Contract number: **20081204**

Project title:

# Eurosupport 6:
# Developing a Training and Resource Package for Improving the Sexual and Reproductive Health of People Living with HIV/AIDS

Acronym: **ES6**

Starting date: 01/03/2009
Duration of the project: 36 months
Reporting period: 01/03/2009 – 31/08/2010

Main partner:
**Institute of Tropical Medicine**
Nationalestraat 155 – 2000 Antwerp - Belgium
Number of associated partners: 10

Total amount of the project : €1.245.819,51
EC Co-funding : € 700.000,-
First prefinancing payment: € 280.000,-
Second prefinancing request: € 210.000,-

## 1. Executive summary

The aim of the Eurosupport 6 project (ES 6) is to develop a training and resource package (TRP) for HIV service providers to support people living with HIV (PLHIV) to improve their sexual and reproductive health (SRH). This requires equipping service providers with the tools to effectively support PLHIV. Sexual risk reduction is the main focus of this project, but it is embedded in an overall context of positive health, dignity and prevention, by linking HIV with SRH and rights and focusing on PLHIV's needs with respect to prevention. The project has two major tracks:

(1) **Research and development track,** to develop and evaluate counselling interventions including computer-assisted interventions for clinical care and community-based settings;

(2) **Capacity building track**, to develop tools for service providers for implementation - including training events and the development of online-training tools ('e-learning') for service providers.

**Background**

The project builds on the evidence accumulated in the previous Eurosupport 5 project (ES 5) and funded under the same health programme, which collected both qualitative and quantitative evidence on SRH related needs and problems of PLHIV, as well as on actual service provision in an integrated field of SRH and HIV care in Europe. ES 6 builds on this evidence and on the state-of-the-art of current prevention research: according to ES 5 data, 32% of PLHIV reported sexual risk behaviour and service providers reported to lack resources to address SRH of PLHIV effectively. Service providers rarely used evidence-based standardized interventions developed elsewhere, and the few existing guidelines in the domain of HIV and SRH were not applied. The few evidence-based interventions targeting PLHIV have mostly been developed in the US, and cannot simply be transferred to the European context. Therefore, ES 6 aims at developing concrete and user-friendly tools for European service providers, adapted to their needs and setting requirements, both in clinical and community-based settings.

The project's **general objective** is to support service providers to deliver effective SRH interventions with a focus on safer sex behaviour (i.e. condom use) among people living with HIV. This has been operationalized at 4 levels:

- Development of evidence-based and theory-guided interventions to improve SRH of PLHA (two target groups: men having sex with men and migrants).
- Development of a training and resource package for service providers in the HIV/AIDS field (target group: service providers).
- Development of organizational policies on how to integrate SRH-related services in routine service delivery.

- Maintaining a network of HIV and SRH experts and field organizations in Europe.

**Current state-of-affairs**

The overall project period is 3 years. At project mid-term (18 months) we have achieved the following milestones:

The evidence assessed in ES 5 was translated into a scientific framework to develop the intervention and the accompanying training and resource package (TRP). The scientific method of intervention mapping has been used as theoretical guidance to develop this framework. Brief counselling interventions, using computer-assisted materials, are the core-piece of the TRP. They are theory-guided and based on existing tools proven to work, such as theory of change and elements of motivational interviewing. An innovative element is the use of computer-assisted intervention modules, which can be integrated by service providers into the individual counselling. The intervention has been labelled CISS (Computer-assisted Intervention for Safer Sex). The CISS has been developed for two different target groups: CISS for gay men (i.e. men having sex with men or MSM) and for heterosexual PLHIV (in gender-specific male and female versions) with an accompanying intervention manual. One training workshop has been held to train the associated partners (10 APs) in the use of the CISS. A study protocol has been developed to test the intervention effectiveness using a prospective experimental design (pre- and post test, plus a 3 months' and a now proposed 6 months follow-up). Draft versions of the other main elements (training manual, reference guide; implementation manual to be developed) of the TRP have also been developed and will be continuously updated while the project progresses and the study findings become available.

**Networking and Dissemination**

The Eurosupport network is used to improve capacity building and for dissemination of the TRP. The ES network maintains contacts with more than 420 organizations or individual experts in an integrated field of HIV and SRH. Three biannual newsletters have been published, in which the project's progress was communicated and relevant information on sexual and reproductive health of PLHIV and positive prevention was disseminated. The project's website is continuously updated and also used for dissemination purposes: http://www.sensoa.be/eurosupport

## 2. Specification of the project:

### *2.1 General Objective of the project*:

The **general objective** is to prevent onwards HIV transmission and other sexually transmitted infections (STI) from people living with HIV (PLHIV) to sexual partners, by supporting service providers (SP) in a variety of service provision settings (such as HIV care settings, but also community based settings) to deliver adequate sexual and reproductive health (SRH)-related services. These services focus on sexual risk reduction, embedded in an overall context of SRH and rights.

### *2.2 Specific objectives of the project*

| Number | Title | Process indicators | WP |
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| 1 | To develop evidence-based and theory-guided target group specific interventions to improve SRH of PLHIV. This will be achieved through the development of 2 sets of brief counselling interventions including computer-assisted tools to be delivered by service providers in clinical and community-based HIV care settings targeting men having sex with men (MSM), and female and male migrants living with HIV. | Service providers' fidelity to the intervention<br><br>Selected variables relating to the implementation of the intervention (task division, cooperation of stakeholders, …)<br><br>10 organizations (associated partners; APs) piloting the intervention to be included in the TRP<br><br>Selected variables relating to integration of the CAI modules | WP 3 on evaluation;<br><br>WP 4 on methodology, i.e. develop-ment of the intervention framework (intervention mapping method);<br><br>WP 5 on the development of the computer-assisted intervention modules;<br><br>WP 6 and 7 resp., for the implementation of the intervention; |
| 2 | To develop an evidence-based training and resource package (TRP) for service providers in clinical care and community-based settings in the HIV/AIDS field | Number of overall participants at the first training events<br><br>Involvement of | WP 4 on methodology;<br><br>WP 8 on TRP development |

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| | working with the two target groups | stakeholders in the development of the TRP<br><br>Quality of the trainings delivered (assessed through AP's for the first training workshop) | |
| 3 | Development of a policy tool which specifies the elements necessary to integrate SRH-related and positive prevention services in routine HIV care by defining mechanisms of effective task division, integration and specialisation, screening, local care pathways, and referral systems. | Involvement of stakeholders in the development of the policy tool | WP 8 on TRP development |
| 4 | Expanding and maintaining a network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe, with the aim to facilitate mutual learning experience and to disseminate the TRP to a substantial number of stakeholders. | Involvement of SRH/HIV stakeholders in the network | WP 2 on dissemination;<br><br>WP 8 on TRP development |

*2.3 Overview of activities for the period covered in the interim report*

| WP | Activities | Outcomes/ deliverables | Month foreseen | Month achieved | Level of achievement (measured by indicators) | Justification/ Problems encountered | Action to be taken to overcome the problem |
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| **WP1** | Scientific project management: fine-tuned intervention plan (→ see WP 4) | Fine-tuned intervention plan (→ see WP 4) | M 3 | M 3 | 1 working document (Intervention mapping method-framework), which is gradually being updated | | |
| | Kick-off meeting (=first project meeting) | Meeting report | M 3 | M 3 | Number of participants: 12 participants (main partner and APs) and EAHC representatives | The feasibility and necessary requirements in relation to the study design for the outcome evaluation of the intervention was discussed (see workshop report); | Following up on the concerns and discussions during the meeting, consensus was achieved on a more rigorous study design with an intervention and a control condition (i.e. standard care) |
| | Building the project steering group (PSG) | PSG installed | M 3 | M 3 | Number of APs in the PSG: the main partner and 5 APS represent the PSG. This includes the WP-leaders: ITM, Sensoa (BE), CNWL (UK), UCM (ES); in addition UM (NL) and IHTM (PO). | Functional on request, no problems encountered | |
| | Installing the external advisory board (EAB) | EAB installed | M 6 | M 6 | Number of international organizations with balanced representation of stakeholders: 7 | Initial bilateral contacts with all 7 AAB-members, one conference | Input was taken into consideration and the study protocol was adapted accordingly. |

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| | | | | organizations<br>ILGA Europe, ICRH (University of Gent), Civil Society Forum, University of Copenhagen, EATG, DG SANCO, UNAIDS; → see list of EAB members annex 3 | call organized in November 2009, to consult on the study protocol. | |
| Bilateral contracts with associated partners (AP) | Bilateral contracts issued | M 6 | M 6 | Number of contracts issued: 10 bilateral contracts issued and signed by APs | | |
| Preparing and submitting an amendment to AEHC | Amendment | M8 | M 10 | Amendment approved | Budget required re-organization to enable partners to prepare for the study participation | |
| Second project meeting(=training workshop for associated partners) | Workshop report | M 12 | M 13 | Number of associated partners participating at the training workshop: 21 participants (MP and APs) | The pilot intervention was not fully finalized and was not available at the moment of organizing the training workshop | An electronic 'e-stream' platform (i.e. server accessible by project partners) was used to deliver missing material to the APs and an training video was developed and disseminated to train the APs on the missing elements |

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| | Financial management | → see Consolidated Financial Statement | M 1 – M 18 | M 18 | 1 Consolidated Financial Statement - reporting period M1-M18. | In many cases, APs seem to have limited capacity to understand the rationale of the budget and follow-up, mainly due to limited communication towards their administrative deptartments | Follow-up and technical assistance was provided by the main partner (ITM), but reporting proved to be very time-consuming and challenging for all parties concerned. |
| | Seeking sponsoring/raising additional funding | Own contribution needed | M 1 – M 18 | M 1 – M 18 | See Consolidated Financial Statement | At M18 €19.385,- in unconditional grants was received, plus €10.000 in M19. A further 5.000€ is awarded in 2011 and 7.000€ remain in negotiation for applicants financial contribution | Efforts (Sensoa, ITM) were made to approach pharmaceutical companies at the XVIII$^{th}$ International AIDS conference in Vienna (July 2010) in order to raise the additional funding needed. |
| **WP2** | Adaptation of the existing Eurosupport website | ES 6 website is updated and functional | M 3 | M 3 | The ES6 website is updated, functional and maintained, i.e. regularly updated with new material, publications, | Website is functional, no problems encountered | |

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| | | | | | etc.<br>→ see:<br>http://www.sensoa.be/eurosupport | | |
| | Establishing cooperation with collaborative partners (CP) | CPs who have agreed to cooperate | M 6 | M 6 | Numbers of CPs: expansion from 15 CPs (at the time of issuing the Grant agreement) to 22 CPs → see annex 1 | CPs were expanded gradually, no problems encountered | |
| | Update of the ES 6 data-base | Number of stake-holders entered into the database | M 6 | M 6 | Number of entries relating to a wider network of stakeholders in an integrated field of HIV prevention and care, and sexual and reproductive health (SRH) organizations: 421 organizations or individual experts | Database is functional, no problems encountered | |
| | Adaptation of the ES 6 website for integration of the computer-assisted counselling modules | Web environment created | M 12 | NA | The strategy was changed due to severe concern expressed by some of the APs that it would not be feasible to work online during counselling sessions | APs were concerned about problems of online connectivity during counselling sessions and how that would interfere with the quality of the | It was decided to work with a counselling tool that is not contingent on internet access: the intervention has been made available on a DVD (for the pilot and the trial). |

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| | | | | | | counselling session | |
| | The ES 6 newsletters | Number of newsletters issued | M 6, M 12, M 18 | M 6, M 12, M 18 | 3 newsletters have been distributed in a timely fashion via electronic mailing to the ES 6 network and are available online via the ES 6 website for downloading | No problems encountered, newsletters issued as planned | |
| | ES 6 brochures and leaflets | Number of leaflets issued | No official deliverable | M 4, M 17 | - 1 brochure for fund raising; it has been distributed to associated partners to be disseminated to potential sponsors.<br>- 1 project folder has been developed to inform and increase number of stakeholders.<br>- 1 flyer has been added to the information brochure to describe the CISS in more detail; i.e. explain the different steps of the intervention; | | |
| **WP3** | Developing the IMM framework document (incl. the evaluation plan) | One IMM framework document developed | M 3 | M 3 | → see WP 4 | | |

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| | Developing the study protocol | One study protocol developed | M 8 | M 9 | Study protocol available (→ see annex 5) | | |
| | Obtaining ethical approval | Ethical approval obtained | M 9 | M 11 | The following countries had to submit their protocols for ethical approval: Belgium, the Netherlands, Italy, Slovakia, UK, Germany. *Note that the study protocol as submitted refers to the originally proposed follow-up period of 9 months instead of the 6 months suggested here to adjust for the delay. The protocol was submitted or ethical approval in December 2009 and cannot be changed.* | No problems encountered | |
| | Developing the evaluation tools | Set of questionnaires to assess the interventions' effectiveness | M 12 | M 14 | The questionnaires are available as online tools in 10 language versions, which have been translated and back-translated by the APs. Quality check for online versions was also done by the APs. | Translation was more time consuming than anticipated. Translation was done by the study coordinators who could not be remunerated for this. | In the remaining running time the accumulated delay should be eliminated (during data collection and TRP preparation, where activities can be carried out simultaneously). |

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| | Evaluation of the first training workshop | 1 document, with results of the workshop's evaluation | M 13 | M 13 | 1 evaluation report on the first training workshop;<br>part 1 referred to results of closed questions, part 2 to the result of open questions. Evaluations questions assessed different aspects of the training workshop (CISS, exercises and logistic support); see also interim evaluation report (→ annex 2). | Intervention was not fully completed. As session 3 was missing, training the partners on how to work with the full intervention was not possible. | Overall training and specific exercises focused on the available CISS modules and general counselling skills.<br><br>APs were asked whether they understood the different steps of CISS, and whether they felt comfortable working with it. |
| | Midterm evaluation report | 1 report | | | Midterm evaluation report → see annex 2 | | |
| **WP4** | Developing the IMM framework | 1 document | M 3 | M 3 | 1 working document containing the intervention map and the IMM matrices → see annex 4 | | |
| | Draft interventions available for the two target groups | Intervention outline available for the CISS ('computerized intervention for safer sex') | M 10 | M 11 | Draft intervention available as flow-charts showing the different modules to be used during three face-to-face counselling sessions;<br>3 flow charts: MSM, female migrants, male migrants | At M 10/11 the flow charts did not contain the full details for session Adaptations made following consultation with local CBOs resulted in | Input to session 3 was given during the training workshop and session 3 was revised thereafter. |

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| | | | | | → see annex 6: intervention flow charts | delaying the CISS development. | |
| **WP5** | Content-related development of the intervention | Fine-tuned intervention plan (→ see WP 4) | M 3 | M 3 | 1 working document (Intervention mapping method-framework) | | |
| | Technical development of the computer-assisted intervention | Multimedia resources produced for intervention | M 4 | M 19 | 20 short films, 30 power-point presentations and 17 flash files were produced for the intervention. | 1) Production team were unable to integrate the interactive flash materials, prepared using raptivity software.<br>2) Compatibility issues between edited films and DVD authoring software.<br><br>3) Poor sound quality on the rushes for the short films<br><br>4) Differences in translations between subtitles for videos and powerpoint presentations | 1) A separate DVD author was engaged who was able to include interactive elements of the intervention alongside the video content.<br><br>2) All films were re-edited and re-uploaded to the server.<br><br>3) Videos were re-edited<br><br>4) Compared versions prepared by different translators; consulted with translators and APs as to which terms should be used. |

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| | | | | | | 5) DVD author was unable to include subtitling in flash files.<br><br>6) Unable to burn Goal Enforcer software (used in session 3 of the intervention) to DVD with correct licensing permissions.<br>7) Editing was also interrupted by the death of the editor's father. | 5) A specialist service was contracted to convert necessary files to XML format for re-uploading.<br><br>6) Currently liaising with software developers to resolve installation problem. |
| | Consultations with community-based organizations on the content of the intervention | Electronic survey to collect feedback on the intervention | M 9 | NA | 4 external CBOs (Terence Higgins Trust, Gay Men Fighting AIDS, NAZ and Positively Women) engaged with the consultation process. The St Mary's Hospital HIV patient group and individual patients of the Health Psychology department were also consulted. | Strategy was changed: due to the complexity and the gradual development of the intervention it was not feasible to carry out a meaningful survey. | CBOs were personally consulted on each step of the intervention development; mainly in the UK, France (via AIDES), and Belgium (Sensoa). |
| | Developing and | Provision of a video | M7 | M11 | e-stream platform | 1) Training for use | Separate computer |

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| | maintaining the e-stream platform | delivery platform acting as a central archive of digital media content. | | | available at http://81.94.200.130/ | of e-stream was delayed, due to restricted availability of software team.<br><br>2) Dedicated internet connection required for the platform at CNWL premises, due to the hospital's firewall restrictions. | with standalone business broadband connection was obtained. |
| | Issuing the pilot DVD for MSM | CISS available on the DVD (for MSM) | M 10 | M 16 | 1 DVD available in English, translations of selected materials to be finalized; | The intervention created needs to be comprehensive, i.e. it covers many issues that influence safer sex behaviour. Therefore, translation was more complex than anticipated. | Professional translators were used instead of having the APs translate all the material. This also ensured the quality of the translation. |
| | Issuing the pilot DVD for migrants | CISS available on the DVD (for migrants) | M 10 | M 16 | 2 DVD (male version, female version) available in English, translations of | The intervention created needs to be | Professional translators were used instead of |

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| | | | | | selected materials to be finalized | comprehensive, i.e. it covers many issues that influence safer sex behaviour. Therefore, translation was more complex than anticipated. | having the APs translate all the material. This also ensured the quality of the translation. |
| **WP6** | Developing standard operating procedures for the implementation | Standard operating procedures (SOP) describe the implementation plan | M 12 | M 12 | 1 document available describing the SOPs for implementation of the trial | Start of the trial has been delayed due to the delay of the intervention development. | |
| | Setting up service providers groups in the clinical settings for the implementation | Key actors and relevant stakeholders involved in setting up the trial at the sites. | M 12 | M 12 | Necessary steps have been taken at the sites to involve the key actors to ensure the implementation of the trial. | | |
| | Developing the draft intervention manual for the implementation phase/study | | M 10 | M 18 | Draft intervention manual issued together with the DVDs | Delay corresponding to intervention development (see above) | |
| **WP7** | Developing standard operating procedures for the implementation | Standard operating procedures (SOP) describe the implementation plan | M 12 | M 12 | 1 document available describing the SOPs for implementation of the trial | Start of the trial has been delayed due to the delay of the | |

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| | | | | | | intervention development. | |
| | Setting up service providers groups in the clinical settings for the implementation | Key actors and relevant stakeholders involved in setting up the trial at the sites. | M 12 | M 12 | Necessary steps have been taken at the sites to involve the key actors to ensure the implementation of the trial. | | |
| | Developing the draft intervention manual for the implementation phase/study | | M 10 | M 18 | Draft intervention manual issued together with the DVDs | Delay corresponding to intervention development (see above) | |
| **WP8** | E survey on draft TRP | | M 9 | - | Draft survey developed but not disseminated to the partners | Intervention was not finalized at month 9. Not to confuse partners TRP was held back (see also above on changed strategy) | E-survey will be applicable in a later phase. |
| | Developing materials for the first training workshop | Training workshop and outline | M 12 | M 13 | Outline and training materials available (training exercises, training videos, …) | Intervention was not fully finalized when the training workshop was scheduled. | Training on session 3 was done online; training video on session 3 of the intervention was developed: |
| | Developing a draft TRP, consisting of a draft intervention | Draft reference guide | - | M 16 | Decision was taken on draft TRP: will consist of intervention manual, | | |

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| | manual (→ see WP 6 and 7), and a draft reference guide. | | | | implementation manual including the policy tools, reference guide (i.e. handbook for service providers) and a training manual. Draft TRP not to be covered in this reporting period, but various draft documents have already been compiled. | | |

## 3. Technical implementation of the project

### *3.1 Activities related to Horizontal Work Packages:*

### WP1: Management of the project

#### 3.1.1 Activities undertaken

**Partnership**

The project partners are a multidisciplinary team of experts achieving the critical mass to develop and evaluate the TRP for diverse European settings. A consortium of 11 partners carries out the project-related activities (see annex 1), among which ITM and Sensoa take on the major coordination tasks. ITM as the main partner is responsible for overall project coordination and the research track, whereas Sensoa, as the main AP, is responsible for the capacity building track (issuing the TRP, delivering training workshops, compiling the trainer manuals, and dissemination). Besides ITM and Sensoa, other APs also take on responsibility for specific work-packages (e.g. University Complutense of Madrid for evaluation; see WP 3; and CNWL based at St. Mary's Hospital, London, for the intervention development; see WP 5).

**Activities relating to overall project management and coordination**

The project coordinator (ITM) provides for overall project management including administrative and scientific project coordination, financial administration and controlling.

***Administrative coordination includes**:*

Reporting to the EAHC/EC and other funding agencies if applicable (i.e. additional funding for applicants' financial contribution); this includes progress reports, technical reports, financial reporting; communication with all partners;

Preparing and submitting an amendment on behalf of the APs

Financial administration and controlling;

Setting up bilateral contracts with APs;

Preparation and organization of project meetings;

Collecting data from APs to compile project-related reports.

***Scientific coordination includes:***

Steering of and assistance to the project's research and policy development part;

Preparing working materials for meetings;

Collecting feedback and input from APs to these materials;
Facilitating and guiding the meetings/capacity building workshops (together with AP Sensoa);
Bilateral close monitoring and follow up of APs activities (to reach milestones).

**Management structure**

ITM has the final responsibility for carrying out the project, both for the administrative, financial and the scientific project management. ITM staff (both scientific and administrative) holds weekly project meetings. ITM works in close collaboration with two of the APs, i.e. Sensoa for the TRP development and the networking, and CNWL for the intervention development.
Sensoa has a crucial role in carrying out activities relating to both the dissemination and the TRP-development, and CNWL in terms of the intervention development (as described in WP 5). ITM and Sensoa hold bilateral personal meeting on a regular basis, i.e. monthly meetings. During the phase of intervention development, weekly telephone conferences have been held with CNWL to discuss practical issues arising. The project's steering group (see section 2.3, table) was consulted on request, whenever major project-related decisions were taken. However, in the majority of the cases, feedback was also asked from all project partners and integrated as much as possible (i.e. adaptations to the study design, changing from online to DVD-version). Internal communication with APs was mainly based on e-mail and phone calls. One additional personal meeting/site visit to CNWL was carried out before organizing the training workshop for better coordination, thus ensuring the quality of the workshop.

**Communication strategy**

Besides regular e-mail communication to channel the information to all APs, project circulars were issued; these are regular project-related documents that summarize main issues and action points for the APs. External communication is mainly done via the project website and the ES 6 newsletters. Bilateral contacts are maintained by the main project partner (ITM). As such, exchange of project-related information with other EU-funded projects took place at the occasion of international meetings such as the European AIDS conference in Vilnius in 2009 and the International AIDS Conference in Vienna in 2010.

### 3.1.2 Problems encountered

The main problem in terms of the **scientific project management** relates to the delay created due to unforeseen technical problems in the electronic intervention development. Two main reasons accounted for that:

1) Although CNWL has substantial expertise in developing computer-assisted interventions, we underestimated the complexity of an intervention that has to be issued for 10 European partners with sub-titling and translation of the relevant written material, included in the computer-assisted intervention.
2) Various adaptations on request of the APs, to increase cultural acceptability created an additional delay.
3) In addition, issuing the intervention on a DVD instead of using an online version also created some delay, in order to maintain the same level of interactivity**.**

Problems encountered in terms of **administrative and financial project management** were minor, but have included the challenge to channel communication about the bureaucratic regulations stipulated by the main funding body (i.e. the European Commission) to the APs. APs all have their own national/local regulations and often do not fully understand how to apply the European requirements to their local situation where requirements in terms of financial reporting an accountability issues may differ. In addition, this was the first time in the collaboration with APs under the framework of the Eurosupport project, that APs were responsible for managing their own national budgets. While ITM still holds the final responsibility, steering and controlling the APs to issue acceptable financial reports is challenging, due to the lack of insight into the required procedures of some of the national organizations we work with.

### 3.1.3 How problems were solved

In order to make up for the delay created, it will probably be necessary to apply for a three month no cost extension, later in the projects' running time. Tightening the time-lines and carrying out activities in parallel, while these were planned in chronological order, will allow for reaching the project milestones and achieve the deliverables within 39 months instead of 36 months overall. In addition, we suggest shortening the follow-up period to 6 months instead of 9 months. While it would be preferable to have a follow-up period as long as possible, we feel that first and foremost the quality of the intervention should get the highest priority. There is sufficient scientific evidence (see below) that also a 6 months follow-up provide sufficient evidence for up-scaling, if an intervention is found to be effective by a combination of a sound process evaluation (which we are carrying out) and an outcome evaluation based on a six month follow-up.

### 3.1.4 Activities planned for the next period

Annex 7 shows the revised timelines, which we consider necessary to correct for the current delay.
Activities planned include:

- Piloting the draft intervention available on DVD
- Finalizing the standard operating procedures (SoP) for the trial
- Issuing packages with study material for the participating centres (stickers, forms, SoP, etc.)
- Enrolling the study participants
- Carrying out the study as planned (however, including a 6 months follow-up instead of a 9 months follow-up; as indicated and explained above)
- Supervision and quality control of the intervention implementation
- Collecting feedback of the CPs to the draft intervention
- Adapting the CISS based on the evaluation outcome and the CPs' feedback
- Developing online training tools for the adapted CISS
- Developing the final TRP
- Holding the final training workshop with APs and CPs
- Final reporting and documentation (including the evaluation report)

**WP2: Dissemination strategy**

**Dissemination plan available** X□ no □ yes (please attach as Annex 1)

The work-package description, as provided in Annex 1 to the Grant Agreement, contains the dissemination plan. Its main cornerstones are integrating a variety of stakeholders via the ES 6 network and beyond, i.e. the APs, the CPs and the larger network which refers to organizations in the ES 6 data-base. Tools for dissemination are the Website and the newsletters. In addition, the project has been presented at the most important scientific meetings in the HIV field and distributes project-related information through project folders, scientific posters, and oral presentations.

### 3.2.1 Activities undertaken

**Target group identification/stakeholder analysis**

The project's primary target group are PLHIV, both MSM and migrants. The project's secondary target group are service providers from an integrated field of HIV and SRH organizations, who deliver care and counselling to the above mentioned two groups of PLHIV. Service providers are essential in delivering prevention services, but need evidence-based tools to deliver such services in a high quality manner. The ES 6 project develops these tools, is testing them for effectiveness in real life settings (HIV care facilities and community-based service organizations), and is developing training tools to support service providers in using them in their own clinical practice. Up-scaling the

intervention, however, is not part of the current project due to its limited time-frame. Therefore, the target-group identification refers only to the project's primary target group.

***Target group identification***

Throughout Europe, two target groups are particularly affected by HIV infections: MSM and heterosexuals, among which migrants, stemming from high endemic regions (such as Sub-Saharan Africa) represent a particularly difficult to reach target group with specific needs. Therefore, the interventions to be developed in the framework of this project are tailored to the specific positive prevention needs of these two target group: MSM and migrants stemming from high endemic regions or sharing a particular vulnerability with respect to HIV.

**Definition of the target groups "MSM" and "migrants and ethnic minorities" within Eurosupport 6**

The term "MSM" pertains to men having sex with other men, independent of whether they self-identify as gay or bisexual. The term "migrants" refers to people with migrant background or belonging to ethnic minorities. A series of underlying issues, tied to socially and culturally grounded factors, makes people with a migrant background and ethnic minorities living in Europe particularly vulnerable with respect to HIV and sexual risk behaviours. This is independent of whether they acquired HIV in a high endemic region (e.g. sub-Saharan Africa), or in the country they currently live in. However, there is epidemiological evidence, that migrants stemming from high-endemic regions comprise a substantial part of people living with HIV in Europe. Therefore, the interventions to be developed within ES 6 will target the diverse group of migrants and ethnic minorities next to MSM. Within ES 6, people with a migrant background comprise the following sub-groups:

People, currently residing in a EU country but with a 'foreign' citizenship from birth, are considered as having a migrant background, whether they were born in the given EU country or abroad. This will include both people from first or second generation migrants and people, who may or may not possess the citizenship of the given EU country. The term 'ethnic minority' refers to a socially subordination ethnic group (understood in terms of language, nationality, religion and/or culture). [1] [2]

HIV-positive people with a migrant background or belonging to ethnic minorities, face different, yet heightened barriers, compared to the general population in accessing HIV services. They are confronted with the double stigma of being a migrant and being HIV positive. Due to a lack of cultural sensitivity within the services, communication problems (pertaining to both language barriers and different perceptions of the service provider-client/patient relationship), as well as the HIV-related stigma, which is particularly pronounced in many migrant communities, HIV services often fail to provide adequate assistance to match the specific needs of these patients. Results from the previous ES 5 project have shown, that in the countries investigated there was a lack on service provision towards the specific needs of migrant drug users (third ES 5 research phase on service provision) and service providers expressed the need for culturally sensitive training on SRH. Therefore, within this project, we deal with the respective MSM and migrant populations within a given health care setting, i.e. at the participating HIV service or community-based service. It has to be recognized that these target groups may be quite heterogeneous in terms of their respective cultural background, however, the common underlying theoretical principles, guiding the intervention development, will account for sufficient comparability across the different settings.

**HIV-Transmission groups and trends in Europe**

Currently, the predominant transmission group in Western Europe is heterosexual (54% equaling more than 10.000 cases, among which 35% are females; data referring to the end of 2006). [3]

A total of 19% all newly diagnosed HIV infections occurred in 2006 in the EU among individuals originating from Sub-Saharan Africa, which makes them the largest group among migrants. At the end of 2006, a further 37% of HIV infections were acquired through homosexual contacts in Europe. Central Europe reported a similar situation: 52% heterosexual and 27% homosexual transmissions, but a relative higher percentage of infections due to intravenous drug use (16% compared to 8% in the West). However, more than 50% of the new infections in 2006 had occurred among MSM in that region.[4] In many European countries MSM are the group most at risk for acquiring HIV and other STIs, with HIV prevalence ranging between 5% and 15%, and HIV incidence of almost 3 % per year. These epidemiological trends provide the rationale for the selection of the two ultimate target groups of this project (subgroups of PLHA) who are the beneficiaries of the pilot interventions to be delivered.

**Dissemination content and means**

In what is too follow we describe the main tools used for disseminating project related information and results.

**The Eurosupport network**

Project-related materials and results are mainly distributed via the ES 6 network. The project currently maintains a database with field organizations, interested in project related results. At the end of the previous project (ES 5), this data base contained contacts of about 360 field organizations. The data-base has been updated and gradually expanded in order to disseminate information about the project's activities and project related results to a large group of organizations in an integrated field of SRH and HIV. By the time of issuing this mid-term report, the database of the Eurosupport network contains entries of 421 organizations and individual experts.

**Collaborative partners**:

At the time when the Grant Agreement was made, 15 collaborative partners had agreed to participate in ES 6. In the meantime there have been 22 additional organizations who became collaborative partners. We are currently further expanding the network of collaborative partners (→ see list Annex 1) and we mention only those in Annex 1, who now officially have the status of CP. Three more organizations have expressed an interest at the time of the submission of this interim report (from Portugal, Austria, and Switzerland resp.), but their status needs to be confirmed.

The CPs' network has been created to maximize the implementation of the CISS and the TRP. However, there is no remuneration, so collaborative partners work purely on a voluntary basis. They receive all project related information (newsletters) and are invited to provide feedback on different parts of the TRP. At the end of the project, CPs , as well as APs are invited to the final project meeting/second training workshop, where the training and resource package (including CISS) will be presented. The original budget covers costs for 15 partners attending this meeting. The new partners agreed to be a CP, although we can not guarantee financial support to attend the final meeting. As we continue our efforts to expand our collaborative network, we have decided to invest more time in contacting potential sponsors to raise extra funding. If this strategy is successful, the costs for additional CPs to participate at the final TRP workshop will be covered, for those who cannot fund their own costs.

**The Eurosupport 6 website**

The project website has been be adapted to the needs of the current project. This includes update of

the relevant information provided via the website, such as newsletters, scientific articles and other project-related information. Links to the EAHC website as well as to other relevant stakeholders (incl. APs, CPs and other European projects) have been integrated. The ES 6 website is accessible at: http://www.sensoa.be/eurosupport

In the project proposal/grant agreement, we proposed that the project-website would also be used for creating an environment, in which the computer-assisted tools can be integrated. However, at the kick-off meeting, the project partners opted for working with a DVD instead of online versions of the interventions in order to avoid problems with connectivity during the patient consultations and counselling sessions. Therefore, we have decided that while the intervention is under development, and tested, the APs will work with DVD-version and only when the intervention is ready for up-scaling it will become available online.

**The Eurosupport 6 newsletters**

As with previous projects, the **Eurosupport 6 newsletters** were issued biannually and disseminated both electronically and via the website to the ES6 network and thus beyond associated and collaborative partners. The newsletters usually contained project results and related relevant information on SRH and HIV/AIDS. The ES 6 newsletters nr. 1 – 3 are available for download via the ES6 website.

**Eurosupport 6 project folder**

A project folder that promotes the overall project has been produced. It has been disseminated to a variety of interested organisations and stakeholders across Europe, e.g. at scientific conferences and policy meetings. The folder is also available (in pdf version) at the Eurosupport 6 website. Associated partners are asked to use this folder to present the project to potential stakeholders.

An extra sponsoring folder has been developed, based on the project folder, but is especially addressing potential sponsors. It clarifies why funding this project is needed and how the unconditional grant will be used.

As the project has evolved, an additional flyer was developed focusing on the intervention (CISS). The flyer can be inserted into the project folder and represents thus an update on the CISS, since this information was not yet available at the start of the project.

**ES6 promotion folder**

A promotion folder promoting the full TRP as a tool for service delivery will also be developed, but its

production does not fall under the current reporting period. This folder will also be disseminated to the ES 6 network and beyond.

**Scientific presentation and publications**

Scientific publications of the scientific project results are planned in peer reviewed international journals, and presentations (posters and oral presentations) at relevant scientific conferences. These are scheduled towards the end of the project's running time, since only then data will be available. However, during the reporting time of this current interim report, a number of relevant publications based on ES5 data, have been published. They include a.o. the following publications in peer reviewed journals and other scientific presentation at conferences:

Victoria G, Fekete EM, Platteau T, Antoni H, Schneiderman N, Nöstlinger C and the Eurosupport Study Group (2009). Emotional support and gender in people living with HIV: effects on psychological well-being. J Behav Med (2009) 32:523–531. DOI 10.1007/s10865-009-9222-7

Coyne C, Mandalia S, McCullough S, Catalan J, Nöstlinger C, Colebunders R, Asboe D 52010). The International Index of Erectile Function: Development of an Adapted tool for Use in HIV-Positive Men who have sex with men. J Sex Med 2010; 7:769-774

Nöstlinger C, Nideroest S, Platteau T, Loos J, Colebunders R, the Swiss HIV Cohort Study and the Eurosupport Study Group (2010). Mirror, Mirror on the Wall: The Face of HIV+ Women in Europe Today. *AIDS Care,* 22: 8, 919-926. DOI: 10.1080/09540121003758564

Nöstlinger C, Nideroest S, Platteau T, Müller MC, Stanekova D, Gredig D, Roulin C, Rickenbach C, Colebunders R, the Swiss Cohort Study and Eurosupport Study Group: Testing a Modified Information-Motivation-Behavioral Skills Mode. In press: Archives of Sexual Behavior.

Nöstlinger C, Nideoest S, Gredig D, Platteau T, Gordillo V, Rickenbach M, Ferreira-Dias S, Rojas Castro D, the Swiss HIV Cohort Study and the Eurosupport 5 Study Group (2010). Gender-related differences in condom-use with steady partners of heterosexual people living with HIV in Europe: Testing the Information-Motivation-Behavioural Skills Model. In press: European Journal of Public Health.

Nöstlinger C. Sexualization of Youth. Current Evidence and Positive Public Health Strategies to Counteract. Oral presentation at the Sexual Health Forum, European Commission, SANCO, DGV, Brussels. 13.3.2009.

Nideröst S, Nöstlinger C, & the Eurosupport Study group (2009): Predictors of condom use in HIV-positive men having sex with men. Testing the IMB Model. Abstract PE3.1/4 at the 5th EUROPEAN CONFERENCE ON CLINICAL AND SOCIAL RESEARCH ON AIDS AND DRUGS, 28-30 April 2009, Vilnius, Lithuania**.**

Nöstlinger C, Platteau T, Borms R, Nideröst S, & Colbunders R & the Eurosupport Study group (2009): The Eurosupport initiative: Positive prevention with people living with HIV in Europe. Oral presentation at the 5th EUROPEAN CONFERENCE ON CLINICAL AND SOCIAL RESEARCH ON AIDS AND DRUGS, 28-30 April 2009, Vilnius, Lithuania**.**

Christiana Nöstlinger, Victoria Gordillo, Erin Fekete, Tom Platteau, Eurosupport V Study Group(2009): Gender differences in social support and mental health among HIV positive women and men living in Europe. Abstract nr P103. 1st German-Austrian-Swiss AIDS Congress (SÖDAK), 26 June 2009, St. Gallen, Switzerland.

Christiana Nöstlinger, Sibylle Nideröst, Daniel Gredig, Tom Platteau, Matthias Müller, the Eurosupport Study Group and the Swiss HIV Cohort Study (2009): Condom use among heterosexual HIV positive men and women: what's in a steady relationship? Results of the Eurosupport V study. Abstract nr P205. 1st German-Austrian-Swiss AIDS Congress (SÖDAK), 26 June 2009, St. Gallen, Switzerland.

Christiana Nöstlinger, Sibylle Nideröst, Rebecca Woo, Tom Platteau, Robert Colebunders, The Swiss HIV Cohort Study & The Eurosupport 5 Study Group: Mirror, Mirror on the Wall: The face of HIV+ women in Europe today. Oral presentation at the 9th International AIDS Impact Conference, Gaborone, Botswana, 22-25 September 2009.

Christiana Nöstlinger: Eurosupport 5 – Improving the Sexual and Reproductive Health of People Living with HIV. Oral Presentation at the European's Commission Civil Society Forum. SANCO DG V. Luxembourg, 16.12.2009.

Christiana Nöstlinger: Positive Prävention – Prävention mit und für Menschen mit HIV. Oral presentation at the 8. Innsbrucker HIV-Tagung, Kühtai, Österreich, 17.4.2010

Christiana Nöstlinger, Tom Platteau & the Eurosupport Study Group. Experiencing discrimination when information needs are unmet: Results from the Eurosupport 5 study. AIDS2010 Vienna, Austria 18-23/7/2010. Posternumber: WEPE0666.

Tom Platteau, Christiana Nöstlinger & the Eurosupport V Study Group: Eurosupport 5: Regional differences in service provision for people living with HIV in Europe. AIDS2010 Vienna, Austria 18-23/7/2010. Posternumber: THPE0579.

Sibylle Nideröst, Christiana Nöstlinger, the Swiss HIV Cohort Study and the Eurosupport Study Group: Gender-related differences in sexual and reproductive health services
for people living with HIV in Europe. Presentation at the Swiss Public Health Conference, 09/09/2010, Nottwil, Switzerland.

### 3.2.2 Problems encountered

No major problems were encountered during the first half of the project in relation to dissemination.

### 3.2.3 How were problems resolved

NA

### 3.2.4 Activities planned for the next period

The dissemination activities will include the following:

- Issuing 3 more newsletters (biannual)

- Ongoing identification of CPs
- Ongoing exchange with other European projects (i.e. dissemination via the AIDS Action Europe website, cooperation with projects such as SIALON II, EMIS …)
- Inviting CPs to the final training workshop
- Participation at scientific conferences
- Making the final adapted version of the CISS available online
- Develop the TRP promotion folder upon availability of the full TRP (as described above)

**WP3: Evaluation of the project**

**Evaluation plan available** □ no X□ yes (please attach as Annex 2)

### 3.3.1 Activities undertaken

The evaluation plan has been fine-tuned. The study protocol has been written. The evaluation tools have been developed. For a more detailed description, see Annex 2.

### 3.3.2. Problems encountered

The delay accumulated made it necessary to postpone the start of the intervention trial. No data have yet been collected.

### 3.3.3. How were problems resolved

The delay accumulated should be made up by the a no cost extension to be applied for at a later point in time should it be necessary, and a decrease in the last follow-up period (see also justification as given under point 3.1.3 above relating to overall management and specific objective 2 below).

### 3.3.4 Activities planned for the next period

- Collecting baseline and follow-up data for the outcome evaluation, as described in the study protocol
- Collecting data for the process evaluation, as described in the study protocol
- Evaluating the final training workshop
- Issuing the final evaluation report

*3.2 Activities related to project objectives (core work packages)*

**Specific Objective 1: To develop evidence-based and theory-guided target group specific interventions to improve the sexual and reproductive health of PLHIV**

**Methodology applied as planned**

In terms of the overall methodologically, how to develop the overall intervention package, we used Intervention Mapping Method [7, 8] as a tool to develop, and implement the intervention. The IMM-framework has been elaborated and can be found annexed to this Report (→ see Annex 4).

The *Information-motivation-behavioural skills model* [9] and the *Stages of Change Model* [10] have been used as the underlying theoretical behavioural change theories. The theoretical guidance in the project was utilized as originally planned. Additionally, we integrated elements of *Motivational Interviewing* for the counselling tools. [11, 12]

Empirical evidence shows that the effectiveness of programmes is highest when based on sound empirically tested theories [13], delivered one-on-one by professional service providers in settings where HIV-infected persons receive medical care, and address a range of coping issues associated with their infection. [6]

An additional body of evidence, which was integrated into the theoretical foundations of the interventions, refers to increased understanding of decision-making and risk evaluation, following on the one hand from experimental cognitive work on motivational states and risk related behaviour [14-17] and on the other from qualitative research on the narrative complexity of how people assimilate HIV prevention messages and negotiate sex [18]. One finding, common to both cognitive and qualitative studies, [19, 20] is that real life risk-taking and risk-reduction strategies are not well described by rational health models. When not in a state of craving, people often form intentions to behave rationally (e.g. in their long-term best interest, according to societal values), however, their experience in motivationally 'hot' situations (e.g. sexual arousal, fear of rejection, need for intimacy [21] is, that attention shifts to immediate goals related to motivational state rather than distal general goals. So they find themselves behaving in ways discordant with their previous intentions.

Within the development of the CISS, we integrate these pieces of evidence to safeguard that the intervention does not refer to cognitive decision-making alone.

**Involvement of partners and target groups**

As it was foreseen in the grant agreement, we created an External Advisory Board, a group of international experts to advise us on methodology. The EAB consists of major European stakeholders in the HIV field, including organizations, representing PLHIV and gay people (e.g. EATG, ILGA). A list of members of the EAB can be found as Annex 3 of this report. A conference call was held on November 17th , 2009, to discuss the methodology of the research design, and the remarks of the EAB were useful to adapt the study protocol.
All APs have been kept informed on a regular basis about the progress of the project. During all phases of the development of the intervention (writing scripts, taping videos, producing powerpoint-presentations for the CISS, etc.), APs were asked for feedback.

Selected collaborative partners (Terrence Higgins Trust, NAZ, Women Positively, ) etc. were involved in the writing of the scripts for the intervention, and gave feedback on the feasibility and acceptability of the various computer-assisted tools for the two target groups.

**Coordination with other projects or activities**

At the European AIDS Conference in Vilnius (2009) and the IAS conference in Vienna (2010), a meeting with all granted projects was organized by EAHC. Networks were strengthened, and content-related co-operation was discussed. Eurosupport 6 participated in both meetings and presented the research-related work at these occasions.

**Outcomes and deliverables achieved**

- IMM framework: this framework has been completed (→ see annex 4).

- Set of 2 intervention manuals: these two draft intervention manuals are completed, however, they have been integrated into one overall manual consisting of two parts (a technical part for the CISS, and a general part for the counselling skills). The final version will be issued upon availability of the trial's results at the end of the CISS study.

- Computer assisted intervention: At the time of completing this interim report selected APs (Belgium, France, the Netherlands, UK, and Germany) have pilot-tested the English version of the CISS, available on a DVD-ROM for MSM, minority women, and minority men. The

audio-files on the DVDs have received sub-titling in all project-languages, and all the written material included has been translated.

- Online training tool for CPs: this tool is still in progress. It is to be completed towards the end of the project. This deliverable does not fall under the reporting period of this project.

**Problems encountered**

***Delay du to technical problems***

The major problem we have encountered is the delay accumulated throughout the development of the intervention. This delay is due to technical difficulties cause in first instance by maintaining the same level of interactivity on a DVD than online (see decision taken during the kick-off meeting), but also caused by the complexity of the intervention development, e.g. several feedback-loops that are integrated into the process of development.

***Translation issues***

Also the translation was more complex than anticipated in the original timelines: when we planned the project milestones, the intervention was not yet fine-tuned, and thus the scope of the intervention not yet fully known. Empirical evidence (see above) has shown that interventions need to be comprehensive, so the CISS intervention contains various determinants of safer sex. For each of them, computer-assisted material had to be produced, sent out to the respective AP for quality check, adapted upon feedback and finally typed out for subtitling. This resulted into 3 target group specific DVDs (MSM, Minority women, Minority men), and 9 languages (including English), which are available now.
Apart from the video-material, translation was also required for the study tools such as the baseline and follow-up questionnaires, and all other documents necessary for the implementation of the CISS trial, i.e. standard operating procedures, informed consent sheets, promotion leaflets. For the study tools, backward translation by the partners was carried out to safeguard the quality of the translations.

In order to obtain sufficient feedback from all APs involved, several additional feedback loops have been organized to safeguard the quality of the intervention. These loops created extra delay.

***Recruitment of patients in Slovakia***

An additional problem encountered refers to the recruitment of patients for the intervention study in Slovakia. The reasons were the following:

When receiving an HIV-positive diagnosis, all HIV-infected patients have to sign a declaration (→ see Annex 9) that they commit to not having unprotected sex with sexual partners, in order to prevent onwards HIV infection. By signing this, patients are also informed that they could be prosecuted according to Slovakian law.

This makes it extremely difficult for PLHIV to admit that they may experience problems with sexual risk behavior and safer sex to service providers (i.e.: physicians, psychologists or counselors) and adds to the stigma related to HIV. Despite of the fact, that within the ES6 project confidentiality was emphasized and assured, patients did not volunteer to be recruited, although several people initially expressed their interest. This problem was unexpected, because the anonymous study, carried out on SRH needs within the framework of ES 5, revealed equal levels of sexual risk behaviour among Slovakian participants. However, the ES 5 survey was anonymous and data were sent directly to the coordinating centre in Belgium. Since there seems to be a high level of hidden discrimination of HIV-positive patients in Slovakia, patients are afraid to discuss their personal problems (including sexuality) with others. They are also afraid to disclose and live openly with HIV, and as a consequence NGOs or self-help groups for HIV-infected people in Slovakia do not exist. In order to deal with this problem, the AP in Slovakia had decided to work with a psychologist, not directly employed at the same facility, in order to create a safe room and confidentiality for patients. This way, it was hoped to facilitate the discussion of sexual problems and adherence to safer sex more openly than they could do with professionals issuing the regular follow-up. As this strategy had not worked out, during the summer months additional efforts were invested to recruit via informal networks, key persons and snowball sampling.

The experience in Slovakia can serve as an example, that legal measures, that criminalize exposure to HIV and HIV transmission risk, may increase the vulnerability of people living with HIV and may have an unintended negative effect on HIV prevention and public health

safety. In this case, PLHIV, who would like to seek professional support for safer sex behaviour, are discouraged to access what potentially could be available to them.

**How were problems resolved**

Strict follow-up and continuous contact with the APs responsible for the intervention development (CNWL) have enabled us to us to identify the problems and react accordingly. This consists of daily email-contacts, and weekly telephone contacts with the APs. We have adapted the time-lines and these revised timelines will help to minimize and control the existing delay.

With regards to the recruitment problem in Slovakia, all efforts invested show that it is highly unlikely that the study can be realized in Slovakia. Therefore, we suggest to involve another partner (from the Czech Republic) to carry out the CISS intervention among gay men. The ideal envisaged partner for carrying out the CISS study is the University Of Prague/Institute of Sexology. This organization is already a CP in ES 6, and was an AP in ES 5. In addition, the Institute of Sexology could work with the same language version of the CISS intervention as the Slovak partner. Contacts have already been established and there is considerable interest to join the study. However, the terms of references for the envisaged cooperation have to be worked out with subsequent submission of an amendment.

**Activities planned for the next period**

The next project phase will be dedicated completely to the implementation and evaluation of the developed intervention.

- Finalizing the pilots in the selected centres
- Establishing the necessary prerequisites (administrative and technical) to carry out the CISS study in the Czech Republic
- Czech organization to become an associated partner (i.e. submitting an amendment and getting approval)
- Recruitment in all participating centres (including the Czech Republic)
- Delivering the intervention within the framework of the CISS intervention study
- Conducting post-test and follow-up data collections (at 3 and 6 months respectively, according to the revised timelines; as suggested above)

- Analysis of the collected data (outcome and process evaluation)
- Adapting the CISS based on the study results (final version for the TRP)

**Specific Objective 2: To develop an evidence-based training and resource package (TRP) for service providers in clinical care and community-based settings in the HIV/AIDS field**

**Methodology applied as planned**

For the TRP development, we have used the available evidence from ES 5 (see also list of publications), and other evidence available on sexual risk reduction interventions in international literature[5] [6]. We have also used an evidence-based public health planning method, i.e. the IMM as a guiding principle for the final TRP development. [7] [8]

By doing so, we have developed the IMM framework (→ see Annex 4), which stipulates the needs assessment (ES 5), the definition of the expected changes in behaviour (in the form of matrices), the selection of theory-based methods and practical strategies, the development of the program as such (i.e. the core piece of the TRP being the CISS intervention), the adoption and implementation plan (as defined in the study protocol) and the evaluation plan (see WP 3 and the interim evaluation report).

The TRP is the final output of the project, and during the first project phase, we have fine-tuned its different parts. The TRP will consist of four main parts:

1) **Intervention manual** on the CISS intervention: available as a draft/pilot version for the CISS trial (→ see Annex 8).

2) **Implementation manual** (for service providers): available as standard operating procedures for the trial implementation. The full implementation manual will be available along with the final TRP, and will also include the policy tools (see below, objective 3).

3) **Training manual:** this will include online training tools on specifically working with the CISS and a training manual, including broader aspects on positive prevention, such as training on different aspects of human sexual behaviour, communication on sexuality, counselling skills, specific aspects of HIV/AIDS, disclosure and safer sex. The training manual includes training tools addressing different aspects of a learning process towards facilitating behaviour change. Training exercises are developed to cover different aspects of this

learning process such as knowledge, attitude, skills, emotions or client support. The training manual is currently available as a first draft version, fine-tuning in order to provide more linkages with the CISS will be added when both CISS DVDs will be available and the pilot study is done. The online training tools will be developed in the second half of the project, contingent on the evaluation results and the final and adapted version of the two target-group specific CISS intervention interventions.
Due to the delay in the development of the CISS, the training delivered focused on general aspects of counselling skills; the part on the CISS intervention was not fully completed (session 3 was still missing) and therefore the training on how to work technically with the CISS focused mainly on session one and two.

4) **Reference guide:** this is an informative handbook for service providers on positive prevention, and SRH of PLHIV, background information on the target groups, on HIV and STI transmission, on sexuality and reproductive choices, risk reduction strategies, new prevention technologies, impact of HIV on the lives of PLHIV, empowerment of PLHIV including aspects of disclosure, SRH and rights, criminalization, role of service providers; contextual aspects. Each of these chapters contains state-of-the-art information, relevant links to positive prevention and references to source documents mostly to websites. The reference guide is now available as a draft version and will be updated for the final TRP development during the second project period, since it should contain most up-to-date and accurate information.

**Involvement of partners and target groups**

Sensoa is the lead partner for the development of the TRP. Sensoa has been developing three elements of the TRP, only the intervention manual has been developed by CNWL as it is closely linked to the CISS intervention.
The electronic tools will also be developed by the CNWL, the AP who also has been responsible for the development of the CISS. Collaborative partners will be invited to provide feedback on different sections of the TRP. To maximize the involvement of PLHIV , the reference guide is going to be developed in close collaboration with the European AIDS Treatment Group (EATG). EATG will also be asked to provide feedback on different sections of the TRP.

The role of ITM has been the coordination of the overall work and the feedback from the steering group and other APs.

**Coordination with other projects or activities**

The TRP development is closely linked to the development of the CISS intervention.

**Outcomes and deliverables achieved**

First training workshop: held in March 2010

Training workshop report: issued in April 2010 (deliverable D7)

Evaluation training workshop: issued in April 2010

Intervention manual: issued in August 2010 (deliverable D4)

Draft reference guide: issued in January 2010

Draft training manual: issued in February 2010

Collaboration with EATG: started in September 2010

**Problems encountered**

Since the TRP development is closely linked to the CISS development, the delay accumulated also had an impact on the TRP development.

**How were problems resolved**

The main parts of the TRP have been developed (currently with the exception of the implementation manual) and will be updated towards the end of the project. Since the work on the TRP can be phased, it will be possible to finalize and update the available drafts when the evaluation results are ready.

**Activities planned for the next period**

- Conceptualizing the implementation manual
- Finalizing the draft version of the intervention manual
- Finalizing the draft versions of the reference guide
- Finalizing the draft version of the training manual
- Developing the electronic training tools
- Developing the materials for the final training workshop
- Holding the final training workshop

**Objective 3: To develop a policy tool which specifies the elements necessary to integrate SRH-related and positive prevention services in routine HIV care**

**Methodology applied as planned**

Activities to achieve this project objective fall under the next project period. Since this tool will be part of the final TRP and its development is contingent on the experiences with the implementation of the CISS (i.e. the evaluation study), achieving this specific project objective is foreseen for the second project phase. The final policy tools will be part of the implementation manual, as described above (see section on objective 2).

Involvement of partners and target groups

*NA*

Coordination with other projects or activities

*NA*

Outcomes and deliverables achieved

*NA*

Problems encountered

*NA*

How were problems resolved

*NA*

**Activities planned for the next period**

- Conceptualizing the policy tool (as integrated part of the implementation manual)
- Developing the implementation manual
- Collecting feedback on the implementation manual among APs and CPs
- Finalizing the implementation manual and integrating it into the TRP

**Objective 4: Expanding and maintaining a network to promote SRH and positive prevention among both HIV and SRH field organizations in Europe**

**Methodology applied as planned**

The Eurosupport network maintains a database with field organizations and/or individual HIV/AIDS experts interested in the project. Information about the project's activities, project related results and related information about SRH related topics are disseminated via this network. Potential stakeholders can subscribe via the ES 6 website or are invited personally at various occasions, such as international conferences or meetings. The database is available online and can be consulted by the associated partners.

**Involvement of partners and target groups**

Associated partners have been asked to promote the project within their region or country. They can appoint or suggest new stakeholders, which are then invited by Sensoa. Associated partners have the possibility to expand the network with interested contacts in their country. This strategy has led to an increase of data entries to more than 420.

**Coordination with other projects or activities**

ES 6 is fairly well integrated into the group of European HIV-related public health projects. More specifically, we collaborate with organisation such as 'AIDS and Mobility', 'SIALON', 'Sunflower', 'H-Cube', 'Everywhere', and the 'Correlation' network. These organizations' logos have been placed on the ES 6 website and provide a direct link to their respective sites. In addition, we also have exchanged research-related information with EMIS, and we have participated in two European meetings of all EC-funded public health projects in the field of HIV/AIDS (at the occasion of the European AIDS Conference in Vilnius, Lithuania, and the XVIIIth International AIDS Conference in Vienna, Austria).

**Outcomes and deliverables achieved**

Compared to the network established during ES 5 (360 contacts), the current network counts 421 contacts. These contacts are persons or organizations , which receive project-related information, such as the ES 6 newsletter, on a regular basis.

**Problems encountered**

No problems were encountered.

**How were problems resolved**

Not applicable

**Activities planned for the next period**

The network will be continuously expanding during the remaining project period.

## 4. Annexes

Annex 1: List of associated partners and collaborative partners
Annex 2: Evaluation report
Annex 3: List of Members of External Advisory Board
Annex 4: IMM framework document
Annex 5: Study protocol
Annex 6: Intervention flow charts
Annex 7: Revised timelines
Annex 8: CISS draft intervention manual (incl. 3 DVDs)
Annex 9: Declaration Slovakia

**References**

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