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High Acceptability and Perceived Feasibility of Long-Acting Injectable Antiretroviral Treatment Among People Living with HIV Who Are Viremic and Health Workers in Uganda

Caitlin E. Kennedy, PhD, MPH,¹ Tongying Zhao, MSPH,¹ Anh Van Vo, MSPH,¹ Rosette Nakubulwa, BA,² Proscovia Nabakka, BA,² Jade Jackson, MSW,³ Joseph G. Rosen, PhD, MSPH,¹ Larry W. Chang, MD, MPH,^{1,4} Steven J. Reynolds, MD, MPH,^{4,5} Thomas C. Quinn, MD, MS,⁵ Gertrude Nakigozi, MBChB, MPH, PhD,² Godfrey Kigozi, MBChB, MPH, PhD,² Joseph Kagaayi, MBChB, MPH, PhD,² Fred Nalugoda, PhD, MPH,² William G. Ddaaki, MSc,² M. Kate Grabowski, PhD, ScM,³ and Neema Nakyango, MA²

Abstract

Long-acting injectable antiretroviral treatment (LAI ART), such as a bimonthly injection of cabotegravir/rilpivirine, is a promising HIV treatment option. LAI ART may particularly benefit people who are reluctant to initiate or are poorly adherent to daily oral pills and not virally suppressed. However, the acceptability and feasibility of LAI ART among individuals with viremia in Africa has not been well studied. We conducted qualitative in-depth interviews with 38 people living with HIV with viral load ≥ 1000 copies/mL and 15 medical and nursing staff, and 6 focus group discussions with peer health workers, to examine acceptability and feasibility of LAI ART in south-central Uganda. Transcripts were thematically analyzed through a team-based framework approach. Most people living with HIV reacted positively toward LAI ART and endorsed interest in taking it themselves. Most felt LAI ART would make adherence easier by reducing the challenge with remembering daily pills, particularly in the context of busy schedules, travel, alcohol use, and dietary requirements. Participants also appreciated the privacy of injections, reducing the likelihood of stigma or inadvertent HIV serostatus disclosure with pill possession. Concerns about LAI ART included side effects, perceived medication effectiveness, fear of injection, and medical mistrust and conspiracy beliefs. Health workers and participants with viremia also noted health system challenges, such as stockouts and monitoring treatment failure. However, they felt the health system could overcome these challenges. Implementation complexities must be addressed as LAI ART is introduced and expanded in Africa to best support viral suppression and address HIV care continuum gaps.

Keywords: long-acting antiretroviral therapy, injectable cabotegravir/rilpivirine, viremia, Uganda

Introduction

LONG-ACTING INJECTABLE ANTIRETROVIRAL TREATMENT (LAI ART), such as a bimonthly injection of cabotegravir/rilpivirine (CAB/RPV), is a new and promising option for HIV treatment. LAI ART has been recommended and approved for use in high-income countries¹ and is currently

being considered in sub-Saharan Africa, where >20 million people are currently taking daily oral ART.² A recent modeling study suggests that in sub-Saharan Africa, injectable CAB/RPV may be best targeted to individuals who might otherwise have suboptimal adherence to ART, as cost-effectiveness is greatest among these individuals, and risk of contributing to further drug resistance is no greater than with

¹Department of International Health, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, USA.

²Rakai Health Sciences Program, Kalisizo, Uganda.

Departments of ³Pathology and ⁴Medicine, School of Medicine, Johns Hopkins University, Baltimore, Maryland, USA.

⁵Division of Intramural Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, US National Institutes of Health, Bethesda, Maryland, USA.

oral ART.³ Small demonstration projects and case studies from the United States have suggested that LAI ART may be a helpful approach for such individuals to improve their viral suppression despite complex adherence challenges,^{4,5} and larger studies are ongoing.⁶

However, trials of the current formulations were only conducted among individuals who were already virally suppressed on oral ART,⁷ and substantial controversy remains about the potential use of LAI ART with individuals who are not virally suppressed. Concerns generally center around the cost of LAI ART and the possibility of drug resistance, as cabotegravir has a long “tail,” where detectable drug remains in the body for months after an injection at levels that may be insufficient to prevent HIV infection but may allow drug resistance.⁸ Even for people who are virally suppressed and successful on oral ART, in sub-Saharan Africa, multiple barriers to LAI ART implementation remain.⁸

Just four studies to date have explored perspectives on LAI ART in sub-Saharan Africa. In rural Tanzania, a mixed-methods study among female sex workers found >90% would be “likely” or “very likely” to use LAI ART if available.⁹ LAI ART was perceived to reduce psychosocial, logistical, and stigma concerns associated with daily pill-taking, including specific contextual concerns around food insecurity and erratic schedules associated with sex work.⁹ In coastal Kenya, a second study conducted focus groups with a range of people living with HIV, including both male and female youth and adults, men who have sex with men, and female sex workers.¹⁰ These groups also held positive attitudes toward LAI ART, anticipating it would alleviate pill burden, reduce stigma, and improve adherence. A third study among adolescents and young adults living with HIV in South Africa found that one in eight would prefer LAI ART to oral ART.¹¹ Finally, a study in western Kenya among women living with HIV who had experience with intermediate or long-acting contraceptives found that two-thirds were interested in a multi-purpose technology that would combine contraception and LAI ART.¹²

To date, no study from sub-Saharan Africa has examined the acceptability and feasibility of LAI ART among people living with HIV who are viremic—arguably the most important potential recipients of LAI ART. We conducted a qualitative study with individuals living with HIV who were viremic (viral load ≥ 1000 copies/mL) and health workers in south-central Uganda to examine acceptability and feasibility of LAI ART in this setting.

Methods

Setting and participants

This study was conducted in the predominantly rural Rakai and Kyotera regions of south-central Uganda, where the Rakai Health Sciences Program (RHSP) has conducted the longitudinal Rakai Community Cohort Study (RCCS) for >30 years. The RCCS regularly surveys all individuals aged 15–49 years living in 41 communities and includes HIV testing for all participants and viral load assessments for all individuals living with HIV.¹³

For this qualitative study, we included both people living with HIV and health workers. People living with HIV were sampled from RCCS participants agreeing to be contacted for future studies. We recruited people living with HIV aged

≥ 18 years and exhibiting HIV viremia (≥ 1000 RNA copies/mL) at the time of survey. We further purposefully sampled for representation from the following groups, to capture diversity in experiences with HIV care and treatment: (1) diagnosed with HIV but has not started or delayed initiation ART; (2) initiated ART but defaulted care; (3) currently on ART, but with a history of treatment interruption(s); and (4) currently on ART with no history of treatment interruptions.

For health workers, we purposefully selected a range of HIV care providers from government, private, and non-governmental organization health facilities. Health workers included nurses, medical officers, and counselors; several were the ART in-charge at their facility. Peer health workers were selected from an RHSP-run cadre of peer health workers living with HIV who conduct community outreach and treatment support.¹⁴

Data collection

People living with HIV participated in two semi-structured qualitative in-depth interviews between May and September 2022. Health workers participated in a single interview or focus group discussion. In-depth interviews were conducted in Luganda or English and lasted about an hour. Focus group discussions were conducted in Luganda and lasted about an hour and a half. Interviews with people living with HIV followed a semi-structured guide that covered a range of topics, including life histories with HIV, and LAI ART was covered in the second interview, with questions about their perspectives on LAI ART, whether they would consider it for themselves, and potential benefits and concerns. At the end of each interview or focus group discussion with health workers, we asked a series of questions about LAI ART, including what participants knew about LAI ART, potential benefits and concerns for their clients, and health system implementation considerations.

Analysis

All interviews and focus groups were transcribed and translated into English (where necessary) for analysis. Following a framework approach,^{15,16} we first read through and discussed emerging findings among the study team. Two coauthors (A.V.V. and T.Z.) drafted an initial set of codes that drew deductively from the interview guides and inductively from the data. After discussing the codebook with the study team, A.V.V., T.Z., and J.J. read all transcripts and populated an analytic matrix with rows (cases), columns (codes), and cells of summarized data and associated key quotes. The lead author (C.E.K.) then reviewed the original transcripts and the summarized matrix data, analyzing the data by case and by code, further developing the codes into subcodes, and writing summary memos for each code, returning to the original transcripts and collaborating with other coauthors where necessary. These summary memos were developed into the results presented hereunder.

Ethics

The study was approved by the Uganda Virus Research Institute Research Ethics Committee, the Johns Hopkins University School of Medicine Institutional Review Board, and the Uganda National Council for Science and

Technology. All participants provided written informed consent and were compensated 10,000 Ugandan shillings for each interview or discussion, plus reimbursement for transportation.

Results

We conducted individual interviews with 38 virologically unsuppressed adults living with HIV and 15 medical providers, and six focus group discussions with 47 peer health workers. Adults with viremia included 26 men and 12 women who ranged in age from 23 to 54 years (median: 34 years) and had been living with HIV from <1 to 27 years (Table 1). We identified no major differences in qualitative themes by sociodemographic factors or the four treatment strata, although alcohol as an adherence barrier was mentioned primarily by men. Hereunder, we present key themes across participants, organized first by potential benefits and concerns perceived by participants who were virologically unsuppressed, and then health worker perspectives and health system considerations.

"An injection simplifies things": benefits of LAI ART

Most people living with HIV reacted positively to the prospect of LAI ART, and many said they would be interested in taking it themselves. Many participants felt LAI ART would be helpful in reducing pill burden. "Although we take these medicines, it is a burden to us," said one woman.

TABLE 1. DESCRIPTIVE CHARACTERISTICS OF VIRALLY UNSUPPRESSED PARTICIPANTS IN QUALITATIVE INTERVIEWS (N=38)

Characteristics	n	%
Age, in years (median, range)	34	23–54
Sex		
Male	26	68%
Female	12	32%
Current marital status		
Married or in union	17	45%
Separated, divorced, or widowed	15	39%
Never married	6	16%
Migration status		
Long-term resident	25	66%
In-migrant	13	34%
Community of residence		
Fishing community	20	53%
Mainland community	18	47%
HIV treatment stratum		
Diagnosed, but has not started or delayed ART	9	24%
Initiated ART but defaulted care	8	21%
Currently on ART with history of treatment interruption(s)	15	39%
Currently on ART without treatment interruption history	6	16%
Geometric mean viral load, in HIV RNA copies/mL (95% CI)	9053	5249–15,612
Time since HIV diagnosis, in years (median, range)	5	1–27

ART, antiretroviral treatment; CI, confidence interval.

"However, if that injection is introduced, we can have a relief from worrying about taking daily medicine." A man agreed, explaining, "an injection simplifies things."

Participants appreciated that LAI ART would circumvent challenges related to daily medication regimens. "The challenge of forgetting one's ART pills does not happen with injectables, that is the beauty of it," said one woman. Another noted, "LAI ART would relieve us from taking the medicine every day, plus forgetting to take the medicine. But with the injection, they inject the medicine into you, and it remains in the body. You do not have to worry about anything. You only must remember the date you are supposed to go back for another injection." Most participants agreed that returning for bimonthly injection appointments would be easier than daily pills.

Several participants explained that work and other life events made it difficult to be home to take ART pills at the same time every day. "[LAI ART] does not put pressure on me, like being strict at 7:00 pm. I have been at the workplace, then I am required to run and go to take my ART pills! [No,] I cannot manage that."

Other participants noted that travel for longer periods of time was a barrier to picking up pill refills and hoped that LAI ART might circumvent these challenges if it provided a longer time between doses. "I support [LAI ART]," said one such man, "It helps, since you have received the medication for a longer period at once. I can move from here to somewhere, where I would have forgotten to go with enough ART pills." Most participants saw no major challenges with transportation and missed appointments. "Just like one goes to get the ART pills, it will be the same way we would go to get the injectable ART as well, so where is the difference?" said one man.

Several men said that alcohol prevented them from taking ART medication regularly. "Sometimes we take alcohol and get drunk," said one man, "and by the time you remember to take your medication, it is already late. You cannot take the medicine, and you miss that day. For this reason, LAI ART will help us not to miss the medicine."

A few participants noted that oral pills are best taken with food, and LAI ART might help people who find this recommendation difficult to follow or might avoid side effects from having to take pills on an empty stomach. "You might be hungry," said one man. "[With LAI ART], there is no worry that it is time for taking ART, but there is nothing to eat first."

A couple of participants noted they sometimes lose pills, or simply disliked pills. "A pill is not easily taken. That is why I got tired of it," said one. "Even if I had to receive an injection twice a month, that would be fine. I cannot manage the pills."

Privacy was described as a major benefit of LAI ART. Many participants said the presence of pills could mark them as HIV-positive, leading to stigma or inadvertent HIV serostatus disclosure. "You see," said one man, "those tablets embarrass us. When you are getting them from the tin, it makes noise, and you get worried that people will know your HIV status." A woman who had not disclosed her HIV status to her husband due to fear of violence said,

I like [LAI ART] so much because I keep the tablets in the house, and I am scared that one day [my husband] may see my tablets. However, with the injection, I can be injected, and the medicine remains in my body. I like this idea so much.

“Basically,” summed up another man, “it is all about other people not knowing that you are using that medicine, so the secret is between you and your doctor. However, with the pills, chances are high for other people to know.”

Trust in the health system seemed to be a major factor related to support for LAI ART. Several participants said they trusted that LAI ART would only be made available by the health system after it was proven to be effective. Others said that they would take it as long as it was recommended by their health providers and was appropriate for their individual health situation. As one woman put it, “Once they tell me that this is the medicine you should take, there is no way I can refuse it.”

A few participants said they liked LAI ART because they were already accustomed to injections for other conditions, such as malaria or contraception, and some reported preferring injections to pills generally. One participant was insistent that she took her ART pills correctly but reported that her provider did not believe her because she was not virally suppressed. She felt that injections, given by a health worker, would make it easier to prove that she was being adherent.

“If you are just starting up something, you get worried in the initial stages”: concerns about LAI ART

Common concerns about LAI ART included potential side effects, perceived efficacy, and lack of trust in a new medication. Less frequent concerns included fears of injection, adherence challenges, conspiracy theories, and medical mistrust.

Side effects were the most frequently mentioned potential concern about LAI ART. “I do not know the side effects of this injection,” said one person. “I do not know whether it will make us weak or affect us in any way. The concern is that if you are just starting up something, you get worried in its initial stages because you do not know how it will make you feel.” Participants gave examples of specific side effects, such as weight change, and worried that injectable medication might be stronger than pills. A few participants described a simple fear of injections. “I will not lie to you,” said one, “I have feared injection since childhood.”

Clients also worried about the efficacy of LAI ART, both overall and for their particular health situation. They noted that LAI ART “may react differently for some patients.” For example, one woman on second-line ART asked, “Do they first test your blood to determine the type of medication you need in form of injection, or they just give you the injection as a new requirement of shifting people from ART tablets to injections?”

Several participants expressed lack of trust in a new medication. As one woman noted, “I was scared to enroll on HIV treatment after I was diagnosed with HIV. People used to say that when you have been on HIV medication for a long time, they give you medication that can kill you. This new type of ART may be a great concern for us.” Others said they would only take LAI ART after seeing others successfully use it. “I first want to see from other people and ask about its side effects,” said one pregnant woman, who also said she would only consider switching to LAI ART after the birth of her child. A couple of participants compared LAI ART with COVID-19 vaccination, their most recent experience with a medication for which “we did not know its repercussions.”

Some participants worried about the same barriers to adherence that they experienced with ART pills. They wondered about the consequences of missing an injection appointment and were concerned if they had to receive injections more often than they had to pick up pills. They also worried about travel and whether LAI ART would be available if they needed to switch clinics. “As a client,” said one woman, “I may be planning to travel somewhere else...Is it possible to ask for referral sheet to help receive this injectable ART from another health facility?” A man noted that injections would not be compatible with existing differentiated service delivery (DSD) models, where clients can have their medications brought to them by others rather than going to the health facility.

Finally, a small number of virally unsuppressed participants expressed profound distrust of the health system, prompting suspicion or outright rejection of LAI ART. Two participants expressed concerns that LAI ART might be a conspiracy to kill people living with HIV. “Probably the intention of administering ART as an injection is to ensure that we die, and the rest of the population remains,” one woman explained. Another man proposed an elaborate conspiracy theory, where the authorities might “switch everyone from taking pills to receiving an injectable, when they are actually interested in reducing the number of people” because “they think that every person living with HIV is actually a murderer.”

This man felt that the authorities would provide LAI ART for a year, but then “in the second year, they might not provide it to you, and then you die.” Peer health workers reiterated these concerns; during a focus group, one said it might be “just like when COVID-19 vaccinations came, and people thought, ‘White people might be motivated to wipe out the African race through vaccination’. Therefore, convincing people to accept this new mode of treatment will take a long time.” Finally, one woman said she simply hated all forms of ART. “I completely do not like ART tablets or the injection,” she said. “Do not even tell me anything to do with that ART injection. I am not interested.”

Health worker perspectives and health system considerations

Health workers, both clinic staff and peer health workers, generally agreed that LAI ART had great potential. Some had heard of LAI ART through the news or local clinical trials. Almost all agreed that LAI ART would reduce pill burden, thereby improving ART adherence for many clients. They felt it would particularly help people who had difficulty disclosing their HIV status or would experience stigma attributed to pill possession. Peer health workers suggested that longer periods between injections would be better, to help minimize transport and mobility-related challenges to adherence, and questioned the duration of efficacy if people missed follow-up injection appointments, asking, “How long does it stay in the body?”

Health workers also asked about eligibility for LAI ART (e.g., eligibility for pregnant women and adolescents) and wondered about side effects, such as injection site reactions, particularly for clients with specific needs (e.g., skin issues). They noted that if a person experienced side effects after an injection, it could not be quickly reversed the way one could

stop taking pills. They also noted the pain of some injections, such as those to treat syphilis, and worry that painful injections, especially in more sensitive areas such as the buttocks, would diminish enthusiasm for LAI ART.

Health workers also discussed considerations for how LAI ART would fit into current health service delivery landscape. They noted that feasibility of LAI ART would depend upon the supply chain and drug availability, provision of syringes, rooms at the health facility for providing injections, and storage requirements. Health workers anticipated the need for enhanced monitoring of side effects and treatment failure. A few participants living with HIV also raised questions about potential health facility challenges, such as stockouts of LAI ART, and wondered how monitoring of viral suppression would occur with LAI ART.

However, health workers generally felt the health system would be prepared to tackle the challenge of LAI ART. "HIV has been dynamic," said one health worker, describing the changes in various ART formulations and approaches over the years from AZT (*zidovudine*), "but with all the changes, people have been accepting the changes." In several focus groups, peer health workers worried that LAI ART might diminish the necessity of their treatment support roles, and they might lose their jobs. All emphasized the importance of training and having their own and their clients' questions answered before rollout, and the importance of community sensitization and trust-building.

Discussion

This qualitative study with health workers and viremic individuals living with HIV found generally strong support for LAI ART, consistent with studies of other populations in East Africa. Although we did not structure data collection in this way, the issues raised by our participants covered all socioecological levels discussed in other studies examining factors potentially shaping LAI ART acceptability and uptake, including intrapersonal, interpersonal, institutional/community, and sociocultural/policy factors.¹⁰

As has been found in other studies in the region, participants in this study felt LAI ART had the potential to improve adherence and alleviate pill burden, including difficulties associated with unpredictable schedules, food insecurity, and alcohol use, whereas avoiding HIV serostatus disclosure and stigma concerns associated with pill possession.^{9,10} Potential side effects were a primary concern, as has been found previously.^{9,10,17} Findings were also broadly similar to findings from previous studies on acceptability of LAI ART among people living with HIV in the United States and Europe,^{18–20} although those studies found some differences by population (e.g., concerns about injections triggering a relapse for people with a history of injection drug use).¹⁹

However, a few of our findings differed from previous studies from Africa, likely due to our purposeful focus on people who are not virally suppressed, selected from a community-based sample rather than clinics. Several of our participants expressed distrust of ART, regardless of delivery modality, and described conspiracy theories. It is possible that these conspiracy theories were related to fears of second-line ART, as they described dying after switching HIV medication, but this was unclear. These findings highlight the importance of trust in the health system and further

reinforce the idea that LAI ART will not address all the complex issues currently preventing some individuals from adhering to ART and achieving viral suppression. Responses from both health workers and people living with HIV highlighted that not all clients will select LAI ART over current oral ART formulations. Decision aids may help facilitate informed choices among future treatment options.²¹ Future study could also explore considerations for specific subpopulations, such as children and adolescents, which may have different potential benefits and barriers to LAI ART,²² and where future study in sub-Saharan Africa is needed, as has been conducted for other potential long-acting HIV treatment options.²³

Health workers in our study also discussed health system considerations for introducing LAI ART. Some of what health workers raised were questions that could be answered through provider training before LAI ART rollout, such as eligibility criteria and injection characteristics. Others reflect health system challenges that remain to be addressed and have been described in previous reviews of introducing injectable antiretroviral drugs to sub-Saharan Africa, including the cost of the drug and the need for viral load monitoring, resistance testing, refrigeration, private spaces for injection administration, and training of health workers in injection administration.^{8,24} In countries such as Uganda, LAI ART will also be one option among a range of DSD options, although currently most DSD options for streamlined ART access are offered only to virally suppressed clients.^{25,26} Further study should consider how LAI ART can be integrated into existing DSD models, and how these models can be expanded to offer as many options as possible for clients who are not virally suppressed. The participants we interviewed were all virally unsuppressed, so under current national guidelines, they are required to visit facilities more regularly than suppressed clients in lower-intensity DSD models, and more regularly than the bimonthly LAI ART injection schedule. However, continued requirements for clinic visits with LAI ART may continue to be a logistical, financial, and stigma-related barrier to use.

Our study presents a prospective assessment of acceptability of LAI ART; questions were hypothetical, and no participants had used LAI ART. Previous studies from high-income settings have shown that most people living with HIV who actually use LAI ART view it very favorably, despite some injection site reactions and continued clinical monitoring and visit requirements.^{27,28} Prospective acceptability assessments such as ours have been noted as providing a more "real-world" assessment of the end-user experience, where individuals have to make choices about new products without any experience using them,²⁹ although in actual rollout and implementation, clients would likely be provided with more information about LAI ART than we provided in this study. Prospective acceptability assessments can also help to inform the design of service delivery approaches to anticipate potential challenges and increase the potential of adoption when new interventions become available.²⁹ However, we also recognize the limitations of this approach, and note that our participants' perspectives may change with actual use of LAI ART. Future retrospective acceptability assessments will be helpful if and when LAI ART is available in Uganda, particularly if LAI ART is offered to individuals who are not virally suppressed.

Other limitations of our study include the potential for social desirability bias, as interviewers were associated with RHSP, which is known to provide HIV services in the region. However, these concerns were mitigated by asking questions on LAI ART in the second interview with people living with HIV, after allowing them to tell their story of living with HIV in their own terms, and after building rapport with interviewers. Interviews with health workers were thoughtful, and focus group discussions with peer health workers were lively and animated, with many negative perceptions expressed, leading us to conclude that most participants were candid in their responses. Interviews with providers also did not discuss specific drug formulations or other details of LAI ART provision that may be relevant to the health system.

In summary, LAI ART has great potential as an additional ART option for people living with HIV. It may be particularly beneficial for those who have difficulty adhering to a daily oral regimen, although substantial controversy remains about whether to extend its use to these populations. In rural Uganda, we found that individuals with viremia and health workers were generally enthusiastic about the potential benefits of LAI ART, while also noting potential barriers to use. Given the challenges with oral ART, future research and programmatic efforts should continue to explore potential benefits and challenges of offering LAI ART to individuals who are virally unsuppressed.

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Authors' Contributions

Conceptualization, funding acquisition, methodology, supervision, formal analysis, and writing—original draft preparation by C.E.K. Investigation, data curation, formal analysis, and writing—reviewing and editing by T.Z. and A.V.V. Investigation, data curation, and writing—reviewing and editing by R.N. and P.N. Project administration, formal analysis, and writing—reviewing and editing by J.J. Methodology, investigation, data curation, and writing—reviewing and editing by J.G.R. Conceptualization, funding acquisition, and writing—reviewing and editing by L.W.C., S.J.R., T.C.Q., G.N., and G.K. Conceptualization, funding acquisition, supervision, and writing—reviewing and editing by J.K. and F.N. Methodology, supervision, project administration, and writing—reviewing and editing by W.G.D. Conceptualization, funding acquisition, methodology, supervision, and writing—reviewing and editing by M.K.G. Conceptualization, funding acquisition, methodology, supervision, project administration, and writing—reviewing and editing by N.N.

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Address correspondence to:
Caitlin E. Kennedy, PhD, MPH
Department of International Health
Bloomberg School of Public Health
Johns Hopkins University
615 N Wolfe Street E5547
Baltimore, MD 21205
 USA

E-mail: caitlinkennedy@jhu.edu