

TECHNICAL REPORT

Developing a national strategy for the prevention and control of sexually transmitted infections

ECDC TECHNICAL REPORT

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Abbreviations

AIDS	Acquired immune deficiency syndrome
AMR	Antimicrobial resistance
BBV	Blood-borne virus
CGB	Coordination and governance body
ECDC	European Centre for Disease Prevention and Control
EEA	European Economic Area
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
HPV	Human papillomavirus
IUSTI	International Union against Sexually Transmitted Infections
LGV	<i>Lymphogranuloma venereum</i>
MSM	Men who have sex with men
PCR	Polymerase chain reaction
PID	Pelvic inflammatory disease
PrEP	Pre-exposure prophylaxis
RACER	Relevant, acceptable, clear, easy, and robust
SMART	Specific, measurable, action oriented, realistic, time-bound
STI(s)	Sexually transmitted infection(s)
SWOT	Strengths, weaknesses, opportunities and threats
TB	Tuberculosis
ToR	Terms of reference
UNGASS	United Nations General Assembly Special Session
WHO	World Health Organization

Glossary

National policy	The result of a political process, describing the outcomes a government strives to deliver, including the (political) vision and goals.
National strategy	The description how policy goals can be achieved, using a combination of systematic analysis of situation, of stakeholders, of strengths and weakness in the prevention & control capabilities leading to a rational choice for actions to be implemented.
Action plan	Document that lists what steps must be taken in order to implement the national strategy. The purpose of the action plan is to clarify what resources are required, formulate a timeline for when specific tasks need to be completed, define responsibilities and what resources are required. An action plan for STI prevention and control may be organised in several programmes.
Programme	A set of related measures or activities with a particular long-term aim [1]. In the context of this report, a programme is a coherent set of activities, that are coordinated together as part of an implemented action plan. A programme may be targeted to specific risk groups.
Elimination	Reduction to zero of the incidence of infection caused by a specific agent in a defined geographical area as a result of deliberate efforts; continued measures to prevent re-establishment of transmission are required [2].
Eradication	Permanent reduction to zero of the worldwide incidence of infection caused by a specific agent as a result of deliberate efforts; intervention measures are no longer needed. Example: smallpox [2].
Prevention	Policies and actions to eliminate a disease or minimise its effects; to reduce the incidence and/or prevalence of disease, disability, and premature death; to reduce the prevalence of disease precursors and risk factors in the population (adapted after [3])
Control	The reduction of disease incidence, prevalence, morbidity or mortality to a locally acceptable level as a result of deliberate efforts; continued intervention measures are required to maintain the reduction [2].
Stakeholders	In the context of a strategy: any person, group or entity that can impact or is impacted by the content, implementation and outcomes of an STI prevention and control strategy.
Partner notification	The act of informing sexual partners of STI patients that they may have been exposed to infection and advise them to consult an STI care provider.
Partner management	An essential part of STI case management, which includes partner notification, testing and follow-up.

Executive summary

This technical report is the main outcome of a project launched by ECDC in 2018 that aims to support the development of national prevention and control strategies for sexually transmitted infections (STIs) in the EU/EEA. It was derived from an ECDC survey in 2012 that found that about two in three (17/28) Member States did not have a national strategy for STIs. A sub-regional ECDC meeting (April 2017) on strengthening national responses to STI epidemics indicated that national strategies would be helpful in supporting STI prevention and control.

Scope, purpose and target readership

This report is primarily targeted at policy advisors, experts involved in the planning and management of national STI strategies and those responsible for the implementation and management of national STI prevention and control programmes and related activities. It may also be of interest for other experts contributing to sexual health at the national level. This report mainly refers to common, curable bacterial STIs in the EU/EEA such as chlamydia, gonorrhoea and syphilis.

Key messages

- During a sub-regional ECDC meeting in 2017, participants from central, eastern and southern EU/EEA countries stressed that a national strategy for STI prevention and control would be helpful in supporting the prevention and control of STIs.
- A strategy should be evidence-based and take into account national STI epidemiological data. Prevention and control activities should consider the determinants of sexual transmission, for example factors such as transmissibility of pathogens, contact rates, and duration of infectiousness. A combination of primary, secondary and tertiary prevention activities may be used, based on their proven effectiveness; equally relevant when selecting prevention activities are strategy objectives and the characteristics of the epidemic in question.
- STI prevention and control falls into three categories:
 - National coordination should ensure an inclusive approach, involving all relevant disciplines and sectors; this implies that national coordinators are responsible for the monitoring and evaluation of activities and strategy implementation.
 - Clinical services should provide easy access to appropriate STI diagnostics, STI treatment and ensure high-quality care – in accordance with evidence-based guidelines for case management and partner notification. Quality care would also benefit from training activities for health professionals.
 - Public health components include population-based activities such as health promotion and behavioural interventions, partner management services, outreach programmes and screening, outbreak response, epidemiological surveillance and research, and biomedical interventions such as vaccinations.
- The development of a new national strategy and action plan should consider alignment with other policies, strategies and action plans – both national and international – in order to create synergies between related policy areas.
- A seven-step approach is proposed for the development, implementation and monitoring of a national strategy and action plan:
 - Establish a national coordination mechanism
 - Engage stakeholders in the process
 - Perform a situation analysis
 - Develop the strategy document
 - Develop an action plan
 - Coordinate and manage the action plan implementation
 - Establish a monitoring and evaluation plan
- Successful implementation of a strategy will be influenced by the level of stakeholder engagement. This can be a two-phase process: produce a stakeholder matrix and create a stakeholder engagement plan. In the matrix, stakeholders will be plotted according to their estimated influence on, and interest in, the strategy. The position in the matrix will influence the approach for engagement of each of stakeholder category. A stakeholder engagement plan can be constructed by mapping current stakeholder engagement and comparing it with the desired activities.

Tools

The Annex contains tools and templates for the development of a national strategy for STI prevention and control.

1. Background – Burden and impact on health of sexually transmitted infections and the need for prevention and control

1.1 Global burden of sexually transmitted infections and the WHO health sector strategy for STIs 2016–2021

Sexually transmitted infections (STIs) are among the most frequently reported infections globally, with an estimated number of one million infections acquired everyday worldwide [4]. Annually, a total of 357 million new infections of *Chlamydia trachomatis* (131 million), *Neisseria gonorrhoeae* (78 million), syphilis (6 million), and *Trichomonas vaginalis* (142 million) are estimated to occur among people aged 15–49 years [5]. In addition, 417 million people are estimated to be infected with herpes simplex type 2, and approximately 291 million women carry the human papillomavirus (HPV) [6]. The prevalence of bacterial and viral STIs varies by region and gender [5,6]. STIs impose a substantial strain on national health systems, particularly in middle- and low-income countries and have a profound impact on the health and lives of children, adolescents and adults worldwide [6]. The burden of morbidity and mortality due to congenital syphilis is high. In 2016, an estimated 661 000 congenital syphilis cases (including associated adverse pregnancy outcomes) were attributed to syphilis worldwide [7].

In 2016, WHO published a strategy document entitled *Global health sector strategy on sexually transmitted infections 2016–2021: toward ending STIs* [6] which aims to reduce incident STIs and associated morbidity and mortality. The strategy will accelerate the use of comprehensive prevention efforts, facilitate access to information on STIs, improve access to STI treatment, and challenge pervasive stigmatisation and discrimination. The strategy positions the health sector response to STI epidemics as critical to the achievement of universal health coverage – one of the key health targets identified in the 2030 UN Agenda for Sustainable Development. WHO recommends that countries set national targets and milestones and identify indicators for the monitoring and evaluation of national STI programmes. National governments should also conduct regular programme reviews to help ensure national strategies; action plans and resource allocation should reflect evolving country needs [6].

1.2 EU/EEA burden and national responses for prevention and control of sexually transmitted infections

Sexually transmitted infections are a common cause of morbidity in the EU/EEA. In 2017, more than 400 000 cases of chlamydia, 89 000 cases of gonorrhoea and 33 000 cases of syphilis were diagnosed and reported to ECDC's TESSy (The European Surveillance System) by the Member States (Table 1) [8].

Table 1. Occurrence of selected bacterial sexually transmitted infections in EU/EEA countries, 2017

	Number of cases	EU/EEA rate per 100 000	Male-to-female ratio
Chlamydia	409 646	146	0.7
Gonorrhoea	89 239	22	3.2
Syphilis	33 193	7	8.5
Lymphogranuloma venereum	1 989	-	-

Source: ECDC Surveillance atlas of infectious diseases [8]

The number and rates of new STI diagnoses have increased in the EU/EEA since the 1990s [9]. This increase has been predominantly due to transmission between men who have sex with men (MSM), except for chlamydia where the increase has been associated with more sensitive diagnostics, for example improved testing methods that detect asymptomatic infections. Although the surveillance methods vary across Member States, the 2017 data suggest that HIV-positive men contribute a significant proportion of cases of syphilis, lymphogranuloma venereum (LGV) and gonorrhoea. With the introduction of pre-exposure prophylaxis (PrEP) to prevent HIV infection among MSM engaging in high-risk sexual practice, it is expected that STIs will also increase among the HIV-negative MSM [10,11]. This calls for the development of effective STI prevention and control strategies targeting the groups at risk.

In 2012, an ECDC survey identified that 11 of the 28 EU/EEA countries that responded, had a strategy or a plan for STI prevention and control, either as a stand-alone document or included in an HIV/AIDS strategy or plan [12]. In 2018 the survey was repeated, and 29 out of 30 countries responded (Table 2). 15 countries reported having a national STI strategy – an increase of 12%. STI strategies were integrated with HIV prevention strategies in nine

countries and with sexual and reproductive health strategies in six countries. Nine countries did not have an STI strategy. Among those, Denmark adopted the practice of multidisciplinary collaboration, consultation and stakeholder involvement as an effective operational structure for STI prevention and control in the absence of a formal STI strategy.

Table 2. Availability of a national STI strategy in EU/EEA countries, July 2018

No STI strategy (n=9)	Integrated STI strategy		STI strategy in development (n=5*)
	HIV strategy (n=9)	Sexual and reproductive health strategy (n=6)	
Austria, Croatia, Denmark, Estonia, Greece, Hungary, Poland, Romania, Slovenia	Bulgaria, the Czech Republic, Germany, Iceland, Latvia, Lithuania, Luxembourg, Spain, Sweden	Finland, France, Ireland, Malta, Netherlands, United Kingdom (England, Northern Ireland, Scotland)	Belgium, Cyprus, Italy, Portugal, Slovakia

* Strategy development was underway in Wales (United Kingdom)

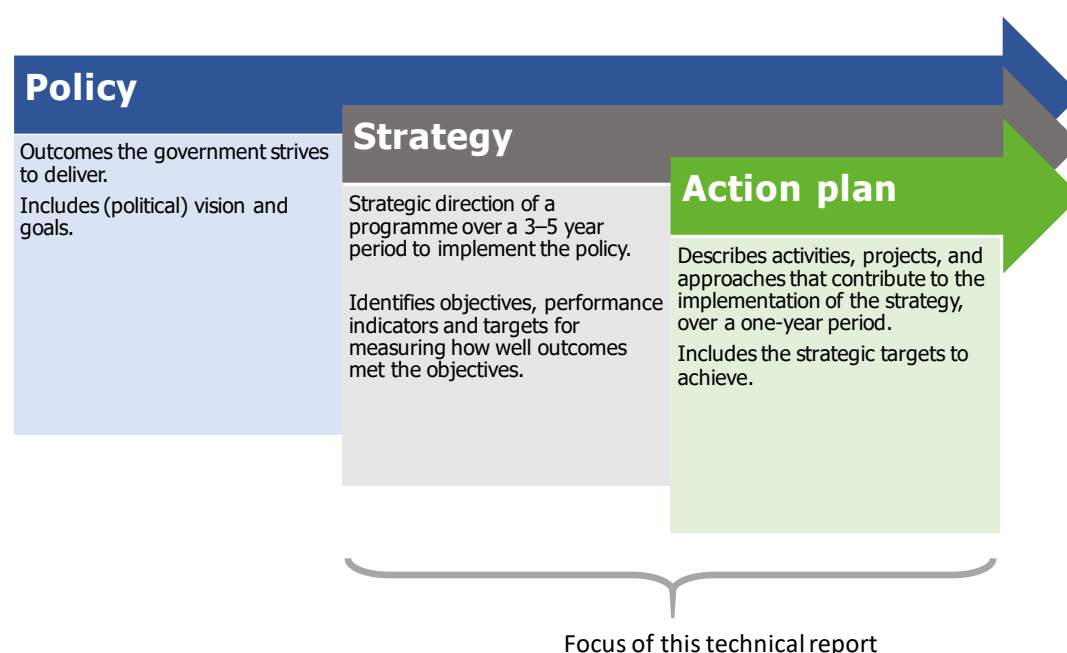
In 2017, ECDC held a sub-regional meeting which included several central, eastern and southern EU/EEA countries entitled 'Strengthening country responses to STI epidemics'. Meeting participants identified the need for strong STI strategies to compensate for limited political support, lack of funding, and competing public health priorities.

Over the years, ECDC has published a series of documents that aim to support policy makers and programme managers in their efforts to prevent and control STIs in the EU/EEA. ECDC's revised guidance on chlamydia control in Europe [13] and the guidance document on prevention of infections among MSM [14] provided a list of evidence-based interventions directed at public health STI programmes. This technical report is the latest addition to this series.

2. Methods and key definitions

This report focusses on the process of strategy development and the subsequent action plan (Figure 1). Various definitions of the terms 'policy', 'strategy' and 'action plan' exist. For the purpose of this report, a 'strategy' is defined as 'the description of how a policy's objectives and goals can be achieved'. More specifically, a strategy includes a combination of systematic analysis of the situation, an analysis of the stakeholders, and an analysis of strengths and weaknesses in the prevention and control capabilities, leading to a rational choice for actions to be implemented (adapted from Mintzberg, 1989 [15]). A policy is the result of a political process, describing the outcomes that a government or an organisation strives to deliver – including (political) vision and goals.

Figure 1. Relation between policy, strategy, action plan and the focus of this report



The approach for the development of this report combines a consultation of relevant scientific literature, expert interviews and discussions of the main elements of strategy development during an ad hoc expert meeting.

The chapter on the theoretical framework was inspired by Holmes et al. [16] and Anderson and May [17], complemented by expert knowledge within the team of authors and contributors.

The chapter on development of a national strategy and action plan was informed by non-systematic literature searches for relevant publications using PubMed, Google Scholar and the Google search engine. In addition, grey literature indicated by experts from Denmark, Germany and Romania through interviews was included. In areas where the literature was not consistent, the authors used expert knowledge and consensus to decide on key definitions and methodology approaches most appropriate to the European context. In principle, priority was given to practical approaches, avoiding theoretic elaborations.

The chapter on stakeholder engagement is based on internal ECDC guidance on stakeholder engagement and selected literature references, further elaborated by expert knowledge and consensus.

A draft version of this technical report was discussed in detail with the participants in an ad hoc ECDC expert meeting on STI strategy development in October 2018 (see Annex 6 for details). The experts favoured an integrated model, i.e. an STI strategy tied to relevant, related strategies. The integration of an STI prevention and control strategy with an HIV strategy was seen as the most logical and advantageous approach/model of practice. Integration with a viral hepatitis strategy was suggested as a second option, given the overlapping issues in the transmission of viral hepatitis. Inclusion in the reproductive and sexual health strategy could be more complicated because in a number of countries reproductive health is not coordinated by the ministry of health. In principle, the integration of a national STI prevention and control strategy with other public health strategies has several advantages compared with a stand-alone STI strategy though it presents the risk that HIV or hepatitis prevention efforts will overshadow STI activities. In order to avoid this, it was suggested that a stand-alone STI action plan should be added. Where integration is not feasible due to political or economic context, a stand-alone STI strategy is still preferred to no strategy at all.

3. Theoretical framework for the prevention and control of sexually transmitted infections

This chapter summarises some of the general characteristics of the most frequently reported sexually transmitted infections in EU/EEA, presents the main determinants of sexual transmission, and introduces the main components of STI prevention and control. The resulting theoretical model can be used as a framework for STI strategy development in the EU/EEA countries.

3.1. Characteristics of STIs most commonly reported in the EU/EEA

Details on the clinical features of the most common STI in EU/EEA are given in Annex 1. The most recent epidemiological data on chlamydia, LGV, gonorrhoea and syphilis are available through the ECDC Surveillance Atlas [8]. Data on congenital syphilis – a rare disease in the EU/EEA – are also available through the ECDC Surveillance Atlas.

While not under the EU/EEA surveillance, several viral STIs such as genital herpes caused by herpes simplex viruses (HSV-1, HSV-2) [18] and genital warts caused by human papilloma viruses (HPV 6, 11) [19] are understood to have a high burden. Their main characteristics are also presented in Annex 1.

Apart from the pathogens described above that are primarily transmitted via sexual intercourse, some other pathogens such as HIV, hepatitis B and C viruses that are commonly described as blood-borne pathogens, can also be transmitted through sexual contact, especially when the mucous membranes barrier is broken by ulcers or through sexual activity. Pathogens generally classified as food- and waterborne pathogens, such as hepatitis A virus, *Shigella*, *Cryptosporidium*, etc., can also be transmitted during sexual activity that involves contact with faeces, often resulting in outbreaks. Several other infections that are not categorised as STI, such as Ebola and Zika virus infections, can be sexually transmissible and pose new challenges to the prevention and control efforts [20]. It is important to acknowledge that sexual behaviour has a broad spectrum of activities that involves a risk of transmission of infections.

3.2. Determinants of sexual transmission

Understanding the dynamics of STI transmission is important for interpreting epidemiological trends, guiding data collection, and designing prevention and control programmes for STIs. Characteristics of STI transmission may be different from other infectious diseases as behavioural components impact the transmission rate in combination with biological factors. For example, people with asymptomatic infections may harbour the pathogen for a long time, which can lead to further spread and transmission [16]. General determinants of STI transmission and further spread in the population include the probability of transmission, the duration of infectiousness, and the rate of new partner acquisition. These factors are included in the basic reproduction number (R_0) which represents the average number of secondary cases that arise from any new case of infection in a population that is fully susceptible and in the absence of any interventions [16,17].

$$R_0 = \beta * c * D$$

β probability of transmission; c contact rate (rate of new sexual partner acquisition), D duration of infectiousness

If R_0 is higher than 1.0, the infection spreads, the incidence increases, and the infection persists in the population. If R_0 equals 1.0, the incidence remains stable. If R_0 is less than 1.0, the infection dies out. However, a population will rarely be fully susceptible, and a number of other factors like prevention and intervention measures will play a role. The effective reproduction rate (R) is used to reflect the effect of these active prevention and intervention measures. The aim is to reduce R below 1.0 by influencing the determinants of transmission as described in the next sections.

Transmissibility per sexual partnership depends on several factors, such as the intrinsic, pathogen-specific probability of transmission (infectiousness); the use of barrier precautions (e.g. consistent and correct use of condoms); the frequency and nature of sexual activities (such as penile-anal sex, penile-vaginal sex or vaginal sex during menstrual periods); the presence of skin/mucosal lesions or ulcers (as demonstrated by the increased transmission probability of HIV in the presence of other STIs); and the presence of disease symptoms (e.g. urethral discharge, genital rash, warts, etc.). (Adapted from Anderson and May, 1992 [17])

Duration of infectiousness of an individual patient varies across pathogens and is affected by the development of symptoms, healthcare-seeking behaviour, and the access to clinical care (e.g. detection and treatment). Early diagnosis and effective treatment will reduce the duration of infection for the individual patient but will also reduce

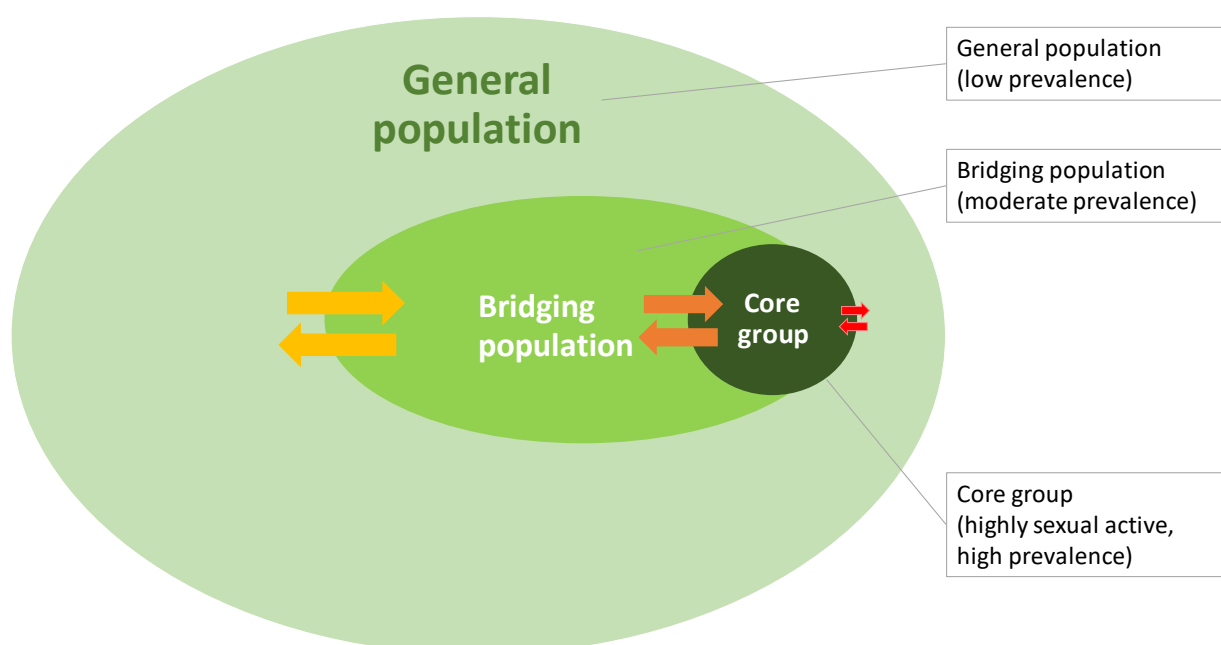
the likelihood of transmission of infection in the community. It is important to note that most STIs do not confer long-lasting immunity and reinfections are possible [21].

The **rate of new partner acquisition (contact rate)** is an important measure for sexual behaviour. Apart from other factors such as frequency and types of sexual activities, the contact rate estimates the frequency of concurrent partnerships, sexual networks and the patterns of mixing between population groups with different sexual activity. Partner change rates vary across communities and are associated with demographic and socio-economic factors such as gender, age, socio-economic status, ethnicity, and education [16,22,23].

Heterogeneity in sexual activity has a major influence on the prevalence or incidence of infections within a community. The concept of a **core group** (a small group of highly sexually active individuals) who play an important role in the persistence of infection is of major importance in the design of policies for the control of STIs [16]. The core group contributes disproportionately to STI transmission. Mixing between and within risk groups is a significant component of STI transmission in populations and identification of bridge populations is important for the design of prevention and control programmes. Characteristics of core groups include: higher rates of concurrent sexual relationships, frequent sexual exposure within that same subpopulation, and moderate sexual 'bridging' to other populations [24].

Understanding the structure of local or regional sexual networks is an important factor for successful STI prevention and control strategies. Meaningful studies on risk behaviour and prevalence of STIs within subgroups of the population would enable countries to close these knowledge gaps.

Figure 2. Transmission dynamics of STIs at the population level



Adapted from: WHO Global strategy for the prevention and control of sexually transmitted infections 2006–2015 [25]

3.3. Prevention and control of sexually transmitted infections

It is important to consider a number of prevention principles and activities when developing a national STI strategy:

- Primary prevention (aiming to prevent the acquisition of the infection) includes: education on sexual and reproductive health (e.g. school educational programmes, public campaigns and/or campaigns targeted to risk groups), promotion and use of safer sex practices that reduce exposure (e.g. use of condoms and spermicides, reduction of the number of sex partners and concurrent partnerships).
- Secondary prevention (aiming to treat promptly the infections to prevent complications or sequelae and reduce further transmission) includes: healthcare-seeking behaviour (in case of exposure, occurrence of STI symptoms), access to STI testing and treatment services (to ensure early diagnosis and effective

treatment), partner management services, screening for asymptomatic infections and outreach programmes for hard-to-reach populations and linking to appropriate treatment.

Primary prevention and secondary prevention can be used at the individual and the population level. For example, early diagnosis and treatment is secondary prevention at the individual level but primary prevention at the population level (e.g. reduction of the duration of infection). Secondary prevention measures also interrupt the chain of transmission and are considered to be part of the control measures.

- Tertiary prevention is not often highlighted in STIs prevention and control. In tertiary prevention, measures are taken for reducing the long-term effects of a disease by helping patients manage their conditions and chronic symptoms, like life-long genital herpes, HIV infection, congenital syphilis, pelvic inflammatory disease, infertility. Tertiary prevention is not covered by this report.

Primary, secondary and tertiary prevention activities should be combined to reflect local circumstances and adjusted in the light of regular monitoring and evaluation results. Tailoring of national responses to STI epidemics is sometimes hampered by the lack of good quality epidemiology data. Robust surveillance data at the national and European level, as well as access to effective patient management – including reliable and accurate diagnostic services for STIs – are cornerstones in the prevention and control of STIs [6,16].

3.4. Components of prevention and control of sexually transmitted infections

National coordination. Considering the complexity of factors that influence STI transmission and the need for a comprehensive approach for STI prevention and control, the introduction of national coordination mechanisms is pivotal. Coordination across disciplines (medicine, nursing, health education, behavioural experts, etc.) and sectors (e.g. law enforcement regarding commercial sex work, human trafficking, drug abuse; and health insurance) is essential to build partnerships with the different actors involved in STI prevention and control. It requires leadership and effective management to set strategic priorities, based on epidemiological situation review, for the planning and implementation of action plans. National coordinators of STI prevention and control strategies should put in place to implement effective monitoring and evaluation processes (see Chapter 4). Evaluation can also be conducted at the local level when interventions are introduced to assess whether prevention and control activities achieve the targets set out in the strategy [26]. The results of monitoring and evaluation will provide relevant input with regard to strategy changes. The process of strategic planning, monitoring and evaluation will be detailed in the next chapter.

STI clinical services should be able to provide early diagnosis and treatment, followed by patient counselling and partner management. STI care services should be easily accessible and delivered in an appropriate supportive environment. Reliable and accurate clinical and diagnostic (i.e. laboratory) services are essential for adequate case management and ensure effective treatment. These need to be supplemented by evidence-based case management guidelines and continuous professional training of staff (e.g. (para)medical, public health, educational experts) and clinical audits. Partner notification, with informed patient consent, is often initiated in the clinical setting and is an essential part of partner management with individual and public health benefits (Figure 3). It should reduce the risk of persistent or recurrent infection in the index patient, identify previously undiagnosed infections, and may thus contribute to reduced transmission in the population [27].

Figure 3. Key components of STI prevention and control

National coordination	STI clinical services	Public health components
<ul style="list-style-type: none"> •Governance, leadership and management •Partnerships •Strategy and action plan •Monitoring and evaluation •Programme evaluation 	<ul style="list-style-type: none"> •Easy access to STI care •Early diagnosis •Accessible clinical and diagnostic services •Effective treatment •Evidence-based case management guidelines •Professional training of clinical and educational staff •Partner management services 	<ul style="list-style-type: none"> •Health promotion and behavioural interventions •Partner notification •Outreach testing and screening programmes •Biomedical interventions (e.g. vaccination) •Outbreak response (clusters of infections) •Surveillance, epidemiological analysis and research

Public health components. Public health activities need to be adapted to the epidemiological situation, the specifics of the national and/or local situation, and consider the risk groups. It may be beneficial for STI prevention and control activities to be linked to other public health programmes, such as sexual and reproductive health, HIV prevention and control, or public health programmes targeting the same risk groups. Approaches may vary between countries and depend on the observed STI epidemiology, prevalence rates and trends, and distribution of risk groups and sexual networks. The approach will also depend on the structure of public health organisations, stakeholders, legislation and budget allocation. Regardless of the organisational structure, the following public health components can be considered:

- **Health promotion and behavioural interventions** may target the general population, school children, adolescents, particular risk groups, and family planning clinics to improve the understanding of sexual and reproductive health in general. Interventions may also increase awareness of safer sex behaviours and tools, e.g. barriers methods (such as condoms), microbicides, vaccines, and pre- and post-exposure prophylaxis. Behavioural interventions may be specifically targeted at groups with high-risk behaviours to promote risk reduction strategies and safer sex practice, e.g. reduction in the number of casual sex partners, consistent condom use [23].
- **Partner management** services include notifications about the exposure of sexual partners after obtaining the index case's informed consent, and offering contacts appropriate testing and treatment options. Partner management services can be offered through the healthcare provider such as a nurse or doctor (provider referral), or as client-initiated notification (patient referral). Patient referral is the preferred approach in many European countries even though there is limited evidence on which strategy is the most effective in reducing the prevalence of re-infection [28]. Partner notification may include electronic communication, i.e. text messaging and web-based systems, and printed materials, i.e. leaflets, cards, etc. Partner management services should be considered for all patients diagnosed with an STI, irrespective of whether the diagnosis was made in specialist clinics or in primary- or community-based settings. All potentially exposed sexual partners need to be reached in order to interrupt transmission chains and prevent clusters and/or outbreaks [27]. Partner management services need to be assessed regularly to ensure quality standards [28]. They also contribute to the understanding of the epidemiology of infection and inform public health responses [29].
- **Outreach testing and screening programmes** can be planned to reach populations at risk (e.g. MSM, sex workers, adolescents or young adults, pregnant women) and aim to detect (asymptomatic) infections, prevent development of complications, and limit further spread of disease. They should be tailored to the epidemiological circumstances and informed by scientific evidence for effectiveness [13,30]. When delivered in a comprehensive manner, they can include health promotion and partner services as well.
- **Biomedical interventions** (e.g. vaccination) can be offered against a limited number of sexually transmitted pathogens, i.e. human papillomavirus (to prevent the development of cervical cancer, genital warts) and hepatitis A and B viruses. In addition to vaccination, other biomedical interventions may be

considered in the prevention of STIs, such as the application of microbicides or male circumcision (for the latter there is less evidence of public health benefits in high-income countries) [31,32].

- **Outbreak response** actions may be needed to investigate clusters of infections, identify early infections and link them to effective treatment. Clusters are generally investigated if the number of notified cases of an STI have increased rapidly, for example a rise in the number of infectious syphilis cases within a certain location or clearly identified risk group (for example cases among sex workers or MSM), or if a previously rare infection re-emerges [33,34].
- **Surveillance, evaluation, epidemiological analysis and research** are needed for informing prevention and control policies and activities. Ideally, comprehensive surveillance data should be combined with behavioural surveillance data, stratified by demographic and sexual determinants (e.g. age, gender, sexual orientation, sex work), in order to inform strategies and to direct prevention and control activities. In general, surveillance is aimed to detect changes in STI epidemiology and has to generate hypotheses regarding the determinants of those changes. The ongoing evaluation of certain additional indicators can help inform future plans and become instrumental in the revision of STI strategies. Subsequently, applied public health research should focus on testing hypotheses and generating robust evidence for decision-making.

3.5. A model for sexual transmission of infections

Sexual transmission of infections may be presented as a compartmental model that includes the susceptible, the infected and the recovered status (SIR) of an infection, as introduced by Anderson and May [17]. Figure 4 presents the determinants of transition from susceptible to infected, as well as the determinants of transition from infected to recovered. It also identifies possible interventions targeting these compartments: 1) reduce the probability of transmission, 2) reduce the contact rate, 3) reduce the duration of infectiousness, and 4) prevent the development of complications.

Susceptible individuals can become infected through sexual contact with an infected partner. This is mainly determined by the transmissibility of the pathogen and degree of risky sexual behaviour of the susceptible individual (e.g. condom use, the rate of new sexual partner acquisition, sex with partners from a high-risk group, roughness of sex acts, etc.). The prevalence of infection within the population or the sexual network from where the sexual partners is recruited is another determinant that will influence the risk of exposure to an infected partner [23]. The transition from susceptible to infected can be interrupted through several prevention and control measures:

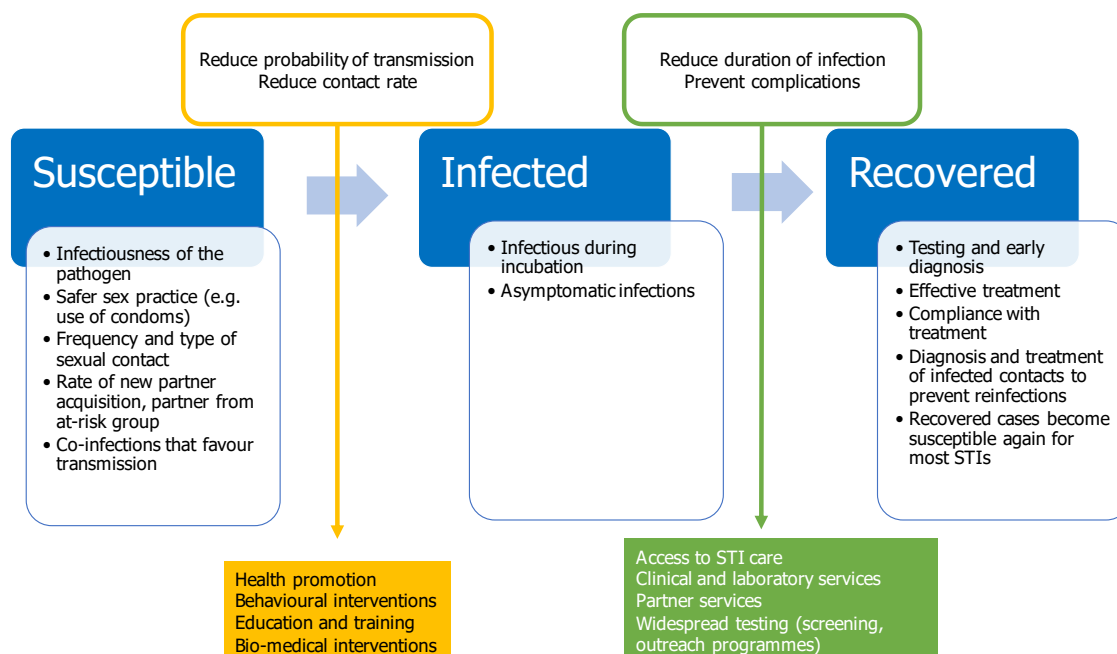
- Reduction of the probability of transmission by engaging in health promotion (to increase general awareness of STIs and induce behavioural changes), education and training (to increase understanding of, and knowledge about, STIs; train staff and teachers) and bio-medical interventions (e.g. vaccines, microbicides).
- Reduction of the contact rate (or the rate of new partner acquisition) by behavioural interventions (e.g. promoting the reduction of the number of new sex partners or abstain from sexual activity). Health promotion, education and training (of medical, public health, educational staff to promote safer sex messages) are additional interventions to reduce the contact rate.
- Interventions that target core groups and bridge populations that have a high rate of sexual partner change; interventions should be effective in reducing transmission and subsequently reduce the prevalence of infection at the population level [16].
- Shortening the duration of infection by initiating public health screening programmes and outreach testing activities that can detect asymptomatic infections at the population level or among specific risk groups; public awareness campaigns that promote and encourage testing; and promotion of self-testing and/or home sampling. Partner management services can detect and cure asymptomatic infections in sexual partners and encourage symptomatic partners to seek medical care. The duration of infection is affected by how early an infection was diagnosed and when treatment started. In the absence of symptoms, there may be no diagnosis and treatment¹ and the infection can either resolve itself or persist and can be transmitted further through sexual contact or during pregnancy.

The interventions mentioned above may help infected people to recover and thus prevent the development of complications and of long-term sequelae that can have a strong impact on sexual and reproductive health, especially among women. Early linkage to care and the provision of effective treatment (i.e. treatment that

¹ Infected individuals may be infectious during the incubation period (the period between exposure and the appearance of symptoms) and they will not be aware of the risk for their sexual partners. In addition, some STI (e.g. chlamydia infection, gonorrhoea) do not always produce symptoms and the infected individuals may be asymptomatic for the entire duration of infection. Since most sexually transmitted infections do not leave long-lasting immunity, infected individuals become susceptible again after treatment and restart the cycle.

eliminates the pathogen) are important factors to prevent complications [16]. Treatment should be based on evidence-based treatment guidelines and ensure the patient's compliance.

Figure 4. Theoretical framework for STIs: main determinants of transmission and possible interventions



4. Developing a national strategy and an action plan for STI prevention and control

4.1. Introduction

This chapter proposes an approach for the development of a national strategy for STI prevention and control in countries where there is no such a strategy or where an existing strategy may need updating. The development of a strategy usually follows a political decision on a vision (future outcomes decided by a government) and the formulation of a policy (general direction and principles of approach). In other words, a strategy is the technical translation of the policy to pave the way toward its practical implementation.

Some guiding principles, such as consistency and alignment with existing national and international relevant strategies, are described in the first part of this chapter. The second part describes the steps proposed for the development of a strategy and an action plan. An action plan involves detailed planning to meet the targets that were set in the strategy [35]. An action plan specifies who does what, how, when and where, and also outlines the required financial and human resources.

4.1.1 Guiding principles

Alignment with relevant national strategies and policies

While not necessarily focused on STIs, certain national strategies may influence STI prevention and control. These may refer to public health or its social determinants in general, or, more specifically, to sexual health, sex education, HIV prevention, etc. [36]. Alignment and (where possible) integration with related strategies within and outside the health sector, as discussed previously, is an important component of a multisectoral approach to the prevention and control of sexually transmitted infections.

Here is a non-exhaustive list of areas that may be covered by national policies, strategies, legislation or regulations:

- Public health
- Communicable disease control
- HIV prevention and control
- TB prevention and control
- Healthcare services – Primary healthcare
- Mother and child health
- Harm reduction services/addiction care
- Commercial sex work policies
- Human trafficking
- Health insurance system.

As STI strategies are commonly implemented by an action plan, activities in related policy areas may be directly affected. Aligning new STI strategies with existing strategies reduces the risk of conflicting interaction and should be based on the principle of complementation rather than competition for resources. This applies to harm reduction services (targeting injecting drug users); TB prevention and control (dealing with social exclusion, homelessness and other factors that may relate to STI determinants); human trafficking; prostitution laws; nosocomial hygiene policies (dealing with prevention and control of blood-borne infections, including HBV and HCV); antimicrobial resistance; food safety policies (e.g. in relation to hepatitis A virus and *Shigella*), etc.

When strategy areas are very closely related in terms of content and stakeholders, an integrated approach to strategy development should be considered, for example in areas such as STI prevention and control, sexual and reproductive health, and HIV prevention and control. Since the organisation of stakeholder networks and (public) health structures varies between countries, any integrated approach will depend on the specific national situation (e.g. national sexual health strategies of France [37] and Ireland [38]).

During the development of a new national STI strategy there may be occasions when revision/updating existing strategies is desirable. The coordination and governance mechanism for the STI strategy development process has to be able to accommodate communication and coordination ('strategic dialogue') between the different public health sectors.

Alignment with international strategies and action plans for STI

STI strategy planners should aim for consistency with relevant international strategies and action plans and align national targets with global or regional targets (where appropriate). The main international STI strategy relevant to the EU/EEA is the WHO *Global health sector strategy on sexually transmitted infections 2016–2021* [6]. The

strategic vision outlined by WHO strategy is 'Zero new infections, zero sexually transmitted infection-related complications and deaths, and zero discrimination in a world where everybody has free and easy access to STI prevention and treatment services, resulting in people able to live long and healthy lives' with an ambitious goal of 'ending sexually transmitted infection epidemics as major public health concerns by 2030'. WHO prioritised and set global targets² for syphilis, a '90% reduction of *T. pallidum* incidence' and gonorrhoea, a '90% reduction in *N. gonorrhoeae* incidence', with 2018 as global baseline. Targets were also set for congenital syphilis and human papillomavirus vaccine coverage (see Box 1). The global strategy is framed within the context of the 2030 UN Sustainable Development Goals and takes a public health approach, instead of restricting activities to healthcare only. WHO states that 'each country should have a national programme focusing on sexually transmitted infections, with the necessary resources and capacity to implement a relevant national strategy and plan, and to monitor and report on progress.' A set of three priority actions is described in the strategy document (Box 2).

Box 1: WHO Global health sector strategy on sexually transmitted infections 2016–2021, global targets for 2030

A concerted effort to rapidly scale up effective interventions and services can achieve the goal of ending sexually transmitted infection epidemics as public health concerns by 2030, by reaching this ambitious set of targets:

- 90% reduction of *T. pallidum* incidence globally (2018 global baseline)
- 90% reduction in *N. gonorrhoeae* incidence globally (2018 global baseline)
- 50 or fewer cases of congenital syphilis per 100 000 live births in 80% of countries
- Sustain 90% national coverage and at least 80% in every district (or equivalent administrative unit) in countries with the human papillomavirus vaccine in their national immunisation programme.

Source: [6]

Box 2: WHO Global health sector strategy on sexually transmitted infections 2016–2021, priority actions for countries

- Strengthen the governance and accountability of programmes relating to STIs and conduct regular programme reviews to help ensure that national strategies, plans and resource allocation reflect actual country needs as they evolve.
- Set national targets and milestones and identify indicators for monitoring and evaluating the national STI programme, as well as for monitoring equity so that countries can assess and regularly report on the status of their response and use those assessments for further programme improvements.
- Ensure that relevant monitoring and evaluation frameworks track the entire continuum of services in both the public and private sectors, and are harmonised with other health information systems, and are set up to track equity through appropriate disaggregation and analysis; use subnational data collection and mapping techniques to detect deficiencies in service provision and infrastructure, and to help inform decisions made on where to place additional services; monitor access to, and uptake and quality of sexually transmitted infection services for specific populations.

Source: [6]

Multisectoral approach

Multisectoral coordination refers to deliberate collaboration among various stakeholder groups (e.g. government, civil society, and private sector) and sectors (e.g. health, education, environment, economy) to jointly achieve a policy outcome [39]. Alignment and (where possible) integration with related strategies within and outside the health sector, as discussed previously, is an important component of a multisectoral approach to prevent and control sexually transmitted infections.

The structure of public health structures in the EU/EEA Member States is characterised by diversity [40]. Moreover, there is no common European format for the public sector: the current situation in each country reflects historical developments and choices in various contexts. For example, Austria used to have a 'Ministry for Health and Women's Affairs' (until January 2018, now renamed), while the Netherlands group public health with welfare and

² WHO targets were selected at a global scale following an expert consultation. Main considerations were the availability of cost-effective interventions and the possible use of existing reporting frameworks to reduce reporting burden. They reflect global priorities, and much of the focus is on the STI burden in Africa.

sports ('Ministerie van Volksgezondheid, Welzijn en Sport'). In the example of Austria, issues of women's rights and health would be close together 'in one sector' while in the Netherlands they would be considered as belonging to different public sectors. This may have consequences for how well aligned policies and strategies are.

Therefore, it will be useful to analyse the general structure of a country's public sector and identify which sectors have a stake in STIs and sexual health. In addition to engaging all relevant sectors in the strategic dialogue, it will be advantageous to also involve all sectors in the implementation of the action plan (see roadmap for 2018–2020 for the French national sexual health strategy for a list of national agencies and institutions, academic societies, professional associations, and other organisations involved in strategy development [41]).

Another vital element is the involvement of civil society. Various non-governmental organisations (NGOs) are active in the area of awareness raising and education or sexual health service provision. These NGOs should be considered when identifying the key stakeholders that should be involved in the strategy [42]. The size of the organisation and the specificity of their activities to the STI field should be assessed prior to selection.

4.2. Process of strategy and action plan development

This document proposes seven steps for the strategy development process (Box 3). The process should start with the formation of a coordinating body in charge of steering the entire process. Early on in the process, key stakeholders should be identified to ensure their input and buy-in. A situation analysis describing the current STI epidemiology (e.g. sub-populations at risk, healthcare service provision) should be performed at an early stage. Once the strategy document is considered complete and endorsed by stakeholders, it should be translated into an action plan that makes the best use of the available resources. When the action plan and the related regulation and funding mechanisms are endorsed, the strategy can be implemented through programme activities. The final step in this strategic planning cycle is monitoring and evaluation.

This strategy development process proposal is not prescriptive; the number of steps and the steps chosen depend on the coordinating body's judgement, the key stakeholders and the national context.

Box 3: Proposal for strategy and action plan development process

- Establish a national coordination mechanism
 - Establish a coordination and governance structure
 - Perform stakeholder mapping and define partnership commitments
 - Define initial country-specific strategic scope
- Engage stakeholders in the process
- Perform a situation analysis
 - Describe STI epidemiology, identify priority groups
 - Perform an inventory of the status of STI prevention and control capacities and capabilities
 - Conduct a national SWOT analysis and a gap-analysis
 - Assess existing relevant strategies (e.g. HIV, hepatitis, sexual health, etc.)
- Develop the strategy document
 - Revise/finalise/establish the scope of the national STI strategy
 - Set strategic objectives
 - Set targets and indicators for monitoring and evaluation (considering international indicators)
 - Define key success factors
- Develop an action plan
 - Translate strategic objectives to timelines and milestones
 - Identify and mobilise resources, both human resources and funding
 - Establish coordination and programme management
 - Perform a risk assessment of barriers to action plan implementation
 - Communication of implementation progress to stakeholders
- Coordinate and manage the action plan implementation
 - This should ensure that STI prevention and control capabilities are in place.
- Develop a monitoring and evaluation plan

It is important to underline that the strategic planning process is not a single linear process, but an iterative one. The monitoring and evaluation step should generate data for an updated situation analysis, in terms of capabilities, capacities, performance and epidemiology. This creates a loop to step 3 of the process ('Perform a situation analysis'). In this loop, we can recognise the generic circular process of strategic planning (Figure 5).

Each of steps in Box 3 are explained in more detail below.

Figure 5. Strategy cycle: planning, implementing, monitoring

4.2.1. Step 1. Establishing a national coordination mechanism

National policies, strategies and action plans are more robust and more likely to be implemented effectively when the development process ensures the inclusion of relevant competent authorities and stakeholders. Sound, transparent governance and oversight are essential at all stages of the preparation as is the sustainable implementation of national strategies [35].

Coordination and governance structure

During the initial phase, a national coordination and governance body (CGB) should be created and appointed. The CGB can be a committee, working group, task force, or organisation. Ideally, the CGB is appointed by the institution responsible for the national STI strategy, which is often the ministry of health. The CGB should include representatives from the political, policymaking level (e.g. ministry of health, health department), as well as representatives from organisations/technical levels that will be responsible for planning, coordination and implementation of the strategy. The CGB will be actively involved in stakeholder mapping and defining the scope of the strategy. It will be responsible for managing and directing the strategic and operational planning process. The CGB may decide to organise technical working groups, with technical experts in STI-related areas, such as public health, epidemiology, health promotion, health services, STI clinical care, laboratory, and guidelines development, which will provide the CGB with technical input.

It may be important to produce dedicated terms of reference that set out the mandate of the CGB. This is not only useful to guide the CGB members, but also to communicate the mandate clearly to all stakeholders. A sample template for terms of reference can be found in Annex 2.

Stakeholders mapping

One of the first activities of the CGB will be the mapping and analysis of stakeholders. Identifying key stakeholders starts with creating a list of all possible stakeholders. These are entities who could have an interest in STI prevention and control strategy at the national level, including persons, structures or organisations outside of the health sector that could affect (or be affected by) the strategy. Stakeholders may be identified among the following sectors: political (legislators, governors), public authorities (ministry of health, social security, ministry of finance), labour (unions, medical associations), commercial/private organisations for profit and non-profit (NGOs, foundations, health insurance companies), civil society, patient interest groups, etc. Identifying the level of engagement of each stakeholder should clarify whether it is necessary to actively engage with them, consult them, or simply keep them informed. International organisations (ECDC, WHO, IUSTI) may also be considered. There are many tools available online for stakeholder analysis (see Chapter 5 of this report).

Definition of the country-specific strategic scope

At this stage, it is important to formulate an initial scope for the national STI strategy to give focus to the situational analysis and the analysis of strengths, weaknesses, opportunities and threats (SWOT analysis, step 3 below). For example, if the strategy is related to a policy which is restricted to bacterial sexually transmitted infections, then the initial scope should be restricted to this type of infection. If the policy framework is broader, for example if sexual health as a whole is covered, the scope of the strategy needs to be enlarged to cover all infections that affect sexual health. If the STI strategy has to be integrated with other relevant strategies, this requires adjusting the scope accordingly.

4.2.2. Step 2. Engaging stakeholders throughout the process

All identified stakeholders should become involved in the strategy development process. Involving stakeholders at an early stage will ensure broad support. Keeping the stakeholders involved for the entire duration of the strategy development process will allow them to contribute knowledge and expertise.

Stakeholders may also help by defining more realistic objectives and targets for the strategy and translate them into practicable action plans. Chapter 5 provides examples of stakeholder engagement.

4.2.3. Step 3. Performing a situation analysis

National situation analysis

A good situation analysis should assess the STI burden, identify population groups at risk, and describe the main drivers of STI transmission. In addition, it should provide an overview of relevant policies, ongoing public health activities related to STI, healthcare system resources for STI case management, and a mapping of partners and their roles and responsibilities. Based on this information, an evidence-base for priority settings for the STI strategy and the action plan linked to it can be produced. International strategies and targets for STI prevention and control may be considered for inclusion in the situational analyses.

Good-quality data on the occurrence of STI may be obtained from national/regional surveillance systems and through research studies. Using national/international standards to set up and evaluate surveillance systems and helps achieve good quality of data.

The situation analysis should include a description of healthcare services for STI case management (diagnosis, treatment, partner services). Clinical care providers are among the primary data sources for epidemiological intelligence (identifying clusters, outbreaks of STIs) and surveillance databases. It will be important to understand if diagnostic capacity is homogenous across country or there are regions without access to laboratory services, and thus STI underdiagnosis and underreporting are expected.

Other elements to be included in a situation analysis are a description of capabilities for public health interventions, prevention programmes targeting STIs, data collection mechanisms, and surveillance systems. At this stage, the situation analysis should provide an overview of STI occurrence in the population and its determinants, an overview of healthcare system capacities and resources for STI case management, and a description of public health prevention and control programmes and their activities. The main elements of a national situation analysis for STIs are listed below.

National situation analysis for STI – recommended elements

- Epidemiological information on STI occurrence and determinants:
 - STI burden and trends, STI epidemiology, risk groups
 - Identification of main drivers of STI transmission in the country
 - Information on antimicrobial resistance (e.g. multidrug-resistant (MDR) gonorrhoea)
- Evidence on perceptions and behaviour related to known drivers of STIs, such as:
 - Awareness and understanding the risk for STIs
 - Stigmatisation of STIs and discrimination
- Capabilities for STI case management:
 - Clinical and laboratory services for STI diagnosis and treatment
 - Description of role, responsibility, mandate and capacity of organisations (public and private) involved in the diagnosis and treatment of STIs
 - Legislation, regulation, policy or planning documents in relation to access to STI care
 - National guidelines related to STI case management and professional standards for effective treatment for STIs
 - Professional training for clinical and educational staff working with STIs
- Capabilities for public health prevention and control programmes:
 - Health promotion and behavioural interventions
 - STI partner management services
 - Capabilities for outbreak response (operational guidelines and trained professionals for investigation of clusters or unusual increases in STI notifications)
 - Screening programmes
 - Biomedical interventions: e.g. vaccination programmes targeting STIs and their coverage; use of micro-biocides
 - Description of existing STI surveillance systems; the STI covered, surveillance system structure and coverage
 - Description of recent STI studies (epidemiological, microbiological, sociological)
 - Description of role, responsibility and mandate of organisations involved in surveillance and research of STIs.

- Level of integration of STI prevention and control activities with activities related to risk populations, for example HIV-positive people, TB patients, and people who inject drugs.

SWOT analysis and gap analysis

An analysis of strengths, weaknesses, opportunities and threats (SWOT) can be useful to better interpret the findings of the situational analysis by identifying factors that influence the overall STI situation, including legal and governance structures [43].

The main objective of the SWOT analysis is to clarify the priorities of the national STI strategy. The results of the situational analysis are categorised into 'strengths' and 'weaknesses'. In addition, it may be that some results are considered as 'opportunities', while others are seen as 'threats'. Once a consensus is reached on how the results are categorised, the CGB should perform a gap analysis [35]. This involves comparing the preferred vision on STI prevention and control (i.e. the 'ideal' or 'desired' situation) with the current situation as described by the situation analysis. The gap analysis should result in a list of characteristics such as attributes, competencies, performance levels of the present situation, and factors needed to achieve future objectives.

If the CBG has not yet been able to develop a detailed vision of the preferred situation, the CBG should focus on the results of the SWOT analysis instead and conduct an additional high-level gap analysis (see Annex 3). Since strategic planning is a cyclical process, it is likely that during the next cycle a more detailed gap analysis will be possible.

4.2.4. Step 4. Developing the strategy document

Four sets of decisions (elaborated below) inform the strategy document.

Finalise the scope of the national STI strategy

In many instances, the scope of the strategy that was formulated in the early development stages needs to be reviewed in order to:

- establish the final focus in the strategy (e.g. priority diseases, priority target groups, etc.);
- help set targets for the strategy;
- identify work priorities and the proportion of health resources to be dedicated to the prevention and control of STIs; and
- indicate contributions to the action plan for all involved stakeholders (e.g. national public health institutes, laboratory services, STI clinics, healthcare organisations, NGOs, civil society organisations, social services, etc.).

Insights from the SWOT analysis should be used to refine and finalise the scope. Since strategic planning is a circular process, the strategic scope is reviewed regularly as part of the strategic planning process.

Understanding the STI policy context is also important in setting the scope for the STI strategy. For example, if a country has defined a policy aiming to enhance sexual health, then it makes sense to choose the broad scope for the strategy, not just including prevention and control of STIs, but integrating this with other determinants of sexual and reproductive health.

Vision and scope are related, as the technical scope should match the vision that is provided by the political level. Box 5 provides an example of a vision statement, translated from the 'National action plan STI, HIV and sexual health 2018–2022' from the Ministry of Health in the Netherlands [44]. This vision focuses on sexual health, providing sufficient room for formulating strategic goals that will guide the national STI prevention and control capabilities. In this example the (technical) strategic scope will need to be broad enough to address all aspects of the vision. Other examples can be found in the documents included in Annex 5.

Box 5: 'National action plan STI, HIV and sexual health 2018–2022', Ministry of Health of the Netherlands

Vision

In the Netherlands, a positive approach to sexuality and comprehensive sex education is seen as the foundation for sexually healthy life. Attention is paid to encouraging sexually healthy choices and sexually healthy relationships, as well as to preventing and reducing problems related to sexual health. The negative effects on health and welfare brought about by the transmission of STIs and HIV, sexual violence and unwanted pregnancies will be curbed as much as possible. Values related to sexual health (personal autonomy, resilience, respect and understanding of reciprocity) and sexuality education are essential; proper and integrated assistance and care for sexual health are ensured [44].

Strategic goals

Strategic goal 1. Residents of the Netherlands are well informed and capable of making choices about their sexual health, aiming for sex that is pleasant, voluntary and safe, and free from STIs and HIV, sexual violence, and unwanted pregnancies.

Strategic goal 2. Residents of the Netherlands have access to appropriate, affordable health facilities, care, advice, support and protection if they need help or have problems related to their sexual health, including STIs and HIV.

Set strategic objectives

Any STI strategy should include objectives that can be achieved over a specific period of time, usually over the next 3–5 years. Strategic goals should comply with the 'SMART' approach: specific, measurable, actionable, realistic, time-bound [35]. To measure the successful achievement of objectives, a strategy should also include indicators and targets for each objective, for example 'eliminate congenital syphilis and other adverse pregnancy outcomes related to syphilis during pregnancy'. Indicators could include the 'annual percentage of pregnant women screened for syphilis during the first trimester of pregnancy' and the 'percentage of syphilis-positive pregnant women treated'. In addition, associated targets could be spelled out: 'By 2020, 95% of the pregnant women will be tested for syphilis in the first trimester', and 'All infected pregnant women receive treatment appropriate for the stage of infection'.

Box 6 presents two of the strategic targets, taken from the Bulgarian 'National Programme for Prevention and Control of HIV and Sexually Transmitted Infections, 2017–2020' [45].

Box 6: Targets of Bulgarian 'National programme for prevention and control of HIV and sexually transmitted infections, 2017–2020'

Target 5: By 2020, antenatal screening coverage for syphilis and HIV reaches 95% and 90%, respectively, of all pregnant women.

Target 6: By 2020, reduce the number of *T. pallidum* infections, the number of *N. gonorrhoea* infections, and the number of congenital syphilis cases by 90%, with 2015 levels as baseline. [45]

Define key success factors

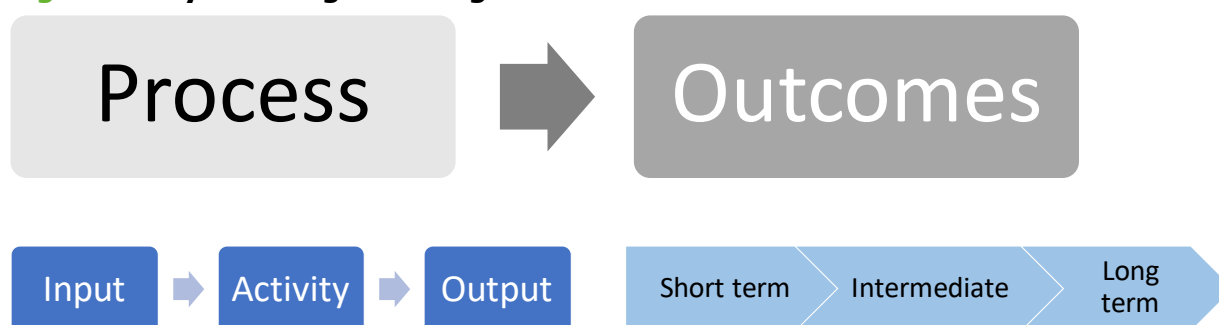
A strategy should include a list of key success factors that are used to measure the success of the strategy, for example factors that need specific attention during strategy implementation in order to achieve the goals and objectives. The government of Queensland, Australia, has chosen ten indicators to measure the success of their sexual health strategy 2016–2021 to realise their public health vision (e.g. 'All Queenslanders experience optimal sexual and reproductive health') [46]. Although the strategy has four strategic directions, the key indicators of success are defined for the strategy as a whole.

Key success factors express what all committed stakeholders must do to achieve the objectives outlined in the strategy. This can, for example, refer to how capacities (e.g. human resource, budget) and capabilities (e.g. surveillance systems, partner management services, behavioural interventions, etc.) are linked. In this context it is not merely sufficient to have staff allocated to behavioural interventions but staff also need to feel confident in their job qualifications and the quality of their work. If a gap analysis shows that some skills are not sufficiently developed, a training and capacity building segment must precede all further actions.

If there is already a culture of accepting clinical standards in the country, this could be a good basis for a consensus on a broader national strategy for STI prevention and control. In addition, awareness of the importance of STIs at the government level is considered another key success factor, as well as ensuring strict monitoring of the progress of the action plan.

Set indicators and targets for monitoring and evaluation

A monitoring and evaluation framework is essential to ensure that the strategy is implemented as planned and targets are achieved. It should be established early during the strategic planning phases [35]. Monitoring and evaluation indicators can be framed according to a general logic model (Figure 6). Process indicators will measure inputs, activities and outputs, and reflect the functioning of the processes [47]. Performance indicators will measure programme outputs and outcomes and monitor progress towards achieving the objectives. They are also useful in evaluating the overall success of the strategy and inform strategy reviews if needed.

Figure 5. Layout of a general logic model

Adapted from CDC evaluation guide: developing and using a logic model [47]

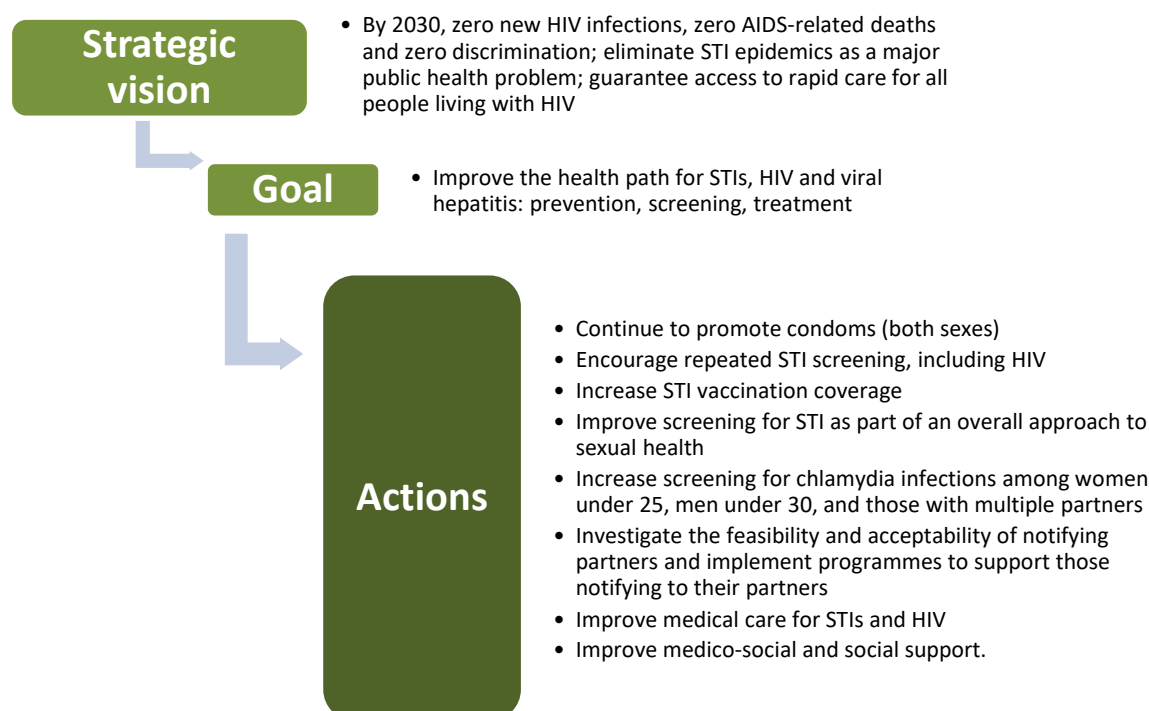
It can be difficult to distinguish between outputs and outcomes, or between outcomes and impact. For example, inputs into the health system (e.g. financing and infrastructure) can be reflected in outputs (e.g. availability of services and interventions) and be associated with outcomes (e.g. intervention coverage) and generate impact (e.g. improved health outcomes) [48].

Objectives need to follow SMART criteria (specific, measurable, action oriented, realistic, time-bound), the indicators – to introduce another acronym – should be RACER (relevant, acceptable, credible, easy, robust). The criterion 'relevant' means that the indicator needs to correlate with the objectives of the action plan. It has to be 'acceptable' for the stakeholders. It has to be 'credible' or unambiguous and easy to interpret. It needs to be 'easy' to document through available resources and with a data collection effort that is proportionate to the task at hand. Finally, it needs to be robust, meaning that it should be sensitive enough to monitor changes [49].

4.2.5. Step 5. Developing an action plan

Once the general strategy has been approved and supported by key stakeholders, it is important to create an action plan to guide the implementation.

An action plan aims to take every single strategic goal of the strategy and define actions, set a timeline, allocate resources, and stipulate performance indicators. One strategic goal may require one or more actions (Figure 6). Every action should have an 'owner', i.e. an organisation responsible for the implementation.

Figure 6. Example of translation of a strategy vision and goal into actions

Adapted from: Feuille de route stratégie nationale de santé sexuelle 2018–2020 [41]

Table 3 provides an example for an operational plan with fictitious objectives and targets for country X (adapted from WHO [35]). For each activity and sub-activity a number of data points are defined: date/period during which the plan will be implemented, the plan's implementation setting, involved people, sector or institution in charge of the implementation, the cost of the implementation, and the funding source. There should also be defined indicators and milestones and targets that can be used to monitor the implementation.

Table 3. Example of an operational plan with objectives and targets

Strategic goal 1: Elimination of congenital syphilis									
Year 1									
Strategic target 1.1: Achieve antenatal screening coverage of 95% for syphilis testing during first trimester of pregnancy									
	Unit	Quantity	Date	Location	Implementer	Cost in EUR	Source of funding	Output	Other
Activity 1.1: Ensure capacity for antenatal screening in each municipality									
Sub-activity 1.1.1									
Certify labs for antenatal screening									
Sub-activity 1.1.2									
Train family doctors, obstetricians and midwives									
Sub-activity 1.1.3									
Provide materials, financing structure and logistics to municipalities									
Activity 1.2: Health education campaigns advocating importance of antenatal screening									
Sub-activity 1.2.1									
...									
Sub-activity 1.2.2									
...									

The action plan should include details on resources, roles, responsibilities and operational steps to implement the strategy. Lack of funding may be a barrier to creating an action plan but not being able to fully fund an action plan should not prevent a Member State from developing a strategy as an important first step.

4.2.6. Step 6. Coordinating and managing the action plan implementation

Once the action plan has been completed, endorsed and supported, it is ready for implementation. Since the action plan will likely be comprehensive, covering national coordination, clinical services and public health components, implementation should be carried out in 'programmes' (e.g. a chlamydia screening programme for young adults).

Each of these programmes should have a programme manager who is responsible for the implementation and operation of all activities. The programme manager is accountable to the CGB and submits regular progress reports. This will be facilitated by the monitoring and evaluation plan as outlined below.

4.2.7. Step 7. Developing monitoring and evaluation plan

There are several reasons for the monitoring and evaluation of STI strategies:

- Monitor implementation: for example, a treatment programme may be very effective for those who complete it, but the number of participants may be low. Programme evaluation seeks to identify possible steps that can improve the situation, e.g. suggest a different physical location of the programme offices or identify the lack of transportation as a barrier to attendance.
- Measure effectiveness: progress is measured towards the goals and the relative effectiveness of the various strategies.
- Ensure accountability: evaluation provides a means of accountability to stakeholders such as policymakers; state, local, and community leaders; and funders.

In general, the evaluation objectives fall into several categories and answer the following questions:

- Implementation: Were the activities actually carried out as originally intended?
- Effectiveness: Have the objectives been able to achieve what was intended?
- Efficiency: Are the activities making the most appropriate use of resources such as budget and staff time?
- Cost-effectiveness: How does the value or benefit of achieving the objectives compare to the cost of producing them?
- Attribution: Can progress on objectives be shown to be related to the strategy activities, as opposed to other developments that are going on at the same time?

The evaluation questions are asked with the intention of documenting the programme's progress, demonstrating accountability to funders/policymakers and in order to identify ways to improve the programme. Annex 4 provides an outline for a strategy document, based on the approach described in this chapter.

4.3. Case studies

The case studies below show different approaches of developing a national strategy and were provided by the participants from Sweden and the Netherlands in the ECDC expert meeting on 'Development of national strategies for the prevention and control of STIs' held on 1–2 October 2018.

4.3.1. Sweden

Developing a strategy to limit the spread of HIV infection and other blood-borne or sexually transmitted infections

Following the 2001 United Nations General Assembly *Declaration of commitment on HIV/AIDS*, the Swedish government established a coordination mechanism group to lead the development of a Swedish STI strategy. The group chose a multi-sectoral joint response to define the national needs and priorities, bringing together government agencies, county councils, municipalities, national and regional civil society organisations, and a range of technical and professional experts.

In 2006, the government adopted *The national strategy against HIV/AIDS and some other communicable diseases, 2006–2016* [50], with the overall objective to limit the spread of HIV infection and other blood-borne or sexually transmitted infections and to minimise the consequences of those infections. The strategy established that the Unit for Sexual Health and HIV Prevention, which is part of Sweden's public health agency, would be given the task to promote the coordination of this joint effort and thus ensure that long-term preventive measures are taken in the area of STI control.

The Ministry of Social Affairs provided annual directives to the Unit for Sexual Health and HIV Prevention and set aside funding for national coordination, which included support to national/regional programmes and civil society organisations. Until recently, funds were also distributed to the county councils and municipalities to complement and strengthen ongoing work. National coordination has been exercised through different constellations of formalised forums and ad hoc reference groups to allow knowledge exchange and cooperation on, for example, policy, sub-strategies, research, pilot projects, information campaigns, and monitoring and evaluation.

In 2007, Sweden experienced a steep increase in the number of chlamydia cases following the identification of a new mutant variant. This led to the development of *The chlamydia action plan, 2009–2014* [51]. This was the only action plan directly linked to the strategy because this was the quickest way to address the needs of different population groups in a country with decentralised administration; the development of local guidelines would have taken much more time. In 2015, the guideline for *Health promotion and prevention work with hepatitis and HIV for people who inject drugs* was published. It successfully promoted – and eventually established – needle exchange programmes across the country. In these two cases, concrete guidance in the form of an action plan and a guideline linked to the STI strategy enabled decision-making at all levels and supported public health programmes in defined disease areas. These plans were developed with the involvement of stakeholders, and the implementation of measures was closely monitored by the Unit for Sexual Health and HIV Prevention. An evaluation of *The chlamydia action plan* was conducted when the programme ended, giving useful insights into what had been done and where improvements should be made.

Based on the changes that have taken place in the last 10 years, not least the development of highly effective treatment for HIV, an updated strategy was launched in 2017, followed by the development of indicators to allow for the monitoring of the strategy [52]. While the updated version is primarily a strategy for combating HIV infection (as well as stigma and discrimination as a result of HIV), in practice it promotes not only HIV prevention measures but prevention measures that are also relevant with regard to other sexually transmitted infections. The Unit for Sexual Health and HIV Prevention is currently supporting dialogue meetings to review the need for action in relation to the growing numbers of gonorrhoea cases.

Coordination and cooperation, follow-up and knowledge building have been the two key pillars of success in the Swedish response. Sufficient funding combined with cross-sectoral cooperation between national stakeholders were crucial in addressing public health needs. While it is clear that all stakeholders have different roles and represent different key populations, it is important to acknowledge the different strengths of each actor and the value they add to the response effort. One lesson learned is that transparent processes and a clear concept of the stakeholders' involvement translates into a meaningful dialogue, a feeling of ownership, and tangible results.

The Swedish response to STIs, with its coordination mechanism for stakeholders, the follow-up on implementation, and the ability to learn and feed knowledge back into the system, has proved to be an essential tool in STI prevention.

4.3.2. The Netherlands

Developing a national action plan on HIV, STIs and sexual health

When the Dutch Ministry of Health commissioned a strategic action plan on STIs from RIVM (National Institute of Health and the Environment), all existing policy documents were outdated: the policy on sexual health originated from 2009 and was updated once in 2011, and the *National plan on STIs and HIV 2011–2016* had expired. Various professionals, municipal public health services and organisations called for an update of the policy documents. RIVM was asked to produce a strategy that would focus on public health and be based on a consensus between key stakeholders working in the field of sexual health – all within existing budget lines.

RIVM held several rounds of meetings with stakeholders and managed to establish a consensus vision, with clearly defined strategic goals/targets and priority actions. The new *National action plan on STIs, HIV and sexual health* is based on an approach where sexuality is seen as a positive part of human experience [44]. The plan has six cornerstones, two of them are overarching topics: sex education and surveillance and monitoring. The other four cornerstones include specific objectives for STIs, HIV, unwanted pregnancies, and sexual violence, particularly among vulnerable groups. Sex education is seen as an important factor for a healthy sexual development and important for preventing STIs, HIV, unwanted pregnancies and sexual violence. Disease surveillance data, on the other hand, are needed for effective public health measures, medical treatment, and policy.

The action plan was presented to the Ministry of Health in December 2017. This approach shows that a consensus strategy can be developed successfully by engaging all stakeholders even though a national policy is absent.

5. Stakeholder engagement

5.1. Introduction

Engaging the right stakeholders to ensure optimal support for the strategy and its implementation is one of the critical success factors for a national STI strategy. This chapter assumes the presence of a coordinating governance body (CGB) as the owner of the strategy and that the CGB includes representatives of both the policy (political) level and the strategic (technical) level. As such, the CGB will be the central actor to perform the stakeholder analysis.

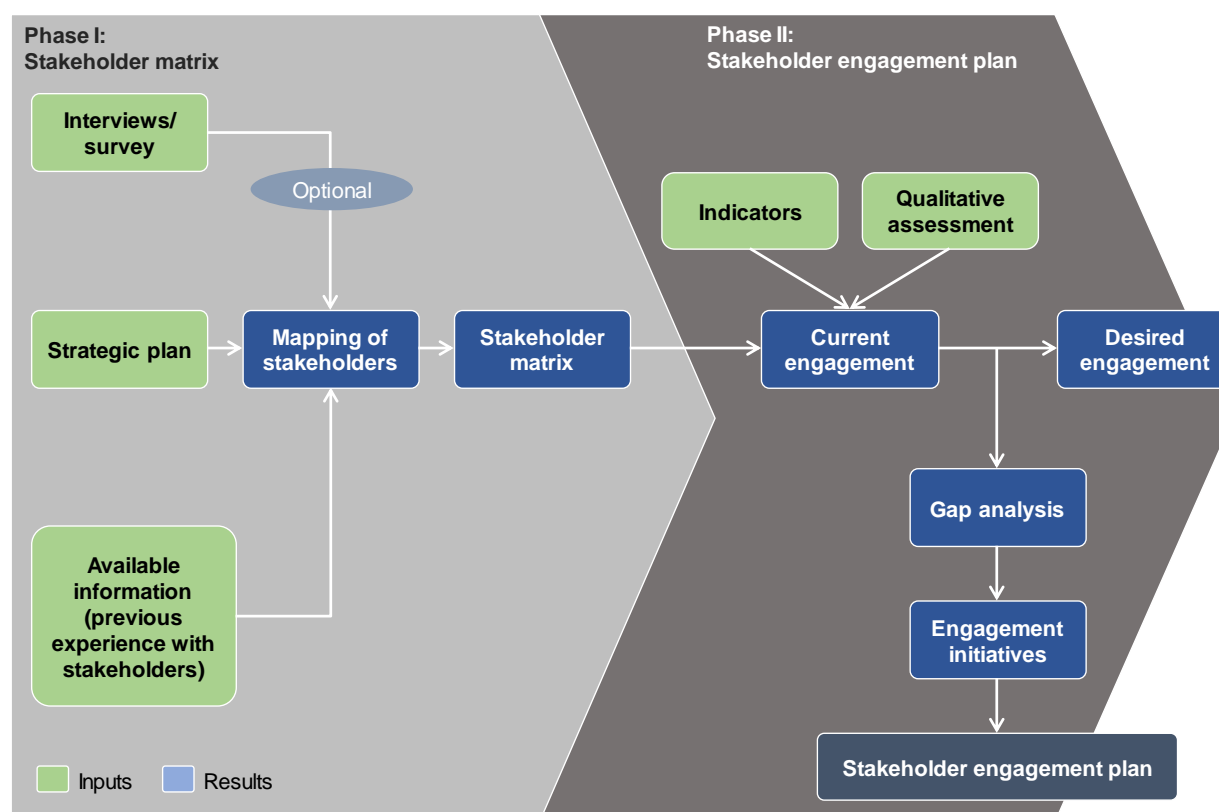
Stakeholders are defined in this context as: 'any group or individual who can affect or be affected by the goal, targets and activities of the STI prevention and control strategy' (paraphrased from Edward Freeman, *Strategic management: a stakeholder approach*, 1984, p. 46).

Stakeholder analysis is a methodology used to facilitate institutional, policy and strategy reform processes by accounting for, and often incorporating, the needs of those who have a 'stake' or an interest in the reform (strategy area) under consideration [53]. With information on stakeholders, their interests, and their capacity to oppose or catalyse reform (in this case, strategy goals), the planners can choose how to best accommodate them, thus assuring that the adopted policies are realistic and sustainable [54].

To ensure optimal conditions for the implementation of the strategy and action plan, the support of stakeholders needs to be carefully managed. The CGB needs to develop a solid stakeholder engagement plan to manage stakeholders' expectations and ensure the active involvement of the key partners. Engaging stakeholders throughout the strategic planning lifecycle gives a sense of accountability and enhances responsibility. In addition, it enables risk identification and response planning. This chapter provides a step-by-step approach to a stakeholder engagement plan.

5.2. Two-phased approach to stakeholder engagement

Understanding who are the stakeholders and recognising their importance is a critical first step for stakeholder engagement. The process of creating the stakeholder engagement plan broadly falls in two phases (see Figure 7).

Figure 7. Stakeholder engagement plan

Source: ECDC internal guidance on stakeholder engagement plan

Phase I starts with developing a stakeholder list/map that will be translated into a matrix that describes the stakeholders' interest in the national STI strategy and their influence on it.

Phase II consists an analysis of the identified stakeholders that will describe their current and desired engagement. A gap analysis between the current state and the desired state will generate a list of activities that can be incorporated in a stakeholder engagement plan.

The next section presents these generic principles of stakeholder engagement in more detail by giving examples related to stakeholders of an STI prevention and control strategy.

5.2.1. Phase I

Stakeholder mapping

The mapping starts with the creation of a list of stakeholders. The following questions can identify potential stakeholders:

- Who will be impacted by the strategy?
- Who will be responsible or accountable for the strategy?
- Who will have decision authority on the strategy?
- Who can support the strategy?
- Who can obstruct the strategy?
- Who has been involved in this type of strategy in the past?

The identified stakeholders can then be categorised in classes which reflect the situation in the country, for example:

- Providers (hospitals, dedicated STI clinics, dermato-venereologists, private clinics, laboratories, insurance companies, etc.)
- Users/beneficiaries (patients, healthcare workers, educators, etc.)
- Governance (ministry of health, ministry of finance, ministry of education, inspectorate of health, national institute of health, auditors, etc.)
- Influencers (media, professional associations, MSM associations, patient associations, civil society, ECDC, WHO, IUSTI, etc.)

The above examples depend on the specific healthcare structure of a country and can vary.

Before moving on to the next step, it may be useful to perform a final check to see if all important stakeholders are included. The following questions may be helpful:

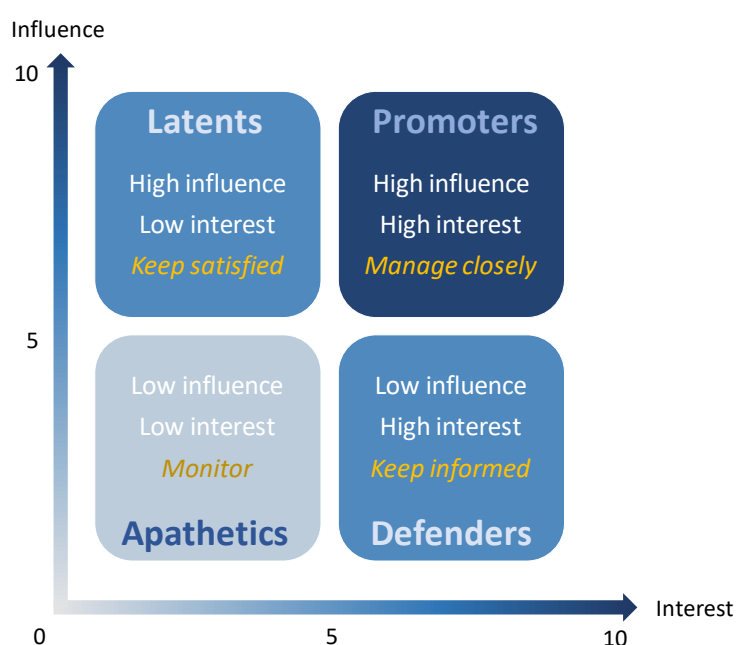
- Are there any other bodies that can make decisions in this area?
- Who is most dependant on the strategy?
- Who is a possible threat to one or more targets of the strategy?
- Who are the people with expert knowledge?
- Are there major activities that are affecting the stakeholders?
- How are we going to communicate the strategy? Who will support us in that task?

Stakeholder matrix

After completing the list, each stakeholder should be rated on a scale from 1 to 10 for the attributes 'influence' and 'interest'. The level of influence depends on a variety of factors such as the quantity and type of resources they have an influence on. The level of interest is defined by the importance that a stakeholder is believed to attach to the strategy. Both attributes signal the capability of the stakeholder to obstruct or promote the strategy. The stakeholder analysis therefore provides some understanding of the political, economic, and social impact of the strategy on interested groups [54].

Ranking stakeholders on a scale is a somewhat arbitrary process and may require discussions within the CGB. Once all arguments have been discussed and the group has decided on the final ranking, the results may be plotted on a matrix in four groups (see Figure 8).

Figure 8. Influence–interest matrix and categorisation of stakeholders



Inspired by World Bank Group, Stakeholder analysis [54] and Ackermann and Eden, Strategic management of stakeholders: theory and practice [55]

Promoters are stakeholders with high influence and high interest in the STI strategy and whose actions can have an impact on the operational plan and its implementation. They are key stakeholders and need to be managed closely.

Defenders are stakeholders with high interest in the STI strategy but whose actions may not really have an impact on the implementation. Though they do not have much formal influence, this group provides relevant context to the strategy and may be a strong defender of the plan. It is important to keep them well informed of the progress.

Latents are stakeholders whose actions can affect the implementation of the strategy but who probably attach a low priority to this policy. The influence of these stakeholders may be supportive or opposing to the strategy. In both situations it will be advisable to keep these stakeholders satisfied. The CGB could decide to try and work on increasing the level of interest of some of them in order to make them 'promoters'.

Apathetics are stakeholders whose actions cannot really affect the implementation of the STI strategy and who attach a low priority to this policy. It will be wise to monitor this group, yet they will not require as much time and energy as the other groups.

5.2.2. Phase II

Current and desired engagement

Once all stakeholders are mapped, the next step will be to address the desired level of engagement of each of them: what actions are needed with regard to this stakeholder, and what action will the stakeholder support? To determine the required actions, it is helpful to have documented the key points of interest for that stakeholder: what are their goals and motivations in general? What are their interests in STI prevention and control? The key question is: what behaviour of the stakeholder will support both the STI strategy and the stakeholder's own interest? This will make it easier to review the current type of engagement and assess if the engagement level is sufficient to achieve the desired action from the stakeholder. If needed, additional engagement activities should be planned to ensure their involvement (e.g. plan a meeting, send written requests, request advice, guidance, support, etc.).

In addition, mapping the stakeholders to the strategic objectives may also be helpful (Table 4).

Table 4. Example of stakeholders mapping by strategy objectives

Strategic objective	Stakeholder 1	Stakeholder 2	Stakeholder 3	Stakeholder N
Objective 1	X			X
Objective 2	X		X	
Objective 3		x		
Objective N	X		x	

Stakeholder engagement plan

The mapping above will provide insight into the type of engagement that will be needed per stakeholder group.

The next step is to decide on a comprehensive list of initiatives for stakeholder engagement: what should be discussed with which stakeholder? Where should this take place? Who will be invited to the discussion? What should be the outcomes of those meetings?

The final step is to incorporate all engagement initiatives into a stakeholder engagement plan. This plan has a description of roles and responsibilities: who does what when? CGB members should familiarise themselves with the details of the stakeholder engagement plan.

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Annex 1. Common STIs in the EU/EEA

Chlamydia trachomatis causes chlamydia infection and is the most commonly reported bacterial STI in Europe [8]. Genital chlamydial infection can cause urethritis, cervicitis, endometritis and salpingitis in women and urethritis and epididymitis in men [16,56]. In both men and women it may lead to conjunctivitis due to autoinoculation or during sex [57-59]. In approximately 70% of women and 50% of the men *Chlamydia* infection produces few or no symptoms and remains undetected and untreated, but can still be transmitted. Between 10% and 30% of women with untreated genital chlamydial infections develop pelvic inflammatory disease (PID), that can result in ectopic pregnancy, infertility and chronic pelvic pain [13]. Perinatal transmission can cause ophthalmia neonatorum and pneumonitis in newborns. Genital chlamydial infection can be effectively treated with antibiotics (single dose of azithromycin or doxycycline for seven days [56]) and is preventable through safer sex practices such as correct and consistent use of condoms. Sexual partners need to be evaluated to detect asymptomatic infections, prevent re-infection of the index patient and to prevent further spread of disease. Risk factors for genital chlamydia infection include young age, female gender, new sexual partner, multiple sexual partners, and inconsistent use of condoms [56]. Chlamydia infection is under epidemiological surveillance in the EU/EEA although with heterogeneous quality of data. The highest notification rates are observed among young people (15–24 years of age), with cases more frequently reported among young heterosexual women than men, which is the likely effect of testing programmes targeting young women. National notification rates of chlamydia infection vary considerably across Europe, between less than 0.1 and more than 600 cases per 100 000 population, with differences in chlamydia testing, case finding and reporting explaining the variation. In 2017, four countries reported 79% of the total of 409 646 chlamydia cases in the EU/EEA, a reflection of ongoing testing policies to detect and treat asymptomatic chlamydia infections and reporting practices. The real burden of chlamydia is likely to be higher, not only due to the considerable underreporting but also due to the high proportion of asymptomatic infections that remain undetected. In EU/EEA countries, chlamydia prevalence was estimated as 3.6% (95% CI 2.4, 4.8, I² 0%) in young women and 3.5% (95% CI 1.9, 5.2, I² 27%) in young men [60].

Lymphogranuloma venereum (LGV) is a systemic STI caused by specific serovars (L1-3) of *Chlamydia trachomatis*. LGV was considered a tropical disease rarely occurring in Europe and other industrialised countries but since 2004, LGV cases started to be more frequently reported in several European countries, mainly among men who have sex with men (MSM) who have practiced unprotected anal sex, many of whom are HIV positive [61] [62]. The clinical presentation ranges from asymptomatic infection (in most cases) to pain in the rectum, lymphatic damage, scarring and fistulae involving inguinal glands, genitalia, anus and rectum, requiring surgical referral. The diagnosis of LGV requires specialised laboratory tests with LGV-discriminatory nucleic acid amplification test (NAAT). Treatment consists of a 3-week course of antibiotics which is recommended also for asymptomatic patients and contacts of LGV cases [63]. LGV is a disease preventable through safer sex such as correct and consistent condom use. According to European guidelines, sexual partners during a three-month look-back period need to be traced, tested and treated to detect asymptomatic infections and prevent re-infection and further spread of the disease [63]. The LGV is under epidemiological surveillance in EU/EEA. In 2017, 1 989 cases were reported to ECDC by 15 countries; nine other countries reported zero cases. Four countries accounted for 86% of all reported cases [8]. The true LGV incidence is likely underestimated because many countries do not have a national surveillance system for LGV, and confirmation of the infection through genotyping is not widely available [64].

Gonorrhoea is the second most common bacterial STI in Europe and is caused by *Neisseria gonorrhoeae*. Clinical presentation of gonorrhoea includes urethritis in men, cervicitis and salpingitis in women and conjunctivitis in both men and women [16]. In approximately 50% of infected women and 10% of infected men gonorrhoea is asymptomatic, but still transmittable, and may remain undetected and untreated. When left untreated, it can progress to severe genital tract complications, including pelvic inflammatory disease (PID) in women and epididymo-orchitis in men. Pharyngeal and rectal infections are usually asymptomatic. Since 1976, gonococci have rapidly developed resistance to a variety of antimicrobial agents which challenged treatment options and, nowadays, have developed resistance to almost all classes of antibiotics [65,66]. Gonorrhoea therapy needs to be informed by local microbiological surveillance of *N. gonorrhoeae* [67]. Current European treatment guidelines recommend the use of ceftriaxone, single dose intramuscularly (or cefixime, single dose orally) together with azithromycin, single dose orally as first-line therapy of uncomplicated infections [68]. Gonorrhoea is a preventable disease (through safer sex practices such as correct and consistent condom use). Sexual partners need to be evaluated and treated to prevent re-infection of the index patient and further spread of disease. Risk factors for gonorrhoea include a range of demographic and sexual determinants, such as young age (<25 years), male gender, MSM sexual orientation, new or multiple recent sexual partners [68]. Gonorrhoea is under epidemiological surveillance in the EU/EEA, with 89 239 cases reported to ECDC in 2017 [8].

Syphilis is a systemic disease caused by *Treponema pallidum* that can cause severe complications and lead to sequelae. Syphilis remains a major public health problem in Europe with the re-emergence of the disease observed since the early 2000s [69]. Painless ulcers of 1–2 cm are the most common symptoms in the primary stage of syphilis [16]. If left untreated they will disappear, but the infection will progress to secondary syphilis, which can

present with a multitude of signs and symptoms and, after a latent period which can last for decades, to tertiary syphilis where the heart, central nervous system and other organs can be affected. Treatment of syphilis consists of one or several injections with antibiotics and requires several follow-up visits [70]. Syphilis is a preventable disease (through safer sex practices such as correct and consistent condom use). Sexual partners need to be evaluated to prevent re-infection and further spread of disease; in case of advanced syphilis this applies to partners in the last 12–24 months. Risk factors for syphilis include a range of demographic and sexual determinants, such as age, male gender, MSM sexual orientation, drug use (injecting drug users and partners), high number of sexual partners, and commercial sex work. Syphilis is under epidemiological surveillance in EU/EEA with 33 193 cases reported to ECDC for 2017, of which about half among MSM [8].

Syphilis can be transmitted during pregnancy from the mother to the child, and it may cause adverse pregnancy outcomes (e.g. stillbirth, prematurity, low birth weight) or severe sequelae in the newborn infant (congenital syphilis). Globally, the burden of morbidity and mortality due to congenital syphilis is high but it varies across the WHO Regions, with estimates for Europe the lowest among the regions [7]. WHO recommends syphilis screening of all pregnant women during the first antenatal care visit [71]. In addition, ECDC recommends that testing offers should be repeated during the third trimester for women from country-specific high-risk groups [72]. Most EU/EEA countries have established screening programmes for syphilis during the first trimester of pregnancy to prevent congenital syphilis [73]. Congenital syphilis is under epidemiological surveillance in the EU/EEA [8]. In 2017, 36 cases of congenital syphilis were reported to ECDC, a likely underestimate of the real burden. Reporting may be incomplete for a variety of reasons: not all countries report to ECDC, congenital syphilis is not notifiable in some countries, and the EU case definition does not include pregnancy complications before birth. In some European countries congenital syphilis is diagnosed and reported more frequently among high risk groups: mothers with a migration background and ethnic groups, women exercising high-risk behaviours such as injecting drug use, a high number of sexual partners, and women presenting late for antenatal care. Countries are advised to identify nationally specific risk groups [72].

Genital herpes is a viral STI caused by herpes simplex virus type 1 (HSV-1) or type 2 (HSV-2). Most people who are infected have none or only very mild symptoms but they are nonetheless infectious. Herpes lesions usually appear as one or more vesicles that progress to ulcers on or around the genitals, rectum or mouth. Genital lesions may disappear but periodic reactivations are possible (more frequently for HSV-2 than HSV-1) since the infection will persist life-long. Antiviral regimens, supportive local treatment and counselling are recommended and may reduce the duration of illness and avoid complications but will not clear the infection [74]. Transmission takes place during anal, vaginal and oral sex and its risk is higher when active lesions are present but it is also possible in the absence of symptoms due to subclinical virus shedding. Using condoms may help lower transmission risk [74]. Genital herpes is not under epidemiological surveillance in the EU/EEA.

Genital warts are viral STI caused by human papilloma viruses (genotypes 6 and 11 in 95% of cases). Most HPV infections are asymptomatic and visible genital lesions appear only in a fraction (14.5 to 64%) of those infected with HPV 6 or 11 [75]. Transmission takes place during anal, vaginal and oral sex or close skin contact and is difficult to prevent. Genital warts usually appear as superficial papular lesions in the genital area. There is no single optimum treatment for anogenital warts and, after treatment, lesions can reoccur in 20–30% of cases [75]. Condoms offer only partial protection against onward transmission but the vaccines that contain HPV 6 and 11 will provide additional protection against infection. Genital warts are not under epidemiological surveillance in the EU/EEA. Estimates from the USA, Canada, Australia and several high-income countries in Europe indicate an annual incidence of 0.1 to 0.2%, with a peak occurring in teenagers and young adults [76].

Annex 2. Options for terms of reference for coordinating governance body

Adapted from: World Health Organization, the Food and Agriculture Organization of the United Nations, and the World Organisation for Animal Health. Antimicrobial resistance: a manual for developing national action plans. WHO: Geneva; 2016 [35].

A good governance mechanism for coordinating the national efforts to prevent and control STIs is essential. The governance mechanism should comprise a national coordinating governance body (CGB), which will establish additional supporting technical working groups if needed. A governance mechanism is far more likely to be effective if it has political support, the authority to act, and dedicated funds. Such a mechanism needs to be transparent and accountable, and receive administrative support from a secretariat.

Political support: As STIs are a human health issue, the ministry of health may be the most likely leader of the CGB. A joint leadership with other relevant ministries or departments may also be preferred. In some countries, inter-ministerial cooperation might require oversight from another authority.

Authority to act: The coordinating group should be given sufficient authority to ensure that its recommendations and plans are implemented.

Accountability: The group should be accountable to the lead minister or cabinet of ministers or a similar government member.

Dedicated funds: The availability of dedicated funds will increase the operational effectiveness of the group. Seed funds from external sources are often required initially, but government funds should be secured as early as possible to ensure political ownership and increase the likelihood of programme sustainability.

Secretariat: Operational sustainability is more likely when sufficient dedicated personnel and funding are available to support administrative activities.

National coordinating governance body

The role of the national coordinating governance body CGB is to oversee and coordinate all activities related to the development and implementation of the strategy for STI prevention and control as well as the strategy's operational plan. The CGB should address all STI-related activities in the country. The scope should be broad enough to address all strategic objectives and the action plan, prioritise activities, and oversee the implementation in a step-wise approach.

Leadership: The CGB is expected to lead and coordinate the activities to implement the operational plan for STI prevention and control. Its leadership could take the form of an officially delegated authority, with more formal procedures and official monitoring, evaluation and reporting. Its role could be extended to include the power to make recommendations, produce progress reports, and provide a platform for programme planning and implementation.

Information sharing: The CGB provides a structure for information sharing to mutually reinforce activities among sectors.

Facilitation and coordination: It is recommended that the CGB builds a collaborative, cooperative, supportive environment for sharing knowledge, information and experience. Each participating party should understand the scope and limits of its own contributions and also its interdependence with other parties and the whole system in order to meet the defined goals. The difficulties of achieving such an environment and building such a system should not be underestimated. Political support and selection of a chairperson with appropriate status and leadership skills are critical factors.

External interactions: Collaboration with internal and external agencies and organisations is essential for many countries. ECDC can usually support Member States in facilitating relations with external partners.

Internal interactions: The national CGB must interact with key players from the healthcare system, public health and existing disease-specific programmes. The nature of these internal interactions will depend on the national context. Furthermore, the CGB must be appropriately integrated into the healthcare system, public health and disease-specific programmes, harm reduction policies, human trafficking, HIV prevention and control, TB programmes and general communicable disease control structures. In all these areas, the role and responsibilities of the CGB should be clearly defined. The cross-cutting nature of the CGB should add value to these systems and programmes, not supersede or replace them.

Members: The national CGB should be composed of members representing all relevant sectors. Members should be given sufficient authority by their institutions to make decisions. While it is important to have sufficient representation of key stakeholders, the CGB should remain small enough to work efficiently, striking a balance between full representation and efficiency.

Meeting format and rules

The meeting format and rules should conform to national norms. If standard operating procedures are used to guide the activities of the CGB, they should be transparent and in accordance with the principles of best practice.

The responsible ministers should select a chairperson from among the members.

If the CGB becomes too large or is given tasks that require specific expertise or input, it is often efficient to form either ad hoc or standing subgroups or technical working groups. Any subgroup should have a clearly defined mandate and a chairperson.

It is suggested that the CGB be supported by an appropriately resourced secretariat to take care of meeting logistics, minute taking, preparation and circulation of documents (e.g. background papers, reports and advisory notes to ministers), and storage and archiving.

The group may use a mechanism (with appropriate records) to ensure that its members have no conflicts of interests and that the work of the CGB in the interest of public health is transparent. Failure to ensure these elements could undermine the credibility and limit the effectiveness of the group.

Annex 3. Template for high-level gap analysis

Strategic objective	Current standing	Deficiency	Action plan
Gaps			
Gaps			
Gaps			
Gaps			

Annex 4. Template for a national prevention and control strategy

This template gives an example of an outline for a generic national STI prevention and control strategy document, based on the previous chapters. This should be considered as a suggestion and not as a fixed, obligatory format.

1. Introduction

- Provides a rationale for STI strategy: provides the background, need for a strategy; political context
- Formulates a strategic vision
- Describes relevant existing national strategies and policies
- Outlines an international dimension with respect to STI prevention and control strategies; international legislation, strategies.

2. Situation analysis and assessment

Provides the outcome of the situation analysis:

- Mapping of existing national healthcare facilities for STI prevention and control (structures, clinical capacity and services, laboratory capacity and services, public health interventions, surveillance activities, existing screening/vaccination programmes, etc.
- Review and analyses of STI epidemiology: occurrence of STIS, sub-populations at high risk for STI
- Description of relevant related strategies
- SWOT analysis and conclusions.

3. Coordination and governance

- Provides the outcome of the stakeholder analysis, including roles of stakeholders, responsibilities related to STIs and related sectors
- Describes coordination structure for STI prevention and control; governance coordinating body, technical working groups
- Oversees the development of the strategic planning, setting priorities and operational planning, implementation of the operational plan.

4. Strategy

- Formulates the strategic scope
- Describes the strategic objectives, targets and milestones
- Defines key success factors
- Provides the legal framework
- Defines the budget and funding principles.

5. Action plan

In the action plan, the strategic objectives are translated into strategic targets and concrete activities (with sub-activities), including a timeline, milestones and a budget. Also, it should be specified who is doing what, roles and responsibilities, contributors, etc.

Countries may consider identifying several STI prevention and control capacities:

- Promotion and education of preventive measures
- Availability of condoms and other prophylactics
- Counselling and testing
- Reliable and accurate laboratory services
- Appropriate treatment capabilities
- Partner management capability: protocols, competent staff, mandate
- Capability for screening activities
- Training and capacity building.

6. Monitoring and evaluation

In the monitoring and evaluation plan, specific indicators need to be selected per strategic objective; the plan needs to specify details on the nature and frequency of analyses and frequency of reporting; it should also address the responsible institution/persons for monitoring and evaluation.

Sample outline

Strategic objective 1: improve awareness and understanding of STI

Target 1.1: Increase national awareness among general public

- Activity 1.1.1. Prepare and conduct national campaign on STI and sexual health, including promoting the use of condoms and safer sex
- Activity 1.1.2. Prepare and implement training modules for school children according to evidence-informed technical guidance

Strategic objective 2: strengthen STI case management among general practitioners

Target 2.1. Review and update STI case management guidelines (or make use of international guidelines)

Activity 2.1.1. Engage experts to review and discuss the current status of the guidelines

Target 2.2. Improve the access to STI laboratory services

- Activity 2.2.1. Set up a laboratory network which ensures accurate and reliable STI laboratory services
 - Sub-activity. Engage microbiologists, technicians and GP in a technical working group to discuss the feasibility of a laboratory network and its capabilities
 - Sub-activity. Train technicians and GP in specimen collection and STI lab techniques

Strategic objective 3: strengthen STI partner management services

Target 3.1: Increase capacity for providing partner management services

- Activity 3.1.1. Increase the availability of partner management services in STI clinics

Annex 5. Useful online resources

This chapter presents a selection of available resources and online tools.

Prevention and control

World Health Organization

- World Health Organization. Global health sector strategy on sexually transmitted infections 2016–2021. WHO: Geneva; 2016. Available from: (<http://www.who.int/reproductivehealth/publications/rtis/ghss-stis/en/>)
- World Health Organization. Global action plan to control the spread and impact of antimicrobial resistance in *Neisseria gonorrhoeae*. WHO: Geneva; 2012. Available from: <http://www.who.int/reproductivehealth/publications/rtis/9789241503501/en/>
- World Health Organization. A manual for developing national action plans. WHO: Geneva; 2016. Available from: http://apps.who.int/iris/bitstream/handle/10665/204470/9789241549530_eng.pdf

European Centre for Disease Prevention and Control (ECDC)

- European Centre for Disease Prevention and Control. Guidance on chlamydia control in Europe – 2015. Stockholm: ECDC; 2016. Available from: <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/chlamydia-control-europe-guidance.pdf>
- European Centre for Disease Prevention and Control. A comprehensive approach to HIV/STI prevention in the context of sexual health in the EU/EEA. Stockholm: ECDC; 2013. Available from: <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/HVI-STI-prevention-comprehensive-approach-in-the-context-of-sexual-health-EU-EEA.pdf>
- European Centre for Disease Prevention and Control. HIV and STI prevention among men who have sex with men. Stockholm: ECDC; 2015. <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/hiv-sti-prevention-among-men-who-have-sex-with-men-guidance.pdf>
- European Centre for Disease Prevention and Control. HIV testing: increasing uptake and effectiveness in the European Union. Stockholm: ECDC; 2010 https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/101129_GUI_HIV_testing.pdf
- European Centre for Disease Prevention and Control. Response plan to control and manage the threat of multidrug-resistant gonorrhoea in Europe. Stockholm: ECDC; 2012. <https://ecdc.europa.eu/sites/portal/files/media/en/publications/Publications/1206-ECDC-MDR-gonorrhoea-response-plan.pdf>

EU Member States

- Department of Health, Ireland. National sexual health strategy 2015-2020. Department of Health: Dublin; 2015. Available from: <https://health.gov.ie/wp-content/uploads/2015/10/National-Sexual-Health-Strategy.pdf>
- Ministry for Health, the Elderly and Community Care. National sexual health strategy. Ministry for Health, the Elderly and Community Care: Valletta; 2011. Available from: https://deputyprimeminister.gov.mt/en/CMO/Documents/sexual_health_strategy_english_version.pdf
- Ministry for Health, the Elderly and Community Care. The national sexual health policy for the Maltese Islands. Ministry for Health, the Elderly and Community Care: Valletta; 2010. Available from: https://sexualhealth.gov.mt/sites/default/files/sexualhealthpolicy_english%5B1%5D.pdf
- Public Health Wales. A review of sexual health & HIV services in Wales. PHW: Cardiff; 2017. Available from: <http://www.wales.nhs.uk/sitesplus/888/page/71723>
- Federal Ministry of Health, Federal Ministry for Economic Cooperation and Development. Integrated strategy for HIV, hepatitis B and C and other sexually transmitted infections. Berlin: Federal Ministry of Health; 2016. Available from: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/5_Publikationen/Praevention/Broschueren/Strategy_HIV_HEP_STI.pdf
- Socialdepartementet, Sweden. Nationell strategi mot hiv/aids och vissa andra smittsamma sjukdomar [National strategy for HIV/AIDS and other infectious diseases; Swedish]. Stockholm; 2017. Available from: <https://www.regeringen.se/informationsmaterial/2017/12/nationell-strategi-mot-hiv-aids-och-andra-smittsamma-sjukdomar/>

- Embætti landlæknis, Velferðarráðuneyti. Kynsjúkdómar á Íslandi; greinargerð og tillögur um aðgerðir [Sexually transmitted diseases in Iceland – statement and proposals for action; Icelandic]. Reykjavík; 2018. Available from: <https://www.stjornarradid.is/lisalib/getfile.aspx?itemid=3b8611b2-04f8-11e8-9425-005056bc530c>
- Ministry of Health, Latvia. Action plan on HIV infection, sexually transmitted infections, hepatitis B and C 2018–2020 [Latvian]. Riga; 2017. Available from: <https://likumi.lv/ta/id/294753-par-hiv-infekcijas-seksualas-transmisijas-infekciju-b-un-c-hepatita-izplatibas-ierobezosanas-ricibas-planu-2018-2020-gadam>
- Ministry of Health, Luxembourg. National action plan HIV 2018–2022 [French]. Available from: <http://sante.public.lu/fr/publications/p/plan-action-national-sida-2018-2022/index.html>
- National Institute for Public Health and the Environment, Netherlands. National action plan on STIs, HIV and sexual health 2017–2022. Netherlands: Bilthoven; 2018. Available from: <https://www.rivm.nl/bibliotheek/rapporten/2017-0158.pdf>
- Ministry of Health, Bulgaria. National Programme for Prevention and Control of HIV and sexually transmitted infections in the Republic of Bulgaria 2017–2020. Sofia; 2017. Available from: <http://www.strategy.bg/FileHandler.ashx?fileId=9303>

Tools for stakeholder analysis

Tools for SWOT analysis

- European Commission, capacity4dev. Evaluation methodological approach – strengths, weakness, opportunities, threats – toolkit [internet]. EC: Brussels; 2015. Available from: https://europa.eu/capacity4dev/evaluation_guidelines/minisite/en-methodological-bases-and-approach/evaluation-tools/swot-strengths-weakness-opportunities

Tools for gap analysis

- Kammi Schmeer. Stakeholder analysis guidelines. Geneva: WHO; 1999. Available from: <https://www.who.int/workforcealliance/knowledge/toolkit/33.pdf>

Tools for developing monitoring and evaluation plans

- Centers for Disease Control and Prevention. Introduction to programme evaluation for public health programs: a self-study guide. Atlanta: CDC; 2011. Available from: <https://www.cdc.gov/eval/guide/CDCEvalManual.pdf>

Treatment guidelines

- International Union against Sexually Transmitted Infections (IUSTI). IUSTI regions – Europe – Guidelines [Internet]. 2012–2019. Available from: <https://www.iusti.org/regions/europe/euroguidelines.htm>
- IUSTI European guidelines treatment pocket guide. 2018. Available from: https://www.iusti.org/regions/Europe/pdf/2018/GuiaSTI-document5conLinks_v4.pdf

Annex 6. Expert meeting on 'Development of national strategies for the prevention and control of STIs', 1–2 October 2018, Stockholm

Background

Sexually transmitted infections (STIs) are a common cause of morbidity in the EU/EEA, with around 400 000 chlamydia cases, 66 000 gonorrhoea cases and 28 000 syphilis cases reported annually. Untreated infections may lead to complications of the genital tract, including infertility, and may increase transmission of HIV infection. In 2013, a survey by ECDC identified 11 countries that published a strategy or national plan for STI prevention and control. Over the years, ECDC published several technical guidance documents to support Member States in developing and implementing prevention and control strategies for STIs and HIV/AIDS. The guidance documents provided policymakers and national programme managers with a range of evidence-based interventions.

In 2017, ECDC convened a sub-regional STI meeting with participants from central, eastern and southern EU/EEA countries. There was a clear need to strengthen national strategies and to address issues such as limited political support, lack of funding, or competing public health priorities. It was also agreed that robust epidemiological data regarding STI among vulnerable groups were needed, which is essential for prevention activities and effective resource allocation. The WHO *Global health sector strategy on STIs 2016–2021* defines global targets and milestones while it invites countries adopt the goal of ending STI epidemics by 2030.

In March 2018, ECDC launched a project to produce this report. It is directed at policymakers, national programme coordinators and other experts working in the field of STI prevention and control in the Member States.

Scope and objectives

The scope of the meeting is to organise an EU/EEA-wide consultation of experts involved in STI prevention and control. The objectives of the meeting are:

- to discuss a consolidated draft of the technical report and collect feedback on the content, and understand how it can best serve national efforts to develop a strategy for STI prevention and control,
- to share national experiences on STI strategy development, and
- to explore whether a core group of experts to support ECDC's future activities in this field should be established.

The meeting will also provide opportunities to discuss stakeholder engagement in STI prevention and control and explore how to communicate efficiently with the policy level.

Suggestions for ECDC's future work in the field of STI prevention and control are expected to emerge from the discussions.

Participants. ECDC will invite participants from several Member States, including national STI programme coordinators, policy advisors, representatives of civil society, and experts from international organisations.

Outcomes. The draft guidance document will be finalised.

Agenda

Day 1. 1 October 2018

Session 1. Introductions and international context

Chair: Josep Jansa, Otilia Mardh

Aim: Introduce background of ECDC project, present global context projected by the WHO global STI strategy and give an overview of the proposal for STI strategy development.

09:00-10:30

- Welcome and introductions (Josep Jansa) 10'
- Scope of the meeting and short summary of the STI strategy project (Otilia Mardh) 10'
- WHO Global Health Sector Strategy for STI 2016-2020 - vision, goal, targets, support for countries (Melanie Taylor) 15'
- Overview of the proposal for STI strategy development (Marita van de Laar) 15'
- Discussions 40'

10:30-11:00 Break

Session 2. Diversity of national STI strategies

Chair: Lina Nerlander, Birgit van Benthem

Aim: Present several models of national strategies, highlight the diversity of approaches, discuss potential benefits of different models.

11:00-12:30

- STI strategy of Ireland (Fiona Lyons) 15'
- STI strategy of Portugal (Teresa Ventura) 15'
- STI strategies in United Kingdom (Kate Folkard) 15'
- Discussions 45' facilitated discussion (Is there an optimal structure, format? How to integrate the key components of STI control in a broader health sector strategy? Advantages and disadvantages of different models.)

12:30-13:30 Break

Session 3. The process of STI strategy development

Chair: Anastasia Pharris, Rigmor Berg

Aim: Share country approaches for the development of STI strategies, highlight the key steps of strategy development

13:30-15:00

- Development of the national STI/HIV strategy in the Netherlands (Silke David) 15'
- Development of the national STI/HIV strategy in France (Aminata Sarr) 15'
- Development of the national STI/HIV strategy in Germany (Gesa Kupfer) 15'
- Key steps in STI prevention and control strategy development (Arnold Bosman) 10'
- Discussions 35'

15:00-15:30 Break

Session 4. Group work: Key components of the strategy development

Facilitators: Arnold Bosman, Marita van de Laar

Aim: Provide feedback on the suggested approach and selected topics (see group instructions)

15:30-17:30

- Introduction to the group work (5')
- Breakout sessions – 3 working groups (85') (see more details on page 5 of this document)
- Rapporteur session (30')

Day 2. 2 October 2018

Session 4. Continued

Facilitators: Otilia Mardh, Arnold Bosman

09:00-10:00

- Recap of day 1; comments, conclusions from the group work, instructions for session 5

Session 5. Stakeholder engagement

Chair: Arnold Bosman

Aim: Exercise to produce a draft agenda for the first meeting of stakeholders

10:00–10:30

- In three working groups: draft an annotated agenda
- Print agenda for discussion during the break

10:30–11:00 Break

Session 6. Key success factors in STI strategic planning

Chair: Gianfranco Spiteri, Raj Patel

11:00–12:00

- Feedback from group work 5'
- Panel discussion 55':
 - The role of STI clinical services in successful STI control (Raj Patel, IUSTI)
 - Building partnership, stakeholders involvement, communication with policy level (Inga Velicko and Gabriella Hök, Sweden)
 - The role of civil society (Mikael Jonsson, Sweden)
 - Interventions from the entire group

Session 7. Conclusion of the meeting

Chair: Otilia Mardh

12:00–12:30

- Final reflections on the technical report – a summary of expert panel contribution (Arnold Bosman and Marita van de Laar) 10'
- Conclusion of the meeting and next steps – how countries see the role of ECDC in STI prevention and control 20'

Participants

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Ndeindo Ndeikoundam	France
Aminata SARR	France
Kupfer Gesa	Germany
Viviane Bremer	Germany
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