Supplementary File S3

Machine-Readable Data Files

Configuration and Patient Input Examples for LAI-PrEP Bridge Period Decision Support Tool

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Viruses Journal Supplementary Materials

Purpose of This File

This supplementary file provides machine-readable data files for the LAI-PrEP Bridge Period Decision Support Tool, enabling complete reproducibility and facilitating independent validation:

1. **Configuration File** (`lai_prep_config.json`): Defines algorithmic parameters, evidence-based interventions, population characteristics, and barrier impacts
2. **Patient Input Examples**: Demonstrates expected input format and provides realistic test cases for tool validation

The configuration-driven architecture enables:

- **Parameter updates** without code modification
- **Institutional adaptation** to local contexts and evidence
- **Transparent review** of all algorithmic assumptions
- **Reproducible research** with versioned configurations
- **Evidence integration** as new research emerges

1 Configuration Structure Overview

The complete configuration file contains six major sections:

1. **Populations** (7 entries): Baseline attrition rates and priority interventions for each population
2. **Barriers** (13 entries): Structural barriers with quantified impacts on bridge period navigation
3. **Interventions** (21 entries): Evidence-based interventions with effect sizes and implementation details
4. **Healthcare Settings** (8 entries): Setting-specific recommendations and resource availability
5. **Risk Categories** (3 entries): Thresholds for risk stratification
6. **Algorithm Parameters**: Technical parameters for probability calculations

2 Representative Examples

The following excerpts demonstrate the structure and content of each section. The complete configuration file (`lai_prep_config.json`) is available in the GitHub repository.

2.1 Population Configuration Example

Populations are defined with baseline attrition rates derived from clinical trials and real-world implementation studies:

Listing 1: Population configuration excerpt

```
"populations": {
  "MSM": {
    "name": "Men who have sex with men",
    "baseline_attrition": 0.45,
    "attrition_range": [0.40, 0.50],
    "evidence_level": "strong",
    "evidence_source": "HPTN 083 (n=4,566)",
    "clinical_notes": "MSM: Address stigma, privacy concerns, and social
       network disclosure. HPTN 083 showed 89% relative risk reduction.",
    "priority_interventions": [
      "PATIENT_NAVIGATION",
      "PEER_NAVIGATION",
      "SAME_DAY_SWITCHING"
    ]
  },
  "CISGENDER_WOMEN": {
    "name": "Cisgender women",
    "baseline_attrition": 0.55,
    "attrition_range": [0.50, 0.60],
    "evidence_level": "strong",
    "evidence_source": "HPTN 084 (n=3,224), PURPOSE-1 (n=5,338)",
    "clinical_notes": "Women: Address medical mistrust, structural
       barriers (transportation, childcare). HPTN 084 showed 89% superior
       efficacy; PURPOSE-1 had zero infections in 5,338 women.",
    "priority_interventions": [
      "PATIENT_NAVIGATION",
      "TRANSPORTATION_SUPPORT",
      "CHILDCARE_SUPPORT",
      "MEDICAL_MISTRUST_INTERVENTION"
    ]
  },
  "PWID": {
    "name": "People who inject drugs",
    "baseline_attrition": 0.75,
    "attrition_range": [0.70, 0.80],
    "evidence_level": "emerging",
    "evidence_source": "Oral PrEP cascade extrapolation, PURPOSE-4 (
       ongoing)",
    "clinical_notes": "PWID: Harm reduction approach essential. No
       abstinence requirement. PURPOSE-4 trial (ongoing) will provide
       critical implementation evidence.",
    "priority_interventions": [
```

```
      "HARM_REDUCTION_INTEGRATION",
      "PEER_NAVIGATION",
      "LOW_BARRIER_PROTOCOLS",
      "MOBILE_DELIVERY"
    ]
  }
}
```

2.2 Barrier Configuration Example

Barriers are quantified based on their impact on bridge period navigation success:

Listing 2: Barrier configuration excerpt

```
"barriers": {
  "TRANSPORTATION": {
    "name": "Transportation barriers",
    "impact": 0.10,
    "evidence_level": "strong",
    "affected_populations": [
      "CISGENDER_WOMEN",
      "ADOLESCENT",
      "PWID",
      "PREGNANT_LACTATING"
    ],
    "description": "Lack of reliable transportation to multiple
       appointments"
  },
  "INSURANCE_DELAYS": {
    "name": "Insurance authorization delays",
    "impact": 0.12,
    "evidence_level": "strong",
    "affected_populations": [
      "MSM",
      "CISGENDER_WOMEN",
      "TRANSGENDER_WOMEN",
      "ADOLESCENT",
      "GENERAL"
    ],
    "description": "Prior authorization requirements causing delays"
  },
  "HOUSING_INSTABILITY": {
    "name": "Housing instability",
    "impact": 0.15,
    "evidence_level": "strong",
    "affected_populations": ["PWID"],
    "description": "Homelessness or unstable housing affecting follow-up"
  }
}
```

2.3 Intervention Configuration Example

Interventions are defined with evidence-based effect sizes and implementation requirements:

Listing 3: Intervention configuration excerpt

```
"interventions": {
  "PATIENT_NAVIGATION": {
    "name": "Patient navigation services",
    "improvement": 0.15,
    "evidence_level": "strong",
    "evidence_source": "RCT meta-analysis (k=23, OR=1.85)",
    "mechanisms": ["STRUCTURAL_BARRIER_REDUCTION", "COORDINATION"],
    "target_barriers": [
      "TRANSPORTATION",
      "SCHEDULING_CONFLICTS",
      "INSURANCE_DELAYS"
    ],
    "implementation_complexity": "moderate",
    "cost_tier": "medium",
    "description": "Dedicated navigator to coordinate appointments,
       address barriers, and provide follow-up"
  },
  "SAME_DAY_SWITCHING": {
    "name": "Same-day switching from oral PrEP",
    "improvement": 0.25,
    "evidence_level": "strong",
    "evidence_source": "OPERA cohort (n=302), Trio Health (n=146)",
    "mechanisms": ["TEMPORAL_COMPRESSION", "ADHERENCE_PRESERVATION"],
    "target_barriers": ["HIV_TESTING_DELAYS"],
    "implementation_complexity": "low",
    "cost_tier": "low",
    "description": "For patients on oral PrEP: skip oral lead-in, test and
        inject same day",
    "eligibility_criteria": "Current oral PrEP use"
  },
  "HARM_REDUCTION_INTEGRATION": {
    "name": "Harm reduction service integration",
    "improvement": 0.18,
    "evidence_level": "moderate",
    "evidence_source": "PWID PrEP cascade studies, harm reduction
       literature",
    "mechanisms": ["STIGMA_REDUCTION", "STRUCTURAL_BARRIER_REDUCTION"],
    "target_barriers": [
      "SUBSTANCE_USE",
      "HOUSING_INSTABILITY",
      "MEDICAL_MISTRUST"
    ],
    "implementation_complexity": "high",
    "cost_tier": "medium",
    "description": "Integrate LAI-PrEP with syringe services, medication-
       assisted treatment, housing support"
  }
}
```

2.4 Healthcare Setting Configuration Example

Healthcare settings specify available interventions and recommended protocols:

Listing 4: Healthcare setting configuration excerpt

```
"healthcare_settings": {
  "COMMUNITY_HEALTH_CENTER": {
    "name": "Community Health Center",
    "available_interventions": [
      "PATIENT_NAVIGATION",
      "TRANSPORTATION_SUPPORT",
      "ACCELERATED_TESTING",
      "INSURANCE_SUPPORT",
      "FLEXIBLE_SCHEDULING"
    ],
    "typical_bridge_period_days": 21,
    "resource_level": "moderate"
  },
  "HARM_REDUCTION_PROGRAM": {
    "name": "Harm Reduction Program/Syringe Services",
    "available_interventions": [
      "HARM_REDUCTION_INTEGRATION",
      "PEER_NAVIGATION",
      "LOW_BARRIER_PROTOCOLS",
      "MOBILE_DELIVERY",
      "FLEXIBLE_SCHEDULING"
    ],
    "typical_bridge_period_days": 28,
    "resource_level": "variable"
  }
}
```

2.5 Risk Stratification Configuration Example

Risk categories define thresholds for clinical decision-making:

Listing 5: Risk category configuration excerpt

```
"risk_categories": {
  "HIGH_RISK": {
    "threshold": 0.60,
    "description": "Predicted success rate <40%",
    "recommended_actions": [
      "Intensive navigation (minimum 3 contacts)",
      "Multiple intervention modalities",
      "Close clinical monitoring",
      "Consider expedited protocols"
    ],
    "intervention_priority": "maximum"
  },
  "MODERATE_RISK": {
    "threshold": 0.40,
    "description": "Predicted success rate 40-60%",
    "recommended_actions": [
      "Standard navigation (minimum 2 contacts)",
      "Targeted barrier-specific interventions",
      "Regular follow-up"
    ],
```

```
    "intervention_priority": "standard"
  }
}
```

2.6 Algorithm Parameters

Technical parameters control calculation methods:

Listing 6: Algorithm parameters excerpt

```
"algorithm_parameters": {
  "barrier_combination_method": "multiplicative",
  "intervention_combination_method": "additive_with_saturation",
  "max_cumulative_intervention_effect": 0.45,
  "use_logit_space": true,
  "mechanism_diversity_weight": 0.10,
  "minimum_intervention_effect": 0.02,
  "description": "Parameters controlling probability calculations and
     intervention recommendations"
}
```

3 Configuration Usage

3.1 Loading the Configuration

The tool loads the configuration at runtime using Python's JSON parser:

Listing 7: Python usage example (pseudocode)

```
import json

# Load configuration
with open('lai_prep_config.json', 'r') as f:
    config = json.load(f)

# Access population data
msm_baseline = config['populations']['MSM']['baseline_attrition']
msm_interventions = config['populations']['MSM']['priority_interventions']

# Access barrier data
transport_impact = config['barriers']['TRANSPORTATION']['impact']

# Access intervention data
nav_improvement = config['interventions']['PATIENT_NAVIGATION']['
   improvement']
```

3.2 Institutional Adaptation

Institutions can modify the configuration to reflect local contexts:

1. **Update baseline rates**: Adjust population-specific attrition rates based on local data

2. **Modify barrier impacts**: Calibrate barrier impacts to local prevalence
3. **Add/remove interventions**: Include locally-available interventions or disable unavailable ones
4. **Adjust effect sizes**: Update intervention effects based on local implementation outcomes
5. **Set resource constraints**: Configure available interventions by healthcare setting

3.3 Version Control

Each configuration file includes version information for reproducibility:

Listing 8: Version metadata

```
{
  "version": "2.0.0",
  "last_updated": "2025-01-12",
  "description": "Configuration file for LAI-PrEP Bridge Period Decision
     Support Tool"
}
```

4 Evidence Integration

All parameters are derived from peer-reviewed literature:

- **Baseline attrition rates**: HPTN 083, HPTN 084, PURPOSE trials, real-world cohort studies
- **Barrier impacts**: PrEP cascade literature, implementation science studies
- **Intervention effects**: Randomized controlled trials, systematic reviews, meta-analyses
- **Population differences**: Clinical trial subgroup analyses, epidemiological data

5 Patient Input Examples

For reproducibility and tool testing, we provide example patient profiles representing diverse clinical scenarios.

5.1 Single Patient JSON Example

Individual patient assessments use JSON format with the following structure:

Listing 9: Example patient input (example_patient.json)

```
{
  "patient_id": "example_001",
  "population": "PWID",
  "age": 35,
  "current_prep_status": "naive",
  "barriers": [
    "HOUSING_INSTABILITY",
    "TRANSPORTATION",
```

```
    "LEGAL_CONCERNS"
  ],
  "healthcare_setting": "HARM_REDUCTION",
  "insurance_status": "uninsured",
  "recent_hiv_test": false,
  "transportation_access": false,
  "childcare_needs": false
}
```

This example represents a person who injects drugs (PWID) with multiple structural barriers - a high-risk scenario requiring intensive navigation support.

5.2 Batch Processing CSV Example

For research or quality improvement projects analyzing multiple patients, CSV format enables efficient batch processing:

Listing 10: Example batch input format (example_patients.csv)

```
patient_id,population,age,current_prep_status,barriers,setting,...
patient_001,MSM,28,oral_prep,SCHEDULING_CONFLICTS,LGBTQ_CENTER,...
patient_002,CISGENDER_WOMEN,32,naive,"TRANSPORTATION,CHILDCARE",...
patient_003,PWID,35,naive,"HOUSING_INSTABILITY,LEGAL_CONCERNS",...
patient_004,ADOLESCENT,17,naive,"PRIVACY_CONCERNS",...
patient_005,TRANSGENDER_WOMEN,26,discontinued_oral,DISCRIMINATION,...
```

The complete example file contains 10 diverse patients spanning all populations and barrier combinations.

5.3 Clinical Scenarios Represented

Example patients cover the full spectrum of bridge period challenges:

- **Low-barrier case**: MSM on oral PrEP, insured, same-day switching candidate
- **Moderate-barrier case**: Cisgender woman, transportation + childcare needs
- **High-barrier case**: PWID, housing instability + multiple barriers
- **Special populations**: Adolescents (privacy), pregnant/lactating (competing priorities)
- **Healthcare settings**: LGBTQ centers, harm reduction programs, community clinics

5.4 Usage Examples

These files enable immediate tool testing:

Listing 11: Command-line usage

```
# Assess single patient
python cli.py assess -i example_patient.json -o results.json

# Batch process multiple patients
python cli.py batch -i example_patients.csv -o batch_results.json

# Validate configuration
python cli.py validate -c lai_prep_config.json
```

6 Data Availability

6.1 Complete Configuration File

The full `lai_prep_config.json` file (558 lines) containing all populations, barriers, interventions, and algorithm parameters is available at:

- **Zenodo DOI**:`https://zenodo.org/uploads/17727117#:~:text=10.5281/zenodo.17727117`

6.2 Patient Input Examples

Example patient files for reproducibility testing:

- **example_patient.json**: Single patient JSON template with inline documentation
- **example_patients.csv**: Batch file with 10 diverse clinical scenarios
- Both available in the GitHub repository under `/examples/` directory

6.3 Supplementary Documentation

Additional implementation materials include:

- **Supplementary File S1**: Clinician Quick-Reference Card
- **Supplementary File S2**: Patient Information Handout
- **Supplementary File S4**: Implementation Guide
- **Supplementary File S5**: Clinical Decision Flowchart
- **Supplementary File S6**: Non-Technical Summary

7 Quality Assurance

The configuration undergoes rigorous validation:

1. **JSON schema validation**: Ensures structural integrity
2. **Parameter range checking**: Validates all values are within reasonable bounds
3. **Reference integrity**: Confirms all intervention/barrier references are valid
4. **Evidence documentation**: Requires citation for all effect sizes
5. **Unit testing**: 18 edge cases verify correct parameter usage (100% pass rate)

8 Future Updates

The configuration is designed to evolve with emerging evidence:

- **New trial data**: PURPOSE-4 (PWID), HPTN 084-01 (adolescents), RUBY-4 (serodiscordant couples)
- **Real-world implementation**: Prospective validation studies in diverse settings
- **Cost-effectiveness data**: Economic evaluations of intervention strategies
- **Health equity research**: Population-specific barriers and interventions

Updates will be versioned and documented with change logs to maintain reproducibility.

Technical Support

For questions about the configuration file or tool implementation:

- Zenodo dataset: LAI-PrEP Bridge Period Clinical Decision Support Tool: Algorithm, Validation Data, and Supporting Evidence for the PrEP Cascade Paradigm Shift
- **Email**: acdemidont@nyxdynamics.org
- **Documentation**: Complete API reference and integration guides in repository