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Long-Acting Cabotegravir for Pre-Exposure Prophylaxis: Efficacy, Implementation, and Global Access

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ABSTRACT

Human immunodeficiency virus pre-exposure prophylaxis had traditionally relied on daily oral tenofovir-based regimens, which demonstrated high efficacy when adherence is maintained but face substantial implementation challenges related to daily pill burden, stigma, and variable adherence patterns across diverse populations. Long-acting injectable cabotegravir represents a paradigm shift in biomedical prevention, offering sustained drug exposure through bimonthly intramuscular administration of a crystalline nanoparticle formulation that maintains therapeutic concentrations for extended periods. This review critically evaluated the efficacy, safety, implementation considerations, and global access challenges of long-acting cabotegravir as pre-exposure prophylaxis for human immunodeficiency virus prevention, examining pharmacological properties, clinical trial outcomes, real-world deployment experiences, and equity implications. A comprehensive synthesis of phase 3 clinical trials, pharmacokinetic studies, implementation science research, health economic analyses, and global health policy documents addressing cabotegravir pre-exposure prophylaxis through early 2025 was utilized in writing this article. Randomized controlled trials demonstrated superior efficacy of long-acting cabotegravir compared with daily oral tenofovir disoproxil fumarate/emtricitabine, with hazard ratios between 0.21 and 0.34 across diverse populations including cisgender women, men who have sex with men, and transgender women. Pharmacokinetic advantages included elimination of daily adherence requirements and prolonged terminal half-life exceeding two months. Implementation barriers included injection site reactions, requirement for specialized healthcare infrastructure, supply chain complexities, high costs limiting accessibility in resource-constrained settings, and potential for resistance emergence during tail phase concentrations following discontinuation. Long-acting cabotegravir represented a transformative advancement in human immunodeficiency virus prevention with demonstrated superiority over oral regimens, though realizing global impact requires addressing substantial implementation, cost, and equity challenges to ensure access extends beyond high-income settings.

Keywords: Cabotegravir, Pre-exposure prophylaxis, Long-acting injectable, HIV prevention, Global access.

INTRODUCTION

Cabotegravir is an integrase strand transfer inhibitor that prevents human immunodeficiency virus replication by blocking the integration of reverse-transcribed viral DNA into host cell chromosomes [1, 2]. As a second-generation integrase inhibitor, cabotegravir exhibits high potency, a favorable resistance profile, and pharmacokinetic properties amenable to long-acting formulation development. The compound demonstrates nanomolar potency against human immunodeficiency virus type 1, with activity across diverse viral subtypes and maintained efficacy against strains harboring resistance mutations to first-generation integrase inhibitors. The long-acting injectable formulation consists of cabotegravir drug substance milled into crystalline nanoparticles suspended in an aqueous vehicle, enabling intramuscular depot administration with gradual dissolution and sustained systemic absorption over weeks to months. Following gluteal injection, cabotegravir nanoparticles form a depot at the injection site from which drug molecules progressively dissolve, enter systemic circulation, and distribute to tissues including genital tract mucosa where prevention of viral transmission occurs. The extended terminal elimination

half-life, ranging from 25 to 54 weeks depending on individual pharmacokinetic variability, maintains plasma concentrations exceeding the protein-adjusted 90% inhibitory concentration for months after a single injection.

Pre-exposure prophylaxis has emerged as a cornerstone of combination human immunodeficiency virus prevention strategies, with daily oral tenofovir-based regimens demonstrating efficacy exceeding 90% when adherence is high but substantially diminished effectiveness under real-world conditions where adherence proves challenging [3, 4]. Behavioral and structural factors including stigma, privacy concerns, daily pill burden, and socioeconomic determinants, contribute to suboptimal adherence patterns that undermine prevention effectiveness. Populations at highest risk for human immunodeficiency virus acquisition, including adolescent girls and young women in sub-Saharan Africa, men who have sex with men, transgender women, and individuals in serodiscordant partnerships, face distinct adherence barriers requiring tailored prevention modalities [5]. Long-acting injectable formulations that decouple protection from daily behavior offer potential to address adherence challenges while providing discretion and convenience. The pharmacological advantage of sustained drug exposure eliminating the adherence requirement theoretically translates to enhanced real-world effectiveness compared with oral regimens, though implementation considerations including healthcare system requirements, acceptability, and access equity introduce complexities. The objective of this review is to critically evaluate the efficacy, safety, implementation considerations, and global access challenges of long-acting injectable cabotegravir as pre-exposure prophylaxis, examining clinical evidence, pharmacological advantages, real-world deployment experiences, and strategies to ensure equitable access across diverse geographic and socioeconomic contexts.

Pharmacology and Mechanism of Action

Long-acting cabotegravir exerts pre-exposure prophylaxis effects through sustained inhibition of human immunodeficiency virus integrase enzyme activity in target cells within genital and rectal mucosal tissues [6, 7]. Following intramuscular injection into the gluteal muscle, cabotegravir nanoparticles undergo gradual dissolution releasing free drug molecules that partition into systemic circulation. Peak plasma concentrations occur approximately one week post-injection, followed by a prolonged absorption phase as depot nanoparticles continue dissolving over subsequent weeks. Cabotegravir demonstrates extensive tissue distribution with a volume of distribution exceeding 12 liters per kilogram, reflecting substantial penetration into peripheral compartments including female and male genital tract tissues where concentrations exceed plasma levels by two to four-fold. This favorable tissue distribution ensures therapeutic drug concentrations at anatomical sites of viral transmission, protecting acquisition during sexual exposure events.

The mechanism of integrase strand transfer inhibition involves cabotegravir binding to the HIV-1 integrase enzyme complexed with viral DNA ends, preventing the strand transfer reaction that inserts proviral DNA into host chromosomes [8]. By blocking this essential replication step, cabotegravir prevents the establishment of integrated provirus in newly infected cells, thereby averting productive infection when administered prophylactically before viral exposure. The protein-adjusted 90% inhibitory concentration for wild-type virus approximates 0.166 micrograms per milliliter, a threshold exceeded by several fold throughout the dosing interval when bimonthly injections are maintained [9]. Pharmacokinetic modeling demonstrates that trough concentrations four weeks after steady-state injections average 1 to 2 micrograms per milliliter, providing a substantial safety margin above inhibitory thresholds [10]. However, considerable inter-individual pharmacokinetic variability, with coefficients of variation exceeding 30% for area under the curve and trough concentrations, means some individuals exhibit lower exposures potentially reducing protective efficacy.

The extended terminal elimination phase following discontinuation presents both advantages and challenges. Protective concentrations persist for several weeks after the final injection, providing a pharmacological forgiveness period during which interruptions in the dosing schedule do not immediately compromise protection. Conversely, the prolonged tail of subtherapeutic concentrations lasting months after discontinuation creates a theoretical window for resistance emergence if individuals acquire human immunodeficiency virus infection during this phase. Resistance mutations selected under suboptimal integrase inhibitor pressure, particularly Q148 pathway mutations conferring cross-resistance to multiple integrase inhibitors, could compromise future treatment options. This pharmacological tail necessitates either transitioning to alternative prophylaxis during the washout period or implementing frequent human immunodeficiency virus testing to detect incident infections promptly, adding implementation complexity that contrasts with the simplicity of oral regimen discontinuation where drug clearance occurs within days.

Clinical Efficacy and Safety Evidence

Pivotal phase 3 clinical trials established the superior efficacy of long-acting cabotegravir compared with daily oral tenofovir disoproxil fumarate/emtricitabine for human immunodeficiency virus prevention across diverse at-risk populations [11]. The HPTN 083 trial enrolled cisgender men and transgender women who have sex with men across multiple countries, randomizing participants to bimonthly cabotegravir injections or daily oral tenofovir disoproxil fumarate/emtricitabine. Results demonstrated 66% lower incidence of human immunodeficiency virus infection in the cabotegravir arm compared with oral pre-exposure prophylaxis, with an incidence rate ratio of 0.34

and confidence interval excluding unity, establishing statistical superiority. The HPTN 084 trial enrolled cisgender women in sub-Saharan Africa, similarly demonstrating 89% lower incidence with cabotegravir compared with the oral regimen, yielding an incidence rate ratio of 0.11 [12, 13]. These remarkable efficacy differences reflect both the inherent pharmacological advantages of sustained drug exposure and the challenges of maintaining daily oral adherence in trial participants, as directly observed therapy studies suggest both regimens provide comparable protection when adherence is optimal.

Secondary analyses explored efficacy across demographic and behavioral subgroups, generally confirming consistent protection though some variability emerged. In HPTN 083, younger participants and those with baseline sexually transmitted infections exhibited higher overall incidence rates but similar relative risk reductions with cabotegravir compared with oral prophylaxis [11, 14]. Importantly, human immunodeficiency virus infections occurring in cabotegravir recipients predominantly reflected acquisition at enrollment before protective drug levels were established, or infection during the oral lead-in phase preceding injectable initiation, rather than breakthrough infections during steady-state injectable prophylaxis. Phylogenetic and resistance analyses of breakthrough infections revealed integrase inhibitor resistance mutations in two individuals, both acquired during subtherapeutic cabotegravir concentrations in the setting of poor adherence to the injection schedule or during the pharmacological tail after discontinuation, validating concerns regarding resistance emergence under suboptimal drug pressure.

Safety profiles proved acceptable with manageable tolerability across both trials. Injection site reactions constituted the most common adverse events, occurring in over 77% of cabotegravir recipients, though most reactions were mild to moderate severity involving pain, swelling, or nodule formation resolving within days [15]. Severe injection site reactions prompting discontinuation occurred in approximately 1 to 2% of participants. Systemic adverse events including nausea, fatigue, and headache occurred at similar frequencies between cabotegravir and oral comparison arms. Weight gain, observed with integrase inhibitors in treatment settings, showed modest increases in cabotegravir recipients compared with oral arms, though clinical significance remains debated. Hepatotoxicity, a theoretical concern given rare cases observed with oral cabotegravir, occurred infrequently without concerning signals in prophylaxis trials. Long term safety data extending beyond trial durations remain limited, necessitating post-marketing surveillance to detect rare adverse events or delayed toxicities. These efficacy and safety findings established regulatory approval pathways while highlighting implementation considerations including injection acceptability, resistance prevention strategies, and monitoring requirements that influence real-world deployment.

Implementation Science and Real-World Deployment

Translation of clinical trial efficacy into population-level impact requires addressing multifaceted implementation challenges spanning healthcare delivery systems, provider training, patient preferences, and programmatic infrastructure. Unlike oral pre-exposure prophylaxis that can be dispensed through pharmacies or community distribution models, long-acting cabotegravir necessitates healthcare facility visits for intramuscular injections administered by trained personnel, creating access barriers in settings with limited clinical infrastructure [16]. The requirement for bimonthly injections demands reliable appointment systems, patient tracking mechanisms, and strategies to minimize missed doses that could compromise protection. Demonstration projects in diverse settings reveal that retention in care and on-time injection receipt present significant challenges, with studies reporting that 20 to 30% of scheduled injections occur outside the recommended window, potentially affecting efficacy.

Patient preferences and acceptability studies demonstrate heterogeneous attitudes toward injectable prophylaxis, with some populations expressing strong preference for injections over daily pills due to discretion and convenience, while others cite injection anxiety, concerns about injection site reactions, or preference for user-controlled methods as barriers. Qualitative research reveals that preferences vary by age, gender, prior healthcare experiences, and cultural contexts, underscoring the need for diverse prevention modalities rather than a one-size-fits-all approach. Adolescents and young adults, populations with substantial human immunodeficiency virus burden, demonstrate particular interest in long-acting modalities that eliminate daily adherence requirements and reduce visibility of prevention product use [17], though concerns about accessing healthcare facilities and potential parental awareness temper enthusiasm in some contexts.

Healthcare provider perspectives identify training needs, workflow integration challenges, and clinical guidance gaps as implementation barriers [18]. Providers require education regarding appropriate candidate selection, contraindications, injection techniques, management of injection site reactions, and protocols for missed doses or discontinuation. Integration into existing sexual health, family planning, or infectious disease clinics offers efficient pathways for service delivery, though siloed healthcare systems in some settings create coordination challenges. The need for cold chain storage, though less stringent than some biologics, adds logistical complexity to supply chain management. Cost considerations fundamentally constrain implementation, with current pricing rendering cabotegravir prohibitively expensive in most low and middle income countries where human immunodeficiency virus burden is highest [19]. Early implementation experiences in high-income settings reveal that even with insurance coverage, prior authorization requirements, high copayments, and pharmacy benefit complexities create access barriers disproportionately affecting marginalized populations. These implementation realities underscore that

clinical efficacy alone is insufficient for public health impact without commensurate investment in delivery systems, health equity interventions, and access expansion strategies.

Global Access, Pricing, and Health Equity

The profound disparity between human immunodeficiency virus burden concentrated in low and middle income countries and cabotegravir access concentrated in high-income settings epitomizes longstanding inequities in biomedical prevention technologies. Sub-Saharan Africa, bearing approximately 70% of global human immunodeficiency virus incidence [20], represents the region where long-acting cabotegravir could achieve greatest population impact, yet current pricing structures render the intervention economically unfeasible for most public health programs in the region. Voluntary licensing agreements negotiated by the Medicines Patent Pool aim to enable generic manufacturing for low and middle-income countries, with projected generic prices potentially reaching $40 to $50 per person annually, figures that remain challenging for programs operating on limited per-capita budgets but represent transformative price reductions compared with originator pricing.

Manufacturing and supply chain considerations present additional access barriers beyond pricing alone. The specialized nanoparticle formulation requires sophisticated production capabilities not widely available among generic manufacturers, potentially limiting competition and price reduction. Quality assurance ensuring bioequivalence of generic formulations demands rigorous testing given the complex physicochemical properties of nanoparticle suspensions. Cold chain requirements for storage and transport, while not requiring frozen temperatures, add logistical complexity in settings with unreliable electricity and limited refrigeration infrastructure. Country regulatory approval processes introduce delays between global licensing and national availability, with many countries lacking expedited pathways for pre-qualified products. These multilayered barriers collectively prolong the timeline from technology development to equitable global access, recapitulating patterns observed with antiretroviral treatment scale-up where decades elapsed before universal access approached reality.

Health equity considerations extend beyond aggregate access to encompass within-country distribution, ensuring that marginalized and criminalized populations facing the highest risk can access services. Structural barriers including stigma, discrimination in healthcare settings, poverty, gender-based violence, and criminalization of key populations create differential access even when services are ostensibly available. Adolescent girls and young women in sub-Saharan Africa, the population demonstrating the greatest relative benefit in clinical trials, face age-related consent barriers, financial constraints, and mobility restrictions limiting healthcare engagement [21]. Transgender women, sex workers, people who inject drugs, and men who have sex with men in criminalized contexts encounter fear of legal consequences or mistreatment deterring healthcare utilization. Addressing these equity dimensions requires not only ensuring product availability but also implementing rights-based service delivery models, legal reforms decriminalizing marginalized populations, and community-led distribution strategies that meet people where they are rather than expecting navigation of discriminatory healthcare systems. Ultimately, realizing the global health potential of long-acting cabotegravir depends on sustained advocacy, political commitment, and resource mobilization to bridge the access chasm between innovation and equitable implementation.

Research Gaps and Future Directions

Despite robust efficacy evidence from pivotal trials, substantial knowledge gaps persist regarding optimal implementation strategies, long-term outcomes, and integration within combination prevention frameworks. Comparative effectiveness research examining long-acting cabotegravir against alternative oral regimens including tenofovir alafenamide-based formulations or event-driven dosing strategies would inform nuanced prevention counseling and resource allocation decisions. Head-to-head comparisons with other emerging long-acting modalities including lenacapavir, a capsid inhibitor with twice-yearly dosing potential, will become increasingly relevant as the long-acting prophylaxis landscape expands. Research characterizing adherence patterns and reasons for discontinuation in real-world settings, as opposed to the supported environment of clinical trials, is essential for designing interventions to optimize retention and persistence.

Safety questions requiring longer observation periods include potential cumulative toxicities, effects on bone mineral density given integrase inhibitor class effects, weight trajectory implications, and reproductive health outcomes in pregnant and breastfeeding individuals [22]. While pharmacokinetic data suggest placental transfer and breast milk excretion, systematic safety data in pregnancy remain limited, creating uncertainty for individuals who become pregnant during prophylaxis. The durability of protection following discontinuation and optimal strategies for transitioning between prophylaxis modalities deserve investigation, particularly given the prolonged pharmacological tail with resistance implications. Mechanistic studies elucidating the relationship between tissue drug concentrations, cellular penetration, and protection against cell-free versus cell-associated virus could refine dosing strategies and predict efficacy against diverse exposure routes.

Implementation science priorities include developing delivery models suitable for resource-constrained settings, such as task-shifting to community health workers or peer navigators for injection administration following appropriate training. Mobile health interventions leveraging text message reminders, telehealth consultations, or app-based appointment scheduling may improve retention and timely injection receipt [23]. Economic evaluations

incorporating local cost structures, health system capacity, and opportunity costs inform resource allocation and value-for-money assessments guiding policy decisions. Formulation innovations potentially enabling self-administration through subcutaneous delivery devices or reducing injection frequency could enhance acceptability and scalability. Pediatric formulations and dosing regimens remain undeveloped despite a substantial adolescent human immunodeficiency virus burden, representing a critical gap. Ultimately, advancing from proof-of-concept efficacy to transformative public health impact requires sustained research investments addressing the full translational spectrum from mechanism to equitable implementation at scale.

CONCLUSION

Long-acting injectable cabotegravir represents a watershed advancement in human immunodeficiency virus pre-exposure prophylaxis, offering superior efficacy compared with daily oral regimens through sustained drug exposure that eliminates adherence as a behavioral determinant of protection. Pivotal clinical trials demonstrated relative risk reductions exceeding 65% in men who have sex with men and transgender women, and 89% in cisgender women, establishing cabotegravir as the most efficacious prevention modality evaluated to date. The pharmacological basis for this efficacy resides in prolonged tissue concentrations maintained by crystalline nanoparticle depot formulation, providing forgiveness for dosing delays while introducing complexities regarding the extended elimination tail and resistance implications. Safety profiles prove acceptable with predominantly local injection site reactions and manageable systemic tolerability. However, translating clinical efficacy into population impact confronts formidable implementation barriers, including healthcare infrastructure requirements, injection acceptability heterogeneity, retention challenges, and monitoring demands. Most critically, access inequities driven by prohibitive costs in low and middle-income countries where human immunodeficiency virus burden concentrates threaten to recapitulate historical patterns of delayed prevention technology diffusion. Generic manufacturing and voluntary licensing initiatives offer pathways to affordability, though manufacturing complexity, supply chain logistics, and regulatory processes introduce delays. Evidence quality from randomized controlled trials is exemplary, though real-world effectiveness data and long-term safety surveillance remain limited. The transformative potential of long-acting cabotegravir for global human immunodeficiency virus prevention will be realized only through sustained commitment to equitable access, health systems strengthening, and integration within comprehensive combination prevention strategies addressing structural determinants of vulnerability. International funding agencies and governments should prioritize procurement agreements, manufacturing capacity building, and delivery system investments to accelerate equitable global access to long-acting cabotegravir, particularly in sub-Saharan Africa, where adolescent girls, young women, and key populations bear disproportionate human immunodeficiency virus burden and would derive the greatest benefit from this transformative prevention modality.

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