Online Supplement
Nighttime Symptom Burden in Chronic Obstructive Pulmonary Disease: A Qualitative Study

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KR2402 INTERVIEW GUIDE AND SURVEY QUESTIONS

a. Instructions to Interviewer

The purpose of this interview is to understand patients' perceptions of nighttime symptoms associated with COPD, their impact on sleep, and preferences and experiences with different treatment regimens and devices. The interview will last approximately 60 minutes. You may adapt the guide based on the flow of the conversation and responses from the participant.

Patients may discuss ways to cope with COPD symptoms in the evening and early morning. For example, they may take additional rescue medication to preemptively treat nighttime symptoms. All such ways of coping with the disease in the evening or early morning may relate to nighttime symptoms. If reported by the patient, the interviewer should probe further how the symptoms relate to their symptoms at night and how this is associated with the frequency of their maintenance medication (once / twice daily).

b. Introduction [5 min]

Thank you for taking the time to speak with me today. My name is [Interviewer's name]. I am a [Role] with Kielo Research.

The purpose of this interview is **to get your experiences with COPD nighttime symptoms, impacts and treatment**. We are interested in your impressions, experiences, and opinions to understand what matters to patients like you. There are no right or wrong answers; we are interested in your personal experiences and opinions.

1. Do you still want to take part in this interview? [If yes, continue; if no, terminate call]

This interview will be audio-recorded to ensure we capture everything you say. This recording will be kept confidential, and your name will not be linked with your responses.

2. Do I have your permission to audio-record the interview? [If yes, proceed with the interview; if no, inform the patient they must be recorded to participate]

i. Discussion Rules

Before we begin, let me suggest some things to make our discussion more productive.

- My role here is to ask questions and to listen. I'll also summarise the information you've said at times to ensure I understand you correctly. I'll ask questions to obtain your feedback, and I'll move the discussion from one question to the next to keep us on track so that we can finish within the time we have.
- Please speak loudly. We're audio-recording the session because we don't want to miss any of your comments.
- I will not use your name during the interview after the recording starts.
- There are just a few other things that I want to let you know.
- I am not a medical doctor. I am a research professional. My background is in conducting various types of research, so I am not qualified to give out medical advice.
- I want to remind you that you are a volunteer in this study, so you can skip any question you do not want to answer or stop the interview at any time. All your responses will be kept confidential.

Do you have any questions before we begin?

I'm going to start the recording.

[Start the Recorder]

This is study KR2402, qualitative interviews, with participant ID [Participant's ID]. Today's date is [Date].

1. Do I have your permission to record our interview?

[If no, please thank the participant and terminate the interview here]

2. Can you confirm that you have read the informed consent, and do you have any other questions you would like us to discuss?

[If needed, share the screen with the consent language on it and read it to the participant or let the participant read it]

3. After having read the consent form, do you agree to participate in this study?

[If no, please thank the participant and terminate the interview here]

c. Part 1: Diagnosis and Nighttime Symptoms [10 min]

i. Diagnosis

1. Can you tell me about when you were first diagnosed with COPD?
2. What symptoms led you to see a doctor?
3. How was your diagnosis explained to you?

ii. Nighttime Symptoms

1. Can you describe the current nighttime symptoms you experience as part of your COPD?

[Let patients describe their symptoms and mark them down (table 1) with S (spontaneous). Then, probe them for symptoms they have not described. Mark any symptoms they now confirm having experienced with P (probed).]

2. How frequently do these symptoms occur?

- Occasionally (or rarely)
- Sometimes (a few times per week)
- Frequently (most days)
- Always/constantly (or every day)

3. Can you describe the timing of your nighttime symptoms? For example, are they typically worse while you are trying to fall asleep or do your symptoms affect your sleep and cause you to wake up through the night?
4. Do you experience symptoms in the early morning when you are starting to wake up?

   Probe: If any, which one is worse in the morning

5. Can you describe the severity of these symptoms on a typical night? (On a scale of 0 to 10, where 0 means not at all and 10 means extremely severe)

[Write down the frequency and severity score (table 1).]

6. Which of these symptoms are the 3 most bothersome for you today? Why?

[Mark down the 3 most bothersome symptoms in the table below]

Table 1 . Nighttime symptoms

Symptoms	Experienced [S/P or No]	Frequency	Symptom severity score [0-10]	3 most bothersome [X]
Shortness of breath/Difficulty breathing				
Persistent Coughing				
Chest pain or tightness				
General pain				
M Wheezing				
Snoring				
Choking				
Mucus/phlegm production				

Difficulty falling asleep				
Difficulty staying asleep/Frequent awakenings				
Prolonged wakefulness				
Sweating/ night sweats				
Anxiety/ panic attacks at night				
Restlessness/ inability to relax				
Other:				

d. Part 2: Impact on Sleep [10 min]

1. Can you describe what impact do these nighttime symptoms have had on your everyday life?

   [Let patients describe their impacts and mark them down (table 2) in the corresponding categories with S (spontaneous). Then, probe them for impacts in categories they have not described. Mark any category of impacts they now confirm having experienced with P (probed).]

   Follow up with a question about early morning symptoms impacting their everyday life

2. How frequently do these impacts occur?
3. How severe are these impacts (On a scale of 0 to 10, where 0 means not at all and 10 means extremely severe)?

   [Write down the frequency and severity score (Table 2), note severity separately for evening and morning]

4. Which of these impacts are the 3 most bothersome for you today? Why?

   [Mark down the 3 most bothersome impacts in Table below.]

Table 2. Nighttime symptom impacts

Impacts	Experienced [S/P or No]	Frequency	Impact severity score [0-10]	3 most bothersome [X]
Reduced sleep quality				
Cognitive (Examples: concentration/focus, alertness, memory)				
Physical: (Examples: Daytime fatigue, exercising, household chores, running errands)				
Activities of self-care: (Examples: bathing, dressing, grooming, eating, toileting, transferring)				
Emotional: (Examples: anxiety, depression, sadness, frustration, embarrassment, guilt, fear of dying, de-motivation/impaired coping)				
Social: (Examples: reduced participation in leisure activities and hobbies, interaction with others or attendance to social gatherings or activities, social or cultural stigma)				
Relations/Intimacy (Examples: relationship with a partner, dating others, close relationships)				
Engaging in unhealthy behaviours (Examples: watching TV to avoid sleeping, snacking)				
Work/Studies				
Increased exacerbations (like hospital/doctor visit)				
Difficulty to manage comorbidities				
Financial impact				
Other:				

5. [If not mentioned:] On a typical night, how many hours of sleep do you get ? Do you feel rested in the morning? How many times do you wake up during the night?
6. Are you using any sleep management strategies to make you sleep better? E.g. sticking to a sleep routing, avoiding naps during the day, reducing media consumption before bedtime
7. What about your sleep environment, have you made any changes to your sleep environment to help you to sleep better?
8. Do you take medication or dietary supplements to help you sleep?

e. Part 3: Managing Around-the-Clock Symptoms [5 min]

1. How do you manage your COPD nighttime symptoms throughout the night or early morning?
   [Probe: Behavior changes, rescue medication use, or other strategies.]

   a. Are there any specific strategies or treatments you rely on more during the night compared to the day?
   b. What do you find helpful in your symptom relief?

   If clarification needed for rescue medicine:

   *A **rescue medication** is a fast-acting inhaler that helps quickly relieve sudden breathing problems. It works by relaxing the muscles around the airways, making it easier to breathe. These are used **only when needed**, not for daily control (maintenance).*

2. How often do you use rescue medication to manage your COPD symptoms?

b. Is the frequency of rescue medication use different during the day versus the night? If so, why?
c. Do you feel your rescue medication is effective in alleviating your symptoms, particularly during the night? Why or why not?
d. Do you ever take rescue medication before going to bed? If so, why? [Probe: is it to prevent nighttime symptoms]

3. Do you feel your current treatment regimen adequately addresses your nighttime and daytime symptoms? Why or why not?
4. In your opinion, what changes would improve your sleep quality while managing your COPD symptoms?

a. Part 4: Preferences for Once- vs. Twice-Daily Therapy [10 min]

1. Have you used both once-daily and twice-daily COPD therapies? If so, can you describe your experiences with each? [Probe: Ease of use, effectiveness, side effects, convenience]

2. If applicable: Do you notice differences in how these therapies impact your nighttime symptoms?

   [For twice-daily therapies:]

   a. What do you find valuable about the second daily dose?
   b. Does the second dose provide additional relief or benefits in your nighttime comfort or sleep?

3. If applicable: How does the dosing schedule (once-daily or twice-daily) fit into your daily routine?
4. If applicable: Have you faced any challenges incorporating the therapy into your schedule?

   [Probe: Have you ever forgotten to take a dose?]

5. [If applicable, for participants who have switched from dual to triple therapy:] How has this transition impacted your preferences for dosing schedules?

   a. Did switching treatments change how you feel about once-daily or twice-daily therapies?

6. If you were to choose a therapy, which dosing schedule would you prefer, and why?

b. Part 5: Experiences with Inhaler Devices [10 min]

1. What type of inhaler are you currently using?
    - [Probe:] Is it a metered dose, dry powder, or soft mist inhaler?

        [If participant needs more information, these inhaler types are:

        1. Metered dose inhaler: Puffs dose of medicine when you press on it. Medicine is held in a pressurized canister.
        2. Dry powder inhaler: Delivers powder medicine when you inhale.
        3. Soft mist: Sprays dose of medicine when you press on it. Medicine comes in a liquid format and is turned into a fine mist when you spray]

2. Can you describe your experience with your current inhaler device?
   [Probe: Ease of use, effectiveness, maintenance requirements, side effects.]
3. Have you used other types of inhalers in the past? How did your experience with those compare to your current device?
4. Does the type of inhaler device impact how well you feel your symptoms are managed? If so, how do you measure that? How do you know you're feeling better?
5. What improvements, if any, would you like to see in your inhaler device?

c. Closing [10 min]

We would now like to complete a questionnaire on you and your current health status. Thank you for your valuable insights so far.

[Complete the online questionnaire (next section) with the participant.]

SHORT QUESTIONNAIRE ON SOCIODEMOGRAPHIC AND CLINICAL INFORMATION

Moderator to enter participant ID [_____]

1. What best describes the area you live in? [implement as radio buttons]
    - Urban
    - Suburban
    - Rural
2. What was your total household income before taxes during the past 12 months? [implement as radio buttons]
    - Less than $25,000
    - $25,000 to $34,999
    - $35,000 to $49,999
    - $50,000 to $74,999
    - $75,000 to $99,999
    - $100,000 to $149,999
    - $150,000 or more
    - Don’t know or prefer not to answer
3. How would you describe your race or ethnicity? (you can choose multiple options) [implement as checkboxes]
    - White
    - Black or African American
    - American Indian or Alaska Native
    - Asian
    - Native Hawaiian or Other Pacific Islander
    - Hispanic

- Other

4. What best describes your marital status? [implement as radio buttons]
    - Married
    - Separated/divorced
    - Widowed
    - Living with partner
    - Single
5. What best describes your employment status? [implement as radio buttons]
    - Employed, full-time
    - Employed, part-time
    - Self-employed
    - Voluntary work
    - Home maker
    - Retired
    - Student
    - Unemployed
    - On sick leave
6. What is the highest level of education you have completed? [implement options as radio buttons]

    - Elementary/primary school
    - Middle school/ junior high school
    - High school
    - Some college/ university

- College/university (BA, BSc)
- Postgraduate degree (Masters, MD, PhD)

7. What type of health insurance do you have? (select all that apply) [implement options as check boxes]

   - Employer-provided insurance
   - Self-provided insurance
   - Veterans Affairs / Military healthcare
   - Medicare
   - Medicaid
   - None (uninsured)

8. How long ago were you diagnosed with COPD? [implement as radio buttons]
   - Less than 1 year
   - 1–5 years
   - 6–10 years
   - More than 10 years

9. What is your current smoking status? [implement as radio buttons]
   - Never smoked
   - Current smoker
   - Former smoker

10. *[Only ask if answer to 7. is 'Current smoker' or 'Former smoker']*
    What is the total number of years you have smoked in your lifetime? Do not include the times when you were smoke free.
    - Less than 5 years
    - 6-9 years
    - 10-19 years
    - 20 years or more

11. What rescue medications do you use for your COPD symptoms?
    (Please select the medication you take to treat symptoms when they get too bad or worsen unexpectedly) [implement as check boxes]
    - Ventolin or other inhaler
    - Nebulizer
    - Other (Specify: _____)
12. How often do you use your rescue medication for COPD symptoms? [Implement as radio buttons]
    - Daily
    - 3-6 days per week
    - 1-2 days per week
    - 0 days per week
13. What time of day you typically use your rescue medication for COPD symptoms (check all that apply)? [Implement as check boxes]
    - Morning
    - Afternoon
    - Evening
    - Night
14. Has a doctor ever told you that you have one of the following conditions? Check all that you have been diagnosed with [implement as checkboxes]
    - Hypertension
    - Diabetes (type 1 or type 2)
    - Cancer (other than a minor skin cancer)
    - Heart attack
    - Heart failure
    - Angina

- Arthritis
- Stroke
- Kidney disease
- Sleep apnea
- Depression
- Anxiety

15. Have you used a continuous positive airway pressure (CPAP) machine to help with breathing while you sleep?
    - Yes, currently using
    - Yes, have used in the past but not currently using
    - No, never used

16. How much of the time during the past 4 weeks did you feel tired? [implement as radio buttons]
    - All of the time
    - Most of the time
    - Some of the time
    - A little of the time
    - None of the time

17. By yourself and not using aids, do you have any difficulty walking up 10 steps without resting? [implement as radio buttons]
    - Yes
    - No

18. By yourself and not using aids, do you have any difficulty walking several hundred yards? [implement as radio buttons]
    - Yes
    - No

19. How much do you weigh with your clothes on but without shoes?
___ KG [allow only numbers between 30 and 300]
or
___ LBS [allow only numbers between 60 and 600]
[Allow only one of these to be filled]

20. One year ago, how much did you weigh with your clothes on but without shoes?
___ KG [allow only numbers between 30 and 300]
___ LBS
[Present only the unit answered in the previous question]

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For each question below, please check □ the response that best represents how you feel. When answering the questions, please think about the impact of breathing problems/COPD/asthma on your sleep during the past week, even if the past week was unusually good or unusually bad.

[implement as radio button group per row]

During the past week, how often did you:	Never	Rarely	Sometimes	Often	Very Often
1. have a bad night's sleep?	☐	☐	☐	☐	☐
2. have problems staying awake during the day?	☐	☐	☐	☐	☐
3. have trouble falling asleep?	☐	☐	☐	☐	☐
4. wake up at night with breathing problems (shortness of breath, coughing, chest tightness, etc.)?	☐	☐	☐	☐	☐

5. wake up during the night and have trouble falling back asleep?	☐	☐	☐	☐	☐

Please think about the <u>impact of your breathing problems during the past week</u>, and check ☑ the response that best represents how you feel.

[implement as radio button group per row]

During the past week, how often did you:	Never	Rarely	Sometimes	Often	Very Often
6. have a good night's sleep?	☐	☐	☐	☐	☐
7. wake up feeling rested?	☐	☐	☐	☐	☐