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Short report

Implementation of a national HIV pre-exposure prophylaxis service is associated with changes in characteristics of people with newly diagnosed HIV: a retrospective cohort study

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ABSTRACT

Objectives To review characteristics of individuals newly diagnosed with HIV following implementation of a national pre-exposure prophylaxis (PrEP) programme (comprehensive PrEP services, delivered in sexual health clinics) to inform future delivery and broader HIV prevention strategies.

Methods We extracted data from national HIV databases (July 2015–June 2018). We compared sociodemographic characteristics of individuals diagnosed in the period before and after PrEP implementation, and determined the proportion of 'potentially preventable' infections with the sexual health clinic–based PrEP delivery model used.

Results Those diagnosed with HIV before PrEP implementation were more likely to be male (342/418, 81.8% vs 142/197, 72.1%, p=0.005), be white indigenous (327/418, 78.2% vs 126/197, 64.0%, p<0.001), report transmission route as sex between men (219/418, 52.4% vs 81/197, 41.1%, p=0.014), and have acquired HIV in the country of the programme (302/418, 72.2% vs 114/197, 57.9% p<0.001) and less likely to report transmission through heterosexual sex (114/418, 27.3% vs 77/197, 39.1%, p=0.002) than after implementation.
Pre-implementation, 8.6% (36/418) diagnoses were 'potentially preventable' with the PrEP model used. Post-implementation, this was 6.6% (13/197), but higher among those with recently acquired HIV (49/170, 28.8%). Overall, individuals with 'potentially preventable' infections were more likely to be male (49/49, 100% vs 435/566, 76.9%, p<0.001), aged <40 years (37/49, 75.5% vs 307/566, 54.2%, p=0.004), report transmission route as sex between men (49/49, 100% vs 251/566, 44.3%, p<0.001), have previously received post-exposure prophylaxis (12/49, 24.5% vs 7/566, 1.2%, p<0.001) and less likely to be black African (0/49, 0% vs 67/566, 11.8%, p=0.010) than those not meeting this definition.

Conclusions The sexual health clinic–based national PrEP delivery model appeared to best suit men who have sex with men and white indigenous individuals but had limited reach into other key vulnerable groups. Enhanced models of delivery and HIV combination prevention are required to widen access to individuals not benefiting from PrEP at present.

BACKGROUND

Oral HIV pre-exposure prophylaxis (PrEP: tenofovir disoproxil/emtricitabine) is efficacious in reducing HIV acquisition in key populations.[1 2] A national state-funded PrEP programme was implemented within specialist sexual health services in our setting (Scotland, UK), from July 2017, when there were around 230 new diagnoses each year.[3] Half of newly identified infections were in men who have sex with men (MSM), approximately 15% in people who inject drugs and 30% were acquired through heterosexual sex. One quarter of infections were recently acquired according to avidity testing.[3]

The PrEP delivery model included free provision of medication and associated monitoring to individuals meeting one or more risk-based eligibility criteria:

1. Current sexual partners, irrespective of gender, of people who are HIV positive who have a detectable viral load.
2. Cisgender and transgender gay and bisexual men, other MSM and transgender women with a documented bacterial rectal STI in the last 12 months.
3. Cisgender and transgender gay and bisexual men, other MSM, and transgender women reporting condomless penetrative anal sex with two or more partners in the last 12 months and likely to do so again in the next 3 months.
4. Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist clinician.[4]

Uptake of PrEP exceeded predictions; 1872 individuals were prescribed PrEP at least once in the first year,[4] 99% of whom were MSM who mostly met criterion 3. As PrEP was only available through sexual health services, we explored the potential for this 'location-specific' PrEP delivery model to prevent new HIV infections, and whether any target groups would be disadvantaged. Specifically, we investigated characteristics of individuals diagnosed before and after implementation of the programme. We also formulated a definition of a PrEP-preventable infection, using two initial stages of an HIV prevention continuum model[5] (negative HIV test and linkage to prevention services) in combination with our PrEP provision protocol.

Table 1 Sociodemographic, HIV acquisition and sexual health characteristics of individuals diagnosed with HIV: comparisons made by timing of HIV diagnosis

Cohort divided by timing of HIV diagnosis	All diagnosed			Pre-PrEP period			PrEP period			
	n	%	CI	n	%	CI	n	%	CI	P value*
Total in cohort	615			418			197			
Patient demographics										
Gender										0.005
Male	484	78.7	75.3% to 81.8%	342	81.8	77.8% to 85.2%	142	72.1	65.4% to 77.9%	0.005
Female	131	21.3	18.2% to 24.7%	76	18.2	14.8% to 22.2%	55	27.9	22.1% to 34.6%	0.005
Age in years										0.437
<20	13	2.1	1.2% to 3.6%	7	1.7	0.8% to 3.4%	6	3.0	1.4% to 6.5%	–
20–29	138	22.4	19.3% to 25.9%	98	23.4	19.6% to 27.7%	40	20.3	15.3% to 26.5%	–
30–39	193	31.4	27.8% to 35.2%	137	32.8	28.4% to 37.4%	56	28.4	22.6% to 35.1%	–
40–49	143	23.3	20.1% to 26.8%	92	22.0	18.3% to 26.2%	51	25.9	20.3% to 32.4%	–
>50	128	20.8	17.8% to 24.2%	84	20.1	16.5% to 24.2%	44	22.3	17.1% to 28.6%	–
Ethnicity										0.002†
White British	453	73.7	70.0% to 77.0%	327	78.2	74.0% to 81.9%	126	64.0	57.0% to 70.3%	<0.001
White other	48	7.8	5.9% to 10.2%	36	8.6	6.3% to 11.7%	12	6.1	3.5% to 10.3%	–
Black African	67	10.9	8.7% to 13.6%	34	8.1	5.9% to 11.2%	33	16.8	12.2% to 22.6%	<0.001
Any other ethnicity	33	5.4	3.8% to 7.4%	20	4.8	3.1% to 7.3%	13	6.6	3.9% to 11.0%	–
Not known	14	2.3	1.4% to 3.8%	1	0.2	0.0% to 1.3%	13	6.6	3.9% to 11.0%	–
Area of residence										0.536
Urban health board (contains city with population >100 000)	449	73.0	69.4% to 76.4%	302	72.2	67.8% to 76.3%	147	74.6	68.1% to 80.2%	–
Rural health board	166	27.0	23.6% to 30.6%	116	27.8	23.7% to 32.2%	50	25.4	19.8% to 31.9%	–
Scottish Index of Multiple Deprivation										0.310†
1 (most deprived)	219	35.6	31.9% to 39.5%	141	33.7	29.4% to 38.4%	78	39.6	33.0% to 46.6%	–
2	123	20.0	17.0% to 23.3%	82	19.6	16.1% to 23.7%	41	20.8	15.7% to 27.0%	–
3	92	15.0	12.4% to 18.0%	70	16.7	13.5% to 20.6%	22	11.2	7.5% to 16.3%	–
4	80	13.0	10.6% to 15.9%	56	13.4	10.5% to 17.0%	24	12.2	8.3% to 17.5%	–
5 (least deprived)	75	12.2	9.8% to 15.0%	53	12.7	9.8% to 16.2%	22	11.2	7.5% to 16.3%	–
Unknown	26	4.2	2.9% to 6.1%	16	3.8	2.4% to 6.1%	10	5.1	2.8% to 9.1%	
HIV acquisition										
Route of HIV transmission										0.006†
Heterosexual sex	191	31.1	27.5% to 34.8%	114	27.3	23.2% to 31.7%	77	39.1	32.5% to 46.0%	0.002
Sex between men	300	48.8	44.8% to 52.7%	219	52.4	47.6% to 57.1%	81	41.1	34.5% to 48.1%	0.014
Intravenous drug use	102	16.6	13.9% to 19.7%	74	17.7	14.3% to 21.7%	28	14.2	10.0% to 19.8%	0.315
Other (including blood/tissue products and mother-to-child transmission)	7	1.1	0.6% to 2.3%	3	0.7	0.2% to 2.1%	4	2.0	0.8% to 5.1%	–
Unknown	15	2.4	1.5% to 4.0%	8	1.9	1.0% to 3.7%	7	3.6	1.7% to 7.2%	–
Country of exposure										0.002†
Scotland	416	67.6	63.8% to 71.2%	302	72.2	67.8% to 76.3%	114	57.9	50.9% to 64.5%	<0.001
Rest of UK	38	6.2	4.5% to 8.4%	24	5.7	3.9% to 8.4%	14	7.1	4.3% to 11.6%	0.001
European region	36	5.9	4.3% to 8.0%	25	6.0	4.1% to 8.7%	11	5.6	3.1% to 9.7%	–
Outwith European region	120	19.5	16.6% to 22.8%	65	15.6	12.4% to 19.3%	55	27.9	22.1% to 34.6%	–
Unknown	5	0.8	0.3% to 1.9%	2	0.5	0.1% to 1.7%	3	1.5	0.5% to 4.4%	–
Sexual health data										
Documented to have met PrEP eligibility criteria at sexual health services										0.114
Met 1 eligibility criterion	41	6.7	5.0% to 8.9%	33	7.9	5.7% to 10.9%	8	4.1	2.1% to 7.8%	–
Met >1 eligibility criteria	38	6.2	4.5% to 8.4%	27	6.5	4.5% to 9.2%	11	5.6	3.1% to 9.7%	–
Criteria 1–3 not met	124	20.2	17.2% to 23.5%	90	21.5	17.9% to 25.7%	34	17.3	12.6% to 23.1%	–
Unknown (no sexual health service attendance)	412	67.0	63.2% to 70.6%	268	64.1	59.4% to 68.6%	144	73.1	66.5% to 78.8%	–
Ever prescribed PEPSE at SHS										0.966

Continued

Table 1 Continued

Cohort divided by timing of HIV diagnosis	All diagnosed			Pre-PrEP period			PrEP period			
	n	%	CI	n	%	CI	n	%	CI	P value*
Prescribed PEPSE previously	19	3.1	2.0% to 4.8%	13	3.1	1.8% to 5.2%	6	3.0	1.4% to 6.5%	–
Not prescribed PEPSE previously	596	96.9	95.2% to 98.0%	405	96.9	94.8% to 98.2%	191	97.0	93.5% to 98.6%	–
Recency of HIV acquisition										0.089
Recent (negative test within 12 months or according to avidity)	170	27.6	24.3% to 31.3%	127	30.4	26.2% to 35.0%	43	21.8	16.6% to 28.1%	–
Established (according to avidity and no negative test within 12 months)	394	64.1	60.2% to 67.8%	266	63.6	58.9% to 68.1%	128	65.0	58.1% to 71.3%	–
Unknown (according to avidity and no negative test within 12 months)	51	8.3	6.4% to 10.7%	25	6.0	4.1% to 8.7%	26	13.2	9.2% to 18.6%	–
Infections which were 'potentially preventable'										0.39
'Potentially preventable'	49	8.0	6.1% to 10.4%	36	8.6	6.3% to 11.7%	13	6.6	3.9% to 11.0%	–
Not 'potentially preventable'	566	92.0	89.6% to 93.9%	382	91.4	88.3% to 93.7%	184	93.4	89.0% to 96.1%	–

*P values compare characteristics of individuals using χ^2 tests. Where findings are statistically significant, the specific characteristics holding the significance also have the p value stated.
†Unknown category excluded in the analysis.
PEPSE, post-exposure prophylaxis for sexual exposure; PrEP, pre-exposure prophylaxis.

We aimed to review characteristics of individuals newly diagnosed with HIV following implementation of a national PrEP programme to inform future delivery and broader HIV prevention strategies.

METHODS

Retrospective cohort study using national surveillance data on newly identified HIV infections including demographic, clinical and transmission information. Sociodemographic data were extracted for all individuals with a first ever positive HIV antigen/antibody test between 1 July 2015 and 30 June 2018. Individuals with previously diagnosed HIV/transfer of care from other nations were excluded.

Potentially preventable with the implemented PrEP delivery model (hereafter referred to as 'potentially preventable' infections) require that an individual has a documented negative HIV test within 12 months, PLUS attendance at sexual health services within 12 months PLUS documented to fulfil one or more of the defined eligibility criteria 1–3.[4] Individuals meeting criterion 4 only (1% of PrEP prescribing in the first year of implementation[4]) were excluded owing to potential variation in interpretation.

A data collection tool was developed and piloted on a sample of 50 case records. Minor adaptations were made. Sexual health data for each case were extracted from the National Sexual Health IT system. Patient-identifiable information was not collected.

Data regarding individuals diagnosed with HIV prior to July 2017 (pre-PrEP period, 24 months) and after July 2017 (PrEP period, 12 months) were collected and stored in accordance with data protection regulations. Diagnoses were assigned as being 'potentially preventable' and not 'potentially preventable' according to the definition outlined previously. χ^2 tests assessed the statistical significance of differences encountered. CIs were documented. No potential sources of bias were identified.

Approval for nationwide access to patient data was granted by the Public Benefit and Privacy Panel for Health and Social Care, West of Scotland NHS Ethics Committee (Reference 19/WS/0055) and National Sexual Health IT System User Group.

RESULTS

A total of 615 individuals were newly diagnosed with HIV across the 3-year study period (418 prior to and 197 following PrEP implementation). Those diagnosed in the pre-PrEP period were more likely to be male (81.8% vs 72.1%, p=0.005), report sex between men (52.4% vs 41.1%, p=0.014), be white British (78.2% vs 64.0%, p<0.001) and to have acquired HIV within Scotland (72.2% vs 57.9%, p<0.001). Following PrEP implementation, individuals newly diagnosed with HIV were more likely to report heterosexual sex as the transmission route than in the pre-PrEP period (39.1% vs 27.3%, p=0.002). There was no statistically significant difference in age, urban or rural residence, or deprivation level between individuals diagnosed in the two periods (table 1).

In total, 31.9% of individuals had previously attended sexual health services before their HIV diagnosis. This was more common among MSM than heterosexual individuals (45.7% vs 13.6%, p<0.001). PrEP use prior to HIV diagnosis was uncommon, noted only for five individuals.

Only 49 (8.0%) new infections met the definition of 'potentially preventable' with this PrEP delivery model. There was no statistically significant difference between the pre-PrEP and PrEP periods (8.6% vs 6.6%, p=0.390). In total, 92.5% of infections were tested for antibody avidity (indicating HIV acquisition within 3–4 months), of which 90.4% provided interpretable results. Overall, 27.6% of infections were defined as 'recently acquired' (negative test within 12 months or avidity test consistent with recent infection). The proportion of 'potentially preventable' infections was higher among recently acquired

infections at 49/170, 28.8% (CI 22.5% to 36.0%). Compared with diagnoses that were not 'potentially preventable', cases which were 'potentially preventable' were more likely to be male (100% vs 76.9%, p<0.001), to report sex between men (100% vs 44.3%, p<0.001), to be aged less than 40 years (75.5% vs 54.2%, p=0.004), to have an infection defined as recently acquired (100% vs 21.4%, p<0.001) and to have been previously prescribed post-exposure prophylaxis for sexual exposure (PEPSE) (24.5% vs 1.2%, p<0.001). Individuals with a 'potentially preventable' infection were less likely to be of Black-African ethnicity (0% vs 11.8%, p=0.010) (online supplemental table).

DISCUSSION

People newly diagnosed with HIV since PrEP implementation were less likely to be male, MSM, white British ethnicity and to have acquired HIV within Scotland than individuals diagnosed with HIV prior to implementation. Total numbers of HIV diagnoses were relatively unchanged in the year before and after PrEP implementation.[3]

Very few HIV diagnoses before (8.6%) and after (6.6%) PrEP implementation were 'potentially preventable'. However, the delivery model had the potential to prevent up to 30% of recently acquired HIV infections (especially among younger white British MSM).

To our knowledge, this is the first study to report sociodemographic characteristics of people newly diagnosed with HIV on a comprehensive national dataset (relatively few people access PrEP outside the National Programme in Scotland) before and after 'real-world' PrEP implementation. However, analysis was limited to the first year of implementation, we were unable to definitively identify transgender individuals because gender was allocated as defined in the health record, and some new diagnoses reflect non-recent transmissions. People starting PrEP early in the Programme may have differing characteristics from those who start PrEP later, so this picture may change as the Programme matures.

The changing patterns of infection after PrEP implementation suggest that services are not meeting the needs of all risk groups equally. The PrEP service model appeared to favour individuals who were male, MSM and white British rather than those who acquired HIV by heterosexual contact or outside Scotland.

Many individuals had not attended sexual health services or had a recent HIV test. Barriers to HIV testing are well recognised[6] and may be similar for accessing PrEP. At an individual level, identification of HIV risk is necessary. MSM were more likely to attend sexual health services than heterosexuals, demonstrating potential higher self-identification of need or understanding of HIV prevention. At system level, restriction of PrEP provision to sexual health services is likely to preclude uptake by those who find these services inaccessible, unacceptable or stigmatising.[7] However, it may be difficult to engage people with PrEP in other medical settings due to limited knowledge about PrEP,[8] challenges in identifying those who may benefit and lack of awareness of referral pathways into PrEP care.

At policy level, several factors may have influenced PrEP uptake; PrEP awareness campaigns were deferred owing to concerns about clinic capacity, therefore education relied on community activism, likely favouring MSM and individuals with higher health literacy. Eligibility criteria outlined some characteristics specific to MSM (criteria 2 and 3)[4] and may have omitted other key groups.

CONCLUSION

The PrEP programme primarily benefited indigenous white MSM, arguably a group with easily identifiable, ongoing risk factors for HIV acquisition.

Widening of eligibility criteria may facilitate identification and initiation of PrEP for individuals at specific additional HIV risk (such as sexual contacts from high prevalence populations, bisexual partners and transactional sex). Clinician (including non-sexual health) professional development around HIV risk identification and PrEP availability in other medical specialties may also be important.

Interventions are required to raise awareness of PrEP in women,[7] men at highest risk of heterosexual transmission, individuals from black and minority ethnic populations, transgender people, those aged over 40 years and particularly individuals who could benefit but are not currently accessing sexual health services. Alternative PrEP delivery models, within combination prevention approaches in a variety of settings potentially including primary care, together with culturally relevant information dissemination, are required if we are to eliminate HIV transmission across the population.

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