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## Qualitative approach to Patient-Reported Outcomes in oncology: study protocol.

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Complete List of Authors:	Orri, Massimiliano; INSERM U1178, Sibeoni, Jordan; INSERM, U-669 , PSIGIAM; AP-HP, Hopital Cochin, , Maison de Solenn, Labey, Mathilde; INSERM, U-1178, Bousquet, Guilhem; APHP Saint-Louis Hospital, Department of Medical Oncology Verneuil, Laurence; CHRU Caen, Department of Dermatology Revah-Levy, Anne; Argenteuil Hospital Centre, Centre de Soins Psychotherapeutiques de Transition pour Adolescents
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**Qualitative approach to Patient-Reported Outcomes in oncology:  
study protocol.**

Massimiliano Orri,<sup>1,2,3</sup> Jordan Sibeoni,<sup>1,2,4</sup> Mathilde Labey,<sup>1,2</sup> Guilhem Bousquet,<sup>5,6</sup> Laurence Verneuil,<sup>7,8</sup> QualiPRO study group,<sup>#</sup> Anne Revah-Levy,<sup>1,2,9</sup>

- <sup>1</sup> INSERM 1178 research unit, Paris, France
- <sup>2</sup> Paris-Sud University and Paris-Descartes University, Paris, France
- <sup>3</sup> University of Picardie Jules Vernes, Department of Psychology, CRP-CPO Lab, Amiens, France
- <sup>4</sup> Maison de Solenn, AP-HP Cochin Hospital, Paris, France
- <sup>5</sup> Department of Medical Oncology, AP-HP Saint-Louis Hospital, Paris, France
- <sup>6</sup> Paris-Diderot University, Paris, France
- <sup>7</sup> Department of Dermatology, CHRU Caen, Caen, France
- <sup>8</sup> Caen Basse Normandie University, Caen, France
- <sup>9</sup> Centre de Soins Psychotherapeutiques de Transition pour Adolescents, Argenteuil Hospital Centre, Argenteuil, France

<sup>#</sup> QualiPRO study group contributors: ARL principal investigator; MO, JS, ML, GB, and LV co-investigators

Correspondence to:

Massimiliano Orri  
INSERM U1178, 97 Boulevard de Port Royal, F-75679 Paris, France  
E-mail: [massimiliano.orri@gmail.com](mailto:massimiliano.orri@gmail.com); Tel: +33 1 58 41 28 52; Fax: +33 1 58 41 28 43

Keywords

Oncology, perspectives on treatment, patient-centred medicine, family, qualitative research

## Abstract

**Introduction:** The last decade has been characterised by a movement from a doctor-centred to a patient-centred approach, in which doctors try to see the illness through their patients' eyes. Patients, family members, and doctors are the 3 protagonists of cancer care, but their perspectives about what have been helpful during cancer treatment have never been compared. The aim of this study project is to explore patients' perspectives about the care they receive, as well as families' and doctors' perspective about what have been helpful for the patient. These three points of view will be compared and contrasted in order to analyse the convergences and divergences in these perspectives.

**Methods and analysis:** This is a national multicentre qualitative study. Participants will be constituted by three different subsamples: (i) patients with cancer (skin, breast, urological, and lung cancers), (ii) their relatives, and (iii) their referring physicians. Recruitment will follow the purposive sample technique, and the final sample size will be determined by data saturation. Data will be collected through open-ended semi-structured interviews and independently analysed by 3 researchers according to the principles of Interpretative Phenomenological Analysis. Nvivo 10 will be used to manage the data and perform the analysis.

**Ethics and dissemination:** The research protocol received approval from the University Paris Descartes review board (IRB number: 20140600001072), and participants will provide written consent. To our knowledge, this is the first study to focus on the simultaneous exploration of the separate points of views of patients, family, and doctors about the care received during the cancer care journey. We expect that our findings will help to improve communication and relationships between doctors, patients, and families. Comparison of these 3 points of view will provide information about the convergences and divergences of these perspectives and how to address the needs of all three groups.

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**Strengths and limitations of this study**

This study has been methodologically designed to ensure validity of our findings, as ensured by methodological accuracies such as the use of purposive sampling, data saturation, and triangulation. Additionally, we will select patients affected by 4 cancer types (skin, urogenital, lung, and breast) which differ in prognosis, treatment and clinical manifestations in order to enhance transferability of the findings.

Potential limitations are: first, the results of our study can be transferred to other healthcare contexts only with caution, because cancer care depends strongly on medical system policies, as well as the economics of the country. Second, nurses’ perspectives are lacking in this study. We made the choice to concentrate only on doctors for feasibility reasons, although we are aware that nurses are often the healthcare professionals with the most patient contact.

## Introduction

Patients' own perspectives and perceptions of the care they receive during their cancer treatment are considered increasingly important today. Accordingly, the third French Cancer Plan 2014-2018 states that "a quality relationship between patients and their healthcare providers is a condition for both care and communication that meet patients' expectations" (p 70).<sup>1</sup>

Advances in modern medicine and the development of evidence-based medicine (EBM) have made possible dramatic progress in oncology, in terms of survival, quality of care, and availability of treatment. At the same time, the doctor-patient relationship has also changed, almost as dramatically.<sup>2</sup> Patients' preferences, choices, and needs have been placed at the core of the decision-making process, because patients' feelings influence therapeutic choices, patient satisfaction, and quality of life during and after the treatment period.<sup>2-5</sup>

Accordingly, the last decade has been characterised by a movement from a doctor-centred to a patient-centred approach, in which doctors try to see the illness through their patients' eyes.<sup>6,7</sup> This shift in the patient's role in care requires medicine to move beyond its traditional biomedical model and paternalistic approach (in which expert doctors based their decisions solely on diagnosis and pathophysiology), to take the patient's subjectivity into account.<sup>3</sup> This patient-oriented approach should be able to capture the dual dimension of every medical act: the *care* and the *cure*.<sup>6,8</sup>

This new context has led to the emergence of patient-reported outcomes (PROs), which can be defined as "any reports coming directly from patients about how they function or feel in relation to a health condition and its therapy".<sup>9</sup> PROs provide patients' perspectives on treatment benefits and outcomes beyond survival, disease, and physiologic markers: they are often the outcomes of greatest importance to patients. PROs are elicited by methods such as interviews, self-completed questionnaires, diaries, and other data collection tools, preferably specific methods that are rigorous, scientific, and validated.<sup>9</sup>

The interest in patients' subjective perspectives has led researchers to recommend the use of interpretative research methods that can directly explore their point of view.<sup>10</sup> Qualitative methods are the gold standard for research seeking to understand in depth complex phenomena from the perspective of the people directly involved.<sup>11</sup> These methods are based on a well-established corpus of

approaches (including phenomenology, grounded theory, and ethnography) having in common the analysis of data collected through interviews, focus groups, or participant observation. The development of qualitative research in medicine is intended to enable better consideration of the lived experience of both patients and other participants involved in healthcare; its aim is to improve practices. In the field of cancer care, qualitative methods have been successfully used to address topics such as barriers in help-seeking,<sup>12</sup> doctor-patient communication,<sup>13</sup> and the needs of families and patients.<sup>14</sup>

This corpus of studies demonstrates the importance of psychosocial issues in the treatment of cancer; it also shows that families follow clear patterns of social, psychological, and spiritual wellbeing and distress throughout the trajectory of their relative's illness.<sup>14</sup> These patterns mirror the patients' experiences, but clinicians appear to be unaware of it – despite its quite negative effect on families' caregiving capacities. Moreover, other studies have shown that oncologists act according to what they think is best for the patient, trying to balance hope and uncertainty, but often resulting in collusion and false optimism.<sup>15</sup> On the whole, the literature clearly shows a divergence between the perspectives of doctors, patients, and families about cancer treatment — a divergence that leave patients' needs substantially unaddressed.

Our project is primarily interested in examining the gap between these perspectives, by comparing the perspectives of patients, families, and physicians about their representation of treatment. We have chosen an original approach that can deal directly with an issue only suggested by others – the goal to integrate these perspectives. To our knowledge, no study has yet attempted to achieve this explicit aim, and notable gaps in the literature remain unfilled.

**Aims**

The aim of this study project is threefold:

- (i) To explore patients' perspective about the care they receive. We will address in particular their perceptions of what helped them during their treatment (in terms of both care and cure), what

made them feel better able to handle their situation, and what made their illness harder for them;

- (ii) To explore doctors' perceptions of what was helpful to patients;
- (iii) To explore families' point of view about what was helpful during their loved one's cancer treatment.

These three points of view will be compared and contrasted to look for the features they share and those that differed in the representations of what was helpful during the treatment period and to analyse the convergences and divergences in these perspectives

### Research team

The QualiPRO research team comprises both experienced qualitative researchers and clinicians working with people with cancer. The main investigators have backgrounds in psychiatry or psychology backgrounds and substantial experience in conducting qualitative research (ARL, a psychiatrist, heads the qualitative research team within national research unit U669; JS is special registrar in child psychiatry; ML is a psychiatrist-researcher; MO is a psychologist and PhD candidate). This team has already conducted several studies in various fields of adult and adolescent health (psychiatry, oncology, surgery, and anaesthesiology). The relations between the perspectives of patients, family, and healthcare providers have become the core topic of this research team, which is especially interested in shared representations of illness and care/treatment among the different stakeholders.

**Methods**

**Setting**

This is a national multicentre study. Four departments are involved (3 in the Paris area: Paris Saint-Louis 1 and 2 and Bobigny–Avicenne; and one in Caen, in northern France; see Figure 1 and Table 1). All are teaching hospitals.

**Participant selection and recruitment**

The final sample will be constituted by three different subsamples: (i) patients with cancer, (ii) their relatives, and (iii) their referring physicians.

We have established a set of inclusion/exclusion criteria for the patients (Box 2). Because a purposive sample technique<sup>16</sup> will be used to obtain a maximum variation sample with a wide range of different experiences, we chose to concentrate on different kinds of cancer sites and different cancer stages (metastatic and non-metastatic, specifically adult cancer patients with the following diseases:

- Skin cancer: lymphoma, melanoma;
- Breast cancer;
- Kidney and urological cancers;
- Lung cancer.

A clinician coordinator has been identified for each participating centre. They will ask patients who meet the inclusion criteria (and their family members and physicians) to participate and seek to recruit both men and women, in different age groups

The size of the sample will be determined by data saturation,<sup>17</sup> defined as the point when no new relevant information that increases our understanding of the phenomenon of interest emerges in the performed analysis. Analysis begins the month after data collection starts.



## Data collection

Data will be collected through open-ended semi-structured interviews with patients, a relative (spouse, sibling, child, or parent), and a doctor directly involved in the patient's care. These interviews will elicit the representations of each of these groups about the actual care process.

The interviews will be conducted by experienced qualitative researchers, 2 men (MO and JS), and 2 women (ML and ARL), whose backgrounds have been described above (see Research team paragraph). A topic guide will be developed on the basis of a preliminary literature review and pilot interviews (with patient, family members, and physicians) conducted by 3 different interviewers, analysed independently and discussed in team (Box 3).

A flexible topic guide – rather than a fixed schedule – was chosen because (i) our aim is to collect in-depth accounts, (ii) the researchers all have substantial experience in conducting both open and semi-structured interviews, and (iii) we want to leave open the possibility of unpredicted issues that might be raised during the interviews.

The setting of these interviews will be the hospital in which the patients are treated. Researchers will meet the patient in a private room, will provide all the explanations necessary, and will obtain written informed consent. The interviews will last for about 30 to 60 minutes; will be audio-recorded, and then transcribed verbatim and anonymised. Every nuance of the participants' narrative will be respected.

## Data Analysis

A phenomenological framework will inform the data analysis. Phenomenology is the most suitable methodology for understanding how people subjectively perceive an important experience of their life and how they make sense of it. We have elected to perform a thematic content analysis according to the principles of Interpretative Phenomenological Analysis (IPA), which seeks to reach this understanding by adopting an "insider perspective".<sup>18</sup> IPA has three principal epistemological underpinnings. First, it is a phenomenological method that seeks to explore the participants' views of

the world. According to Husserl,<sup>19</sup> the objective of phenomenology is to understand how a phenomenon appears in the individual's conscious experience. Hence, experience is conceived as uniquely perspectival, embodied, and situated.<sup>19</sup> Second, IPA is based on interpretative activity (hermeneutics): Smith & Osborn<sup>18</sup> define interpretation as a dual process in which the "researcher is trying to make sense of the participant trying to make sense of what is happening to them". During the analysis, the researcher might move dialectically between the whole and the parts, as well as between understanding and interpretation. Third, the idiographic approach emphasizes a deep understanding of each case from the perspective and within the context of the individual.<sup>20</sup>

Five subsequent steps will follow:

1. Three of the researchers, independently for all interviews, will begin by reading and rereading the entirety of each interview, to familiarize ourselves with the participant's expressive style and to obtain an overall impression of the interview.
2. We will make initial notes, corresponding to the fundamental units of meaning. These notes will be descriptive and use the participants' own words; we will pay particular attention to linguistic details, such as the use of metaphors.
3. Conceptual notes will then be drafted, through processes of condensation, comparison, and abstracting of the initial notes.
4. Connections with notes will be mapped and synthesized, and emergent themes developed. Each interview will be separately analysed in the same way.
5. Afterwards, the analysed interviews will be compared to enable us to cluster themes into categories and subcategories.

The independent analyses will be compared throughout the process to reach agreement. Every discrepancy will be negotiated within the research team and during regular meetings. Nvivo 10<sup>21</sup> will be used to manage the data and perform the analysis.

## Ensuring validity of the findings and methodological quality

Several procedures will be followed to ensure the validity and rigour of our findings. First, the purposive sample technique we are adopting (the best validated sampling method in qualitative research) aims to select participants for their diversity – rather than for their homogeneity. This ensures that stereotypical and common findings are challenged and enables us to describe the phenomenon under study in all its nuances. Second, the criteria of data saturation – rather than setting a fixed sample size – will enable us to stop inclusions only when the phenomenon we are investigating has been fully explored. Third, independent analysis by 3 researchers and the subsequent triangulation and discussion within the multidisciplinary research team will ensure the validity and inter-subjectivity of the analytic process. Fourth, we will pay careful attention to negative cases during the data analysis to integrate the participants' convergent but also divergent voices. Lastly, to ensure our report meets high methodological standards, it will use the 32-item COREQ (consolidated criteria for reporting qualitative research) checklist.<sup>22</sup>

## Reflexivity

An important issue that we want to address is reflexivity, which can be defined as the reflection by the researchers of their role in the study and its effects on their findings at every step of the research process.<sup>23</sup> To account for these influences, the researchers will share their preconceptions and make their positions clear during group meetings. We will also consider the emotional impact of the research subject on researchers themselves. For this reason, after each interview, researchers will complete a sheet (composed by 7 open questions, see Box 4) about their own feelings and emotions during the interview. These sheets will be analysed and discussed during supervision sessions.

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5 **Ethics**  
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10 Participants will receive complete written information about the scope of the research, the identity and  
11 affiliation of the researchers, the possibility of withdrawing from the study at any point,  
12 confidentiality, and all other information required in accordance with French policies for biomedical  
13 research and with the Helsinki Declaration, as revised in 1989. Participants will provide written  
14 consent. The research protocol received approval from the University Paris Descartes review board  
15 (Conseil d’évaluation éthique pour les chercheurs en santé, CERES; IRB number: 20140600001072).  
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29 number 00050334.  
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36 **Timeline**  
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41 This is a two-year project. Figure 2 sets forth the planned timeline. After a 2-month coordination  
42 phase, study team organisational meetings, and allocation of resources, we will start 3 pilot interviews  
43 to verify the pertinence of our question guide. These interviews and their analysis and discussion will  
44 take 1 month. After the pilot phase, we will start data collection, which will take 7 months. Analysis  
45 will start almost simultaneously, a month after the interviews begin, and will be completed at month  
46 18 after the beginning of the study. The remaining time will be dedicated to the diffusion of our results  
47 (drafting journal articles and conference presentations) and to the preparation of the final report for the  
48 funders.  
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## Conclusion

To our knowledge, this is the first study to focus on the simultaneous exploration of the separate points of views of patients, family, and doctors about the care received during the cancer care journey.

We expect that our findings will help to improve communication and relationships between doctors, patients, and families. Communication is the starting point for reaching a common representation of care, which is essential in meeting patients' needs in cancer care, especially within the medical model that emphasises shared decision making and patient participation in choosing the treatment that best reflects their preferences and priorities.<sup>2,3</sup> Comparison of the perspectives of patients, their families, and their doctors will provide information about the convergences and divergences of these perspectives and how to address the needs of all three groups; it should therefore help to promote their collaboration.

### Potential strengths and limitations.

This study has been methodologically designed to ensure validity of our findings, as discussed above.

Additionally, we will select patients affected by 4 cancer types (skin, urogenital, lung, and breast).

Although this study will not address all types or sites of cancer, we believe that our findings will be transferrable to a large proportion of cancer patients, because they are usually treated with a wide range of therapies (chemotherapy, surgery, hormone therapy, and radiation therapy) and have a wide variety of prognoses (from melanoma with its high mortality rate to lymphoma and its low mortality).

Moreover, cancer care is a model of chronic disease and our findings may be transferred to other contexts such as severe diabetes care.

However we are aware of potential limitations. First, the results of our study can be transferred to other healthcare contexts only with caution, because cancer care depends strongly on medical system policies, as well as the economics of the country. Second, nurses' perspectives are lacking in this study. We made the choice to concentrate only on doctors for feasibility reasons, although we are

aware that nurses are often the healthcare professionals with the most patient contact. Other studies will be conducted to address this point.

**Authors’ contribution**

MO, JS, ML, GB, LV, ARL elaborated the study protocol. MO wrote the initial manuscript. MO, JS, ML, GB, LV, ARL reviewed the initial version of the manuscript and approved the final version.

**Competing interests**

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

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**Box 1 Article Summary****Article focus**

- Perspective of patients, their family members, and their doctors on the care received during treatment for cancer
- Comparison of the three perspectives using a qualitative phenomenological method.

**Key messages**

- Understanding what the three sets of participants have perceived as helpful or detrimental during the care process will provide knowledge about met and unmet needs
- Understanding the convergences and divergences of these perspectives will help to improve communication and relationships between doctors, patients, and families.

**Methodological strengths and limitations**

- Strengths: multicentre study making the following methodological choices: purposive sampling, data saturation, triangulation
- Limitations: transferability of findings to different healthcare contexts; lack of nurses' perspectives.

Table 1. Description of the study sites

Study site	Geographical location	Department	Cancer pathologies
Paris Saint-Louis 1	Paris – Ile de France	Medical Oncology	Breast, lung, urogenital cancer
Paris Saint-Louis 2	Paris – Ile de France	Dermatology	Melanoma, skin lymphoma
Caen	Caen – Basse Normandie	Dermatology	Melanoma, skin lymphoma
Avicenne	Bobigny – Ile de France	Radiation therapy	Breast, lung, urogenital cancer

For peer review only

**Box 2 Inclusion and exclusion criteria****Inclusion Criteria**

- Age: 18 years or older (no upper limit)
- Cancer site: breast, kidney, skin, urological
- In treatment for cancer for more than 6 months
- A close relative agrees to participate in the research
- Referring doctor agrees to participate in the research
- Able to communicate in French

**Exclusion Criteria**

- Age: < 18 years
- Cancer site other than the selected ones
- In the terminal phase (expected survival less than 6 months)
- No relative or referring doctor willing to participate in the research

Box 3 Interview topic guide

- Topic 1: Story of the illness

Topic 2: Focus on the care received

  - Pharmacological treatments (chemotherapy, radiotherapy, surgery)
  - Complementary treatments (non-conventional treatments, psychosocial treatment, self-help group)
  - Relationship with doctors/nurses

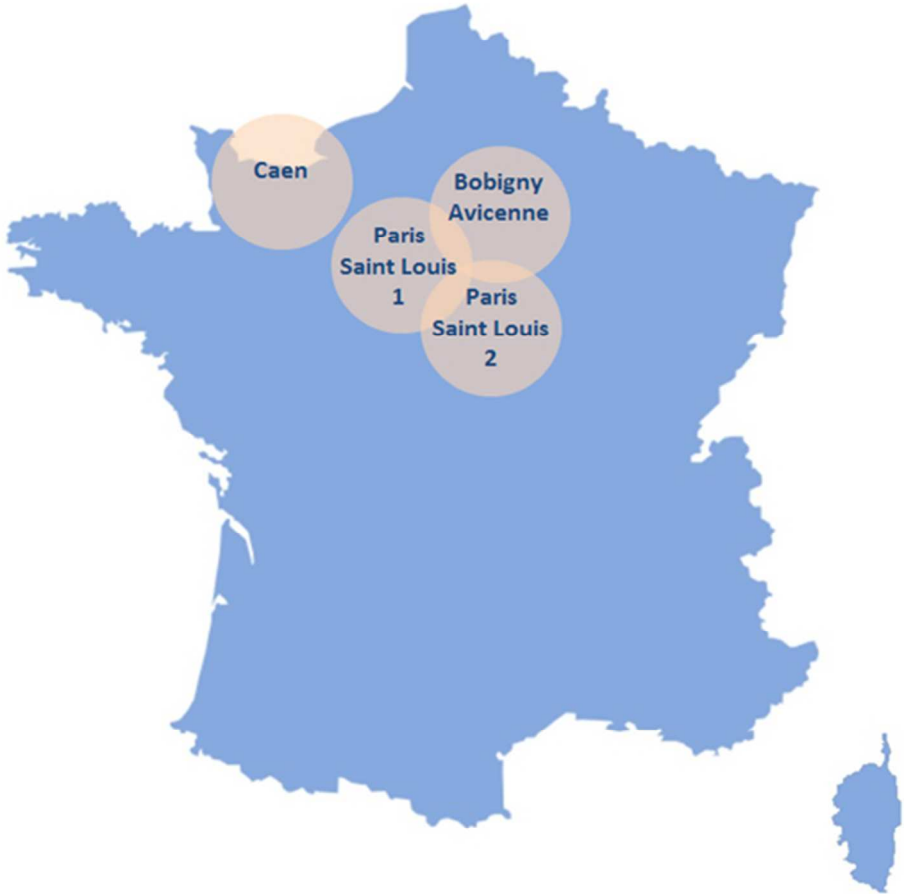
Topic 3: Coping with the emotional burden

For peer review only

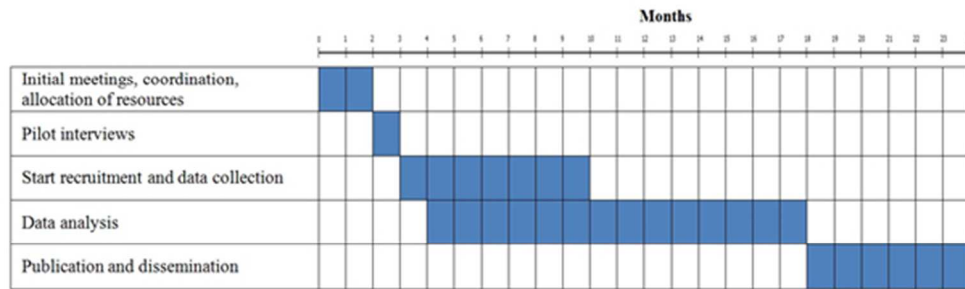
**Box 4 Researchers sheet**

- Q1. Describe your emotions before the interview?  
Q2. Describe your emotions during the interview?  
Q3. What were you thinking during the interview?  
Q4. Did you modify the way of conducting the interview according to what you were feeling? If yes, how?  
Q5. Are there any topics that you regret having broached?  
Q6. Are there any topic/aspect you didn't investigate because of your feelings, even though you were supposed to, and if so, which?  
Q7. Did you have any recurrent or embarrassing feelings which make you feel uncomfortable during the interview?

For peer review only



Geographical location of study sites  
160x158mm (96 x 96 DPI)



Gantt diagram of study timescale  
164x53mm (96 x 96 DPI)

# BMJ Open

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- <sup>1</sup> INSERM 1178 research unit, Paris, France
- <sup>2</sup> Paris-Sud University and Paris-Descartes University, Paris, France
- <sup>3</sup> University of Picardie Jules Vernes, Department of Psychology, CRP-CPO Lab, Amiens, France
- <sup>4</sup> Maison de Solenn, AP-HP Cochin Hospital, Paris, France
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Correspondence to:

Massimiliano Orri  
INSERM U1178, 97 Boulevard de Port Royal, F-75679 Paris, France  
E-mail: [massimiliano.orri@gmail.com](mailto:massimiliano.orri@gmail.com); Tel: +33 1 58 41 28 52; Fax: +33 1 58 41 28 43

Keywords

Oncology, perspectives on treatment, patient-centred medicine, family, qualitative research

## Abstract

**Introduction:** The last decade has been characterised by a movement from a doctor-centred to a patient-centred approach to treatment outcomes, in which doctors try to see the illness through their patients' eyes. Patients, family members, and doctors are the 3 participants of cancer care, but their perspectives about what have been helpful during cancer treatment have never simultaneously and explicitly compared in a same qualitative study. The aim of this study project is to explore patients' perspectives about the care they receive, as well as families' and doctors' perspective about what have been helpful for the patient. These three points of view will be compared and contrasted in order to analyse the convergences and divergences in these perspectives.

**Methods and analysis:** This is a national multicentre qualitative study. Participants will be constituted by three different subsamples: (i) patients with cancer (skin, breast, urological, and lung cancers), (ii) their relatives, and (iii) their referring physicians. Recruitment will follow the purposive sample technique, and the final sample size will be determined by data saturation. Data will be collected through open-ended semi-structured interviews and independently analysed with Nvivo-10 software by 3 researchers according to the principles of Interpretative Phenomenological Analysis.

**Ethics and dissemination:** The research protocol received approval from the University Paris Descartes review board (IRB number: 20140600001072), and participants will provide written consent. To our knowledge, this is the first study to focus on the simultaneous exploration of the separate points of views of patients, family, and doctors about the care received during the cancer care journey. We expect that our findings will help to improve communication and relationships between doctors, patients, and families. Comparison of these 3 points of view will provide information about the convergences and divergences of these perspectives and how to address the needs of all three groups.

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**Strengths and limitations of this study**

This study has been methodologically designed to ensure validity of our findings, as ensured by methodological accuracies such as the use of purposive sampling, data saturation, and triangulation. Additionally, we will select patients affected by 4 cancer types (skin, urogenital, lung, and breast) which differ in prognosis, treatment and clinical manifestations in order to enhance transferability of the findings. Sample size will be adequate to ensure sufficient data concerning these 4 different cancer experiences (and avoid loss of precision).

Potential limitations are: first, the results of our study can be transferred to other healthcare contexts only with caution, because cancer care depends strongly on medical system policies, as well as the economics of the country. Second, nurses’ perspectives are lacking in this study. We made the choice to concentrate only on doctors for feasibility reasons, although we are aware that nurses are often the healthcare professionals with the most patient contact.

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## Introduction

Patients' own perspectives and perceptions of the care they receive during their cancer treatment are considered increasingly important today.<sup>1</sup> Accordingly, the third French Cancer Plan 2014-2018 states that "a quality relationship between patients and their healthcare providers is a condition for both care and communication that meet patients' expectations" (p 70).<sup>2</sup>

Advances in modern medicine and the development of evidence-based medicine (EBM) have made possible dramatic progress in oncology, in terms of survival, quality of care, and availability of treatment. At the same time, the doctor-patient relationship has also changed, almost as dramatically.<sup>3</sup> Patients' preferences, choices, and needs have been placed at the core of the decision-making process, because patients' feelings influence therapeutic choices, patient satisfaction, and quality of life during and after the treatment period.<sup>3-6</sup>

Accordingly, the last decade has been characterised by a movement from a doctor-centred to a patient-centred approach, in which doctors try to see the illness through their patients' eyes.<sup>7,8</sup> This shift in the patient's role in care requires medicine to move beyond its traditional biomedical model and paternalistic approach (in which expert doctors based their decisions solely on diagnosis and pathophysiology), to take the patient's subjectivity into account.<sup>4</sup> This patient-oriented approach should be able to capture the dual dimension of every medical act: the *care* and the *cure*.<sup>7,9</sup>

This new context has led to the emergence of patient-reported outcomes (PROs), which can be defined as "any reports coming directly from patients about how they function or feel in relation to a health condition and its therapy".<sup>10</sup> PROs provide patients' perspectives on treatment benefits and outcomes beyond survival, disease, and physiologic markers: they are often the outcomes of greatest importance to patients. PROs are elicited by methods such as interviews, self-completed questionnaires, diaries, and other data collection tools, preferably specific methods that are rigorous, scientific, and validated.<sup>10</sup>

The interest in patients' subjective perspectives has led researchers to recommend the use of interpretative research methods that can directly explore their point of view.<sup>11</sup> Qualitative methods are the gold standard for research seeking to understand in depth complex phenomena from the

perspective of the people directly involved.<sup>12</sup> In the field of cancer care, qualitative methods have been successfully used to address topics such as barriers in help-seeking,<sup>13</sup> doctor-patient communication,<sup>14</sup> and the needs of families and patients.<sup>15</sup>

This corpus of studies demonstrates the importance of psychosocial issues in the treatment of cancer; it also shows that families follow clear patterns of social, psychological, and spiritual wellbeing and distress throughout the trajectory of their relative's illness.<sup>15</sup> These patterns mirror the patients' experiences, but clinicians appear to be unaware of it – despite its quite negative effect on families' caregiving capacities. Moreover, other studies have shown that oncologists act according to what they think is best for the patient, trying to balance hope and uncertainty, but often resulting in collusion and false optimism.<sup>16</sup> On the whole, the literature clearly shows a divergence between the perspectives of doctors, patients, and families about cancer treatment — a divergence that leave patients' needs substantially unaddressed.

Our project is primarily interested in examining the gap between these perspectives, by comparing the perspectives of patients, families, and physicians about their representation of treatment. We have chosen an original approach that can deal directly with an issue only suggested by others – the goal to integrate these perspectives investigating simultaneously patients', families' and physicians' point of views about the same situation (i.e. the cancer management of the patient). To our knowledge, no study has yet attempted to achieve this explicit aim, and notable gaps in the literature remain unfilled.

**Aims**

The aim of this study project is threefold:

- (i) To explore patients' perspective about the care they receive. We will address in particular their perceptions of what helped them during their treatment (in terms of both care and cure), what made them feel better able to handle their situation, and what made their illness harder for them;
- (ii) To explore doctors' perceptions of what was helpful to patients;

- (iii) To explore families' point of view about what was helpful during their loved one's cancer treatment.

These three points of view will be compared and contrasted to look for the features they share and those that differed in the representations of what was helpful during the treatment period and to analyse the convergences and divergences in these perspectives

## Research team

The QualiPRO research team comprises both experienced qualitative researchers and clinicians working with people with cancer. The main investigators have backgrounds in psychiatry or psychology backgrounds and substantial experience in conducting qualitative research (ARL, a psychiatrist, heads the qualitative research team within national research unit U669; JS is special registrar in child psychiatry; ML is a psychiatrist-researcher; MO is a psychologist and PhD candidate). This team has already conducted several studies in various fields of adult and adolescent health (psychiatry, oncology, surgery, and anaesthesiology). The relations between the perspectives of patients, family, and healthcare providers have become the core topic of this research team, which is especially interested in shared representations of illness and care/treatment among the different stakeholders.

## Methods

### Setting

This is a national multicentre study. Four departments are involved (3 in the Paris area: Paris Saint-Louis 1 and 2 and Bobigny–Avicenne; and one in Caen, in northern France; see Figure 1 and Table 1). All are teaching hospitals.

**Participant selection and recruitment**

The final sample will be constituted by three different subsamples: (i) patients with cancer, (ii) their relatives, and (iii) their referring physicians.

We have established a set of inclusion/exclusion criteria for the patients (Box 2). Because a purposive sample technique<sup>17</sup> will be used to obtain a maximum variation sample with a wide range of different experiences, we chose to concentrate on different kinds of cancer sites and different cancer stages (metastatic and non-metastatic, specifically adult cancer patients with the following diseases:

- Skin cancer: lymphoma, melanoma;
- Breast cancer;
- Kidney and urological cancers;
- Lung cancer.

A clinician coordinator has been identified for each participating centre. They will ask patients who meet the inclusion criteria (and their family members and physicians) to participate and seek to recruit both men and women, in different age groups

The size of the sample will be determined by data saturation,<sup>18</sup> defined as the point when no new relevant information that increases our understanding of the phenomenon of interest emerges in the performed analysis. Analysis begins the month after data collection starts.

**Data collection**

Data will be collected through open-ended semi-structured interviews with patients, a relative (spouse, sibling, child, or parent), and a doctor directly involved in the patient's care. These interviews will elicit the representations of each of these groups about the actual care process.

The interviews will be conducted by experienced qualitative researchers, 2 men (MO and JS), and 2 women (ML and ARL), whose backgrounds have been described above (see Research team paragraph). A topic guide will be developed on the basis of a preliminary literature review and pilot interviews (with patient, family members, and physicians) conducted by 3 different interviewers, analysed independently and discussed in team (Box 3).

A flexible topic guide – rather than a fixed schedule – was chosen because (i) our aim is to collect in-depth accounts, (ii) the researchers all have substantial experience in conducting both open and semi-structured interviews, and (iii) we want to leave open the possibility of unpredicted issues that might be raised during the interviews.

The setting of these interviews will be the hospital in which the patients are treated. Researchers will meet the patient in a private room, will provide all the explanations necessary, and will obtain written informed consent. The interviews will last for about 30 to 60 minutes; will be audio-recorded, and then transcribed verbatim and anonymised. Every nuance of the participants' narrative will be respected, by transcribing pauses, silences, and other non-verbal cues in the narratives.

### Data Analysis

A phenomenological framework will inform the data analysis. Phenomenology is the most suitable methodology for understanding how people subjectively perceive an important experience of their life and how they make sense of it. We have elected to perform a thematic content analysis according to the principles of Interpretative Phenomenological Analysis (IPA), which seeks to reach this understanding by adopting an “insider perspective”.<sup>19</sup> IPA has three principal epistemological underpinnings. First, it is a phenomenological method that seeks to explore the participants' views of the world. According to Husserl,<sup>20</sup> the objective of phenomenology is to understand how a phenomenon appears in the individual's conscious experience. Hence, experience is conceived as uniquely perspectival, embodied, and situated.<sup>20</sup> Second, IPA is based on interpretative activity (hermeneutics): Smith & Osborn<sup>19</sup> define interpretation as a dual process in which the “researcher is trying to make sense of the participant trying to make sense of what is happening to them”. During the



analysis, the researcher might move dialectically between the whole and the parts, as well as between understanding and interpretation. Third, the idiographic approach emphasizes a deep understanding of each case from the perspective and within the context of the individual.<sup>21</sup>

Five subsequent steps will follow:

1. Three of the researchers, independently for all interviews, will begin by reading and rereading the entirety of each interview, to familiarize ourselves with the participant's expressive style and to obtain an overall impression of the interview.
2. We will make initial notes, corresponding to the fundamental units of meaning. These notes will be descriptive and use the participants' own words; we will pay particular attention to linguistic details, such as the use of metaphors.
3. Conceptual notes will then be drafted, through processes of condensation, comparison, and abstracting of the initial notes.
4. Connections with notes will be mapped and synthesized, and emergent themes developed. Each interview will be separately analysed in the same way.
5. Afterwards, the analysed interviews will be compared to enable us to cluster themes into categories and subcategories.

The independent analyses will be compared throughout the process to reach agreement. Every discrepancy will be negotiated within the research team and during regular meetings. Nvivo 10<sup>22</sup> will be used to manage the data and perform the analysis.

**Ensuring validity of the findings and methodological quality**

Several procedures will be followed to ensure the validity and rigour of our findings. First, the purposive sample technique we are adopting (the best validated sampling method in qualitative research)<sup>17,23</sup> aims to select participants for their diversity – rather than for their homogeneity. This ensures that stereotypical and common findings are challenged and enables us to describe the phenomenon under study in all its nuances. Second, the criteria of data saturation – rather than setting

a fixed sample size – will enable us to stop inclusions only when the phenomenon we are investigating has been fully explored. Third, independent analysis by 3 researchers and the subsequent triangulation and discussion within the multidisciplinary research team will ensure the validity and inter-subjectivity of the analytic process. Fourth, we will pay careful attention to negative cases during the data analysis to integrate the participants' convergent but also divergent voices. Lastly, to ensure our report meets high methodological standards, it will use the 32-item COREQ (consolidated criteria for reporting qualitative research) checklist.<sup>24</sup>

## Reflexivity

An important issue that we want to address is reflexivity, which can be defined as the reflection by the researchers of their role in the study and its effects on their findings at every step of the research process.<sup>25</sup> To account for these influences, the researchers will share their preconceptions and make their positions clear during group meetings. We will also consider the emotional impact of the research subject on researchers themselves. For this reason, after each interview, researchers will complete a sheet (composed by 7 open questions, see Box 4) about their own feelings and emotions during the interview. These sheets will be analysed and discussed during supervision sessions.

## Ethics

Participants will receive complete written information about the scope of the research, the identity and affiliation of the researchers, the possibility of withdrawing from the study at any point, confidentiality, and all other information required in accordance with French policies for biomedical research and with the Helsinki Declaration, as revised in 1989. Participants will provide written consent. The research protocol received approval from the University Paris Descartes review board (Conseil d'évaluation éthique pour les chercheurs en santé, CERES; IRB number: 20140600001072).

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3 **Funding**  
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8 number 00050334.  
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15 **Timeline**  
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18 This is a two-year project. Figure 2 sets forth the planned timeline. After a 2-month coordination  
19 phase, study team organisational meetings, and allocation of resources, we will start 3 pilot interviews  
20 to verify the pertinence of our question guide. These interviews and their analysis and discussion will  
21 take 1 month. After the pilot phase, we will start data collection, which will take 7 months. Analysis  
22 will start almost simultaneously, a month after the interviews begin, and will be completed at month  
23 18 after the beginning of the study. The remaining time will be dedicated to the diffusion of our results  
24 (drafting journal articles and conference presentations) and to the preparation of the final report for the  
25 funders.  
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42 **Conclusion**  
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45 To our knowledge, this is the first study to focus on the simultaneous exploration of the separate points  
46 of views of patients, family, and doctors about the care received during the cancer care journey.  
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48 We expect that our findings will help to improve communication and relationships between doctors,  
49 patients, and families. Communication is the starting point for reaching a common representation of  
50 care, which is essential in meeting patients’ needs in cancer care, especially within the medical model  
51 that emphasises shared decision making and patient participation in choosing the treatment that best  
52 reflects their preferences and priorities.<sup>3,4</sup> Comparison of the perspectives of patients, their families,  
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and their doctors will provide information about the convergences and divergences of these perspectives and how to address the needs of all three groups; it should therefore help to promote their collaboration.

### **Potential strengths and limitations.**

This study has been methodologically designed to ensure validity of our findings, as discussed above. Additionally, we will select patients affected by 4 cancer types (skin, urogenital, lung, and breast). Although this study will not address all types or sites of cancer, we believe that our findings will be transferrable to a large proportion of cancer patients, because they are usually treated with a wide range of therapies (chemotherapy, surgery, hormone therapy, and radiation therapy) and have a wide variety of prognoses (from melanoma with its high mortality rate to lymphoma and its low mortality). Moreover, cancer care is a model of chronic disease and our findings may be transferred to other contexts such as severe diabetes care.

However we are aware of potential limitations. First, the results of our study can be transferred to other healthcare contexts only with caution, because cancer care depends strongly on medical system policies, as well as the economics of the country. Second, nurses' perspectives are lacking in this study. We made the choice to concentrate only on doctors for feasibility reasons, although we are aware that nurses are often the healthcare professionals with the most patient contact. Other studies will be conducted to address this point.

### **Authors' contribution**

MO, JS, ML, GB, LV, ARL elaborated the study protocol. MO wrote the initial manuscript. MO, JS, ML, GB, LV, ARL reviewed the initial version of the manuscript and approved the final version.

### **Competing interests**

We have read and understood BMJ Open policy on declaration of interests and declare that we have no competing interests.

### **Acknowledgements**

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**Figure legends**

**Figure 1. Geographical location of study sites**

The figure shows the geographical location of the 4 centres participating in the study in the French territory.

**Figure 2. Gantt diagram of study timescale**

The figure represents how the 5 the main phases of the study are organised in the 2 years project.

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**Box 1 Article Summary****Article focus**

- Perspective of patients, their family members, and their doctors on the care received during treatment for cancer
- Comparison of the three perspectives using a qualitative phenomenological method.

**Key messages**

- Understanding what the three sets of participants have perceived as helpful or detrimental during the care process will provide knowledge about met and unmet needs
- Understanding the convergences and divergences of these perspectives will help to improve communication and relationships between doctors, patients, and families.

**Methodological strengths and limitations**

- Strengths: multicentre study making the following methodological choices: purposive sampling, data saturation, triangulation
- Limitations: transferability of findings to different healthcare contexts; lack of nurses' perspectives.



Table 1. Description of the study sites

Study site	Geographical location	Department	Cancer pathologies
Paris Saint-Louis 1	Paris – Ile de France	Medical Oncology	Breast, lung, urogenital cancer
Paris Saint-Louis 2	Paris – Ile de France	Dermatology	Melanoma, skin lymphoma
Caen	Caen – Basse Normandie	Dermatology	Melanoma, skin lymphoma
Avicenne	Bobigny – Ile de France	Radiation therapy	Breast, lung, urogenital cancer

For peer review only

**Box 2 Inclusion and exclusion criteria****Inclusion Criteria**

- Age: 18 years or older (no upper limit)
- Cancer site: breast, kidney, skin, urological
- In treatment for cancer for more than 6 months
- A close relative agrees to participate in the research
- Referring doctor agrees to participate in the research
- Able to communicate in French

**Exclusion Criteria**

- Age: < 18 years
- Cancer site other than the selected ones
- In the terminal phase (expected survival less than 6 months)
- No relative or referring doctor willing to participate in the research

Box 3 Interview topic guide

- Topic 1: Story of the illness

Topic 2: Focus on the care received

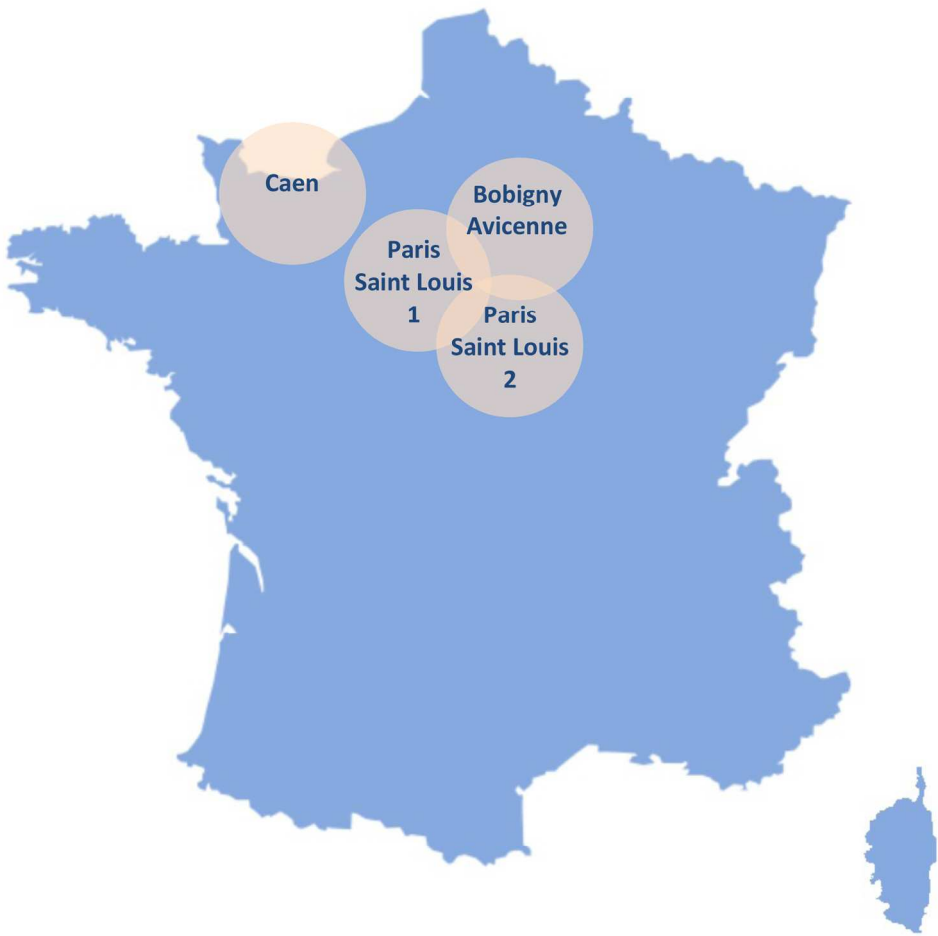
  - Pharmacological treatments (chemotherapy, radiotherapy, surgery)
  - Complementary treatments (non-conventional treatments, psychosocial treatment, self-help group)
  - Relationship with doctors/nurses

Topic 3: Coping with the emotional burden

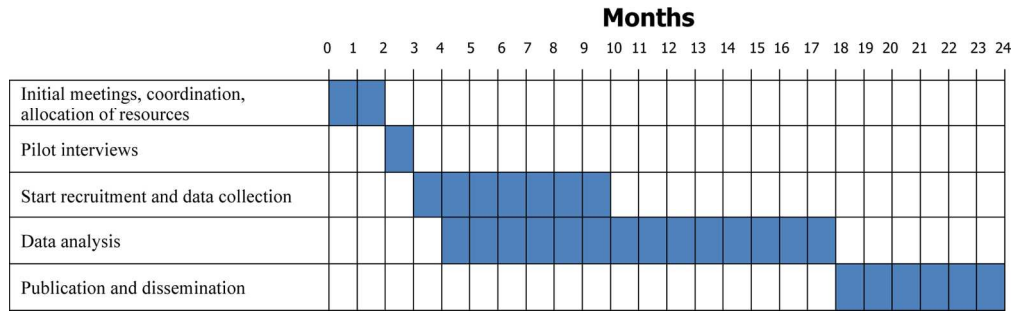
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**Box 4 Researchers sheet**

- Q1. Describe your emotions before the interview?  
Q2. Describe your emotions during the interview?  
Q3. What were you thinking during the interview?  
Q4. Did you modify the way of conducting the interview according to what you were feeling? If yes, how?  
Q5. Are there any topics that you regret having broached?  
Q6. Are there any topic/aspect you didn't investigate because of your feelings, even though you were supposed to, and if so, which?  
Q7. Did you have any recurrent or embarrassing feelings which make you feel uncomfortable during the interview?



The figure shows the geographical location of the 4 centres participating in the study in the French territory.  
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The figure represents how the 5 the main phases of the study are organised in the 2 years project.  
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