Risk Management Matrix For Hazards Associated with ChatRx Antimicrobial Assessment Device

Objective: Implement a risk management process according to ISO 14971 to ensure compliance with FDA requirements for ChatRx, considering the assessment and prescription of 32 antimicrobial conditions.

2.1 Hazard Identification

Step 1: Identify potential hazards associated with ChatRx

1. **Antimicrobial Resistance Development:**
    - Potential for microbes to develop resistance to prescribed antimicrobial treatments.
2. **Misdiagnosis or Incorrect Assessment:**
    - Risk of incorrect assessment leading to ineffective treatment or inappropriate antimicrobial prescription.
3. **Device Malfunction:**
    - Potential for device malfunction resulting in incorrect assessment or prescription errors.
4. **Patient Overuse:**
    - Risk of patients using the device excessively, potentially leading to over-reliance on antimicrobial treatments.
5. **Misuse of Proxy Features for Minors and Dependents:**
    - Risk of unauthorized access or misuse of proxy features by caregivers or family members, leading to incorrect assessments or prescriptions for minors or dependents.
6. **Patient Misuse:**
    - Risk of patients misusing the device, leading to incorrect data input or misinterpretation of results.

Step 2: Document identified hazards in a Hazard Identification Worksheet

- Use the Hazard Identification Worksheet to document each identified hazard, its potential consequences, and initial risk assessment.

2.1.2 Risk Assessment

Step 1: Assess the severity of each identified hazard

1. **Antimicrobial Resistance Development:**
    - **Severity:** Major
        - Consequence: Reduced effectiveness of antimicrobial treatments, potentially leading to treatment failure in patients.
2. **Misdiagnosis or Incorrect Assessment:**
    - **Severity:** Major
        - Consequence: Incorrect treatment regimen, which can exacerbate patient condition or contribute to antimicrobial resistance.
3. **Device Malfunction:**
    - **Severity:** Moderate
        - Consequence: Temporary interruption of service or inaccurate assessment results.
4. **Patient Overuse:**
    - **Severity:** Moderate
        - Consequence: Increased risk of antimicrobial resistance due to excessive use, potentially compromising treatment efficacy.
5. **Misuse of Proxy Features for Minors and Dependents:**
    - **Severity:** Moderate
        - Consequence: Incorrect assessments or prescriptions for minors or dependents, leading to potential harm or ineffective treatment.
6. **Patient Misuse:**
    - **Severity:** Minor
        - Consequence: Data input errors leading to inaccurate assessment but no immediate patient harm.

Step 2: Assess the likelihood of occurrence for each hazard

- **Likelihood Assessment:** Evaluate the likelihood of each hazard occurring based on the described operational controls and risk mitigation measures.
    - **Antimicrobial Resistance Development:**
        - **Likelihood:** Low
            - Explanation: The ChatRx device aims to reduce unnecessary antibiotic use through objective assessments.
    - **Misdiagnosis or Incorrect Assessment:**

        - **Likelihood:** Low
            - Explanation: The AI assessment is thoroughly validated for accuracy with ongoing oversight by the product team and a licensed physician.
    - **Device Malfunction:**
        - **Likelihood:** Low
            - Explanation: Regular maintenance and stringent quality control measures minimize the risk of device malfunction.
    - **Patient Overuse:**
        - **Likelihood:** Low
            - Explanation: Strict protocols and algorithms qualify consumers for treatment, reducing the likelihood of overuse.
    - **Misuse of Proxy Features for Minors and Dependents:**
        - **Likelihood:** Low
            - Explanation: Access controls and caregiver training mitigate the risk of misuse of proxy features.
    - **Patient Misuse:**
        - **Likelihood:** Low
            - Explanation: User education and intuitive design minimize the likelihood of patient misuse.

Step 3: Calculate the initial risk level (risk = severity × likelihood)

- Assign a risk level (minor, moderate, major) based on the calculated risk matrix:

Severity / Likelihood	Low (1)	Medium (2)	High (3)
Minor	Low	Medium	High
Moderate	Medium	High	High
Major	High	High	High

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- **Antimicrobial Resistance Development:**
    - **Risk Level:** Major (Severity: Major × Likelihood: Low)
        - **Rationale:** Although likelihood is low, the severity remains major due to potential consequences of antimicrobial resistance.
- **Misdiagnosis or Incorrect Assessment:**
    - **Risk Level:** Major (Severity: Major × Likelihood: Low)

        - **Rationale:** Despite low likelihood, the severity warrants ongoing validation and oversight.
- **Device Malfunction:**
    - **Risk Level:** Moderate (Severity: Moderate × Likelihood: Low)
        - **Rationale:** Low likelihood with moderate severity indicates effective maintenance and controls.
- **Patient Overuse:**
    - **Risk Level:** Moderate (Severity: Moderate × Likelihood: Low)
        - **Rationale:** Rigid protocols mitigate risk, but ongoing monitoring is essential.
- **Misuse of Proxy Features for Minors and Dependents:**
    - **Risk Level:** Moderate (Severity: Moderate × Likelihood: Low)
        - **Rationale:** Low likelihood with moderate severity necessitates robust access controls and training.
- **Patient Misuse:**
    - **Risk Level:** Minor (Severity: Minor × Likelihood: Low)
        - **Rationale:** Low likelihood and minor severity indicate effective user education and interface design.

2.2 Risk Evaluation

2.2.1 Risk Acceptability

Step 1: Determine if the calculated risks are acceptable

- **Risk Acceptability Criteria:** Evaluate risks against FDA guidelines, company policies, and patient safety considerations.
    - **Antimicrobial Resistance Development:** Acceptable with continued monitoring and mitigation efforts.
    - **Misdiagnosis or Incorrect Assessment:** Manageable with ongoing validation and oversight processes.
    - **Device Malfunction:** Acceptable with regular maintenance and quality control measures.
    - **Patient Overuse:** Manageable with strict protocols and ongoing monitoring.
    - **Misuse of Proxy Features for Minors and Dependents:** Mitigation required through access controls and caregiver training.
    - **Patient Misuse:** Acceptable with ongoing user education and usability enhancements.

Step 2: Document the rationale for risk acceptability decisions

- Document decisions regarding risk acceptability, including justification for risks deemed acceptable or actions required to mitigate unacceptable risks.