

# Developing a patient-reported outcome (PRO) measure for Japanese patients with non-metastatic castration resistant prostate cancer (nmCRPC)

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## BACKGROUND

- Previous qualitative interviews with Japanese nmCRPC patients highlighted many symptoms and impacts that are not yet covered in existing PC PROs,<sup>1</sup> and there were no dedicated nmCRPC measures
- We aimed to develop a new PRO with potential utility in clinical practice among Japanese urologists to better assess the effects of nmCRPC and treatment and for patients to better understand their health-related quality of life (HRQOL)

## OBJECTIVES

- Develop a content-valid PRO instrument to assess HRQOL in Japanese nmCRPC patients
- Evaluate and refine the draft PRO instrument through iterative cognitive debriefing interviews with nmCRPC-diagnosed patients
- Evaluate the wording, response options, instructions, and overall suitability and content validity of the resulting PRO instrument

## METHODS

- Trained, native Japanese-speaking interviewers conducted qualitative cognitive debriefing interviews with adult nmCRPC patients who were previously treated with ≥1 line of androgen deprivation therapy
- The cognitive interviews assessed patient comprehension, perceived relevance, and appropriateness of the recall period of the 14-item draft PRO instrument and an accompanying 12-item draft checklist
- Four waves of interviews (n=8, n=4, n=4, n=3) allowed for iterative analysis and revision of the draft PRO based on interview findings
- All interviews were recorded, transcribed, and coded for analysis using ATLAS.ti

## RESULTS

### Study Participants

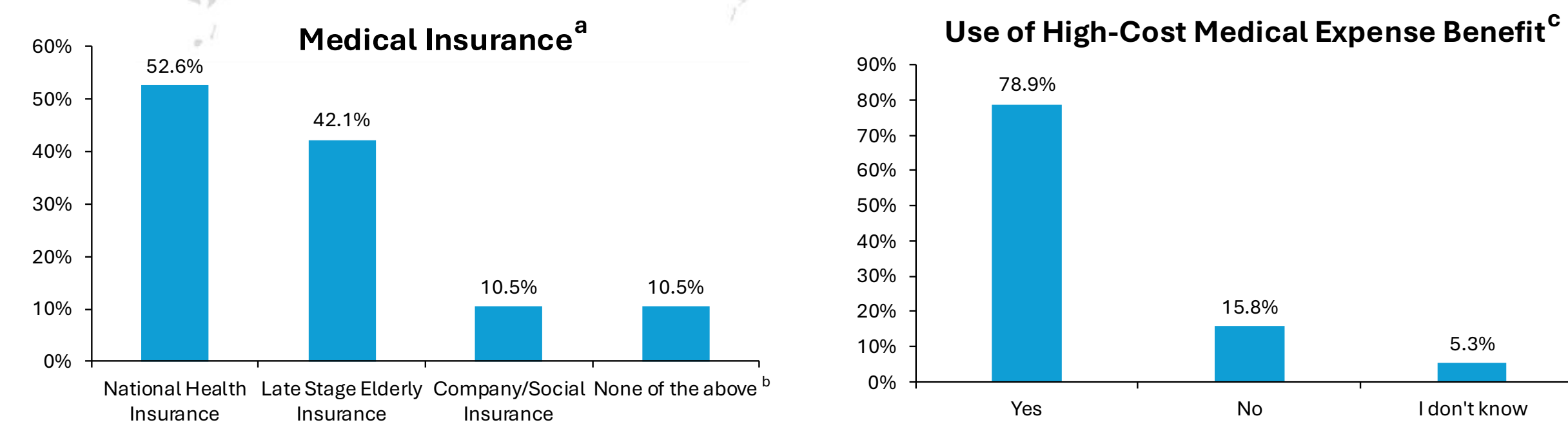
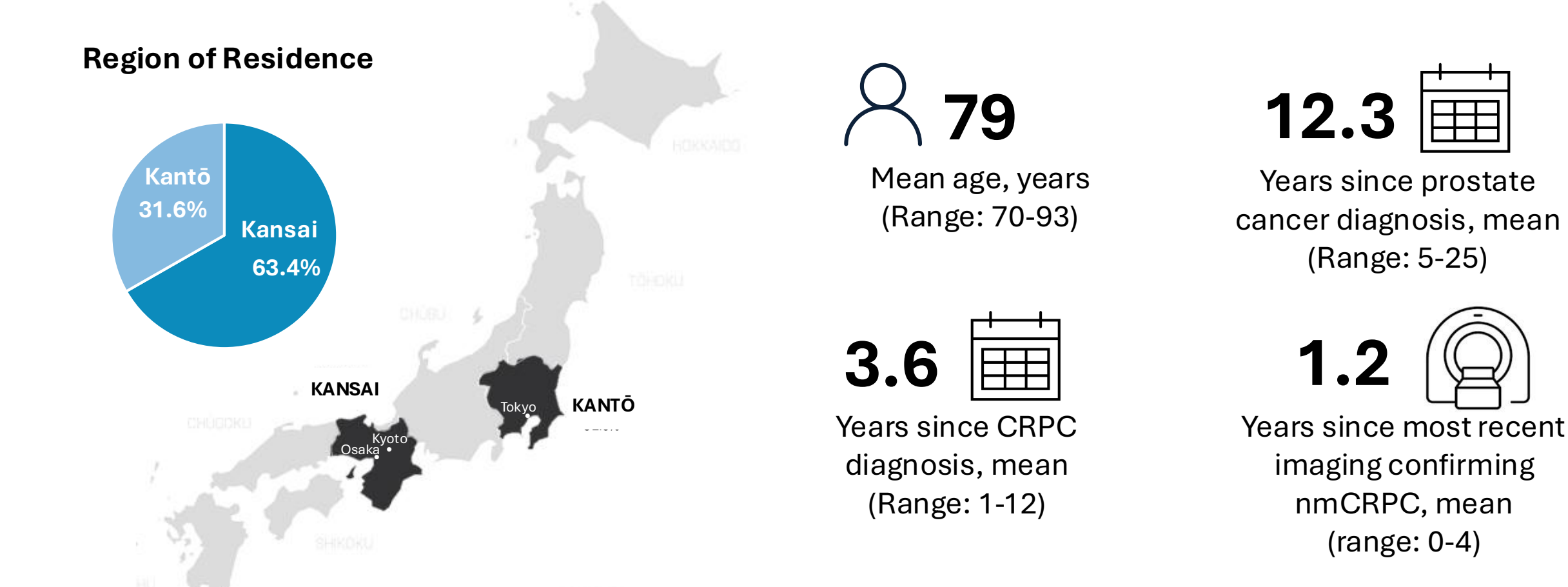
- Twenty patients were recruited to participate in the study; data from 19 participants were used in the analysis
- Mean age was 79 years (Figure 1), 100% were asymptomatic at enrollment

### PRO Measure

- The draft PRO instructions were well understood (overall comprehension rate: 89%)
- Participants reported minimal difficulty with the 7-day recall period instructions and difficulty lessened with iterative updates (from 25% to 0%)
- Comprehension of individual items was high (84%-100%), suggesting participants understood the content and intent

## RESULTS (cont'd)

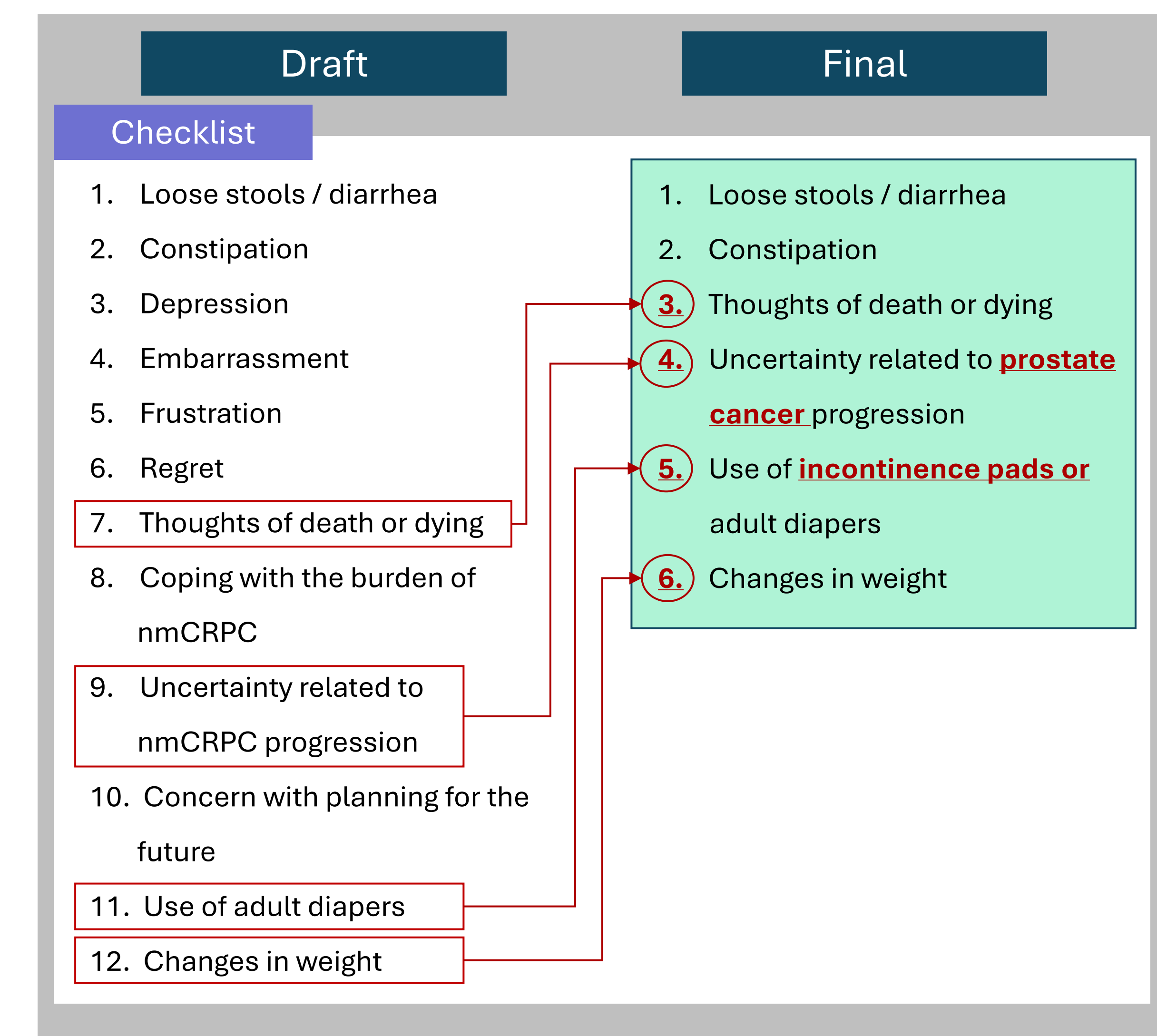
Figure 1. Participant Characteristics



<sup>a</sup> Some participants selected more than one response; therefore, the percentages may add up to more than 100%. <sup>b</sup> Presented to participants as "None of the above (all treatment costs paid by myself/my family)" in the demographic and health information form. <sup>c</sup> The high-cost medical expense benefit system subsidizes medical costs that exceed monthly out-of-pocket maximums (determined according to a beneficiary's income and age).

- Participants had minimal difficulty in answering most items. Most were able to select a response option and articulate their reasoning
- Item 5 (sexual function) posed challenges in Waves 1-3 for participants experiencing a total loss of sexual function. Refined response options in Wave 4 saw 100% of participants able to select a response without difficulty
- The most reported symptoms were urinary frequency during waking hours (100% [relevance: 79%]) and at night (89% [74%]) and difficulty urinating (89% [74%])
- All 14 draft PRO items were retained (Figure 2)

Figure 3. Items in Checklist (Draft and Final)

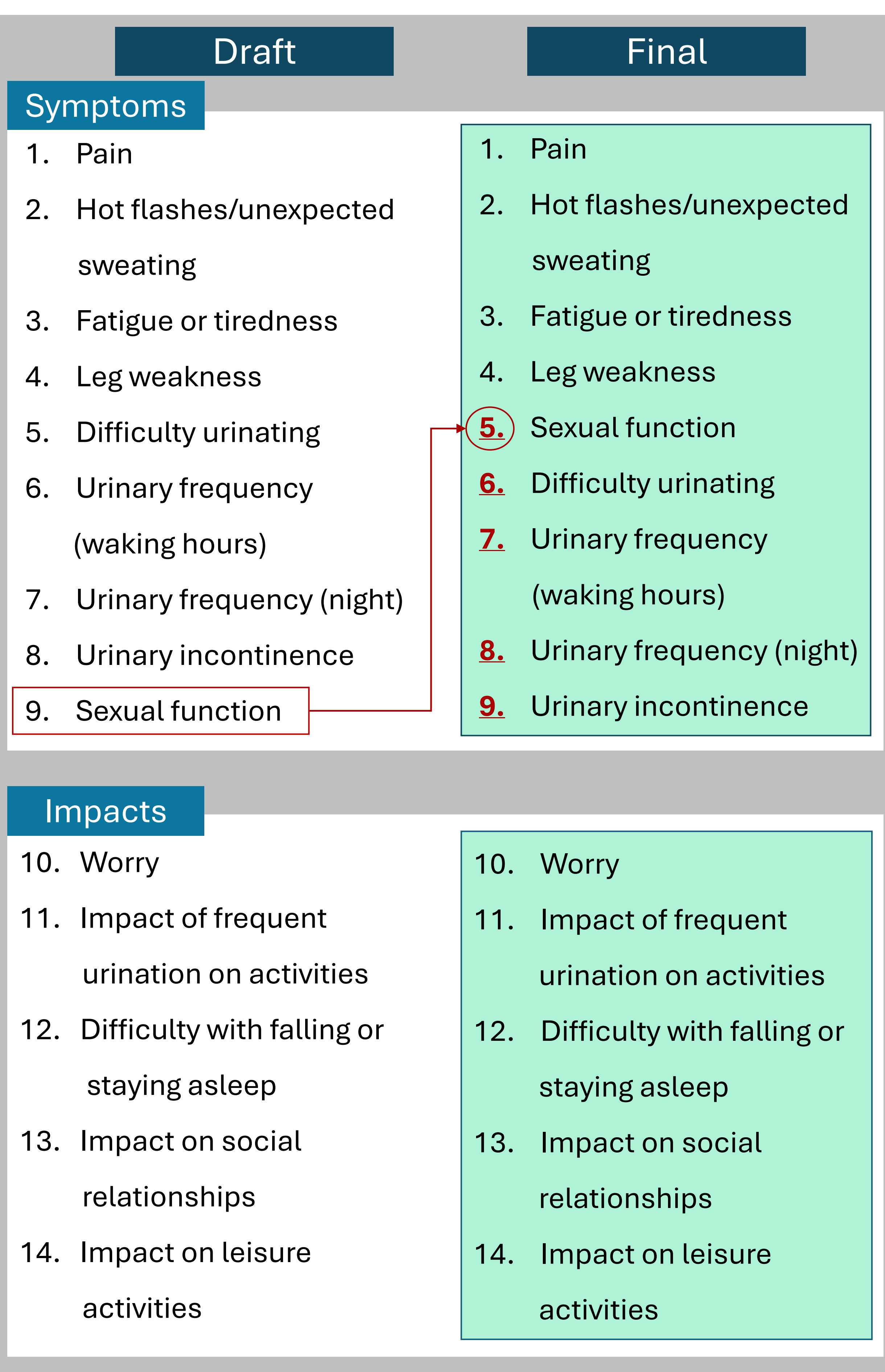


<sup>a</sup> Changes indicated in red. Shapes and lines used to indicate where items changed order. Abbreviations: nmCRPC, non-metastatic castration resistant prostate cancer; PRO, patient reported outcome.

## CONCLUSIONS

- This study supports the content validity of the PRO measure as a valuable tool for capturing patient-reported HRQOL impacts in Japanese nmCRPC patients
- The refined checklist ensures that the most relevant items are retained while minimizing patient burden
- The findings support the measure's integration into clinical settings to support patient-centered evaluation of treatment risks and benefits and enhance patient-clinician communication

Figure 2. Items in PRO Measure (Draft and Final)



<sup>a</sup> Changes indicated in red. Shapes and lines used to indicate where items changed order. Abbreviations: nmCRPC, non-metastatic castration resistant prostate cancer; PRO, patient reported outcome.

### Checklist

- Checklist instructions were well understood (84.2%)
  - Early terminology-related difficulties in Wave 1 were resolved by replacing "nmCRPC" with "prostate cancer," eliminating issues in later waves

- Participants reported minimal difficulty with the "past month" recall period instructions (comprehension: 50% to 100% across waves)
- Comprehension rates for individual items ranged from 57.9% to 100% of responding participants, with most items demonstrating high understanding
- The perceived relevance of draft checklist items varied. Physical symptom-related items were widely applicable, while emotional and psychological items were considered less relevant by some participants. Items such as "Thoughts of Death or Dying" and "Coping with the Burden of Prostate Cancer" received mixed perceptions of relevance, as participants often linked these concerns more to aging or general life experiences rather than specifically to prostate cancer
- The final checklist retained 6 items that were commonly reported and considered relevant by participants (Figure 3)

## LIMITATIONS

- Qualitative observational design and a targeted sample may introduce selection or interpretation bias
- Clinician interpretability and workflow fit were not assessed
- Developed in an urban Japanese nmCRPC cohort so generalizability to other settings and populations is untested

## FUTURE DIRECTIONS FOR RESEARCH

- Psychometric validation of the PRO measure and conducting longitudinal studies to assess how HRQOL evolves over time, ensuring this tool continues to provide meaningful patient-centered insights

## REFERENCE

1. Nishimura K, Shiota M, Eto M, et al. *Cancer Med*. 2022;12(2):1762-78.

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