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Cross-Cultural Adaptation of the Oral Frailty Index-8 for United States English-Speakers

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Abstract

Objective. Oral frailty, the age-related decline in oral and pharyngeal function, is associated with physical frailty, sarcopenia, and cognitive decline. The Oral Frailty Index-8 (OFI-8) is a patient-reported outcome measure developed in Japan to assess oral frailty risk. This study aimed to culturally and linguistically adapt the OFI-8 for English-speaking older adults in the United States.

Study Design. Cross-cultural and cross-linguistic adaptation of the OFI-8 by an expert committee, followed by administration of the adapted OFI-8 and structured cognitive interviews with 22 English-speaking adults aged 65 years and older.

Setting. Outpatient tertiary academic voice and swallowing center in New York City.

Methods. Following the Professional Society for Health Economics and Outcomes Research (ISPOR) guidelines, the OFI-8 underwent forward translation, back translation, expert committee review, and reconciliation. Cognitive interviews were then conducted with 22 participants aged 65 years and older. A think-aloud and verbal-probing approach was used to evaluate comprehension, clarity, and cultural appropriateness. Interviews were transcribed and analyzed using thematic analysis.

Results. Several cultural adaptations were made, including replacing Japanese food examples with US-familiar foods of similar texture. Three questionnaire items and the instructions were refined following participant feedback to improve syntactic flow, clarity, and understanding. The final US-English version maintained conceptual equivalence of the original OFI-8 while adapting language and examples for US cultural relevance.

Conclusion. A culturally adapted US-English version of the OFI-8 was developed through structured translation, expert review, and cognitive interviews. Further validation studies are necessary to establish its clinimetric properties and

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support clinical application for early detection of oral frailty in US older adults.

Keywords

aging, cross-cultural adaptation, dysphagia, oral frailty, patient-reported outcomes measures

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ral health is a requirement for longevity. 1-3 Oral frailty refers to an age-related decline in oral function considering the number of remaining teeth, oral hygiene, oral muscular strength, and coordination in activities such as chewing, swallowing, and speaking.4 The concept was initially introduced in Japan in 2014, reflecting the unique role and contributions of dentists in swallowing care in the country with the oldest population in the world. This early research into oral frailty was spearheaded by Japanese gerontologists in response to the initiation of public government programs in Japan starting in 2006, which aimed to reduce the long-term care needs of the country's growing population of older patients.^{5,6} The term "oral frailty" was first operationalized by the team of Tanaka et al of the Institute of Gerontology at the University of Tokyo in a study that confirmed poor oral status—oral frailty—as a statistically significant predictor of present and future physical frailty.7

Oral frailty leads to an inability to attain proper nutrition through one's diet. Specifically, poor oral function has been shown to cause decreased dietary protein intake, loss of appetite, weight loss, sarcopenia, and chronic malnutrition. 8-11 Such malnutrition, particularly in older patients, leads to physical frailty, which further exacerbates oral frailty. 8 Oral and general frailty function in a vicious cycle in which one exacerbates the other. Thus, oral frailty is a key component of a larger geriatric frailty syndrome. In their pioneering 2018 study, Tanaka et al of the University of Tokyo laid out six statistically significant clinical criteria for diagnosing oral frailty. These include the number of remaining natural teeth, masticatory performance, maximum tongue pressure, articulatory motor skill, subjective difficulty eating tough foods, and subjective difficulty swallowing.⁷ The study concluded that poor function in at least three out of these six domains is associated with a 2.4-fold increased risk of physical frailty, 2.2-fold increased risk of sarcopenia, 2.3-fold increased risk of disability, and 2.2-fold increased risk of mortality, and is therefore diagnostic of oral frailty.7

The Oral Frailty Index (OFI-8) is an eight-item patient-reported outcome measure (PROM) developed by Tanaka et al (2018) to screen community-dwelling older adults at risk of oral frailty and facilitate early intervention. ^{7,12} It includes eight items addressing tooth loss, oral function, health-related behaviors, and reduced social

participation. A score of four or more indicates a high risk of oral frailty. Broad implementation of the OFI-8 may also help raise awareness and improve oral health literacy among older adults. ¹²

Developed and validated in Japan, the OFI-8 includes culturally specific references, such as foods typical of the Japanese diet. To ensure meaningful use in other populations, PROMs must undergo not only linguistic translation but also cultural adaptation. Without this process, results may fail to capture the intended constructs. Cross-cultural adaptation helps maintain both conceptual equivalence and cultural relevance, supporting the instrument's reliability and validity. 13,14

This study aims to develop a culturally and linguistically adapted version of the Japanese OFI-8 for English-speaking older adults in the United States. The adaptation process followed established guidelines to ensure semantic, idiomatic, experiential, and conceptual equivalence. By aligning the content with the US cultural and linguistic context, the resulting US-OFI-8 seeks to improve the early detection of oral frailty and support clinical decision-making in diverse care settings.

Materials and Methods

The study was conducted in six stages to ensure an accurate and applicable version of the OFI-8 for US-English-speaking populations. These stages included translation, back translation, reconciliation, an expert committee review, and cognitive interviews to validate the adaptation. Written permission was obtained from the original developers of the original OFI-8 in its Japanese version to adapt and translate the instrument.

Stage I: Project Initiation and Permission

A core committee was established to oversee the adaptation process. It included a laryngologist (A.R.), speech-language pathologists (SLPs) with expertise in swallowing disorders and PROM research (V.M., J.A.C.), a researcher and medical student (C.J.K.), and one member with specific experience in cross-cultural linguistic validation (A.C.-A.). The committee collaboratively planned the workflow and methodology, following ISPOR guidelines for the cultural adaptation of PROMs. A summary of the translation process is presented in **Figure 1**. This protocol followed the ISPOR Principles of Good Practice for translating and cultural adaptation of PROMs. A flowchart detailing the translation process is presented in **Figure 1**.

Stage II: Translation Process

Forward translation was carried out independently by two bilingual experts fluent in Japanese and English. A third expert (J.K.) reconciled both versions into a unified draft, prioritizing clarity, naturalness, and fidelity to the original meaning. This reconciled version was then

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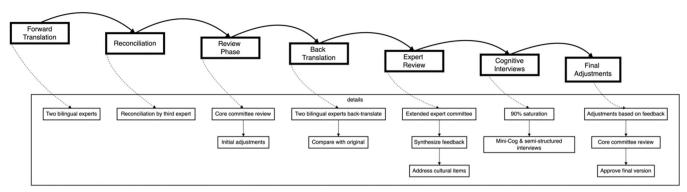


Figure 1. Flowchart of the translation and adaptation process for the Oral Frailty Index-8 (OFI-8) into US English.

back-translated into Japanese by two additional bilingual experts blinded to the original. Discrepancies between the back translations and the original Japanese version were analyzed to identify ambiguities or shifts in meaning. Revisions were made accordingly to ensure conceptual equivalence and cultural relevance. The resulting version was then submitted to the expert committee for further review and refinement (stage III).

Stage III: Expert Committee Review and Reconciliation

An extended Japanese-English expert committee was established to ensure comprehensive feedback on the project. This committee included a laryngologist (R.U.), a dentist (K.M.), gerontologists (T.I., T.T., and K.I.), a rehabilitation medicine physician (E.S.), an academic speech pathologist (Y.I.), and a representative from the target population (K.K.). Additionally, two English-speaking SLPs with experience in research and working with the target population (S.M., N.R.-P.) were invited to provide feedback.

The initial review involved core committee members assessing the reconciled translation, with a focus on cultural and linguistic appropriateness. Both bilingual and monolingual experts reviewed the translation based on four main criteria: semantic, idiomatic, experiential, and conceptual equivalence. Each expert provided written feedback individually, which was compiled by the core committee and then discussed collectively to reach consensus, consistent with published recommendations for PROM development and adaptation. 15 Additionally, monolingual experts focused on ensuring that all expressions sounded natural and familiar to an Englishspeaking audience. Meanwhile, bilingual experts assessed if the translation conveyed the same meaning as the original Japanese text. Special attention was given to the adaptation of culturally specific items, such as comparing food textures (eg, takuan and dried squid), to identify analogous items in a US-based diet with similar texture, consistency, and frequency of consumption.

Feedback was synthesized and discussed by the core committee to produce a harmonized version that preserved the instrument's conceptual integrity while improving clarity and relevance for the US context.

Stage IV: Cognitive Interviews

To assess the clarity, cultural appropriateness, and interpretability of the adapted OFI-8, cross-cultural cognitive interviews (CCCIs) were conducted with English-speaking adults aged 65 and older. CCCI involves probing participants' understanding of each item, their response processes, and any areas of confusion, thereby confirming that the intended meaning is conveyed in the adapted version. ¹⁶⁻¹⁸

Participants were recruited from the Sean Parker Institute for the Voice—an outpatient voice and swallowing center within the Department of Otolaryngology Head and Neck Surgery at Weill Cornell Medicine, an academic hospital in New York City. Participants met the following inclusion criteria: age ≥ 65, English fluency, born in the United States or having lived/worked in the country for at least 40 years, and scoring ≥3 on the Mini-Cog, a screening test that assesses intact cognitive function. Diversity in racial, ethnic, and educational backgrounds was documented following the classifications set by the US Census classifications. ^{19,20}

Interviews were guided by a semi-structured script (Appendix 1) and conducted by a coauthor (V.M.) and a research collaborator.²¹ Participants read each item aloud, verbalized their thought processes, and identified any unclear terms. Probing questions explored their interpretation of meaning and response rationale. Interviews were recorded, stored in REDCap, and transcribed using Microsoft Word Transcribe.

Transcripts underwent thematic analysis. Comments were categorized into themes such as grammar/syntax, synonyms, cultural context, comprehension, and suggestions. When unclear, transcripts were verified against the original audio. The most prevalent issues were collaboratively extracted by V.M. and A.C.-A.

Stage V: Final Adjustments and Expert Consensus

Based on the findings from the cognitive interviews, final adjustments were made to the OFI-8. The core committee synthesized feedback from the cognitive interviews and the expert committee to develop a harmonized translation. The revised draft was circulated to the full expert panel, who provided written feedback. The core committee then met to

review these comments and reached consensus on the final wording, ensuring that all revisions adequately addressed the concerns raised.

Ethical Considerations

The study protocol was reviewed and approved by the Institutional Review Board (ID: 23-12026852) at Weill Cornell Medical College as an Exempt study. Informed consent was waived for this study, as no personal health information was collected. Participants were provided an overview of the study and an information sheet. Participants were assured that their responses would be anonymized, and confidentiality was maintained throughout the study.

Results

Translation and Expert Review

The initial translation of the OFI-8 into US English underwent forward and backward translation by independent translators. Discrepancies were reconciled by a core committee composed of bilingual experts, and refinements were made in collaboration with an extended expert committee. Changes focused on improving clarity, ensuring cultural relevance, and preserving conceptual equivalence.

Aspects such as item structure, syntactic flow, and terminology were adjusted to reflect common US-English usage while maintaining the Japanese version's original intent. Several culturally specific references, such as references to Japanese foods, were replaced with familiar US alternatives. A summary of item-level modifications, including all changes across translation stages and cognitive interviews, is provided in **Table 1**.

In addition to modifications to individual items, adaptations were made to other structural components of the instrument. The scoring system in the original Japanese version categorized respondents into three risk levels based on their total score: 0 to 2 points indicated low risk of oral frailty (「危険性は低い」), a score of 3 indicated moderate risk (「危険性あり」), and 4 points or more indicated high risk (「危険性が高い」). These categories were retained in the US-English version, but the phrasing was adjusted to align with health communication norms in the United States. The final Englishlanguage categories read: "0-2 = You are at low risk of oral frailty," "3 = You are at moderate risk of oral frailty," and "4 or more = You are at high risk of oral frailty."

The consultation message included in the original Japanese version—「かかりつけの歯科医院にご相談ください」 ("Please consult your regular dentist")—was also revised. In the adapted version, the phrase "Please consult a healthcare professional if your score is 3 or more" was adopted.

Cognitive Interviews

Cognitive interviews were conducted with 22 English-speaking participants aged 65 and older (mean age: 75.04;

range: 66-92 years), consisting of 19 patients and 3 caregivers seeking voice and swallowing care at the Sean Parker Institute for the Voice. Demographic characteristics are reported in **Figure 2**. Interviews followed a think-aloud and verbal-probing methodology to assess item clarity, cultural appropriateness, and ease of understanding.

Thematic analysis of transcripts revealed areas for improvement related to syntax, cultural references, and clarity, leading to revisions in three of the eight items and the instructional text. Item 1 was revised to improve fluency. The phrase "such as" was added and "foods" was repeated for clarity. Item 2 was revised for familiarity and clarity. The term "broth" was replaced with "tea", and "sometimes" was removed. Item 3 was revised to specify the type of dentures considered.

The instructional text was expanded in the US version to include a clear response prompt, as the original Japanese version did not contain an equivalent directive: "This is a simple checklist to identify oral frailty. A more in-depth evaluation of oral health and swallowing is recommended for those who get 3 or more points. Read the below statement and answer yes or no based on your experience."

No changes were made to the remaining five items, which were consistently understood and deemed culturally appropriate. Overall, the revised US-OFI-8 was consistently well understood by participants and was perceived as culturally appropriate and clear across diverse backgrounds.

Discussion

The present study aimed to adapt the OFI-8, originally developed in Japanese, to create a linguistically and culturally appropriate version for English-speaking older adults in the United States. Through a rigorous process of translation, expert review, and cognitive interviews, the resulting US-OFI-8 retained the conceptual integrity of the original instrument while incorporating important modifications to improve clarity, relevance, and comprehensibility.

Across the adaptation process, several items required meaningful revision. Cultural references, such as the inclusion of Japanese foods like $\ref{thm:eq}$ (dried squid) and $\ref{thm:eq}$ (pickled radish), were replaced with equivalents familiar to a US audience, including beef jerky and raw carrots. Linguistic adjustments were also necessary to ensure idiomatic and natural phrasing, as in the revision of "I use dentures" to "I wear removable dentures (complete or partial)" to reflect common usage and clarify scope. Following consultation with Japanese coauthors and participant feedback, the item addressing choking/coughing on liquids was also refined to emphasize coughing (as a more typical interpretation of the verb $\ref{thm:eq}$) and include examples familiar to the target population.

Cognitive interviews played a critical role in confirming the understandability of each item and informing the refinement of items that generated confusion or

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lable I. Cross-C	ultural and Linguisuc Adaptation Frocess	lable 1. Cross-Cutural and Linguisuc Adaptation Process of the Oral Itality Index-6 (OFI-6) to O5 English	nglisn	
Sections	Original Japanese item	Forward-translation phase	Revisions after expert feedback	Revisions after cognitive interviews
Name	オーラルフレにルのスクリーニ ング問診票	Oral Frailty Screening Questionnaire.	United States English Oral Frailty Index-8 (US-OFI-8).	No change
Instructions	オーラルフレにルをどこでも簡 単にチェックできる問診票	This is a simple checklist to identify oral frailty. Those who get 3	This is a simple checklist to identify oral frailty. A more in-depth	This is a simple checklist to identify oral frailty. A more in-depth
	です。 3点以上の「危険性あり」	points or more have potential	evaluation of oral health and	evaluation of oral health and
	となった人には、専門的な対 応が必要です。	risk, thus needing professional care.	swallowing is recommended for those who get 3 or more points.	swallowing is recommended for those who get 3 or more points.
				Read the below statement
				and answer yes or no based on your experience.
Item I	半年前と比べて、かたいものが	Compared to 6 mo ago, it became	Compared to 6 mo ago, it has	Compared to 6 mo ago, it has
	食べにくくなった	more difficult for me to eat	become more difficult for me to	become more difficult for me to
		something hard.	eat hard foods (eg, tough, chewy,	eat hard foods such as tough,
			dry, and crunchy).	chewy, dry, and crunchy
				foods.
Item 2	お茶ば汁物でむせることがある	Liquid like tea and soup sometimes	I sometimes cough when drinking	I sometimes cough when drinking
		get stuck in my throat.	liquids such as water and broth .	liquids such as water or tea.
Item 3	義歯を使用している	l use dentures.	I wear dentures.	l wear removable dentures
				(complete or partial).
Item 4	口の乾きが気になる	I am often aware that my mouth	I am often bothered by a sensation	I am bothered by dry mouth.
		gets dried.	of dry mouth.	
Item 5	半年前と比べて外出の頻度が少	Compared to 6 mo ago, I do go	I go out less now than I did	l go out less often than I did
	なくなった	out less.	6 mo ago.	6 mo ago.
Item 6	さきいか・たくあんくらいの硬	I am able to chew food as hard as	I can chew hard food such as beef	I can chew hard foods such as beef
	さの食べ物が噛める	dried squid or pickled radish.	jerky or raw carrot.	jerky or raw carrot s.
Item 7	1日に2回以上は歯を磨く	I brush my teeth twice or	I brush my teeth at least	No change
·	2 H T A D D L T H M R P B P B	more a day.	twice a day.	-
Item 8	1年に1回父上は圏や医院を支診している	l get dental checkups at least once a year.	No change	No change
	:	,		

Boldface indicates revisions after cognitive interviews.

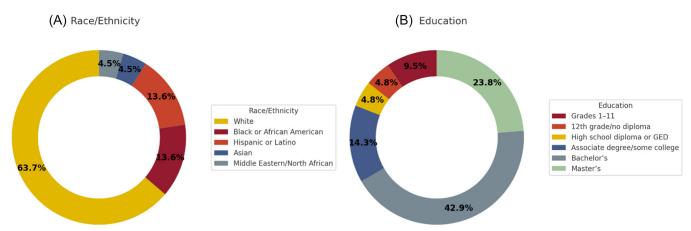


Figure 2. Participant demographics from the cognitive interview phase (N = 22). (A) Race/ethnicity: distribution of participants by self-reported race/ethnicity. (B) Education: distribution of participants by highest level of education attained. GED, general educational development.

ambiguity.^{22,23} These interviews revealed specific instances where additional clarification or rephrasing improved respondent comprehension without altering the conceptual meaning. Only three of the eight items underwent wording changes after the interviews, suggesting that the translation and expert review stages were largely successful in producing an accessible and culturally appropriate draft.

Additional modifications were made to the instructions and structural components of the tool. The instruction section was expanded to include a clearer directive on how to respond, which was not present in the original Japanese version but proved necessary to guide participants during interviews. Similarly, the consultation message was adapted to reflect a broader scope of health professionals typically involved in oral frailty management in the US healthcare context.

Unlike many speech-language pathology and otolaryngology instruments that originate in English and are subsequently adapted for international use, the OFI-8 was developed in Japanese. This "import" pathway makes rigorous cross-cultural adaptation indispensable before meaningful use in US settings. Professional guidance emphasizes that non-validated translations can undermine both research and clinical decision-making; best practice requires structured translation, expert review, cognitive debriefing, and subsequent psychometric validation in the target context.²⁴ Situating the US-OFI-8 within the broader literature, widely used swallowing-related PROMs such as the Eating Assessment Tool-10 (EAT-10) and the Dysphagia Handicap Index (DHI) have demonstrated across multiple languages that formal transcultural adaptation and validation are necessary to preserve reliability and interpretability. 25-28 This trend reinforces the field-wide consensus that ad hoc translations are inadequate for clinical or research use.^{29,30} For English-speaking patients and providers, an adapted OFI-8 addresses a practical gap; few oral frailty screeners have been available in English despite growing evidence linking oral status to sarcopenia, disability.

mortality.^{12,31-33} The US-OFI-8 therefore provides the first linguistically and culturally valid English-language instrument to screen for oral frailty, supporting early detection and multidisciplinary care for older adults in the United States.

This study has some limitations. While participants in the cognitive interviews represented a diverse range of racial, ethnic, and educational backgrounds, no specific demographic targets were established during recruitment. Future studies should consider setting such targets to ensure broader representativeness of the US older adult population. Offering compensation may also help support inclusive participation. Additionally, this study focused on linguistic and cultural adaptation and did not assess psychometric properties such as reliability or construct validity.

Future research should focus on validating the US-OFI-8 in larger and more heterogeneous samples. This includes determining clinically appropriate cutoff scores to classify low, moderate, and high oral frailty risk, and evaluating the tool's sensitivity, specificity, and predictive value. Cross-sectional and longitudinal studies examining associations with outcomes such as nutritional status, physical frailty, and quality of life may help confirm its clinical utility. Incorporating clinician perspectives could also support implementation research and facilitate integration into routine care.

Another area of interest is the recently introduced Oral Frailty 5-item Checklist (OF-5), developed in 2023 by the same team at the University of Tokyo. Tokyo. Designed to be more user-friendly and suitable for broader use in community-based settings, the OF-5 is presented as a distinct screening tool and does not directly reference the OFI-8, despite overlapping authorship. Given their structural differences—where the OFI-8 includes behavioral and preventive health components, and the OF-5 focuses solely on oral function—a comparative study could offer valuable insights into their respective utility, predictive value, and applicability across diverse clinical and community contexts.

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Conclusion

This study resulted in a culturally adapted US-English version of the OFI-8 through a structured translation, expert review, and cognitive interview process. Modifications addressed linguistic clarity, cultural relevance, and item comprehension, ensuring alignment with the original Japanese version. While participants understood the final version well, further research is needed to validate its clinimetric properties and determine clinical cutoff scores for use in US populations.

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Author Contributions

Adrián Castillo-Allendes, Investigation, methodology, project administration, manuscript writing, manuscript editing; Carolyn J. Khoury, Methodology, project administration, manuscript writing, manuscript editing; James A. Curtis, Methodology, manuscript editing; Valentina Mocchetti, Investigation, manuscript writing, manuscript editing; Johji Kuroda, Supervision, expert advising; Keiko Kuroda, Supervision, expert advising; Tomoko Ikeuchi, Supervision, expert advising; Eiichi Saitoh, Supervision, expert advising; Yoko Inamoto, Supervision, expert advising; Rumi Ueha, Supervision, expert advising; Koichiro Matsuo, Supervision, expert advising; Nicole Rogus-Pulia, Supervision, expert advising; Sonja Molfenter, Supervision, expert advising; Tomoki Tanaka, Conceptualization, supervision, expert advising; Katsuya Iijima, Conceptualization, supervision, expert advising; Anaïs Rameau, Conceptualization, funding acquisition, manuscript editing.

Disclosures

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Appendix I

Cognitive Interview Script and Probes for AE-OFI-8

Introduction

Hello (participant's name), thank you for agreeing to participate in this interview. My name is (Your Name), and I am working on a project to improve a questionnaire designed to identify oral frailty. Oral frailty refers to the decline in oral function and health, which can affect chewing, swallowing, and overall quality of life.

Your feedback is really important to make sure the questions are clear and easy to understand. I want to assure you that your answers will be anonymized, and no one will be able to identify you from your responses. We will record this conversation for later analysis. Is it okay if I start recording now?

Instructions for Interviewer:

- 1. Explain the purpose of the interview and assure the participant that their feedback is valuable and confidential.
- 2. Ask the participant to read each OFI-8 question out loud.
- 3. After the participant reads each question, use the following questions and probes to explore their understanding and reactions:

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Interview Questions and Probes:

1. Can you read the question out loud and tell us what's going through your mind?

Probes:

- What was your first thought after reading the question?
- Did any particular words stand out to you?
- Can you describe any specific memories or experiences this question made you think of?
 - 2. How did you understand that question? Was anything confusing?

Probes:

- Can you explain what this question means to you?
- Were there any words or phrases that you found confusing?
- What part of the question, if any, did you have to read more than once?
 - 3. In your own words, what do you think this question is asking?

Probes:

– How would you rephrase this question in your own words?

- Do you think this question is asking for information about your current habits or past experiences?
- Can you give an example of what this question is trying to find out?
 - 4. Did any of the terms in the question seem unclear to you?

Probes:

- Which term did you find unclear and why?
- How would you define the unclear term in your own words?
- Do you have any suggestions for making this term clearer?
 - 5. Why did you select (Yes/No) for this question?

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Probes:

- What factors influenced your choice of (Yes/No)?
- Can you describe a specific situation that helped you decide on your answer?
- Was your answer based on a recent experience or a general habit?

Closing:

Thank you for your time and valuable feedback. Your insights will help us improve the questionnaire to ensure it is clear and effective for everyone.