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RESEARCH ARTICLE

Nurse-led HIV Preexposure Prophylaxis in the United States: Landscape, Opportunities and Challenges

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ABSTRACT
Preexposure prophylaxis is a powerful biomedical intervention for prevention of human immunodeficiency virus. However, its implementation has been slow and uneven in the United States. Research into innovative agents, formulations and implementation, for preexposure prophylaxis, is ongoing, and a number of new and improved methods of delivery have been developed. However, the delivery of preexposure prophylaxis primarily by nurses, has not received much attention. We overview the global evidence and programs for nurse-led preexposure prophylaxis, and propose this as a feasible and promising implementation strategy for the United States.

Key Words: HIV, PrEP, preexposure prophylaxis, EHE, ending HIV epidemic, nurse-led

Introduction

Preexposure prophylaxis (PrEP) is a key pillar of the Ending the HIV Epidemic initiative in the United States (US) [1]. A groundbreaking biomedical intervention for HIV prevention [2], PrEP has high efficacy [3] and is effective among all populations [4]. Research focusing on novel agents, formulations and delivery platforms, for PrEP, is ongoing [5]. However, due to various challenges, the implementation of PrEP has been low and disparate in the US [6]. Innovation in PrEP implementation, therefore, is of immense importance for harnessing the optimal individual and public health benefits of PrEP [7]. To address this issue, besides scaling up the traditional model of PrEP delivery involving in-person clinic visits with physicians, several new and improved models of PrEP implementation have been proposed [8-11]. These include models that are telemedicine-based, community-based, self-management-based and home-based. However, nurse-led PrEP has not been advanced for wide-scale PrEP implementation in the US.

The objectives and scope of our paper are the following: i) to review nurse-driven PrEP programs across the world; and ii) to examine nurse-led PrEP as a method of PrEP delivery in the US, which has received little consideration to date, but has the potential to significantly expand access.

Overseas Experience

Nurses, including registered nurses (RNs) and advanced practice registered nurses (APRNs) such as nurse practitioners (NPs), have been at the forefront of HIV prevention and care efforts since the beginning of the pandemic. However, nurse-led programs for HIV prevention including PrEP, have gained popularity since the promotion of task-shifting by the World Health Organization [12]. Several investigators have described promising PrEP programs with nurses in crucial and/or lead positions in various countries including Australia [13], Canada [14-17], Kenya [18,19], and the United Kingdom [20].

Schmidt et al. [13] were the first to describe a standardized model for nurse-led PrEP, that was implemented in 2016 by public health clinics in the state of New South Wales, Australia, with widespread support across the health sector, for rapid expansion of PrEP access. Under this model, trained RNs were responsible for all PrEP-related services, including in-clinic physician-authorized, PrEP supply.

O'Byrne et al.[14] conducted a prospective cohort study of fully nurse-led PrEP delivery, from 2018 to 2020, in an urban public health unit and community-based sexually transmitted infection (STI) clinic in Ottawa, Canada. Public health nurses working at the public health unit, identified and referred high-risk subjects to the STI clinic where RNs working under directives from NPs, performed all study tasks. PrEP was offered to 347 persons who met high-risk criteria (contact of HIV, diagnosis of bacterial STI or use of postexposure prophylaxis, PEP). Of these, 69% attended their intake visit, 66% were retained in care and 50% continued PrEP for the study duration (1 year). There were no significant differences in PrEP uptake, acceptance, engagement and attrition based on subjects' characteristics. Also, there were no HIV diagnoses among subjects after PrEP initiation and just three subjects discontinued PrEP due to abnormal creatinine. These investigators found nurse-led PrEP to be a feasible [14] and potentially cost-reducing [21] strategy for PrEP delivery in Ottawa, Canada.

Irungu et al. [19], as part of Kenya's national PrEP roll-out, conducted a large stepped-wedge cluster-randomized pragmatic trial during 2017-2019, to enhance scale-up of PrEP delivery integrated in 25 public HIV care clinics. Healthcare providers received training and ongoing technical support to provide PrEP services. Of the 716 trained healthcare providers, 75% were nurses, clinical officers or HIV counselors. Among 4898 individuals initiating PrEP, 2640 (54%) were women, the median age was 31 years (interquartile range 25-39), and 4092 (84%) reported having a partner living with HIV. The mean monthly number of PrEP initiations per clinic was 0·1 (standard deviation 0·5) before the intervention and 7·5 (2·7) after intervention introduction (rate ratio 23·7, 95% confidence interval (CI) 14·2-39·5, p<0·0001). PrEP continuation was 57% at 1 month, 44% at 3 months, and 34% at 6 months. Of those who missed a refill, 12% returned later for PrEP re-initiation. Tenofovir diphosphate was detected in 68 (96%) of 71 blood samples collected from a randomly selected subset of subjects. Six HIV infections were observed over 2531 person-years of observation (incidence 0·24 cases per 100 person-years), and while three of these occurred at the first visit after PrEP initiation, drug resistance data were not reported. Thus, the study showed high uptake, reasonable continuation with high adherence, frequent PrEP restarts, and low HIV incidence, and

that integration of PrEP services within public HIV care clinics in Africa was feasible.

US Experience

According to estimates, 1.2 million persons have indications for PrEP in the US [22], yet currently only 25% are using it [6]. Updated PrEP guidelines incorporate new agents and procedures and recommend that all sexually active adults and adolescents should be informed about PrEP for prevention of HIV acquisition, and that PrEP should be offered not only to those determined to be at substantial risk for HIV but also anyone who requests PrEP [23]. Thus, new models of PrEP implementation are required to meet the EHE targets for PrEP coverage by 2030 (50%) and beyond [1].

STI clinics are well-recognized as opportune venues for PrEP implementation in the US [24]. Several studies [25] have examined PrEP delivery in this setting where nurses play a prominent role, including public health / safety net clinics [26-28].

Ramchandani et al. [29] conducted a retrospective cohort analysis of PrEP patients, from 2014 to 2020, to assess the number of patients served and factors associated with PrEP discontinuation, in a sexual health clinic in Seattle, Washington. The clinic's PrEP program task-shifted most PrEP operations to nonmedical staff, disease intervention specialists (DIS; public health workers who provided partner services for HIV/STI). Clinicians provided same-day PrEP prescriptions, while the DIS coordinated the program, acted as navigators, and provided most follow-up care. During 2014 to 2019, 1387 patients attended an initial PrEP visit, of whom 93% were men who have sex with men (MSM). The number of individuals initiating PrEP per quarter year increased from 20 to 81. PrEP starts doubled when the clinic shifted from PrEP initiation at scheduled visits to initiation integrated into routine walk-in visits. The percentage of visits served by DIS increased from 3% in 2014 to 45% in 2019. Median duration of PrEP use was 11 months. PrEP discontinuation was associated with non-Hispanic black race/ethnicity [hazard ratio (HR) 1.34, 95% CI 1.02 to 1.76], age of 20 years (HR 2.17, 95% CI: 1.26 to 3.75), age between 20 and 29 years (HR 1.55, 95% CI: 1.06 to 2.28), and methamphetamine use (HR 1.98, 95% CI: 1.57 to 2.49). There were 750 patients on PrEP in the final quarter of 2019. This study demonstrated that demedicalized PrEP delivery in a sexual health clinic could provide PrEP at scale to high priority populations. Notably, of the 6887 PrEP program visits over the analysis period, 3896 (57%) were with a clinician, 2963 (43%) were with a DIS, and just 28 (0.4%) were with nurses.

In the US, nurse-led PrEP programs are currently limited in number and scope, for a variety of reasons including nurses' scope of practice laws and paucity of health-sector support and logistics. We summarize state prescribing laws and describe some pioneering nurse-led PrEP programs in the US, below.

Scope of Practice Laws

Healthcare delivery by healthcare providers is regulated through state scope of practice laws, state board regulations, professional licensing and other laws. The American Medical Association has been addressing issues related to the scope of practice at the federal and state level for over 30 years and is the champion of physician leadership and patient safety in the delivery of health care [30]. A counter argument is that expanding scope of practice could mitigate physician shortage [31] and has been proposed as a solution to increase PrEP access and uptake [32-34].

A study of NP scope of practice and prescribing authority in 2019 found that the laws in 21 jurisdictions did not allow NPs to practice independently (requiring NPs to always have an oversight relationship e.g. with a physician), while those in 30 did allow independent practice [33]. Of these 30 states, 27 had laws that allowed unrestricted practice, two had laws that allowed independent practice if not prescribing medications, while one allowed if not prescribing scheduled drugs. Moreover, 10 of the 30 states required NPs to practice under an oversight relationship during a transition period, ranging from 1040 hours to 5 years. Figure 1 shows the 2022 NP state practice environment [35], where states / jurisdictions allowing full practice are shown in green, those allowing reduced practice are shown in orange, while those restricting practice, in red.

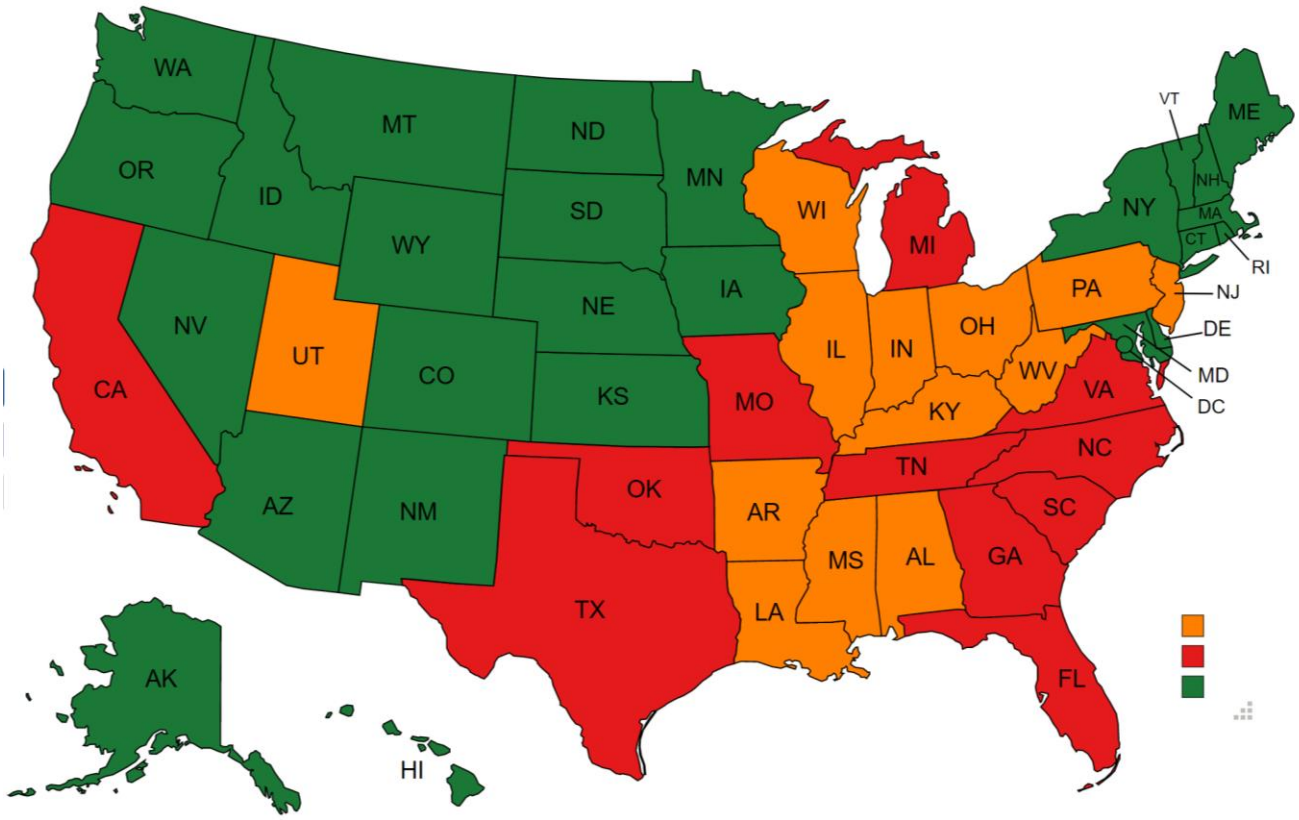

Figure 1: 2022 Nurse Practitioner Practice Environment

Nurse-led PrEP Programs

Georgia

The Georgia Department of Public Health (DPH) has bridged the gap in the HIV prevention workforce through the innovative use of nurse protocols. Counties within Georgia are divided into 18 Public Health Districts, that are comprised of one to several counties and are overseen by a District Health Director (Director), a licensed physician. Standard Nurse Protocols allow RNs to receive training to evaluate patients and deliver a specific set of expanded care services while working under the licensure of the Director. Nurse protocols have been used in Georgia since 1989, with PrEP protocols being implemented in 2014. Protocols are reviewed biennially, and amended as needed, by a multidisciplinary clinical team, to ensure consistency with current guidelines [23] and best evidence-based practices. PrEP protocols guide nurses in all aspects of PrEP care, and patients falling outside the protocol must be reviewed with the Director.

At present, 16 Health Districts provide PrEP services under the nurse protocols, at local health department clinics and HIV specialty clinics under the Georgia DPH umbrella, with approximately 325 patients currently on PrEP. The overall PrEP coverage in Georgia in 2021, was 27.5%, modestly ahead of the national average (26.1%).

The Living Bridge Center-South (TLBC-S) was established in December 2017 and serves the rural population of the North Georgia Health District comprised of six counties along with its sister site, The Living Bridge Center-North. TLBC-S provides Ryan White-funded HIV specialty and primary care, HIV case management, non-occupational PEP, PrEP, and STI services. Onsite is an APRN, 2 RNs, a laboratory technician, benefits coordinator, and an administrative support person. Nurse-led PrEP program at TLBC-S was launched in 2019 and offers daily, on-demand, and injectable PrEP,

including the option of same-day start. RNs initiate PrEP, provide follow-up care, and authorize a 90-day refill. All abnormal and/or off-protocol cases are reviewed with the Director. Since the program's inception, approximately 150 STI clients were screened; no data is available on potential PrEP patients scheduled, 49 initiated, and 34 remain on PrEP. The retention rate at three months is 82% and at one year is 47%.

Kansas City, Missouri

BlaqOut was founded in 2017 in Kansas City, Missouri, to provide PrEP and STI services to the area's Black queer/LGBT+ community. The clinic utilizes an onsite family nurse practitioner (FNP) and collaborative care approach to provide HIV prevention and STI screening and treatment to the priority populations, with a particular focus on individuals aged 18-34 years, the population at greatest risk for acquiring HIV in the Kansas City area. A family physician, well experienced in the screening and management of STIs with a focus on HIV prevention and care, supervises the FNP during biweekly sessions, that include review of charts and laboratory reports and guidance regarding the development of individualized care plans, to ensure programmatic compliance. Patients are provided PrEP in the manner that best suits their lives and lifestyles, including daily PrEP usage, PrEP on demand, or periodic PrEP. BlaqOut offers HIV screenings at its own location and within the community, at local LGBTQI+ bars and other establishments, universities, and dedicated events. Free home test kits are also available for screening of syphilis, gonorrhea, chlamydia, and hepatitis C. Utilizing creative, state-of-the-art interventions, BlaqOut has consistently achieved a 90% adherence rate with its PrEP patients, who are supported by a Collaborative Care Team, consisting of a family physician, a FNP, a director of health equity and research, patient care specialists, phlebotomists, community outreach organizers and empowerment coaches (peer mentors). Through its services, which soon will include HIV primary care, BlaqOut reaches upwards of 1,000-1,300 individuals a year with its services, with 300 persons reached who are living with HIV; it maintains approximately 100 patients on PrEP.

San Francisco, California

The San Francisco AIDS Foundation's Magnet sexual health clinic was founded in 2003, and serves clients in the historic LGBTQI+ Castro neighborhood in San Francisco. Initially, it was staffed by RNs working under an expanded scope of practice with a physician and provided STI diagnostic and treatment services including medications from an in-house dispensary. This program was developed in close collaboration with the San Francisco Department of Public Health which covered the STI testing through the public health laboratory. In response to community need, a PrEP program was established in 2014, where PrEP evaluation and initiation was done by NPs and follow-up by RNs under an expanded scope of practice. In addition, there was allowance for RNs to release a prescription based on review criteria, with availability of support and additional review by NPs. The physician's role is to review charts, oversee the laboratory activity as laboratory director, conduct regular protocol reviews, and assure programmatic quality and competence.

Currently, the clinic employs 5 NPs, 4 RNs, as well as approximately 5 PrEP and health navigators and serves approximately 3,000 individuals on PrEP, with approximately 70 PrEP starts per month. The clinic has an onsite moderate complexity CLIA laboratory, which supports rapid point of care testing including creatinine, hepatitis B, and HIV testing (for screening and confirmatory testing), and offers same-day PrEP. The clinic has used innovation to manage the increasing volume of PrEP visits, including implementing an option for "PrEP Express" visits, which are lab-only quarterly visits for people who are stable on PrEP without adherence challenges. In response to increasing PrEP options, the clinic supports on-demand PrEP dosing for MSM, and recently began offering long-acting cabotegravir, after regulatory approval in the US. In terms of the PrEP care continuum in 2021, among all those who screened for PrEP, 58% scheduled a PrEP intake appointment, 44% initiated PrEP, and 29% remained on PrEP at 3 months.

Potential Benefits and Pitfalls

The potential advantages of nurse-led PrEP include: 1) increased PrEP providers; 2) decreased physician work-load; 3) increased convenience and timeliness of PrEP access; 4) enhanced patient experience; 5) serving hard to reach populations; 6) potential cost-reduction; 7) improved surveillance and treatment of STIs; 8) enhanced speed and 9) scale of PrEP implementation.

Some hypothetical disadvantages may be: 1) compromised patient safety; 2) health-care cost-increase, e.g. from a large number of referrals; 3)

suboptimal PrEP care continuum [35] e.g. due to limited resources or low engagement; 4) inferior quality, e.g. as a consequence of inadequate staffing including nursing shortage [36], limited training and supervision, and excessive demand and/or competing issues such as Covid and monkey pox epidemics.

Conclusions

Nurse-led PrEP is a feasible model of PrEP delivery in the US. Judicious regulations, standardized and validated protocols, evidence-based knowledge, adequate training and support, and continued involvement of physicians in programmatic design, education and oversight [30,37], will be conducive towards its wide-scale and successful deployment.

Conflict of Interest Statement

The authors have no conflicts of interest to declare. D.Rashaan Gilmore is the Founder and President of Baqout Inc.

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