Eurosupport 6

Interim Evaluation Report

Period: March 1st 2009 - August 31st, 2010

"Developing a training and resource package for improving the sexual and reproductive health of people living with HIV/AIDS"

Institute of Tropical Medicine

October 2010

Grant nr. 20081204

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Abbreviations

AP	Associated partner
CAI	Computer-assisted intervention
CBO	Community-based organization
CISS	Computerized intervention for safer sex
CP	Collaborative partner
ES	Eurosupport
IMM	Intervention Mapping Method
ITM	Institute of Tropical Medicine
MSM	Men having sex with men
NGO	Nongovernmental organization
PLHIV	People living with HIV
SRH	Sexual and Reproductive Health
STI	Sexually transmitted infections
TRP	Training and resource package
WP	Work package

Executive Summary

The objective of this interim self-evaluation report is to assess the progress of the project so far, looking at whether the project milestones have been achieved in a qualitative and timely fashion. Next to that, the main evaluation component of this project comprises of assessing the effectiveness of the intervention, developed within the framework of Eurosupport 6 (ES 6), i.e. a brief counselling intervention for service providers to support people living with HIV (PLHIV) in maintaining and improving their sexual and reproductive health (SRH). The main emphasis is given to sexual risk reduction and condom use, however, using a comprehensive and rights-based positive prevention framework. With respect to the latter objective, the achievements during the first 18 project months relate mainly to the development of the evaluation plan and tools.

Since evaluation is such an important and integrated part of the overall project, i.e. adopting a randomized controlled study to assess the interventions' effectiveness, the grant agreement did not foresee an external evaluation.

The aim of ES 6 is to develop a training and resource package (TRP) for HIV service providers to support PLHIV in improving their SRH. This requires equipping service providers with the evidence-based tools to effectively support their clients. The project has two major tracks for the research and development (R&D) part:

(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.

(3) Networking and Dissemination

In addition to R&D, dissemination is also an important component of ES 6. The ES 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: they informed about the project's progress and disseminated relevant information relating to SRH of PLHIV and positive prevention. The project website is continuously updated and also used for dissemination purposes: http://www.sensoa.be/eurosupport

In this report, a number of indicators on various levels have been developed to assess whether the project objectives have been reached. We look at process indicators, output indicators, effect indicators and impact indicators respectively to answer the main evaluation questions. The evaluation focuses mainly on process- and output indicators, whereas effect and impact indicators have been developed, but cannot be assessed within the project's running time either due to time, resource or methodological constraints.

Main problems encountered during the first 18 months, were related to technical problems in the intervention development of the computer-assisted tools, which resulted in a number of consequences on other project related outputs. However, the remaining outputs were achieved as planned. Overall, we may conclude that the TRP development is well under way, and a number of measures are suggested in this report on how to minimize the consequences of the delay and improve overall project performance during the second project phase. These include adopting parallel, rather than chronological working procedures, reducing the follow-up time of the CISS trial and if necessary, applying for a no cost extension towards the end of the project. All of this will require stream-lined coordination efforts, in which we are prepared to invest.

1. Introduction

EUROSUPPORT is a research and networking initiative in the field of HIV/AIDS, which has received support from the European Commission since 1996. Ever since, its overall goal has been to gain scientific insight into newly emerging and quickly changing HIV-related problems by using a flexible and multidisciplinary approach. The network includes HIV-treatment centres, community-based organizations delivering HIV-related services and patient organizations in many European countries to carry out targeted empirical research on the needs of people living with HIV. Since its start, five specific research projects (EUROSUPPORT I – 5) were carried out and the network has constituted a forum for the participating centres to exchange information and expertise, relating to issues of care and support, aiming at patients' direct benefit of the evidence and the research findings accumulated by this initiative. The current project ES 6, approved by the European Commission's Public Health Programme 2008, addresses service providers' capacity to improve the SRH of PLHIV. As such, it is a logic continuation from ES 5, which assessed evidence on SRH-related needs and factors influencing risk and protection behavior among PLHIV. In addition, ES 5 assessed the needs of service providers to more adequately support PLHIV in SRH and adoption of safer sex practices and issued counseling recommendations for an integrated field of HIV and SRH service delivery. But counseling guidelines alone are not sufficient to change practices, when service providers lack the capacity and practical tools for implementation. Based on the ES5 evidence, as well as on the current state-of-the-art literature, ES 6 aims at equipping service providers in an integrated HIV and SRH field with such effective, theory-based and easy to use tools to deliver effective counseling. They must be able to be integrated in routine service provision, with not much effort in additional time or resources in a busy clinical care routine to be used a wide scale.

2. Objectives of this report

Evaluation is a built-in component to this project. It is a cross-cutting activity through all work-packages and project-related activities. However, work-package 3 (for WP structure, see the technical implementation report) of the project is made up by all specific actions undertaken to verify if the project's objectives are being reached. Lead partner for this work-package is University of Complutense, Faculty of Psychology, Madrid.

According to Annex 1 of the Grant Agreement, the project foresees two main evaluation

components, which intend to answer two main evaluation questions:

1) **Has the overall project been carried out in an effective and qualitative manner?** This refers to the documentation of project management processes, such as internal monitoring and quality control through the regular project management. These activities are mainly linked to WP 1 (overall project management and coordination).
2) **Is the intervention (i.e. the CISS or *computerised intervention for safer sex*), which has been developed as core piece of the training and resource package (TRP) effective in reducing sexual risk behaviour and its related determinants?** This refers to the scientific evaluation of selected project related outputs, i.e. the scientific evaluation study or the CISS intervention trial.

In what is to follow we will first report on the project's progress, using some selected process and output indicators, relating to the project's performance. In the following section we will then report on the evaluation plan, presenting the specific evaluation strategy and the tools used. Finally, we will draw some conclusions on what has been achieved so far and present suggestions on the way forward, i.e. necessary adaptations and improvements which should take place in the forthcoming second project period.

3. The evaluation strategy employed in Eurosupport 6

The main evaluation question, which we aim to answer throughout the course of the project by applying different evaluation strategies and tools, is whether the project's objectives have been reached in a qualitative and timely manner. For each of the project's specific objectives we have therefore developed specific indicators to be used to verify the specific project objectives, formulated according to SMART[1] criteria for assessing the project's effectiveness, both in relation to the overall project results as well as relating to some of its specific outputs (i.e. long-term follow up of the intervention, indicators relating to the training modules and the TRP).

[1] SMART stands for:

1. Specific – Objectives should specify what they want to achieve.
2. Measurable – You should be able to measure whether you are meeting the objectives or not.
3. Achievable - Are the objectives you set, achievable and attainable?
4. Realistic – Can you realistically achieve the objectives with the resources you have?
5. Time – When do you want to achieve the set objectives?

However, not all these indicators can be measured throughout the project's lifetime, since some of them are only measurable at medium or long-term. For instance, indicators that measure the project's impact on the level of the target group in a long-term perspective, cannot be measured during the project's running time.

The specific objectives below are formulated in a realistic way, in the sense that they are achievable within the contextual conditions of the project (e.g. the organizational environments in which the partners work; target group specific conditions, etc.) and the given resources (i.e. the budget available). The specific indicators (see below) serve to verify whether the objectives set will have been achieved at the end of the project, and for this report to give an idea of where the project stands at the moment. We differentiate between process indicators, output indicators, effect- and impact indicators. For each set of indicators we will briefly describe the respective achievements and potential improvements.

3.1 The specific project objectives and their respective indicators

Specific objective 1:

To develop evidence-based and theory-guided target group specific interventions to improve the SRH of PLHIV. This will be achieved through the development of 3 sets of brief counselling interventions using computer-assisted tools (targeting MSM, migrant women, and migrant men living with HIV) to be delivered by service providers in clinical and community-based HIV care settings.

This specific objective aims at reducing sexual risk behaviour in the target groups envisaged (MSM and migrants). The change to be achieved will be measured through a pre- and post test experimental design; see the study protocol, annex 5 to the interim technical implementation report). In addition, and to support the assessment of the effectiveness, an intervention method matrix has been developed, which contains the change objectives and the relating specific indicators how to measure them. The development, adoption and evaluation of the CISS are being guided by a scientific health promotion planning method (i.e. the IMM, intervention mapping method; → see annex 4 to the interim technical implementation report). Table 1 gives an overview on the indicators developed to measure the achievements relating top the first specific project objective.

Table 1: Process indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Process indicator	Description
Service providers' fidelity to the intervention	Measured through self-reported assessment tool (check-list, → see study protocol; annex 5 to the technical interim report) upon completion of the CISS intervention
Implementation of the intervention: integration in routine clinical care (standard care);	Selected variables relating to the implementation of the intervention (e.g. task division, cooperation of stakeholders, developing a multi-disciplinary team) will be collected during the CISS implementation. This indicator relates also to the specific objective 3 (i.e. developing a policy tool) since the experiences accumulated during the implementation of the trial can give valuable guidelines about how to integrate the CISS into routine clinical care.
Number of organizations participating in the CISS trial	10 organizations (main partner and APs) are implementing the CISS intervention to be included in the final TRP

Table 2: Output indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Output indicator	Description
1 Working document containing the intervention mapping matrix	IMM framework document → see annex 4 of the technical interim report)
3 target-group specific draft interventions	During the process of fine-tuning the intervention planning, it was decided (→ see report on the kick-off meeting, available on request and sent earlier to EAHC) that the draft intervention should be made available on a DVD and not via internet in order to prevent problems with online internet access during counselling sessions. Three target group specific DVDs are available containing all the developed computer-assisted intervention tools have been made available (CISS for MSM, CISS for female migrants, CISS for male migrants). The CISS aims at counsellor-supported self-regulation of sexual risk behaviour and positive prevention for the selected target groups.
1 draft intervention manuals	The originally foreseen two intervention manuals have been combined into one manual for service providers. Part I contains the technical description of the CISS, part III the general counselling instructions. The counselling manual is available on the project's e-

	stream platform and has been e-mailed to all project partners. The final intervention manual will be adapted and made available after the completion of the CISS trial study.

Table 3: Effect indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Effect indicator	Description
Reduced sexual risk behaviour at post test measurement	This will be measured at the end point of the CISS trial: 9 months after intervention completed (this time period for follow-up was suggested in the original proposal). Because of the delay occurred, we now suggest 6 months in order to be able to complete the overall project on time.
Reduction of onwards HIV transmission	It is to be expected that if the intervention is effective, onwards HIV transmission should be reduced. However, this would require using biological markers as endpoints in the trial including those of participants' sexual partners, which would raise a number of practical and ethical questions. It is thus not feasible within the current project.

Table 4: Impact indicators for specific objective 1 (i.e. to develop evidence-based and theory-guided target group specific interventions)

Impact indicator	Description
Target group members' improved health-related quality of life	To measure impact, variables such as overall health-related quality of life could be assessed. Currently, we have not foreseen such a global measure in our trial, since we are interested in learning primarily which determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduced HIV-related societal stigma	Stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008[2]; Nöstlinger et al. 2010[3]). In the current self-assessment of the scientific evaluation of study

[2] Rojas Castro D, Le Gall JM, Spire B (2010). Stigma, discrimination, and sexual (dis)satisfaction among people living with HIV: results from the "*AIDES et toi"*survey. AIDS Care, 22(8), pp. 961 – 969.

[3] Nöstlinger C, Rojas D, Platteau T & the Eurosupport Study Group (2010). Experiencing discrimination when information and support needs are unmet: results from the Eurosupport 5 study. Poster presentation WEPE0666 at the XVIII. Intrenational AIDS Conference, Vienna, 18-23 July 2010.

	participants, some variables on HIV related stigma are integrated.

Overall achievements relating to the specific project objective 1:

To evaluate the achievement of specific objective 1, a number of indicators have been compiled on different levels. With respect to the process indicators, the main problem has been the delay accumulated due of the intervention development. Due to technical problems, and the amount of translations that were required for all the CISS material, the CISS-intervention was available later than planned. Subsequently, the trial to assess the interventions' effectiveness could not start as planned (see below, point 3.2). However, all the necessary tools for the evaluation of the intervention have been developed and are available. Preliminary results of the piloting the CISS also show, that the interventions complies to high quality standards and patients participating in the pilot were quite satisfied with the intervention materials. In order to achieve objective 1 within the time-frame of the current project, we suggest applying for a no-cost extension of 3 months towards the end of the project while at the same time reducing the second follow-up period of three months, i.e. evaluating the CISS' effectiveness on behaviour change after 3 and 6 months post intervention.

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 working with the two envisaged target groups (the final TRP development refers mainly to the activities related to WP 8).

The achievement of this specific objective can be measured by the timely delivery of the two training events foreseen (month 12 and month 36), of which only the first falls under the current reporting period. Both the development of the online training tools to reach a larger group of stakeholders (incl. collaborative partners) and the delivery of the full TRP will fall under the second project reporting period. Both these deliverables will only be available after the completion of the CISS trial in their final form, since its results need to be integrated into their development.

Table 5: Process indicators for specific objective 2 (i.e. to develop the training and resource package)

Process indicator	Description
Number of overall participants at the first training workshop	The first training workshop was held in March 2010 and all APs participated with all the coordinators and some HIV counsellors present. The total number of participants was 21 (administrative staff excluded).
Involvement of stakeholders in the development of the TRP	For the development of the CISS, the main AP responsible for this consulted with a small number of community-based organization and set up a close cooperation with them during the process of the intervention development. These organizations covered all target groups of then CISS (Terence Higgins Trust, Gay men Fighting AIDS; the NAZ project and Positively Women). In addition, HIV patient groups at CNWL/St; Mary's hospital and selected key patients of the health Psychology department were also consulted and their feedback was integrated into the CISS development. Also in France and Belgium, community-based organizations were consulted (Sensoa, AIDES). The strategy of consulting a broad variety of collaborative partners was not feasible to implement, since it was too difficult to meaningfully involve them into the intervention development. However, their feedback on the draft version of the CISS and the TRP will be integrated before the finalization of all materials. Therefore, the e-survey to CPs was postponed.
Quality of the trainings delivered (assessed through AP's feedback)	The quality of the first training was assessed by means of a self-reported survey. An evaluation report was compiled, which has been sent to the EAHC. Overall rate of satisfaction with the workshop was 7.7 on a scale ranging from 1-10 (for more details see below, section on evaluation of the training workshop).

Table 6: Output indicators for specific objective 2 (i.e. to develop the TRP)

Output indicator	Description
1 draft TRP	The final TRP will consist of 4 parts: the intervention manual plus DVDs with the CISS, a reference guide containing background information, an implementation manual describing how to integrate the CISS into routine clinical care settings (containing also the policy tool), and a training manual. Currently, the draft intervention manual is available; there are also working documents of the reference guide and the implementation manual/ the training manual will have to be developed in close cooperation between three partners (CNWL,

	Sensoa and the ITM), since it needs to be fully coherent with the intervention. Also for this manual, a working document is in progress.
1 training workshop for APs	The first training workshop has been organized in March 2010 and evaluated (→ see section on the training workshop and evaluation below) A report on the training workshop is also available and has been disseminated earlier.

Table 7: Effect indicators for specific objective 2 (i.e. to develop the TRP)

Effect indicator	Description
Improved capacity and skills of service providers to deliver SRH and positive prevention interventions	The final TRP contains both the intervention and the accompanying training materials. The implicit objective of the CISS is to increase the service providers' capacity to deliver meaningful SRH interventions for PLHIV. This objective cannot be measured within the time framework of this project. According to the proposal submitted we have chosen to evaluate the CISS' effectiveness on the level of the service users instead because PLHIV are the main beneficiaries of this project. However, or future research, evaluating the effect of the TRP on the service providers could be a useful indicator.

Table 8: Impact indicators for specific objective 2 (i.e. to develop the final TRP)

Impact indicator	Description
Reduction of onwards HIV transmission	Hard biological outcome indictors are the best way o evaluate behavioural interventions in a randomized design. While self-reported data on sexual behaviour will also be subject to social desirability and to a certain degree will also depict the way people see themselves as sexual beings, thus not necessarily depicting the sexual behaviour but partly sexual norms, biological outcome data could reveal the true effect of a behavioural intervention. This could be onwards HIV infection, which is due to practical and ethical issues complicated to measure. Another option would be STI testing among the participants. This could be a relevant outcome indicator for future trials.
Target group members' improved health-related quality of life	To measure impact, variables such as overall health-related quality of life could be assessed. Currently, we have not foreseen such a global measure in our trial, since we are interested in learning primarily which determinants of sexual risk behaviour can be changed with which type of intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.

Reduced HIV-related societal stigma	Stigma could be another suggested impact measure. HIV-related stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008). In the current self-assessment of the scientific evaluation of study participants, some variables on HIV related stigma are integrated.

Overall achievement relating to the specific project objective 2:

The achievements of the indicators relating to this project objective show that overall the TRP development is well under way, expect for the delay created with respect to the CISS development. Obviously, this had consequences on the development of all other parts of the TRP. However, the different TRP manuals are now being developed in parallel and are currently available as draft manuals (with different stages of progress); they will be continuously adapted on the basis of the CISS trial results. While originally we had foreseen to carry out the project-related activities in a chronological sequence, we will now we work using rather parallel procedures. This requires more coordination efforts, but will help to safeguard reaching the overall project deadlines, as suggested above.

Specific objective 3:

Within the framework of ES 6, we will develop 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. Such a tool will be part of the final TRP and will provide guidance on how to integrate specific positive prevention counselling in routine clinical care in HIV–settings will be delivered through the final TRP. Since this will be based on all the evidence accumulated throughout the project including the service providers' experiences during the CISS trial, the policy tool can only be available at the end of the project. For completeness, however, we provide Table 9, relating to the specific project objective 3, which displays process, output, effect- and impact indicators.

Table 9: Indicators for specific objective 3 (i.e. to develop a policy tool for integration of SRH and positive prevention services in routine HIV care)

Description	Process indicator	Output indicator	Effect indicator	Impact indicator
Development of a policy tool for integration of SRH and positive prevention services in routine HIV care	Involvement of stakeholders in the development of the policy tool	1 policy tool (specifying mechanisms of effective task division, integration and specialisation, screening, local care pathways, and referral systems integrated in the final TRP	Improved capacity of HIV care settings to deliver SRH and positive prevention interventions A larger number of HIV service providers integrate SRH and positive prevention intervention in their routine services	Reduction of onwards HIV transmission Target group members' improved health-related quality of life Reduced HIV-related societal stigma

Specific objective 4:

Expanding and maintaining a network to promote SRH and positive prevention of both HIV and SRH field organizations in Europe, with the aim to facilitate mutual learning experience and to disseminate the TRP to a substantial number of stakeholders.

This specific objective aims at increasing the number of stakeholders to be involved in the Eurosupport 6 network, which will be gradually expanded throughout the projects running time. Specific tools such as the adapted website and the ES 6 newsletters serve to disseminate information (incl. the TRP) and to facilitate mutual exchange of expertise. The TRP will be disseminated electronically to all stakeholders at the end of the project. The number of organizations reached, and the number of dissemination tools to be developed and distributed, serve as indicators for reaching this specific objective.

Table 10: Process indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organisations in Europe

Process indicator	Description
Involvement of SRH/HIV stakeholders in the network	The stakeholders and organizations being part of the ES 6 network have been gradually expanding and updated and now contain more than 420 organizations and/or individual experts. In addition, the APs have set up their local networks for the service provision working individually with a small number of organizations for the implementation of the CISS. Some of them have also become collaborative partners. The number of CPs has increased from 15 at the start of the project to currently 22 and we will continue to raise interest in the project to further increase the number of CPs.

Table 11: Output indicators for specific objective 4 (i.e. to expand and maintain the Eurosupport 6 network to promote SRH and positive prevention of both HIV and SRH field organizations in Europe

Output indicator	Description
ES 6 website adapted to the requirements of the project	The update ES 6 website is available and maintained on a regular basis. However, the strategy to integrate the CISS into a web-based environment was changed, due to AP's concerns about internet access and confidentiality (see report project kick-off meeting). The CISS is available as a separate tool on a DVD, and the ES 6 website functions as a project-related tool for information dissemination.
Six ES 6 newsletters issued (for the whole project, three for the first 18 months)	Three ES 6 newsletters have been published and disseminated electronically. They are also available via the project's website.
> 360 organizations and individual experts receiving project-related information through the ES newsletter	More than 420 have been receiving this content by the end of the mid-term reporting period.

Table 12: Effect indicators for specific objective 4 (i.e. to expand/maintain the ES 6 network to promote SRH and positive prevention among HIV and SRH field organisations in Europe)

Effect indicator	Description
Improved exchange of expertise and mutual learning among network members	This indicator could be suggested to measure frequency of occasions on which network members actually exchange expertise and to what extent such a network creates opportunities for mutual learning. This could be interesting, given the stark differences between European countries, not only with respect to the epidemiology of the HIV epidemic, but also its underlying fuelling factors and the perceptions and ideologies people hold, relating to potential solutions. Maintaining a web-based forum or a project-related blog, could for instance, inspire such a dialogue across Europe. However, these tools need to be maintained intensively, something that ES6 cannot achieve, given the resources available. There are some examples for such a dialogue on the web, mainly initiated by community-based organizations. A recent example is for instance the discussion forum on issues of criminalization relating to HIV transmission and exposure maintained by the UK-based NAM. There may also be other means to measure the increase in exchange of expertise and mutual learning among network members, however, measuring this effect is not foreseen in the current project.
Increased knowledge of stakeholders with respect to SRH and positive prevention	This indicator could be suggested to the increased or changed knowledge, that network members potentially could be observed among network members, due to their participation in the network. Being exposed to occasions of mutual exchange of knowledge and expertise, indeed could foster a new and different type of expertise. Since it will be difficult to discriminate between different influences, one would have to ask network members about their own perception of personal gains due to participation in the network. There may also be other means to measure the effect of network participation on knowledge in relation to SRH and positive prevention. However, measuring this effect is not foreseen in the current project.

Table 13: Impact indicators for specific objective 4 (i.e. to expand and maintain the ES 6 network to promote SRH and positive prevention of both HIV and SRH field organizations in Europe

Impact indicator	Description
Reduction of onwards HIV transmission	Ultimately, the intervention should enable PLHIV not only to protect their own health but also to protect the health of their sexual partners. This can be measured by a reduction on onwards HIV infections, or by a reduction in HIV incidence among the target groups' partners. The latter show how difficult it would be to establish this effect. Hard biological outcome indictors are the best way to evaluate behavioural interventions in a randomized design.

Improved health-related quality of life of PLHIV	To measure impact, variables such as overall health-related quality of life could be assessed. Currently, we have not foreseen such a global measure for assessing the overall impact of the TRP in a long term perspective (which would clearly go beyond the project's life cycle), since we are interested in learning primarily which determinants of sexual risk behaviour can be changed with that specific type of counselling intervention. However, for future research, it could be relevant to include more global health measures such as health-related quality of life.
Reduced HIV-related societal stigma	Stigma could be another suggested impact measure. HIV-related stigma has been shown to also have an impact on sexual risk behaviour of PLHIV (Rojas et al. 2008; Nöstlinger 2010). In the current self-assessment of the scientific evaluation of study participants, some variables on HIV related stigma are integrated.

Overall achievement relating to the specific project objective 4:

The indicators relating to maintaining and expanding the ES 6 network with the ultimate objective to disseminate the knowledge and expertise accumulated within the project have been achieved; while a change of strategy was necessary, in order to obtain a meaningful involvement of the collaborative partners on the CISS development, the alternative strategy to work more closely with local community-based organizations was adopted. The expansion of both CPs and the ES 6 network has progressed smoothly and the dissemination tools, such as the ES 6 newsletters have been disseminated as planned.

3.2 Detailed description of activities relating to scientific evaluation of the intervention

Table 14 gives an overview of the milestones relating to the scientific evaluation of the intervention, i.e. the preparation of the CISS trial study and the respective milestones, and other activities relating to the evaluation of the project-related activities.

Table 14: Milestones relating to the project's evaluation

Date	*Milestone*
M3	Developing the IMM framework which establishes the evaluation plan
M8	Fine-tuning the evaluation plan and developing a scientific study protocol
M9	Approval of the study protocol by Ethical review board
M12	Developing the study tools (questionnaires, etc.)
M	Evaluation of the first training workshop
M18+2	Midterm evaluation report
M36	Evaluation of the final training workshop/dissemination workshop
M36+2	Final evaluation report workshop

Theoretical guidance

To guide our project, we have been using the Intervention-Mapping method (or IMM); this is an evidence-based public health planning method[4], which has been used to fine-tune all steps necessary to develop, implement, and evaluate the intervention and the accompanying training materials. IMM guides the TRP development as an iterative process, which specifies a number the steps to be taken to achieve the desired outcome. For a more detailed description we refer to the IMM framework document (→ see annex 4 to the interim technical implementation report). Each step in the IMM process is based on the outcome of the previous step. In addition, in the context of a European project with 10 different countries represented by the APs, IMM is used as an overall methodological framework to safeguard sufficient comparability of the intervention across the different settings. However, at the same time it assures sufficient room for target group specific and local/regional adaptations since the same underlying methodological principles are being used.

[4] Bartholomew LK, Parcel GS, Kok G, Gottlieb NH (2006). Planning Health Promotion Pograms. An Intervention Mapping Approach. Second Edition. Jon Wiley & Sons, San Francisco

Table 15: Milestones relating to the theoretical guidance/IMM framework

Date	*Milestone*
M3	Developing the IMM framework
M5	Disseminating of the IMM framework to APs
M10	Draft interventions available

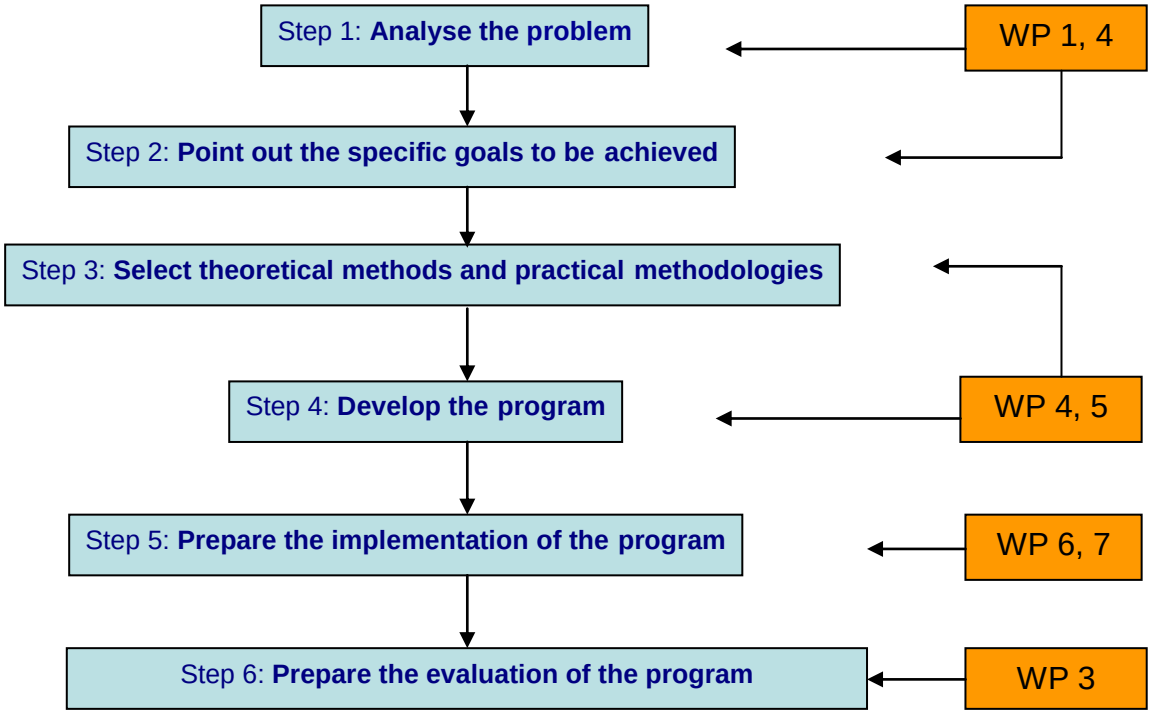
Developing the IMM framework

IMM guides the TRP development as an iterative process, in which each step is based on the outcome of the previous step. Together, they contribute to the following envisaged outcomes:

- enabling service providers to deliver effective positive prevention interventions
- enable people living with HIV/AIDS (PLHA; two target groups as mentioned above) to make informed decisions about sexual risk reduction and to adopt positive prevention principles;

In the context of a European public health project with 10 different countries participating, IMM as an overall methodological framework (see figure 1 below) safeguards sufficient comparability of the interventions across the different settings, as they will all adopt the same theoretical strategies and underlying principles. At the same time, this allows for the needed flexibility to develop target group specific and local/regional adaptations.

Figure 1: Linkages between IMM steps and Eurosupport 6 work-packages (WP)



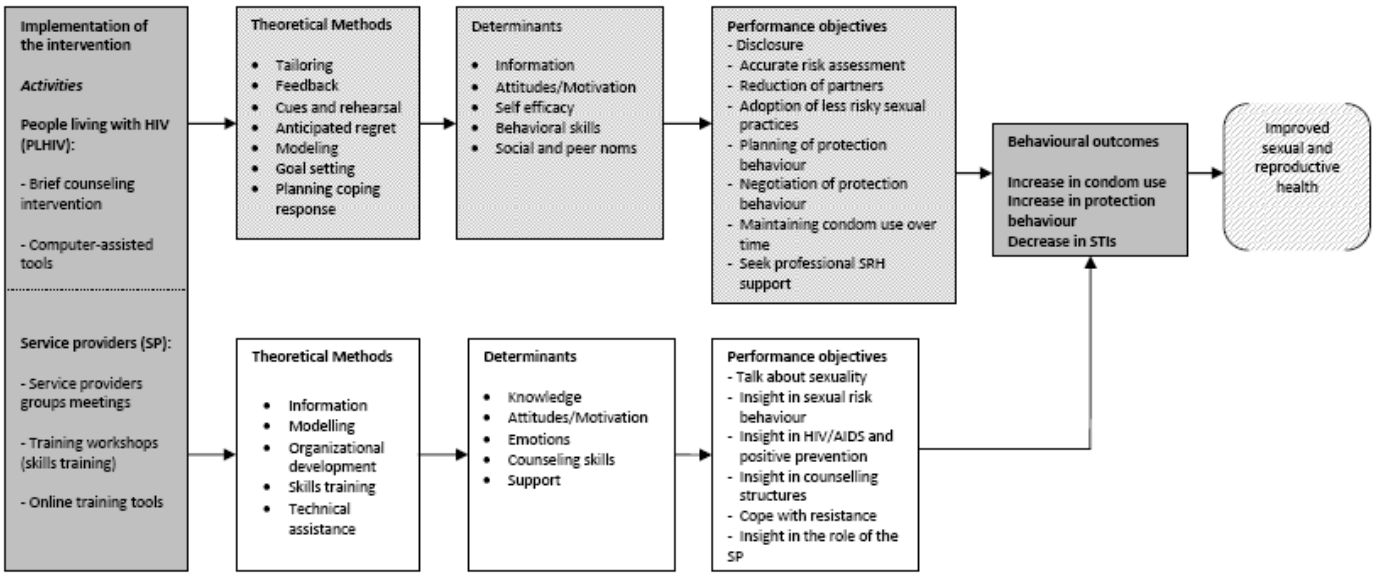
The IMM framework (→ see annex 4 to the interim technical implementation report) contains all necessary working documents containing the proximal programme objectives, the specification of the performance objectives, the respective matrices, and we formulated the specific change objectives. The evidence used were the results of ES 5, as described in the rationale and methodology sections of the grant proposal, and a thorough literature review on SRH interventions for PLHIV covering all EU MS+ EFTA/EEA and acceding countries, and selected national studies carried out by the APs. This evidence was scrutinized for an elaborated target group specific needs assessments. On the basis of this, theory-based strategies and tools were selected to implement the targeted intervention (brief face-to-face counselling interventions using elements of motivational interviewing with complementary computer assisted tools, i.e. the CISS). The IMM framework document also operationalizes the intervention plan, considering sufficient comparability and adaptation to settings requirements. A number of accompanying documents have also been set up and distributed to the

partners, which describe the standard operating procedures as a guideline on how to implement the intervention in their own settings.

It is important to stress that the IMM framework has been a work in progress, i.e. it has been regularly updated through continuous feedback received by the APs.

The IMM framework in particular stipulates the evaluation plan. The following figure shows the logic of intervening and how to assess the interventions' effectiveness.

Figure 2: Logic model for the intervention (CISS)



Assessing the intervention's effectiveness

This logic model has been translated into an evaluation, using a mixed method approach, consisting of two main components: an outcome evaluation and a process evaluation. For the former, a prospective experimental design with randomized assignment of PLHIV to either intervention- or control group condition will be employed. Participants have to undergo screening for sexual risk behaviour during the last 3 months, based on specific screening questions (this is described in detail in the ES 6/CISS see study protocol, annex 5 to the interim technical implementation report).

The experimental pre- and post-test design compares 2 conditions (a brief counselling intervention, i.e. the CISS as described in the respective work-packages vs. standard care): behavioural indicators relating to sexual risk behaviour and other relevant variables (e.g. disclosure, attitudes and motivation to sexual risk reduction, perceived self efficacy in adopting

sexual risk reduction, and outcome behaviours) are measured by validated comparable tools, which allows for pooling the data (pre-test at baseline, post-test and three and suggested six months follow-up after completion of the intervention). Self-reported outcome measures can be incorporated into the site using on-line questionnaires to measure frequency of condom use, perception and choice of partners, as well as meta-cognitions referring to sexual risk and sexual decision-making.

In addition, for the process evaluation (which is described in more detail below and in the study protocol) data are collected on the level of the service provider (post-test only) about feasibility, fidelity to the intervention, and specific questions to assess the standard care condition in order to control for the comparability of the intervention across sites.

The study protocol also contains a detailed description of the study variables (see table 16 below), the measures used to assess them, as well as a description of the procedures that study participants have to undergo (such as informed consent procedures, data collection, and storage, protecting the privacy of the participants; measures to safeguard confidentiality).

Approval of the study protocol

While the IMM framework describes the evaluation plan, the study protocol describe din detail the study design and the ethical implications and considerations of the study. The study protocol (→ see annex 5 to the interim technical implementation report) was submitted by the main partner (ITM) to the Institutional review Board of ITM and the University of Antwerp. Approval was obtained in January 2010 (protocol ref. nr. 0947 5 690 IRB/ITM and Ethical Commission of the University of Antwerp). In addition, the following APs also had to submit to their respective ethical review boards: Belgium (ITM, Antwerp), the Netherlands (University of Maastricht), Germany (Ludwig Maximilians University, Munich), Italy (Fondazione Centro San Raffaele del Monte Tabor, Milan), and the United Kingdom (Central North West London, NHS Trust).

Developing the study tools for the CISS trial

We developed and submitted a study protocol that contains a detailed description of the study variables and the study tools/questionnaires, and all related procedures.

Table 16: Overview of study variables and points of measurements

Variable	Screening	Baseline assessment	Post-intervention	3-months follow-up	6-months follow-up
Primary outcome: Sexual risk behaviour	**X**	**X**		**X**	**X**
Socio-demographic information		**X**	Only if any changes have occurred	Only if any changes have occurred	Only if any changes have occurred
Important life-events			**X**	**X**	**X**
Health-related characteristics		**X**		**X**	**X**
Reproductive health characteristics		**X**		**X**	**X**
Sexual Behaviour		**X**		**X**	**X**
Disclosure of HIV-status		**X**	**X**	**X**	**X**
Self-efficacy		**X**		**X**	**X**
Attitudes and motivation to adopt protection behaviour		**X**	Only "Stages of change for condom use"	**X**	**X**
Social and peer norms		**X**		**X**	**X**
Behavioural skills		**X**		**X**	**X**
Mental Health		**X**		**X**	**X**
Evaluation of the intervention			**X**		
Exposure to prevention in standard care			**X**		

Wherever appropriate, we used empirically validated scales or questions developed in previous ES surveys. We also integrated comparable items with UNGASS indicators and other European surveys, such as the EMOS survey for instance. With the latter, full comparability was not possible, since item development could not be done due to different, project timelines.

The ES6 study tools have been translated into 8 European languages and back-translated by the APs and were transformed into online version using SNAP software.

The process evaluation

In addition to the effectiveness trial, the CISS will also undergo a process evaluation. It consists of a systematic and continuous documentation and monitoring of key aspects of the program

performance, i.e. the intervention implementation. The evaluation questions of this process evaluation to be answered are:

- Is it feasible to implement a brief counselling intervention, using computer-assisted tools in HIV care settings?
- Is the intervention perceived as relevant by the key target groups of PLHIV?
- Is the intervention delivered in a qualitative manner?

These three evaluation questions are assessed though the following data:

Feasibility of the intervention

To assess the feasibility of the CISS, process data are collected process about participant inclusion, follow-up and attrition; sufficient staffing; consistent delivery of the intervention; effective coordination with referral agencies. This includes an assessment-form for service providers delivering the intervention (to be completed at each intervention visit) to assess whether the intervention was delivered as planned:

- Recording the CISS modules used (time used and sequence)
- Did you discuss individual barriers to implementing protection behaviour?
- Did you negotiate concrete next steps to improve specific HIV protection behaviours?
- Did you negotiate concrete home assignments?
- Description of specific problems encountered during this session?
- Referrals provided

After the last intervention session, a final assessment form for service providers, delivering the intervention, is completed (including the following additional questions):

- Did you negotiate a tailored risk reduction plan?
- Do you intend to work with the CISS in the future (i.e. if found to be effective after the evaluation and outside the study?)
- Would you recommend the CISS to colleagues working in the field? If yes, why? If no, why not?
- Evaluation of the CISS intervention to be assessed by the following questions:

  "How much did this intervention help you in…

  - supporting this client in making informed choices on protection behaviour?
  - talking to this client in an understandable way about sexual and reproductive health?
  - talking to this client in an informal way about sexual protection behaviour?
  - accepting this client's sexual behaviour?

- collaborating on an equal basis with this client?
- developing a useful plan for behaviour change with this client?"

Clients' perceived quality of the intervention implementation:

Participants' perceived satisfaction with and relevance of the intervention (assessed at the first post-intervention follow-up).

Scope of the intervention:

Will be assessed by the frequency of using the CD-Rom/DVD outside the counselling sessions (post-intervention assessment, at 3-months and 6-months follow-up respectively).

Evaluation of the first training workshop

The first training workshop was held on March 10-11, 2010 in Antwerp.

It was both a feedback and training moment for the associated partners. The workshop was evaluated by the participants in terms of their satisfaction with the workshop and usefulness for preparing themselves to work with the intervention. To assess this, a short survey was developed by Sensoa for the participants. The detailed results of this evaluation are available on request and were sent to EAHC earlier (i.e; upon its completion).

Overall, participants were quite satisfied with the workshop and gave an average score of 7.7 (on a scale between 1-10) for the overall quality of the training workshop. Looking more closely at the specific components of the training workshop, participants rated the training on the CISS intervention (facilitated by the UK partner, CNWL) in the following way:

- Most of the participants found that the CISS presentation was clear and to the point (23% strongly agreed and 61.5% agreed, while 15%, i.e. 2 people disagreed)
- The goal of the first CISS session was clear (54% strongly agreed and 46% agreed)
- The goal of the second CISS session was clear (46% strongly agreed and 54% agreed)
- The goal of the third CISS session was clear (38.5% strongly agreed and 38.5% agreed)
- The presenter was responsive to participants (54% strongly agreed and 46% agreed)
- 85% agreed that the visual aids distributed were useful
- 70% felt confident to implement the CISS and 15% felt very confident (agreed strongly). Two people disagreed.

The second part of the training workshop was dedicated to general counselling skills. This was facilitated by Sensoa. Participants evaluated this second part also generally very positive:

- 93% found the exercises interesting (and 7% very interesting; agreed strongly)

- 93% found that the exercises had helped to practise counselling skills
- 100% found the visual aids useful
- 46% strongly agreed and 54% agreed that the presenters were responsive to the participants
- The same proportion of participants found that the exercises were well guided.

Logistic support before and during the workshop were evaluated positively (e.g. practical information, lunch and dinner arrangements, and sufficient time during the workshop related to practical aspects). In conclusion, the workshop was evaluated positively, considering the main draw-back that the intervention was not fully available as planned.

Deliverables relating to the scientific evaluation

During the period of the first 18 months of the project, the following deliverables have been produced within WP 4 (numbers in brackets refer to the grant agreement; here we refer only to the deliverables as mentioned in the official grant agreement):

✓ Intervention map and IMM matrices (D2) (→ see IMM framework document; annex 4 to the interim technical implementation report)

✓ Evaluation tools (D8) (→ see study protocol; annex 5 to the interim technical implementation report)

✓ Interim evaluation report (D10)

5. Conclusions and way forward

This interim self-evaluation report assesses the project's achievements at project mid-term, i.e. 18 months reporting period. It describes the development of indicators chosen, and assesses the level of achievement where actual indicators have been adopted to measure the progress of this project. For the effect- and impact indicators, which cannot be measured during the project's running time, either due to methodological or resource-related constraints, we have elaborated them theoretically on suggested ways how to measure them. The major problem, confronted by the project during the first 18 months, has been the overall project delay, accumulated due to the delay of the CISS intervention development. These were related to mainly technical problems, but resulted in a number of consequences on other

project related outputs as well. However, all the necessary tools for the evaluation of the intervention have been developed and are readily available. It can be expected that once the trial is under way that the project will further progress as planned. Overall, we may conclude that the TRP development is well under way, expect for the delay created with respect to the CISS development. Safeguarding the quality of the CISS development, resulted in unexpected delays as described in more detail in this report and the interim technical implementation report, but this constitutes a worthwhile investment. The indicators relating to maintaining and expanding the ES 6 network, with the ultimate objective to disseminate the knowledge and expertise accumulated within the project, have been achieved as planned.

A number of measures have to be introduced to safeguard the timely achievements during the second project phase, and these include adopting a parallel rather than a chronological working procedures, reducing the follow-up time of the CISS trial and if necessary, applying for a no cost extension towards the end of the project. This will require stream-lined coordination efforts, in which we are prepared to invest.