

ECDC SPECIAL REPORT

**Midterm review of the implementation
and impact of Germany's BIS 2030
strategy for the prevention and control of
HIV, hepatitis B and C, and other STIs**

May 2024



Acknowledgments

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Abbreviations

BIS 2030	Integrated Strategy for HIV, Hepatitis B and C and other Sexually Transmitted Infections
BZgA	German Federal Centre for Health Education
CT	<i>Chlamydia trachomatis</i>
DAA	direct-acting antiviral
DAH	Deutsche Aidshilfe
ECDC	European Centre for Disease Prevention and Control
EMIS	European MSM Internet Survey
GP	general practitioner
HBV	hepatitis B virus
HCV	hepatitis C virus
HID	health insurance data
HIV	human immunodeficiency virus
HPV	human papilloma virus
MoH	Ministry of Health
MSM	men who have sex with men
NG	<i>Neisseria gonorrhoeae</i>
NGO	non-government organisation
NSP	needle and syringe exchange programme
OST	opioid substitution therapy
ÖGD	local public health departments
PEP	post-exposure prophylaxis
PLHIV	people living with HIV
PrEP	pre-exposure prophylaxis
PWID	people who inject drugs
PWUD	people who use drugs
RKI	Robert Koch Institute
SDGs	Sustainable Development Goals
SHI	statutory health insurance
STI	sexually transmitted infection
SW	sex worker
TV	<i>Trichomonas vaginalis</i>

Executive summary

In 2016, the German Federal Ministry of Health and Federal Ministry for Economic Cooperation and Development published a national Integrated Strategy for HIV, Hepatitis B and C and other Sexually Transmitted Infections (BIS (Bedarfsorientiert, Integriert und sektor-übergreifend) 2030). The strategy was developed in the context of the United Nations Sustainable Development Goals (SDGs) and sets an innovative, demand-oriented, integrated, and cross-sectoral approach for Germany to pursue the SDG target 3.3 to end the epidemics of AIDS and tuberculosis and combat hepatitis and other communicable diseases by 2030. It is implemented under the guidance of a Coordination Committee consisting of a broad range of national stakeholders.

In 2023, the national BIS 2030 strategy reached midterm status. At the request of the Coordination Committee and the German Federal Ministry of Health, ECDC has undertaken a programmatic review of the midterm implementation of the strategy. The main aim of the review was to assess the implementation and impact of the strategy and to propose recommended priority actions to further support its ongoing implementation.

The assessment consisted of three parts – an online stakeholder survey, a rapid desk review and an in-country assessment mission conducted between 22 and 26 January 2024 – and was structured according to the five key areas of action of the strategy: 1) creating an enabling environment; 2) expanding needs-oriented services; 3) developing integrated services; 4) promoting networking and cross-sectoral cooperation; and 5) generating and expanding strategic information and data.

The stakeholder survey was disseminated to a wide range of stakeholders involved in the strategy implementation (Annex 1) and assessed perceived progress towards achieving the objectives of the BIS strategy, areas needing improvement and proposed actions for Germany to reach the goals of the strategy. The desk review covered publicly available resources as well as documents requested and received via the Robert Koch Institute (RKI) and was supplemented by a situation analysis providing an overview of the epidemiology and response to the HIV, hepatitis B & C and STI epidemics in Germany (section 4). The in-country mission team spent five days in Germany and met with a broad range of stakeholders at Federal, Länder and local levels during the week of the country visit (Annexes 2).

Overall, Germany is on track to reach the HIV goals regarding the proportion of people treated and successfully achieving viral suppression, but a gap persists for the proportion of people who are aware of their HIV infection, suggesting that current HIV prevention and HIV testing strategies need to be improved. Regarding STIs, Germany is on track concerning congenital syphilis and the 2025 target for HPV vaccination among girls – but not for the 2030 target nor for other STI targets. Major efforts are needed to establish the required set of indicators and data systems needed to monitor the status and progress toward the STI-related targets. For viral hepatitis B and C, Germany has concentrated epidemics in key populations. Insufficient data are available to fully assess the burden and progress toward the prevention, testing and treatment targets. Incidence and mortality data to measure impact are not available at all. From the available data, progress toward the prevention targets seem to be partly on track, while testing and treatment targets are lagging behind.

The strategy remains an excellent and comprehensive policy paper with a strong focus on integration of services and population specific needs and contexts. However, several areas are not sufficiently covered in the strategy from 2016, for example insufficient mention of transgender and gender-diverse people, no recommendation of PrEP, no mention of tuberculosis and the need for integration of TB services, new challenges related to migrants from Ukraine, and new epidemics such as mpox and no monitoring and evaluation framework with core indicators.

To address the identified gaps and challenges of the strategy and its implementation, several priority actions for the five areas of action were suggested (section 5). The six key overarching priority actions are listed below (see also section 6):

1. Ensure Universal Health Coverage for all in need, including those without adequate health insurance.
2. Improve the quality of life of people living with HIV and viral hepatitis, addressing stigma and discrimination in the community and in healthcare settings.
3. Expand and refine needs-oriented, culturally sensitive, participatory, affordable and integrated prevention, testing and treatment services for key and underserved populations, including people in prison settings.
4. Provide political leadership, coordination, steering and inclusiveness to pursue further engagement and diversity in priority setting and reduce inequity in service delivery and access across Länder.
5. Monitor implementation of the strategy by defining and monitoring a set of core indicators per disease area on an annual basis and addressing key data gaps.
6. Identify threats to the successful implementation of the strategy and propose mitigating solutions, including advocacy work to ensure that addressing these disease areas remain high on the political agenda.

The mission did not find that an amendment or update of the strategy itself was needed but rather recommends that efforts focused on translating the strategy and its elements into action.

1 Background

Based on the request of the German Federal Ministry of Health, ECDC was invited to undertake a programmatic review of the implementation of the national Integrated Strategy for HIV, Hepatitis B and C and other Sexually Transmitted Infections (STIs) (BIS 2030) (2).

The BIS 2030 strategy was developed in 2016 by the German Federal Ministry of Health and Federal Ministry for Economic Cooperation and Development aligned to the United Nations Sustainable Development Goals (SDGs). The BIS 2030 strategy is implemented under the guidance of a Coordination Committee consisting of stakeholders from the Federal Government, the Federal States, local self-government, public health offices, self-help groups and civil society organisations, community led-initiatives, science and research, professional and medical associations (3). To achieve the SDG Target 3.3 'By 2030, end the epidemics of AIDS, [...] combat hepatitis, [...] and other communicable diseases' the national BIS 2030 strategy pursues a demand-oriented, integrated, and cross-sectoral approach focusing on five areas of action:

- Creating an enabling environment;
- Further expanding demand-oriented services;
- Refining integrated prevention, testing and care services;
- Promoting cross-sectoral networking and cooperation; and
- Further expanding the knowledge base and data utilisation.

In 2023, the national BIS 2030 strategy reached midterm status. In this context, the coordination committee recommended that an independent programme review of the implementation of the strategy be undertaken. To this end, an assessment of the implementation status was conducted by ECDC through a stakeholder survey, a rapid desk review, and a country visit conducted between 22 and 26 January 2024.

2 Purpose and objectives

The main purpose of the assessment was to review the implementation and impact of the national BIS 2030 strategy for the prevention and control of HIV, hepatitis B and C, and other STIs, as well as to develop further solutions and action recommendations. The specific objectives of the assessment were to:

- Review the incidence, prevalence, morbidity and mortality of HIV, hepatitis B and C and other STIs, with a focus on high-risk populations.
- Review the national surveillance system and data utilisation for HIV, hepatitis B and C, and other STIs and identify further research needs.
- Review current testing, prevention, treatment, and harm reduction measures for high-risk populations and their development since the adoption of the national BIS 2030 strategy.
- Review the interconnectivity of the various actors to improve the target group specific testing, prevention, treatment, and harm reduction measures.
- Identify gaps in the strategy as well as in the implementation of the BIS 2030 strategy.
- Suggest key actions to strengthen surveillance, testing, treatment, harm reduction and prevention of HIV, hepatitis B and C and other STIs for different target groups in various settings.
- Describe national case examples of innovation and good practice in prevention, diagnosis, treatment and care of HIV, hepatitis B and C, and other STIs including best practice examples of digital solutions.
- Develop possible solutions and recommend possible actions to adjust the BIS 2030 strategy.
- Provide recommendation for the development of a possible action plan and for the establishment of the included targets, milestones, and indicators.

3 Methods

The assessment consisted of three parts: An online stakeholder survey, a rapid desk review and an in-country assessment mission and was structured according to the five key areas of action of the BIS 2030 strategy: 1) Creating an enabling environment; 2) Expanding needs-oriented services; 3) Developing integrated services; 4) Promoting networking and cross-sectoral cooperation; and 5) Generating and expanding strategic information and data – as well as a sixth section covering Germany's international aid and global contributions toward the SDGs. In agreement with the MoH, the sixth section was omitted from the review since the aim was to assess the domestic implementation of the strategy.

3.1 Stakeholder survey

A stakeholder survey was designed to provide thorough insights from as many stakeholders involved in the strategy implementation as possible on progress made towards achieving the planned objectives of the BIS strategy, areas needing improvement and action to be taken in the coming period for Germany to reach the goals of the strategy.

The survey was designed in REDCap (Research Electronic Data Capture, an online application for building and managing online surveys and databases (4)) – and consisted of 18 main questions, organised in sections corresponding to the five strategic areas of areas of the BIS 2030 strategy.

All main questions assessed the extent to which action had been taken by the relevant stakeholders – from the point of view of the responding agency – and specifically assessed the concrete interventions outlined in the BIS strategy under each area of action. Likert scale response options covered from 0 to 5, with 0 being no action taken and 5 being the highest possible amount of action taken. In the analysis phase, responses were grouped into four categories: a) 0-1: no/low extent; b) 2-3: medium extent; c) 4-5: high extent; and d) no opinion. Additional questions assessed whether national, regional and local efforts have generated satisfactory results or impact as of 2023 and, if not, what actions are needed to for Germany to reach the goals of the strategy. Lastly, the survey also included open-ended questions for stakeholders to provide further information and/or comments.

Overall, 46 stakeholders, mostly representing the BIS Strategy Coordination Committee members, were invited to respond to the survey between 5 September 2023 and 31 January 2024. Of these, four were Federal level agencies, 16 were 'Länder' (Federal states) or city level entities, 12 were medical societies, 11 were NGO/community/patient organisations, and three were health insurance groups. A detailed list of the stakeholders who received and responded to the survey can be found in Annex 1.

3.2 Desk review

The desk review covered both publicly available resources (published articles, reports, data) and several documents requested and received via the Robert Koch Institute (RKI) (see reference list). In addition, colleagues of the Robert Koch Institute drafted a situation analysis providing an overview of the epidemiology and response to the HIV, hepatitis B & C and STI epidemics in Germany and outlining how Germany is progressing toward the SDGs based on key selected indicators per disease area (section 4.2).

3.3 Country visit and stakeholder interviews

The key part of the assessment was an in-country mission conducted by an assessment team consisting of two ECDC staff members (Teymur Noori and Charlotte Deogan), three ECDC consultants (Dorthe Raben and Annemarie Stengaard (CHIP, Denmark), and Jürgen Rockstroh (University of Bonn, Germany) between 22 and 26 January 2024. The mission team met with and received input from a broad range of stakeholders during the week, including representatives of the Robert Koch Institute (RKI), the Federal Centre for Health Education (BZgA), German AIDS Aid (Deutsche Aidshilfe (DAH)), selected medical societies, prison health services, hospital doctors, representatives of three to four selected Federal states (Länder) and local public health departments ('Gesundheitsämter'), checkpoints, NGOs involved in implementing services and working with various key population groups, representatives of local communities and affected people as well as representatives of the Federal Ministry of Health. The programme for the country visit was developed in close collaboration with the Federal Ministry of Health and the Coordination Committee. A detailed list of the organisations visited or interviewed is provided in Annex 2.

All key stakeholders with whom a meeting or interview was planned were asked to reflect on three key questions beforehand, namely:

- What is working well in terms of implementing the national BIS 2030 strategy and which positive developments have you observed since the adoption of the strategy?
- What are the main challenges or barriers that impede implementation of the national BIS 2030 strategy?
- What changes would be needed to strengthen implementation of the strategy (at national, regional and local levels) and support Germany in reaching the 2030 goals of the strategy?

A first draft of the report was shared with the Federal Ministry of Health and the BIS strategy Steering Committee members for comments. These comments were taken into account when revising and completing the final mission report.

4 Situation analysis

4.1 Country context

Germany is a democratic, Federal parliamentary republic in the middle of Western Europe with around 83 million inhabitants in 16 Federal states (5). The Federal states are further divided into rural (Landkreise; n=294) and urban districts (Stadtkreise; n=107). Within the limits of the policy guidelines set by the Federal Chancellor, each Federal Minister – including the Minister of Health – conducts the affairs of his or her department independently and on his or her own responsibility. Therefore, the organisation of Germany into a Federal system might complicate broad national strategies.

The German healthcare system is one of the oldest national social health insurance systems. Due to the Federal structure in Germany, some key policy areas such as health (i.e., the planning and regulation of healthcare with the two major areas public health service and hospital planning), education, and cultural affairs are organised at the level of the 16 Federal states based on several Federal laws (social security code, Sozialgesetzbuch) (6). Within the states there are several authorities involved in the implementation of public health services: state and local public health departments as well as certain institutions of veterinary and food inspection (7). The urban and rural districts (Landkreise and Stadtkreise) are usually covered by one local health department (Gesundheitsamt) which vary in size, structure and tasks. Tasks could include the prevention of infectious disease (e.g. case notifications, contact tracing, implementation of measures), counselling services (e.g. psychosocial, sexual health), prevention and health education, as well as supervision of hygiene in institutions, such as kindergartens, schools, retirement homes and other health settings (7, 8). Therefore, services available for patients might vary depending on the specific urban or rural district, once again possibly complicating national strategies. Most Gesundheitsämter offer HIV testing and some offer STI and hepatitis testing.

The German healthcare system is mainly financed by statutory and private health insurance, made mandatory in 2007, supplemented by yearly government subsidies. Statutory health insurance (SHI) is financed mostly through income-related contributions equally shared between employer and employees. Since 2009 everyone registered or usually resident in Germany is required to take up health insurance. However, some population groups do not have insurance due to lack of legal coverage, administrative hurdles or problems paying premiums.

4.2 Epidemiology and response overview

4.2.1 HIV

Table 1. HIV-related indicators, targets and status of progress toward the targets

	Indicator	Data available	Target 2025	Source	Status
Prevention	PrEP uptake and coverage	Yes		PrEPSurv	40.000 (2023) ~50% coverage large regional differences
	New PreP users	Yes		PrEPSurv	~11.500 (2019); 10.500 (2020); 9.000 (2021);10.500 (2022)
	Recent PrEP use among people newly diagnosed with HIV	Yes		PrEPSurv	HIV incidence 0.08/100.000 PY;0.001 HIV incidence among PrEP users
Incidence	Number of new HIV infections (adult and child) per year	Yes	75% reduction by 2025 and 90% reduction by 2030 from 2010 baseline	Yearly estimation	1.900 (2022); 2900 (2010); -35%
Testing and treatment	Percentage of people living with HIV (PLHIV) who know their status	Yes	95%	Yearly estimation	90% (2021)

	Indicator	Data available	Target 2025	Source	Status
	Percentage of PLHIV diagnosed at late stage of disease	Yes		Yearly estimation	33 % (2021) with advanced immunodeficiency ; 14% with AIDS defining diagnosis
	Percentage of PLHIV diagnosed and on treatment	Yes	95%	Yearly estimation	96% (2021)
	Percentage of PLHIV on treatment and achieve viral suppression	Yes	95%	Yearly estimation	96% (2021)
	% of all PLHIV who achieved viral suppression	Yes	86%	Yearly estimation	84%
Stigma	% of PLHIV experiencing stigma and discrimination	Yes	10%	Positive Stimmen (Positive Voices) 2.0 (8)	52% (prejudice related to HIV impacting negatively life); and 56% (experienced at least one negative experience related to HIV in the healthcare system in the last 12 months) (2021) (9)
Mortality	Number of people dying from HIV/related causes per year	Partially	90% reduction in new AIDS-related deaths compared to 2010 baseline	Yearly estimation; death statistics	640 (2021)

Source: RKI

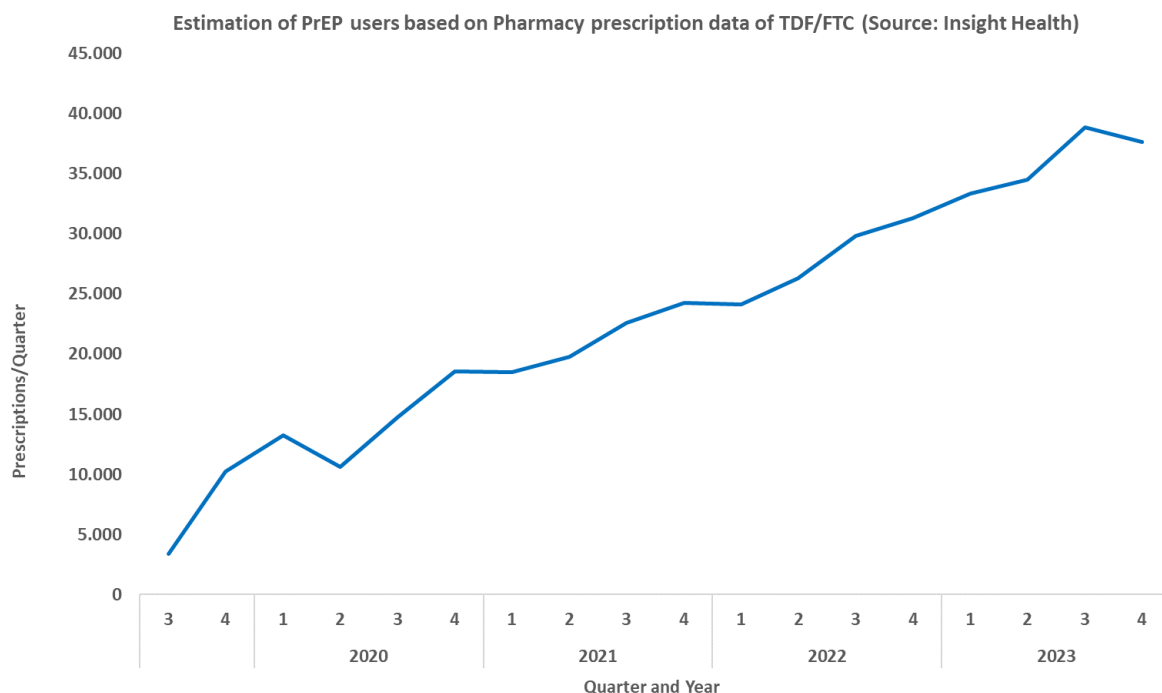
Prevention

Uptake and coverage of PrEP

Since September 2019, people with statutory health insurance (SHI) who are at substantial risk of HIV infection have been entitled to be covered with HIV pre-exposure prophylaxis (PrEP). Currently, 40.000 users are estimated in Germany in 2023. PrEP use is accessible and reimbursed by SHI including counselling and regular STI testing for SHI members. Surveillance data on PrEP are generated on the basis of pharmaceutical prescription data by pharmacy billing centres and by the analysis of health insurance data. Moreover, an ongoing nationwide biannual survey is repeatedly performed among HIV treatment specialists regarding the biannual number of PrEP users, demographic data, HIV and STI testing and HIV infection under PrEP use as well as other current questions relevant to PrEP care.

Since the introduction of PrEP as part of the SHI, the number of PrEP users almost continuously increased. This growth was only interrupted in Germany during the stay-at-home measures due to the COVID-19 pandemic. Furthermore, reported PrEP shortages appear to become visible at the end of the observation period in December 2023 (Figure 1). A total of around 40,000 people (including persons without SHI and event driven use) are estimated to be using PrEP at the end of 2023.

Figure 1. Estimation of the number of PrEP users in Germany based on pharmacy prescription data from Insight Health over time in Germany

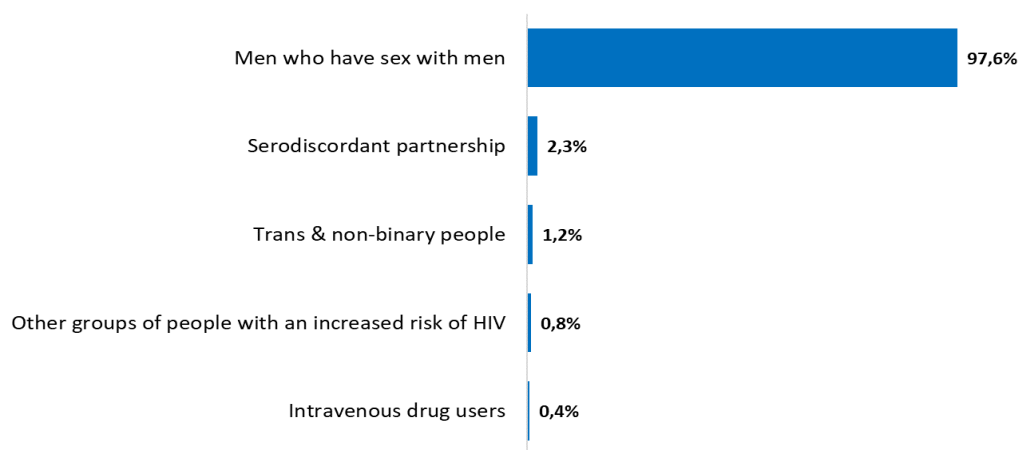


Source: RKI

In Germany, PrEP is used almost exclusively by males, specifically in the group of MSM. Other key populations and females show little use of PrEP (Figure 2) and often have little knowledge about PrEP (10). Additionally, large regional differences in PrEP uptake and coverage are observed in Germany which are related to regional PrEP provider distribution and structural barriers (11).

There is need for education and information about PrEP in communities beyond MSM, such as among people from the African community, people from trans* and non-binary communities, sex workers and people who use intravenous drugs. Further, there is need to enable and ensure access for people without health insurance or a valid residence permit as well as the reduction of other structural barriers to PrEP access. There is a lack of availability of PrEP prescribers, especially outside of metropolitan areas.

Figure 2. PrEP users by PrEP indication according to guidelines and legal regulations in 2022. Multiple answers possible



Source: RKI

New PrEP users

In 2022 10,500 new PrEP users were recorded based on health insurance data that was extrapolated to the entire population. The number dropped during the Covid-19 pandemic due to several lockdowns, reduced offers and overall decrease in event driven mobility. Since November 2023 Germany has experiences shortages in the stock of

generic PrEP medication. However, there are actions underway to ease the prescription of other drugs without financial restrictions and to increase stock of other drugs in pharmacies. As of March 2024, the situation appears to have eased somewhat, thanks to the joint efforts of many stakeholders in this field.

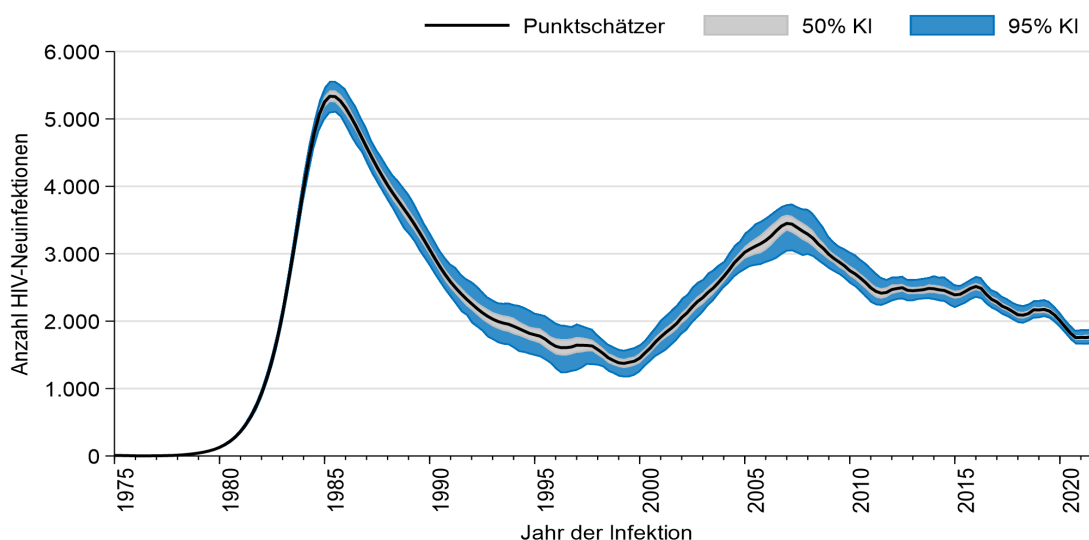
HIV infections among PrEP users and recent PrEP use among people newly infected with HIV

The HIV incidence among PrEP users as recorded in a survey among HIV treatment specialists conducted in the PrEP evaluation in 2020 was low with 0.08 new HIV infections/100 person years (12). Recent aggregated data collected in HIV specialist clinics showed an HIV incidence of 0.1% among PrEP users. In the national HIV surveillance, there is the possibility to record PrEP use in free text in the HIV notification records. This will be formalised with the introduction of the electronic notification system for HIV in 2024.

Incidence

The incidence of newly infected HIV cases is estimated yearly by a model based on imputation of several data sources. Data sources include the HIV notifications, the pharmaceutical prescriptions, death statistics, data from long term observational HIV cohorts and health insurances data. In 2022, 1.900 new HIV infections were estimated. Compared to 2010 where an estimated 2900 people were newly infected, this is a decrease of 35% (Figure 3).

Figure 3. New HIV infections in Germany (1980–2021)



Source: RKI

The 2025 target to reduce the HIV incidence by 90% compared to 2010 is not achieved and the reasons for failing this goal are multifaceted. The most important reason is the need for scale up the HIV testing offers and testing campaigns in primary healthcare and for vulnerable groups other than MSM. This is influenced by the lack of access to testing and treatment for those people who are not health insured.

Testing and treatment

Percentage of people living with HIV who know their status

The first 95 target to diagnose 95% of people living with HIV was not achieved by Germany in 2021. Only 90% (82.100/90.800) of people living with HIV were aware of their status in 2021 (Figure 4). This percentage is based on data sources used for the yearly model to estimate the German HIV epidemic. There is no HIV cascade of care available for different key and vulnerable groups, because not all the data sources necessary to estimate the HIV cascade are available by sex or HIV transmission group.

In addition, some analyses of health insurances data (HID) were performed regarding HIV screening in pregnant women (one of several key indicators needed for countries to assess progress toward triple elimination of mother-to-child transmission) demonstrating that >95% of women were screened for HIV in 2022, an increase from around 50% in 2001.

Percentage of people diagnosed in late stage of HIV disease

The number of people diagnosed at a late stage of HIV disease (CD4 cell count below 350) or with advanced immune deficiency syndrome (CD4 below 200) was stable at 33% and 14%, respectively, in 2021 and has been since 2001. The goal to end AIDS by 2030 will not be achieved. The numbers of people diagnosed late varies slightly between the different transmission routes, however, they are highest among people acquiring HIV by

heterosexual transmission, being female and originating from countries with high HIV prevalence. That indicates that people are tested often too late and that there are many missed opportunities for HIV testing for people in primary healthcare in Germany. People who are not health insured and do not have access to the German healthcare system are also a hidden population.

Percentage of people diagnosed with HIV on treatment

The second 95 target of people diagnosed and treated with antiretroviral therapy has been achieved by Germany in 2021. Since 2017 the recommendation to treat every newly diagnosed person with HIV immediately irrespective of CD4 cell count was implemented in the German antiretroviral treatment guidelines (13). The number of people living with HIV who receive treatment are calculated by using ART prescription data from pharmaceutical billing centres and by treatment data from long term observation HIV cohorts (14).

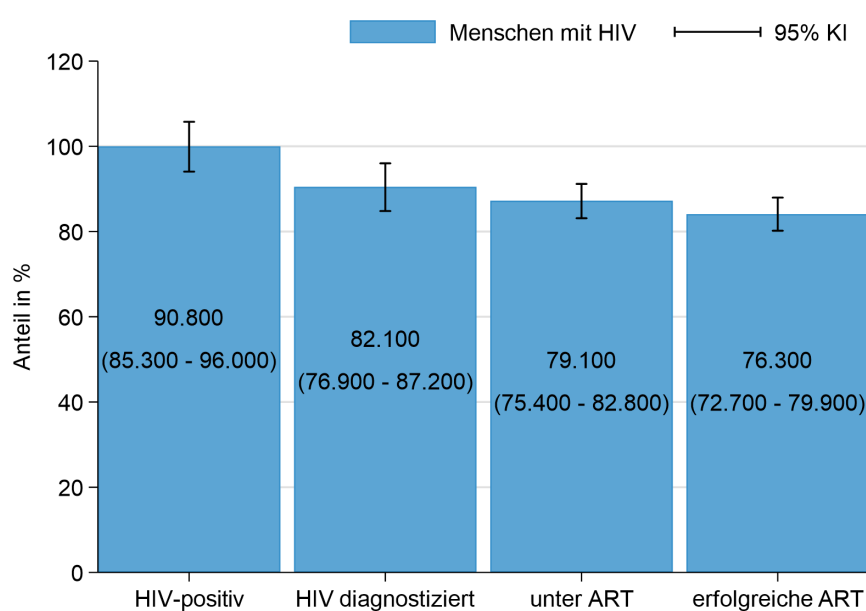
Percentage of people on antiretroviral treatment who achieve viral suppression

Germany also reached the third 95 target of people living with HIV on antiretroviral treatment who are virally suppressed below the detection limit in 2021 (79.100 on treatment/76.300 with viral suppression). The numbers were calculated based on data from HIV cohorts (14).

Percentage of people living with HIV who achieve viral suppression

Lastly, Germany is very close to reaching the overall target of 86% of all people living with HIV achieving viral suppression. As of 2021, this indicator stood at 84%.

Figure 4. HIV Continuum of care, Germany, 2021*



Source: RKI

* HIV infections among undiagnosed migrants are not included. Antiretroviral therapy (ART) is considered successful if less than 200 viral copies per ml are detectable in the blood. CI: Confidence interval.

Stigma

Despite some shifts towards creating an enabling environment, HIV-related stigma persists and remains a key challenge. According to the 2021 Positive Voices 2.0 survey, 56% (of n=935) people living with HIV reported at least one negative experience in the healthcare setting in the last 12 months (for example, unwanted disclosure of HIV status, separate appointments or refusal of care). Consequently, 25% of respondents do not disclose their HIV status in healthcare settings outside of their HIV treatment centre. Overall, 90% of respondents reported that they live well with their HIV infection, however, 52% (of n=932) stated that HIV-related prejudice negatively impacts their life. 70% reported difficulties disclosing their HIV infection to others and 44% never talk about their HIV infection in work settings.

Mortality

Number of people dying from HIV-related causes per year

This indicator is only partially available. 640 HIV-related deaths were recorded in 2021.

Conclusion

Germany has established a national BIS strategy for the prevention and the control of HIV, viral hepatitis and STI. An imputation model was implemented to estimate the continuum of HIV care on a yearly basis. The country is on track to reach the UNAIDS goals until 2025 regarding the proportion of people living with HIV treated with antiretrovirals as well as the goal of those who are successfully virally suppressed. However, the country is still facing a gap in the first 95 goal regarding those who are aware of their HIV status. This reveals gaps in HIV prevention and HIV testing strategies in key populations as well as for the general population in primary healthcare settings. It is currently not possible to estimate the HIV continuum of care for different key populations, due to a lack of information upon sex and mode of HIV transmission in the respective data sources used for the imputation model (pharmaceutical prescription data). No data are available regarding stigma. The national surveillance on mortality was implemented in 2021 and will be used for the HIV estimates for 2022.

PrEP was successfully implemented in 2019 and is available for all people at risk, however only for those who are members of a health insurance. Still, many key populations, beyond MSM communities are lacking knowledge and information about PrEP use and PrEP provision by the doctors. It is noteworthy that the prescription of PrEP is highly medicalised. PrEP covered by SHI can only be prescribed by specialised doctors, who are mainly HIV specialists. Therefore, new modes of PrEP provision that involve community structures and lower the requirements for SHI PrEP prescription have to be established to cover also rural regions and reach populations beyond MSM in Germany.

4.2.2 Sexually transmitted infections

Table 2. STI-related indicators, targets and status of progress toward the targets

	Indicator	Data available	Target 2025	Target 2030	Source	Status
Impact	Number of new cases of syphilis, gonorrhoea, chlamydia and trichomoniasis in adults (aged 15–49 years) per year	Partially	-20%	-90% NG + TP	Notifications (NG, TP), CSS (CT)	↑ (for TP and probably NG); insufficient notification data for CT & TV
	Number of new cases of syphilis in adults (age 15–49) per year	Yes	-20%	-50% CT + TV	Notifications	↑
	Number of new cases of gonorrhoea in adults (age 15–49) per year	Partially	-20%	-90%	Notifications	↑ (notification data from one Federal state)
	Congenital syphilis cases per 100 000 live births	Yes	≤10	-90%	Notifications	↓ 0,4
	Syphilis prevalence in women attending antenatal care	Partially	>0.05%	≤1	Health insurance data (HID)	↓ (probably, but not implemented yet)
	Syphilis and gonorrhoea prevalence among men who have sex with men, and female sex workers	Partially	<3% NG <2% TP	>0.01%	IBBS (15-17), ÖGD	↑ NG 8.9% in MSM, 4.3% in FSW (outdated; no data on TP)
Testing and treatment	Percentage of pregnant women attending antenatal care who were screened for syphilis/percentage treated if positive	Partially	>95% / >95%	<0.5% NG	HID	↑ 95.3% screened, % treated unknown
	Percentage of priority populations screened for syphilis/percentage treated if positive	No	>80% / >90%	<0.5% TP	Potentially: IBBS, HID, ÖGD	Populations to be defined
	Percentage of priority populations screened for gonorrhoea/ percentage treated if positive	No	20% / >90%	>95% / >95%	Potentially: IBBS, HID, ÖGD	Populations to be defined
	Percentage of women screened for cervical cancer using a high-performance test, by the age of 35 years and again by 45 years	Partially	40% / >40%	>70% / 90%	HID	Analysis not implemented yet
	Percentage of women screened and identified as having pre-cancer treated or invasive cancer managed	Partially	>40%	90%	HID	Analysis not implemented yet
Prevention	Percentage of girls fully vaccinated for HPV by the age of 15 years	Yes	35%	90%	HID	↑ 51%
Supporting environment	Number of countries with national STI plans updated and funded within last 5 years		70%	90%		↑ BIS 2030 → funding
	Number of countries with national STI case management guidelines updated within last 3 years		>90%	95%		↑ guidelines → regular revisions missing partially
	Number of countries with strong STI surveillance systems that allow monitoring of STI burden and progress towards elimination		75%	90%		↑ TP, mpox, NG-AMR → NG + CT under way, standardised secondary data analysis lacking
	Number of countries reporting AMR in <i>Neisseria gonorrhoeae</i> to Euro-GASP		>90%	95%		↑

* Aims for 2025 and 2030 compared to baseline year 2020 as suggested by WHO.

Situation and development of indicators on STI

To date – and as opposed to the situation for HIV and for hepatitis B and C – there are no indicators for regular reporting on impact and coverage regarding STI in place in Germany. Such a process is however in progress, as the WHO Regional Office for Europe suggested such a set of indicators in its combined 'regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022–2030' (18). On this basis, also the European Centre for Disease Prevention and Control (ECDC) started a process in 2023 in collaboration with the EU member states, to define a set of indicators which can be used to measure impact and coverage of STI and related services and to monitor progress which is made within the European Union.

In the following sections, indicators as proposed by the WHO European Action Plan will be evaluated in terms of data availability and, if possible, of the current status in Germany regarding the specific indicator. The baseline year to assess the situation regarding to the specific impact and coverage indicators suggested by WHO is 2020.

Impact

Number of new cases of syphilis, gonorrhoea, chlamydia and trichomoniasis in adults (aged 15–49 years) per year

This indicator combines incidence data of four different pathogens according to the method used to estimate the disease burden of these pathogens by WHO worldwide as well as for the WHO regions. Regarding the German situation on STI, RKI assume that the incidence of trichomoniasis is not of central public health importance currently. The yearly number of new cases of syphilis and gonorrhoea are addressed by the two specific indicators and will be discussed in the following.

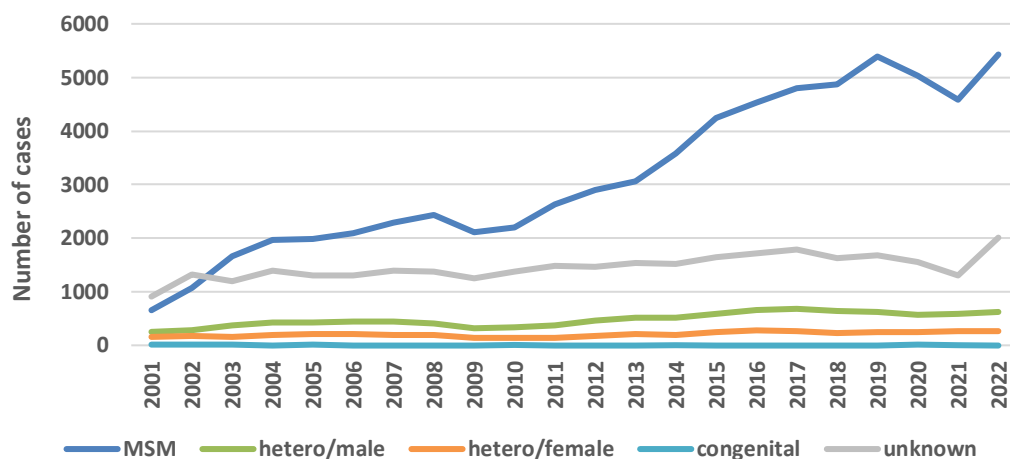
As there is no mandatory notification of infections with *Chlamydia trachomatis*, data on incidence of chlamydia is not available in Germany at present. Currently, the Robert Koch Institute (RKI) is establishing a sentinel surveillance system for reporting *Chlamydia trachomatis* on basis of §13 Infectious Disease Act and the Antibiotic Resistance Surveillance (ARS) system at RKI, which is in the process of digitalisation and covers a large number of laboratories in Germany. In this novel surveillance instrument for *Chlamydia trachomatis*, all tests for *Chlamydia trachomatis* as well as the individual test results and a small number of epidemiological information will be reported by the participating laboratories in an automated manner. Therewith, it will also be possible to calculate the positivity rate for *Chlamydia trachomatis*, and results will be extrapolated to the overall epidemiological situation in Germany.

Number of new cases of syphilis in adults (age 15–49) per year

The incidence of syphilis in Germany was 10.0 cases per 100.000 inhabitants in 2022. In the baseline year 2020, the incidence was 8.9 cases per 100.000 population. The incidence in the preceding year 2019, which was not already influenced by the COVID-19-pandemic, was fairly higher with 9.5 cases per 100.000 population. Preliminary notification data for 2023 show a further slight increase of notifications.

In 2022, 8288 syphilis infections were reported. Following declines in 2020-2021 (likely due to COVID-19-related restrictions), the number of cases increased by 23% in 2022 (Figure 5). Sex between men was the predominant transmission mode and the increase in new infections since 2010 was almost entirely driven by MSM. Cases were predominantly reported among men (male female-ratio of 16:1 in 2022) and predominantly acquired in Germany (for 93% of cases with information about country of origin). Only few cases were reported in the context of sex work (1% reported contact to a sex worker or being actively engaged in sex work).

Figure 5. Number of notified syphilis cases by mode of transmission and sex, 2001-2022, Germany



Source: RKI

RKI assume that the steady increase in syphilis incidence, which started in 2010, is a multifactorial event. Following early initiation of antiretroviral therapy against HIV, condom use became less frequent in populations with higher risk of acquiring HIV. Subsequently, HIV pre-exposure prophylaxis (PrEP) was introduced in Germany widely since 2019, which most probably also led to less frequent condom use. Therewith, the risk of acquiring syphilis increases, especially in highly active sexual networks of MSM with a higher population prevalence of syphilis. Another factor for the increasing incidence of syphilis is more frequent screening for syphilis infections in the scope of PrEP programmes. Through this, especially clinically inapparent syphilis infections will be diagnosed more frequently, which might lead to a decreasing incidence in the medium term.

Against this background, RKI do not expect that the aim to reduce syphilis incidence by 20% by 2025 compared to 2020 will be reached and most probably also not the aim of a 90% incidence reduction by 2030.

Number of new cases of gonorrhoea in adults (age 15–49) per year

Currently, a general national notification of infections with *Neisseria gonorrhoea* is in implementation (expected for second half of 2024) Therefore, the incidence of gonorrhoea in Germany cannot be determined currently. There is a mandatory notification of gonorrhoea in the Federal state of Saxony since 2001, and despite this data cannot be generalised to the national level, it showed a distinct increase of the incidence from 15.5 cases/100.000 population in 2020 (19.8 in pre-pandemic year 2019) to 27.8 in 2022. This increase is in line with notification data from other European countries. RKI do not expect a decrease in incidence by 20% between 2020 and 2025, as well as a decrease by 90% by 2030.

Possible reasons for this increase might be similar to those for syphilis (changes in sexual behaviour, screening effects), but several European countries also experienced increases in gonorrhoea incidence specifically in young heterosexual men and women within the last two years, which are not clearly understood currently and might contribute additionally to an increasing incidence of gonorrhoea.

Congenital syphilis cases per 100 000 live births

The number of congenital syphilis cases per 100 000 live births was 0.4 in 2022 in within the range of the prior years. RKI do not expect distinct higher numbers of cases within the next year. Despite potential single cases that might be overlooked, this indicator can be considered as met currently (aim 2025: ≤ 10 ; aim 2030: ≤ 1) as well as in the future. This is due to an extensive screening programme for syphilis infections in pregnant women in Germany, which proves to be highly effective (s. b.).

Syphilis prevalence in women attending antenatal care

Data on this indicator is not available yet but could be addressed by analysing secondary data from public health insurance. From syphilis notification data and due to the extensive regarding screening programmes, RKI do not have any indication that syphilis prevalence in women attending antenatal care is of high concern in Germany.

Syphilis and gonorrhoea prevalence among men who have sex with men, and female sex workers

For this indicator, IBBS and, if available, data of STI services of local public health authorities could be used. The prevalence of infections with *Neisseria gonorrhoeae* in MSM was surveyed in the nationwide, multicentre 'MSM screening study' in 2018. Prevalence was 8.9% and was higher in MSM using PrEP (14.8%) as in MSM with HIV diagnosis (8.6%) and in non-PrEP using MSM without HIV diagnosis (7.4%) (15). The study aimed at including not only highly sexually active MSM, but a general sample of MSM visiting MSM friendly practices also for general medical care, so the prevalence found could be assessed as fairly generalisable. On basis of the prevalence found in this study, the indicator will not be met for 2025.

Prevalence of infections with *Neisseria gonorrhoeae* in female sex workers were measured in the 'STI outreach study' (data collection in 2012/13), which addressed female sex workers with no or limited access to medical healthcare and therewith assumed to be at higher risk for acquiring STI. In this study, the prevalence was 4.3% (16). In the 'KAPB-Surv STI study' (data collection 2010/11), a more general population of female sex workers attending accepting and low threshold services of local public health authorities showed a somewhat lower prevalence of infections with *Neisseria gonorrhoeae* of 3.2% (17), which meets the target for 2025, but not for 2030.

Both studies on female sex workers in Germany are outdated, so there is no current prevalence estimate available for this population. The same applies to prevalence studies on infections with syphilis in MSM as well as in female sex workers. For the second half of 2024 a second wave of the MSM screening study is envisaged covering infections with *Neisseria gonorrhoeae* as well as syphilis, so updated prevalence data will be available for MSM in 2025.

Testing and treatment

Percentage of pregnant women attending antenatal care who were screened for syphilis/percentage treated if positive

The percentage of pregnant women attending antenatal care who were screened for syphilis was evaluated by analysing secondary data from public health insurance covering the years 2010-2015. According to this analysis 95.3% of all pregnant women were screened for syphilis, with barely any fluctuation over time. As early testing for

syphilis is a standard procedure in medical care while pregnant to avoid congenital syphilis cases and well established, this indicator can be assumed to be met according to the aims for 2025 as well as for 2030 (95% each).

The analysis did not cover the percentage of pregnant women tested positive for syphilis and being treated. As the given analysis is outdated and missing the percentage treated, an updated analysis should be conducted.

Percentage of priority populations screened for syphilis/percentage treated if positive

Within its action plan, WHO suggests countries to define priority populations based on the national epidemiological and social context to address those most at risk of STIs. For Germany, such populations were not yet defined regarding syphilis, but could include pregnant women (already covered by specific indicator), sex workers and their clients, MSM (including those enrolled in PrEP programs), transgender people, people with a prior STI and people living with HIV. According to the outcomes of a pilot study in homeless people in Berlin, this group may also be considered a priority population for syphilis.

Currently, there are no data available yet regarding this indicator. Data sources for this indicator could be integrated bio-behavioural surveillance (IBBS) studies, secondary data from public health insurances and, if available, data of STI services of local public health authorities could be used.

Percentage of priority populations screened for gonorrhoea/percentage treated if positive

According to the preceding indicator, priority populations are to be defined also in terms of gonorrhoea. These could include young people aged 15–25 years old, sex workers and their clients, MSM (including those enrolled in PrEP programmes), transgender people, people with a prior STI and people living with HIV.

In addition, there are no data available yet regarding this indicator. Potential data sources would be similar to the previous indicator.

Percentage of women screened for cervical cancer using a high-performance test, by the age of 35 years and again by 45 years

For this indicator, data are not available yet, but could be assessed by secondary analysis of data from health insurance companies.

Percentage of women screened and identified as having pre-cancer treated or invasive cancer managed

For this indicator, data are not available yet, but could be assessed by secondary analysis of data from health insurance companies.

Prevention

Percentage of girls fully vaccinated for HPV by the age of 15 years

The percentage of girls fully vaccinated for HPV by the age of 15 years is assessed on a yearly basis as part of the 'KV-Impfsurveillance' (surveillance of vaccination coverage on basis of health insurance data) at RKI. The most recent analysis showed a coverage of 54.0% in 2021 as the most recent year with available data. This meets the indicator according to the year 2025 (35%). As the percentage increased only slowly over the years (by ca. 3% points yearly since 2015), RKI do not assume that the aim of this indicator for 2030 (90%) will be met. Therefore, additional measures should take place as educational and vaccination campaigns at school, intensified educational campaigns for parents in the scope of regular preventive examinations for children etc.

Supporting environment

Number of countries with national STI plans updated and funded within last 5 years

This indicator is met for Germany by adopting the BIS 2030 strategy in 2016 by the German government.

Number of countries with national STI case management guidelines updated within last 3 years

In Germany, clinical guidelines are available and updated regularly for *Chlamydia trachomatis* including LGV, human papilloma viruses (HPV), *Neisseria gonorrhoea* and *Treponema pallidum*. A clinical guideline for *Mycoplasma genitalium* is under development currently. A clinical guideline on management of urethritis in male adolescents and males is finalised currently.

Number of countries with strong STI surveillance systems that allow monitoring of STI burden and progress towards elimination

For syphilis, mpox and infections with *Neisseria gonorrhoeae* with antimicrobial resistance, there are robust, extensive and effective notification systems in place in Germany. Notifications for infections with *Chlamydia trachomatis*, strains L1-L3 (causing LGV) as well as with *Neisseria gonorrhoea* in general were added to the Infectious Disease Act lately and are in implementation currently.

Number of countries reporting antimicrobial resistance (AMR) in *Neisseria gonorrhoeae* to Euro-GASP

RKI reports data on AMR in *Neisseria gonorrhoeae* to Euro-GASP yearly.

Potential additional indicators

There are some other potential indicators that are not within the range of those proposed by WHO but could shed light on the epidemiological situation of STI in Germany in specific populations or setting being of public health impact in Germany. These are:

- Percentage of antimicrobial resistance against key antibiotics in infections with *Neisseria gonorrhoeae*;
- Number of new cases of mpox per year/percentage of sexually active MSM vaccinated;
- Number of tests for Chlamydia trachomatis and percentage of tests positive per year, priority populations screened for chlamydia/percentage treated if positive;
- Number of MDR/XDR infections of *Shigella* spp. in MSM or other priority populations;
- Number of MSM (and other priority populations) using antibiotic STI prophylaxis ('Doxy-PrEP/PEP')

Conclusion

An internationally agreed set of indicators to monitor core dynamics in terms of impact and coverage of STI is currently under development but was not previously in place. Many of the discussed indicators also have to be implemented in Germany, with a specific focus of making use of secondary data from health insurance, but also from newly introduced notification systems.

Where data are already available, they show that congenital syphilis is not of concern in Germany due to highly effective screening measures for pregnant women. For other indicators where data are already available, only the aim for 2025 of a 35% HPV vaccination coverage of girls has been reached. This indicator will probably be missed in regards to the aim for 2030.

In summary, Germany is most likely not on track to reach the key targets as defined by the indicators stated above. Major efforts should be made to establish the set of indicators as stated above needed to monitor the status of STI in Germany and the progress that is made in this regard.

4.2.3 Viral hepatitis B and C

Table 3. Viral hepatitis related indicators, targets and status of progress toward the targets

	Indicator	Data available	Target 2025	Target 2030	Source	Status
Epidemic pattern	Prevalence of chronic HBV infections (general population)	Yes	-	-	Sperle et al. 2020 (19) Steffen et al. 2022 (20)	↓ 0.14–0.7%
	Prevalence of chronic HCV infections (general population)	Yes	-	-		↓ 0.2–0.4%
	Prevalence of chronic HBV infections (key populations)	Partially	-	-		Migrants: ↑ 2.3–3.6% HIV+ MSM: ↑ 1.7–4,5% PWID and people in substitution: ↑ 1.1–1.3% Homeless people: ↑ 1.9% People in prisons: not available (or outdated)
	Prevalence of chronic HCV infection (key populations)	Partially	-	-		Migrants: ↑ 0.7% HIV+ MSM: ↑ 4.0–4.3% PWID and people in substitution: ↑ 27–44% Homeless people: ↑ 16% People in prisons: not available (or outdated)
	Reduction in viraemic HCV prevalence in PWID	Partially	80% reduction		DRUCK-Study (21, 22) DRUCK 2.0 pilot study (23)	HCV-RNA 44 % (2011–14) → HCV-RNA 27 % (2021–22) (↓ 61% reduction)
Impact	Hepatitis B surface antigen (HBsAg) prevalence among children under 5 years old	Yes	0.5%	0.1%	KIGGS study (24) Cai et al. 2011 (25)	2003–2006: ↓ 0.2% 2014–2017: ↓ 0 HBsAg positive cases
	Number of new Hepatitis B infections per year	No	11 per 100 000	≤2 per 100 000		No direct incidence data available

	Indicator	Data available	Target 2025	Target 2030	Source	Status
	Number of new Hepatitis C infections per year	No	13 per 100 000	5 per 100 000		No direct incidence data available
	Number of new Hepatitis C infections per year among PWID	Partially	3 per 100	2 per 100	Enkelmann et al. 2020 (26)	↑ 19.6 infections/100 PY at risk (95% CI 16–24)
	Number of deaths due to Hepatitis B per year	Partially	7 per 100 000	Combined ≤6 HCV-related and HBV-related deaths/100 000	Mårdh et al. 2020 (27)	2015: Mortality for all HBV and HCV associated deaths
	Number of deaths due to Hepatitis C per year	Partially	3 per 100 000			↑ 11.6/100 000
Prevention	Percentage of newborns who have benefitted from interventions to prevent vertical (mother-to-child) transmission of HBV	No	70%	90%		
	Hepatitis B vaccine coverage among children (third dose)	Yes	90%	90%	Rieck et al. 2022 (28)	2021: 87 % for children 4–7 years of age and 79% for children up to 2 years of age
	Coverage of HBsAg testing of pregnant women	Yes		≥90%	Beermann et al. 2020 (29)	2015: ↑ 93%
	Number of needles-syringes distributed per person who injects drugs	Yes	200	300	SaferKONSUM project Hommes et al. 2023 (30)	2021: On average, ↓ 127 needles /84 syringes per PWID
	Coverage (%) of opioid agonist maintenance therapy (OAMT) among PWID	Yes	≥40%	≥40%	Estimate by EMCDDA, based on published number of opioid-dependent (n=166,294) (ref); and number of people in OST, 2021 (n=81,300) (31)	↑ 49%
Testing and treatment	Hepatitis B – Percentage of people living with Hepatitis B diagnosed	Partially	60%	90%	Steffen et al. 2020 (32)	↓ 15-66% of HBs Ag positive patients knew about their Hepatitis B infection
	Hepatitis B – Percentage of diagnosed who are under treatment	Partially	50%	80%	Maisa et al. 2021 (33)	Not possible to calculate percentage treated. Numbers of those under treatment steadily increasing.

	Indicator	Data available	Target 2025	Target 2030	Source	Status
	Hepatitis C – Percentage of people living with Hepatitis C diagnosed	Partially	60%	90%	Steffen et al. 2020 (32) Tergast et al. 2022 (34)	<p>↓ 35–86% of anti HCV+ and 48–81% of RNA-positives knew about their HCV infection</p> <p>↓ 37% according to a modelling study for 2020</p>
	Hepatitis C – Percentage of diagnosed who are treated/cured	Partially	50%	80%	Tergast et al. 2022 (34) Steffen et al. 2022 (35) Meyer et al. 2023 (36)	<p>↓ 11% of diagnosed were treated and of those treated 97% were cured, according to a modelling study for 2020.</p> <p>↓ Annual treatment numbers have decreased since a peak in 2015, and remain low: In 2020, 6 500 patients were treated, in 2021 5 600 and in 2022 6 000 patients covered by statutory health insurance were treated with DAA in Germany. To calculate the proportion treated, the number diagnosed is currently missing.</p>

Source: RKI

¹ General population refers to the population of Germany not belonging to specified vulnerable key population groups.

Viral hepatitis epidemic pattern

Prevalence

General population

Germany is a low prevalence country for hepatitis B and C infection in the general population (see definition). In a population-based study (not including special groups at increased risk) conducted in 2008-2011, 0.3% of adults had active hepatitis B infection (HBsAg-positive), 0.3% were anti HCV positive and 0.2% had active hepatitis C infection (HCV-RNA-positive) (37). In a systematic review conducted by the RKI further 11 studies were identified providing data on HBsAg prevalence that ranged between 0.3 and 0.7% and one further study reporting HCV-RNA prevalence of 0.7% (19). The data on prevalence in general adult population in Germany are robust, however, the estimates from population-based studies are more than 10 years old.

Key population groups

The data on prevalence in other key-populations, where prevalence is generally higher, are rather limited, especially among migrants and people in prisons.

People who inject drugs

A national PWID population size estimate is not available, there is only a national estimate of the number of opioid dependant people (n=166.294 (164.794-167.794)) (38).

Two IBBS studies were conducted in the last ten years among PWID, both addressing people who reported injecting within the past 12 months (23, 39, 40). These studies combine data from PWID on testing for From the DRUCK-Study 2011-14 among 2077 PWID in 8 cities which found an overall HCV viraemic prevalence of 44%, to 2021/22 RKI saw a 61% reduction in viraemic prevalence (not reaching the 80% reduction target) (22, 40).

In the recent pilot study DRUCK 2.0 2021/22 in Berlin and 6 cities of Bavaria the overall viraemic HCV prevalence was 27%, however RKI found large heterogeneity in prevalence across Federal states and study cities, ranging from 15-32% (23).

The HBsAg prevalence was similar in both studies, 1.2% of the study population in 2011-14 and 1.2% in the 2021/22 pilot study DRUCK 2.0, with huge variation across study cities (0-6.3%) (23, 41).

A monitoring system of drug-related infectious diseases in around 15 sentinel cities in Germany is planned and will be based on methods of the pilot DRUCK 2.0. RKI are still waiting for the confirmation of setting this monitoring system up in a two-year project, planned to start in April 2024.

Homeless people

The official size of the homeless population is estimated at 607,000 people, and is increasing (42). Homeless people are a heterogenous group, overlapping with other vulnerable populations, e.g. PWUD, sex workers, refugees, undocumented migrants and others. Representative or robust HBV and HCV prevalence data are not available for the homeless. Data from a small pilot IBBS study 2021 (POINT study among homeless people in Berlin) found a prevalence of HBV of 1.9%; viraemic HCV 16% (20). Striking was the high proportion of uninsured persons (56%) in the study population. RKI found insufficient access to vaccination and testing, only 44% of the study population were ever tested for HCV. A roll-out to other cities of the POINT study is planned since 2021, but funding by the MoH and the RKI was deprioritised.

Men who have sex with men

Data from HIV-coinfected MSM are available from the HIV-1 seroconverter cohort study (43). Hepatitis B prevalence for acute/chronic and resolved infections decreased from 4.1% and 45% in 1996–1999 to 1.3% and 16% in 2019, respectively. Simultaneously, participants with a serological status indicating HBV vaccination increased from 25% in 1996–1999 to 69% in 2019. The HBV incidence rate in 565 participants decreased from 6.9/100 person-years in 2004–2007 to 0.45/100 person-years in 2015. Hepatitis C prevalence for acute/chronic and resolved infection increased until 2014 to 12% (44). Since then, prevalence of acute/chronic HCV infection rapidly decreased and prevalence of resolved infections showed a steady increase. HCV incidence was highest in 2010 and lowest in 2017; however, no significant change in HCV incidence could be seen over the years. Introduction of direct-acting antiviral agents for HCV treatment notably decreased prevalence and potentially incidence of acute/chronic HCV infection. Nevertheless, prevalence and incidence of HCV among these HIV-1-positive study participants remain high compared with the general population and justify the need for continuous HCV prevention and treatment efforts among HIV-positive individuals.

Migrant populations

Published data on prevalence of HBV and HCV among specific migrant populations in Germany are scarce, as a scoping review with systematic data collection shows: the prevalence of HBsAg ranged between 2.3%-3.6% and the prevalence of anti HCV from 0.4-1.9% in four studies, respectively. Only one study assessed HCV-RNA prevalence (0.7%) (19). As prevalence is highly dependent of the country of origin, RKI recommend to separately investigate the biggest migrant populations for HBV and HCV. In the HepMig pre-study (10/2022-04/2024) includes background information on populations size of HBV/HCV-infected migrant groups in Germany, how to reach them with an IBBS study, and this study piloted a study design among people born in Romania and Türkiye in the city of

Frankfurt. This study is to be rolled out to further migrant populations and other cities in Germany. A proposal is planned to be submitted to the MoH later in 2024.

People in prison

In 2022, 57,465 people were imprisoned in the German prison system (45). Prevalence of HBV and HCV is only available from an outdated cross-sectional study in six prisons 2006/7: Weighted prevalence for antiHBc, HBsAg, antiHCV and antiHIV were 11% (95% confidence interval (CI): 10.6-11.3), 4.2% (95% CI: 4.0-4.5), 20.6% (95% CI: 20.1-21.0) and 0.7% (95% CI: 0.6-0.8), respectively (unpublished report to the MoH). RKI assessed pharmacy sales data on medications for HBV, HCV, HIV, TB treatment and OST in prisons of several Federal states in Germany and estimated the numbers of treated people in prisons in 2013 (46). RKI found heterogeneity of treatment numbers across Federal states, and too low treatment numbers for the assumed numbers of HBV and HCV-infected people in prison. These data are as well outdated, as the study was conducted before DAA treatment was available.

A model project to support expansion of HCV treatment is currently being conducted in three prisons of two Federal states (NRW and Hesse), results are not yet reported.

Number of people infected with HBV and HCV

There are several approaches made to estimate number of people infected with hepatitis B and C in Germany. RKI prefer to use two of them – one is a study done by RKI for year 2013 and another is a study done by ECDC for year 2019.

A study done by RKI uses the workbook method, a technique that utilises population size together with prevalence data to estimate the total number of infected people. For 2013, RKI estimated 228,000 (170,000 – 338,000) HBV-infected people in Germany, of whom 40% were adults (18 years and older) in the general population. Another 58% were migrants, 1.0% people who inject opioids and 0.4% were HIV+MSM. A total of 235,000 (111,000–469,000) viraemic HCV-infected people were estimated for Germany in 2013, of whom 52% were adults in the general population, 24% were migrants, 23% were people who inject opioids, and 1% were HIV+MSM, respectively [manuscript in preparation].

In a modelling study done by ECDC that considered hepatitis C therapy, the total number of persons with viraemic HCV infection in 2019 was 196,671 [137,555 – 279,639] (47). This is line with findings of a modelling study, estimating the number of viraemic infections in Germany in 2020 at 189,000 [76,700–295,000] (34).

To generate more updated estimates new data points are necessary, i.e. representative seroprevalence study in general population.

Impact

Hepatitis B surface antigen (HBsAg) prevalence among children under 5 years old

HBV prevalence among children has been measured in two population-based studies. In the first study conducted between 2003-2006 a weighted prevalence of 0.2% was found (25). In the latest study conducted between 2014 and 2017 there were no HBsAg positive cases [manuscript in preparation].

Number of new Hepatitis B and C infections per year

No incidence data are available. Notification surveillance data capture also longstanding infections that were recently diagnosed.

Viral hepatitis B and C are notifiable diseases in Germany, however, there have been many changes in the notification system and case definitions influencing the number of reported cases. Since the end of 2021 there has been a steep increase of notified cases for both hepatitis B and C. This is due to a combination of causes like better case-finding due to new screening programme in the general population that was introduced at the end of 2021. This coincided with refugee migration from Ukraine with known viral hepatitis infection starting in early 2022, catch up effect after dip during COVID-19 pandemic as well as change to electronic reporting by the labs. Therefore, notification data cannot be used to reliably describe epidemic patterns of viral hepatitis infection in Germany.

HCV incidence among PWID

RKI estimated HCV incidence based on prevalence in new injectors with data from an IBBS study 2011-14 at 19.6 infections/100 person-year at risk [95% CI 16–24] (26). Newer estimates and direct estimates from cohort data are not available.

Mortality

Currently, only one study has been carried out by ECDC for the year 2015, which calculated mortality due to viral hepatitis B and C in Germany on the basis of Eurostat data and attributable fraction. Total estimated number of deaths attributable to HBV and HCV in 2015 in Germany was 9,528. Resulting in mortality for all HBV and HCV associated deaths of 11.6/100 000 (27). New estimates could be produced with data from the statistical office, but precise attributable fraction data are missing.

Prevention

Prevention of mother to child transmission

Germany applies a targeted strategy for prevention of mother-to-child-transmission implying that pregnant women are screened for HBsAg during pregnancy. Children born to HBsAg positive mothers receive a targeted birth dose of hepatitis B immunoglobulin within the first 24 hours of birth.

Data on HBsAg screening in pregnancy are available for years 2011-2015, ranging between 92% and 93%. Currently data are updated for years up to 2022.

There are no data on coverage of targeted post-exposure prophylaxis as well as no reliable data on mother to child transmission rate.

Prevalence among children has been measured in two population-based studies. In a first study conducted between 2003-2006 a weighted prevalence of 0.2% was found (25). In the latest study conducted between 2014 and 2017 there were no HBsAg positive cases [manuscript in preparation].

Vaccination

An effective vaccine is available and has been part of the recommended standard vaccinations for infants, children, adolescents and adults with certain indications since 1995. However, vaccination coverage among children is still below the target of 95%, ranging between 85% and 88% among children in the last years (28, 48, 49).

In some indication groups the vaccination coverage is still low, like for example among men who have sex with men vaccination coverage is below 60% (50).

Harm reduction: Number of needles and syringes distributed per person who injects drugs

According to a nationwide survey in 2022 to low threshold harm reduction services, on average, 127 needles and 84 syringes per PWID were distributed via the participating services to their clients in 2021 (30). Compared with a first round of the survey in 2018 we found even a decrease in the numbers of needles/syringes distributed to PWID (30, 51).

There was large heterogeneity across Federal states: The WHO 2020 target for needles and syringes, was reached by 6 and 4 Federal states in the 2021 survey, respectively.

The current national estimates and changes from 2018 to 2021 for drug paraphernalia distribution seem far from meeting the WHO target. Reasons could include a change in drug consumption behaviour towards less injecting use and more inhaling, and effects of the COVID-19 pandemic (supply difficulties, social distancing, lockdown, reduced opening hours of services).

RKI did not consider distribution of sterile equipment via pharmacies in the last two survey rounds. A new survey on needle and syringe distribution via pharmacies is being conducted in 2024.

Harm reduction: Coverage (%) of opioid agonist therapy (OAT) among PWID

The coverage of OAT among PWID in Germany was estimated at 49% [48-49%] by EMCDDA, based on published number of opioid-dependent (n=166.294) (38); and number of people in OST, 2021 (n=81.300). The WHO 2020 target of 40% of PWID in OST was reached (31).

Testing and treatment

Proportion diagnosed with HBV and HCV infection

Data from a systematic review indicate that in large screening studies 2012-16 in A&E units and GP practices 15-66% of HBsAg-positive patients knew about their Hepatitis B infection and that 35-86% of anti HCV+ and 48-81% of RNA-positives knew about their HCV infection (32).

Since October 2021, a new once-in-life screening programme for HBV and HCV in the frame of a general health check-up for adults aged 35 years+ was introduced. It seems that more patients from the general population are being diagnosed, however, an evaluation of this programme is planned by the RKI, but not yet funded (52).

Number of people under HBV treatment

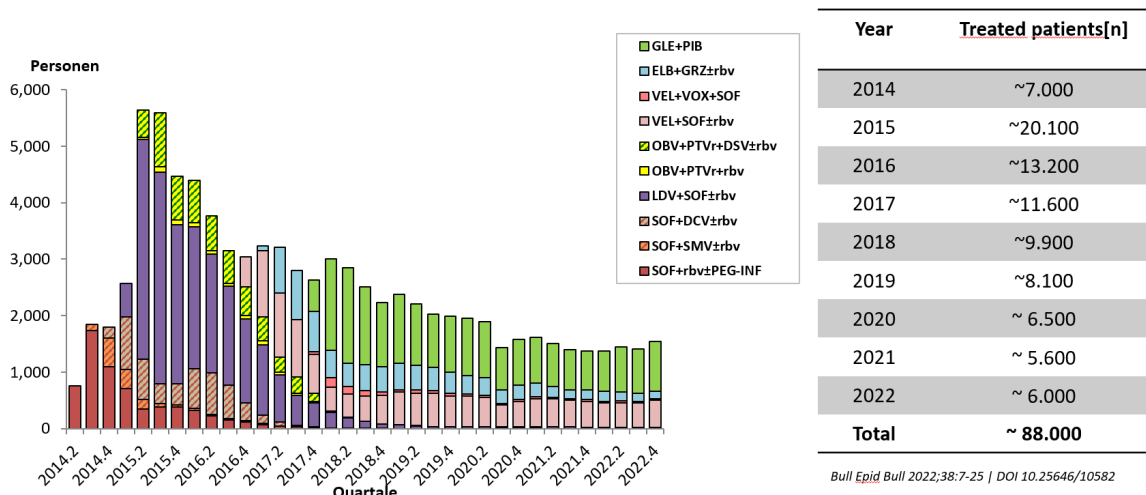
RKI provide yearly estimates of the number of people treated with nucleos(t)ide analogues (NUCs) from pharmacy sales data. These data contain package numbers of all medications prescribed for persons covered by statutory health insurance in Germany (covering about 85% of the population) by substance. There is a continuous steady increase of number of people receiving hepatitis B therapy in Germany. The average number of patients being treated was 14.453 per month in 2008 increasing to 24.868 per month in 2019 and to 31.400 in 2022 (33).

Number of people annually treated for HCV

RKI provide yearly estimates of the number of people treated with direct acting antivirals from pharmacy sales data. These data contain package numbers of all medications prescribed for persons covered by statutory health insurance in Germany (covering around 85% of the population) by substance. The number of people treated is

calculated by the number of packages and standardised treatment duration according to clinical guidelines (35, 36). The course of DAA prescriptions and the estimated number of people treated is shown below (Figure 6).

Figure 6. Number of people treated for hepatitis C, 2014-2022, Germany



Source: RKI

Treatment numbers have decreased during the pandemic and do not seem to have increased sufficiently since.

According to the modelling study for 2020 (based on back-calculation of surveillance and survey data and expert opinion) the proportion of people diagnosed with HCV among those infected in 2020 was estimated at 37%, 11% of those diagnosed with HCV were treated, and of those treated 97% were cured (34).

There is concern that in particular groups at increased risk, e.g. PWID, vulnerable migrant populations, the homeless, and people in prisons have limited access and encounter various barriers to access HCV treatment (53). Those without health insurance do not have access to HCV treatment.

In the 2021/22 DRUCK 2.0 pilot IBBS among PWID, of 435 PWID with previous or current HCV, 196 (45%) reported ever or current treatment. RKI found heterogeneity across study sites. This study only included recent injectors (having injected within the last 12 months).

Limitations: Constructing a cascade of care out of a cross-sectional IBBS study with a mixture of self-reported and testing data is challenging and overestimates the proportion of diagnosed and treated, as different infection episodes cannot be captured (23).

Conclusion

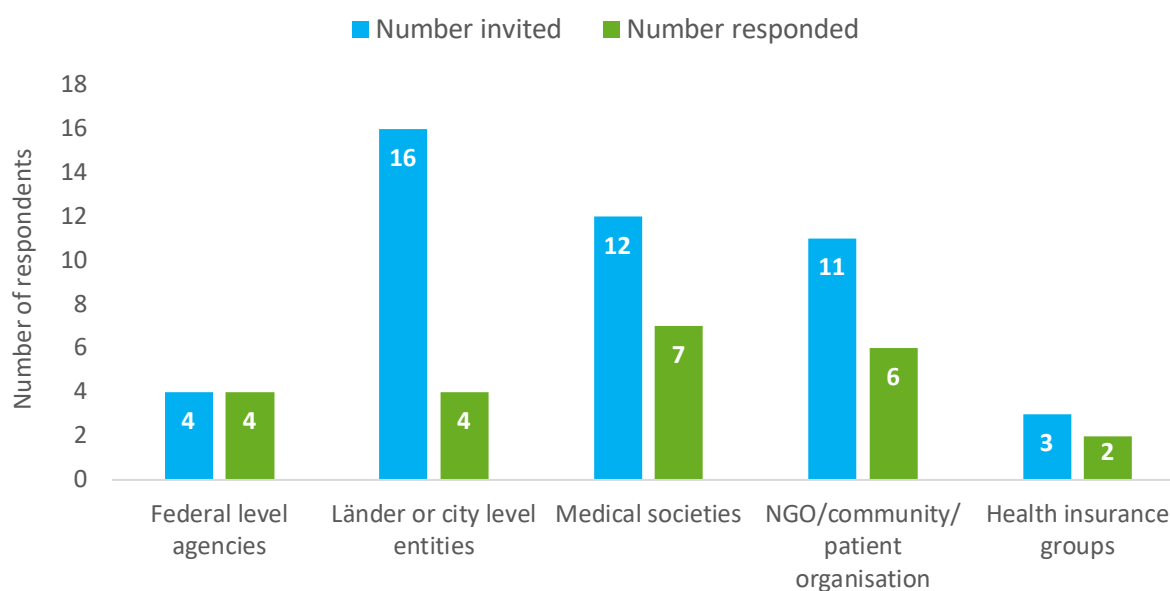
For viral hepatitis B and C, Germany is a country with concentrated epidemics in key-populations like migrants from higher burden countries, people who inject drugs, and other subgroups at increased risk. Insufficient data are available to fully assess burden, prevention and especially progress toward the testing and treatment targets in respect of general and key-populations. For people in prisons, specific migrant groups, people experiencing homelessness up to date data are lacking at all. Incidence and mortality data to measure impact are not available. While prevention targets partly seem to be on track, testing and treatment are lagging behind.

5 Findings

This section reports on the findings from the stakeholder survey and the country mission, supplemented with information and data from the desk review and situation analysis. The findings are structured according to the BIS 2030 strategy's five areas of action, with each section covering the three main questions asked of all stakeholders interviewed by the mission team during the in-country visit (what is working well, what are the main challenges and what changes would be needed to strengthen implementation of the strategy, see also section 3.3).

An overview of the organisations who responded to the **stakeholder survey** is provided in Figure 7 (see also 3.1). The response rate was highest for the Federal level agencies, followed by health insurance groups, NGOs/community organisations and medical societies while the Federal states (Länder) had the lowest response rate. A full list detailing the names of each invited and responding organisation is provided in Annex 1.

Figure 7. Stakeholder survey response overview, by stakeholder category



5.1 Creating an enabling environment

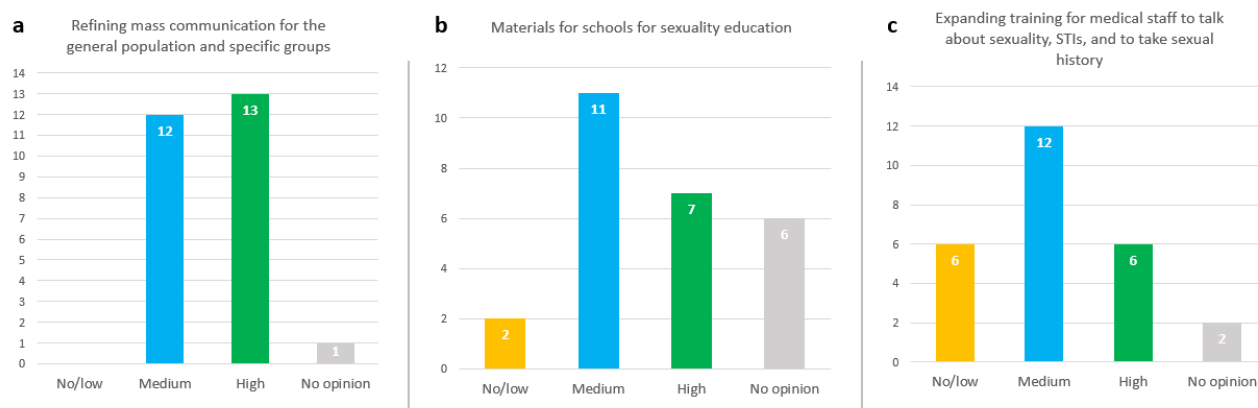
The first area of action of the BIS 2030 strategy focuses on creating and enabling environment, focusing on a) the need to **remove the taboo from sexually transmitted infections** by reducing shame, promoting open communication and increasing knowledge around HIV, hepatitis B and C, and other STIs; and b) the importance of **reducing stigmatisation and discrimination** to accept diversity and safeguard the rights of those concerned.

5.1.1 Findings from the stakeholder survey

As of 2023, 31% of respondents agreed that national, regional, and local efforts to create an enabling environment have generated satisfactory results and/or impacts, while 58% only partially agreed, and 11% did not agree.

With regards to **removing the taboo from STIs**, the BIS 2030 strategy proposes to: a) refine mass communication for the general population and specific groups, b) draft and provide materials for schools for sexuality educations, and c) expand the basic and further training available to the medical profession and medical staff to make it easier to talk about sexuality and STIs in the doctor-patient relationship, as well as to draw up materials enabling a better sexual medical history to be drawn up. The survey showed that some action has been taken to refine mass communication for the general population and specific groups (with 12 respondents reporting medium action, and 13 reporting high action (Figure 8a). According to 2 respondents, no to low action has been taken to draft and provide materials for schools to deal with the topic within sexuality education, while 11 respondents believe medium action has been taken and, 7 respondents reported high action (Figure 8b). On the other hand, less action has been taken towards expanding training for medical staff to talk about sexuality, STIs, and to take sexual history (with 6 stakeholders reporting no to low action, 12 reporting medium action, and 5 high action) (Figure 8c).

Figure 8. Survey responses on extent of action taken* to remove taboo from STIs: three interventions (a-c)

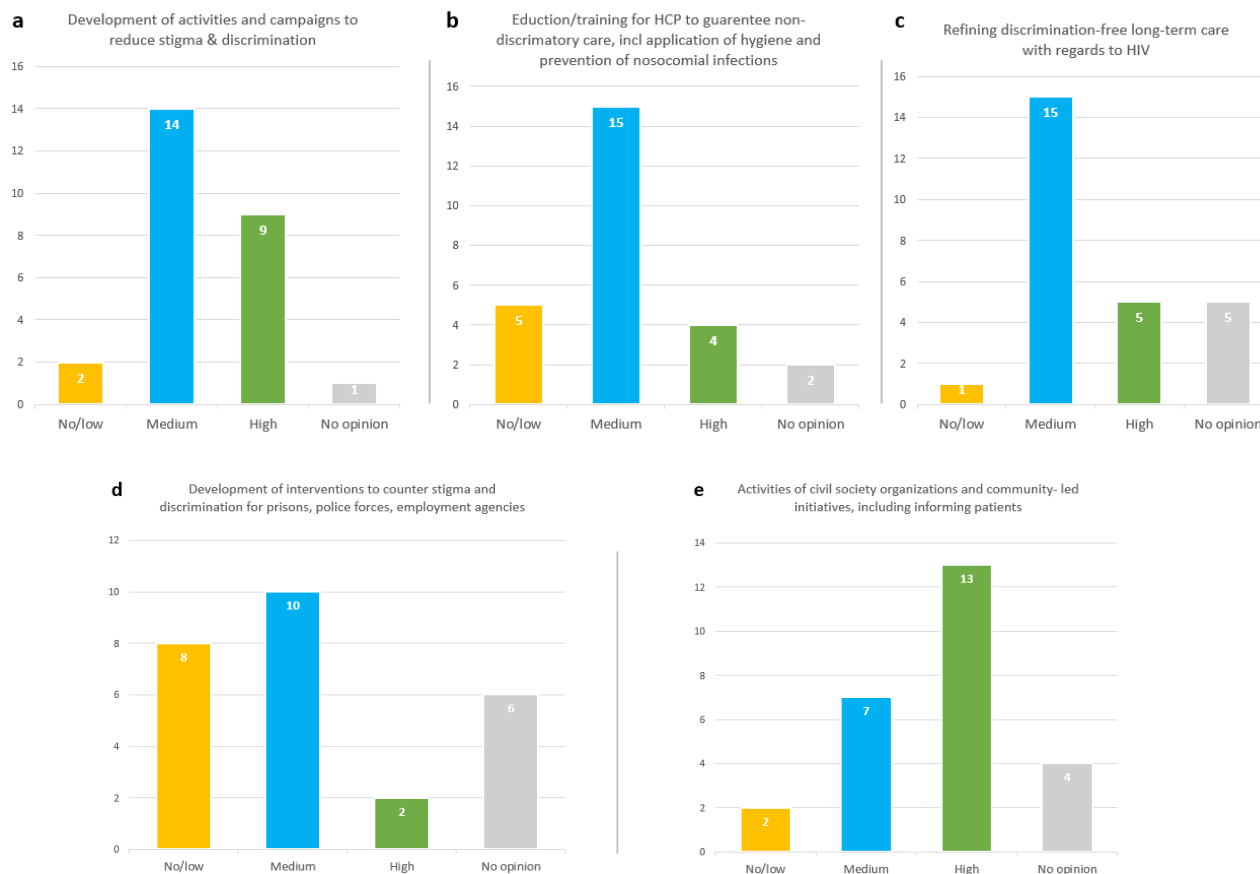


* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation (response scale 0–5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0–1); medium degree of action taken (2–3); high degree of action taken (4–5).

In relation to **reducing stigmatisation and discrimination**, the BIS 2030 strategy proposes the following interventions: a) continue and refine activities and campaigns to reduce stigma and discrimination; b) continue and create additional further training for healthcare providers to guarantee non-discriminatory care, including the application of hygiene and prevention of nosocomial infections; c) refine discrimination-free long-term care with regards to HIV; d) develop interventions to counter stigma and discrimination in institutions such as prisons, police forces and employment agencies; and e) continue the activities of civil society organisations and community-led initiatives, including informing patients. The survey showed that activities and campaigns to reduce stigma and discrimination have been developed to a medium/high extent (2 respondents reported no/low action, 14 reported medium action, and 9 reported high action) (Figure 9a). Within the healthcare sector, education and training for healthcare providers to guarantee non-discriminatory care have been implemented to a medium degree (Figure 9b). Similarly, in terms of refining discrimination-free long-term care with regards to HIV, medium action has also been taken (Figure 9c). However, within institutions such as prisons, police forces, and employment agencies, fairly low action has been taken towards developing interventions to counter stigma and discrimination, with 8 stakeholders reporting no/low action, 14 reporting medium action, and only 2 reporting high action (Figure 9d). This could suggest that more work should be done within these institutions. On the other hand, the activities of civil society organisations and community-led initiatives have contributed to reducing stigma and discrimination to a medium/high extent, with only 2 stakeholders reporting no/low action, 7 reporting medium action, and 13 reporting high action (Figure 9e). This suggests that civil society and community-led organisations have been particularly engaged in efforts to reduce stigma and discrimination.

Figure 9. Survey responses on the extent of action taken* to reduce stigma and discrimination: 5 interventions (a-e)

* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation



(response scale 0–5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0–1); medium degree of action taken (2–3); high degree of action taken (4–5).

5.1.2 What is working well

During the mission, several stakeholders mentioned that the BIS 2030 strategy has been helpful for local stakeholders to seek funding and advocate for political support, and some major city health departments are well positioned to promote and create an enabling environment encompassing acceptance of sexual diversity and addressing intersectional risks.

Blood donation laws have become less discriminatory and do no longer exclude MSM from being donors.

Additionally, among migrant communities, the availability of HIV self-testing has increased the opportunity to talk about testing. In some regions, trainings for healthcare providers and medical students on sexuality, LSTBQ*-inclusive sexual history taking and sexual/gender diversity have been implemented by NGOs and included in the curriculum for medical students in some universities, mainly implemented by DAH through a programme support by BZgA.

5.1.3 Challenges identified

Despite some shifts towards creating an enabling environment, HIV-related stigma persists and remains a key challenge, in particular in healthcare settings and migrant communities (see 4.3). Knowledge about HIV is generally good in the general population but considerably lower for other STIs (54, 55). The mission heard about increasingly unfriendly attitudes in some segments of the general population toward MSM and gender diverse people, adding barriers to acceptance and openness. According to the Federal Centre for Health Education (BZgA), funding to sustain some of the existing mass communication campaigns has been substantially reduced.

General capacity and motivation among healthcare providers and physicians to address or talk about sexuality issues is low. In part due to the lack of financial incentive to do so as sexual health counselling, sexual anamnesis, or the testing of asymptomatic STIs are not reimbursed, thus not adding motivation or favouring an enabling

environment. Low awareness among prison staff and to some extent prison healthcare providers of blood borne infections and sexual/gender diversity issues is another area needing improvement (see also 5.2.3).

Transgender issues are often not well understood or addressed in a comprehensive manner, neither by healthcare providers nor in many communities. There is a need to address issues around communication and use of terminology around and with transgender and non-binary people, and it would be ideal if service providers would also represent TG people for clients to feel more understood.

5.1.4 Priority actions

- Existing efforts to address and monitor HIV-related stigma and discrimination in healthcare settings should be continued and reinforced. Trainings on sexuality, sexual diversity and intersecting stigma should be continued and expanded throughout the country, covering non-HIV specialists (GPs, gynaecologists, dermatologists, dentists, prison settings, public health services (ÖGD) etc.) as well as medical students, also utilising new models for health education (e-learning).
- Increase awareness of HCV (testing and treatment) among non-specialists, including GPs and others who conduct the 'Check-up 35+' screening as well as prison health staff.
- Efforts to enable LSTBIQ*-inclusive sexual health counselling in medical provider-patient communication should be expanded.
- Ensure that non-HIV medical specialists are well aware that people with undetectable viral loads do not transmit HIV (U=U). Also ensure that U=U messages are included in information campaigns targeting young people and school settings and that websites of medical associations, university hospitals, etc. actively highlight U=U.
- Consider targeting communication and awareness efforts more – focusing on healthcare staff, adolescents and young adults (schools and virtual world), prisons, law enforcement and other authorities.
- Involve the relevant stakeholders in development of training materials (e.g. community representatives, medical societies, MoJ (Federal and/or Länder levels), and others).
- Increase knowledge among migrant communities of blood borne and sexually transmitted infections, including self-testing, PrEP, U=U and hepatitis vaccination and treatment. Increase peer involvement to decrease stigma & discrimination against people who use drugs, prisoners, homeless people and migrant communities.
- Involve community representatives when designing and delivering needs-based services for key populations, considering, for example, population-specific representation among staff, availability of services in relevant languages and culture-sensitive service provision.
- Consider undertaking a broad review of laws and regulations to remove discriminatory legislation related to HIV or other infections, for instance in the fields of employment, insurance, sports, and public services. Experience gathered through a similar exercise conducted by the Spanish Ministry of Health could be consulted. Documents published under the UNAIDS 'Global Partnership for Action to Eliminate All Forms of HIV-Related Stigma and Discrimination' might also serve as inspiration (56).

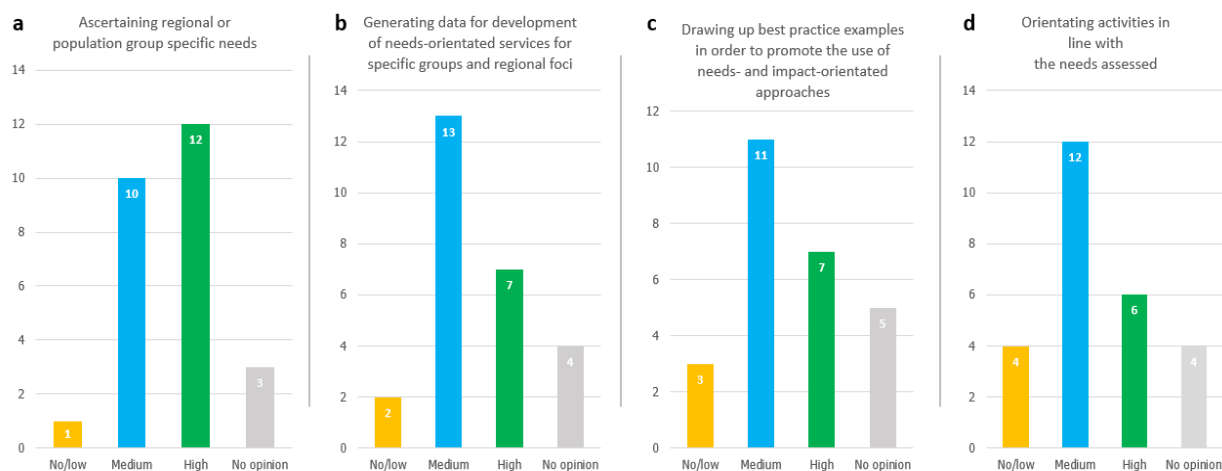
5.2 Further expansion of demand-oriented services

Prevalence and incidence of HIV, hepatitis B and C and other STIs vary across population groups and geographic regions in Germany. To achieve greater impact and be able to respond to the specific needs, vulnerabilities, and risk factors of different population groups, the second action area of the BIS 2030 strategy focuses on expanding demand-oriented services with a **focus on specific populations**, specifically young girls, adolescents, MSM, PWID, migrants, sex workers, transgender communities, pregnant women, and prisoners, as well as a **focus on specific regions** in Germany.

5.2.1 Findings from the stakeholder survey

As of 2023, 21% of respondents agreed that national, regional, and local efforts to further expand demand-oriented services have generated satisfactory results and/or impacts, while 71% partially agreed, and 8% did not agree.

To further expand demand-oriented services, the BIS 2030 strategy proposes to: a) ascertain regional and/or group-specific needs; b) generate data for the development of needs-orientated services for specific groups and regional foci; c) draw up best practice examples to promote the use of needs- and impact-oriented approaches; and d) orientate activities in line with the needs assessed. According to the survey results, medium (10 respondents) to high (12 respondents) action has been taken by relevant stakeholders to ascertain the regional or population group specific needs, (10a). However, in response to such assessment, respondents believed that action has been taken only to a medium extent for the analysis and evaluation of existing data for the development of needs-oriented services (10b), to drawing up best practice examples to promote the use of needs-and impact-oriented approached (10c), and to orientating activities in line with the needs assessed (10d).

Figure 10. Survey responses on the extent of action taken* to further expand demand-oriented services: 4 activities

* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation (response scale 0-5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0-1); medium degree of action taken (2-3); high degree of action taken (4-5).

The strategy details further actions to be taken within specific population groups. In the **general population**, the knowledge about protective behaviours, and about HIV, viral hepatitis, and other STIs should be established and expanded. According to the survey responses, this has been expanded to a medium extent, with 17 stakeholders reporting medium action and 7 reporting high action (Figure 11). The strategy also indicates that freely accessible educational media on HIV and other STIs, prevention services on social media, and quality-assured sexuality education in schools should be made available to **adolescents and young people**. According to the survey, this has been achieved to a medium to high extent. **Pregnant women** should also be targeted, in particular with regard to adjusting and taking into account new medical knowledge, such as in the refinement of the Maternity Directive. The survey suggests that action is being taken towards this, with 2 stakeholders reporting no action, 7 reporting medium action and 10 indicating high action. In the case of **migrants**, the strategy advocates for culturally sensitive, appropriate prevention, advice, testing and care services on HIV, viral hepatitis, and other STIs. Low-threshold, culture-sensitive information portals in different languages, culture-sensitive advice and care services, as well as the increased use of interpreters would further reduce existing obstacles. According to the survey responses, medium action has been taken towards offering culturally sensitive and appropriate prevention, advice, testing, and care services, with 4 respondents reporting no/low action, 14 reporting medium action, and 6 reporting high action (Figure 12). Similarly, 2 respondents reported no/low action towards providing low-threshold and culture-sensitive information portals, advice, and care services in different languages, 15 reported medium action, and 5 reported high action. However, the opinion on the increased use of interpreters seems to be varied, with 9 stakeholders reporting no/low increased use, 7 reporting medium increased use, and 8 reporting high increased use.

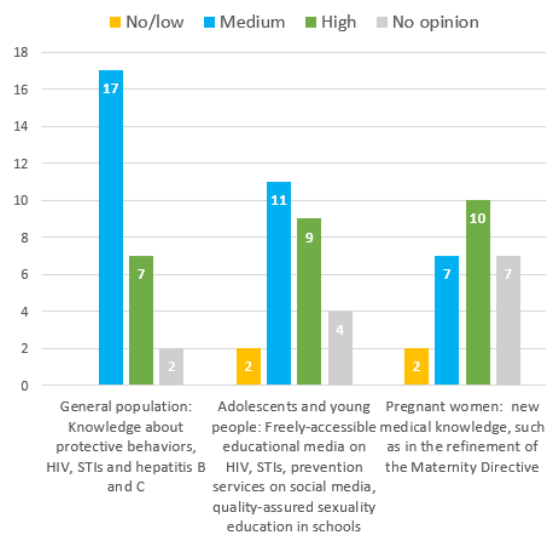
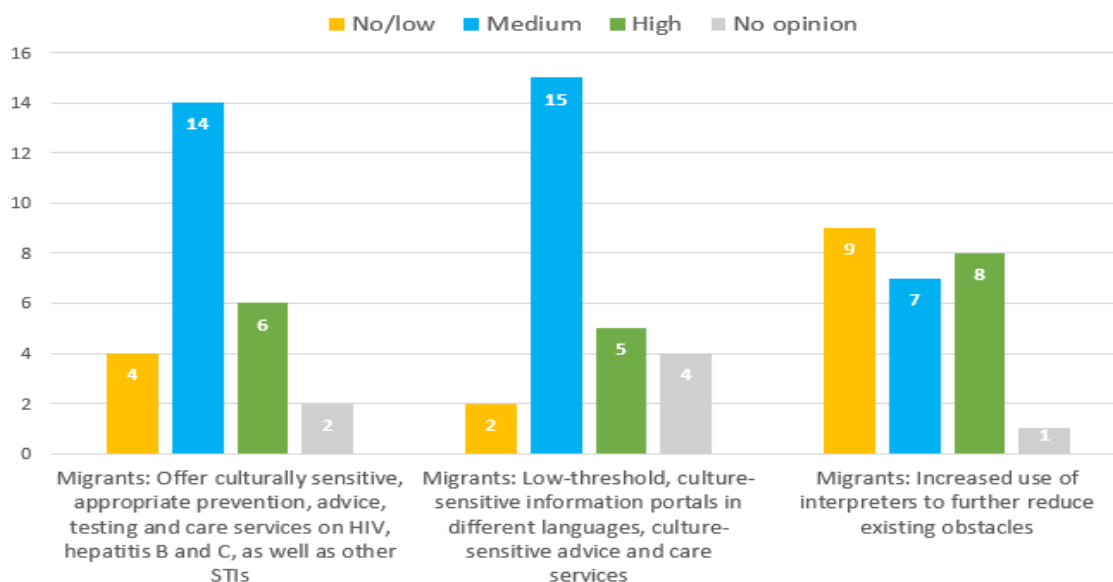
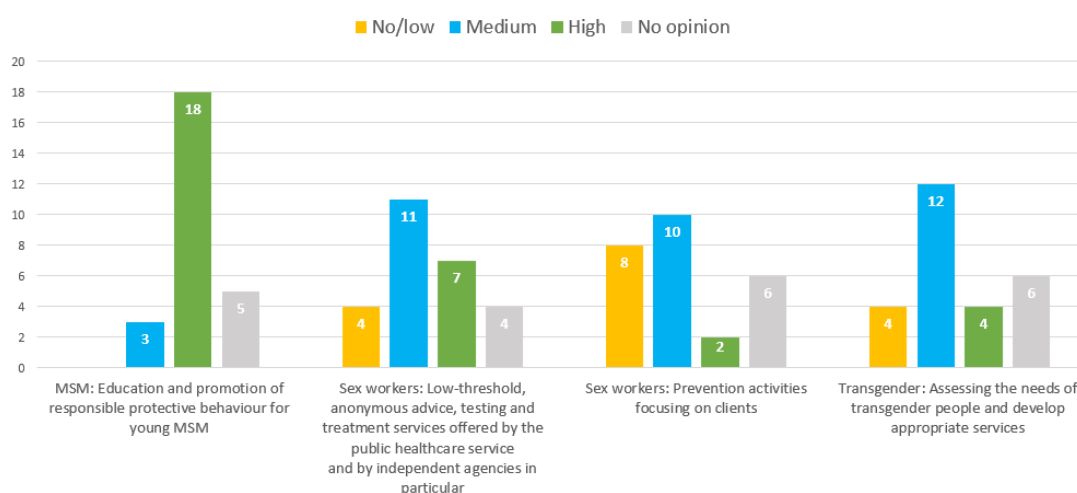
Figure 11. Survey responses on the extent of action taken* to further expand group-specific service needs: general population, adolescents and young people, and pregnant women

Figure 12. Survey responses on the extent of action taken* to further expand group-specific service needs: migrants



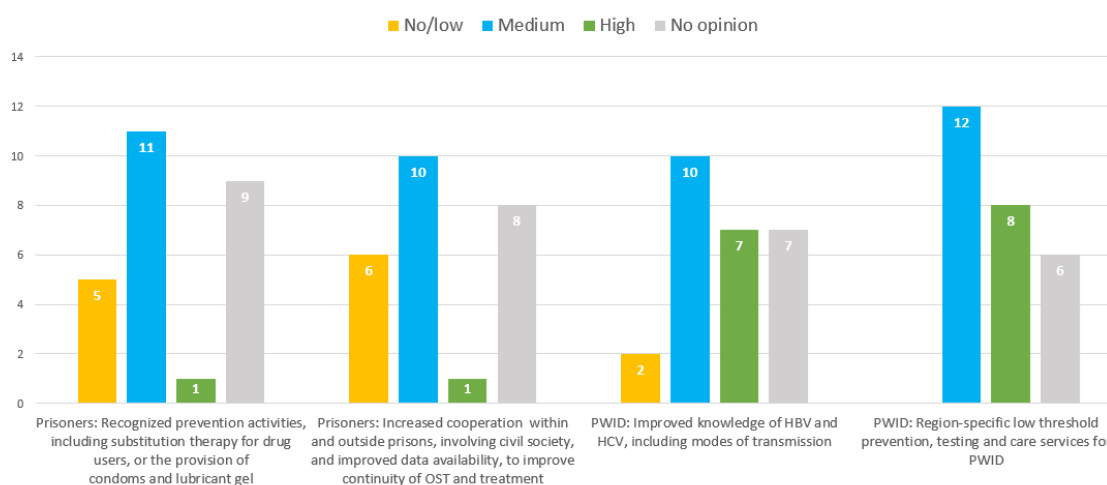
* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation (response scale 0-5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0-1); medium degree of action taken (2-3); high degree of action taken (4-5).

In Germany, **men who have sex with men (MSM)** constitute the largest group of people living with HIV. According to the BIS 2030 strategy, knowledge about HIV and other STIs, as well as the protective behaviour of MSM, remains at a high level as a whole. However, the strategy highlighted the need to place a special focus on the education and promotion of responsible protective behaviour for young MSM. Among the stakeholders who responded to the survey, there was a general agreement that action is being taken to a high extent towards this (Figure 13). The BIS 2030 strategy highlights the need for **sex workers** to be offered low-threshold, anonymous advice and testing services by the public healthcare service and by independent agencies. According to the survey results, this has been carried out to a medium extent. The strategy also highlights the need to include clients in prevention activities. This has been accomplished to a low to medium extent, suggesting the need to continue the focus on clients. With regard to **transgender people**, little was known at the time of the BIS 2030 strategy as to the prevalence of HIV infections, viral hepatitis and other STIs, or about the risks of, and the need for, prevention and care. The strategy thus encouraged to assess the needs of this population group and develop appropriate services. According to the survey results, this has been accomplished only to a medium extent (Figure 13).

Figure 13. Survey responses on the extent of action taken* to further expand group-specific service needs: men who have sex with men, sex workers, and transgender people

* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation (response scale 0-5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0-1); medium degree of action taken (2-3); high degree of action taken (4-5).

There are particular challenges in **prisons** with regard to the prevention and care of HIV, viral hepatitis, and other STIs. Higher prevalence rates among prison inmates compared to the overall population is caused, among other things, by the large share of people who inject drugs (PWID) among prisons. The BIS 2030 strategy recommended a) recognised prevention activities, including substitution therapy for drug users, and the provision of condoms and lubricant gel, as well as b) increased cooperation within and outside prisons, involving civil society, and improved data availability to improve continuity of OST and treatment. Based on the survey results, both recommendations have been achieved to a low to medium extent, with only one respondent in both cases reporting high action (Figure 14). This suggests that more work should be carried out within the context of prisons. When it comes to **people who inject drugs** (PWID), the strategy highlighted the need to improve their knowledge specifically on viral hepatitis. This has been achieved to medium to high extent. The strategy also recommended the continuation and expansion of region-specific, low-threshold prevention, testing, and care services for PWID. Similarly, the survey showed that medium to high action has been taken to achieve this, with 12 respondents reporting medium action, and 8 respondents reporting high action (Figure 14).

Figure 14. Survey responses on the extent of action taken* to further expand group-specific service needs: prisoners and people who inject drugs

* Degree of action taken by the relevant stakeholders in Germany, from the point of view of the responding organisation (response scale 0-5; 0 being no action and 5 being the highest possible amount of action): No/low action taken (0-1); medium degree of action taken (2-3); high degree of action taken (4-5).

5.2.2 What is working well

Germany has a strong system in place to provide prevention, testing and care services for **MSM** – the population group accounting for the majority of new HIV diagnoses up until 2022 when notifications due to heterosexual transmission increased sharply following a high number of refugees from Ukraine testing positive upon arrival to Germany. Most major cities have checkpoints or similar community-based services available that offer MSM friendly counselling, social support, testing and prevention services. Deutsche Aidshilfe and other organisations provide instrumental work to promote prevention of HIV and other STIs for key population groups at the national and regional/local levels. In addition, around 130 regional AIDS service and other DAH member organisations offer information, counselling, support and testing services throughout the country. As a result of combined efforts, including early initiation of HIV treatment and the roll-out of PrEP, new HIV diagnoses among MSM have decreased since 2014.

There are several good examples of community-based low-threshold services being available for other key populations, for example outreach services for **sex workers**, culturally sensitive services for **migrants** and integrated low-threshold services for **people who use drugs** with consumption rooms and peer outreach including testing – many of which have the potential to serve as model project for scale-up in other regions and settings (Box 1). Also, migrants from Ukraine are covered by the statutory health insurance and have easy access to the healthcare system.

Box 1. Good practice example of a community-based service for people who inject drugs (Vision e.V., Cologne)

Vision e.V is a non-governmental community organisation working with and for people who use drugs and particular vulnerable populations to make harm reduction services available and reduce stigma. They provide harm-reduction and social services, including needle and syringe-exchange, substitution therapy and safe drug consumption rooms. Vision e.V. also provides peer-to-peer outreach with very promising results in case finding of hepatitis C. Staff members together with a peer person reach out to hot spots for drug consumption and homeless people to provide support services, including viral hepatitis testing. Via the peer-outreach testing, the project tested 87 people for hepatitis C among whom 26 were positive (positivity rate of 30%) and 16 received treatment.

Prison settings offer an excellent opportunity to address the prevention and control of infectious diseases among an often underserved and most at-risk population group in a cost-effective manner, as all prisons could in principle provide free of charge testing and treatment, including OST, syringes and vaccination for HBV. There are positive examples where hospital prisons have negotiated and increased medicine budget to cover DAA treatment for hepatitis C (Box 2).

Germany has implemented many successful national campaigns to increase knowledge of HIV and STIs for **young people** and the general population, focusing mainly on chlamydia and HPV (the latter to increase vaccination uptake). Resulting knowledge levels are higher for HIV than for STIs.

Box 2. Good practice example from Berlin State Prison Hospital of the Plötzensee Correction Facility

The Plötzensee Correction Facility in Berlin has a hospital department serving several prisons within and outside Berlin. Prisoners do not have health insurance while in prison, where health expenses are covered under the budget of the relevant (Länder specific) Ministry of Justice.

In 2021, the hospital employed an infectious diseases specialist to improve testing and treatment of infectious diseases, in particular HIV, Hepatitis B and C and TB. The hospital approached the local government and got permission to increase the budget for medicine to include DAA treatment. OST is also offered. The hospital has introduced a policy that all inmates requiring treatment for HCV are offered it if they are imprisoned for more than 6 months. This time restriction is enabled for people to be able to finalise the treatment as linkage to care outside of prison settings is still an area requiring more collaboration between stakeholders.

During a two-year period, 107 people received DAA therapy for their chronic HCV infection. 12 patients are missing SVR results at 12 weeks and for 1 patient the treatment was interrupted due to early release. The treatment success rate so far is 86%. Around 40-50 cases of TB are treated upon admission on an annual basis.

The infectious diseases specialist has been working on sensitising prison staff to increase test offers at admission. A lack of knowledge among providers as well as difficulties in recruiting qualified staff was raised as a concern. The introduction of HCV treatment has resulted in a higher acceptance rate of testing and has also been used as an opportunity for counselling on both hepatitis and HIV.

The hospital is struggling with data collection and the lack of a national reporting system. They try to get data from the laboratory to create their own overview in combination with the data on people receiving treatment. No resources or expertise are assigned for this activity to make sure that data can be used to inform action. Support from the Ministry of Health or other national structures would be greatly welcomed.

5.2.3 Challenges identified

The availability of demand-oriented services that meet the specific needs of different population groups is uneven across populations. This means that some groups are less likely to access the prevention, testing and treatment services they are in need of – notably so in rural areas. But even in some cities, people-centred services tailored to the needs of specific population groups are insufficient (or lacking), resulting in several remaining challenges.

An increasing proportion of new diagnoses in Germany are made among **migrants** (nearly half in 2022). The majority originate from sub-Saharan Africa (among whom most are infected heterosexually) but many also originate from other countries in western Europe (mostly MSM). There is insufficient availability of culturally and language sensitive services for migrant populations, including mobile MSM and sex workers. Existing checkpoints are often tailored to gay and bisexual men and many people belonging to migrant communities do not feel comfortable going there. Heterosexual migrants from sub-Saharan Africa are particularly difficult to reach as they are often not part of a community and few organisations work with this specific group, resulting in limited knowledge about HIV prevention, including PrEP. To reach the heterosexual migrant group, efforts should be mainly channelled through migrant communities, also as testing in primary practice could be challenging, while some MSM migrants might be reached by MSM friendly services.

Continuity of care is a challenge, notably for people living in rural areas or smaller towns with service availability constraints due to unaffordable cost of public transportation. Further, the BIS strategy does not address **tuberculosis** (TB) except in the international section – neither as a co-infection nor overall. However, the situation has evolved since the strategy was adopted as TB has become more prevalent, both among migrant communities and people who inject drugs. Multidrug resistant strains are also a new threat that has evolved notably with the increased influx of migrants from Ukraine. For this reason, there is a need for community-based services seeing migrant and people who inject drugs to also offer TB counselling and screening (or referral).

There is also insufficient availability of integrated services for **people who use drugs**, offering harm reduction services such as needle and syringe exchange, opioid substitution therapy, safe consumption rooms, testing, treatment and even HBV vaccination in one location.

The current Prostitution Protection Act has introduced compulsory health counselling for **sex workers** by health authorities. In addition, condom use is obligatory. Voluntary counselling and testing for STI is offered by the same authorities or sometimes even by the same healthcare workers. This has led to a decreased use of the voluntary counselling by sex workers. The planned new law prohibiting purchase of sex risks creating further barriers for reaching sex workers with prevention and control interventions. Not all cities have dedicated services for sex workers and therefore some will use checkpoints (if available) or general public health clinics (which are not specifically tailored to sex workers) instead. Knowledge about PrEP is limited, and an unmet need for PrEP has been identified by key stakeholders, particularly among sex workers without health insurance. In addition, many sex workers are migrants and do not have a health insurance coverage. There is a need for more services offering anonymous, voluntary, free of charge, multilingual, outreach services.

Services – both in clinical and community settings – and ability to cover demands for **transgender and gender diverse** people need to be strengthened, with services organised in a way that meet and understand the specific and comprehensive needs of this population group, preferably using an intersectional approach and organised in a peer-to-peer manner.

Prison health services are highly dependent on political support and priority settings in each region (Länder) and individual prison institution, resulting in great variation in service coverage and implementation, both for harm reduction, prevention, testing and treatment. Prevention services are not well covered which is a missed opportunity as the prison setting offers an excellent one-stop-shop opportunity to strengthen infectious disease awareness, screening, treatment and prevention, including vaccination for Hepatitis B. Needles and syringes are only available in one single prison for female inmates in Berlin, a reduction from 20 years ago when NSP were available in several (6-8) prisons. Hepatitis B vaccination and hepatitis B and C treatment is only available for long-term prisoners in many prisons, some of which have long waiting lists for HCV treatment, and regulations vary from prison to prison. Discrimination is also reported in some prisons, with inmates living with HIV or hepatitis rarely accepted to work in kitchen and housework settings although a ban has been recently lifted. A coordinated monitoring and reporting system is lacking, leaving Germany with no data on the burden of disease in prisons and implementation of disease control programmes across the country's prison system.

Access to STI testing for **young people** with or without clinical symptoms is another challenge. There is a general lack of STD clinics. Only some few dermatologists cover venerology; most do not actively offer STI diagnosis and

treatment, and those who do often have long waiting lists. Moreover, the cost of STI testing is only covered for symptomatic patients. Many young people therefore visit gynaecologists or checkpoints for STI testing but these are only available in major cities and are quite costly (some physicians ask up to 70€ for a simple chlamydia test). Local public health departments also offer testing, but some only offer HIV testing and not STI or hepatitis testing. The cost of testing is likely a significant barrier in increasing testing and diagnosis, in particular for vulnerable young people. The cost varies across cities and regions, depending on whether or not funding is available from the given city administration.

Across key population groups, a considerable – but unknown – number of people at increased risk of HIV, hepatitis B and C and other STIs (sex workers, migrants, ex-prisoners, people who use drugs, homeless and others) are left **without adequate health insurance** and therefore lacking access to essential services. This means that infections are left undiagnosed and untreated, leading to ongoing transmission in the society. The mission heard of different estimates: that the total uninsured population could be in the range between 100 000-300 000 and that the proportion of people without insurance was around 10% among clients seeking counselling in a single checkpoint and as high as 56% among homeless people in Berlin.

A general lack of binding **national policies and guidelines** is another challenge and source of frustration expressed by several stakeholders, leading to substantial inequities in the availability and access of services across Germany and leaving clinics much too dependent on regional and local policies and available funding. This challenge was specifically highlighted in relation to prison health and testing services where more national guidance and coordination was requested.

5.2.4 Priority actions

The following priority actions are proposed:

- Expand low-threshold prevention, harm reduction and testing services for underserved populations – notably migrants, sex workers, people who use drugs, prisoners, homeless, transgender and gender diverse people, including individuals without health insurance and public health services for those living in rural areas.
- Ensure that services are sensitive and tailored to the specific needs and vulnerabilities of each group – seeking to address the specific challenges outline in section 5.2.3 above and preferably organised in a participatory manner with the respective communities.
- Increase awareness about tuberculosis and integrate TB screening (or referral) into existing services where relevant, notably for migrants and people who inject drugs.
- Strengthen national guidance and steering in priority areas of the strategy.
- For prison settings specifically, there is a need to strengthen collaboration between the Federal Ministry of Health, Federal Ministry of Justice and justice ministries of the Federal states to ensure implementation of a minimum package of HIV, Hepatitis B and C and STI prevention, testing and treatment services with clear criteria in all prison settings. This would be in line with the *United Nations Standard Minimum Rules for the Treatment of Prisoners*, funded by the Government of Germany, which stipulates that 'prisoners should enjoy the same standards of health care that are available in the community (i.e. outside the prison setting) and should have access to necessary health care services free of charge without discrimination on the grounds of their legal status' (57). A joint ECDC/EMCDDA European toolkit on hepatitis B and C micro elimination in prisons will be published in 2024 which might serve as a source of inspiration. It is also proposed that the system for ensuring continuation of care after release be improved – either by automated re-activation of national health insurance after incarceration or a general expansion of health insurance to cover prison settings as well. Lastly, it is recommended to establish a mechanism to support implementation of a basic routine national prison health monitoring and reporting system which might be less costly than research studies in the long run.
- Continue and strengthen ongoing work to ensure that all people are covered by adequate health insurance, and no one is left behind, in line with the UN General Assembly Political Declaration on Universal Health Coverage (58). This may require revising legislation or implementing practical solutions at the local level (see also Box 4).

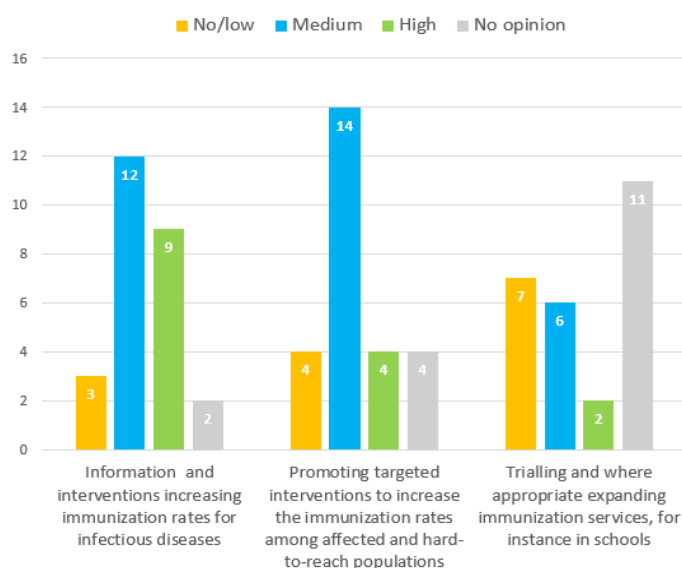
5.3 Refining integrated prevention, testing, and care services

The third area of action of the BIS 2030 strategy focuses on refining integrated prevention, testing and care services. The proposed interventions seek to 1) **reduce transmission**, 2) **increase diagnosis rates and reduce late diagnoses**, and 3) **refine care services** through interlinked, person-centred, gender-sensitive education, prevention, testing, treatment, and care services.

5.3.1 Findings from the stakeholder survey

As of 2023, 26% of respondents agreed that national, regional, and local efforts to refine integrated services have generated satisfactory results and/or impacts, while 63% only partially agreed, and 11% did not agree.

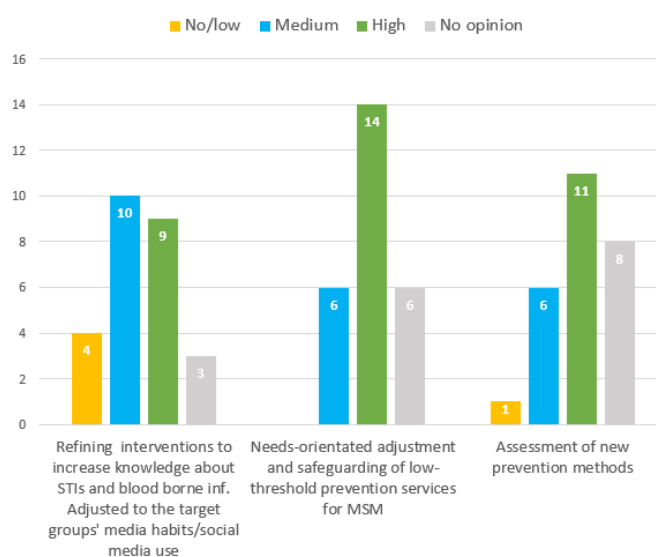
Figure 15. Survey responses to extent of action towards reducing transmission: three interventions



Regarding the **reduction of transmission**, the strategy laid down a series of interventions to be considered. The survey respondents shared their opinions on the extent to which these actions have so far been taken up. Developing information materials and promoting interventions for increasing the immunisation rates with infectious diseases that can be prevented through immunisation has been carried out to medium to high extent, with 3 respondents reporting no to low action, 12 respondents reporting medium action, and 9 respondents reporting high action (Figure 15). Medium action was reported regarding promoting targeted interventions to increase the immunisation rates among affected and hard-to-reach populations, while lower action was reported concerning trialling and, where appropriate, expanding immunisation services, for instance in schools.

The respondents of the survey reported higher action with respect to adjusting and refining the prevention interventions, adjusted to the target groups' media habits and the use of social media and apps, to increase the level of knowledge about sexually transmitted and blood borne infections, as well as the skills (Figure 16). While 4 respondents reported no to low action, 10 stakeholders reported medium action, and 9 reported high action. The intervention of making needs-oriented adjustments and safeguarding low-threshold prevention services for MSM was reported as the highest-ranking action, with 6 stakeholders reporting medium action, and 14 reporting high action. This is in line with the findings from Section 5.2, where MSM were also prioritised. Similarly, the respondents to the survey believed that medium to high action is being taken towards assessing new prevention methods, with 1 respondent reporting no to low action, 6 reporting medium action, and 11 reporting high action (Figure 16).

Figure 16. Survey responses to extent of action towards reducing transmission: three more interventions



The BIS 2030 strategy also defined a set of interventions that should be implemented to **increase diagnosis rates and reduce late diagnosis**.

According to the survey respondents, standards, recommendations, and guidelines for (regular) testing of the various infectious diseases have been updated and refined to a medium to high extent (Figure 17). The promotion of studies for evaluating new testing procedures and technologies has been carried out to a medium extent, with 5 respondents reporting no to low action, 10 respondents reporting medium action, and 3 respondents reporting high action. Studies to assess specific needs and approaches for optimising the testing and diagnosis services among specific groups have been promoted to a medium extent. Projects to monitor and evaluate target group-specific advice and testing service models have also been promoted to a medium extent, according to the survey results. The development and implementation of interventions, including information material for the medical profession, as well as patients, on specific STIs and blood-borne infections that aim to improve utilisation of testing and treatment services have been carried out to a medium extent by relevant

stakeholders, with 3 respondents reporting no to low action, 12 respondents reporting medium action, and 6 respondents reporting high action. Drawing up further training material for the medical profession has been carried out to no to a low extent according to 3 respondents, to a medium extent according to 13, and to a high extent according to 6 respondents. Lastly, training services offered by Medical Societies, Medical Associations, and independent agencies have been expanded to a medium extent, with 3 stakeholders reporting no to low action, 11 reporting medium action, and 6 reporting high action (Figure 17).

Figure 17. Survey responses to extent of action towards increasing diagnosis rates and reducing late diagnosis: seven interventions

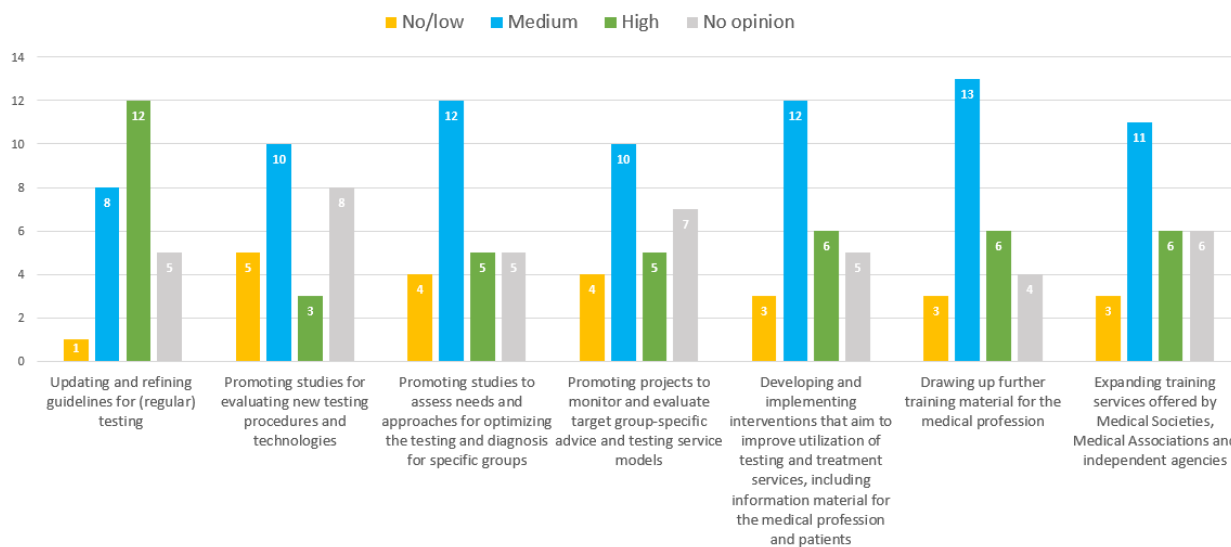
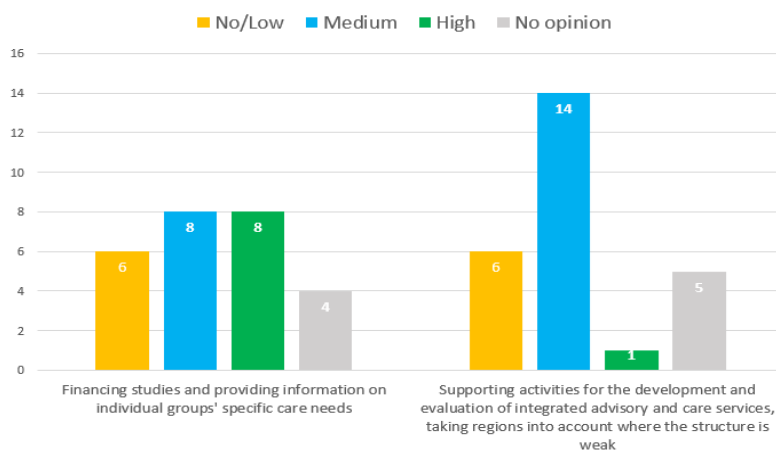


Figure 18. Survey responses to extent of action towards refining care services: two interventions



Lastly, concerning the **refinement of care services**, the strategy suggests that the interventions should be a) to finance studies and provide information on individual groups' specific care needs, and b) to support activities for the development and evaluation on integrated advisory and care services, taking regions into account where the structure is weak. The opinions of the respondents to the survey with respect to the first intervention are mixed, with 6 respondents reporting no to low action, 8 respondents reporting medium action, and 8 reporting high action (Figure 18). As to the second intervention, 6

respondents reported no to low action, 14 reported medium action, while only one respondent reported high action.

5.3.2 What is working well

This and the following sections of chapter 5.3 follow the same structure as the previous sections but reports some findings grouped into sub-sections covering prevention, testing and treatment & care – in line with the structure of the BIS strategy. However, cross-cutting findings covering across the continuum of care are highlighted in the beginning of each section.

While dedicated sexual health clinics are not widely available in the national healthcare system in Germany, there are some excellent 'good practice' model examples in place of facilities that provide integrated, cross-sectoral, low threshold services, including anonymous STI/HIV counselling, diagnostics, treatment and PrEP in one site. The mission visited the checkpoint in Berlin (Checkpoint BLN) (Box 3) and was informed about similar centres in

Bochum (Walk In Ruhr (WIR) Center for Sexual Health and Medicine) and Frankfurt am Main (Checkpoint Frankfurt) (59).

Box 3. Case example from Berlin (Checkpoint BLN)

Checkpoint BLN is a sexual health facility for gay, bisexual and other men who have sex with men, as well as trans*, inter* people and their sex partners. They provide PrEP, STI treatment, vaccination for hepatitis A and B, post-exposure prophylaxis (PEP) indication, PEP, medical advice, referral and care as well as needs-oriented adaptations of services such as translation and anonymous services. Given the comprehensive list of services available, Checkpoint BLN is perceived as a hub which is 'gluing the gaps'. It should be kept in mind though that the provision of all these services is made possible because physicians from private practices are working in the checkpoint – which is far from the case in all other checkpoints across the country. Also, Checkpoint BLN is in a favourable situation due to financial support from the Fast Track City Berlin programme.

A high proportion of clients belong to high-risk key populations, including MSM, young migrant men, sex workers and people with unstable housing situation. Checkpoint BLN has good quality data available on client flows, sociodemographic background on key populations, client drug consumption, experiences of buying and receiving payment for sex as well as testing rates and positivity rates (60).

Checkpoint BLN estimates that 10% of their clients are uninsured and that 50% of staff time is used to support people without health insurance through an access program for people living with HIV without adequate health insurance.

Checkpoint BLN also has an 'Anonymous Area' in their facility providing anonymous testing consultations, including testing for HIV, hepatitis and STIs, psychosocial counselling or counselling series on sexual health issues ('Talk simply'), PrEP consultations, and anonymous test consultations on TIN Day (Trans Inter Non-binary Day).

Checkpoint BLN data accounts for about 20% of all German data on HIV and STI testing in community based VCT centres (60).

The mission also visited two excellent examples of public health clinics ('Gesundheitsamt') in Hamburg ('Casablanca') and Cologne where comprehensive services were provided to people without health insurance (in addition to those with insurance) (Box 4).

Box 4. Good practice example from Cologne (Gesundheitsamt Köln, Fachdienst STI und sexuelle Gesundheit, Aidskoordination Köln)

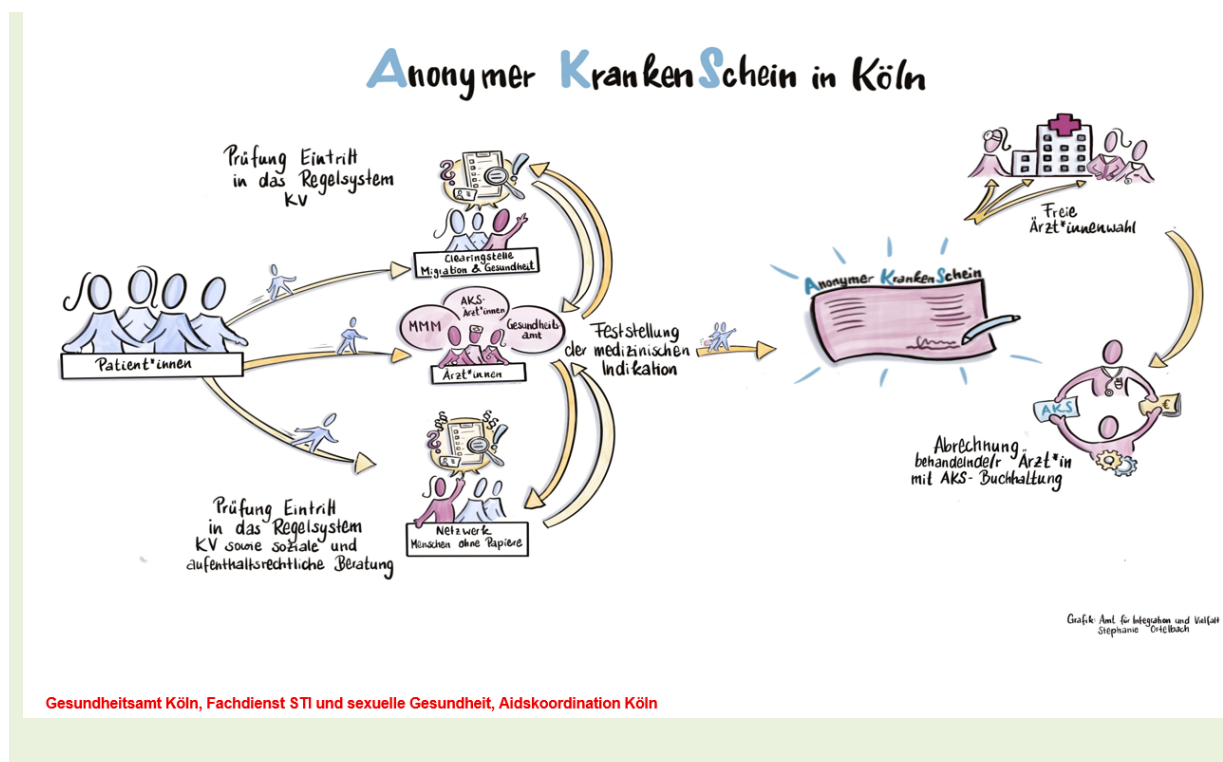
'Anonymous treatment certificate'

The 'anonymous treatment certificate' is a collaboration project on access requirements for health insurance in relation to treatment. Important to note is that existing structures continue to be used, no parallel mechanism was built for this purpose.

The person seeking advice gets checked and their HIV/hepatitis status confirmed by an advisor at the Migration Clearing Center/Network for people without papers. The person seeking advice then confirms that their main place of residence has been in Cologne for at least three months. The consultation investigates whether the person seeking advice has no short-term access to standard health insurance and that there is a financial need for support.

The patient gets examined by a doctor (Cologne Health Department/Malteser Medicine for people without health insurance) and if from a medical perspective, further medical treatment is necessary, the Cologne Health Department assumes the cost for treatment.

Ensuring medication for HIV by the Anonymous Treatment Certificate in 2024 identified four HIV-positive people with no short-term access to standard health insurance (patients from Romania, Ghana, Venezuela, Ukraine). The medical consultation cost was € 76.53 and the medication cost €3951.27.



Prevention

As outlined in section 5.2, the availability of prevention services varies by population group, by geographic location (by region, city and rural/urban area) and by setting (community-based, public health, private clinic, prison setting etc.). Community based prevention services are particularly well established for MSM and are available across most of the country, in particular in urban areas – but less available for other population groups and in rural areas.

New HIV infections among MSM have declined consistently since 2014 (with the exception of 2022 which likely reflects catching-up on diagnoses after the COVID-19 pandemic), which is believed to be the result of a combination of earlier HIV treatment initiation treatment and the roll-out of PrEP.

PrEP has become available under the statutory health insurance as HIV prevention for people at risk of HIV since September 2019. PrEP and PEP is also accessible in a few community-based organisations (in addition to being available in clinic settings).

There are good efforts taking place to increase HPV vaccination rates in some cities and regions and a national campaign seeking to increase vaccination coverage and reduce vaccine hesitancy is in place. That said, large variation in access and resulting vaccination coverage rates persists across the country.

There are also good structures in place to allow for efficient distribution of vaccines and implementation of vaccination for emerging infections (mpox, for example).

Testing

Testing is identified as a key focus area in the BIS strategy and also highlighted as such among stakeholders during the mission. Several positive improvements have been introduced since the release of the BIS strategy as described below.

In 2020, the physicians' prerogative 'Arztvorbehalt', which only allowed physicians to conduct HIV testing, was removed. This change has made it easier for community organisations to offer testing, as it is allowed for lay providers to conduct the screening testing in community settings. This is also in line with European and international recommendations.

Also in line with European recommendations, self-testing has become available in pharmacies for sale. It seems that more low-threshold testing services have become available in recent years, although the mission could not collect quantitative data on this. There are good examples of selected checkpoints for MSM with free tests and some examples of testing in harm reduction projects.

In 2021, the 'Check-up 35+' for HBV and HCV was introduced in healthcare settings, recommending all people over 35 to have a least one test for HBV and HCV during their lifetime when doing a medical check-up at their GP practice. Some data on the implementation of the 'Check-up 35+' are provided below (Figure 19).

Figure 19a. Implementation of the 'Check-up 35+', 2022

THU-168 Wiegand: Results of the hepatitis B and C screening within the "Check-Up35+" in the German primary care setting 1 year after implementation by the federal joint committee

Objective

To investigate the results one year after implementation of the structured screening program "Check-up 35+".

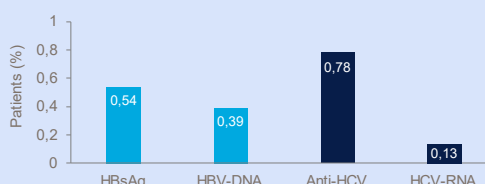
Method

- Investigation of the implementation of "Check -Up35+" in people aged ≥35 years at the primary care level in 11 ambulatory health care centers (October 2021 – September 2022)
- HBsAg and anti-HCV screenings were identified by the billing categories GOP 01865. The codes GOP 01866 and 01867 were used for HBV-DNA and HCV-RNA (PCR) reflex testing results in case of positive HBsAg and anti-HCV screening tests
- HBsAg and anti-HCV prevalence data of the prospective study period were retrospectively compared to a corresponding 12 months period prior to the COVID-19 pandemic (Oct 2018 – Sept 2019) and during the COVID-19 pandemic (Oct 2020 – Sept 2021)

Results

286,192 Lab requisitions | 56% ♀ | Median (SD) age: **61.2 (14.0)** years
44% ♂

Prevalence of patients with HBV and HCV infection



Adapted from Wiegand J, et al. EASL 2023 THU -168

Figure 19b. Implementation of the 'Check-up 35+', 2022

THU-168 Wiegand: Results of the hepatitis B and C screening within the "Check-Up35+" in the German primary care setting 1 year after implementation by the federal joint committee

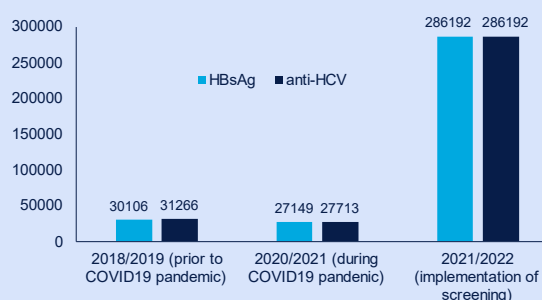
Results

Age category (years)	HBsAg		HBV DNA		Anti-HCV		HCV-RNA	
	Male	Female	Male	Female	Male	Female	Male	Female
35–44	1.00	0.66	0.86	0.52	1.11	0.58	0.24	0.08
45–54	0.88	0.55	0.66	0.43	1.19	0.70	0.24	0.10
55–64	0.61	0.43	0.45	0.30	1.00	0.76	0.14	0.10
65–74	0.55	0.47	0.36	0.33	0.73	0.67	0.09	0.10
75–84	0.26	0.32	0.16	0.17	0.53	0.64	0.10	0.11
>84	0.17	0.21	0.07	0.11	0.46	0.77	0.04	0.21

Data are %

The highest HCV-RNA prevalence was observed in young men and was 2.4–3 times higher than in young women

Number of Hepatitis Tests per Year



A structured hepatitis screening program at the primary care level could be successfully established and leads to a large number of tests within the first year of implementation

Adapted from Wiegand J, et al. EASL 2023 THU -168

Treatment

Germany is very well on track when it comes to providing HIV treatment to people living with HIV who have been diagnosed: 96% of those diagnosed are receiving antiretroviral therapy and 96% of those receiving ART have achieved viral suppression.

Guidelines for the treatment of HIV, hepatitis B and C and other STIs are in place and are regularly reviewed and updated by the relevant medical societies.

While not widespread, some very successful models of HCV treatment provision with high coverage exist in some selected prisons and OST centres in Germany but this is not the case in the majority of sites.

Treatment for STIs is generally provided in private or public health clinics only, however, some exceptional examples of STI treatment provision in community settings (a few checkpoints with physicians working on-site) are also available.

As HIV treatment eligibility criteria have expanded and PrEP been rolled-out, systems for monitoring the emergence of HIV and gonorrhoea drug resistance have been established to detect, prevent and minimise development and transmission of potential resistant strains.

5.3.3. Challenges identified

Despite the many positive developments and achievements made by Germany since implementation of the BIS strategy, challenges and service gaps remain.

Prevention

While new HIV diagnoses have declined among MSM over the past decade, the incidence of bacterial STIs has increased considerably since 2010 – notably among men/MSM – suggesting high levels of risk taking and low levels of condom use in certain groups of the population.

More than 98% of people accessing PrEP in Germany are MSM, highlighting the disproportionate levels of access to PrEP in this particular group compared with other groups in need. Yet, with an estimated 32 000 PrEP users by the end of 2022, the estimated PrEP need among MSM (between 52 000 and 66 000) remains only partially covered. Knowledge and awareness of and access to PrEP beyond MSM is low, particularly among sex workers, migrants, prisoners, people who use drugs and transgender and non-binary people (61-63). There are long and increasing waiting lists for accessing PrEP in many clinics and uneven access across the country. Existing capacity constraints are exacerbated by the complicated requirements for non-HIV specialists to prescribe PrEP. PrEP access is very medicalised in Germany based on special education rules given by the health insurances and the National association of statutory health insurances physicians. Also, people without health insurance do not have free access to PrEP. Since November 2023 Germany has experienced shortages of generic PrEP medication (which is also used for HIV treatment in some instances, notably for people without health insurance given the low cost of the drug), possibly related to gaps in the procurement or supply management chains.

Unfortunately, the mission could not meet a representative from the society for addiction medicine during the country visit. Although available studies suggest that OST coverage is reasonably high in the surveyed populations (61% (range: 53-65%) currently in OST among 582 PWID recruited in 20 low threshold drug services and five OST-practices in Berlin and Bavaria) (23), a national estimate suggests that only 49% of 166 000 opioid-dependent users in Germany (see section 4.2). While this is above the WHO 2020 target of 40%, it is much lower than in many other EU/EEA countries (for example Norway, Spain and France where 85% are substituted). Another challenge is getting OST institutions to offer integrated HIV, hepatitis and STI testing and treatment services beyond substitution.

HBV vaccination coverage stood at 87% for birth cohorts from 2012-2015 % (28, 49), somewhat below the WHO target of 95% for 2025. Among MSM, coverage was reported to be 60% (64) and among migrants, self-reported coverage was 40% (61, 62).

While consistently increasing since 2012, HPV vaccination coverage remains relatively low in Germany in comparison with other European countries with 51% of 15-year-old girls and 17% of boys having completed the final dose in 2020 and 67% girls versus 30% of boys having initiated the first dose (65).

Testing

Several challenges and remaining service gaps related to testing were identified as part of this assessment.

As outlined in section 4.3, there is a gap in reaching all people living with undiagnosed HIV, as currently only an estimated 90% of people living with HIV have been diagnosed. Also, there are indications that the estimated number of people living with HIV is underestimated, suggesting that the gap could be bigger. Furthermore, existing data show no decrease in the percentage of people diagnosed late over the last 10 years – and this is consistent across population groups. This is contrary to some other European countries that have seen a decrease in late diagnosis in particular among MSM where efforts have been focused on testing in checkpoints and in connection with PrEP. The stable number of people diagnosed late is an indication that the testing programme is not efficient enough in reaching people in need of testing, with many missed opportunities for testing, including in the healthcare system, and insufficient integration of testing for multiple infections in the same testing site.

There are some promising projects being carried out to implement routine testing for HIV and HCV in emergency department settings in large cities, however, the continued need for written consent poses a barrier for implementation of the project as an opt-out testing approach similar to what has been very successfully implemented in other European countries (66, 67).

A clear barrier to accessing testing is related to cost. During the mission, this was identified as an issue both for client-initiated and provider-initiated testing offers – and both in community and healthcare settings. In the vast majority of sites, including many checkpoints and other community-based testing sites, the mission was informed that there are cost for the test for both HIV and other STIs which creates a barrier for testing for vulnerable and low-income people at increased risk of infection. A key problem in healthcare settings is that testing for HIV and other STIs is only reimbursed for people with symptoms, an identified risk behaviour (e.g. a positive partner), who are using PrEP or for women younger than 25 years or pregnant (for chlamydia). This means that screening tests are not reimbursed which may lead to clinicians becoming more reluctant to offer testing. Further, many clients are unaware of their right to get tested for free even if they meet the eligibility criteria and, vice-versa, some non-HIV specialists are unaware that symptomatic tests should be offered for free, believing they will not get reimbursed and therefore not testing even symptomatic individuals for free – nor treating the partner.

In recent years, to make testing more accessible, all European and international guidelines and standards recommend that individualised pre-test counselling and written consent for HIV testing should no longer be required when undertaking HIV testing. Data shows that both measures create barriers for accessing testing as well as adding additional cost in terms of time and resources needed for the service or provider performing testing. Among stakeholders interviewed during the mission, there seems to be a continued insistence on pre-test counselling and written consent as a prerequisite for testing while European and international guidelines call for opt-out testing (in certain settings) and only pre-test information (1, 68). Implementation of international recommendations around pre-testing information is shown to minimise time needed for testing, make test offers in healthcare more attractive to health providers and support de-stigmatisation by normalising testing.

Finally, there is no systematic monitoring of public health testing programmes in place, and no appropriate surveillance tool for use in the testing sites, meaning that no coordinated structure is in place outside the checkpoints to systematically collect data on HIV testing and by indication and to evaluate whether testing programmes are (cost)effective or not. Also, no data are available on where the diagnoses are made (i.e. recording of the setting where first reactive test was performed among people diagnosed with HIV). Only limited attempts at implementing repeated surveys of testing coverage in low threshold community testing sites for MSM and people who use drugs are taking place. Laboratory surveys to obtain the number of HIV tests were conducted in the past but abandoned since labs could not differentiate between first positive test and repeat diagnosis. However, data from the health insurance system have been extracted once and will be done again in the future once consolidated health insurance data are available.

Treatment

Germany has observed a steady increase in number of people treated for HBV under the social health insurance, from 14 400 in 2008 to 26 700 in 2021, yet treatment coverage for those diagnosed remains below target. For hepatitis C, an estimated 88 000 people have been treated under the health insurance since 2014, with a peak in 2015.

However, data do not appear to be available to gauge to what extent these numbers cover the need. No estimates are available on the total number of people living with – diagnosed or undiagnosed – HBV or HCV infection, the proportion of people with chronic HBV or HCV who have been diagnosed nor the proportion diagnosed (and eligible, for HBV) who receive treatment. Mortality data, for example estimates of the number of deaths from liver disease that are attributable to HBV and HCV, are not available either, as described in a recent scoping review (32).

A key challenge in Germany is that many people at increased risk of, and living with diagnosed or undiagnosed, HBV, HCV and HIV are not currently covered by the health insurance. In addition to lacking data on the total number of uninsured people living in Germany, there are no estimates of the number of people in need of treatment (diagnosed or undiagnosed) who do not have access to treatment.

The fact that HCV is generally treated in specialised clinics or private practices pose a barrier for many people who inject drugs who may never turn up for care. The lack of integrated OST/HCV and other harm reduction services lead to reduced retention and treatment completeness rates.

In prison settings, data from a recent survey conducted by DAH suggest that HBV treatment is 'offered if required' in 41% of prisons and HCV treatment is offered 'if required' in 29% of prisons. The mission was also anecdotally informed of instances where HIV medications used inside the prisons differed from the regimens taken by the patient outside the prison.

Concerns about increasing levels of antimicrobial resistant gonorrhoea were raised by a few stakeholders, based on a 60% increase in cases with reduced susceptibility observed between 2021 and 2022 (from 0.5 to 0.8 per 100.000 population). Highest levels of resistance were reported in Hamburg and Berlin.

5.3.4 Priority actions

Based on the positive developments and the remaining challenges described above, several priority actions are proposed in the areas of prevention, testing and treatment.

- Across the continuum of prevention, testing and care, it is recommended to scale-up existing model examples of dedicated public and community-based sexual health clinics to provide integrated low threshold services offering STI/HIV counselling, testing, treatment and PrEP, including for those without health insurance.

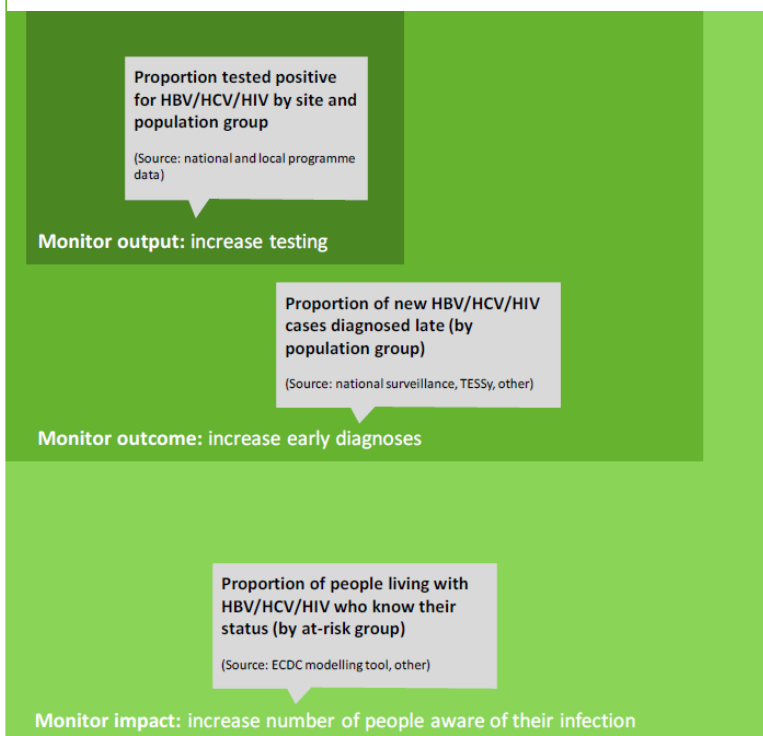
Prevention

- Ensure continued funding for prevention services and prioritise community-led prevention programmes. Allocate funding to serve the full range of population groups in need and design services to fit their specific circumstances and needs as described in sections 5.2.3 and 5.2.4.
- Expand access to PrEP beyond MSM; provide education and information about PrEP to groups at high risk of infection but with low awareness levels; address capacity constraints by easing requirements for non-HIV specialists to prescribe PrEP; expand access via health insurance to cover PrEP on demand.
- Ensure equitable access to harm reduction services in all regions and settings of the country.
- Increase vaccination coverage for HBV and HPV: Expand needs-based information measures and options for accessing vaccinations, including through low-threshold services for HPV vaccination and integration of HBV vaccination into existing services for migrants, PWID and MSM, including in public health clinics and prison settings plus awareness raising among healthcare providers, for example GPs. Ensure use of procured mpox vaccines before expiry date.
- Expand integrated people-centred services by removing rules and regulations that the mission was informed currently prevent inclusion of psychologist support, sexuality counselling, mental health and chemsex counselling in community settings.
- Due to increased prevalence of TB, especially among migrant communities, and the appearance of new multidrug resistant TB strains, there is a need for community-based services seeing migrant and people who inject drugs to also offer TB counselling and screening (or referral).

Testing

- There would be a great benefit in strengthening programme monitoring of different testing interventions in community and healthcare settings to enable analysis of where diagnoses are made and to evaluate the (cost)effectiveness of different programmes. It is recommended to establish a system to harmonise data collection and reporting to RKI and use resources better to collect and analyse programmatic data.
- The ECDC integrated testing guidance recommends a framework for monitoring of testing programmes (Figure 20) and recommends that the following basic data items are collected: number of tests; basic demographic data of the person tested (e.g. age, sex and population group); location/setting of the test and number of reactive/positive tests (1).
- It is further recommended to ensure that testing is expanded and actively offered in settings where people at increased risk are seen, i.e. PWID, migrants, sex workers, transgender and gender diverse people, people in prisons, as well as in healthcare settings including primary care, to move beyond risk-based and client-initiated testing, and to ensure care pathways are clear. This also includes consideration of the cost of testing – and lack of reimbursement in some circumstances, including for those without health insurance – given that cost pose a considerable barrier to testing and exclude the most

Figure 20. Monitoring and evaluation of testing programmes (1)



vulnerable groups from accessing testing. Lastly, it is recommended that missed opportunities for testing are identified and improved, e.g. by paying attention to indicator conditions and ensuring that STI and hepatitis testing is integrated when testing a person for HIV and the other way around in relevant settings (e.g. consumption rooms, OST sites, healthcare settings, prisons, GPs and emergency departments).

- It is a strong recommendation that Germany revisits the requirement for written and/or documented informed consent and extended pre-test counselling as a pre-requisite for testing, as this is not in line with European and international guidelines and present important barriers to increasing testing offers in healthcare and other settings where risk population are seen.
- Consider implementing an emergency department HIV, HBV and HCV testing project using an opt-out testing approach and evaluate the results. Opt-out testing in prison settings could also be considered and potentially tested in a pilot project.
- It is also proposed to develop national HIV/STI/hepatitis testing guidelines or recommendations, specifically for use in public health settings and clearly outlining who to test, how often, for which infections, aiming to ensure greater equity across Länder, support local funding allocations and facilitate progress toward the diagnosis targets in the respective disease areas.

Treatment

- Ensure access to HIV, viral hepatitis and STI treatment for all in need, regardless of insurance, (leave no one behind) – a legal obligation based on the national infectious diseases projection act to 'prevent spread of infection' and protect the uninfected population (TasP) – i.e. including PrEP and OST. Ensuring availability of treatment for all will also remove barriers for testing for people who might not want to get diagnosed knowing that treatment would be unaffordable. Further, treating the most vulnerable might help stabilise their life circumstances and motivate them to apply for asylum and eventually access the insurance that many are legally eligible for.
- It is important to strengthen linkage to care and access to comprehensive integrated treatment services for key population groups with high incidence and prevalence, notably people who inject drugs, migrants, prisoners, sex workers and transgender and non-binary people.
- To increase treatment access and coverage for people who use drugs, it is proposed to establish mechanisms to integrate HCV/HIV treatment into OST centres and prisons and optimise care pathways, especially for inmates upon release. Experience from other countries suggest that innovative models of care for people who inject drugs, with integrated evaluation of severity of liver disease and treatment of HCV into drug dependence treatment centres, is feasible and helps break down barriers and facilitate diagnosis and treatment of HCV locally (69-71). Collaborative telehealth interventions offering support by experienced HCV clinicians can also help support and empower clinicians in drug dependence centres to develop the required knowledge and self-efficacy about HCV care, which has otherwise not been part of their clinical scope.
- Strengthen management of multimorbidity through provision of integrated and people-centred care to an ageing population of people living with HIV is a priority in line with the new UNAIDS and WHO indicators and targets on integrated care (72, 73).

5.4 Promoting cross-sectoral networking and collaboration

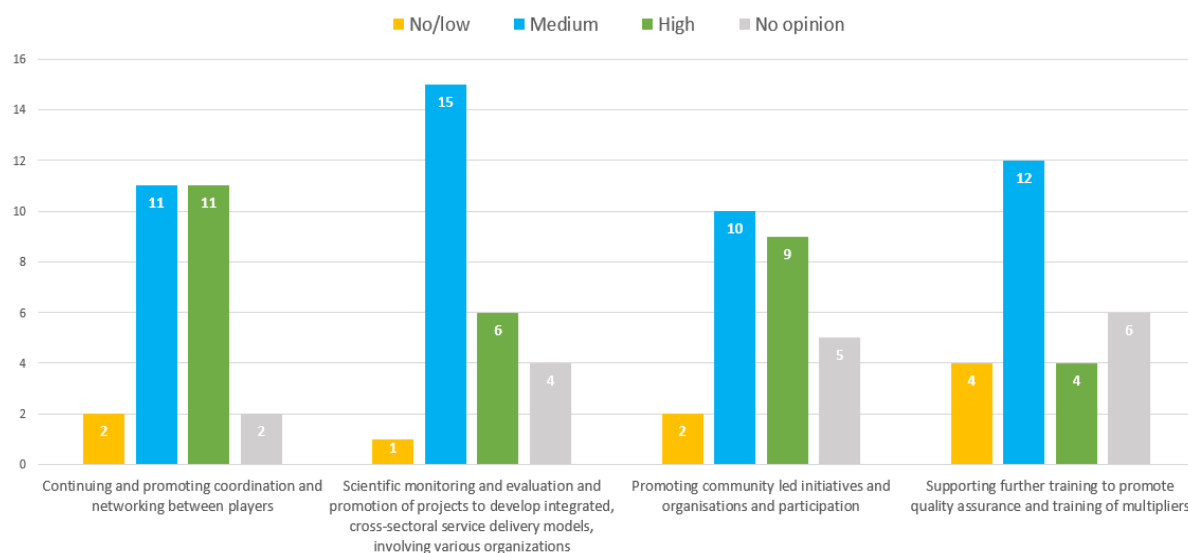
The fourth area of action of the BIS 2030 strategy emphasises the need to promote cross-sectoral networking and collaboration – both across disease areas, professions and across sectors. Empowerment and community participation are flagged as key measures to promote health and increase engagement alongside good examples of networked cooperation in structurally weak areas that should be expanded in collaboration between relevant public, private, community and independent stakeholders.

5.4.1 Findings from the stakeholder survey

As of 2023, 46% of respondents agreed that national, regional, and local efforts to further expand demand-oriented services have generated satisfactory results and/or impacts, while 50% partially agreed, and 4% did not agree.

To assure the quality of the services, the BIS 2030 strategy recommends a series of interventions: a) continue and promote coordination and networking between players; b) scientific monitoring and evaluation and where appropriate promotion of projects to develop integrated, cross-sectoral service delivery models, involving various organisations, such as patient organisations, non-governmental AIDS support and service organisations and other independent agencies; c) promote community-led initiatives and organisations and participation; and d) support further training to promote quality assurance and training. According to the stakeholders who responded to the survey, action has been taken to a medium to high extent in all the above areas (Figure 21).

Figure 21. Survey responses to extent of action towards assuring quality of the services through cross-sectoral networking and collaboration



5.4.2 What is working well

The BIS strategy has improved coordination and collaboration between some stakeholders, notably at the national level where the strategy supports networking and cross-sectoral cooperation between members of the steering group and to some extent between members of the BIS strategy coordination committee and the Länder coordination group.

At the regional level, the BIS strategy has been used to keep HIV, hepatitis and other STIs on the political agenda in some Länder and to support fundraising in some community-based organisations. In other regions, the strategy has been used for developing a regional action plan to support local implementation and funding of the area.

In terms of cross-sectoral corporation, the strategy has served as a 'door opener' for community organisations to bring workshops into prison setting to raise awareness among staff and inmates around HIV, hepatitis and STIs, including prevention, transmission, U=U, testing, treatment and related topics, including gender/sexual diversity.

In the major cities visited by the mission (Hamburg, Cologne), cross-sectoral collaboration and coordination between involved stakeholders at public health, community and clinical levels appeared to be working very well.

Further, the strategy offers an excellent opportunity for organising structured exchanges of experiences between Länder and a great opportunity for stakeholders both at regional and national levels to receive updates from each other. Some topic specific working groups do exist across Länder, for example on safe consumption rooms – these should be expanded to other areas.

5.4.3 Challenges identified

The German healthcare system and Federal governance structure, where key policy areas, including health, are the independent responsibility of each Federal state, leads to a lack of centralised authority. This in turn limits national level ability to define and implement national level policy, resulting in service delivery and implementation being highly dependent on Länder level policies and funding allocations.

The BIS strategy Coordination Committee was established in 2016 to oversee implementation of the BIS 2030 Strategy. The role and mandates of its members are however not clear and would need to be specified in some level of detail to strengthen its operation. Also, the coordination committee has not met face-to-face since 2019, resulting in waning motivation and engagement of its members.

The Länder working group does not have an official 'order' – meaning that there is a limited mandate to bring up topics.

Although the cross-sectoral cooperation at Länder-level was exceptional in the cities visited by the mission, it is unclear if the collaboration between the private practitioners and the public health and/or community level services is working sufficiently well across the country. The mission also learned about examples of sub-optimal collaboration between community and public health services in some regions where it was felt that testing services provided in public health clinics were inadequate and communication/collaboration could be improved.

5.4.4 Priority actions

- Regarding the Coordination Committee, it is suggested that the Federal Ministry of Health organises two face-to-face meetings annually. It is also proposed that the coordination committee be expanded to include a representative from the Federal Ministry of Justice in order to address the issue of prisoners. Further, it should be considered to rotate the chair of the coordination committee to ensure further engagement and diversity in priority setting. It is also suggested that meeting minutes and other relevant documents be shared with interested stakeholders outside the committee for better transparency.
- For the Steering Committee and the Coordination Committee, consider rotating membership on a regular (2-5 year) basis to strengthen inclusiveness and diversity and make sure that different Länder, different public health offices and different representatives of key populations are heard.
- The Länder working group could also be used more efficiently and member engagement be strengthened, for example by allowing the Länder themselves to coordinate the group under a rotating chairmanship allowing for the members to set priorities and propose topics for discussion and to allow for establishment of sub working group as relevant.
- It is recommended that clear terms of reference be developed both for the coordination committee, the steering committee and the Länder working group with clear aim, roles, format and goals on how to improve implementation of the BIS 2030 Strategy.
- The BIS Coordination Committee should consider developing stronger national recommendations on service requirements in priority areas of action, aiming to reduce inequity in access to services across the country.
- For prison settings specifically, there is a need to strengthen collaboration between the Federal Ministry of Health, Federal Ministry of Justice and justice ministries of the Federal states to harmonise HIV, Hepatitis B and C and STI prevention, testing and treatment services across prison settings and implement a minimum package of interventions with a harmonised routine monitoring system.
- Overall, it is suggested that this assessment be used to reinvigorate the various groups with assignment of clear roles and responsibilities for who should coordinate which actions – potentially with the creation of topic specific working groups for the priority actions identified.

5.5 Further expanding the knowledge base and data utilisation

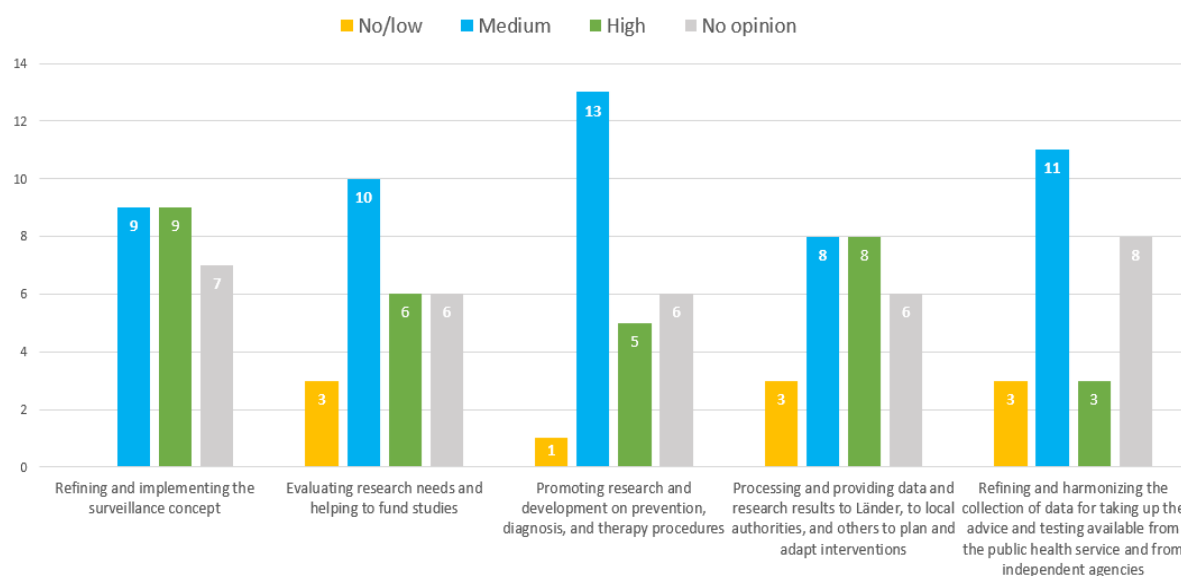
Research and surveillance provide a sound foundation for the planning and implementation of evidence-based prevention, testing and treatment approaches. By developing a comprehensive surveillance concept, the Federal Ministry of Health has established a system which makes relevant information available to monitor the epidemiological progress of HIV and other STIs, as well as for the planning and implementation of interventions. The fifth area of action of the BIS 2030 strategy highlighted the need for a) refining and implementing the surveillance concept; b) evaluating research needs and helping to fund studies; c) promoting research and development on prevention, diagnosis, and therapy procedures; d) processing and providing data and research results to Länder, to local authorities, as well as to other players, in order to plan and, where appropriate, adapt interventions; and e) refining and harmonising the collection of data for taking up the advice and testing available from the public health service and from independent agencies.

5.5.1 Findings from the stakeholder survey

As of 2023, 45% of respondents agreed that national, regional, and local efforts to further expand demand-oriented services have generated satisfactory results and/or impacts, while 45% partially agreed, and 10% did not agree.

Overall, the survey responses showed that relevant stakeholders in Germany have taken a medium level of action to further expand the knowledge base and data utilisation (Figure 22). Specifically, with regards to refining and implementing the surveillance concept, nine respondents reported medium action and nine respondents reported high action, while with regards to evaluating research needs and helping to fund studies, three respondents reported no to low action, 10 reported medium action, and six reported high action. Action on promoting research and development on prevention, diagnosis, and therapy procedures has been rated as between none and low by one respondent, medium by 13 respondents, and high by five respondents. With regards to processing and providing data and research results to Länder, to local authorities, and other to plan and adapt interventions, three stakeholders believed no to low action has been taken so far, eight stakeholders believed medium action has been taken, and eight stakeholders believed high action has been taken. Lastly, refining and harmonising the collection of data for taking up the advice and testing available from the public health service and from independent agencies has been rated as between none and low by three respondents, medium by 11 respondents, and high by three respondents (Figure 22).

Figure 22. Survey responses to extent of action towards further expanding the knowledge base and data utilisation



5.5.2 What is working well

In general, the strategic information systems (surveillance and monitoring data) for HIV, viral hepatitis and STIs at national and Länder level are strong and working well and are continuing to improve.

There are strong electronic notification systems in place for hepatitis B, hepatitis C and mpox and detailed data are available at Länder level which enables comprehensive data analysis and use at local levels.

Surveillance of laboratory diagnosed gonorrhoea with reduced susceptibility to either azithromycin, cefixime or ceftriaxone has been introduced since March 2020. This system is complemented by a strong sentinel surveillance system of local laboratories sending gonococcal isolates to RKI for central high-quality phenotypic AMR testing and further genotypic characterisation and analysis.

An electronic national notification system for HIV, syphilis, chlamydia/LGV and gonorrhoea (regardless of drug susceptibility) is underway and expected to be introduced in summer 2024.

Overall, Germany conducts a lot of high-quality research studies on epidemiology and behavioural concepts related to HIV, hepatitis B and C and other STIs, covering risk groups and the general population and service provision in various settings.

5.5.3 Challenges identified

Accessing and routinely collecting data from the fragmented German healthcare system is a key challenge. In many instances, the only available data source on service provision or coverage is secondary healthcare data from insurance prescriptions or bills – concerning data on treatment, testing and PrEP.

Very strong data protection regulations appear to be a major barrier in many situations as well.

There is a lack of harmonised monitoring systems in place to collect data from public health services to the national and regional levels, for example on testing. Multiple attempts at generating a standardised data collection system have been ongoing for years but has not yet been possible to implement due to funding gaps to implement the already elaborated and extensive monitoring concepts.

Research studies are expensive and where feasible it would appear more cost-effective for Germany to implement routine surveillance and monitoring systems. On the other hand, demands for surveillance and research data are high and do not always seem well aligned with the available funding.

There appears to be a need for strengthening the capacity for conducting surveillance and for strategically analysing and using available data to inform the design of services at local levels.

Data on HIV and syphilis are currently (expectedly until summer 2024) reported to RKI via a paper-based notification system. This leads to some delay in reporting data back to the Länder and limits the level of detail being made available for data analysis and use at the Länder level.

Up until now (until launch of the new electronic system), there is no national surveillance system and no data available on chlamydia/LGV and gonorrhoea in Germany (except for Saxony).

5.5.4 Priority actions

- It is imperative to invest in and improve programmatic data collection for hepatitis B and C as well as for STIs.
- Ensure that robust estimates of the number of people living with HIV, hepatitis B and C exist. Modelling support may be required and can be requested from ECDC.
- Integrate data sources where feasible and relevant, for example by using data generated as part of digitalisation of the healthcare system or establishing AIDS surveillance from secondary healthcare data.
- Improve general and key population continuum of care estimates for hepatitis B and C. It is strongly recommended that clinical and public health bodies work together and share available data.
- Attempt at generating mortality data for hepatitis B and C, for example estimates of the number of deaths from liver disease that are attributable to HBV and HCV, to enable monitoring of progress toward the 2030 WHO hepatitis mortality targets (18, 74).
- Prioritise generation of disaggregated 95-95-95 HIV estimates for key populations – since worse outcomes are expected for some key populations and available data would help inform policy and planning.
- Ensure continued PrEP surveillance to monitor PrEP delivery and identify gaps.
- Attempt at estimating the total number of people living without health insurance in Germany, including the number of uninsured people living with HIV, hepatitis B and C.
- Implement a harmonised monitoring system to collect testing data from public health services and other relevant organisations and to allow for analyses of data of this important provider of service especially for several key populations also on national level.
- It is also recommended to establish a relevant coordination mechanism to support implementation of a basic routine national prison health monitoring and reporting system in coordination with the Federal and Länder level Ministries of Justice (see also 5.4.4 and 5.2.4).
- Make sure that detailed surveillance data are being shared with the Länder, local authorities and other stakeholders in a timely manner. Consider conducting capacity building activities to strengthen local expertise in surveillance, monitoring, analysis and strategic use of available data to inform local programme planning and design of services and interventions.
- Strengthen operational research and translation of research findings into practice (ensure that action is taken from the many important research findings).
- Create a dashboard (or similar system) to track how Germany is progressing toward the SDGs and other WHO and UNAIDS targets for HIV, viral hepatitis and STIs – based on agreed minimum core set of indicators per disease area.

6. Overarching priority actions

This final section summarises the overarching priority actions arising from the assessment which are based on the main observed challenges and gaps in the BIS 2030 strategy and its implementation.

The mission found that the strategy remains an excellent and comprehensive policy paper with a strong focus on integration of services and population specific needs and contexts. It did, however, identify several gaps and developments that have occurred since adoption of the national BIS 2030 strategy, including but not limited to insufficient mention of transgender and gender diverse people and their health needs, no recommendation of PrEP as a key HIV prevention tool, no mention of tuberculosis and the need to integrate TB services into existing services where relevant, new challenges related to migrants from Ukraine and new epidemics such as mpox, and the lack of a simple framework with core indicators to monitor Germany's progress toward the SDGs and other key global, European and national targets.

Several proposed actions to address the identified gaps, developments (and other observed challenges) are included in the key recommendations below. The mission did not find that an amendment or update of the strategy itself was needed but rather recommends that efforts focused on translating the strategy and its elements into action.

6.1 Overarching priority action 1: Ensure 'Universal health coverage'

The objective of the BIS 2030 strategy is to achieve the SDGs ('Ending AIDS' and 'combating viral hepatitis'). Not all people living with HIV, viral hepatitis and STIs in Germany are covered by statutory health insurance (either because they are not entitled or are unaware or incapable of activating their entitlement). This means that sub-groups of the population in Germany at risk of or living with HIV, viral hepatitis and STIs, do not have access to essential testing, prevention, treatment and care services, notably those most vulnerable and at increased risk of infection and further transmission. This in turn means that Germany will not reach several of the SDGs.

- For Germany to reach the global targets and leave no one behind, there is a need to create mechanisms or legal options to ensure that ALL people have access to the services they need, regardless of insurance status. This would be in line with the *UN General Assembly Political Declaration on Universal Health Coverage* and a legal obligation of the national infectious diseases projection act to 'prevent spread of infection' and protect the uninfected population through 'treatment as prevention'.
- Great model examples are already in place of facilities that provide essential services to those without health insurance (Box 4) – models that could be expanded throughout the country – ideally based on government funding for those uninsured, alternatively through innovative suggestions for how to advocate for such services at Länder level which should be further discussed in the coordination committee and the Länder working group.
- Consider undertaking a rapid evaluation of the cost incurred by the stepwise efforts required to support one person without insurance into the system and subsequently address the persons need of further testing, treatment, vaccination etc. as a potential powerful argument. Staff resources are used disproportionately (in some organisations up to 50% of staff time) to find solutions when an uninsured person tests positive – time that could rather be used for serving more clients if everyone had access to treatment. Staff resources include clinical staff time, social workers time, administrative staff time for example.
- For prison settings specifically, improve the system for ensuring continuation of care after release – either by automated re-activation of national health insurance or a general expansion of health insurance to cover prison settings as well.

6.2 Overarching priority action 2: Improve the quality of life of people living with HIV and viral hepatitis

Evidence shows that HIV-related stigma and discrimination in the community and in healthcare setting is very high.

- A holistic approach to addressing experienced stigma and mental health is needed.
- Concerted efforts to tackle stigma and discrimination of people living with HIV and viral hepatitis are also needed, entailing dedicated and tailored training of medical staff, including in prisons; supporting campaigns targeting the community and healthcare workers; and scaling-up of mental health services.
- It is proposed to set up a working group under the coordination committee with the task of developing an action plan on how to address stigma and discrimination to meet global targets.

6.3 Overarching priority action 3: Expand and refine needs-oriented and integrated services

- There is a continued need to expand low-threshold prevention, harm reduction, testing and treatment services for underserved populations in line with the recommendations laid out in sections 5.2.4 and 5.3.4 – notably migrants, sex workers, people who use drugs, prisoners, homeless and transgender and non-binary people, including individuals without health insurance and those living in rural areas – and use the opportunities that integrated care models provide.
- Ensure that services are culturally sensitive and tailored to the specific needs and vulnerabilities of each group – seeking to address the specific challenges outlined in section 5.2.3 and preferably organised in a participatory manner with the respective communities.
- Ensure that testing is expanded and actively offered in settings where people at increased risk are seen, to move beyond risk-based and client-initiated testing and ensure care pathways are clear. Consider ways to decrease or remove the cost of testing – and revise the lack of reimbursement to health providers in some circumstances – as cost is a considerable barrier and exclude the most vulnerable groups from accessing testing.
- It is a strong recommendation that Germany revisits the requirement for written and/or documented informed consent and extended pre-test counselling as a prerequisite for testing, as this is not in line with European and international guidelines and present important barriers to increasing testing offers in healthcare and other settings where risk population are seen.
- For prison settings, define a minimum package of HIV, Hepatitis B and C and STI prevention, testing, vaccination and treatment services for nationwide implementation – in line with the *United Nations Standard Minimum Rules for the Treatment of Prisoners* (57).

6.4 Overarching priority action 4: Provide political leadership and coordination

The sustainability of programmes is currently heavily dependent on Länder level political support, limiting centralised authority and ability to define and implement national level policy. Stronger national coordination, steering, guidance, political support and facilitation of learning should however be pursued to facilitate greater equity across Länder.

- The BIS Coordination Committee should consider initiating development of stronger national recommendations on service requirements in priority areas of action, aiming to reduce inequity in access to services across the country. Clear national guidelines on testing specifically for use in public health settings appears to be a specific need.
- Develop clear 'terms of reference' for the BIS strategy steering committee, coordination committee and the Länder working group with clear goals and roles for how to improve implementation of the BIS 2030 strategy. Also consider rotating the chair of these bodies to pursue further engagement and diversity in priority setting.
- Allow for establishing of broader topic specific sub working groups under the coordination committee and Länder working group in key areas of action (allowing working group members who are not standing members of the main committees).
- For prison settings specifically, strengthen collaboration between all relevant departments of the Federal Ministry of Health, the Federal Ministry of Justice and justice ministries of the Federal states and set common goals. It is also suggested that a representative from the FMOJ be included in the coordination committee.

6.5 Overarching priority action 5: Monitor implementation of the BIS strategy

Accessing and routinely collecting data from the fragmented German healthcare system is a key challenge, with secondary healthcare data from insurance prescriptions or bills often being the only available data sources. Strong data protection regulations pose a major barrier as well. The BIS 2030 strategy does not have a monitoring and evaluation framework attached to it and progress toward its goals are not routinely monitored.

- It is recommended that a BIS strategy implementation dashboard is created to show how Germany is progressing toward the SDGs and other WHO and UNAIDS targets for HIV, viral hepatitis and STIs. This means that the indicators and targets will be tied to the SDGs and related regional and global targets and only indirectly monitor implementation of the strategy. RKI is well placed to provide this dashboard on an annual basis up until 2030.
- It is further proposed that the coordination committee, under the guidance of RKI, agrees on a minimum core set of indicators per disease area. A dedicated working group could be created under the coordination committee to develop a proposal for the next meeting.
- There is also a need to address specific data gaps, notably for viral hepatitis (estimated burden, service coverage/continuum of care, mortality), STIs (impact and service coverage) and to some extent for HIV (95-95-95 for key populations) and for testing (testing reach and yield in different settings). It is further necessary to ensure continuity of surveillance systems, including for drug-related infectious diseases and continued PrEP surveillance to monitor PrEP delivery and identify gaps.
- To support priority action 1 above, it is recommended to attempt at estimating the total number of people living without health insurance in Germany, including potentially also the number of uninsured people living with HIV, hepatitis B and C. Explore ways of evaluating how this ultimately impacts progress towards the SDGs in Germany.

6.6 Overarching priority action 6: Identify threats to the successful implementation of the BIS 2030 strategy and propose mitigating solutions

Although the SDGs represent priority areas, the diseases covered by the BIS 2030 strategy are not necessarily political priorities and funding is not linked to implementation of the strategy.

- A key objective of the coordination committee should be to ensure that the diseases it covers remain high on the public health agenda.
- The coordination committee should consider conducting brief risk and/or impact assessments on potential threats to the successful BIS strategy implementation on national and Länder level and propose mitigating solutions.
- Identified risks communicated in this assessment include:
 - Lack of dedicated funding to support and monitor implementation of the strategy.
 - Creation of the new Federal Institute for Prevention and Education in Medicine (BIPAM) and its knock-on effects on the ability to provide strategic information and sustain communication campaigns.
 - Lack of access to prevention, testing and treatment services for people without health insurance.

References

1. European Centre for Disease Prevention and Control. Public health guidance on HIV, hepatitis B and C testing in the EU/EEA: An integrated approach. Stockholm: ECDC; 2018.
2. German Ministry of Health, Ministry for Economic Cooperation and Development. Integrated Strategy for HIV, Hepatitis B and C and Other Sexually Transmitted Infections. Berlin: Ministry of Health; 2016.
3. Bundesministerium für Gesundheit. Koordinierungsgremium zur Umsetzung der Strategie BIS 2030 [updated 2 October 2023]. Available from: <https://www.bundesgesundheitsministerium.de/themen/praevention/gesundheitsgefahren/hiv-hepatitis-und-sti/koordinierungsgremium.html>.
4. REDCap. REDCap (Research Electronic Data Capture) 2024 [26 February 2024]. Available from: <https://www.project-redcap.org/>.
5. Statistisches Bundesamt (Destatis), Wissenschaftszentrum Berlin für Sozialforschung (WZB), Bundesinstitut für Bevölkerungsforschung (BiB). Datenreport 2021: Ein Sozialbericht für die Bundesrepublik Deutschland. Bonn: Bundeszentrale für politische Bildung; 2021. Contract No.: 24 January 2024.
6. Busse R, Blümel M. Germany: health system review. Health Systems in Transition. 2014;16(2):1-296.
7. European Observatory on Health Systems and Policies, WHO Regional Office for Europe DoHSaPH. Organization and financing of public health services in Europe - Country reports. Copenhagen: WHO Regional Office for Europe; 2018.
8. Ehrich J, Grote U, Gerber-Grote A, Strassburg M. The Child Health Care System of Germany. J Pediatr. 2016;177s:S71-s86.
9. Deutsche Aidshilfe, Institut für Demokratie und Zivilgesellschaft. Positive Stimmen 2.0. Living with HIV, Breaking Down Discrimination: Insights and results from a participatory research project on living with HIV in Germany. Berlin: Deutsche Aidshilfe; 2021.
10. Schmidt D, Kollan C, Schewe K, Hanhoff N, Rösenberg R, Friebe M, et al. [Evaluating the introduction of HIV pre-exposure prophylaxis as a benefit of statutory health insurance (EvE-PrEP) : Highly effective protection against HIV without an increase in sexually transmitted infections]. Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz. 2023;66(9):1008-18.
11. Schmidt D, Kollan C, Marcus U, Iannuzzi S, von Kleist M. Dynamics of HIV PrEP use and coverage during and after COVID-19 in Germany. BMC Public Health. In revision.
12. Schmidt D, Kollan C, Bartmeyer B, Bremer V, Schikowski T, Friebe M, et al. Low incidence of HIV infection and decreasing incidence of sexually transmitted infections among PrEP users in 2020 in Germany. Infection. 2023;51(3):665-78.
13. Deutsche AIDS-Gesellschaft (DAIG). S2k-Leitlinie Deutsch-Österreichische Leitlinien zur antiretroviralen Therapie der HIV-1-Infektion. Hamburg: Deutsche AIDS-Gesellschaft (DAIG); 2021.
14. Schmidt D, Kollan C, Stoll M, Stellbrink HJ, Plettenberg A, Fätkenheuer G, et al. From pills to patients: an evaluation of data sources to determine the number of people living with HIV who are receiving antiretroviral therapy in Germany. BMC Public Health. 2015;15:252.
15. Jansen K, Steffen G, Potthoff A, Schuppe AK, Beer D, Jessen H, et al. STI in times of PrEP: high prevalence of chlamydia, gonorrhoea, and mycoplasma at different anatomic sites in men who have sex with men in Germany. BMC Infect Dis. 2020;20(1):110.
16. Jansen K, Bremer V, Steffen G, Sarma N, Nielsen S, Münstermann D, et al. High prevalence of chlamydia, gonorrhoea, mycoplasma and trichomonas in female sex workers reached at their working place in Germany. Brisbane, Australia: World STI&HIV Congress 2015, September 13-16; 2015.
17. Bremer V, Haar K, Gassowski M, Hamouda O, Nielsen S. STI tests and proportion of positive tests in female sex workers attending local public health departments in Germany in 2010/11. BMC Public Health. 2016;16(1):1175.
18. WHO Regional Office for Europe. Regional action plans for ending AIDS and the epidemics of viral hepatitis and sexually transmitted infections 2022–2030. Copenhagen: WHO Regional Office for Europe; 2023.
19. Sperle I, Steffen G, Leendertz SA, Sarma N, Beermann S, Thamm R, et al. Prevalence of Hepatitis B, C, and D in Germany: Results From a Scoping Review. Front Public Health. 2020;8:424.
20. Steffen G, Weber C, Cawley C, Sarma N, Jansen K, Leicht A, et al. Prävalenz von sexuell und durch Blut übertragene Infektionen und Tuberkulose bei Menschen in Wohnungslosigkeit in Berlin – Erste Ergebnisse der Pilotstudie POINT. Epidemiologisches Bulletin. 2022(13):25-32.
21. Derks L, Gassowski M, Nielsen S, An der Heiden M, Bannert N, Bock CT, et al. Risk behaviours and viral infections among drug injecting migrants from the former Soviet Union in Germany: Results from the DRUCK-study. Int J Drug Policy. 2018;59:54-62.
22. Robert Koch Institut. Abschlussbericht der Studie „Drogen und chronischen Infektionskrankheiten in Deutschland“ (DRUCK-Studie). Berlin: RKI; 2016.
23. Zimmermann R, Krings A, Steffen G. DRUCK 2.0 - Pilotierung eines Surveillance-Systems zu durch Blut und sexuell übertragene Infektionen bei Drogengebrauchenden. Berlin: Robert Koch-Institut; 2024.

24. Hölling H, Schlack R, Kamtsiuris P, Butschalowsky H, Schlaud M, Kurth BM. [The KiGGS study. Nationwide representative longitudinal and cross-sectional study on the health of children and adolescents within the framework of health monitoring at the Robert Koch Institute]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2012;55(6-7):836-42.
25. Cai W, Poethko-Müller C, Hamouda O, Radun D. Hepatitis B virus infections among children and adolescents in Germany: migration background as a risk factor in a low seroprevalence population. *Pediatr Infect Dis J*. 2011;30(1):19-24.
26. Enkelmann J, Gassowski M, Nielsen S, Wenz B, Roß S, Marcus U, et al. High prevalence of hepatitis C virus infection and low level of awareness among people who recently started injecting drugs in a cross-sectional study in Germany, 2011-2014: missed opportunities for hepatitis C testing. *Harm Reduct J*. 2020;17(1):7.
27. Mårdh O, Quinten C, Amato-Gauci AJ, Duffell E. Mortality from liver diseases attributable to hepatitis B and C in the EU/EEA - descriptive analysis and estimation of 2015 baseline. *Infect Dis (Lond)*. 2020;52(9):625-37.
28. Rieck T FM, Siedler A. Impfquoten von Kinderschutzimpfungen in Deutschland – aktuelle Ergebnisse aus der RKI-Impfsurveillance. *Epidemiologisches Bulletin*. 2022;48:3-25.
29. Beermann S, Jacob J, Dudareva S, Jansen K, Marcus U, Zimmermann R, et al. [How well is the screening of pregnant women for HIV, syphilis, and hepatitis B implemented in Germany? An analysis based on routine data]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2020;63(9):1143-50.
30. Hommes F, Krings A, Dörre A, Neumeier E, Schäffer D, Zimmermann R. International harm reduction indicators are still not reached: results from a repeated cross-sectional study on drug paraphernalia distribution in Germany, 2021. *Harm Reduct J*. 2023;20(1):137.
31. European Monitoring Centre for Drugs and Drug Addiction. Viral hepatitis elimination barometer among people who inject drugs in Europe 2023 [updated November 2023]. Available from: https://www.emcdda.europa.eu/publications/data-factsheet/viral-hepatitis-elimination-barometer-among-people-who-inject-drugs-in-europe_en#section5.
32. Steffen G, Sperle I, Leendertz SA, Sarma N, Beermann S, Thamm R, et al. The epidemiology of Hepatitis B, C and D in Germany: A scoping review. *PLoS One*. 2020;15(3):e0229166.
33. Maisa A, Kollan C, An der Heiden M, van Bömmel F, Cornberg M, Mauss S, et al. Increasing Number of Individuals Receiving Hepatitis B nucleos(t)ide Analogs Therapy in Germany, 2008-2019. *Front Public Health*. 2021;9:667253.
34. Tergast TL, Blach S, Tacke F, Berg T, Cornberg M, Kautz A, et al. Updated epidemiology of hepatitis C virus infections and implications for hepatitis C virus elimination in Germany. *J Viral Hepat*. 2022;29(7):536-42.
35. Steffen G BA, Dudareva S, Hommes F, Krings A, Kollan C, Schmidt D, Zimmermann R. Virushepatitis C im Jahr 2021. *Epidemiologisches Bulletin*. 2022;38:7-25.
36. Meyer ED, Dudareva S, Kollan C, Mauss S, Wedemeyer H, Schmidt D, et al. Additional challenges in reaching hepatitis C elimination goals in Germany due to the COVID-19 pandemic - descriptive analysis of drug prescription data from January 2018 to June 2021. *Front Public Health*. 2023;11:1149694.
37. Poethko-Müller C, Zimmermann R, Hamouda O, Faber M, Stark K, Ross RS, et al. [Epidemiology of hepatitis A, B, and C among adults in Germany: results of the German Health Interview and Examination Survey for Adults (DEGS1)]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2013;56(5-6):707-15.
38. Kraus L, Seitz NN, Schulte B, Cremer-Schaeffer P, Braun B, Verthein U, et al. Estimation of the Number of People With Opioid Addiction in Germany. *Dtsch Arztebl Int*. 2019;116(9):137-43.
39. Zimmermann R, Marcus U, Schäffer D, Leicht A, Wenz B, Nielsen S, et al. A multicentre sero-behavioural survey for hepatitis B and C, HIV and HTLV among people who inject drugs in Germany using respondent driven sampling. *BMC Public Health*. 2014;14:845.
40. Wenz B, Nielsen S, Gassowski M, Santos-Hövenner C, Cai W, Ross RS, et al. High variability of HIV and HCV seroprevalence and risk behaviours among people who inject drugs: results from a cross-sectional study using respondent-driven sampling in eight German cities (2011-14). *BMC Public Health*. 2016;16(1):927.
41. Haussig JM, Nielsen S, Gassowski M, Bremer V, Marcus U, Wenz B, et al. A large proportion of people who inject drugs are susceptible to hepatitis B: Results from a bio-behavioural study in eight German cities. *Int J Infect Dis*. 2018;66:5-13.
42. Bundesarbeitsgemeinschaft Wohnungslosenhilfe (BAG W) e.V. Mindestens 607.000 Menschen in Deutschland wohnungslos 2023 [cited 2024 21 February]. Available from: <https://www.bagw.de/de/themen/zahl-der-wohnungslosen/uebersicht>.
43. Krings A, Schmidt D, Kollan C, Meixenberger K, Bannert N, Münstermann D, et al. Increasing hepatitis B vaccination coverage and decreasing hepatitis B co-infection prevalence among people with HIV-1 in Germany, 1996-2019. Results from a cohort study primarily in men who have sex with men. *HIV Med*. 2024;25(2):201-11.
44. Krings A, Schmidt D, Meixenberger K, Bannert N, Münstermann D, Tiemann C, et al. Decreasing prevalence and stagnating incidence of Hepatitis C-co-infection among a cohort of HIV-1-positive patients, with a majority of men who have sex with men, in Germany, 1996-2019. *J Viral Hepat*. 2022;29(6):465-73.
45. Schneider FK, Krystallia; Neumerier, Esther. Bericht 2023 des nationalen REITOX-Knotenpunkts an die EMCDDA (Datenjahr 2022 / 2023). Munich: EMCDDA; 2022.

46. Müller J, Schmidt D, Kollan C, Lehmann M, Bremer V, Zimmermann R. High variability of TB, HIV, hepatitis C treatment and opioid substitution therapy among prisoners in Germany. *BMC Public Health*. 2017;17(1):843.
47. Thomadakis C, Gountas I, Duffell E, Gountas K, Bluemel B, Seyler T, et al. Prevalence of chronic HCV infection in EU/EEA countries in 2019 using multiparameter evidence synthesis. *Lancet Reg Health Eur*. 2024;36:100792.
48. Steffen G, Sperle I, Harder T, Sarma N, Beermann S, Thamm R, et al. Hepatitis B vaccination coverage in Germany: systematic review. *BMC Infect Dis*. 2021;21(1):817.
49. Robert Koch Institut. Impfquoten bei der Schuleingangsuntersuchung in Deutschland 2017. *Epidemiologisches Bulletin*. 2019;18:147-53.
50. Brandl M, Schmidt AJ, Marcus U, An der Heiden M, Dudareva S. Are men who have sex with men in Europe protected from hepatitis B? *Epidemiol Infect*. 2020;148:e27.
51. Zimmermann R, Krings A, Schneider F, Schäffer D, Neumeier E. Konsumutensilienvergabe in Deutschland: Ergebnisse einer Befragung von Einrichtungen der Drogenhilfe und Suchttherapie zur Ausgabe von Utensilien zum sicheren Drogenkonsum 2018. *Suchttherapie*. 2022;23(03):130-40.
52. Bätz O, Petroff D, Joachim-Richter A, Jedrysiak K, Wolfram I, Berg T, et al. Results of the hepatitis B and C screening within the "Check-Up 35+" in the German primary care setting one year after implementation by the joint committee. *Journal of Hepatology*. 2023;78:S1176.
53. Buggisch P, Heiken H, Mauss S, Weber B, Jung MC, Görne H, et al. Barriers to initiation of hepatitis C virus therapy in Germany: A retrospective, case-controlled study. *PLoS One*. 2021;16(5):e0250833.
54. Briken P, Dekker A, Cerwenka S, Pietras L, Wiessner C, von Rügen U, et al. [The German health and sexuality survey (GeSiD)-a brief introduction to the study]. *Bundesgesundheitsblatt Gesundheitsforschung Gesundheitsschutz*. 2021;64(11):1334-8.
55. Ludwig J, Brunner F, Wiessner C, Briken P, Gerlich MG, von dem Knesebeck O. Public attitudes towards sexual behavior-Results of the German Health and Sexuality Survey (GeSiD). *PLoS One*. 2023;18(3):e0282187.
56. UNAIDS. The Global Partnership for Action to Eliminate all Forms of HIV-related Stigma and Discrimination 2024 [cited 2024 26 February]. Available from: <https://www.unaids.org/en/topic/global-partnership-discrimination>.
57. UN General Assembly. The United Nations Standard Minimum Rules for the Treatment of Prisoners (the Nelson Mandela rules) 2016 [cited 2024 26 February]. Available from: <https://www.refworld.org/legal/resolution/unqa/2016/en/119111>.
58. UN General Assembly. Political declaration of the high-level meeting on universal health coverage 2019 [cited 2024 26 February]. Available from: <https://www.un.org/pga/73/event/universal-health-coverage/>.
59. Müller MC, Usadel S, Zimmermann S, Fahrhöfer A, Kern WV, Hoffmeister U, et al. Closing Sexual Health Service Gaps With a New Service Model in Germany: Performance of an on-Site Integrated, Cross-Sectoral, Low Threshold Sexually Transmitted Infections/HIV Counseling and Treatment Service. *Front Public Health*. 2022;10:793609.
60. Schmidt AJ KC, Kimmel S, Dorsch H-P, Knoll C. Half-Year Report 2/2023. HIV- and STI-testing in community-based VCT centres in Germany. Berlin: Deutsche Aidshilfe; 2024.
61. Koschollek C, Kuehne A, Müllerschön J, Amoah S, Batemona-Abeke H, Dela Bursi T, et al. Knowledge, information needs and behavior regarding HIV and sexually transmitted infections among migrants from sub-Saharan Africa living in Germany: Results of a participatory health research survey. *PLoS One*. 2020;15(1):e0227178.
62. Kuehne A, Koschollek C, Santos-Hövener C, Thorlie A, Müllerschön J, Mputu Tshibadi C, et al. Impact of HIV knowledge and stigma on the uptake of HIV testing - Results from a community-based participatory research survey among migrants from sub-Saharan Africa in Germany. *PLoS One*. 2018;13(4):e0194244.
63. Koppe U, Spurgat C, Knoop JM, Hahne A, Appenroth MN, Pöge K, et al. Up to the TASG: a participatory study on sexual health of trans and non-binary persons in Germany. *Eur J Public Health*. 2022;32(Suppl 3).
64. EMIS Network. EMIS-2017 – The European Men-Who-Have-Sex-With-Men Internet Survey. Key findings from 50 countries. Stockholm: European Centre for Disease Prevention and Control; 2019.
65. World Health Organization. Human Papillomavirus (HPV) vaccination coverage 2024 [cited 2024 26 February]. Available from: <https://immunizationdata.who.int/pages/coverage/hpv.html>.
66. EuroTEST. HepHIV 2023 Madrid Conference. Presentations, Parallel abstract driven session 1: Improving BBV Testing Strategies in Emergency Departments [cited 2024 4 April]. Available from: <https://eurotest.org/conferences/hephiv-2023-madrid-conference/presentations/>.
67. UK Health Security Agency. Emergency department bloodborne virus opt-out testing: 12-month interim report 2023. UK Health Security Agency; 2023.
68. World Health Organization. Consolidated guidelines on HIV testing services. Geneva: WHO; 2019.
69. Butsashvili M, Kamkamidze G, Kajaia M, Gvinjilia L, Kuchuloria T, Khonelidze I, et al. Integration of hepatitis C treatment at harm reduction centers in Georgia-Findings from a patient satisfaction survey. *Int J Drug Policy*. 2020;84:102893.

70. Catie. Hepatitis C treatment in harm reduction programs for people who use drugs 2020 [cited 2024 19 March]. Available from: <https://www.catie.ca/prevention-in-focus/hepatitis-c-treatment-in-harm-reduction-programs-for-people-who-use-drugs>.
71. Centre of Excellence for Health Immunity and Infections (CHIP). SACC - Shared Addiction Care Collaboration 2024 [cited 2024 19 March]. Available from: <https://chip.dk/Clinical-programs/SACC>.
72. UNAIDS. Global AIDS Strategy 2021–2026: End Inequalities, End AIDS. Geneva: UNAIDS; 2022.
73. World Health Organization. Global health sector strategies on, respectively, HIV, viral hepatitis and sexually transmitted infections for the period 2022-2030. Geneva: WHO; 2022.
74. World Health Organization. Interim guidance for country validation of viral hepatitis elimination. Geneva: WHO; 2021.

Annex 1. List of stakeholder survey recipients and respondents

Federal level agencies	Responded to survey
Federal Ministry of Health (MoH)	Yes
Robert Koch Institute (RKI)	Yes
Federal Centre for Health Education (BZgA)	Yes
Federal Anti-Discrimination Agency	Yes
Länder level	Responded to survey
16 Federal States (Länder)	Berlin, Hamburg, Schleswig-Holstein, Nordrhein-Westfalen
NGOs/community/patient organisations	Responded to survey
Deutsche Aidshilfe (DAH)	Yes
Akzept e.V./Fixpunkt e.V.	Yes
German Society for Family Planning, Sexual Education and Sexual Counselling (Pro Familia)	Yes
Professional association for erotic and sexual services (BesD)	Yes
African Health and HIV Network in Germany (AGHNIID)	Yes
National Network of junkies, former drug users and people on OST (JES Bundesverband)	Yes
Deutsche AIDS-Stiftung (DAS)	No
Deutsche Leberhilfe e.V.	No
Professional Association for Drug and Addiction Assistance (FDR)	No
Federal Association of Non-statutory Welfare	No
Representative of Positive Self-help	No
Medical societies	Responded to survey
German Dental Association (Bundeszahnärztekammer)	Yes
German AIDS Society (Deutsche AIDS-Gesellschaft)	Yes
German Association of Outpatient Doctors for Infectious Diseases & HIV Medicine (dagnä)	Yes
German STI Society (Deutsche STI-Gesellschaft)	Yes
German Society for Gastroenterology, Digestive and Metabolic Disease (DGVS)	Yes
Medical Society for Health Promotion (ÄGGF)	Yes
German Society for General Medicine and Family Medicine (DEGAM)	Yes
Federal Association of Physicians of German Public Health Departments (BVÖGD)	No
German Medical Association (Bundesärztekammer)	No
German Liver Foundation (Deutsche Leberstiftung)	No
German Society for Addiction Medicine (DGS)	No
German Society for Sexual Research (DGfS)	No
Health insurance groups	Responded to survey
Association of Private Health Insurance (Verband der Privaten Krankenversicherung e.V.)	Yes
National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung)	Yes
The National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)	No

Annex 2. List of organisations met during country visit

Federal level agencies
<p>Federal Ministry of Health (MoH)</p> <ul style="list-style-type: none"> - Directorate 63 – Health Protection - Division 631 – Infectious Diseases - Division 213 – Federal Joint Committee, Disease Management Programmes (DMP), General Medical Issues Concerning the Statutory Health Insurance System
<p>Robert Koch Institute (RKI)</p> <ul style="list-style-type: none"> - Abt. 3 – Infectious Disease Epidemiology - FG 34 – HIV, STI and Blood-borne Infections
<p>Federal Centre for Health Education (BZgA)</p> <ul style="list-style-type: none"> - Department T “Theme-Specific health education” - Unit T3 “Sexual health, Prevention of HIV and other sexually transmitted infections (STI)”
Länder or city level public health entities
<p>Hamburg</p> <ul style="list-style-type: none"> - Ministry of Social Affairs, Department of Health - Hamburg Centre for HIV, STI and sexual health in Altona (Casablanca) - Hamburg Institute for Hygiene and Environment
<p>Cologne</p> <ul style="list-style-type: none"> - City of Cologne, Department of Health - Cologne public STI clinic (Gesundheitsamt Köln)
<p>Saxony</p> <ul style="list-style-type: none"> - Saxon State Ministry for Social Affairs and Social Cohesion - Gesundheitsamt Amt für Gesundheit und Prävention, Gesundheitsamt, Sachgebiet Sexuelle Gesundheit, Beratungsstelle für AIDS und sexuell übertragbare Infektionen - Gesundheitsamt Leipzig, Sachgebiet Infektionskrankheiten/Prävention, Beratungsstelle für sexuell übertragbare Infektionen und AIDS - Landratsamt Meißen, Gesundheitsamt, AIDS-Beratung und Beratung zu anderen sexuell übertragbaren Krankheiten - Landratsamt Nordsachsen, Dezernat Soziales und Gesundheit, Gesundheitsamt, Sachgebiet Gesundheitsförderung/Prävention/Beratung - Amt für Gesundheit und Prävention, Sachgebiet Spezieller Infektionsschutz, Beratungsstelle sexuelle Gesundheit
NGOs/community/patient organisations
<p>Berlin</p> <ul style="list-style-type: none"> - Deutsche Aidshilfe (DAH) - Fixpunkt e.V. - African Health and HIV Network in Germany (AGHNiD) - Checkpoint BLN
<p>Cologne</p> <ul style="list-style-type: none"> - Aidshilfe Köln - Vision e.V. - Deutsche Leberhilfe e.V
<p>Hamburg</p> <ul style="list-style-type: none"> - Checkpoint Hein & Fiete

<p>Saxony</p> <ul style="list-style-type: none"> - Aidshilfe Dresden e.V. - Aidshilfe Leipzig e.V. - Aidshilfe Westsachsen e. V. - Lesben- und Schwulenverband Sachsen, Projekt Queer am Arbeitsplatz - Landesarbeitsgemeinschaft Queeres Netzwerk Sachsen - Trans-Inter-Aktiv in Mitteldeutschland e.V. (TIAM)
Medical societies or clinics
German Association of Outpatient Doctors for Infectious Diseases & HIV Medicine (dagnä)
German Society for Gastroenterology, Digestive and Metabolic Disease (DGVS)
German Liver Foundation (Deutsche Leberstiftung)
St Josef Hospital, Emergency Department, Berlin
Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden, Klinik und Poliklinik für Dermatologie, HIV-Ambulanz
HIV-Schwerpunktpraxis und Infektiologie, Dr. R., Leipzig
Other
Berlin State Prison Hospital, Plötzensee Correction Facility, Berlin