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HIV pre-exposure prophylaxis (PrEP) for transgender and nonbinary persons. Literature review and guidelines for professionals

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Summary

Transgender and nonbinary (TG/NB) persons are listed as one of the key populations in the context of HIV, due to increased risk of HIV infection in this group. HIV prevention, which includes a variety of available methods, should therefore be included in the comprehensive health care for TG/NB persons. One such method is the pre-exposure prophylaxis (PrEP), whose high effectiveness in preventing HIV transmission has already been demonstrated in numerous studies conducted in the cisgender population. However, the available empirical data on its use in TG/NB persons are limited in many respects. This issue is also practically absent in the Polish literature; as a consequence, there are significant gaps in recommendations for professionals involved in the prevention of HIV among TG/NB persons and professionals involved in the comprehensive health care for TG/NB persons.

This article 1) outlines the issue of the use of PrEP among TG/NB persons, including the associated challenges for professionals (specialising in physical, as well as mental health); 2) demonstrates the possible applicability of PrEP in TG/NB populations based on available research findings; 3) summarises good practices in counselling and PrEP-related psychoeducational activities, as part of the comprehensive health care for TG/NB individuals.

Key words: pre-exposure prophylaxis, transgender, health services for transgender persons

Introduction

Pre-exposure prophylaxis (PrEP) is one of the most effective methods of HIV prevention [1, 2]. Available empirical data on its use among transgender and nonbinary (TG/NB) individuals have numerous limitations, including constraints associated with the applied methodology [3]. This subject is also virtually absent from the national literature and, as a consequence, there are significant gaps in recommendations for professionals involved in the prevention of HIV among TG/NB persons. The aforementioned issues are also rarely the subject of the specialist training for psychiatrists and sexologists, who are most often involved in the comprehensive health care for TG/NB people. The aim of this article is to summarise the available literature and to formulate practical guidelines for professionals supporting transgender and nonbinary persons.

HIV infections among gender diverse persons

Transgender people are identified in the literature as one of the 'key populations' in terms of risk of HIV infection and other sexually transmitted and blood-borne infections (STBBIs) [4, 5]. This is due to factors such as high prevalence of HIV in this group, exposure to multiple discrimination, limited access to health services, socioeconomic disadvantages and minority stress [6]. According to the World Health Organization (WHO), one in five transgender women worldwide is living with HIV, and the prevalence rate is 49 higher in this group than in cisgender women at reproductive age [4]. Prior studies on HIV prevalence among transgender men were primarily based in North America and indicated a lower rate of infection, comparing to transgender women [7]. According to data from studies examining the prevalence of HIV infection among transgender men, HIV prevalence (both self-reported and laboratory-confirmed) in this group ranged between 0.9% and 4.3% for populations from the United States [8]. In only five existing studies from outside the US, summarised in a systematic review by T. Poteat et al., the prevalence of HIV infection among transgender men ranged from 0% to 8% [8]. A significant limitation of the forementioned research projects is their small sample size – in four of five studies analysed, the number of participants did not exceed 100 people [8]. The literature also suggests that transgender men who have sexual contacts with men are among the populations at highest vulnerability to HIV infection [9-11]. There are no corresponding statistics for nonbinary individuals, regardless of the participants' gender assigned at birth. An important methodological difficulty associated with research addressing HIV infection among gender diverse people is the assumption of homogeneity of this group and its members' experiences. This leads to under-representation of a significant proportion of transgender and nonbinary persons, both in the area of clinical research, as well as in prevention-related and educational activities.

Previous studies on the effectiveness of HIV pre-exposure prophylaxis using either F/TDF (emtricitabine/tenofovir disoproxil fumarate) or F/TAF (emtricitabine/tenofovir alafenamide) among transgender people focus almost exclusively on the population of transgender women who have sexual contacts with cisgender men [3].

Clinical research projects did not include intrinsic diversity among transgender and nonbinary people, omitting, among others, individuals who have sexual contacts with same-gender partners and people who choose not to undergo genital surgery from the study sample selection. The subgroup with the least representation in clinical trials examining PrEP use is the population of TG/NB individuals who were assigned female at birth (AFAB persons) [3].

HIV prevalence among transgender and nonbinary persons in Poland

The topic of HIV prevention among TG/NB people has hitherto been neglected in projects aimed at reducing the number of new HIV infections in Poland. Available informational and educational campaigns do not address the specific needs and diversity of social groups that may be targeted by prevention activities. There are no statistics from Polish research centres on HIV prevalence among TG/NB persons. The National Department of Hygiene reports the number of HIV infections and the incidence of AIDS among women and men, with no distinction between transgender and cisgender people or inclusion of nonbinary persons [12]. The result of this methodological decision is the lack of existing data on the number of HIV infections, the incidence of AIDS and AIDS-related deaths among TG/NB persons in Poland. This situation also makes it difficult to plan adequate preventive measures tailored to the needs of the Polish gender diverse community.

The forementioned data, in comparison with existing statistics on HIV incidence among TG/NB persons, indicate the need to include this area of study in clinical research, educational activities and counselling.

Use of pre-exposure prophylaxis (PrEP) among transgender and nonbinary persons

So far only a few clinical trials assessing the safety and efficacy of the use of F/TDF or F/TAF, which included transgender people in the sample, have been conducted. The first one was the *Global iPrEX* project [13]. Of the 2499 participants, 14% (N = 339) were transgender women. Transgender men and nonbinary people did not participate in the study. Transgender women were less likely to reach protective levels of F/TDF in tissues compared to other participants, especially if they were taking oestrogen preparations in the course of hormonal replacement therapy (HRT), which was due to lower adherence in this group [13]. The *DISCOVER* study [14] examined the efficacy of F/TAF compared F/TDF. No significant differences in the frequency of reaching protective drug concentrations in the body were observed. Only a small group of transgender women (N = 73) who reported sexual contacts with cisgender men participated in the study.

Another study worth mentioning is the HIV Prevention Trials Network (HPTN) 083 [15], whose objective was to compare the efficacy of orally administered F/TDF with long-acting injectable cabotegravir (CAB-LA). A total of 12.5% of the study sample were transgender women who have sex with men (N = 570), although no separate

analysis of this group was performed. Fewer new HIV infections were detected among persons receiving CAB-LA than those who received F/TDF [15].

The remaining studies on the efficacy of F/TDF or F/TAF in the population of transgender people did not meet the relevant methodological requirements for clinical trials (randomisation, double-blind procedure and placebo control group).

The TG/NB population is also characterised by a low prevalence of PrEP use [3]. According to the study conducted by Jae Sevelius et al. [16] among a gender diverse population in the U.S., only 3% of sexually active transgender persons disclosed use of F/TDF, compared to 35% of MSM (men who have sex with men) in the U.S. [16]. Among the solutions aiming at increasing the rate of PrEP use among transgender people, the role of educational activities tailored to the needs of this population has been pointed out (e.g. concerning the language used in the recommendations) [16]. The authors did not include nonbinary people in the sample.

Studies on the effectiveness of F/TDF in transgender women have also indicated a significantly decreased adherence to medical recommendations in this group compared to the MSM population [17, 18]. Qualitative studies revealed that transgender women often prioritised medical transition-related health care over HIV prevention [3, 17, 20]. It has been suggested that this is due to the unfounded belief that there are negative interactions between oestrogen preparations and pre-exposure prophylaxis among participants [3]. One of the responses to this problem that has been proposed in the literature is the integration of PrEP into the field of TG/NB health care [21]. The effectiveness of such a solution is illustrated by the results of studies conducted among seropositive transgender women, in the case of whom the integration of hormone substitution with HIV infection-related care resulted in an increase in adherence to medical recommendations, probability of achieving undetectable viral load during the treatment and also in the frequency of use of health services [21]. Similar activities in Polish conditions can be implemented, i.e. during psycho-educational activities preceding gender-affirming medical interventions (GAMI) in which a sexologist is usually involved, as well as in the course of hormonal substitution.

An important limitation of the F/TDF efficacy research is the lack of inclusion of transgender men and nonbinary AFAB individuals. The available recommendations for professionals in this respect are based on the results obtained in cisgender women, with a notion that the dosage should be dependent on the types of sexual contacts reported by the patient [22]. There is evidence suggesting that tenofovir and emtricitabine, which are part of PrEP, achieve lower concentrations in the vagina, compared to the rectum [23, 24]. Moreover, the time required to reach the maximum drug concentration in vaginal tissues is significantly longer [23, 24]. The above-mentioned results seem to indicate that strict adherence to daily PrEP dosing may be particularly important for transgender men and nonbinary AFAB individuals who have condomless receptive vaginal (frontal) contacts, in order to maintain protective drug levels.

Transgender men and nonbinary AFAB people who have sexual contacts with cisgender men are a population overlooked in clinical trials that include MSM, despite having a similar risk of HIV infection [25]. The area requiring exploration is the frequency of behaviours rated as risky practices for MSM among transgender

men and nonbinary AFAB persons, such as unprotected anal and frontal contacts (*bareback*), and chemsex (engaging in sexual contacts under the influence of psychoactive substances).

The issue that has not been addressed in the previous research on PrEP is its effectiveness in populations characterised by diverse sex development (intersex persons). Available research did not collect information on this topic as part of the demographic data. As a result, there is limited knowledge about the applicability of PrEP among intersex persons.

Given the state of knowledge outlined above regarding the feasibility of PrEP in TG/NB individuals, directions for further research should include:

- Assessment of the awareness of PrEP among TG/NB persons.
- Evaluation of the effectiveness of F/TDF or F/TAF in TG/NB individuals, particularly AFAB persons.
- Evaluation of the effectiveness of F/TDF or F/TAF in persons who have a surgically created vagina (neovagina), labia majora or penis (neophallus).
- Assessment of the feasibility and safety of PrEP in TG/NB persons who are pregnant, planning their pregnancy and breastfeeding (chestfeeding).
- Evaluation of the effectiveness of pharmacological and educational preventive interventions in TG/NB who practise chemsex.
- Evaluation of the applicability and effectiveness of PrEP in TG/NB intersex persons.

Good practices in counselling and psychoeducation focused on pre-exposure prophylaxis

A significant part of effective pre-exposure prophylaxis is its informational and psycho-educational component. Psychoeducation is understood here according to the definition proposed by Roffman [26] as 'means of removing barriers to participants' understanding of complex, emotionally charged information and developing strategies for using the information in a constructive manner. The targets of change in psychoeducation may include the participants themselves, their significant others (usually family members) or the larger community (through promotion of advocacy efforts)'. According to the latest, seventh edition of the World Professional Association for Transgender Health (WPATH) Standards of Care [27], prevention of sexually transmitted infections is considered as one of the areas of comprehensive health care for TG/NB persons in the life course. Due to the paucity of empirical knowledge at the time regarding the applicability of PrEP among gender diverse persons, the recommendations do not mention this method as part of HIV prevention and sexual health care. Among the reasons stressing the importance of inclusion of PrEP into the comprehensive care for TG/NB individuals, it is worth considering: experience of multiple discrimination, including in access to health care, and exclusion from existing educational programmes aimed at the wider populations [19, 25, 28, 29].

The sexual health of TG/NB persons has been a neglected and marginalised area; furthermore, the dominant belief in the professional discourse was that gender dysphoria, as an inherent part of the clinical picture of 'transsexualism', prevents sexual activity [30]. Another aspect is that some of the changes observed as a result of GAMI may facilitate HIV transmission (such as difficulties with vaginal lubrication and hypertrophy of clitoral foreskin) [28, 29, 31]. At the same time, it is worth noting that while general guidelines for HIV screening, prevention and care do not differ for transgender people, HIV services should also take into account the specific anatomical, social and psychological needs of this population [28].

According to the guidelines of the U.S. Centers for Disease Control and Prevention (CDC) and the U.S. Preventive Services Task Force (USPSTF), universal HIV screening in the general population is recommended, taking into account the specific needs of gender diverse persons [32, 33]. After initial screening of all patients, follow-up screening schemes should be based on individual assessment of the frequency of behaviours that may be associated with HIV transmission [32, 33]. Such assessment is based on the review of a history including sexual behaviours and anatomical setup [34]. Among transgender women and nonbinary AMAB (assigned male at birth) persons who had not undergone surgical genital correction, it is recommended to consider the possibility of engaging in sexual contacts as an insertive and receptive partner. In transgender women and AMAB individuals who had undergone neovaginoplasty, as well as transgender men and nonbinary AFAB individuals who have not undergone metoidio – or neophalloplasty, attention should be paid to the ability to engage in receptive vaginal (frontal) and anal contacts.

Available data do not allow to precisely estimate the risk of infection from receptive vaginal contact in patients who had undergone neovaginoplasty, as well as in the case of insertive contact in patients after metoidio – and neophalloplasty. Similar difficulty concerns data on the concentration and pharmacodynamics of F/TDF in the surgically created vagina. Due to the variety of surgical methods used in the above-mentioned procedures, it is advisable to perform an individual risk assessment each time, including other factors important in the context of HIV prevention (e.g. preferred sexual techniques).

Open-ended questions that do not assume a specific anatomical setup of the person, their gender identity, or the gender of their partners are considered to be the most appropriate and informative in case of gender diverse populations [34]. For example, in the case of a socially female-presenting person, instead of inquiring about vaginal contacts, one may ask the patient to describe their preferred sexual techniques. In addition, the World Health Organization and the UCSF Center for AIDS Prevention Studies (CAPS) emphasise that prevention efforts should be undertaken in gender-affirming clinical settings, as well as through community and peer education [35-37].

Taking the diversity and the specificity of the TG/NB population into consideration, targeted educational activities and counselling aimed at HIV and STBBI prevention should address the following areas:

– Already introduced and planned gender-affirmative medical interventions (GAMI; hormonal substitution and genital surgeries, mainly neovaginoplasty, labiaplasty, metoidioplasty and neophalloplasty).

- Sexual partners and types of sexual activities that the patient engages in.
- Available and preferred types of protection against sexually transmitted and blood-borne infections (STBBIs).
- Attitudes towards the prevention of STBBIs.
- Experienced gender dysphoria, particularly focused on certain body parts.
- Patient's knowledge of pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).
- Substance use (especially injection and intranasal use) and engagement in chemsex.
- Contraceptive methods (if applicable).
- Strategies to increase adherence.
- Diverse sex development (in the case of intersex persons).

The most commonly recommended method of protection against sexually transmitted infections is the use of external condoms (i.e. conventional condoms). Not all gender diverse persons, however, are able to benefit from this method, which is due to reasons such as individual anatomical characteristics and the level of gender dysphoria. During counselling, establishing medical history and preventive psychoeducational activities, it is worth outlining the available alternatives for external condoms, such as internal condoms, oral tissues (dental dams) and external condoms in smaller sizes (for AFAB patients taking testosterone preparations, before and after metoidioplasty).

According to the *LifeSkills* study [38], the use of behavioural-only, psychoeducational pre-exposure prophylaxis led to a reduction in the frequency of behaviours associated with HIV infection. From baseline to one year after the intervention, the experimental group had a 39.8% greater mean reduction in condomless sex acts compared with the control group [38]. As only transgender women were included in the study, the effectiveness of the said interventions among transgender men and nonbinary persons is yet to be explored.

A significant gap in empirical knowledge of PrEP use in TG/NB persons relates to the possible dosage of the preparations. The following alternative models are currently used: a daily intake (one tablet of F/TDF or F/TAF once a day[1]) and an 'on-demand' dosing (two tablets 2-24h before sexual contact, then one tablet 24h after the first dose, followed by one tablet 48h after the first dose) [39]. It is also possible to begin the administration with two tablets 2-24h before sexual contact and then following on a continuous regimen (currently recommended for MSM only) [1]. Due to the lack of sufficient clinical data on the efficacy of the on-demand dosing, it is currently recommended only for MSM and transgender women who have unprotected anal sex [40]. Furthermore, the use of F/TAF is discouraged for persons who engage in receptive vaginal (frontal) contacts [39].

[1] Polish Scientific AIDS Society recommends using only F/TDF in both the continuous (daily) and on-demand regimen [1].

Due to the lack of data in this area, an individual consultation regarding the use of PrEP in the case of intersex patients is advised. Factors that should be taken into consideration include: anatomical characteristics, and gender-affirming medical interventions (GAMI) that had been introduced, such as HRT (hormonal replacement therapy), as well as genital surgeries.

Table 1. **Possible dosing models of F/TDF and F/TAF for TG/NB persons, depending on the previously introduced GAMI**

Subpopulation (division based on the introduced gender-affirming medical interventions)	Recommended models of PrEP assessment
AFAB persons HRT (testosterone preparations) – Metoidioplasty/ neophalloplasty –	Daily intake; 7 days to saturation of rectal tissues, 20 days to saturation of vaginal tissues* [1]. Feasibility of an on-demand dosing for persons who do not engage in receptive vaginal (frontal) contacts [39]. No mutual reduction in efficacy has been demonstrated with concomitant use of F/TDF and hormonal contraceptives [41-43].
AFAB persons HRT (testosterone preparations) + Metoidioplasty/ neophalloplasty –	Daily intake; 7 days to saturation of rectal tissues, 20 days to saturation of vaginal tissues* [1]. Feasibility of an on-demand dosing for persons who do not engage in vaginal (frontal) contacts [40]. No mutual reduction in efficacy has been demonstrated with concomitant use of F/TDF and testosterone preparations, as well as hormonal contraceptives [41-43].
AFAB persons HRT (testosterone preparations) + Metoidioplasty/ neophalloplasty +	There is no sufficient data concerning the possibility of applying the 'on-demand' dosing in the case of patients who have insertive contacts after metoidioplasty or neophalloplasty [40]. No mutual reduction in efficacy has been demonstrated with concomitant use of F/TDF and testosterone preparations [3, 42].
AMAB persons HRT (oestrogen preparations) – Neovaginoplasty –	Both daily intake and 'on-demand' dosing can be administered [1, 13].
AMAB persons HRT (oestrogen preparations) + Neovaginoplasty –	Both daily intake and 'on-demand' dosing can be administered [1, 13]. Previous studies demonstrated a decrease in the saturation of F/TDF in plasma in the case of concomitant use of F/TDF and oestrogen preparations [44]. Despite these changes, drug concentrations in tissues remained at the level that provided protection against HIV infection [44]. Moreover, no decrease in the effectiveness of oestrogen preparations has been observed [45].

table continued on the next page

AMAB persons HRT (oestrogen preparations) + Neovaginoplasty +	Daily intake can be administered [1]. Available data concerning the applicability of the 'on-demand' dosing in the case of patients who have receptive vaginal contacts is limited [3]. Previous studies demonstrated a decrease in the saturation of F/TDF in plasma in the case of concomitant use of F/TDF and oestrogen preparations [44]. Despite these changes, drug concentrations in tissues remained at the level which provided protection against HIV infection [44]. Moreover, no decrease in the effectiveness of oestrogen preparations has been observed [45].

AFAB persons – persons who had been assigned female at birth

AMAB persons – persons who had been assigned male at birth

"-" and "+" signs indicate whether or not the person had undergone above-mentioned gender-affirming medical interventions (GAMI)

*The recommendations of some scientific associations, e.g. the European AIDS Clinical Society, state that 7 days of PrEP use is necessary to efficiently saturate the vaginal epithelial cells in order to protect against the infection. However, further research is needed.

Significance of gender-affirming language in PrEP-related psychoeducation and counselling

One of the most important aspects of affirmative practice with TG/NB people is the focus on the use of non-stigmatising vocabulary that does not trigger gender dysphoria or significant discomfort in patients. Prior studies indicate a positive effect of the use of affirmative terminology on adherence rates in transgender persons [19]. *Regendering* is considered to be an example of such practice. This phenomenon consists in referring to one's genitalia using terms that do not imply any specific gender or are associated with a gender other than the one assigned at birth. This is a particularly challenging task in the Polish language; however, this area is being dynamically and continuously developed by the gender diverse community. One of the essentials of good practice is asking the patients about their preferred vocabulary related to sexual practices and body parts.

The following table lists affirmative language alternatives for selected phrases central to the PrEP-related medical interview and psychoeducation.

Table 2. **Selected examples of alternative phrases which may be utilised in the course of practice with transgender and nonbinary persons**

Professional phrase	Alternative phrase*
Vagina	Bottom, front, front hole, bonus hole
Penis	Front, bottom, clitoris, tail, growth, girldick

table continued on the next page

Clitoris	Penis, micropenis, growth
Vaginal contact	Frontal contact

* Not each of the proposed alternative phrases will be equally acceptable for all TG/NB persons. We encourage prior consultation of the preferred phrases with the TG/NB patients.

One of the key challenges in public health is the need to work towards increasing access to health care for groups at risk of marginalisation. In pursuing the goal of providing the transgender and nonbinary community with adequate HIV prevention, it is worth being mindful of both the specificity of their experience and the methodological challenges involved in such actions. One of the first steps towards the change may be the very notion of this group as diverse in terms of their needs for affirmative sexual and reproductive health care.

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