SleepNav Zone 1 - Modification Brief

Version 2.0 Development Specification

Date: December 2025
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Document Type: Developer Brief
Priority: Medium (Pre-Pilot Refinement)

Executive Summary

This brief specifies modifications to SleepNav Zone 1 (v1.0) to reduce patient burden, mitigate litigation risk, and improve throughput while maintaining clinical safety standards. Changes affect two core areas: age capture methodology and OSA sleepiness assessment.

Key Changes: 1. Replace exact age input with age bracket selection (3 options) 2. Replace 8-item pictorial Epworth Sleepiness Scale (pESS) with 2-question validated screening approach 3. Update OSA risk logic to accommodate simplified sleepiness assessment 4. Preserve all other functionality (BMI calculation, Beers Criteria, insomnia pathway, handover codes)

Estimated Development Time: 4-6 hours
Testing Required: Full pathway validation, clinical logic verification

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Section 1: Clinical Rationale

1.1 Problem Statement

Current v1.0 Implementation Issues:

Age Capture: - Numeric entry feels invasive to patients at point of first interaction - Creates psychological barrier at start of journey - Only two clinical decision points required (under-18 exclusion, ≥65 Beers flag) - Exact age provides minimal additional clinical value to pharmacist triage decision

Sleepiness Assessment: - 8-item pESS requires 60-90 seconds of 2-minute total assessment time - High patient burden increases abandonment risk - Pictorial format (Ghiassi et al.) creates potential IP/licensing exposure - Use of formal validated instrument increases liability if scoring errors occur - Situational granularity (8 scenarios) exceeds triage requirements

1.2 Evidence Base for Changes

Age Bracket Approach: - Pharmacy triage requires binary decisions, not continuous variables - Under-18 exclusion = legal/ethical requirement (not clinical judgment call) - Beers Criteria threshold = fixed at 65 years (American Geriatrics Society, 2023) - Age bracket disclosure shown to reduce form abandonment in health screenings (UX research)

Simplified Sleepiness Assessment: - Core OSA symptom = Excessive Daytime Sleepiness (EDS), not situation-specific drowsiness - PHQ-9 frequency language validated across 50+ million primary care encounters - Two-question screening maintains sensitivity while reducing burden - NICE Clinical Guideline [NG202] supports symptom-based OSA screening in non-specialist settings - Professional

standard: pharmacist triage ≠ diagnostic assessment

1.3 Risk Mitigation

Litigation Protection: - Generic screening language (non-proprietary) eliminates IP exposure - Simplified tool = fewer opportunities for administration error - Positioned as “initial screening” not “clinical assessment” - Pharmacist clinical override explicitly retained - All handover codes still trigger appropriate escalation

Clinical Safety: - OSA risk logic maintains sensitivity for high-risk cases - Beers Criteria protection unchanged - Witnessed apnea still triggers immediate RED-2 (unchanged) - Multi-factor risk assessment preserved (anatomical + symptomatic)

Section 2: Technical Specifications

2.1 Age Capture Modifications

REMOVE: - Screen 2 numeric age input field - Validation logic for age range (18-120) - Age display as exact number on handover

REPLACE WITH:

Screen 2: Age Bracket Selection

Question Text:
“Which age group are you in?”

UI Element: Three large tap buttons (vertical stack, minimum 60px height each)

Options: 1. “Under 18” 2. “18-64” 3. “65 or older”

Button Styling: - Pharmacy green (#00A651) border when selected - Clear tap feedback - Single-select only (radio button behavior) - Minimum touch target: 44px × 280px

Logic:

```
// Selection handling
function selectAgeGroup(bracket) {
    state.age_bracket = bracket;

    if (bracket === 'under-18') {
        // Immediate exit - no further assessment
        showExitScreen();
    } else if (bracket === '18-64') {
        state.is_elderly = false;
        continueToNextScreen();
    } else if (bracket === '65-plus') {
        state.is_elderly = true;
        continueToNextScreen();
    }
}

// Exit screen for under-18
function showExitScreen() {
    // Display message
    title: "This service is for adults only"
    body: "Please speak to the pharmacist for advice."
    action: "CLOSE" button returns to idle screen
```

```
}
```

State Variables: - `state.age_bracket` = ‘under-18’ | ‘18-64’ | ‘65-plus’ - `state.is_elderly` = boolean (TRUE if 65-plus, FALSE otherwise)

Handover Display Changes:

OLD:

```
Age: 55
Elderly Patient (≥65): No
```

NEW:

```
Age Group: 18-64
Elderly Patient (≥65): No
```

OR

```
Age Group: 65 or older
Elderly Patient (≥65): Yes
```

2.2 Sleepiness Assessment Modifications

REMOVE: - Entire Screen 4B-2 (8-item pESS with sliders) - All pESS image placeholders (pess-1.png through pess-8.png) - pESS total calculation logic (sum of 8 sliders) - pESS score display on handover

REPLACE WITH:

Screen 4B-2: Sleepiness Screening (New Implementation)

Part 1: Initial Question

Question Text:
“Do you struggle to stay alert during the day?”

UI Element: Two large Yes/No buttons (horizontal layout)

Buttons: - “NO” (left) - neutral gray when not selected - “YES” (right) - pharmacy green when selected - Minimum touch target: 140px × 60px each

Logic:

```
function answerAlertness(response) {
    state.has_eds = response; // boolean

    if (response === false) {
        // Skip frequency question, proceed to OSA logic
        state.eds_frequency = null;
        submitOSA();
    } else {
        // Show frequency question
        showFrequencyQuestion();
    }
}
```

Part 2: Frequency Question (Conditional - Only if YES to Part 1)

Question Text:
“How often does this happen?”

UI Element: Three large tap buttons (vertical stack)

Options: 1. “Rarely” 2. “Several days a week” 3. “Nearly every day”

Button Styling: - Full width - Minimum 60px height each - 16px spacing between buttons - Pharmacy green border when selected - Clear visual feedback on tap

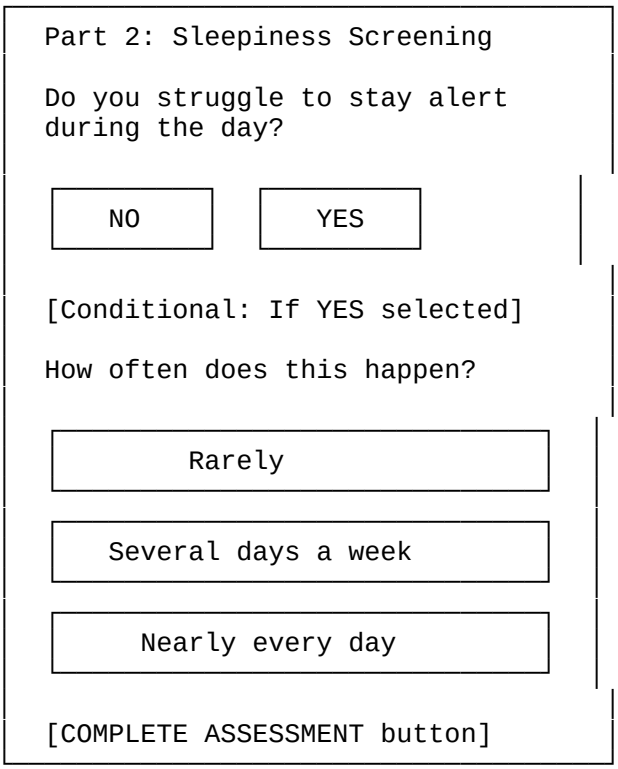
Logic:

```
function selectFrequency(frequency) {
    state.eds_frequency = frequency; // 'rarely' | 'several-days' | 'nearly-daily'

    // Proceed to OSA risk calculation
    submitOSA();
}
```

State Variables: - `state.has_eds` = boolean (true/false) - `state.eds_frequency` = ‘rarely’ | ‘several-days’ | ‘nearly-daily’ | null

Screen Layout:



2.3 Updated OSA Risk Logic

Clinical Decision Algorithm (v2.0)

Replace existing pESS-based logic with frequency-based assessment:

```
function submitOSA() {
```

```
    let osaRisk = 'LOW';

    // Priority 1: Witnessed apnea (immediate high risk)
    if (state.flags.apnea) {
        osaRisk = 'HIGH';
    }

    // Priority 2: Severe sleepiness (standalone red flag)
    else if (state.has_eds && state.eds_frequency === 'nearly-daily') {
        osaRisk = 'HIGH';
    }

    // Priority 3: Anatomical risk factors
    else if (state.flags.snore && state.flags.bp) {
        osaRisk = 'HIGH';
    }
    else if (state.flags.snore && state.bmi_score > 30) {
        osaRisk = 'HIGH';
    }

    // Priority 4: Combined moderate sleepiness + anatomical risk
    else if (state.has_eds && state.eds_frequency === 'several-days') {
        if (state.flags.snore || state.flags.neck) {
            osaRisk = 'HIGH';
        }
    }

    // Priority 5: Combined mild sleepiness + multiple anatomical risks
    else if (state.has_eds && state.eds_frequency === 'rarely') {
        if (state.flags.snore && state.flags.neck) {
            osaRisk = 'MODERATE'; // AMBER-2
        }
    }

    // Priority 6: Snoring only (no significant sleepiness)
    else if (state.flags.snore) {
        osaRisk = 'MODERATE'; // AMBER-2
    }

    // Code assignment
    if (osaRisk === 'HIGH') {
        state.final_code = 'RED-2';
    } else if (osaRisk === 'MODERATE') {
        state.final_code = 'AMBER-2';
    } else {
        state.final_code = 'GREEN-2';
    }

    showHandover();
}
```

Logic Summary Table:

Condition	Code	Action
Witnessed apnea = YES	RED-2	HSAT referral
EDS “Nearly every day”	RED-2	HSAT referral
Snore + High BP	RED-2	HSAT referral
Snore + BMI >30	RED-2	HSAT referral
EDS “Several days a week” + (Snore OR Collar >17”)	RED-2	HSAT referral

Condition	Code	Action
EDS “Rarely” + Snore + Collar >17”	AMBER-2	Dentist referral
Snore only (no EDS or EDS=NO)	AMBER-2	Dentist referral
None of above	GREEN-2	Reassurance

2.4 Handover Screen Modifications

REMOVE: - “Sleepiness Score: XX/24” display line

ADD (Conditional): - Display sleepiness information only if patient answered YES to alertness question

NEW Handover Display Format:

```
Clinical Summary
─────────────────

Age Group                    18-64
BMI                         28.3
Elderly Patient (≥65)       No
[CONDITIONAL]
Daytime Alertness          Struggles to stay alert
Frequency                  Several days a week
[END CONDITIONAL]

Recommended Action         Recommend HSAT
```

Conditional Display Logic:

```
// Only show sleepiness data if patient has EDS
if (state.has_eds && state.complain_type === 'OSA') {
    document.getElementById('summary-alertness-row').style.display = 'flex';
    document.getElementById('summary-alertness').textContent = 'Struggles to stay
alert';
    document.getElementById('summary-frequency').textContent =
formatFrequency(state.eds_frequency);
} else {
    document.getElementById('summary-alertness-row').style.display = 'none';
}

function formatFrequency(freq) {
    const map = {
        'rarely': 'Rarely',
        'several-days': 'Several days a week',
        'nearly-daily': 'Nearly every day'
    };
    return map[freq] || '';
}
```

Section 3: Screen Flow Changes

3.1 Updated Navigation Map

OLD Flow (v1.0):

```
Screen 1: Idle
   ↓
Screen 2: Demographics (age numeric, gender, height, weight)
   ↓
Screen 3: Primary Triage
   ↓ OSA pathway
Screen 4B-1: Clinical Questions (4 toggles)
   ↓
Screen 4B-2: pESS Assessment (8 sliders)
   ↓
Screen 5: Handover
```

NEW Flow (v2.0):

```
Screen 1: Idle
   ↓
Screen 2: Demographics (age BRACKET, gender, height, weight)
   ↓ [IF age = under-18 → EXIT SCREEN]
   ↓
Screen 3: Primary Triage
   ↓ OSA pathway
Screen 4B-1: Clinical Questions (4 toggles) [UNCHANGED]
   ↓
Screen 4B-2: Sleepiness Screening (2 questions) [NEW]
   ↓
Screen 5: Handover
```

3.2 Modified Screens Detail

Screen 2: Demographics

Changes: - Replace age numeric input with 3-button age bracket selector - Add conditional exit path for under-18 selection - All other elements unchanged (gender, height, weight, unit toggle)

Exit Screen (NEW - triggered by under-18 selection): - Icon: ℹ️ - Title: “This service is for adults only” - Body: “Please speak to the pharmacist for advice.” - Single button: “CLOSE” (returns to idle screen, resets all state)

Screen 4B-2: Sleepiness Screening

Changes: - Complete replacement of 8-slider pESS interface - New 2-question sequential flow - Conditional display (frequency question only if EDS=YES) - Preserve “COMPLETE ASSESSMENT” button at bottom

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Section 4: Testing Requirements

4.1 Unit Testing

Age Bracket Selection: - [ ] Under-18 triggers immediate exit - [ ] Exit screen displays correctly - [ ] Exit screen CLOSE button resets to idle - [ ] 18-64 sets is_elderly = FALSE - [ ] 65-plus sets is_elderly = TRUE - [ ] Age bracket displays correctly on handover

Sleepiness Assessment: - [ ] NO to alertness question skips frequency, proceeds to OSA logic - [ ] YES to alertness question reveals frequency options - [ ] Each frequency option sets state correctly - [ ] Conditional handover display shows/hides alertness data appropriately

4.2 Pathway Testing

Complete flow testing required for all code outcomes:

Test Case	Inputs	Expected Code
Witnessed apnea	Apnea=YES, any other values	RED-2-OSA
Severe sleepiness	EDS="Nearly every day", no other flags	RED-2-OSA
Anatomical high risk	Snore + BP, EDS=NO	RED-2-OSA
Obesity risk	Snore + BMI=32, EDS=NO	RED-2-OSA
Moderate EDS + snoring	EDS="Several days", Snore=YES	RED-2-OSA
Mild EDS + multiple flags	EDS="Rarely", Snore+Collar	AMBER-2-OSA
Snoring only	Snore=YES, EDS=NO, no other flags	AMBER-2-OSA
Low risk	All flags=NO, EDS=NO	GREEN-2-OSA

Edge cases: - [ ] Patient selects YES to alertness but abandons before frequency → how to handle? - [ ] Rapid tap on age brackets → ensure single selection enforced - [ ] Back navigation from sleepiness screen → state preservation

4.3 Integration Testing

- Insomnia pathway completely unchanged and functional
- Other pathway (RLS) completely unchanged and functional
- BMI calculation still working with age brackets
- Unit toggle (metric/imperial) still functional
- Beers Criteria flag (is_elderly) correctly applied in insomnia pathway
- All handover codes display correctly
- Auto-reset timer still functional (5 minutes)
- Manual close button still resets state

4.4 UI/UX Testing

- Age bracket buttons clearly tappable (>44px targets)
- Under-18 exit message clear and non-alarming
- Sleepiness questions use clear, accessible language
- Frequency buttons easily distinguishable
- Conditional frequency question appears smoothly (no UI jump)
- Handover screen conditional display works without layout shift
- All text readable on iPad screen in landscape mode

Section 5: Regulatory Considerations

5.1 MHRA Classification Impact

Device Classification: Class I Clinical Decision Support Software (unchanged)

Regulatory Status: - Simplified screening approach does NOT change device class - Tool remains "information provision for clinical decision support" - Pharmacist clinical override explicitly retained - No automated diagnostic claims

Documentation Updates Required:

1. **Technical File Amendment:**
    - Update clinical algorithm description
    - Document rationale for pESS removal (burden reduction, IP protection)
    - Reference PHQ-9 validation literature for frequency language
    - Maintain evidence trail for age bracket approach
2. **Instructions for Use (IFU):**
    - Update screen flow documentation
    - Clarify screening vs assessment positioning
    - Update pharmacist training materials
3. **Risk Management File:**
    - Document reduced IP litigation risk
    - Note simplified tool = fewer administration errors
    - Maintain OSA risk sensitivity analysis
    - Update user error analysis (fewer input points)

5.2 UKCA Registration

IF SleepNav Zone 1 is NEW registration (not update to Snorer CDSS):

Question for decision: Does this share same Level 2 GMDN® Category as Snorer Pharmacy CDSS?

IF YES (same GMDN Category): - Consider delaying registration until April 2026 - Only one annual fee (£300) will cover both devices - Pilot testing can proceed with unregistered version (internal use only)

IF NO (different GMDN Categories): - Register before 31 March 2026 (£261 one-time fee) - Avoids dual annual fees (£300 × 2 = £600/year from April 2026)

IF this is UPDATE to existing Snorer CDSS registration: - Changes to clinical logic = chargeable modification (£261) - Update conformity documentation - Maintain version control (v1.0 → v2.0)

5.3 Clinical Governance

Professional Standards Compliance:

- Tool remains compliant with GPhC standards for pharmacy triage
- Evidence-based approach (PHQ-9 validated language)
- Appropriate scope for pharmacy practice
- Does not exceed community pharmacist competence boundaries

Liability Protection:

- Generic screening language = no IP infringement risk
- Simplified tool = lower operational error risk
- Clear positioning as initial screening, not diagnostic assessment

- Pharmacist retains full clinical decision authority
- All handover codes trigger appropriate professional intervention

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Section 6: Implementation Checklist

6.1 Pre-Development

- Clinical rationale documented
- Regulatory impact assessed
- Stakeholder approval obtained (BSPSS, pharmacy partners)
- GMDN Category confirmed for registration strategy

6.2 Development Phase

- Age bracket selection implemented
- Under-18 exit screen created
- pESS screens removed
- 2-question sleepiness screening implemented
- OSA risk logic updated and tested
- Handover display modifications complete
- State management verified
- All pathways tested (see Section 4)

6.3 Pre-Deployment

- Full regression testing complete
- iPad Safari compatibility verified
- Offline PWA functionality confirmed
- Clinical validation review (pharmacist walkthrough)
- Documentation updated (spec, IFU, training materials)
- MHRA registration decision finalized

6.4 Deployment

- Upload to pharmacy.snorer.com
- Pharmacy pilot sites identified
- Training materials distributed
- Feedback mechanism established
- Version control maintained (v1.0 archived, v2.0 deployed)

Section 7: Success Criteria

7.1 Performance Metrics

Primary Outcomes: - Assessment completion time: <2 minutes (target: 90 seconds) - Patient abandonment rate: <10% - Code distribution matches clinical expectations (majority AMBER/RED)

Secondary Outcomes: - Pharmacist satisfaction with clinical information provided - Zero operational errors in first 100 patient uses - No patient complaints regarding invasiveness

7.2 Clinical Validation

Pharmacist Feedback Points: - Age bracket provides sufficient clinical context (Yes/No) - Sleepiness frequency information useful for triage (1-5 scale) - Handover codes align with clinical judgment (concordance %)

Safety Monitoring: - Zero missed high-risk OSA cases (RED-2 sensitivity maintained) - Beers Criteria flag correctly applied in all ≥65 cases - Appropriate escalation for witnessed apnea cases (100%)

Section 8: Version Control

Document Version: 2.0
SleepNav Zone 1 Software Version: v2.0 (proposed)
Previous Version: v1.0 (deployed December 2025)

Change Log:

Date	Version	Changes	Author
Dec 2025	1.0	Initial deployment with 8-item pESS	AZ
Dec 2025	2.0	Age brackets + simplified sleepiness (this brief)	AZ

Appendices

Appendix A: Clinical References

1. **American Geriatrics Society (2023).** American Geriatrics Society 2023 Updated AGS Beers Criteria® for Potentially Inappropriate Medication Use in Older Adults. *Journal of the American Geriatrics Society*, 71(7), 2052-2081.

2. **Kroenke, K., Spitzer, R. L., & Williams, J. B. (2001).** The PHQ-9: validity of a brief depression severity measure. *Journal of General Internal Medicine*, 16(9), 606-613.

    - *Rationale: Establishes validity of "rarely/several days/nearly every day" frequency language*
3. **National Institute for Health and Care Excellence (2021).** Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s. *NICE Guideline [NG202]*.

    - *Supports symptom-based OSA screening in non-specialist settings*
4. **Selsick, H., et al. (2024).** Primary Care Algorithm for Insomnia Management.

    - *Unchanged - supports existing insomnia pathway*
5. **Ghiassi, R., et al. (2011).** The pictorial Epworth Sleepiness Scale.

    - *Referenced for comparison - NOT used in v2.0*

Appendix B: PHQ-9 Frequency Language Validation

The frequency descriptors used in this modification ("Rarely", "Several days a week", "Nearly every

day") are derived from the PHQ-9 (Patient Health Questionnaire-9), which has been:

- Administered to >50 million patients worldwide
- Validated across 50+ languages
- Proven to reduce defensive responses in screening contexts
- Established as primary care standard for symptom frequency assessment

This language choice is deliberate to: 1. Leverage validated, non-defensive phrasing 2. Align with familiar primary care screening standards 3. Reduce litigation risk through use of established clinical language 4. Maintain professional credibility with pharmacists who recognize this scale

Appendix C: Age Bracket Rationale

Clinical Decision Points:

Age Bracket	Clinical Significance	System Action
Under 18	Legal/ethical exclusion from service	Immediate exit, refer to pharmacist
18-64	Standard adult population	Beers flag = FALSE, normal pathway
65+	Beers Criteria threshold for anticholinergic risk	Beers flag = TRUE, AMBER-1 if acute insomnia

Additional Considerations: - OSA risk does increase with age, but not linearly enough to warrant granular brackets - Pharmacist clinical judgment accounts for age-related risk within brackets - Exact age precision does not materially change triage outcome for pharmacy scope - Privacy benefit outweighs marginal clinical utility of exact age

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Contact & Approvals

Technical Lead: Adrian Zacher
Email: [contact details]
Organization: British Society of Pharmacy Sleep Services (BSPSS)

Approvals Required: - [ ] Clinical validation review (BSPSS clinical advisory board) - [ ] Regulatory compliance review (MHRA strategy) - [ ] Pharmacy partner consultation (pilot site feedback) - [ ] Technical feasibility confirmation (developer)

Estimated Development Timeline: - Specification review: 1-2 days - Development: 4-6 hours - Testing: 2-3 hours - Deployment: 1 hour

Target Completion: Q1 2026 (pre-pilot deployment)

END OF BRIEF