

Supplementary Materials: SUPPLEMENTARY FILE S1: MACHINE READABLE CONFIGURATION for COMPUTATIONAL VALIDATION OF A CLINICAL SUPPORT ALGORITHM FOR LAI-PREP BRIDGE PERIOD NAVIGATION AT UNAIDS SCALE

A.C Demidont, DO¹ 

Supplementary File S1: Machine-Readable Configuration Files

This supplementary file provides the machine-readable configuration files and parameter specifications that drive the LAI-PrEP bridge period decision support algorithm. These files enable reproducibility, external validation, and adaptation of the model to different clinical contexts and populations.

S1.1 Configuration File Structure

The algorithm implements a configuration-driven architecture using JavaScript Object Notation (JSON) format. This approach separates algorithmic logic from clinical parameters, enabling:

- Rapid updates as new evidence emerges without modifying code
- Version control and comparison across parameter sets
- External audit and sensitivity analysis
- Local adaptation based on implementation experience
- Prospective validation with alternative assumptions

S1.2 Core Configuration Parameters

The configuration file specifies:

Population Baseline Rates Success rates by population, source evidence, and confidence tier (Tier 1: LAI-PrEP data; Tier 2: Oral PrEP data; Tier 3: Cross-therapeutic extrapolation)

Structural Barriers Barriers to bridge period completion (n=21), with impact weights as percentage-point reductions in success probability, evidence sources, and implementation indicators

Evidence-Based Interventions Interventions to address barriers (n=21), effect sizes, evidence levels (High/Moderate/Emerging), mechanisms of action, overlap penalties, and implementation complexity ratings

Modeling Parameters Diminishing returns factors (default 70%), barrier combination method (multiplicative default), overlap penalty structure, and validation checksums

Version Control Configuration version number, timestamp, change log, and backward compatibility settings

S1.3 Population-Specific Baseline Rates

31

Table S1. Population-Specific Bridge Period Success Rates (Baseline)

Population	Baseline Success (%)	Source Tier	Evidence Reference
Cisgender men who have sex with men (MSM)	52.9	Tier 1	HPTN 083, PURPOSE-1
rrrr Transgender women People who inject drugs (PWID) Adolescents (13–24 years) Sub-Saharan Africa (general population) North America/Europe (high-income)	38.4	Tier 2	PURPOSE-2 trial analysis
	24.6	Tier 3	Oral PrEP cascade data
	28.3	Tier 3	HVTN 702 analog, expert consensus
	31.2	Tier 2	HPTN 084 implementation data
	48.7	Tier 1	Trial data + implementation

S1.4 Structural Barriers (n=21) with Impact Weights

32

Table S1.1 in the complete configuration file documents all 21 barriers with:

33

- Barrier name and category (financial, logistic, clinical, educational, social)
- Impact weight as percentage-point reduction in baseline success
- Evidence source (published literature, qualitative studies, expert consensus)
- Implementation indicators (how to identify barrier presence)
- Mitigation requirements for each barrier

34

35

36

37

38

S1.5 Evidence-Based Interventions (n=21) with Effect Sizes

39

Table S1.2 documents all 21 interventions with:

40

- Intervention name and mechanism of action
- Effect size (percentage-point improvement in bridge period success)
- Evidence level (High: RCT or robust implementation data; Moderate: quasi-experimental or observational with controls; Emerging: pilot or expert consensus)
- Published references for effect size derivation
- Complexity rating (Low/Medium/High) for implementation
- Overlap penalties with other interventions (to account for synergistic effects and ceiling constraints)

41

42

43

44

45

46

47

48

S1.6 Validation Checksums and Data Integrity

49

All configuration files include SHA-256 checksums for each parameter section. These enable:

50

51

- Detection of unintended modifications
- Verification that external users are working with identical configuration
- Retrospective confirmation of which version was used for published analyses

52

53

54

S1.7 Configuration Version History

The configuration file maintains a complete version history:

v1.0.0 Initial configuration (used for primary validation analysis)

v2.0.0 Updated intervention effect sizes based on 2024 real-world implementation data
(HPTN 083-02, Trio Health Cohort)

v2.1.0 (Current) Includes new published evidence on transportation barriers and financial navigation support

Each version includes timestamp, substantive changes, and backward compatibility notes.

S1.8 JSON Configuration File Example Structure

The complete machine-readable configuration file follows this structure:

Listing 1: Configuration File Structure Example

```

1  {
2      "metadata": {
3          "version": "2.1.0",
4          "date": "2025-12-12",
5          "algorithm_name": "LAI-PrEP Bridge Period Decision Support",
6          "doi": "10.5281/zenodo.17873201"
7      },
8      "populations": [
9          {
10             "name": "MSM",
11             "baseline_success_rate": 0.529,
12             "source_tier": "Tier 1",
13             "evidence_reference": "HPTN_083_2024"
14         }
15     ],
16     "barriers": [
17         {
18             "id": "B001",
19             "name": "Financial barriers",
20             "impact_weight": -0.12,
21             "evidence_level": "High",
22             "mechanism": "Insurance gaps, copayment burdens"
23         }
24     ],
25     "interventions": [
26         {
27             "id": "I001",
28             "name": "Financial navigation support",
29             "effect_size": 0.15,
30             "evidence_level": "High",
31             "complexity": "Medium"
32         }
33     ],
34     "modeling_parameters": {
35         "diminishing_returns_factor": 0.70,

```

```
36     "barrier_combination_method": "multiplicative",  
37     "max_attrition_ceiling": 0.95  
38   }  
39 }
```

S1.9 Accessing Configuration Files

Complete machine-readable configuration files are available at:

- GitHub Repository: <https://github.com/nyx-dynamics/lai-prep-decision-support>
- Zenodo Archive: DOI <https://doi.org/10.5281/zenodo.17873201>
- MDPI Supplementary Materials: Attached configuration files with checksums

S1.10 Customization and Adaptation

Sites implementing this tool can adapt configurations by:

1. Modifying population baseline rates based on local epidemiology
2. Adjusting barrier impact weights using local implementation data
3. Updating intervention effect sizes as new evidence emerges
4. Maintaining version control to document all modifications
5. Validating checksums before deployment to ensure data integrity

All changes should be documented with timestamp, rationale, and evidence source.

S1.11 Validation and Testing

All configuration parameters undergo automated validation:

- Parameter bounds checking (probabilities constrained to 0–1 range)
- Mathematical consistency (no circular dependencies, invalid diminishing returns)
- Evidence source verification (all cited references available)
- Sensitivity analysis across parameter ranges
- Robustness testing with alternative assumptions

S1.12 Documentation and Audit Trail

Each configuration file includes:

- Complete data dictionary with definitions
- Source documentation for every parameter value
- Confidence intervals or uncertainty ranges where available
- Date of last validation
- Contacts for questions about specific parameters

References

1. Barzilay, R.; Jaakkola, T.; Bertsimas, D.; Katabi, D.; Sontag, D.; Stultz, C. Artificial Intelligence in Health Care. MIT Sloan Executive Education, Massachusetts Institute of Technology, 2025.
2. Baeten, J.M.; Donnell, D.; Ndase, P.; Mugo, N.R.; Campbell, J.D.; Wangisi, J.; Tappero, J.W.; Bukusi, E.A.; Cohen, C.R.; Katabira, E.; et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *New England Journal of Medicine* **2012**, *367*, 399–410. <https://doi.org/10.1056/NEJMoa1108524>.
3. Bahner, J.E.; Hüper, A.D.; Manzey, D. Misuse of automated decision aids: Complacency, automation bias and the impact of training experience. *International Journal of Human-Computer Studies* **2008**, *66*, 688–699. <https://doi.org/10.1016/j.ijhcs.2008.01.001>.

4. Baugher, A.R.; Wejnert, C.; Kanny, D.; Broz, D.; Feelemyer, J.; Hershow, R.B.; Burnett, J.; Chapin-Bardales, J.; Haynes, M.; Finlayson, T.; et al. Are we ending the HIV epidemic among persons who inject drugs?: key findings from 19 US cities. *AIDS* **2025**, *39*, 1813–1819. <https://doi.org/10.1097/QAD.0000000000004249>. 145
146
147
148
5. Bekker, L.G.; Das, M.; Abdool Karim, Q.; Ahmed, K.; Batting, J.; Brumskine, W.; Gill, K.; Harkoo, I.; Jaggernath, M.; Kigozi, G.; et al. Twice-Yearly Lenacapavir or Daily F/TAF for HIV Prevention in Cisgender Women. *New England Journal of Medicine* **2024**, *391*, 1179–1192. <https://doi.org/10.1056/NEJMoa2407001>. 149
150
151
152
6. Biello, K.B.; Bazzi, A.R.; Mimiaga, M.J.; Biancarelli, D.L.; Edeza, A.; Salhaney, P.; Childs, E.; Drainoni, M.L. Perspectives on HIV pre-exposure prophylaxis (PrEP) utilization and related intervention needs among people who inject drugs. *Harm Reduction Journal* **2018**, *15*, 55. <https://doi.org/10.1186/s12954-018-0263-5>. 153
154
155
156
7. Calabrese, S.K.; Underhill, K.; Earnshaw, V.A.; Hansen, N.B.; Kershaw, T.S.; Magnus, M.; Krakower, D.S.; Mayer, K.H.; Betancourt, J.R.; Dovidio, J.F. Framing HIV Pre-Exposure Prophylaxis (PrEP) for the General Public: How Inclusive Messaging May Prevent Prejudice from Diminishing Public Support. *AIDS and Behavior* **2016**, *20*, 1499–1513. <https://doi.org/10.1007/s10461-016-1318-9>. 157
158
159
160
161
8. Centers for Disease Control and Prevention. PrEP Coverage in the United States, 2023, 2024. 162
9. Centers for Disease Control and Prevention. US Public Health Service: Preexposure Prophylaxis for the Prevention of HIV Infection in the United States—2021 Update: A Clinical Practice Guideline, 2021. 163
164
165
10. Chan, P.A.; Glynn, T.R.; Oldenburg, C.E.; Montgomery, M.C.; Robinette, A.E.; Almonte, A.; Raifman, J.; Mena, L.; Patel, R.; Mayer, K.H.; et al. Implementation of Preexposure Prophylaxis for Human Immunodeficiency Virus Prevention Among Men Who Have Sex With Men at a New England Sexually Transmitted Diseases Clinic. *Sexually Transmitted Diseases* **2016**, *43*, 717–723. <https://doi.org/10.1097/OLQ.0000000000000514>. 166
167
168
169
170
11. Chan, P.A.; Patel, R.R.; Mena, L.; Marshall, B.D.L.; Rose, J.; Levine, P.; Nunn, A. A panel management and patient navigation intervention is associated with earlier PrEP initiation in a safety-net primary care health system. *J. Acquir. Immune Defic. Syndr.* **2018**, *79*, 347–351. <https://doi.org/10.1097/QAI.0000000000001801>. 171
172
173
174
12. Chin, M.H.; Clarke, A.R.; Nocon, R.S.; Casey, A.A.; Goddu, A.P.; Keeseker, N.M.; Cook, S.C. A Roadmap and Best Practices for Organizations to Reduce Racial and Ethnic Disparities in Health Care. *Journal of General Internal Medicine* **2012**, *27*, 992–1000. <https://doi.org/10.1007/s11606-012-2082-9>. 175
176
177
178
13. Cox, S.; Andreatta, K.; Hendricks, M.R.; Li, J.; Kintu, A.; Brown, L.B.; Carter, C.C.; Callebaut, C. Resistance Analyses of Lenacapavir, Emtricitabine/Tenofovir Alafenamide and Emtricitabine/Tenofovir Disoproxil Fumarate in the PURPOSE 1 and 2 Studies. *The Journal of Infectious Diseases* **2025**, p. jiaf533. <https://doi.org/10.1093/infdis/jiaf533>. 179
180
181
182
14. Craig, P.; Dieppe, P.; Macintyre, S.; Michie, S.; Nazareth, I.; Petticrew, M. Developing and evaluating complex interventions: the new Medical Research Council guidance. *BMJ* **2008**, *337*, a1655. <https://doi.org/10.1136/bmj.a1655>. 183
184
185
15. Crooks, N.; Donenberg, G.; Matthews, A. Barriers to PrEP uptake among Black female adolescents and emerging adults. *Prev. Med. Rep.* **2023**, *31*, 102092. <https://doi.org/10.1016/j.pmedr.2022.102092>. 186
187
188
16. Delany-Moretlwe, S.; Hughes, J.P.; Bock, P.; Ouma, S.G.; Hunidzarira, P.; Kalonji, D.; Kayange, N.; Makhema, J.; Mandima, P.; Mathew, C.; et al. Cabotegravir for the prevention of HIV-1 in women: results from HPTN 084, a phase 3, randomised clinical trial. *The Lancet* **2022**, *399*, 1779–1789. [https://doi.org/10.1016/S0140-6736\(22\)00538-4](https://doi.org/10.1016/S0140-6736(22)00538-4). 189
190
191
192
17. Delany-Moretlwe, S.; Hughes, J.P.; Bock, P.; Ouma, S.G.; Hunidzarira, P.; Kalonji, D.; Kayange, N.; Makhema, J.; Mandima, P.; Mathebula, M.; et al. Cabotegravir for the prevention of HIV-1 in women: Results from HPTN 084. *N. Engl. J. Med.* **2022**, *387*, 2043–2055. <https://doi.org/10.1056/NEJMoa2115829>. 193
194
195
196
18. Delany-Moretlwe, S.; Hughes, J.P.; Bock, P.; Ouma, S.G.; Hunidzarira, P.; Kalonji, D.; Kayange, N.; Makhema, J.; Mandima, P.; Mathew, C.; et al. Cabotegravir for the prevention of HIV-1 197
198

- in women: results from HPTN 084, a phase 3, randomised clinical trial. *The Lancet* **2022**, *399*, 1779–1789. [https://doi.org/10.1016/S0140-6736\(22\)00538-4](https://doi.org/10.1016/S0140-6736(22)00538-4). 199
19. Deutsch, M.B.; Glidden, D.V.; Sevelius, J.; Keatley, J.; McMahan, V.; Guanira, J.; Kallas, E.G.; Chariyalertsak, S.; Grant, R.M. HIV pre-exposure prophylaxis in transgender women: a subgroup analysis of the iPrEx trial. *The Lancet HIV* **2015**, *2*, e512–e519. [https://doi.org/10.1016/S2352-3018\(15\)00206-4](https://doi.org/10.1016/S2352-3018(15)00206-4). 200
20. Fauci, A.S.; Redfield, R.R.; Sigounas, G.; Weahkee, M.D.; Giroir, B.P. Ending the HIV Epidemic: A Plan for the United States. *JAMA* **2019**, *321*, 844. <https://doi.org/10.1001/jama.2019.1343>. 201
21. Greene, G.J.; Swann, G.; Fought, A.J.; Carballo-Díaz, A.; Hope, T.J.; Kiser, P.F.; Mustanski, B.; D'Aquila, R.T. Preferences for Long-Acting Pre-exposure Prophylaxis (PrEP), Daily Oral PrEP, or Condoms for HIV Prevention Among U.S. Men Who Have Sex with Men. *AIDS and Behavior* **2017**, *21*, 1336–1349. <https://doi.org/10.1007/s10461-016-1565-9>. 202
22. Grimsrud, A.; Bygrave, H.; Doherty, M.; Ehrenkranz, P.; Ellman, T.; Ferris, R.; others. Reimagining HIV service delivery: The role of differentiated care from prevention to suppression. *J. Int. AIDS Soc.* **2016**, *19*, 21484. <https://doi.org/10.7448/IAS.19.1.21484>. 203
23. Grinsztejn, B.; Hoagland, B.; Moreira, R.I.; Kallas, E.G.; Madruga, J.V.; Goulart, S.; others. Retention, engagement, and adherence to pre-exposure prophylaxis for men who have sex with men and transgender women in PrEP Brasil: 48 week results of a demonstration study. *Lancet HIV* **2018**, *5*, e136–e145. [https://doi.org/10.1016/S2352-3018\(18\)30008-0](https://doi.org/10.1016/S2352-3018(18)30008-0). 204
24. Group, T.H.R. Persistence rates in cabotegravir recipients. *Trio Health Cohort Study* **2024**. 205
25. Haser, G.C.; Balter, L.; Gurley, S.; Thomas, M.; Murphy, T.; Sumitani, J.; Leue, E.P.; Hollman, A.; Karneh, M.; Wray, L.; et al. Early implementation and outcomes among people with HIV who accessed long-acting injectable cabotegravir/rilpivirine at two Ryan White clinics in the U.S. South. *J. Acquir. Immune Defic. Syndr.* **2024**, *96*, 383–390. <https://doi.org/10.1097/QAI.00000000000003439>. 206
26. Hosek, S.G.; Landovitz, R.J.; Kapogiannis, B.; Siberry, G.K.; Rudy, B.; Rutledge, B.; Liu, N.; Harris, D.R.; Mulligan, K.; Zimet, G.; et al. Safety and Feasibility of Antiretroviral Preexposure Prophylaxis for Adolescent Men Who Have Sex With Men Aged 15 to 17 Years in the United States. *JAMA Pediatrics* **2017**, *171*, 1063. <https://doi.org/10.1001/jamapediatrics.2017.2007>. 207
27. Kamitani, E.; Higa, D.H.; Crepaz, N.; Wichser, M.; Mullins, M.M.; The U.S. Centers for Disease Control and Preventionâ€™s Prevention Research Synthesis Project. Identifying Best Practices for Increasing HIV Pre-exposure Prophylaxis (PrEP) Use and Persistence in the United States: A Systematic Review. *AIDS and Behavior* **2024**, *28*, 2340–2349. <https://doi.org/10.1007/s10461-024-04332-z>. 208
28. Kelley, C.F.; Acevedo-Quiñones, M.; Agwu, A.L.; Avihingsanon, A.; Benson, P.; Blumenthal, J.; Brinson, C.; Brites, C.; Cahn, P.; Cantos, V.D.; et al. Twice-Yearly Lenacapavir for HIV Prevention in Men and Gender-Diverse Persons. *New England Journal of Medicine* **2025**, *392*, 1261–1276. <https://doi.org/10.1056/NEJMoa2411858>. 209
29. Lancaster, K.E.; Endres-Dighe, S.; Sucaldito, A.D.; Piscalko, H.; Madhu, A.; Kiriazova, T.; Batchelder, A.W. Measuring and Addressing Stigma Within HIV Interventions for People Who Use Drugs: a Scoping Review of Recent Research. *Current HIV/AIDS reports* **2022**, *19*, 301–311. <https://doi.org/10.1007/s11904-022-00619-9>. 210
30. Landovitz, R.J.; Donnell, D.; Clement, M.E.; Hanscom, B.; Cottle, L.; Coelho, L.; Cabello, R.; Chariyalertsak, S.; Dunne, E.F.; Frank, I.; et al. Cabotegravir for HIV prevention in cisgender men and transgender women. *N. Engl. J. Med.* **2021**, *385*, 595–608. <https://doi.org/10.1056/NEJMoa2101016>. 211
31. Landovitz, R.J.; Donnell, D.; Clement, M.E.; Hanscom, B.; Cottle, L.; Coelho, L.; Cabello, R.; Chariyalertsak, S.; Dunne, E.F.; Frank, I.; et al. Cabotegravir for HIV Prevention in Cisgender Men and Transgender Women. *New England Journal of Medicine* **2021**, *385*, 595–608. <https://doi.org/10.1056/NEJMoa2101016>. 212
32. Marshall, B.D.L.; Goedel, W.C.; King, M.R.F.; Singleton, A.; Durham, D.P.; Chan, P.A.; Townsend, J.P.; Galvani, A.P. Potential effectiveness of long-acting injectable pre-exposure prophylaxis for HIV prevention in men who have sex with men: a modelling study. *The Lancet HIV* **2018**, *5*, e498–e505. [https://doi.org/10.1016/S2352-3018\(18\)30097-3](https://doi.org/10.1016/S2352-3018(18)30097-3). 213

33. Marzinke, M.A.; Hanscom, B.; Wang, Z.; Safran, S.A.; Psaros, C.; Donnell, D.; Richardson, P.A.; Sullivan, P.; Eshleman, S.H.; Jennings, A.; et al. Efficacy, safety, tolerability, and pharmacokinetics of long-acting injectable cabotegravir for HIV pre-exposure prophylaxis in transgender women: a secondary analysis of the HPTN 083 trial. *The Lancet HIV* **2023**, *10*, e703–e712. [https://doi.org/10.1016/S2352-3018\(23\)00200-X](https://doi.org/10.1016/S2352-3018(23)00200-X). 253
254
34. Marzinke, M.A.; Hendrix, C.W.; others. Pharmacokinetics and HIV pre-exposure prophylaxis. *Curr. Opin. HIV AIDS* **2021**, *16*, 1–8. <https://doi.org/10.1097/COH.0000000000000641>. 258
259
35. Mayer, K.H.; Agwu, A.; Malebranche, D. Barriers to the Wider Use of Pre-exposure Prophylaxis in the United States: A Narrative Review. *Advances in Therapy* **2020**, *37*, 1778–1811. <https://doi.org/10.1007/s12325-020-01295-0>. 260
261
262
36. Mayer, K.H.; Beyer, C.; Cohen, M.S.; El-Sadr, W.M.; Grinsztejn, B.; Head, J.M.; Keuroghlian, A.S.; Miller, V.; Phanuphak, N.; Rees, H.; et al. Challenges and opportunities in developing integrated sexual and reproductive health programmes. *The Lancet* **2025**, *406*, 2168–2190. [https://doi.org/10.1016/S0140-6736\(25\)01246-2](https://doi.org/10.1016/S0140-6736(25)01246-2). 263
264
265
37. Meyers, K.; Rodriguez, K.; Moeller, R.W.; Gratch, I.; Markowitz, M.; Halkitis, P.N. High Interest in a Long-Acting Injectable Formulation of Pre-Exposure Prophylaxis for HIV in Young Men Who Have Sex with Men in NYC: A P18 Cohort Substudy. *PLoS ONE* **2014**, *9*, e114700. <https://doi.org/10.1371/journal.pone.0114700>. 266
267
268
269
38. Miller, S.J.; Harrison, S.E.; Sanasi-Bhola, K. A Scoping Review Investigating Relationships between Depression, Anxiety, and the PrEP Care Continuum in the United States. *International Journal of Environmental Research and Public Health* **2021**, *18*, 11431. <https://doi.org/10.3390/ijerph182111431>. 271
272
273
39. Mixson, L.S.; Zule, W.; Ruderman, S.A.; Feinberg, J.; Stopka, T.J.; Sibley, A.L.; Walters, S.M.; Bobashev, G.; Cook, R.; Hochstatter, K.R.; et al. Prevalence and correlates of multiple injections per injection episode among people who inject drugs in rural U.S. communities. *The International Journal on Drug Policy* **2025**, *143*, 104837. <https://doi.org/10.1016/j.drugpo.2025.104837>. 275
276
277
40. Mohsin Khan, M.; Shah, N.; Shaikh, N.; Thabet, A.; Alrabayah, T.; Belkhir, S. Towards secure and trusted AI in healthcare: A systematic review of emerging innovations and ethical challenges. *International Journal of Medical Informatics* **2025**, *195*, 105780. <https://doi.org/10.1016/j.ijmedinf.2024.105780>. 279
280
281
282
41. Natale-Pereira, A.; Enard, K.R.; Nevarez, L.; Jones, L.A. The role of patient navigators in eliminating health disparities. *Cancer* **2011**, *117*, 3543–3552. <https://doi.org/10.1002/cncr.26264>. 283
284
42. Nijhawan, A.E.; Metsch, L.R.; Zhang, S.; Feaster, D.J.; Gooden, L.; Jain, M.K.; Walker, R.; Huffaker, S.; Mugavero, M.J.; Jacobs, P.; et al. Clinical and Sociobehavioral Prediction Model of 30-Day Hospital Readmissions Among People With HIV and Substance Use Disorder: Beyond Electronic Health Record Data. *JAIDS Journal of Acquired Immune Deficiency Syndromes* **2019**, *80*, 330–341. <https://doi.org/10.1097/QAI.0000000000001925>. 285
286
287
288
289
43. O'Neil, C. *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy*; Crown Publishing Group: USA, 2016. 290
291
44. Obermeyer, Z.; Powers, B.; Vogeli, C.; Mullainathan, S. Dissecting racial bias in an algorithm used to manage the health of populations. *Science* **2019**, *366*, 447–453. <https://doi.org/10.1126/science.aax2342>. 292
293
294
45. O'Neil, C. *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy*; Crown: New York, 2016. 295
296
46. Parasuraman, R.; Riley, V. Humans and Automation: Use, Misuse, Disuse, Abuse. *Human Factors* **1997**, *39*, 230–253. <https://doi.org/10.1518/001872097778543886>. 297
298
47. Paskett, E.D.; Harrop, J.P.; Wells, K.J. Patient navigation: An update on the state of the science. *CA: A Cancer Journal for Clinicians* **2011**, *61*, 237–249. <https://doi.org/10.3322/caac.20111>. 299
300
48. Patel, R.R.; Hoover, K.W.; Lale, A.; Cabrales, J.; Byrd, K.M.; Kourtis, A.P. Clinical Recommendation for the Use of Injectable Lenacapavir as HIV Preexposure Prophylaxis â€” United States, 2025. *MMWR. Morbidity and Mortality Weekly Report* **2025**, *74*, 541–549. <https://doi.org/10.15585/mmwr.mm7435a1>. 301
302
303
304
49. Patel, P.; Celum, C.; Bekker, L.G. Implementation of HIV prevention strategies globally. *The Lancet HIV* **2023**, *10*, e492–e494. [https://doi.org/10.1016/S2352-3018\(23\)00139-X](https://doi.org/10.1016/S2352-3018(23)00139-X). 305
306

50. Patel, V.V.; Mayer, K.H.; Makadzange, T.; Mena, L.A.; Rolle, C.P.; Jandl, T.; Thompson, D.; Corado, K.; Nkwihereze, H.; Giguere, R.; et al. Real-world implementation of cabotegravir long-acting injectable PrEP: The CAN Community Health Network Study. *AIDS* **2023**, *37*, 1847–1854. [307
https://doi.org/10.1097/QAD.0000000000003627](https://doi.org/10.1097/QAD.0000000000003627).
308
51. Price, D.M.; Unger, Z.; Wu, Y.; Meyers, K.; Golub, S.A. Clinic-Level Strategies for Mitigating Structural and Interpersonal HIV Pre-Exposure Prophylaxis Stigma. *AIDS Patient Care and STDs* **2022**, *36*, 115–122. [311
https://doi.org/10.1089/apc.2021.0176](https://doi.org/10.1089/apc.2021.0176).
312
52. Pridgen, B.E.; Bontemps, A.P.; Lloyd, A.R.; Wagner, W.P.; Kay, E.S.; Eaton, E.F.; Cropsey, K.L. U.S. substance use harm reduction efforts: a review of the current state of policy, policy barriers, and recommendations. *Harm Reduction Journal* **2025**, *22*, 101. [314
https://doi.org/10.1186/s12954-025-01238-4](https://doi.org/10.1186/s12954-025-01238-4).
315
53. Psaros, C.; Goodman, G.R.; Lee, J.S.; Rice, W.; Kelley, C.F.; Oyedele, T.; Coelho, L.E.; Phanuphak, N.; Singh, Y.; Middelkoop, K.; et al. HPTN 083–02: factors influencing adherence to injectable PrEP and retention in an injectable PrEP study. *Journal of the International AIDS Society* **2024**, *27*, e26252. [318
https://doi.org/10.1002/jia2.26252](https://doi.org/10.1002/jia2.26252).
319
54. Ramgopal, M.; Brown, C.A.; Frick, A.; Radtchenko, J.; Sridhar, G.; Ragone, L.; Van Wyk, J.A.; Mounzer, K.; Benson, P.; Santiago, S.; et al. 505. Real-World Use of Cabotegravir Long-Acting for Pre-Exposure Prophylaxis: Data from Trio Health Cohort. *Open Forum Infectious Diseases* **2025**, *12*, ofae631.157. [322
https://doi.org/10.1093/ofid/ofae631.157](https://doi.org/10.1093/ofid/ofae631.157).
323
55. Randolph, S.D.; Johnson, R. A Salon-Based Intervention to Improve PrEP Uptake among Black Women. *New England Journal of Medicine* **2024**, *390*, 776–777. [326
https://doi.org/10.1056/NEJMmp2313708](https://doi.org/10.1056/NEJMmp2313708).
327
56. Richardson, S.; Seekaew, P.; Koblin, B.; Vazquez, T.; Nandi, V.; Tieu, H.V. Barriers and facilitators of HIV vaccine and prevention study participation among Young Black MSM and transwomen in New York City. *PLOS ONE* **2017**, *12*, e0181702. [329
https://doi.org/10.1371/journal.pone.0181702](https://doi.org/10.1371/journal.pone.0181702).
330
57. Rousseau, E.; Julies, R.F.; Madubela, N.; Kassim, S. Novel Platforms for Biomedical HIV Prevention Delivery to Key Populations – Community Mobile Clinics, Peer-Supported, Pharmacy-Led PrEP Delivery, and the Use of Telemedicine. *Current HIV/AIDS Reports* **2021**, *18*, 500–507. [332
https://doi.org/10.1007/s11904-021-00578-7](https://doi.org/10.1007/s11904-021-00578-7).
333
58. Scott, R.K.; Hull, S.J.; Kerrigan, D.; Pratt-Chapman, M.; Mathias-Prabhu, T.; Zack, J.; Xu, M.; Sadauskas, M.; Moriarty, P.L.; Hanson, T.L.; et al. Development of a Clinic-Based, Sociostructural Intervention to Improve the Provision of Pre-Exposure Prophylaxis for Cisgender Women: Formative Study Using the Assessment, Decision, Adaptation, Production, Topical Experts, Integration, Training, and Testing (ADAPT-ITT) Framework. *JMIR Formative Research* **2025**, *9*, e75922. [336
https://doi.org/10.2196/75922](https://doi.org/10.2196/75922).
337
59. Serrano, V.B.; Moore, D.J.; Morris, S.; Tang, B.; Liao, A.; Hoenigl, M.; Montoya, J.L. Efficacy of Daily Text Messaging to Support Adherence to HIV Pre-Exposure Prophylaxis (PrEP) among Stimulant-Using Men Who Have Sex with Men. *Substance Use & Misuse* **2023**, *58*, 465–469. [342
https://doi.org/10.1080/10826084.2023.2165409](https://doi.org/10.1080/10826084.2023.2165409).
343
60. Seyedroudbari, S.; Ghadimi, F.; Grady, G.; Uzosike, O.; Nkwihereze, H.; Jemmott, J.B.; Momplaisir, F. Assessing Structural Racism and Discrimination Along the Pre-exposure Prophylaxis Continuum: A Systematic Review. *AIDS and Behavior* **2024**, *28*, 3001–3037. [346
https://doi.org/10.1007/s10461-024-04387-y](https://doi.org/10.1007/s10461-024-04387-y).
347
61. Shade, S.B.; Kirby, V.B.; Stephens, S.; Moran, L.; Charlebois, E.D.; Xavier, J.; Cajina, A.; Steward, W.T.; Myers, J.J. Outcomes and costs of publicly funded patient navigation interventions to enhance HIV care continuum outcomes in the United States: A before-and-after study. *PLOS Medicine* **2021**, *18*, e1003418. [350
https://doi.org/10.1371/journal.pmed.1003418](https://doi.org/10.1371/journal.pmed.1003418).
351
62. Shah, M.; Gillespie, S.; Holt, S.; Morris, C.R.; Camacho-Gonzalez, A.F. Acceptability and barriers to HIV pre-exposure prophylaxis in Atlanta's adolescents and their parents. *AIDS Patient Care STDS* **2019**, *33*, 425–433. [354
https://doi.org/10.1089/apc.2019.0117](https://doi.org/10.1089/apc.2019.0117).
355
63. Shoptaw, S.; Montgomery, B.; Williams, C.T.; El-Bassel, N.; Aramrattana, A.; Metzger, D.; Kuo, I.; Bastos, F.I.; Strathdee, S.A. HIV prevention awareness, willingness, and perceived barriers among people who inject drugs in Los Angeles and San Francisco, CA, 2016–2018. *J. Addict. Med.* **2020**, *14*, e260–e267. [357
https://doi.org/10.1097/ADM.0000000000000645](https://doi.org/10.1097/ADM.0000000000000645).
358
- 360

64. Siegler, A.J.; Mouhanna, F.; Giler, R.M.; Weiss, K.; Pembleton, E.; Guest, J.; Jones, J.; Castel, A.; Yeung, H.; Kramer, M.; et al. The prevalence of pre-exposure prophylaxis use and the pre-exposure prophylaxis-to-need ratio in the fourth quarter of 2017, United States. *Annals of Epidemiology* **2018**, *28*, 841–849. <https://doi.org/10.1016/j.annepidem.2018.06.005>. 361
362
65. Sittig, D.F.; Wright, A.; Osheroff, J.A.; Middleton, B.; Teich, J.M.; Ash, J.S.; Campbell, E.; Bates, D.W. Grand challenges in clinical decision support. *Journal of Biomedical Informatics* **2008**, *41*, 387–392. <https://doi.org/10.1016/j.jbi.2007.09.003>. 363
364
365
366
367
66. Smith, D.K.; Van Handel, M.; Grey, J. Estimates of adults with indications for HIV pre-exposure prophylaxis by jurisdiction, transmission risk group, and race/ethnicity, United States, 2015. *Annals of Epidemiology* **2018**, *28*, 850–857.e9. <https://doi.org/10.1016/j.annepidem.2018.05.003>. 368
369
370
67. Spinelli, M.A.; Scott, H.M.; Vittinghoff, E.; Liu, A.Y.; Morehead-Gee, A.; Gonzalez, R.; Gandhi, M.; Buchbinder, S.P. Brief Report: A Panel Management and Patient Navigation Intervention Is Associated With Earlier PrEP Initiation in a Safety-Net Primary Care Health System. *Journal of Acquired Immune Deficiency Syndromes* **2018**, *79*, 347–351. <https://doi.org/10.1097/QAI.0000000000001828>. 371
372
373
374
375
68. Spinelli, M.A.; Grinsztejn, B.; Landovitz, R.J. Promises and challenges: cabotegravir for preexposure prophylaxis. *Current Opinion in HIV and AIDS* **2022**, *17*, 186–191. <https://doi.org/10.1097/COH.0000000000000733>. 376
377
378
69. Starbird, L.E.; DiMaina, C.; Sun, C.A.; Han, H.R. A Systematic Review of Interventions to Minimize Transportation Barriers Among People with Chronic Diseases. *Journal of Community Health* **2019**, *44*, 400–411. <https://doi.org/10.1007/s10900-018-0572-3>. 379
380
381
70. Starbird, L.E.; DiMaina, C.; Sun, C.A.; Han, H.R. A systematic review of interventions to minimize transportation barriers among people with chronic diseases. *Journal of Community Health* **2019**, *44*, 400–411. <https://doi.org/10.1007/s10900-018-0572-3>. 382
383
384
71. Strathdee, S.A.; Kuo, I.; El-Bassel, N.; Hodder, S.; Smith, L.R.; Springer, S.A. Preventing HIV outbreaks among people who inject drugs in the United States: plus Ää change, plus Ää mÄame chose. *AIDS* **2020**, *34*, 1997–2005. <https://doi.org/10.1097/QAD.0000000000002673>. 385
386
387
72. Sullivan, P.S.; Mena, L.; Eloppe, L.; Siegler, A.J. Implementation Strategies to Increase PrEP Uptake in the South. *Current HIV/AIDS Reports* **2019**, *16*, 259–269. <https://doi.org/10.1007/s11904-019-00447-4>. 388
389
390
73. Touger, R.; Wood, B.R. A Review of Telehealth Innovations for HIV Pre-Exposure Prophylaxis (PrEP). *Current HIV/AIDS Reports* **2019**, *16*, 113–119. <https://doi.org/10.1007/s11904-019-00430-z>. 391
392
393
74. UNAIDS. Global AIDS Update 2024: The Path That Ends AIDS, 2024. 394
75. Villaire, S.; Sease, T.; Pankow, J.; Bennett, A.; Pulitzer, Z.; Hansen, L.; Frank, C.; Di Paola, A.; Lehman, W.; Sanchez, M.; et al. A qualitative examination of barriers and facilitators to HIV prevention and treatment for people involved with the criminal justice system. *Health & Justice* **2025**, *13*, 37. <https://doi.org/10.1186/s40352-025-00344-6>. 395
396
397
398
76. Violette, L.R.; Zewdie, K.; Gitahi, N.; Beima-Sofie, K.; Heffron, R. The pathway to delivering injectable CAB for HIV prevention: strategies from global PrEP leaders leveraging an adapted version of the Intervention Scalability Assessment Tool (ISAT). *Implementation Science Communications* **2024**, *5*, 101. <https://doi.org/10.1186/s43058-024-00637-1>. 399
400
401
402
77. Wood, S.M.; Morales, K.H.; Metzger, D.; Davis, A.; Fiore, D.; Petsis, D.; Barnett, K.; Koenig, H.C.; Dowshen, N.; Gross, R.; et al. Mental Health, Social Influences, and HIV Pre-exposure Prophylaxis (PrEP) Utilization Among Men and Transgender Individuals Screening for HIV Prevention Trials. *AIDS and Behavior* **2021**, *25*, 524–531. <https://doi.org/10.1007/s10461-020-3004-y>. 403
404
405
406
407
78. Organization, W.H. *Guidelines on lenacapavir for HIV prevention and testing strategies for long-acting injectable pre-exposure prophylaxis*; WHO Guidelines Approved by the Guidelines Review Committee, World Health Organization: Geneva, 2025. 408
409
410
79. World Health Organization. Task Shifting: Rational Redistribution of Tasks Among Health Workforce Teams. Global Recommendations and Guidelines, 2008. 411
412
80. Zamantakis, A.; et al. Barriers to Same-Day Pre-exposure Prophylaxis (PrEP) Implementation in Federally Funded HIV Clinics Within High-Burden Areas of the U.S.: A Coincidence Analysis. *AIDS and Behavior* **2025**. <https://doi.org/10.1007/s10461-025-04898-2>. 413
414
415

81. Zhang, J.; Li, C.; Xu, J.; Hu, Z.; Rutstein, S.E.; Tucker, J.D.; Ong, J.J.; Jiang, Y.; Geng, W.; Wright, S.T.; et al. Discontinuation, suboptimal adherence, and reinitiation of oral HIV pre-exposure prophylaxis: a global systematic review and meta-analysis. *The Lancet HIV* **2022**, *9*, e254–e268. [416
https://doi.org/10.1016/S2352-3018\(22\)00030-3](https://doi.org/10.1016/S2352-3018(22)00030-3).
417
82. Wikipedia contributors. Automation Bias, 2025. Comprehensive overview of automation bias phenomena, causes, and mitigation strategies across clinical, aviation, and other domains. [420
https://doi.org/10.1016/S2352-3018\(22\)00030-3](https://doi.org/10.1016/S2352-3018(22)00030-3).
421
83. Center for Digital Health and Artificial Intelligence. Automation Complacency: Risks of Abdicating Medical Decision Making. *AI and Ethics* **2025**. Examines automation complacency in healthcare AI, factors exacerbating over-reliance (fatigue, understaffing, workload), and organizational mitigation. [422
https://doi.org/10.1016/S2352-3018\(22\)00030-3](https://doi.org/10.1016/S2352-3018(22)00030-3).
423
84. White, J.A.; Adedinsewo, D.; et al. Bias Recognition and Mitigation Strategies in Artificial Intelligence Healthcare Applications. *npj Digital Medicine* **2025**, *8*. Comprehensive review of deployment-stage biases including automation bias, alert fatigue, and feedback loop bias, with human-in-the-loop and monitoring recommendations, [424
https://doi.org/10.1038/s41746-025-01503-7](https://doi.org/10.1038/s41746-025-01503-7).
425
85. U.S. Centers for Disease Control and Prevention. Guide to Taking a Sexual History, 2024. [426
https://doi.org/10.1038/s41746-025-01503-7](https://doi.org/10.1038/s41746-025-01503-7).
427
86. Bogaert, E.; Roels, R. Sexual health in patient care: shortcomings in medical training and experienced barriers in sexual history taking. *BMC Med Educ* **2025**, *25*, 338. [428
https://doi.org/10.1186/s12909-025-06850-3](https://doi.org/10.1186/s12909-025-06850-3).
429
87. American Health Information Management Association. Definition of the Health Record for Legal Purposes. *Journal of AHIMA* **2001**, *72*, 88.
430
88. Wikipedia contributors. Algorithmic Bias, 2025.
431
89. O’Neil, C. *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy*; Crown Publishers, 2016. Seminal work defining mathematical algorithms as opaque, unregulated, difficult to contest systems that embed and amplify existing biases while appearing objective.
432
90. O’Neil, C. Do Algorithms Perpetuate Human Bias?, 2018. Discusses how algorithmic decisions generate data that feeds back into training systems, reinforcing biases over time.
433
91. Agarwal, R.; Bjarnadottir, M.V.; Rhue, L.; Dugas, M.; Crowley, K.; Clark, J.; Gao, G. Addressing Algorithmic Bias and the Perpetuation of Health Inequities: An AI Bias Aware Framework. *Health Policy and Technology* **2023**, *12*, 100702. Describes four-step analytical process for building and deploying AI/ML algorithms; addresses unintended feedback bias where algorithmic decisions become training data, potentially amplifying discrimination over time, [434
https://doi.org/10.1016/j.hplt.2022.100702](https://doi.org/10.1016/j.hplt.2022.100702).
435
92. Massachusetts Institute of Technology. AI in Healthcare: Clinically Intelligent Machines. MITx Micromasters Program in Artificial Intelligence in Healthcare, 2024–2025.
436
- 437
- 438
- 439
- 440
- 441
- 442
- 443
- 444
- 445
- 446
- 447
- 448
- 449
- 450
- 451