Manufactured Death:

R(0) = 0 as the Unsolvable Closed-Form Solution for HIV Prevention in People Who Inject Drugs

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Abstract

Background: HIV pathogenesis involves irreversible seeding of CNS and lymphoid tissue compartments within hours of exposure. Reservoir dynamics have exactly one closed-form solution: $R(0) = 0$. We hypothesized that this solution is unsolvable for people who inject drugs (PWID) under current policy, irrespective of long-acting injectable pre-exposure prophylaxis (LAI-PrEP) availability.

Methods: We systematically evaluated both biomedical pathways to $R(0) = 0$. For post-exposure prophylaxis (PEP), we analyzed the 2025 CDC guidelines specifying 12–24 hour initiation for parenteral exposure against achievable access times. For PrEP, we evaluated: FDA approval status (44 years of epidemic); trial inclusion patterns; implementation study quality against Proctor et al. standards; and cascade completion probability via Monte Carlo simulation. We analyzed US outbreak patterns across political and socioeconomic environments.

Findings: *PEP pathway:* The 2025 CDC guidelines recommend initiation "as soon as possible, ideally within 12–24 hours" for parenteral exposure. Nested barriers (criminalization, medical policing via unnecessary toxicology testing, EHR documentation fear, stigma, provider knowledge gaps regarding new testing algorithms) render this window unachievable. $P(\text{PEP}|\text{PWID}) \approx 0{\cdot}0003$.

PrEP pathway: Zero FDA-approved agents for PWID (44 years, 0/4 agents). Bangkok TDF (2013) demonstrated efficacy but no approval was sought. PWID excluded from 9/11 major PrEP trials despite same companies conducting HCV trials in this population. Implementation science database built entirely on non-PWID populations. 2025 HIV testing algorithms (requiring HIV RNA) designed for settings without PWID infrastructure. Cascade completion: 0·04%. $P(\text{PrEP}|\text{PWID}) \approx 0{\cdot}00007$.

Outbreak pattern: HIV outbreaks occur uniformly in PWID regardless of political environment (Scott County IN, red/rural; Lawrence MA, blue/$<$50 miles from Harvard), wealth, or resource proximity. Policy responses (SSP defunding, increased policing) consistently backfire, escalating outbreak risk.

Interpretation: No biomedical pathway to $R(0) = 0$ exists for PWID. The only remaining "prevention" is stochastic avoidance—not encountering HIV-positive individuals. This is chance, not prevention. We formalize this as *Manufactured Death*: policy architecture that renders the only solvable equation unsolvable. This is not a PWID behavioral issue. It is policy failure producing mathematical impossibility.

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Introduction

HIV pathogenesis involves irreversible integration of proviral DNA into host chromosomes and early seeding of sanctuary compartments—central nervous system microglia, lymphoid tissue, and long-lived memory T cell subsets—within hours of exposure.(1; 2)

Once established, the reservoir persists for the lifetime of infected cells and cannot be eliminated by any known therapeutic intervention. This biological reality constrains the mathematics of prevention: the reservoir equation has exactly one closed-form solution.

$$R(0) = 0 \implies R(t) = 0 \quad \forall t \tag{1}$$

If no infected cells exist at initial condition, no infected cells will exist at any future time. This is the **Prevention Theorem**. It is not a policy recommendation but a mathematical necessity with the same epistemic status as fundamental theorems of calculus (Figure 1).

For any individual, only two pathways exist to achieve $R(0) = 0$:

1. **Stochastic avoidance:** Not encountering HIV-positive individuals capable of transmission. This is chance, not prevention, and cannot constitute public health strategy.

2. **Biomedical prevention:** Pharmacological maintenance of $R(0) = 0$ via post-exposure prophylaxis (PEP) or pre-exposure prophylaxis (PrEP).

We hypothesized that for people who inject drugs (PWID), $R(0) = 0$ is unsolvable under current United States policy—that both biomedical pathways are foreclosed by nested policy barriers, rendering HIV prevention mathematically impossible regardless of available pharmacology. This paper presents the proof.

Historical Context: 44 Years of Exclusion

The architecture of HIV prevention policy reveals systematic exclusion of PWID across regulatory, research, and implementation domains (Table 1).

The PEP timeline

From the earliest years of the epidemic, occupational post-exposure prophylaxis (oPEP) was implemented to protect healthcare workers from accidental HIV exposure. Non-occupational PEP (nPEP) for sexual exposure remained largely unavailable outside of sexual assault contexts for over two decades, contributing to epidemic expansion.(3)

The 2016 CDC PEP guidelines established a 72-hour initiation window for all exposure types. These guidelines remained static for nine years despite introduction of new antiretroviral agents.(4) The 2025 update maintained the 72-hour window but added critical language: “as soon as possible, ideally within 12–24 hours” for parenteral exposure, reflecting the biological reality that direct bloodstream inoculation compresses the effective intervention window.(5)

The 2025 guidelines also integrated data from HPTN 083 and HPTN 084, which demonstrated high-level integrase strand transfer inhibitor (INSTI) resistance in individuals who seroconverted after discontinuing long-acting cabotegravir.(6; 7) This necessitated fundamental changes to HIV testing algorithms: initiation now requires HIV RNA testing (viral load), not merely antibody/antigen testing, to detect acute infection before resistance-conferring mutations can be selected.

The PrEP timeline

Following the iPrEx trial demonstrating efficacy in men who have sex with men (MSM),(8) oral PrEP (tenofovir disoproxil fumarate/emtricitabine) received FDA approval in 2012—over 20 years into the epidemic—for prevention of sexual HIV acquisition in cisgender men, cisgender women, and transgender women.(9)

The Bangkok Tenofovir Study (2013) demonstrated 49% relative risk reduction in PWID,(10) yet no FDA approval was sought and none has been granted. This remains the only completed efficacy trial of any HIV prevention agent in PWID in 44 years of epidemic.

Subsequent approvals—Descovy (2019), Apretude (2021), Sunlenca (2024)—have included MSM, transgender women, and cisgender women, but

none have included PWID indication.(11; 12; 13) PURPOSE-4 represents the first trial of LAI-PrEP in PWID.(14)

The trial exclusion pattern

The pattern of exclusion is systematic (Table 2). Of 11 major PrEP trials conducted since 2010, only 2 (18%) included PWID. Notably, the same pharmaceutical companies conducting these trials simultaneously pursued hepatitis C virus (HCV) cure trials in PWID populations (sofosbuvir/ledipasvir, sofosbuvir/velpatasvir, glecaprevir/pibrentasvir), demonstrating capacity and willingness to conduct research in this population when commercially motivated.

The HIV prevention implementation science database was therefore generated entirely from trials excluding PWID. Testing algorithms, rapid-start protocols, same-day initiation procedures, cascade metrics, and provider training materials were all designed for non-PWID populations.(16) No validated implementation pathway for PWID exists because none was ever designed.

Methods

Proof structure

We evaluated both biomedical pathways to $R(0) = 0$ against empirical constraints, computing the probability of achieving sustained HIV prevention for PWID under current policy.

PEP pathway analysis

We analyzed the 2025 CDC PEP guidelines(5) and constructed a cascade model for PEP access following parenteral exposure. For each step, we estimated probability of success given nested barriers:

$$P(\text{PEP}) = \prod_{j=1}^{n} \left(p_j^{\text{base}} - \delta_j^{\text{crim}} - \delta_j^{\text{police}} - \delta_j^{\text{stigma}} - \delta_j^{\text{knowledge}} \right) \tag{2}$$

Parameters were derived from literature on healthcare access barriers for PWID.(17; 18; 19)

PrEP pathway analysis

We evaluated: (a) FDA approval status; (b) trial inclusion patterns; (c) implementation study quality against Proctor et al. standards(15) as assessed by Kametani et al.;(16) (d) 2025 testing algorithm complexity; and (e) cascade completion probability.

We constructed a Monte Carlo simulation ($n = 100{,}000$) of the LAI-PrEP cascade for PWID with eight sequential steps. Probability at each step was modeled as:

$$p_j = p_j^{\text{base}} - \delta_j^{\text{crim}} - \delta_j^{\text{defund}} - \delta_j^{\text{stigma}} \tag{3}$$

Final probability incorporated drug efficacy ($\varepsilon = 0{\cdot}99$) and 5-year incarceration survival:

$$P(R(0) = 0 | \text{PrEP}) = \varepsilon \times \prod_{j=1}^{8} p_j \times (1 - r)^5 \tag{4}$$

where $r = 0{\cdot}30$ is annual incarceration rate for active PWID.(20)

Outbreak analysis

We reviewed US HIV outbreaks in PWID populations from 2015–2024, analyzing geographic distribution, political environment, and resource proximity.(21; 19; 22)

Comparator analysis

We compared PWID outcomes to MSM using identical drug efficacy assumptions, with MSM cascade parameters derived from HPTN 083, PURPOSE-2, and real-world PrEP implementation.(6; 25)

Results

The Prevention Theorem

Analysis of reservoir dynamics confirmed Equation 1 (Figure 1). For any $R(0) > 0$, even optimal antiretroviral therapy initiated during acute infection leaves persistent reservoir due to long-lived cellular compartments (stem cell memory T cells, CNS microglia)

Table 1: Timeline of HIV prevention policy and PWID exclusion

Year	Event	PWID Status
1980s–90s	Occupational PEP implemented for healthcare workers	Not applicable
1990s–2012	Non-occupational PEP unavailable outside sexual assault	Excluded
2010	iPrEx trial demonstrates oral PrEP efficacy in MSM	Excluded
2012	FDA approves Truvada for sexual acquisition (MSM, women)	**Not approved for PWID**
2013	Bangkok TDF demonstrates 49% RRR in PWID	**No FDA approval sought**
2016	CDC PEP guidelines: 72-hour window	No PWID-specific guidance
2018	CDC expands to universal HIV testing recommendations	Testing, not prevention
2019	FDA approves Descovy (MSM, TGW)	**Not approved for PWID**
2021	FDA approves Apretude/CAB-LA (MSM, TGW, women)	**Not approved for PWID**
2024	FDA approves Sunlenca (cisgender women, PURPOSE-1)	**Not approved for PWID**
2025	CDC PEP guidelines updated: "ideally 12–24h" for parenteral; HIV RNA testing required	Complex algorithms, no PWID infrastructure
2025	PURPOSE-4 ongoing	First LAI-PrEP trial in PWID (44 years)

Table 2: PrEP trial inclusion by population

Trial	Population	PWID?
iPrEx (2010)	MSM/TGW	No
Partners PrEP (2012)	Heterosexual couples	No
TDF2 (2012)	Heterosexual	No
Bangkok TDF (2013)	**PWID**	**Yes**
PROUD (2015)	MSM	No
DISCOVER (2019)	MSM/TGW	No
HPTN 083 (2020)	MSM/TGW	No
HPTN 084 (2020)	Cisgender women	No
PURPOSE-1 (2024)	Cisgender women/girls	No
PURPOSE-2 (2024)	MSM/TGW	No
PURPOSE-4 (ongoing)	**PWID**	**Yes**
Total including PWID		**2/11 (18%)**

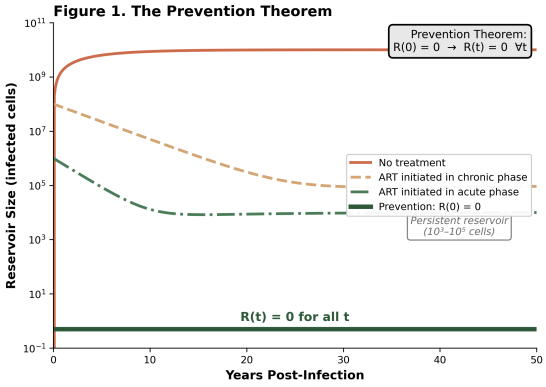

Figure 1: **The Prevention Theorem.** Reservoir trajectories under different interventions. Only $R(0) = 0$ yields $R(t) = 0$. All other conditions leave persistent reservoir (10^3–10^5 cells) due to long-lived cellular compartments.

with half-lives exceeding the human lifespan.(1; 2) Prevention is not one option among many—it is the only option that solves the equation.

Pathway 1: PEP impossibility

The 2025 CDC guidelines specify that PEP for parenteral exposure should be initiated "as soon as possible, ideally within 12–24 hours."(5) This language—absent from prior guidelines—represents embedded acknowledgment that the 72-hour window is insufficient for direct bloodstream inoculation.

For PWID to receive effective PEP within 12–24 hours, multiple sequential barriers must be overcome (Table 3). These barriers are nested and multiplicative:

Layer 1—Criminalization: Fear of arrest upon disclosure of injection drug use; fear of EHR documentation creating legal liability; avoidance of healthcare settings entirely.

Layer 2—Medical policing: Unnecessary urine toxicology testing upon ED presentation; "drug-seeking" documentation; creation of legal paper trail that follows patient across healthcare encounters, producing disengagement from care.

Layer 3—Stigma: Provider bias; triage deprioritization; judgment-laden clinical encounters that reinforce avoidance.

Layer 4—Knowledge gap: 2025 guidelines are new; HIV RNA testing algorithms are complex; no evidence of successful dissemination to providers or community members serving PWID.

$$P(\text{PEP}|\text{PWID}) = \prod_{j=1}^{7} p_j \approx 0{\cdot}0003 \tag{5}$$

This is not a PWID behavioral issue. It is policy architecture—criminalization, medical policing, stigma, and knowledge gaps—that renders the 12–24 hour window unachievable.

Pathway 1 is closed.

Table 3: PEP cascade for PWID: parenteral exposure

Step	Primary barrier	P(success)
1. Recognize exposure	Intoxication, chaos	0.30
2. Know PEP exists	No outreach to PWID	0.20
3. Access care <24h	Transportation, hours	0.15
4. Disclose IDU	EHR documentation fear	0.10
5. No medical policing	Urine tox, legal trail	0.30
6. Provider willing	Bias, "drug-seeking"	0.40
7. First dose received	Pharmacy, insurance	0.50
Product		**0.0003**

Pathway 2: PrEP impossibility

Regulatory void

Zero FDA-approved HIV prevention agents carry indication for PWID. The Bangkok Tenofovir Study demonstrated 49% relative risk reduction,(10) yet no approval was sought. For 44 years, the population with the highest per-exposure transmission risk has had zero approved prevention options.

Implementation science failure

The HIV prevention implementation science database was built entirely on trials excluding PWID. Kametani et al. evaluated implementation studies against Proctor et al. standards(15) and found systematic failure to meet criteria for adoption, fidelity, penetration, and sustainability.(16)

Testing algorithms, rapid-start protocols, and cascade metrics were designed for clinical settings with established ID infrastructure, provider familiarity, insurance pathways, and same-day laboratory access—none of which characterize PWID healthcare touchpoints (syringe service programs, emergency departments, street medicine).

The 2025 HIV testing requirements for LAI-PrEP initiation (HIV RNA in addition to antigen/antibody) add complexity without addressing infrastructure gaps. No validated implementation pathway for PWID exists.

Cascade impossibility

Under current policy, cascade completion approaches zero (Table 4, Figure 2):

$$\prod_{j=1}^{8} p_j = 0{\cdot}30 \times 0{\cdot}40 \times 0{\cdot}35 \times 0{\cdot}30 \times 0{\cdot}55 \times 0{\cdot}45 \times 0{\cdot}45 \times 0{\cdot}30 = 0{\cdot}000 \tag{6}$$

No individual step probability falls below 30%, yet the product approaches zero. This is the mathematical signature of nested multiplicative barriers: crimi-

nalization → defunding of SSPs → stigma, each decaying probability independently.

Including drug efficacy and 5-year incarceration survival:

$$P(R(0) = 0|\text{PrEP, PWID}) = 0{\cdot}99 \times 0{\cdot}0004 \times 0{\cdot}168 = 0{\cdot}00007 \quad (7)$$

Current policy achieves sustained protection for 7 in 100,000 PWID.

Pathway 2 is closed.

Table 4: LAI-PrEP cascade for PWID: current policy

Step	Primary barrier	P(success)
1. Awareness	Marketing to MSM	0.30
2. Willingness	Criminalization fear	0.40
3. Healthcare access	No PWID infrastructure	0.35
4. Disclose IDU	EHR documentation	0.30
5. Provider willing	Bias, unfamiliarity	0.55
6. Testing complete	Complex RNA algorithm	0.45
7. First injection	Scheduling, pharmacy	0.45
8. Sustained Q6M	Incarceration, instability	0.30
Cascade product		**0.0004**
With incarceration survival		**0.00007**

The outbreak evidence

HIV outbreaks occur almost uniformly in PWID populations, irrespective of political environment, wealth, or resource proximity (Table 5):

- **Scott County, IN (2015):** Rural, impoverished, conservative—215 cases(21)
- **Lawrence/Lowell, MA (2018–2024):** Urban, liberal, <50 miles from Harvard/Tufts/UMass—205+ cases, ongoing(22)
- **Seattle, WA (2018–2019):** Urban, wealthy, progressive—ongoing transmission(23)
- **Philadelphia, PA (2018):** Urban, major medical infrastructure—outbreak

No protective factors exist. The only intervention demonstrating outbreak termination is comprehensive policy overhaul (Vancouver 2018: supervised injection, housing-first, decriminalization).(24)

Policy responses to outbreaks—defunding SSPs, increased policing, criminalization of paraphernalia—consistently backfire, driving PWID away from healthcare and increasing transmission.(20; 18) Strathdee et al. characterized this as "plus ça change, plus c'est la même chose"—the more things change, the more they stay the same—warning of escalating outbreak patterns toward a potential tipping point.(19)

Table 5: US HIV outbreaks in PWID: no protective factors

Location	Political	Resources	Cases
Scott County, IN	Red/rural	Remote	215
Lawrence, MA	Blue/urban	Harvard nearby	205+
Seattle, WA	Blue/wealthy	Major centers	Ongoing
Philadelphia, PA	Blue/urban	Major centers	Outbreak
Cabell Co., WV	Red/rural	Remote	Outbreak

The privilege comparison

MSM achieve 53% cascade completion using identical pharmacology (Figures 3–4). The 1,325-fold difference reflects systematic architectural advantages:

- Trial inclusion: 100% (11/11) vs 18% (2/11)
- FDA approvals: 4/4 vs 0/4
- Implementation pathways: Validated vs nonexistent
- Provider familiarity: Established vs absent
- Insurance pathways: Developed vs absent

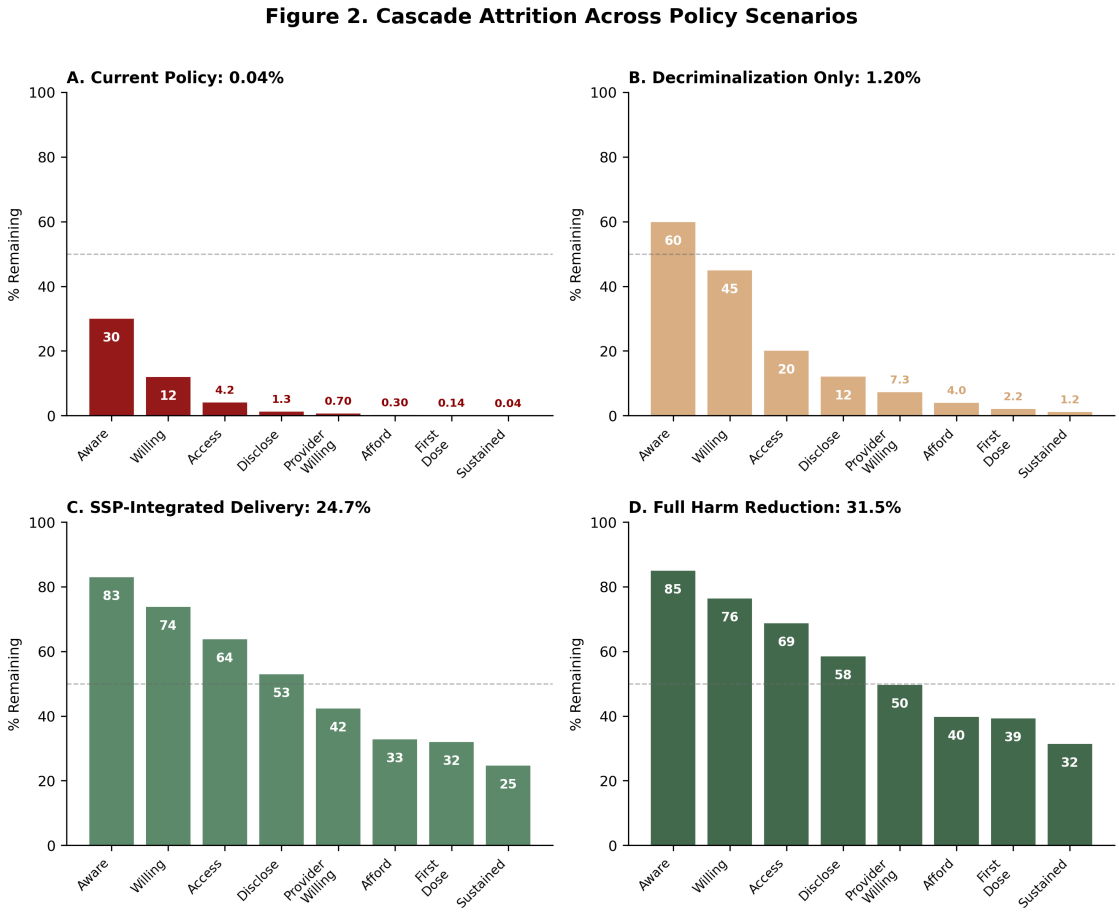

Figure 2: **Cascade attrition across policy scenarios.** (A) Current policy: 0·04%. (B) Decriminalization: 1·20%. (C) SSP-integrated: 24·7%. (D) Full harm reduction: 31·5%. Nested multiplicative barriers decay probability at each step.

The difference is not biological. It is not behavioral. It is architectural. The cascade works for MSM because policy built it for them. It fails for PWID because policy did not.

Discussion

Manufactured Death: formal definition

We define *Manufactured Death* as the systematic creation of conditions under which the only solvable equation—$R(0) = 0$—cannot be solved for a defined population.

For PWID under current US policy:

$$P(R(0)=0|\text{PWID}) = \underbrace{P(\text{PEP})}_{\approx 0} + \underbrace{P(\text{PrEP})}_{\approx 0} + \underbrace{P(\text{stochastic})}_{\text{chance}} \tag{8}$$

Both biomedical pathways are closed. The only remaining "prevention" is stochastic avoidance—not encountering HIV-positive individuals capable of transmission. This is chance, not prevention. It cannot constitute public health strategy.

This is not a behavioral issue

The framing of HIV in PWID as a "behavioral" problem locates failure in patients. Our analysis demonstrates the opposite: failure is architectural.

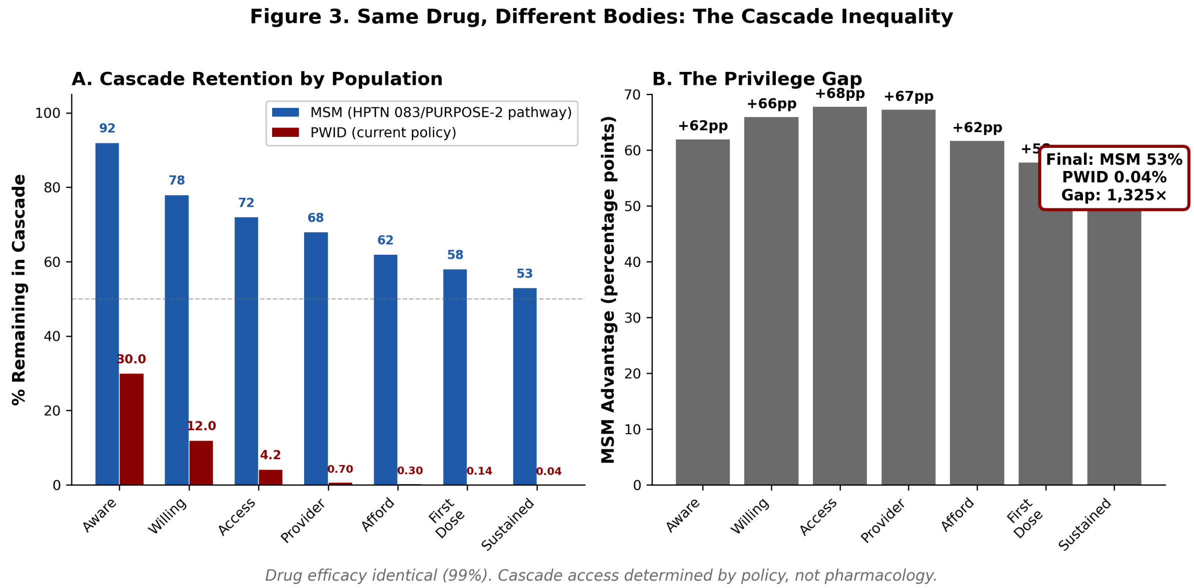

Figure 3: **Same drug, different bodies.** (A) Cascade retention: MSM 53%, PWID 0·04%. (B) Privilege gap at each step. Final difference: 1,325-fold. Drug efficacy identical (99%).

- PEP fails not because PWID refuse care but because the 12–24 hour window is unachievable given criminalization, medical policing, and stigma
- PrEP fails not because PWID are "hard to reach" but because no approved agent exists, no implementation pathway was designed, and the cascade was built for other populations
- Outbreaks occur not because of PWID behavior but because policy responses (defunding, policing) predictably worsen conditions

The mathematical proof demonstrates that even with 99% drug efficacy, policy architecture reduces $P(R(0)=0)$ to effectively zero. **Drug efficacy is irrelevant when every other term approaches zero.**

The policy lock

The complete equation for HIV prevention in PWID:

$$P(R(0)=0) = \varepsilon_{\text{drug}} \times P(\text{cascade}) \times P(\text{no incarceration}) \times P(\text{PEP if exposure}) \tag{9}$$

$$P(R(0)=0) = 0{\cdot}99 \times 0{\cdot}0004 \times 0{\cdot}168 \times 0{\cdot}0003 \approx 0 \tag{10}$$

The equation is **policy-locked**, not pharmacology-locked. PURPOSE-4 can demonstrate perfect efficacy and it will not matter. The policy architecture guarantees that the drug cannot reach the people who need it within windows that permit $R(0)=0$.

Implications

If seroconversions occur in PURPOSE-4 or subsequent implementation, they will be attributed to "adherence challenges," "chaotic lifestyles," or "complex social circumstances"—framing that blames patients. Our model provides the alternative interpretation: seroconversions are the predictable consequence of policy architecture that forecloses both pathways to $R(0)=0$.

The 85,000 preventable infections over 5 years (Figure 5) are not epidemic outcomes. They are policy choices—the enumerable body count of Manufactured Death.

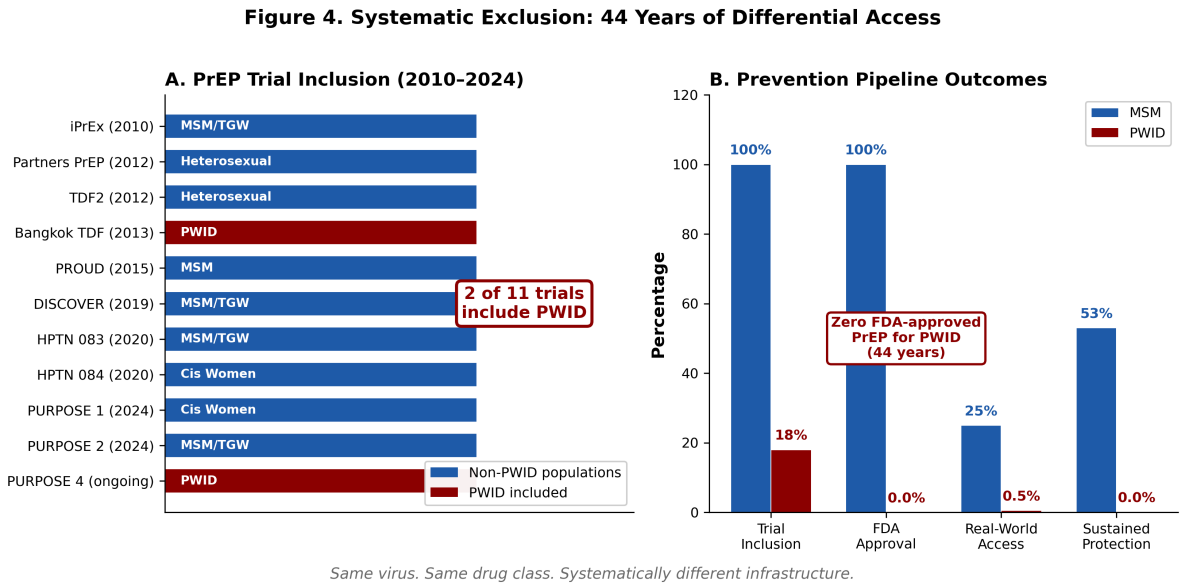

Figure 4: **44 years of differential access.** (A) Trial inclusion: 2/11 include PWID. (B) Pipeline outcomes: MSM 100% FDA approval; PWID 0%. Same virus, same drug class, systematically different infrastructure.

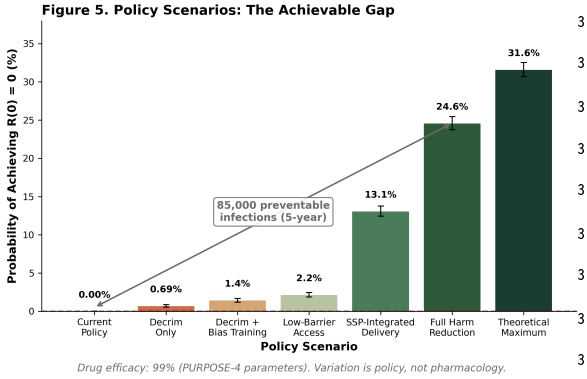

Figure 5: **The achievable gap.** Current policy: 0·00%. Full harm reduction: 24·59%. The difference—85,000 infections over 5 years—is policy choice, not epidemic dynamics.

Conclusion

HIV reservoir dynamics have exactly one closed-form solution: $R(0) = 0$. We have proven that this solution is unsolvable for PWID under current US policy.

PEP pathway: The 12–24 hour window for parenteral exposure (2025 CDC guidelines) is unachievable given nested barriers of criminalization, medical policing, stigma, and provider knowledge gaps. $P \approx 0$.

PrEP pathway: Zero FDA approvals (44 years). Implementation science built on non-PWID trials. Cascade completion 0·04%. $P \approx 0$.

Remaining option: Stochastic avoidance. This is chance, not prevention.

We have named this *Manufactured Death* because precision matters. The mathematics are not opinion. The proof is complete. Policy has constructed conditions under which the only solvable equation cannot be solved.

Policy can change. The mathematics cannot.

Declarations

Contributors: ACD conceived the study, developed the mathematical framework, conducted analysis, and wrote the manuscript.

Declaration of interests: ACD was previously employed by Gilead Sciences, Inc. This manuscript was developed independently.

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