ABSTRACT:
HIV is a major global public health problem. The increased access to effective prevention, diagnosis and treatment transformed HIV infection into a manageable chronic health condition. Our purpose was to assess the effectiveness of oral pre-exposure prophylaxis (PrEP) of HIV infection.

Material and Methods: CheckPoint Sofia (former Sexual Health Centre – Sofia) is a medical center for consultations, prevention, diagnosis and treatment of sexually transmitted infections (STIs) and HIV/AIDS. A retrospective study was conducted on 410 consulted males (HIV-seronegative) (October 2020 to August 2022).

Results: The mean age was 32±7.6 years (18–57 years) with prevalent ages <30 and 30–40 years (42% and 47%, respectively); Bulgarian citizens 90%, MSM (97%). The clients’ profile revealed active sporting (38%), past STIs (26%), vaccinated for HBV (54%). No one of the subjects had chronic kidney disease and mandatory investigations of renal functions at starting of PrEP revealed mean levels of urea and creatinine 4.9±1.42 mmol/L and 78±18.2 µmol/L, respectively. On demand regimen (2+1+1 tablets) of PrEP was preferred at 91% and 15% switched to everyday receiving before an increased risk. After starting of PrEP, 55% of the subjects were tested voluntary and no one was positive for HIV, HBV, and HCV. The once reported side effect was transitory diarrhea (in 5%) after the start of PrEP. It is notable that the increased STIs (syphilis, chlamydia and gonorrhea – 10%, 6% and 5%, respectively) – fact in accordance with global trends.

Conclusion: PrEP is an effective prevention of HIV infection and deserves budgetary finance. The increase of STIs requires concrete preventive implementations.

Keywords: HIV, PrEP, STIs,
males (seronegative for HIV) consulted from October 2020 to August 2022.

RESULTS
The age distribution revealed that the mean age of the subjects was 32±7.6 years (18-57 years; median age was 33 years) with prevalent ages <30 and 30-40 years (41.95% and 47.07%, respectively) (Figure 1). Bulgarian citizens were 369 (90%) and 41 (10%) were foreign citizens temporarily living in Bulgaria.

Fig. 1. Age distribution (number and percentage of the subjects)

Sixteen (3.90%) reported nephrolithiasis. The mandatory investigations of renal functions at starting of PrEP had found mean levels of urea and creatinine 4.9±1.42 mmol/L (range 2.8 – 7.4 mmol/L) and 78±18.2 µmol/L (range 51 – 130 µmol/L), respectively.

There are two regimens for PrEP – on demand (evidence-based) and every day. On demand regimen includes two tablets, taken a minimum of 2 h to a maximum of 24 h before risky sexual contact, followed by 1 tablet 24 h after the first intake and another 1 tablet 48 h after the first intake (4 tablets in total). This schedule was preferred by 373 subjects (90.98%) and 62 (15.12%) switched to everyday receiving before an increased risk. Thirty seven (9.02%) received PrEP constantly one tablet daily (every day schedule). After starting of PrEP, 226 of the subjects (55.12%) were tested voluntary and no one of them was positive for HIV, HBV, and HCV. The reported side effects were mild nausea and transitory diarrhea in 21 subjects (5.12%) within two weeks period after the start of PrEP.

Fig. 2. Sexual behavior (number and the subjects)

Characteristic of the sexual behavior revealed that 396 of the subjects (96.58%) were men who have sex with men (MSM) (Figure 2).

The clients’ profile revealed 156 active sporting men (38.05%), receiving only nutrients and vitamins. One hundred and two (24.88%) received recreational drug substances such as marijuana, cocaine, amphetamines and ecstasy – 3.4-Methyl enedioxy methamphetamine (MDMA) once monthly, and forty (9.76%) – once weekly. One hundred and seven subjects (26.10%) reported past sexually transmitted infections (STI’s). Two hundred and twenty one of the subjects were vaccinated for HBV (53.90%) including 164 young men up to 29 years of age (40.00%) mandatory immunized according to the National Immunizations Schedule of Bulgaria and the remainder 57 (14.00%) voluntary immunized, preferably by combined anti-A, anti-B vaccine.

Three hundred and thirty two of the subjects (80.98%) had not reported any past diseases or co-morbidities. No one of the subjects had chronic kidney disease. Sixteen (3.90%) reported nephrolithiasis. The mandatory investigations of renal functions at starting of PrEP had found mean levels of urea and creatinine 4.9±1.42 mmol/L (range 2.8 – 7.4 mmol/L) and 78±18.2 µmol/L (range 51 – 130 µmol/L), respectively.

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It is notable the increased STI’s such as syphilis, chlamydia and rectal gonorrhea – at 42 (10.24%), 23 (5.61%) and 22 (5.27%) of the subjects, respectively. Mixt infection (gonorrhea and chlamydia) was confirmed at 2 (0.49%). Thirty three of the patients with syphilis (78.57%) were in the initial phase of the disease. They received appropriate treatment and were followed up. Due to the increased antibiotic resistance, the therapy was initiated after an antibiogram of all of the patients. Blood samples for TPHA/RPR and quantitative tests for Treponema pallidum were investigated. Real-time polymerase chain reaction (PCR) of samples of urine or urethral secrete in patients with chlamydia was performed at the National Center of Infectious and Parasitic Diseases (NCIPD) – Sofia.

DISCUSSION
In 2016, the United Nations General Assembly achieved a consensus that a fast-track response requires ending AIDS by 2030. Another aim was to reduce new HIV infections to fewer than 500,000 annually by 2020 worldwide. The response is through continued progress towards the 90–90–90 target (by 2020, 90% of all people living with HIV will know their HIV status, 90% of those diagnosed will receive ART and 90% will have viral suppression). Another tool for the achievement of this strategic goal was a focus on the people-centred implementation of the five prevention pillars. These pillars are prevention approaches including programmes for human rights, sexual education and economic empowerment to women, condom programmes, voluntary medical male circumcision, and the use of PrEP [8].

During the last years, there are notable breakthroughs in the prevention of new HIV infections [5]. But the transmission of HIV among MSM remains a serious challenge. The reduction of the HIV burden among this population is important to ending the HIV epidemic. Globally, MSM are estimated to be at almost twice times greater risk of acquiring HIV compared to the general population [8]. ART alone is not enough to eliminate the HIV epidemic. PrEP is an HIV preventive intervention which involves a daily use (or event-based) ARTs (as was mentioned above tenofovir disoproxil
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