Country case studies

HIV Pre-exposure Prophylaxis in the EU/EEA and the UK: implementation, standards and monitoring



Contents

PrEP implementation in Belgium	
PrEP implementation in Croatia	
PrEP implementation in Czechia	
PrEP implementation in England	C
PrEP implementation in Finland	
PrEP implementation in France	
PrEP implementation in Germany	
PrEP implementation in Greece	20
PrEP implementation in Ireland	
PrEP implementation in Italy	
Prep implementation in Malta	
PrEP implantation in the Netherlands	29
PrEP implementation in Poland	
PrEP implementation in Scotland	34
PrEP implementation in Spain	37
PrEP implementation in Sweden	
PrEP implementation in Switzerland	

PrEP implementation in Belgium

The case study has been developed to capture practical details about the implementation of PrEP programmes in Belgium and was submitted to ECDC on 30 October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Marie Laga Jessika Deblonde
Clinical focal point:	Eric Florence
Civil society/PrEP user representative:	Mark Sergeant

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

In Belgium, health insurance is compulsory and administered by non-profit making health funds. Contributions are collected and redistributed, covering virtually the entire Belgian population with a generous package of healthcare and prevention (incl. HIV prevention services). Yet co-payments usually remain, as not all services and therapies are fully reimbursed. The delivery of prevention services is regulated on a regional level, while healthcare delivery is under federal authority.

HIV prevention services are delivered mainly in primary care, such as HIV testing by family physicians, or in specialised STI clinics (with free and anonymous testing in some STI clinics). The delivery of antiretrovirals (either for people living with HIV (PLHIV), or as PrEP) is centralised in 11 specialised HIV Reference Centres.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

The care and follow-up for PLHIV is centralised in 11 specialised HIV Reference Centres (HRCs) across the country. These centres are also entitled to provide multidisciplinary care to PLWH, such as delivering antiretrovirals, psycho-social counselling, sexual health counselling etc.

Antiretrovirals for PLWH are fully reimbursed by the health insurance system (as described above), and services at HRCs are provided for free.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words) STI and sexual health services are mainly provided in primary care, by family physicians. Services are covered by the health insurance system, added with co-payments of care recipients. There are a few dedicated specialised STI clinics in Belgium, offering low-threshold (free and anonymous) STI and HIV testing.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM MSM

□Migrants

■Trans-people

□Sex workers

□People who inject drugs

□Other, please describe below

Prep Service Delivery Model(S):

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

☑HIV specialist model

□Primary care model

□Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

PrEP service delivery is largely centralised in 11 specialised HIV clinics (i.e. HRCs) across the country. Reimbursement for PrEP is only obtained if clients had at least one PrEP-related visit per year at a certified HRC. Follow-up visits and refill prescriptions can in theory be provided by any physician (e.g. a family physician), yet in practice this is probably still very uncommon.

Advantages (100 words)

- The experience of delivering antiretrovirals is centralised in dedicated centres of expertise.
- HRCs have a long-standing experience in delivering STI testing and sexual health counselling through their multidisciplinary HIV programs.

Limitations (100 words)

- Accessibility remains challenging (HRCs are only open during office hours, and all are located in semi-urban or urban areas).
- Cost: PrEP and related services are not fully reimbursed, which is a barrier especially for underprivileged socio-economic groups.

¹ This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

- □Based on modelling
- □Based on PEP use
- □Other

Give details below (50 words)

Existing data from previous surveys was used to make a rough estimate of the total number of men who have sex with men (MSM) in Belgium. From there, further estimates were made about the proportion of HIV-negative MSM eligible to use PrEP. Ultimately an estimate of those PrEP-eligible MSM willing to use PrEP when it would be offered to them was made based on studies available at that time (e.g. IPERGAY in France).

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings:

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

- □Nurse
- □Pharmacist
- □Other

Give details below (50 words)

To obtain reimbursement, at least one prescription for PrEP per year needs to be delivered by a physician affiliated to a certified HRC. In-between refills can theoretically be provided by any physician, but it is currently unclear to what extent this practice occurs.

 Rather client-initiated model for PrEP: due to a lack of a formal referral system, clients usually have to make the appointment at the HRC themselves. This can present barriers related to time investment, difficulty navigating the health system, or anticipated stigma at the healthcare facility.

PrEP programme funding:

Select how the PrEP programme(s) is funded

- □National programme without co-payments □Private prescription and online purchase
- □Other

Give details below (50 words)

The national health insurance system partially reimburses PrEP to those who are eligible according to pre-established PrEP eligibility criteria. Currently, a copayment of 8.00 or 12.10 Euro (depending on socioeconomic status) is charged for 30 tablets, or 15.00 Euro for 90 tablets. In addition, there remains a co-payment for the PrEP visit and related HIV and/or STI tests.

There have been a limited number of private initiatives from community-based organisations to offer PrEP for free, for instance to vulnerable migrant people with no (or a pending) legal status.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

- $\square HIV/STI/Infectious \ disease \ Clinic$
- ⊠Pharmacy
- □Community setting
- $\square Other$

Give details below (50 words)

All antiretrovirals (incl. PrEP) are dispensed through a broad network of community pharmacies.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- The conduct of a PrEP demonstration study: this study offered evidence for the feasibility and safety of providing PrEP to a cohort of Belgian MSM, and facilitated the national roll-out for PrEP.
- Inclusion of PrEP in the national HIV plan: giving PrEP a clear position in the national strategy to fight the HIV epidemic
- Creating community support for PrEP: Communitybased organisations actively promoting PrEP, resulting in a great demand and willingness to use it among community members.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- Setting up and agreeing upon a monitoring system from the start (as there was no monitoring system in place at the time PrEP services became operational in Belgium)
- Defining of an evidence-based minimal (not gold standard) package of PrEP care and of comprehensive sexual health
- Exploring beforehand the different attitudes and perceptions of healthcare providers towards integrating PrEP into their practice

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

- Understand the stakes for different healthcare workers in PrEP care, including possible resistance to taskshifting and decentralisation to primary care practitioners and community-based models.
- Understand the community perspectives beyond the 'easy-to-reach or motivated MSM' (i.e. other population

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

Currently, a large research project (i.e. PROMISE, www.promise-prep.be) is investigating how the roll-out of PrEP in Belgium can be improved to have a maximum impact on HIV prevention and sexual health. This project will provide an estimated number of MSM and people with a migrant background that are eligible for PrEP. In addition, it

groups that could potentially benefit from PrEP, such as sex workers, drug users, and people with a migrant background) in order to remove barriers towards sexual health for all, incl. possible barriers in accessing PrEP services.

 Understand the social dynamics that may influence the framing of PrEP within different communities (e.g. perceptions of and attitudes towards the use of PrEP and towards PrEP users in the community). will explore patterns of PrEP use and PrEP users' needs and care preferences. Finally, barriers within the current PrEP service delivery model will be investigated, and opportunities to involve other providers in the delivery of PrEP (e.g. family physicians) will be explored.

PrEP implementation in Croatia

The case study has been developed to capture practical details about the implementation of PrEP programmes in Croatia and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Tatjana Nemeth Blažić
Clinical focal point:	Josip Begovac Šime Zekan
Civil society/PrEP user representative:	Zoran Dominković

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

The framework for HIV prevention is given by the national HIV-prevention program, which is regularly updated. HIV prevention funding includes funding from different sources including special programs funded by the Ministry of Health, local governments, Croatian Health Insurance Fund (HZZO), the private sector, or international funds. Targeted interventions for at-risk populations (MSM and PWID) are mainly carried out by NGOs and delivered in the community. Many prevention tasks (including HIV-testing, health care promotion, education etc.) are also delivered through the national and county Public Health Institutes and the Reference centre for diagnosis and treatment of HIV/AIDS in Zagreb.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

Croatia has a universal healthcare system providing a form of mandatory insurance of all people.

The population is covered by a basic health insurance plan as required by law and administered by the Croatian Health Insurance Fund (HZZO). All residents of Croatia are required to have insurance through HZZO even if they choose not to use it or if they choose to use private insurance.

HZZO and other providers offer supplementary health insurance (9.4 euros/month). Every citizen must have a general practitioner (GP) and the GP should always be the first stop when seeking healthcare. A referral from a public GP with a contract with HZZO, is needed for access specialised care in hospitals. However, access to HIV-care is allowed without referral from the GP. HIV care for citizens with HZZO insurance is completely free and no complementary insurance is needed. HIV care in Croatia is centralised and all patients are treated in one centre at the University Hospital of Infectious Diseases in Zagreb. Antiretrovirals are also dispensed centrally from the hospital pharmacy.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
STI prevention is mainly in the scope of the national and regional Public Health Institutes. There is also limited involvement of NGOs, mainly NGOs that focus on MSM health. Persons with STI can get care and treatment in different healthcare settings: primary care providers, dermato-venerology services, private health care providers (outside the National Health Insurance scheme) and in some infectious diseases settings. To access specialised services through the National Health Insurance (dermato-venerology and ID services) patients need a referral from a GP. Testing for STIs, particularly chlamydia and gonorrhoea are usually done in specialised laboratories either in public health institutes or hospitals. Testing for STIs can also be obtained at private laboratories as a paid service.

and gonorrhoea are usually done in specialised laboratories ei can also be obtained at private laboratories as a paid service.	ther in public health institutes or hospitals. Testing for STIs
Population groups most likely to benefit from accessin MSM ☐ Migrants ☐ Trans-people ☐ Sex workers ☐ People who inject drugs ☐ Other, please describe below	g PrEP, as an additional HIV prevention tool:
PrEP SERVICE DELIVERY MODEL(S) ⁱⁱ : PrEP service delivery model(s): □Clinic-based model □Community-based model ☑HIV specialist model □Primary care model □Peer/Population/Online-based model □Other, please describe below	Advantages (100 words) There are several advantages of the HIV specialist model: 1) there is expertise (both nurses and physicians), 2) availability of tenofovir/emtricitabine at the HIV centre 2) integration of those diagnosed with HIV into HIV care 3) STI diagnostics done at the place of clinical visit 4) STI treatment can be given on-site.
Describe the main PrEP service delivery model used in your	

4

ⁱⁱ This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

The PrEP service was introduced as a pilot project in September 2018. The service was established at the only HIV treatment centre in Croatia, at the HIV Outpatient Department at the University Hospital for Infectious Diseases in Zagreb.

Limitations (100 words)

- Additional workload for HIV nurses and physicians who already provide care to PLHIV, so the delivery currently depends on the enthusiasm of devoted health care professionals.
- The capacity to including larger number of PrEP users is currently limited.
- PrEP is prescribed at only one centre
- Referral from GP is needed after the first visit
- PrEP access requires basic and supplementary health insurance or out-of-pocket payments.
- The cost of diagnostics (particularly testing for Chlamydia and Gonorrhea testing) is considerable for the hospital budget.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other

Give details below (50 words)

- There have been two RDS (respondent driven sampling) studies on MSM giving a prevalence of HIV infection of 2.8% (2010) and 4.5% (2006).
- Based on the abovementioned surveys and an estimation of the sexual active MSM population using EMIS study numeric targets could be established.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

- □Clinical doctor (other setting)
- □Nurse
- □Pharmacist
- □Other

Give details below (50 words)

PrEP is prescribed by HIV-physicians and given on-site from the hospital pharmacy.

PrEP programme funding:

Select how the PrEP programme(s) is funded

oxtimes National programme with co-payments

- \square National programme without co-payments
- $\hfill\square\mbox{Private}$ prescription and online purchase
- □Other

Give details below (50 words)

The PrEP service is free of charge for people who have insurance but supplementary insurance is needed. PrEP is budgeted from the hospital budget (not directly from the National Health Insurance) – this may result in delays in performing NAAT tests for Chlamydia and Gonorrhoea (up to one month).

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:
⊠HIV/STI/Infectious disease Clinic

- □Pharmacy
- □Community setting
- □Other

Give details below (50 words)

Antiretrovirals for PrEP are dispensed from the hospital pharmacy of the HIV treatment centre.

The physician knows whether the drugs have been taken from the pharmacy.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Including PrEP in the National HIV/AIDS prevention program
- Gaining approval from the National HIV/AIDS prevention Committee to establish PrEP services
- Agreement with the National Health Insurance to cover the cost of PrEP

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

Perhaps an earlier start of PrEP might have been possible. To negotiate with National Health insurance Fund, the same model for PrEP as for HIV patients – no referral from GP needed because the formal referral system turns away a great number of potential users.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

In countries where MSM are living in a stigmatised environment, the PrEP service can be introduced in a quiet way through existing programs and services. A public debate would probably not help in establishing the service.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

The plan is to diversify PrEP in other parts of the country. The immediate plan is to establish PrEP services at major cities in Croatia. The plan is to use existing infectious disease facilities to deliver PrEP. There are also plans to build-up community-based and home-testing STI projects. We plan to negotiate the removal of the referral system for PrEP.

PrEP implementation in Czechia

The case study has been developed to capture practical details about the implementation of PrEP programmes in Czechia and was submitted to ECDC in March 2021. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Anna Kubátová, M.D.
Clinical focal point:	Milan Zlámal, M.D.
Civil society/PrEP user representative:	Robert Hejzák, M.A.

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

In Czechia, HIV prevention is provided by all clinicians, especially infectious diseases specialists, venereologists, gynaecologists and general practitioners. Persons at high risk for HIV infection are counselled and tested for anti-HIV antibodies and p24 antiqen. Testing costs are covered by compulsory health insurance.

Counselling and testing services are also provided by the National Institute of Public Health, public health institutes counselling centres in every region and by various non-governmental organisations (NGOs). In all of these cases, testing is anonymous, free of charge and always accompanied by pre- and post-test counselling. Some NGOs also provide HIV self-tests

HIV testing is obligatory for all blood, tissue, organ and sperm donors prior to each donation and also for all pregnant women. It is covered by health insurance.

Private laboratories perform HIV testing for self-payers on request. In such cases pre- and post-test counselling is not provided.

All laboratories testing for HIV are required to participate in an external quality assessment system. Positive test results must be confirmed by the National Reference Laboratory before being issued.

PrEP counselling is provided by PrEP centres affiliated to HIV centres. While examinations and testing are covered by health insurance, prescribed PrEP drugs must be paid for by each client.

An important step in removing barriers is the provision of PrEP in the community PrEP Point (Lighthouse) in Prague.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

In Czechia, HIV positive patients are treated in centres set up at infection clinics. Currently there are eight centres of this kind. Treatment is provided by physicians with postgraduate specialisation in infectology and fully covered by public healthcare insurance (those insured in the healthcare system). Treatment is widely available and used in compliance with guidelines based on international recommendations. Regular monitoring of patients is conducted in the centres. Current system of HIV care funding does not allow providing care to persons without health insurance (e.g. undocumented migrants).

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)

All-round clinical care of patients at risk of HIV infection or with present sexually transmittable disease in Czechia is widely available at facilities of all clinical specialisations, and particularly dermatovenerologists, gynaecologists, infectologists, and GPs. Patients have unlimited direct access to treatment. Treatment of insured patients is fully covered by general healthcare insurance. Syphilis serology test is mandatory in the donors of blood, tissues, reproduction cells and organs, and in the pregnant.

A number of diagnostic laboratories test the most relevant STI directly, with patients paying themselves. Prevention care is provided also in public as well as private centres that deal with HIV prevention.

Similar to HIV care, the current system of STI/sexual health care funding does not allow providing care to persons without health insurance (e.g., undocumented migrants).

nealth insurance (e.g. undocumented migrants).	
Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool:	
⊠MSM	
□Migrants	
□Trans-people	
□Sex workers	
□People who inject drugs	
□Other, please describe below	

PrEP SERVICE DELIVERY MODEL(S) iii:

PrEP service delivery model(s):

- □Clinic-based model
- □Community-based model
- □Primary care model
- □Peer/Population/Online-based model

Describe the main PrEP service delivery model used in your Member State (100 words)

Czechia currently applies a combined PrEP service delivery model based on HIV specialist model and community-based model.

PrEP is available in all eight HIV centers throughout the country and since 2019 in the MSM community center 'Lighthouse' in Prague.

An infectologist with experience in the diagnosis and treatment of HIV infection and sexually transmitted diseases and in working with people with risky behavior is authorised to provide PrEP.

The initial visit should be divided into two visits, with the drugs being dispensed after HIV negativity has been verified, along with a communication of the results. VHB, VHC, STI are tested simultaneously. Counseling is provided with special emphasis on adherence, offering vaccinations against VHA + B.

HIV testing is performed every three months, creatinine examination once every 6 months, STI examination once every six months, hepatitis examination (HBV, HCV) once a year.

Testing is free, PreP is paid by the user (38 Euros / month).

Advantages (100 words)

Advantages of HIV specialist model:

Awareness of possible adverse events of administered PrEP. Availability of laboratories for HIV outpatients facilities. Comprehensive knowledge of HIV infection, STI´s, and comorbidities, availability of other specialisations if consultation need on healthcare of PrEP clients.

Advantages of the community-based model:

Low threshold facility

Low stigma

Thorough knowledge of the target MSM community and health risks occurring in the community (e.g. chemsex) LGBT (MSM) friendly service providers

Anonymous environment

Limitations (100 words)

Accessibility barrier (time slots, proximity from residence), mental barrier for PrEP administration in HIV centres, no possibility to undergo PrEP anonymously.

PrEP programme funding:

Select how the PrEP programme(s) is funded

- □National programme with co-payments
- $\square \mbox{National programme}$ without co-payments
- $\hfill\square\mbox{Private}$ prescription and online purchase

⊠Other

Give details below (50 words)

Clinical examinations and laboratory tests in HIV centres as well as in the community PrEP Point, are paid from the public health insurance budget, the client pays for the PrEP drugs.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

⊠Clinical STI/HIV doctor

□Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

Give details below (50 words)

Guidelines in Czechia recommend procedure for clinics to administer PrEP in people who are at risk. The guidelines specify clinical examination, recommended laboratory and microbiologic examinations and recommendation of regular check-ups over time. Practical information for clients is also included.

The drug as such may be prescribed by other doctors, but this option is not widely used.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

□HIV/STI/Infectious disease Clinic

⊠Pharmacv

□Community setting

□Other

Give details below (50 words)

The doctor prescribes the drug on prescription, the pharmacy dispenses the drug.

This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Inclusion of PrEP in the document National Program for HIV/AIDS in the Czech Republic for the period 2018 - 2022 (2017).
- Guidelines in Czechia recommend procedure for clinics to administer PrEP in people who are at risk of human immunodeficiency virus (HIV) infection (2018).
- 3. Opening the debate on the issue of PrEP under the National Coordination Group (2019).

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

The EMIS 2017 study is a great support. Monitoring situation in other countries and benchmarking PrEP delivery system elsewhere helps.

Community PrEP price sensitivity survey helped to understand price limits for potential PrEP users.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

Setting up the monitoring system from the very beginning (the monitoring system is not yet in place and anchored in the legislation).

Considering access to PrEP outside HIV clinics – prescribing PrEP in eight centres in the whole country limits PrEP accessibility.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

Establish a national system for monitoring and evaluation of PrEP care.

Achieve a broader consensus on the use of PrEP as part of combined HIV / AIDS prevention.

To support the expansion of knowledge about the possibilities of using PrEP.

Ensure access and availability of PrEP, so that uncontrolled purchases over the Internet (gray zone) do not take place. Better access concerns information provision, physical access and price accessibility.

PrEP implementation in England

The case study has been developed to capture practical details about the implementation of PrEP programmes in England and was submitted to ECDC on 30 November 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	John Saunders
Clinical focal point:	Ann Sullivan
Civil society/PrEP user	Will Nutland
representative:	

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

Funding is provided through a Department of Health and Social Care (DHSC) grant to a local authority (local government) that commissions services locally. Nationally, Public Health England (PHE) contract the Terrence Higgins Trust (THT) to deliver the national HIV Prevention England Programme. HIV Pre-Exposure Prophylaxis is delivered through local authority-commissioned sexual health services. These services are responsible for the clinical care related to PrEP delivery (STI testing and treatment, HIV testing, renal monitoring). However, the drug costs are covered by NHS England. (See PrEP service delivery models helow)

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

Funding is provided by NHS England via specialised commissioning. HIV care is delivered through a number of different clinical models: integrated with sexual health clinics; HIV services within acute NHS Trusts and Infectious Disease services.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
This is primarily through the same route as HIV prevention; DHSC grants to local authorities that commission services locally.
However, STI testing provided as part of abortion pathways is commissioned and funded by Clinical Commissioning Groups and STI testing and treatment, including HIV testing, where provided as part of 'essential services' under General Practice contracts in primary care is commissioned by NHS England.

For further details about responsibilities for commissioning sexual health and HIV services in England please see: 'Making it work: A guide to whole system commissioning for sexual health, reproductive health and HIV.'

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408357/Making_it_work_r evised_March_2015.pdf

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: ■MSM

⊠Migrants; some

▼Trans-people

Sex workers; some

☑People who inject drugs, specific subsets as low prevalence in UK

☑Other, please describe below – Black African and some other minority ethnic groups

Prep Service Delivery Model(S)iv:

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

□HIV specialist model

□Primary care model

□Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

DHSC via Public Health grants (ring fenced for first year) to local authority commissioners covers all aspects apart from drug costs which is reimbursed by NHSE. Local contracts then determine level of service provision and volume, though estimates are provided by PHE based on Impact trial data. This is all delivered via Level 3 sexual health clinics.

Advantages (100 words)

Simple commissioning models with statutory data reporting making monitoring and evaluation easier and more likely to be comprehensive. More likely to be delivered more consistently, adhering to guidelines and able to deal medically with potential complications. Staff have a level of awareness and familiarity with the drug in the majority of services involved.

Limitations (100 words)

Many at risk have low level of knowledge and many do not attend these services. Higher cost of delivery. Less convenient for people taking or wanting to take PrEP.

^{iv} This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

There is also a significant number of people 'informally' accessing PrEP via online suppliers. These individuals are able to access STI screening and safety tests via sexual health services.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

□Based on population survey(s)

□Based on PEP use

☑Other Impact trial and information from community websites and annual survey

Give details below (50 words)

The Impact trial was designed to inform a future commissioned PrEP programme regarding the need, uptake and patterns of use in those attending level 3 sexual health services in England. Preliminary analysis was used by PHE to provide service and area level estimates of future PrEP need.

<u>PrEPster</u> and **<u>iwantprepnow</u>** in collaboration with PHE run an annual community survey to provide additional information regarding those who access PrEP through both formal and informal means.

Modelling has also been used to inform estimates of PrEP need. Inputs include data from established surveillance systems, the PrEP Impact Trial and published findings from international studies and implementation programmes.

PrEP programme funding:

Select how the PrEP programme(s) is funded □National programme with co-payments

□Private prescription and online purchase

□Other

Give details below (50 words)

NHSE provide the drug via recharge payments direct to the clinics. Local government authorities locally commission each service for all other aspects of PrEP delivery, including STI screening and safety monitoring; this can be via block contract or tariff per attendance.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

□Clinical doctor (other setting)

☑Nurse - can be by either professional prescriber or via Patient Group Direction (PGD)

□Pharmacist

□Other

Give details below (50 words)

Clinical staff in SHS can prescribe PrEP (doctors and senior nurses who are prescribers; other nurses via PGD). Health advisors can deliver PrEP; this means they do the full PrEP assessment and advice and the doctor reviews the information with them and prescribes PrEP which the health advisor then give to the patient.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed: ⋈HIV/STI/Infectious disease Clinic

□Community setting

□Other

Give details below (50 words)

In many SHS, routinely prescribed medicines are kept in the clinic and provided by staff from on-site pharmacy stores as over-labelled drugs. Where this is not the case, the drugs would be dispensed by a pharmacy -either hospital outpatient pharmacy or one based in the community.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Providing local evidence base via PROUD study.
- Community activism including legal challenge to NHSE regarding their responsibility to provide PrEP.
- Impact trial demonstrating previous official needs estimate was a significant underestimate.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- Ability to deliver in other settings, e.g. primary care, community-based settings.
- Well-funded national programme launched alongside the service to address the significant problems regarding access by all those at risk, including awareness.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

v https://prepster.info

vi https://www.iwantprepnow.co.uk

Close working with all stakeholders, including community groups. Recognise one size won't fit all and consider the needs and barriers for the different groups. Reinforce it is part of combination prevention and all other components also need to be made easily accessible. Consider what parts of the pathways can be safely de-medicalised

It will be regularly reviewed via data returns for SHS to inform future funding requirements and coverage of the different groups at risk. Pathways from other settings to SHS are being developed, but currently there are no plans for it to be delivered outside SHS

PrEP implementation in Finland

The case study has been developed to capture practical details about the implementation of PrEP programmes in Finland and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Finnish Institute for Health and Welfare
Clinical focal point:	Helsinki University Hospital
Civil society/PrEP user representative:	Hivpoint

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

NGOs are the main operator in HIV prevention targeted to the groups at highest risk. Their main sponsors are municipalities and the Funding Centre for Social Welfare and Health Organisations in connection with the Finnish Ministry of Social Affairs and Health.

HIV care: funding and delivery:

HIV care is integrated into public health care. It is provided by specialist care through regional health districts. HIV care, including testing and treatment, is free of charge for all permanent/long-term legal residents and it is funded by municipalities.

STI and sexual health: funding and delivery:

Sexual health services are integrated into public services. Municipal authorities have a responsibility for providing sexual health services including promotion of sexual health as well as STI prevention, testing and treatment. STI testing and treatment are available at local public health care centres free of charge and are funded by municipalities. The private sector offers same services on charge.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: **⊠**MSM

□Migrants

⊠Trans-people

Sex workers

□People who inject drugs

□Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)vii:

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

☑HIV specialist model TÄHÄNKIN RASTI

□Primary care model

□Peer/Population/Online-based model

⊠Other, please describe below TÄMÄKIN?

- The main provider of PrEP is the public healthcare and it is offered at infectious diseases or sexual diseases
- In addition, private healthcare offers PrEP services.
- NGO which provides HIV testing and counselling services runs counselling, including internet-based information in Finnish on PrEP, and referral services on PrEP.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

□Based on population survey(s)

□Based on modelling

□Based on PEP use

⊠Other

Advantages/ limitations

The strong position of public health care as a PrEP provider has several advantages e.g.

- Equal access to treatment
- Possibility to provide referral to other services e.g. sexual health services and services for substance abusers to reduce HIV risk behaviour
- Established co-operation with NGO's
- Potential for national monitoring and evaluation of PrEP care

There are both advantages and limitations when PrEP is mainly provided by special healthcare.

- Advantages: the providers have good knowledge of HIV infection, sexual diseases and behaviours
- Limitations: special health care is given at central and university hospitals which make them sometimes hard to reach due to long distances.

PrEP programme funding:

Select how the PrEP programme(s) is funded

- □National programme without co-payments
- □Private prescription and online purchase
- □Other
 - In public health care, PrEP visits and laboratory test are free of charge and funded by municipalities.

vii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

 Demand and targets for PrEP programmes are based on national HIV surveillance data.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

- Clinical doctors can prescribe PrEP.
- According the national guidelines a clinical doctor who starts PrEP needs to have knowledge of HIV treatment.

- Prep-medicines users pay themselves.
- Generic TDF/FTC is currently available in Finland.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:
□HIV/STI/Infectious disease Clinic

_--

⊠Pharmacy

 $\square \text{Community setting}$

□Other

PrEP is sold at pharmacies and purchased with doctor's prescription.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Finland's HIV strategy and national PrEP guidelines were prepared by an expert group consisting of several authorities including members from Ministry of Health.
- Expert and clinicians of infectious and sexual diseases together with HIV-related civil society organisations have informed decision makers on the benefits of PrEP.
- Public statements on the need of generic TDF/FTC for PrFP.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- It would have been better to publish national PrEP guidelines earlier because they turned to be one of the most crucial issues in the PrEP implementation.
- To have some modelling on the number of subjects needing PrEP.
- Raise more public awareness on PrEP.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

- Cooperation between authorities, healthcare and organisations is needed to promote PrEP.
- Funding is needed at all levels to develop and implement efficient PrEP programmes.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

Goals:

- Educate the public and healthcare professionals about PrFP
- Reaching larger proportion of those who would benefit from PrEP.
- PrEP-medication free of charge to those who meet the national criteria for PrEP.
- Building an national monitoring and evaluation system of PrEP care

PrEP implementation in France

The case study has been developed to capture practical details about the implementation of PrEP programmes in France and was submitted to ECDC in September 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Zinna Bessa and Jean- Christophe Comboroure, Ministry of Health
Clinical focal point:	Jeremy Zeggagh and Jean- Michel Molina
Civil society/PrEP user representative:	AIDES (NGO) Stephane Morel

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

In France, HIV prevention is free (PrEP and PEP), delivered and funded by public services and NGOs. Sexual health clinics called CeGIDD (Centers for free testing and diagnosis of HIV, hepatitis and sexually transmitted infections) are located in hospitals or outside hospitals, some are community-based and particularly adapted for the most vulnerable populations (MSM, trans people, migrants, sex workers, drug users). CeGIDD are involved in HIV testing, PrEP and PEP delivery.

NGOs also have an important role in reaching specific communities for HIV testing and referring to HIV care or prevention services (PEP, PrEP).

General practitioners have an increasing role in HIV testing and PrEP since they can renew PrEP prescriptions (not yet initiate) and monitor patients on PrEP.

Specialised HIV clinics in hospitals continue to provide the majority of PrEP and PEP prescriptions today. Condoms can be reimbursed with a prescription.

HIV care: funding and delivery:

In France, HIV care is mainly delivered by hospitals in infectious diseases departments.

Monitoring of HIV infection is increasingly shared with general practitioners who can renew prescriptions (but cannot initiate).

For people living with HIV, antiretroviral treatment is free, blood tests and medical visits are fully reimbursed by social security, and patients do not have to advance any fee. For those who have been residing illegally in France for over three months, the same free access is applied under a specific state medical assistance system.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
Sexual health, STI prevention, testing and treatment services are delivered in CeGIDD. Some of those centres are coupled with family planning centres. These CeGIDD can be located within or outside public hospitals.

These services can also be delivered in community-based sexual health clinics, that are also CeGIDD, but they are only seven in France (three in Paris, one in Lyon, Marseille, Montpellier and Nice respectively).

This CeGIDD are funded by a national program and are completely free, even for migrants without resources and health coverage.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM MSM

⊠Migrants

■Trans-people

⊠People who inject drugs

 \square Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)viii:

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

☑HIV specialist model

□Primary care model

□Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

In France, the main PrEP service delivery model is clinicbased, with HIV specialists.

Indeed, 88 % of PrEP users get their first prescription from hospitals.

Initially PrEP prescription was restricted to doctors in hospitals experienced in the management of HIV infection but in June 2016, initial prescription expanded to sexual health clinics (CeGIDD)

Since March 2017, PrEP can be renewed by any doctor including GP but prescription must be renewed every year by a doctor practicing in hospital or in CeGIDD

Following discussion with Ministry of Health GPs will also soon be able to initiate PrEP (before end of 2020).

Drug dispensation is available and free in all hospital and city pharmacies.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other

Give details below (50 words)

It is estimated that 10-20% of MSM in France (representing an average of 2% of the male population) may need PrEP. Current estimates for PrEP among MSM are in the range of 100 to 200 000 PrEP users.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

Give details below (50 words)

- Initially HIV specialist only, then any doctor can renew PrEP
- Soon: Any doctor including GP will be able to initiate PrEP
- In the future: a 'task delegation protocol' is being drafted to allow nurses to renew the prescription for PrEP

Advantages (100 words)

1/ Clinic based model

- Good knowledge of antiretrovirals
- Large patient capacity
- Multidisciplinary team (proctologist, MD, nurse, mental health, chemsex)

Limitations (100 words)

1/ Clinic based model

- Substantial medicalisation of sexual health
- Fear of going to a hospital
- Lack of community counselors in most clinics
- Locations distant from communities living areas

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments

National programme without co-payments

 $\Box \mbox{Private}$ prescription and online purchase

□Other

Give details below (50 words)

- TDF / FTC for PrEP nationally available and fully subsidised since 01/2016
- Blood test with STI screening and medical visit every three months are also 60% reimbursed by the national health system (sécurité sociale)

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

 \square HIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

□Other

Give details below (50 words)

- Generic TDF/FTC available since 07/2017 and can be dispensed in all pharmacies (in hospitals or cities)
- But we are working on different projects of PrEP delivery in community setting

viii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Long discussions with the Ministry of Health to explain the reason why PrEP has to be fully subsidised
- The completion of a major randomised study showing the effectiveness of PrEP (ANRS IPERGAY trial)
- Informing the Ministry of Health of illegal importation and distribution of generic PrEP in 2015 (AIDES).
- Lobbying from medical experts

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

- They should leverage on the very good results of PrEP, and the decrease of new HIV infections among PrEP users in big cities like San Francisco, London or Paris
- Working hand in hand between Public health, clinicians and civil society (NGOs)
- Be sure to first work on demand creation toward key populations and to consult communities on how they want PrEP to be delivered

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- France imagined hospitals and CEGIDDs as entry doors for PrEP, but we should have included primary care earlier so that they could take better ownership of PrEP and plainly play their role in follow-up of PrEP, avoiding thus overwhelming hospitals and CEGIDDs capacities to initiate PrEP with new users.
- We should have been better prepared to absorb all new requests for PrEP initiations (800 new initiations per month since January 2019) and to manage follow up and management of intercurrent STI
- We are still trying to deal with a lasting Chemsex Crisis

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

- Reduce structural barriers to PrEP access for young adults (ensure confidentiality from parents and free of charge) and all migrants.
- Extend PrEP to other key populations: especially foreign-born men (heterosexual or MSM) and heterosexual women, young adults
- Involve PrEP in a more global sexual health service with Chemsex support, STI prevention, contraception, gender-affirming hormone therapy, psychological and social support
- Extend PrEP prescription, and assess Telehealth and initiation/follow up visits by nurses and initiation/follow up visits by community workers
- Promote online programs for STIs testing and PrEP initiation/follow up
- Expand community-based PrEP delivery

PrEP implementation in Germany

The case study has been developed to capture practical details about the implementation of PrEP programmes in Germany and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Daniel Schmidt
	(Robert Koch Institute)
Clinical focal point:	Knud Schewe
	(ICH Study Center Hamburg)
Civil society/PrEP user	Helge Tietz
representative:	(PrEP-User / Checkpoint BLN Berlin)
	Emmanuel Danan
	(PrEP.jetzt)

HEALTHCARE CONTEXT:

In Germany, STI and HIV services can be accessed in three ways 1) government health clinics, 2) through CBOs/CSOs which are low threshold and receive some government funding and 3) private physicians (mainly STI/HIV specialists).

In case of 1) and 2) there are nominal charges for HIV or STI testing and fees can be waived for low income persons. STI and HIV treatment cost are mainly covered by the statutory health insurance. HIV treatment and PrEP has to be prescribed by HIV specialists (who are mainly in the private sector, some are in government clinics and CBOs).

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

HIV prevention services are provided by NGO/CSO, governmental and private physicians.

HIV testing is for example offered at checkpoints/counselling centers for family planning and sexual health, including counselling for drug users, sex workers, LGBTQIs* and governmental sexual health counselling centers. Further at HIV/STI specialists and other mostly private physicians.

HIV prevention services are funded via statutory and private health insurance when provided at HIV/STI specialists and other physicians. Counselling centres receive municipal and state funding to offer their services at a nominal charge or free of charge for people with low income.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

Care for people living with HIV in Germany is funded and delivered through health insurance schemes. Health insurance is mandatory in Germany and provided by statutory health insurances (coverage is high $\sim\!87\%$ of the population) and private health insurances. For those who are uninsured (estimated <1.0% of the population) including undocumented migrants, NGOs can provide healthcare for acute conditions but not for chronic diseases.

General medical care is decentralised, there is free choice of healthcare providers in outpatient care. In contrast, HIV care and treatment is mainly provided by highly specialised and HIV certified doctors.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words) Delivery and funding of STI prevention, testing and treatment services works like HIV prevention service delivery and funding. Except for the treatment of STIs.

In contrast to HIV treatment and PrEP which is mainly carried out by HIV/STI specialists, short term STI treatment is offered at counselling centres as well. Or often the tests are done in counselling centres/checkpoints but the treatment is carried out at specialised private physicians, dermatologists, urologists, etc. depending on who is regionally interested and committed. STI treatment costs are covered by the statutory health insurance.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM

- □Migrants
- □Trans-people
- □Sex workers
- □People who inject drugs

☑Other, please describe below

The indication for PrEP as per the law and the guidelines is based on high risk behavior rather than belonging to a specific group. Currently, mostly MSM access PrEP because of the way PrEP is delivered through HIV specialists (see below).

However, an ongoing PrEP evaluation is assessing whether other groups should benefit from PrEP and how to reach them such as female sex workers, PWID, migrants including refugees in Germany.

PrEP service delivery model(s):

- □Clinic-based model
- □Community-based model

☑HIV specialist model

- □Primary care model
- □Peer/Population/Online-based model
- □Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

Since September 2019, PrÉP is covered by statutory health insurances in Germany. HIV specialists are allowed to prescribe PrEP covered by statutory insurance. Services include quarterly counselling, medication and testing for STIs (HIV, chlamydia, gonorrhoea quarterly, HCV twice a year, HBV at PrEP initiation) and renal function markers.

Some private health insurances cover PrEP too. Non-HIV specialist doctors can undergo a qualification that allows them to prescribe PrEP as part of the statutory health insurance. All doctors are allowed to prescribe PrEP for people who pay out of pocket.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

- □Based on population survey(s)
- □Based on modelling
- □Based on PEP use

⊠Other

Give details below (50 words)

- Subject of future investigation within and following the German PrEP evaluation project.
- We will likely use population surveys and modelling.

Advantages (100 words)

Standardised qualified PrEP care by HIV specialists which includes quarterly counselling, medication and testing. This model allows the coupling of PrEP with STI testing and treatment (as opposed to a model that takes only HIV into account). This also allows a certain standard of care. Informal PrEP sources are associated with a higher risk of insufficient support and STI testing.

Limitations (100 words)

PrEP access is limited due to the need for HIV specialists who are predominantly located in urban areas. Therefore, mostly MSM access PrEP. This means limited outreach to other populations and in non-urban areas. PrEP is only available through medical set ups.

Barriers for people without statutory health insurance or for people who are not able to pay privately.

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments

□National programme without co-payments

□Private prescription and online purchase ⊠Other

Give details below (50 words)

- Statutory health insurance (see also service delivery
- In the German statutory health insurance system there is a co-payment on prescribed medications in pharmacies.
- The co-payment for PrEP is usually 10 euros for a 90 day package.

Describe the settings in which PrEP is/could be dispensed:

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

- □Nurse
- □Pharmacist
- □Other

Give details below (50 words)

- PrEP via statutory health insurance is prescribed by HIV specialists.
- Doctors from other specialties can attend training courses to prescribe statutory health insurance-covered PrEP.
- All physicians can prescribe self-paid PrEP.

□HIV/STI/Infectious disease Clinic

□Community setting □Other

Dispensing PrEP:

☑Pharmacv

Give details below (50 words)

PrEP is dispensed in pharmacies upon prescription from a doctor usually an HIV specialist (see also section who can describe PrEP).

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- High demand of self-paid PrEP and price reductions of generic PrEP (>90% due to clever negotiations of a pharmacist) supported PrEP as prevention tool.
- Legal framework was not specified which provided opportunities for activists, interest groups, the community, medical professional societies and politicians.
- Intensive lobbying of various players. It became clear that PrEP is cost effective and even cost saving for the statutory health insurance system in Germany.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- HIV/STI notification should include information on former PrEP use.
- Prescription data should allow to distinguish between TDF/FTC for PrEP and HIV.
- We implemented a separate code for PrEP in the International Statistical Classification Of Diseases System (ICD-10-GM).
- This ICD-10 code for PrEP will help us when analysing secondary routine data of statutory health insurances.

 Highlighting to politicians that the choice is not between PrEP or no PrEP, but between supervised PrEP and black market PrEP without any safety mechanism or testing.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

- Negotiating reasonable prices with pharma companies helps to support PrEP.
- Information about previous PrEP use on HIV and STI notifications is very useful.
- A marker to distinguish PrEP and HIV treatment in drug prescription data might be helpful.
- Integration of PrEP services in sexual health and STI clinics - and depending on the local setting - HIV specialised physicians.
- Evaluating the implementation of PrEP within a short time frame is very useful to gain first insights and possibly readjust the PrEP system.
- A continuous PrEP monitoring and surveillance which includes the outcomes from the PrEP evaluation should follow.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

- Introduction of PrEP coverage by statutory health insurance in Germany is currently investigated in a dedicated PrEP evaluation project in Germany.
- We aim to transfer this project into a continuous PrEP monitoring and surveillance in Germany.
- We aim to focus on additional population groups who might benefit from PrEP and will also ask whether or not the specialist centred system is appropriate to meet the PrEP demand.
- Possibly open up other venues to make PrEP more accessible to non MSM high risk populations.

PrEP implementation in Greece

The case study has been developed to capture practical details about the implementation of PrEP programmes in Greece and was submitted to ECDC on 10/01/2021. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Dr Vasilios Raftopoulos
Clinical focal point:	Associate Prof Mina Psichogiou
Civil society/PrEP user	
representative:	

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

According to the taxonomy of healthcare systems based on their funding, Greece has a mixed model incorporating both tax-based financing and social health insurance. It is highly centralised and medicalised. According to the Greek healthcare funding scheme, the Ministry of Health, allocates the economic resources to a grid of entities at regional and local level and a number of public health organisations (under the auspices of the Ministry of Health) that operate as autonomous legal bodies and provide various preventive interventions. Regarding HIV prevention in Greece there is neither a dedicated fund nor a formal strategy and thus it is a matter of fragmented decisions.

In addition, there are a number of NGOs, universities, institutions, ministries and scientific bodies, which operate several preventive services under their own resources or external funding. The Hellenic Public Health Organization (HPHO) operates several HIV prevention activities including health education at secondary and post-secondary education level, condom promotion to youth and populations with high risk behaviors, free and anonymous testing, pre- and post- HIV testing counseling, and provision of psychosocial support and counseling to people living with HIV (PLHIV) etc.

HIV care: funding and delivery:

HIV multidisciplinary and integrated care as well as antiretroviral therapy to PLWH are provided by 16 hospital-based Infection Units and nine outpatient clinics across the country covering the major geographic areas. HIV care and antiretroviral therapy for PLWH are fully reimbursed by the National Health Insurance scheme without any limitation for the insured and the uninsured who hold a registration number (AMKA or ΠΑΥΠΑ). The antiretroviral drugs are provided to the PLWH only by the pharmacies of the public hospitals across the country that are affiliated with an Infection Unit or an HIV outpatient clinic. The PEP (occupational and non-occupational) is also available through this process free of charge.

STI and sexual health: funding and delivery:

STI and sexual health services are provided in primary and secondary healthcare settings by the public and private healthcare sector. These services are covered by the National Health Insurance in the public sector with some co-payment on some occasions. There is one STI clinic that is also a STI reference centre located in Athens, the capital of Greece. STI testing is provided free of charge by public healthcare organisations. It is also provided by private labs (not free of charge). Several NGOs and municipal entities operate anonymous testing free of charge to high-risk groups and to the general public. NAAT tests for chlamydia and gonorrhea are not covered by the National Health Insurance.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool:

⊠MSM

- □Migrants
- □Trans-people
- □Sex workers
- □People who inject drugs
- □Other, please describe below

Prep Service Delivery Model(S) ix:

PrEP service delivery model(s):

- ☑Clinic-based model
- □Community-based model
- ☑HIV specialist model
- □Primary care model
- $\square Peer/Population/Online-based\ model$
- □Other, please describe below

A pilot study for PrEP delivery to high-risk MSM population for one year has already been completed (2018) [Sophocles/P4G study]. It was located in one HIV hospital-based clinic in Athens (First Dept of Internal Medicine, University of Athens) and offered evidence for the feasibility and safety of providing PrEP.

Advantages

- HIV physicians have long-standing experience in delivering sexual health services, including vaccinations and HIV care
- 2) HIV clinics have established a sustainable collaboration with NGO's
- HIV Clinics are directly linked with the National Surveillance System for HIV care

Limitations

- Accessibility is challenging. HIV clinics operate only during the office hours. Availability of appointments is already problematic due to the staff shortage
- 2) Additional heavy workload for HIV clinics

ix This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

clinics) to deliver PrEP and then to decentralise PrEP to authorised and trained physicians reaching a larger proportion of those who could benefit from PrEP. There are several urgent issues (legislation, dedicated budget, clinical guidelines, training of the HCP, quality assurance etc) that should be resolved before the

implementation of PrEP in Greece.

P4G study examined the feasibility of PrEP intervention among MSM. P4G study aimed to engage individuals considered most vulnerable for HIV infection.	HIV and PrEP care together in the same setting may exacerbate stigma
Demand and targets for PrEP programmes: □Based on population survey(s) □Based on modelling □Based on PEP use ☑Other There is no estimation of the PrEP-eligible MSM willing to use PrEP. According to the Sophocles RDS study, among 308 participants, P4G enrolled 106 individuals for delivering	PrEP programme funding: □National programme with co-payments □National programme without co-payments □Private prescription and online purchase ☑Other In Greece the provision of PrEP and its management have been described in the National Plan for HIV/AIDS that has been submitted for ministerial approval in 2019, but
PrEP.	approval is still is pending. Thus, PrEP currently is not provided in Greece.
Prescribing PrEP: ☑Clinical STI/HIV doctor ☑ Clinical doctor (other setting) ☐Nurse ☐Pharmacist ☐Other To obtain reimbursement, a prescription for PrEP must be delivered by an authorised physician. Today PrEP cannot be prescribed due to the lack of a ministerial approval.	Dispensing PrEP: □HIV/STI/Infectious disease Clinic ☑ Pharmacy □Community setting □Other Although PrEP is not provided in Greece, HIV/STI/Infectious disease clinics as well as primary care, family and private physicians could prescribe the regimens and the diagnostics following national guidelines for PrEP. These physicians theoretically should be certified after following a training program and be affiliated with an Infection Unit and a public
	hospital- based pharmacy.
REFLECTIONS:	
Prioritising PrEP:	Learning from the past:
 Approval of the National HIV/AIDS strategic plan and inclusion of PrEP as a priority in this initiative with dedicated sustainable funding and successful coordination Negotiating a reasonable price with pharma companies to support PrEP Decentralise PrEP care to authorised primary care physicians (in public and private healthcare sector) Ensuring NGO's support for PrEP (i.e. raise awareness, referral services for those who could potentially benefit from PrEP) Quality assurance of PrEP provision and care as well as data quality verification. 	 There is a considerable workload for to provide. Investment in staff is mandatory. HIV clinics are already overwhelmed Definition and reimbursement of a package for PrEP and STI care Organise HIV care and PrEP in separate settings Chemsex crisis needs a specialised and integrated support.
Advice for other Member States:	Looking to the future:
	The immediate plan is to use the existing facilities (HTV

PrEP implementation in Ireland

The case study has been developed to capture practical details about the implementation of PrEP programmes in Ireland and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Derval Igoe
Clinical focal point:	Fiona Lyons
Programme focal point	Caroline Hurley
Civil society/PrEP user representative:	Andrew Leavitt

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

We utilise a combination HIV/STI prevention approach, including HIV/STI testing and treatment; condoms; vaccination; health promotion and risk reduction education and support around sexual behaviour, alcohol and substance misuse and antiretroviral therapy for HIV prevention (PrEP, post-exposure prophylaxis (PEP) and treatment as prevention (TasP).

The National Health Service Executive (HSE) Sexual Health programme is responsible for the implementation of the <u>Sexual health Strategy 2015-2020</u> which includes actions on HIV prevention. The HSE funds HIV/STI prevention services and health promotion information and campaigns.

Community organisations receive funding for HIV testing and prevention activities and for their work with at risk populations.

Free condoms are available from the **National Condom Distribution Service** to sexual health services, universities and community organisations.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

The <u>HSE recommends</u> that all people living with HIV attending HIV services in Ireland are offered antiretroviral therapy as early as possible.

HIV treatment and care in Ireland is funded by the HSE and free for everyone. HIV care is currently available in nine public hospital settings, seven adult HIV services and a joint paediatric service (in two paediatric hospitals in Dublin). Antiretroviral therapy is dispensed from the hospitals providing HIV care.

Some people choose to attend private physicians for their care, but they can still avail of free treatment.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)

A mix of public, private and community organisations provide sexual health services in Ireland, based in primary care, community and hospital settings.

Public STI services are not funded from a single budget; they receive funding from primary care, public health or the acute hospitals division. The majority of laboratory services used by clinics and primary care are publicly funded.

Public STI services provide testing, treatment and vaccinations at no cost to the service user.

Student health and community STI services are provided either free or at a subsidised cost.

Private STI services are provided at a cost to the patient.

In general practice, patients pay for STI consultations, testing and treatment. Just over 30% of the population are entitled to free GP services, but there is no specific provision of free STI testing, treatment or vaccinations through GPs. Hepatitis B vaccine is provided as part of the routine childhood vaccine schedule and HPV vaccine to all boys and girls aged 12/13. **Hepatitis A, B and HPV vaccination** is also provided for free to those at higher risk, within public STI and HIV services.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: $\boxtimes \mathsf{MSM}^*$

□Migrants

■Trans-people

□Sex workers

□People who inject drugs

□Other, please describe below

*includes MSM migrants

Prep Service Delivery Model(S)*:

x This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

 \square HIV specialist model

☑Primary care model

□Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

PrEP is primarily delivered through public STI services.

National standards were developed for the provision of PrEP and approved PrEP services must meet these core national standards.

National PrEP guidance includes eligibility criteria, baseline assessment, testing and monitoring.

An individual attends a PrEP service, clinical eligibility is confirmed, baseline assessment includes testing, vaccinations, support, etc. PrEP dosing schedule is agreed and a prescription provided (up to three months).

A medicines approval system for PrEP was established within the national medicines reimbursement system, which allowed PrEP be dispensed through community pharmacies. The individual is registered on the system and attends a community pharmacy where the approval is visible and PrEP can be dispensed for free. The pharmacy is then reimbursed.

Individuals attend the PrEP service for 1-3 monthly monitoring and re-assessment.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

□Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other

Give details below (50 words)

In the absence of a sophisticated surveillance system within STI services, available **MSM survey data** was used to produce an **estimates report** on the proportion of MSM likely to benefit from PrEP^{xl}. There was no similar information for other groups and it was considered that the upper CI boundary would include these.

A national PrEP Health Technology Assessment

(HTA) also conducted modelling on the number of people estimated to join a potential PrEP programme in Year 1. More recent data was available at this time (e.g. EMIS data), as well as documented experiences from other countries.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

⊠Nurse

Advantages (100 words)

The advantages of the PrEP service being delivered through public STI services include already qualified and trained clinical staff (including health advisors for partner notification etc.), and that STI testing, treatment and vaccinations are all already available for free to the service user.

Limitations (100 words)

The limitations include service users having to attend an STI clinic, most of which are hospital based.

There were also limitations in regard to the use of the national reimbursement system for dispensing PrEP, in particular for some migrant populations.

Some individuals, who were clinically eligible for free PrEP under the national programme, were unable to obtain the documentation required for the medicines reimbursement system, causing some delays in access. A temporary workaround was devised, and the system is currently being modified to remedy this issue.

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments ☑National programme without co-payments

□Private prescription and online purchase

□Other

Give details below (50 words)

The HSE provide funding for the national PrEP programme which includes funding for PrEP medication and staff resources for public STI/PrEP services.

The PrEP service is free to the service user through approved public STI clinics, this includes assessment and monitoring visits, tests, including STI testing and treatment if required, vaccinations, etc.

Some individuals may opt to attend a private service where fees may apply for consultation and tests etc. PrEP drug is free for everyone who attends an approved PrEP service and meets clinical eligibility.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:
□HIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

in the Member State and may not be a comprehensive summary of the PrEP delivery model.

xi Nic Lochlainn Laura , O'Donnell Kate , Hurley Caroline , Lyons Fiona , Igoe Derval. Using data from a behavioural survey of men who have sex with men (MSM) to estimate the number likely to present for HIV pre-exposure prophylaxis (PrEP) in Ireland, 2017. Euro Surveill. 2017;22(48):pii=17-00768. Available at: https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2017.22.48.17-00768

□Pharmacist □Other

Give details below (50 words)

Clinical STI/HIV doctor in approved public STI clinics. General practitioner in approved primary care services. Advanced nurse practitioner (ANP)/nurse prescribers in approved public STI clinics.

□Other

Give details below (50 words)

PrEP is dispensed through community pharmacies. A medicines approval system for PrEP was established within the national medicines reimbursement system, to facilitate the dispensing of PrEP through community pharmacies. The pharmacy dispenses PrEP for free to those approved through the electronic system. The pharmacy then applies for reimbursement.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Publication of Ireland's first national SH strategy which included specific action on the evaluation of ART for HIV prevention.
- Established a multisectoral national PrEP working group to develop clinical guidelines and standards in relation to the use of HIV PrEP in Ireland.
- Sought a national Health Technology Assessment (HTA) from the Department of Health. Following completion of the HTA the Minister for Health was advised that the successful implementation of a national PrEP programme in Ireland would be safe, effective and cost-saving but would require significant investment.
- Consistent community lobbying.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Think outside the box, work with what you have and remember that perfection is the enemy of progress. Look around for solutions that have been identified in other areas. Work in a multisectoral way, find champions, advocates and develop alliances with people in charge.

Partner with NGOs, keep them involved in the processes needed to implement, and this helps wider understanding (and acceptance to some degree) of reasons why implementation can take time.

Link to national strategic documents supportive of prevention.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

A key learning was the important of collaborative working, flexibility and consistent pressure.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

The national PrEP programme is continuing to expand. Through national funding provided to public STI services for PrEP, more public STI services are starting to provide PrEP as staff capacity improves.

PrEP implementation in Italy

The case study has been developed to capture practical details about the implementation of PrEP programmes in Italy and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Vincenzo Puro, INMI Lazzaro Spallanzani, Rome
Clinical focal point:	Massimo Cernuschi, Ospedale San Raffaele / Milano Checkpoint, Milano
Civil society/PrEP user representative:	Sandro Mattioli, PLUS / BLQ Checkpoint, Bologna

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

In Italy, healthcare and prevention programmes fall under regional authority. However, there is a certain degree of harmonisation at the national level for HIV prevention: a HIV plan was developed at the Ministry of Health and discussed with and approved by regional authorities. National funding should be established for this plan, but it has not yet been approved. 'Usual' regional funding can be in certain cases used to fund specific interventions. Decisions about how to deliver interventions presented in the plan are taken at the regional or local level. HIV testing is usually free of charge.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

HIV care is organised at the regional level, too, although there are certain requirements agreed at the national level that must be met. Anyway, HIV care, including provision of ARV treatment, is always delivered for free in specialised HIV clinics at the hospitals all over Italy: only infectious diseases specialists can prescribe and monitor HIV treatment and care. As per funding, budgets are determined at the regional level and there is a certain degree of autonomy for the single local area (called Azienda Sanitaria Locale - Local Health Unit): this can lead to differences in the availability of some HIV drugs.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words) STI and sexual health care are organised and funded at the regional level. There can be huge differences among regions about sexual health care funding and delivery. Anyway, usually there are different ways to deliver care for STIs, and in most settings you can have more than one: you can get STI care at the infectious diseases department or specific public STI clinics at the hospitals, at specialised centres outside of the hospitals, and in some settings even in NGO premises (only screening is performed, though). People are requested for a co-payment to get access to STI testing and treatment but, again, this varies among regions. In some regions STI care and treatment may be free of charge.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM

□Migrants

⊠Trans-people

□People who inject drugs

□Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)xii:

PrEP service delivery model(s):

□Clinic-based model

⋈HIV specialist model

□Primary care model

 \square Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

PrEP service is delivered in some HIV specialist clinics at the hospital and in few community-based centres. A list of these centres can be found at www.prepinfo.it/chi-ti-segue. PrEP can be obtained under prescription by an infectious disease specialist doctor, who releases it after a specific check-up

Advantages (100 words)

Since PrEP users are followed up and monitored by infectious diseases specialists, the professional level is usually high.

Limitations (100 words)

The first limitation is related to costs: PrEP users should pay for specialist visits, tests and drugs (up to 40-50 € per test every 3 months and 60€ for a 30-pills box), so access to PrEP is limited only to those who can afford it. Also, going to the hospitals for tests and prescriptions can be perceived as a barrier by many. Since there is no national PrEP programme and campaign, awareness about PrEP is low and can limit access.

xii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

(in most centres people must co-pay for tests). The drug can be bought at the local pharmacy. Demand and targets for PrEP programmes: PrEP programme funding: Select how the PrEP programme(s) is funded Select how demand for PrEP/a target number of PrEP users is established: □National programme with co-payments \square Based on population survey(s) □National programme without co-payments □Based on modelling □Private prescription and online purchase □Based on PEP use **⊠Other** ⊠Other Give details below (50 words) Give details below (50 words) No attempt to assess demand and targets for PrEP No public funding for PrEP programme People must obtain a private prescription and buy the programme drug at local pharmacies Online purchase is illegal in Italy, although some may do so for saving money Prescribing PrEP: **Dispensing PrEP:** Describe who can prescribe PrEP, and in which settings. Describe the settings in which PrEP is/could be dispensed: ⊠Clinical STI/HIV doctor □HIV/STI/Infectious disease Clinic □Clinical doctor (other setting) **⊠**Pharmacy □Nurse □Community setting □Pharmacist □Other □Other

Give details below (50 words)

Only infectious disease doctors can prescribe PrEP **REFLECTIONS:**

Give details below (50 words)

PrEP can be bought at local pharmacies

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Spontaneous 'PrEP clinics' set up at hospitals and community-based centres to provide services for PrEP users; this can be presented as an example of what can be done, and is also an opportunity to collect data to be used for advocacy with decision makers.
- Having PrEP guidelines in national HIV guidelines helped setting up a standard of care for PrEP use, although it can limit flexibility.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- Public funding support is crucial. The first priority should be having public health authorities understand the importance of PrEP and establishing a road map for access (possibly for free).
- The COVID-19 emergency and crisis shows the need to organise PrEP services, to make them available and accessible also during lockdowns, for example by creating remote counselling sessions and organising the delivery of self-test kits.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Having community organisations leading the efforts is very important, but they should receive adequate support from health professional organisations and any other stakeholder involved.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

There is still a strong need for public funding for PrEP, as well as for STI prevention and care. There is no way to expand access to PrEP if people are requested to cover all the expenses necessary for its uptake. Also, information campaigns should be promoted, because there is a huge need to have PrEP presented as a tool supported by public health authorities.

PrEP implementation in Malta

The case study has been developed to capture practical details about the implementation of PrEP programmes in Malta and was submitted to ECDC in October 2020 This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Tanya Melillo
Clinical focal point:	Valeska Padovese
Civil society/PrEP user representative:	Mark Josef Rapa

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

HIV prevention services are funded by the government of Malta and fall under the Ministry of Health. There are mainly two services dealing with HIV prevention: the genitourinary clinic (GUC) at Mater Dei Hospital, which is the only public sexual health clinic in Malta for referral, diagnosis and care of STIs, and the Health Promotion and Disease Prevention Directorate (HPDPD) within the Department of Public Health. HIV and other STIs tests are delivered for free and a POCT HIV test is also available at GUC. STIs screening is by appointment although urgent cases may walk in the clinic. The civil society also plays an important role in HIV prevention through community mobilisation campaigns eg. HIV testing week, World AIDS Day, Malta Pride, talks and other initiatives.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

HIV care is delivered by the Infectious Diseases Unit at Mater Dei Hospital (MDH) and is free for Maltese nationals and non-Maltese residents paying National Insurance (NI) and entitled to social security services. Treatment is not delivered for free to irregular migrants, third country nationals, VISA holders and students not paying NI. Refugees in Malta have free access to health care. Asylum seekers may also be eligible to free treatment. Patients may elect to access HIV care privately. PLHIV attend the HIV clinic every 6 months to perform follow up tests and renew prescription. The same day patients in need are referred for STIs testing at the GUC or to other services if required.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words). The Sexual Health Clinic in Malta is funded by the Ministry of Health and STIs testing is delivered for free to all: Maltese nationals and non-nationals, including irregular migrants. Access to testing and common STIs treatment is given on anonymous basis and delivered by the GUC. Tests and treatments are done by appointment though a walk-in service is available for urgent referrals A telephone triage system is also in place.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool:

⊠MSM

Migrants

☑Trans-people

☑People who inject drugs

□Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)xiii:

PrEP service delivery model(s):

☑Clinic-based model

□Community-based model

☐HIV specialist model

□Primary care model

□Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

A PrEP service is delivered at GUC, including counselling on safer sex, daily or on demand PrEP, Chemsex and substance misuse. Prescription for PrEP can be obtained from the GUC after a negative HIV test and a normal renal function test (minimum standard for PrEP prescription). Testing for HIV/STIs including Hepatitis B and C is provided for free every three months to patients on PrEP and prescription renewed at each follow-up appointment. Monitoring of renal function is done before starting PrEP and every six months.

Advantages (100 words)

- Better control over prescription and patients' follow-up.
- Monitoring STIs prevalence in key populations
- Surveillance of STIs antimicrobial resistance
- Picking up early HIV seroconversion on PrEP
- Offering ARV treatment to those patients who test positive after presenting for a PrEP consultation and a sexual health screening
- Becoming a reference service and PrEP user-friendly clinic

Limitations (100 words)

- Sustainability of this model when expanding PrEP delivery.
 To run such a model effectively we need to increase clinic
 capacity or decentralise GUC services eg screening of
 asymptomatic patients through home testing, expansion
 of GUC at primary care level
- Waiting list of the clinic

xiii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

Generic PrEP can be purchased against a prescription from the majority of pharmacies in Malta at 57€. Patients may also access PrEP online. However, the medication will only be released from customs after presentation of the valid prescription signed by a GU or an infectious diseases specialist working in the public and private sector. Over-testing and overtreating bacterial STIs (Ct, GC) in asymptomatic patients and, as consequence, decreasing antimicrobial susceptibility of *Mycoplasma genitalium*.
 Following the scientific community's recent debate about frequency of testing patients on PrEP, and in order to face the increased waiting list at GUC, consequence of Covid-19 pandemic, the GUC is delivering a new package of care for PrEP patients, offering syphilis-HIV testing every three months and GU screening inclusive of Chlamydia and Gonorrhoea PCR testing from throat, rectum and urine every six months. Hepatitis B and C screening and renal function tests are performed twice per year.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

□Based on modelling

□Based on PEP use

⊠Other

Give details below (50 words)

- PrEP programme is not officially implemented in Malta.
 A PrEP service is delivered and offered by clinicians at GUC to key population following risk assessment.
- The number of PrEP users is based on patients demand, self-estimation of risk and clinicians' assessment (recent history of STIs, condomless sex, PEPSE use, chemsex/groupsex, serodiscordant couple)

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

□Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

Give details below (50 words)

 Only GUC specialists and infectious diseases doctors are legally allowed to prescribe PrEP

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments

□National programme without co-payments ⊠Private prescription and online purchase

⊠Other

Give details below (50 words)

 PrEP service is implemented and delivered by the public sexual health clinic based on personal initiative of GUC medical staff since a program has never been officially implemented at national level.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

□HIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

□Other

Give details below (50 words)

PrEP is dispensed only by private pharmacies

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- To achieve the 90/90/90 goal.
- Reduce STI rates with increased testing.
- Efficient use of resources to improve HIV care.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

Since Malta has not set up a national PrEP program yet, if the government is willing to officially implement PrEP in the country, Malta may wish to carry out a PrEP trial and use a mixed method research study (qualitative and quantitative research) to focus on behavioural interventions in combination with biomedical interventions in key populations

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

We would encourage colleagues from countries that have not started implementing PrEP yet, to assess feasibility of PrEP implementation and choose their own model of implementation (STIs or HIV clinic based, community based etc), then measure population size (number of beneficiaries/target population) and perform a cost/effectiveness analysis. We would also recommend liaising with civil society/NGOs to collaborate in PrEP campaigns among the populations they represent.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words) Should an agreement be reached with the government on a national PrEP implementation programme, We would propose a PrEP trial including key populations other than MSM, i.e. sex workers, Trans people, and non-European migrants. We would also propose the integration of biomedical interventions with behavioural interventions and a mixed method study based on qualitative and quantitative research concerning risk behaviour/risk compensation pre- and post-PrEP, cultural acceptability of PrEP, STIs prevalence in key population on PrEP and cost effectiveness analysis of the intervention.

PrEP implantation in the Netherlands

The case study has been developed to capture practical details about the implementation of PrEP programmes in the Netherlands and was submitted to ECDC in September2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Silke David
Clinical focal point:	Elske Hoornenborg
Civil society/PrEP user	Sebastian Verboeket represents
representative:	PrEP-NU

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

HIV prevention in the Netherlands is part of a broader STI/HIV prevention approach including provisions for sexual healthcare directed towards young people up to 25 years.

In this approach, governmental organisations (Ministry of Health, RIVM), municipal public health care services (MPHCS) as well as NGO's work together. The MPHCS's and NGO's (STI Netherlands, the HIV monitoring foundation and the HIV patient organisation) receive subsidies to enable preventive as well as monitoring activities.

Testing for STI and HIV is offered free of charge at the MPHCS's STI-clinics to people with a high risk of acquiring STI and HIV infections. Due to limited financial resources prioritisation for people at highest risk is necessary.

HIV care: funding and delivery:

HIV care is delivered by specialised HIV-care centres. Funding is through mandatory health insurance without limitations.

STI and sexual health: funding and delivery:

People living with HIV are tested for HBV, HCV and syphilis on a regular basis, in accordance with the professional guidelines. PLWH are referred to their GP or the MPOCS's STI-clinics. This is especially the case for MSM living with HIV.

HIV treatment centres employ specialised nurse practitioners for consultation about sexual health and other (medical) issues in connection with their HIV infection.

Funding is through health care insurance.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool:

 \boxtimes MSM

⊠Migrants

☑Trans-people

Sex workers

□People who inject drugs

□Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)xiv:

PrEP service delivery model(s):

□Clinic-based model

□Community-based model

☐HIV specialist model

□Primary care model

□Peer/Population/Online-based model

☑Other, please describe below

In the Netherlands, a five year pilot programme (2019-2024) is financed by the Ministry of Health. The National Health Institute (RIVM) is in charge of coordinating and monitoring this programme in which the MPHCS's deliver services. The programme is directed mainly towards MSM with a maximum of 6 500 people. Other groups at risk of acquiring HIV can be included after a review of their individual situation. Within this programme PrEP care is free of charge, but a contribution in PrEP medication costs is required (euro 7.50 for 30 pills).

Advantages (100 words)

The MPHCS that are responsible for PrEP provision already are very experienced in STI and HIV testing as well as counselling the main target group (MSM). This guarantees high quality services.

During this pilot, preparations for knowledge improvement about PrEP provision and care can be implemented in curricula or further training of GP's and other care providers.

Limitations (100 words)

- The maximum of 6 500 MSM being able to access the pilot programme is regarded as a limitation. Due to the corona pandemic the numbers of users are not rising as fast as foreseen.
- Currently GP's are playing a minimal role in PrEP provision, mostly due to minimal financial compensation for these kind of services, requiring extra time and knowledge.
- Communication about PrEP is mainly directed toward MSM. Other target groups might not profit equally from this provision.

xiv This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

A steering group of the RVM together with the MPHCS's is advised by a working group including clinicians, NGO's, PrEP user representatives, pharmacist MPHCS, and RIVM. At this moment it is unclear if and how PrEP provision will be financed in the future. An evaluation before the end of the programme will provide advice in this matter.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

□Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other

Give details below (50 words)

- Through our regular surveillance of STI and HIV in MSM, visiting the STI-clinics we were able to estimate the number of MSM at highest risk and for whom the definitions for PrEP use were applicable (as described in the professional PrEP guidance).
- In the estimate the experience of the AMPrEP programme regarding willingness to use PrEP was incorporated.
- The estimate was shared with the above-mentioned working group for review.
- NB: Ultimately, the decision for the maximum number of PrEP users in the pilot was political.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

□Nurse

⊠Pharmacist

□Other

Give details below (50 words)

 Prescription and dispensing of PrEP requires registration is the medical profession registry

PrEP programme funding:

Select how the PrEP programme(s) is funded

National programme with co-payments

 $\square \mbox{National}$ programme without co-payments

 $\hfill\square\mbox{Private}$ prescription and online purchase

□Other

Give details below (50 words)

- Financing through subsidy by Ministry of Health
- Access for 6 500 MSM at municipal STI-clinics
- PrEP service free of charge
- Co-payment for PrEP medication (euro 7.50 for 30 pills)
- Coordination and monitoring by National Institute of Health and the Environment (RIVM)
- See also above for details

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

MHIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

□Other

Give details below (50 words)

idem

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- The National Action plan on STI, HIV and sexual health (2017-2022) mentions PrEP as one of the core prevention strategies for reduction of new HIV infections. The plan is endorsed by the Ministry of Health.
- 'Nederland naar 0' refers to the movement of the NGO STI Aids Netherlands with the target to reduce new HIV infections to zero. It encompasses all sorts of activities like setting up extra testing activities, communication of prevention strategies, involvement of communities and municipalities as well as target groups.
- Regular meetings with the MoH addressing the subject and necessary amendments to the current pilot.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

Before the start of the current pilot programme much information was gathered from the Amsterdam demonstration project, AmPrEP. The project provided much useful data for the current programme.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Demonstration projects deliver useful insights of a country situation and are therefore useful for a detailed planning of a national programme.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

- The current pilot programme lasts until 2024. The midterm evaluation will advise the MoH for future possible adjustments and/or continuation of the programme.
- There is much discussion going on about financial compensation of PrEP and PrEP care within regular healthcare insurance. These are processes that take a lot of time.

PrEP implementation in Poland

The case study has been developed to capture practical details about the implementation of PrEP programmes in Poland and was submitted to ECDC in January 2021 This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kinadom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Justyna Kowalska
	Miłosz Parczewski
Clinical focal point:	Bartosz Szetela
Civil society/PrEP user representative:	Wiktor Lukasik

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

In Poland, state funding is currently not provided for HIV prevention services, except for the delivery of post-exposure prophylaxis, which is funded in case of accident-related exposure via National AIDS Centre and Health insurance. Preexposure prophylaxis services are paid for by the client, including the cost of medical consultation, lab testing and drugs. The largest share of the cost is related to the consultation and laboratory parameters, with the generic TDF/FTC price being ~25-30 Euros, which is generally affordable. HIV pre-exposure prophylaxis (PrEP) is largely prescribed by private practices, generally provided by the ID specialists. National guidelines for PrEP use are issued yearly and freely available, and do not limit the provider group to any speciality. PrEP delivery is local with the medication available via open market pharmacies, based on prescription.

The key steps to increase PrEP availability would be to cover medical and laboratory expenses via public health insurance.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

HIV care is provided by the HIV clinics approved by the Polish National AIDS Centre and contracted by National Health Service (in Polish: NFZ), Antiretrovirals and all laboratory tests including CD4 counts, viral load and resistance assays are provided free of charge via clinics. Treatment selection is largely unrestricted and remains on the physician discretion. Care is provided by ID specialists. Access is dependent on the available medical insurance, which may restrict treatment to the undocumented migrants or uninsured Polish citizens.

STI and Sexual Health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words) STI care is provided by the public and private clinics and NGOs. Services are covered by the medical insurance. NGOs provide free and anonymous HIV and STI testing. Co-payment may be required for the treatment of the STI. A limited number of public healthcare STI clinics operate in the largest cities. Private practices offer promotional private collective insurance covering cost of the STI treatment, often provided by the employer.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: **⊠**MSM

- □Migrants
- □Trans-people
- □Sex workers
- □People who inject drugs
- □Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)xv:

PrEP service delivery model(s):

- ☑HIV specialist model
- □Primary care model
- □Peer/Population/Online-based model
- □Other, please describe below

Describe the main PrEP service delivery model used in your

PrEP services are provided as described above, via private specialist centres largely led by HIV physicians.

Member State (100 words)

Advantages (100 words)

- PrEP and medical consultation is provided by an experienced practitioner
- Low drug cost
- Currently, private clinics commonly manage considerate cohorts of PrEP users due to independent funding and provide the model of care.

Limitations (100 words)

- Cost of care must be covered by the user, which limits access for socioeconomically underprivileged clients.
- Funding of public health prevention is limited, with no state funded information on PrEP.
- Awareness on PrEP outside the MSM communities is low.

xV This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

- □Based on population survey(s)
- □Based on modelling
- □Based on PEP use
- □Other

Give details below (50 words)

No systematic state funded surveys or HIV prevention programmes which include PrEP are available, therefore there is no estimation on the need for PrEP programmes.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings. ☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

Give details below (50 words)

PrEP is prescribed by medical practitioners, there are no speciality restrictions, but in general it is provided by the HIV/ID specialist.

Other medical specialities, including gynaecologic and dermato-venerologist do not provide comprehensive information for the populations at risk of HIV and STI acquisition

PrEP programme funding:

Select how the PrEP programme(s) is funded

- □National programme with co-payments
- □National programme without co-payments

⊠Other

Give details below (50 words)

PrEP is purchased by the participant, based on the prescription in selected local pharmacies. Full cost of the medication must be covered by the patient. To a limited extent, PrEP is purchased on-line. Medical consultation and laboratory testing are privately coved. Public STI clinics do not provide PrEP prescription.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

□HIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

□Other

Give details below (50 words)

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- To build a national strategy for PrEP and cover it via the public healthcare system.
- Promote PrEP via educational platforms targeting broad number of medical providers and specialities, with the special focus increasing the knowledge of general practitioners on PrEP and STIs
- Development of the programmes focused on the other key populations such as people who use psychoactive substances and chemsex, as well as heterosexual populations at risk.
- Sexual education with the aspects of the STI prevention should be emphasised in the teaching curriculums for younger audiences.
- Increase the number of pharmacies having the discounted price PrEP in stock

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

- Proof of concept medical PrEP programme should have been established to provide arguments for effective HIV prevention
- Focus to include other medical specialists who are able to prescribe prep should be stronger

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

It is already possible to offer free PrEP visits and free testing (with the exclusion of PCR smears for gonorrhoea and chlamydia) in the public HIV out-patient clinics. The visits are actually PEP visits and are covered by the National Health Fund. However, this is still unofficial and no PrEP visits exist in the system. With scarcity of HIV/STI specialists in these clinics it might be difficult to offer visits for a larger number of patients. PrEP visits should be added in the contracts of HIV clinics, as well as STI/GP clinics, and be reimbursed accordingly to allow to have more medical professionals available.

Therefore, further development of the PrEP programmes is necessary with the involvement of the national Ministry of Health-related institutions. STI counselling and access to screening should be expanded. Public surveillance should inform the necessity for the PrEP and other STI screening and prevention programmes.

PrEP implementation in Scotland

The case study has been developed to capture practical details about the implementation of PrEP programmes in Scotland and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	David Goldberg
Clinical focal point:	Claudia Estcourt Rak Nandwani
Civil society/PrEP user representative:	Nathan Sparling Dave Bingham Waverley Care

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

HIV prevention services (and healthcare more broadly) are free at the point of access, as part of the National Health Service (NHS) and/or provided by local government. Combination prevention (HIV testing, condoms, health promotion) is delivered through primary care, sexual health services and third sector organisations. However, PrEP is currently only available from specialist sexual health services (clinics).

Third sector organisations (NGOs) make important contributions to health promotion, providing all communities at risk of HIV with up-to-date, relevant information on HIV prevention, harm reduction and testing (though a range of community-based and online HIV testing services to complement those offered by the NHS).

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

Specialist HIV care is provided according to national guidelines (BHIVA https://www.bhiva.org/quidelines) within dedicated HIV, genitourinary medicine and infectious disease services. All care and medication is free at the point of access to UK residents and for 'emergency care' to non-UK residents. There is close collaboration between the specialist HIV service and primary care in a shared care model.

Third sector organisations (NGOs) make important contributions to health promotion, advocacy, policy support, peer support and local interventions to ensure PLWHIV are able to engage in treatment and access services that improve their health and well-being. The third sector provides responsive services, tailored to the needs of distinct communities including Africans, people who inject drugs, MSM and those living in remote and rural areas.

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
High quality integrated sexual healthcare (STI and reproductive health) services are provided nationwide within specialist clinics providing all levels of care, often linked with 'satellite clinics' providing less complex interventions, asymptomatic screening and some contraception. Care incorporates British Association for Sexual Health & HIV (BASHH) national guidance (www.bashh.org) with local adaptation as appropriate. Prevention is an integral part of service delivery and a service user would typically access health information, health promotion, screening treatment and contact tracing from the clinics or outreach services (e.g. for MSM, young people, people who inject drugs, sex workers). STI and BBV postal self-sampling services are at pilot stage. For many years, demand for these services has exceeded capacity.

NGOs make important contributions to health promotion and provide communities with accurate, relevant and community led information on a range of issues relating to sexual health and testing.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM

⊠Migrants

☑Trans-people

Sex workers

☑People who inject drugs

☑Other, please describe below

Our PrEP programme provides free medication and associated monitoring to individuals (irrespective of membership of the above groups) providing they meet one or more of the following risk-based eligibility criteria:

- 1. Current sexual partners, irrespective of gender, of people who are HIV positive who have a detectable viral load.
- Cis and transgender gay and bisexual men, other men who have sex with men, and transgender women with a documented bacterial rectal sexually transmitted infection in the last 12 months.
- 3. Cis and transgender gay, bisexual men and other men who have sex with men, 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 three months.

4. Individuals, irrespective of gender, at an equivalent highest risk of HIV acquisition, as agreed with another specialist

There is an ongoing HIV outbreak in people who inject drugs (PWID) in Glasgow, Scotland's largest city. PrEP is delivered to individuals who inject drugs who have sexual risk of HIV. Although overall numbers are low, it appears highly acceptable to service-users. PrEP is not currently approved in Scotland for PWID whose only risk is via sharing injecting equipment. An evaluation is in process. Please contact us for more information.

PrEP SERVICE DELIVERY MODEL(S)xvi:

PrEP service delivery model(s):

☑Clinic-based model

- □Community-based model
- □HIV specialist model
- □Primary care model
- □Peer/Population/Online-based model
- □Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

PrEP has been delivered in Scotland using the existing network of specialist sexual health services since July 2017. There has been strong national coordination, monitoring and evaluation

(https://www.hps.scot.nhs.uk/web-resourcescontainer/implementation-of-hiv-prep-in-scotland-secondyear-report/).

The Programme includes combination prevention, comprehensive BBV and STI testing, all associated monitoring and generic oral Tenofovir/emtricitabine), in line with national guidance (https://www.bhiva.org/Prepguidelines).

Care models include face-to-face and telephone consultations (largely since the Covid-19 pandemic) every three months, postal self-sampling (pilot stage), and postal medication. Care is provided by doctors and nurses, often using local/national protocols. We are developing an online PrEP service.

Advantages (100 words)

Our model is clinically robust and comprehensive. For the user, it is convenient in that STI and HIV screening, treatment of any infections and dispensing of medication is all done in the same place. It has allowed the development of high-level competences in clinical staff as almost all PrEP in Scotland is delivered through sexual health services.

Limitations (100 words)

People who do not attend sexual health services are unlikely to find out about PrEP in other health settings. If they do not find attending sexual health services acceptable, they are very unlikely to get access to PrEP at all. This is a real problem for women as highlighted by our recent research

(https://sti.bmj.com/content/sextrans/early/2020/06/12/sextrans-2020-054457.full.pdf)

The workload associated with PrEP services has been considerable and has caused a shift in clinic attender profiles (fewer women and more MSM), creating inequalities in access to some sexual health services.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

- □Based on modelling
- □Based on PEP use
- □Other

Give details below (50 words)

A short life working group of clinicians, public health, NGOs and researchers recommended the implementation of a targeted national PrEP programme. The case was based on research evidence from relevant Scottish studies on PrEP intent, MSM behavioural surveys and justified on financial grounds.

(https://www.thelancet.com/pdfs/journals/lanhiv/PIIS235 2-3018(17)30078-4.pdf)

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments

□National programme without co-payments

□Private prescription and online purchase

□Other

Give details below (50 words)

- PrEP formed part of wider HIV combination prevention.
- The report defined eligibility criteria and estimated the number who would likely commence PrEP in year one.
- Expenditure was estimated using the full costs of branded medication, but generic drug was delivered from November 2017.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

- ☑Clinical STI/HIV doctor
- ☑Clinical doctor (other setting)
- ⊠Nurse
- □Pharmacist
- □Other

Give details below (50 words)

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

- ⊠HIV/STI/Infectious disease Clinic
- □Pharmacy
- □Community setting
- □Other

Give details below (50 words)

xvi This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

The majority of PrEP is prescribed by doctors, nurses who can prescribe independently and other specialist nurses working to strict protocols.

Many sexual health services dispense PrEP from their own pharmacy stores in clinic. Others have arrangements with their hospital pharmacy and or local community pharmacies.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Joint working between key stakeholders including NGOs, advocacy groups, PrEP users, clinicians, researchers and decision makers, to build a consensus for PrEP in Scotland.
- Articulating a proposed delivery model utilising existing infrastructure. This included national data collection
- Advocating for a single national approach to maintain consistency and prevent duplication of effort and a desire to reduce health inequalities.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country?
(100 words)

- There is a considerable workload associated with training, even staff who are familiar with antiretrovirals, to prescribe them in the context of prevention (rather than HIV treatment). Investment in staff education and support should be prioritised. Sharing 'lessons learned' in real time is helpful.
- We launched HPV vaccination in MSM around the same time as we launched PrEP – although it was a good way of getting MSM vaccinated, it placed strain on the clinics.
- A successful PrEP programme might displace other services/people attending for non-PrEP reasons, so evaluation is essential.
- PrEP is for all who may benefit and not just MSM ensure awareness raising and educational materials are relevant and culturally appropriate to all groups.
- Outputs from concurrent programmatic research including epidemiological and mixed methods evaluation (funded by Scotland's Chief Scientist's Office, HIPS/17/47, Optimising PrEP Services will be published end 2020/early 2021), national monitoring and clinical audit, exploratory social science have framed these points.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

- Having a national programme is key to success; direction is clear, educational materials and processes can be shared and evaluation is implicit from the start.
- Public health, clinicians, civil society and NGOs working together can be a formidable force for good.
- Demonstrating the financial benefit / costeffectiveness of PrEP is helpful.
- A human rights-based argument may change opinions and aligns with governmental commitment to reduce inequalities.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

We are working on a proposed HIV transmission elimination strategy within our national framework for sexual health & BBV. Although successful, our PrEP programme remains inaccessible / unacceptable to some who could benefit. We are exploring alternative delivery models in different settings informed by our research (https://sti.bmj.com/content/96/5/349). These include an online PrEP clinic (state funded) and provision in 'non-sexual health' healthcare settings.

PrEP implementation in Spain

The case study has been developed to capture practical details about the implementation of PrEP programmes in Spain and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Julia del Amo
Clinical focal point:	Pep Coll
Civil society/PrEP user	Ramón Espacio (civil society
representative:	representative)

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

Article 43 of the 1978 Spanish Constitution establishes the right to health protection and healthcare for all citizens. Spain has a National Health System –NHS– which is configured as a coordinated set of health services from the Central Government Administration and the Autonomous Regions that integrates all healthcare functions and benefits for which public authorities are legally responsible. The NHS is publicly funded and provides universal coverage and free healthcare services. It is characterised by political decentralisation of healthcare, which is entrusted to the autonomous communities. The Central Government is responsible for basic health principles and coordination, foreign health affairs and policy on medicines, the Autonomous Regions for health planning, public health and healthcare services management, and local councils for health and hygiene and cooperation in the management of public services. Additionally, and specifically for HIV, NGOs have a key role on HIV prevention. In Spain, the National Plan on AIDS (NPA) in the Ministry of Health (MoH) includes the NGO council (COAC) as one of its governance structures.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

As explained in the previous section, the NHS is publicly funded and provides universal coverage and free healthcare services. In July 2018, the Ministry of Health of Spain reversed the decision to deny undocumented migrants access to universal healthcare. Healthcare planning and service delivery is entrusted to the Autonomous Regions. Antiretroviral Treatment (ART) for HIV is fully covered for people living with HIV and also for PrEP users. ART is exclusively provided within hospital pharmacies; HIV care in Spain is largely based in hospital settings. Primary healthcare has a role in HIV testing and specialist referral but less so in the follow-up of common health conditions (such as hypertension) of persons with HIV

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
As explained above, the NHS is publicly funded and provides universal coverage and free healthcare services. Healthcare planning and service delivery is entrusted to the Autonomous Regions. Given the public health nature of STI prevention and HIV testing, local councils also have a role in some areas. HIV/STI testing is free in Spain; it can be requested within primary healthcare, STI clinics, hospital settings and at NGO services throughout the country. Whereas Antiretroviral Treatment (ART) for HIV is fully covered for people living with HIV and also for PrEP users, this is not the case for other infectious diseases (i.e. gonorrhea) which may require small amounts of co-payment according to personal income.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MMSM

☑Migrants (*please note that not all migrants are at risk for HIV and therefore PrEP need)

■Trans-people

Sex workers

☑People who inject drugs

⊠Other, please describe below

Adolescents at risk for HIV and heterosexuals at risk for HIV

PrEP SERVICE DELIVERY MODEL(S)xvii:

THE SERVICE DELIVER HODEL(S)	
PrEP service delivery model(s):	Advantages (100 words)
☑Clinic-based model	HIV clinic-based model provides experience in ART use and
☑Community-based model	established links with Hospital Pharmacies.
☑HIV specialist model □Primary care model □Peer/Population/Online-based model □Other, please describe below	There are HIV clinics in most cities in Spain, which could implement PrEP, whereas there are fewer STI clinics in the country, a limiting factor.
Describe the main PrEP service delivery model used in your Member State (100 words)	Community settings and non-hospital-based STI clinics are closer to the community, avoid hospital visits and hospital costs

xvii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

PrEP delivery in Spain is based in HIV clinics model as it is mandatory to have an established formal link with a hospital pharmacy in order to provide the antiretroviral medication. This model can be combined with a community-based model, such as in the PrEP Point in Barcelona or and STI-clinic model such as in Sandoval Clinic in Madrid or Drassanes in Barcelona, provided the links with hospital pharmacies can be ensured.

Limitations (100 words)

Primary healthcare services in Spain are not playing a significant role in PrEP delivery but are key in PrEP referral.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

☑Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other HIV case reporting, expert consultation

Give details below (50 words)

PrEP reimbursement at Central government level required an estimated figure of PrEP candidates. This figure was developed based on the eligibility criteria for PrEP use designed by the NPA which resulted in 15 000 MSM and Trans people and 2 000 female sex workers. This number, broken down by Autonomous regions, was estimated based on surveys, expert consultation and modelling work from various countries establishing relationships between numbers of PrEP users and numbers of new HIV diagnoses reported to surveillance system.

PrEP programme funding:

Select how the PrEP programme(s) is funded

□National programme with co-payments

□National programme without co-payments

□Private prescription and online purchase

□Other

Give details below (50 words)

As previously explained, policy on medicines is Central Government's responsibility, specifically of the General Directorate of Pharmacy. Therefore, in collaboration with the National Plan on HIV and AIDS, within the General Directorate of Public Health, approval was granted in October 2019 by the Public Health Commission to include full funding of PrEP medication. However, since healthcare planning and service delivery is the responsibility of the autonomous regions, it is up the regions to take actions for effective PrEP implementation.

Private prescriptions in private hospitals is also available in Spain

On-line purchase of PrEP in Spain is illegal although support for informal PrEP users is available in some clinics.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

□Clinical doctor (other setting)

□Nurse

□Pharmacist □Other

Give details below (50 words)

- In early 2018, the NPA, from the Ministry of Health produced the first set of PrEP Guidelines.
- In November 2019, PrEP became publicly reimbursed for MSM, transgender persons and female sex workers, over 18 years old, at high risk of HIV infection.
- In February 2020, the NPA, from the Ministry of Health, published PrEP Implementation guidelines; stating the minimum requirement a centre should have to implement a PrEP programme.

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

⊠HIV/STI/Infectious disease Clinic (provided a link to hospital pharmacy is in place)

⊠Pharmacy (only hospital pharmacy)

□Community setting

□Other

Give details below (50 words)

See answer in previous section:

- In December 2019, the NPA, from the Ministry of Health, published the report on the PrEP implementation study describing models of implementation in different settings
- In February 2020, the NPA, from the MoH, published PrEP Implementation guidelines
- In June 2020, the NPA, from the MoH, published the national PrEP monitoring system, SiPrEP, to support PrEP follow-up, in collaboration with the autonomous communities, the National Centre for Epidemiology of the Instituto de Salud Carlos III (ISCIII) and the Spanish Network of HIV research (RIS) of the ISCIII. By October 2020, 33 PrEP dispensing sites from 8 autonomous regions have registered in a webpage created to that end (https://siprep.es/) with public and private access. The public section contains information about PrEP provider centers with other documents and links of interest. The private section allows PrEP providers to fill in data regarding PrEP monitoring.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Spain is still in early stages of PrEP implementation and there are currently regional differences in how PrEP programmes are being set up and delivered. Political will varies by region and resources are allocated differently. For example, there are regions as Canarias and Asturias were PrEP is still not available, Madrid has only allowed PrEP implementation in a single STI clinic in the city centre (insufficient for an area of 6.7 million people), whereas Catalonia has allowed PrEP delivery in close to 20 clinics (for a population of 7.6 million people), but not all them are currently providing PrEP. The 17 autonomous regions are now beginning to implement PrEP delivery models in STI centres, HIV units, and Check Points. As everywhere else, COVID-19 has jeopardised a number of initiatives and at present it is difficult to foresee the date of availability and access to PrEP throughout the Spanish territory.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

Actions to be implemented by the Ministry of Health

- 1. Expand current criteria for PrEP reimbursement to include adolescents, Persons who inject Drugs, and heterosexual population at high risk. Advance in the authorisation of new forms of PrEP delivery.
- 2. Promote the national PrEP monitoring system, **SiPrEP**, to serve the information needs of PrEP providers at clinic level, regional level and national levels

Actions to be implemented by the Autonomous Regions

- 1.Increase the number of PrEP centres throughout the regions.
- 2. Promote and engage with the national PrEP monitoring system, SiPrEP to provide real-time information.

Actions to be implemented by NGOs/Community

- 1. Provide information regarding PrEP to potential PrEP users and support adherence and follow-up.
- 2. Identify PrEP candidates and refer to PrEP centers.

Common

Engage with national, regional and local administrations, scientific societies, political actors, affected communities and society to support for PrEP implementation.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

The decision to reimburse PrEP was made collectively with the community, scientific societies and of course, central and autonomous administration. This facilitated accountability among the different regions. The decision regarding public reimbursement of PrEP in Spain was reached three years after approval by the Spanish Agency for Medicines (AEMPS) (equivalent to EMA), and with early engagement of all the relevant actors (at technical and political levels), alongside public discussions.

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

A closer and more meaningful engagement with all relevant actors from stage one would have diminished the misunderstandings and mistrust regarding PrEP..

Providing the scientific facts regarding pros and cons of PrEP implementation before minds are set in positions for and against PrEP would have been very useful.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

Spain needs to include additional criteria for PrEP reimbursement (including adolescents, Person who inject Drugs, and heterosexual population at high risk). There is a need to improve STI prevention and control nationally. The availability of free condoms should be actively promoted.

It is essential to ensure that adequate resources are allocated to PrEP implementation at central, regional and local levels.

Relevant links

https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/PROFILAXIS PREEXPOSICION VIH.pdf https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/INFORMEFINAL.pdf https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/docs/MANUAL PREP.pdf https://www.mscbs.gob.es/ciudadanos/enfLesiones/enfTransmisibles/sida/PrEP/SIPrEP(1).pdf https://siprep.es/

PrEP implementation in Sweden

The case study has been developed to capture practical details about the implementation of PrEP programmes in Sweden and was submitted to ECDC in September 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Charlotte Bjorkenstam
Clinical focal point:	Finn Filén
Civil society/PrEP user	Malin Falknert
representative:	

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

Describe how HIV prevention services are funded and delivered (100 words)

Funded by government. HIV/STI health promotion and preventive approaches are delivered in relevant sectors such as the education and healthcare sectors, complemented by targeted efforts by NGOs.

HIV care: funding and delivery:

Describe how care for people living with HIV is funded and delivered (100 words)

Funded by government. Visits, examinations and treatment is free of cost for the patient and offered in infectious diseases clinics at hospitals (28 clinics throughout the country).

STI and sexual health: funding and delivery:

Describe how sexual health, STI prevention, testing and treatment services are funded and delivered (100 words)
Funded by government. STI testing is available all over Sweden, free of cost for the patient. It is mainly offered as a basic package in the primary healthcare centres and youth health clinics in the municipalities, gynaecological clinics in public hospitals, and at a specialised level in the STI clinics (45 clinics in public hospitals throughout the country).

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: ■MSM

□Migrants

⊠Trans-people

□Sex workers

□People who inject drugs

□Other, please describe below

Prep service delivery model(s)xviii:

PrEP service delivery model(s):

□Clinic-based model

□Community-based model

☑HIV specialist model

□Primary care model

 $\square Peer/Population/Online-based\ model$

 \square Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

PrEP is recommended for MSM who are assessed as being at high risk for HIV acquisition and for whom other preventative measures are rendered insufficient. PrEP can also be considered for persons in other groups where the individual risk for HIV in a particular person is assessed as high. Screening, start and follow up of PrEP is done in parallel with other risk reduction measures (targeting STIs, condoms, drug use, counselling). The aspect of adherence to treatment is always addressed. Presciption of PrEP is recommended to be done by, or in close collaboration with clinics having experience in treatment of HIV (in practice: infectious diseases clinics working in collaboration with local STI clinics).

Advantages (100 words)

Familiarity with the particular drug (FTC/TDF), ability and experience in dealing with side effects and persons testing HIV+ at baseline or during follow up.

Limitations (100 words)

Accessibility and slow roll out due to high demand, particularly in the capital area (Stockholm). Infectious diseases clinics normally refer all STI screening and treatment to STI clinics, which becomes impractical for the patient as opposed to a one-stop service.

(The covid-19 pandemic severely affected PrEP delivery at our clinic in Stockholm for the period March to August 2020, mainly due to outpatient staff being reassigned to covid inpatient wards. PrEP screening visits have since then resumed at our clinic.)

xviii This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

□Based on population survey(s)

■Based on modelling

□Based on PEP use

□Other

Give details below (50 words)

 The Swedish Reference Group for Antiviral Therapy issued a recommendation in 2017, following an expert group meeting. Based on their recommendation, the main target group was set as MSM.

PrEP programme funding:

Select how the PrEP programme(s) is funded

☑National programme with co-payments

☐National programme without co-payments

☐Private prescription and online purchase

☐Other

Give details below (50 words)

 After the screening visit, an electronic prescription is sent to the national pharmacy database and can be picked from any pharmacy. The combined cost for prescription drugs over 12 months for one particular patient is capped at a ceiling of currently 2350kr per year (225 EUR).

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

- □Clinical doctor (other setting)
- □Nurse
- □Pharmacist
- □Other

Give details below (50 words)

 Any doctor in the country can send a prescription for the tablets, however the recommendation in the 2017 national guideline is that prescriptions are done only at clinics with experience of HIV treatment (or in close collaboration with such).

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:

□HIV/STI/Infectious disease Clinic

⊠Pharmacy

□Community setting

□Other

Give details below (50 words)

 The tablets can be collected from any pharmacy in the country. Only larger pharmacies routinely carry the tablets in stock, smaller pharmacies can order them for the patient to pick up within 24 hours.

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrEP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- Since 2016, Truvada as PrEP is included and subsidised in the high-cost threshold in the national pharmaceutical benefit system (i e the person doesn't pay more than 2350 SEK per 12 month period for all prescribed medicines).
- The Public Health Agency published national guidance for PrEP in 2017 to promote the use of PrEP for persons with high risk to get infected by HIV.
- The Public Health Agency economically support a cohort study of patients on PreP in the healthcare service (led by Uppsala university hospital).

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

In hindsight, we should have put more time and effort in getting the regions to realise that the demand for PrEP requires organising of special units, reimbursement of costs for personnel and increase in screening, especially in larger cities where the regular HIV clinics don't have the economics to handle PrEP visits too.

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Within our particular clinic, there seems to be a tendency of declining numbers of new HIV cases since 2018 within the MSM group (NB: preliminary data, not yet confirmed)

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

Within Stockholm county, there are current discussions on widening the PrEP delivery from only one infectious disease outpatient clinic to some selected STI clinics.

PrEP implementation in Switzerland

The case study has been developed to capture practical details about the implementation of PrEP programmes in Switzerland and was submitted to ECDC in October 2020. This case study can be used by countries at different stages of PrEP implementation, including 'pre-PrEP', 'new PrEP', 'established PrEP' programmes in EU/EEA Member States and the United Kingdom.

COUNTRY FOCAL POINTS:	Name:
Public health focal point:	Axel J Schmidt
Clinical focal point:	Benjamin Hampel
Civil society/PrEP user	Andreas Lehner
representative:	

HEALTHCARE CONTEXT:

HIV prevention: funding and delivery:

National campaigns for HIV prevention are sponsored by the Federal Office of Public Health (FOPH).

All targeted campaigns are funded, planned and executed by the community-based NGO Swiss Aids Federation, and cofunded by FOPH. Free condom provision is not part of the National Programme, but condoms are often distributed free of charge at Checkpoints, other voluntary counselling and testing centres (VCT), sex clubs, *etc*.

VCT is available in each canton and all larger cities, some specialised in risk populations like the Checkpoints for MSM, but HIV tests are not free. PrEP is available, but not for free. Prior to the start of *SwissPrEPared*, most PrEP was purchased online and imported.

HIV care: funding and delivery:

HIV care is covered by the obligatory health insurance. Everybody who is officially living in Switzerland has mandatory universal health coverage. In Switzerland, co-payment is larger than in most other European countries. Monthly fees vary across cantons and providers, and largely depend on the amount of yearly private co-payment (standard deductible ranging from 300 CHF to 2500 CHF, plus a retention fee of 10% up to 700 CHF per year). For people with HIV, a deductible of 2 500 CHF is not cost-effective. Average monthly costs for health insurance in Switzerland (based on a deductible of 300 CHF) are about 550 CHF per month (range 440–700). Undocumented migrants can be insured too; however no HIV care programs exists for undocumented migrants without health insurance.

https://www.bag.admin.ch/bag/en/home/versicherungen/krankenversicherung/krankenversicherung-versicherte-mitwohnsitz-in-der-schweiz/praemien-kostenbeteiligung/kostenbeteiligung.html

STI and sexual health: funding and delivery:

Costs for STI and HIV tests can only be covered by the health insurance under certain conditions: HIV: once a year for people who belong to a risk population, STI: when symptoms are present.

The problem for most sexually active people without chronic disease is that not only screening, but also symptomatic testing has to be paid out of pocket until the standard deductible is reached.

A current grey zone is the reimbursement of tests during PrEP consultations. Yearly campaigns with reduced costs exist since 2014 for special populations, funded by the FOPH.

Population groups most likely to benefit from accessing PrEP, as an additional HIV prevention tool: MSM

□Migrants

▼Trans-people

□Sex workers

□People who inject drugs

□Other, please describe below

PrEP SERVICE DELIVERY MODEL(S)xix:

PrEP service delivery model(s):

☑Clinic-based model

☑HIV specialist model

☑Primary care model

Peer/Population/Online-based model

□Other, please describe below

Describe the main PrEP service delivery model used in your Member State (100 words)

In Switzerland, Gilead holds the patent for TDF/FTC as Truvada® which is not reimbursed by the health insurance at the current price of 671 CHF.

Advantages (100 words)

- Wide range of different providers:
 - Community health centres (Checkpoints)
 - Hospitals
 - o GP:
- National programme with a research project in form of a cohort study, with a direct surveillance response to constantly monitor and improve delivery of care
- Cooperation and involvement of community, science and clinic
- Holistic approach with special training for health care providers not only to prescribe PrEP but also to recognise special needs like mental health problems or problematic substance use, both of which are also risk factors for HIV and other STIs
- Open programme: Not limited to MSM

xix This section describes an example of a PrEP delivery model. The description may not fully reflect all PrEP delivery models used in the Member State and may not be a comprehensive summary of the PrEP delivery model.

Re-imbursement of tests during PrEP consultations see above. In April 2019, the national programme and research project *SwissPrEPared* started with the aim to improve the situation. At the moment there are 29 *SwissPrEPared* centres, including hospitals, GPs and community health centres. The FOPH is co-funding the research-part. Thanks to an agreement with Gilead participants can receive Truvada® for a reduced price of 40 CHF per month. The programme does not cover consultation fees or STI-testing, but some cantons have special funding for people with low income.

Limitations (100 words)

- High barrier for people with low income or other barriers to health care access due to high co-payments
- TDF/FTC currently not reimbursed through health insurance
- Unclear legal situation for the reimbursement of STI and HIV testing for PrEP users.

Demand and targets for PrEP programmes:

Select how demand for PrEP/a target number of PrEP users is established:

■Based on population survey(s)

■Based on modelling

■Based on PEP use

□Other

PrEP programme funding:

Select how the PrEP programme(s) is funded

☑National programme with co-payments

□National programme without co-payments

□Private prescription and online purchase

⊠Other: Private prescription and online purchase, or import from e.g. Germany through a Swiss pharmacy, is possible for people not enrolled in *SwissPrEPared* (not recommended)

Give details below (50 words)

- SwissPrEPared is a cohort study where the results have direct impact on the programme (Surveillance response concept)
- Different models exist about the impact of PrEP and the amount of people benefitting from PrEP in Switzerland.
- Online community surveys were done and helped to plan the needs.

Give details below (50 words)

- Thanks to an agreement with Gilead, participants can purchase Truvada® for 40 CHF, until generics can be legally distributed in Switzerland.
- Costs for consultations are paid by the PrEP-user until the standard deductible is reached. Beyond the deductible, coverage of STI-testing by health-insurance is currently a grey zone. Amount of standard deductibles and monthly costs of health insurance see above.
- Some regions have special funding for people with low income.

Prescribing PrEP:

Describe who can prescribe PrEP, and in which settings.

☑Clinical STI/HIV doctor

☑Clinical doctor (other setting)

□Nurse

□Pharmacist

□Other

Dispensing PrEP:

Describe the settings in which PrEP is/could be dispensed:
⊠HIV/STI/Infectious disease Clinic

⊠Pharmacy

oxtimesCommunity setting

⊠Other: SwissPrEPared

Give details below (50 words)

- Every physician can prescribe PrEP.
- For the 40 CHF Truvada®, the physician must be part of the *SwissPrEPared* programme.

Give details below (50 words)

- Participants of the SwissPrEPared program get drugs delivered to their home by an online pharmacy
- It is allowed to import a one month supply of generic TDF/FTC

REFLECTIONS:

In this section, consider political, economic, social, technological, legal, environmental, and epidemiological factors which affect PrFP delivery.

Prioritising PrEP:

Describe three key actions taken to prioritise PrEP in national HIV prevention strategies and gain active support from governmental leaders, such as Ministry of Health (100 words):

- PrEP will be part of the new FOPH National Programme on STIs
- FOPH supports and co-funds SwissPrEPared
- The Federal Commission for Issues relating to Sexually Transmitted Infections (FCSTI) is supporting the call for reimbursement of PrEP through health insurance, as well as the general access to PrEP

Learning from the past:

Use this space to outline anything you would do differently/wish that you knew when setting up a PrEP programme in your country? (100 words)

Advice for other Member States:

What advice would you give to colleagues in neighbouring countries to support efforts to include PrEP in national HIV prevention programmes? (100 words)

Be brave but think stepwise. Be polite but persistent.

Looking to the future:

Describe any plans for next steps for your country's PrEP programme. How will it be expanded/ developed? (100 words)

- Reimbursement of PrEP and PrEP consultations, through health insurance free of co-payments.
- STI-testing for people at risks for STIs (including PrEP users) independent of standard deductible in the interest of public health
- Access to PrEP for all people at risk for HIV, not only MSM
- Better understanding of risk behaviour and development of more holistic prevention concepts, including mental health