comme collaborateur dans la recherche	○	○	○	○	○
Les contraintes matérielles et logistiques sont trop importantes	○	○	○	○	○

Voici la liste des critères que vous retiendriez pour faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager de ne pas impliquer des patients dans un projet de recherche spécifique.

Quels sont pour vous les critères les plus importants à prendre en compte? (max 5)

*

ⓘ Cochez la ou les réponses
ⓘ Veuillez sélectionner 5 réponses maximum
Veuillez choisir toutes les réponses qui conviennent :

- ☐ Il s'agit d'un projet méthodologique
- ☐ Il s'agit du développement d'un modèle économique
- ☐ Il s'agit d'une étude recourant uniquement à une approche quantitative
- ☐ Le projet consiste uniquement en une revue de la littérature scientifique
- ☐ La question de recherche est plus orientée vers les prestataires
- ☐ La question de recherche concerne une maladie très grave
- ☐ La question de recherche peut impliquer un risque émotionnel pour le patient impliqué dans la recherche
- ☐ La question de recherche soulève des aspects éthiques complexes
- ☐ La question de recherche est trop abstraite
- ☐ La question de recherche est trop théorique
- ☐ Le sujet est trop douloureux pour le patient
- ☐ Il s'agit d'un sujet controversé
- ☐ Les résultats de l'étude sont attendus rapidement
- ☐ Les ressources humaines disponibles sont trop limitées
- ☐ Il sera trop difficile d'identifier des patients à impliquer comme collaborateur dans la recherche
- ☐ Les contraintes matérielles et logistiques sont trop importantes

Si vous souhaitez ajouter quelque chose à cette enquête, merci de nous en faire part ici

Veuillez écrire votre réponse ici :

Nous vous remercions pour vos réponses.

Celles-ci nous permettront de finaliser notre process note.
Le rapport final sera disponible fin avril 2021 au plus tard.
Vous serez averti de sa publication par e-mail.

A bientôt !
L'équipe de recherche

17.02.2021 – 16:43

Envoyer votre questionnaire.
Merci d'avoir complété ce questionnaire.

Dutch-speaking questionnaire

Criteria voor het betrekken van patiënten bij KCE-projecten - 2de ronde

Dank u voor uw deelname aan deze tweede enquête.

Gelieve te antwoorden vóór 15 februari 2020, 10 uur.

Er zijn 7 vragen in deze enquête.

Mevrouw, Meneer,

Hartelijk dank u voor uw deelname aan de eerste fase van onze bevraging.
We ontvingen 56 zeer rijke en soms uiteenlopende antwoorden.

We hebben de ideeën over criteria, waarmee rekening moet worden gehouden bij de reflectie over de wenselijkheid en haalbaarheid van het betrekken van patiënten bij specifieke KCE projecten, gegroepeerd.
Wij willen u nu vragen naar uw standpunt ten aanzien van elk van deze criteria.

De antwoorden die we hebben ontvangen bevatten ook vaak aspecten die betrekking hebben op het nut van het betrekken van patiënten bij KCE-onderzoek in het algemeen, de voorwaarden voor een effectieve betrokkenheid van patiënten en de potentiële risico's voor het onderzoek en voor de patiënten. Hoewel deze aspecten zeker onze aandacht hebben getrokken, zullen zij niet voorkomen in dit deel van de bevraging. Dit deel spitst zich toe op concrete criteria die de reflectie moeten voeden over het al dan niet zinvol en haalbaar zijn van patiëntenbetrokkenheid bij elk van de projecten op het jaarprogramma van het KCE. Deze andere aspecten zullen echter wel aan bod komen in de procesnota.

U beantwoordt deze vragenlijst als (meerdere antwoorden mogelijk) *

Meerdere antwoorden mogelijk
Selecteer alle mogelijkheden:

- ☐ Vertegenwoordiger van een koepel van patiëntenverenigingen
- ☐ Vertegenwoordiger van een landsbond (mutualiteit)
- ☐ Patiëntenvertegenwoordiger / patiënt
- ☐ Lid van het Observatorium voor Chronische Ziekten
- ☐ Uitgebreide KCE Directie
- ☐ KCE Expert
- ☐ Overige: _____

Hieronder vindt u de lijst van criteria die uit de eerste vragenlijst naar voor zijn gekomen.

In hoeverre vindt u van elk criterium dat het deel moet uitmaken van de reflectie van de KCE-directie, koepels van patiëntenverenigingen en ziekenfondsen, om patiënten te betrekken bij een specifiek onderzoeksproject?

Ter herinnering: het gaat hier over het betrekken van patiënten bij het onderzoeksproces als onderzoeksmedewerkers, niet als deelnemers aan een activiteit die als doel heeft gegevens bij patiënten te verzamelen (interviews, enquêtes, enz.).

*

Kies het toepasselijke antwoord voor elk onderdeel:

	Heel relevant	Tamelijk relevant	Niet erg relevant	Helemaal niet relevant	Ik begrijp dit criterium niet
Het onderzoeksvoorstel werd ingediend door een patiëntenvertegenwoordiger of patiënt	◯	◯	◯	◯	◯
Het betreft onderzoek dat betrekking heeft op de perceptie van burgers	◯	◯	◯	◯	◯
Het onderzoeksproject betreft een interventie, behandeling, geneesmiddel, zorgverstrekking of gezondheidstechnologie die door patiënten wordt (of zal worden) gebruikt	◯	◯	◯	◯	◯

	Heel relevant	Tamelijk relevant	Niet erg relevant	Helemaal niet relevant	Ik begrijp dit criterium niet
Het onderzoeksproject betreft een interventie, behandeling, geneesmiddel, zorgverstrekking of gezondheidstechnologie waarbij de wijze van toediening/gebruik een actieve rol van de patiënt impliceert	○	○	○	○	○
Het onderzoeksproject heeft als doel om (onder meer) de levenskwaliteit of het welzijn van patiënten te bestuderen	○	○	○	○	○
Het onderzoeksproject bestudeert een interventie, behandeling, medicijn, gezondheidstechnologie... met mogelijke bijwerkingen	○	○	○	○	○
Het onderzoeksproject heeft als doel om de relatie tussen zorgverleners en patiënten te bestuderen	○	○	○	○	○
De pathologie waarop het onderzoek betrekking heeft, is niet acuut	○	○	○	○	○
Het is mogelijk patiënten te identificeren die verband houden met het onderzoeksonderwerp	○	○	○	○	○

	Heel relevant	Tamelijk relevant	Niet erg relevant	Helemaal niet relevant	Ik begrijp dit criterium niet
Er is een patiëntenorganisatie die verband houdt met het onderzoeksonderwerp	○	○	○	○	○
De onderzoeksresultaten kunnen een impact hebben op de levenskwaliteit van de patiënten	○	○	○	○	○
De onderzoeksresultaten kunnen financiële gevolgen hebben voor patiënten	○	○	○	○	○
Het onderzoek vereist mogelijks het verzamelen van gegevens bij patiënten	○	○	○	○	○
De onderzoeksresultaten kunnen een invloed hebben op de tevredenheid van patiënten	○	○	○	○	○
De onderzoeksresultaten kunnen een invloed hebben op de relatie tussen zorgverleners en patiënten	○	○	○	○	○
Het betrekken van patiënten zal een duidelijke meerwaarde hebben voor het onderzoek	○	○	○	○	○

	Heel relevant	Tamelijk relevant	Niet erg relevant	Helemaal niet relevant	Ik begrijp dit criterium niet
We weten van tevoren dat patiënten terughoudend zullen zijn om deel te nemen aan een gegevensverzameling bij patiënten	○	○	○	○	○
De inzichten van de patiënten kunnen niet op een andere manier worden verkregen	○	○	○	○	○
Patiënten moeten altijd betrokken worden bij KCE studies	○	○	○	○	○

Dit is de lijst van criteria die u zou gebruiken bij de reflectie van de KCE-directie, de koepels van patiëntenverenigingen en de ziekenfondsen, over het betrekken van patiënten bij een specifiek onderzoeksproject.

Wat zijn voor u de belangrijkste criteria om te overwegen? (max 5)

*

ⓘ Meerdere antwoorden mogelijk
ⓘ Kies maximaal 5 antwoorden
Selecteer alle mogelijkheden:

- ☐ Het onderzoeksvoorstel werd ingediend door een patiëntvertegenwoordiger of patiënt
- ☐ Het betreft onderzoek dat betrekking heeft op de perceptie van burgers
- ☐ Het onderzoeksproject betreft een interventie, behandeling, geneesmiddel, zorgverstrekking of gezondheidstechnologie die door patiënten wordt of zal worden gebruikt
- ☐ Het onderzoeksproject betreft een interventie, behandeling, geneesmiddel, zorgverstrekking of gezondheidstechnologie waarbij de wijze van toediening/gebruik een actieve rol van de patiënt impliceert
- ☐ Het onderzoeksproject beoogt (onder meer) de kwaliteit van leven of het welzijn van patiënten te bestuderen
- ☐ Het onderzoeksproject bestudeert een interventie, behandeling, medicijn, gezondheidstechnologie... met mogelijke bijwerkingen
- ☐ Het onderzoeksproject heeft als doel om de relatie tussen zorgverleners en patiënten te bestuderen
- ☐ De pathologie waarop het onderzoek betrekking heeft, is niet acuut
- ☐ Het is mogelijk patiënten te identificeren die verband houden met het onderzoeksonderwerp
- ☐ Er is een patiëntenorganisatie die verband houdt met het onderzoeksonderwerp
- ☐ De onderzoeksresultaten kunnen een invloed hebben op de levenskwaliteit van de patiënten
- ☐ De onderzoeksresultaten kunnen financiële gevolgen hebben voor patiënten
- ☐ Het onderzoek vereist mogelijks het verzamelen van gegevens bij patiënten
- ☐ De onderzoeksresultaten kunnen een invloed hebben op de tevredenheid van patiënten
- ☐ De onderzoeksresultaten kunnen een invloed hebben op de relatie tussen zorgverleners en patiënten
- ☐ Het betrekken van patiënten zal duidelijk een meerwaarde hebben voor het onderzoek
- ☐ We weten van tevoren dat patiënten terughoudend zullen zijn om deel te nemen aan gegevensverzameling bij patiënten
- ☐ De inzichten van de patiënten kunnen niet op een andere manier worden verkregen
- ☐ Patiënten moeten altijd betrokken worden bij KCE studies

Hieronder vindt u de lijst van criteria die uit de eerste vragenlijst naar voor zijn gekomen om patiënten niet bij een KCE onderzoek te betrekken.

In hoeverre vindt u van elk van deze criteria dat de KCE-directie, de koepels van patiëntenverenigingen en de ziekenfondsen ze moeten meenemen in de reflectie om patiënten **niet** bij een specifiek onderzoeksproject te betrekken?

*

Kies het toepasselijke antwoord voor elk onderdeel:

	Heel relevant	Tamelijk relevant	Niet erg relevant	Helemaal niet relevant	Ik begrijp dit criterium niet
Het betreft een methodologisch project	○	○	○	○	○
Het betreft de ontwikkeling van een economisch model	○	○	○	○	○
Het betreft een studie met een uitsluitend kwantitatieve benadering	○	○	○	○	○
Het project bestaat uitsluitend uit een wetenschappelijke literatuuroverzicht	○	○	○	○	○
De onderzoeksvraag is meer gericht op de zorgverstrekkers	○	○	○	○	○
De onderzoeksvraag betreft een zeer ernstige ziekte	○	○	○	○	○
De onderzoeksvraag kan een emotioneel risico inhouden voor de patiënten die betrokken worden bij het onderzoek	○	○	○	○	○
De onderzoeksvraag roept complexe ethische vragen op	○	○	○	○	○
De onderzoeksvraag is te abstract	○	○	○	○	○
De onderzoeksvraag is te theoretisch	○	○	○	○	○
Het onderwerp is te pijnlijk voor de patiënt	○	○	○	○	○
Het betreft een controversieel onderwerp	○	○	○	○	○
De resultaten van de studie worden op heel korte termijn verwacht	○	○	○	○	○
De beschikbare middelen in termen van personeel zijn te beperkt	○	○	○	○	○
Het zal te moeilijk zijn om patiënten te identificeren om betrokken te worden als onderzoeksmedewerker	○	○	○	○	○
De materiële en logistieke beperkingen zijn te groot	○	○	○	○	○

Dit is de lijst van criteria waarvan u vindt dat ze moeten worden meegenomen in de reflectie om patiënten niet te betrekken bij een specifiek onderzoeksproject.

Wat zijn voor u de belangrijkste criteria? (max 5)

*

ⓘ Meerdere antwoorden mogelijk
ⓘ Kies maximaal 5 antwoorden
Selecteer alle mogelijkheden:

- ☐ Het betreft een methodologisch project
- ☐ Het gaat om de ontwikkeling van een economisch model
- ☐ Het betreft een studie met een uitsluitend kwantitatieve benadering
- ☐ Het project bestaat uitsluitend uit een wetenschappelijke literatuuroverzicht
- ☐ De onderzoeksvraag is meer gericht op de zorgverstrekkers
- ☐ De onderzoeksvraag betreft een zeer ernstige ziekte
- ☐ De onderzoeksvraag kan een emotioneel risico inhouden voor de patiënten die betrokken worden bij het onderzoek
- ☐ De onderzoeksvraag roept complexe ethische vragen op
- ☐ De onderzoeksvraag is te abstract
- ☐ De onderzoeksvraag is te theoretisch
- ☐ Het onderwerp is te pijnlijk voor de patiënt
- ☐ Het betreft een controversieel onderwerp
- ☐ De resultaten van de studie worden op heel korte termijn verwacht
- ☐ De beschikbare middelen in termen van personeel zijn te beperkt
- ☐ Het zal te moeilijk zijn om patiënten te identificeren om betrokken te worden als onderzoeksmedewerker
- ☐ De materiële en logistieke beperkingen zijn te groot

Wenst u nog iets toe te voegen aan uw antwoorden?

Vul uw antwoord hier in:

Dank u voor uw antwoorden.

Deze zullen ons in staat stellen de laatste hand te leggen aan onze procesnota.
Het eindrapport zal uiterlijk eind april 2021 beschikbaar zijn.
U zult per e-mail op de hoogte worden gebracht van de publicatie ervan.

Tot binnenkort!
Het onderzoeksteam

17-02-2021 – 16:43

Verzend uw enquête.
Bedankt voor uw deelname aan deze enquête.

Results after two rounds

Nombre total d'enregistrements pour ce questionnaire :	66	

Vous répondez à ce questionnaire en tant que (plusieurs réponses possibles)

Réponse	Décompte	Pourcentage
Représentant d'une coupole d'associations de patients	9	13.64%
Représentant d'une mutualité	6	9.09%
Représentant de patient/patient	21	31.82%
Membre de l'observatoire des maladies chroniques	17	25.76%
Direction élargie du KCE	4	6.06%
Expert KCE	29	43.94%
Autre	3	4.55%

Voici la liste des critères qui se dégagent des réponses reçues via le 1er questionnaire. Dans quelle mesure pensez-vous que chacun d'entre eux devrait faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités, pour envisager d'impliquer des patients dans un projet de recherche spécifique ? Pour rappel il s'agit bien d'impliquer les patients dans le processus de recherche et pas comme participants à une collecte de donnée (entretien, enquête, etc.)

Le sujet a été introduit par un représentant de patient ou un patient Réponse	Décompte	Pourcentage
Tout à fait pertinent	39	59.09%
Assez pertinent	10	15.15%
Peu pertinent	11	16.67%
Pas du tout pertinent	3	4.55%
Je ne comprends pas ce critère	3	4.55%

Il s'agit d'une recherche qui touche à la perception des citoyens

Réponse	Décompte	Pourcentage
Tout à fait pertinent	26	39.39%
Assez pertinent	23	34.85%

Peu pertinent	11	16.67%
Pas du tout pertinent	1	1.52%
Je ne comprends pas ce critère	5	7.58%

Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé utilisé(e) ou qui sera utilisé(e) par le patient

Réponse	Décompte	Pourcentage
Tout à fait pertinent	46	69.70%
Assez pertinent	14	21.21%
Peu pertinent	6	9.09%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%

Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé dont le mode d'administration/utilisation implique un rôle actif du patient

Réponse	Décompte	Pourcentage
Tout à fait pertinent	46	69.70%
Assez pertinent	17	25.76%
Peu pertinent	3	4.55%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%

Le projet de recherche vise à étudier (entre autre) la qualité de vie ou le bien-être des patients

Réponse	Décompte	Pourcentage
Tout à fait pertinent	52	78.79%
Assez pertinent	12	18.18%
Peu pertinent	1	1.52%
Pas du tout pertinent	1	1.52%
Je ne comprends pas ce critère	0	0.00%

Le projet de recherche vise à étudier une intervention, un traitement, médicament, technologie de santé…qui peut avoir des effets secondaires		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	24	36.36%
Assez pertinent	27	40.91%
Peu pertinent	13	19.70%
Pas du tout pertinent	2	3.03%
Je ne comprends pas ce critère	0	0.00%
Le projet de recherche vise à étudier la relation entre les prestataires de soins et les patients		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	40	60.61%
Assez pertinent	24	36.36%
Peu pertinent	2	3.03%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%
La pathologie concernée pas la recherche n'est pas aiguë		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	8	12.12%
Assez pertinent	13	19.70%
Peu pertinent	22	33.33%
Pas du tout pertinent	13	19.70%
Je ne comprends pas ce critère	10	15.15%
Il est possible d'identifier des patients en lien avec le sujet de la recherche		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	20	30.30%
Assez pertinent	15	22.73%
Peu pertinent	18	27.27%

Pas du tout pertinent	4	6.06%
Je ne comprends pas ce critère	9	13.64%
Il existe une association de patients en lien avec le sujet de la recherche		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	18	27.27%
Assez pertinent	22	33.33%
Peu pertinent	15	22.73%
Pas du tout pertinent	9	13.64%
Je ne comprends pas ce critère	2	3.03%
Les résultats de la recherche sont susceptibles d'avoir un impact sur la qualité de vie des patients		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	45	68.18%
Assez pertinent	16	24.24%
Peu pertinent	5	7.58%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%
Les résultats de la recherche sont susceptibles d'avoir une implication financière pour les patients		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	32	48.48%
Assez pertinent	25	37.88%
Peu pertinent	9	13.64%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%
La recherche comportera probablement une collecte de données auprès de patients		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	31	46.97%
Assez pertinent	24	36.36%

Peu pertinent	8	12.12%
Pas du tout pertinent	3	4.55%
Je ne comprends pas ce critère	0	0.00%

Les résultats de la recherche sont susceptibles d'avoir un impact quant à la satisfaction des patients

Réponse	Décompte	Pourcentage
Tout à fait pertinent	26	39.39%
Assez pertinent	25	37.88%
Peu pertinent	11	16.67%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	4	6.06%

Les résultats de la recherche sont susceptibles d'avoir un impact sur la relation entre les prestataires de soins et les patients

Réponse	Décompte	Pourcentage
Tout à fait pertinent	29	43.94%
Assez pertinent	28	42.42%
Peu pertinent	9	13.64%
Pas du tout pertinent	0	0.00%
Je ne comprends pas ce critère	0	0.00%

Il y aura clairement une valeur ajoutée à l'implication des patients

Réponse	Décompte	Pourcentage
Tout à fait pertinent	56	84.85%
Assez pertinent	6	9.09%
Peu pertinent	3	4.55%
Pas du tout pertinent	1	1.52%
Je ne comprends pas ce critère	0	0.00%

On sait par avance que les patients seront réticents à participer à une collecte de données

Réponse	Décompte	Pourcentage

Tout à fait pertinent	18	27.27%
Assez pertinent	21	31.82%
Peu pertinent	17	25.76%
Pas du tout pertinent	4	6.06%
Je ne comprends pas ce critère	6	9.09%

La vision des patients ne peut être obtenue par d'autres biais

Réponse	Décompte	Pourcentage
Tout à fait pertinent	39	59.09%
Assez pertinent	13	19.70%
Peu pertinent	5	7.58%
Pas du tout pertinent	4	6.06%
Je ne comprends pas ce critère	5	7.58%

Il faut toujours impliquer les patients dans des études du KCE

Réponse	Décompte	Pourcentage
Tout à fait pertinent	12	18.18%
Assez pertinent	18	27.27%
Peu pertinent	19	28.79%
Pas du tout pertinent	16	24.24%
Je ne comprends pas ce critère	1	1.52%

Voici la liste des critères que vous retiendriez pour faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager d'impliquer des patients dans un projet de recherche spécifique. Quels sont pour vous les critères les plus importants à prendre en compte? (max 5)

Réponse	Décompte	Pourcentage
Le sujet a été introduit par un représentant de patient ou un patient	23	34.85%
Il s'agit d'une recherche qui touche à la perception des citoyens	13	19.70%
Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé utilisé(e) ou qui sera utilisé(e) par le patient	24	36.36%

Le projet de recherche vise à étudier une intervention, traitement, médicament, service de soins ou une technologie de santé dont le mode d'administration/utilisation implique un rôle actif du patient	28	42.42%
Le projet de recherche vise à étudier (entre autre) la qualité de vie ou le bien-être des patients	42	63.64%
Le projet de recherche vise à étudier une intervention, un traitement, médicament, technologie de santé…qui peut avoir des effets secondaires	7	10.61%
Le projet de recherche vise à étudier la relation entre les prestataires de soins et les patients	16	24.24%
La pathologie concernée pas la recherche n'est pas aiguë	0	0.00%
Il est possible d'identifier des patients en lien avec le sujet de la recherche	8	12.12%
Il existe une association de patients en lien avec le sujet de la recherche	12	18.18%
Les résultats de la recherche sont susceptibles d'avoir un impact sur la qualité de vie des patients	29	43.94%
Les résultats de la recherche sont susceptibles d'avoir une implication financière pour les patients	14	21.21%
La recherche comportera probablement une collecte de données auprès de patients	12	18.18%
Les résultats de la recherche sont susceptibles d'avoir un impact quant à la satisfaction des patients	4	6.06%
Les résultats de la recherche sont susceptibles d'avoir un impact sur la relation entre les prestataires de soins et les patients	8	12.12%
Il y aura clairement une valeur ajoutée à l'implication des patients	36	54.55%
On sait par avance que les patients seront réticents à participer à une collecte de données	3	4.55%
La vision des patients ne peut être obtenue par d'autres biais	18	27.27%
Il faut toujours impliquer les patients dans des études du KCE	11	16.67%

Voici la liste des critères qui se dégagent des réponses reçues via le 1er questionnaire pour envisager de ne pas impliquer les patients. Dans quelle mesure pensez-vous que chacun d'entre eux devrait faire partie de de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager de ne pas impliquer des patients dans un projet de recherche spécifique ?

Il s'agit d'un projet méthodologique

Réponse	Décompte	Pourcentage
Tout à fait pertinent	21	31.82%
Assez pertinent	26	39.39%
Peu pertinent	12	18.18%
Pas du tout pertinent	5	7.58%

Je ne comprends pas ce critère	2	3.03%

Il s'agit du développement d'un modèle économique

Réponse	Décompte	Pourcentage
Tout à fait pertinent	17	25.76%
Assez pertinent	22	33.33%
Peu pertinent	19	28.79%
Pas du tout pertinent	8	12.12%
Je ne comprends pas ce critère	0	0.00%

Il s'agit d'une étude recourant uniquement à une approche quantitative

Réponse	Décompte	Pourcentage
Tout à fait pertinent	10	15.15%
Assez pertinent	24	36.36%
Peu pertinent	20	30.30%
Pas du tout pertinent	11	16.67%
Je ne comprends pas ce critère	1	1.52%

Le projet consiste uniquement en une revue de la littérature scientifique

Réponse	Décompte	Pourcentage
Tout à fait pertinent	21	31.82%
Assez pertinent	17	25.76%
Peu pertinent	19	28.79%
Pas du tout pertinent	9	13.64%
Je ne comprends pas ce critère	0	0.00%

La question de recherche est plus orientée vers les prestataires

Réponse	Décompte	Pourcentage
Tout à fait pertinent	9	13.64%
Assez pertinent	25	37.88%

Peu pertinent	25	37.88%
Pas du tout pertinent	7	10.61%
Je ne comprends pas ce critère	0	0.00%

La question de recherche concerne une maladie très grave

Réponse	Décompte	Pourcentage
Tout à fait pertinent	3	4.55%
Assez pertinent	8	12.12%
Peu pertinent	23	34.85%
Pas du tout pertinent	31	46.97%
Je ne comprends pas ce critère	1	1.52%

La question de recherche peut impliquer un risque émotionnel pour le patient impliqué dans la recherche

Réponse	Décompte	Pourcentage
Tout à fait pertinent	9	13.64%
Assez pertinent	17	25.76%
Peu pertinent	28	42.42%
Pas du tout pertinent	12	18.18%
Je ne comprends pas ce critère	0	0.00%

La question de recherche soulève des aspects éthiques complexes

Réponse	Décompte	Pourcentage
Tout à fait pertinent	13	19.70%
Assez pertinent	8	12.12%
Peu pertinent	20	30.30%
Pas du tout pertinent	24	36.36%
Je ne comprends pas ce critère	1	1.52%

La question de recherche est trop abstraite

Réponse	Décompte	Pourcentage

Tout à fait pertinent	12	18.18%
Assez pertinent	20	30.30%
Peu pertinent	19	28.79%
Pas du tout pertinent	14	21.21%
Je ne comprends pas ce critère	1	1.52%

La question de recherche est trop théorique

Réponse	Décompte	Pourcentage
Tout à fait pertinent	13	19.70%
Assez pertinent	27	40.91%
Peu pertinent	16	24.24%
Pas du tout pertinent	9	13.64%
Je ne comprends pas ce critère	1	1.52%

Le sujet est trop douloureux pour le patient

Réponse	Décompte	Pourcentage
Tout à fait pertinent	5	7.58%
Assez pertinent	18	27.27%
Peu pertinent	22	33.33%
Pas du tout pertinent	20	30.30%
Je ne comprends pas ce critère	1	1.52%

Il s'agit d'un sujet controversé

Réponse	Décompte	Pourcentage
Tout à fait pertinent	4	6.06%
Assez pertinent	11	16.67%
Peu pertinent	24	36.36%
Pas du tout pertinent	25	37.88%
Je ne comprends pas ce critère	2	3.03%

Les résultats de l'étude sont attendus rapidement		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	4	6.06%
Assez pertinent	22	33.33%
Peu pertinent	21	31.82%
Pas du tout pertinent	18	27.27%
Je ne comprends pas ce critère	1	1.52%
Les ressources humaines disponibles sont trop limitées		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	8	12.12%
Assez pertinent	18	27.27%
Peu pertinent	22	33.33%
Pas du tout pertinent	15	22.73%
Je ne comprends pas ce critère	3	4.55%
Il sera trop difficile d'identifier des patients à impliquer comme collaborateur dans la recherche		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	8	12.12%
Assez pertinent	25	37.88%
Peu pertinent	21	31.82%
Pas du tout pertinent	11	16.67%
Je ne comprends pas ce critère	1	1.52%
Les contraintes matérielles et logistiques sont trop importantes		
Réponse	Décompte	Pourcentage
Tout à fait pertinent	11	16.67%
Assez pertinent	22	33.33%
Peu pertinent	24	36.36%

Pas du tout pertinent	8	12.12%
Je ne comprends pas ce critère	1	1.52%

Voici la liste des critères que vous retiendriez pour faire partie de la réflexion du management du KCE, des coupoles d'associations de patients et des mutualités pour envisager de ne pas impliquer des patients dans un projet de recherche spécifique. Quels sont pour vous les critères les plus importants à prendre en compte? (max 5)

Réponse	Décompte	Pourcentage
Il s'agit d'un projet méthodologique	29	43.94%
Il s'agit du développement d'un modèle économique	25	37.88%
Il s'agit d'une étude recourant uniquement à une approche quantitative	17	25.76%
Le projet consiste uniquement en une revue de la littérature scientifique	28	42.42%
La question de recherche est plus orientée vers les prestataires	15	22.73%
La question de recherche concerne une maladie très grave	3	4.55%
La question de recherche peut impliquer un risque émotionnel pour le patient impliqué dans la recherche	7	10.61%
La question de recherche soulève des aspects éthiques complexes	10	15.15%
La question de recherche est trop abstraite	15	22.73%
La question de recherche est trop théorique	19	28.79%
Le sujet est trop douloureux pour le patient	5	7.58%
Il s'agit d'un sujet controversé	1	1.52%
Les résultats de l'étude sont attendus rapidement	6	9.09%
Les ressources humaines disponibles sont trop limitées	16	24.24%
Il sera trop difficile d'identifier des patients à impliquer comme collaborateur dans la recherche	12	18.18%
Les contraintes matérielles et logistiques sont trop importantes	21	31.82%
Non affiché	2	3.03%

APPENDIX 5. RESULTS OF THE EVALUATION OF THE PILOT PROJECT

First round of evaluation

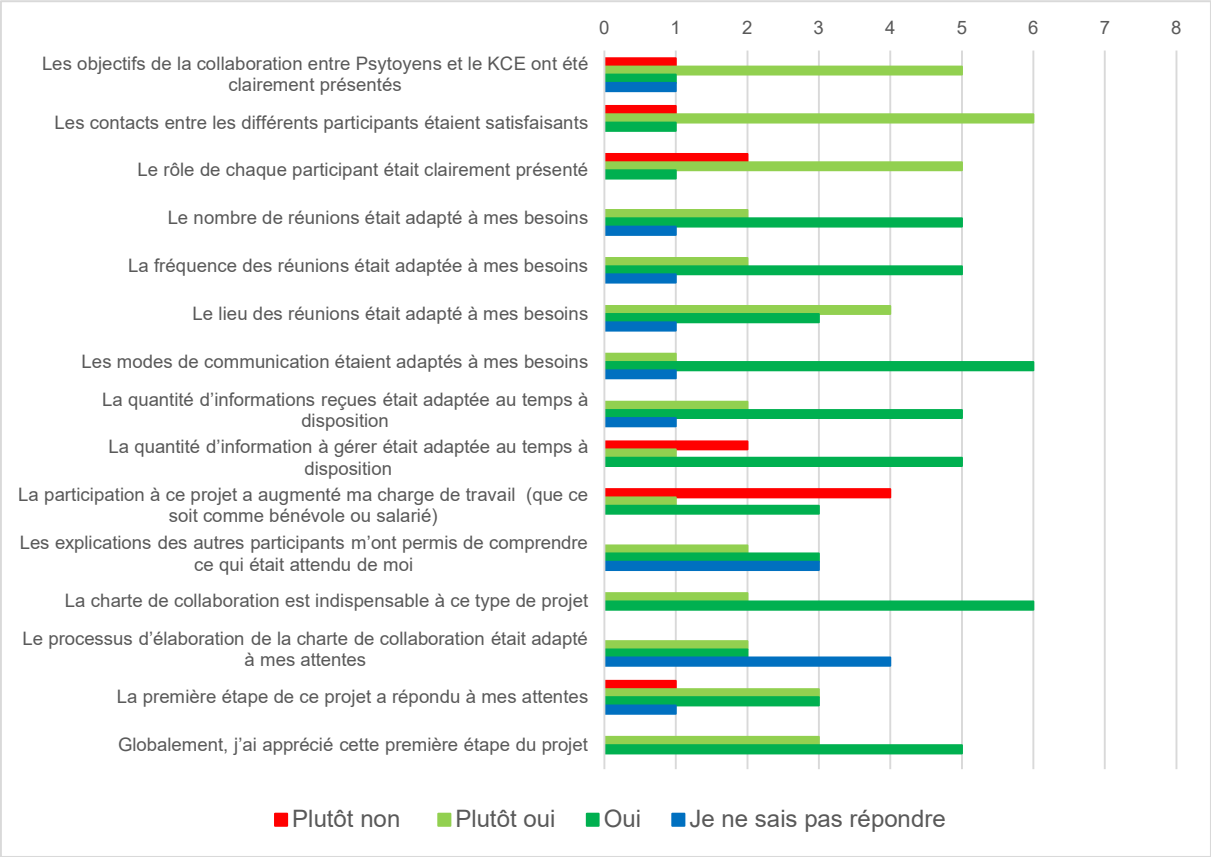
Eight out of the nine invited guests answered the first evaluation questionnaire, i.e. 3 patient representatives and 5 KCE experts.

Regarding their expectations of participating in the project, seven participants hoped that this project would enable them to work together to integrate the patient perspective. Three wished to enrich themselves personally and mutually in this collaboration - including on methodological aspects. For one participant, participating in this project aimed at enabling the establishment of a formal link between psychological and physical illnesses, while another hopes to be able to defend the rights of patients affected by psychological and physical problems. One researcher expected to be able to recruit patients for the Psychomatic Care project but also to experience a patient-patient partnership in the research.

During the first step, 6 participants saw their role as giving advice and opinions on decisions (4 experts and 2 patient representatives). Two participants, one expert and one patient representative, saw their role as fully collaborating in the decisions.

Figure 8 shows the participants' assessment of the different tasks and activities during the first phase of the project. Overall, **all participants appreciated the first step of the project**. All participants also agreed that the **Collaboration Charter is indispensable for this kind of project**, although half of the participants could not say whether the development process met their expectations.

Figure 8 – Participants' appreciation of the tasks and activities of the first phase of the research project



To complete Figure 1, some participants pointed out that the involvement of Psytoyens was not initially foreseen and that some activities were launched too late, such as the definition of the objectives of collaboration and of the role of each collaborator and the elaboration of the charter. Ideally, this **involvement should start earlier**. One person emphasised the **workload** linked to the involvement of patients: it is necessary to plan long discussion times and the presence of a moderator appeared to be indispensable. Although, for one participant, the objectives of the collaboration were initially clear, these evolved after the first contacts and a certain vagueness may have set in during the process. Another participant emphasised that internal changes in the organisations involved also had an impact on the process and complicated exchanges.

Strengths of the first step

Respondents primed the experience **of patient involvement**, leading to the acquisition **of new expertise, as the main strength of this first step**. The use of different methodologies and the involvement of patients and the LUSS was highlighted as a plus of this first step, especially in order to know the possible recruitment channels.

The ability to adapt and listen, without judgement, the good organisation within KCE, despite the Covid context, was also underlined. The **availability** of the participants and the **proactivity** of the researchers were also pointed out as positive.

The theme of the project itself is cited as a strong point: « *nommer l'importance, en santé mentale, de travailler autant sur le psychisme que sur les symptômes physiques du patient* ! »

Points of attention in the first step

As highlighted above, the majority of respondents stressed the need to have a clear initial definition of the objectives, expectations and implications of each party from the very beginning of the project. This initial clarification can be done through a **collaboration charter** or any other written support.

One participant questioned the need for greater speed in exchanges. The involvement of patients was also pointed out as being able to **slow down certain steps** of KCE projects, with consequences for the entire project schedule. As a mirror image, researchers should not forget that patient representatives can be patients themselves and, as a consequence, prioritise their health, or experience fluctuations in their health status, limiting their participation. A better follow-up of the patients is desired, as well as a good knowledge of the partner.

A participant drew attention to the importance of having a **stable team** present at each meeting to avoid re-discussing decisions already made during previous contacts.

The **rigidity of the ethics committee** was pointed out as a problem. Finally, a participant pointed out that a full translation of the report into French would have been a plus.

Practices to keep and avoid

All participants agreed that the integration of patients should be maintained, as well as a clear presentation of the participants and objectives at the beginning of the project. However, one participant emphasised the need to ensure that the opinion of all stakeholders is considered as equal and therefore avoid giving priority to the opinion of "politicians" over that of patients. The development of a “collaboration charter” should be kept, as should good procedures. One participant stressed that once the charter is established, all parties should stick to it. For a participant, it is important to listen to the needs of patients, the association and researchers. For example, asking for reviewing the protocol 3-4 days before the deadline of submission to the Ethics Committee should be avoided. As one participant points out : « *les patients et les coupoles seront toujours vigilants par rapport aux documents de consentement, et cette revue externe est enrichissante, mais ne doit pas se faire à la va-vite ».*

Having an intermediary / **mediator** was a plus according to two participants.

The importance of **face-to-face contact** was underlined by one participant, with one participant stating that the use of Zoom is not to be kept.

Concerning decision making, one participant suggested to keep a majority opinion.

Feelings at the end of the first step

At the end of this first step, 3 participants felt "optimistic", 3 "cautious" and one participant declared himself "exhausted". One participant added feeling "confident" in addition to feeling "cautious".

Expectations for Step 2

Two participants stated that they had no specific expectations as their involvement would be limited.

On the researchers' side, they expected:

- a well-considered selection of participants
- support from Psytoyens in case of difficulties with a participant
- help in identifying issues to be analysed/interpreted

Patient representatives expected to be able to participate "sans prendre trop de place" and that their contributions would be recognised. They would make sure that what users say was understood and well translated. They also hoped that there would not be too many requirements in terms of the number/type of patients, particularly given the difficulties in terms of recruitment and openness in terms of data analysis.

Conclusion of the first step

If the involvement of patients is not questioned and is perceived as beneficial, it seems essential to **clearly and formally define its contours and objectives as soon as possible in the project**.

The point of attention concerns the **time** required for patient involvement, both in terms of the process but also in terms of investment by researchers and patients. Particular attention must be paid to the compatibility of the pace of the research and that of the patients.

Second round of evaluation

Five participants on a total of 9 expected participants replied to the second round of evaluation: 3 KCE researchers, 1 patient representative and 1 representative of the LUSS. Two reminders were sent but did not improve the participation rate. Four respondents already participated in the first round of evaluation.

Regarding expectations for this second step, one participant joining for the first time was expecting “en apprendre [plus] sur le processus de recherche mené le KCE”.

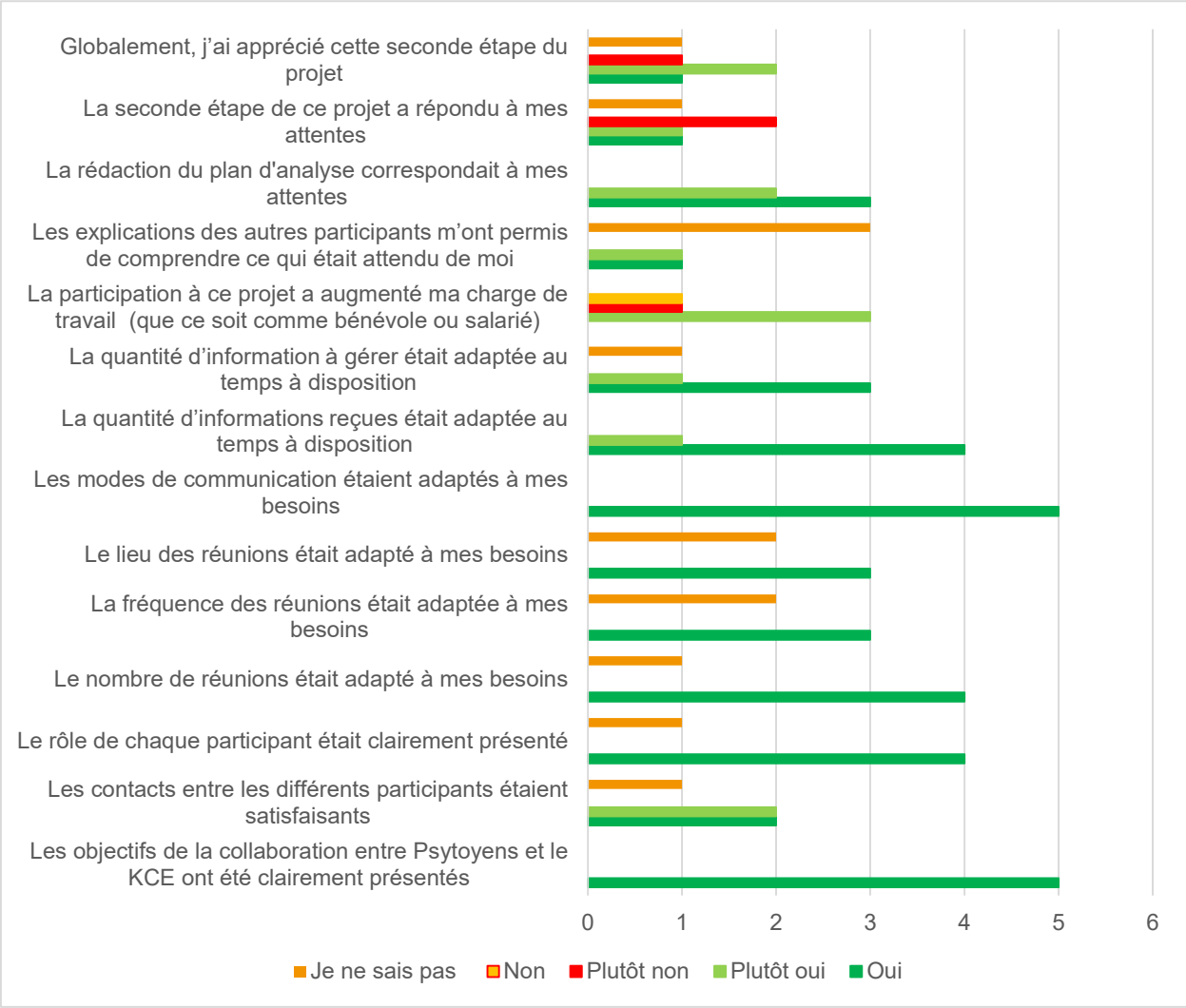
One participant reported not being – by its own choice – involved in this step of the process but remained available for consultation while another participant had no particular expectations. The two remaining participants were willing to continue the process of patient involvement; one participant had very clear expectations:

> “*Optimiser le recrutement [des patients], optimiser la sécurité et la participation des patients dans la collecte des données et garantir que les aspects analysés soient pertinents, aussi dans la perspective [des] patients*"

Two participants declared being involved to give advice and opinions regarding decision making, two reported being informed of the decisions and one participation – a researcher – reported being in control of the decisions made.

Figure 9 presents the appreciation of the different tasks and activities in the second step of the project. Three participants were globally satisfied at the end of this second step but two participants also reported that this second step did not fulfil their expectations. For three participants, this second step also increased their workload.

Figure 9 – Participants' appreciation of the tasks and activities of the second step of the research project



For a patient representative, the communication was easy with KCE. Two KCE researchers were unsatisfied because they were expecting tasks from the patient representatives that were not achieved: this had consequences on the recruitment process of the participants to the Brussels focus groups. The Covid crisis also negatively impacted the participation in the data collection and in the research process.

Strengths of the second step

Participants highlighted the positive communication between actors, including the capacity to resolve misunderstandings: trust between participants was established. The clarity of deadlines seemed to play a role in the positive communication.

This second phase allowed also for experimenting limits to patient involvement: KCE researchers were expecting a high number of participants thanks to the support of Psytoyens.

Points of attention in the second step

The principal investigator of the project was not involved in this step of the process and was perceived by other researchers as not being very interested in the added value of patient involvement. This induced a perception of a fragmented project, only supported by a part of the KCE research team.

There was a need for a better follow-up of the patient representatives to ensure the tasks are fulfilled on time: a participant suggested an increased communication or an (in)formal follow-up. This follow-up should avoid being perceived as “harassment” or “micromanagement”.

Practices to keep and avoid

All participants, but one, wish to keep patient involvement, supported by a **clear communication** and a **clear planning of activities – with regular updates**. One researcher also recommends involving patients as observers to guarantee patient safety and to increase trust between patients and researchers. Patients should also be better involved in the recruitment of the peers.

For a KCE researcher, in general, a research project should not continue if the principal investigator is not involved.

Feelings at the end of the second step

At the end of this second step, two participants declared themselves confident, one prudent, one optimist and one happy.

Expectations for Step 3

Three respondents expect finding the patient perspectives and interests reflected in the documents (synthesis and recommendations): it should be found in the content but also in the way results are presented (formulation and readability of the text). One participant hoped for a greater involvement of the patient association in the step 3 while acknowledging that the frame of the project should be respected. Keeping the project in the defined planning of the project is also expected by another participant. The umbrella of patient association hoped having time to discuss the documents with the patient association, before sending comments to the KCE researchers.

Conclusion of the second step

Having only 5 participants, including only one patient association member, limits the conclusions we can draw for this step.

Nevertheless, we could point two major points:

- **The whole research team** should commit to the patient involvement if it has been decided to involve patients in a project
- **When it comes to practical tasks having a direct impact on the research process, clear deadlines and regular (informal) contacts should be made between the researchers and the patients.**

Third round of evaluation

Only two participants completed the final online questionnaire: their responses have been included in the next section. One participant started completing the questionnaire but excused herself as feeling not able to respond the questions as her personal involvement was quite limited in the project.

As this third round was close to the final evaluation, this low participation rate was not considered as jeopardising the evaluation process.

Global evaluation of the process

At the end of the project, a final evaluation was conducted to assess the overall process of collaboration. Four interviews and a focus group were organised in February 2021 via the Zoom platform.

Overall, none of the participants regret the patient involvement, although the experience led, for some participants, to mitigated feelings. For some participants, the experience was exhausting but none of them regretted having joined this project. It needed growing a trust relationship, “s’apprivoiser l’un l’autre”.

On the positive side, involving patients was perceived as bringing additional expertise and to increase attention to key points in the project. More precisely, researchers realised that using “severe mentally ill” was hurtful for the patients and may negatively impact the recruitment process. The vocabulary used in the project was then adapted to be more careful regarding patients’ feelings.

Involving patients also made KCE researchers more conscious about the real humans” behind the scientific work. One researcher said:

> *“J’ai eu beaucoup plus conscience qu’il y avait des patients derrière le rapport, j’ai été plus sensible à l’impact émotionnel du rapport”.*

On the negative side, involving patients was perceived as time-consuming and energy-consuming for, as perceived by researchers, a rather disappointing result. Researchers expected having a facilitated recruitment process because of the support of the patient association but, in one setting, only one patient was recruited. Researchers also pointed out that patients had to be clearly informed about their role(s), otherwise it could be frustrating for them. Some researchers found the meetings too long and exhausting: some considered it difficult to interrupt patients when they were diverging from the topic. In that sense, having a researcher on the project who is trained as mediator was a plus.

For the patients, the last contact with KCE was disappointing and gave the feeling that their experiences and contributions were diluted into scientific data. They expressed it by saying “l’expérience théorique a pris le pas sur la pratique”. They were also quite unsatisfied about the final stakeholder meeting where no translation was provided. They felt put apart, without possibilities of interacting or sharing their perspectives. For them, the patients’ voice was lost of sight by the participants to the stakeholder meeting. They also regretted that patients who participated to the group discussion were not invited to that meeting. A researcher also suggested to hold a final meeting with all the patients involved in the research project (those involved as consulting patients and those joining in the data collection phase).

KCE researchers also pointed out that the overall study program has to be adapted: the number of studies per year should be reduced. In that sense, one researcher highlighted the importance of the Delphi criteria. **Patient involvement requires researcher involvement.** The whole research team needs to support the patient involvement, otherwise it generates stress and tensions within the team. Asking patients to review the synthesis complicated the end of the process: it put too much pressure on the communication cell.

Even if the process did not lead to all expected results, participants appreciated the experience in itself. Both patients and researchers acknowledged that, despite the attention points and aspects that could be improved, it was really positive to conduct this first experiment. As stated by one patient, “nous sommes des pionniers”. Patients and researchers also underlined that the state-of-mind should change to better work with patients:

some of them are aware that not all KCE researchers are convinced of the importance of patient involvement.

> *« Nous sommes dans un couloir avec plein de portes, mais on a déjà franchi la première porte »*
>
> *« On a un sentiment de trop peu mais on est super content. […] Je remercie le KCE d'avoir fait le premier pas ».*
>
> *Patients*
>
> *« Le fait même de faire ce test est déjà une avancée »*
>
> *KCE researcher*

Both patients and researchers stressed the need for an adapted language to ensure appropriate communication between patients and researchers. For the researchers, the KCE communication cell has a role to play to help researchers when writing documents for patients.

> *« On est tellement dedans qu'on ne se rend pas compte du jargon, du fossé »*
>
> *KCE researcher*

Finally, **a common collaboration charter** – signed by researchers, patients and umbrella of patient associations – is **a must-have** for all participants.

Contextual and specific aspects

Patient involvement was not envisioned from the start of the project but came rather progressively when the research team decided to launch qualitative interviews. To validate the interview guide and help for the recruitment, two patient associations were contacted, one on the Flemish side and another on the French-speaking side. On the French-speaking side, the patient association was already thinking about a project on the side-effects of medications for the somatic health. The patient association then asked to be more involved in the KCE project, that is not only to validate the interview guide or to find patients. The Flemish patient association did not make such request.

The psychosomatic care project was severely impacted by the Covid-19 pandemic. Contacts between KCE researchers and the patient association shifted from face-to-face to virtual. Besides, as support for patients, the patient association has to cope with increased demands for help from their members, preventing them from a regular participation. Moreover, at the time they asked to join the research project, the patient association was also busy (re)thinking their missions and objectives.

Being a pilot for testing patient involvement led to confusion in the research team: although patient involvement was supposed to support the Psychosomatic Care, at some points, some team members had the feeling that two parallel projects were conducted.

When contacted by KCE, Psytoyens was already working on a project aiming at documenting the impact of the treatment of psychiatric diseases on somatic health. At the beginning of the collaboration, this led to some tensions as the role of each actor was not clear. Psytoyens had the feeling that the issue was stolen from them. This led to a discussion regarding the posture given to the patients by researchers. Patients, from their diverse experiences, not only with KCE, perceived that they ware often presented as "demanding", although in a research process, the demanders are the researchers rather than the patients (in the so-called "up-bottom" perspective). In their experience with KCE, they felt they had to adapt themselves to the KCE process rather than the other way round. In that sense, patients insisted on the need that patient involvement should be a win-win transaction. A 90%/10% relationship, in which the patients are only involved for a 10%, is declared as non-sufficient for proper patient involvement.

Advice to researchers

- **Don't be afraid of patients**
- Be open, transparent and empathic with patients
- Understand patients' personal constraints due to their disease, be sensitive to their situation

- Understand what the association can / cannot do in your project and write it down
- Do not overestimate patient contributions, have realistic expectations of patients
- Accept that patients' contributions may occur where you don't expect it
- Be clear about deadlines and expected deliverables from patients, have an easy and clear planning
- Include follow-up checkpoints during recruitment phase
- Avoid jargon
- Pay attention to the vocabulary used as some may hurt
- Do not work with patients if you don't like having human contacts
- Be aware of digital constraints
- Do not plan unrealistic deadlines, establish the planning with the patients
- Assess whether patients need a training or not (but you don't have to be the ones doing it)
- Do not hesitate to invite a "go-between" actor to act as intermediary / mediator, call for help as quickly as possible
- Be aware of unexpected events and constraints
- Support the patient involvement as a team
- Identify a clear contact person in the research team for the patients
- Clarify the role of all the team members and staff for the patients
- Ensure having informal contacts with patients (before or after the meetings) to gain their trust
- Avoid contacting patients in English
- Make room for "experience of experiences" in your research project
- Plan a meeting with all patients who have been involved in the project
- Define clear and concrete tasks to be performed by the patients
- Listen to the facilitators as they are your experts in planning management
- Work in pairs

Advice to patients

- Take time to understand how KCE is working, the roles and missions of KCE and its researchers
- Be clear about why you wish to be involved in the project and communicate it to the researchers
- Clarify how you want to be involved and assess the resources you need for it
- Write down roles, responsibilities, motivations for involvement, resources and modalities of involvement
- Consider carefully the time needed and the related constraints to be involved in such projects
- Do not become involved if you don't have time to do it properly
- Understand the time constraints of the KCE researchers
- Identify one contact person among the patient group, able to follow the project and endorse responsibilities for the project
- Be aware that researchers might use specific jargon
- Understand the added-value and be aware of the stakes
- Be aware that frustration may occur
- Plan concertation meetings, do not wait for researchers to contact you
- Be clear about your expectations regarding the project
- Do not let down your aim and objectives as patient association

- Join the project if you believe that it will have an added value for you
- Plan time and resources to do it properly

Advices to umbrella of patient associations

- Explain clearly your role to patients and KCE researchers
- Be a moderator between patients and KCE researchers
- Define the limits of your involvement
- Contact regularly patients to check whether they need support
- Debrief activities with patients
- Debrief activities with researchers
- Find the balance between empowering the patient association and participating yourself as umbrella organisation

Conclusion

This first and pioneering experience should serve as inspiration for other KCE researchers and patients to work together. Future experiences should be evaluated and their lessons should serve to improve patient involvement at KCE. This evaluation should therefore not be done at the end of the project but rather be organised after key steps in order to adjust – whenever possible – the research process. As final conclusion, it is worth recalling that **patient involvement requires researcher involvement.**

REFERENCES

1. Cleemput I, Dauvrin M, Kohn L, Mistiaen P, Christiaens W, Léonard C. Position of KCE on patient involvement in health care policy research. Method. Brussels: Belgian Health Care Knowledge Center (KCE); 2019 11/2019. KCE Reports 320 Available from: https://kce.fgov.be/sites/default/files/atoms/files/KCE_320_Patient_involvement_health_care_policy_research_Report_2.pdf
2. 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 Center (KCE); 2019 11/2019. KCE Reports 320Cs Available from: https://kce.fgov.be/sites/default/files/atoms/files/KCE_320C_Patient_involvement_health_care_policy_research_Synthesis_0.pdf
3. Murgado-Armenteros EM, Torres-Ruiz FJ, Vega-Zamora M. Differences between Online and Face to Face Focus Groups, Viewed through Two Approaches. Journal of theoretical and applied electronic commerce research. 2012;7:73-86.
4. 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.
5. NIHR, INVOLVE.;2019 [cited 4/07/2019]. Available from: https://www.invo.org.uk/
6. National Institute for Health Research. National Standards for Public Involvement in Research. 2018.
7. Witteman HO, Chipenda Dansokho S, Colquhoun H, Fagerlin A, Giguere AMC, Glouberman S, et al. Twelve Lessons Learned for Effective Research Partnerships Between Patients, Caregivers, Clinicians, Academic Researchers, and Other Stakeholders. J Gen Intern Med. 2018;33(4):558-62.
8. Pandya-Wood R, Barron DS, Elliott J. A framework for public involvement at the design stage of NHS health and social care

research: time to develop ethically conscious standards. Res Involv Engagem. 2017;3:6.

9. de Wit M, Bloemkolk D, Teunissen T, van Rensen A. Aanbevelingen voor succesvolle betrokkenheid van patiënten/cliënten bij medisch wetenschappelijk onderzoek. PGO Support; 2016.
10. Hughes M, Duffy C. Public involvement in health and social sciences research: A concept analysis. Health Expectations. 2018;0(0).
11. G-I-N Public working group. G-I-N Public Toolkit: Patient and Public Involvement in Guidelines 2015.
12. Bruneel E, Colemont P, Gielen P, Ector S, Tambuyze E. Het inschakelenvan ervaringsdeskundigen in de gezondheidszorg. Vlaams Patiëntenplatform vzw 2020. Beleidsnota Available from: http://vlaamspatientenplatform.be/_plugin/ckfinder/userfiles/files/2020_06_19%20Beleidsnota%20inschakeling%20ervaringsdeskundigen.pdf
13. Castro EM. Patient participation and empowerment. The involvement of experts by experience in hospitals KU Leuven; 2018.
14. Neumeyer A. Steering Committees: Everything You Should to Know [Web page].2021 [cited 02/03/2021]. Available from: https://www.tacticalprojectmanager.com/steering-committee/
15. Phillips J. How to run effective meetings. Five principles for getting more done as a team [Web page].2018 [updated 2021; cited 02/03/2021]. Available from: https://slack.com/intl/fr-be/blog/productivity/run-effective-meetings
16. Gallo A. The Condensed Guide to Running Meetings Harvard Business Review. 2015.
17. Crocco K. What Does Research Say About the Best Practices for Company Meetings? [Web page].2017 [updated 2021; cited 02/03/2021]. Available from: https://business101.com/research-say-best-practices-company-meetings/
18. Cohen MA, Rogelberg SG, Allen JA, Luong A. Meeting Design Characteristics and Attendee Perceptions of Staff/Team Meeting Quality. Psychology Faculty Publications. 2011;96.
19. Victoria T. Patient and Carer Involvement in NICE Clinical Guidelines. In: Littlejohns P, Rawlins M, editors. Patients, the Public and Priorities in Health Care. Oxford: Radcliffe; 2009.
20. Brouwer H, Brouwers J. The MSP Tool Guide: Sixty tools to facilitate multi-stakeholder partnerships. Companion to The MSP Guide. . Wageningen: Wageningen University and Research, CDI.; 2017. Available from: http://www.mspguide.org/resource/msp-tool-guide
21. Slocum N. Participatory methods toolkit. A practitioner's manual. King Baudouin Foundation, Flemish Institute for Science and Technology Assessment (viWTA); 2003.
22. PAQS asbl. Participation du patient/résident. Aperçu d'outils et méthodologies. Bruxelles: PAQS; 2018.
23. Rosenbaum MS, Otalora ML, Ramírez GC. How to create a realistic customer journey map. Business Horizons. 2017;60(1):143-50.
24. ZonMW. Een 10 voor patiëntenparticipatie. Available from: https://www.elsi.health-ri.nl/sites/elsi/files/ELSI/Harteraad%20Pati%C3%ABntparticipatie-in-cardiovasculair-onderzoek.pdf