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SCIENTIFIC ADVICE

Public health guidance on prevention and control of blood-borne viruses in prison settings

Prevention and control of communicable diseases in prison settings

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ECDC AND EMCDDA SCIENTIFIC ADVICE

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for Drugs and Drug Addiction

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Abbreviations

AIDS	Acquired immune deficiency syndrome
ALT	Alanine aminotransferase
ART	Antiretroviral therapy
BBV	Blood-borne virus
CD4	Cluster of differentiation 4
DAAAs	Direct-acting antivirals
DOT	Directly observed therapy
EEA	European Economic Area
EFTA	European Free Trade Association
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EU	European Union
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IFN	Interferon
MSM	Men who have sex with men
NR	Not reported
NSP	Needle and syringe programme
OST	Opioid substitution treatment
PEP	Post-exposure prophylaxis
PLHIV	People living with HIV
PrEP	Pre-exposure prophylaxis
PWID	People who inject drugs
RBV	Ribavirin
RCT	Randomised controlled trial
SAT	Self-administered treatment
SSTI	Skin and soft tissue infection
SVR	Sustained viral response
WHO	World Health Organization

Glossary

Acceptability	The degree to which a given intervention is acceptable to the target population in relation to the effect of the intervention
Accessibility	The degree to which a given intervention is accessible to the target population (availability of good health services within reasonable reach and when needed)
Active case finding	Interventions aimed at promoting early diagnosis by means of provider-initiated systematic offer for testing, at entrance and/or during stay (including at release)
Client-initiated testing	Testing which is voluntary and performed as the result of individual's health-seeking behaviour, triggered by symptoms development or other reasons (i.e. passive case finding)
Comparative study	A study designed to compare two or more groups (e.g. types of testing offers or testing timings), and a statistical measure is provided for that comparison
Descriptive study	A study concerned with and designed only to describe the existing distribution of variables, without regard to causal or other hypotheses
Directly observed therapy (DOT)	An approach which seeks to improve treatment adherence by active monitoring and recording of the consumption of each and every drug dose by an 'observer' acceptable to the patient and the health system [7]
Evidence-based guideline	A guideline that is largely based on the scientific literature to generate a recommendation; good clinical practices or expert opinions could be used to supplement the scientific literature
Feasibility	The degree to which it is feasible to implement an intervention in terms of time, money, or other circumstances
Harm reduction interventions	Interventions aiming at reducing the harm/risk (e.g. transmission of infectious diseases) associated with drug use disorders
Jail	Locally-operated, short term facilities that hold adults awaiting trial or sentencing or both, and people sentenced mostly to a term of less than one year
Mandatory testing	Testing which is offered to all eligible individuals, and the person is obliged to be tested
Opt-in	Testing which is voluntary and offered to all eligible individuals, often on the basis of identified risk factors, and the person chooses whether or not to have the test
Opt-out	Testing modality where all eligible individuals are informed that the test will be performed unless they actively refuse; testing is voluntary.
People in prison	Adult individuals aged 18 and older detained in prison for custody, remand or awaiting trial. In certain instances, the term may include individuals visiting correctional facilities, intervening in various capacities or prison staff working also in various capacities. This population includes vulnerable groups, i.e. MSM, transgender, PWID, foreign-born persons, homeless, people with mental health and/or substance misuse needs (including alcohol), and others.
Practice-based guideline	A guideline that reflects expert opinion or information derived from good clinical practices; some literature references (not systematic) may be included
Prison	All institutions where a state holds adults deprived of their liberty (e.g. prison or jail), either sentenced or on pre-trial detention (remand), excluding migrant centres, and police detention rooms, and other facilities such as juvenile prisons or secure training centres for children & young people.
Provider-initiated testing	Testing which is voluntary and offered to eligible individuals by health-care providers. In this document we use the term provider-initiated to describe both opt-in and opt-out testing offers.

Self-administered treatment (SAT)	The patient is given the prescribed medications in possession and is responsible for the assumption of the correct dose without supervision
Service model	An operational approach to deliver an intervention, defined by descriptors such as time (e.g. at entry, during stay, at release), target population (e.g. universal), modality of offer/service delivery (e.g. healthcare provider, DOT), etc.
Throughcare (or through the gate)	It entails continuity of care when transitioning from the community to prison settings, as well as from prison settings back into the community. The latter covers both interventions starting in prison settings aimed at prevention of BBVs post-release, as well as interventions starting in prison settings to increase linkage to care for BBVs or drug addiction post-release.

Executive summary

Compared with the general public, people in prison in the EU/EEA have a higher burden of communicable diseases such as human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis, gonorrhoea, chlamydia and tuberculosis (TB). Increased disease prevalence in this population is recognised as a significant public health concern, both for people living and working in prisons and for the general population at large because the vast majority of people held in prisons eventually return to their communities. Yet, incarceration may represent a unique opportunity to make adequate healthcare services available to people and target groups that are usually hard to reach when in the community. Effective prevention and control interventions aimed at reducing blood-borne viruses' transmission and at ensuring entry into treatment and care for those individuals in need are available and may be considered for broader implementation in prison settings.

The successful implementation of evidence-based interventions in prison settings requires an in-depth knowledge of structural hurdles, individual barriers, and the characteristics and behaviours of the prison population.

To this aim, the European Centre for Disease Prevention and Control (ECDC) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) have joined forces to develop a common evidence-based guidance for the prevention and control of communicable diseases in prison settings in the EU/EEA. This document provides EU/EEA Member States with evidence-based scientific advice on available options, when planning and implementing prevention and control interventions for blood-borne viruses in prison settings.

Scope

This guidance focuses on prevention and control measures for high-burden communicable diseases in prison settings, i.e. viral hepatitis B and C, HIV. The target population is adult individuals aged 18 and older detained in prison for custody, remand or awaiting trial. In certain instances, individuals visiting correctional facilities, intervening in various capacities or prison staff may also be included.

Target audience

The target audiences for this guidance are national policymakers, professionals and institutions responsible for the planning of healthcare services in the national/subnational custodial system, professionals and entities responsible for the planning and provision of healthcare services in prison institutions, civil society organisations, and non-governmental organisations with an interest in prison health.

Evidence-based public health guidance

Research findings relevant to this guidance have been reviewed and assessed using evidence-based medicine (EBM) principles adapted within a public health framework. To produce the guidance, scientific evidence from peer-reviewed and grey literature has been comprehensively assessed, and the results were combined with expert advice and considerations on benefits and harms, human rights, equity, ethics and user preferences. Country specific care models have also contributed to the development of options for implementation to be considered for inclusion in national and subnational public health programmes in European prison settings.

Key conclusions

ECDC and EMCDDA assessment of blood-borne viruses prevention in prison settings: The evidence on blood-borne viruses (BBVs) prevention in prison settings is limited and restricted to some of the existing preventive measures. The evidence suggests that provision of condoms and the implementation of behavioural interventions may promote safer sex behaviours in prison settings. Studies on opioid substitution treatment (OST) consistently show that while patients are in prison, treatment reduces opioid use, injecting, and sharing of injecting equipment. After release, prison OST patients are more likely to continue treatment, achieving the same benefits, and facing a lower risk of drug-related death. Injecting drug use bears the highest risk of transmission of BBVs among prisoners, due to the re-use of contaminated injecting equipment. Whilst more limited, the available evidence suggests that the successful implementation of needle and syringe programmes (NSP) in prison is possible and may lead - as part of a comprehensive response - to a reduction of BBVs transmission among incarcerated people who inject drugs (PWID). These findings are consistent with the evidence derived from community settings.

The range of existing BBVs preventive measures include interventions which should be considered for implementation in prison settings alongside those mentioned above. These include early diagnosis, HBV vaccination, treatment as prevention, safe tattooing and body piercing as well as pre- and post-exposure prophylaxis, prevention of vertical transmission and safe healthcare service. National (or supranational) guidelines providing recommendations on these measures should apply the same standards in prison settings.

ECDC and EMCDDA assessment of active case finding for blood-borne viruses in prison settings:

Based on the available evidence on BBVs active case finding in prison settings and considering the high prevalence of infection in the prison population alongside the availability of effective prevention and control measures, it is advisable to offer testing for HBV, HCV and HIV to all people in prison.

The evidence suggests that provider-initiated strategies for HIV testing yield a higher uptake than client-initiated strategies. However, the evidence does not provide a clear indication on the most effective timing and testing modality for BBVs case finding in prison settings.

Provider-initiated testing is also consistent with the general principle of disease prevention to not delay diagnosis, in order to offer appropriate treatment and to prevent further transmission within the prison setting as far as possible. The available evidence indicates that health promotion and peer-education directed towards people in detention are effective in increasing testing uptake at least for HIV in prison settings. Few additional interventions to increase the uptake of testing could be considered, although the level of evidence for the effectiveness of any specific approach is very low.

ECDC and EMCDDA assessment on HBV vaccination in prison settings: Considering the high prevalence of BBV infection in the prison population, the available evidence on HBV vaccination in prison settings and on HBV vaccination effectiveness in the community, it is advisable to offer vaccination for HBV to people in prison. The offer of HBV vaccination at entrance to all individuals with no/unknown vaccination history and/or negative serology is consistent with the general principle of disease prevention, in order to avoid further transmission within the prison setting as far as possible.

The evidence on HBV vaccination strategies in prison settings is limited and weak. The evidence suggests that provision of HBV vaccination using the rapid or very rapid schedule may result in higher vaccination completion rate in prison settings. However, the available evidence does not provide clear indication on the most effective timing and strategy for HBV vaccination in prison settings.

Several implementation strategies could be considered, although the level of evidence for the effectiveness of any specific approach is very low.

ECDC and EMCDDA assessment on HIV treatment in prison settings: The available evidence indicates that HIV treatment in prison settings is feasible and should be implemented. There is a strong public health rationale to provide access to HIV treatment and care without delay to all people living and HIV (PLHIV) in prison settings.

However, the evidence on models of care delivery in prison settings is limited and does not point towards a specific model to achieve retention in care and adherence to HIV treatment. Interventions to increase adherence and treatment outcomes could be considered, although the level of evidence for the effectiveness of any specific approach is very low.

ECDC and EMCDDA assessment on viral hepatitis treatment in prison settings: The evidence indicates that HCV treatment in prison settings is feasible irrespective of the regimen and should be implemented. There is a strong public health rationale to provide access to state-of-the-art HCV treatment and care without delay in prison settings.

However, the evidence on models of care delivery in prison settings is limited and does not point towards a specific model to achieve retention in care and completion of HCV treatment. Interventions to increase adherence and treatment outcomes could be considered, although the level of evidence for the effectiveness of any specific approach is very low.

Despite lack of evidence on HBV treatment provision in prison settings, people in prison should have access to HBV care by the same standard as offered in the community.

ECDC and EMCDDA assessment on throughcare: Transitional care for people entering and being released from prison is an essential component of quality healthcare services for people at higher risk of acquiring a BBVs infection and for individuals with HIV, chronic viral hepatitis or with problematic drug use.

The available evidence suggests that behavioural and skills building interventions aimed at promoting BBV prevention post-release may result in improved behavioural outcomes, at least for sexual transmission risk.

However, the evidence on service models for throughcare is limited and does not point towards a specific model to achieve continuity of care when transitioning in or out of prison for individuals with HIV, chronic viral hepatitis or with problematic drug use. Some interventions, such as comprehensive pre-release preparation and active referral to community health services or drug dependency services, could be considered to increase linkage to care and promote treatment adherence, although the level of evidence for the effectiveness of any specific approach is very low.

Introduction

1.1 Rationale

More than 10 million people are held in prison worldwide, most are convicted and sentenced but there is also a substantial group held in remand prison until trial or sentencing. On 1 September 2015, just above 600 000 people were being held in prisons of the European Union (EU)/European Economic Area (EEA). The imprisonment rate varied from 21.3 per 100 000 in Liechtenstein followed by 53 per 100 000 in the Netherlands to 277.7 per 100 000 in Lithuania [8]. The median age of the prison population ranged from 31 years in France to 40 years in Latvia and 41 years in Liechtenstein, while the average age ranged from 33.8 years in France to 40 years in Italy and 41.3 years in Liechtenstein. When considering all of Europe, the median length of a prison stay was seven months [8].

Compared with the general public, people in prison in the EU/EEA have a higher prevalence of infection with human immunodeficiency virus (HIV), hepatitis B, hepatitis C, syphilis, gonorrhoea, chlamydia and tuberculosis (TB) [9]. While in detention, individuals, including those who are healthy on entry, are at higher risk of exposure to communicable diseases such as TB, HIV and viral hepatitis. They are also at a higher risk to develop substance use disorders or mental illnesses than the general population [10-14].

Most of the of the people in prison in Europe are from poor communities and vulnerable social groups, with an increasing proportion of migrants and people with a minority ethnic background; there is, however, substantial variation between countries [8,15]. People with drug use disorders form a large part of the imprisoned population. A recent study estimates a prevalence of drug use disorders of 30% among men and 51% among women in detention [16, 17].

The increased prevalence of communicable diseases among people in prison can constitute a risk for the health of people who live/work in prison settings and for the general population, as the vast majority of people in prison eventually return to their communities. There are several risk factors associated with increased transmission rates in prison settings, e.g. proximity (aggravated by overcrowding), which is common in some EU/EEA correctional facilities; high-risk sexual behaviour; injecting drug use; sharing of injecting equipment; and tattooing and piercing [8, 10 15-18, 19]-, Diet and individual hygiene are also important risk factors, at least for TB. In addition, lack of awareness of infection status (often combined with substandard healthcare) appear to have substantial implications for public health. There are excellent opportunities for primary, secondary and tertiary prevention measures in prison settings, provided they are coupled with adequate linkage to care during detention and after release. Prison settings can be used to reach vulnerable groups of the population and provide adequate care for them. However, large heterogeneity exists between EU/EEA prison settings in communicable disease prevention and care, particularly with regard to active case finding [20,21].

The 2010 Madrid Declaration emphasised that health protection in prison settings is an essential part of public health and should be based on the principle of equivalence of health for people in prison. Building on the Madrid Declaration, several international organisations, such as the United Nations Office on Drugs and Crime (UNODC) and the World Health Organization (WHO), published documents highlighting the importance of health protection in prison settings [15,22]. A recent briefing on prison conditions in the Member States by the Policy Department on Citizens' Rights and Constitutional Affairs of the European Parliament addresses the issue of healthcare in prison. It states that the 'general principle is that people in prison should enjoy an equivalent standard of care to persons outside prisons, yet their needs tend to be greater than those of free persons, as they often lead a marginalised life before entry to prison and as imprisonment may put a strain on their mental health and physical well-being' [23]. This underlines the need for up-to-date, evidence-based guidance on prison health. This report is an effort to provide such guidance. It is also the first such guidance project for the EU/EEA.

1.2 Guidance on communicable diseases in prison settings

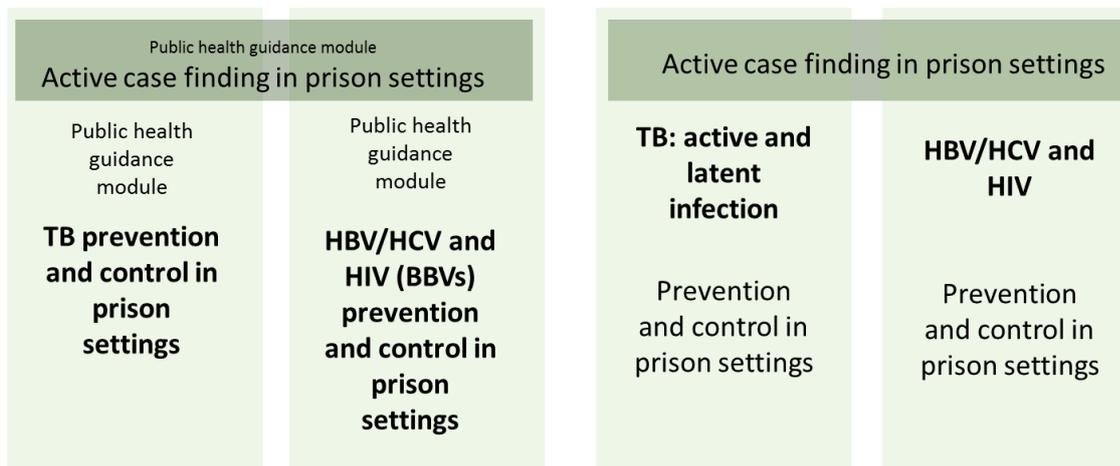
In 2015, the European Centre for Disease Prevention and Control (ECDC) launched the project 'Guidance on prevention of infectious diseases in prison settings'.

ECDC collaborated closely with the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) throughout the development of this evidence-based guidance document. This document also marks the first time that ECDC and EMCDDA to develop a common evidence-based guidance for the prevention and control of communicable diseases in prison settings in the EU. During a scoping phase, evidence on the burden of communicable diseases, preventive measures and costs in prison settings in the EU published between 2000 and 2014 was assessed, and existing knowledge gaps on prison settings and communicable diseases were identified. An evidence mapping tool was developed, and findings were complemented with information from EU/EEA experts in order to define thematic areas to be addressed by the guidance document.

The overall objective of this project was to develop an evidence-based guidance on prevention, diagnosis and control of communicable diseases in prisons and other custodial settings, with a clear focus on the situation in the EU/EEA.

The guidance follows a modular structure: thematic areas are grouped together as guidance modules (Figure 1). In addition to active case finding for selected communicable diseases, the project also addresses several thematic areas, namely vaccination strategies (including vaccination at prison entry and vaccination in outbreak situations); HIV prevention, care and treatment; viral hepatitis prevention, care and treatment; TB prevention, diagnosis, care and treatment; and prevention and control of blood-borne viruses among people who inject drugs.

Figure 1. Schematic representation of the public health guidance modules on communicable diseases in prison settings ensuing from the ECDC and EMCDDA joint project



The purpose of this guidance is to provide EU/EEA Member States with evidence-based scientific advice on options for active case finding when planning and implementing interventions aimed at the early diagnosis of selected communicable diseases in prison settings.

The target audiences for the document are national policymakers, professionals and institutions responsible for the planning of healthcare services in national/subnational custodial systems, professionals and entities responsible for the planning and provision of healthcare services in prison institutions, civil society organisations, and non-governmental organisations with an interest in prison health.

1.3 Objective and scope

This document provides an evidence-based guidance on prevention and control of blood-borne viruses (BBVs) in prison settings, with a special focus on the EU/EEA. It is focused on three high-burden communicable diseases in prison settings, namely hepatitis B, hepatitis C and HIV. These diseases are characterised by the same modes of transmission and similar prevention and control interventions, and therefore, are combined in this guidance module covering BBVs prevention and control in the prison population, including among people who inject drugs (PWID). Active case finding strategies relevant for BBVs prevention and control, although covered elsewhere (Figure 1), are also included in this guidance module to provide the reader with a comprehensive overview of the available interventions and options for implementation. Finally, the findings concerning HBV vaccination from a separate systematic review on vaccination strategies in prison settings, conducted in the frame of this project are also included in this guidance module.

The guidance target population is adults aged 18 years or older in prison settings, including individuals detained or in remand, and prison staff, when and where appropriate. Prison settings refer to prisons, jails and other criminal justice custodial facilities, excluding detention facilities for people held under aliens' legislation and police jails.

1.4 Aim of the guidance and target audience

This guidance aims to provide EU/EEA Member States with support, in the form of evidence-based scientific advice on available interventions, when planning and implementing programmes to prevent and control BBVs infections in prison settings.

The target audiences for the document are national policymakers, professionals and entities responsible for the planning of healthcare services in the national/subnational custodial system, professionals and entities responsible for the planning and provision of healthcare services in prison institutions, civil society organisations and non-governmental organisations with an interest in prison health.

2. Background

2.1 Blood-borne viruses in the prison setting

The burden of certain communicable diseases such as HIV, viral hepatitis and TB, is higher in prisons than in the general population in most countries worldwide [9]. Prisons are considered a risk environment with increased disease prevalence. [10]. The prison population consists mainly of individuals of lower socio-economic status and under-served communities. Most people in prison have a high risk of acquiring infections before incarceration, partly due to behavioural and structural factors that are associated with increased likelihood of imprisonment [24]. The risk to acquire a communicable disease increases further during incarceration because prisons settings amplify health conditions due to overcrowding, poor infrastructure, and often inadequate access to healthcare services [10,15].

According to a recently published systematic review, substance use disorders are highly prevalent in people in prisons and much more common than in the general population [16]. The pooled prevalence estimate for drug use disorders (i.e. substance abuse and/or dependence, excluding nicotine-related disorders) in the prison population was 30% among males and 51% among females [12]. Data reported to the EMCDDA showed large variations in the proportion of people in prisons with experience of drug use, depending on the country and on the substance [13]. In particular, people in prisons differ greatly from the general population in their reported experience with opioid and cocaine. The lifetime prevalence levels among people held in prisons in the EU/EEA ranged between 10% and 43% for heroin, between 2 % and 46% amphetamines and between 9% and 57% for cocaine, versus less than 1%, less than 1.5% and less than 2%, respectively, of the general population who have ever used these drugs [13]. Harmful drug use patterns are common among people in prisons, with between 6% and 48% of people reporting injecting drug use prior to imprisonment [13]. Studies among high risk drug users show that many have spent time in prison [17,25]. Problem drug use and drug dependence increase the risk of imprisonment, due to the illegality of the drugs market and high cost of drug use. Incarceration and problematic drug use are intertwined and result in overlapping vulnerability, increased risks of infection with communicable diseases and worse health outcomes [17,25,26].

A recent analysis based on EMCDDA data has evaluated the association between a history of incarceration and risk of HIV and HCV infection among PWID in Europe. Seventeen out of 30 countries provided aggregated HIV and/or HCV prevalence among PWID for the period 2006–2015 by prison history. Data analysis shows a strong association between both HIV and HCV prevalence and prison history among PWID in some European countries with longer periods in prison associated with higher levels of infection[27].

During incarceration, the following practices are observed: exchange of contaminated/used needles, sharp objects and/or other paraphernalia for injecting drugs, tattooing, and piercing, consensual or coercive (including violently coercive sex and rape) sexual activity, sharing of shaving razors, episodes of violence. These behaviours are associated with an increased risk of the transmission of HIV and hepatitis B and C [28–30], and with the occurrence of outbreaks in prison establishments [31]. In a recent systematic review of the literature coordinated by ECDC, HBV prevalence estimates that were considered representative for people in prisons were available for 12 countries, ranging from 0.3%–25.2%, as compared to a prevalence range of 0.1%–4.4% in the general population [32]. HCV prevalence estimates were available for 11 countries, ranging from 4.3%–86.3%, as compared to a prevalence range of 0.1%–5.9% in the general population. Prevalence estimates for HIV among the prison population are reported in the frame of the Dublin Declaration monitoring [26]. In 2016 15 EU/EEA countries reported estimates ranging from 0.2%–15.8%, with Estonia, Italy, Spain and Latvia reporting a prevalence above 5%¹. According to a recent study assessing the global burden of infections among the prison population, the prevalence of HBV, HCV and HIV in Western Europe was estimated to be 2.4%, 15.5% and 4.2%, respectively [9].

The silent nature of BBVs chronic infections in the early stages, limited health literacy coupled with suboptimal access to care in prison setting are factors contributing to the challenge of diagnosing infectious diseases in the prison population. Recent epidemiological data show that among individuals testing positive in prison, a sizeable proportion were unaware of their status: 3.4% of those were HIV-positive, 11.6% of those were HCV-positive and 52.7% of those were HBV-positive [33]. The high percentage of unaware people in prison also increases the risk for transmission, with the available evidence indicating a transmission rate six times higher in unaware HIV-infected patients than among those aware of their status (10.2% vs. 1.7%) [34].

¹ According to data collected by ECDC from Dublin Declaration monitoring

In conclusion, while the prison setting represents a well-known high-risk environment for BBVs acquisition, incarceration may represent a unique opportunity to make adequate healthcare services available to target groups which are usually hard to reach when in the community. However, to successfully implement interventions aimed at prevention and control of communicable diseases in prison settings, in-depth knowledge of the specific structural and individual barriers as well as of the characteristics and behaviours of the prison population is necessary.

2.2 Prevention of blood-borne viruses

Available evidence shows that prevalence of BBVs is high at when entering prison [35]. As risk behaviours for BBVs transmission in prison settings are common, there is great potential for prevention measures to be implemented to control onward transmission among the prison population.

The similarities in modes of transmission of BBVs mean that measures for their prevention are almost all valid for the three diseases in focus [15]. A solid evidence base exists for a number of public health interventions to reduce and control BBV infections in the community, HIV Pre-Exposure Prophylaxis (PrEP) being the latest addition to existing prevention options, which include HBV vaccination, use of condoms, use of sterile injecting and tattooing equipment, early diagnosis and treatment as prevention, harm reduction interventions, universal precautions, prevention of mother-to-child transmission (PMTCT), post-exposure prophylaxis (PEP) for HIV and HBV.

However, little data are currently available on the coverage of those interventions in EU/EEA prison settings. According to the 2016 Dublin Declaration monitoring round (a survey among ECDC key informants from 52 countries in the broader European region), only six EU/EEA countries attribute high priority to HIV prevention targeting prison populations² [26]. While in 2016, 12 EU/EEA countries reported having laws or policies in place that authorise the provision of condoms in prison settings and 15 countries reported implementing condom distribution and promotion programmes. In contrast, lubricant promotion and distribution programmes were reported by five EU/EEA countries only. HIV PrEP was reportedly implemented in prison settings in one country, while HIV Post-Exposure Prophylaxis (PEP) was implemented in 13 countries. Half of countries reported having in place health promotion or behaviour change programmes [26].

As injecting drug use is one of the most important risk behaviours for BBVs infection in prison settings, measures specifically aimed at prevention of injecting-related infections are of utmost importance. A solid evidence base exists for a number of cost-effective public health interventions to reduce and control infections among drug users in the community [36]. Besides testing, vaccination and treatment of infections, harm reduction interventions, such as access to sterile injection equipment, opioid substitution treatment (OST), naloxone programmes, are necessary to reduce drug use and injecting-related harm [36]. However, according to latest EMCDDA data and the 2016 Dublin Declaration monitoring round, harm reduction coverage is low in prison settings [13,26,37]. OST is reported to be available in principle in the prisons of 27 EU/EEA countries but still not allowed in prisons in Lithuania and in the Slovak Republic³ [13,37]. Levels of provision do not match those in the community, and often results in detoxification treatment of those who enter prison while on OST [13,38]. Based on available information, OST can be initiated in prison in 24 EU/EEA countries. However, it is not possible to start OST in prison in Cyprus, Czech Republic and Latvia, while those who are receiving this treatment when entering prison are allowed to continue [13,37]. Prison-based needles and syringes programmes (NSPs) are far less available; mostly due to structural barriers such as unfavourable laws and policies, only three EU/EEA countries (Spain, Luxembourg and Germany) report NSP availability in all or some prisons, while Romania reports no use of the available prison-based NSP [13,37].

2.3 Treatment of blood-borne viruses

Treatment with combination antiretroviral therapy (ART) enables people with HIV infection to live a long and healthy life. Early treatment of HIV infection has been associated with both individual patient clinical benefits and with a dramatic decrease in the risk of transmission to sexual partners [39,40]. The effectiveness of HIV treatment as prevention (TasP) depends on starting treatment early and adhering to it. Retention in care is an essential component of HIV care, to correctly monitor treatment and to provide for other health issues such as co-morbidities, mental health etc.

Direct acting antivirals (DAAs) for HCV now provide highly effective treatment options for the infection. Evidence is accumulating on the high rates of safety, tolerability and efficacy of DAA regimens for the treatment of HCV-infected and HIV-HCV co-infected patients compared with interferon/ribavirin (INF/RBV) [41,42]. However, affordability has been a substantial barrier to DAAs treatment scale up in the EU/EEA, and restricted access to DAAs is in place in most EU/EEA countries [43].

² According to data collected by ECDC through Dublin Declaration monitoring

³ No available data for Iceland

Treatment for chronic HBV infection is also available. However, cure is not currently attainable, and the main endpoint of all current treatment strategies is the induction of long-term suppression of HBV DNA levels, rather than virus eradication. Treatment outcomes have improved over the past few decades, and current recommendations to include nucleos(t)ides analogues [44,45].

While prisons may offer a suitable platform to scale-up treatment for viral hepatitis and HIV among higher risk population groups, data on coverage in prison settings in the EU/EEA are currently not available. Barriers still exist limiting treatment coverage and uptake in the EU/EEA and broader European region, including economic barriers and treatment rationing (i.e. DAAs for HCV) as well as structural barriers such as unfavourable laws and policies. More specifically, criminalisation of drug use is reported to be a potential barrier to treatment access or uptake in one EU/EEA country. Half of the countries in the EU/EEA do not provide HIV treatment for undocumented migrants and in some countries, undocumented migrants are only entitled to emergency healthcare, in the absence of legal residence status and/or health insurance [37,46].

2.4 Throughcare

Transition planning has long been identified as the weakest link in the effective management of the admission into prison and/or the re-entry into community of individuals with drug use disorders, or with special health needs (e.g. chronic diseases, TB treatment, HIV treatment, mental disorders)[47-51]. This is of great relevance in the context of prevention and control measures for BBVs infections, for the need to ensure continuity of and adherence to treatment for HIV, HBV and drug use disorders (i.e. OST). While HCV treatment with current DAA regimens may offer the opportunity for in-prison treatment completion, HBV vaccination may require long-term follow up and booster shots when administered according to the rapid and very rapid schedules, and HBV and HIV treatments are lifelong. The long-term efficacy of healthcare interventions and programmes for risk reduction are greatly diminished if intervention and care provision are terminated or disrupted when the individual transitions from one institution to another or from a custodial institution back into the community. Many factors may contribute to such situations, for example, limited budget and resources, including staff and infrastructure, separate sphere of influence and institutional responsibility over prison and community health, and challenges in inter-sectorial cooperation.

2.5 Human rights in prison settings and prison health

Several guidance documents define the principles and standards of prison healthcare delivery [47,52-56]. Together with the rich international human rights case law, these documents offer a wide variety of tools, helping prison healthcare services to deliver their services in line with human rights requirements and based on the principle of equivalence of healthcare between prison and community.

The enjoyment of the highest attainable standard of physical and mental health is an internationally recognised fundamental right of every person, i.e. a human right]. As described in the documents mentioned above, people in prison are entitled to the right to health and – subject only to the deprivation of liberty itself and to the limitations that are inescapable for its effective enforcement – all other human rights.

In consideration of the recognition of people in prison as a key population in a variety of policies and strategic documents aiming at controlling infectious diseases [58], it may be argued that there is an opportunity to move from the principle of equivalence of standards and care to an equivalence of objectives and health outcomes [59,60]. Success in improving the health of people in prison requires adequate conditions of detention, appropriate hygiene and avoidance of overcrowding. Conversely, there is evidence that poor conditions of detention may contribute to the dissemination of communicable diseases and add an additional risk of infection; for example, increased risk taking practices in prison are often related to drug use, tattooing, and sexual activities [13,15].

The public health relevance of early diagnosis is reflected in international human rights case law: '[...] the spread of transmissible diseases should be a major public-health concern, especially in prisons [...] it would be desirable if, with their consent, [people] could benefit, within a reasonable time after being committed to prison settings, from free screening' for different types of viral hepatitis, HIV and TB[49].

Similar arguments are equally valid for drug use disorders, considering, as noted above, the substantial number of people held in prison who use drugs or are addicted before admission or while in detention. Responding to the drug-related healthcare needs of people in prison has been identified as a public health priority by the European Union and Member States. This is evident in the EU drugs action plan 2009–12 [61], which sets the objective for Member States to provide drug users in prison with improved access to healthcare, in order to prevent and reduce health-related harm associated with drug dependence. It is also expressed in the Dublin Declaration on Partnership to fight HIV/AIDS in Europe and Central Asia, which identifies people in prison as a vulnerable population and sets time-bound targets for national governments to provide comprehensive HIV/AIDS services for them [62].

3. Guidance development

3.1 Systematic review

A systematic literature review was performed to assess the evidence base around the effectiveness and suitability of active case finding in correctional facilities. The best available evidence and scientific knowledge was collected, reviewed and appraised in a transparent and systematic way. The review covers peer-reviewed and grey literature and follows international standards, such as Cochrane and PRISMA ('preferred reporting items for systematic reviews and meta-analyses'). A predefined list of databases and websites was searched for relevant articles, reports, conference abstracts, guidelines or other documents. A call for papers was also used to elicit submission of relevant unpublished materials.

The systematic review was designed to answer the following questions:

- Which prevention, care and treatment interventions for BBVs are effective in prison settings?
- Which service models for prevention, care and/or treatment of BBVs are effective in prison settings?
- Which prevention, care and/or treatment interventions aimed at control of HIV are cost-effective in prison settings?
- Which service models for prevention, care and/or treatment of BBVs are cost-effective in prison settings?
- What is the acceptance/uptake/coverage of prevention, care and/or treatment of BBVs in prison settings?
- How to improve the acceptance/uptake/coverage of prevention, care and/or treatment of BBVs in prison settings?
- Who should be targeted for prevention, care and/or treatment of BBVs in prison settings?

The systematic review is described in extensive detail in the 'Systematic review on the prevention and control of blood-borne viruses in prison settings' to be published by ECDC.

In addition, the evidence base on active case findings for BBVs and HBV vaccination included in this guidance derives from two systematic reviews previously performed in the frame of the project [35].

3.1.1 Evidence synthesis and grading

The quality and risk of bias of all included studies from the peer-reviewed literature and the quality of the grey literature documents were graded as stated in the systematic review report [REF SR BBV report]. The level of evidence of peer-reviewed studies was determined based on the study design and the risk of bias, following Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria ('grading of recommendations assessment, development and evaluation'). Since significant heterogeneity existed between the included studies, the strength of evidence was not assessed beyond individual studies.

Grey literature documents were included only if they used transparent methods for collecting and compiling data and/or provided data sources/references. Relevant conference abstracts/unpublished research reports were checked for duplicity with peer-reviewed literature. Relevant guidelines were critically appraised with a selection of criteria derived from the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument ('appraisal of guidelines for research and evaluation') and were categorised as either evidence-based guidelines or practice-based guidelines (with the former considered as higher quality; see Glossary).

To structure the evidence, the evidence base from the systematic review was compiled by developing a specific summary for hepatitis, HIV, STIs and TB. The evidence was further analysed by:

- outcomes: uptake, positivity rate, effectiveness (change in number/percentage tested, change prevalence/incidence, other), treatment initiation, cost-effectiveness, acceptability, feasibility, accessibility, and
- intervention descriptor/modality: timing (at entry, during imprisonment, at release), offer (mandatory, opt-in, opt-out, not specified), testing promotion (e.g. education, counselling).

The evidence synthesis for BBVs active case finding and HBV vaccination followed the same approach and is described in details elsewhere [REF SR ACF report; and ECDC unpublished].

3.2 Role of the ad-hoc scientific panel

A multi-sectoral ad hoc scientific panel on active case finding interventions was established to contribute to evidence gathering, analysis and interpretation.

The scientific panel members were selected based on their expertise in prison health, prevention and control of communicable diseases and their experience in the development of guidance documents. Experts came from a variety of constituencies, such as clinical professional associations, public health institutions, national ministries,

EU-funded initiatives, international agencies, and civil society organisations from various countries, namely the Czech Republic, Estonia, France, Germany, Italy, Romania, Spain, Switzerland and the UK (Appendix 1).

The members of the scientific panel were invited based on their professional and scientific experience and do not represent the interests of any commercial body, Member State, or professional body. All panel members signed declarations of interest, which were reviewed by ECDC's compliance officer. None of the members of the panel declared a conflict of interest. The panel was chaired by one of its members, and ECDC and EMCDDA acted as secretariat.

The scientific panel held four teleconferences and one face-to-face meeting. The first teleconference was held in November 2015 and discussed the prioritisation of topics, methodology, and evidence gathering. A Delphi process to collect panel opinions on human rights aspects and guiding principles for the guidance was performed ahead of the face-to-face meeting. The findings of the systematic review and the results of the Delphi process were discussed at a panel meeting in Stockholm on 23–25 May 2016 and during three teleconferences later that year. Members of the scientific panel provided valuable input and agreed, through a consensus building approach, on several evidence-based guidance statements and human rights considerations which were later included in the guidance document. During the face-to-face meeting, participants also identified additional peer-reviewed literature and grey literature documents with potentially relevant data, which were then assessed for inclusion in the systematic review.

Active case finding for BBVs and HBV vaccination were discussed in previous expert panel meetings during 2016, as reported elsewhere [35]. In particular the findings of the systematic review on active case finding and vaccination strategies were presented and discussed at the panel meeting, held at ECDC in Stockholm on 23, 24 and 25 May 2016, and during two teleconferences later that year.

The scientific panel members contributed to the drafting and remotely reviewed subsequent versions of the guidance document during the second half of 2017.

3.2.1 Guidance statement development

ECDC and EMCDDA developed summary assessments of the evidence base, which are presented in Chapter four alongside the conclusions of the scientific panel. The scientific panel members formulated their conclusions based on the evidence base (peer-reviewed literature and grey literature), their expert opinion and the following criteria:

- Prison population subgroup considerations (e.g. migrants, PWID, prison staff)
- Implementation considerations
- Equity, ethics and human rights considerations
- Risks and benefits considerations
- Supplementary evidence (e.g. evidence derived from community settings)
- Existing EU/EEA service models for care delivery in prison settings

For stronger statements, the phrasing 'it is advisable' was used; 'could be considered' was used for less strong statements.

Considerations for implementation are discussed in Chapter 5, which presents an evidence base heavily indebted to expert opinions.

4. Conclusions

With the ultimate objective of interrupting communicable disease transmission within prisons and between prisons and the community, by preventing infections occurring and by testing and treating infected persons, the most effective and cost-effective interventions and service models for prevention and control of BBVs were sought. The resulting evidence was complemented by expert opinion and insights from country-specific service models. However it is important to note that specific interventions for which the evidence base was lacking, but may still be of relevance in prison settings, are not discussed in this section.

4.1 Prevention of blood-borne viruses infections

Evidence base

The evidence base on prevention of BBVs in prison settings was very limited. A total of twelve studies were included from the peer-reviewed and grey literature, of which three were a randomised controlled trial (RCT), one was a RCT follow-up study, two were cost-effectiveness studies, five were non-comparative studies reporting on interventions effectiveness, and one was a descriptive study of acceptability of prevention measures⁴. The available evidence reported on the following prevention measures: condom distribution (three studies), safe tattooing (one study), behavioural interventions (two studies), prison-based NSP (three studies), and prison OST programme (three studies). Only a subset of studies assessing intervention effectiveness (three studies on NSP and two on OST) reported on communicable diseases related outcomes (i.e. changes in incidence, seroconversions) following the implementation of the interventions, the remainder reported on behavioural-associated outcomes only (e.g. drug injecting behaviours). Overall, the level of evidence was low or very low. The evidence base was very heterogeneous as it derived from a broad geographical area within and beyond the EU/EEA, over a long period of time. Also, the evidence covered a subset of available prevention interventions. As a result, it is challenging to develop any evidence-based conclusion regarding the most effective BBVs prevention approach in prison settings. Tables 1, 2, 3 provide an overview of the evidence base; more information is available in the upcoming systematic review technical report to be published by ECDC.

Additionally, three national guidelines [63-65] and four supranational guidelines [15,22,55,66] covering BBVs prevention in prison settings were identified. Overall, these documents recommended a comprehensive package of prevention measures to be implemented in prison settings, including health promotion and education, condom distribution, OST, vaccination, pre- and post-exposure prophylaxis, early testing and treatment, prevention of mother-to-child transmission and safe health services. Further to these, four non-prison specific supranational guidelines [36,58,67] recommended a similar prevention toolkit for PWID [36] and key populations [58].

Table 1. Evidence for the effectiveness of interventions for prevention of BBVs in prison settings

Intervention description	Studies included [No. of studies, design, reference, sample size, no. of studies from EU/EEA]	Outcome 1: Sero-conversion	Outcome 2: behaviour change	Other outcomes	Level of evidence
Condom distribution	N=1 study; Cross-sectional [Dolan, 2004 [68]], sample size (606) EU/EEA (0)	NR	Frequency of condom use among sexually active inmates for anal and oral intercourse was every time (52%, 28%), often (7%, 2%), sometimes (16%, 22%), never (21%, 44%) and no sex since condom availability (4%, 4%)	294 853 condoms dispensed during study period; 24 571 per month Use condom machine: 28% 40% used condoms for sex, 25% for self-masturbation, 19% used the sealable disposal bags for storage of substances	Very low

⁴ Acceptability/feasibility studies are not included in the table and details of the findings are presented in the systematic review technical report elsewhere [REF SR BBV report]

Intervention description	Studies included [No. of studies, design, reference, sample size, no. of studies from EU/EEA]	Outcome 1: Sero-conversion	Outcome 2: behaviour change	Other outcomes	Level of evidence
Safe tattooing program	N=1 study; conference abstract [Humet, 2012 [69]], sample size (90) EU/EEA (1)	NR	68% of those who requested, performed safe tattooing (69.5% had previously been tattooed, mostly using uncontrolled equipment and often during imprisonment)	66% requested safe tattoos	N/A
Group behaviour intervention vs. usual care	N=1 study; RCT [Lehman, 2015 [70]], follow-up [1 week post-intervention], sample size (1 257) EU/EEA (0)	NR	Greater improvement in intervention group and higher mean score at post-test in intervention group than control group for: HIV knowledge confidence, avoiding risky sex, avoiding risky drug use, HIV services and testing, and risk reduction skills	NR	Low
Group skills-building intervention vs. discussion intervention	N=1 study; RCT [St Lawrence, 1997 [71]], follow-up [6 months post-intervention], sample size (90) EU/EEA (0)	NR	Skills building intervention greater improvements in acknowledging a partner's request and condom application skills Discussion intervention greater improvements in commitment to change	NR	Very low

NR: not reported, RCT: randomised controlled trial

Table 2. Evidence for the effectiveness of interventions to prevent injecting-related infections among PWID in prison settings

Intervention description	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: seroconversion	Outcome 2: adverse events/attrition ¹	Other outcomes	Level of evidence
NSPs	N=3 studies; 2 longitudinal studies [Stark, 2006 [72]; Heinemann, 2001 [73], Arroyo, 2015 [74]], follow-up [median 12 months; NR], sample size (174, 231, NR) EU/EEA (3)	<i>Median 12 months follow-up:</i> - HIV: 0 - HBV: 0 - HCV: 4 out of 22 HCV seronegative at baseline (IR 18/100 person-years) - 12 HBV and 11 HCV seroconversions, of which at least 5 HBV and 2 HCV during imprisonment, occurred during the study observation period - No seroconversions were observed during the intervention period - Between 1998 and 2014 the prevalence of HCV and HIV infection in Spanish prison system decreased from 48.6% to 20% and from 12% to 5.8%, respectively [temporal association, causality not assessed].	No adverse events possibly related to the programme (n=1 study) Attrition: 28.7%	-3 383 – 10 439 syringes exchanged - All seroconverters denied tattooing, piercing, sexual risk behaviour, sharing syringes in prison, but 3 reported front-loading ² or sharing of spoons for drug preparation prior to seroconversion (1 study) - Almost all subjects reported frequency of needle sharing as unchanged or only slightly decreased (1 study) -The number of syringes exchanged rose from 2 582 to nearly 23 000 in 2004 and decreased since then to 4 393 in 2014	All very low

Intervention description	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: seroconversion	Outcome 2: adverse events/attrition ¹	Other outcomes	Level of evidence
Opioid substitution treatment	N=2 studies; 2 RCTs [Dolan, 2003 [75]; Dolan, 2005 [76]], follow-up [4 months; 4 years], sample size (both studies 191 OST, 191 control) EU/EEA (0)	~4 months follow-up: - HIV: 0 at baseline and follow-up - HCV: 4 out of 32 OST and 4 out of 35 control HCV-negative subjects at baseline (12.5% and 11.4%, resp., p=ns) Median 4.2 years follow-up: /: 39 of 95 HCV-negative subjects (IR 21.3/100 person-years, 95% CI 15.6-29.2), p=ns between original RCT groups - HIV: 2 (seronegative at baseline NR; IR 0.276/ 100 person-years, 95% CI 0.033-0.996)	Adverse events: NR Attrition: - 22.5% in OST and 26.6% in control group - 80.6% dropped out of their first OST episode over 436 person-years at risk (attrition rate 63.1 per 100 person-years, 95% CI 56.1-71.0)	Significant association with increased risk of HCV seroconversion (n=1 study): periods of imprisonment of <2 months (p≤0.001), OST periods of <5 months (p=0.01)	All very low

CI: confidence interval, HBV: hepatitis B virus, HCV: hepatitis C virus, HIV: human immunodeficiency virus, NR: not reported, NSP: needle and syringe programme, OST: opioid substitution treatment, RCT: randomised controlled trial

Table 3. Evidence base for the cost-effectiveness of interventions for prevention of BBVs in prison settings

Intervention description	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Scenarios	Conclusions	Level of evidence
Condom distribution vs. no condom distribution	N=1 study [Leibowitz, 2013 [77]], perspective [societal], time horizon (32 years) EU/EEA (0), USA (1)	Condom distribution: staff visit the unit once a week, at which time inmates line up and may receive a single condom vs. No condom distribution	- 25% of HIV transmissions averted, reducing the number of new infections from 0.8 to 0.6 per month - Cost savings over the next 32 years of \$74 777	Low
Opioid substitution treatment	N=1 study [Warren, 2006 [78]], perspective provider/funder of prison services, time horizon NR EU/EEA (0), Australia (1)	OST programme for 1 year vs. No OST program	- Incremental cost per additional heroin-free day: AUD \$38 - Incremental cost per death avoided: AUD \$458 074 - Incremental cost per HCV case avoided: AUD \$40 428 - OST programme in prison is no more costly than community programs	Low

AUD: Australian Dollar, HCV: hepatitis C virus, HIV: human immunodeficiency virus, NR: not reported, OST: opioid substitution treatment

Ad-hoc scientific panel opinion

In consideration of the overall low-level evidence and the lack of conclusive studies on BBVs prevention in prison settings, the ad-hoc scientific panel considered it important to rely on indirect evidence from the community. The ad-hoc scientific panel shared the opinion that, as in the community, prevention of BBVs in prison settings should be part of a comprehensive package of measures. In addition, it was suggested not to implement interventions in isolation and to secure the engagement of a wide range of stakeholders.

The ad-hoc scientific panel recognised the important role prison health contributes to public health and the fundamental principle of equivalence of care, while considering the existing guidelines and integrating them with the available research evidence and models of service delivery in prison settings collected through the systematic

review and the indirect evidence from the community setting (see section 5.1.4 and 5.1.5). The ad-hoc scientific panel concluded that a comprehensive prevention and response to BBVs in prison settings is advisable. Such comprehensive package would preferably consist of [very low level of evidence]:

health promotion and education; active case findings⁵; vaccination treatment as prevention; post-exposure prophylaxis⁶ and pre-exposure prophylaxis access to condoms; access to safe tattooing and body piercing tools; access to clean drug injecting equipment for PWID; access to OST and other effective treatments of drug dependence; prevention of mother to child transmission and safe medical services and infection control.

While it was recognised that structural barriers, such as a restrictive legal and regulatory framework (especially related to drug use and injecting behaviour in prisons) may hamper the implementation of one or more prevention measures, the ad-hoc scientific panel shared the opinion that the combination of these interventions enhances prevention synergies and their effectiveness in the response to BBVs in prison settings.

ECDC and EMCDDA assessment: The evidence on BBVs prevention in prison settings is limited and restricted to some of the existing preventive measures. The evidence suggests that provision of condoms and the implementation of behavioural interventions may promote safer sex behaviours in prison settings. Studies on OST consistently show that while patients are in prison, the treatment reduces opioid use, injecting, and sharing of injecting equipment. After release, prison OST patients are more likely to continue treatment, achieving the same benefits, and they face a lower risk of drug-related death. Injecting drug use bears the highest risk of transmission of BBVs among prisoners, due to the re-use contaminated injecting equipment. Whilst more limited, the available evidence suggests that the successful implementation of NSP in prison is possible and may lead - as part of a comprehensive response - to a reduction of BBVs transmission among incarcerated PWID. These findings are consistent with the evidence derived from community settings (see sections 5.1.4 and 5.1.5).

The range of existing BBVs preventive measures includes additional interventions which should be considered for implementation in prison settings alongside those mentioned above. These include early diagnosis (see sections 4.2 and 5.1.6), HBV vaccination (see sections 4.3 and 5.1.7), treatment as prevention (sections 4.4, 4.5 and 5.1.8), safe tattooing and body piercing as well as pre- and post-exposure prophylaxis, prevention of vertical transmission and safe health care service (section 5.1.4). National (or supranational guidelines) providing recommendations on these measures should apply by the same standards in prison settings.

4.2 Active case finding for blood-borne viruses

Evidence base

The evidence on active case finding for BBVs in prison settings was weak. For HBV, no comparative studies were found, and the evidence is confined to nine relevant descriptive studies reporting on uptake and positivity rates. For HCV, in addition to sixteen descriptive studies reporting on uptake and positivity rates, three comparative studies and five cost-effectiveness studies were found. Two of the comparative studies were RCTs focused on comparing testing methods rather than offer and timing modalities (which was the focus of the review). For HIV, thirty-seven descriptive studies were included, reporting on uptake, positivity rates and, to a lesser extent, on treatment initiation. Seven comparative studies and one relevant cost-effectiveness study were also retrieved. Overall, the evidence base was very heterogeneous as it derived from a broad geographical area within and beyond the EU/EEA. It reported on different testing modalities, and their combinations, targeting a range of distinct subpopulations. As a result, it is challenging to develop any evidence-based conclusion regarding the most effective testing approach for BBVs in prison settings. Tables 4 and 5 provide an overview of the evidence base; more information is available in the systematic review technical report [35].

Additionally, three national guidelines [79-81] and three supranational guidelines [56,82], covering BBVs testing in prison settings were identified. Two of these documents recommended BBVs provider-initiated testing at entry and during imprisonment [80,81]; two recommended BBVs testing without providing details on when and how it should be performed [56,79]; the remaining two recommended voluntary HIV testing [58,82]. One of the documents, from the United Kingdom recommended offering universal opt-out testing for BBVs within 72 hour from admission using either dry blood spot (DBS) or venous blood [81].

⁵ See dedicated sections in this guidance for more details on this prevention intervention

⁶ These prevention measures will not be discussed in details in this guidance as no research evidence was identified and these are covered elsewhere. Existing national and/or supranational guidelines on the implementation of these measures, whether or not prison-specific, should apply by the same standards in prison settings.

Table 4. Evidence for the effectiveness of BBVs active case finding in prison settings

Intervention description - how - when - who	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: Uptake	Outcome 2: Positivity rate	Other outcomes	Level of evidence
- Provider-initiated - At entry - Universal	N=4 studies; 1 cross-sectional [83]*, sample size (702) 1 descriptive [84] ^a , sample size (946) 1 conference abstract [85], sample size (711) 1 unpublished research [86], sample size (~2 000) EU/EEA (3)	>91.3%	0.6%-16.5%	NR	All very low
- Provider-initiated - During imprisonment - Universal	N=4 studies; 1 cross-sectional [33]*, sample size (3 468) 3 conference abstracts [87-89]*, sample size (4 072, 2 233, 7 767) EU/EEA (4)	56.3%-83.8% 55% Higher uptake after peer-education % tested increased from 10% to 42.9% after testing promotion initiatives (peer educators, leaflets, posters and staff training)	4.4%-13.2%	NR	All very low
- Provider-initiated (mandatory) - At release - Universal	N=1 study; 1 cross-sectional [90], sample size (916) EU/EEA (0)	NR	0.5%	NR	Very low
- Provider-initiated - At entry - Universal	N=6 studies; 1 cross-sectional [83]*, sample size (702) 3 descriptive [84] ^{a,b,c} , sample size (946, 3034, 1 618) 1 conference abstract [85], sample size (711) 1 unpublished research [91], sample size (~2 000) EU/EEA (5)	9%-91.5%	4.7%-73.5%	NR	All very low
- Provider-initiated - At entry - High risk (HIV, self-reported IDU)	N=1 study; Cross-sectional [92], sample size (51 562) EU/EEA (0)	NR	57%	Risk-based active case finding failed to capture 76% of predicted HCV positives	Very low
- Provider-initiated - During imprisonment - Universal	N=4 studies; 2 cross-sectional [33,93]*, sample size (3 468, 957) 2 conference abstracts [87,88]*, sample size (4 072, 2 233) EU/EEA (3)	26%-83.8% Higher uptake after peer-education % tested increased from 20.5% to 42.0% after testing promotion initiatives (peer educators, leaflets, posters and staff training)	10%-32.8%	NR	All very low
- Provider-initiated - At entry and during imprisonment - Universal	N=1 study; Cross-sectional [94]*, sample size (2 716) EU/EEA (0)	21.9%	20.5%	NR	Very low

Intervention description - how - when - who	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: Uptake	Outcome 2: Positivity rate	Other outcomes	Level of evidence
- Provider-initiated - NR - Universal	N=1 study; 1 cross-sectional and qualitative [95]*, sample size (30) EU/EEA (1)	63.3%	36.8%	NR	All very low
- Provider-initiated - At entry - High risk vs. - Client-initiated - NR - Universal	N=1 study; Before-after [96]*, sample size (12 297), follow-up [NA] EU/EEA (0)	Provider-initiated at entry for high-risk: 80.7%	Provider-initiated at entry for high-risk: 25.4% 1.9 cases/month (provider-initiated at entry, high risk) vs. 0.7 cases/month (client-initiated, universal)	NR	Very low
- Provider-initiated - At entry - Universal vs. - Routine testing (for females only) - NR - Universal	N=1 study; Stepped-wedge cluster RCT [97]*, sample size (~3 600), follow-up [18 months] (focus on testing method – DBST vs. venepuncture) EU/EEA (1)	Higher HCV test rates using DBST at entry vs. venepuncture; insufficient evidence of effect of the intervention on uptake	NR	NR	Low
- Provider-initiated - NR - Universal vs. - Client-initiated - NR - Universal	N=1 study; Cluster RCT [98]*, sample size [NR], follow-up (6 months) (focus on testing method – DBST vs. venepuncture) EU/EEA (1)	Increase of HCV tested using DBST vs. client-initiated regular practice	NR	NR	Moderate
- Provider-initiated (mandatory) - At release - Universal	N=1 study; Cross-sectional [90], sample size (916) EU/EEA (0)	NR	1.7%	NR	Very low
- Provider-initiated - At entry - Universal	N=18 studies; 10 cross-sectional [84,99-103]*,a,b,c,d,e, sample size (680, 2791, ~1 700, 977, 100, 9 405, 550 000, NR, 30 799, NR) 5 descriptive [84]f,g,h,i,j, sample size (946, 39 073, 140 739, NR, 129 084) 2 prospective controlled trials [84]k,l, sample size (323, 298), follow-up [NR] 1 conference abstract [85], sample size (711) EU/EEA (1)	6%-98%	0%-5.4%	99.9-100% of HIV positives received their test results The opt-in strategy failed to detect 28%-91% of HIV cases Acceptance increased from 43% with opt-in to 64% with opt-out	All very low
- Provider-initiated - At entry and during imprisonment (at regular intervals) - Universal	N=1 study; Cross-sectional [30]*, sample size (3 289) EU/EEA (1)	97.3% at entry; 96% during imprisonment	12.5% at entry; 0.06% during imprisonment	NR	Very low

Intervention description - how - when - who	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: Uptake	Outcome 2: Positivity rate	Other outcomes	Level of evidence
- Provider-initiated - At entry or during imprisonment - Universal	N=8 studies; 1 comparative (focusing on testing method – blood vs. oral) [104]*, sample size (1 314), follow-up [NA] 2 cross-sectional [94,105]*, sample size (NR, 2 716) 5 conference abstracts [87,88,106-108], sample size (4 072, 2 233, 19 772, 1 410, 6 691) EU/EEA (5)	24.6%-83.8% 63% increase in testing uptake when blood or oral testing offer instead of blood only 42% increase in testing uptake testing promotion initiatives (peer educators, leaflets, posters and staff training)	0.8%-17%	Treatment initiation: 59.1%	All very low
- Provider-initiated - NR - Universal	N=4 studies; 1 cluster-randomised trial (focusing on promotion intervention) [109], sample size (3 300), follow-up [NR] 1 longitudinal (focusing on promotion intervention) [110], sample size (3 096), follow-up [12 and 18 months] 2 conference abstracts [111,112], sample size (10 857, 320) EU/EEA (2)	82.5% When implementing a model where staff receive HIV service training and are coached in the model uptake was 48-53% vs. 49-44% where staff only receiving the HIV service training. OR=0.16 (not significant) Significant increase in uptake of testing after peer education programme vs. no intervention (at 12 months: OR=2.76; at 18 months: OR=1.78)	9.9%-26.5%	Treatment initiation: 78% Significantly more attendees indicated they planned to schedule an HIV test after peer-education	Moderate-low
- Provider-initiated - At entry and release - Universal	N=1 study; Cross-sectional [83]*, sample size (702) EU/EEA (1)	91.3% at entry; 4.2% on release	0.3% at entry; 0% on release	NR	Very low
- Provider-initiated - During imprisonment - Universal	N=1 study; Cross-sectional [33]*, sample size (3 468) EU/EEA (1)	67.4%	3.8%	NR	Very low
- Provider-initiated - At entry - Universal vs. - Client-initiated - At entry - Universal	N=2 studies; Descriptive (comparing different offer types) [84] ^m , sample size (opt-in 16 908, opt-out 5 168) Before-after [84] ⁿ , sample size (2 886), follow-up (NA) EU/EEA (0)	Increase from 5% (testing on request) to 72% (opt-in) to 90% (opt-out) Increased from 18% (client-initiated) to 73% (provider-initiated)	0.1% new (opt-in and opt-out) 0.3% (provider-initiated)	100% HIV positives received results	All very low
- Provider-initiated - At release - Universal	N=1 study; Cross-sectional [113]*, sample size (507) EU/EEA (0)	60%	0.3%	100% received test results	Very low
- Provider-initiated - At entry - Universal vs. - Client-initiated - During imprisonment - Universal	N=2 studies; Cross-sectional [114], sample size (54 664) Surveillance [115], sample size (22 338) EU/EEA (0)	34-39% provider-initiated at entry; 6% client-initiated during imprisonment	3.3% provider-initiated at entry; 12% client initiated during imprisonment	NR	All very low

Intervention description - how - when - who	Studies included [No. of studies, design, reference, sample size, No. of studies from EU/EEA]	Outcome 1: Uptake	Outcome 2: Positivity rate	Other outcomes	Level of evidence
- Provider-initiated - At entry and during imprisonment - High risk (PWID)	N=1 study; Conference abstract [116], sample size (144) EU/EEA (1)	NR	35.4%	Treatment initiation: 35.2%	
- Provider-initiated - NR - Universal	N=2 studies; 2 surveillance [117,118], sample size (NR, NR) EU/EEA (0)	Increased by 194% from 1992 to 1998 Increased from 2009 to 2012 and decreased slightly in 2013, estimated annual percent change of 2.7%	3.4% of tests were HIV-positive. The percentage of all tests that were HIV-positive decreased nearly 50% from 1992 to 1998 From 2009 to 2013, HIV-positive cases increased significantly with an annual percent change of 4.4%	Treatment initiation: The percentage of HIV-positive people in detention linked to medical care significantly increased by 27% between 2009 and 2013	All very low
- Provider-initiated (mandatory) - At release - Universal	N=1 study; Cross-sectional [90], sample size (916) EU/EEA (0)	NR	0.1%	NR	Very low

DBST: dried blood spot testing, HCV: hepatitis C virus, HIV: human immunodeficiency virus, NA: not applicable, NR: not reported, OR: odds ratio, PWID: people who inject drugs, vs.: versus

* Used different promotion strategies: posters and personalized information presentation [83]; letters on advantages of screening by peer-educators and pamphlets on importance of screening [33]; peer-educators, leaflets, posters and staff training [87]; informational video, post-testing counselling, appointment reminder card [93]; mandatory education session on hepatitis [94]; Information sheets about study, no reimbursements/inducements [95]; staff educational seminar on benefits identifying acute HCV/on acute HCV [96]; pre-and post-test counselling [97]; staff training on counselling, pre-and post-test counselling [98]; pre-and post-test counselling [102]; group-based HIV education while waiting for test results, post-test counselling [103]; advertising for rapid HIV tests, pre-test counselling, active follow-up and referral for positive testers [100]; counselling and active referral of positives [101]; counselling [30]; pre-test HIV counselling [104]; mandatory HIV education session before choice to test [94]; Disease education, post-test counselling [105]; peer educators and ID specialists [87]; posters, personalised information letters [83]; presentation on advantages of screening by peer-educators, pamphlets on importance of screening [33]; educational materials, pre-and post-counselling, active referral of positive testers to community-based care [113]; presentation on BBDs [114]; counselling [115]; modified NIATx process improvement model (staff receive HIV service training and are coached in the model or only receive HIV service training) [109]; peer educator inmates and student inmates or peer-education programme (intensive training for peer educators, ongoing HIV education sessions given by peer educators to inmates [110])

^{a-n} The following articles from the review by Rumble et al. [84] were part of the evidence base: a. Cotton-Oldenberg, b. Behrendt, c. Hoxie, d. Andrus, e. Beckwith 2007, f. Watkins, g. Spaulding, h. Beckwith 2010, i. Beckwith 2011, j. Beckwith 2012, k. Kavasery 2009a, l. Kavasery 2009b, m. Strick, n. Liddicoat

Table 5. Evidence for the cost-effectiveness of BBVs active case finding in prison settings

Intervention description - how - when - who	Studies included	Scenarios	Conclusions	Level of evidence
- Provider-initiated - At entry - High risk vs. - Client-initiated - NR - High risk	N=2 studies [119,120], perspective (healthcare provider), time horizon (30 years, 80 years) EU/EEA (2), UK (2)	1. HCV test following a lecture (general or IDU-focused) 2. Symptom-based HCV case finding	In one study, in PWID, case-finding at entry compared to symptom-based case finding was likely cost-effective based on reported ICER below 30 000 GBP per QALY, with the scenario using an IDU-focused lecture being the most cost-effective. In the other study contradicting results were found, whereby testing at entry after a lecture for PWID is likely not cost-effective compared to client-initiated HCV case finding based on reported ICER.	All moderate
- Provider-initiated - NR - High risk	N=1 study [121]; perspective (healthcare provider), time horizon (100 years) EU/EEA (1), UK (1)	1. DBST for HCV 2. Venepuncture for HCV	Among PWID, DBST is likely not cost-effective under UK commonly used willingness-to-pay thresholds of 30,000 GBP.	Moderate
- Provider-initiated - At entry - Universal or after verbal screening vs. - No active case finding	N=1 study [122]; perspective (healthcare provider), time horizon (NR) EU/EEA (1), UK (1)	1. No active case finding 2. Verbally screening for past positive HCV test and ever having injected illicit drugs, or only one of each 3. No verbal screening (lecture only)	The incremental cost-effectiveness analysis revealed that verbally screening for past positive HCV test and ever having injected illicit drugs prior to opt-in HCV testing at entry is the most cost-effective option.	Low
- Provider-initiated - One-time and at entry - High-risk or universal vs. - No active case finding	N=1 study [123]; perspective (societal), time horizon (30 years) EU/EEA (0), USA (1)	1. No active case finding 2. HCV active case finding of active/former currently incarcerated PWIDs and active/former PWIDs at entry for up to 1 year 3. HCV active case finding of all currently incarcerated persons and all entrants for up to 1, 5 or 10 years	The authors concluded that universal opt-out active case finding in prison for HCV is highly cost-effective (ICER below 50 000 USD per QALY) for at least 10 years. Scenarios for former and current PWID were also assessed.	Moderate
- Provider-initiated - At or near release - Universal vs. - No active case finding	N=1 study [124], perspective (societal), time horizon (NR) EU/EEA (0), USA (1)	1. HIV active case finding 2. No active case finding	Offering HIV counselling and testing to 10 000 inmates resulted in 50 new or previously undiagnosed infections and averts 4 future cases at a cost of \$125 000 to prison systems while saving to society over \$550 000.	Low

DBST: dried blood spot testing, HCV: hepatitis C virus, HIV: human immunodeficiency virus, IDU: injecting drug use, NHS: National Health Service, NR: not reported, PWID: people who inject drugs, vs.: versus

Ad-hoc scientific panel opinion

As reflected by the high positivity rate of chronic HBV, HCV and HIV infections reported by the included studies (Table 4), the prevalence of BBVs in prison settings, and in particular of HCV, is considerably higher than that in the general population [9,20,32]. The transmission risk for BBVs is also heightened in prison settings due to a combination of structural and behavioural risk factors, as is higher proportion of worse clinical outcomes due to a higher prevalence of co-infection with HBV/HCV or HIV [9,56,125]. Despite the overall low-level evidence and the lack of conclusive studies on active case finding modalities in prison settings, the ad-hoc scientific panel shared the opinion that BBVs testing should be actively promoted in order to offer appropriate and timely interventions, such as vaccination (HBV) and treatment, and reduce the risk of further disease transmission.

Since BBVs infections may remain asymptomatic for many years, a large proportion of infected individuals may be unaware of their status. Reducing the undiagnosed fraction of HBV, HCV and HIV is a major global priority and a key requirement to attain the WHO goal of viral hepatitis elimination [126] and the target of 90% of people living with HIV (PLHIV) diagnosed [127]. Due to stigma and criminalising laws, PWID have the higher risk of low adherence to 'testing and treatment' policies. These considerations alongside the notion of a heightened HIV

transmission risk due to structural and behavioural factors operating in prison [9,56,125], provide a strong argument for testing scale-up in this setting.

In this frame, targeted testing for higher risk subgroups, such as former and current PWID or migrants originating from endemic countries was considered based on some included studies reporting on selective testing approaches [96,119-122]. The ad-hoc scientific panel members expressed concerns relative to implementation challenges, the potential for discrimination and, not least, the sensitivity of risk assessment approaches. In consideration of the findings from more recent studies [92,123] and the existing recommendation from national guidelines [4,81], universal testing approaches aimed at all individuals in the prison setting were considered advisable.

While the ad-hoc scientific panel agreed that active case finding for BBVs should be provided in the context of adequate confidentiality, counselling and linkage to care, it also pointed out the opportunity offered by post-test prevention and control measures such as HBV vaccination for unvaccinated HBV negative individuals and effective therapy for chronic viral hepatitis and HIV.

Although it was not possible to conclude on the ideal timing and modality of testing for BBVs in prison settings based on available evidence, the ad-hoc scientific panel developed consensus on active case finding for HBV, HCV and HIV, provided that the 7Cs principles⁷ are guaranteed. It was considered beneficial to offer universal provider-initiated combined BBVs testing at entry followed by appropriate linkage to care to reduce the risk of transmission within prison [very low level of evidence]. However, since transmission may still occur within the prison setting, for example through unsafe sex and needle sharing, it is also advisable to offer provider-initiated testing to high-risk groups, such as men who have sex with men (MSM) and PWID during incarceration, at regular intervals or after an exposure incident [very low level of evidence]. Client-initiated testing was considered a valid approach to complement and enhance these efforts and thus could be continuously promoted during incarceration [very low level of evidence].

ECDC and EMCDDA assessment: Based on the available evidence on BBVs active case finding in prison settings, considering the high prevalence of infection in the prison population and the availability of effective prevention and control measures, it is important to offer testing for HBV, HCV and HIV to all people in prison.

The body of evidence suggests that provider-initiated strategies for HIV testing yield a higher uptake than client-initiated strategies. However the evidence does not provide clear indication on the most effective timing and testing modality for BBVs case finding in prison settings.

Provider-initiated testing is also consistent with the general principle of disease prevention to not delay diagnosis, in order to offer appropriate treatment and prevent, as much as possible, further transmission within the prison setting. The available evidence indicates that health promotion and peer-education directed towards people in detention are effective in increasing testing uptake, at least for HIV in prison settings. Few additional interventions to increase the uptake of testing could be considered, although the level of evidence for the effectiveness of any specific approach is very low (see section 5.1.6).

4.3 HBV vaccination

Evidence base

The evidence on HBV vaccination strategies in prison settings was limited. Only one comparative study (open label RCT) reported on the coverage of the third vaccination dose with the standard and the very rapid schedules. In addition, eight non-comparative studies were included covering a range of different vaccination schedules. One of these studies reported on the offer of hepatitis A virus (HAV) and HBV combined vaccine to MSM. One additional study reported on the comparison between two different HBV vaccines using the rapid schedule. As assessing the effectiveness of different vaccine products is not in the scope of this document, the results of the two study arms have been merged in Table 6. Two studies (not reported in Table 6) explored HBV vaccine acceptability in the prison setting. Finally, three cost-effectiveness studies were retrieved, of which two assessed the cost-effectiveness of combining HAV and HBV vaccination, either adding single dose monovalent HAV vaccine or using the combined HAV/HBV vaccine. Overall, the evidence base was very heterogeneous as it derived from a broad geographical area within and beyond the EU/EEA, it reported on different vaccination schedules, vaccine combinations, and targeting distinct subpopulations. As a result, it is challenging to develop any evidence-based conclusion regarding the most effective vaccination strategy for HBV in prison settings. Tables 6 and 7 provide an overview of the evidence base.

⁷ 7Cs principles: Consent, Confidentiality, Counselling or Communication, Correct test results, Connection to care and treatment, supportive Culture of the prison system, and Continuity of Care post-release. See chapter 5 for an explanation of these principles.

In addition, three supranational guidelines/document [15,58,128] and two national guidelines [63,129] recommend the HBV vaccine for individuals entering prison. One explicitly recommends a vaccination offer after an individual vaccination history has been taken [129], while some others support a vaccination offer irrespective of an individual's serological status [15,63]. HBV vaccination for prison staff is also recommended by two supranational guidelines/documents [15,128]. Finally, HAV vaccination is mentioned in three guidelines/documents [15,128,129] as a measure to be considered for specific subgroups such as PWID, MSM and individuals with chronic HCV infection.

Table 6. Evidence on effectiveness of HBV vaccination strategies in prison settings

Intervention description	Studies included	Outcome 1: Acceptance	Outcome 2: Uptake	Outcome 3: Seroprotection	Level of evidence
Standard schedule [0, 1, 6 months]	N=2 studies; 1 cross-sectional [Devine, 2007], sample size (391) 1 unpublished research report [Gabbuti 2014], sample size (1 408-2 376) EU/EEA (1)	83% 12.9% (2009)-24.3% (2014)	Dose 1: 43% Dose 2: 48% Dose 3: 19% Dose 3: 76.1% (35/46) in 2009 – 51.7% (185/358) in 2014	NR	Very low
Rapid schedule [0, 1, 2 months]	N=1 study; 1 cross-sectional [Awofeso, 2001], sample size (1 037) EU/EEA (0)	NR	NR	69.6%–82.5% after dose 3	Very low
Very rapid schedule [0, 7, 21 days; booster 12 months]	N=3 studies; 1 longitudinal (HBV vaccine) [Christensen, 2004], follow-up [NR], sample size (566) 2 cross-sectional (one with HAV/HBV combined vaccine) [Gilbert 2004; Costumbrado, 2012], sample size (1 363; 4 719) EU/EEA (2)	100%; NR (HBV) 34% (HAV/HBV offered to MSM only)	HBV Dose 1: 100%; NR Dose 3: 81%; 29% Booster: 42%; 6%-24% HAV/HBV Dose 1: NR Dose 2: 77% Dose 3: 58% Booster: 11%	HBV 67% at median 209 days from first dose; NR	Low/very low
Very rapid schedule Vs Standard schedule	N=1 study; 1 RCT [Christensen, 2004], follow-up [NR], sample size (72) EU/EEA (1)	100%	Very rapid Dose 3: 63% Standard Dose 3: 20% Difference in uptake was significant ($p=0.017$)		Low
Other schedule [0, 1-90, 50-360 days]	N=1 study; 1 cross-sectional [Bayas, 1997], sample size (705) EU/EEA (1)	76%	Dose 1: 31% Dose 2: 81% Dose 3: 43%	33% after dose 2 6% after dose 3	Very low
Schedule not specified	N=2 studies; 2 cross-sectional [Jacomet, 2016; Clarke, 2003], sample size (357; 236) EU/EEA (1)	54%-93%	Dose 1: 23%-67% Dose 2: 73% Dose 3: 40%	NR	Very low

HAV: hepatitis A virus, HBV: hepatitis B virus, NR: not reported, RCT: randomised controlled trial

Table 7. Evidence for the cost-effectiveness of HBV vaccination strategies in prison settings

Intervention description	Studies included	Scenarios	Conclusions	Level of evidence
HBV vaccination at entry Vs No vaccination	N=1 study [Pisu, 2002], perspective [prison and healthcare], time horizon [NR] EU/EEA (0)	At intake inmates receive the first vaccine dose (including those who had natural immunity)	Vaccinating inmates at intake, is not cost-saving from the prison perspective, but it is from the healthcare system perspective under a wide range of input values	Low
HAV & HBV vaccination Vs HBV vaccination only	N=1 study [Jacobs, 2004;], perspective (NR), time horizon (lifetime) EU/EEA (0)	HAV rates in the prison population: >200% the national average 100-200% the national average <100% the national average	The cost-effectiveness of substituting HAV and HBV vaccine (addition of one hepatitis A dose) for HBV vaccine (3 doses) would be US\$ <0; 2 131, and 22 819 per life-year saved depending on the HAV rates in the prison population.	Low
Timing and administration of HAV, HBV or HAV/HBV combined vaccine [HAV/HBV 0,1,6 months; HAV 0,6 months; HBV 0,1,6 months]	N=1 study [Jacobs, 2003], perspective (health system), time horizon (1 year) EU/EEA (0)	Individual aged 25 and 35 entering prison; Scenario 1: Vaccination after receiving hepatitis screening results Scenario 2: Immediate vaccination with first bivalent hepatitis vaccine dose, then continuing with appropriate vaccine after receiving hepatitis screening results Scenario 3: Vaccination with bivalent vaccine without screening	The most favourable average cost-effectiveness ratio for individuals aged 25 years and 35 years was scenario 3 and scenario 1, respectively. In both groups scenario 3 dominated scenario 2. In individuals aged 25 years, scenario 3 also dominated scenario 1, in individuals aged 35 years this was less clear.	Low

HAV: hepatitis A virus, HBV: hepatitis B virus, NR: not reported

Ad-hoc scientific panel opinion

The ad-hoc scientific panel agreed that HBV vaccination is a key prevention measure to be implemented in prison. There is strong evidence that HBV vaccination (either as monovalent or as hepatitis B-containing combination vaccine) is effective in providing protection against the infection [130,131].

People in prisons have a higher HBV prevalence than the general population [32], and the changing prison population demographics with rising numbers of detained individuals with a migration background [132] may result in an increasing prevalence of chronic HBV infection in this setting. People in detention are at higher risk for HBV acquisition as a consequence of the higher prevalence of risk behaviours such as injecting drug use, tattooing and other activities typical of the prison subculture (e.g. blood-brothers) [29], and may not have sufficient level of vaccination coverage, at least among PWID, as shown in a recent study from Germany [133]. The ad-hoc scientific panel considered that scaling up HBV vaccination in prison would reduce virus circulation, and result in decreased transmission within the prison population and in the community at large. Recent evidence from Scotland, where no routine universal childhood HBV vaccination was implemented until very recently, indicates that HBV universal vaccination in prison settings is effective in reducing HBV prevalence among PWID in the community [1].

HBV vaccination (as monovalent vaccine, or as hepatitis B-containing combined vaccine) is a recommended intervention for patients with chronic liver disease, including those with hepatitis C, and those with HIV [130]. The prevalence of these diseases, and particularly of HCV among the prison population is higher than the general population, and HBV vaccination is beneficial [26,32]. On similar grounds, the ad-hoc scientific panel considered that HAV vaccination (as monovalent vaccine, or as hepatitis A-containing combined vaccine) may be warranted [134,135].

Finally, the ad-hoc scientific panel considered that prison staff, and particularly correctional officers and healthcare workers, are at increased risk of acquiring HBV as result of occupational hazards. HBV vaccination may be considered as a relevant prevention measure for these groups as also recommended by existing supranational guidelines [15,36,130].

Although it was not possible to conclude on the ideal timing and strategy for HBV vaccination in prison settings based on available evidence, the ad-hoc scientific panel developed consensus. The panel considered that it would be advisable to offer HBV vaccination to all individuals with no or unknown vaccination history at reception following the rapid or very rapid schedule, depending on the period of stay and in alignment with national guidelines (very low level of evidence). It was also considered beneficial to offer HBV vaccination to prison staff

with no or unknown vaccination history (no evidence). The offer of HBV vaccination after needle-stick injuries, other acute exposure and to all babies born to incarcerated mothers – including vaccination at birth – as appropriate and in accordance with national guidelines, was considered highly relevant.

The ad-hoc scientific panel agreed that it would be advisable to offer HAV vaccination (as monovalent vaccine, or as hepatitis A-containing combined vaccine) to patients with chronic liver disease, including chronic HBV and HCV infection and HIV. The ad-hoc scientific panel also considered the opportunity of combining the offer of HAV vaccine with HBV vaccination for high risk groups, including MSM and PWID.

ECDC and EMCDDA assessment: Considering the high prevalence of BBVs infection in the prison population, the available evidence on HBV vaccination in prison settings and on HBV vaccination effectiveness in the community, it is advisable to offer vaccination for HBV to people in prison. The offer of HBV vaccination at entrance to all individuals with no/unknown vaccination history and/or negative serology is consistent with the general principle of disease prevention, in order to avoid, as much as possible, further transmission within the prison setting.

The body of evidence on HBV vaccination strategies in prison settings is limited and weak. The evidence suggests that provision of HBV vaccination using the rapid or very rapid schedule may result in a higher vaccination completion rate in prison settings. However, the available evidence does not provide clear indication on the most effective timing and strategy for HBV vaccination in prison settings.

Several implementation strategies could be considered, although the level of evidence for the effectiveness of any specific approach is very low (see section 5.1.7).

4.4 HIV treatment

Evidence base

The evidence on HIV treatment in prison settings was sizeable, with twenty-one studies included from the peer-reviewed and grey literature. Nineteen studies reported on the effectiveness of different models of care to achieve retention and adherence to HIV treatment in prison settings, of which four had a comparative approach (including one RCT), and the remainder were descriptive studies. Three additional studies were included focusing on acceptability and barriers to HIV treatment provision in prison settings. No cost-effectiveness studies were found. Overall, the level of the evidence was very low. The evidence was heterogeneous as it derived from a broad geographical area within and beyond the EU/EEA. None of the comparative studies were generated within the EU/EEA. Table 8 provides an overview of the evidence; and more information is available in the upcoming systematic review technical report to be published by ECDC.

Additionally, two national guidelines [28,65] and three supranational guidelines [15,55,58], covering HIV treatment in prison settings were identified. Overall, these documents recommend to offer ART to every HIV-infected individual in the prison setting, according to the same general principles and recommendations as for the general population. One guidance document explicitly recommends using directly observed therapy (DOT) [65]. The European AIDS Clinical Society recommends to start ART in all adults with chronic HIV infection, irrespective of CD4 counts [67].

Table 8. Evidence on effectiveness of different models of care to achieve retention and adherence to HIV treatment in prison settings

Intervention description	Studies included	Outcome 1: Adherence	Outcome 2: Viral suppression	Attrition	Level of evidence
Usual care - SAT	N=6 studies; 2 longitudinal [Herraiz, 2008 [136]; Orly de Labry Lima, 2007 [137]], follow-up (6 months; 12 months), sample size (75; 281); 1 cross-sectional [Inés, 2008 [138]], sample size (50) 3 conference abstracts [Prestileo, 2006 [116]; Gallego, 2010 [139]; Botana Pazos, 2012 [140]], sample size (144; 600; 102) EU/EEA (6)	42%–72% No significant changes over time reported in n=2 studies	46%–82.8% No significant changes over time reported in n=1 study on people on ART; significant decrease in viral load in n=1 study on people started on ART	30%–45%	All very low
Usual care - Combination of DOT and SAT	N=7 studies; 3 longitudinal [Kirkland, 2002 [141]; Meyer, 2014 [142]; Springer, 2004 [143]], follow-up (24 weeks; until release; until release), sample size (108; 882; 1 099); 3 cross-sectional [Soto Blanco, 2005 [144]; Altice, 2001 [145]; Mostashari, 1998 [146]], sample size (177; 205; 102) 1 conference abstract [Manzano, 2010 [147]], sample size (170) EU/EEA (2)	62%–94%	23%–62% Significant decrease in viral load in n=2 studies, decrease without reported significance in n=1 study, from baseline to follow-up	6%	All very low
Comparison DOT vs. SAT	N=3 studies; 2 longitudinal [Wohl, 2003 [148]; Babudieri, 2000 [149]], follow-up (3–4 months), sample size (31); 1 RCT [White, 2015 [150]], follow-up (48 weeks), sample size (43) EU/EEA (1)	No significant difference between DOT and SAT [measured by electronic monitoring, pill-count or self-reported]	No significant difference between DOT and SAT 62.1% of patients in DOT group had viral load <400 copies/ml vs 34% in the non-DOT group (p=0.01)	5%–52%	All very low
Telemedicine with HIV specialist	N=1 study; 1 comparative [Young, 2014 [151]], sample size (1 201), follow-up (18 months) EU/EEA (0)	NR	Significant increase in likelihood of achieving viral suppression in telemedicine group	NR	Very low
Clinical pharmacist-lead treatment	N=1 study; 1 longitudinal [Bingham, 2012 [152]], follow-up [NR], sample size (135) EU/EEA (0)	73%	Increased from 32% to 66% following intervention (significance NR)	NR	Very low

ART: antiretroviral therapy, DOT: directly observed therapy, NR: not reported, RCT: randomised controlled trial, SAT: self-administered therapy

Ad-hoc scientific panel opinion

The prison population is disproportionately affected by HIV. For this reason, people in prison were identified as a key target population to fast-track the ending of the AIDS epidemic at global level [127]. Expansion of testing coverage and uptake to achieve early HIV diagnosis is crucial as it provides the entry point to HIV care and treatment (see section 4.2) [35,127,153].

Based on the existing evidence from community settings, the ad-hoc scientific panel concluded that there is a strong rationale to provide ART to all HIV-positive individuals in prison settings, both for individual and public health benefit [40,154]. The available body of evidence shows that ART provision is feasible in prison settings. Hence, according to the ad-hoc scientific panel there is no reason to either withhold or delay ART for people living with HIV (PLHIV) in prison settings [very low level of evidence]. People in prison with a HIV diagnosis should be treated by the same standards as people in the community, including initiating ART regardless of CD4 count, in accordance with current European guidelines [67]. However, the ad-hoc scientific panel recognised that the challenge of ensuring continuity of care after release, along with other possible barriers, may influence the decision to initiate PLHIV on ART (see section 5.1.8).

Despite the global call for differentiated care and service delivery models for key populations, including people in prison [58,127], the existing research evidence on models of care is limited and does not point towards a specific model. While multidisciplinary approaches including specialist care may increase adherence and treatment outcomes, the evidence does not indicate an advantage of using DOT versus self-administered therapy (SAT). However, the ad-hoc scientific panel expressed some concerns on these findings as the evidence base is limited and non EU/EEA specific. DOT is effectively implemented in a number of EU/EEA countries and it was the opinion of the ad-hoc scientific panel that, when appropriate, patients may be offered the opportunity to choose the most suitable treatment administration option, be it DOT or SAT (very low level of evidence).

ECDC and EMCDDA assessment: The available evidence indicates that HIV treatment in prison settings is feasible and can be implemented. There is a strong public health rationale for providing access to HIV treatment and care to all PLHIV in prison settings with no delays.

However, the body of evidence on models of care delivery in prison settings is limited and does not point towards a specific model to achieve retention in care and adherence to HIV treatment. Interventions to increase adherence and treatment outcomes could be considered, although the level of evidence for the effectiveness of any specific approach is very low (see section 5.1.8).

4.5 Viral hepatitis treatment

Evidence base

The evidence on viral hepatitis (HCV) treatment in prison settings was sizeable, with 33 studies included from the peer-reviewed and grey literature, while no studies were retrieved reporting on HBV treatment in prison settings. Twenty-nine studies reported on the effectiveness of different models of care to achieve a sustained viral response (SVR) and completion to HCV treatment. Of these, 20 focused on IFN-based regimens using ribavirin (RBV) and interferon (IFN) (IFN-based), with 15 descriptive studies, two comparative studies (including one RCT) assessing DOT versus SAT models, one comparative study reporting on a telemedicine service delivery approach and two comparative studies evaluating community-based treatment versus prison-based treatment outcomes. The remaining nine studies, all conference abstracts, reported descriptive data on directly acting antiviral (DAA) treatment in prison settings. In addition, one study reporting only on acceptance and barriers to HCV treatment in prison was included, alongside three cost-effectiveness studies. Among the latter three studies, two reported on service delivery models for IFN-based treatment, and one on the cost-effectiveness of substituting DAA-based treatment for IFN-based treatment. The level of evidence was very low for all descriptive studies and moderate-to-low for all but one of the comparative and cost-effectiveness studies. Overall, the evidence base was heterogeneous as it derived from a broad geographical area within and beyond the EU/EEA. The evidence was dominated by studies generated in the IFN-based HCV treatment era. While the recent advent of DAAs and the shift in HCV treatment paradigm is a highly relevant topic for prison settings, the existing evidence base is entirely derived from grey literature. Tables 9 and 10 provide an overview of the evidence base; more information is available in the upcoming systematic review technical report to be published by ECDC.

In addition, two national guidelines [155,156] and one supranational guideline [15], covering HCV treatment in prison settings were identified. Overall, these documents recommend to offer antiviral therapy to individuals chronically infected with HCV in prison setting, according to the same general principles and recommendations as for the general population. One national guidance document explicitly recommends initiating treatment using DOT only for individuals with an imprisonment duration that allows the completion of treatment or when the linkage and continuity of care is guaranteed [155]. The European Association for the Study of the Liver (EASL) recommends the use of IFN-free regimens to treat treatment-naïve and treatment-experienced individuals with chronic HCV infections. It also recognises people in prison as one of the priority groups for treatment initiation [157].

Table 9. Evidence for the effectiveness of different models of care to achieve sustained viral response and HCV treatment completion in prison settings

Intervention description	Studies included	Outcome 1: SVR	Outcome 2: Treatment completion	Attrition	Level of evidence
Usual care – SAT IFN+RBV	N N=11 studies; 7 longitudinal [Strock, 2009 [158]; De Juan, 2014 [159]; Bate, 2010 [160]; Farley, 2005 [161]; Farley, 2005 [162]; Simonović Babić, 2016 [163]; Chew, 2009 [164]], follow-up (all 24 weeks/6 months after end treatment), sample size (268; 431; 79; 114; 90; 32; 71) 1 cross-sectional [Marco Mouriño, 2010 [165]], sample size (162) 1 nested case-control [Boonwaat, 2010 [166]], follow-up [NR], sample size (185) 2 conference abstract [Marco, 2010 [167]; Pallás, 2010 [168]], sample size (513; 41) EU/EEA (5)	27.6%–67.1%	46.5%–91.4%	5.8%–50.0% before SVR assessment	All very low
Usual care - Combination of DOT and SAT IFN+RBV	N=4 studies 4 longitudinal [Iacomi, 2013 [169]; Allen, 2003 [170]; Maru, 2008 [171]; Sterling, 2004 [172]], follow-up (24 weeks; 12 months; 6 months; 24 weeks after end treatment), sample size (50; 90; 68; 59) EU/EEA (1)	28.9%–50.0%	45.6%–98.3%	13.6%–14.4% before SVR assessment	All very low
Comparison DOT vs. SAT IFN+RBV	N=2 studies 1 RCT [Saiz de la Hoya, 2014 [173]], follow-up (24 weeks after end of treatment), sample size (244) 1 conference abstract [Saiz de la Hoya, 2010 [174]]; follow-up (24 weeks after end of treatment), sample size (244) EU/EEA (2)	Overall: 63.5%, 62.2% - DOT: 60.6%, 58.5% - SAT: 65.9%, 65.9% No significant difference	Overall: 83.0%, 79.8%	4.9% before completion of treatment	Very low
Telemedicine IFN+RBV	N=1 study 1 longitudinal [Lloyd, 2013 [175]], follow-up (24 weeks after end of treatment), sample size (108) EU/EEA (0)	43.5%	69.4%	26.9% before SVR assessment	Very low
Comparison community-based vs. prison-based treatment IFN+RBV (+ or – a protease inhibitor in n=1 study)	N=2 studies 1 matched cohort [Aspinall, 2016 [176]]; follow-up (24 weeks after end of treatment), sample size (1 428) 1 comparative [Rice, 2012 [177]], follow-up (≥24 weeks after end of treatment), sample size [553] EU/EEA (1)	- Inmates: 42.9%– 73.6% - Community: 38.0%–62.9% No significant difference in SVR between inmates and community members in n=2 studies	- Inmates: 75.0%–73.5% - Community: 86.6% No significant difference in completion between inmates and community members in n=1 study	NR	Moderate; low
Provision of first generation DAAs ⁴	N=2 studies 2 conference abstracts [Marco, 2014a and b [178,179]]; follow-up [NR; NR], sample size (24; 32) EU/EEA (2)	62.5% eRVR (time period NR) 85.7% (as treated, time period NR)	87.5%	NR	NA

Intervention description	Studies included	Outcome 1: SVR	Outcome 2: Treatment completion	Attrition	Level of evidence
Provision of second generation DAAs	N=7 studies 5 conference abstracts [Touzón-López, 2016 [180]; Jiménez-Galán, 2016 [181]; Mínguez-Gallego, 2016 [182]; Fernández-González, 2016 [183]; Pontali, 2017 [184]; Domínguez, 2017 [185], Meroueh, 2017 [186]], follow-up [12 weeks after end of treatment in n=5; NR in n=2], sample size (207; 50; 40; 83; 142; 23; 141) EU/EAA (7)	85.0%–94.7%	90.0%–95.5%	10% (time period NR)	NA

DAAs: direct-acting antiviral agents; DOT: directly observed therapy, eRVR: extended rapid virologic response⁸, IFN: interferon, NR: not reported, RBV: ribavirin, SAT: self-administered therapy, SVR: sustained viral response

¹ Proportion achieving undetectable viral load at 24 weeks/6 months after treatment completion or – in case of DAAs – 12 weeks/3 months after DAAs therapy completion

² Proportion completing the treatment course

³ Proportion lost to follow-up during study

⁴ This HCV treatment regimen (PI-based) is no longer recommended [157]

Table 10. Evidence for the cost-effectiveness of models of care for HCV treatment in prison settings

Intervention description	Studies included	Scenarios	Conclusions	Level of evidence
No treatment vs. 2 drug therapy vs. 3-drug therapy	N=1 study; [Liu, 2014 [187]], perspective (societal), time horizon (lifetime) EU/EEA (0), USA (1)	1. No treatment 2. 2-drug therapy (pegylated IFN + RBV for 48 weeks) 3. 3-drug therapy with either boceprevir or sofosbuvir (4 weeks of pegylated IFN + RBV followed by 24 weeks of triple therapy)	According to the reported ICER, sofosbuvir-based treatment is cost-effective for incarcerated persons (28 800 USD per QALY gained). Given the high price of sofosbuvir, affordability is an important consideration	Moderate
Treatment with or without elevated ALT or liver biopsy	N=1 study; [Sterling, 2005 [188]], perspective (Virginia Department of Corrections), time horizon (until 24 months after end of treatment) EU/EEA (0), USA (1)	1. Treating (IFN + RBV) all patients without a liver biopsy 2. Treating (IFN + RBV) only those with elevated ALT without performing a liver biopsy 3. Liver biopsy and examination of liver histology to define sufficient liver injury from chronic HCV (Knodell score <5 and no fibrosis) prior to treatment (IFN + RBV)	A strategy in which inmates with chronic HCV undergo liver biopsy and only those with a histologically significant liver disease undergo therapy with standard IFN and RBV is cost-effective compared to treating all inmates without a biopsy or elevated ALT, based on reported cost per treatment and cost per SVR.	Low
Treatment with or without liver biopsy	N=1 study; [Tan, 2008 [189]], perspective (US prison healthcare system), time horizon (lifetime) EU/EEA (0), USA (1)	1. No liver biopsy prior to starting treatment (pegylated IFN + RBV) 2. Liver biopsy prior to beginning therapy (pegylated IFN + RBV) in order to determine stage of fibrosis	Pegylated IFN and RBV combination therapy is cost-effective in the prison population. The strategy with pre-treatment biopsy was the most cost-effective, however not for inmates between 40 and 49 years old with genotype 1 and no fibrosis, based on reported ICER.	Moderate

ALT: alanine transaminase, IFN: interferon, QALY: quality-adjusted life year, RBV: ribavirin, SVR: sustained viral response

⁴ This HCV treatment regimen (PI-based) is no longer recommended [157]

Ad-hoc scientific panel opinion

The prison population is disproportionately affected by viral hepatitis and by HCV in particular. For this reason, people in prison have been identified as a key target population in order to achieve the goal of global elimination of viral hepatitis [190]. Expansion of testing coverage and uptake to achieve early diagnosis of chronic viral hepatitis is crucial as it provides the entry point to specialised care and treatment (see section 4.2) [35,190,191].

It was the opinion of the ad-hoc scientific panel that individuals diagnosed with chronic HCV in prison should be prioritised for treatment due to the heightened risk of transmission within prison, during leave and upon release. This is in line with recommendations of EASL to fast-track treatment for those individuals at high risk of HCV

⁸ eRVR indicates an undetectable viral load at week 4 of treatment and maintenance of viral load suppression through week 12

transmission, such as people in detention [157]. The available evidence indicates that HCV treatment with interferon (IFN) -based regimens is feasible in prison settings and it results in comparable outcomes to community settings [176,177,192].

The ad-hoc scientific panel also shared the view that people in prison with chronic HCV should be treated by the same standards as people in the community. IFN-free regimens based on oral DAAs are shown to be highly effective and tolerable when delivered in community settings [41,42,157] and there is no reason to believe the outcome would be different in prison settings. Accumulating evidence from modelling studies indicates that scaling up HCV treatment with DAAs in the prison setting is likely to be cost-effective and to significantly reduce HCV incidence and prevalence among PWID and in the community at large [123,193,194].

Based on these considerations, the ad-hoc scientific panel concluded that there is no reason to either withhold or delay DAAs treatment for eligible individuals in prison (very low level of evidence). However, the ad-hoc scientific panel recognised the affordability challenges posed by the high cost of DAAs and the treatment rationing currently applied in most EU/EEA countries [43]. These, alongside other possible barriers such as the need of ensuring treatment completion, may influence the decision to initiate people on DAAs treatment (see Section 5.1.8). Treatment initiation as early as possible following entry to prison would increase the chance of treatment completion during incarceration.

Despite a WHO call for adapting care and service delivery models for key populations, including people in prison [9,58,127,190], research evidence on models of care is limited and does not point towards a specific model. The research evidence does not indicate an advantage of DOT versus SAT in terms of adherence or treatment outcomes in prison settings. However, the ad-hoc scientific panel expressed some concerns on these findings as the evidence is limited and non EU/EEA specific. DOT is effectively implemented in a number of EU/EEA countries and it was the opinion of the ad-hoc scientific panel that, when appropriate, patients may be offered to choose the most suitable treatment administration option, be it DOT or SAT [very low level of evidence].

ECDC and EMCDDA assessment: The available evidence indicates that HCV treatment in prison settings is feasible irrespective of the regimen and should be implemented. There is a strong public health rationale for providing access to state-of-the-art HCV treatment and care in prison settings with no delays.

However, the evidence on models of care delivery in prison settings is limited and does not point towards a specific model to achieve retention in care and completion of HCV treatment. Interventions to increase adherence and treatment outcomes could be considered, although the level of evidence for the effectiveness of any specific approach is very low (see section 5.1.8).

Despite the lack of evidence on HBV treatment provision in prison settings, people in prison should have access to the same standard of HBV care as offered in the community.

4.6 Throughcare

Evidence base

The evidence on throughcare was composed of nineteen studies. Of these, eight reported on effectiveness of interventions to prevent BBVs post-release, and eleven reported on the effectiveness of intervention to establish linkage to care post-release. No study was found on linkage to care at entry into prison. Fifteen of the included studies were comparative (including eleven RCTs), however none were conducted in the EU/EEA. In addition, throughcare interventions were largely focused on HIV, with some studies reporting on outcomes related to injecting-drug use; few studies reported on OST and none on viral hepatitis. None of the studies on prevention of BBVs infections post-release reported on BBVs infection-related outcomes (i.e. seroconversions). Overall, the included studies investigated a range of different interventions, used different comparison groups and reported on different sets of outcomes, and as a result it was not possible to group the studies. The level of evidence was mostly low to very low. Tables 11 and 12 provide an overview of the evidence; more information is available in upcoming the systematic review technical report to be published by ECDC.

Additionally, four national guidelines [65,195-197] and three supranational guidelines [15,55,58], covering throughcare were identified. The documents primarily focused on linkage to care post-release for HIV, viral hepatitis and drug-dependence treatments. Overall, the guidelines recommend active referral post-release, including arrangements of follow up visits at the suitable healthcare provider/drug service in the community, provision of medication treatment into their possession or treatment prescription at the time of release.

Table 11. Evidence for the effectiveness of interventions to prevent BBVs post-release

Intervention description	Studies included	Outcome 1: sero-conversion	Outcome 2: behaviour change	Attrition ¹	Level of evidence
Individual counselling and case management services (7 modules before release)	N=1 study; Longitudinal study [Bauserman, 2003 [198]], follow-up [NR], sample size (745) EU/EEA (0)	NR	Significant improvement after intervention in: attitude towards condoms, self-efficacy to use condoms, self-efficacy to reduce injecting drugs and other substances risk, safe sex intentions and likelihood having HIV/AIDS	NR	Very low
Individual 30-minute peer-education session before release vs. no intervention	N=1 study; RCT [Grinstead, 1999 [199]], follow-up (2 weeks after release), sample size (404) EU/EEA (0)	NR	After release, intervention group significantly more condom use during first time sex after release compared to control, but no significant difference in drug use, IDU and sharing needles since release	- Intervention: 42.5% - Control: 42.0%	Very low
Individual enhanced multisession intervention (2 before, 4 after release) vs. individual single-session intervention (before release)	N=1 study; RCT [Wolitski, 2006 [200]], follow-up (24 weeks after release), sample size (522) EU/EEA (0)	NR	24 weeks after release, significantly less unprotected sex with any partner, main partner, and at-risk partner, but not with non-main partner in enhanced intervention compared to single-session intervention group No significant differences at 1 and 12 weeks post-release	- Single session: 17.8% - Other: 16.7%	Low
Group sessions skills building and social support intervention (16 before, 6 after release) vs. standard care (3 AIDS information group sessions before release)	N=1 study; RCT [El-Bassel, 1999 [201]], follow-up (1 month after release), sample size (145) EU/EEA (0)	NR	Significantly greater improvement post-release in the intervention group compared to standard care in safer sex behaviour, coping skills, and perceived emotional support, but no significant difference between groups in perceived vulnerability to HIV, sexual self-efficacy and AIDS knowledge	- Intervention: 26.9% - Control: 33.3%	Very low
Group sessions behavioural intervention (9 before, 3 short phone calls after release) vs. standard care (single STI education in 1 st 3 months of incarceration)	N=1 study; RCT [Fogel, 2015 [202]], follow-up (6 months after release), sample size (521) EU/EEA (0)	NR	Significantly more improvement post-release in intervention group compared to standard care in HIV knowledge, health-protective communication, motivational barriers to condoms, physical spousal abuse (all at 3 months after release), and unprotected vaginal sex outside monogamous relationships, condom use during sex with main partner, HIV knowledge, motivational, partner and physical effect barriers to condom use, and tangible support (all at 6 months after release)	- Intervention: 40.4% - Control: 44.5%	Moderate
Group sessions relationship-focused intervention (5 before, 1 after release) vs. standard care (short HIV/AIDS information video)	N=1 study; RCT [Knudsen, 2014 [203]; Leukefeld, 2012[204]], follow-up (90 days), sample size (378/344) EU/EEA (0)	NR	Intervention group reported post-release significantly fewer past-month unprotected sexual behaviours than control group; greater improvement in intervention group in overall HIV knowledge of HIV risk behaviours, self-esteem, sexual relationship power, relationship control, specific HIV risk knowledge items, and specific thinking myths	9%	Low

Intervention description	Studies included	Outcome 1: sero-conversion	Outcome 2: behaviour change	Attrition ¹	Level of evidence
Group educational sessions intervention (4 before release) vs. standard of care (no health education)	N=1 study; Comparative [Magura, 1995 [205]], follow-up (median 7months after release), sample size (101) EU/EEA (0)	NR	No significant difference at post-release between both groups in drug injection, needle/syringe sharing and sterilisation, heroin use, crack use, multiple sexual partners, high-risk sexual partners, condom use, and enrolling or remaining in drug dependency treatment Being in drug dependency treatment at the time of follow-up was associated with reductions in heroin use and drug dealing	- Intervention 48.5% - Control: 55.6%	Very low

NR: not reported, RCT: randomised controlled trial

¹Proportion lost to follow-up during study

Table 12. Evidence for the effectiveness of interventions to increase linkage to care post-release

Intervention description	Studies included	Outcome 1: Linkage to care	Outcome 2: behaviour change	Attrition ¹	Level of evidence
HIV treatment					
Ecosystem vs. individually focused (both medication supply at release)	N=1 study; 1 RCT [Reznick, 2013 [206]], follow-up (12 months post-release), sample size (151) EU/EEA (0)	Ecosystem significantly less likely to be taking anti-HIV medications and to be adherent at 4 months post-release (both groups significant decrease vs. baseline), but no significant difference in groups and between groups at 8 and 12 months post-release	No significant difference between both groups on sexual behaviour after release	15%	Moderate
Individual-level educational and skills-building intervention vs. usual care (medication supply at release NR)	N=1 study; 1 RCT [MacGowan, 2015 [207]], follow-up (3 months post-release), sample size (73) EU/EEA (0)	No significant change in taking HIV medications from at release to 3 months post-release in both groups and between groups Intervention recipients reported a statistically significant increase in receiving healthcare at HIV clinics at 3-month post-release (62.5–84.4 %); no significant difference between groups	No significant change in unprotected vaginal or anal sex, IDU, and STI diagnosis from 3 months pre-incarceration to 3 months post-release between groups	14%-25%	Low
Individual-level intensive case management vs. usual care (both 30-day medication supply at release)	N=1 study; 1 RCT [Wohl, 2011, [208]], follow-up (48 weeks post-release), sample size (89) EU/EEA (0)	No significant difference between both groups in % medical care access \geq once, median time to clinic access, mean number of clinic visits, rate of hospitalisations, ER or urgent care centre visits, and outpatient substance abuse care post-release	NR	40%-46%	Low
Being met at the gate vs. Not being met at the gate	N=1 study; 1 longitudinal [Jacob Arriola, 2007 [209]], follow-up (6 months post-release), sample size (226) EU/EEA (0)	Those being met at the gate were since release significantly more participating in drug/alcohol treatment than those not met at the gate	Those being met at the gate were since release significantly less engaging in sex exchange and use of street drug than those not met at the gate	35%	Very low
Provision of OST for PWID on ART vs. No OST (ART administered either DOT or SAT)	N=1 study; 1 comparative [210], follow-up (6 month post-release), sample size (94) EU/EEA (0)	Retention on OST (Buprenorphine) was significantly associated with increased likelihood of achieving viral suppression (<50 copies/ml) (p=0.03) Receiving DOT or Methadone were not associated with viral suppression post-release	NR	8%	Low

Intervention description	Studies included	Outcome 1: Linkage to care	Outcome 2: behaviour change	Attrition ¹	Level of evidence
Usual care (active referral after release, with or without medication supply)	N=1 study; 1 longitudinal [White, 2001 [211]], follow-up [NR], sample size (77) EU/EEA (0)	69% received 3-day supply prescription, of whom 71% picked it up 46% of those re-jailed received HIV medications in community	NR	NR	Very low
Usual care (referral after release only, unclear if active or passive)	N=1 study; 1 longitudinal [Beckwith, 2014 [212]], follow-up [NR], sample size (64) EU/EEA (0)	58% linkage to care No significant association between length of incarceration and linkage to care	NR	NR	Very low
Opioid substitution treatment					
No OST in prison without (Group 1)/with (Group 2) referral to community OST Vs OST in prison and referral	N=1 study; 1 longitudinal [213], follow-up (12-month), sample size (204) EU/EEA (0)	<ul style="list-style-type: none"> Group 1: 25% enrolled in care; 0% were on OST at 12-month Group 2: 53.6% enrolled in care; 17.3% were on OST at 12-month Group 3: 70.4% enrolled in care; 36.7% were on OST at 12-month Pairwise comparison all significant (p<0.01)	Positive urine test for opioid at 12-month post-release: -Group 1: 65.6% -Group 2: 48.7% -Group 3: 25% Group 3 significantly less as compared to Group 1 & 2.	3.3%	Low
No OST in prison with referral to community OST Vs OST in prison and referral	N=1 study; 1 RCT [214], follow-up (12-month), sample size (211) EU/EEA (0)	Participants in the in-prison BPN group were significantly more likely (p=0.012) of enrolling into community OST programmes (47.5% vs. 33.7%).	No statistically significant difference for days of heroin use and crime, and opioid and cocaine positive urine screening test results (all Ps>0.14)	NR	Low
OST in prison and financial support (Arm 1) Vs. No OST in prison with (Arm 2)/without (Arm 3) financial support All participants received referral	N=1 study; 1 RCT [215], follow-up (6-month), sample size (90) EU/EEA (0)	Participants on OST prior to release were significantly more likely to enter treatment post-release (P < 0.001); Among participants who enrolled in community OST, those who received OST in prison did so within fewer days (P =0.03).	Participants on OST prior to release reported less heroin use (P = .008), other opiate use (P = .09), and injection drug use (P = .06) at 6 months	30%	Very Low

BNP: Buprenorphine, ER: emergency room, OST: Opioid Substitution Treatment, NR: not reported, RCT: randomised controlled trial

¹Proportion lost to follow-up during study

Ad-hoc scientific panel opinion

Despite the lack of conclusive studies on models of transitional care, the ad-hoc scientific panel agreed that, as in the community, adherence to and continuity of HIV, viral hepatitis and drug dependency treatment, as well as any other chronic disease treatment is a fundamental right of the patient [216]. Considering the important role of prison health for public health and the fundamental principle of equivalence of care, the ad-hoc scientific panel agreed that ensuring continuity of treatment at entry, during and after incarceration is an essential element of HIV, viral hepatitis and drug dependency care as well as treatment for people in prison.

Research evidence indicates that the main reason for the failure to follow up and/or treatment discontinuation is transfer or release from prison, a barrier specific to the prison environment [217]. The impact on retention and continuity of care is substantial [143]. Research evidence also indicates a heightened risk of HCV transmission and an excess mortality in the immediate post-release period, particularly for PWID [194,218]. For PWID, provision of OST during incarceration is associated with a higher likelihood of engagement into care upon release, retention on drug dependency care and reduced behaviours at risk [219], as well as better adherence and clinical outcomes for those on ART [210].

Based on these considerations, the ad-hoc scientific panel agreed that provision of health education and effective continuity of care are interventions to be implemented within a comprehensive assessment of individual needs while transitioning into/out of prison [very low level of evidence]. While the research evidence on models of care is limited and does not point towards a specific throughcare model, the ad-hoc scientific panel considered that options to be considered to facilitate continuity and linkage to community care upon release [very low level of evidence] are the provision of a certain amount of treatment doses to the patient (i.e. treatment in possession), treatment prescription and pre-arranged consultation/s at the healthcare provider of choice in the community, including for drug dependency treatment.

Furthermore, the ad-hoc scientific panel agreed that the responsibility of ensuring continuity of care at release cannot just rest on the medical treatment provider in prison, but rather on the responsible authorities, which is country specific. It is the shared opinion of the ad-hoc scientific panel that responsible authorities would need to organise and guide all elements involved in the system of care of people in prison before, during and after incarceration, including effective health insurance coverage at release in accordance with national legal provisions, in order to assure continuity of treatment and care [no evidence].

ECDC and EMCDDA assessment: Transitional care for people entering and being released from prison is an essential component of quality healthcare services for people at higher risk of acquiring a BBVs infection and for individuals with HIV, chronic viral hepatitis or with problematic drug use.

The available evidence suggests that behavioural and skill-building interventions aimed at promoting BBVs prevention post-release may result in improved behavioural outcomes, at least for the risk of sexual transmission.

However, the evidence on service models for throughcare is limited and does not point towards a specific model to achieve continuity of care when transitioning in or out of prison for individuals with HIV, chronic viral hepatitis or with problematic drug use. Some interventions, such as comprehensive pre-release preparation and active referral to community health services or drug dependency services, could be considered to increase linkage to care and promote treatment adherence, although the level of evidence for the effectiveness of any specific approach is very low (see section 5.1.8).

5. Implications for public health practice and research

5.1 Public health practice

This section presents specific considerations related to the implementation of BBVs prevention and control interventions in prison settings. It encompasses a number of various issues, ranging from human rights aspects to modalities of service delivery and other disease-specific or population-specific considerations. This section is meant to complement Chapter 4 and to provide evidence-based and practice-based information to support designing and planning of BBVs prevention and control programmes in prison settings in the EU/EEA.

5.1.1 Equivalence of care and human rights considerations

A large number of guidance documents defines the principles and standards of prison healthcare delivery [47,52-56,220].

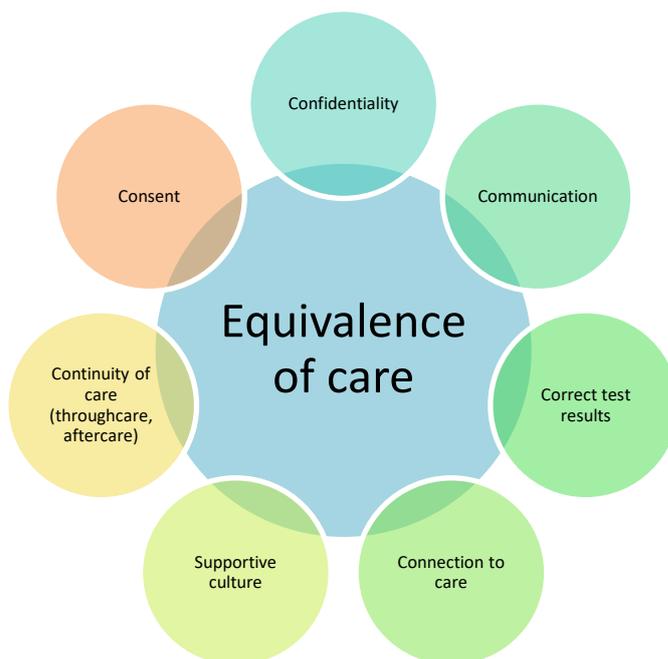
One of these principles maintains that people in prison have the same right to care as those in the community. This so-called 'principle of equivalence of care' is an internationally agreed minimum [47,49,54]. It aims to secure, as much as possible, the same standards of healthcare for people in and outside of prison. However, based on the principle of equitable care or equivalence of health objectives, people in prison are entitled to expect services and interventions over and above those that are available in the community: this is due to the higher burden of, for example, viral hepatitis, HIV and TB and the increased responsibility of the state, which is based on human rights obligations [59,60]. Failure to detect or properly treat a health problem or adequately assess treatment needs, may raise human rights issues, as do malpractice, negligence or errors in medical treatment [221,222]. The combination of measures and recommendations set forth by applicable national and international guidelines, alongside normative provisions, constitute a set of standards that can serve as an indicator of compliance with human rights requirements.

In practice, an approach to communicable diseases that is also sensitive to human rights should translate into proactive engagement of healthcare staff, early disease detection, awareness and application of medical standards and ethics, prevention and vaccination, and treatment [221]. As in other settings, early detection allows for preventive measures. In the context of highly infectious airborne diseases (such as TB), isolating a patient during the infectious period might be justified, as this would be in accordance with medical standards and guidance [82]. By contrast, medically unjustified segregation of imprisoned people who suffer from certain conditions (e.g. HIV) would violate human dignity or be considered degrading and discriminatory [223].

Equivalence of prevention, treatment, care, and support can best be achieved by ensuring continuity and coordination of care between community and prison services, and would also avoid the duplication of efforts. In some countries, the responsibilities for healthcare in prison settings and healthcare in the community lie with separate government departments/health authorities. If this is the case, a joint strategic approach to promote continuity and coordination of care between community and prison services is advisable.

5.1.2 The 7 Cs principles

The active case finding process in prison settings poses a number of specific challenges. Most people held in prison, especially at the early stages of their incarceration, are in a state of considerable fragility and vulnerability, at times combined with aggressiveness and distrust; the reasons for this are complex, but can include general psychological problems, substance use, poor health, educational deficits, and poor social skills. It is advisable to take these aspects into consideration during the planning and implementation of active case finding initiatives in prison settings. In this context, WHO formulated five principles and called them the 'five Cs': consent, confidentiality, counselling (or communication), correct test results, and connection to prevention, care, and treatment [153]. These principles should constitute the foundation of active case finding, both in prison settings and the community. With regard to the prison system, the ad hoc scientific panel endorsed two additional principles as particularly relevant: continuity of care post-release and an overall supportive culture within the prison system.

Figure 2. The seven Cs principles

In accordance with recognised international standards [15,58,153], active case finding should be voluntary and based on informed consent. People who get tested, including people in prison, would need to be informed about the testing procedures and their right to decline testing. Regardless of whether the offered interventions are opt-in or opt-out, seeking consent for testing would need to take into account that people in prison often feel vulnerable and disempowered. This is often aggravated by language problems, developmental and educational deficits, and poor social skills [15,220]. It is therefore advisable to train staff members (e.g. physicians, nurses), support staff (e.g. from non-governmental organisations) or peers in counselling. Legal parameters for consent may differ between countries; national requirements should be taken into account when designing testing programmes.

In accordance with international standards, every person undergoing testing should receive his/her results as soon as possible, and, if tested positive, receive appropriate care and treatment. If tested negative, preventive care should be offered, for example HBV vaccination. Active case finding alone is insufficient if not followed up by appropriate control and prevention measures. Given the transitory nature of incarceration, continuity of care post-release is essential to reap the rewards of testing interventions in prison settings.

A supportive culture is crucial to the success of prevention and control interventions. Trust and confidence in the prison healthcare services should be encouraged, not only among people in detention but also among prison staff, especially correctional officers. Health promotion, peer-education, training and information sessions for staff and people held in prison may be considered (see section 5.1.4). A high level of healthcare services, as envisioned by the 7 Cs, can be attained if staff members work together and focus on common goals, for example by providing continuous feedback and sharing intervention outcomes related to the virtuous circle of the quality improvement process⁹.

Skilled and motivated healthcare workers in sufficient numbers are necessary to respond to health needs in prisons; shortage of skilled clinical staff is a common problem in prison settings.

5.1.3 Prison settings

Prisons and custodial institutions differ from other settings in a number of ways when it comes to healthcare delivery. Structural barriers, such as lack of adequate health facilities, limited resources, high turnover of the prison population (average detention period in Europe is seven months [8]) [95,96] are coupled with individual barriers such as lack of trust in prison institutions, concern about confidentiality in prison settings, and difficult living conditions [93,103,224,225].

⁹ The EU-funded project 'Joint action on improving quality in HIV prevention' (quality action) developed a basket of practical tools and materials to maximise the quality of HIV prevention projects and programmes. More information is available from: <http://www.qualityaction.eu/choosetool.php>

While structural and organisational challenges may affect healthcare service delivery in prison settings, according to the available evidence, the single most relevant barrier to testing uptake, result notification, treatment initiation and continuity of care across all communicable diseases covered in this document was transfer or sudden release from prison [REF BBV & ACF SR report]. This may be a factor of greater relevance to jails or remand prisons, where individuals are generally incarcerated for shorter periods, rather than prisons where individuals are usually incarcerated for longer periods of time. However, such differences may be country-specific and subject to local prison system set-up.

In addition, prison settings may differ from each other in the demographics of the incarcerated population (nationalities, minorities, etc.). These differences may have implications for the specific needs of the respective prison populations and need to be taken into consideration, alongside local availability of healthcare, diagnostic services and medical commodities, when planning and implementing BBVs prevention and control initiatives. Experiences from the community show that direct engagement of healthcare users in designing and implementing services is a successful way of improving their uptake and utilisation. However, this is uncommon in prison settings, despite the need for developing and implementing differentiated and tailored care delivery models [127]. Existing evidence from peer-led or peer-supported services indicates an increase in acceptance and uptake in prison settings [33,87].

Prison staff may also influence the implementation of prevention measures and other healthcare interventions in prison settings. Apart from the well-recognised need for dedicated training for healthcare staff [56], education interventions targeting correctional officers may increase cooperation between different groups, create awareness about the right to health, and ultimately ensure the successful implementation of healthcare interventions.

Special attention should be paid to those factors that make prison settings a disease transmission prone environment. Conditions of detention, poor hygiene, overcrowding and under-resourced healthcare services are major obstacles to upholding the right to health of people in prison and to effectively prevent disease transmission. BBVs prevention and control interventions will not be sufficient to curb the burden of HIV and viral hepatitis in prison setting if implemented in isolation and without properly addressing these adverse circumstances and structural barriers.

5.1.4 Prevention interventions

Considering the high prevalence of BBVs among the people entering prison [32,35]; prevention of onward transmission within prison settings is of utmost importance. While the body of evidence in prison settings is scarce, evidence from the community indicates that prevention is best achieved when a comprehensive package of interventions is implemented with a coherent and structured approach including by integrating services and programmes [36,58,226]. Based on this pragmatic approach, existing prison specific guidelines recommend multiple prevention measures to be implemented in prison settings [15,22,63-66].

Health education and health promotion

Besides active case finding and vaccination (see sections 5.1.6 and 5.1.7), health education and health promotion programmes are a key component of BBVs prevention approaches. Despite the heterogeneity in study designs, intervention approaches and outcomes measurements, available evidence indicates that health education and skills-building programmes in prison settings may improve individuals' awareness and reduce risk-behaviours. Peer-led initiatives have also been shown to be effective, at least in increasing acceptance to testing [33,87], and might be employed to deliver a variety of healthcare messages to people in detention. In the view of the *ad hoc* scientific panel, health education interventions should be tailored to the specific needs and circumstances of prison settings. A 'whole prison approach'¹⁰ encompassing specific health information and health promotion messages for people in detention and prison staff, including correctional officers, would be aligned with the principle of promoting a supportive culture for health in prison settings (see section 5.12). Specific communication needs should also be taken into consideration, including those related to cultural differences and language competency.

Condom distribution

Despite the lack of evidence showing the effectiveness of condom distribution programmes to prevent sexual transmission of BBVs in prison settings, this is a well-established measure in the community. The evidence and the anecdotal reports from EU/EEA countries where condom distribution programmes are implemented in prison settings suggest no reason for security concerns, dispelling the fear that availability of condoms may increase sexual violence. However, acceptability among prison staff may be suboptimal due to the concerns around inconsistent messages being sent to people in detention regarding tolerance of sex in prison and endorsement of same sex intercourses [68,77]. Of note, in some EU/EEA countries the existing regulation prohibiting sexual activities in prison settings, or incorrect assumptions or narratives about it based on ideology or dogma, prevent

¹⁰ A whole-prison approach relies on three key elements: (i) prison policies that promote health; (ii) an environment in a prison that is supportive of health; and (iii) disease prevention, health education and other health promotion initiatives that address the health needs assessed within each prison [15]

the implementation of condom distribution programmes. However, when feasible, condom distribution programmes may be implemented through the installation of vending machine or via hand-to-hand distribution mediated by a healthcare workers or other staff. The first approach has the advantage of promoting confidentiality and availability of condoms at different locations, mostly on a 24/7 basis within prison (e.g. showers), while the latter may result in lower acceptability (e.g. stigma, perceived judgment) even if it may offer an opportunity for engagement with healthcare workers and for providing health messages. In fact, according to existing guidelines, condoms should be easily and discreetly accessible without the need to request them [82].

Focus on implementation: piloting condom distribution in prison in the Czech Republic

In the HA-REACT project (www.hareact.eu), a pilot project to implement condom distribution in one Czech prison was developed. Under the leadership of the National Monitoring Centre for Drugs and Addiction, a working group was established with participation of the pilot prison and national prison service authorities. The preparatory phase included the development of a concept pilot project and a study visit to a prison institution in Germany where a condom programme was running. Following the signature of a written agreement with the pilot prison authorities, the 12-month pilot programme started in August 2017 with an integrated evaluation exercise. Four vending machines were installed in bathrooms/toilets in two prison units, alongside dedicated waste containers. Information leaflets for staff and inmates were developed and distributed. Follow-up after the 1st month of implementation indicated a change in opinion of the staff from a quite conservative to a more neutral attitude towards the condom programme; people in detention had shown a generally positive attitude from the beginning; no major operational or implementation challenges were encountered [5].

Additional resources on how to set-up a condom distribution programme in prison are available here <https://www.harmreduction.eu/courses/available-courses/cdp>

Pre- and post-exposure prophylaxis

Post-exposure prophylaxis (PEP) is an effective measure to reduce the risk of infection after exposure to HIV. It is advisable for this measure to be available to all people in prison, including but not limited to people in detention, as per applicable national and international guidelines [58,67]. Pre-exposure prophylaxis (PrEP) has been recently recognised as one additional effective measure to prevent HIV transmission. WHO recommend offering it as an additional prevention choice for all key populations at substantial risk, including people in prison, as part of a comprehensive package of measures [58]. However desirable, the *ad hoc* scientific panel did not consider it to be an essential component of a HIV prevention package in prison settings, including for PWID, for whom harm reduction is preferable.

Safe tattooing and body piercing

Tattooing and piercing are activities that are part of prison subculture. However, when performed in unregulated settings and with non-sterile equipment, they may result in the spread of BBVs among tattoo and piercing recipients. Safe tattooing and piercing initiatives have been reported in the literature [69] and anecdotally at least in France and in Luxembourg¹¹. While no effectiveness data is available on the impact of these measures on BBVs transmission, the acceptability is reportedly high among people in prison. In Luxembourg detained individuals interested in becoming tattooists operating in prisons are required to receive a dedicated training. The safe tattooing program is managed by nurses, who are present and supervise the tattooing sessions, thus taking the opportunity to deliver additional health information.

¹¹ HA-REACT "Needle exchange and other harm reduction measures in prison settings" Conference, Luxembourg June 2017. <http://www.hareact.eu/en/event/%E2%80%9Cneedle-exchange-and-other-harm-reduction-measures-prison-settings%E2%80%9D-conference>

Focus on implementation: safe tattooing in prison setting – the example of France

In France the non-governmental organisation AIDES (<http://www.aides.org/en>) organised short harm reduction sessions on tattooing/piercing on a monthly basis in the prison of Pau for a year. These sessions were facilitated by a tattoo artist, a professional piercer and a stakeholder from AIDES. A group of people in prisons (tattoo artist or wanting to get tattooed) was set up to mobilise other people involved in unsafe tattooing and piercing practices. Because of the short period of incarceration related to the type of penal institution, the workshops were open, allowing incoming people to participate and there were up to 10–15 participants for each workshop. The activity promoted discussions around topics such as: unsafe tattooing techniques; infectious and health risks; aesthetics (meaning of tattoos in prison, training in drawing); safe practices (technical skills, disinfection, assembling needles, etc.) and care. A brochure explaining safe tattooing and a harm reduction kit suitable for tattooing practices in prison was distributed to participants. The participants had the opportunity to get tattooed for free during the harm reduction action within the activity room, subject to certain conditions: hateful or racist tattoos, visible tattoos (such as neck, head and hand), etc. were prohibited. These tattooing sessions helped to avoid unsafe tattooing practices between people in prison and to articulate the theory on safe tattooing through practice. This intervention increased safe tattooing practices of inmates in prison and helped interested inmates to be trained in safe tattooing [6].

Other interventions

Sharing of personal items such as razors and toothbrushes may also be considered as a potential source of BBVs transmission. Besides advising people in prison not to share their personal items, prison authorities could consider simple measures such as providing personal items (e.g. toothbrushes, razors) in different colours to increase identification. Provision of disinfectants for the cleaning of personal items could also be considered. However, this measure may potentially lead to self-harm and should be accompanied by adequate education on its appropriate use. It is the opinion of the *ad hoc* scientific panel that it is not advisable to recommend the use of disinfectants, including bleach, to clean needles and injecting equipment in prison settings based on the existing evidence derived from community settings. Instead, clean needles and syringes for PWID in prisons should be made available through syringe distribution programmes in prisons (see section 5.1.5).

Pregnant women in detention may need special attention, including for the prevention of vertical transmission of HIV and HBV. Ante-natal care should be provided to the same standards as in the community and in accordance with applicable national and international guidelines [45,67,227].

Finally, when providing healthcare services, including dental care in prison settings, infection control procedures should be in place to the same standards and according to the same requirements applicable in the community and in line with national and international guidelines [15].

5.1.5 Prevention interventions targeting PWID

People who inject drugs are overrepresented in prison settings in the EU/EEA and have been shown to have a considerably higher prevalence level of HIV and viral hepatitis infections, and particularly of HCV [17,32]. Over and above the comprehensive package of prevention measures described above (see section 5.1.4), tailored prevention interventions are available. International and European guidance recommends a number of public health interventions to reduce and control infections among drug users in the community, including prison-based NSP, OST and health promotion [36,82,228]. However, due to a lack of studies, evidence on the effectiveness of these interventions to prevent BBVs transmission in prison settings is limited. Still, it is the opinion of the *ad hoc* scientific panel that a comprehensive set of drug treatment and harm reduction interventions, tailored to local needs is advisable in prison settings [15,50,58,82].

Focus on implementation: a toolbox for comprehensive harm reduction package in prison setting

In the EU-funded project HA-REACT (www.hareact.eu), an online platform was developed with the aim of promoting and supporting the implementation of harm reduction measures in prison settings in Europe. The platform www.harmreduction.eu provides free access to online courses, information material, case studies and links to existing projects in the European region.

Opioid substitution treatment

Opioid substitution treatment (OST) has been shown to be highly effective in the community in reducing drug use and injecting-risk behaviours, preventing drug-induced deaths and improving the mental health of dependent opioid users [229-231]. A review of its use in prison concludes that it provides benefits that are similar to those in community settings if doses are adequate [230]. Findings show that OST presents an opportunity to recruit problem opioid users into treatment, to reduce illicit opioid use and risk behaviours in prison and potentially minimise the risk of overdose on release. In addition, one Scottish study suggests that high coverage of OST in prison is associated in reducing the incidence of HCV in the prison population [232]. If liaison with community-based programmes exists, prison OST facilitates continuity of treatment and longer-term benefits can be achieved. For prisoners in OST before imprisonment, prison OST provides treatment continuity, while disruption of the treatment, especially due to brief periods of imprisonment, was associated with very significant increases in HCV incidence [76,233]. Despite such programmes having been introduced in prison settings in almost all EU/EEA countries bulletins [13], provision levels are low in several countries and thus do not meet the standard that services inside should be equivalent to those provided to the community in general [17,26,37,38]. The existing literature primarily reports on injecting-related outcomes rather than on communicable diseases transmission [75,76,230]. Still, the evidence on proxy measures indicates that OST reduces injecting risk behaviours and has a protective effect against opioid overdose death after release from prison for opioid-dependent individuals [230]. Further evidence shows a higher occurrence of injecting drug-related HIV risk behaviours among individuals enrolled on OST in the community undergoing forced tapered withdrawal from methadone, compared with those that continued OST during incarceration [234]. Uptake or continuation on OST during imprisonment has also been associated with increased likelihood of retention on OST treatment and HIV treatment, and reduced drug injecting behaviour post-release [219]. Importantly, the protective effect of OST on mortality (all causes and drug-related) is all the greater in the period immediately following release - those continuously retained in OST after being released from prison (continuity of care) had a reduced risk of mortality [218,235] constituting a strong rationale for OST to be provided in prison and for an effective linkage to care post-release.

Distribution of clean needles and syringes

Despite being an effective and low cost intervention for the prevention of HIV and HCV in community settings [229,236], research evidence on the distribution of clean needles and syringes and its effectiveness in prison setting is extremely limited [17]. Also, needle and syringe programmes (NSPs) are scarcely implemented in prison settings in the EU/EEA with only four countries reporting prison-based NSP availability of which two countries have the scheme in all prisons [14,26,36,37]. Experiences from Germany [71,72], Spain [74], Luxembourg¹² and Switzerland [237], where prison-based NSPs initiated by engaged prison doctors and nurses have been implemented at the national scale for more than ten years, suggest that this intervention is safe and well accepted among people in prison. In Spain, where the comprehensive harm reduction package (including large scale NSPs) implemented in the community has been translated into prison settings, a drop in seroconversions during incarceration has been registered [74]. Different models for syringes distribution may be implemented in prison. These primarily include hand-to-hand exchange managed by healthcare workers or other responsible staff, and vending machines installed in secluded areas [72-74]. While the first approach provides an opportunity for engagement with healthcare workers and for providing health messages, the latter has the advantage of promoting confidentiality.

In all models, participants need to enrol in the programme to be able to access syringes. Confidentiality and individual needs (e.g. frequency of injection, number of syringes per day) need to be taken into account when designing such programmes. However, available evidence and anecdotal reports identify fear or hostility on the part of prison staff and/or authorities as a major barrier to the implementation of prison-based NSPs, largely based on perceptions that they might be seen as promotion of drug use in prison, result in increased risk of overdose or that syringes might be used as potential weapons. While it may be challenging to uplift political and legal barriers to operate prison-based NSP, reports from countries where this intervention is widely implemented suggest that trust of prison authorities and correctional officers can be built through the promotion of an informed dialogue between stakeholders and engagement in programme planning and evaluation.

¹² HA-REACT "Needle exchange and other harm reduction measures in prison settings" Conference, Luxembourg June 2017. <http://www.hareact.eu/en/event/%E2%80%9Cneedle-exchange-and-other-harm-reduction-measures-prison-settings%E2%80%9D-conference>

Focus on implementation: prison-based needle and syringe programme – the COMATEP project in Luxembourg

The COMATEP (Consultation infirmière de maladies transmissibles aux établissements pénitentiaires) project was launched in 2009 in the two existing prisons in Luxembourg. The aim of the project was to provide dedicated health services for HIV, viral hepatitis, STIs and tuberculosis in prison settings. The project involved a number of activities, including education sessions on primary prevention measures for HIV and viral hepatitis for healthcare staff working in prison and people in detention, and the establishment of a prison-based needle and syringe programme. The prison-based NSP is operated by nurses in the prison healthcare facility. PWID in detention willing to enter into the programme need to request a consultation with one of the nurses. Once registered into the programme (all information is confidential), each individual receives a rigid plastic container for the storage of syringes and up to two sterile syringes. Syringes are exchanged one-to-one during individual consultations with one of the nurses. People in prison may request an *ad hoc* consultation with a nurse during the day. Monitoring of the service is done by the service providers in full respect of participants' anonymity. No adverse events (e.g. episodes of violence or injuries) have been registered so far. Prison staff and in particular correctional officers were initially opposed to the introduction of the programme. The provision of dedicated information sessions and engagement in programme planning and evaluation have resulted in a more tolerant attitude.

The distribution of disinfectants, including bleach, to clean injecting equipment is implemented in prison settings in several EU/EEA countries. Despite some studies showing that bleach can eliminate HIV and HCV in needles and syringes in a laboratory setting, this effectiveness may not translate to the real world, with no evidence of the protective effect of bleach on HIV transmission and conflicting evidence on HCV transmission [238-241]. While it could be argued that using bleach in settings where the introduction of prison-based NSP is not possible would be an option, it is the opinion of the *ad hoc* scientific panel that such practice could confer a false sense of security among users and authorities, and may therefore be undesirable in prison settings and not to be considered a NSP substitute. Still, disinfectants may have a role in reducing the risk of infection from contaminated surfaces or objects etc. in the prison setting (see section 5.1.4)..

Other interventions

Furthermore, many countries provide psychosocial drug counselling services and abstinence-based residential treatment options inside penal institutions. Available evidence indicates that therapeutic communities and individual education sessions pre-release are effective when compared to control conditions (no treatment) in the short-term, rather than longer term for reducing rates of re-incarceration among participants, and to a slightly lesser extent, drug misuse relapse [207,209,231,242]. Among female drug-using offenders, the addition of psychosocial interventions to 'treatment as usual' has been shown to reduce criminal activity (re-incarceration) [243]. Drug treatment for adult offenders works to lower criminal recidivism rates, but the reduction is not large. Programmes that are run outside prison are more effective than those within, and treatment programmes that link up with services in the community, prepare the release and provide aftercare achieve better results. Such successive combinations of treatment facilities have shown positive effects on recidivism of both addiction and crime, but treatment has still to be planned on a case-by-case basis, analysing the drug use- and criminal career of the detainee.

Injecting-related infections are not confined to BBVs. PWID are also at increased risk for bacterial skin and soft tissue infections (SSTIs) and other bacterial infections (e.g. botulism). Although these infections pose significant health risks, little is known about their prevalence and characteristics in this population, and less so in the prison subpopulation. Reports from the community of severe illnesses among PWID due to hygiene-related bacterial infections, including those caused by *Staphylococcus aureus* and group A streptococci, continue to occur and are often associated with hospital admission [244]. Cases of injecting-related botulisms have been reported among PWID in the community, possibly related to contamination of the injecting substance [245,246]. Harm reduction measures, including measures for hygienic injection, may play an important role in preventing SSTIs in prison settings.

5.1.6 Active case finding modalities (offer, timing and promotion)

There are several modalities in which testing can be offered. While mandatory testing is one of those, it will not be considered further for the purpose of this guidance, given that it runs contrary to the principle of informed consent. Mandatory testing will seldom meet medical ethics and human rights requirements. It would amount to an interference with the right to private life and would therefore have to meet requirements of the European Convention on Human Rights and the tests developed by the European Court of Human Rights.

Voluntary testing may be initiated by the healthcare provider (provider-initiated), i.e. by offering the opportunity to test for one or more communicable diseases to the person held in prison, or may be initiated by the individual and triggered by e.g. symptoms, self-perception of risk (client-initiated). Voluntary provider-initiated testing can be offered in two modalities: 1) opt-in, where testing is offered to all eligible individuals, who choose whether or not to have the test, and 2) opt-out, where all eligible individuals are informed the test will be performed, unless the person actively refuses. Due to differences in the perception of opt-in and opt-out in different countries and settings, the term 'provider-initiated' is preferred for the purpose of this guidance as it comprises both opt-in and/or opt-out approaches.

However, some specific considerations on these two approaches may be relevant when planning to develop an active case finding approach in the prison setting. An individual's consent for screening and testing is a requirement for any testing service provided in the prison setting and it is grounded on the fundamental right to a private life (see section 5.1.2). While both the opt-in and opt-out approaches foresee the individual's consent prior to testing, the implementation of opt-out testing in prisons may raise concerns over possible coercive or intimidating attitudes, or perceived attitude, of the service providers and the potential interference with the free right to private life and free consent. People in detention may lack self-determination and may fail to reject testing as they may not fully understand their right to refuse without any consequences [247]. Well-constructed, thoroughly explained and non-imposing opt-out testing would appear consistent with the obligation of the state to uphold a person's right to the highest standard of health and associated healthcare, which might fail with a soft opt-in approach in an environment that might appear as discouraging. On the other hand, opt-out approaches have been shown to result in higher uptake rates and consequently in a greater coverage of testing in the prison population, as compared to opt-in [3,84,248]. Opt-in approaches failing to achieve a sufficient level of coverage, may not succeed in adequately preventing further disease transmission within prisons [84,92,99]. On a human rights ground, the state's responsibility for upholding human rights will be respected if opt-in does not result in under-testing. Finally, opt-out testing might be more favourable as it is less subject to stigma and discrimination. As an example, preliminary data from the UK suggest a near doubling of BBVs testing uptake following the introduction of an opt-out testing policy [3]. Yet, opt-out testing approaches may not be legally supported in some Member States, and their feasibility may be influenced by the existing system of healthcare delivery in prison settings. Whereby in countries where prison health is under the responsibility of the Ministry of Health, the likelihood of a coercive approach to testing services is lower.

The optimal timing for active case finding initiatives was barely researched in the available evidence. However, it is evident that performing active case finding as soon as possible after entry into the correctional facility is essential to prevent further transmission of disease within the prison population as well as to offer adequate care to diagnosed individuals, including initiation or continuation of treatment. The medical examination upon admission to the prison setting [47] may offer a good opportunity for offering testing services. However, the emotional and psychological status of individuals entering detention need to be taken into full consideration. Even more so as the stress factor, the lack of agency and the perception of the surrounding environment may impact an individual's understanding and freedom of choice.

Based on these considerations, active case finding may not necessarily need to be conducted at entry but could be reiterated in the days following admission (i.e. within seven days), once the so-called 'entry trauma' has been overcome [249,250]. From a different perspective, early detection may also help dispel unfounded claims that infection took place after admission to a prison establishment, or serve to allocate or apportion responsibility. Although greater individual and public health benefits of active case finding will be gained when this is implemented at entry, testing opportunities, either provider- or client-initiated during imprisonment could be considered, for instance targeting those who refused testing at entrance or high-risk groups, following an exposure incident or during an outbreak.

Reports from the available evidence refer to the implementation of targeted active case finding approaches for high risk groups within the prison population, most commonly HCV testing among PWID and PLHIV [92,96,251]. A number of studies analysed alternative scenarios of targeted HCV testing for PWID including the cost-effectiveness of a variety of risk assessment approaches (Table 5) [98,119-123]. However, targeted HCV testing is shown to capture only a limited fraction of all HCV cases [92], and to result in partial achievement of the potential health benefits for the individual patient and the community at large of a more effective active case finding approach [123]. Concerns over the sensitivity of the risk assessment preliminary to risk-based targeted testing; the need to tackle the undiagnosed fraction of HIV and chronic viral hepatitis; and, the availability of effective prevention and control measures, are valid arguments in favour of universal active case findings for BBVs in prison settings. Regular and continuous opportunities to test during incarceration should also be considered, either client-initiated or targeted at higher risk groups, at least in settings where the prevalence of BBVs infections is high [30]. Of note, international [227] or national guidelines on antenatal screening for HBV and HIV should apply to people in prison to the same standard.

Focus on implementation: universal screening for BBVs at admission into prison – the Pathfinder Programme in the UK

Since 2014, Public Health England (PHE) Health and Justice has been supporting the HM Prison and Probation Service (previously the National Offender Management Service) and the National Health Services (NHS) England in the delivery of 'opt-out' testing for blood-borne viruses (BBVs) in all adult prisons in England. The evaluation of phase two pathfinder prisons was published by PHE Health and Justice in October 2016 with phase three evaluation slated for publication in Q4 of the 2017/18 financial year [3,4]. Roughly, 70% of the prison estate in England was implementing BBV opt-out testing as of Q4 2016/17, with full implementation expected by the end of the 2017/18 financial year. Performance in relation to BBVs opt-out testing programme is measured by NHS England through the collection of data via the Health and Justice Indicators of Performance (HJIPs). These metrics include specific reports of offer and uptake of HIV, Hepatitis B and Hepatitis C testing within 72 hours of reception to prison as well as referral for treatment for those found infected. These data show that in England in 2016–17, 16 321 tests were done for hepatitis B infection, 21 268 for hepatitis C infection and 37 474 for HIV infection. The proportion of new receptions receiving tests for HCV increased from 5.3% in 2010/2011 to 11.5% in 2015/2016 [4].

Additional information and supporting documents on The Pathfinder Programme and on BBVs opt-out testing implementation are available here: <https://www.gov.uk/government/publications/improving-testing-rates-for-blood-borne-viruses-in-prisons-and-other-secure-settings>

Several initiatives to increase testing uptake in prison settings have been described, though the level of the corresponding evidence is generally low or very low. These include health promotion and peer-lead education interventions targeted at people in detention. A combination of different approaches was reported, encompassing enhanced pre-test counselling, distributing leaflets, personalised information letters and other informative material, education sessions on communicable diseases and the advantages of testing, and peer-led education or support programmes [33,87,105,110]. While a significant change in testing uptake was reported by one single study [110], increases were observed in all. In addition, training of healthcare staff working in prison about communicable diseases and the benefits of active case finding may increase participation and offer rate [98,109].

Focus on implementation: the role of peer-educators in prison setting: 'Free to live well with HIV in prison' in Italy

The project 'Free to live well with HIV in prison' is the result of a consolidated collaboration between NPS Italia Onlus (Network of PLHIV), SIMSPe (Italian Society for Prison Health and Medicine) and the University Ca' Foscari Venice. During 2016, 677 people in prison (20.5% of the overall number of prisoners), 107 prison officers, 112 healthcare professionals, 70 educators and office staff, 28 volunteers were contacted and administered a questionnaire with the aim of assessing their knowledge on HIV, means of transmission and level of stigma among prisoners, but also among prison officers, educators and healthcare professionals. For example, almost 60% of those interviewed did not believe that having a fistfight could expose them to the risk of HIV transmission, a situation in which bleeding is very common. The training/educational activities have seen the participation of prisoners, prison officers and educators from 10 prisons across seven Italian regions. The work of peer educators (people living with HIV who experienced life in prison) has been fundamental to achieve the project goals of improving HIV prevention in prisons, fighting stigma, and improving the quality of life of PLHIV, creating a model adaptable in other prisons.

A further innovative element has been the introduction of HIV rapid testing in prison settings. Over 650 tests were requested both by people in prison and prison staff who favourably accepted this testing opportunity. Additional information is available here: <http://www.npsitalia.net>

As suggested by the retrieved evidence, the diagnostic methods may influence acceptability and uptake of testing services among people in prison. The choice of the diagnostic method for a given communicable disease depends on a broad spectrum of factors, such as test characteristics, national and/or European regulations, available facilities and resources at national and local level, and characteristics of the people in prison. However, it would be important to consider that invasive methods and/or diagnostics relying exclusively on venous blood may discourage uptake [83,84]. In general, higher acceptance and uptake of testing services was reported when oral tests or dry blood spots were used to complement routine venipuncture [97,98,104]. For a detailed presentation of HIV and HBV/HCV testing methods and algorithm refer to the most recent WHO guidelines [153,252].

Lastly, a specific point of concern regarding HIV active case finding is that diagnosis may lead to unjustified segregation and discrimination of HIV-positive patients in certain prison institutions. The full endorsement and fulfilment of the 7Cs principles (section 5.1.2) by the single prison institution and by the prison system at large is of utmost importance to guarantee the full respect of individual's rights, while maximising the prevention potential of active case finding initiatives.

5.1.7 HBV vaccination strategies

HBV vaccination in prison settings may be considered an effective catch-up vaccination strategy in those countries where universal routine vaccination is already performed. Similarly, in those countries where targeted HBV vaccination is implemented, it may offer the opportunity to reach under-served and hard-to-reach communities that may benefit from this intervention.

While HBV vaccination should always be voluntary and based on informed consent (see section 5.1.2), there are several possible strategies to deliver it in prison settings. With regards to timing, offer of vaccination at reception into prison is probably the most effective and least operationally demanding implementation approach. Despite the public health relevance of providing the first dose of vaccine at entrance, operational challenges coupled with the personal situation of disempowerment and vulnerability of individuals entering prison may result in the need to postpone vaccination. In such circumstances, it is important to repeat the offer again as soon as appropriate. In case of vaccine hesitancy, provision of accurate and user-friendly information on the benefit of vaccination may help increase acceptance and uptake. As reported in one study from Italy, the availability of dedicated healthcare staff resulted in increased vaccination acceptance over time [253].

HBV vaccination may be administered according to different vaccination schedules. In consideration of the high turnover of the prison population and the short average duration of prison sentences [8], release or transfer from prison are recognised as one of the key structural barriers to completion of the vaccination course [83,254-257]. Rapid and very rapid HBV vaccination schedules may result in increased rates of vaccination completion as suggested by available evidence [254] and as recommended in existing guidelines [15,63] and in a rapid induction of protection. While both schedules foresee the administration of the third vaccination dose within days or weeks after the first, they also require a booster after a 12-month period [130]. Coverage of the booster dose may however be suboptimal when and if the individual has left prison, due to existing challenges in post-release continuity of care (see section 5.1.8) [256]. Despite the very limited implementation in EU/EEA prison settings, electronic immunisation information systems (IISs) for vaccination may help record the number of doses received while in prison and thereby help achieve a higher coverage and completion of HBV vaccination post-release. The use of IISs can provide a reliable tool to assess an individual's vaccination history at entrance into prison and thereby avoid unnecessary and repeated vaccination.

The assessment of vaccination history prior to the HBV vaccination offer is reported in at least one national guideline [129] and in the literature [258]. In such instances HBV vaccination is offered to those individuals with either no, unknown or incomplete vaccination history. In other countries, such as Spain and France, HBV vaccination is offered following the assessment of individual HBV serology to exclude either previous vaccination or infection [83]. While serology may offer the advantage of providing vaccination only to those in need, especially when it is performed routinely as part of the medical assessment work-up at prison entrance, it may result in the delayed start of a vaccination course [83], and is not considered relevant in some national and supranational guidance documents [15,63].

Focus on implementation: universal HBV vaccination at admission into prison – the example of Scotland

In Scotland, HBV vaccination for all prisoners was introduced in 1999 in the absence of a universal childhood vaccination programme. A recent evaluation found that uptake of HBV vaccination among PWID in the community had significantly increased since the introduction of universal prison vaccination, and that current levels of HBV infection among PWID were low in Scotland compared with other European countries. Data were collected via serial cross-sectional surveys reaching more than 10 000 PWID through services providing injecting equipment and drug treatment and street sites in Glasgow (1993–2002) and throughout Scotland (2008–14). Among recent-onset PWID in Glasgow, vaccine uptake increased from 16% in 1993 to 59% in 2008–14 (i.e. pre and post the prison programme, respectively) ($p < 0.001$). Among all PWID in Scotland, uptake increased further from 71% in 2008–09 to 77% in 2013–14 ($p < 0.001$) and was associated with incarceration [adjusted odds ratio (aOR) = 2.91, 95% confidence interval (CI) = 2.23–3.79] [1].

While HAV vaccination is not the focus of this document, some considerations may be warranted given the availability of a bivalent HAV/HBV combined vaccine. The evidence from an included cost-effectiveness study indicates that substituting the combined vaccine for the monovalent HBV vaccine may only be justified in settings

with high HAV incidence [259]. However, HAV vaccination is currently recommended for PWID, MSM, people with chronic liver disease, and people in prison in several EU/EEA countries [36,260,261]. Furthermore, the increasing susceptibility to the infection in younger age groups [260], the potential for outbreaks occurrences, and the challenge in identifying individuals at risk (e.g. MSM), may be factors to consider when assessing the need for HAV vaccination in prison settings [259,262].

Mounting evidence suggests that single dose monovalent HAV vaccination may provide adequate levels of protection, thus minimising the cost and the operational requirements for such an intervention [134]. However, PLHIV may fail to mount an adequate immune response to HAV following single dose vaccination [134,135].

Finally, in the event of a HAV outbreak or of an acute exposure to HAV or HBV it is advisable to offer vaccination for HAV and/or HBV to all inmates and prison staff, in line with national/international guidelines.

5.1.8 Care and service delivery models for HIV, viral hepatitis, drug dependency treatment and linkage to care

Provision of OST and treatment for BBVs infections in prison settings not only has a direct individual health benefit, but may lead to a substantial community dividend resulting from the decreased risk of onward transmission, reduced healthcare burden due to ill health, lowered prevalence of behaviours at risk and post-release mortality [39,40,76,192,194,218,235]. Moreover, improving HIV, HCV treatment and OST coverage in prison settings would bring significant public health gains by fast-tracking the achievement of global goals such as the ending the AIDS epidemic and the elimination of viral hepatitis as a public health threat [127,190]. However, to achieve the highest possible impact, such potential for healthcare gains needs to be paired with effective linkage to care post-release. Failing to ensure linkage with community care services for individuals on treatment upon release may result in unplanned and unstructured treatment discontinuation potentially leading to virus rebound, appearance of clinical symptoms, development of acquired drug resistance, recurrence of drug injecting behaviour, increased risk of onward transmission and mortality [76,194,218,235].

Individuals diagnosed with HIV, HBV or HCV in prison settings should be offered appropriate treatment, in line with national and/or international guidelines. While it is internationally recognised that ART should be offered to all people with an HIV diagnosis irrespective of CD4 T-cell count [67], the offer of HBV, HCV treatments as well as OST may be subject to several factors, including clinical ones (e.g. stage of disease, co-morbidities and other health conditions) [45,157,263]. In addition, structural factors such as availability of necessary infrastructure, financial considerations, treatment rationing and legal framework (e.g. OST) may play an important role in securing treatment access for the prison population [38]. As these factors are largely country-specific, each Member State should consider performing an assessment of the treatment initiation pathway in prison settings to identify existing barriers and design tailored interventions to overcome those, when possible and appropriate.

The available evidence shows that, at least for HCV IFN-based treatment, there is no difference between prison-based and community-based treatment models with respect to treatment outcomes [176,177], unless individuals in detention are transferred or released. Prison population turnover is the single most important barrier for treatment continuation in prison settings [176,177], and may also impact treatment access. Treatment initiation is influenced by the expected duration of incarceration and by the anticipated likelihood of linkage to care post-release [150,160,163,166,170,177,264], as reported in the literature. Anecdotal reports from healthcare providers from various EU/EEA countries also confirm such an approach for HCV treatment. In particular, the conditionality of treatment initiation to the length of incarceration is specifically mentioned when provision of DAAs is considered, mostly due to the high cost of the treatment course and the often rationed access. The issue is all the greater for individuals with a migration background and undocumented migrants. While these individuals may have access to treatment and care while incarcerated, this may not be the case in the community depending upon the type of migrant status and the country [37,46]. With this premises and the changing demographics of the prison population at least in some part of the EU/EEA, access to and continuity of care for undocumented migrants may require further attention, including at normative level. Of note, lack of treatment offer and/or adequate care to incarcerated individuals in need may have legal implications, as demonstrated by court cases brought to the European Court of Human Rights [222].

Focus on implementation: scaling up DAAs in prison setting – the example of France

In France, the Ministry of Health has granted universal access to DAAs, including in the prison setting, since 25 May 2016. Following this declaration the French guidelines recommend testing all prisoners for HCV at the point of entry and to retest during incarceration. To provide adequate linkage to care, an HCV treatment specialist should be identified in all units in and outside prison where inmates are referred to. This link should facilitate pre-treatment screening, support training and coaching of prison doctors, facilitate DAAs treatment initiation and prescription. The identification of partner institutions for after release care or transfer is also recommended alongside the rapid activation of health insurance and the preparation of appropriate documents before prison release [2].

If access to treatment is warranted, an individual's preferences may influence treatment uptake. The available evidence indicates that personal reasons to refuse treatment are varied and include the preference to be treated after release, co-existing health conditions, lack of motivation and awareness, peer-influence, fear of adverse events and lack of confidence in health professionals.

While the literature on IFN-based HCV regimens reported largely on concurrent health conditions preventing treatment initiation, the improvements brought about by the DAAs in prison settings have yet to be reported on in the peer-reviewed literature. Finally, two studies reported that untreated patients (HIV and HCV) were significantly more likely to be PWID as compared to the treated ones [166,265], highlighting the need to address issues hindering equitable access.

Differentiated care and service delivery models for prison settings are needed. According to the available evidence, treatment for HIV, HCV and OST is provided either as SAT, DOT or as a combination of the two. A limited number of comparative studies on the impact of DOT versus SAT on HIV and HCV treatment adherence and completion is available [148-150,173,174]. With the exception of one study, the findings concurrently show no difference on treatment outcomes between the two models of care. However, administration of treatment such as DOT may offer some advantages and is the preferred model of care in some EU/EEA countries such as Italy and Portugal. According to a US developed guidelines, DOT for HIV positive people in prison could be considered as a measure to be continued after release [266]. The use of DOT in prison settings may bring patients into daily contact with health services/healthcare providers, thus offering an opportunity for additional interventions, when needed. Also, delivering all treatments as DOT in prison settings may contribute to reduce the stigma associated with certain conditions (e.g. HIV).

On the other hand, the strict use of DOT in a highly regulated environment such as prison, may result in an inadequate treatment management capacity of the individual and an insufficient preparation for self-administration post-release, possibly leading to adherence disruption. Evidence from the literature indicates that voluntary transition from DOT to SAT is not infrequent among the prison population, when this is possible [142,147,173]. On the other hand, DOT may limit the chance for diversion of medication, creation of a black market within the prison and injection of diverted medication using contaminated injecting equipment, which is an issue of special concern for OST, which is in fact commonly dispensed as DOT [263]. While rates of diversion of methadone are low, increased supervision may be needed with other treatments (e.g. buprenorphine), such as filming dosing, ensuring hands remain behind the back of the patient during dosing and inspecting the mouth after dosing [263].

Focus on implementation: provision of HCV and HIV treatments in Portuguese prisons

In Portugal all individuals admitted into prison are tested for HIV and HCV at entrance and at least once one year afterwards, following a specific clinical protocol including additional communicable diseases. For those individuals who test positive for either HIV or HCV at the confirmatory test, the linkage to the National Health Services Hospital of reference is arranged and the first appointment is booked. When the detained individual is already in care at prison entry, prison healthcare providers make an effort to maintain the provision of care in the same hospital in order to preserve the existing link to community services. All the therapeutics are supplied by National Health Services or by the Prison Hospital and distributed to the detained patients in individual doses per intake by a health professional, following the principle of DOT. In July 2017 an agreement was established between the Ministry of Health and the Ministry of Justice that allows National Health Services Hospital doctors to provide follow-up care to incarcerated patients inside prison setting.

Task shifting, telemedicine and multidisciplinary approaches are also considered as additional service delivery models in prison settings. According to the available evidence, and anecdotal reports from EU/EEA countries, the challenges in the provision of and access to specialised care in prison settings may be partially overcome with the use of telemedicine [151,175], coupled with task shifting, such as nurse-initiated HCV treatment and follow-up [175]. Pharmacist-led HIV treatment was also shown to improve treatment outcomes (though no evidence of significant effect provided) [152]. As suggested by the *ad hoc* scientific panel, availability of point-of-care diagnostic services on site, such as Fibroscan units, may greatly reduce the time to treatment initiation and facilitate patients follow up. Clinical protocols for the clinical follow up of treated patients should follow national and international standards and are covered in detail in existing guidelines [67,157,196,263].

There might be several barriers to adherence and completion of treatment, some specific to the prison environment. Among the latter, release or transfer within prison institutions are the most relevant [176,177]. According to a study on OST [76], drop-out was significantly higher during short sentences (≤ 1 month), while longer sentences (≥ 5 months) has a protective effect on retention. Correctional officers were also identified as having a role in promoting adherence, by opening the cell for detainees to self-administer their medication [144]. Personal factors associated with higher adherence were motivation, trust in the healthcare providers, having an occupation within the prison and having support inside and outside prison. On the other hand, injecting drug use was associated with poorer adherence and with treatment discontinuation.

The healthcare provision system in prison settings may impact on the delivery of treatment and care to the individuals in need while in prison and when transitioning from/into the community.

The EU/EEA is heterogeneous with respect to the allocation of the responsibility to provide healthcare services in prison settings between national institutions, e.g. Ministry of Justice, Ministry of Health. Even so, within each model, healthcare delivery may rely on different arrangements such as, for example, the utilisation of community health services, including community-facilities and their healthcare staff. As anecdotally reported, in some EU/EEA Member States specialised care for HIV and viral hepatitis is provided for in the community (e.g. Portugal and the United Kingdom), thus securing a direct link with community-provider already during incarceration.

In some other countries specialised healthcare is provided to the prison population in prison. Whatever the context, the *ad hoc* scientific panel agreed that a patient's referral may not be sufficient to ensure effective linkage to community health services. In the UK, the proportion of prisoners which are successfully engaged in community-based structured drug abuse treatment following release (within 21 days) is 30.3% with a wide variation among different regions (20.1-44.4%) [217]. Some projects in Italian and Portuguese prisons have been established through non-governmental organisations and penitentiary institution's partnerships in order to improve HIV prevention and care and the linkage to care between in and outside prison. However, the limited evidence and anecdotal reports from EU/EEA countries indicate a drop in the level of adherence to treatment post-release for all conditions [75,76,206,207,211,212]. This is particularly concerning for OST, as even small gaps in the continuity of treatment are distressing for the patient and risk the person relapsing to illicit opioid use, with the associated risk of overdose [218,263]. It is advisable to make arrangements so that there is minimal interruption of treatment on transfer to the community, and when it is not possible, the patient should be medically assisted for withdrawal to ensure continuity of treatment [263].

The available evidence on interventions to increase linkage to care is scarce, entirely derived from non-EU/EEA settings and skewed towards HIV treatment. Individual-level approaches to prepare detained persons for release may result in an increased rate of linkage to community care and treatment retention, however the effect may be short-lived [206,207]. One study reported a significantly higher rate of engagement with substance abuse community services among those receiving individual post-release case management by social workers or system navigators [209], however this approach may be resource intensive and of limited feasibility. Still, it is the opinion of the *ad hoc* scientific panel that individual-based assessment is an essential component of an effective throughcare process, encompassing a broader range of needs, including, but not limited to, healthcare. According to the findings of the EU Throughcare project¹³, a successful throughcare programme should be based on four key areas of interventions, namely healthcare, family, finance and housing, employment.

Active referral to community care services is considered the cornerstone of an effective linkage to care post-release, and is widely recommended by existing guidelines [15,58,65,195,196]. In consideration of the specificities of EU/EEA Member States national healthcare systems and arrangements with respect to provision of prison health, active referral may take different approaches. Provision of medicines into their possession (the supply of an adequate amount of drugs to the individual upon release) is implemented in countries such as France, Italy and Portugal in order to cover the transition period until effective linkage with community services is established, or for the entire duration of the treatment as currently done in some countries for HCV treatment with IFN-free regimens.

Provision of prescription is preferred in countries such as the United Kingdom or for drug dependency treatment. For the latter, in particular DOT in the community may be desirable, and active referral to a suitable service

¹³ EU project Throughcare for prisoners with problematic drug use – <http://www.throughcare.eu/index.html>

provider pursued. In fact, linkage to low-thresholds drugs services in the community may provide an effective entry point for PWID on OST to access a broader basket of services such as specialised HIV and HCV care. The existing body of evidence indicates that uptake of OST during incarceration results in a higher likelihood of retention in drug dependency care after release [213-215,219], and in better adherence to HIV treatment among PWID [210]. Post-release care for PWID may be particularly important in light of the heightened mortality risk in the immediate post-release period [217,267]. Accumulating evidence, including from the EU/EEA, attests the protective effect of OST on all cause and drug-related mortality after release [76,218,235]. As a further measure to prevent overdose mortality, provision of naloxone in possession at release has been shown to be successful in a large-scale programme implemented in Scotland [268]. The forthcoming availability of nasal naloxone distributor may increase acceptability and expansion of this measure across the region [269-271]

Finally, notification to community health facilities in the jurisdiction of residence, booking follow-up visits and similar active referral initiatives may be effective strategies to improve retention in care after release. However, in certain EU/EEA countries, access to care is regulated by health insurance coverage. Suspended or delayed access to insurance coverage in the immediate post-release period may result in deferred healthcare/clinic appointments and linkage to appropriate care, incomplete sharing of health information, and gaps in treatment continuity and adherence. Importantly, challenges with obtaining/having the right to health insurance are more significant for migrants, including those whose stay in the country is not in line with immigration law, and who constitute a sizeable proportion of the prison population in at least in some EU/EEA countries.

Integration of prison and community health services could contribute to streamlining continuity of care pathways both at entry into and at release from prison. In particular, integrated services could possibly result in an easier and faster referral system for patients as well as in a less demanding process for the responsible healthcare worker. It was the opinion of the *ad hoc* scientific panel that, while the prison healthcare worker is necessarily involved in the referral process, the ultimate responsibility of ensuring continuity of care would need to be shared with the responsible institution/s, which is country specific [47,54].

5.1.9 Other people in prison settings

People in prison not only include people in detention, but also visitors, certain support and service providers from the community, and staff (e.g. guards, administrators, cooks, etc.) who serve in prison settings. These individuals, and specifically prison staff, are exposed to a potentially higher risk of acquiring communicable diseases while visiting or working in prison. Conversely, people entering the prison environment can also be the inadvertent source of infection for the prison population, for instance during an seasonal influenza wave in the community.

It is important to pay close attention to the fundamental right to health of people working and visiting prisons, and primarily of prison staff, bearing also in mind the implications for employment and labour law. This is all the more important when prison staff are called upon to work in places with poor hygiene, squalid material conditions or working environments and prison overcrowding, or where there is a high prevalence of people with mental problems, physical illness or infectious disease [272].

It is essential for prison staff to be empowered to take informed decisions in respect of their own safety and health and to be offered adequate occupational health services [273]. It is also appropriate to consider other people in prison as potential target groups for active case finding at entrance into service or, when appropriate, at regular intervals or following acute exposure thereafter. HBV vaccination is a safety measure that is advisable to offer to newly employed staff in consideration of the potential for occupational exposure and increased risk of infection acquisition [15,36,273]. Vaccination is advised for prison staff members, based on the relative exposure risk (e.g. healthcare staff and correctional officers versus clerks). Also, provision of vaccination may be subject to national arrangements related to prison staff management responsibilities allocated to different authorities (e.g. Ministry of Health, Justice or Interior). Post-vaccination testing to assess seroconversions and the acquisition of an adequate level of protection may be considered for at least healthcare staff working in prison. In the case of an exposure event, prison staff would need to have access to the highest standard of post-exposure prevention in accordance to national and/or international guidelines, as appropriate [273]. Informed decisions taken by staff or other people attending prisons may be relevant from an employment or labour law perspective, in case of subsequent infection or diagnosis.

5.1.10 Monitoring healthcare services in prison

Prison health is an essential part of public health and it would be advisable that prison health is integrated into national monitoring systems, which is rarely the case in EU/EEA countries. It is essential to actively monitor all elements of healthcare provision in prisons by using standardised data collection tools because only monitoring makes it possible to assess the effectiveness of interventions, identify existing barriers, and inform planning and resource allocation. Collecting standardised data with a breakdown by risk group would be particularly helpful, especially with a focus on people with drug use disorders and drug use patterns (before, during, after prison). For example, it would be particularly helpful to collect data on the number of new diagnoses that were reported to national communicable disease surveillance schemes after active case finding interventions in prison settings. This

would not only allow for a comprehensive assessment of the individual and public health benefits of these interventions, but also contribute to a better understanding of the burden of disease in the prison population and the related health needs of this population, which, in turn, would provide the basis for adequate resource allocation.

Ideally, an effective disease monitoring system for prison systems should generate reliable data, which could also be shared with stakeholders. These data could provide critical evidence when developing tailored interventions for prison settings and support the timely and effective resolution of service delivery challenges.

Ultimately, epidemiological and programmatic data from the prison system should be integrated with national/international data collection systems in order to inform comprehensive health policy and planning. The WHO Regional Office for Europe, as part of the Health in Prison Project (HIPP), began collecting data for a minimum public health dataset for prison health in October 2016. HIPP wants to establish a monitoring framework that regularly collects data on the main areas of prison health, including prison health systems (such as financing and governance); the prison environment; risk factors for diseases; and the screening, prevention, treatment and prevalence of communicable and non-communicable diseases. The data are stored in the Health in Prison European Database (HIPED) and are available on the WHO Global Health Observatory.

5.1.11 Effective ways of reducing the number of drug users in prisons

People with drug use disorders, drug offenders and former drug users constitute a large proportion of the prison populations in Europe and the burden of infectious diseases among this group is high. Implementing policies that reduce the number of drug users in prisons is an effective measure to reduce the prevalence of infections in prisons [228].

Firstly, there are a range of measures available that aim at reducing the number of drug-addicted offenders who get a criminal record. In case of 'minor' drug law offences, usually defined as use or use-related offences, legal action is often administrative, or stopped before the case comes to the court. These latter actions are usually based on discretionary powers at police or prosecution level.

Secondly, most EU countries have legal frameworks in place which open the possibility of rehabilitative measures for delinquent addicts, in order to reduce relapse into drug use and subsequent re-offending. People with drug use disorders can be diverted into treatment by court order - a measure commonly applied to first offenders and acquisitive crime. Other sanctions can also be given as an alternative to a prison sentence - the prison sentence is suspended, or another form of punishment is applied.

While research on the impact of alternative measures to punishment as well as the impact on the effects of in-prison treatment on recidivism has gained pace over the past decade, more information is still needed to assist decision-makers in directing scarce public resources toward successful programmes and away from unsuccessful programmes.

5.2 Research

5.2.1 Challenges of research in prison settings

Prison settings are probably one of the most challenging environments for conducting scientific research, given the ethical implications and the complexity of the prison population. People living in prison often belong to one or multiple vulnerable groups, such as migrants, PWID, homeless people, socially marginalised and uneducated people. In addition, there is a high prevalence of mental disorders. This heterogeneity, combined with mistrust towards prison institutions and the inherently problematic doctor-patient relationship in prisons, makes it difficult for people in prison to give an informed consent to participate in health interventions and research initiatives. People in prison are generally considered a population that is 'hard to reach' and 'hard to treat'.

The high turnover of the prison population negatively impacts the participants' retention and hampers the capacity to measure the outcomes of scientific research in prison facilities. This is particularly challenging for the conduct of interventional studies, since longitudinal data are difficult to collect.

Research is further hampered by suboptimal cooperation between prison personnel of different professions and roles, shortage of staff trained in conducting research, the lack of economic resources devoted to prison health management, and a lack of interest in the institutions responsible for prison healthcare. Research targeting prison populations has the potential to expose service gaps, indicate risk behaviours, and point toward unlawful practices in prison settings, thus raising issues that some of the responsible authorities may be reluctant to address.

The lack of public interest in the 'world behind the walls' is probably another important reason for the relatively low amount of studies conducted in this setting.

5.2.2 Research gaps and future research

While this guidance focuses on the EU/EEA, a sizable portion of the evidence was derived from studies conducted in the USA. Due to the differences in terms of healthcare systems, correctional systems, and population demographics, findings are not always applicable to EU/EEA settings. Moreover, there is a large heterogeneity between studies, both in the peer-reviewed and the grey literature, and the general lack of comparative studies makes it difficult to compare data and results. Overall, the level of evidence of the included peer-reviewed literature studies is quite low. Studies of higher quality and with conclusive evidence are needed as a basis for guidance development.

Operational research on active case findings in prison settings could provide practical and operational insights into the implementation of such interventions. In particular, topics such as timing of testing offer, reiteration and appropriate time intervals, interventions to increase testing uptake, and risk-assessment criteria for STI and LTBI testing are scarcely researched. Long-term follow-up data are needed to assess the benefits of active case finding in terms of treatment uptake, adherence to/completion of treatment, cure rates (TB, HCV), and reactivation rates following treatment (LTBI).

In order to fill the knowledge gaps on interventions such as active case finding in prison settings, future research, conducted in the EU/EEA, is needed to provide evidence on the feasibility, (cost-)effectiveness, and impact of such interventions in the EU/EEA. Studies should have a comparative study design and focus on population and test characteristics, health interventions, and intervention outcomes, based on sample sizes that are large enough to detect and measure relevant effects.

The Worldwide Prison Health Research & Engagement Network (WEPHREN; <https://wephren.tghn.org>), an open access collaborative forum on the health of people in prison, tries to catalyse research activities that focus on prison settings through the development of an evidence base and capacity building measures.

6. Next steps

This guidance will be reviewed five years after publication to determine whether all or part of it should be updated due to new evidence or new developments in EU/EEA Member States.

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Appendix. Ad-hoc scientific panel members

Expert panel members

Name	Organisation	Country
Viktor Mravcik	Government of the Czech Republic	Czech Republic
Fadi Meroueh	Association des Professionnels de Santé Exerçant en Prison	France
Laurent Michel	Centre Pierre Nicole, Croix Rouge Française	France
Heino Stöver	HA-REACT	Germany
Ruth Zimmerman	Robert Koch Institute	Germany
Roberto Ranieri	Società Italiana di Medicina e Sanità Penitenziaria	Italy
Erica Cardoso	Direcção-Geral de Reinserção e Serviços Prisionais (DGRSP), Ministério de Justiça	Portugal
Teresa Galhardo	Direcção-Geral de Reinserção e Serviços Prisionais (DGRSP)	Portugal
Rui Morgado	Direcção-Geral de Reinserção e Serviços Prisionais (DGRSP), Ministério de Justiça	Portugal
Lucia Mihailescu	Formerly with Romanian National Administration of Penitentiaries	Romania
Jose-Manuel Arroyo-Cobo	General Secretariat of Penitentiary Institutions	Spain
Stefan Enggist	Federal Office of Public Health	Switzerland
Hans Wolff	University of Geneva	Switzerland
Sharon Hutchinson	NHS National Services Scotland & Glasgow Caledonian University	UK
Eamonn O'Moore	Public Health England	UK
Alison Hannah	Penal Reform International	International
Jan Malinowski	Council of Europe	International
Lars Møller	WHO	International
Ehab Salah	United Nations Office on Drugs and Crime	International

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