TECHNICAL REPORT

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Evaluation of the impact of the ECDC guidance on *HIV testing: increasing uptake and effectiveness in the European Union*

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The annexes referenced in this report can be found as separate documents linked to this publication under the HIV health topic http://ecdc.europa.eu/en/healthtopics/aids/Pages/publications.aspx

Erratum 10 January 2017. Table 15: the percentages in the second column, row 1 and 3 were corrected.

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Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
ART	Antiretroviral therapy
CD4	Cluster of differentiation 4
CSO(s)	Civil Society Organisation(s)
EACS	European AIDS Clinical Society
EEA	European Economic Area
EU	European Union
HIDES	HIV Indicator Diseases Across Europe
HiE	HIV in Europe
HIV	Human Immunodeficiency Virus
IUSTI	International Union against Sexually Transmitted Infections
IV	Intravenous
MSM	Men who have sex with men
NGO(s)	Non-governmental organisation(s)
OptTEST	Optimising testing and linkage to care for HIV across Europe
PEP	Post-exposure prophylaxis
PrEP	Pre-exposure prophylaxis
PLHIV	People living with HIV
PWID	People who inject drugs
STI(s)	Sexually transmitted infection(s)
TB	Tuberculosis
TESSy	The European Surveillance System
UNAIDS	the Joint United Nations Programme on HIV/AIDS
UNODC	United Nations Office on Drugs and Crime
WHO	World Health Organization

Key terms

Advocacy: Actions that seek to engage with decision makers and influence policies.

Best practice examples: HIV testing service models or case studies from EU/EEA Member States effectively increasing testing coverage and/or uptake and/or linkage to care in one or more target groups.

Broader Target Group: Includes representatives from a broad array of organisations and institutions at international and EU level and at national and local level

Evaluation: A collection of activities designed to determine the value or worth of a specific programme, intervention or project.

Guidelines: Are normative recommended, but non-mandatory standards, e.g. operational recommendations for healthcare workers conducting HIV testing.

Indicator: A measure used to determine, over time, performance of functions, processes, and outcomes.

Indicator condition-guided HIV testing: Routine HIV testing of individuals who attend healthcare settings with certain medical conditions linked to possible undetected HIV infection, e.g. STI, Hepatitis B and C.

Monitoring: Refers to the simple description, counting, and tracking of processes or events, without in-depth analysis or comparisons.

Most at-risk groups: Populations that are at-risk of HIV given their behaviour or the environment they live in. They usually include men who have sex with men, people who inject drugs, sex workers, people with other STIs, people with multiple sex partners, sex partners of HIV-infected persons, and people originating from high HIV prevalence areas. However groups most at risk may differ depending on the country.

Normalisation of HIV testing: Making the process similar to other screening and diagnostic tests.

Policy: E.g. a national testing policy that is targeted towards health professionals ordering HIV related tests, and receiving and interpreting results, which sets out the framework for providing quality testing and removing real and perceived barriers to testing, including ethical issues.

Primary Target Group: Includes national policymakers, programme managers and decision makers such as the Ministry of Health, HIV specialists and the National Board of Health. The group also includes ECDC national focal points for HIV and STI, the ECDC HIV and STI Disease Network experts, as well as other relevant national policymakers and/or programme managers (for example STI or TB/Hepatitis programme managers)

Programme: A combination of interventions or activities that a country establishes as a fundamental part of its structure and mission. Programmes tend to focus on a specific area (e.g. improving HIV testing rates) and operate over the long term.

Services: Sub-national testing services or general HIV testing services in the healthcare system.

Strategy: A comprehensive action plan that identifies critical goals and objectives, and defines actions to achieve these, e.g. a five-year plan that details principles, priorities, and actions to guide the collective national response to the HIV epidemic.

Executive summary

In response to the continuous challenges in HIV testing across Europe, the European Centre for Disease Prevention and Control (ECDC) commissioned the development of the ECDC guidance *HIV testing: increasing uptake and effectiveness in the European Union* [1] which was published in December 2010 in parallel with a literature review, *HIV testing: increasing uptake and effectiveness in the European Union. Evidence synthesis for Guidance on HIV testing [2]* .

The guidance was designed to inform the development, monitoring and evaluation of national HIV testing strategies or programmes in the European Union (EU) and European Economic Area (EEA) Member States. The 2010 ECDC HIV testing guidance describes its primary target audience as EU/EEA Member State stakeholders including policymakers, national programme managers/coordinators, decision-makers and ECDC national focal points and disease network experts.

In 2015, ECDC commissioned an evaluation of the *HIV testing: increasing uptake and effectiveness in the European Union* guidance. The aim of the evaluation was to understand the use and impact of the 2010 ECDC HIV testing guidance in the EU/EEA, and to make recommendations for future steps by ECDC in this area, including, potentially, an updated guidance.

The evaluation, conducted by a team within the HIV in Europe[1] initiative (HiE), was based on a number of activities. A survey was distributed in October 2015 to nominated EU/EEA Member State representatives, the Primary Target Group, and to a Broader Target Group of representatives from organisations and institutions active in the field of HIV testing across the EU/EEA, asking respondents about use and impact of the guidance. Qualitative data were collected from moderated focus group discussions at the European AIDS Clinical Society (EACS) Conference in Barcelona in October 2015. A review of webpage access data and literature citation was performed. Finally, an ECDC expert meeting was held in Stockholm in January 2016.

Twenty-eight Primary Target Group respondents from 23 of the 31 EU/EEA Member States submitted the ECDC 2010 guidance evaluation survey. Twenty-four of the 28 Primary Target Group respondents reported working in the public health sector (86%). Fifty-one Broader Target Group respondents from 18 EU/EEA countries and one multi-national organisation (WHO) submitted the ECDC 2010 guidance evaluation survey. Twenty-three of 51 Broader Target Group respondents (45%) reported working in an NGO and 18 of 51 (35%) in the public health sector.

The results of the survey showed that Primary Target Group respondents reported that the most utilised HIV testing documents at a national level are:

- a national HIV strategy/policy that includes recommendations on testing (68%)
- a national HIV testing guidelines document (57%)
- guidelines on HIV testing issued by professional societies (50%).

All primary and most broader target group respondents indicated having knowledge of the existence of the ECDC HIV testing guidance (100% and 82%, respectively); almost half reported having used the guidance in their work and/or having distributed the guidance to their networks.

The majority of both primary and Broader Target Group respondents (82 and 61%, respectively) reported the 2010 ECDC HIV testing guidance as the most relevant among international guidelines, and although published more than 5 years ago, most still considered it relevant today.

The majority agreed the ECDC 2010 guidance was easily accessible, user-friendly and clearly written, and had a clear structure and format. A higher percentage in the Broader Target Group (>30%) found it problematic that the guidance was not available in their own language than in the Primary Target Group (11%).

Thirteen of 28 (46%) of the Primary Target Group respondents reported having used the ECDC 2010 guidance for the development, monitoring and/or evaluation of their national HIV testing policy/guidelines/programme/strategy. Twenty-nine of 51 (56%) of the Broader Target Group respondents reported having used the ECDC 2010 guidance for developing information materials or advocacy activities.

The majority of both primary and Broader Target Group respondents have observed important changes, and some considered the ECDC guidance as having contributed to these.

[1] http://hiveurope.eu/

More than half of Member States (13/23; 57%) indicated that their national guidelines are closely or somewhat closely aligned to the 2010 ECDC guidance, including guidance on, for example, voluntary and confidential testing, counselling, access to care and testing of pregnant women and at risk populations. Other important topics from the 2010 ECDC HIV testing guidance, which are reported to be less frequently included in national testing guidelines or programmes are recommendations on offering HIV testing in general practice (35%), testing frequency (30%), HIV testing in emergency departments (17%) and on normalisation of HIV testing through less demanding counselling requirements (17%). Almost half of Member States (48%) reported inclusion of indicator condition-guided (IC) HIV testing, and 39% reported having a monitoring and evaluation programme in place.

A large majority of primary (82%) and broader (90%) target group respondents considered it important to have an EU level HIV testing guidance, in particular for developing national guidelines and programmes (84% and 72%), for advocacy (56% and 62%) and monitoring and evaluation purposes (48% and 52%, respectively).

Respondents indicated several areas where ECDC could play an important role in relation to HIV testing, including a recommendation to publish an updated guidance. It was recommended that this should include guidance on new testing technologies and approaches. It was a common view, particularly among Primary Target Group respondents, that an improved monitoring and evaluation framework is needed. Both groups of respondents, but to a greater extent the Broader Target Group, suggested including service models examples from the EU/EEA. Also, regular updates of the guidance document would be needed to account for changes in the rapidly evolving field of HIV testing, and to increase its relevance and use.

Possible limitations to the evaluation exercise include response bias, with individuals more familiar with the guidance being more likely to complete the survey and/or participate in focus groups. The survey was rolled out in English only and this may have constituted a significant barrier to engagement. The number of Broader Target Group respondents was lower than anticipated and the overall EU/EEA geographical coverage was limited. As a result, the representativeness of the sample may have been sub-optimal and caution must be applied when extrapolating these findings to the whole EU/EEA.

In conclusion, the results of this evaluation showed that the ECDC 2010 guidance has been referenced and widely used to develop policies, guidelines and/or programmes/strategies in the EU/EEA. The findings suggest that it has contributed to changes in HIV testing strategies across EU/EEA countries. In addition, the ECDC 2010 guidance has reached a wider audience than intended and has proven to be useful to a broader range of stakeholders, as an authoritative reference document as well as for advocacy purposes. According to the evaluation findings, the ECDC 2010 guidance was considered relevant and of added value by a wide range of stakeholders as it provides a unique EU-level perspective. Updating the guidance and developing complementary products was identified as an urgent need and recommended for future ECDC action.

1. Introduction

1.1 Overview

In 2015, ECDC commissioned an evaluation of the ECDC guidance *HIV testing: increasing uptake and effectiveness in the European Union* published in December 2010. The aim of the evaluation was to review the impact of the ECDC 2010 guidance and to assess the current need for ECDC HIV testing guidance in the EU/EEA.

This technical report presents the findings and conclusions from the evaluation. It presents the results of a survey of primary and Broader Target Groups on the use and impact of the guidance, an analysis of citations and webpage access of the guidance, and a qualitative analysis of moderated focus group discussions with key informants about awareness and use of the guidance. An ECDC hosted Expert Panel meeting was held in order to review and discuss the results of the interim analysis and contribute to the interpretation of the findings and advice on next steps.

This report concludes with a list of recommendations for the next steps for ECDC in guidance on HIV testing.

1.2 ECDC HIV testing guidance in the EU/EEA 2010

In response to the continuous challenges in HIV testing across Europe, ECDC commissioned the HIV testing guidance launched in 2010, which was published in parallel with a guidance in brief, and the technical report of the literature review, *HIV testing: increasing uptake and effectiveness in the European Union. Evidence synthesis for Guidance on HIV testing* [2].

The ECDC 2010 guidance was designed to inform the development, monitoring and evaluation of national HIV testing strategies or programmes in the EU/EEA. The primary target audience of the guidance was EU/EEA Member States stakeholders including policymakers, national programme managers and coordinators, decision-makers, ECDC national focal points and ECDC disease network experts.

The ECDC 2010 guidance contains the following sections related to HIV testing strategies and programmes: 1) core principles; 2) development of a national HIV testing strategy; 3) ensuring access to HIV treatment, care and prevention and 4) monitoring and evaluation (Table 1).

Table 1. Sections in the ECDC 2010 guidance

Core principles for national HIV testing strategies and programmes
HIV testing should be voluntary, confidential and with informed consent
Ensure access to treatment, care and prevention services
Show political commitment
Reduce stigma
Remove legal barriers
Remove financial barriers
Make access to HIV testing an integral part of national strategies
Develop and implement an HIV testing strategy with the participation of stakeholders
Developing a national HIV testing strategy
Whom to test? (identify groups most at risk)
Where to test? (offer testing in a variety of settings)
When to test? (testing frequency)
How to test? (awareness, confidentiality, counselling, results)
Routine offering in general practice
Routine offering in emergency departments
Outreach services/community based testing
Ensuring access to HIV treatment, care and prevention
Access to antiretroviral therapy (ART), psychosocial support and prevention services
Monitoring and evaluation
Assessing local level initiatives
Appendices
Appendix A. Table 1. Monitoring and evaluation at the national/international level
Table 2. Monitoring and evaluation in specific settings
Appendix B. Clinical indicator conditions for HIV Infection. Table 3. AIDS-defining illness and other illnesses strongly associated with immunodeficiency in HIV-infected populations
Table 4. HIV prevalence in patients with clinical indicator conditions in Europe

The ECDC 2010 guidance was officially launched at an ECDC seminar on World AIDS Day (1 December 2010) in the European Parliament. At this seminar, leading HIV experts and EU policymakers in Europe gathered to discuss the importance and benefits of increasing access to HIV testing. The guidance was made available for download from the ECDC website and uploaded to the AIDS Center website. Hard copies of the ECDC 2010 guidance were distributed via the ECDC standard recipient and HIV specific circulation lists to 473 recipients in total, as well as to the relay centres specialising in public health.

1.3 Setting the scene: data and trends in HIV testing

Data on the number of HIV tests by country and risk groups are scarce and not all countries routinely collect these data; making analysis of changes over time and by country and region difficult. Data on the number of tests performed are collected annually through The European Surveillance System (TESSy) and reported in the ECDC annual surveillance report [3]. Nevertheless, the lack of a standard approach in collection methods across the EU/EEA hinders the ability to perform comparative and trend analyses.

Since 2012, ECDC has been monitoring implementation of the Dublin Declaration on partnership to fight HIV/AIDS in Europe and Central Asia. HIV testing coverage and uptake are key indicators to monitor the effectiveness of the response in the region. According to the latest report [4], testing coverage remains low as indicated by the reported low rates of testing in key populations, and the high rate of late diagnosis (up to 47%) among those who test positive.

Despite the observed small increase in the total number of tests performed [3,5], targeting HIV testing programmes to those who are most at risk remains a challenge in many countries. This may be due to lack, or ineffective use, of data on key populations who are at increased risk of HIV infection, or to barriers in effectively reaching those groups with testing services.

The most recent ECDC HIV/AIDS surveillance report shows no decline in the number of new HIV diagnoses in the region the last 10 years [3]. Data on late presentation for HIV care (CD4 <350 cells/uL) have been routinely collected by ECDC since 2010, although not all countries report these data. The proportion of late presenters is a good proxy for evaluating the effectiveness of a testing strategy. In 2013, the most comprehensive study on late presentation was published using data from January 2000–January 2011 from the Collaboration of Observational HIV Epidemiological Research Europe (COHERE) cohort collaboration of more than 80 000 HIV patients across Europe. The study showed that late presentation decreased among men who have sex with men (MSM) and heterosexuals in both Central and Northern Europe, increased among female heterosexuals and males who inject drugs in Southern Europe and also increased among people who inject drugs (PWID) in Eastern Europe [6]. A recently published update of this study with patients enrolled from 1 January 2010 found that 47.5% were presenting late for care, reflecting no overall change in the late presentation across Europe. Furthermore, the analysis showed that late presentation has increased significantly in PWID, but decreased in Northern Europe compared with other regions of Europe [7].

In addition to the above, new technologies and new approaches to the implementation of testing [8] have emerged since 2010. These include :

- more sensitive tests and improved home sampling and testing devices
- evidence for clinically-based strategies including new evidence on indicator condition (IC) guided testing and (lack of) linkage to care
- wider acceptance of and evidence supporting task sharing and diversification of testing approaches including testing in non-traditional settings (e.g. peer led community based testing)
- debate around pre-test counselling/discussion.

1.4 Aim of the 2010 ECDC HIV testing guidance evaluation

The aim and objectives of this evaluation, five years after the publication of the ECDC 2010 guidance, are to understand the use and impact of the ECDC 2010 guidance in the EU/EEA, and to make recommendations for future steps by ECDC in this area, including the need for and possible content of an updated guidance.

Conceptual overview

Research questions were developed on the basis of the aim and objectives of the evaluation (Table 2).

Table 2. Aim and objectives

Aim	Objectives
Understanding the use and impact of the ECDC 2010 testing guidance in the EU/EEA and to make any recommendation for future steps by ECDC in this area, including the need for and possible content of an updated guidance.	Assess the relevance and usability of the ECDC 2010 guidance for the Primary Target Group, i.e. national experts, programme managers and policymakers.
	Assess the relevance and usability of the ECDC 2010 guidance for a Broader Target Group, e.g. non-governmental organisations (NGOs), clinicians and international agencies.
	Assess awareness of the ECDC 2010 guidance among the Primary Target Group and the Broader Target Group. Assess to what extent the guidance has added value to or complemented existing documents.
	Assess the impact of the ECDC 2010 guidance on supporting the development, monitoring and evaluation of national HIV testing strategies or programmes in EU/EEA countries.

2. Methods

The evaluation methodology was adapted from a previous ECDC project (Chlamydia guidance impact evaluation[2]) and from the European Commission 'Better Regulation Toolbox'[3]. The conceptual framework for this work is summarised in Table 3 below.

Table 3. Summary of methods used to address specific questions

Primary evaluation questions	Source of information	Indicators and qualitative input
Awareness (section 3.3.1): What is the level of awareness about the ECDC 2010 guidance among the primary and the Broader Target Group?	Survey data (Primary and Broader Target Groups) Web page and citation analysis data Analysis of national guidelines	% of respondents indicating awareness of the ECDC 2010 guidance by having: • knowledge of its existence • accessed it • discussed it in professional settings/networks • used it in their work • distributed it to national/professional networks • citations in national documents • translated the guidance into local/common language
	Free text answers in surveys Qualitative data from moderated focus group discussions Expert panel consultation	Qualitative input on the perceived level of awareness and possible reasons for high/low awareness.
Relevance (section 3.3.3): Does the HIV testing guidance address the needs of Member States in developing, monitoring and evaluating HIV testing strategies and/or programmes? Does the ECDC 2010 guidance address the needs of non-Member State actors in developing, monitoring, evaluating or advocating for HIV testing strategies and programmes	Survey data (Primary and Broader Target Groups)	% of respondents indicating that the ECDC 2010 guidance was relevant for their work on: • developing a national HIV testing policy/strategy/programme • monitoring their national HIV testing policy/strategy/programme • evaluating their national HIV testing policy/strategy/programme
	Qualitative data from moderated focus group discussions Expert panel consultation	Qualitative input on aspects of the guidance in terms of relevance and usefulness.
Coherence/complementarity (section 3.3.5): To what extent is the ECDC 2010 guidance aligned and complementary to existing documents and interventions?	Survey data (Primary and Broader Target Groups)	% of respondents indicating that their national HIV testing policy/guidelines/ programmes align with the ECDC 2010 guidance
	Free text answers in surveys Qualitative data from moderated focus group discussions Analysis of national policy documents by HiE	Qualitative input on the guidance's alignment and factors that may explain the extent of use

[2] Chlamydia control in Europe: Qualitative evaluation of the impact of the 2009 ECDC guidance. Available at: http://ecdc.europa.eu/en/publications/_layouts/forms/Publication_DispForm.aspx?List=4f55ad51-4aed-4d32-b960-af70113dbb90&ID=1284

[3] European Commission Better Regulation Agenda. Available at: http://ec.europa.eu/smart-regulation/index_en.htm

Primary evaluation questions	Source of information	Indicators and qualitative input
Effectiveness/impact (3.3.6): What was the impact of the ECDC 2010 guidance on developing, monitoring and evaluating HIV testing strategies and/or programmes at a national level? How was the ECDC 2010 guidance used, if at all, by the primary/Broader Target Group?	Survey data (Primary and Broader Target Groups) Analysis of selected national policy documents	% of respondents indicating no use of the ECDC 2010 guidance in their work, due to: • lack of awareness • a national testing policy/strategy was already in place • the release was untimely • it not being aligned with existing national HIV testing policy/strategy • using other guideline documents • other % of respondents indicating use of the ECDC HIV testing guidance document in their work on national testing policy/strategy/ programme in respect of: • development • revision • monitoring • evaluation • advocacy % of respondents indicating that usage of the ECDC 2010 guidance in their work led to changes in national HIV testing policies/strategies/ programmes within the areas of: • testing strategies • monitoring testing • evaluation of testing • advocacy for testing % of respondents indicating that their country has produced ECDC 2010 guidance since 2010 and used the ECDC 2010 guidance to do so.
	Free text answers in surveys Qualitative data from moderated focus group discussions Expert panel consultation	Qualitative input on the possible use of the guidance, factors hindering use, and any possible impact on testing.
EU added value (3.4.1): Was there any added value of the ECDC guidance for the primary/Broader Target Group? What was, if any, the added value of the ECDC 2010 guidance over similar products at national or international level (e.g. national guidance, WHO guidance)?	Survey data (Primary Target Group)	% of respondents indicating that the ECDC 2010 guidance has been useful in their work to develop HIV testing policies at the national level.
	Survey data (Broader Target Group)	% of respondents indicating that the ECDC 2010 guidance has been or is useful in their work to • advocate for HIV testing • influence policymakers • raise awareness
	Survey data (Primary and Broader Target Groups)	% of respondents indicating that the ECDC 2010 guidance is important for improving HIV testing in their country is: • very important • important • not important
	Free text answers in surveys Qualitative data from moderated focus group discussions Expert panel consultation	Qualitative input on the guidance's EU status provides added value, e.g. whether it is considered important that a guidance exists at EU level.
Usability (3.3.4): Was the ECDC 2010 guidance designed to respond to users' needs?	Survey data (Primary and Broader Target Groups)	% respondents indicating that the ECDC 2010 guidance was • in a user friendly format • written in accessible/comprehensible language • contained sufficient details • was brief and easy to read • was easily accessible as a report
	Free text answers in surveys Qualitative data from focus group Expert panel consultation	Qualitative input on the usability of the ECDC 2010 guidance, its format and suggestions for any changes in its format.

2.1 Methods for data collection

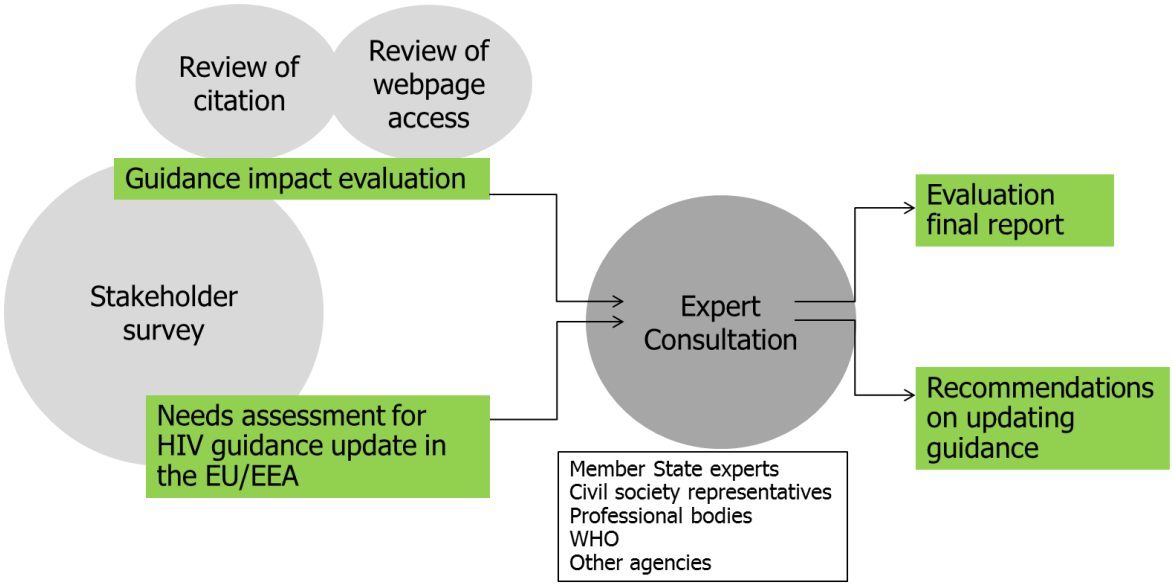
In order to answer the primary evaluation questions (Table 3), different methods were employed to collect and analyse the data (Figure 1). Based on a mixed methods approach the following data were collected:

- quantitative survey data (Primary Target Group/Broader Target Group)
- qualitative data from moderated focus group discussions (at the EACS conference in Barcelona in October 2015)
- webpage access data and review of literature citation
- expert consultation meeting (28–29 January 2016).

Two surveys were developed, reflecting the different backgrounds and potential use in the two target groups (Primary and Broader), and therefore some questions differed between the two surveys (Table 3).

Additionally, there were complementary data from other sources including national testing polices or guidelines and research activities conducted by HIV in Europe (HiE), such as findings from the HIV Indicator Diseases Across Europe (HIDES) study [9,10] and the OptTEST survey[4] on national HIV testing. Results from these have been incorporated into the discussion of the evaluation findings. In addition to the most-used guidelines uploaded by survey respondents, the Study Group searched online to find national HIV testing guidelines for a review and comparison, further explained in section 2.7.

Figure 1. Overview of data collection and evaluation process



2.2 Target group of respondents for the analysis

The Primary Target Group for the ECDC 2010 guidance evaluation was designed to match the guidance target audience (Figure 2). It included ECDC national focal points for HIV and STI and ECDC HIV and STI Disease Network experts, as well as other relevant national policymakers and/or programme managers (for example STI or TB/Hepatitis programme managers).

[4] http://www.opttest.eu/

The Broader Target Group includes representatives from a broad array of organisations and institutions (Figure 2):

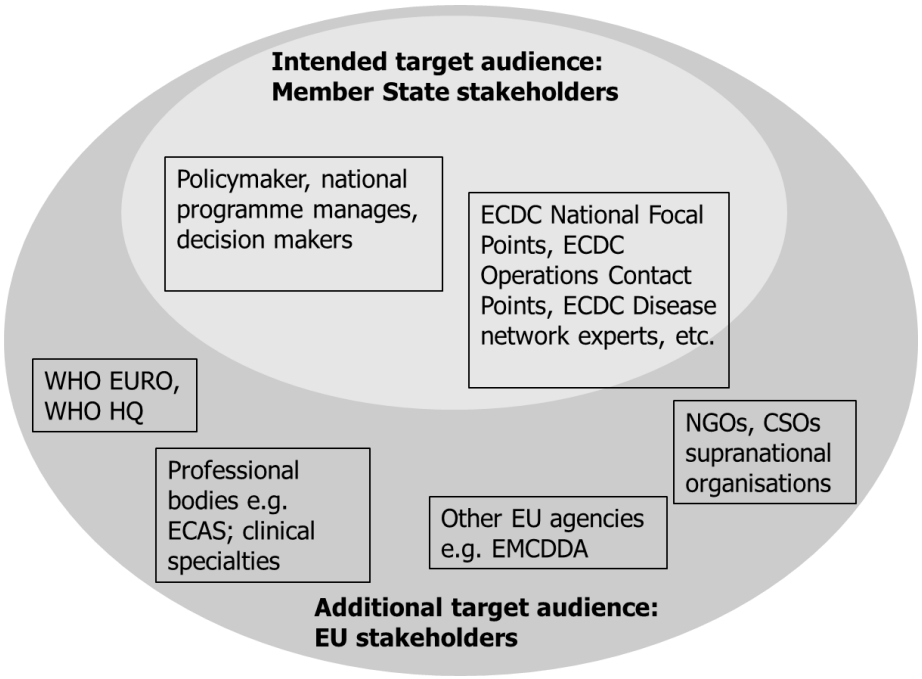
At international/EU level:

- WHO Regional Office for Europe/WHO Headquarters
- The Joint United Nations Programme on HIV/AIDS (UNAIDS), United Nations Office on Drugs and Crime (UNODC)
- Professional bodies (e.g. European AIDS Clinical Society - EACS)
- Clinical specialities (HIV, STI, TB, hepatitis)
- EU agencies (e.g. The European Monitoring Centre for Drugs and Drug Addiction Reitox network)
- NGOs and civil society organisations (CSOs) – for example, Civil Society Forum, Eurasian Harm Reduction Network, Aids Action Europe, European AIDS Treatment Group, Global Network of People living with HIV, Network of Low HIV Prevalence Countries in Central and South-east Europe, International Union against Sexually Transmitted Infections (IUSTI).

At national/local level:

- Institutions responsible for clinical guidance dissemination/quality management in healthcare (e.g. universities, research institutions and clinical departments)
- Local public health stakeholders (e.g. NGOs/CSOs working with specific target groups, Checkpoints)
- People Living with HIV (PLHIV) organisations and organisations for other vulnerable groups (Sex workers and men who have sex with men)

Figure 2. Target audiences



2.3 Survey

Two structured surveys were developed: one targeting the Primary Target Group and one targeting the Broader Target Group (Annex 1–2 – see note on page ii). The indicators listed in Table 3 formed the basis of the surveys. In addition to pre-defined answer categories, the surveys also included open questions allowing the respondents to qualify and further explain their answers.

Data were entered into the Research Electronic Data Capture system hosted at CHIP, Rigshospitalet, University of Copenhagen. This is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for validated data entry, audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages, and procedures for importing data from external sources. The two surveys were reviewed internally and by ECDC, and were piloted across five Member States. Five people piloted the survey targeting the Primary Target Group (from Estonia, Greece, Norway and UK) and three the survey for the Broader Target Group (from Spain and UK). Pilot feedback was incorporated into the final versions of the two surveys.

2.3.1 Selection of respondents

The Primary Target Group was identified by consulting with the ECDC Coordinating Competent Bodies, National Coordinators and National Focal Points for HIV, who were invited (in August/September 2015) to nominate one or more appropriate respondents for the survey covering the following expertise/roles: policymakers/technical advisors and technical experts at national level with responsibility for and/or expertise in the areas of HIV testing and guidance development/implementation. For those Member States that did not provide a nomination, National Focal Points for HIV were directly addressed. For the Primary Target Group, a purposive sampling approach was used with the aim of having at least one response for each Member State. If more than one response was received from a Member State, and conflicting answers were provided, responses were analysed more closely taking the background of the respondents into consideration; responses from the public health sector/national institute received more weight. In addition, where country level information was required, e.g. content of national HIV guidelines, the denominator employed was the number of Member States providing a response, and single country responses were included in the analysis (Primary Target Group-Member State). Where individual opinion was required, all responses were included in the analysis.

Respondents from the Broader Target Group were selected via opportunistic sampling, with the aim of obtaining different responses and insights to the impact and use of the ECDC 2010 guidance. While representativeness was not required for this group, the goal was to distribute the survey widely, aiming for approximately 150 responses. As a consequence, the final number of people reached by the invitations is unknown.

2.4 Focus group discussions

Two focus group discussions of one hour each were conducted during the EACS conference in Barcelona, Spain, in October 2015. Participants were selected on the basis of ability to inform the evaluation by using both purposive sampling and snowball sampling. Participants within the HiE network were invited on the basis of their knowledge of HIV testing in Europe and were asked to invite colleagues to join the focus group discussions. An open invitation was also given during a presentation on HIV testing and information leaflets were available at the registration desk at the IUSTI conference in Sitges, Spain in September 2015. Invitations were distributed widely and the final number of people reached by the invitations is unknown.

A semi-structured interview guide was developed to lead the focus group discussions and ensure that relevant topics were covered (Table 4), and the discussions were moderated. A written summary of the discussions was prepared with emerging key themes. A deductive approach was selected for data analysis and the research questions were the basis for grouping data according to themes, similarities and differences resulting in a descriptive content analysis. Identified themes from the focus group discussions provide anecdotal evidence for the quantitative survey data throughout the report.

Table 4. Summary of moderated topics during the focus group discussions

Topic	Examples of questions
Level of awareness of the guidance	In your opinion, are HIV policymakers and national programme managers aware of the ECDC 2010 guidance? If so to what degree? What about the broader audience?
Relevance	In your opinion, how good was the ECDC 2010 guidance in addressing the needs of the Member States? In your opinion, what needs to change to make the ECDC 2010 guidance more relevant?
Coherence/complementarity	Are there areas/topics in the ECDC 2010 guidance that you consider to be contradictory to other existing guidelines/policies?
Effectiveness/impact	Are you aware of any examples of who has used the ECDC 2010 guidance and how? Do you have any suggestions as to how the ECDC 2010 guidance could be updated and developed in order to increase its use in the future?
EU added value	Do you consider there is EU added value of having an ECDC HIV testing guidance? If so, in what way?
Usability	What are the important usability factors for you in terms of format, availability etc.?

2.5 Organisation of the expert meeting

An Expert Panel was established by ECDC to provide expert opinion on the interpretation and presentation of the findings from the evaluation, and to contribute to the identification of priorities for actions and next steps for ECDC in guidance on HIV testing in the EU/EEA.

The Expert Panel consisted of 18 members representing different constituencies and stakeholders active in the field of HIV testing in the EU/EEA as summarised in Figure 2. Members of the Expert Panel were selected on the basis of recognised expertise and contributions in the field of HIV testing, public health and policy decision making. Geographical representativeness and gender balance were also taken into account in the selection of the experts.

Targeted presentations and moderated discussions during the meeting were used to obtain in-depth information about the experience and opinions of Member States and other stakeholders on the six dimensions of the evaluation: awareness, relevance, coherence/complementarity, effectiveness/impact, EU added value and usability. The topic areas were defined or developed iteratively by the Study Group and ECDC in a process informed by the findings from the survey results and focus group discussions. Preparation for these discussions and the necessary background and information to stimulate discussion was provided to the Expert Panel members prior to and during the meeting.

2.6 Webpage access data and review of literature citation

2.6.1 Webpage access data

The ECDC guidance was published on the ECDC website on 1 December 2010. An analysis of the webpage traffic related to the 2010 ECDC HIV testing guidance webpage was performed in January 2016. The analysis covered the period 1 June 2011 to 31 December 2015, with an interruption of a few months in 2013 due to platform migration. Number of page-views, sources of traffic and access country were analysed for the page with the Guidance document and the page with the Guidance in brief.

Number of page views was categorised as unique views, corresponding to user sessions per page and total views, including all page views (e.g. multiple views during the same session, page refresher). It was not possible to obtain the number of downloads of the guidance as a PDF file with the existing analytics tool.

2.6.2 Citation review

Citation screening was conducted to identify relevant citations of the ECDC 2010 guidance. Searches in Scopus and Google Scholar were performed on 8 January 2016 to retrieve articles and documents in all languages citing the guidance in the period December 2010 to December 2015. The search methodology used the title in the 'references' field and parts of the URL in the 'website' tag in the advance search in Scopus. These searches were repeated in Google Scholar as free text.

The list of records with all the relevant details was compiled in an Excel spreadsheet and also as an EndNote library. A citation analysis was performed focusing on the following variables: time of publication, type of publication and authors' affiliation/geographical coverage (Annex 3 – see note on page ii).

The full text of the records was screened to identify the context and purpose of the citation according to the following categorisation:

- background information on the HIV epidemic and existing testing guidance/policies
- HIV testing as a public health priority
- report or reference to guidance recommendations or core principles
- HIV testing guidance comparative analysis.

2.7 Additional sources of data

2.7.1 Data from other HIV in Europe activities

Within the HiE initiative several ongoing activities are related to HIV testing. Of particular relevance is the HIDES Study and a recent study on the counselling process, the results of which are used to aid interpretation of our findings. Also, as part of the European Commission funded OptTEST project (2014–2017, www.opttest.eu) mapping of HIV testing guidelines was carried out for the Czech Republic, Estonia, France, Greece, Poland, Spain and the UK and these results are also considered.

2.7.2 Data from other ECDC activities

ECDC collects yearly national data on HIV tests performed by EU/EEA Member States in the frame of TESSy. The data, published in the annual HIV surveillance report [3], have been taken into account in the interpretation of findings.

Data on HIV prevalence and testing rates among key populations collected in the framework of the last round of the Dublin Declaration monitoring are also incorporated where relevant [4].

3. Results

3.1 Respondents

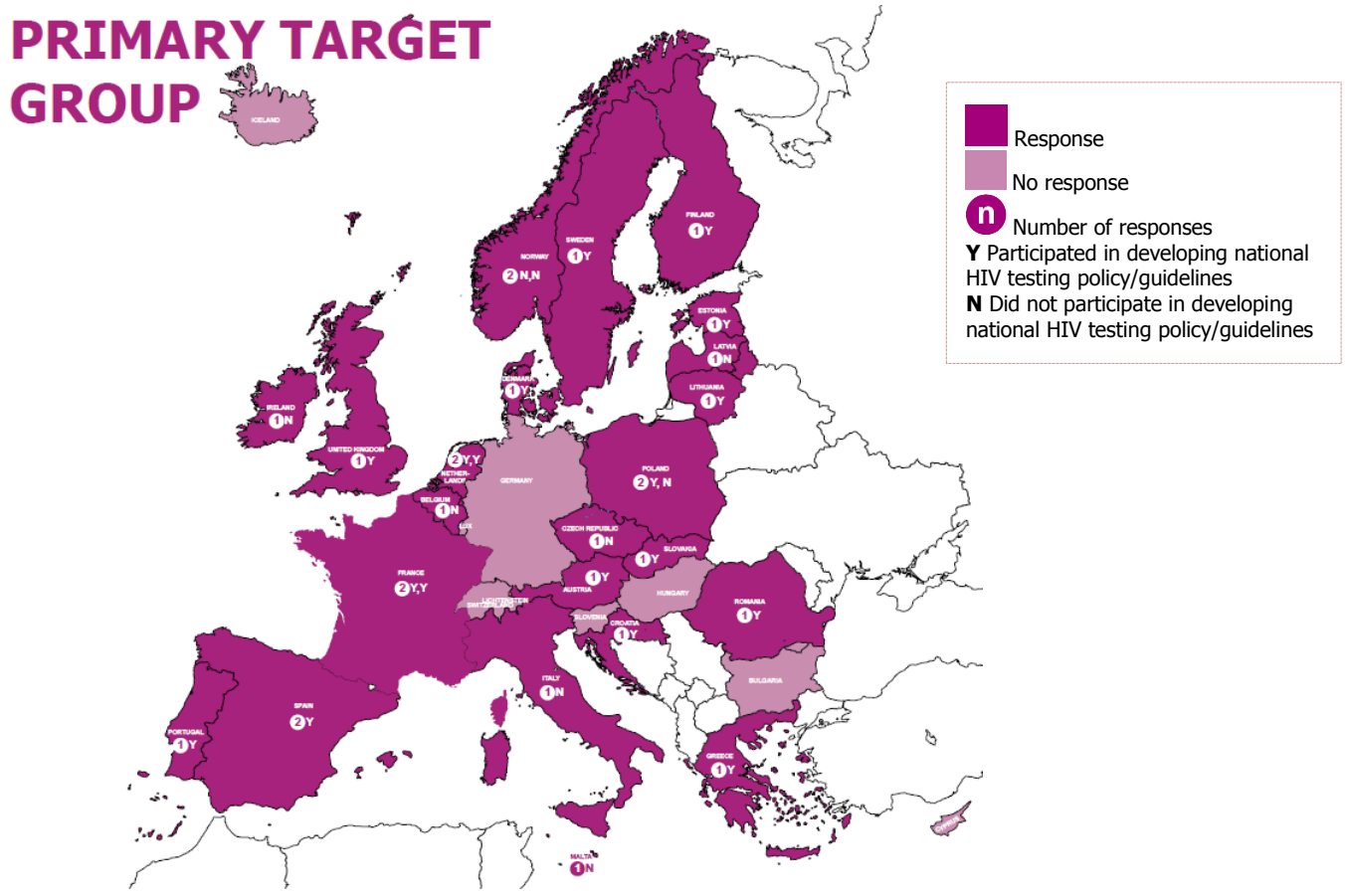
3.1.1 Primary Target Group: Member States representatives

Twenty-eight Primary Target Group respondents from 23 of the 31 EU/EEA Member States responded to the ECDC 2010 guidance evaluation survey, a Member State response rate of 74%. Two responses were submitted from France, Netherlands, Norway, Poland and Spain. Twenty-four of 28 respondents (86%) reported working within the public health sector and two within health research/academia (7%) and NGOs (7%) respectively (Table 5). The reported main area of work was surveillance (13/28 = 46%). Nineteen of 28 respondents (68%) reported having participated in developing national HIV testing guidelines in their country, and further specified that they primarily worked as HIV experts or coordinators of the national working groups.

Table 5. Sectors and countries in which respondents work (N=28)

Sector	Countries
Public health sector (N=24)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France (2), Greece, Ireland, Latvia, Lithuania, Malta, Netherlands, Norway, Poland (2), Portugal, Romania, Slovakia, Spain (2), Sweden, UK
Health research/academia (N=2)	Austria, Italy
NGOs/CSOs (N=2)	Netherlands, Norway

Figure 3. Primary Target Group respondents (N=28)



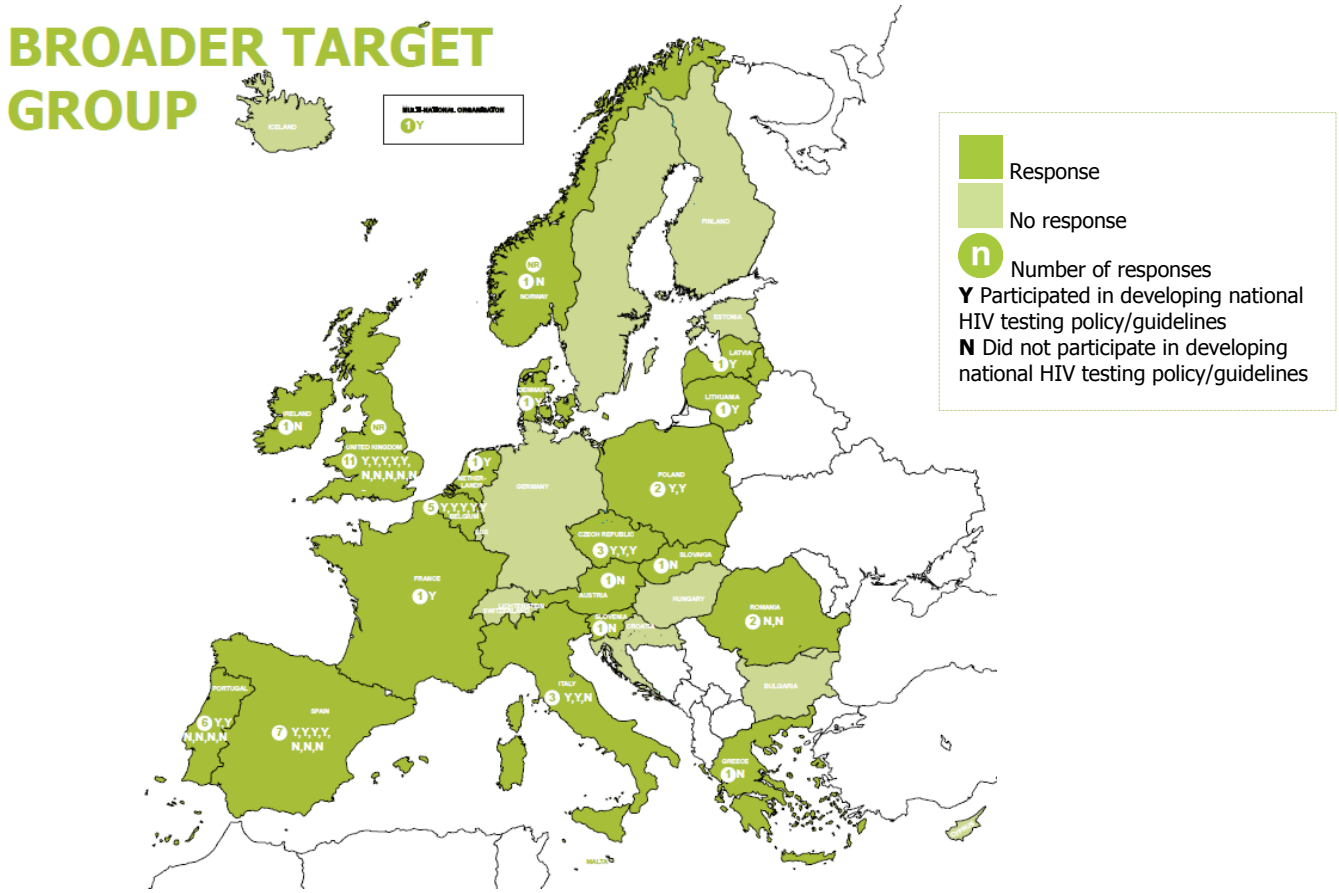
3.1.2 Broader Target Group

Fifty-one Broader Target Group respondents from 18 EU/EEA countries and one multi-national organisation (WHO) responded to the ECDC 2010 guidance evaluation survey (Annex 1 – see note on page ii). Twenty-three of 51 respondents (45%) reported working in an NGO and 18 of 51 (35%) in the public health sector (Table 6). Fifteen of 51 (29%) reported healthcare service provision as their main area of work, ten of 51 (20%) programme/project coordination and eight of 51 community work (16%). Twenty-nine respondents (57%) reported having participated in developing national HIV testing policy/guidelines in their country.

Table 6. Sectors and countries in which respondents work (N=51)

Sector	Countries
Research/academia (N=4)	Belgium, Italy, Portugal, Spain
NGOs/CSOs (N=23)	Austria, Belgium (2), Czech Republic (2), France, Greece, Ireland, Italy, Latvia, Lithuania, Poland, Portugal (3), Romania (2), Slovakia, Slovenia, Spain, UK (3)
Public health sector (N=18)	Belgium, Czech Republic, Denmark, Italy, Poland, Portugal (2), Spain (4), Netherlands, UK (6)
Other (N=3)	Belgium, international organisation (WHO), UK
Sector not specified (N=3)	Norway, Spain, UK

Figure 4. Broader Target Group respondents (N=51)



3.2 Current situation of national HIV testing guidelines, programmes and initiatives

3.2.1 Availability and use of national HIV testing guidelines, strategy and policy documents

Respondents from the Primary Target Group (N=28) were asked to indicate on a rating scale to what degree a presented list of documents was used nationally; rating the use from not at all (corresponding to 1) to very widely used (corresponding to 5). The most utilised national documents were national HIV strategy/policy documents that included recommendations on testing (68%), national HIV testing guidelines documents (57%) and guidelines on HIV testing issued by professional societies (50%) (Table 7). Primary group respondents were also asked to provide a link to or upload the most used documents; of which 21 of 28 (75%) did (Table 8).

Table 7. Documents reported most used nationally (N=28)

Document	Reporting use of document (%)*	Median Score	Countries
A national HIV strategy/policy that includes recommendations on testing	68% (N = 19)	5 [1-5]	Austria, Croatia, Czech Republic, Denmark, Estonia, Finland, France (2), Greece, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Slovakia, Spain
National HIV testing guidelines document	57% (N =16)	3.5 [1-5]	Austria, Czech Republic, Denmark, Estonia, Finland, France (2), Greece, Latvia, Lithuania, Malta, Netherlands, Norway, Portugal, Slovakia, Spain
Guidelines on HIV testing issued by professional societies	50% (N = 14)	4 [1-5]	Austria, Belgium, Croatia, Czech Republic, Estonia, Ireland, Italy, Latvia, Lithuania, Netherlands (2), Norway, Poland, Portugal
A national HIV testing policy document	36% (N=10)	4 [1-5]	Austria, Denmark, Czech Republic, France, Latvia, Lithuania, Netherlands, Norway, Portugal, Romania
A national HIV testing strategy document	36% (N=10)	3 [1-5]	Czech Republic, France (2), Latvia, Lithuania, Netherlands (2), Norway, Portugal, Slovakia
A specific policy concerning provider initiated testing and counselling	21% (N = 6)	4 [3-5]	Czech Republic, Lithuania, Netherlands (2), Norway, Portugal
A specific policy concerning client initiated testing and counselling	21% (N = 6)	2.5 [1-4]	Czech Republic, Latvia, Lithuania, Netherlands, Norway, Portugal

**Respondents could report multiple answers*

Table 8. Most-used documents uploaded by Primary Target Group-Member State respondents

Member State*	Most-used document#	Released	Planned update
Austria	AIDS act of 1993 [11]	1993 – amended in 2001	Updated regularly by national AIDS commission
Croatia	A) National HIV programme 2011–2015 (new version 2016–2020) [12] B) Recommendations for prevention of occupational exposure to healthcare workers infections transmitted in blood [13]	A) 2010 B) 2004	A) 2016 B) No information
Czech Republic	The National Programme for HIV/AIDS in the Czech Republic 2013–2017 [14]	2012	2016
Denmark	A) New strategy for HIV testing [15] B) Recommendations on prevention, diagnosis and treatment of STIs [16]	A) 2009 B) 2015	A) Not planned** B) Not planned
England	A) HIV testing brief, NICE [17] B) British HIV Association /British Association for Sexual Health/British Infection Association guidelines on testing [18]	A) 2014 B) 2008	A) Not planned*** B) No information
Estonia	Estonian National HIV and AIDS Strategy[19]	2005	2015
Finland	A) Finland HIV-strategy, 2013–2016 [20] B) The principles of HIV testing. The recommendation for basic healthcare work for points, and a low threshold [21]	A) 2012 B) 2010	A) 2016 B) No information
France	A) Public health guidelines: HIV infection screening in France, laboratory tests and algorithms [22] B) Screening for HIV infection in France, Strategies and screening system [23]	A) 2008 B) 2009	A) No information B) 2016
Greece	Guidelines for the diagnosis of HIV infection in clinical and non- clinical settings [24]	2009	2016
Ireland	AIDS strategy 2000, Report of the national AIDS Strategy Committee [25]	2000	No information
Italy	A) Consensus document on policy for HIV testing in Italy [26] B) Consensus Conference on HIV testing: Questions and answers [27]	A) 2011, updated 2013 B) 2012	A) No Information B) No information
Latvia	A) Human immunodeficiency virus (HIV) infection diagnosis, treatment and prevention clinical guidelines [28] B) Procedures for obstetric care [29]	A) 2014 B) 2003	A) Updated regularly by national AIDS commission B) No information
Lithuania	Link to webpage: Communicable Diseases and AIDS [30]	No information	No information
Netherlands	A) National STI/HIV plan 2012–2016 - Consolidating and strengthening [31] B) LCI guideline for HIV infection [32] C) For GPs: HIV - floor next to the Dutch College of General Practitioners – standard - sexually transmitted diseases[33]	A) 2011 B) 2014 C) 2013	A) No information B) No information C) No information
Norway	D) Online guide in communicable disease control for the municipal health service [34] E) Acceptance and coping - National HIV strategy (2009–2014)[35] F) Revitalisation and concretisation (2013–2015), Additions to the National HIV Strategy 'Acceptance and Coping' [36]	A) 2011 B) 2008 C) 2012	A) No information B) No information C) No information
Poland	Implementation Schedule of a National Program for Prevention of HIV Infections and Combating AIDS, 2012–2016 [37]	2012	2017
Portugal	A) Diagnostics and Laboratory Screening for infection with HIV [38] B) Pregnancy and Human Immunodeficiency Virus HIV [39]	A) 2011, revised 2014 B) 2004	A) No information B) Updating planned
Romania	A) Law no. 584/2002 on measures to prevent the spread of AIDS in Romania and to protect persons infected with HIV or suffering from AIDS [40] B) Programme: Strengthening the prevention and control of HIV/AIDS, HVB, HVC in Romania 2009–2014 [41]	A) 2002 B) 2008	A) No information B) No information
Slovakia	National Programme for HIV / AIDS Prevention in the Slovak Republic 2013–2016 [42]	2000	2016

**Of the 28 respondents 21 from 19 countries uploaded national documents; #As reported by respondents; **Updated in 2015; ***Will be updated in 2016*

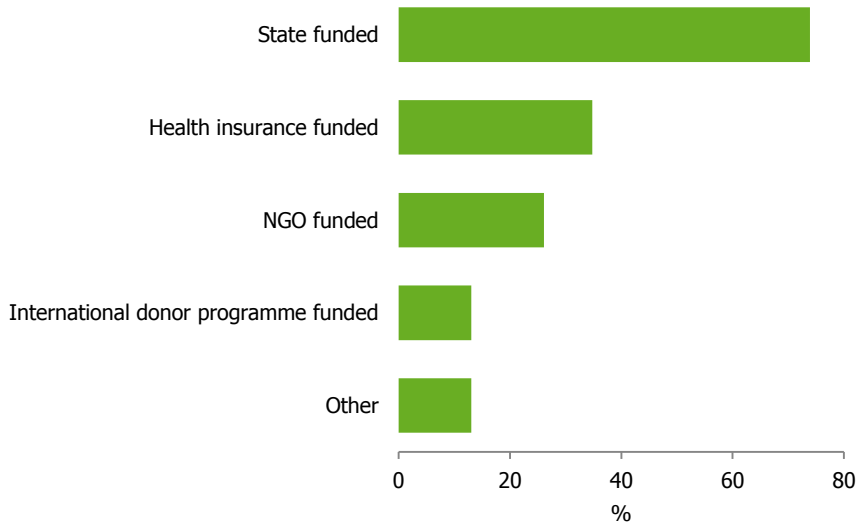
3.2.2 HIV testing programmes in the EU/EEA

Of the 23 Primary Target Group Member States, seven (30%) (Croatia, France, Greece, Ireland, Netherlands, Portugal and Romania) reported that there is a national HIV testing programme in their country. For the other countries, nine (39%) (Austria, Belgium, Denmark, Estonia, Finland, Latvia, Lithuania, Norway, and UK) reported that their health system conducts HIV testing, and seven (30%) (Belgium, Czech Republic, Finland, Italy, Malta, Norway and Sweden) reported that testing programmes and services are ongoing at subnational level.

The seven Primary Target Group Member States reporting having a national HIV testing programme, were also asked whether there is a national monitoring and evaluation plan of national HIV testing in their country. Four countries reported having such a plan in place (Croatia, France, Greece and Romania), while three did not have a monitoring and evaluation plan (Ireland, Netherlands and Portugal).

The financing of the existing programmes, both nationally and sub-nationally, was reported as being state funded by 17 of 23 (74%) Primary Target Group Member States, funded through health insurance by eight (35%), by NGOs by six (26%), and through international donor programmes by three (13%). While 11 of the 23 (48%) Member States provided only one source of financing, nine (39%) Member States reported mixed financing, primarily including both state-funded and health insurance funded programmes (three Member States did not report on the type of financing) (Figure 5).

Figure 5. Financing of existing HIV testing programmes (N=23)



3.2.3 Elements included in HIV testing practice in Member States

The Primary Target Group Member States reported the following elements as the most frequently included in HIV testing practice:

- post-test access to treatment, care and prevention services (N=17)
- voluntary, confidential testing with informed consent (N=16)
- testing of all pregnant women for HIV (opt-out) (N=16)
- dedicated HIV testing centres (N=15).

Areas less frequently mentioned were

- written informed consent (N=2)
- home testing/self-testing (N=1)
- routine HIV test offer in emergency departments (N=4) (Table 9).

Table 9. Elements included in HIV testing practice (N=23)*

Elements	% (N)	Member States
Goals and principles		
Post-test access to treatment, care and prevention services	78% (17)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Ireland, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Slovakia
Voluntary, confidential testing with informed consent	70% (16)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Slovakia
Post-test counselling	70% (16)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Slovakia
A defined target audience	65% (15)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, Greece, Ireland, Italy, Lithuania, Netherlands, Norway, Portugal, Romania, Slovakia
Pre-test counselling or pre-test discussion	57% (13)	Belgium, Croatia, Czech Republic, Estonia, Finland, Greece, Italy, Lithuania, Malta, the Netherlands, Norway, Portugal, Romania
Desirability or requirement to remove legal or financial barriers	43% (10)	Belgium, Czech Republic, Croatia, Denmark, France, Greece, Italy, Norway, Portugal, Slovakia
Raise professional awareness and train the workforce	43% (10)	Croatia, Czech Republic, Denmark, France, Greece, Italy, Lithuania, Malta, Portugal, Romania
Monitoring and evaluation programme	39% (9)	Croatia, Czech Republic, Denmark, Finland, France, Greece, Netherlands, Portugal, Romania
Partner notification	35% (8)	Czech Republic, Denmark, Estonia, Greece, Lithuania, Malta, Netherlands, Norway
Testing conducted by lay providers	22% (5)	Czech Republic, Denmark, France, Greece, Portugal
Streamlining of counselling process (less demanding)	17% (4)	Croatia, Denmark, Finland, Greece
Written informed consent	9% (2)	Lithuania, Romania
Settings		
Dedicated HIV testing centres (e.g. for people at high risk, PWID services)	65% (15)	Belgium, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Greece, Italy, Malta, Netherlands, Norway, Portugal, Romania, Slovakia
Outreach services	43% (10)	Belgium, Croatia, Denmark, Finland, Greece, Lithuania, Netherlands, Portugal, Romania, Slovakia
Routine offering in general practice	35% (8)	Belgium, Estonia, France, Malta, Norway, Portugal, Romania, Slovakia
Non-medical, non-traditional alternative settings (saunas, field visits, etc.)	30% (7)	Belgium, Denmark, Finland, France, Netherlands, Norway, Portugal
Routine offering in emergency departments	17% (4)	Belgium, Malta, Norway, Romania
Home testing/self-testing	4% (1)	France
Sub-groups		
Testing of all pregnant women for HIV (opt-out)	70% (16)	Austria, Belgium, Czech Republic, Estonia, Finland, France, Greece, Ireland, Italy, Lithuania, Malta, Netherlands, Norway, Portugal, Romania, Slovakia
Testing of all most-at-risk population groups	57% (13)	Belgium, Croatia, Czech Republic, Estonia, Finland, France, Greece, Italy, Lithuania, Netherlands, Norway, Portugal, Romania
Testing of sero-discordant couples (routine testing of HIV negative partner)	52% (12)	Croatia, Czech Republic, Estonia, Finland, France, Greece, Lithuania, Malta, Netherlands, Norway, Portugal, Romania
Testing of people with an indicator condition, e.g. pneumonia, mononucleosis-like illness	48% (11)	Belgium, Croatia, Estonia, Finland, France, Greece, Italy, Lithuania, Netherlands, Portugal, Romania
Testing frequency	30% (7)	Estonia, France, Greece, Malta, Norway, Portugal, Romania
Tandem Hep C or B/C and HIV testing	22% (5)	Estonia, Finland, Greece, Malta, Romania

**Respondents could provide multiple answers*

3.3 Impact assessment

3.3.1 Who was reached and how

All 28 (100%) Primary Target Group respondents were aware of the ECDC 2010 guidance and 50% have used it for their work. Of the 42 (82%) Broader Target Group respondents aware of the guidance, 36% used it for their work (Table 10).

Table 10. Awareness and use of ECDC testing guidance*

Level of awareness	Primary Target Group (N=28)	Broader Target Group (N=51)	Total (N=79)
Knowledge of its existence	100% (N =28)	82% (N=42)	89% (N=70)
Have looked at it	36% (N=10/28)	26% (N=11/42)	27% (N=21/70)
Have discussed it in professional settings/networks	29% (N=8/28)	31% (N=13/42)	30% (N=21/70)
Have used it for work	50% (N=14/28)	36% (N=15/42)	41% (N=29/70)
Have distributed it in national/professional networks	43% (N=12/28)	55% (N=23/42)	50% (N=35/70)
Translated into local language	0% (0=0/28)	5% (N=2/37)**	3% (N=2/65*)

**Respondents could provide multiple answers*

***Five respondents responded not applicable as English is local language*

Nineteen of the 28 (70%) Primary Target Group respondents who were aware of the guidance, reported becoming aware of it via the ECDC website, 16 (59%) from professional networks and meetings/conferences and 15 (56%) from searching online. Twenty-one (75%) reported more than one source of information about the existence of the ECDC 2010 guidance. Seventeen of the 42 (40%) Broader Target Group respondents who were aware of the ECDC 2010 guidance, reported becoming aware of it via the ECDC website, 24 (57%) from professional networks, 22 (52%) from meetings/conferences and 15 (36%) from a national document which referenced the guidance. Thirty-two of the Broader Target Group respondents (76%) reported more than one source of information about the existence of the ECDC 2010 guidance.

Only 13 of the 28 (46%) Primary Target Group and 15 of the 51 (29%) Broader Target Group respondents were familiar with the brief version of the guidance, and of those, 12 (92%) Primary Target Group respondents found it to be useful or very useful, and all (100%) of the Broader Target Group respondents found it to be useful or very useful.

3.3.2 Citation and web access review

3.3.2.1 Website access of the 2010 ECDC guidance

Guidance documents are the third most popular type of publication accessed on the ECDC website, after surveillance and technical reports. Within guidance documents, HIV/STI is the second most popular topic, after influenza.

During the time period when data collection was possible, i.e. June 2011 to December 2015 with a few months gap in 2013, the guidance had a total of 619 page-views (530 unique views), of which 71% were via Google and 22% via direct access. The main access countries were Greece, Poland, Portugal and the UK. In the same period, the brief version had 233 page-views (180 unique views), via email referral (23%), Google (48%), direct access (25%) or via Eurosurveillance (12%). Main access countries were Serbia, Sweden, South Korea and Turkey.

No data were available for the period of time immediately subsequent to the documents release, nor were data on direct access to and download of pdf files.

3.3.2.2 Citation of the 2010 ECDC guidance

In the period from December 2010 to end December 2015 the guidance was cited 79 times; the full list is provided in Annex 3 (see note on page ii). The majority of citations were from journal articles (65, 82%), however other sources of citations included journal reviews (4, 5%), reports (3, 4%), editorials (3, 4%) and one each in a book and one thesis.

The citation linear trend is upwards until 2014 and then the number of citations is maintained in 2015.

Table 11. Number of citations received per year

Year	Number of citations
2010 (December month only)	2
2011	2
2012	14
2013	21
2014	21
2015	19
Total	**79**

Half of the records (40/79, 51%) report or reference the recommendations or core principles of the guidance and around a third (25/79, 31%) use it as a reference for HIV testing being a public health priority. It is also referenced as background information on the HIV epidemic and existing testing guidance/policies (10/79, 13%), and as part of comparative analyses of HIV testing guidance (4/79, 5%) (Table 5).

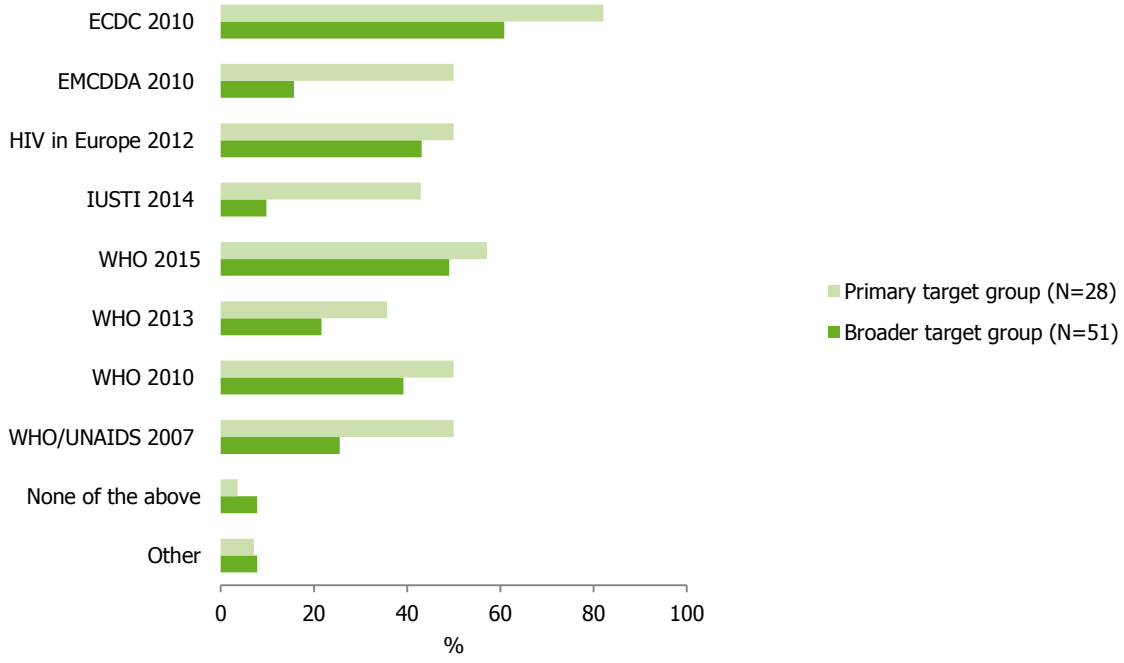
Table 12. Guidance citation content

Category: type of information	No. of records	Citation example
Background information on HIV epidemic and existing testing guidance/policies	10[43-52]	The large majority of sexually transmitted infection (STI) prevention, diagnosis, and treatment occurs in primary care centres.
HIV testing as a public health priority	25[6,53-76]	Early testing for HIV infection is known to be an economically and medically effective strategy, but is under-used across Europe.
Report or reference to guidance recommendations or core principles	40[77-116]	HIV testing has been a cornerstone of AIDS prevention strategies, as early diagnosis and treatment have both individual and public health benefits. Most-at-risk populations have been specifically targeted, and it has been recommend that MSM should be tested annually, or more often depending on sexual behaviour.
HIV testing guidance comparative analysis	4[117-120]	Advocating for multiple pathways in the provision of HIV testing services is also reflected in the international policy discourse.

3.3.3 Relevance of the ECDC HIV testing guidance

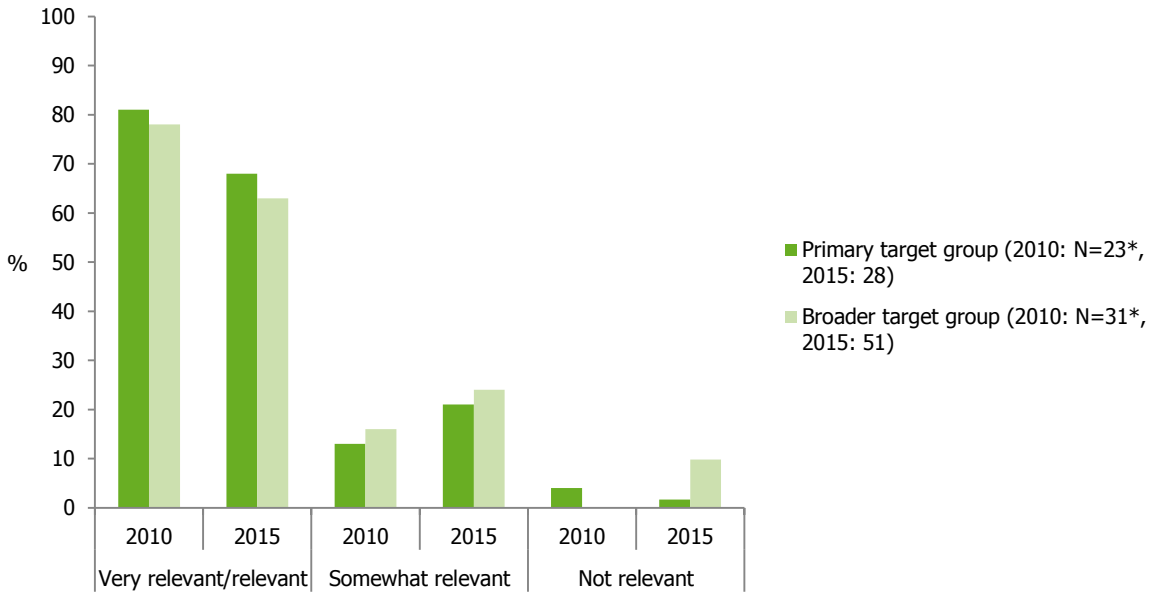
Twenty-three of the 28 (82%) Primary Target Group respondents and 31 of 51 (61%) Broader Target Group respondents indicated that the ECDC 2010 guidance is the most relevant guidance among several international guidance/guidelines listed (Figure 6).

Figure 6. Most relevant international HIV testing guidelines/guidance



Most primary (18 of 23, 81%) and broader (18 of 31, 81%) target group respondents indicated that the ECDC 2010 guidance was very relevant or relevant when published in 2010, and for their current work (2015) (Figure 7).

Figure 7. Relevance of ECDC 2010 guidance in 2010 and 2015



** All respondents were asked if relevant in 2015, while only the ones that ticked ECDC as a relevant guidance were asked if relevant in 2010.*

Those respondents reporting the ECDC 2010 guidance of any degree of relevance when published in 2010 (21 of the primary and 30 of the Broader Target Group), were asked for which areas of their work the ECDC 2010 guidance was considered most relevant (Table 13).

Table 13. Areas for which the ECDC 2010 guidance was considered to be relevant*

	Primary Target Group respondents (N=21)	Broader target group respondents (N=30)	Total (N=51)
As a reference policy document	86% (18)	63% (19)	65% (31)
General information about approaches to HIV testing	76% (16)	57% (17)	60% (29)
For national HIV testing policy/ guidelines/strategy development/monitoring/evaluation	76% (16)	37% (11)	49% (22)
For HIV testing programme development/monitoring/evaluation	62% (13)	47% (14)	44% (21)
For comparison between different countries' testing policies	38% (8)	20% (6)	25% (12)
To provide technical feed-back to policymakers/decision-makers	33% (7)	20% (6)	19% (9)
Other	2 (10%)	7% (2)	4% (2)
To support advocacy work on HIV testing/influence decision makers/raise awareness about HIV testing	NA**	53% (16)	NA**
To fundraise /mobilise resources for HIV testing	NA**	10% (3)	NA**

**Respondents could provide multiple answers*

***Response option not available to Primary Target Group respondents*

For the Primary Target Group respondents, the 2010 ECDC HIV testing guidance was most useful as a reference policy document (86%), as general information (76%) and for national HIV testing policy/ guidelines/strategy development/monitoring/evaluation (76%). For the Broader Target Group, the 2010 ECDC HIV testing guidance was most relevant as a reference policy document (63%), for general information (57%) and for advocacy purposes (53%), and less so for national HIV testing policy/ guidelines/strategy development/monitoring/evaluation (37%) (Table 13).

Reasons reported by the two respondents from the Primary Target Group who indicated that the ECDC 2010 guidance was not useful included that another testing policy/strategy/programme not quite corresponding to the ECDC 2010 guidance was already in place (N=1), and use of other HIV testing guidance (N=1).

From the two focus group discussions it was clear that the ECDC 2010 guidance was considered by most participants to be relevant when it was published in 2010, and had been used for national guideline development and for influencing policymakers.

However, the focus group participants agreed that the guidance is outdated; not least because of the paradigm shift due to recent evidence on Treatment as Prevention [121] and the benefits of starting ART regardless of disease stage [122], which places even more urgency on HIV testing to deliver benefit. Bluntly put by one participant:

> "As it stands the document needs to be withdrawn! ECDC should notify the countries that this is withdrawn until a new accurate guidance is ready."

3.3.4 Usability of guidance

In order to see whether the ECDC 2010 guidance was designed to respond to the needs of the primary and Broader Target Group, respondents were asked about the usability of the ECDC 2010 guidance (Figures 8 and 9).

Figure 8. Reported usability of the ECDC 2010 guidance by the Primary Target Group (N=28)

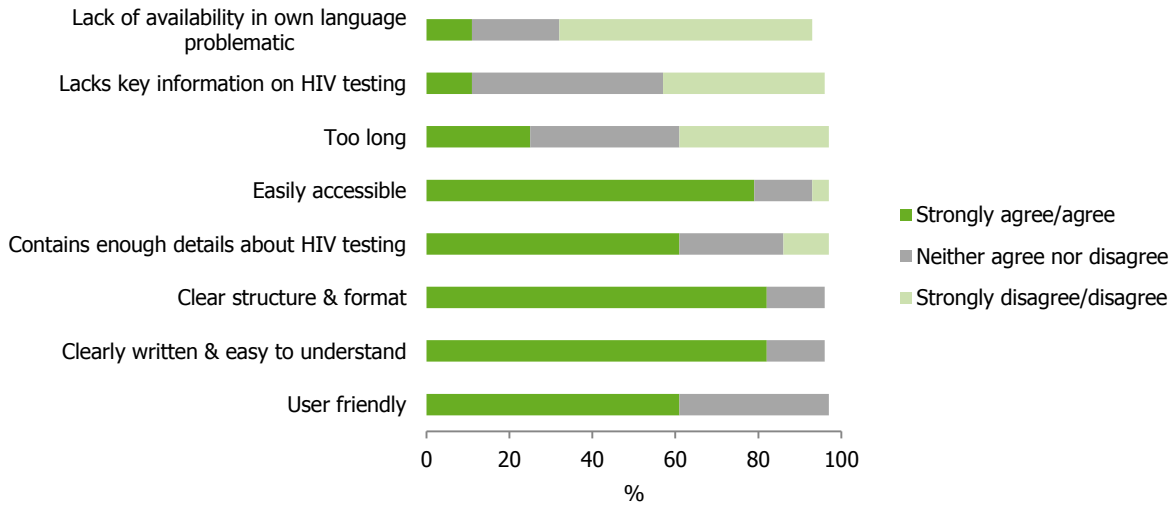
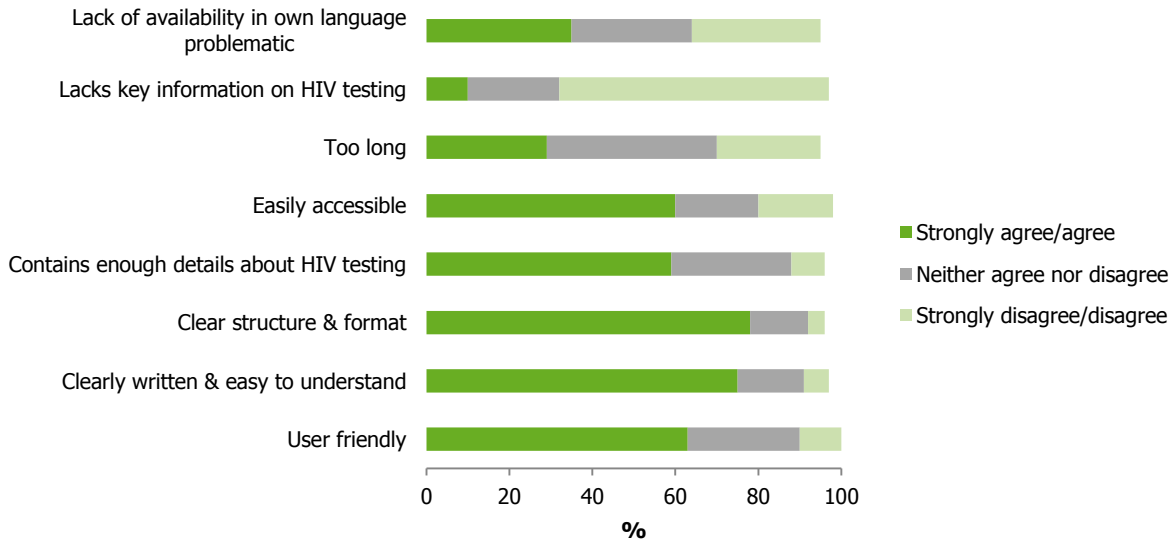


Figure 9. Reported usability of the ECDC 2010 guidance by the Broader Target Group (N=51)



As shown in Figures 8 and 9, the majority agreed that the ECDC 2010 guidance was good in terms of being easily accessible, having a clear structure and format, being user-friendly and clearly written. A higher percentage in the Broader Target Group (>30%) found it problematic that the guidance was not available in their own language than in the Primary Target Group (11%). More Primary Target Group respondents (80%) than those in the Broader Target Group (60%) found the report easily accessible.

On the usability of the guidance, the two focus group discussions acknowledged the trade-off between comprehensiveness and user-friendliness. Some argued in favour of a shorter document and others found that it is too general and therefore difficult to implement. One participant said:

> "The guidance document was useful, but provides very large lines (general lines). It is not specific enough, so therefore difficult to include (in national guidelines)."

3.3.5 Alignment between the ECDC 2010 guidance and national testing programmes

In order to determine the extent to which the ECDC 2010 guidance is aligned with and complementary to existing national documents and interventions, Member States were asked to indicate to what extent their national HIV testing policy/guidelines/programmes align with the ECDC 2010 guidance.

Thirteen of the 23 (57%) Member States reported the ECDC 2010 guidance as being very closely or somewhat aligned, and one (4%) as slightly aligned (Table 14).

Table 14. Extent to which the ECDC guidance is aligned with recommendations and/or technical content of the most widely used national policy/guidelines in their country (N=23)

Level of alignment	N (%)	MS
Closely aligned/somewhat closely aligned	13 (57%)	Croatia, Czech Republic, Denmark, Estonia, Finland, Greece, Lithuania, Malta, Portugal, Romania, Slovakia, Spain, Sweden, UK
Slightly aligned	1 (4%)	Italy
Not at all aligned	2 (9%)	Ireland, the Netherlands
Do not know	7 (30%)	Austria, Belgium, France, Latvia, Norway, Poland, Spain

3.3.6 How was the ECDC 2010 guidance used in developing guidelines?

To evaluate the impact of the ECDC 2010 guidance on developing, monitoring and evaluating HIV testing strategies and/or programmes at national level, primary and Broader Target Group respondents were asked if they actively used the ECDC 2010 guidance and for what purpose.

Ten of 23 (43%) Primary Target Group Member States reported having used the ECDC 2010 guidance in the development, monitoring and/or evaluation of their national HIV testing policy/guidelines/programme/strategy. Seven Primary Target Group Member States reported that the ECDC 2010 guidance was not used. Of these, five reported this was because a national testing policy/guideline or strategy/programme was already in place. One reported that it was because the release of the ECDC 2010 guidance was untimely, and one that other HIV testing guidelines were used [123].

From the Broader Target Group, 29 of 51 (56%) respondents reported having used the ECDC 2010 guidance for developing information materials or advocacy activities. Of the 11 Broader Target Group respondents who reported not using the ECDC 2010 guidance, four reported that this was because a national testing policy/guideline, or strategy/programme was already in place, and five because other testing guidelines were used. Four of five clarified which other guidelines were used [17,18,124].

The Primary Target Group Member States and Broader Target Group respondents who reported using the ECDC 2010 guidance (10 and 29, respectively) were asked how it was used, and the answers differed between the two groups (Table 15).

Table 15. Reported use of the ECDC 2010 guidance*

Use of the ECDC guidance by primary and Broader Target Group	Primary Target Group Member States (N=10)	Broader Target Group (N=29)
To revise an existing HIV testing policy/guidelines/programme (Primary Target Group Member States), HIV testing principles/guidance documents (Broader Target Group)	**6 (60%)** Croatia, Greece, Malta, the Netherlands, Portugal, Romania	**19 (66%)** Public health sector (5): Denmark, Italy, Spain (2), UK Private health sector (1): Belgium Research/Academia (1): Spain NGOs/CSOs (10): Belgium (2), Czech Republic (2), Ireland, Italy, Portugal (3), Romania Other (2): Belgium, multinational organisation
To support/inform the monitoring/evaluation of HIV testing	**5 (50%)** Croatia, Greece, the Netherlands, Portugal, UK	**9 (31%)** Public health sector (4): Belgium, Spain (3) Private health sector (0): -- Research/Academia (1): Italy, NGOs/CSOs (4): Belgium, Greece, Italy, Portugal
To develop a new HIV testing policy/guidelines/programme (Primary Target Group Member States) Information materials on testing/ NGO testing guidance principles (Broader Target Group)	**3 (30%)** Belgium, Croatia, Estonia	**12 (41%)** Public health sector (2): Spain, UK Research/Academia (2): Belgium, Spain NGOs/CSOs (6): Ireland, Italy, Poland, Portugal (2), Romania Other (2): Belgium, Spain
To advocate for HIV testing raise awareness on HIV testing (Broader Target Group)	**3 (27%)** Greece, Lithuania, Norway	**18 (62%)** Public health sector (4): Belgium, Spain (2), UK Research/Academia (2): Belgium, Spain NGOs/CSOs (11): Austria, Belgium (2), Czech Republic, Greece, Ireland, Portugal (2), Romania (2), Spain Other (1): Belgium
To fundraise/mobilise resources for HIV testing programmes	**2 (18%)** Lithuania, Spain	**13 (45%)** Public health sector (3): Spain (2), UK Research/Academia (2): Belgium, Spain NGOs/CSOs (7): Belgium (2), Czech Republic, Ireland, Portugal (2), Spain Other (1): Belgium
Other	**2 (18%)** Belgium, Spain	**1 (3%)** Research/Academia (1): Portugal
To influence decision makers (Broader Target Group)	NA (--)	**4 (14%)** Public health sector (1): Spain Research/Academia (1): Portugal NGOs/CSOs (3): Portugal (2), Ireland

**Respondents could provide multiple answers*

The Primary Target Group Member States (10 of 23) and Broader Target Group respondents (29 of 51) who reported having used the ECDC 2010 guidance, further specified which parts of the guidance was utilised (Table 16).

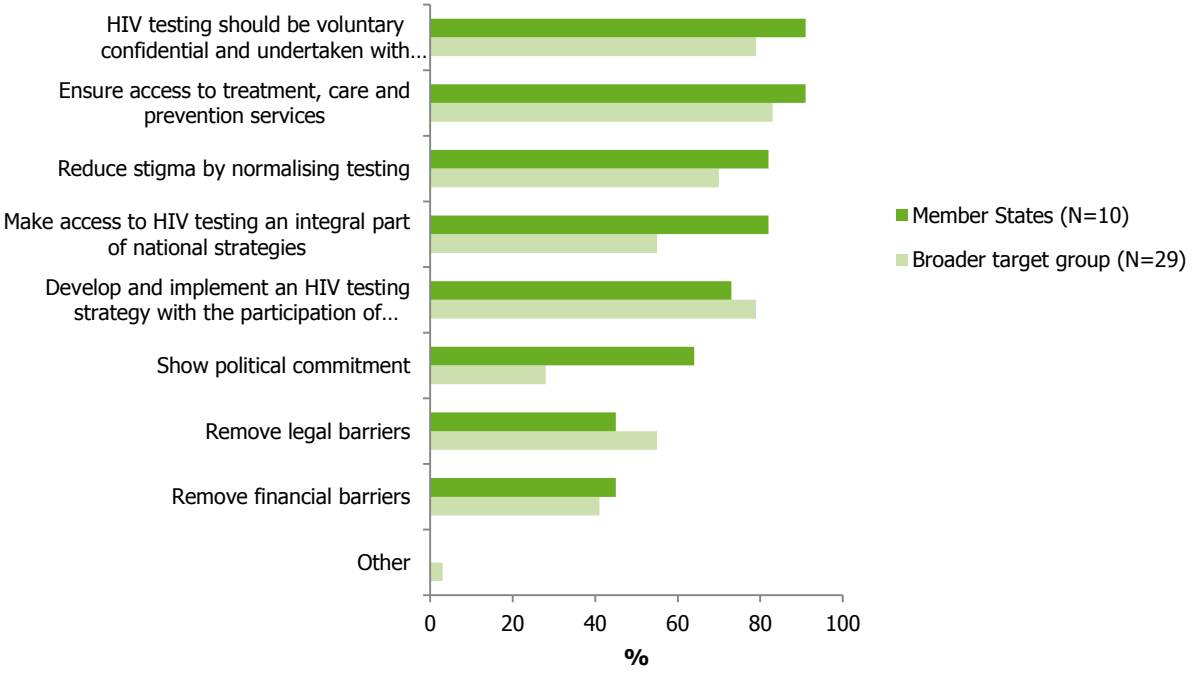
Table 16. Parts of the ECDC 2010 guidance utilised*

Part of the guidance most used	Primary Target Group Member States (N=10)	Broader Target Group (N=29)	Total (N=39)
Core principles for national HIV testing strategies and programmes	100% (10)	69%(20)	77% (30)
Whom, where and when to test	80% (8)	90% (26)	87% (34)
How to test	50% (5)	45% (13)	46% (18)
Ensuring access to HIV treatment, care and prevention	40% (4)	66% (19)	59%(23)
Monitoring and evaluation	40% (4)	24% (7)	28% (11)

**Respondents could provide multiple answers*

The Primary Target Group Member States (10 of 23) and Broader Target Group respondents (29 of 51) who reported having used the ECDC 2010 guidance reported the following core principles as the most frequently utilised (Figure 10).

Figure 10. Utilisation of core principles in the ECDC 2010 guidance*



**Respondents could provide multiple answers*

3.3.7 Changes in national HIV testing policies/practices

Thirteen of the 28 Primary Target Group respondents reported having used the guidance for the development, monitoring and/or evaluation of their national HIV testing policy/guidelines/programme/strategy (46%). Twelve of the 13 (92%) Primary Target Group respondents who reported having used the ECDC 2010 guidance reported it was of some importance (either very important/important or somewhat important) for changes in national HIV testing policies/guidelines or strategies/programmes in their country. None of the Primary Target Group respondents specified within which areas these changes were important.

Twenty of the 28 (71%) Primary Target Group respondents and 38 of the 51 (75%) Broader Target Group respondents reported having seen changes in HIV testing practices in their country since 2010. Eighty percent of primary (N=16/20) and 42% of Broader Target Group respondents (N=16/38) reported that in their opinion these changes have led to an improvement in HIV testing in their country. Of these, seven (35%) primary and nine (24%) Broader Target Group respondents indicated that in their opinion the ECDC 2010 guidance had an impact on the changes. The 20 primary and 38 Broader Target Group respondents reported the introduction of rapid HIV testing and expanded testing in non-conventional settings (Table 17) among the observed changes in HIV testing practices in their country.

Table 17. Description of observed changes in HIV testing practices since 2010

	Primary Target Group (N = 20*)	Broader Target Group (N =38*)	Total (N=58)	Examples of reported changes
Rapid HIV tests	7	14	21	HIV testing using rapid tests increased in last years
More focus on community based and outreach testing in alternative settings	6	15	21	We offer outreach testing to try to reach MSM and migrants better
Increased targeted testing of high risk groups	5	5	10	New identifiable target groups (i.e. Sex workers, PWID Migrants etc.)
Availability of home or self-testing	2	9	11	Introduction of home based testing (via online services)
Increased testing in general health care setting/ intensification of HIV indicator based HIV testing	2	7	9	Intensification of HIV indicator condition guided HIV testing and more awareness among general practitioners
Testing provided by lay providers	2	4	6	Focus on MSM and rapid testing performed by lay personnel
Testing algorithm updates	1	2	3	Widespread introduction of point of care testing and 4th generation tests
New technologies for detection of acute infection	-	1	1	There were new technologies applied, people were trained according to new standards
Integration of high impact prevention PEP, PrEP, early treatment	-	1	1	Testing as key factor for integration of three high impact prevention: PEP, Early Treatment and PrEP
Tandem testing (e.g. STIs-HIV, HIV-HBV, HIV-HCV)	-	1	1	Syphilis testing is now more often involved in HIV voluntary counselling and testing (MSM and negative partners of PLWHA). Rapid syphilis tests allow keeping the anonymity of the clients.

**Respondents could provide multiple answers*

3.3.7.1 Case study: Indicator condition guided HIV testing

The ECDC 2010 guidance highlights indicator condition (IC)-guided HIV testing as an important intervention, and a number of countries report that this is included in their national programmes; namely Belgium, Croatia, Estonia, Finland, France, Greece, Italy, Lithuania, Netherlands, Poland, Portugal, Romania and Spain. In the review of documents, nine recommend IC-guided HIV testing (Croatia, Denmark, Greece, Italy, Latvia, Netherlands and the UK (five with reference to HiE guidance)[5]. Other studies however demonstrate poor implementation of this approach as HIV test offer rates in people presenting with ICs remain low across Europe, as shown in the HIDES study on auditing HIV testing [9]. The offer rate for HIV testing among patients presenting with an IC was 86% overall (IQR 60–100%), with the lowest offer rate in Northern Europe (median 69%, IQR 33–70) and the highest in Eastern Europe (median 100%, IQR 97–100%).

3.3.8 ECDC 2010 guidance impact evaluation – summary

3.3.8.1 Awareness

All 28 Primary Target Group respondents (100%) and 42 of 51 (82%) Broader Target Group respondents were aware of the guidance.

3.3.8.2 Relevance

Twenty-three of the 28 (82%) Primary Target Group respondents and 31 of 51 (61%) of the Broader Target Group respondents indicated the ECDC 2010 guidance is the most relevant guidance among several international guidance/guidelines listed.

3.3.8.3 Usability

The majority agreed the ECDC 2010 guidance was easily accessible, user-friendly and clearly written, and had a clear structure and format. A higher percentage in the Broader Target Group (>30%) than in the Primary Target Group (11%).found it problematic that the guidance was not available in their own language

[5] Available at: http://newsite.hiveurope.eu/Ongoing-Projects/Guidance-HIV-Indicator-Conditions

3.3.8.4 Impact

Thirteen of 28 (46%) of the Primary Target Group respondents reported having used the ECDC 2010 guidance for the development, monitoring and/or evaluation of their national HIV testing policy/guidelines/programme/strategy. Twenty-nine of 51 (56%) of the Broader Target Group respondents reported having used the ECDC 2010 guidance for developing information materials or advocacy activities.

The majority of both primary and Broader Target Group respondents have observed important changes and some considered the ECDC guidance as having contributed to these.

3.3.8.5 Alignment

The majority of the Primary Target Group respondents (64%) reported that the ECDC 2010 guidance was closely or somewhat closely aligned with the recommendations and/or technical content of the most widely used national policy/guidelines in their country.

3.4 Gaps analysis – needs and priority areas

3.4.1 EU added value

Twenty-three of 28 (82%) Primary Target Group respondents and 46 of 51 (90%) Broader Target Group respondents considered it very important/important to have an EU-level HIV testing guidance. One respondent from each target group considered it not important (Table 18).

Table 18. Importance of having an EU-level HIV testing guidance

Importance of having an EU level HIV testing guidance	Primary Target Group (N=28)	Broader Target Group (N=51)	Total (N=79)
Very important	**32% (9)** Belgium, Croatia, Finland, Greece, Italy, Latvia, Lithuania, Spain, Sweden	**55% (28)** Public health sector (8): Belgium, Czech Republic, Poland, Portugal (2), Spain (2), UK Research/Academia (3): Belgium, Portugal, Spain NGOs/CSOs (14): Austria, Czech Republic, Greece, Ireland, Italy, Poland, Portugal (3), Slovenia, Spain, UK (3) No response (2): Norway, Spain Other (1): Belgium	**47% (37)**
Important	**50% (14)** Czech Republic, Estonia, France (2), Ireland, Malta, Netherlands (2), Norway, Poland (2), Portugal, Romania, Spain	**35% (18)** Public health sector (9): Denmark, Italy, Spain (2), Netherlands, UK (4) Research/Academia (1): Italy NGOs/CSOs (6): Belgium (2), Czech Republic, Romania (2), Slovakia No response (1): UK Other (1): multinational organisation (WHO)	**41% (32)**
Somewhat important	**7% (2)** Austria, Slovakia	**8% (4)** NGOs/CSOs (3): France, Latvia, Lithuania Other (1): UK	**8% (6)**
Not important	**4% (1)** Norway	**2% (1)** Public health sector (1): UK	**3% (2)**
No response	**4% (1)** UK	**0% (0)**	**1% (1)**
Other	**4% (1)** Denmark	**0% (0)**	**1% (1)**

The Primary (25 of 28) and Broader (50 of 51) Target Group respondents who reported that it was important to have an EU-level guidance, were asked to describe in which ways the EU-level guidance provides added value. The majority (65%) responded that it influences the development of national policies in EU/EEA countries (Table 19).

Table 19. Added value afforded by the ECDC 2010 guidance

	Primary Target Group (N=25)	Broader Target Group (N=50)	Total (N=75)
It is well accepted as a reference policy document	18 (72%)	26 (52%)	44 (59%)
Fosters change in individual countries in EU/EEA by providing an EU/EEA standard	15 (60%)	26 (52%)	41 (55%)
Saves time/resources by providing up to date review of evidence relevant to the EU/EEA country	15 (60%)	30 (60%)	45 (60%)
Influences the development of national policies in the EU/EEA countries	14 (56%)	35 (70%)	49 (65%)
Provides a benchmark	13 (52%)	26 (52%)	39 (52%)
Provides leverage for advocacy purposes	12 (48%)	25 (50%)	37 (49%)
Other	0 (0%)	1 (2%)	1 (1.3%)

Twenty-four of 28 (86%) Primary and 36 of 51 (71%) Broader Target Group respondents reported that there is an added value of having an up-to-date HIV testing guidance at EU level.

The following are examples of how the ECDC 2010 guidance provides added value at an EU level, provided by the survey respondents and focus groups:

> "For countries like [country], where access to free of charge, anonymous testing for vulnerable groups is non-existent, it is important to have updated information and guidance in order to put pressure on public institutions and to get results and changes in this field."
>
> "Yes really important in that people will know what procedures to follow in the EU."
>
> "Procedures and standards based specifically on the EU epidemiology."
>
> "European guidelines help to change national guidelines; it needs to be innovative though and updated continuously. It is good if it is innovative, because that helps you to change national guidelines."
>
> "We need European guidelines in order to understand what people are doing in other European countries. It is a way to be on the same track."

3.4.2 Needs and update - input for an updated ECDC guidance

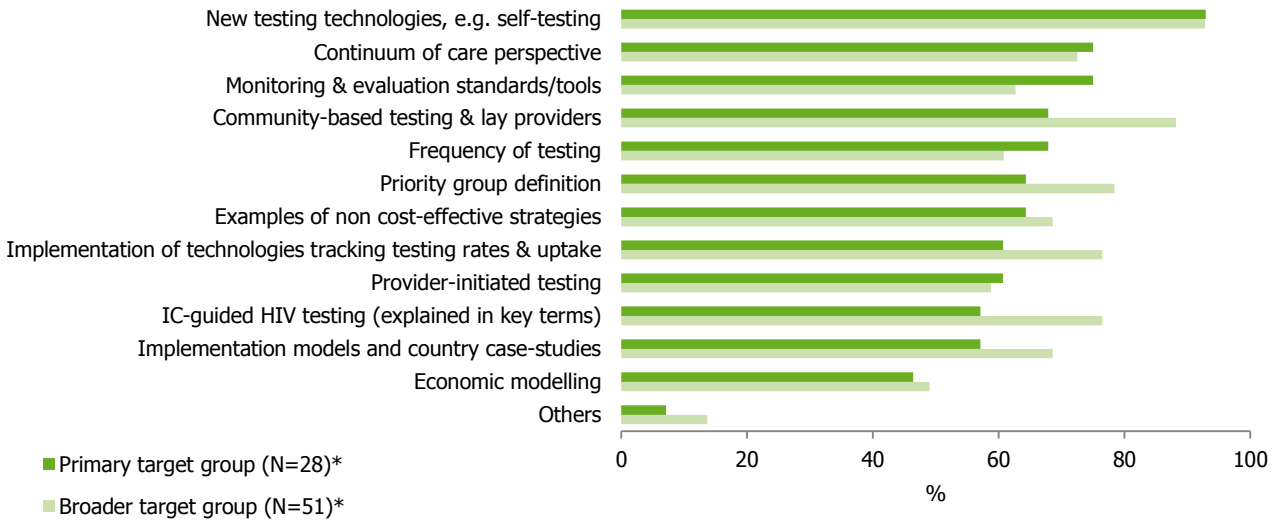
This section gathers data from the surveys, including specification provided in free text boxes, as well as input from the focus group discussions and the Expert Panel meeting. Many contributions were provided to the question of a revised ECDC guidance. The section is divided into the following themes:

- content of a new guidance document
- format of the guidance
- audience
- dissemination
- leadership role by ECDC.

3.4.2.1 Content

As part of the assessment of the needs for an EU-level HIV testing guidance from ECDC, the Primary and Broader Target Group respondents were asked to indicate areas they thought should be removed or deprioritised, and areas that should be added or prioritised in a potential update of the guidance. While very few respondents pointed to areas that should be removed, there were several areas or topics that both Primary and Broader Target Group respondents thought should be added or prioritised. For the majority, these included new testing technologies, a continuum of care perspective and monitoring and evaluation standards/tools (Figure 11).

Figure 11. Areas/topics to be added/prioritised*



**Respondents could provide multiple answers*

Both Primary and Broader Target Group respondents provided qualitative inputs, recommendations and suggestions for a possible future updated version of the ECDC 2010 guidance in the survey's free text sections. The focus group discussions also produced a range of suggestions for a revised ECDC HIV testing guidance. The inputs were collated and presented during the Expert Panel meeting. From the subsequent discussion, a set of key recommendations was distilled (Table 20).

Table 20. Topics to include in an updated ECDC testing guidance

Testing approaches
New technologies and innovative testing approaches (e.g. IC guided testing, community testing, self-testing/sampling)
Diversification and complementarity of testing approaches
Economic appraisal elements
Testing approaches for high risk groups and other vulnerable groups (e.g. minorities, higher risk MSM, PrEP users)
Diagnostic window and testing strategies
Frequency of testing
Comprehensive testing approaches (e.g. STI, HBV, HCV)
Partner notification
Regulatory issues
Testing among youth (under 18 years)
Confidentiality and anonymity of testing
De-medicalisation of testing and task-shifting
Monitoring and evaluation
Monitoring and evaluation of HIV testing interventions

It was stressed that regular updates, e.g. annually, was important for the document to remain relevant and to include and review the newest evidence in the field.

3.4.2.2 Format

To increase the relevance and use of the ECDC 2010 guidance for their work, a majority of respondents from the Primary Target Group stated that the guidance should provide a framework for monitoring and evaluation of testing programmes, whereas the majority of respondents from the Broader Target Group wanted the guidance to provide best-practice examples from the EU/EEA.

Discussions at the expert meeting supported these results as there was consensus on the need for an updated guidance which should be complemented by practice and implementation-oriented products. In particular on monitoring and evaluation to support monitoring at national and/or regional level, programmatic planning and decision-making, service provider quality management or local implementation.

In addition, an interactive format was preferred over a static printed one to improve user friendliness.

When combining the input from the different data sources in order to design the format of a new ECDC guidance, a comprehensive package including a guidance and a set of companion products was envisioned.

Table 21. Updated ECDC testing guidance: proposed set of complementary products

Complementary products to the guidance document
Tool on how to develop national testing guidelines, including a template.
Monitoring and evaluation tool with specific indicators to evaluate the effectiveness of testing programmes and support the collection of testing performance data.
Country case studies and service models repository (as an online tool).
Implementation tool (e.g. set of context-specific testing approaches, economic appraisal).

3.4.2.3 Audience

An updated ECDC HIV testing guidance shall aim at providing recommendations at strategic level. Findings from the surveys and input from the focus groups and expert panel participants contributed to the definition of primary target audience as all the professionals engaged in developing HIV testing guidelines at national level. Depending on national set-up, this may be a diverse group constituted by:

- policy advisers and programme managers
- service providers, including health care workers, clinicians, civil society organisation members etc.
- advocacy activists.

A secondary and much broader target audience was identified as constituted by technical experts with an interest in HIV testing, including policymaker/advisor, program managers, service providers, clinicians, clinical societies, civil society organisations, etc.

Although not within the mandate of ECDC to address countries outside the EU, the importance and possible use of the guidance in EU neighbouring countries was discussed and recognised. Also, the need to involve other medical specialties/clinical societies and communicate benefits of HIV testing to a wider group of health professionals was highlighted.

3.4.3 Dissemination

To improve the dissemination of the ECDC 2010 guidance, both Primary and Broader Target Group respondents suggested that it should provide service models and case study examples, be more practically oriented by providing guidance and tools, as discussed under previous section, and that it should be translated into other EU/EEA languages (Table 22).

Table 22. How to improve dissemination of the ECDC 2010 guidance

	Primary Target Group (N=28)*	Broader Target Group (N=51)*	Total (N=79)
Be practical oriented e.g. with a toolkit with implementation-oriented tools	57%(16)	55% (28)	56%(44)
Provide service models and case study examples from EU/EEA countries	54%(15)	61% (31)	58%(46)
Produce a collection of documents tailored to specific users (e.g. policymakers, advocacy activists)	50%(14)	45% (23)	47%(37)
Translation into other EU/EEA languages	36%(10)	65% (33)	54%(43)
Organise workshops for Member States and other stakeholders to promote its implementation	36%(10)	43% (22)	41%(32)
Complement the guidance with a peer-reviewed publication	32% (9)	15% (15)	34%(24)
Upload the guidance on additional websites other than ECDC	29% (8)	51% (26)	43%(34)
Supplement the guidance with additional resources like information leaflets and posters for download	21%(6)	31% (16)	28%(22)
Other	4% (1)	2% (1)	3%(2)

**Respondents could provide multiple answers*

When merging inputs from the survey with inputs from the focus groups and expert panel, the proposed dissemination plan was structured into two main phases: dissemination at the time of the launch, and, subsequent ongoing stakeholder engagement following the release.

Table 23. Proposed strategies for dissemination and engagement of target audience

Proposed strategies to increase dissemination at the launch of a new guidance
The use of 'teasers' to be sent out ahead of the release via social media
Identification of 'country ambassador'
Time the launch alongside established events such as the 'European HIV testing week'
Devise a set of key messages tailored to different audience groups.
Proposed strategies to ensure continuous engagement of the target audience
Email at launch, with follow-up emails at six months and annually thereafter
Organise face-to-face workshop with country representatives to support Member States in developing national guidelines and/or facilitate implementation at national level
Engage national clinical specialties societies (e.g. national society of hepatology) (see also section 3.4.2;
Ensure continuous updates of the guidance, e.g. on yearly basis (see also section 3.4.2)
Service model/case study spotlight – identify and disseminate service model/case study examples on a regular basis (e.g. 6 monthly) to highlight specific guidance content
Foster exchanges between EU countries through newsletters and/ or meetings to discuss new guidelines.

3.4.4 ECDC leadership

In relation to the role of ECDC, both primary and Broader Target Group respondents had several recommendations and suggestions, with many of these being recurrent themes (Table 24).

It was also mentioned by some respondents that ECDC has a role to play in advocacy, such as promoting changes in the legal barrier framework (e.g. who can perform testing). Innovation was a key theme, as reported in the words of focus group and Expert Panel participants:

> "Be more bold and on the forefront with new knowledge and evidence."
>
> "Include a discussion about new methods and possibilities even before they are thoroughly evidence based."
>
> "Secure regularly updates of the document – yearly updates of the guidance to cover emerging evidence and new testing approaches."

Table 24. The role of ECDC and type of guidance needed

Leadership on data, standards, compliance, implementation, rights
Play a leadership role in its areas of competency by setting best practice and identify core recommendations
More urgent language
Be more specific on achieving concrete goals in the EU
Define criteria to evaluate the effectiveness of HIV testing policies and monitor each country's level of complementation of National and ECDC Guidelines or ask the countries for national evaluation reports
Alignment and collaboration with other European agencies, WHO Europe and IUSTI

4. Discussion

The aim of this evaluation was to describe the use and impact of the 2010 ECDC HIV testing guidance, in view of formulating recommendations for future ECDC actions in the field.

Despite the limitations, the evaluation exercise succeeded in collecting reliable information on five of the six identified dimensions, namely awareness, relevance, effectiveness, usability and EU-added value. The findings showed that both primary and broader audiences were aware of the ECDC 2010 guidance and that many had used it in their work and/or having distributed the guidance in their networks. The ECDC 2010 guidance was broadly considered relevant and having good usability. Furthermore, the ECDC 2010 guidance was broadly recognised as having a role in fostering changes at national level and in being of value as a reference policy document. In addition, and specifically for smaller and low resourced EU/EEA Member States, where capacity and resources to develop a national guidance may be limited, an EU level document may be of greater value.

The evaluation set out to evaluate the overall impact, if any, and use of the ECDC 2010 guidance. As the evaluation was mostly based on self-reported data, objectively measuring the impact of the ECDC 2010 guidance was unfortunately beyond reach. The lack of standardised data on HIV testing coverage and uptake across the EU/EEA makes it difficult to accurately measure changes in testing across the region, and any possible impact ECDC guidance may have had. If any changes are observed in testing levels, the underlying reasons are very likely to be multifactorial and it would be unrealistic to solely attribute these directly to the guidance. Moreover, a lag time will exist between the development of guidance and the implementation of programmes resulting from guidance-driven policy changes and this needs to be considered in any evaluation.

The ECDC 2010 guidance has still proven to be effective in reaching the set target and in engaging a broader group of relevant stakeholders in the EU/EEA and beyond. Along this line, the findings indicate a strong need for an update of the previous guidance and for ECDC to continue paying a pivotal role in promoting HIV testing coverage and uptake in the EU/EEA.

A compelling outcome of the evaluation was the identified need for a greater focus on monitoring and evaluation of HIV testing to provide strategic information towards the monitoring of broader regional and global goals, such as UNAIDS 90-90-90. Also, the target audience of ECDC outputs and activities should not be confined to Member State actors only, but include a broader group of stakeholders who are engaged in guidance development and implementation within and possibly beyond the EU/EEA region.

The employed evaluation methodology included several sources of data collection and their triangulation. This study design was selected with the aim of minimising information gaps and selection and response bias, and improving validity. Nevertheless, there are some important limitations related to the validity of data sources, data collection methods, and the representativeness of the sampling approaches which may influence the evaluation results.

In the planning of the methodology the respondents were divided into two groups, the Primary and Broader Target Group; each with their own survey to complete based on their professional profile and role in HIV testing in their country. However, while this division made sense in theory, in practice, respondents overlapped more than anticipated. For example, some individuals working for NGOs, who are part of the Broader Target Group, had played an important role in developing national guidelines and therefore received the survey from the Primary Target Group contact person in their country.

Different sampling methods were used between the two respondent groups for the survey – each with a potential selection bias. For the Primary Target Group, ECDC asked the ECDC Coordinating Competent Bodies, National Coordinators and National Focal Points for HIV, to identify one or more appropriate respondents for the survey. However, if no response was received, the National Focal Points for HIV were contacted directly, resulting in a mixed group of diverse professionals in different countries. Since these professionals have a working relationship with ECDC, there is the potential that they have a greater awareness, use and relevance than is actually the case.

The Broader Target Group was selected via convenience sampling through mailing list contacts, with no monitoring of the end recipients nor structured follow up to ensure representativeness. The number of responses from the Broader Target Group was lower than anticipated. Possibly, people who were already familiar with the ECDC 2010 guidance were more likely to respond to the survey and/or to participate in focus groups. This may have resulted in finding a higher awareness of the guidance in this evaluation than is the case. On the other hand, 20% of BTG respondents indicate that they had no awareness of the ECDC 2010 guidance, which may raise doubts about the relevance of their survey answers.

For both respondent groups, language barriers may have hindered response among non-English native speakers as the survey and focus groups were developed in English only.

While the majority of the survey respondents reported good usability of the ECDC 2010 guidance, focus group discussion participants were particularly concerned about the need for updated information and guidance, and the conversations tended to focus more on current needs and content updates rather than the 2010 ECDC guidance, which they considered to be outdated. The fact that not all had used the guidance or found it relevant, may also reflect a change in position since the release of the guidance in 2010.

The questions and response categories in the surveys were largely pre-defined and there may have been topics or issues that the Study Group has failed to appropriately capture. Despite the round of piloting, some inconsistencies in the survey findings have raised concerns regarding the validity of some questions. Inconsistent feedback may have been caused by lack of attention and/or focus when filling in the survey, misinterpretation of the question and/or of answer options, and overlapping options in multiple answer questions. In addition, where country level information was required and more than one response was received, conflicting answers were sometimes observed. This may reflect poor wording of the question or poor selection of response categories. Finally, despite inclusion of a terminology glossary, some of the definitions used in the surveys, e.g. policy, strategy, programme may have been open to different interpretation by respondents.

The citation review was only performed in Scopus and Google Scholar. References of the ECDC 2010 guidance in national policy documents are not reflected in this citation review, and thereby the use, for what the ECDC 2010 guidance was intended, is likely to be higher than that reflected in a citation review performed in this restricted arena. The website access analysis was constrained by limited data availability due to the platform migration of the ECDC website, the following change of landing page for the ECDC 2010 guidance, and lack of data in the period immediately following guidance launch. These limitations, coupled with the inability to track PDF downloads, are likely to have resulted in an underestimation of the true number of page views.

There is scope for further improvement of the methodology when undertaking any similar exercise in the future. In particular the dimension of 'coherence/complementarity' may require the development of a more objective scoring system, while the division of the target audience into two groups may not be needed. Finally the inclusion in the Broader Target Group of non-EU/EEA actors would be desirable, and of particular relevance for EU/EEA neighbouring countries.

Survey findings in the context of other HIV testing data: assessing external validity

Findings of the ECDC 2010 guidance evaluation exercise have also been compared with available results from other current projects.

In particular, commissioned by HIV in Europe, the Centre for Social Research in Health (University of New South Wales, Australia) has undertaken a review of testing and counselling guidelines relevant to the WHO European Region, and a survey of perceptions of current HIV testing and counselling practice in the same region. In alignment with the findings from the ECDC 2010 guidance evaluation exercise, recommendations emerging from this consultation focused on the need for tailored, specific novel guidance for home-based sampling/self-testing and new technologies for delivering results, taking into account the different settings and contexts across Europe.

As highlighted in section 3.3.7.1, IC-guided HIV testing, is poorly implemented across Europe although included in many national guidelines. The EU-funded project OptTEST reviewed national HIV testing guidelines and audited implementation of IC-guided HIV testing in seven pilot countries. The results demonstrate low levels of HIV testing in patients presenting with ICs as well as sub-optimal inclusion of IC-guided testing recommendations both in national HIV testing guidelines and the relevant specialty guidelines. As identified during the ECDC evaluation exercise, this is an area that may deserve further attention.

According to the latest ECDC surveillance report, significant HIV transmission continues in Europe and nearly half (47%) of those tested were diagnosed late. While the results from the evaluation indicate that the ECDC 2010 guidance reached its target audience (and beyond) and has been used to revise and/or develop national HIV testing policies, this does not appear to have translated into improving HIV testing coverage and reducing the number of late presenters in the EU/EEA. This may be due to policies not being effectively implemented and lack of effective monitoring and evaluation of policies (as highlighted in this evaluation), coupled with inconsistent HIV testing data reporting across the region.

5. Conclusion and recommendations

The aim of this evaluation was to understand the use and impact, if any, of the 2010 ECDC guidance in the EU/EEA and to make any recommendations for future steps to be taken by ECDC in this area, potentially including an updated guidance.

The results of this evaluation showed that the ECDC 2010 guidance has been referenced and widely used to develop policies, guidelines and/or programmes/strategies in the EU/EEA. The findings suggest that it has contributed to changes in HIV testing strategies across EU/EEA countries. In addition, the ECDC 2010 guidance has reached a wider audience than intended and has proven to be useful to a broader range of stakeholders, as an authoritative reference document as well as for advocacy purposes.

According to the evaluation findings, the ECDC 2010 guidance was considered relevant and of added value by a wide range of stakeholders as it provides a unique EU-level perspective. Update of the guidance and development of complementary products was identified as an urgent need and recommended for future ECDC action.

A set of key recommendations was distilled with the support of the Expert Panel and based on the findings of the evaluation:

- A collaborative approach and engagement with different constituencies and organisations (e.g. WHO, CSOs, clinical specialties professional societies) is recommended to be an essential component of future ECDC activities on HIV testing, with the potential expansion to include clinical professional societies.
- A comprehensive package of products to foster HIV testing coverage and uptake is needed. It is recommended ECDC embarks on an update of the guidance and consider complementing it with specific companion products to promote monitoring and evaluation as well as the development and implementation of national guidelines/guidance documents.
- The guidance document should be regularly updated, and the updates promoted.
- Collection and dissemination of country level case studies and service models, economic appraisal and assistance with implementation are considered key components of future ECDC outputs, e.g. with benchmarking data on testing uptake for comparison among EU countries.
- The target audience of ECDC outputs and activities should not be confined to Member State actors only but include a broader group of stakeholders who are engaged in guidance development and implementation within (and beyond) the EU/EEA region and across a range of clinical specialties.
- Appropriate and continuous dissemination of the guidance is needed. ECDC should devise an effective and multi-layered communication plan to maintain interest and momentum.

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