The Journal for Nurse Practitioners xxx (xxxx) xxx

Contents lists available at ScienceDirect

The Journal for Nurse Practitioners

journal homepage: www.npjournal.org

Lenacapavir for HIV PrEP: Interim Phase III Clinical Data Evaluation

Christopher W. Blackwell, Frances Armstrong, Humberto López Castillo

Keywords:
lenacapavir
Phase III clinical trials
pre-exposure prophylaxis (PrEP) for HIV

A B S T R A C T

Lenacapavir is an antiretroviral medication injected every 6 months as pre-exposure prophylaxis (PrEP) for HIV that is currently undergoing Phase III clinical trials worldwide. Interim data suggest lenacapavir is highly efficacious, distinctly being the first PrEP regimen to ever show zero infections during Phase III clinical trials. Lenacapavir is being lauded as a major advancement in the eradication of HIV as a major public health threat. This article provides an overview of current clinical trial data regarding lenacapavir, discusses its current research and development, provides comparison between lenacapavir and cabotegravir, and provides implications for nurse practitioners and other clinicians regarding PrEP.

Pre-Exposure Prophylaxis (PrEP) in the Prevention of HIV

Prevention of infection with type 1 HIV (HIV-1) using daily oral pre-exposure prophylaxis (PrEP) regimens was initiated in the United States when the US Food and Drug Administration (FDA) approved emtricitabine/tenofovir fumarate (FTC/TDF) 200/300 mg in 2012.[1] Emtricitabine/tenofovir alafenamide (FTC/TAF) 200/25 mg, a second daily oral agent for PrEP, was approved by the FDA in 2019.[2] Efficacy data of these 2 agents are similar, and when those on either regimen maintain safer sex practices, their risk of sexually transmitted HIV-1 acquisition is reduced by approximately 99%.[2] Some examples of safer sex practices are outlined in Table 1.

Common causes of incident HIV infection while on PrEP include contact with specific drug-resistant viruses.[3,4] The major clinical trial that reinforced FTC/TDF as efficacious was the 2010 Pre-exposure Prophylaxis Initiative (iPrEx) study.[5]

When participants in this study showed detectable serum levels of FTC/TDF, their risk of HIV acquisition was reduced by 90%.[5] Continued clinical trials and research on FTC/TDF for PrEP further bolstered evidence for its efficacy.[2] The high rate of efficacy in the 2015 Prevent the Acquisition of HIV-1 Infection (PROUD) study resulted in participants in the deferred arm of the study being promptly offered PrEP when early data strongly supported its efficacy.[2,4]

Furthermore, participants of the PROUD study had no major adverse events. The most common adverse events associated with use of FTC/TDF for PrEP included nausea, headache, and arthralgia.[2,4] Indications for FTC/TDF for PrEP grew to include HIV prevention in adolescents in 2018.[5] Like FTC/TDF, FTC/TAF also has FDA approval for use as HIV PrEP in both adults and adolescents.[6] Lower incidence of renal toxicity and bone demineralization are often cited as an advantage of FTC/TAF over FTC/TDF. A publication by Blackwell and López Castillo provides a comprehensive comparison between these 2 oral PrEP regimens.[2]

A more novel approach to PrEP was introduced with the 2021 FDA approval of injectable cabotegravir.[7] After initiation, cabotegravir is administered via intramuscular injection by a health care professional every other month.[7,8] A 2022 work by Blackwell and López Castillo provides a comprehensive overview of cabotegravir, including its indications, efficacy, safety, contraindications, and associated adverse events.[7] Because of its longer duration and need for less frequent administration, injectable PrEP may be preferable for individuals at increased risk of HIV infection who may be less adherent to a daily oral regimen or who may want to maintain privacy regarding their use of PrEP.[7] Lenacapavir is a first in-class capsid inhibitor injectable antiretroviral medication currently undergoing Phase III clinical trials in South Africa, Uganda, Argentina, Brazil, Mexico, Peru, Puerto Rico, Thailand, and the United States.[9]

The regimen for lenacapavir differs from cabotegravir in that it is administered as 2 subcutaneous abdominal injections every 6 months.[9] Clinical trial data thus far have indicated the regimen as being highly efficacious, distinctly being the first PrEP regimen ever to show zero infections during Phase III clinical trials.[10] Public health and HIV advocates are lauding lenacapavir as a major advancement in the strategy to eradicate HIV as a major public health threat:

> Lenacapavir represents more than just a breakthrough in HIV prevention and treatment. It is a chance to rewrite the trajectory of the pandemic, and, together with successful treatment efforts, end HIV as a public health threat by 2030.[11]

The emerging data surrounding lenacapavir is so astounding that the drug's development was identified as the 2024 Breakthrough of the Year by the journal *Science*, which described it as "a pivotal step toward diminishing HIV/AIDS as a global health

https://doi.org/10.1016/j.nurpra.2025.105360

Table 1
Examples of Safer Sex Practices[15]

- Discussing HIV serostatus with sexual partners
- Having sex with people who aren't living with HIV
- Having sex with people who are living with HIV, on antiretroviral treatment, and who have an undetectable viral load
- Having sex in geographic areas where HIV is less common
- Avoiding sex while under the influence of substances, which can increase risk by lowering people's inhibitions and reducing safer sex practices
- Using condoms consistently during every sexual encounter

crisis."[12,13] In addition, *Science* selected lenacapavir's development as its Breakthrough of the Year because of its unique antiretroviral pharmacologic properties:

> The off-the-charts success of the drug as PrEP sprang from a basic research advance: a new understanding of the structure and function of HIV's capsid protein, which lenacapavir targets. Many other viruses have their own capsid proteins, which form a shell around their genetic material, so this drug's triumph raises the exciting prospect that similar capsid inhibitors could fight other viral diseases.[12]

Because this drug has the potential to have such a major future influence on HIV prevention globally, nurse practitioners and other clinicians should understand its current state in scientific discovery and the outcome data being supported in its clinical trials thus far. This article provides an overview of the current clinical trial data regarding lenacapavir, discusses its current research and development, provides a comparison of lenacapavir to cabotegravir, and provides implications for nurse practitioners and other clinicians regarding PrEP.

Defining Clinical Trial Phases

To comprehend the outcome data from the clinical trials of lenacapavir thus far, an understanding of the phased processes in which clinical trials for pharmaceutical agents occur is essential. This background information concerning clinical trial phases provides a perspective on the evolution of lenacapavir's formative clinical data. Phase I trials primarily focus on a new drug's safety and dose range in smaller samples (n = 20–100) of healthy volunteers.[14] Phase I trials focus on establishing the pharmacokinetics of an investigational drug, determining the physiological means by which the drug is absorbed, distributed, metabolized, and excreted.[14] Determining ideal dosing, therapeutic range, and establishing safe and effective dosing parameters while avoiding toxicity are all examples of some of the main facets of Phase I clinical trials.[14] Approximately 70% of drugs are passed from Phase I to Phase II clinical trials.[14]

In Phase II clinical trials, effectiveness of a particular drug on a specific condition or disease is determined using a larger sample of volunteer participants (n = 100–300), who are typically randomized into treatment or placebo study arms.[14] The timeline for this phase can range from a few months to 2 years.[14] Questions regarding dosing frequency are answered, and the larger sample sizes involved in Phase II studies yield emerging data regarding adverse effects associated with the drug.[14] Only 30% of drugs pass Phase II clinical trials to enter Phase III clinical trials.[14]

Phase III clinical trials are conducted among multiple clinical study sites and typically involve several thousand participants who, as in Phase II studies, are randomized into treatment versus placebo arms.[14] Because Phase III trials involve much larger sample sizes than Phase I or Phase II trials, they help to generate the bulk of the experimental drug's data regarding safety and efficacy.[14] The majority of the information provided on package inserts and drug labeling are derived from Phase III clinical trial data.[14] The overall process for FDA approval through the 3 clinical trial phases can take years, with only 25% to 30% of all drugs passing Phases I, II, and III. Once a drug passes Phase III, its manufacturer can request FDA approval for marketing of the drug by filing a new drug application, which contains all scientific data obtained throughout all phases of the drug's trials.[14] Lenacapavir as PrEP is currently in 4 Phase III studies, with a fifth planned to evaluate samples in France and the United Kingdom.[9]

Current Clinical Trials of Lenacapavir

The current Phase III clinical trials evaluating lenacapavir as PrEP are the PURPOSE 1, PURPOSE 2, PURPOSE 3, and PURPOSE 4 trials. Interim data are available for PURPOSE 1 and PURPOSE 2.

Purpose 1

This clinical trial, which is scheduled to end in July 2027,[9] enrolled more than 5,300 cisgender women (persons born female at birth who identify as female) in South Africa and Uganda.[9,15] Participants were randomized into a treatment group (receiving 2 subcutaneous injections of lenacapavir every 6 months) or an FTC/TAF or FTC/TDF group (considered ethically responsible because efficacy and safety of oral daily FTC/TAF and FTC/TDF have already been established).[15]

Background HIV incidence was used as a comparator. Interim results of PUROPSE 1 indicate zero cases of HIV infection among women in the lenacapavir group, which was superior to daily oral FTC/TDF.[15] In PURPOSE 1, no new safety concerns were identified, and the drug was generally well-tolerated by participants.[15] The most common adverse events, aside from injection site reactions, were headache (n = 285; 13.3%), urinary tract infection (n = 307; 14.4%), and genitourinary chlamydia infection (n = 300; 14%).[16] In addition, the incidence of adverse events was similar across treatment arms; however, the lenacapavir arm had less incidence of nausea and vomiting than those in the FTC/TDF and FTC/TAF arms.[16]

Continued condom use was emphasized alongside the PrEP interventions in PURPOSE 1.[15] However, sexually transmitted infections have been reported as adverse events in the study. This may suggest inconsistent adherence to condom use among participants. Consequently, the finding of zero new HIV infections in the interim data may ultimately bolster the evidence supporting the drug's efficacy as HIV PrEP. No new data indicating safety concerns arose in those taking FTC/TDF or FTC/TAF in PURPOSE 1, which is also the first Phase III clinical trial to ever include pregnant and lactating women (either in or outside the United States). This might ease efforts for use in these populations if the drug is ultimately approved.

Purpose 2

This clinical trial, scheduled to conclude in April 2027,[9] is being conducted on more than 3,000 men who have sex with men (the population at most risk for HIV infection in the United States), gay men, transgender men (persons born female at birth who identify as male), transgender women (persons born male at birth who identify as female), and gender nonbinary people (persons who identify as being a man and a woman, somewhere in between, or falling completely outside of these categories) in Argentina, Brazil, Mexico, Peru, Puerto Rico, South Africa, Thailand, and the United States. Participants were randomized into a treatment arm (receiving 2 subcutaneous injections of lenacapavir every 6 months) or an FTC/TDF daily oral treatment arm.[17]

Like the PURPOSE 1 trial, background HIV incidence was used as a comparator. Interim data showed administration of subcutaneous lenacapavir every 6 months was superior to daily FTC/TDF; thus,

Table 2
Major Differences Between Cabotegravir and Lenacapavir[9,18]

General Characteristics	Cabotegravir	Lenacapavir
Approval as PrEP date	2021	Pending
Brand name	Apretude	Branded as Sunlenca in some countries
Antiretroviral drug class	Integrase strand transfer inhibition	Capsid inhibitor
Injection administration route	Intramuscular	Subcutaneous
Injection administration site	Dorsal gluteal	Abdomen
Injection volume	One 3-mL injection	Two 1.5-mL injections
Dosing frequency	First injection followed by a second 1 month later, then every 2 months	First injection along with 2 oral tablets, followed by 2 more oral tablets on day 2, and then injections every 6 months
Efficacy	Very high efficacy in all populations	Results from PURPOSE 1 and PURPOSE 2 report high efficacy in all populations; PURPOSE 4 investigating efficacy in injection drug users
Regulatory approvals/guidelines	56 regulatory approvals as of December 2024, WHO recommendation as preventative option in July 2022	Regulatory submissions and potential normative guidance anticipated in 2025
Cost	Varies; 90% of patients pay $10 or less through specialty pharmacy; $160/year in low/middle income countries	To be determined
Manufacturer	ViiV Healthcare	Gilead Sciences
Generic	Expected earliest access in 2027	Expected earliest access in 2027
Assistance	Available	To be determined

PrEP = pre-exposure prophylaxis; WHO = World Health Organization.

the study was unblinded in September 2024 after it met this primary endpoint.[9] No safety concerns were identified in PURPOSE 2. However, 26 of 2,183 (1.2%) participants in the lenacapavir arm discontinued the trial because of injection site reactions.[17] Other common adverse events reported in PURPOSE 2 included rectal chlamydial infections (n = 289; 13.2%), oropharyngeal gonococcal infections (n = 283; 13%), and rectal gonococcal infection (n = 99; 9.1%). Overall, the incidence of Grade 2 or higher adverse events was similar between the 2 PURPOSE 2 treatment arms.[17]

Purpose 3

This clinical trial is being conducted on cisgender women living in the United States and is scheduled to run until July 2027.[9]

Purpose 4

This clinical trial is being conducted on people who inject drugs (PWIDs) in the United States and is scheduled to run until July 2027.[9] It is the first study to intentionally recruit PWIDs since a 2013 study by Choopanya and colleagues assessing efficacy of tenofovir as PrEP in PWIDs.[19]

Purpose 5

Exact sample populations and a timeline for PURPOSE 5 have yet to be announced, but its focus will be on HIV prevention among people who may benefit from PrEP but who are PrEP naive in France and the United Kingdom.[9]

Cabotegravir and Lenacapavir: A Focused Comparison

Although cabotegravir and lenacapavir are both injectable agents used for PrEP, their differences are important to denote. Table 2 provides a comparison between the 2 agents.

Global Cost, Accessibility of Lenacapavir, and the Role of Nurse Practitioners

A major concern being voiced by public health advocates is the potential cost of lenacapavir and equitable access to the drug, particularly in low- and middle-income countries where HIV is driving global health infections.[20] Unitaid (an organization that partners with the World Health Organization in HIV prevention) has indicated that lenacapavir remains more than 1,000 times more expensive than current oral PrEP regimens.[11]

This is somewhat complicated in that Gilead Sciences is the single developer of lenacapavir and will be the sole supplier of the drug during its initial introduction period, estimated to be between 2 and 3 years.[20] Although Gilead Sciences has granted direct voluntary licenses to 6 generic drug manufacturers, the price and availability volume during this initial introductory period is currently unknown.[20] This provides an opportunity for nurse practitioners and other public health advocates to work directly with industry leaders in the design of a comprehensive mechanism to scale and accelerate

Table 3
Cross-Stakeholder Advocacy Access[19]

Advocacy Points	Examples of Implementation
Demand equitable PrEP access and programming for choice	• Securing national/international funding commitments from governments, health ministries, and other organizations • Setting bold targets to meet supply and distribution demands worldwide • Embracing innovation and applying new strategies to meet goals/objectives
Advocate for affordable pricing and building a sustainable market	• Advocate for pricing transparency and acceleration of pathways to cost-effective PrEP over the next 3 years
Hold procurers and donors for lenacapavir accountable	• Demand clarity about the necessary steps for access and distribution of lenacapvir globally • Establish targets and milestones • Advocate for adequate funding and product availability for rollout • If a phased rollout approach is used, participate in decisions related to the prioritization of distribution
Work locally with research sites and PrEP programs	• Integrate clinical knowledge, advocacy, and know-how in ongoing PrEP research initiatives • Ensure open communication channels are used to enhance access to meet demands for PrEP

PrEP = pre-exposure prophylaxis.

introduction of lenacapavir to the vulnerable populations in need of it most. The AIDS Vaccine Advocacy Coalition recommends those mechanisms occur parallel with research, implementation science, design of scale programs, funding, and implementation.[20] Nurse practitioners and other clinicians also have the potential to help augment participation in the current PURPOSE Phase III clinical trials. While enrollment in PURPOSE 1 and PURPOSE 2 is complete, participants are still being recruited for PURPOSE 3 and PURPOSE 4. Nurse practitioners can identify patients who potentially qualify for these trials and refer them to the proper screening channels by accessing the PURPOSE study website.[21,22]

Summary and Conclusion

Coupled with safer sex behaviors, daily oral PrEP regimens with FTC/TDF or FTC/TAF can reduce sexual transmission of HIV by 99%.[11] Cabotegravir, the only currently FDA-approved injectable agent for PrEP, is also highly efficacious.[7,8] Lenacapavir is an emerging injectable form of PrEP that has enormous potential to make a major impact in the global HIV pandemic.[11,12]

Some sources have taken the extraordinary position that the drug even has the potential to end HIV as a public health threat by 2030.[11] Interim data from 2 Phase III clinical trials (PURPOSE 1 and PURPOSE 2) have shown lenacapavir as having high efficacy in certain vulnerable populations, surpassing that of daily oral FTC/TDF. The PURPOSE 1 trial was the first PrEP Phase III clinical trial ever to show zero infections.[10] Ongoing Phase III clinical trials will expand critical inquiry as to lenacapavir's efficacy and indication in cisgender women (PURPOSE 3) and injectable drug users (PURPOSE 4) in the United States. Nurse practitioners and other clinicians can increase enrollment in these trials by identifying appropriate study patients and assisting them with navigation to the PURPOSE studies website.[21,22]

Because this novel agent is being developed by a single pharmaceutical company, concerns regarding its accessibility and cost have been expressed. Nurse practitioners and other clinicians are uniquely positioned to begin planning the mechanisms needed to scale up and accelerate production now to help overcome some of these challenges. The AIDS Vaccine Advocacy Coalition has published a blueprint that can serve as a guide to bridge clinical trial efficacy to public health impact by accelerating access to lenacapavir.[20] Highlights of the cross-stakeholder advocacy priorities from this blueprint are found in Table 3.

Prescribing of PrEP is currently failing to reach public health targets.[23] Therefore, nurse practitioners and other clinicians have a responsibility to become familiar with the implementation of PrEP within their practices and should be proactive in preventing HIV in patients at increased risk of HIV infection.

CRediT authorship contribution statement

Christopher W. Blackwell: Writing – review & editing, Writing – original draft, Supervision, Resources, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Frances Armstrong:** Writing – review & editing, Writing – original draft, Investigation, Formal analysis, Conceptualization. **Humberto López Castillo:** Writing – review & editing, Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of competing interest

In compliance with standard ethical guidelines, the authors report no relationships with business or industry that may pose a conflict of interest.

Funding

No external or internal funding was provided.

References

1. Tracing the path of PrEP: A brief history of HIV prevention. Accessed January 6, 2025. https://www.prep2me.com/blog/tracing-the-path-of-prep-a-brief-history-of-hiv-prevention#:~:text=Nearly%2030%20years%20after%20the,a%20second%20PrEP%20medication%2C%20Descovy
2. Blackwell C, López Castillo H. Human immunodeficiency virus pre-exposure prophylaxis: use of emtricitabine/tenofivir alafenamide. *J Nurse Pract.* 2021;17(6):673-676.
3. Markowitz M, Grossman H, Anderson PL, et al. Newly acquired infection with multidrug-resistant HIV-1 in a patient adherent to preexposure prophylaxis. *J Acquir Immune Defic Syndr.* 2017;76(4):e104-e106.
4. McCormack S, Dunn D, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): Effectiveness results from the pilot phase of a pragmatic open-label randomised trial. *Lancet.* 2016;387(10013):53-60.
5. Blackwell C. Preventing HIV infection in high-risk adolescents using pre-exposure prophylaxis. *J Assoc Nurses AIDS Care.* 2018;29(5):770-774.
6. DISCOVER is the largest PrEP clinical trial, with over 5300 patients. Updated September 2020. Accessed November 7, 2020. https://www.descovyhcp.com/discover-clinical-trial
7. Blackwell C, López Castillo H. Injectable cabotegravir: a new approach to HIV pre-exposure prophylaxis. *J Nurse Pract.* 2022;18(9):947-950.
8. Apretude getting started: FAQs. Updated in 2024. Accessed January 6, 2025. https://apretude.com/getting-started/faqs
9. AIDS Vaccine Advocacy Coalition. Accessed January 8, 2025. https://www.prepwatch.org/products/lenacapavir-for-prep/
10. Gilead. Gilead's twice-yearly lenacapavir demonstrated 100% efficacy and superiority to daily Truvada for HIV prevention. 2024. Accessed January 8, 2025. https://www.gilead.com/news/news-details/2024/gileads-twice-yearly-lenacapavir-demonstrated-100-efficacy-and-superiority-to-daily-truvada-for-hiv-prevention
11. Unitaid. From promise to impact: unlocking lenacapavir's potential to end HIV. https://unitaid.org/news-blog/from-promise-to-impact-unlocking-lenacapavirs-potential-to-end-hiv/#:~:text=Lenacapavir%20represents%20more%20than%20just,act%20decisively%20and%20with%20urgency
12. Cohen J. 2024 Breakthrough of the Year. Science. Published December 12, 2024. Accessed January 8, 2025. https://www.science.org/content/article/breakthrough-2024#section_breakthrough
13. Cox D, Barros Guinle MI. This drug is the breakthrough of the year—and it could mean the end of the HIV epidemic. *Goats and Soda* [Blog]. Published December 12, 2024. Accessed January 8, 2025. https://www.npr.org/sections/goats-and-soda/2024/12/12/g-s1-37662/breakthrough-hiv-lenacapavir#:~:text=The%20emerging%20data%20surrounding%20lenacapavir,as%20a%20global%20health%20crisis.%22
14. University of Cincinnati College of Medicine. Clinical trials phases defined. Published 2025. Accessed on January 8, 2025.
15. Gilead. PURPOSE 1. Accessed January 8, 2025. https://www.purposestudies.com/purpose1
16. Bekker LG, Das M, Abdool KO, et al. Twice-yearly lenacapavir of daily F/TAF for HIV prevention in cisgender women. *N Engl J Med.* 2024;391(13):1179-1192. https://doi.org/10.1056/NEJM032407001
17. Kelley CF, Acevedo-Quinones M, Agwu A, et al. Twice-yearly lenacapavir for HIV prevention in men and gender-diverse persons. Online ahead of. N Engl J Med.. Accessed January 9, 2025. http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=ovftz4&NEWS=N&AN=00006024-900000000-96477
18. ViiV Healthcare. Apretude access and support. 2024. Accessed January 9, 2025. https://apretude.com/access-and-support/?cc=ps_YLDMMWQZBAIYW592109404&utm_source=google&utm_medium=cpc&utm_term=apretude+cost&gad_source=1&gbraid=0AAAAAoLQ48bDGEaDjQhZmZWxc0MdWaWKh&gclid=Cj0KCQiA4fi7BhC5ARIsAEV1YiaxOSwxblvEya3VsgMOslOzqdSBAFLvoWP2tTPeCijN48wYbpP9_sAaAib7EALw_wcB&gclsrc=aw.ds
19. Choopanya K, Martin M, Suntharasamai P, et al. Antiretroviral prophylaxis for HIV injecting drug users in Bangkok, Thailand (the Bangkok Tenofovir Study): a randomized, double-blind, placebo-controlled phase 3 trial. *Lancet.* 2013;9883(381):2083-2090.
20. AIDS Vaccine Advocacy Coalition. From clinical trial efficacy to public health impact: a plan for accelerating access to injectable lenacapvir for PrEP. Updated in October 2024. Accessed January 9, 2025. https://www.prepwatch.org/wp-content/uploads/2024/11/PlanForLEN_Oct4_2024.pdf
21. Gilead. PURPOSE 3. Accessed January 9, 2025. https://www.purposestudies.com/purpose3
22. Gilead. PURPOSE 4. Accessed January 9, 2025. https://www.purposestudies.com/purpose4
23. Bonacci RA, Smith DK, Ojikutu BO. Toward greater pre-exposure prophylaxis equity: increasing provision and update for Black and Hispanic/Latino individuals in the US. *Am J Prev Med.* 2021 Nov;61(5 suppl 1):S60-S72. https://doi.org/10.1016/j.amepre.2021.05.027

Christopher W. Blackwell, PhD, APRN, ANP-BC, AGACNP-BC, CNE, FAANP, FAAN, is an associate professor and the director of the Adult-Gerontology Acute Care Nurse Practitioner Programs and Frances Armstrong, DNP, APRN, AGACNP-BC, AGPCNP-BC, is an assistant professor and graduate simulation coordinator, Adult-Gerontology Acute Care Nurse Practitioner Programs, Department of Nursing Practice, College of Nursing, Academic Health Science Center, University of Central Florida, Orlando, FL. Dr. Blackwell can be reached at christopher.blackwell@ucf.edu. Humberto López Castillo, MD, PhD, CPH, CMI-Spanish, is an assistant professor in the Department of Health Sciences, College of Health Professions and Sciences, Department of Population Health Sciences, College of Medicine, Academic Health Science Center, University of Central Florida, Orlando, FL.