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Ending the epidemic

An assessment of HIV policy in Germany and recommendation to improve the lives of those living with, and at risk of, HIV

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The report was compiled by KPMG LLP UK (KPMG) and guided throughout by an independent Steering Group comprising of policy, clinical and patient experts in HIV. The Steering Group had editorial control of the report.

01 Executive summary

Germany's response to the HIV epidemic has made a real impact. The number of new HIV infections have stabilised since 2006, and more and more people are on anti-retroviral therapy (ART) and are virally supressed. Germany has done particularly well against the UNAIDS 90-90-90[1] treatment targets, reaching 92% and 95% on the 2nd and 3rd target respectively [1]. Services are generally available to those who need them, and its expected that pre-Exposure Prophylaxis (PrEP) for high risk populations will be available later this year.

But the epidemic is far from over and Germany still faces a number of critical challenges. Close to 11,500 people living with HIV are unaware of their status, and a high proportion of people are diagnosed late each year. While services are generally available, there are inequalities in access - with people from certain sub-populations (such as newly arrived migrants) and those living in rural areas facing greater barriers. These include both the more limited availability of HIV specialised services as well as a higher prevalence of stigma, which may prevent uptake.

Germany's current response to the epidemic is outlined in its framework, "The Integrated Strategy for HIV, Hepatitis C and Other Sexually Transmitted Diseases" launched in 2016. To understand how successful Germany's new HIV strategy will be, the Steering Group[3] assessed each step across the HIV care continuum of Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health. They identified both areas of strength and those with room for improvement.

1. The UNAIDS 90-90-90 targets set in 2014 are targets for the treatment of people with HIV – 90% of people with HIV will know their status, 90% of people diagnosed with HIV will be receiving ongoing antiretroviral therapy, and 90% of people with HIV on treatment will be virally supressed by 2020. These targets are based on the assertion that it is not possible to end the HIV epidemic without treating all of those with HIV that need it [2]
2. A 'late' diagnosis is one which is made at a point in time after which HIV treatment should have been started. Currently, a CD4 cell count below 350 cells/mm3 at time of diagnosis is considered 'late' [1]
3. For full list of Steering Group members, see Methodology section, Table 1

Awareness

Large scale national and regional interventions exist, and are effectively targeting high risk populations[4]. Room for improvement exists in increasing consistency across Länder (regions) and putting greater focus on eradicating stigma.

Prevention

Interventions are well implemented. The recent inclusion of PrEP within statutory health insurance is a milestone in strengthening a combined strategy. Some room for improvement exists in addressing certain sub-populations, such as prisoners.

Testing and Screening

Testing is offered through multiple settings, which are more commonly found in urban areas. Stigma and limited access (particularly in rural areas) means room for improvement exist.

HIV specific clinical treatment

HIV specific clinical treatment is delivered to a high standard, in line with prescriptive guidelines. Time to initiation of treatment may not be consistent across all Lander (although data is limited), and the undocumented migrant population does not yet have access to treatment

Long-term Holistic Care

Greater focus is needed for improving long term holistic health of people living with HIV, including more prescriptive policy, guidelines and funding for implementation. Actions across the Länder are patchy and overall are lacking in drive.

4. See Methodology section for list of high risk populations

To drive improvements in the lives of those with, or at risk of HIV in Germany, the Steering Group put forward a number of recommendations:

- **Tackle HIV related stigma through national level interventions** - Run more campaigns targeting stigma, distributed throughout the year to maintain momentum.
- **Increase inclusive, community-based testing centres** - Apply lessons from successful models in other countries and adapt them to Germany, expanding the number and capacity of facilities to cover a wider population
- **Improve harm reduction services in prisons** - Develop policy to mandate and provide guidelines on harm reduction in prisons, to ensure coverage throughout the Länder
- **Allow ART to be provided to undocumented migrants** - Update policy to allow long term ART therapy for undocumented migrants
- **Focus more on chronic care for people living with HIV** - Conduct a study to assess the gaps in chronic care services required to address the long term needs of people living with HIV, to support evidence based discussions on policy change

02 HIV in Germany, the wider context

Brief epidemiology and 90-90-90 overview

The impact of Germany's response to the HIV epidemic is evident. 86,100 [80,100-92,600] people are estimated to be living with HIV/AIDS in 2017, many of who are on anti-retroviral therapy (ART) and virally supressed (see Figure 1 90-90-90 data) [1].

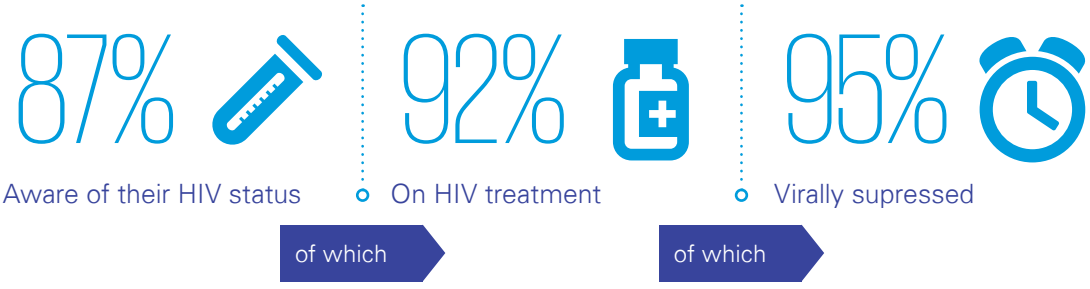
However there is still much to be achieved. Reaching the undiagnosed HIV population remains one of the key challenges, which was estimated to be ~11,400 or 13% of people living with HIV at the end of 2017 [1]. The inability to effectively reach this population exerts significant pressure on efforts to minimise the onward transmission of the disease. Furthermore, while incidence has broadly stabilised since 2006, around 3,000 new HIV diagnoses are still made each year (2,700 in 2017) [1], [2]. Partial data indicated that of the 772 new diagnoses where CD4 data at time of diagnosis was available, 51% had less than 350 CD4 cells per mm^3 [2], thereby falling into the category of 'late diagnosis' associated with higher rates of mortality and morbidity [3], [4].

There is inequity in healthcare services, which means people living in certain regions (e.g., rural locations) or certain sub populations may face greater barriers in accessing healthcare services. Stigma, particularly prevalent in rural areas, may exacerbate the problem. For example, while total incidence has stabilised, the number of new infections in heterosexuals has risen since 2010, reaching 670 in 2017 and accounting for 24.8% of new infections. In contrast, the estimated new infections in men-who-have-sex-with-men (MSM) has seen a decreasing trend in recent years.

Another key challenge is provision of multi-disciplinary support to adequately manage the health and wellbeing of the ageing cohort of people with HIV.

Ensuring Germany's current response to tackling the HIV epidemic, and in particular the remaining key challenges, are outlined in its intergrated strategy for HIV and other common co-infections (see Chapter 3). The wider legal and policy environment also continues to impact current efforts towards HIV, contributing towards the quality of life of people living with HIV and efforts to limit the spread of the epidemic (see Box 1).

Figure 1. Performance towards the 90-90-90 targets



Source: Robert Koch Institut [1]
Notes: Data from 2017.

Box 1. The wider legal and regulatory landscape

As outlined in the Methodology section, a deep assessment of the wider legal and policy landscape and its impact on the HIV response is not within the scope of this project. However, outlined below is Germany's current position on three common potential barriers:

1) Legal protection against stigma and discrimination:

Germany's General Equal Treatment Act (Allgemeines Gleichbehandlungsgesetz)[6],[7], provides protection from discrimination to all individuals, regardless of their residence status, on six grounds: race and ethnic origin, gender, religion, disability and chronic disease, age and sexual orientation [7]. The act further prohibits discrimination in the workplace as well as daily affairs such as renting a house. While this law protects HIV patients, recognition of stigma as a key challenge in BIS2030 indicates room for improvement exists (see Chapter 2) [8].

2) Free, non-discriminatory access to healthcare:

Germany's high performing healthcare system revolves around an insurance-based system, where the vast majority of citizens are covered by statutory health insurance (Gesetzliche Krankenversicherung (GKV)), with a small proportion covered by private health insurance (Private Krankenversicherung (PKV))[9].

While healthcare is accessible to vast majority of the population, a small proportion may be left out. These are the undocumented migrants who have not gained or have been refused legal status in the country (e.g., refugee or asylum status). Any undocumented migrants (recorded at 167,000 in 2016 [10]), who do gain legal status or have existing health insurance are provided access, although they may face some delay (e.g., it may take up to 15 months to receive a health insurance card).

3) Decriminalisation of behaviours such as sex work and drug use:

Germany is one of the few countries included in our study which provides comprehensive protection for sex workers, however the effectiveness of this protection is debated. This is achieved through 2002 legalisation of sex work [11], and new legislation of 2017, providing protection including regulations making health consultations every 12 months and condom use mandatory [12]. A 2012 report by the ECDC indicated a high rate (>60%) of HIV testing, and high rate (>90%) of condom use among sex workers in Germany [13].

On drug use, while under *The German Narcotics Act* prosecutors have discretion to refrain from imprisonment if an individual possesses drugs in small quantities for personal use, it does not explicitly specify what constitutes as a small quantity [14] [15] and Länder are in general able to determine limits. Multiple harm reduction policies exist (see Chapter 3), and the incidence of HIV among PWIDs have remained low (5%) and generally stable [16].

03 Assessment of HIV policy in Germany

This chapter outlines the Steering Group's assessment of the current HIV policy in Germany, and its effectiveness in tackling the new and continuing challenges of the epidemic. It is broken down by stages of the HIV care continuum, covering Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health. Recommendations for improving the lives of those with, and at risk of HIV are outlined in the next chapter.

3.1 Overview of national HIV policy

The Federal Government of Germany adopted a new framework and strategy to tackle HIV in 2016. The "Integrated Strategy for HIV, Hepatitis B and C and Other Sexually Transmitted Infections" was jointly developed by the Federal Ministry of Health (BMG) and the Federal Ministry for Economic Co-operation and Development (BMZ). Also called BIS2030 (By 2030), the document describes priorities for both the national level and for Germany's international contributions, and replaces the government's 2005 HIV policy.

For the first time, the strategy jointly addresses HIV and other common co-infections. This has risen from an acknowledgement of the common transmission routes, rates of co-infections, and the need to create synergies across the patient journey through common interventions.

> "Integration is a good step forwards as we are talking about the same at risk populations"
>
> **HIV HCP, Germany**

It aims to create a more enabling environment and greater cross-sectoral collaboration. Specific objectives include: creating an enabling environment promoting acceptance of sexual orientations and different lifestyles, expanding needs oriented services (e.g., taking into account regional prevalence), developing integrated services through provision of co-ordinated services, promoting cross-sectoral co-operation, and expanding on use of information and data for planning and implementation of interventions.

A continued feature of Germany's HIV response is its close collaboration with NGOs. Driven by the acknowledgement that marginalised communities may be reluctant to engage with state-run services, Germany has formed a long standing and successful collaboration with community groups to deliver key services. Today, Deutsche AIDS-Hilfe, the largest umbrella organisation representing local / regional NGOs across Germany, is instrumental in leading many interventions in awareness, prevention and testing for high risk populations.

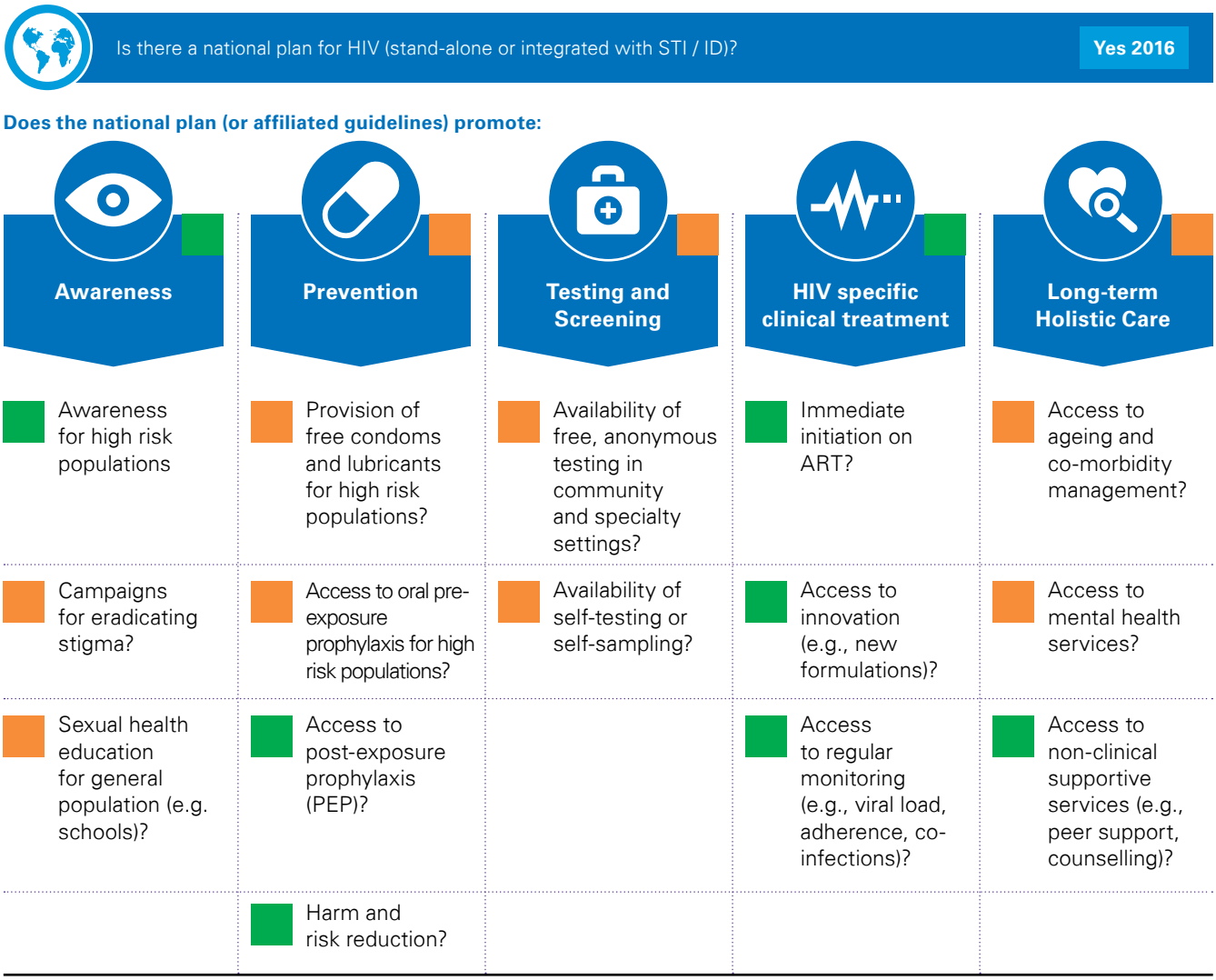
The Ministry of Health is committed to furthering efforts to eradicate HIV, evidenced by the recent availability of self-tests in pharmacies and the announcement to include PrEP within statutory health insurance.

While experts acknowledge the ambitions of the current strategy and welcome the recent developments in policy, they also note a number of limitations in the current response. In particular, BIS2030 provides limited guidance on long term holistic health of people living with HIV, for example interventions for tackling mental health. In addition, the federal structure of Germany which gives responsibility to Länder for implementation means discrepancies in services and care may exist.

To understand the ability of Germany's HIV strategy in tackling the new and emerging challenges of the epidemic, the Steering Group undertook an assessment. Going step by step across the HIV care continuum of Awareness, Prevention, Testing and Screening, HIV-specific Clinical Treatment and Long Term Holistic Health, they identified areas of strength and those with room for improvement.

Figure 2 summarises their findings, and further details on the policy position are available in chapter 5.

Figure 2: Assessment of HIV policy in Germany



Note on methodology: the assessment underlines the view of the Steering group on current policy and its effectiveness, broken down by stage of the HIV care continuum. Additional in-country experts provided input, and findings were supplemented through secondary research. Full details of the policy, as related to stage of the HIV care continuum, is available in section 5.

Awareness

- Effective national, regional and local campaigns target awareness in high risk populations
- Discrepancies across Länder can be improved, and underserved populations (e.g., prisoners) better targeted
- Stigma persists, more national-level and regional/local funding may be required to ensure continuity and scale-up of campaigns and activities

What is the policy position?

BIS2030 recognises the importance of awareness, stating the requirement for personal communication campaigns for the general population and for specific target groups, and encouraging the use of social media and culturally sensitive information [8].

Stigma is covered extensively. BIS2030 cites the need to promote acceptance of sexual orientations and lifestyles, and proposes interventions to ensure HIV care is free of discrimination [8]. It further proposes interventions aimed at removing taboo, including refining campaigns to reduce stigma, expanding training for healthcare professionals to ensure care is provided in a non-discriminatory manner and promoting community-led initiatives.

What happens in practice?

BZgA, the Federal Centre for Health Education predominantly develops campaigns aimed at the general population, whilst NGO Deutsche AIDS-Hilfe works towards addressing high risk populations.

"Subgroups are included in all our awareness and prevention work."

HIV prevention coordinator, Germany

The German government consistently funds large scale, national-level campaigns. One of the largest and most comprehensive campaigns in existence is the "Give AIDS No Chance" *(Kein AIDS für alle)*, which has been targeting specific populations for over 30 years. As of 2016, this campaign has been rebranded under the "Love life" (Liebesleben) brand, in order to include and raise awareness not only for HIV, but also other STIs [17]. It extends to social media including Twitter and Facebook, where information is provided on sexual health as a whole, including HIV.

Targeted campaigns for high risk populations also exist. These include the "I know what I do" *(Ich weiss was ich tu)* campaign aimed at the MSM population [18], and the APiS (AIDS Prevention in the Sex Industry) programme for sex workers with a migrant background.

When tackling stigma, government-backed campaigns and continuous efforts exist in Germany. A recent example was the solidarity campaign held over World AIDS Day 2017, which aimed to reduce the fear of contact and to show that people with and without HIV can live together positively.

What do the experts say?

On the whole, awareness campaigns in Germany are effective. They are well funded, targeted and use channels that are best suited to reaching the desired population, e.g., social media or community (see case study).

Where significant effort is required is in eradicating stigma. Experts stress the importance of consistency of campaigns throughout the year and across Länder. Limitations in funding and devolution of responsibility has resulted in sporadic, localised efforts. For example, large scale programmes on stigma are only common around World AIDS Day.

> "Exploiting new trends e.g., mobile phones is important to continue being impactful"
>
> **HIV HCP and policymaker, Germany**

There is also a need to address stigma among healthcare professionals (HCPs) through training and education programmes. Experts' consensus is that real or perceived stigma continues to exist, with HCPs concerned about asking a patient their HIV status or being reluctant to offer a test. People living with HIV are at times left feeling discriminated against.

Although now dated, continued stigma in society was reflected in the Positive Voices study people living with HIV Stigma Index from 2013 *(Positive Stimmen)*, where 33% of people received discriminatory reactions from their sex partners, and 18% from family [19], following disclosure of their HIV status.

> "Daily clinical care of patients shows that stigma is very present in 2018 and remains a major barrier in all kinds of services. BIS2030 is a declaration that everything should be stigma-free but there is no funding or resources for implementation of the strategy"
>
> **HIV HCP, Germany**

Sexual health education varies across regions, and at times is met with resistance from parents, educators or community groups

What is the policy position?

Health education is the responsibility of the Ministry of Education and Cultural Affairs (Kultusministerium) in each Länder, which outline for their respective Federal state the corresponding curriculum. BZgA usually works in consultation with each Länder to develop educational material and other programmes [20].

BIS2030 details the need to provide materials to schools in order to provide comprehensive sexual education. It highlights the requirement for needs orientated, gender-sensitive and age-specific education and cites education as a major component to Germany's strategy [8].

Case study: Your Health, Your Faith

What is it?

"Your Health, Your Faith" is a project aimed to improve the involvement of African faith-based communities in HIV awareness and prevention services, created by national AIDS service organisations in collaboration with African pastors and Institute of Sociology, University of Munich. The aim of the project is to empower African pastors and enable them to communicate HIV-related messages in a culturally sensitive manner within their communities.

What are the key features?

- A sermon highlighting key messages such as:
  - to get tested earlier on
  - to take medication (ART) when you are diagnosed
  - to ensure solidarity and non-discriminatory behaviour towards people living with HIV
- An interactive open discussion to address HIV-related topics

Why is it a good practice?

- Interventions are held in culturally sensitive areas such as churches, where information can be delivered in a targeted manner to a specific population
- Events are planned collaboratively (involving the African churches, African HIV activists and representatives from HIV NGO's or the local authority)

What happens in practice?

Devolved responsibility to Länder means consistency of sexual health education differs by region but it does exist. It can also be a controversial topic in Germany, a contributory factor to varying consistency. However, in addition to the school curriculum, multiple examples of interventions for the general population and youth are available:

- BzGA events, including information for parents and training for teachers.
- Government funded NGO events at community level, including the Federal Association of Family Planning and Counselling *(pro familia)* events on issues such as contraception and sexual relationships.
- Multiple events from different regional AIDS-Hilfen providing sexual health education across Germany.
- Non-governmental funded events through organisations such as Youth Against AIDS to provide education of HIV and sexual health among youth (e.g., peer education programmes – see case study).

What do the experts say?

Expert opinions state sexual health education is an area for improvement, and more consistent efforts are required. Good practice examples exist, however these are often led by self-funded efforts from NGOs. Current government-led interventions, although available, are often met with resistance (e.g., by parents, individuals and organisations with conservative viewpoints which are becoming more prevalent, and teachers who are reluctant to address sensitive topics), are not well targeted (e.g., missing key sub-populations such as young men who may not be aware of their sexual orientation), and are not implemented to scale.

> "We're informing the wrong people. For example, we should be talking to a young gay man who doesn't know he is gay yet."
>
> **HIV HCP and policymaker, Germany**

Futhermore, although it is in school curriculums, experts indicate sexual health education is not given the same importance as core subjects, and often it is unclear who is responsible for delivery in the schools.

> "Sexual health is not mentioned enough. It is not instituted or mandated. We need more detail and it should be in the curriculum of each grade."
>
> **HIV prevention coordinator**

Case study: "Do what you want; do it with love, respect and condoms"

What is it?

A peer-to-peer sex education in schools run by the youth charity, Youth Against AIDS, Germany. The aim of the programme is to provide sex education run by young people in school and youth facilities, in an effort to make discussions about safe sex more accessible and easier. The programme is funded through private and public sector (Ministry of Health).

What are the key features?

- Free speaking sessions on safe sex, disease prevention, HIV / AIDS and any other sexual topic run by young people
- Provision of a safe, peer-to-peer environment, without the presence of teachers or other adults
- Training for young adults to become 'peers' through a two-day seminar (YAA Academy)
- Regular revision to ensure age-specific and current content to ensure relevance, e.g., Zika virus, the multidrug-resistant gonorrhoea bacteria or labiaplasty surgery
- Industry collaboration (e.g., with Levi Strauss & Co.) to increase appeal to young people and secure funding

Why is it a good practice?

- Service is run by young people for young people, making the message easier to relate to and more impactful
- Collaboration with industry partners / brands (such as Levi Strauss & Co) increases engagement from young people, who are generally very image and brand conscious

Prevention

- Combined prevention, including condoms, PrEP, PEP and harm / risk reduction promoted by BIS2030
- Recent announcements regarding inclusion of PrEP in health insurance offering (expected 2019) considered a key milestone in strengthening existing strategy

What is the policy position?

BIS2030, complimented by medical guidelines, promote a combined prevention strategy: condoms, PrEP, PEP, treatment as prevention (TasP) and harm/risk reduction.

Policy recognises the importance of a high degree of condom use. BIS2030 outlines the need for promotion of non-discriminatory access to safe and affordable contraceptives, however stops short of specifying interventions for provision of free condoms and lubricants [8].

The role of PrEP in the reduction of HIV transmission is acknowledged, with areas for research identified. BIS2030 recognises there is limited data on risk of drug resistance or behaviour change associated with PrEP use, and therefore states it is yet unclear to what degree oral PrEP is recommended as a supplementary prevention tool.

However, in July 2018, the German Minister of Health announced that the cost of PrEP will be covered by statutory health insurance funds [21]. The German cabinet have approved the legislation and the provision of PrEP is undergoing legislative processes. Once implemented every citizen within the at-risk population who meets the criteria for PrEP will have the same right to access. To supplement this, *German-Austrian guidelines for HIV PrEP* exist which detail the pre-requisites for PrEP, situations in which it should be prescribed (including which high risk populations are at substantial risk) [22], and provides some indication as to how PrEP may be administered when included in health insurance funds.

PEP is acknowledged as a component for prevention but BIS2030 does not detail any specific interventions. The *German-Austrian guidelines for PEP of HIV infection* refer to the use in both occupational and non-occupational settings, and provides treatment guidelines such as timescales in which to start PEP and further procedural check-ups [23].

Harm reduction is a major element in the prevention policy for people who inject drugs (PWIDs) with programmes including NSP and OST identified as key to minimising the risk of transmission of HIV, which should be continued in low-threshold settings [8]. It also recognises the changing patterns of drug consumption, including Crystal, Speed, GHB and other party drugs, and the need to develop targeted new interventions aimed at chemsex[4], e.g., in sex/party settings or through dating portals. Aside from BIS2030, harm reduction has also been identified as one of the four pillars of the German National Strategy on Drug and Addiction Policy, highlighting the importance placed on the

4. Chemsex is the practice of consuming drugs recreationally in order to facilitate sexual activity – typically this refers to one or a combination of three drugs: methamphetamine (crystal meth), mephedrone (M-cat), and GHB/GBL (G). Consumption of these drugs reduces inhibitions and therefore increases risky behaviours, whilst also exacerbating an individual's mental health [31]

relationship between drug consumption and infectious diseases [24].

What happens in practice?

Access to the different modes of prevention is currently varied. Condoms, while often not free, can be easily accessed by those willing to pay. As contraception in general (including condoms and hormonal contraceptives) are viewed as 'lifestyle choices', they are not covered through statutory health insurance and need to be bought out of pocket. Condoms are fairly low cost and available for sale in drugstores, supermarkets, pharmacies, sex shops, and condom vending machines [25].

Free condoms are available through a number of settings, however these are considered to be limited and may vary by region. These include NGO offices (e.g., Deutsche AIDS-Hilfe), public health centres, medical centres and social settings (e.g., gay bars). There are also periodic campaigns that target high risk populations and distribute free condoms. For example, in efforts to tackle negative perceptions about sex and asylum seekers, Deutsche AIDS-Hilfe worked with German condom manufacturers to distribute 150,000 free condoms to migrant camps [26].

While there has been pressure from various political parties (e.g., the Green Party) [27] to change the stance on free condoms, there has been no change to date.

> "Even people living under social welfare have no access to free condoms regularly. It's hard to get free condoms as it's a lifestyle problem, not a disease problem."
>
> **HIV NGO, Germany**

Until legislative processes have been completed and eligible risk groups have been defined (expected mid-2019), availability of PrEP remains limited. From the end of September 2017, PrEP has been available in generic form in Germany from manufacturer Hexal in packs of 28 tablets, costing approx. EUR 40, paid entirely out of pocket. Whilst this acts as a work-around, this severely limits access to certain subpopulations who may find the cost unaffordable. An estimated 4,500 people are currently using PrEP in Germany [28].

> "You have to pay for it which means there will be people e.g., sex workers, who won't be able to afford this cost."
>
> **HIV HCP and policymaker, Germany**

PEP can be prescribed by HCPs and is covered entirely under statutory health insurance [29]. Access is generally easier in larger cities and, while available in rural areas, it has been noted that there is less familiarity among healthcare professionals. While non-occupational exposure may require a conversation with insurance, reimbursement is not considered an issue.

> "PEP is widely available, if it's an occupational accident then it's covered by the insurance. If it's a private risk then you have to discuss with the insurance, but we have treatment guidelines and recommendations from the G-BA, so normally it will be covered."
>
> **HIV HCP, Germany**

Harm and risk reduction is regulated on a regional level. The full range of harm reduction services are available, such as needle and syringe programmes, take-home naloxone programmes, and heroin-assisted treatment, however these services vary greatly by region. Germany extends further than most Western European countries in that it also provides modern initiatives e.g., supervised drug consumption rooms in 6 regions [30] and syringe vending machines (where it is recognised as having the highest number in the world at 160 machines) [31].

> "We have done a good job and have good needle exchange programmes. The infection rate amongst PWIDs has gone down substantially."
>
> **HIV HCP, Germany**

What do the experts say?

Expert consensus is that policy against prevention is largely effective, recognising efforts in awareness, harm / risk reduction and medical interventions. The proposed inclusion of PrEP in statutory health insurance is a key win and is expected to drive even greater awareness and testing among the population.

> "The inclusion of PrEP in health insurance will be an enormous step in prevention work in Germany."
>
> **HIV prevention co-ordinator, Germany**

Areas for improvement exist, particularly with regards to current level of access to condoms. While experts consider inclusion of condoms within statutory health insurance a possible step, thereby making access free, it is recognised that this would require large scale changes to current reimbursement policies around lifestyle choices and other modes of contraception. Therefore, as a shorter term step, experts agree more efforts are required to ensure sufficient distribution of free condoms, e.g., through large scale campaigns.

> "Condom provision is not available. In some of our campaigns, we provide free condoms for promotion but this is exceptional."
>
> **HIV NGO, Germany**

While harm reduction is considered to be effective in general, experts identified the need for better coverage of prison populations, citing needle exchange programmes are lacking. Furthermore, emerging trends in risky behaviour, such as chemsex, need to be better recognised and addressed. Interventions are common in the most prevalent areas but there is a need to ensure these are scaled up across the country, e.g., NGOs in Berlin are increasingly present in the party / night life scene, providing information, awareness, and in some cases, distributing self-testing kits. Finally, there is concern over the lapse in knowledge among HCPs (e.g., GPs) in having informed conversations with individuals on risky sexual behaviours.

> "The general knowledge among GP's [on chemsex] is close to zero – there is no real strategy or guidelines on how to deal with it."
>
> **HIV policymaker and HCP, Germany**

Testing and screening

- Free testing is available in multiple settings, however is often non-anonymous
- Anonymous testing is primarily limited to public health centres and NGOs, which may prevent certain high risk populations from regular access
- Efforts by state and NGOs, together with recent introduction of self-tests may enable greater access

What is the policy position?

Policy outlines testing comprehensively. Various settings and service providers available for testing are noted, including anonymous testing in the form of public health services, low-threshold advisory and testing provided by NGOs, and free testing in clinics by registered physicians. It highlights the need for specific and effective services targeting high risk populations, and proposes interventions such as evaluating new testing procedures, updating guidelines and providing training for HCPs [8]. Guidelines exist which complement policy, e.g., specifying indications to HCPs to initiate testing.

In accordance with the Act on Medical Devices, HIV self-tests are legal and permitted in Germany [32]. Recently, pharmacies and drug stores have been permitted to sell CE marked self-tests [33]. Self-sampling is also available in some regions, in the form of pilot projects.

> "It would be better to have more anonymous ways of testing with low barriers."
>
> **HIV HCP and policymaker, Germany**

What happens in practice?

Testing is available through multiple settings, however, those that are both free and anonymous remain limited. BIS2030 itself acknowledges this, particularly the challenge it poses for marginalised groups [8], a point corroborated by experts.

> "It is a good idea to give people self-testing kits, instead of them coming in to get tested every few months."
>
> **HIV prevention co-ordinator**

Testing that is free but non-anonymous is available throughout the country. These can be accessed through primary (GPs, medical centres) and specialty care (hospitals including Emergency Rooms). Testing in these settings requires opt-in (informed consent) and is fully reimbursed under statutory health insurance when an infection is suspected. If a patient requires to be anonymous, an out of pocket fee for the test can be paid.

Testing that is free and also anonymous is also available, however regional discrepancies exist. State-run Public Health Authorities and NGO-run community programmes provide these, and

are generally considered to be a more accessible option for high risk populations (e.g., migrants). The frequency of state-run Public Health Authorities vary across the Länder, and some may have limited opening hours creating barriers to those at work during the day. Community-run programmes, such as CB-VCT clinics for MSM or checkpoints (e.g., Cologne, Berlin, Munich and Hamburg) also exist.

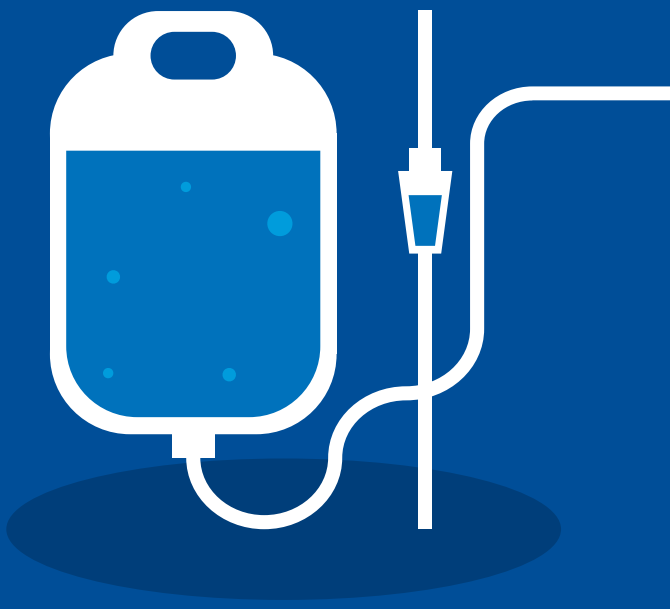
Since September 2018, self-tests have become widely available in pharmacies and drug stores, costing approx. EUR 26, which experts have cited as a barrier for repeated use.

> "Self-testing will ensure there are less barriers to testing in the future."
>
> **HIV NGO, Germany**

To enable awareness and correct use, the Ministry of Health and the Paul Ehrlich Institute (PEI) have launched an extensive information campaign, including assistance on the various tests available, how they work, instructions on when to use it, and advice on dealing with a positive or negative result [34].

While self-sampling is not yet widely available in Germany, several pilots are underway to gauge interest among the public, e.g.:

- In Bavaria, there is a trial for a year where participants can register online, have an initial consultation at a checkpoint and can proceed to decide how often they would like to receive the kit, at a price of EUR 32 per test process [35]. Information on linkage is provided via SMS
- In North-Rhine Westphalia, a teSTIt kit has been released for HIV and other STI's including syphilis and chlamydia [36].



What do the experts say?

Room for improvement exists in current policy and its implementation, which are impeding the effectiveness of HIV testing in Germany. This is reflected in the large undiagnosed population, currently standing at 13% of people living with HIV, and also the rate of late diagnosis [1].

More opportunities for free and anonymous testing are needed. Currently Public Health Authorities offer this, however challenges exist in convenience (due to location in larger cities) and perception as populations from marginalised communities may be reluctant to visit state-run services. Evidencing this, there is generally a low number of positive tests in these settings.

> "It is an official setting, and has high barriers for people to go, with very few positive test results."

HIV HCP, Germany

Testing services that are accessible to all populations are another requirement. Experts note that while targeted community-run services for certain subpopulations exist (e.g., CB-VCT for MSM), these may have the effect of deferring other populations thereby missing opportunities. Therefore, more efforts towards establishing inclusive environments may be required.

> "As soon as the centre hired one black African woman, we had loads of women coming in to get tested."

HIV policymaker and clinician, Germany

Experts also cited the need to train and educate HCPs, particularly those in primary care on current guidelines on HIV-testing and in tackling fear of real or perceived stigma. It was mentioned that HIV-tests are rarely offered, even to patients who present with STIs or other indicator diseases (see indicator disease list by EACS guidelines) thereby missing opportunities to test patients for HIV with significantly increased HIV infection risk.

> "The GP is a challenging area, they don't classify the symptoms correctly and don't do an HIV test, so quite frequently, patients come to treatment too late. GP's need more awareness on patient symptoms."

Patient group representative, Germany

Finally, removal of opt-in may encourage more routine testing (e.g., in emergency rooms, routine testing in hospitals or primary care) thereby providing more opportunities.

> "The biggest barrier on testing is the consent form and opting-in."

HIV HCP, Germany

HIV specific clinical treatment

- Immediate initiation on ART is recommended and considered to be well implemented
- Fast access to new medication is available, with each physician free to determine optimised therapy for each people living with HIV

What is the policy position?

Policy and guidelines mandating clinical treatment are effective; recommending initiation on ART (irrespective of CD4 count), early treatment initiation, and continuous monitoring.

The *German-Austrian guidelines on anti-retroviral therapy of HIV infection* are prescriptive, and are regularly adapted to reflect the most advanced clinical practice. Accordingly, the guidelines recommend treatment to be commenced as soon as possible after diagnosis and following a risk assessment, including CD40 count [8], [37]. They also provide details on different treatments depending on CD40 count, cover alternatives to traditional ART that have been shown to reduce side effects or are required when other lines of treatment fail [37].

> "Other countries could learn from Germany that everyone is covered under innovative medicines and new treatment methods are usually reimbursed very quickly."
>
> **HIV HCP, Germany**

Germany is unusual among the Europe5 in that it allows new medicines to be prescribed immediately following European Medicine Agency (EMA) marketing authorisation, prior to pricing and reimbursement decisions have taking place. Under the Arzneimittelmarkt-Neuordnungsgesetz (AMNOG), the German law related to marketing of pharmaceutical products (adopted in 2010), the prices set by manufacturers for newly approved prescription medicines are evaluated by the Federal Joint Committee (Gemeinsamer Bundesausschuss/G-BA) together with research from the Institute for Quality and Efficiency in Health Care (IQWIG) as needed, to assess the added value compared to appropriate and established therapies. This process results in the decision on pricing and reimbursement.

Should a medicine not be available through statutory health insurance, physicians can still prescribe EMA approved medicines to be paid for out of pocket or through private health insurance.

The need to jointly address HIV with co-infections is recognised. BIS2030 emphasises the importance of integrated treatment and further extends to note needs for specific sub-populations need to be taken into account [8]. The *German-Austrian guidelines for post-exposure prophylaxis of HIV infection* detail the need for Hepatitis B and C and other STI tests in addition to a HIV test, after sexual exposure [23].

Guidelines also cover monitoring including adherence therapy, and detail interventions based on success or failure of therapy, including simplification of therapy.

What happens in practice?

Patients who enter care are very well managed. Physicians typically have no restrictions in medications they can prescribe, and have the freedom to develop optimised, personalised treatment plans taking into account patient condition, psychological state and behavioural aspects.

"Within 2-3 weeks, everyone gets started on therapy, and that's uniform across Germany."

HIV HCP, Germany

The ability of German physicians to prescribe medication immediately following EMA approval has enabled fast access for patients, believed to contribute to the high clinical outcomes seen today (in HIV and other therapeutic areas).

"If you have a new drug licensed by the European agency, all the other countries first have cost negotiations before the drug becomes available, whereas in Germany, once it's approved, it gets licensed and can be prescribed, and then cost negotiations start."

HIV HCP, Germany

With regards to co-infection testing, physicians typically test for Hepatitis A, B and C, syphilis and other STI screening when testing for HIV. Testing is also available through public health centres for free.

Viral load monitoring is consistent, supported by guidelines from Deutsche AIDS-Gesellschaft e.V. Patients are generally screened every 3-6 months.

"In Germany, there is very close viral load monitoring."

HIV HCP, Germany

What do the experts say?

Experts agree clinical management of HIV is of a very high standard. Those who are linked to care are initiated on ART irrespective of CD4 count. While national level data on time to initiation of treatment is not available, good practice examples indicate treatment starts within 2-3 weeks of diagnosis - however, this may not be consistent everywhere. The effectiveness of the current policy and practice is evidenced by research from the Robert Koch Institute, which shows that from those who have been diagnosed with HIV infection the proportion of individuals receiving antiretroviral therapy has increased from 74% in 2006 to 87% in 2017 [1]. Furthermore, Germany has achieved the 2nd and 3rd of the UNAIDS 90-90-90 targets, further reinforcing its success in initiating people with HIV in ART and virological supression [1].

Experts noted that undocumented migrants, i.e., those who have not applied or have had their asylum or refugee applications denied, cannot at present access healthcare, which includes HIV treatment. Although this is a small number of the total of people living with HIV, ensuring this population is able to access ART is important in improving individual health as well as minimising onward transmission of infection [8].

"Insurance is a big problem, especially for uninsured migrants that we can't bring into treatment."

Prevention coordinator, Germany

Some interventions to tackle this challenge exist. For example, as part of Fast-Track Cities initiative, Berlin has secured EUR 1.5 million to offer medical care to those without health insurance, including undocumented migrants[39]. However, this is restricted to Berlin and is in the budget for the forthcoming year so has not yet been secured (and the real needs will be much higher).

A minor concern noted by experts is the pressure on individual physicians to be accountable for drug spending. This may place an administrative burden on the physician due to the need to demonstrate clinical need when prescribing a more expensive medication if there is a cheaper, but equally efficacious treatment available.

While reforms including AMNOG has resulted in price controls, experts note that the current cost effective analyses do not take into consideration surrogate parameters. This is an important consideration for HIV, particularly for accurately capturing benefits of long term care and the promotion of healthy aging.

Finally, experts also note there is a push from health insurers to prescribe generics version of drugs where available. While not a major concern at present, it may present a challenge in the future when more generics medicines are available thereby making access to newer / innovative and more expensive drugs more restricted.

"We are personally liable for our prescriptions. So if there is a price difference between equally efficacious treatments, we can be denied reimbursement. It's a very frightening prospect, especially for high cost medicine"

HIV HCP and policymaker, Germany

Long-term holistic care

- Limited or no HIV-specific policy and German-specific guidelines on ageing, co-morbidity management and mental health for people living with HIV
- Strong collaboration with NGO's ensures effective widespread non-clinical supportive services e.g., counselling and peer-support

What is the policy position?

BIS2030 is limited in its coverage of elements of long-term care. Ageing and co-morbidity care are not covered, and while the *German-Austrian guidelines on anti-retroviral therapy of HIV infection* detail the need for the choice of drug combinations to be based on aspects such as co-morbidities, it provides no further detail on the management of comorbidities itself [37]. Germany typically refers to European EACS guidelines for ageing and comorbidity care [40].

"Co-morbidities are a significant future challenge, e.g., oncology. In general the system is aware of this and trying to put new guidelines in place."

HIV HCP, Germany

Mental health is highlighted as an issue, however no interventions are detailed in regards to providing or improving access to mental health services for people living with HIV [8]. Various guidelines are available, including the German guidelines produced by *Deutsche Gesellschaft für Neuro-Aids und Neuro-Infektiologie e.V.(DGNANI)* in addition to EACS guidelines.

Similarly, BIS2030 indicates the need for integrated advisory and care services, but does not explicitly state what care services should be included [8]. Multiple state-funded programmes (often delivered by NGOs) exist, including those targeting specific sub-populations.

"We give money to NGO's for counselling work for different subpopulations."

HIV prevention co-ordinator

What happens in practice?

Experts note that the EACS guidelines, which are prescriptive and cover multiple indications, are heavily relied on for co-morbidity management and care. Referral routes are generally well established.

"EACS guidelines are well used in Germany and we are very familiar with ageing and comorbidity management."

HIV HCP, Germany

Mental health services are available, however challenges in access exist. While HIV specialists are able to refer patients to counselling or other psychosocial support as required, there are capacity constraints with referred patients often waiting up to 6 months to get an appointment. There is also at times a lapse of knowledge among mental health professionals in managing people living with HIV.

With regards to non-clinical support, despite limited reference in BIS2030, expert consensus is that supportive services for HIV is an area that is well provisioned, particularly due to the action of state and privately-funded NGOs. State funded NGO's such as Deutsche AIDS-Hilfe provide extensive supportive services including free, anonymous telephone, online and personal counselling and information about testing or treatment. The NGO is also able to refer patients to self-help, HIV specialist doctors and peer support groups.

"In Berlin alone, we have 13 different projects at NGO level, working in fields from counselling to caring for people at home."

HIV HCP, Germany

There are services dedicated to sub-populations, e.g., Live Chat for Gay Men. Often NGOs also visit hospitals, providing non-medical support services to in-patients.

"We give money to NGO's for counselling work for different subpopulations."

HIV prevention co-ordinator, Germany

What do the experts say?

Expert consensus is that while certain elements, such as non-clinical supportive services, are very effective, there is room for improvement in policy and in the other areas of long-term holistic care.

There is a lack of focus on these issues in policy and strategy which results in coverage for addressing long-term care and ageing being limited, with prescriptive policy, guidelines and funding for implementation all requiring improvement.

In improving management of co-morbidities, experts note the need for shortening wait times post-referral to other specialists (although not unusual to HIV) and the lack of reimbursement for certain preventative tests, e.g., bone mineral density (when there is no clinical need, i.e., osteoporosis, there can be difficulties in obtaining approval for a test). Expert opinion further states that there is sometimes a lack of interest or knowledge in best practice in managing co-morbidities, with HIV specialists often preferring to manage the infection only, and GPs / primary care providers lacking knowledge and training to effectively manage multi-morbid HIV patients.

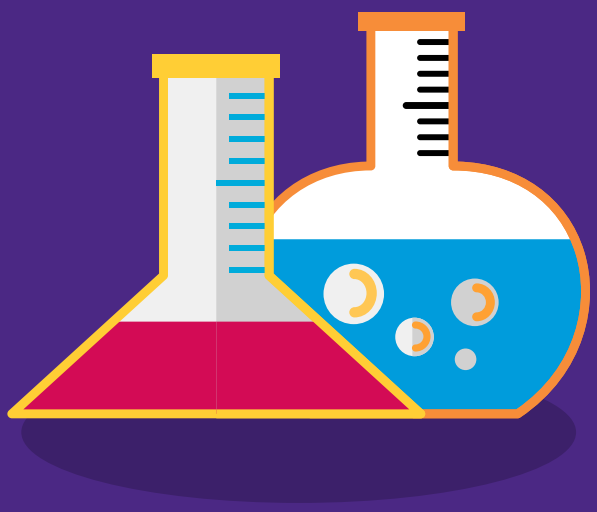
"Some doctors don't go to conferences or training. We need to raise the interest of co-morbidities among GPs and other specialists."

HIV NGO, Germany

With regards to mental health, expert consensus is that there is room for improvement, citing long waiting times and lapse in knowledge of best practice care of people living with HIV among mental health professionals. This is corroborated by a 2017 survey undertaken by Deutsche AIDS-Hilfe, where only 16% of over 170 people living with HIV participants indicated their psychotherapist had good knowledge of HIV, and almost a quarter of participants stopped therapy early [41].

"Although possible, if you want to see a psychologist for depression, or a neurologist, it can take months to get an appointment."

HIV HCP and policymaker, Germany



04 Recommendations

4.1 Tackle HIV related stigma through national level interventions

What is the issue?

Although addressed by the national strategy, actions to tackle stigma lack consistency through regions and throughout the year. There is a further gap in addressing stigma among HCPs, where expert consensus is that real or perceived stigma continues to exist resulting in HCPs being concerned about asking patients their HIV status or being reluctant to offer a test.

What is the recommendation?

Run an increased number of national level campaigns targeting stigma against people living with HIV. Current campaigns are sporadic, with events around World AIDS Day and one or two others (e.g., spring and late summer). New campaigns should be distributed throughout the year in order to provide more continuous exposure to the messaging and a greater impact.

In order to address stigma among HCPs, HIV awareness and stigma training should be integrated into health care professionals' and social workers training curriculums. Training could be incorporated with training on other aspects relevant to equal treatment such as gender and sexuality in order to widen the impact.

4.2 Increase community-based testing centres

What is the issue?

Testing is offered through HCPs, Public Health Authorities, and NGOs. The latter was initiated to particularly target high risk populations (MSM and PWID) who may not engage with state-run services. This has since seen good uptake. However, certain hard to reach populations remain, such as migrants from areas where HIV is endemic, and are not effectively targeted by existing services.

What is the recommendation?

Increase the number and type of testing facilities in community settings. These should include, among others, targeted services for hard to reach populations such as migrants. To enable this, walk-in services with convenient hours, free (and anonymous) access, supportive services such as counseling and an inclusive, stigma-free environment would be required. Supporting awareness campaigns that effectively target key populations and encourage uptake of testing would need to be developed.

Good practice examples, such as Dean Street Clinic in London can be adapted for the larger cities (Berlin, Cologne, Hamburg and Munich) - enabling both wider uptake of testing as well as efficient linkage to care.

4.3 Improve harm reduction services in prisons

What is the issue?

BIS2030 recognises the need for prevention and care of HIV (and other co-infections) in prisons and the National Drug Plan outlines harm reduction steps. There is acknowledgment there is room for improvement with regards to HIV prevention, diagnosis and treatment in prisons, as prevention measures haven't been equally implemented. Besides suggesting collection of data to inform and adjust prevention measures in prisons, there is no specific policy to support PWIDs in prisons is available, and the devolution of responsibility for administering the penal system to the Länder means regional discrepancies in services exist. While various programmes, such as condom distribution, psychosocial counselling, OST are found, availability varies. Further, needle exchange programmes are rare, with possibly just one syringe distribution project in existence at present (women's prison in Berlin).

What is the recommendation?

Policy and implementation guidelines on harm reduction strategies for prisons need to be developed. To inform policy, a small pilot could be initiated in a large city (e.g., Berlin or Hamburg) to trial a series of comprehensive harm reduction services and capture data on effectiveness. Lessons can also be learnt from programmes available in other countries, such as Australia and Switzerland. A small-scale trial in a larger city prison could enable good practice to be established and lessons learnt for scale up. A first step could be a round table discussion on good practice (e.g., from other countries) and design of a pilot.

This effort will contribute towards minimising transmission of communicable infectious diseases in prisons.

4.4 Enable provision of ART for undocumented migrants

What is the issue?

Undocumented migrants, i.e., those who have not applied or have had their application for refugee / asylum status denied and do not possess health insurance currently cannot access ARV therapy for HIV / AIDS. Whilst migrants who have legal status are able to access the healthcare system, those who don't are hindered. Further, fear of deportation and reluctance to engage with state-run services means undocumented migrants often do not engage with social welfare offices or local Public Health Authorities (which provide anonymous, free HIV testing and counselling). While undocumented migrants from Eastern European may be covered for 'emergency care' from their home national insurance, however, ART does not constitute as an emergency and therefore, is not covered.

What is the recommendation?

A policy change is needed to enable ART for undocumented migrants. Lessons can be taken from current management of chronic conditions such as tuberculosis (TB), where undocumented migrants can access long-term treatment though local Public Health Authorities and outpatient clinics.

Treating HIV among the undocumented migrant population is critical for minimising onward transmission of the virus as well as engaging people in care. This is a key step in ensuring Germany reaches the ambitious 90-90-90 treatment targets and ends the epidemic by 2030.

4.5 Ensure greater focus on chronic care for people living with HIV

What is the issue?

People living with HIV have chronic care needs that are currently not always met by the German healthcare system due to policy not existing in areas such as comorbidity management, mental health services and care for people ageing with HIV.

Comorbidity management often sees patients subject to lengthy waiting times for appointments with specialists, and reimbursement is not available for some important preventative tests (such as bone mineral density) when there is no clinical need (i.e. exiting osteoporosis). Further to this, HCPs may sometimes lack interest in or knowledge of HIV, reducing the quality of care that people living with HIV receive.

Similarly, whilst people living with HIV suffer from mental health issues disproportionately to the general population and require more extensive support, appointment wait times are long and there continues to be a shortage of mental health professionals (especially in more rural areas). Again, professionals may be limited in their knowledge of HIV.

These shortcomings mean that management of HIV as a chronic condition in Germany could be improved.

What is the recommendation?

Develop policy on chronic care for people living with HIV in order to address these challenges, first by studying the gaps in services that are required to effectively address the long-term requirements of people living with HIV. There is a need to increase ease of access to specialists and capability of specialists in managing patients with HIV, and a more complete view of the current challenges would enable evidence-based discussions on required policy changes.

Successful integration of chronic care services in HIV treatment and care is imperative to ensuring long-term health and wellbeing as well as the provision of person-centred care.

05 Policy Assessment

Is there a national plan for HIV? Yes

In April 2016, Germany adopted a national level plan on HIV, as part of a cohesive infectious disease strategy, titled "BIS 2030 – Integrated strategy for HIV, Hepatitis B and C and other sexually transmitted infections". BIS2030 is a needs-based, integrated and cross-sectoral joint strategy presented by the Federal Ministry of Health and the Federal Ministry for Economic Cooperation and Development [8].

BIS2030 follows the previous "National Strategy of the Federal Government to Fight HIV/AIDS", launched in 2005 and the accompanying "Action Plan to implement the Strategy of the Federal Government to fight HIV / AIDS", launched in 2007 [42].

As sexually transmitted infections were included in the previous strategy, BIS2030 acts an update and extension to include infectious diseases such as Hepatitis B and C for the first time as they share comparable transmission routes with HIV and have higher incidence in similar risk groups [8].

BIS2030 strives to achieve the goal set by the international community in the 2030 Agenda for Sustainable Development, to end the AIDS epidemic, and specifically outlines objectives including:

01 Creating an enabling environment which promotes acceptance of sexual orientations and different lifestyles

02 Further expanding needs-orientated services for populations at risk, considering variances in regional prevalence

03 Developing integrated services which address different infections and coordinate prevention, testing and care services to prevent transmission and co-infection

04 Promote networking and cross-sectoral cooperation to reach people in their respective circumstances to facilitate coordinated integration in prevention, testing and care services

05 Generating and expanding strategic information and data as the basis for planning and implementation

Does the national plan (or affiliate guidelines) promote?

Awareness

Awareness for key populations?

BIS2030 recognises the importance of awareness; stating the requirement for personal communication campaigns for the general population and for specific target groups.

It acknowledges campaigns need to be adjusted according to the target populations, and details requirements for specific subgroups, e.g., use of social media, culturally sensitive awareness information for migrants [8].

BZgA, the Federal Centre for Health Education, predominantly develops campaigns aimed at the general population, whilst NGO Deutsche AIDS-Hilfe works towards addressing high risk populations.

"Subgroups are included in all our awareness and prevention work" – HIV prevention coordinator, Germany

Campaigns for eradicating stigma?

BIS2030 extensively covers stigma and discrimination, citing the need to promote acceptance of sexual orientations and lifestyles, and proposes interventions to ensure HIV care is free of discrimination [8].

BIS2030 proposes interventions aimed at removing taboo from STI's including:

- Refining campaigns to reduce stigma and discrimination,
- Expanding basic and further training available to healthcare professionals to ensure care is provided in a non-discriminatory manner, and enable sexuality and STI conversations in doctor-patient relationships,
- Developing interventions aimed at reducing stigma in institutions such as prisons, police forces and employment agencies,
- Continuing activities of civil society organisations and community-led initiatives, including informing patients.

Sexual health education for general populations (e.g., schools)?

Sexual health education in schools is mandated across Germany, and comes under the BzGA and authorities of each federal state [20]. The content of each curriculum may differ by state, depending on the Ministry of Education and Cultural Affairs (Kultusministerium).

BIS2030 also details the need to provide materials to schools in order to provide comprehensive sexual education. It highlights the requirement for needs orientated, gender-sensitive and age-specific education and cites education as a major component to Germany's strategy [8].

Key

Policy available and effective | Room for improvement | Policy not available

Prevention

Provision of free condoms / lubricants for high risk populations?

BIS2030 outlines the need for a high degree of condom acceptance and use, the need for promotion of non-discriminatory access to safe and affordable contraceptives, and the provision of condoms for prisoners. However, it does not specify mandatory interventions ensuring free condom and lubricant provision [8].

Access to oral PrEP for high risk populations?

BIS2030 recognises that PrEP can reduce the risk of HIV transmission, although it recognises there is limited data at present on risks of drug resistance or behaviour change as a result. It therefore states it is yet unclear to what degree oral PrEP is recommended as a supplementary prevention tool in future in Germany.

While there is no current policy, in July 2018, the German Minister of Health announced that the cost of PrEP will be covered by statutory health insurance funds [21]. Whilst the German cabinet have approved the legislation and the provision of PrEP is undergoing legislative processes, once implemented every citizen who meets the criteria for PrEP will have the same right to access. Expert opinions states this should be in place in by late 2019.

German-Austrian guidelines for HIV pre-exposure prophylaxis exist, detailing pre-requisites on PrEP, situations in which it should be prescribed including which high risk populations are at substantial risk. The guidelines also detail the dosage requirements and advice for all-round care [22], which provides some indication as to how PrEP may be administered when included in German policy.

Access to post-exposure prophylaxis (PEP)?

BIS2030 recognises PEP as a component for prevention but does not detail any interventions aimed at furthering the access to PEP.

The *German-Austrian guidelines for post-exposure prophylaxis of HIV infection* refer to the use of PEP in both occupational and non-occupational settings, detailing various different scenarios in which PEP should be taken in both settings. This extends to providing treatment guidelines, such as timescales in which to start PEP and further procedural check-ups [23].

Key

Policy available and effective | Room for improvement | Policy not available

Harm and risk reduction (e.g., needle and syringe programmes (NSP), opioid substitution therapy (OST), chemsex)

BIS2030 recognises harm reduction as a major element of its prevention policy for PWIDS, with programmes including NSP and OST identified as key to minimising risk of transmission of HIV [8]. It further states OST as well as other low-threshold prevention services should be expanded across Germany.

The strategy further recognises the changing patterns of drug consumption, including Crystal, Speed, GHB and other party drugs, and the need to develop targeted new interventions, e.g., in sex/party settings or through dating portals.

Aside from BIS2030, harm reduction has also been identified as one of the four pillars of the German National Strategy on Drug and Addiction Policy [24].

Testing and screening

Availability of free, anonymous testing in community and specialty settings?

BIS2030 outlines various service providers and settings available for testing: anonymous testing in the form of public health services; low-threshold advisory and testing provided by NGO; testing in clinics by registered physicians.

It also highlights the requirement for specific testing and diagnosis services for high risk populations and proposes interventions to evaluate new testing procedures, update existing testing guidelines and provide further training for the medical profession [8].

BIS2030 also refers to guidelines which specify indications for providers to initiate testing.

Availability of self-testing or self-sampling?

In accordance with the Act on Medical Devices, HIV self-tests are legal and permitted in Germany [32], and pharmacies can sell CE marked self-tests [33].

Self-sampling is currently not covered in German policy.

Key

Policy available and effective | Room for improvement | Policy not available

Clinical management

Immediate initiation on ART?

BIS2030 refers to guidelines on HIV and other STIs as being established, regularly adapted and updated by Medical Societies.

Accordingly, the *German-Austrian guidelines on anti-retroviral therapy of HIV infection* are prescriptive and recommend treatment to be commenced early, as soon as possible after diagnosis and following a risk assessment, including CD4 count [8], [37]. They also provide details on different treatments depending on CD4 count and follow-up and management of therapy in the event of success and failure [37].

Access to innovative medicine?

The *German-Austrian guidelines on anti-retroviral therapy of HIV infection* guidelines cover alternatives to traditional ART that have been shown to reduce side effects or are required when other lines of treatment fail [37].

Guidelines state alternate regimes should include at least 2 new substances that are considered to be resistant, and should take into account previous resistance and ART regimes. Decisions about second and subsequent combinations require specialised knowledge and so, selection of alternative retroviral treatment requires specific medical expertise and an exact knowledge of the individual case from an economic point of view.

Under The Act on the Reform of the Market for Medical Products (Arzneimittelmarkt-Neuordnungsgesetz – AMNOG), introduced in 2011, IQWiG, Germany's Health Technology Assessment agency, can be invited to undertake an Early Benefit Assessment of new medication approved by the EMA, and to provide a recommendations for inclusion in the federal health service. This recommendation is taken into account by G-BA (The Federal Joint Committee), who ultimately decide on the level of added benefit provided and reimbursement.

Access to regular monitoring (e.g., viral load, adherence, co-infections)?

BIS2030 highlights the need for integrated prevention, testing and treatment services which also address co-infections, and are tailored to needs of specific groups [8]. The *German-Austrian guidelines for post-exposure prophylaxis of HIV infection* detail the need for Hepatitis B and C and other STI tests in addition to a HIV test, after sexual exposure [23].

Viral load monitoring is also covered by guidelines, detailing CD40 counts and HIV RNA levels should be determined subsequently in 2 to 3 monthly intervals, and every 2-4 months once HIV RNA levels have decreased.

Guidelines also cover adherence to therapy, and details interventions based on success or failure of therapy, including simplification of therapy.

Key

Policy available and effective | Room for improvement | Policy not available

Long-term holistic care

Access to ageing and co-morbidity management?

BIS2030 does not cover the issue of ageing and co-morbidity management. The German-Austrian guidelines on anti-retroviral therapy of HIV infection detail the need for the choice of drug combinations to be based on aspects such as co-morbidities, but provides no further detail on the management of co-morbidity itself [37].

Germany typically refers to European EACS guidelines for ageing and comorbidity care [40].

Access to mental health services?

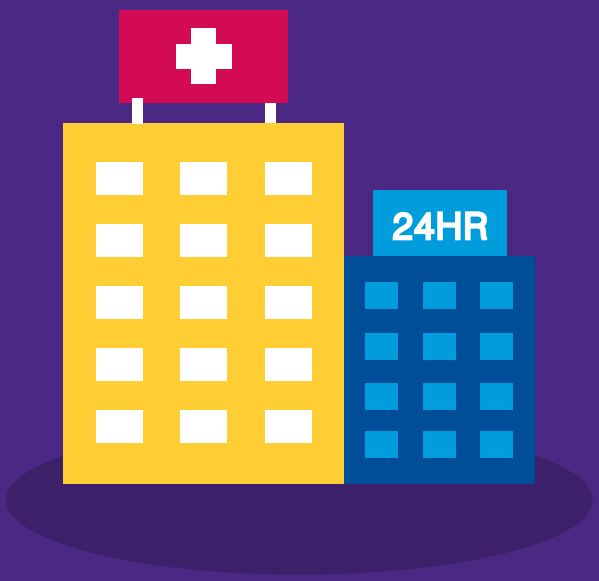
In BIS2030, mental health has been highlighted as an issue to consider in relation to stigma and discrimination. However, no interventions are detailed regarding providing or improving access to mental health services for people living with HIV [8].

Various guidelines are available, including the German guidelines produced by Deutsche Gesellschaft für Neuro-Aids und Neuro-Infektiologie e.V.(DGNANI) in addition to EACS guidelines.

Access to clinical supportive services (e.g., peer support, counselling)?

BIS2030 indicates the need for integrated advisory and care services, but does not explicitly state what care services should be included [8].

Multiple state-funded programmes (often delivered by NGOs) exist, including those targeting specific sub-populations.



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