



## **MISSION REPORT**

# **Technical missions: HIV, STI and viral hepatitis in Bulgaria**

**19-21 September 2016  
14-15 November 2016**

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This report from the European Centre for Disease Prevention and Control (ECDC) was coordinated by Teymur Noori and Gianfranco Spiteri. Team members included Teymur Noori, Anastasia Pharris, Hans Blystad, Roger Drew and Dagmar Hedrich (EMCDDA) for the first mission and Gianfranco Spiteri, Erika Duffell, Frantiska Hruby (ECDC) and Nick Bundle (UK Field Epidemiology Training Programme, Public Health England) for the second mission.

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## Abbreviations

AIDS	Acquired immunodeficiency syndrome
ART	Antiretroviral therapy
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency (formerly EAHC)
EAHC	Executive Agency for Health and Consumers (now CHAFEA)
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
ELISA	enzyme-linked immunosorbent assay
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMIS	European MSM Internet Service
EPIET	European Programme for Interventional Epidemiology Training
EU	European Union
EUPHEM	European Programme for Public Health Microbiology Training
Euro-GASP	European Gonococcal Antimicrobial Surveillance Programme
FETP	Field Epidemiology Training Programme
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency Virus
HPV	Human papillomavirus
IFH	Initiative for Health
LGBT	Lesbian, gay, bisexual and transgender
LGV	Lymphogranuloma venereum
MSM	Men who have sex with men
NAAT	nucleic acid amplification testing
NCDA	National Centre for Drug Addictions, Bulgaria
NCIPD	National Centre for Infectious and Parasitic Diseases, Bulgaria
NCPHA	National Centre for Public Health and Analysis, Bulgaria
NGO	Non-governmental organisation
OST	Opioid substitution treatment
PEP	Post-exposure prophylaxis
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
STI	Sexually transmitted infection
TB	Tuberculosis
VCT	Voluntary counselling and testing
VPD	Vaccine-preventable diseases

## Executive summary

Bulgaria has seen relatively low rates of Human Immunodeficiency Virus (HIV) infection with and in recent years around 200 new cases have been reported annually. Although the number of new cases diagnosed annually among people who inject drugs (PWID) was rising until 2009, it has since stabilised and even begun to fall. However, as in many other European countries, the number of new HIV cases among men who have sex with men (MSM) is rising. In 2016, more than half of all new HIV cases reported were among MSM.

Bulgaria has had an effective national HIV programme financed through government resources and, from 2004, by the Global Fund to Fight AIDS, Tuberculosis and Malaria. The national programme has established a range of measures including support for non-governmental organisations (NGOs) to provide HIV prevention services for PWID and MSM across a number of cities. Services for PWID include provision of syringes, other clean injecting equipment and disinfectants; counselling and testing for HIV, hepatitis and syphilis; training and counselling for safe injection, HIV and AIDS, hepatitis, sexually transmitted infections (STIs) etc.; information about and referrals to treatment services; and case management for people living with HIV and other health problems. Services for MSM include provision of counselling; distribution of condoms, lubricants and health education materials; voluntary counselling and HIV testing; testing for syphilis and hepatitis; diagnosis and treatment of STIs; education of popular opinion leaders in the community; education campaigns and case management for people most at risk.

HIV testing is available in a range of settings including through health facilities, regional health inspectorates and through services provided by NGOs. Since June 2016, antiretroviral therapy (ART) has been offered to all those diagnosed with HIV regardless of CD4 count. At the time of the visit, 824 people out of an estimated 2 500 people living with HIV in Bulgaria were reported to be receiving ART. However, it is understood that a substantial number of people with HIV have either not yet been diagnosed or have not been linked to/retained in care and treatment services. The number of people reported to have effective viral suppression is therefore low. ART is financed by the state budget but unit costs for treating one person per year (over USD 9 000) are high compared to some other European countries.

The current national HIV programme ended in 2015. Although a new programme for 2016–2020 has been developed, at the time of the mission it had not yet been approved or funded. Global Fund financing for Bulgaria has already ended, although some services have been continuing on the basis of no-cost extensions. These are not likely to continue beyond the end of 2016. Therefore there is a very urgent need for the new national programme to be approved and funded. The cost for the entire programme is extremely modest at around EUR 2 million per year. This is less than the annual cost of treating 250 people with ART at current prices.

If the new programme is not approved and funded, there is a risk that effective services which have been carefully established over many years will reduce or cease operations. There is already evidence of service decline in some geographical areas and sectors. If this is allowed to continue, there is a risk that the number of HIV cases among MSM or among PWID will escalate. This will mean that even more people will be demanding costly ART.

The national HIV programme for 2016 to 2020 needs to prioritise focused HIV testing among those most likely to be HIV infected (MSM and PWID) and treatment of those diagnosed with HIV infection. Services provided by NGOs have contributed significantly to meeting the need for HIV prevention services for MSM and PWID, and therefore these NGO services need to be prioritised for financial support following the cessation of Global Fund financing.

Another important aspect reviewed is the surveillance system for viral hepatitis and sexually transmitted infections (STIs). The surveillance arrangements and epidemiological data for STI and hepatitis were reviewed and plans for further surveillance development were discussed.

Bulgaria has a well-established system for surveillance of communicable diseases at the national level, coordinated by the National Centre for Infectious and Parasitic Disease (NCIPD). Epidemiology staff at the centre have extensive experience in the surveillance of notification data relating to different communicable diseases and have maintained a functioning system despite limited resources.

The surveillance of hepatitis B and hepatitis C is well established within the national surveillance system and based on notifications from clinicians. The detection of outbreaks of acute hepatitis B at the local level appears to be effective, with follow-up of contacts by local epidemiologists to collect detailed epidemiological data. The data collected at the local level is not collated nationally and the current system is based on the reporting of basic aggregated data from the regional level to the NCIPD. Although Bulgaria has adopted the EU 2012 case definitions for hepatitis B and C, the current system does not really allow differentiation between acute and chronic hepatitis cases and this is a major barrier to understanding the epidemics of these infections in the country. The main barriers to progress appear to be the lack of sustained financing and associated human resource shortages at all levels, which challenge the effective functioning of the current surveillance system and make the realisation of case-based reporting unlikely. There is evidence to suggest that there may be under-notification of newly diagnosed cases of hepatitis B and C in Bulgaria. It is possible that some clinicians may only be notifying acute cases, resulting in the under-notification of all other newly diagnosed cases. In addition, there are many private laboratories undertaking hepatitis B and C diagnostic tests and it is likely that notification from the private sector may also be sub-optimal. A further issue concerns the challenge of obtaining accurate sero-prevalence estimates which would provide a more complete epidemiological picture for viral hepatitis. While studies estimating

prevalence among risk groups have been carried out as part of the HIV programme the results do not seem to have been widely disseminated and used to inform prevention and control programmes.

In Bulgaria, there is a need to further develop detailed, specific objectives for the surveillance of hepatitis B and C along with appropriate allocation of resources to support the implementation of a shift towards case-based reporting and proper differentiation of cases as acute or chronic. The surveillance objectives should be defined in the context of the WHO European Action Plan and the Global Health Sector Strategy elimination goals. In relation to the issue of under-reporting, it is suggested that a study be conducted to investigate the root cause of under-reporting for viral hepatitis, with subsequent development of a strategy to address this issue and improve the completeness of the data. An opportunity exists to make better use of the epidemiological data collected at regional level and there needs to be broader dissemination of the surveillance outputs to clinicians and laboratories involved with the notification of cases. In addition, there might be some opportunities for augmenting the basic surveillance data through participation in a number of ECDC-led projects, such as exploring a morbidity and mortality sentinel system, seroprevalence surveys, and the development of sentinel systems to collect specific data.

The mission team found that the STI surveillance system in Bulgaria has been recently strengthened through the implementation of case-based reporting at the national level, as well as through new legislation. These changes should result in a substantial improvement in the understanding of the data reported both at national and European level. Nevertheless, there are a number of challenges for surveillance of STI in Bulgaria. The private healthcare sector provides the vast majority of clinical consultations for sexual health issues and it appears that there is extensive under-reporting by private clinicians. Moreover, in most cases, patients have to pay for their own laboratory diagnostics which results in most of the diagnoses of STI being made syndromically. There are also no national guidelines on STI diagnosis and management and many diagnoses are apparently made using inappropriate laboratory tests (for example certain serological tests for chlamydia).

There are significant opportunities for improving surveillance of STI in Bulgaria. The case-based reporting system can provide a wealth of data for improving services, for example through assessment of diagnostic methods, risk groups, and general epidemiology of STI. Further strengthening of the system should be considered, for example through development of validation checks to further improve quality and the introduction of a web-based reporting system. The possibility of collaborating with the demato-venerological society in Bulgaria could be investigated in order to start tackling the issue of under-reporting and to consider the need for development of national STI diagnostic and treatment guidelines. One approach to tackling the issue of under-reporting could be to develop a sentinel surveillance system focusing on a selection of clinicians with a particular interest in public health. Further efforts need to be made to strengthen STI laboratory diagnostics, starting with a mapping project to ensure an understanding of the services provided by laboratories in Bulgaria. In addition, surveillance of *Neisseria gonorrhoeae* antimicrobial resistance should be considered.

# 1. Objectives

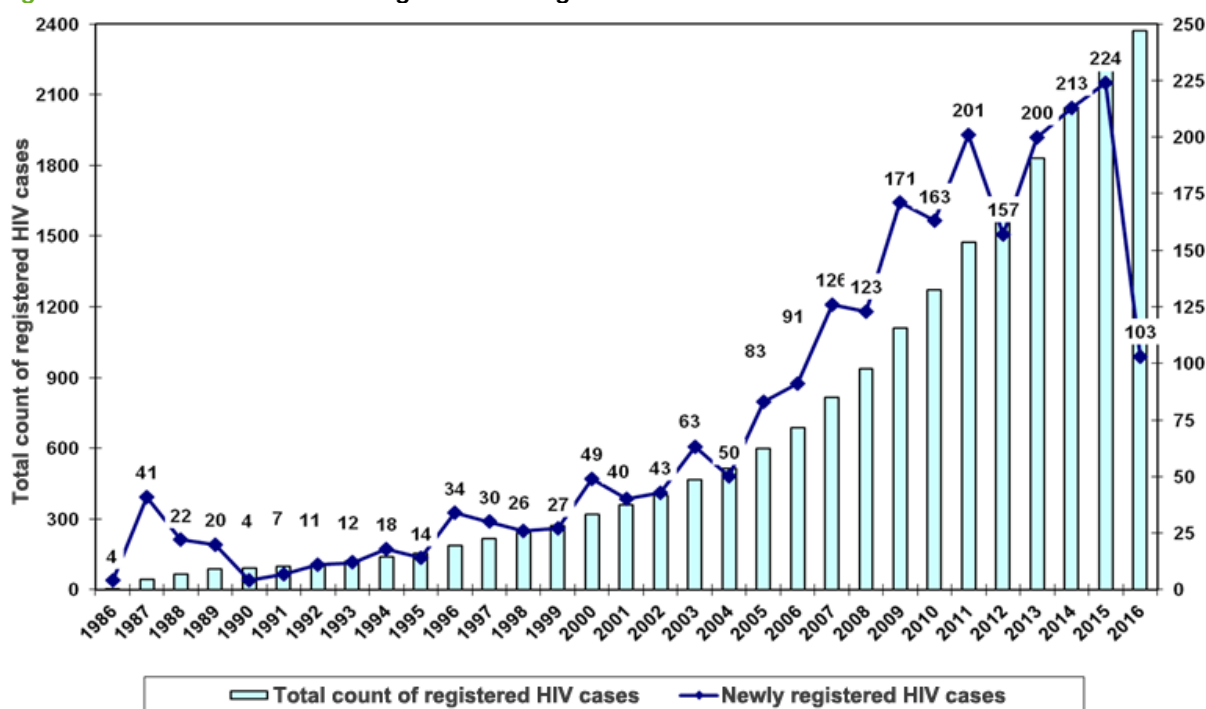
## 1.1 Background

The Ministry of Health in Bulgaria invited ECDC to prepare an assessment of the current national HIV programme and to review the STI and Hepatitis surveillance system. Following discussions between ECDC and representatives of the Bulgarian national programme, it was decided to split the assessment into two separate country missions. The first mission would focus on HIV epidemiology and response and the second would focus on STI and hepatitis surveillance. ECDC has conducted similar missions in a number of other EU countries including Cyprus, Estonia, Finland, Greece, Latvia, Poland, Portugal and Romania.

### 1.1.1 HIV

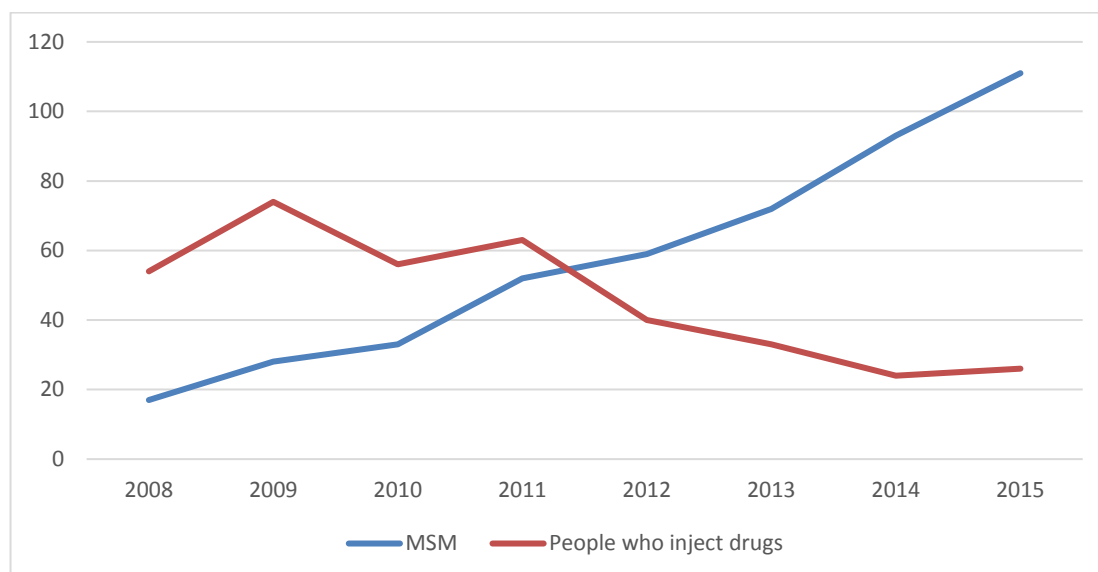
Bulgaria has relatively low levels of HIV infection although the number of new HIV diagnoses per year has been increasing since records began in 1986, particularly since 2004 (see also Figure 2). The number of new diagnoses per year among MSM has risen sharply, from less than 20 in 2008 to over 100 in 2015. During the same period, the number of new diagnoses per year among PWID fell from over 50 to less than 30 (Figure 2).

**Figure 1. Number of new HIV diagnoses in Bulgaria: 1986–2016\***



\*Note figures for 2016 are for part of the year only.  
Data source: Ministry of Health, Bulgaria



**Figure 2. Number of new HIV diagnoses in Bulgaria among MSM and PWID 2008–2016\***

\*Note figures for 2016 are for part of the year only.  
Data source: Ministry of Health, Bulgaria

From 2008 to 2015, Bulgaria has been implementing a national programme for HIV and STI prevention and control. Plans are currently being finalised to continue this programme from 2016 to 2020. In addition to domestic financial resources, since 2004 the national HIV programme has received financial resources of up to USD 50.9 million from the Global Fund to Fight AIDS, Tuberculosis and Malaria. However, the Global Fund financing is now coming to an end.

### 1.1.2 Hepatitis and STI

Robust and reliable surveillance data are critical in order to monitor and inform public health responses in an accurate and timely fashion. Sexually transmitted infections (STIs), hepatitis B and C are serious public health issues in Bulgaria and across Europe. The epidemiology of these infections is constantly evolving and it is important that surveillance systems keep pace with changing epidemics at both national and European levels. Detailed data on new diagnoses, routes of transmission and patient outcomes are needed to monitor the epidemiology of infection and to inform national programmes and plans.

Despite efforts to harmonise data collection across Member States by the European surveillance programmes for STIs and hepatitis B and C, differences in reporting and problems with data completeness continue to hinder comparisons of data. ECDC offers support to countries to facilitate the collection of complete and robust case-based data and to gain a better understanding of the local issues along the surveillance pathway. To date, Bulgaria has provided aggregate data to ECDC for STIs, hepatitis B and C. Aggregate data limit the analyses that can be undertaken and aggregate datasets are often incomplete, containing only a limited number of variables.

Following discussions between ECDC and representatives of the Bulgarian national programme, it was decided to split the assessment into two separate visits. This first mission, which took place on 19–21 September 2016, focused on HIV epidemiology and response. The second mission focused on STI and hepatitis surveillance.

## 1.2 Scope and purpose

### 1.2.1 HIV

The scope of this technical mission was to assess Bulgaria's HIV epidemiology and response, with particular emphasis on (i) ensuring the continuation of prevention activities related to HIV and STI after Global Fund resources are discontinued at the end of 2016 and (ii) the observed increase in HIV among MSM.

The main objective of the technical mission is to provide an evidence-based assessment of the HIV programme and share recommendations with the Ministry of Health on how to maintain the high level of prevention and control measures in Bulgaria after the Global Fund financing comes to an end. A specific focus of the mission was the observed increase in HIV among MSM. The ECDC team, together with experts from the Ministry of Health, were expected to discuss key aspects of the HIV prevention programme for the populations most at risk.

Topics identified for discussion included:

- an epidemiological and behavioural overview of HIV among key populations in Bulgaria;
- a brief description of the HIV surveillance system, including an overview of HIV testing policies and practices;
- an overview of prevention activities among key populations in Bulgaria;
- the role of NGOs in HIV prevention;
- the sustainability of prevention activities in light of the Global Fund withdrawing its funding from Bulgaria at the end of 2016;
- effective interventions to prevent HIV and STI among MSM, including subgroups of MSM at increased risk of acquiring HIV (i.e. sex workers, minorities, illiterate migrants and refugees who do not speak the Bulgarian language);
- behaviour-change strategies targeting MSM;
- campaigns and communication channels for effective messages about changing behaviour, aiming to reduce stigma, discrimination and the risk of HIV incidence among MSM;
- MSM/gay-friendly centres to provide services for curbing HIV and STI prevalence in the MSM group.

### 1.2.2 Hepatitis and STI

The scope of the second technical mission was to provide support for the surveillance of STIs, hepatitis B and hepatitis C. The main objectives were to:

- review Bulgaria's STI and hepatitis B and C surveillance systems, in the context of implementing the current ECDC meta-datasets;
- define key issues with regard to the effective reporting and interpretation of the surveillance data;
- identify any areas where ECDC might provide support for Bulgaria to improve the quality of the data and transition from aggregate to case-based reporting.

The ECDC team, together with experts from the Ministry of Health and the National Centre for Infectious and Parasitic Diseases (NCIPD), aimed to discuss the following issues:

- Surveillance and epidemiology of STIs (chlamydia, gonorrhoea, syphilis), hepatitis B and C in Europe and Bulgaria;
- Surveillance systems for STI and hepatitis B and C in Bulgaria, including plans for surveillance development;
- Organisation of hepatitis and STI diagnostic and treatment services in Bulgaria, including microbiology services;
- Opportunities and challenges facing current surveillance systems in Bulgaria.

### 1.3 Teams

The team for the HIV mission was composed of staff and consultants from ECDC and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Team members included:

- Teymur Noori, ECDC
- Anastasia Pharris, ECDC
- Hans Blystad, ECDC consultant
- Roger Drew, ECDC consultant
- Dagmar Hedrich, EMCDDA.

The team for the second mission was composed of experts from ECDC and Public Health England (PHE). Team members included:

- Erika Duffell, ECDC
- Frantiska Hruha, ECDC
- Gianfranco Spiteri, ECDC
- Nick Bundle, UK Field Epidemiology Training Programme, PHE.

Throughout the missions the teams were supported by Bulgarian colleagues, in particularly representatives from the Ministry of Health. A full list of mission participants is presented in Annex 2.

## 1.4 Organisation

### 1.4.1 HIV

The mission was organised around a three-day visit to Bulgaria. Full details of the mission programme are provided in Annex 1. On the first day, a series of presentations were made by representatives of the Ministry of Health and NGOs. In the afternoon, a visit was made to an NGO in Sofia. On the second day, visits were made to NGOs in Blagoevgrad and to organisations working on drug-related issues in Sofia. On the final day, a debriefing session was held with representatives of the Ministry of Health. A wide range of documents were provided to and identified by the mission team. These are documented in Annex 5.

### 1.4.2 Hepatitis and STI

The mission was organised around a two-day visit to Bulgaria. Full details of the mission programme are provided in Annex 1. Documents and presentations made available to the mission team are listed in Annex 5.

## 2. HIV epidemiology

### 2.1 Overview of HIV surveillance

There are a number of data sources on HIV and AIDS in Bulgaria. These include:

- A system of HIV and AIDS case reporting based on routine testing and screening for HIV in a number of settings including five blood banks; the National Centre of Infectious and Parasitic Diseases (NCIPD); the National Centre for Drug Addictions (NCDA); 28 regional health inspectorates; eight dermato-venereological dispensaries and more than 180 laboratories.
- A national HIV patient monitoring system which records AIDS cases, CD4 counts, viral load levels and incidents of treatment failure. This system has been computerised since 2008.
- A system for conducting integrated bio-behavioural surveillance among key populations.
- Data from the national programme including results of HIV tests conducted in voluntary counselling and testing centres operated by regional health inspectorates and NGOs; in harm reduction and needle and syringe programmes run by NGOs and in drug treatment programmes.

From 1986 to 2016, almost 2 400 people were diagnosed with HIV infection in Bulgaria (Figure 1). Prior to 2003, the number of new diagnoses per year was less than 50 but in 2011 and from 2013 to 2015, the number of new diagnoses was over 200 per year. An increasing proportion of these are being detected among MSM. For example, in 2015, almost half (49.6%) of all new HIV infections were reported among MSM. To date, in 2016, more than half (52.4%) of all new HIV infections have been reported in MSM. In addition, HIV surveillance data show that around 80% of new HIV infections occur in men and that around three quarters of new infections occur among those aged 20–39 years.

### 2.2 HIV surveillance among key populations

#### 2.2.1 Men who have sex with men (MSM)

From 2006 to 2012<sup>1</sup>, annual integrated bio-behavioural surveys were conducted among MSM in Bulgaria. A similar survey was also conducted in 2016, with convenience samples identified from intervention sites in Sofia, Plovdiv, Blagoevgrad, Burgas and Varna<sup>2</sup>. In the surveillance data from 2006 to 2012, among MSM, rates of HIV infection ranged from 0–3.3%, rates of hepatitis B infection ranged from 4–10%, rates of hepatitis C infection ranged from 2–11% and rates of syphilis seropositivity ranged from 3–5%. Preliminary national results from 2016 showed that 3.9% of MSM were positive for HIV, 3.0% for hepatitis B, 3.9% for hepatitis C and 5.7% for syphilis. However, these results masked considerable regional variation. For example, no positive cases of HIV were found in Burgas or Plovdiv but rates of HIV infection were 1.0% in Blagoevgrad, 3.0% in Varna and 12.7% in Sofia.

Based on bio-behavioural surveillance carried out among MSM since 2006, it is reported that:

- One third of the target group do not regularly and correctly use condoms and lubricants during sex, regardless of the gender of their partner. Reasons for this vary.
- Additional efforts are necessary to motivate members of this group to find out their HIV status. According to surveillance data from 2012, 54% of MSM knew their HIV status.
- Half of the respondents in 2011–2012 reported between six to 30 sexual contacts monthly.
- A high proportion of MSM report having had a non-regular sexual partner (2/3 in 2008; 4/5 in 2012).
- Between a third and half of the respondents reported they used a condom every time during anal contacts with non-regular partners.
- A quarter of respondents in 2008 reported that they had had sex with a woman in the past year.

In addition, the 2010 European MSM Internet Survey (EMIS) provides some behavioural data on MSM in Bulgaria. EMIS was an Executive Agency for Health and Consumers<sup>3</sup>-funded survey among MSM across Europe<sup>4</sup>. The national sample provided information on MSM in Bulgaria between June and August 2010 and yielded 1 084 valid responses. EMIS was a wide-ranging survey covering a number of themes, including sexual orientation and practices; coming out; sexual encounters with stable and casual partners; HIV testing and care; STI care; access to healthcare and social services; antiretroviral therapy; meeting points for sex; behaviour of sero-divergent couples; drug use; post-exposure prophylaxis; and stigma and discrimination.

<sup>1</sup> Apart from 2010

<sup>2</sup> The intention was to include 100 people at each site. However, it was only possible to recruit 35 in Burgas and 99 in Blagoevgrad. An additional 10 were included in Sofia, bringing the total sample to 444.

<sup>3</sup> Now CHAFAA.

<sup>4</sup> As such, it was a convenience sample and may not be nationally representative.

Data from Bulgarian EMIS responses showed that:

- Almost two thirds (65.3%) of respondents lived in large cities, compared to less than half (44.3%) across all EU countries.
- Relatively few MSM were 'out' concerning sex with men – 12.5% were out to all or almost all while 21.2% were out to none. A total of 24.6% had had female sexual partners in the last 12 months.
- While 89.8% had visited gay websites in the last seven days, during the last four weeks only 24.8% had visited a gay commercial venue; only 28.0% had visited a gay sex venue and only 5.3% had visited a gay community centre, organisation or social group.
- Almost half (47.0%) were unhappy with their sex life. This was associated with a low rate (34.7%) of men reporting they were in a steady relationship with a man. The most common reason given for sexual unhappiness was wanting a steady partner (29.2%).
- Some MSM (6.6%) reported buying sex in the last 12 months. 6.0% reported having been paid for sex in the last 12 months. In many cases, this sex took place while travelling abroad.
- A relatively small proportion of MSM (8.3%) reported that HIV testing was inaccessible. A total of 36.7% had never been tested for HIV while 41.6% had been tested in the last 12 months. Rates of self-reported HIV among those who had ever been tested for HIV were 2.4%. At the last test, around one third (39.3%) reported they were dissatisfied with the counselling received or that they had received no counselling. There were significantly fewer who reported being dissatisfied with confidentiality (8.3%) or respect (5.9%).
- Only 29.3% of MSM reported an STI test during the previous 12 months. Of those, 85.6% reported having had a blood test while only 10.4% reported having had a penile or anal inspection during STI testing. A total 71.2% of MSM considered STI testing to be affordable or free.
- Almost two thirds (62.5%) reported having had unprotected anal intercourse during the previous 12 months. A total of 17.9% reported unprotected anal intercourse during the previous 12 months solely because of the absence of condoms.
- Overall, 5.0% reported self-injecting. Drugs used in the previous four weeks included poppers (6.4%); cannabis (7.0%); Viagra (2.4%); benzodiazepine (5.3%); party drugs (4.7%); and hard drugs (0.2%).
- Levels of HIV-related knowledge (70.7% overall) were lower than average for Europe, as was the estimated coverage of prevention programmes (54.7%).

## 2.2.2 People who inject drugs (PWID)

From 2004 to 2012<sup>5</sup>, annual integrated bio-behavioural surveys were conducted among PWID in Bulgaria. A survey of this type was also conducted in 2016 and convenience samples were identified from intervention sites in Sofia, Pazardjik, Blagoevgrad, Burgas and Varna<sup>6</sup>. From 2004 to 2012, rates of HIV infection rose from 0.5% to 10.6%. Rates of hepatitis B infection were reported to be 'relatively constant', while rates of hepatitis C infection were reported as 'high'. Preliminary national results from 2016 showed that 1.7% of survey respondents were positive for HIV, 8.6% for hepatitis B, 68.5% for hepatitis C and 0.8% for syphilis.

According to data reported by the National Focal Point to EMCDDA, only sporadic cases of HIV related to injecting drug use were notified in Bulgaria prior to 2004. However, from 2004 to 2009, the number of new HIV cases linked to injecting drug use rose steeply and peaked above 70 in 2009. In 2014, among more than 600 drug treatment clients in Sofia, HIV prevalence was 3.8%, hepatitis B prevalence 6% and hepatitis C prevalence 66.7%. Based on data from clients entering drug treatment, use of heroin as a primary drug has declined in recent years with an increasing use of amphetamine being reported.

## 2.2.3 Other key populations

Bio-behavioural studies have been conducted for a number of other key populations in Bulgaria including:

- The Roma population – such studies were conducted prior to 2013 but they were not included as a distinct risk population in 2016. This was partly due to members of the Roma population being included within other key populations (e.g. MSM and PWID)<sup>7</sup>. The Roma population may also be over-represented among some other populations (e.g. prisoners).
- Sex workers – bio-behavioural surveillance was conducted among sex workers in Sofia, Plovdiv, Burgas and Varna in 2016. Preliminary biological results show HIV prevalence of 0.3%, hepatitis B prevalence of 0.8%, hepatitis C prevalence of 2.0% and syphilis prevalence of 7.3%. It is reported that sex workers are mainly of Bulgarian origin.

<sup>5</sup> Apart from 2010

<sup>6</sup> The intention was to include 100 people at each site. However, it was only possible to recruit 55 in Sofia and 64 in Burgas, bringing the total sample to 421.

<sup>7</sup> Another reason was that the contracts with NGO sub-recipients working with this population had come to an end.

- Prisoners – bio-behavioural surveillance was conducted among male prisoners in Sofia, Plovdiv and Pazardzik in 2016. Preliminary biological results show HIV prevalence of 1.7%, hepatitis B prevalence of 5.3%, hepatitis C prevalence of 13.7% and syphilis prevalence of 1.7%. A recent report from the Centre for the Study of Democracy reported that between 10–15% of prisoners are drug users. In a representative survey on drug use among 3 009 prisoners, carried out at the end of 2014 by the EMCDDA National Focal Point, injecting use of drugs (lifetime) was reported by 21.3% of prisoners (641); 8% (241) reported having injected at least once during their current imprisonment term and 5.4% (163) reported having injected in the previous 30 days.

## 2.3 Gaps in HIV surveillance

In general, Bulgaria has developed a strong HIV surveillance system and this certainly provides sufficient data for decisive action to respond effectively to HIV in the country. However, there are concerns that some of this system was highly dependent on Global Fund financing (e.g. the bio-behavioural surveys), and that it may not be possible to continue these in future. Although such surveys are important, they do not need to be carried out on an annual basis to inform and evaluate HIV programmes. It may be better to plan for surveys of this type periodically (e.g. every 3–5 years), funding permitting, and to maximise usefulness of data from other sources (e.g. the European MSM Internet Survey (EMIS) which is about to be repeated).

The available data does not appear to be being used sufficiently to guide decisions and actions. It will be important to ensure that the results from the all bio-behavioural studies, including those conducted in 2016, are fully analysed and used to inform future funding and activities.

An area where greater understanding might be needed relates to HIV incidence trends and the number of people with HIV in Bulgaria who have not yet been diagnosed. To date, Bulgaria has been relying on spectrum-based estimates which may not be particularly reliable, given the concentrated and low level nature of Bulgaria's HIV epidemic. It may be possible to collaborate with ECDC to generate more robust estimates, using the ECDC HIV Modelling Tool and support provided through this project. It will be important to try to understand risk-group and region-specific HIV incidence and the numbers of those living with undiagnosed HIV in order to target testing and offer prompt treatment. This will probably be essential if Bulgaria's new policy of offering HIV treatment to all those living with HIV is to be implemented effectively.

In connection with this, it might be useful to gain a greater understanding of the different forms of HIV testing being carried out in Bulgaria and to know which are proving most effective in identifying people with HIV who have not yet been diagnosed. Given that financial resources are likely to be more limited in the future, it may be important to focus public resources on the most efficient methods of HIV testing (i.e. those which identify most people with HIV per test conducted and per cost unit/in terms of cost).

Finally, there may be need for better information about Bulgaria's continuum of care and, in particular, to determine why people may be dropping out between the various stages (e.g. from diagnosis to linkage to care, from treatment to viral suppression). One option may be to have more intensive follow-up of those who fail to move from one element of the continuum to another. For example, it may be important to determine the extent to which a decrease in numbers between levels is due to outward migration from the country.

## 3. Response to HIV in Bulgaria

### 3.1 Targeted interventions for key populations

#### 3.1.1 Men who have sex with men (MSM)

Activities to prevent HIV among MSM in Bulgaria have been delivered as part of the national HIV programme with financial support received from the Global Fund. The national HIV programme supports HIV prevention activities for MSM through NGOs that are willing to work in this area. Activities take into account that MSM are a heterogeneous hard-to-reach group in Bulgaria. There are high levels of seasonal migration and foreign travel for a range of reasons including tourism, education and work.

A key challenge has been that, although there are some organisations working on LGBT issues in the country (e.g. LGBT Action and Bilitis) their main focus has been on issues relating to human rights, including the organisation of 'Sofia Pride'. To date, these groups have not focused significantly on HIV prevention activities. The 'Queer Bulgaria Foundation' did carry out activities related to HIV prevention but the organisation's activities dwindled following the death of a key person. The NGOs working with HIV prevention among MSM include Health without Borders in Sofia and Blagoevgrad, the Avis Vita Foundation in Plovdiv, the Dose of Love Association in Burgas and SOS Families in Risk Foundation in Varna. Services are provided by teams consisting of medical staff, other professionals and representatives from communities of MSM (see Box 1). Figure 3 shows how services provided by the national HIV programme for different key populations are distributed across the country. Condoms are also reported to be available to MSM through the Voluntary Counselling and Testing (VCT) centres operated by regional health inspectorates.

#### Box 1. HIV prevention activities provided for MSM in Bulgaria

There are health education centres for MSM in Sofia, Blagoevgrad, Varna, Plovdiv and Burgas. These are also used as a basis for outreach work providing counselling and distribution of condoms, lubricants and health education materials. Voluntary counselling and HIV testing are provided in the centre and through mobile medical units.

Other services include:

- Testing for syphilis and hepatitis.
- Diagnosis and treatment of STIs.
- Education of popular opinion leaders in the community.
- Case management for people most at risk.
- Campaigns for popularising services and messages on gay websites and social media.
- Seminars to reduce stigma and discrimination towards MSM among representatives of public administration.
- Training for staff of NGOs.
- Exchanges of experience.
- An internship programme – involving representatives from the gay community in outreach work.

Highlighted results include:

- 11 111 MSM reached through health services in 2015.
- Around 500 000 condoms distributed to MSM annually.
- Over 5 000 MSM receiving HIV testing and counselling.

**Figure 3. Map of activities supported by the national HIV programme**



Source: Ministry of Health, Bulgaria

ECDC has produced guidance on HIV and STI prevention among MSM which identifies, based on evidence, seven key components for consideration by programmes in Europe. Table 1 looks at the extent to which these components are currently provided in Bulgaria. In addition, given that many of the activities have been implemented by NGOs with financing from the Global Fund, the table also looks at the extent to which these might be at risk once the financing from the Global Fund comes to an end.



**Table 1. Assessment of the extent to which key components for HIV prevention among MSM are available in Bulgaria**

Item	Description	Availability	Risk
Condoms	Provide easily accessible condoms and condom compatible lubricants and promote their use. Promotion and provision should be based on population and venue mapping and could include internet-based promotion, sex-venue based outreach interventions, including condom distribution, to promote and provide use of condoms and lubricants.	With funding from the Global Fund, it has been possible to implement activities related to distribution of condoms, consulting on the correct way to put on a condom and on the regular use of condoms and lubricants among MSM in Sofia, Varna, Burgas, Plovdiv and Blagoevgrad. Condoms are also available to MSM through VCT centres in regional health inspectorates. The condoms were designed for anal sexual intercourse and small amounts, designed for vaginal and oral intercourse, were distributed too, mainly for educational purposes. More than half a million condoms have been distributed annually. But, the number distributed has declined since 2011. There is no information about how MSM get condoms in other towns.	The national programme 2016-2020 envisages continued distribution of condoms/lubricants through the existing network. But, this programme has not been approved. It is not clear if funding to NGOs will be prioritised – particularly for work with MSM. Without funding, it is unlikely that NGOs will continue to promote condoms among MSM as they have.
HIV and STI Testing	Provide various types of voluntary and confidential HIV and STI counselling and testing that are easy to access by the target group, including provider-initiated offering of tests, outreach and community-based testing programmes. Voluntary and anonymous partner referral should be offered routinely when a person is diagnosed with HIV or another STI.	With funding from the Global Fund, it has been possible to provide free, voluntary and anonymous HIV testing (with rapid test – oral or with peripheral blood) in the VCT centres or at the health-educational centres for MSM, as well as at meeting places for those at-risk (with a medical mobile unit, according to a schedule). Testing for HIV and STIs (hepatitis B and C, syphilis) has been offered in the mobile units as well, though it takes longer (about a week) to process the blood samples in the regional health inspectorate labs. There is less information about STI testing apart from syphilis. It seems likely that the increased detection of HIV among MSM is, in part, due to a greater focus on HIV testing among MSM.	The national programme 2016–2020 envisages continuation of services. However, this programme has not been approved. It is likely that some HIV testing will continue – e.g. through regional health inspectorates – but it is unclear the extent to which this would reach MSM. If funding is not provided to NGOs, it is likely that their VCT activities will decline and cease. This may result in reduced detection of HIV among MSM.
Treatment for HIV, viral hepatitis and STIs	Timely provision of antiviral treatment of HIV, including PEP, and of hepatitis B and C according to individual needs and also taking into account principles for treatment as prevention and national clinical guidelines. Provision of targeted antibiotic treatment for different STIs.	ART is available in five infectious disease hospitals financed by the Ministry of Health. However, unit costs are high. From June 2016, the policy is to offer all PLHIV treatment regardless of CD4. Relatively few PLHIV appear to receive treatment. PEP is not available except for occupational exposure. Hepatitis treatment is provided by specialists and is reported to be covered by the health insurance fund. But, there are concerns that the health insurance fund does not cover the treatment of STIs and it is reported that antibiotics can be purchased without prescription from pharmacies. As most STIs are treated privately and there is no requirement for private practitioners to report these, STIs are considered to be under-reported nationally.	Although it seems likely that the government will continue to finance ART from the state budget, it is unclear how people will be identified for treatment if NGOs are not supported to continue to offer testing to MSM and other key populations. In the future, STI treatment is likely to only be available for those able to make out-of-pocket payments.
Health promotion	Provide accurate and accessible information that enables men to understand and judge sexual health-related risks and prevention efficacy, and that promotes awareness of one's own HIV status. Health promotion could take place in counselling sessions, peer support groups, outreach interventions for MSM and via public or targeted campaigns promoting sexual health among MSM.	This has been supported through different NGOs in five locations in Bulgaria. This has included conventional materials, such as pamphlets and brochures, which are distributed in a range of sites including parks, gardens, toilets, saunas, cafeterias and disco clubs. NGOs are also working through social media and popular opinion leaders. There is a desire to work more through social media.	It is unclear if the Ministry of Health would be well-placed to provide such services directly. It therefore looks as though these services will be at risk if the government does not find ways of funding NGO activities in this area once money is no longer being received from the Global Fund. It is reported that these activities are partially covered in the national HIV programme 2016 to 2020, although this is not yet approved.
Delivery of MSM-competent health services	MSM-competent points of care offering a comprehensive sexual health programme including health promotion, counselling, peer support, prevention, adequate diagnostic and treatment. The design/implementation of services to be organised with target group involvement. Any health facility that targets sexual health should provide training for those offering comprehensive care for MSM.	Five health education centres for MSM have been established. These offer health promotion, consulting, rapid HIV testing, individual case management, and training of leadership groups. MSM also have access to health services in the same way as others would in Bulgaria. However, it is unclear the extent to which some particular services (e.g. high quality STI treatment) would be available to MSM. There were some reports that MSM face negative attitudes from health workers if their sexual orientation or positive HIV status becomes known. While some health education centres for MSM provide treatment for STIs, many MSM are dependent on access to 'gay-friendly doctors' for proper treatment.	It is reported that the activities of the five centres are expected to continue under the national HIV programme 2016–2020. However, this has not yet been approved. If there is a reduced focus on the needs of MSM in future (e.g. if NGOs are no longer supported to work in this area), it is hard to see how work in this area would be prioritised.
Targeted care for MSM living with HIV	Early ART for HIV based on current guidelines, comprehensive and specific treatment for STIs including hep B and C. Offer and supply regular STI screening, including anal swabbing and LGV-testing if positive for Chlamydia, as well as vaccination for hepatitis B and regular testing for hepatitis C. Offer individual counselling, sexual health promotion and organise counselling and peer-support groups.	It is reported that all MSM newly-diagnosed with HIV are provided case management, which is, specific services for psycho-social support – consulting, advising, motivating for out-of-anonymity status, motivating for sending a blood sample to the national HIV confirmation lab, protocol, appointment for initial exam in a treatment ward, guidance, offering of services for PLHIV. However, it appears that relatively few people with HIV are being diagnosed and then linked to and retained in care and treatment.	It is reported that the activities of the five centres are expected to continue under the national HIV programme 2016–2020. However, this has not yet been approved. If there is a reduced focus on the needs of MSM in future (e.g. if the work of NGOs is no longer supported in this area) it is hard to see how work in this area would be prioritised.
Vaccinations	Promote and deliver vaccination to protect against: Hepatitis A and B. Consider vaccination against HPV.	Vaccination against hepatitis A and B is not currently available to MSM. However, vaccination is available if paid for.	Not likely to be addressed.

Availability colour code: green – good availability; amber - limited availability; red – not available. Risk colour code: green – low risk; amber – medium risk; red – high risk. (Risk here relates to future risk to the intervention as a result of funding uncertainty)

### 3.1.2 People who inject drugs (PWID)

The national HIV programme has supported HIV prevention services for PWID across several sites in Bulgaria including in Sofia, Pleven, Varna, Burgas, Plovdiv, Pazardzik and Blagoevgrad. Drop-in centres provide services at their premises and also through outreach work. Services include needle exchange; providing clean injecting equipment and disinfectants; counselling and testing for HIV, hepatitis and syphilis; training and counselling for safe injecting, HIV and AIDS, hepatitis and STIs; information about and referrals to treatment services; overdose prevention and case management for people living with HIV and other health problems. For details of the results achieved by the Initiative for Health Foundation programme in Sofia see Box 2.

Nationally, the number of PWID reached through the national HIV programme remained at around the same level (>7 000) per year between 2009 and 2015. However, the number of safe injecting kits distributed fell from a peak of 676 898 in 2010 to 364 111 in 2015. There were reported to be a number of reasons for this. During 2012 and 2013, there was a lack of injecting kits because of delays in delivering medical supplies due to the rapid turnover of administrative management in the Ministry of Health. However, since 2014, there have been adequate supplies of injecting kits, although there have been reports that clients were dissatisfied with the quality of the equipment distributed for free. Since the financing from the Global Fund came to an end in 2014, there has been uncertainty concerning the continuation of prevention activities among most at-risk groups, despite these activities continuing under a no-cost extension from the Global Fund. This meant that contracts with NGOs were signed late in 2015 and it is reported that some NGO staff became demotivated and started looking for other jobs.

There are reports that some sub-groups of people who use drugs are more difficult to reach than others. These include members of the Roma community and younger Bulgarian drug users who meet in private homes to use drugs, particularly oral amphetamines. Apparently, needles and syringes are available for sale from pharmacies, however, pharmacists may be reluctant to sell injecting equipment to PWID.

According to EMCDDA data, in 2014, there were 30 specialised units delivering opioid substitution therapy (OST) in 14 cities and towns. A total of 3 414 people were undergoing OST, most (96%) with methadone. Around one third of clients were reported to be treated through programmes funded by the Ministry of Health or municipalities. According to the most recent data available there were a total of 4 632 people receiving OST in Bulgaria. Of these, 541 (12%) were receiving OST in state-funded methadone programmes; 850 (18%) were receiving OST in municipal-funded methadone programmes; and 3 241 (70%) were receiving OST in private programmes (including 241 receiving morphine sulphate pentahydrate). Private and governmental OST services are licensed by the Ministry of Health and accredited by the National Addiction Centre. Methadone itself is funded by the state but clients have to pay other costs.

During the visit to Blagoevgrad, it was reported that there was no publicly-funded OST programme available in the area because there was no psychiatrist who was willing to run this. Anyone wishing to receive OST in the area needed to pay for it. This was reported to be a particular problem for those who were HIV positive as, in the absence of affordable OST, it had proved difficult for PWID to either start ART or to take it consistently. It was reported that two HIV positive people who had been injecting drugs had died without receiving ART or OST. In commenting on this issue, one expert reported that outside large cities in Bulgaria it may be difficult for PWID to access OST and ART and this is particularly the case for the most vulnerable drug users.

In Sofia, the public OST programmes apparently have long waiting lists. It was also reported that the number of opioid users attending the outreach syringe programme close to Pirotska church had declined following the introduction of OST programmes. However, those who continue to attend tend to have low health, educational and social status. Among street users, the combined use of methadone and stimulants had become more common, with the declining quality of heroin, and the appearance of methadone on the black market at low price. Many come from the Roma community and face a range of problems including unemployment, poverty, lack of identity documents, multiple infections and social isolation, including from families.

#### Box 2. Results achieved by the Initiative for Health (IFH) Foundation HIV prevention programme for PWID in Sofia

IFH provides services for people who inject drugs in Sofia. Each year, its outreach team has around 6 370 contacts with 1 450 people who inject drugs. They distribute around 59 000 syringes and 5 670 condoms. They collect and destroy around 120 kg of used injecting equipment. They provide safer injecting counselling, collect blood samples for diagnostic testing for around 300 people and currently provide intensive case management for around 37 people, helping them to obtain identity documents, enter methadone programmes and receive ART.

Relatively little information was available about HIV and drugs-related services in the prison system. Responsibility for this comes under the Ministry of Justice and this area has not specifically been covered by the national HIV programme, although it appears there are proposals to include prisoners in the next HIV programme (2016–2020). Concerns were raised that many PWID spend time in prisons. According to EMCDDA data, it is possible for people on methadone to continue this treatment in prison, but in 2014, only 77 prisoners passed through maintenance programmes (40 of them in Sofia prison). In five of the 13 regional prison services, no OST services are provided. Clean injecting equipment is not currently available in the prison system.

ECDC and EMCDDA have produced joint guidance on prevention and control of infectious diseases among PWID which identifies, based on evidence, seven key components for consideration by programmes in Europe. Table 2 looks at the extent to which these components are currently provided in Bulgaria. In addition, given that many of the activities have been implemented by NGOs with financing from the Global Fund, the table also looks at the extent to which these might be at risk once the financing from the Global Fund comes to an end.

**Table 2. Assessment of the extent to which key components for prevention of infectious diseases among PWID are available in Bulgaria**

Item	Description	Availability	Risk
Injecting equipment	Provision of, and legal access to clean drug injection equipment, including a sufficient supply of sterile needles and syringes free of charge, as part of a combined multi-component approach, implemented through harm-reduction, counselling and treatment programmes.	The national HIV programme, funded by the Global Fund, involved distribution of materials for safe injecting and counselling for correct and consistent use of protective materials among PWID in Sofia, Varna, Plovdiv, Burgas, Pazardzhik, Pleven, Kyustendil, Ruse, Pernik and Blagoevgrad. NGOs that are sub-recipients of grants to work on harm reduction among PWID have also identified other sites, such as Nova Zagora, Sliven, Yambol, etc. Although more than 7 000 PWID are reached with such services annually, the number of safe injecting kits distributed fell from 676 898 in 2010 to 364 111 in 2015. It is reported that one of the reasons for this was a lack of kits because of delays in delivering medical supplies due to the rapid turnover of administrative management in the Ministry of Health between 2012 and 2103. Since 2014, there have been enough kits although there are reports that clients were unhappy with their quality. In addition, uncertainty over future funding resulted in contracts with NGOs being signed late in 2015, with reports that some NGO staff were demotivated and looking for other jobs.	The national HIV programme 2016–2020 envisages continuing these services. However, the programme is not yet approved so funding is not guaranteed. There is a risk that the human capacity within NGOs working with PWID could be lost if sustainable funding is not guaranteed.
Testing	Voluntary and confidential testing with informed consent for HIV, hepatitis C (hepatitis B for unvaccinated) and other infections, including TB, should be routinely offered and linked to referral to treatment.	The national HIV programme, funded by the Global Fund, has provided free, anonymous, rapid HIV testing for PWID in nine low-threshold, drop-in centres at meeting places for PWID, typically using mobile medical units; in the National Centre for Drug Addiction and in VCT centres. The same facilities also offer free testing for syphilis and hepatitis B and C.	The national HIV programme 2016–2020 envisages continuing the provision of such services. However, the programme is not yet approved so funding is not guaranteed. The money envisaged under the national strategy for combating drugs would also be expected to help with this.
Infectious disease treatment	Antiviral treatment based on clinical indications for those who are infected with HIV, hepatitis B or hepatitis C. Anti-tuberculosis treatment for active TB cases. TB prophylactic therapy should be considered for latent TB cases. Treatment for other infectious diseases should be offered as clinically indicated.	Control and treatment of HIV in Bulgaria has been carried out in five treatment wards at infectious disease hospitals in the country. ART is paid for by the Ministry of Health. The treatment of hepatitis B and C has been provided by medical specialists and it is covered by the national health insurance fund. Treatment of different STIs mainly needs to be self-funded. There are concerns that not everyone who needs ART is currently receiving it. In particular, it was reported that PWID find it difficult to access and sustain ART if they cannot access affordable OST.	Although it seems likely that the government will continue to finance ART from the state budget, it is unclear how people will be identified for treatment if NGOs are not supported to continue offering testing to PWID and other key populations. In the future, STI treatment is likely to only be available to those able to make out-of-pocket payments.
Health promotion	Health promotion focused on safer injecting behaviour; sexual health, including condom use; and disease prevention, testing and treatment.	These services have been provided to PWID by outreach workers at a variety of sites. Outreach workers are consulted on the risks of STIs and ways to prevent HIV and STIs, as well as on the opportunities offered by the drop-in centres, VCT centres and the National Centre for Drug Addiction within the programme funded by the Global Fund. Outreach workers also disseminate health education brochures. Some activities have been conducted through the Internet, direct mailing and mobile apps. Electronic health education materials are also available.	It is reported that these activities will be partly covered by the national HIV programme but this is not yet approved or funded. If NGOs are not funded to provide these services, there is a high risk that they will not be provided.
Drug dependence treatment	Opioid substitution treatment and other effective forms of drug dependence treatment.	While there are some established OST programmes in Bulgaria, many require some financing from clients. Only 30% of clients receiving OST obtain it from fully state-funded programmes. In Sofia, the main public treatment programme has a long waiting list. There are reports of people who want treatment not being able to get this. There are particular problems for PWID wishing to access treatment, yet this group has the highest level of risk behaviour and is socially the most marginalised. Although some OST is available in the prison system, this is not extensive.	While it is likely that OST services will continue at some level, it seems unlikely that they will be expanded to the extent needed in the near future.
Vaccination	Hepatitis A and B, tetanus, influenza vaccines, and, in particular for HIV-positive individuals, pneumococcal vaccine.	There is no special vaccination programme for PWID as this is not assessed to be a priority service in Bulgaria.	Not likely to be addressed.
Targeted delivery of services	Services should be combined, organised and delivered according to user needs and local conditions; this includes the provision of services through outreach and fixed site settings offering drug treatment, harm reduction, counselling and testing, and referrals to general primary health and specialist medical services.	Case management is considered to be a key service for PWID who are HIV infected in order to support them in getting started and adhering to ART. This service is highly valued by clients of NGOs. Case management includes a set of services for psychological and social support for PLHIV – counselling, advising, blood testing, confirmatory test for HIV, protocol, appointment for first medical tests upon discovery of positive HIV status, guidance and accompanying the client to various health and social institutions. While NGOs are providing case management services, the numbers of people receiving these services are relatively low to date.	The national HIV programme 2016–2020, in collaboration with the national strategy to combat drugs 2014–2018, plans to continue to support and maintain the nine drop-in centres for prevention of HIV/STIs among PWID. However, this programme is not yet approved or funded.

Availability colour code: green – good availability; amber - limited availability; red – not available. Risk colour code: green – low risk; amber – medium risk; red – high risk. (Risk here relates to future risk to the intervention as a result of funding uncertainty.)

## 3.2 HIV testing: policies and practice

The objectives of HIV testing policy in Bulgaria are to reduce the risk of HIV spread; promote early diagnosis of HIV-infected individuals so they can be provided with treatment, care and support and provide timely counselling and testing of the sexual partners of HIV-infected people. Testing can be initiated by either the provider of services or the client. HIV testing is available in a number of settings including 190 diagnostic laboratories; hospitals; eight dermatovenereological medical centres; five blood banks; 28 regional health inspectorates; 19 voluntary counselling and testing (VCT) centres<sup>8</sup> and 17 mobile medical units. HIV testing is not provided at primary healthcare facilities, including family doctors' surgeries. In some settings (e.g. diagnostic laboratories), client payment of around EUR 7–8 is required while in others (e.g. VCT centres and mobile medical units), testing is free to the client as it is paid for by the Ministry of Health. Table provides details of the numbers of HIV tests conducted in Bulgaria from 2009 to 2015. Health providers are not legally obligated to conduct partner notification and there is uncertainty about the extent to which partner notification is actively used as an HIV prevention measure.

**Table 3. Number of people tested for HIV annually: 2009–2015**

	2009	2010	2011	2012	2013	2014	2015
Number tested in medical facilities		221 421	272 471	294 437	286 301	280 858	299 574
Number tested in regional health inspectorate VCT	61 284	61 581	58 303	47 704	36 314	30 565	29 662
Number of members of key populations tested in NGO VCT	16 430	21 920	26 360	23 988	18 636	22 839	22 143
<b>TOTAL</b>		<b>304 922</b>	<b>357 134</b>	<b>366 129</b>	<b>341 451</b>	<b>334 262</b>	<b>351 379</b>
Percentage among key populations		7.2	7.4	6.6	5.5	6.8	6.3

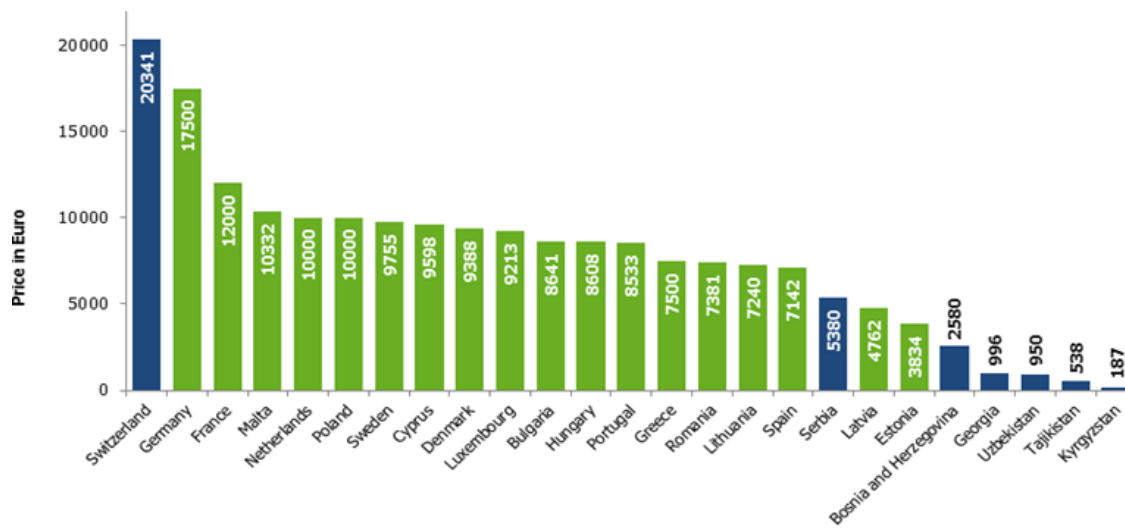
Information was not provided on the form of HIV testing identifying most new HIV infections. However, based on surveillance data, it is known that from 2009 to 2014, between 53% and 63% of all new HIV diagnoses annually occurred among MSM or PWID. During that time, between 5.5% and 7.4% of all HIV tests specifically targeted these and other key populations.

Although there has been some discussion of the use of home and self HIV testing and there do not seem to be legal barriers preventing their use in Bulgaria, there do not appear to be active plans to consider these approaches to identify people with HIV infection more efficiently. Concerns were raised as to how people taking such tests could receive counselling, particularly if they tested positive. Although it appears that Bulgaria has, to some extent, moved away from a focus on high levels of pre- and post-test counselling, there does still seem to be more focus on counselling than on ensuring people diagnosed with HIV are linked to care, and started on antiretroviral treatment. For example, when concerns were raised about private laboratories giving people their HIV results by phone or via the Internet, this was seen in the context of the lack of availability of suitable counselling, rather than the need to link people to care and treatment.

## 3.3 HIV treatment and care

Since June 2016, the policy in Bulgaria is to offer ART to everyone diagnosed with HIV. Prior to that, treatment was offered to those with a CD4 count  $\leq 500$ . Treatment is provided free of charge to all Bulgarian citizens financed from the state budget. ART is reported to be available from five infectious diseases hospitals across the country. According to data reported to ECDC, the mean cost of ART per person in 2015 was USD 9 262 (approximately EUR 8 200). Comparative data for 2013 from ECDC (Figure 4) shows that Bulgaria's unit costs were relatively mid-range for EU countries, but higher than those for Hungary, Portugal, Greece, Romania, Lithuania, Spain, Latvia and Estonia. If Bulgaria could reduce its unit costs to the same level as Spain, this would save the country more than EUR 1 million per year and, if unit costs could be reduced to those of Estonia, this would save the country almost EUR 4 million per year. The latter saving would be enough to fund the entire national HIV programme twice over.

<sup>8</sup> It was reported that only 13 of these were operating at the time of the visit.

**Figure 4. Reported average cost of ART per patient per year, 2013**

Data source: ECDC

Since 1986, 2 267 Bulgarian citizens are reported to have been diagnosed with HIV. The number reported to have ever initiated treatment is 1 722, which is 76% of those ever diagnosed. A total of 715 people were reported to be virally suppressed ( $\leq 200$  copies per ml at last visit), corresponding to 41.51% of all those on treatment.

Based on data presented during the visit and related discussions:

- Concerns were raised about the accuracy of estimates for people living with HIV in Bulgaria.
- Figures of those ever diagnosed or ever started on ART may not be that useful as people may have left the country.
- The number of people living with HIV in treatment sites in 2015 was 1 086, 824 of whom were currently on ART.

Although respondents were aware of both post-exposure and pre-exposure prophylaxis (PEP and PrEP), it was reported that PEP was only available to health workers for occupational exposure to HIV. PrEP was reported not to be available.

There were reports of people with HIV experiencing stigma and discrimination in healthcare settings. MSMS were also reported to have experienced stigma and discrimination in such settings because staff feared they might become HIV infected once they learned of their sexual orientation.

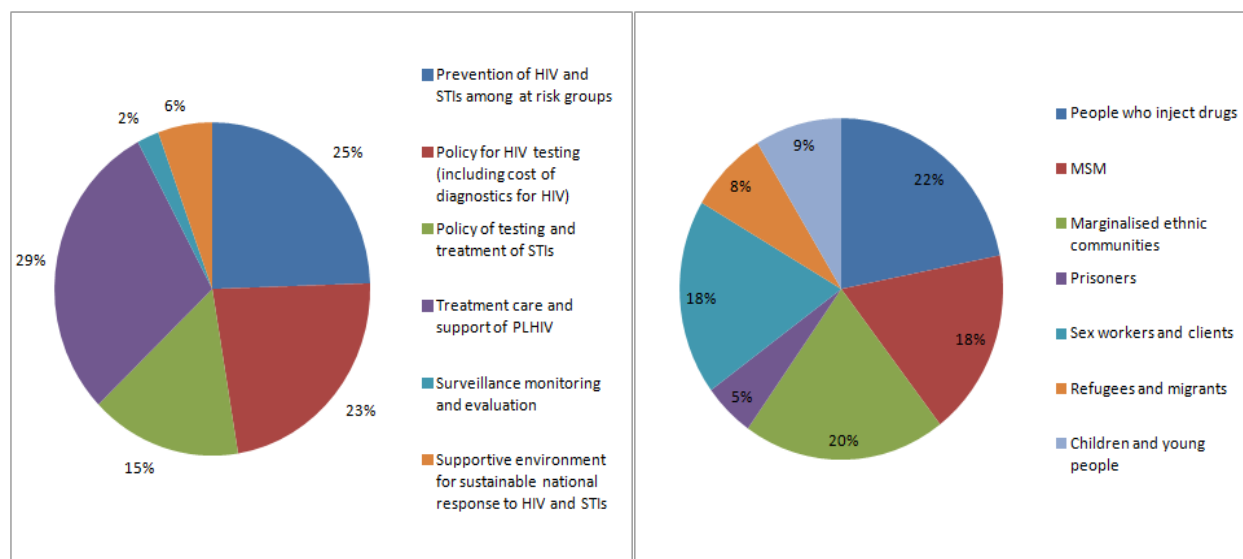
### 3.4 Coordination of and funding for HIV services

Bulgaria has a National Council on HIV and AIDS which includes representatives from ten government ministries, NGOs and people living with HIV. It meets twice per year and is responsible for coordinating and approving the national HIV programme. Although the Council can establish working groups, it has not yet done so. By way of an alternative, representatives on the Council can raise issues for discussion and approval. Issues relating to a particular key population would tend to be raised by Ministry of Health staff working in that particular area.

The national HIV programme has also established agreements with the 21 largest of the 265 municipalities in Bulgaria. In nine of these, local coordination committees have been established. Municipalities can establish local policies on HIV and can support activities by providing premises and small grants.

A new national programme has been designed for the period 2016–2020 but this has not yet been approved. The five year budget is for BGN 20.4 million (approximately EUR 10.5 million), that is approximately BGN 4 million or EUR 2 million annually. Figure 5 shows how the proposed budget is divided among particular groups of activities and how the proposed prevention budget would be distributed among key populations. One quarter (25%) of the budget is proposed for prevention of HIV and STIs among at-risk groups. Just over one quarter (29%) of the budget is set aside for treatment, care and support for PLHIV. Almost one quarter (23%) of the budget is set aside for the policy of HIV testing which includes the cost of diagnostics for HIV. Of the budget for HIV prevention among risk groups, less than half (45%) is allocated to PWID, MSM and prisoners. This appears to be only 11% of the total budget of the national programme, which seems to compare poorly with the 20% set aside for services for PWID and for MSM in the current national programme.



**Figure 5. Proposed distribution of the national HIV programme budget, 2016–2020**

Data source: Ministry of Health, Bulgaria

NGOs have some concerns about the proposed new national HIV programme including plans to channel funds to NGOs through calls for tenders at municipal level. Although NGOs were involved in drafting the new HIV programme, they report that they were not involved in the development of the budget.

From 2004 onwards, Bulgaria received financing of up to USD 50.9 million from the Global Fund to Fight AIDS, TB and Malaria in order to support the country's national response to HIV. According to the Global Fund's website, USD 49.96 million has been committed, of which USD 49.35 million has been disbursed. It appears that the programme was expected to have been completed by the end of 2014 but commitment and disbursement of funds has lagged behind budget. This means that support has continued by means of no-cost extension(s). It was reported that sub-recipients had been told on two previous occasions that the programme would be ending, only for an extension period to be announced. While it was reported that Global Fund financing will cease at the end of September 2016, it is unclear whether funds are available for a further no-cost extension. It certainly appears that some sub-recipients have finances and resources available to continue some services after the end of September. For example, some needle and syringe programmes reported that they had enough injecting equipment to allow them to continue to operate until the end of 2016. However, if further funding is not found through the approval of the national programme, services - particularly those operated by NGOs - will inevitably cease. It is reported that some services have already begun to wind down because of uncertainty over ongoing funding. For example, an NGO working in Sofia reported that it no longer provides free sexual healthcare to clients or outreach in prisons. Several staff members had already left for jobs with a more stable outlook. Other staff are either now working part-time for the project or are transferring to work more on TB because there is ongoing Global Fund financing for Bulgaria's TB response.

In 2015, Optima conducted an analysis of HIV funding in Bulgaria concluding that to optimise funding there needed to be increased domestic HIV spending, scaled-up ART at reduced unit cost and a focusing of all HIV prevention spending on PWID and MSM. This analysis warned that if prevention programmes for key populations were not funded there could be a substantial increase in new infections. Although an abstract based on this work was presented at a scientific conference and findings from Bulgaria were compared with findings from Macedonia and Georgia in a publicly-available report, the status of this report and analysis is unclear. It is not cited as a country case study on the Optima website and respondents were unclear as to whether this report and analysis had been accepted by the Ministry of Health.

What is clear is that following the end of financing from the Global Fund, Bulgaria will be increasingly dependent on domestic funding for its response to HIV. In particular, this will depend on funding of the national HIV programme and other health expenditure, such as ART and HIV testing in health facilities. Some additional funding may be available from other ministries and/or local municipalities. However, while municipalities may be able to disburse and manage funds received from the national programme, their own contributions are currently modest in most cases, limited to the provision of premises and very small grants.

Other possible funding sources that are being considered include:

- The national health insurance fund, which currently does not cover HIV services, with the exception of treatment of opportunistic infections. Plans are being considered to try and finance some HIV testing through this fund.
- Other external funds, including resources from the EU and EEA. One option might be the use of European structural funds.
- Direct fundraising by NGOs. However, this is reported to be difficult because of the nature of the work, reduced funding for HIV (particularly in European countries) and the requirement of many funders that there be a significant element of co-financing.

Although it is not strictly a funding source, securing ART at a lower unit cost could result in very large financial savings that could potentially be used for other HIV-related purposes.

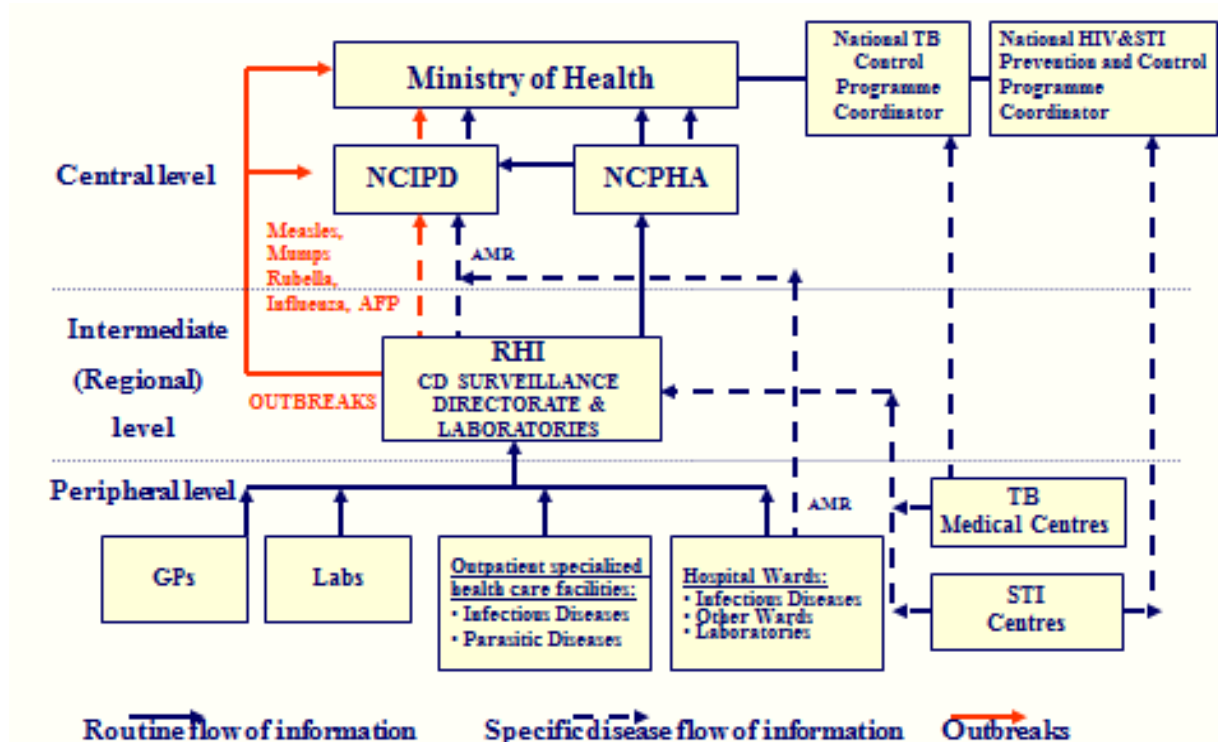


## 4. Hepatitis and STI surveillance in Bulgaria

### 4.1 Surveillance system description

Infectious disease notification and surveillance in Bulgaria occurs within the legal framework set out in Ordinance 21 (Regulating the Registration, Notification and Reporting of Infectious Diseases, 2005). Important implications of a 2014 update to Ordinance 21 include reference to the 2012 EU case definitions (2012/506/EU) and a shift towards collection and recording of case-based data at all levels of the system.

**Figure 6. Data flow for the infectious disease surveillance system in Bulgaria**



Source: National Centre of Infectious and Parasitic Diseases

Data for general communicable disease surveillance follow the routine information flow of aggregate data reporting shown by the solid blue line in Figure 6. Within each of the 28 regional health inspectorates in Bulgaria, the same epidemiologist is responsible for managing notifications and responding to outbreaks occurring within their region. Case-based paper notifications are not recorded in an electronic database. Instead, regional health inspectorate epidemiologists create an electronic aggregate summary of all diseases reported before sending this to the National Centre for Public Health Analysis (NCPHA). NCPHA cleans and compiles the data from each of the 28 regional health inspectorates in country level reports that are sent to NCIPD and the Ministry of Health. NCIPD produces manually weekly operational reports, which are published on their website. The operational reports consist of:

- An epidemiological bulletin for 26 diseases under EU surveillance
- Influenza and acute respiratory infections information system
- Information from the National Reference Laboratory for influenza and acute respiratory infections, NCIPD
- Web-based data collection and dissemination system for epidemiological surveillance of measles, mumps and rubella
- Web-based data collection and dissemination system for surveillance of acute flaccid paralysis.

Every April, NCIPD sends annual reports on analysis of communicable diseases to the Ministry of Health and these are also published on the NCIPD website<sup>9</sup> in Bulgarian.

Case-based reporting systems are currently implemented as three separate surveillance systems for HIV/AIDS, TB (both shown by the dashed blue line in Figure 6), and measles/mumps/rubella/acute flaccid paralysis (shown by the dashed red line in Figure 6).

<sup>9</sup> [http://www.ncipd.org/index.php?option=com\\_docman&view=list&slug=analizi-na-zaraznite-zabolyavaniya&Itemid=1127&lang=bg](http://www.ncipd.org/index.php?option=com_docman&view=list&slug=analizi-na-zaraznite-zabolyavaniya&Itemid=1127&lang=bg)

### 4.1.1 Overview of hepatitis B and C surveillance

The Bulgarian team reported the following national objectives for hepatitis surveillance:

- to follow trends in the infected population and distinguish between acute and chronic cases;
- to detect and respond to local outbreaks, including those in nosocomial settings.

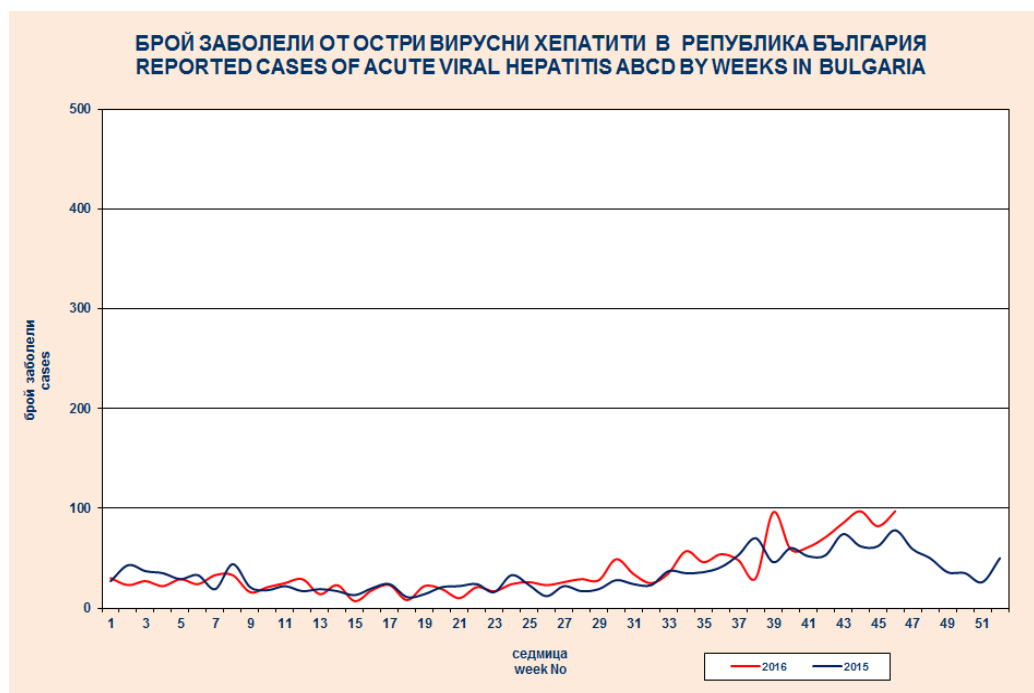
Data for hepatitis B and C surveillance follow the routine information flow shown by the solid blue line in Figure 6. A notifiable disease registration book (Annex 3) is maintained by primary care providers to record all newly diagnosed cases. Within 24 hours of diagnosis, peripheral (local) level providers, including blood transfusion centres, notify their regional health inspectorate via email, fax or phone and send a follow-up rapid notification form on paper (Annex 3). Notification can also occur following blood-borne virus screening results if these are carried out alongside HIV testing. Testing may also be conducted by private doctors and under-reporting of infectious diseases from private laboratories and clinics is an issue.

The epidemiological information collected on the rapid notification form includes information on risk factors, possible transmission routes and the details of case contacts. An epidemiologist at the regional health inspectorate investigates cases and suspected outbreaks of acute hepatitis, visiting cases in hospital, making home visits and investigating potential nosocomial transmission.

Weekly information flows from the regional health inspectorate to the NCPHA contain counts of hepatitis cases, with no differentiation by type. Monthly summaries are also sent from the regional health inspectorate to the NCPH which are able to distinguish between hepatitis A, B, C, D and 'non-specified'. Totals are available differentiated by age category and sex.

At the national level, regional level data are reviewed by NCPID which is able to follow up with the regional health inspectorate if they identify anything of concern. Each week, NCPID updates a time series of hepatitis cases (ABCD combined) which is published in English and Bulgarian on the centre's website (Figure 1), accompanied by commentary on the differences between the previous week this year and the same week the previous year. These trends are driven largely by cases of hepatitis A, which makes up the around 70% of the hepatitis disease burden in Bulgaria.

**Figure 7. Reported weekly counts of cases of hepatitis A, B, C and D by week in Bulgaria, 2015–16**



Source: NCIPD website [http://www.ncipd.org/index.php?option=com\\_biuletin&view=view&month=44&year=2016&lang=en](http://www.ncipd.org/index.php?option=com_biuletin&view=view&month=44&year=2016&lang=en)

In the NCIPD annual report, viral hepatitis is reported separately as hepatitis A, B, C, D, and non-specified.

## 4.1.2 Overview of STI surveillance

The main national objective of the STI programme identified by the Bulgarian team was to strengthen the STI network and enlarge the number of people receiving testing, consultations and treatment, including those in the most at-risk groups.

STI services are provided by the public sector and by private dermato-venereologists. Although precise data are not available, it is considered that private dermato-venereologists account for the vast majority of STI consultations in Bulgaria. The services provided by the public sector included regional dermato-venereology clinics supported by laboratories. These clinics and laboratories are, however, slowly being phased out. People tend to prefer to use private clinics as they are perceived to be more confidential and there is a strong financial incentive for specialists to offer private STI clinics. Consultations with a doctor are covered by health insurance but the patient has to pay out of pocket for STI testing, with the exception of free ante- and neonatal testing for syphilis, and also for treatment. Patients are referred to private laboratories to provide samples and upon receipt of their result they go back to their doctor for treatment. There are no recent national diagnostic and/or treatment guidelines for STI in Bulgaria. Clinicians noted that there are occasionally problems sourcing benzathine penicillin and ceftriaxone which are often used for treatment of syphilis in Bulgaria.

Under the National Programme for Prevention and Control of HIV and STIs, supported by the Global Fund, the Bulgarian government set up free STI testing for high-risk groups including Roma, PWID, MSM, sex workers and prisoners. Services were provided by NGOs who signed agreements with dermato-venereologists to provide STI services via private STI clinics. Under these arrangements, diagnoses were mainly syndromic, with little ongoing confirmatory testing, and there were no opportunities to provide free of charge treatment. Global Fund financing ceased at end of 2014 and a no-cost extension was granted for 18 months, which has now ended, leaving Bulgaria in a period of transition with only some activities continuing for the most at-risk groups. The number of public STI clinics has decreased from 28 (one per region) to the current total of seven for the entire country. Although a large number of private dermato-venereology clinics remain, access depends on the ability to pay.

Cases of chlamydia, gonorrhoea and syphilis are usually diagnosed by dermatologists in dermato-venereology clinics and/or via laboratories to which patients are referred for testing. From here, cases are notified to the regional health inspectorate. Since mid-2016, case-based data has been reported directly to the National HIV and STI Prevention and Control Programme Coordinator at the Ministry of Health (Figure 6). Prior to the introduction of case-based data flows, STI data flowed via the same routine data flow as hepatitis B and C, however since this introduction the regional health inspectorate sends data directly to the Ministry of Health. The case-based reporting system collects all the key variables required to assess case confirmation and report to ECDC. However, based on a very limited assessment, it appears that the quality of the reported data and the coding of some variables need improvement.

Congenital syphilis surveillance has recently been assessed through a WHO country visit in relation to the global targets for elimination of mother-to-child transmission of syphilis. The visit identified issues relating to case validation and possible over-reporting of cases of congenital syphilis in Bulgaria. These issues are currently being addressed through a comprehensive retrospective review of cases and ongoing improvement in prospective case surveillance. There are, however, issues with the clinical management of diagnosed cases and the availability of treatment.

Contact tracing is carried out mostly by dermato-venereologists (both public and private) following diagnosis and can also be done as part of the epidemiological survey on each case following notification to the regional health inspectorate. However patients are not always cooperative, making it very challenging to find partners/contacts. Treatments are commonly given to cases to be passed on to their partners. Files are maintained on each patient to allow longitudinal comparison of results.

NCIPD writes reports for the Minister of Health every six months, summarising the epidemiology of each STI and these reports are used to inform Ministry decision-making.

## 4.2 Opportunities for the overall surveillance system

The ECDC team was encouraged by the high levels of experience and expertise among national professionals from within NCIPD, the Ministry of Health and clinicians and laboratory staff.

The description of the regional health inspectorates suggests that, if human resources allow it, they are well positioned to respond in a timely manner to local signals detected from the infectious disease notification system.

A shift towards a case-based system could be facilitated by building upon what is already in place. Case-based data for measles, rubella, influenza and acute flaccid paralysis currently flows between regional health inspectorate, NCIPD and Ministry of Health, as shown in red on Figure 6, via a web-based system. There may be potential for expanding this to incorporate other diseases. Furthermore, all family doctors now have computers which could be an opportunity to facilitate electronic reporting and notification, thus reducing the burden on regional health inspectorates to manually process paper notifications.

The Bulgarian team expressed a desire to be able to use surveillance system outputs for regular mapping of disease burden and statistical exceedance detection. Much of this, as well as existing manual processes, such as weekly updating of web-based disease reporting, could be automated using software such as 'R', which would free up NCIPD staff time for other activities.

### 4.3 Gaps in the overall surveillance system

The following overarching surveillance system challenges were identified during the visit.

Firstly, appropriate human resources are extremely limited. At regional level, it is difficult to find trained epidemiologists able to cover the caseload. At all levels of the system there is a lack of young people emerging from training in these specialities. Within NCIPD there are currently only two individuals producing annual reports on all diseases. These human resource constraints make it very difficult to envisage moving towards case-based reporting of hepatitis B and C, despite widespread support for the concept in principle.

Secondly, the flow of information between different parts of the system is very restricted. This appears to be the case at national level, where an apparent disconnection between the Ministry of Health's HIV/STI special programmes and NCIPD is further exacerbated by the existence of a parallel system of data flow. There also appear to be communication challenges between NCIPD and regional health inspectorates, with very limited understanding at NCIPD of the day-to-day challenges facing regional health inspectorates. It was not clear how well the implications of the recent update to Ordinance 21 have been communicated to the regional health inspectorates and it appeared that there was very little support available for implementing these changes. Many of these issues are linked to the limited human resources outlined above and NCPID staff expressed a desire to work more closely with regional health inspectorates if they had more capacity.

Thirdly, despite the mandatory nature of the communicable disease notification system there is a problem of under-notification, particularly from private laboratories and clinics and with regard to STIs.

There was also a likelihood that using aggregated data has a negative impact on data quality, making it difficult to remove duplicate entries and use the data for more advanced and timely analysis.

In addition, the system of requiring patients to pay for testing services may act as a potential disincentive among many high-risk groups (who may be likely to have a limited income), raising concerns about inequity in access and representativeness of the data on those diagnosed.

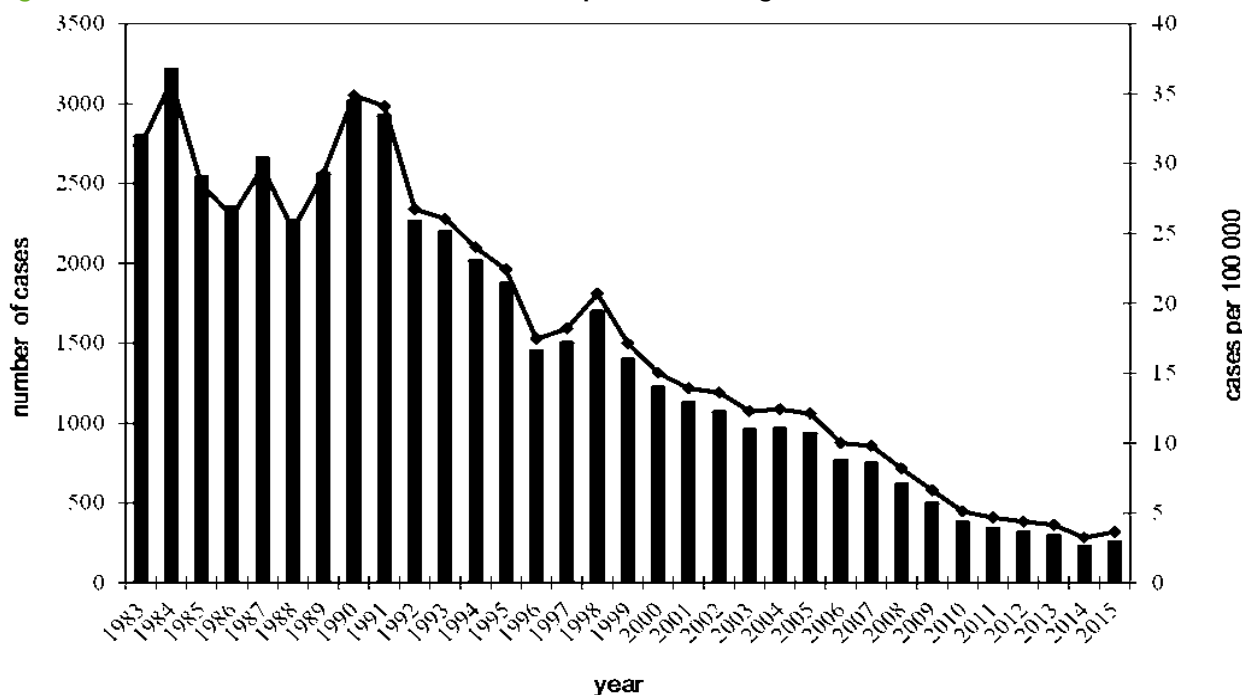
Finally, the existing surveillance system is not ideally suited to outbreak detection. Although regional health inspectorates appear to be well-placed to detect local outbreaks, with the current data flows it is not possible for NCIPD to detect diffuse outbreaks occurring in multiple regions. Although there is a live system for sharing information between regional health inspectorates, if the inspectorates suspect that a cross-border outbreak is occurring, there is no electronic system for recording outbreaks centrally, with outbreak reports simply being sent to the Ministry of Health.

# 5. Hepatitis B and C

## 5.1 Epidemiology

Previous seroprevalence studies in Bulgaria have estimated prevalence of hepatitis B (HBsAg) to be between 2% and 7%. In terms of incidence, there has been a decreasing trend in HBV since the introduction of universal HBV vaccination of new-borns and healthcare workers in 1991 (Figure 2). HBV vaccine coverage is estimated to have reached 97% in 1998/9 and 92% in 2015. The incidence of newly diagnosed hepatitis B infection is now very low among children under five years, increasing with age to a peak in 30–34 year olds (Figure 3).

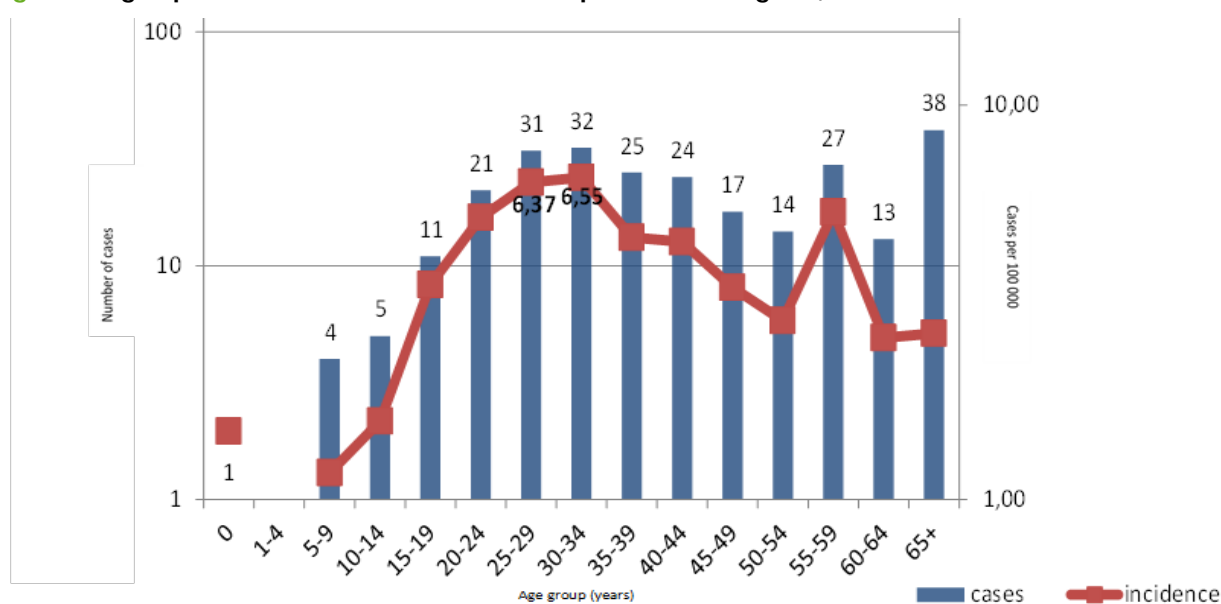
**Figure 8. Annual case counts and incidence of hepatitis B in Bulgaria, 1983–201**



Bars: number of cases, Line: cases per 100 000.

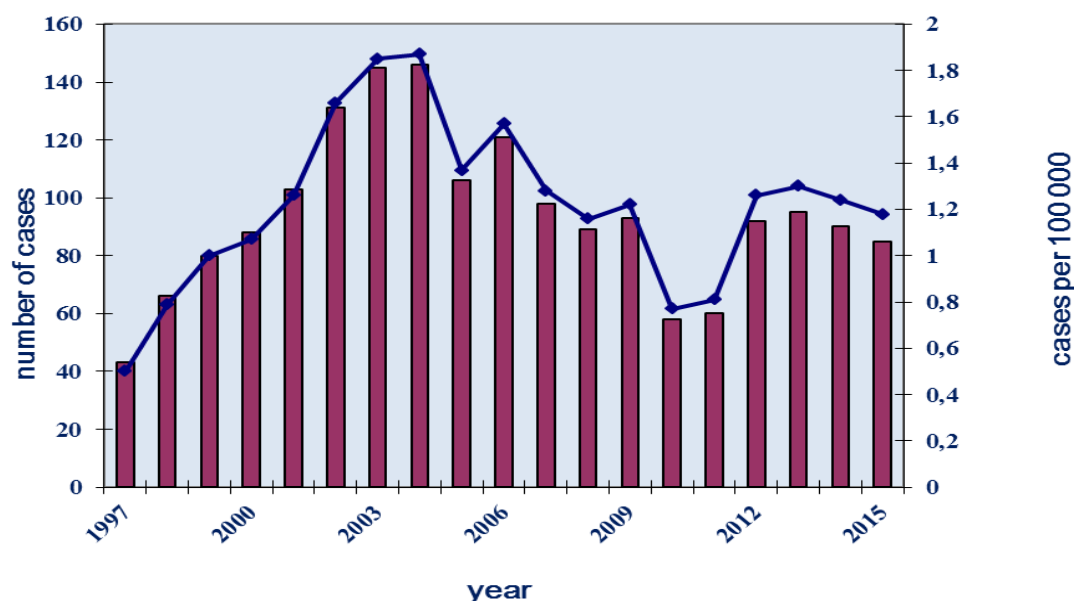
Source: Vladimirova, N. (2016) *Viral Hepatitis B and C in Bulgaria: epidemiology, prevention, surveillance* [Presentation]

**Figure 9. Age-specific counts and incidence of hepatitis B in Bulgaria, 2015**



The estimated prevalence of hepatitis C is 1.3% (anti-HCV). Overall, there has been a decreasing trend in the incidence of newly diagnosed hepatitis C cases since 2004, punctuated by a notable increase between 2011 and 2012 (Figure 10).

**Figure 10. Annual case counts and incidence of hepatitis C in Bulgaria, 1997 -2015**



Source: Vladimirova, N. (2016) *Viral Hepatitis B and C in Bulgaria: epidemiology, prevention, surveillance* [Presentation]

Prevalence estimates for HBV, HCV and syphilis are available for particular high-risk groups from bio-behavioural surveys, conducted as part of the Programme for the Prevention and Control of HIV/AIDS, financed by the Global Fund. Results from the most recent set of surveys in 2016 are summarised in Table 1. These figures are based on convenience sampling at a limited number of intervention sites for HIV/STI prevention and they cannot therefore be generalised to the wider population of these risk groups in Bulgaria. Similar studies were conducted with the Roma population prior to 2013, but they were not included as a distinct risk population in 2016. This was partly because members of the Roma population were included within other key populations (e.g. MSM and PWID). The Roma population may also be over-represented in other population groups (e.g. among prisoners). A high proportion of HBV diagnoses in Bulgaria reportedly occur among members of the Roma population.

**Table 4. Observed prevalence of hepatitis B, C and syphilis among convenience samples from MSM, PWID, sex workers and prisoners in Bulgaria, 2016**

Risk group	Sample description	HBV	HCV	Syphilis
MSM	Intervention sites at Sofia, Plovdiv, Blagoevgrad, Burgas and Varna <sup>10</sup> (n=444)	3.0%	3.9%	5.7%
PWID	Intervention sites in Sofia, Pazardzik, Blagoevgrad, Burgas and Varna <sup>11</sup> (n=421)	8.6%	68.5%	0.8%
Sex workers	Intervention sites in Sofia, Plovdiv, Burgas and Varna, reported to be mainly of Bulgarian origin (n=361)	0.8%	2.0%	7.3%
Prisoners	Male prisoners in Sofia, Plovdiv and Pazardzik (n=300)	5.3%	13.7%	1.7%

Source: Naseva, E. (2016). *Mission report. Technical mission: HIV in Bulgaria 19–21 September 2016 and Preliminary results of the integrated bio-behavioural surveillance 2016* [Presentation]

<sup>10</sup> The intention was to include 100 people at each site. However, it was only possible to recruit 35 in Burgas and 99 in Blagoevgrad. An additional 10 were included in Sofia, bringing the total sample to 444.

<sup>11</sup> The intention was to include 100 people at each site. However, it was only possible to recruit 55 in Sofia and 64 in Burgas, bringing the total sample to 421.

## 5.2 Opportunities for hepatitis surveillance

One area in which the system of surveillance does appear to trigger public health action is that taken by regional health inspectorates in response to notification of potential acute HBV cases. At the regional level an epidemiologist investigates all reported cases and suspected outbreaks of acute hepatitis, and will visit the cases to collect detailed epidemiological information and investigate the causes of nosocomial outbreaks. The epidemiological information collected as part of these investigations is an untapped data resource that is currently not being utilised.

There is an increasing focus on hepatitis within Europe, with a WHO Regional Action Plan, an agenda for elimination and an expert meeting planned for 2017. The aim is to reduce the incidence and mortality, which has implications for the type of surveillance required. Hepatitis surveillance within Bulgaria will need to be improved, with the collection of more robust data on the incidence of new acute and chronic infections for hepatitis B and C and hepatitis-specific mortality data at national level. ECDC could offer some technical support if required.

A high level of HBV vaccination coverage has been achieved in Bulgaria. Work is underway to implement an immunisation register which will be operational in one region from 2017 and will contain information on vaccine coverage and adverse events. It is unclear whether it will be feasible to maintain this register, but the inclusion of real time data from family doctors is regarded as increasing the likelihood of the successful uptake of this system.

Opportunities exist to set up sentinel surveillance sites based on the following:

- Existing active follow-up of notified HBV cases to collect comprehensive transmission route/risk factor information;
- Data from antenatal screening for HBV to inform population prevalence estimates.

The project that has recently been launched by ECDC to help support countries in developing estimates of prevalence using standardised methodologies was discussed and the involvement of Bulgaria in this project was identified as a potential opportunity for collaboration in 2017.

NCIPD expressed support for the data requirements of both WHO and ECDC to be streamlined to remove the need for submission of separate, overlapping datasets. Harmonising the ECDC/WHO dataset requirements would reduce the time needed by staff to prepare these datasets, giving them more time to work on other projects. Streamlining would also ensure that there is consistency in the national figures for Bulgaria.

## 5.3 Gaps in hepatitis surveillance

Five main challenges in hepatitis surveillance were identified.

Firstly, one of the key problems with the HBV data at national level is that the data is that acute and chronic cases are not differentiated. The inability to differentiate between acute and chronic HBV and accurately identify transmission routes linked to acute cases really hinders Bulgaria's ability to understand what is driving its HBV epidemic and to monitor progress towards the elimination agenda. The 2012 EU case definitions are used to define the data (Annex 4) but these were intended for use with case-based datasets where data is differentiated during a second step using the stageHEP variable in the case-based metadata set.

Secondly, the data at national level is only available in aggregate format with a restricted dataset. Aggregate data restricts the data analysis that may be undertaken to provide a more detailed understanding of the epidemics of hepatitis B and C.

Thirdly, obtaining accurate estimates of seroprevalence is challenging. The in-depth studies estimating prevalence among risk groups mentioned above were carried out as part of the HIV programme, but the results were poorly disseminated nationally and were not integrated into hepatitis B and C surveillance systems within NCIPD to gain a more complete overview of the epidemiological picture. It is also unclear whether the data have been used to inform prevention measures such as vaccination.

It is also hard to understand how complete notification actually is and the data presented to ECDC suggest that there may be under-notification of cases. Although notification of acute and chronic hepatitis cases should take place, it is possible that, as in many other countries, clinicians are only reporting acute cases. This results in the under-notification of all newly diagnosed cases. There are many private laboratories undertaking tests ordered by private doctors which have to be paid for by patients and this results in a very disjointed system. Despite mandatory notification, the level of completeness for notification of newly diagnosed cases from the private sector is unclear.

Finally, surveillance of disease outcomes related to hepatitis B and C is currently limited. Mortality data relating to hepatitis B or C is only recorded when hepatitis is specifically mentioned as the underlying cause of death. There is no system to record the number of hepatitis C patients being treated.



## 6. Sexually transmitted infections

### 6.1 Epidemiology

Data on the epidemiology of sexually transmitted infections in Bulgaria is mostly available through the national surveillance programme in Bulgaria. In addition, estimates of syphilis prevalence among risk groups are available through bio-behavioural surveys, conducted as part of the Programme for the Prevention and Control of HIV/AIDS financed by the Global Fund, as described above.

Bulgaria reported 255 cases of chlamydia infection in 2015 which results in a rate of 3.5 cases per 100 000. This is one of the lowest rates of chlamydia infection in the EU/EEA, and well below the EU average of 173 per 100 000, which suggests a high level of underreporting. Trends in chlamydia infection rates in Bulgaria had been increasing until 2014, but decreased in 2015 (6.8). The male-to-female ratio was 0.9. The highest reported rates were among 25–34 year-olds (14 per 100 000) and 20–24 year-olds (11 per 100 000).

ECDC's publication 'Chlamydia control in Europe: literature review'<sup>12</sup> did not identify any population-based representative studies from Bulgaria assessing chlamydia prevalence. The 2012 ECDC survey on chlamydia control in Europe<sup>13</sup> reported that Bulgaria did not have a national strategy for STI control. Although there was a plan addressing sexual health promotion this did not specifically mention chlamydia infection. There was also a set of clinical guidelines for chlamydia infection which recommended partner notification, testing of pregnant women and opportunistic testing for chlamydia infection, however in practice this was rarely carried out.

Bulgaria reported 119 cases of gonorrhoea infection in 2015, resulting in a rate of 1.7 cases per 100 000. Once again, this was one of lowest rates of gonorrhoea in the EU/EEA and well below the EU average of 19 per 100 000. Trends in gonorrhoea rates in Bulgaria had fluctuated between 1.3 and 2.7 per 100 000 since 2006. The male-to-female ratio was 2.1. Age-group and transmission category were not reported.

Bulgaria reported 465 cases of syphilis infection in 2015 resulting in a rate of 6.5 cases per 100 000, which is almost at the EU average of 6 per 100 000. In Bulgaria, trends in syphilis rates had been decreasing until 2012 but have since increased by 55%. The male-to-female ratio was 2.7 in 2015. Age-group and transmission category were not reported. Bio-behavioural surveys (see Table 1 above) report high syphilis prevalence among MSM and sex workers. The contribution of MSM, sex workers and their clients to the epidemiology cannot be assessed using the surveillance data as currently reported.

### 6.2 Opportunities for STI surveillance

It is very encouraging that case-based surveillance has been in place for the last three months. This has the potential to improve the quality of data at national level and facilitate a better understanding of the epidemiology of STI in Bulgaria.

There are significant opportunities for improving surveillance of STI in Bulgaria. The case-based reporting system can provide a wealth of data for improving services, for example through assessment of diagnostic methods, risk groups, and general epidemiology of STI. Detailed analysis of the data could be presented to the dermato-venerological society in Bulgaria. Collaboration with this society could be a means for tackling surveillance of STI and under-reporting. ECDC could provide technical support to this collaboration.

In addition, collaboration with the dermato-venereological society could lead to the development of national STI diagnostic and treatment guidelines which could improve practice at national level. ECDC could possibly provide technical support through clinical, microbiologist or epidemiological expertise to help develop such guidance.

ECDC could also provide support through expert exchanges (both for microbiologists and epidemiologists) and specific country visits with a view to developing surveillance for gonococcal antimicrobial resistance, as well as identifying training opportunities for dermato-venereologists.

The European Gonococcal Antimicrobial Surveillance Programme (Euro-GASP) currently has 23 countries taking part and the programme is looking for additional countries to participate. Benefits from involvement in the programme could include additional country support visits and the development of guidelines around resistance, which could highlight the importance of testing and obtaining cultures for resistance profiling.

<sup>12</sup> <http://ecdc.europa.eu/en/publications/publications/chlamydia-control-europe.pdf>

<sup>13</sup> <http://ecdc.europa.eu/en/publications/Publications/chlamydia-control-survey-europe-2012.pdf>



## 6.3 Gaps in STI surveillance

Under-reporting is a key issue for STI surveillance in Bulgaria. The move to private service provision, combined with the poor reporting from private clinicians means that a very small subset of diagnosed cases are reported in the surveillance system. In addition, data completeness is likely to be poor. Clinicians consider notification to be an additional burden and since there are no financial incentives for them to report, it is unlikely that the situation will improve significantly. Given the limited resources, one approach could be to develop a sentinel surveillance system focusing on a selection of motivated clinicians with a particular interest in public health.

The introduction of case-based data collection is a step in the right direction, however the system still involves considerable manual work and reporting via email and Excel files. There is a risk that poor quality data enter the system which necessitate additional effort, both at central and regional health inspectorate level for validation and cleaning. It is unclear how much additional effort is required from regional health inspectorates to produce these case-based monthly Excel sheets and there is a risk of delays in reporting, quality issues and under-reporting. The parallel data flows of this system, compared to the system used for other infectious diseases, further contribute to the inefficiencies. Further development of the reporting system to a fully web-based system with appropriate automated reminders, checks and validation and reporting facilities would reduce the effort needed at all levels and lead to better quality data being collected at national level.

In addition, there are clearly issues with diagnostics of STI in Bulgaria. For example, ELISA<sup>14</sup> is mostly used for chlamydia, and use of NAAT<sup>15</sup> is not widespread. There is limited understanding about how appropriately antimicrobials are used; the extent of gonococcal antimicrobial resistance within Bulgaria and no surveillance in place for *Neisseria gonorrhoeae* antimicrobial susceptibility surveillance. Addressing this gap would require collection of isolates for sensitivity testing, however private laboratories tend to prefer microscopy to culture (even for women where this is not recommended), and are often unwilling to send viable cultures to the reference laboratory. Limited availability of gonococcal isolates at the National Reference Laboratory is the main challenge for Bulgaria's participation in Euro-GASP.

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<sup>14</sup> enzyme-linked immunosorbent assay

<sup>15</sup> Nucleic acid amplification testing

## 7. Conclusions and recommendations

### 7.1 Conclusions and priorities for action

#### 7.1.1 HIV epidemic in Bulgaria

According to the Global Fund to Fight AIDS, TB and Malaria, 'Bulgaria's HIV burden has been kept low through the comprehensive HIV prevention and treatment programs implemented with the support of the Global Fund.' It is definitely a major achievement that Bulgaria has been able to keep its HIV epidemic at a low level, particularly given the significant HIV outbreaks occurring in neighbouring countries, such as Romania and Greece, and the significant HIV epidemics occurring in countries within the region (e.g. Ukraine).

Although early cases of HIV have been found among PWID, the number of new cases diagnosed in this group has stabilised and declined. Bio-behavioural surveillance studies show that HIV prevalence has not risen significantly in this group. Therefore it seems that the interventions under the national programme have been successful in this regard. However, it is of great concern that these programmes have been largely dependent on the activities of NGOs financed by the Global Fund and that the national HIV programme, which would provide some funding to these programmes, has not yet been agreed and is as yet unfunded.

There are also indications that, in common with many other European countries, there are an increasing number of HIV infections diagnosed among MSM in Bulgaria. The number of new cases diagnosed among MSM annually is rising and, according to the most recent biological surveillance data, some areas of Bulgaria (notably Sofia) appear to have high rates of HIV prevalence among MSM.

#### 7.1.2 Strategy for preventing HIV

Given the decision in Bulgaria to offer ART to all those diagnosed with HIV, the country is potentially in a position to adopt 'test and treat' as a prevention strategy. However, to do this, Bulgaria would need to intensify the work to diagnose all those currently infected with HIV and to ensure they are linked to care and supported in accessing ART. This will require even more extensive HIV testing among key populations, particularly among MSM and PWID (also in prison settings). Given that much of the testing to date has been conducted by NGOs with funding from the Global Fund, there are real concerns as to whether this testing will even continue at current levels since the national HIV programme is not yet approved or funded. It is likely that new approaches to testing (e.g. home and self-testing) are going to be important if the number of people living with HIV in Bulgaria, but not yet diagnosed, is to be reduced. Reimbursing the cost of HIV testing through the national health insurance fund may improve access to testing for some people. The use of mobile phones and other services for voluntary partner notification could also be considered. Similarly, support for people to receive ART will probably need to include OST for those HIV-positive PWID. More involvement of the primary care health system in both testing, follow-up and treatment may be necessary to secure a high testing coverage and longer-term counselling services for people living with HIV.

In terms of programmes for MSM, a great deal of excellent work is being done. Perhaps more effort could be made to engage LGBT and MSM communities in designing and delivering the HIV response. One possibility might be to establish an MSM community organisation/checkpoint. There might be opportunities to develop links with those working on HIV prevention among MSM communities in other European countries in order to share experience. HIV prevention services for PWID are also of critical importance. Reaching marginalised groups of PWID depends on community-based outreach as well as improved services in prisons.

#### 7.1.3 Financing the HIV response

Bulgaria's national HIV response is facing a serious funding challenge. Over the past 12 years, significant financial support has been received from the Global Fund and this, along with domestic resources, has enabled the country to develop a strong and effective HIV response. However, financing from the Global Fund is ending. It is not yet clear if the government will approve and fund the national HIV programme for 2016 to 2020. If not, there is a serious risk of a rapid rise in new HIV infections, initially among MSM and PWID, given that some of Bulgaria's neighbours are experiencing much more severe HIV outbreaks and epidemics.

While it is excellent that Bulgaria is funding ART from domestic resources and has committed to offer this to all people diagnosed with HIV, there is a need to drive down unit costs for ART. Even if this is done, the cost of treating a person with HIV will be significantly higher than the cost of preventing the infection in the first place. Failing to finance prevention activities which are known to be effective (e.g. services for PWID and MSM through NGOs) is likely to represent a very poor-value-for-money choice for the Bulgarian government.

While recognising the contentious and controversial nature of some of the interventions required, there is strong evidence that HIV prevention activities should be highly focused on those most at risk of HIV infection, that is, MSM and PWID. Often NGOs are better able to provide these services than governments.

While emphasising the need to continue providing direct HIV services after financing from the Global Fund comes to an end, it is also important to note that Bulgaria has developed strong HIV monitoring, evaluation and surveillance systems with Global Fund support. It is essential that these continue although there is no need for annual bio-behavioural surveillance studies.

In addition to providing national level funding, the Ministry of Health needs to continue working with municipalities to encourage their involvement and contribution. Consideration should also be given to how to make better use of EU mechanisms (EU Structural Funds, CHAFEA Health programme projects, EU Commission Joint Actions and the EU Commission Health Security Committee, etc.)

### 7.1.4 Surveillance of viral hepatitis and STI

Bulgaria has a well-established system for national surveillance of communicable diseases. Epidemiology staff at national level have extensive experience in the surveillance of notification data relating to different communicable diseases and have maintained a functioning system, despite limited resources. The recent significant loss of experienced staff at national level may influence the sustainability of the current communicable disease surveillance services.

Surveillance of hepatitis B and hepatitis C is established within the national surveillance system and based on notifications from clinicians. Detection of outbreaks of acute hepatitis B at local level appears to be effective, with contacts being followed up and detailed epidemiological data being collected. The data collected at local level needs to be collated nationally as case-based reports to replace the current system which is based on the reporting of aggregated data at regional level. The current system also suffers from underreporting and does not facilitate differentiation between acute and chronic hepatitis B and this is a major barrier to understanding the epidemic in the country. There is a need to further develop clear objectives for surveillance and appropriate allocation of resources to support the implementation of the proposed shift towards case-based reporting. Major barriers to progress appear to be the lack of sustained financing and associated human resource shortages at all levels, which threaten to undermine the current surveillance system and make the realisation of case-based reporting unlikely.

Case-based reporting for STIs commenced mid-2016. While encouraging, it is too early to assess how well this system functions and there are concerns about the future of programmes linked to the Global Fund for HIV/STIs. Additionally, services for testing, treatment and notification of STIs in Bulgaria have limited public financial support, with the risk that data quality may be further undermined. STI data flows largely via a parallel surveillance system established with Global Fund financing and this system is poorly-connected to the routine data flow for hepatitis and other infectious diseases. This results in a disjointed system, further compounded by limited communication between the teams responsible for the different parts.

There are a number of opportunities available to overcome some of the above challenges, including possible support from ECDC and involvement in European initiatives. The recommendations below outline the broad steps required to improve the quality of data collected and move towards a surveillance system that creates information for timely public health action.

## 7.2 Specific recommendations

### 7.2.1 HIV

In summary, the mission recommends the following actions:

1. Strengthen responses to HIV among MSM and PWID in Bulgaria, including:
  - Sustaining and expanding existing programmes including the offer of condoms, testing and treatment for MSM and needle and syringe programmes, OST and testing and treatment for PWID.
  - Considering the establishment of an MSM community/organisation/checkpoint.
  - Seeking to expand HIV testing of MSM and linkage to care by reimbursing HIV testing through the health insurance fund; providing free testing for those not covered by insurance; expanding community-based testing, including through self-testing and home-sampling; and expanding voluntary partner notification using mobile phones and other technology.
2. Improve the entry and retention of people living with HIV in the continuum of care, including:
  - Expanding the diagnosis of HIV infection through broader HIV testing among MSM and PWID, including through community-based services and outreach.
  - Examining and understanding why people are lost to follow up at different stages of the HIV care continuum.
  - Establishing specific continuums of care for MSM and PWID.
3. Approve and fund the national HIV programme 2016–2020 as a matter of urgency, including:
  - Providing funding to NGO-run services for MSM and PWID
  - Securing the current HIV monitoring, evaluation and surveillance system
  - Considering increasing the focus of activities on MSM and PWID.

4. Examine issues of ART pricing including benchmarking against other EU countries.
5. Build a sustainable strategy involving the municipalities.
6. Consider making better use of EU funding mechanisms.

There are a number of areas in which ECDC could support Bulgaria's response to HIV, including:

- Supporting additional exchanges of best practice with regard to prevention activities for MSM and PWID (country visits).
- Helping Bulgaria's NGOs to connect with internationally experienced NGOs that have well-developed HIV and STI prevention programmes for MSM (e.g. checkpoints); experience of running MSM campaigns and of using new technology (mobile apps, Twitter, Facebook, YouTube) for outreach to MSM.
- Supporting a better understanding of HIV incidence (through an ECDC Modelling Tool project).
- Supporting the development of disaggregated continuums of care (e.g. for MSM and PWID) through an ECDC project on the HIV continuum of care.

There are a number of areas in which EMCDDA may be able to support Bulgaria's response to HIV, including:

- Supporting the EMCDDA National Focal Point to make a new estimate of the number of PWID: assessment of capacity and training needs underway.
- Providing tailored technical support while preparing the estimate - on demand and in close collaboration with the EMCDDA National Focal Point.
- Assessing the capacity and performance of Bulgaria's drug treatment system including assessment of OST programmes.
- Assessing service needs for imprisoned drug users, based on a representative prison study.
- Exchange of good practice in response to new drugs.

## 7.2.2 General surveillance

1. Bulgaria should consider taking part in an ECDC assessment of the overall communicable disease surveillance system. This assessment would:
  - need to be initiated at the request of the Ministry of Health in Bulgaria and be followed up with a report and funding for an action plan to improve the system (further follow up to review progress would also be expected);
  - include a review of the communicable disease surveillance system in selected regions, together with the Ministry of Health/NCIPD;
  - include a review of training needs and resource requirements;
  - consider ways to promote greater integration of surveillance across diseases.
2. There are too few experts working on the surveillance of communicable diseases. Additional resources need to be allocated to communicable disease surveillance at both regional and national levels, including recruitment of trained individuals to cover gaps left by recent loss of experienced staff. A review of training and resource requirements would be included in an ECDC surveillance assessment.
3. Consider making mandatory the reporting of communicable diseases from results of the laboratory system, including the private sector (perhaps by making it a requirement of laboratory registration and licencing).
4. Develop a medium-term plan for the transition from parallel systems of communicable disease surveillance to one surveillance system across all communicable diseases. This would allow greater sharing of information relating to communicable disease surveillance across all aspects of the system and more efficient use of the allocated resources for communicable disease surveillance in the country.
5. Develop one case-based notification system for all communicable diseases in Bulgaria with defined specific access to all actors in communicable disease prevention and control. Consider the use of web-based application technology and automatic or semi-automatic reporting from healthcare systems and laboratory systems when developing such a system. This would allow timely information on communicable disease epidemiology in Bulgaria and detection of clusters. It would also improve the quality control of data on reported cases and the understanding of data reliability. There would be a greater understanding of risk factors for priority diseases which could inform development of disease programmes and less manual work in public health institutes at regional and national level.
6. Train NCIPD staff in the use of appropriate software for automation of surveillance outputs, updating of the website mapping, and statistical exceedance detection (e.g. 'R').

### 7.2.3 Hepatitis B and C surveillance

1. National colleagues should review ECDC stage HEP differentiation criteria together with staff from regional health inspectorates and develop a common approach to differentiating between acute and chronic cases, either based on the ECDC criteria or the adoption of practical local definitions combining clinical and serological markers.
2. Set a goal for the introduction of case-based data collection for hepatitis B and C, building on the existing case based data collection system for STIs, ideally using on-line reporting systems.
3. Develop detailed objectives for hepatitis surveillance in the context of the WHO European Action Plan and the Global Health Sector Strategy elimination goals.
4. Identify regions that have the resources to produce reports based on the epidemiological data collected during follow-up of cases and/or with good antenatal screening data. Consider these regions as possible sentinel sites for the ongoing collection of detailed hepatitis B and C data and consider a sentinel project in this area in collaboration the EPIET programme.
5. Conduct a study to investigate the root cause of under-reporting for viral hepatitis. Consider conducting this survey in collaboration with the EPIET programme and follow up the study with the development of a strategy to address under-reporting in order to increase the completeness of the data.
6. Improve the dissemination of hepatitis B and C surveillance outputs to ensure these reach clinicians and laboratories involved with the notification of cases.
7. Ensure that the existing action plan for hepatitis B and C already been developed and submitted to the Ministry of Health, which includes surveillance as a key area, is taken forward and implemented.
8. Further strengthen collaboration with the ECDC team, especially with regard to work on differentiation of hepatitis B and C cases as acute or chronic; the hepatitis B and C seroprevalence project and collection of hepatitis specific mortality data.

### 7.2.4 STI surveillance

1. Allocate funding to support the continuation and further development of case-based STI surveillance, with the addition of validation checks to ensure high quality data is reported at national level and reduce the efforts needed for validation both at national and regional health inspectorate level. In addition, consider developing a web-based system to reduce the reporting burden for the regional health inspectorate.
2. Identify strategies to reduce under-reporting of STI surveillance data. Involvement of clinicians and laboratories is the key to ensuring successful development of the surveillance system. Approaches which could be considered include the development of a sentinel surveillance approach for chlamydia, gonorrhoea and syphilis, with a focus on a limited number of clinicians reporting from key dermato-venereology clinics.
3. Perform a mapping exercise to identify laboratories performing STI testing in Bulgaria and the diagnostic methods being used. The possibility of harmonising the tests and of introducing laboratory reporting systems should be considered.
4. Assess the feasibility of Bulgarian involvement in the EuroGASP project:
  - through the mapping exercise and discussions with the dermato-venereological society, identifying laboratories and linked dermato-venereology clinics which are undertaking culture of gonorrhoea and focus on these for inclusion in Euro-GASP;
  - continue Bulgaria's participation in Euro-GASP training, ideally also from outside Sofia, to increase capacity in this area.
5. Develop clinical guidelines for the diagnosis and treatment of STIs in Bulgaria, based on locally available antibiotics that are in line with both European guidelines and findings from Euro-GASP.
6. Share surveillance outputs with members of Bulgaria's dermato-venereological society to promote the importance of reporting STI cases identified in private clinics.

# Annex 1. Programme of the missions

Monday, 19 September 2016	Location	Participants	Activities and topics
9:30 – 13:00	Meeting of ECDC representatives and experts from the Ministry of Health (Bulgaria) at the Conference Hall of the HIV Programme, Yanko Sakazov 26, fl. 4.	Bulgarian team: Tonka Varleva, Ministry of Health, Vyara Georgieva, Ministry of Health, Petar Tsintsarski, long-term consultant on MSM, Emilia Naseva, Sociologist, Denitsa Bancheva, Ministry of Health, Svetlana Dimitrova, PR, Elena Kabakchieva, long-term consultant on Roma Tsveta Raycheva, long-term consultant on IDUs, Rayna Dimitrova, Health and Social Development Foundation, Ani Liubenova, Initiative for Health Foundation, Elena Birindzhieva, Health Without Borders Association. ECDC team – Teymur, Anastasia, Roger, Hans, Dagmar (EMCDDA)	Presentation by Bulgarian team:
10.45-11.15 Coffee break			Review of the HIV surveillance system, HIV testing practices and policies, and an overview of the epidemiological situation in Bulgaria. Dr. Viara Georgieva
			Review of the structure of healthcare services for HIV and STIs in Bulgaria. Tonka Varleva, MD
			Discussion on the preliminary results of the latest Integrated Biological and Behavioural Surveillance among MSM in Bulgaria. Emilia Naseva, PhD
			Review of Global Fund activities in Bulgaria Review of HIV prevention programmes for key populations in Bulgaria
			<ul style="list-style-type: none"> <li>Including an overview of the breakdown of funding for key populations T. Varleva/S. Dimitrova</li> </ul>
Overview of HIV policies and services targeted for MSM in Bulgaria			
<ul style="list-style-type: none"> <li>Including an overview of HIV testing services for MSM. P. Tsintsarski</li> <li>Overview of prevention activities, related to MSM in Sofia. E. Birindzhieva</li> <li>Overview of prevention activities, related to IDUs in Sofia. A. Liubenova</li> <li>Outreach work with male and female sex workers – effective intervention to reduce HIV spread in Bulgaria. R. Dimitrova.</li> </ul>			
Review of the national legislation concerning human rights, gender equality, stigma and discrimination towards People living with HIV. D. Bancheva			
			Feedback and discussion
13:00 – 14:00			Lunch
14:00 – 16:00	Meeting of ECDC team with representatives from Association 'Health without Borders' in Sofia.	Petar Tsintsarski, Elena Birindzhieva, chair of Association 'Health without Borders' in Sofia, Anelia Angelova, coordinator.  ECDC team – Teymur, Anastasia, Roger, Hans, Dagmar (EMCDDA).	Meeting with representatives of Association 'Health without Borders' in Sofia (Gay-friendly services provider)  ECDC Guidance: HIV and STI prevention among men who have sex with men  Ongoing work to support EU/EEA countries with outreach to MSM.

Tuesday, 20 September 2016			
	Location	Participants	Activities and topics
9.00- 15.30 - Site visit to Blagoevgrad  Lunch 12.30-13.30  Return to Sofia 15.30-17.00	Site-visit in Blagoevgrad	Petar Tsintsarski, Svetlana Dimitrova, Borislav Stoyanchoy, MD Coordinator of HIV, Health without Borders, prevention activities among MSM in the Blagoevgrad region Blagoevgrad, Mariyana Stankova, Chairman of 'Adaptation' – HIV prevention among IDUS in Blagoevgrad region.  ECDC team – Teymur, Anastasia, Roger, Hans.	Meeting with representatives of Association 'Health without Borders in Sofia'- branch Blagoevgrad (Gay-friendly services provider) 10.30- 12.00 'Adaptation' Association, Low-threshold Centre for IDUs  14.00 – 15.30 Visit of the Centre for Health-Education Services for MSM Presentation of the prevention activities Fieldwork visit  Discussion
10.00-16.00	Meetings in Sofia	Initiative for Health Foundation, Anna Lyubenova, Elena Yankova.  EMCDDA National Focal Point Momtchil Vassilev, Violeta Bogdanova, Centre for the Study of Democracy, Atanas Rusev, Dimitar Markov.  Team member – Dagmar (EMCDDA)	Outreach session  Meeting and visit to OST programme  Meeting to discuss study on drugs and prisons
21:00 – 01:00	Site-visit and outreach work at ID MIX CLUB with a dark room in Sofia/ Secret Garden (alternative spot)	Petar Tsintsarski, outreach workers from the Association 'Health without Borders' in Sofia.  ECDC team – Teymur, Roger, Hans, Dagmar (EMCDDA)	Participatory observation
Wednesday 21 September 2016			
	Location	Participants	Activities and topics
9:30 – 13:00	Meeting of the ECDC and experts from the Ministry of Health (Bulgaria) at the Conference Hall of the HIV Programme, Yanko Sakazov 26, fl. 4.	Bulgarian team: Vyara Georgieva, Petar Tsintsarski, Emilia Naseva, Denitsa Bancheva, Svetlana Dimitrova.  ECDC team ECDC team - - Teymur, Roger, Hans, Dagmar (EMCDDA)	Discussions/reflections  ECDC guidance on HIV/STI prevention among MSM and other related work in the pipeline  Discussions/reflections
Closing/Lunch 13:00 – 14:00			

## Hepatitis and STI

### 14 November 2017

- 09:30–09:45: Introductions and scope of mission
- 09:45–10:00: STI surveillance in Europe (Gianfranco Spiteri)
- 10:00– 10:15: Hepatitis surveillance in Europe (Erika Duffell)
- 10:15–10:30: European surveillance activities, focusing on country support and comparability (Frantiska Hrubá)
- 10:30–10:45: Coffee break
- 10:45–11:30: Surveillance arrangements and epidemiology of STI and Hepatitis in Bulgaria; plans for surveillance development
- 11:30–12:30: Organisation of Hepatitis and STI diagnostic and treatment services in Bulgaria, including microbiology services
- 12:30–13:30: Lunch
- 13:30–17:30: Split discussions STI/hepatitis

### 15 November 2017

- 09:30–10:00: Summary of previous day's split discussions
- 10:00–10:30: ECDC group meeting
- 10:30–10:45: Coffee break
- 10:45–11:30: Initial recommendations and discussion
- 11:30–12:30: Conclusions and next steps.



## Annex 2. List of participants

Anelia Angelova, Coordinator, Health Without Borders, Sofia  
Denitsa Bancheva, Ministry of Health  
Elena Birindzhieva, Health Without Borders Association  
Violeta Bogdanova, National Centre for Addictions  
Asen Dimitrov, Outreach Worker, Health Without Borders, Sofia  
Rayna Dimitrova, Health and Social Development Foundation  
Svetlana Dimitrova, Public Relations  
Elitsa Golkocheva-Markova, National Reference Laboratory for Viral Hepatitis, NCIPD  
Vyara Georgieva, Ministry of Health  
Teodora Ivanova, Senior Programme Assistant, Prevention and Control of HIV and AIDS  
Elena Kabakchieva, Long-term consultant on Roma  
Yanislava Koleva, 'Adaptation' Association, Blagoevgrad  
Albert Krumov, Health Without Borders, Blagoevgrad  
Radoslav Krustev, Health Without Borders, Blagoevgrad  
Anna Kurchatova, NCIPD  
Anna Lyubenova, Initiative for Health Foundation  
Dimitar Markov, Centre for the Study of Democracy  
Vesela Mirkhova, 'Adaptation' Association, Blagoevgrad  
Emilia Naseva, Sociologist  
Tihomir Nenov, Outreach Worker, Health Without Borders, Sofia  
Elena Petrova, Department of Dermatology and Venereology, Sofia Medical University  
Ivva Philipova, National Reference Laboratory, Mycology and STIs, NCIPD  
Tsveta Raycheva, Long-term consultant on IDUs  
Atanas Rusev, Centre for the Study of Democracy  
Mariyana Stankova, 'Adaptation' Association, Blagoevgrad  
Borislav Stoyanchov, Health Without Borders, Blagoevgrad  
Mariya Tjufekchieva, Ministry of Health  
Petar Tsintsarski, Long-term consultant on MSM  
Tonka Varleva, Ministry of Health  
Momtchil Vassilev, National Centre for Addictions  
Nadezhda Vladimirova, NCIPD  
Elena Yankova, Initiative for Health Foundation  
Mariya Zamfirova, Ministry of Health

## Annex 3. Data collection tools

Tools translated from Ordinance 21 by Savina Stoitskova, EU-track EPIET fellow, cohort 2015

### A. Infectious disease registration book

No. (Serial)	Name Surname Family name	Age	Permanent address	Date of onset	Date of visit to physician	Case category	Date and place of hospitalisation	Outcome	Notes

#### Rules for entering information into the infectious disease registration book

1. Certain pages in the book are allocated to each disease.
2. In the Case category, date of classification must be entered in each of the respective categories – possible, probable, confirmed or carrier.
3. If the diagnosis is changed:
  - if the new diagnosis is another disease which requires mandatory registration, the data for the respective cases are transferred to the respective page of the book. In such a case the number of the page to which/from which the information has been copied is noted down under 'Notes'.
  - If the new diagnosis is of a disease which is not subject to mandatory registration, the whole line is underlined, and the new diagnosis is written under 'Changed diagnosis', after which the case is removed from reporting.
4. When cases are confirmed, the results from the respective laboratory tests are entered under 'Notes'.
5. Only cases which are just carriers, are entered as 'carriers'. If carriage is confirmed in a case post-recovery, this is entered under 'Outcome'.
6. If a family doctor receives a quick notification or other information from another hospital concerning an infectious disease diagnosed in one of their patients, the family doctor registers the case in the infectious disease registration book. The healthcare facility which notified the case in the first place is entered in the 'Notes' section.

### B. Rapid notification form

For a case (possible, probable, confirmed), carrier, or a person who died as a result of an infectious disease  
 Diagnosis – possible, probable, confirmed.

Name, surname, family name.

Sex

Date of birth

Age

Profession

Workplace

Date of last visit to workplace

Onset: City/village

Date

First visit to physician

A. City/village

B. Date.....Healthcare facility

C. Primary diagnosis

The case has been found through: active case finding.....

Passive .....

Final diagnosis.....Date

Healthcare facility

Confirmation of diagnosis and results

- A. Laboratory results
- B. Para-clinical
- C. Pathological anatomy

The case has been:

- advised to stay home
- hospitalised
- date.

Death

- A. City/village
- B. Date
- C. Healthcare facility

Immunisation against the disease

- A. Primary immunisation series 1.....2.....3
- C. Booster dose/s 1.....2

Previous contact of case with a person having the same diagnosis.

YES

Name of the case

Date of the contact

NO

Contacts of this case

At home.....

At work.....

To: Name and address of healthcare facility

From: Physician who diagnosed the case (name, family name, position, healthcare facility, address)

Date/signature.

Annex 7 to Article 10

Hospital

Ward

Notification of hospitalised/discharged infectious disease cases:

Name Surname Family name	Age	Address	Diagnosis	Family doctor, workplace

Laboratory result protocol (data collected on sample type, method).

## Annex 4. Case definitions for hepatitis B/C

### Case definitions: clinical and laboratory criteria and case classifications for hepatitis B and C

Disease	Clinical Criteria	Laboratory criteria	Case Classification
HBV	Not relevant for surveillance purposes	Positive results of at least one or more of the following tests or combination of tests: – IgM hepatitis B core antibody (anti-HBc IgM) – Hepatitis B surface antigen (HBsAg) – Hepatitis B e antigen (HBeAg) – Hepatitis B nucleic acid (HBV-DNA)	A. Possible case NA B. Probable case NA C. Confirmed case Any person meeting the laboratory criteria
HCV	Not relevant for surveillance purposes	At least one of the following three: – Detection of hepatitis C virus nucleic acid (HCV RNA) – Detection of hepatitis C virus core antigen (HCV-core) – Hepatitis C virus specific antibody (anti-HCV) response confirmed by a confirmatory (e.g. immunoblot) antibody test in persons older than 18 months without evidence of resolved infection)HCV- RNA	Possible: NA Probable: NA Confirmed: Case is lab confirmed

The following combination of laboratory tests shall not be included or reported for HBV:

- Resolved hepatitis - hepatitis B total core antibody (anti-HBc) positive and hepatitis B surface antibody (anti-HBs) positive
- Immunity following vaccination - hepatitis B total core antibody (anti-HBc) negative and hepatitis B surface antibody (anti-HBs) positive
- Anti-HBc IgG positivity only.

The following combination of laboratory tests shall not be included or reported for HCV:

- Resolved infection: detection of hepatitis C virus antibody and no detection of hepatitis C virus nucleic acid (HCV RNA negative result) or hepatitis C virus core antigen (HCV-core negative result) in serum/plasma.

#### Differentiation of hepatitis C by stage of infection (STAGEHEP)

<b>Codes</b>	<b>Description</b>
<b>Acute</b>	<b>Recent HCV seroconversion (prior negative test for hepatitis C in last 12 months)</b> <i>or</i> <b>Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C virus core antigen (HCV-core) in serum/plasma and no detection of hepatitis C virus antibody (negative result)</b>
<b>Chronic</b>	<b>Detection of hepatitis C virus nucleic acid (HCV RNA) or hepatitis C core antigen (HCV-core) in serum/plasma in two samples taken at least 12 months apart<sup>1</sup></b>
<b>UNK</b>	<b>Any newly diagnosed case which cannot be classified according the above description of acute or chronic infection</b>

<sup>1</sup> In the event that the case was not notified the first time.

## Annex 5. Bibliography

### Legal framework

Ordinance 21 dated 18 July 2005 Regulating the Registration, Notification and Reporting of Infectious Diseases.

Commission Implementing Decision 2012/506/EU of 8 August 2012 amending Decision 2002/253/EC laying down case definitions for reporting communicable diseases to the Community network under Decision No 2119/98/EC of the European Parliament and the Council

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Dimitrova, R. (2016) Outreach Work with Male and Female Sex Workers – Effective Intervention to Reduce HIV Spread in Bulgaria

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Documents relating to the Global Fund grant to Bulgaria for HIV are available at:

<http://www.theglobalfund.org/en/portfolio/country/?loc=BGR&k=783da83c-cc7d-4eac-8145-d4deba77606d> These include documents relating to the HIV grant and grant performance report; programme grant agreement; grant closure letter; grant score card; RCC grant score card and implementation letter.

Details of the abstract of the Optima report presented to the EUHEA Conference in 2016. This was entitled 'Optimising Investments in Bulgaria's HIV Response'. There is also a publicly available report entitled 'Allocating Efficiently with Optima in Georgia, Macedonia and Bulgaria'. (See the Optima website <http://optimamodel.com/>)

Material describing HIV-related work with MSM including document entitled 'Bulgaria: Training of MSM Leaders to Deliver Behavioural Change Communication Interventions'. There is also an operational survey to identify an interventional package for effective HIV prevention among MSM from 2010.

Reports of bio-behavioural surveys [in Bulgarian with English summaries]. Covers injecting drug users 2004–2012; prisoners 2006–2011; Roma community 2005–2012; MSM 2006–2012 and sex workers 2004–2012. The English summaries are published in a special edition of 'Problems of Infectious and Parasitic Diseases' from 2015 (Vol 43, supplement). The reports are:

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