

**Part B: DESCRIPTION OF THE RESEARCH WORK**

**B1.1 Proposal full title:**

**“Promoting sexual and reproductive health. School-based HIV/AIDS intervention in Sub-Saharan Africa”**

**This is a proposal to develop and scientifically evaluate data- and theory-based community interventions aiming at the promotion of adolescent sexual and reproductive health at selected locations in South Africa and Tanzania.**

**B1.2 Proposal acronym: SATZ**

**B1.3 Call identifier: ICFP501A4PRO3 (INCO-DEV)**

**B1.4 Region: ACP**

**B1.5 Research area: b.ii-1 (Health systems)**

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**References: Included in Part C**

## B2 Objectives

### B2.1 General objectives

Sub-Saharan Africa (SSA) is facing a number of critical health problems and preventive action is urgently needed.<sup>107,108</sup> The most important current social and public health challenge in SSA is the HIV/AIDS epidemic. About 71% of all adults and children living with HIV are located in Sub-Saharan Africa. In 1999, more than 4 million new cases were registered.<sup>99</sup> The transmission of the virus takes place mainly through heterosexual unprotected penetrative sex and spreads rapidly among young people. In addition to the emphasis on vaccine development it is of utmost importance to focus on behaviour change approaches in order to prevent sexual transmittance. Stigma, shame and denial are factors that hamper an open communication about sexuality, risk behaviours and the epidemic. These are serious challenges in the fight against HIV/AIDS. There is an urgent need to find new, systematic and sustainable ways to provide the young generation with sound information, skills and health services. Since the UN Population Conference in Cairo in 1994, the vulnerability of adolescents who tend to engage in unprotected sexual relations increasing the risk associated with HIV/AIDS infection has increasingly been highlighted. Prevention should start during early adolescence, before the age when most young people become sexually active. **Preventive actions were called for by the ACP-EU Joint Assembly Resolution of March 2000.**

Demand is growing throughout the developing world for sexual and reproductive health programs for young people. During the last decade a variety of pilot activities have been initiated in Africa to try to address this and related problems, but they have not been systematic nor taken to scale.<sup>109</sup> Little scientific evidence exists about which approaches are most effective in these cultural and societal contexts.<sup>51</sup> There is an urgent need to design, implement and evaluate interventions which are relevant, effective, make optimal use of scarce resources, and are sensitive to local cultural and societal contexts. To achieve this, local expertise and experience are crucial.

The overall objective of this research project is therefore to **develop interventions which are effective in reducing the spread of sexually transmitted HIV by changing sexual- and reproductive behaviours among adolescents in Sub-Saharan Africa.** In addition, it will provide a setting for exchange of expertise and collaboration among participating research groups through research activities, project meetings and workshops, and provide opportunities for post-graduate training (master and doctoral degree programmes) for candidates from participating African countries. The present research project builds on earlier supported EU initiatives.

More precisely the objective of the proposal is to develop, implement and evaluate a programme for students aged 12-14 years in one Tanzanian and two South African sites to postpone the onset of sexual activity (in students who are not yet sexually active) and increase the use of safe sex practises (in those who are already sexually active).

### B2.2 Specific objectives

The project involves researchers from three African universities (two universities in South Africa, and one in Tanzania) and four European universities. We have identified the following specific objectives:

1. To develop a **research based framework** for cost-effective and culturally sensitive **sexual and reproductive health (SRH) interventions** targeting adolescents. These interventions will be based on reviews of previous studies, a state of the art theoretical framework, and systematic situation analyses in the intervention sites. We shall focus on determinants of unsafe sexual

behaviour. The school system, which represents an important arena for health promotion and disease prevention, will constitute the primary setting. The larger local community will be involved through the participation of parents, health personnel and community (including religious) leaders.

2. To **conduct and evaluate interventions** at selected sites in order to document and improve the efficacy and relevance of the intervention.
3. To test the usefulness of and, if necessary, **change or expand existing theoretical models** for predicting sexual and reproductive behaviours in SSA.
4. To contribute to the **development of expertise and scientific excellence** in the field of health behaviour intervention and research, among all partners.

The development of an intervention framework (objective 1) will be documented and described in a report to be finalised within 15 months after start of the project. The evaluation study (objective 2) will examine the usefulness of the intervention framework and its practical implementations by examining changes in outcome measures such as self-reported sexual-and reproductive behaviour, behavioural intentions, outcome expectancies, self efficacy, attitudes, and subjective norms. The outcomes will be compared with similar outcome measures in previous evaluation studies. Selected parts of the theoretical model for prediction of sexual- and reproductive behaviours (objective 3) will be tested with statistical techniques employing goodness of fit measures. Contributions to development of scientific excellence (objective 4) can be measured by the number of successful master's and doctoral candidates and by the number and quality of scientific publications generated by the project. We expect at least 6 master candidates to have graduated, and 3 doctoral candidates to have started their programmes within 42 months. We expect each partner to have submitted at least two scientific articles (as first author) based on project data within 42 months, in addition to three joint publications presenting selected findings from the baseline studies, the theoretical rationale of the interventions, and the intervention outcomes respectively.

## B3 Contribution to the INCO-II programme activities

### B3.1 Relationship to the call for proposals including regional priorities

The project is consistent with the INCO Work Programme in that it aims to **mobilise European and African research teams jointly** in order to tackle important challenges facing the African countries involved. The HIV/AIDS epidemic is presently the single most important public health challenge in SSA. Health is one of the main priorities, and cost-effective tools for improved health are emphasised.

Under b.ii-1 (Health systems), the INCO Work Programme emphasises the need for **improving health systems**. This is an important aspect of the present research proposal. Furthermore, according to the Work Programme, attention should be given to **youth, reproductive health and major infectious diseases**. HIV/AIDS is explicitly mentioned. Sexual and reproductive health as well as preventing the spread of HIV/AIDS is the focus of the present proposal. Also, adolescents constitute a highly vulnerable segment of the population and a high priority target group for interventions.

In the section dealing with developing countries, the INCO part of the Fifth Framework Programme favours **inter- and multidisciplinary approaches** to research. The present proposal has been developed by a group of researchers representing a number of disciplines and research traditions, including medicine, psychology, epidemiology, sociology, anthropology and health education and promotion. Collaboration across sectors is encouraged. The present proposal implies research on **cross-**

**sectorial collaboration** with the purpose of promoting health and preventing disease. The Work Programme distinguishes three categories of research. The third category is research on specific scientific and technological problems to **generate tools for sustainable development**, which can be used in a particular context of system management or policy development. The present proposal describes a research project aiming at developing tools for combating diseases which represent overwhelming challenges to health systems management and health policy and which threaten social and economic development. Also, the African programme development and research capacity that will develop through this project will continue to exert an influence on the development of the African countries after the project has been completed.

Under section c.i (Tools for health improvement: attacking the major infectious diseases), in the 2001 Work Programme, control of the HIV/AIDS epidemic is highlighted as one of the top priorities.

An important component of the present research project is to **provide postgraduate training opportunities** at the master's and doctoral levels to candidates from the African countries involved, and to stimulate north-south as well as south-south contact and collaboration. This is consistent with the approach described in the Work Programme of the section dealing with developing countries in INCO.

### **B3.2 Key scientific issues for achieving programme objectives**

The project aims at promoting research cooperation internationally, primarily among the five countries involved. Building on the scientific excellence and strengths of each partner, the competence and capacity within the network of collaborating institutions will improve and meet the highest scientific standards in the field of research on health behaviour change. The approach to intervention and scientific evaluation correspond well to EC policies in the field of health promotion and health education. The present project aims at strengthening the European profile of such research on the international arena, while also taking account of the social and cultural needs of the African countries involved. Consistent with the aims of the INCO research programme, the present project aims at developing tools for attacking major health problems facing developing countries.

## **B4. Innovation**

### **B4.1 Review of literature**

Research on health behaviour (including sexual and reproductive behaviour) and health promotion among adolescents has emerged primarily in the United States and Europe, and gained strength during the 1980's and 1990's. A substantial body of knowledge has developed. Over the years, a large number of behaviour change interventions have been designed, implemented and evaluated. Although there are several examples of unsuccessful interventions,<sup>46,101</sup> evaluations of data- and theory-based interventions have provided extensive evidence that health practices can be changed. The evidence is particularly convincing for addictive behaviours<sup>14,22,47,48,82,73,95</sup> and sexual and reproductive behaviours.<sup>49,50,54,55,58,59,61,77,89</sup> Evaluations of programmes which are not securely based on data and theory have shown less convincing behavioural effects or no effects on behaviours at all.<sup>11,60</sup>

#### **Theoretical framework**

The purposes of the theoretical models used in this project are (a) to provide a conceptual framework to assist with understanding empirical findings and (b) to stimulate new ideas and perspectives in order to inform the development of interventions. An important scientific contribution of this project is to determine to what extent models for the prediction and change of health behaviours must be revised and adapted for SSA. If this is the case, there will be important implications for the design and

evaluation of health promotion programs.

The broad range of theoretical models and concepts that are relevant in planning health behaviour change interventions have been reviewed by several authors.<sup>1,19,93</sup> The most widely used theories include Social Cognitive Theory<sup>10</sup> and the expectancy-value theories.<sup>3-5,64</sup> However, there is considerable overlap between these theories. Recently a consensus has been emerging regarding the most important predictors of behaviour change.<sup>33</sup> These include:

- behavioural **intentions** or proximal goals;
- outcome expectancies, beliefs, evaluation of beliefs or **attitudes** towards the actual behaviour;
- subjective norms or **social influences**; and
- perceived behavioural control or **self efficacy**.

The state of the art is well reflected in a recent European model<sup>64</sup> (Fig.1). In addition to these predictors, the model includes two sets of moderators: barriers and skills. The former includes contextual factors such as the **availability and prices of products, legislation, organisation of services and threats of or actual violence**. The latter refers to the skills that are necessary to perform the behaviour. These skills could include instrumental skills such as the ability to put on a condom and social skills such as the assertiveness skills required to insist that a partner wears a condom. In addition, recent studies have demonstrated the usefulness of adding **cultural orientation** when predicting health behaviour in a Sub-Saharan African context.<sup>24-27</sup>

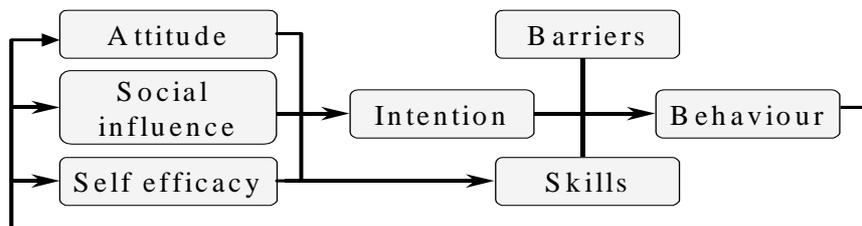


Fig.1: The Attitude-Social influence-Efficacy (ASE) model<sup>64</sup>

A further theory which specifically deals with health-related behaviour of young people is Problem Behaviour Theory.<sup>56</sup> Problem behaviours are behaviours that depart from the norms of the larger society, such as the use of alcohol and tobacco in early adolescence, use of illegal drugs, early sexual debut and other unsafe sexual behaviours. What is regarded normative varies across cultures and changes over time. Problem behaviours have been found to be intercorrelated, thus constituting a cluster of behaviours both in the developed world<sup>42,56</sup> and Africa.<sup>34,40,41</sup> It has also been found that use of alcohol as well as other psychoactive substances contributes to unsafe sexual behaviour.<sup>94,21</sup> The implication of this finding for programme development is that interventions should not focus on single domains of risk behaviour but rather include a broad range of risk behaviours. For example, an intervention to reduce unsafe sexual behaviour (which is associated with alcohol bingeing) is unlikely to be optimally effective if alcohol use is not also addressed.<sup>98</sup> The role of alcohol use in increasing the risk of unsafe sexual practices are therefore going to be addressed.

As already documented above: Although there is some disagreement as to which theories are the most

useful to apply when designing health behaviour interventions, researchers generally agree that interventions based on the systematic application of relevant theory are more likely to be successful than interventions based on good intentions and enthusiasm only. This implies that, in order to elicit sexual reproductive health behaviour change, interventions should at least address factors such as risk communication, attitude formation, mobilising of social support, and training of behaviour-specific skills (e.g. specific resistance skills, condom use skills) as well as life skills (e.g. social skills; decision-making skills; planning skills).<sup>85</sup>

With regard to African target populations, it has been suggested that a combination of current social cognition models and a value utilisation/norm change model based on a systematic ethnographic approach for determining adolescents' cultural beliefs, core values and social norms, may enhance the effectiveness of aids prevention programs. Central components of such a program should be improving coping behaviours and strategies, emotional reinforcing of core values, and critiquing or bolstering of social norms.<sup>32</sup>

In the application of these theoretical principles, it has been found that the use of the following basic educational principles increases impact:<sup>13,52,53,80,81,111,113</sup>

- a case description approach to risk communication;<sup>97</sup>
- an emphasis on the short-term consequences of behaviour;<sup>71</sup>
- the teaching of social skills to improve self efficacy;<sup>10,14,30</sup>
- mobilising social support by involving "significant others", for example parents;<sup>85</sup>
- peer education and influence;<sup>17,28,29,48,69</sup>
- active involvement as opposed to passive reception,<sup>79,83</sup> and
- "inoculation" against negative influences.<sup>70, 84</sup>

### The school as a setting for health education and health promotion in the community

A number of studies have demonstrated that health education administered through schools (but normally involving parents, health professionals and community leaders) has a significant impact on health behaviour of school-age children<sup>14,81,82</sup>. There are several reasons that the school is an important setting for health education and health promotion:

- Large numbers of young people attend school and are thus easily accessible for interventions.
- There are substantial barriers to receiving services at health facilities for poor and marginalised groups in the developing world. However, many poor and marginalised adolescents attend school. Thus, interventions that are school-based (as opposed to clinic-based) can contribute to reducing inequities in access to public services.
- The existing infrastructure, facilities and personnel at schools can be used for health education and health promotion activities.
- Much risk behaviour in adolescence takes place under the influence of social networks, many of which are located in the school. School-based interventions have the potential of intervening in the social ecology of adolescents by directly addressing the norms characterising such networks.
- Schools can serve as gatekeepers for access to other community groups such as parents and sports organisations as well as health services and community (including religious) leaders.
- Educational and health outcomes are inextricably linked. Unhealthy or addicted adolescents, for example, are unlikely to achieve their educational potential. Likewise, a student who is failing at school is at risk for adverse health outcomes such as depression, suicidality and sexual acting out. It is thus necessary to improve health outcomes if one is to improve educational outcomes, and *vice versa*.

### Research on health behaviour in Sub-Saharan Africa

In Sub-Saharan Africa, research on adolescent health behaviour is still in its infancy. Examples of

relevant studies conducted in South Africa and Tanzania include studies on unsafe sexual behaviours<sup>36,62,63,76,87,102-105</sup> and on addictive behaviours such as alcohol use.<sup>2,23,27,37,38,39</sup> For a review of about 35 studies involving sexual behaviour and about 10 studies involving alcohol use of South African adolescents, see Department of Health, Republic of South Africa (2000).<sup>20</sup> These studies have demonstrated the feasibility of conducting such surveys, and have served as valuable pilot studies for the proposed project.

There have been a number of evaluations of school-based interventions in Sub-Saharan Africa.<sup>7,31,35,62,63,65-68,72,74,78,91,92,100</sup> However, most of these evaluations involved small numbers of students, and had weak designs so one cannot be confident that changes manifest after the programme were caused by the programme. Most of the programmes demonstrated positive effects on knowledge and attitudes, and negligible or no effects at all on susceptibility to infection, self efficacy, behavioural intention and behaviour itself.

## B4.2 Innovative features

The innovation inherent in the present proposal stems from the synergistic application **in the same project** of a number of cutting-edge developments in the domains of **theory, evaluation methodology** and **programme development**, and their **implementation in novel contexts**. We shall deal with each of these innovative elements separately.

### Theory

As described above, the intervention will draw on the most advanced theoretical approaches that exist in the field of health promotion. This will be facilitated by the fact that the research team includes scientists who have contributed personally to the development of these advanced theoretical approaches. This will ensure that any developments since the grant is submitted will be incorporated in the project.

### Evaluation methodology

The evaluation will draw on state-of-the-art evaluation methodology. Again, the research team includes experts in this field. Some of the elements of state-of-the-art evaluation methodology include:

- taking design effects and covariates into account when estimating sample sizes and conducting definitive analyses;
- applying multilevel as well as covariance structure statistical analyses; and
- utilising quantitative as well as qualitative approaches such that they complement and inform each other.

### Programme development

There are several key elements of the development of the actual programme that situate it among the most modern programmes internationally.

- The planning of interventions will be based on a **situation analysis** that is consistent with WHO recommendations.<sup>109</sup> While such analyses are frequently advocated, they are infrequently carried out, and when they are it is often in a superficial and truncated manner. The current proposal allocates a considerable amount of resources and personnel to ensure that the situation analysis achieves its maximum influence on the design and implementation of the programme.
- The development of the programme will be guided by the **intervention mapping** approach.<sup>8,9,45,88</sup> This is a modern protocol that provides guidelines for the use of empirical data and theoretical insights, and collaboration with target populations and organisations, when designing health education interventions. After careful assessment of needs, intervention mapping describes five steps to improve the relevance, effectiveness/efficiency and the overall quality of a proposed intervention: program goal specification; linking goals to theoretical methods for changing

behaviour; translating useful methods in program materials and activities, and program design; development of a map for program adoption and implementation; and development of a map for program evaluation. The present project is one of the few in which this technique will be applied in a systematic and thorough manner, and the only one in Africa or elsewhere in the developing world.<sup>90</sup>

- An **anthropological perspective** will inform the development and implementation of the programme. Central components of this approach will be contemporary theories of youth culture and agency and gender as a social construction. Specifically, young men and women have been perceived of as passive recipients of adult culture and activity, as learning culture rather than creating it. Youth culture theory sees young people as active agents in the production and management of culture. In different ways and with varying force, depending on gender, age and social setting, they participate in the interpretation of messages and in the construction of meaning and symbolic forms which make up their cultures.<sup>6,16</sup> When planning health behaviour interventions, familiarity with the local youth culture as well as active involvement of young people in every stage of the process is a prerequisite for succeeding.
- Related to the above point is that the project follows a **participatory approach** by systematically involving young people in the design, implementation and evaluation of the intervention. This is seldom done but has been endorsed as effective by the scientific community.<sup>109,110</sup>
- The approach is consistent with the modern emphasis on a **comprehensive** approach to risk behaviours; for example, the influence of alcohol on unsafe sexual practices will be addressed, and the intervention programmes will address a broad range of behavioural determinants.<sup>42</sup>
- The project will establish and foster **co-operation and collaboration between sectors**, especially between the education and health sectors. At all study sites the school-based interventions will involve health personnel (nurses and medical doctors) as well as community leaders (including religious leaders) and parents. In addition, the local clinics will be approached with a view to ensuring that they respond appropriately if a student were to approach them for advice, contraception provision, or medical intervention.

### Implementation in novel contexts

The above innovative features are to be applied in novel context, namely one university in Tanzania and two in South Africa. Clearly, social and cultural conditions pertaining in these sites differ markedly from those in the developed world. For example, it has been argued that the majority of countries in which school-based health behaviour interventions have cultures that can be characterised as individualist.<sup>96,57</sup> However, most of the cultures in South African and Tanzania may be more accurately described as collectivist. The extent to which the latter generalisation is valid will be examined in the situation analysis, and clearly the anthropological approach to which we are committed will cast further light on this issue. Regardless of what conclusions are reached in this regard, it is an international research, policy and programmatic priority to develop, implement and evaluate health promotion interventions under varied cultural conditions. By so doing, we will enhance our understanding of the personal, interpersonal and cultural processes underlying health behaviours and health-related lifestyles, as well as cast light on the generalisability of findings from other contexts.<sup>12</sup> It is important to emphasise that even though all three sites are in Africa, there are profound differences between them in terms of factors such as:

- socio-economic status,
- culture,
- language,
- race,
- urbanicity (two sites are urban while one is largely rural),
- national identity (two sites are South African while the third is Tanzanian),
- extent of diversity within the site (for example, one site is very diverse in terms of language and

- culture while another site is populated almost entirely by one ethnic and language group), and
- the associated universities (for example one university is relatively well-resourced while one of the other universities has been systematically disadvantaged under apartheid)

Thus, there will be substantial opportunities to explore diverse aspects of the programme under varied circumstances.

## B5 Work plan

### B5.1 Introduction

#### Design and methodology of the intervention study

The present project aims at developing a research-based intervention in order to change sexual- and reproductive behaviours among adolescents in three selected sites in Sub-Saharan Africa. The interventions will be based on a thorough **situation analysis**, systematic **Intervention Mapping**, and they will be informed by previous research. The interventions will be theory-based and data-based.

At each intervention site (two in South Africa and one in Tanzania) one university is responsible for the overall administration of the project. The intervention component, which is school-based, will involve **relevant NGO's** as well as **health personnel, community leaders, religious leaders, and parents**, and existing infrastructure will be utilised. Existing material and packages will be screened and used whenever reasonable quality standards are met. New material will be developed whenever deemed necessary. The role of the research teams will be to initiate and coordinate the development and implementation processes as well as to carry out evaluation research related to the actual packages. The main intervention will take during one school semesters (approximately five months) and 15-20 school hours will be allocated for administering the intervention in class. Boosters will be administered throughout the second semester. Health personnel will be involved in the planning of the interventions at school, and pupils will be encouraged to utilise health services for counselling on sexual- and reproductive issues. Community leaders and religious leaders will be involved in the project and encouraged to contribute to the community dialogue on safer sexual practices and the health advantages of postponing the age of the sexual debut.

The evaluation of the interventions is based on an experimental design with schools allocated to control group and intervention group. Pupils in grades which correspond to the age groups 12-14 are to be included. A pre-test will be carried out before any intervention activities have taken place, immediately after the main intervention (by the end of the first semester) and again five months later (by the end of the second semester). Parallel data collections will be carried out in control schools.

In the control schools, delayed interventions will be offered towards the end of the present project.

The minimum number of pupils needed in each group (in each site) depends on properties of the outcome variable (level of measurement, reliability), effect size, size of clusters, homogeneity of the dependent variable within clusters, type of statistical analysis, and magnitude of non-response.<sup>66,18,86</sup> Based on experiences from previous intervention studies, the initial sample size should be at least 12 schools and 1200 students in each group and each site. The exact sample size for each site will be determined during the planning of the evaluation, taking all the above mentioned factors including cluster size, homogeneity within clusters, and possible covariates into account.<sup>75</sup> The level of statistical significance will be set at .05, and power at .80 or higher. If effect size turns out to be smaller than expected, statistical power can be improved by carrying out statistical analyses for all intervention sites combined.<sup>81</sup>

The instruments for data collections will be based on a standard English-language version which will be translated into the relevant languages. The quality of the translations will be carefully examined by independent experts, and back-translations will be mandatory.<sup>106</sup> In addition to the quantitative approach just outlined, qualitative studies including observation in class as well as interviews with pupils will be conducted.<sup>43</sup>

The research training component of the project will go on throughout the programme. The recruitment of the first six master programme students (two from each of the African sites involved) will take place immediately after the start of the programme and their graduation will take place within 30 months. At least three of these students will proceed to relevant doctoral programmes. Relevant master programmes are available in all the European universities involved in the study as well as in one of the South African universities. During the annual project meetings, seminars on intervention methodology, on relevant theory, and on research methodology will serve the purpose of contributing towards developing expertise in health behaviour change and intervention research among the participating researchers. Coordination of the research training component and exchange of expertise activities are the responsibility of the coordinating centre.

### Adequacy of the chosen approach

Based on a thorough situation analysis and administration of the intervention mapping (see Work Packages described below), the actual interventions will be carefully prepared. This preparation will include printing of new materials to be used in class as well as during the training of teachers and administration of teacher training courses. Materials to be used in class will be designed consistent with **the entertainment education approach**. A number of core components are common to all three interventions. These components include:

- Meetings with community and religious leaders in order to mobilise support and encourage parallel communication through other channels (orchestrated community action)
- Meetings for parents where the intervention plans are presented and parents are asked to support and reinforce messages communicated to the students
- Involvement of health personnel in the planning of the intervention and collaboration between schools and health personnel in order to improve young people's use of health services for the purpose of avoiding risky sexual practices
- Classroom sessions where a number of key topics are covered
- Involvement of students in selected exercises requiring creativity and efforts
- Involvement of health personnel in classroom discussions

In addition there will be optional components to be carried out dependent on local resources and circumstances:

- A peer education component where selected students are involved in the administration of classroom sessions
- A sexual education exhibition for parents developed and prepared by the students.

The intervention approach is based on relevant theory (social psychological models, anthropological and cross-cultural research) as well as an accumulated body of knowledge stemming from a large number of studies carried out over the past 20 years. Most of this research has, however, taken place in affluent Western countries. Few well planned and carefully evaluated sexual- and reproductive behaviour intervention studies have been conducted in developing countries, and this is also the case for Sub-Saharan Africa. A major challenge in the present project is to develop an intervention approach which is relevant and effective in a new cultural context and within a different organisational infrastructure. In order to meet these challenges local Sub-Saharan African expertise plays a central role in every stage of the project, and scientists with relevant anthropological background are involved.

The evaluation approach (large-scale field experiment with control groups, pre-test, multiple post tests and questionnaires) has been successfully utilised in a number of previous studies. One important methodological problem is connected to the randomisation into intervention schools and control schools. When randomising clusters instead of individuals, the statistical analysis of differences between intervention and control groups must be taken into account. This requires use of statistical packages particularly designed for this purpose, for instance STATA or MLwiN. By applying multilevel analysis with school class as one level of analysis and individual pupils as the other level, modelling of social processes taking place in classes will be possible.<sup>15,44</sup> The groups involved in the project has considerable experience with such statistical tools as well as with administration of large-scale field experiments.

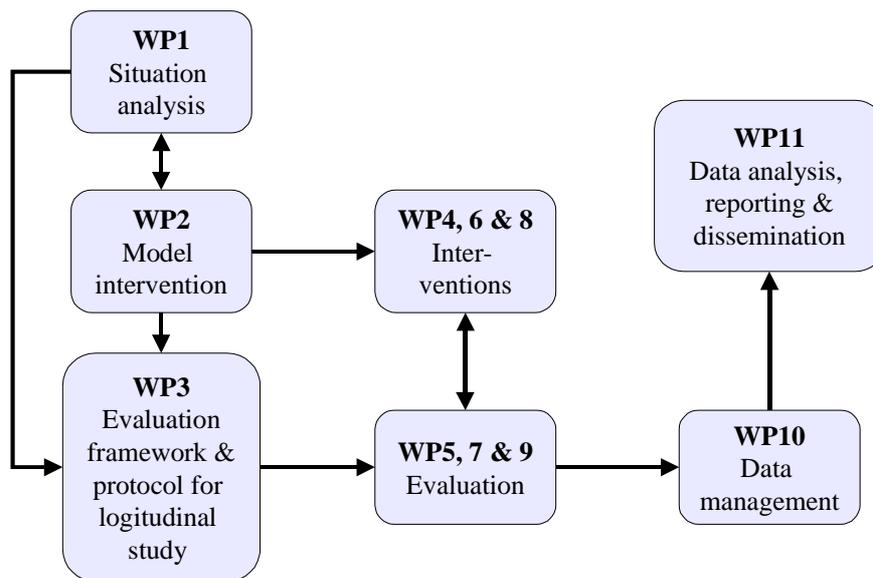
Merging of data across sites increases the statistical power of the comparisons between control and intervention groups considerably and will allow for more detailed analysis of a number of mediating and moderating factors. Such merging of data requires a high degree of standardisation of interventions and data collections across sites. A number of endpoints beyond actual behaviours will also be used, first of all behavioural intentions, self efficacy, attitudes, and outcome expectancies. Such outcomes are more easily influenced through interventions than actual behaviour.

## **B5.2 Work packages**

The project work will be divided into the following Work packages:

- WP1: Situation analysis in all three sites
- WP2: Development of a data- and theory-based framework for the development of community (school-based) health behaviour interventions which is relevant in Sub-Saharan cultural and societal contexts. The role of alcohol use and use of other psychoactive substances in connection with risky sexual practices will be particularly addressed.
- WP3: Development of a model protocol for evaluation of such interventions.
- WP4-9: Adapt and test the intervention framework at three sites (2 sites in South Africa; 1 in Tanzania)
- WP10: Data management.
- WP11: Data analyses, publication and dissemination.

Each partner will have the responsibility for one or two work packages. On the African side, the three partners will be responsible for one intervention package and one evaluation package each (Work Packages 4-9). On the European side, each institution has the responsibility for co-ordinating the development of one particular aspect: the situation analysis (WP1), the intervention framework (WP2), the evaluation framework (WP3), handling of the data bank (WP10), and co-ordination of data analysis and scientific publishing and dissemination (WP11). For a more detailed description of work packages including detailed overviews of tasks, see Work Package descriptions. For an overview of the work packages and the relationships between them, see Fig.2. African partners are strongly involved also in the research on situation analyses, data analyses, scientific reporting and dissemination.



**Fig.3:** Graphical presentation of project components - how workpackages relate to each other



Table 2: Workpackage list

| Work Package No. <sup>1</sup> | Work package title              | Lead contractor No. <sup>2</sup> | Persons-Months <sup>3</sup> | Start month <sup>4</sup> | End month <sup>5</sup> | Deliverable No. <sup>6</sup> |
|-------------------------------|---------------------------------|----------------------------------|-----------------------------|--------------------------|------------------------|------------------------------|
| WP1                           | Situation analysis              | 2                                | 45                          | 1                        | 12                     | D1-D2                        |
| WP2                           | Model intervention              | 3                                | 35                          | 1                        | 15                     | D3-D6                        |
| WP3                           | Evaluation protocol             | 4                                | 35                          | 4                        | 15                     | D7-D8                        |
| WP4                           | Intervention, Tanzania          | 5                                | 21                          | 19                       | 24                     | D9                           |
| WP5                           | Evaluation, Tanzania            | 5                                | 21                          | 19                       | 33                     | D10-D13                      |
| WP6                           | Intervention, South Africa 1    | 6                                | 21                          | 19                       | 24                     | D9                           |
| WP7                           | Evaluation, South Africa 1      | 6                                | 21                          | 19                       | 33                     | D10-D13                      |
| WP8                           | Intervention, South Africa 2    | 7                                | 21                          | 19                       | 24                     | D9                           |
| WP9                           | Evaluation, South Africa 2      | 7                                | 21                          | 19                       | 33                     | D10-D13                      |
| WP10                          | Data management                 | 1                                | 30                          | 19                       | 36                     | D14-D18                      |
| WP11                          | Data analysis and dissemination | 1                                | 33                          | 1                        | 42                     | D19-D25                      |
| <b>TOTAL</b>                  |                                 |                                  | 304                         |                          |                        |                              |

<sup>1</sup> Work package number: WP 1 – WP n.

<sup>2</sup> Participant number of the leader of the work in this work package (as used in Part A).

<sup>3</sup> The total number of person-months allocated to each work package.

<sup>4</sup> Start date of work in the specific work package, month 0 being the start of the project and all other start dates being relative to this.

<sup>5</sup> End date, months from start of project.

<sup>6</sup> Deliverable number: Number for deliverable(s)/result(s) as mentioned in the work package description: D1 to Dn

Table 3: List of deliverables

| Deliverable No.1 | Deliverable title  | Delivery date <sup>2</sup> |
|------------------|--|----------------------------|
| D1               | SA (Situation Analysis) protocol   | 4                          |
| D3               | IM (Intervention Mapping) protocol                                       | 4                          |
| D2               | SA report  | 12                         |
| D4               | IM – intervention mapping report   | 15                         |
| D7               | EP – protocol for standardised data collection                           | 15                         |
| D8               | EP – protocol for training of field workers                              | 15                         |
| D10              | EVA (evaluation) instruments   | 15                         |
| D14              | DM (data management) master code-book for baseline data collection ready | 16                         |
| D5               | IM health education programmes   | 18                         |
| D6               | IM delivery/implementation maps  | 18                         |
| D15              | DM master code-books for first post-tests                                | 18                         |
| D11              | EVA pre-test data  | 22                         |
| D9               | Intervention conducted   | 24                         |
| D16              | DM – baseline data files checked, merged and ready                       | 24                         |
| D12              | EVA – data from post-test 1 computerised                                 | 28                         |
| D17              | DM – post-test 1 data quality checked and merged                         | 30                         |
| D13              | EVA – post-test 2 data computerised                                      | 33                         |
| D18              | DM – post-test 2 data sets merged and ready                              | 35                         |
| D19              | Joint articles on theoretical model and baseline findings                | 39                         |
| D20              | Joint articles on intervention effects                                   | 39                         |
| D21              | Workshops at each African site   | 40                         |
| D22              | National dissemination   | 40                         |
| D23              | Articles in national or regional journals                                | 40                         |
| D24              | Presentation of findings on project home page                            | 42                         |
| D25              | Final project report to EC   | 42                         |

<sup>1</sup> Deliverable numbers in order of delivery dates: D1 – Dn

<sup>2</sup> Month in which the deliverables will be available. Month 0 being the start of the project and delivery dates being relative to this.

## Detailed Work Package Descriptions

|                                     |                                      |    |   |   |    |    |    |
|-------------------------------------|--------------------------------------|----|---|---|----|----|----|
| Work package number :               | <b>WP1 - Situation analysis (SA)</b> |    |   |   |    |    |    |
| Relative start month <sup>1</sup> : | 1                                    |    |   |   |    |    |    |
| Participant number:                 | 1                                    | 2  | 3 | 4 | 5  | 6  | 7  |
| Person-months per participant:      | 1                                    | 12 | 1 | 1 | 10 | 10 | 10 |

1 Month 0 being the start of the project.

### Objectives:

- 1) To develop the protocol for conducting 'situation analysis' of adolescent sexual and reproductive health (SRH) to each country and setting to establish a sound information base.
- 2) To assess existing information according to quality/adequacy criteria for following key themes:
  - Psychosocial correlates/ determinants of behaviour: adolescents status, behaviours and relationships, risk and protective factors.
  - Health status: conditions of diseases and ill-health affecting adolescent SRH.
  - Institutional responses: promotive, preventive and care interventions. Policy recommendations.
- 3) To judge relevance of information gathered, decide what 'new' information to be collected (re. sources and settings).
- 4) To organise community including student involvement (to ensure the relevance, acceptability and sustainability). Creating local ownership.
- 5) To identify 'gatekeepers' (those who influence adolescents' behaviour and those who may deliver intervention).
- 6) To identify opportunities and barriers in the school system as well as in the larger community (organisational, attitudes, skills and efficacy of teachers, number of students, trust, links to health services).
- 7) To identify (and pre-select) current information and education (IEC) material.

### Description of work:

- 1) Planning Phase – 'situation analysis' local African team selected, priority information needs identified, strategies for primary and secondary data collection (questionnaires, focus groups, essays, value clarification, adapting WHO situation analysis to the local context). Approval from authorities, detailed work-plan set up.
- 2) Training of site teams for South Africa and Tanzania
- 3) Data Collection Phase – collecting and assessing existing, available secondary material, identify gaps (outdated, Imprecise or incomplete). Identifying settings for the collection of new data (selected schools, home, health centres etc.) and sources (boys, girls, 'gatekeepers'). Collecting new information and filling knowledge gaps.
- 4) Analysis Phase – analysis undertaken at three levels. The first describes the core issue and the current situation with respect to SRH of adolescents. The second level explores relationship between core issues to explain why the situation is as it is. The third level identifies emerging issues and sheds light on concerns revealed but not considered in the outset.
- 5) Bridge to Action Phase - what should be changed among whom and what changes seem feasible;
- 6) Program goals in terms of health and behaviour changes, the starting point of intervention mapping

### Deliverables:

- D1 Situation Analysis protocol.  
D2 Site specific reports from South Africa and Tanzania.

**Milestones:**

Month:

- 4 Situation analysis protocol ready
- 5 Approval of situation analysis data collection from authorities
- 6 Training of teams ended
- 9 Data collection finalised
- 12 Report from situation analysis

**Expected results:**

A situation description which is important for adequate planning of the intervention in each of the intervention sites.

|                                     |   |   |    |   |   |   |   |
|-------------------------------------|---|---|----|---|---|---|---|
| Work package number :               | <b>WP2 – Model intervention development<br/>(Intervention mapping - IM)</b> |   |    |   |   |   |   |
| Relative start month <sup>1</sup> : | 1   |   |    |   |   |   |   |
| Participant number:                 | 1   | 2 | 3  | 4 | 5 | 6 | 7 |
| Person-months per participant:      | 1   | 2 | 10 | 1 | 7 | 7 | 7 |

<sup>1</sup> Month 0 being the start of the project.

### Objectives:

- 1) To adjust and specify the 'Intervention Mapping' protocol for data and theory-based health education program design, into a protocol providing specific guidelines for the planning and development of community-based programs in the local sites.
- 2) To build the capacity of local staff in the use of the 'Intervention Mapping'-protocol for the development of education programs focusing on improving sexual and reproductive health.
- 3) To build the capacity of teachers and health professionals in the use of a social cognitive & social influence approach for changing adolescent sexual and reproductive behaviours.
- 4) To do a theoretical evaluation of currently available programs, methods and materials addressing adolescents' sexual and reproductive health.
- 5) To design a specified 'intervention map' of data and theory-based sexual and reproductive health education programs for schools in each site, based on a combination of currently available and new materials.

### Description of work:

- 1) The general Intervention Mapping protocol will be specified for the development of intervention programs for the relevant South African and Tanzanian settings. Local staff will be trained in use of the specified protocol, its methods and its tools.
- 2) The outcomes of the situational analysis (WP1; for each site: needs assessment among adolescents, diagnosis of the health and school system and policy, and diagnosis of resources) will be incorporated in the reproductive health specific 'Intervention Mapping' protocol. Based on the situational analysis for each site, program goals will be defined specifying desired health change, behaviour and environmental conditions.
- 3) For each site program goals will be specified into proximal program objectives specifying what adolescents should be able to do after the intervention program.
- 4) For each site proximal program objectives will be linked to theory-based methods and materials that are currently available for each site. Available materials will be subjected to a theoretical evaluation and screened on potential efficacy in accomplishing program objectives. Special attention will be given to the transfer of facts and value-loaded information, to risk communication, to attitude formation and change, to dealing with social influences, and to skills training (social skills, assertiveness). Methods and materials that seem to be useful will be subjected to quality pilots among youth (n=100 per site) and a panel of intermediaries (e.g. teachers, health service associates, communication experts). If needed, additional educational activities will be designed in concept, and will be subjected to similar pilots.
- 5) Useful materials will be combined to a school-based intervention package with approximately 20 hours teaching time. Site-specific decisions will be made regarding the role of teachers or health professionals in program delivery and implementation. In addition to educational methods and materials focussing at youth, for each site a 'map' will be developed describing the planning and process of program delivery and implementation.

**Deliverables:**

- D3 Specific protocol for the design of data and theory-based school programs aimed at the enhancement of adolescent reproductive health.
- D4 Three site-specific 'Intervention Maps' describing objective-theory-material links regarding adolescent reproductive health
- D5 Three site specific concept school-based reproductive health education programs.
- D6 Three site-specific delivery/implementation maps.

**Milestones:**

Month:

- 4 Intervention Mapping protocol for the design and delivery of school-based reproductive health programs
- 5 Training of staff finalised
- 12 Site-specific Intervention Maps
- 13 Site-specific theoretical evaluations of available educational methods and materials
- 18 Pilot results
- 18 Site-specific sexual and reproductive health education programs (materials and manuals)

**Expected results:**

- Intervention packages which are well adjusted to local circumstances and cultures.
- Intervention packages which ensure a high degree of comparability of interventions across sites.

|                                     |                                       |   |   |    |   |   |   |  |
|-------------------------------------|---------------------------------------|---|---|----|---|---|---|--|
| Work packages number :              | <b>WP3 - Evaluation protocol (EP)</b> |   |   |    |   |   |   |  |
| Relative start month <sup>1</sup> : | 4                                     |   |   |    |   |   |   |  |
| Participants number:                | 1                                     | 2 | 3 | 4  | 5 | 6 | 7 |  |
| Person-months per participant:      | 2                                     | 1 | 1 | 10 | 7 | 7 | 7 |  |

1 Month 0 being the start of the project.

### Objectives:

- 1) To design a valid and reliable instrument for assessing reproductive behaviours and their predictors among adolescents in South Africa and Tanzania cross-sectionally, longitudinally, as well as before and after intervention
- 2) To design valid and reliable instruments for assessing the quality of intervention implementation (process evaluation), including instruments for direct observation and assessment of students', parents', teachers' and school health care workers' own evaluation of the implementation process
- 3) To design the final data collection protocol including quality assurance, as well as local ethical and research clearance

### Description of work:

- 1) Based on previous research by the researchers behind this application, we will pilot-test (n=40) the applicability of a draft questionnaire assessing reproductive behaviours as well as predictor variables identified by the theoretical model applied in this project (i.e. including attitudes, social influences, self-efficacy, intention, barriers and skills);
- 2) Following revisions based on the results from the pilot-test, test the validity and the reproducibility of the revised instrument (n=200), followed by adjustments and revision if necessary. Re-testing if necessary; The final version of the instrument will be translated and back-translated to the different languages required;
- 3) Pre-test draft instruments assessing the quality of the intervention implementation. These instruments will be pre-tested during pilot-testing of intervention components at the various sites. The methods applied will consist of a mix of qualitative and quantitative approaches. The validity and reproducibility will be tested whenever applicable, followed by revisions and translation/back-translation to the different languages required;
- 4) Writing a protocol for standardised use of the methodology, including the pre- and post surveys Assessing the intervention impact and outcome, as well as the quality assurance instruments; Writing a protocol for standardised training of field workers responsible for data collection.

### Deliverables:

- D7 A protocol for standardised data collection including instruments for assessing reproductive behaviours and their predictors, as well as instruments for assessing the quality of intervention implementation
- D8 A protocol for standardised training of field workers responsible for data collection

**Milestones:**

Month:

- 06 Pre-testing and first revision of instruments
- 10 Validity and reliability tests finished, second revision finished
- 12 Final instrument developed
- 15 Delivery of final instrument
- 15 Delivery of final protocols for data collection and training of field staff finished

**Expected results:**

Valid and reliable instruments that can be used across African sites;

Final evaluation protocols

Three articles in international peer-reviewed journals concerning

- 1) the applicability of the conceptual framework of the theoretical model used in the area of adolescent sexual and reproductive health in Africa,
- 2) a comparison of the validity of the theoretical constructs at the three different sites, and
- 3) development, validity and reliability of process evaluation instruments

See WP 11.

|                                     |   |   |   |   |    |    |    |
|-------------------------------------|---|---|---|---|----|----|----|
| Work packages number :              | <b>WPs 4,6,8 - Intervention implementation</b>    |   |   |   |    |    |    |
| Relative start month <sup>1</sup> : | 16 (actual intervention in class starts month 19) |   |   |   |    |    |    |
| Participants number:                | 1   | 2 | 3 | 4 | 5  | 6  | 7  |
| Person-months per participant:      | 0   | 3 | 3 | 0 | 15 | 15 | 15 |

<sup>1</sup> Month 0 being the start of the project.

### Objectives:

Carry out carefully adapted and culturally sensitive theory- and data-based interventions according to the intervention framework (WP2) in three sites in Africa.

### Description of work:

Once the protocol has been finalised, the fieldworkers will be trained in the procedures for the intervention.

At each site, the site co-ordinator and the work package leader will train teachers from each intervention school to implement the intervention in accordance with the protocol. An aspect of the intervention will include linkage with the health system at the levels of training of teachers and referrals. The programme will be implemented by teachers in close collaboration with the site co-ordinator and work programme leader who in turn will be in close consultation with the work programme leaders for situation analysis (WP1) and model intervention (WP2). More specifically the following will be conducted:

- 1) Recruit and train site co-ordinators
- 2) Obtain consent from statutory ethics committees, education authorities, schools and parents
- 3) Recruit and train site research assistants
- 4) Select the intervention and comparison schools
- 5) Conduct the intervention

**Deliverables:** (All three sites are involved, D18-23 are to be delivered by each)

D9 Intervention conducted

### Milestones

Month:

- 12 Consent obtained
- 12 Research assistants recruited and trained
- 12 Intervention and comparison schools selected
- 18 Intervention refined
- 24 Intervention conducted

### Expected results:

Theory-based, data-based and culturally relevant (state of the art) interventions are carried out, having a significant impact on sexual- and reproductive behaviours as well as determinants of such behaviours.

|                                     |  |   |   |   |    |    |    |
|-------------------------------------|--|---|---|---|----|----|----|
| Work packages number :              | <b>WPs 5,7,9 - Evaluation implementation (EVA)</b> |   |   |   |    |    |    |
| Relative start month <sup>1</sup> : | 16 (actual intervention in class starts month 19)  |   |   |   |    |    |    |
| Participant number:                 | 1  | 2 | 3 | 4 | 5  | 6  | 7  |
| Person-months per participant:      | 0  | 0 | 0 | 3 | 18 | 18 | 18 |

1 Month 0 being the start of the project.

### Objectives:

The overall objective is to evaluate the interventions which are carried out by three of the African partners according to the evaluation protocol (see WP3).

### Description of work:

Once the evaluation protocol has been finalised, translation and adaptation of the instruments to local circumstances must be carried out. Furthermore the fieldworkers will be trained in the procedures for the evaluation.

The questionnaires will be self-report, administered in a classroom context by members of the research team. Confidentiality and anonymity will be ensured. In order to link each student's questionnaires across data collections, each student will receive an identification code. In order to guarantee anonymity, the list linking codes with names will never be available to those who handle and analyse data, and after the completion of the last data collection, the lists are to be destroyed.

The site co-ordinator will ensure that all protocols for data collection are adhered to by the responsible research assistants and will also be responsible for checking data entry forms and report at least weekly to the work package leader. Double data entry will be completed with suitable software that allows for validation checks. The work package leader will ensure that cleaned data are sent to the co-ordinating centre.

More specifically the following must be done:

- 1) Recruit and train site co-ordinators
- 2) Recruit and train research assistants
- 3) Administer the instruments at baseline, immediately after intervention and 6 months after end of intervention, Carry out data collections and analyses of results related to the qualitative process evaluation (see WP3)
- 4) Enter, clean the despatch the data to data co-ordinating centre

**Deliverables:** (All three are involved, D24-27 are to be delivered by each)

- D10 Site-specific evaluation instruments finalised
- D11 Baseline data ready for analysis (internal to project consortium)
- D12 Data from first post-test collected, entered, cleaned and despatched to data co-ordinating centre (internal to project consortium)
- D13 Data from second post-test collected, entered, cleaned and despatched to data co-ordinating centre (internal to project consortium)

**Milestones:**

Month:

- 15 Site-specific evaluation instruments finalised
- 18 Research assistants trained
- 22 Baseline data collected and computerised
- 27 First post-test data collected and computerised
- 33 Second post-test data collected, computerised and despatched to data co-ordinating centre

**Expected results:**

An evaluation study that provides high quality data (quantitative as well as qualitative) and which enables the research group to demonstrate effects of the interventions on a hierarchy of outcomes, to identify important factors (moderators and mediators) explaining programme outcomes, and to provide insights in the processes of program implementation and behaviour change in order to improve the quality of future interventions.

|                                     |                               |   |   |   |   |   |   |
|-------------------------------------|-------------------------------|---|---|---|---|---|---|
| Work package number :               | <b>WP10 - Data management</b> |   |   |   |   |   |   |
| Relative start month <sup>1</sup> : | 16                            |   |   |   |   |   |   |
| Participant number:                 | 1                             | 2 | 3 | 4 | 5 | 6 | 7 |
| Person-months per participant:      | 12                            | 0 | 0 | 0 | 6 | 6 | 6 |

<sup>1</sup> Month 0 being the start of the project.

### Objectives:

To ensure standardisation of computerising of data across sites, to merge data files, and to conduct quality control of data.

### Description of work:

In order to enable analysis of data across sites, standard procedures for coding of information and computerising of the data have to be developed. All discrepancies between model data collection methodology and actual local evaluation methodology must be documented. Data must be checked for inconsistencies and irregularities. Merging data from the different countries is a prerequisite for effective comparisons and statistical testing of differences across countries. After merging and quality checking, data will be made available to all partners.

### Deliverables:

Month:

D14 Master code-book for baseline data and for longitudinal study completed (internal to project consortium)

D15 Master code-books for post-tests 1 and 2 completed (internal to project consortium)

D16 Checked, documented and merged data-files from baseline (internal to project consortium)

D17 Checked, documented and merged data-files from first post-test (internal to project consortium)

D18 Checked, documented and merged data-files from second post-test (internal to project consortium)

### Milestones:

Month:

16 Master code-book for baseline

18 Master code-book for post-tests

24 Baseline data files ready

30 Post-test 1 data ready

35 Post-test 2 data ready

### Expected results:

Code-books which ensure standardised and high quality coding and computerising of data.

Delivery of quality checked and merged data sets ready for statistical analyses on standard as well as specialised statistical software.

|                                     |  |   |   |   |   |   |   |
|-------------------------------------|--|---|---|---|---|---|---|
| Work package number :               | <b>WP11 - Analysis, publishing and dissemination</b> |   |   |   |   |   |   |
| Relative start month <sup>1</sup> : | 1  |   |   |   |   |   |   |
| Participant number:                 | 1  | 2 | 3 | 4 | 5 | 6 | 7 |
| Person-months per participant:      | 12   | 2 | 2 | 2 | 5 | 5 | 5 |

1 Month 0 being the start of the project.

### Objectives:

The main objectives are to have data analysed with appropriate and state of the art statistical techniques and to have all partners involved in reporting and dissemination of results. This will be a central part of the research training component of the project. Results and outcomes will be communicated to relevant authorities, professionals, policy makers and the general public in the SATZ partner countries. Furthermore, results will be published in African Journals (e.g. South African Medical Journal, East African Medical Journal), in international journals (e.g. Health Education Research, Health Promotion International, European Journal of Public Health), at international conferences and made available through the home page of the project.

### Description of work:

Already before making data available to the partners, the co-ordinating centre must prepare a proposal on how the data analyses and publishing can be carried out while involving all partners in this process. Each partner will have the responsibility for co-ordinating the work on at least two scientific publication. In addition main results must be published jointly in peer review international journals. As soon as findings have been published, summaries and reference to the publications will be presented on the home page of the project. The co-ordinating centre will also be responsible for exchange of information across sites regarding relevant international conferences where results from the study could be presented. Each partner must be responsible for national publication of results and dissemination of findings to relevant authorities, to schools, and to parents and pupils. Towards the end of the project one workshop will be arranged in each African site in order to effectively communicate findings to local school and health authorities as well as to teachers and health personnel.

### Deliverables:

- D19 Joint articles on theoretical model and baseline findings submitted
- D20 Joint articles on intervention effects submitted
- D21 Workshops at each African site
- D22 National dissemination
- D23 Articles in national or regional journals
- D24 Presentation of main findings on the project home page (home page established already at the start of the project)
- D25 Final project report to the EC

**Milestones:**

Month:

- 39 Joint articles on the theoretical model and baseline findings submitted
- 39 Joint articles on the intervention outcomes submitted
- 40 Preliminary communication of results and implications with national health and education authorities
- 40 Articles from partners submitted
- 42 Presentation of main findings on the homepage
- 42 Final report to EC

**Expected results:**

Effective communication and dissemination of findings through a variety of channels including international scientific journals, national journals and magazines, press releases, conferences and meetings and by the project homepage.