SUPPLEMENTARY MATERIALS

for

Quality of life and disease experience in patients with heart failure with reduced ejection fraction in Spain: a mixed methods approach to go beyond standardized data

by Raül Rubio et al.

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1. SEMI-STRUCTURED INTERVIEW GUIDELINE [Notes for RESEARCHER in blue].

Presentation

Thank you for taking part in this interview.

Please note that:

- Your responses are confidential and anonymous. Under no circumstances will your personal data be shared when the results are published. All answers will be treated in aggregate form.
- A Piece of Pie complies with all European and North American data protection laws and complies with the guidelines set by the EphMRA (European Pharmaceutical Market Research Association) codes of conduct for market research.
- You may discontinue your participation in this research at any time and, as well as the right not to answer any questions you do not wish to answer.

With your permission, we will audio record your responses to facilitate our analysis.

[RESEARCHER: Start recording audio.]

I will now introduce myself. My name is [XXX], I work for A Piece of Pie, an innovation consulting firm.

We are currently conducting a study on behalf of a pharmaceutical company, which would like to better understand the experience of patients suffering from Heart Failure.

We would be very grateful if you could share with us your personal experience and help us identify areas for improvement throughout your experience, from the moment of the first symptoms to the present.

Please note that there are no right or wrong answers, as we are interested in your opinions and your personal experience with the condition.

The interview (90 min.)

RESEARCHER: Tailor the questions to the way the patient refers to the disease and use the term provided by the patient to make him/her feel more comfortable. Whenever you believe that the caregiver could provide us with additional information on any of the topics discussed, please direct questions to him/her as well. If, on the other hand, you have the impression that it will be more valuable to ask certain questions only to the caregiver, do so after the interview with the patient. Always ask the patient for permission before talking to the caregiver.

Exploration area	**1. KNOW THE PATIENT (15 min)**
Goals	• **Generate a relationship with the patient** • **Better understand the person and their context** • **Understand your daily habits and routines**
Ethnographic explanation	*To begin with, I would like to get to know you as a person and familiarize myself with your personal situation...*

1. **Person:** I would like you to introduce yourself and explain to me:
   a) How old are you? Who do you live with?
   b) Tell me a little more about yourself, what do you like to do? What are your hobbies? What do you do? What do you value most now in your life? Why?
2. **Self-description:** If you were to describe yourself, what 3 words would you use? What comes to mind when you think of yourself?
3. **The patient's day-to-day life:** Tell me what a "typical" day looks like. What do you do from the time you wake up until you go to sleep? Differentiate weekday from weekends (i.e., hobbies). *RESEARCHER: be sure they explain their day to day routines to be able to refer to them later when exploring the impact of the disease. Write down on post-its moments with the greatest impact.*
   a) What time of day would you say you like best? When do you feel most at ease? Why?
   b) And what moment do you like the least? Why?
   c) What things do you have the hardest time doing?
   d) Is there anything you've had to give up in recent times? What do you miss?
4. **Outside view:** What do you think a good friend of yours or family member would say to me if I asked them what [patient's name] is like?
5. **Values:** If you were to tell a young family member what is most important in life, what would you say to them? Do you have any kind of personal "maxim"? Why do you think it's important? *[RESEARCHER: If health-related issues arise, ask when it became important to have a healthy life in your family and/or social environment]*

Exploration area	**2. MEANING OF QUALITY OF LIFE (15 min)**
Goals	• **Understand what they associate to quality of life** • **Understand the impact of different HF symptoms on their quality of life**
Ethnographic explanation	*Now I would like us to talk about those things that for you represent quality of life.*

6. **Quality of Life.** Definition: Now that you have completed this map, how would you define quality of life?
    a) What things allow you to have quality of life? How do you feel about them?
    b) What other things keep you from having a better quality of life? How do you feel about them?
7. **Current feeling:** How do you feel at this moment in your life? Do you have any small rituals that help you in your day to day? *RESEARCHER: Ask about eating habits, physical activity, cultural activities, etc.*
    a) Is there anything that particularly bothers you? Could you give me an example?
    b) What makes you happy?
    c) If you could improve 3 things from your day to day, what things would you choose? What would you give up?

Exploration area	**3. HEART FAILURE (15 min)**
Goals	• **Understand the impact of HF on the patient's life** • **Understand the patient's perception of HF**
Ethnographic explanation	*Now I would like you to tell me specifically about the disease you suffer...*

8. **HF:** I would like you to explain to me in your own words how do you see heart failure.

9. **Explanation of the disease**: Do you remember how they explained to you what HF was? What words did they use? Who did so? Could it have been done better? What did they miss?

10. **Living with HF:** What is it like to live with HF? When do you feel it becomes more "uphill"? What helps you overcome it?

11. **Other diagnoses:** Are you diagnosed with other diseases? Were they prior to HF? Are they related in any way?

Exploration area	**4. LIFE JOURNEY (15 min)**
Goals	- **Understand the impact of HF on the patient's life** - **Understand the patient's perception of HF**
Ethnographic explanation	*To continue I would like us to briefly talk about the most important moments with the disease ...*

12. **Significant moments with the disease:** Now I would like you to think about 5-6 significant moments since you were diagnosed with the disease. *RESEARCHER: Write down every moment in a post-it. Pay attention to whether hospitalization, transplant or heart attack arise spontaneously and if not, ask if you have experienced any of these moments and if so write them down next to the other moments.*
    a) Why have you precisely chosen these moments?
    b) How did you experience each of these moments?
    c) Which one of them was the best moment for you? *RESEARCHER: Ask what "the best" means to this patient*
    d) Which one of them was the worst moment for you? *RESEARCHER: Ask what "the worst" means and, if it is related to the patient's illness, ask:* → Is there anything that could have better helped you cope during those times?
    e) Which of these moments changed your life the most? Why?

13. **Life before HF**: What was your life like before you were diagnosed with HF? What things have changed the most? What do you miss?
    c) Since you were diagnosed… how has your lifestyle changed? How do you feel about it? What could help you?
    d) At the beginning of the interview, you explained to me what a day in your life looks like. How would this change if life were the way it used to be?
    e) Could you specify how you think the disease changed your life? *[RESEARCHER: dig into issues such as new interpretations of reality, changes in values, etc.]*

Exploration area	**5. CARE AND EMOTIONAL PROCESS (20 min.)**
Goals	- **Understand the HF Patient Journey** - **Identify unmet needs** - **Understand the perception of the different treatments that the patient has gone through**
Ethnographic explanation	*Now I would like us to delve into the journey you have followed since the beginning of the risk factors until now…*

Let's assume that you meet a person who has just been diagnosed with heart failure and does not know what it means to suffer from this condition. If you asked him to tell you about your experience, from the first symptoms until today

14. **Life without the disease**: What was your life like before the disease? If you look back, what do you miss the most?
15. **Previous diseases:** What diseases have you been diagnosed with? Who diagnosed you?
    a) Were you warned of the risk of developing heart failure?
    b) What did they explain to you?
    c) Were you advised to make lifestyle changes? *RESEARCHER, ask about exercise, diet, tobacco, or alcohol consumption...*
    d) Were you given any preventive treatment?
16. **First symptoms:**
    a) What changes did you experience that made you think something was wrong? For how long?
    b) What did you think might be going on?
17. **Diagnosis:**
    a) Do you remember what was explained to you?
    b) What tests have you done? Was the process burdensome?
    c) What doubts did you have?
    d) What did you think was going to happen at the time?
    e) Did you search for information on the internet?
    f) Did you contact any patient associations?
    g) Have you met anyone with this condition during the process? How has it affected you?
18. **First treatment:**
    a) Do you remember the name of your treatment?
    b) How was the first medication taken?
    c) Did you have any routines to do so?
    d) Did you stop taking the treatment at some point?
19. **Follow-up visits:**
    a) What were the routines of the visits like?

   b) Was it hard for you to make them? Currently, how do you feel when you must go to the doctor?

20. **Evolution of the disease:**
    a) How did you find out that the disease was changing? Were there any significant moments?

21. **Hospital admission** (if applies)**:**
    a) What was the process like? How many days last the hospital admission?

    b) How was the experience in the emergency room?

    c) Have you had more than one hospital admission?

22. **Surgery** (if applies)**:**
    a) What kind of device was implanted? Would you be able to explain how it works?

    b) What things does it allow you to do that you couldn't do before? How does this make you feel?

    c) What things can't you do now? How does this make you feel?

23. **Experience PROM questionnaires:** before the interview you answered a set of questionnaires about your symptoms and quality of life.
    a) From what we talked about during the interview, what things do you think should be included in these questionnaires?

    b) What things should your cardiologist know to make decisions?

Exploration area	**6. HOME TOUR (10 min.)**
Goals	• **Complement and contrast the information obtained during the interview with the patient's environment.** • **Understand the immediate context in which patients live (routines, rituals, and concessions to the HF)**
Ethnographic explanation	*For us it would be very useful to be able to understand how the disease affects your day to day. If you could show us your house, please, I'm sure it would help us understand...*

RESEARCHER: The home visit should be made at the appropriate time during the interview. It should be done naturally as a continuation of the conversation: asking for places and things inside the house (medicines, refrigerator, sofa, bedroom) that are important in terms of the impact that HF has on your life be shown.

For instance, ask whether there has been any home reform since they have had HF diagnosed. As you walk around, ask the patient about their daily routines and their life under treatment. Try to understand how the patient has adapted his/her life to the disease and his/her level of activity.

If the participant does not mention anything spontaneously, focus on:

- *Evidence that signals his/her 'lifestyle', hobbies.*
- *Written information about HF.*
- *Evidence of contact with HCPs.*

- *Rooms where she/he takes treatment or workout.*
- *Rooms where medicines are stored.*

Please, contrast the information mentioned during the interview with what you observe in the house. If allowed by the participant, take pictures of everything the patient deems relevant to treatment and their life with HF.

With this we would conclude the interview. Thank you very much for your time and participation. Do you have any comments or questions you want to share?

[END RECORDING]

2. OBSERVATION GUIDE OF MEDICAL APPOINTMENTS WITH HCPS

This guide is intended to guide the observation before, during and after the medical visit of selected patients. During the appointment, neither the patient nor the doctor will be asked questions by the researcher.

The objectives of the visit are:

1. Observe whether which topics are discussed during the medical appointment, and whether any of them is directly related to quality of life with the condition.
2. Understand the language that is used by both parties when talking about the condition.

RESEARCHER, prior to the visit, make sure that the patient understands the purpose of the observation within the study.

I – PRE-VISIT: Observation of the hospital environment

RESEARCHER, indicate the center, scheduled time of the visit and the start time of the observation.

Begin by observing the ***hospitals environment.*** *What surprises you the most? Why?*
Focus on:

- Occupancy of the center: number of patients in the waiting room, number of health workers.
- Space: design, decoration, lighting, colors, atmosphere.
- Organization: Allocation and ease of access.

Observe the ***interviewee.*** *What does he/she look like? (For example, tired, relaxed, irritated, etc.) Is there anything that stands out? Inquire about your expectations before the visit.*
Focus on:

- Arrival time, ease of access, companions (if applies).
- Body posture and non-verbal signs (facial expression, comfort level with the accompanying situation).
- Preparation for the visit: if the patient brings documents, medical tests, notebooks or tracking applications.
- Waiting times for the visit.
- If applies: Interaction with other health agents (residents, reception, nursing).

II – DURING THE VISIT: Observation of the patient medical interaction

RESEARCHER: Describe the physical space, organization, and arrangement of furniture. Also write down the ***exact time of the start of the visit.***
Focus on:

- Initial time of the visit.
- Initial greeting, use of gestures and non-verbal cues.
- Initial conversation. How general are they? How specific?
    - Questions from the doctor, order, and type.

        - On quality of life and/or impact of HF on a day-to-day basis.
        - Type of assessment and use of questionnaires.
        - Types of recommendations (functional, social, quality of life).
        - How the patient responds.
    - Questions from the patient, order, and type.
        - On quality of life and/or impact of HF on a day-to-day basis.
        - How your doctor responds
- Central conversation:
    - Topics of conversation that arouse greater patient attention (e.g., quality of life, impact on daily activity).
    - Topics of conversation that arouse greater attention from the doctor (e.g., clinical, psychological, or social, quality of life or other aspects).
    - Dominant language; use of colloquial language vs medical language.
- Body posture, proxemics and physical distance from the patient and the doctor during the visit.
- Use of silences and non-verbal gestures (gestures of approval, doubt, or confusion).
- Closing of the visit
    - Time and language used for the closing of the visit.
    - Approach of next steps by the doctor and the patient.
    - Farewell, use of gestures and non-verbal cues.
- If applies: interaction with other health agents (residents, receptionist, nursing).

III – AFTER THE VISIT: Observation of the patient

RESEARCHER: Write down the exact ***time of the end*** *of the visit. Accompany the patient at the exit of the visit and / or another instance of contact related to the visit (reception desks). If possible, know your perception about the results of the visit.*

Focus on:

- End time/duration of the visit.
- The patient's body posture and non-verbal gestures.
- Language used to assess the visit.
- If applies: interaction with other health agents (residents, reception, nursing).

End of observation.***