

**GRANT AGREEMENT 2004310**

**DIABETES IN EUROPE - PREVENTION USING LIFESTYLE, PHYSICAL ACTIVITY AND NUTRITIONAL INTERVENTION (DE-PLAN)**

**2nd interim technical implementation report**

**Period from 1/03/2006 to 01/03/2007**

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**National Public Health Institute**  
Mannerheimintie 166  
FI - 00300 Helsinki  
Phone +358 (0) 9 47 441  
[info@ktl.fi](mailto:info@ktl.fi)

**DE-PLAN**  
**Diabetes in Europe**  
**- Prevention using Lifestyle, Physical Activity and Nutritional Intervention**



[Internal web pages of DE-PLAN](#)  
[European Commission DE-PLAN hyperlink](#)

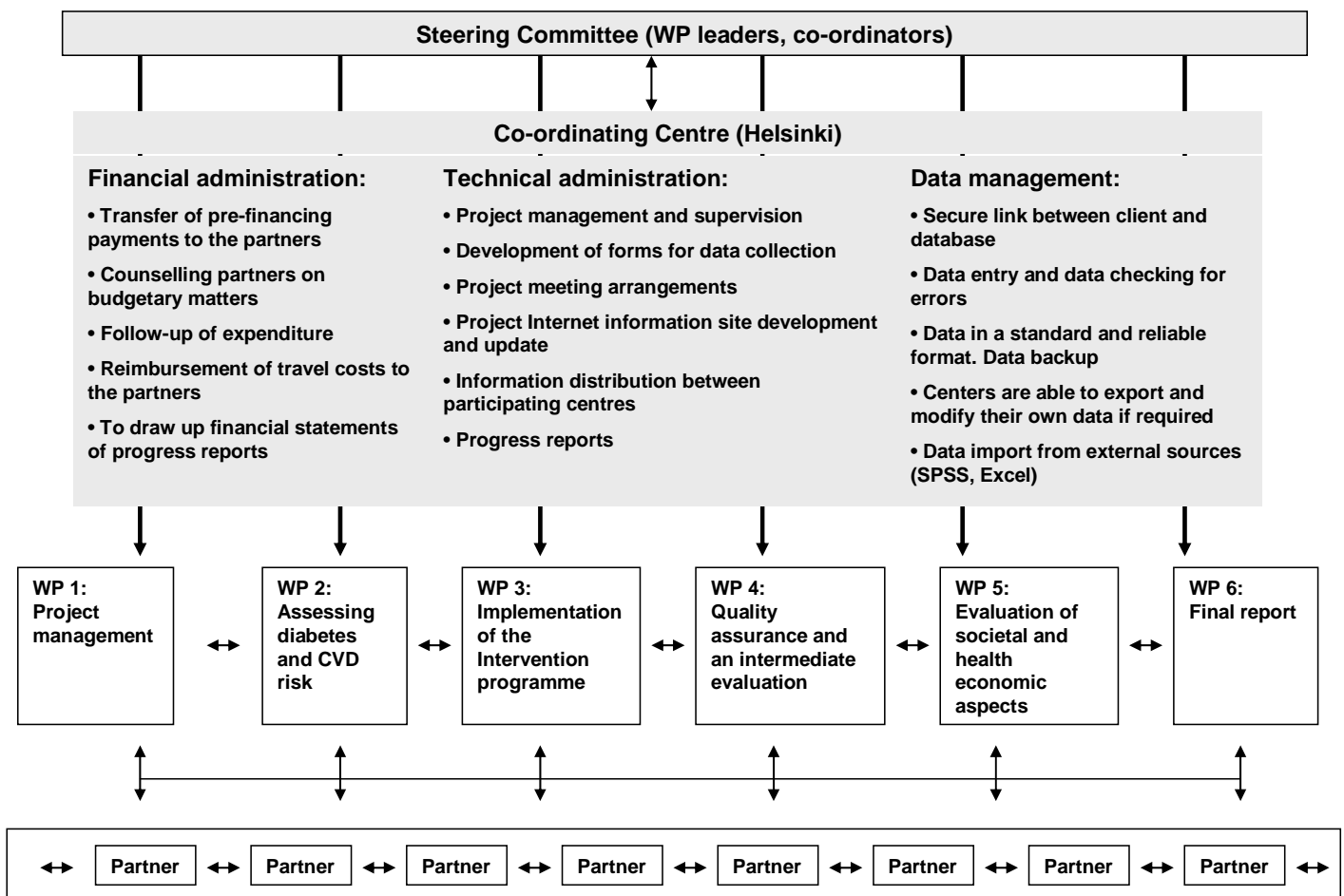
**Meetings during the reporting period:**

Two project group meetings were held:  
Krakow, Poland, May 23-24 (**Appendix 1**)  
El Escorial, Spain, October 4-5, 2006 (**Appendix 2**).

Intervention workshop gathered together in Frankfurt, Germany on January 5-6, 2007 (**Appendix 3**).

The formal Steering Committee meeting was held in El Escorial, Spain, October 4, 2006 (**Appendix 4**). In addition, the steering committee had an inofficial work meeting during the project group meeting in Krakow, Poland.

## DE-PLAN organization overview



**Figure 1: The organization chart of the DE-PLAN project.**

## Work package n° 1 – project management/training of participants

Lead Partner: Jaakko Tuomilehto.

The organization chart of the DE-PLAN project is presented in Figure 1.

There are 20 original partners and 4 new centres (Belgrad I , Belgrad II, Tilburg and Salzburg; external partners without financial support of any kind by the project).

Project co-ordinating centre is located in the University of Helsinki. The core tasks of the co-ordinating centre are financial administration, technical administration and support for the project, and data management.

The progress of the project in different participating centres in relation to work packages (WPs) is monitored by a 2-monthly check-lists. All but 2 centres have sent their checklists to Helsinki (**Appendix 5**).

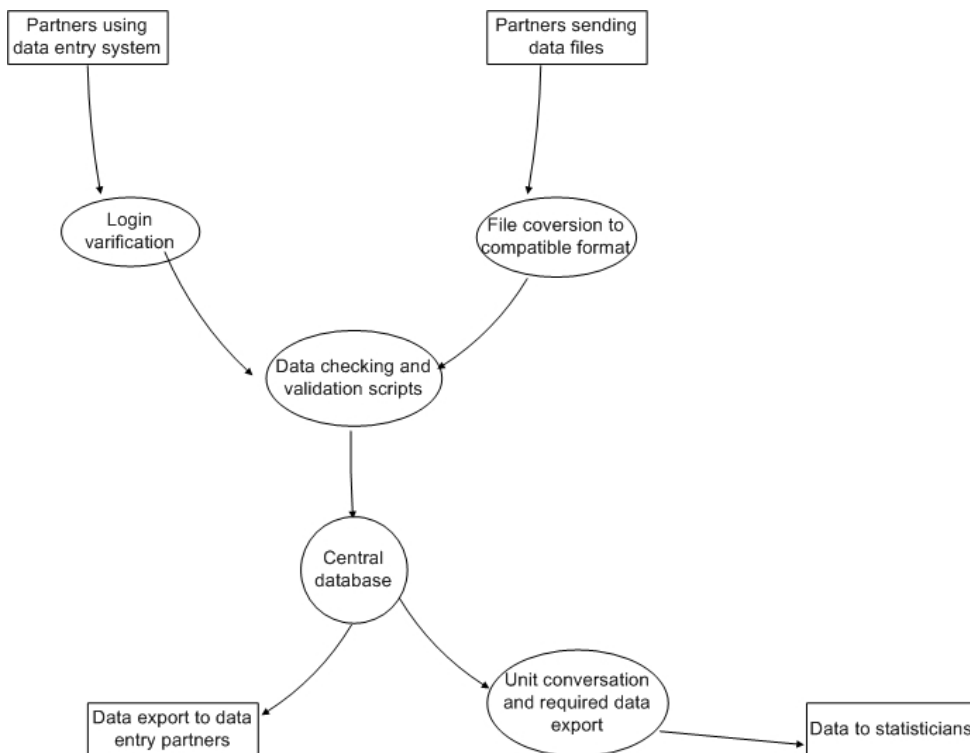
### • Results obtained

Internet information site for the DE-PLAN partners is working in: [www.ktl.fi/deplan](http://www.ktl.fi/deplan)

The starting page is open for all visitors, but the internal pages can only be accessed with username ('DEPLAN') and password ('prevT2D'). The DEPLAN home page contains all information concerning the project (protocols, manuals, forms, literature, meeting minutes) and is used as a method to deliver information for and between the partners.

Data entry site for the DE-PLAN partners is working in: <https://www-hotell1.it.helsinki.fi/~deplan/database/>

Partners may either use the data entry system, with unique username and password assigned to them, or send their data as data files which are then imported into the central database (see Figure 2). Partners are also able to download their own data from the central database.



**Figure 2: Data flow chart.**

- **Deviations from the work programme**

The project contract was signed the 13<sup>th</sup> of September 2005 and most of the partners were not able to start their practical work before they had a signed contract. Therefore, the initiation of the project was delayed from the originally planned 1<sup>st</sup> of March 2005. The preparation phase (training, material development, translations etc.) has taken more time than originally estimated, but most participants have now either completed tasks related to WPs or they are ongoing.

- **Work programme planned for the following period**

The monitoring of the project and centralized clinical data collection will continue until the end of year 2007. The analyses of data for the final report will start in January 2008.

The next Project Group meeting will take place in January, 2008. The special focus of that meeting is the preparation of final report and specifying other deliverables of the project.

The Steering Committees work will be done via e-mail and telephone.

## **Work package n° 2 – Assessing Diabetes and CVD risk**

Lead Partner: Jaakko Tuomilehto

Co-ordinator: Noel Barengo

The aim of the WP2 is to provide a complete new and unique database for the T2D and CVD risk throughout populations in Europe by obtaining information regarding T2D risk factors and CVD risk factors in the general population. To assess the T2D risk the FINDRISC (Figure 3) has been used. For the CVD risk estimation the European Society of Cardiology HeartScore has been used.

Further planning of data collection in collaboration with the partners has been conducted. Additional instructions of how to complete WP2 have been delivered to the partners.

### **• Results obtained**

The majority of the local project centers provide the coordination center the necessary information about the sampling methodology to obtain the representative population sample (**Appendix 6**). Furthermore, the local centers sent information regarding the specific variables they will obtain from the sample (**Appendix 7**). Four local centers have finished the data collection and WP2. These centers have sent the data (in SPSS) to the coordination center in Helsinki. Two of the local centers will not conduct WP2 and from four centers no information is available, yet regarding their WP2 methodology. In addition, WP2 developed a questionnaire for collecting the necessary data based on the FINDRISC and the Heart Score to ease data collection in the local centers (**Appendix 8**).

### **• Deviations from the work program**

The recommendation was that a minimum of 3-5% of the population in the study area of the participating centre is invited to fill out the questionnaire developed for WP 2. Since this has not been feasible in all participating centres, a secondary approach in form of opportunistic screening strategies has been applied to estimate the risk factor distribution in the population. This approach affected only little the general aim of the WP2. Even though, WP2 will give some estimates of glucose metabolism disorders, only four local centers will be able to provide data on a representative sample of the population. The other local centers will provide data from volunteers (13 centers) or high-risk subjects alone (2 centers). For the HeartScore a single blood pressure and serum cholesterol measurement are necessary. Unfortunately, not all local centers can provide the coordination center with all measurements (blood pressure and blood lipids) required due to financial restrictions. It has to be kept in mind that the final prevalence of glucose metabolism disorders may not reflect the true prevalence in the general population. However, these estimates will give a general idea about the overall problem of glucose metabolism disorders in Europe. Screening a large proportion of population to find individuals with high diabetes risk or 'prediabetes' (IGT or IFG) without adequate resources to offer counselling or treatment in line with the findings from recent diabetes prevention studies would be utterly unethical.

### **• Work program planned for the following period**

The local centers will continue to collect the data and finish the survey. All data will be sent to the coordinating centre where it will be stored in SPSS. As soon as all the data has been received, the data will be analyzed and a final report will be given about estimated of glucose metabolism disorders. The current status of the local centers regarding data collection is summarized in table 1.

**Table 1. Current status of WP2 data collection of the local DE-PLAN centers.**

<b>Local center</b>	<b>Data collection</b>	<b>End of collection</b>
Athens	Finished	Finished
Barcelona	Finished	Finished
Belgrad I	Started	
Belgrad II	March 2007	June 2007
Dresden	Started	April 2007
Düsseldorf	n/a	n/a
Genoa <sup>1</sup>	----	----
Graz	Started	April 2007
Helsinki	Finished	Finished
Istanbul	n/a	n/a
Kaunas	Started	January 2008
Krakow	Started	
Krems	Finished	Finished
Leicester	Started	
Madrid	Started	
Oslo	Started	2008
Paris	April 2007	October 2007
Pisa	n/a	n/a
Salzburg	n/a	n/a
Santa Maria Imbaro	Finished	Finished
Sofia	Started	Spring 2007
Tartu	Started	2008
Tilburg <sup>1</sup>	----	----
Verdal	n/a	n/a

<sup>1</sup>will not conduct WP2

## TYPE 2 DIABETES RISK ASSESSMENT FORM

Circle the right alternative and add up your points.

**1. Age**

- 0 p. Under 45 years
- 2 p. 45–54 years
- 3 p. 55–64 years
- 4 p. Over 64 years

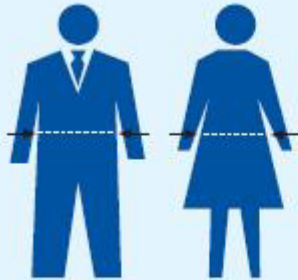
**2. Body-mass Index**

(See reverse of form)

- 0 p. Lower than 25 kg/m<sup>2</sup>
- 1 p. 25–30 kg/m<sup>2</sup>
- 3 p. Higher than 30 kg/m<sup>2</sup>

**3. Waist circumference measured below the ribs (usually at the level of the navel)**

- |      | MEN              | WOMEN           |
|------|------------------|-----------------|
| 0 p. | Less than 94 cm  | Less than 80 cm |
| 3 p. | 94–102 cm        | 80–88 cm        |
| 4 p. | More than 102 cm | More than 88 cm |



**4. Do you usually have daily at least 30 minutes of physical activity at work and/or during leisure time (including normal daily activity)?**

- 0 p. Yes
- 2 p. No

**5. How often do you eat vegetables, fruit or berries?**

- 0 p. Every day
- 1 p. Not every day

**6. Have you ever taken medication for high blood pressure on regular basis?**

- 0 p. No
- 2 p. Yes

**7. Have you ever been found to have high blood glucose (eg in a health examination, during an illness, during pregnancy)?**

- 0 p. No
- 5 p. Yes

**8. Have any of the members of your immediate family or other relatives been diagnosed with diabetes (type 1 or type 2)?**

- 0 p. No
- 3 p. Yes: grandparent, aunt, uncle or first cousin (but no own parent, brother, sister or child)
- 5 p. Yes: parent, brother, sister or own child

**Total Risk Score**

The risk of developing type 2 diabetes within 10 years is

- Lower than 7 Low: estimated 1 in 100 will develop disease
- 7–11 Slightly elevated: estimated 1 in 25 will develop disease
- 12–14 Moderate: estimated 1 in 6 will develop disease
- 15–20 High: estimated 1 in 3 will develop disease
- Higher than 20 Very high: estimated 1 in 2 will develop disease

Please turn over

Test designed by Professor Jaakko Tuomilehto, Department of Public Health, University of Helsinki, and Jaana Lindström, MFS, National Public Health Institute.

Figure 3: The FINDRISC questionnaire

## **Work package n° 3 – Implementation of the Intervention programme**

Lead Partner: Peter Schwarz

The intervention consists of a 3 step programme:

1. Identification of the individuals at high risk to develop Type 2 Diabetes
2. General intervention step based on individual choice
3. Continuous intervention with motivation maintenance

### **• Results obtained**

Number of FINDRISC questionnaires distributed: **266 668**

Number of subjects identified and contacted with high FINDRISC score: **9031**

Number of people in the interventions in total: **6233**

Strategies to identify persons at high risk for type 2 diabetes were issue for controversy discussion in the past. The effort performed to identify subjects which fulfil inclusion criteria for the larger prevention studies consumes large scale resources and is difficult to realize for a large number of persons. As we aimed for including persons with elevated diabetes risk and not only persons with IGT/IFG made it necessary to use a test that identifies persons at disease risk. An efficient test should also recognize persons having a predictive diabetes risk with a good ratio between specificity and sensitivity, should be simple to handle, transparent to both sides (physician and the affected person), widely accessible and basically cost free. Furthermore the test should intend an empowerment as feeling “being at risk” and not “being sick”.

The FINDRISC questionnaire was chosen as the first step of the DE-PLAN prevention management program to estimate the individual 10-year risk of T2D. This questionnaire comprises validated eight items and is available in various settings in the participating partner countries i.e. via the internet, information material by the health care and social institution, occupational health care and public health. People are asked to fill out the questions whenever they have time and interest. At the end of the questionnaire a contact opportunity is given using a local telephone or internet address for contacting a prevention manager. The answers of the FINDRISC questionnaire add up to a score of 26 points. Persons who will have a low score will receive written information about healthy diet and exercise benefits. Subjects with a high FINDRISC score will be offered an opportunity to participate in the intervention program performed in group sessions. Persons having a very high score (20 and higher) have a high chance of suffering from undiagnosed diabetes. They are getting suggested to visit a medical doctor for diabetes diagnosis or exclusion. If diabetes is excluded these persons can participate in the intervention program.

All of the local project centres has started with Identification of Individuals being at high risk developing Type 2 Diabetes. The implementation of this step was done in most of the countries differently addressing the local environment. (Step 1) A large number of people in different European countries has been screened and will be achieved while distributing the FINDRISC. The distributing Strategies are very different and flexible as much as the screening procedures. Additional strategies try to modify the whole Identification procedure for each centre, country and population.

Also the most strategies are evaluated at the centres whether the response rates could be improved. The strategies have been changed and the new ones have been tested or will be tested in the next month. In the majority of the local project centres the General intervention (Step 2) has started too. The first significant results for that step could be made at the end of 2007 but it is to foresee that the results would be promising.

### **• Deviations from the work program**

The initiation of the project was delayed from the originally planned 1<sup>st</sup> of March 2005. The preparation phase (training, material development, screening) has taken more time than originally estimated. Therefore, the originally planned 2-year evaluation of intervention effectiveness will only be possible for minority of participants. However, since the overall aim of the project is to embed preventive interventions to be part of health care provider's normal activities, it was decided that screening and recruitment of participants and interventions can continue throughout the project period.



- **Work program planned for the following period**

Further recruitment of people at high risk of T2D and continuous implementation of the lifestyle intervention programme developed in the DE-PLAN project to prevent T2D in the primary care setting. In addition, this WP tries to expand the intervention program to different minority groups.

The local centres will continue to distribute the FINDRISC questionnaire. The started intervention programs will be transferred into the continuous intervention and motivation phase also further intervention programs with modified settings will start.

Attached is a summary of the questionnaire which was filled in by the most centres will show some more details about the work package 3 and its enforcement (**Appendix 9**) .

## **Work package n° 4 – Quality assurance and an intermediate evaluation**

Lead Partner: Gerhard Zednik

The purpose of quality assurance is to ensure quality input and output and presents simultaneously a feedback tool to enable a learning process for making improvements of the different steps of the intervention. Special attention is given to all points of interface or point of contact between the different working steps in the intervention process. This will help to achieve greater efficiency and effectiveness of the program. A guiding thought to remember is “every error, complaint or mistake offers the opportunity to improve”. For this project, the quality (coverage and accuracy) of the self-report information on parameters will also be evaluated. Changes in these parameters will reflect the efficacy of the T2D prevention efforts.

### • **Results obtained**

#### **Overall project management assessment**

Quality criteria of the DE-PLAN project coordination may be the concerted comparative effort and methods applied within the different partner regions (countries). Essential for enabling this concerted effort is an efficient project management, frequent and clear communication for the transfer of know-how and an efficient support system. Indicators for the overall assessment of the quality of the project coordination and processing may then be the support mechanism provided to the project partners.

This support mechanism is seen in

- The project management organization (coordination center, positions responsible for project coordination, for IT support and data management, administrative support) that assists project partners and assures a concerted program implementation. The organization chart is shown in Figure 1.
- Selection of experienced and motivated project partners in the different countries. The project partners show a high compliance with the different DE-PLAN requirements and their successful local implementation of the DE-PLAN is showing high professionalism. Only one partner, for internal administrative reasons, could not comply.
- Meetings to coordinate activities, ensure knowledge transfer, training and sharing of experiences, enable personal communication and to develop project group identification (typical agenda points: introduction of partner participants, reports by all partners on methods and systems used for local project implementation, periodic status reports by the partners on their local project implementation including their approach for recruitment and means for ensuring motivation of their subjects to participate in the program, problems encountered and solutions proposed and implemented, as well as interim results). Steering committee meetings and DE-PLAN meetings were scheduled and proved to be an invaluable coordination and training tool. For a list of DE-PLAN meetings (attended by all project partners), project meeting minutes, as well as steering committee meetings minutes are shown in the appendixes.
- Providing appropriate documentations and tools for project implementation: **Project Manual, Questionnaires (FINDRISC Questionnaire, Subject’s Consent Form, Quality of Life Questionnaire/15D questionnaire, Basic Questionnaire, Clinical Data Collection, Semi-annual Self Measurement Form)**, guidelines for questionnaires distributed, guidelines for laboratory work, guidelines for data entry and data transfer to the coordination center, etc. (the English questionnaires can be downloaded from the project Internet site). Cooperation and sharing of diverse training materials between different project partners, assisting in training deliveries, e.g. invitation of the project quality assurance responsible (Austrian project partner) to an annual meeting of the Spanish project participants in Madrid to talk on “**Aspectos prácticos del programa de intervención para la prevención de diabetes, mediante modificación del estilo de vida**” (See **Appendix 10**), frequent e-mail contacts and telephone conferences between project partners to enable knowledge transfer, to reduce or solve difficulties in the project implementation. An additional avenue for sharing information and materials was also made possible through the internet media, via the DE-PLAN homepage ([www.ktl.fi/deplan](http://www.ktl.fi/deplan)), accessible for all project partners.

- Periodic request of feedback from the project partners (via e-mail), e.g. **DE-PLAN Project checklist** (bi-monthly) (see **Appendix 5**) to be filled out by the partners to assess on a continuous basis the implementation status from each participating country
- Central data management, data collection and analysis at the coordination center in Helsinki
- Central reporting system to ensure consolidation of country specific project reports into consolidated DE-PLAN project reports through the coordinating center.

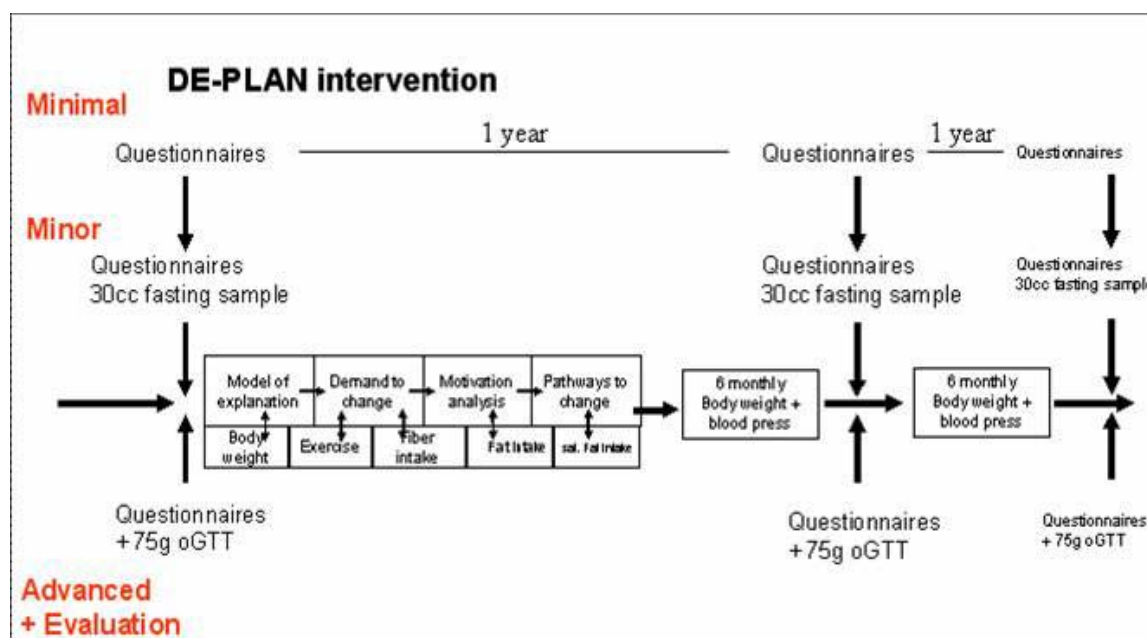
Integration of the **quality assurance work package (WP 4)** as a feedback tool within the above mentioned support mechanism made a continuous learning and improvement of different aspects of the project implementation possible. Recognizing improvement possibilities is one of the goals for QA. A living **Quality Assurance System** enhances the learning process, viz., learning from mistakes or from implementation of steps, which did not work out or bring the desired results. Thus, project partners were asked to record outputs and results and consider measures for improvement whenever appropriate. For this purpose, a simple recording system was to be kept by all project partners (see below). This made possible to create sensibility and awareness for the persons responsible in the country-specific implementations and resulted in the high quality of the DE-PLAN implementation.

### DE-PLAN Quality Assurance Report

Partner:

Date	Subject's ID-number	Type of error / Complaint description	Person (function) filing complaint	Date of discontinuity	Reasons given / Possible causes	Recommendations / Comments / Corrective actions
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Transition points within the intervention process are also points where QA steps are taken, with the purpose to ensure that the implementation steps are done in accordance to the manual and are suitable to achieve the expected outcome. Thus, quality checks are made during transition points of the implementation process, record keeping, data entry and communication processes with subjects. Points of contact are shown in the Figure 4.



**Figure 4: Intervention and evaluation outline**

## Furthermore, the quality of the intervention depends on the quality of

- Subject-selection
- Information provided to the participants (public relations-, training- and information materials)
- Training delivery
- Laboratory work
- Data management (questionnaires for data generation, data entry, data processing)
- Relationship between subjects and project staff
- Long-term intervention impact on the subjects' life-style changes and achieving the 5 goals of the intervention program for each participating subject, and
- A conclusive project report.

## Intervention quality assurance

Quality assurance system implementation and record keeping has been ongoing. Thus **error management** was done well as it is apparent that errors were corrected to achieve the high standard of intervention as reported by the project partners. Equally, **drop-out/discontinuity management** was done by the project partners to record and assess the reasons for dropout. Detailed assessment will be done after the interventions.

### ○ Subject selection

The use of the **FINDRISC questionnaire** was recommended as the main screening tool to identify high-risk subjects. Preference was given for using this questionnaire as this ensures a uniform and validated methodology for selection of the subjects. Project partners were asked to record the number of FINDRISC questionnaires sent out, number of respondents, number of subjects identified with a score of equal or greater than 15, final number of subjects recruited for the project. (See **DE-PLAN project checklist** in the **Appendix 5**). Some country-specific adjustments had to be made with respect to the score values of the FINDRISC by reducing the cut-off point to equal or greater than 12 in consideration of the profile prevalence of the country population (based on validation of the FINDRISC)

Subject recruitment in the different countries is greatly dependent on the local culture, socio-economical standing of the target group, as well as the local health care system. In particular it is important to consider the population's degree of health awareness and about the population's willingness to initiate preventive steps in matters on health maintenance, viz., curative versus preventive orientation. Another important factor for the recruitment of subjects is the willingness of medical professionals to participate and take a leading role in preventive health care for their patients. Countries where subjects were recruited through medical institutions (general practitioners, primary care centers and health centers, ambulances, hospitals) were generally more successful in recruitment than project partners who tried to recruit through the media (TV, radio, newspapers and announcements using diverse channels). The return rate of people who were contacted through the media (people who returned the **FINDRISC** questionnaire) was extremely low (1-2%) as compared with those who were contacted through health care professionals or health care institutions (25-50%). Some project partners subsequently changed their recruitment efforts from a media-based to recruitment through health care institutions (general practitioners).

The majority of people who responded when initial contact was made through the media had a lower **FINDRISC** score than what was the cut-off point to participate in the DE-PLAN program, perhaps showing that persons who show self-initiation and who are sensitive to a healthy life style are more willing to participate in preventive health care measures. While clearly the quality of media presence and public relation materials are an influential factor, there is an apparent unwillingness by the public to initiate measures towards possible life style changes and preventive health care behaviors on their own initiative if only contacted through the media.

Basic aim of the media information campaign was to adequately inform the public about the project, project aim and project goals. Quality indicators for the information flow may be:

- The **frequency of request for clarification** by interested parties in response to public media materials. Preliminary analysis showed basically no clarification requests by the general public (the reader). However institutions in the health care sector (apothecaries, general practitioners,

health care centers, as well as associations for health care professionals) did request at time further clarification. Points of clarification were the possibility of participation (as distributors of **FINDRISC** questionnaires) or if there was an agreement with the different associations (association of apothecaries, medical association, etc.) and hence a sanctioning of the DE-PLAN activities. It is recommended that for future similar exercises all relevant associations within the health care sector as well as political representatives active or responsible for public health be informed before the public media campaign is initiated.

- **Mistakes made by the subjects** based on misunderstanding. From the **FINDRISC** questionnaires returned by subjects as a result of the media campaign approximate 1% were incomplete and subjects could not be contacted for further arrangements (name missing, mailing address missing, multiple answers, etc.) Also, many subjects apparently did not read the instructions in respect to who could not participate in the DE-PLAN, viz., if below the age of 45 years. Additional mistakes in filling out the **FINDRISC** were incorrect BMI values, waist circumferences. If there was an apparent incongruence between different values, the values were later corrected (telephone contact, during visit at the health care institution, or at the first training or workshop).
- The **response rate** was relatively low (returning the **FINDRISC** 1-2%) when public media was used as the channel of recruitment.

Media, as a means to recruit subjects for the program, was not a successful approach, due to problems of low returns and incomplete forms returned. References in the media to the homepages of local DE-PLAN projects had equally extremely low responses. It is apparent that self-initiation, that subjects make a decision for a focused health check (diabetes risk) and to participate in a prevention program based on general information is not forthcoming.

Recruitment at companies (place of work for the subjects) was only partially successful. While management was in parts cooperative, occupational medical doctors frequently denied participation due to lack of time. Even in cases where companies informed their employees, there was extremely low interest by employees. Reasons given were often the apparent fear, that their company would learn if they were high risk subjects and subsequently were afraid of losing their job as per information from e.g. Sofia, Krems, Salzburg.

When subjects filled out the **FINDRISC** form, where assistance was available and where completeness of the form was checked at the time of turning in the form, the quality of data was excellent. Completeness and plausibility was the highest when nurses, medical doctors or other health care professional asked the questions to the subject and filled in the form him/herself.

Supervision, checking for completeness and plausibility as well as filling out the questionnaire for the subject increases the reliability of the data collected.

Based on the preliminary outcome of the recruitment phase, it is recommended that health care professionals play a key role in the recruitment phase as they have a positive effect on the individual's willingness to assess their own health risk state. The likelihood for subjects to participate in a prevention program is much greater if the subject is invited directly and personally by a health care professional (medical doctor, nurse, therapist, etc.)

Of all the respondents in the different countries, subjects who filled in the **FINDRISC** questionnaire, there were between 20-25% identified with a **FINDRISC** score of 15 or more, thus identified as high-risk subjects. Of those about 20-30% are participating in the DE-PLAN intervention program.

#### ○ **Training delivery**

The question how quality will be assessed and ensured is a major issue for the success of the training (intervention). Quality control and success evaluation means to guarantee that all persons directly involved in the project related prevention program not only know about the 5 core goals defined in the manual but that people intervened in the prevention program show effects of these core goals by a minimum means of measures like blood pressure, waist circumference and body weight.

➤ **Training programs (lifestyle intervention):**

Quality criteria for the conception and delivery of training are: focused presentation of materials, understandability, practicability (applicable) and reliability, informative, effective and with a lasting effect (motivational). Immediate feedback after the delivery of a training module would allow adjustments in the materials used, infrastructure and organizational matters. Quality indicators could be: **wrong behavior of subjects, clarification questions from the subjects, information applied and results achieved by the subject.** The same criteria are applicable for the training materials and/or handouts.

Of great importance is that the **expectations** of all parties (subjects and trainers) involved in this project are in agreement. This was generally accomplished during the first workshop which was aimed at introducing the goals of the local DE-PLAN intervention and ensuring an understanding by the subjects that there are ways to reduce the risk of getting diabetes 2 through life style changes (through changes in the food intake and exercises).

Throughout all partners, but depending on the degree of supports offered to the individual subjects, training of the trainers (nurses, dieticians, sport therapists, physical activity specialist, etc.) was done by the local project managers and supported by specialists (e.g. psychologists, physicians, dietitians, sport therapists). This assured potentially a high quality of training deliveries.

Although not all project partner have commenced with the training of the subjects at the present, all developed and prepared their training and educational materials in line with the project manual and recommendations given in the manual. In all countries all training materials were developed and written by specialists in their field. The different training materials viewed from the different project partners showed excellent quality in terms of clarity, pedagogically structured, motivational and educational. Furthermore, in view of the target groups, training materials were simple, practical, structured and allowed individualized scheduling. (E.g. a calendar and diary with relevant information on food and physical activities, as well as information on issues related to diabetes prevention, as done by Germany and Austria). The attachments (**Appendix 11 – 13**) show some examples of training materials used at the different locations by the project partners.

Training delivery was done generally in smaller groups (4 -15 participants), allowing for individualized interactions between the subjects and the trainers, allowing answering questions and decide on the subject's individualized intervention goals. Training delivery for larger groups (up to 20 participants) are planned to compare the efficacy of deliveries (e.g. by the project partner at Kaunas University). Single sessions and telephone counseling services are offered on demand by one project partner (Belgrade)

Evaluations of training delivery are done through a written feedback system by the participants (questionnaire). Questions asked are about satisfaction with their progress toward their personal goals, support given through the workshops, about possible problems or concerns and any recommendations.

No complications were reported (due to wrong behavior of subjects or unclear instructions about actions or behaviors). It is presently too early to determine information applied and results achieved by the individual subjects.

➤ **Continuous support of the subjects:**

Continuous support of the participants/subjects is to be assured. The main aim is to ensure motivation of the subjects to continue with the program and aim to meet the set goals. This can be supported through a coaching approach, frequent contacts with the subjects, providing periodic information materials and giving them feedback on terms of their accomplishments. Other supportive tools are an interactive project home page, hot line, and access to other forms of support mechanism.

The ultimate measure of quality is few dropouts and achievement of the set 5 goals for each individual subject.

Quality indicators may be: **frequency of contact** (Telephone, e-mail, regular mail, SMS, personal), **compliance with the desired behavior** (dietary habits, exercises), continued participation in the project measured through the **dropout rate**, success in **reaching individual goals** (weight reduction, stop smoking, etc) and **lasting changed behavior in line with the 5 project goals**.

Within the quality assurance system motivation maintenance is an important factor. For motivation maintenance the subjects should be continuously monitored through regular contacts using different delivery channels including written information, telephone support and multimedia contact including the Internet and a quality control system implemented through a **questionnaire requesting feed-back on quality control information to determine the motivational state of the subject** (asking if there are any **problems, concerns or questions pertaining to the intervention process, drop-outs**).

For information purposes as well as a means of contact media all project partners installed a project homepage, in most cases interactive, however there was only small number of access by subjects reported. A free hot line was installed in most places (where the subject was able to call free of charge to seek advice or support while on the program). Only limited information have been given so far on their use due to the fact that the intervention period is still ongoing. Many partners have scheduled SMS contact with subjects weekly to bi-weekly (e.g. Madrid has informative SMS, questions/answer SMS, appointment/schedule reminder SMS). The project partners in Spain also developed a computer aided contact control system, which allows scheduling of contacts, gives feedback on the frequency of contacts as well as basic content information. Further contacts are through letters, only in a few cases are e-mails used as a communication tool. Clearly, the means of communication media is dependent on the general behavior of the population group (dependent on ethnic culture, urban/rural area residency).

Feedback over subject compliance with the desired behavior (dietary habits, exercises) is accomplished through solicited information on the subjects' behavior through questionnaires (administered during workshops, sent via mail or electronically, or through SMS contacts). Whereby the feedback during workshops or visits at the health centers is surely the most effective as the subjects are then in personal contact with the health care professional and thus are obliged to respond. Additionally, personal, one-one-contact has a motivational character and is thus the most successful way to obtain feedback, set measures for encouragement and to motivate the subject.

Initial response rate is good by all local interventions, however a final assessment can only be made after some length of the intervention has been implemented.

The dropout rate of participants in the early phases of the intervention was between 2-25%. Reasons given were personal reasons and statements that the individual subject was continuing independently with the life style changes. Further analysis will have to be done to analyze the dropout reasons. This process is ongoing.

➤ **Intervention outcome:**

The quality of the intervention may be indicated through the measurement of **blood pressure and waist circumference every six months**. Hence, the achievement of the subjects' 5 main goals (in line with the core intervention protocol) is another indicator of the quality of the intervention delivery. (Measuring the continuous implementation of the 5 goals.)

Initial feedback is positive. Detailed analysis will be done later on these measures due to ongoing intervention activities in all local DE-PLAN projects.

➤ **Laboratory work**

Professionalism of project partners is reflected in their choice of laboratories. To ensure comparability of laboratory data, it is recommended that laboratory work be conducted through only one laboratory for the local partner. International quality standards for laboratories should be met. If several laboratories will be used, the **quality standards** of the laboratories should be clearly assessed.

Depending of the individual local settings laboratory work is/was either done through on central laboratory or through several laboratories with equal quality standards meeting the pre-conditions for the OGTT as well as other blood analysis described in the DE-PLAN project manual.

- **Data management**

- **Questionnaires:**

- Questionnaires (and questionnaire instructions) as provided by the main partner were used by the project partners. They were linguistically and culturally adapted to meet the local requirements. The filled out questionnaires were locally **checked for completeness, readability and plausibility** at the time of handing-in the questionnaires by the subject to the contact person. Unclear responses were clarified.

- **Data entry:**

- Local data entry was initiated and is still ongoing. The system used by the data management (main partner) minimizes errors by limiting the possible answers and does not allow continuation of the data entry process if the answers to the questions in the masks are apparently not correct (not coherent or contradictory). This results in minimal data entry errors.

- **Data processing:**

- DE-PLAN data processing is done with the provided software (by the main partner) to ensure comparability with data from other locations and to enable the final analysis of the DE-PLAN project. Data processing is ongoing.

- **Deviations from the work programme**

- No deviations

- **Work programme planned for the following period**

- Parallel with clinical data collection and analysis, as well as life style interventions, quality will be assessed. Furthermore, detailed evaluation of the project will be continued in terms of error management and dropout management, as well as intervention management.



## **Work package n° 5 – Evaluation of societal and health economic aspects**

Lead Partner: Zbigniew Szybinski / Katarzyna Kissimova-Skarbek

Recommendations developed within the DE-PLAN economic evaluation may contribute as an important component in making decisions by Governments, health insurance companies, diabetes societies about diabetes prevention and allocating public resources in European Countries.

Work package n° 5 is aimed to propose a form of Cost Effectiveness Analysis to provide policy makers with a set of results that are more generalisable across settings. It does this by evaluating the costs and effectiveness of:

- new lifestyle interventions provided as a single separated intervention,
- existing (ongoing) lifestyle interventions (example of Finland and Germany),
- existing (ongoing) lifestyle intervention as a part of more complex prevention intervention (example of Verdal-Norway).

### **• Results obtained**

- Capacity building:

**I.** Extended version of Manual (**Appendix 14**) including data collection forms for cost-effectiveness evaluation for the European T2D prevention programme have been developed. The detailed instructions for data collection were provided. Principles of cost-effectiveness assessment developed by the US Diabetes Prevention Programme were considerably complemented with the concepts of WHO-CHOICE project (developed in year 2000). Original tools (forms and methods to assure high quality of cost data and possibly minimal necessary effort from the DE-PLAN Partners' site) are created within the DE-PLAN.

Set of data collecting forms was organized to mirror different aspects of assessment of resources used during the DE-PLAN:

- the main steps of DE-PLAN – Work package n° 3: Questionnaires: E01 and E02 are used for Step 1: “Identification and Selection of the Subjects”; E04 is applied for Step 2: “Intensive intervention”; E05 is for Step 3: “Continuous intervention” evaluation;
- different levels of costs assessment: “PROGRAMME LEVEL” which includes management of the intervention in Participating Centers (including planning, organising, monitoring and supervision, training), (Questionnaire E06) and “PARTICIPANT’S LEVEL” which includes all costs at the point of delivery (facility) such as screening, testing with OGTT and other biochemical examinations, educating, exercising etc (Questionnaires used: E01, E02, E03, E04, E05, E08). Results on costs of one average participant will allow public health planners to estimate the costs needed for extension of the programme in specific country context (and for different strategies applied);
- different periods of the programme implementation: “START-UP period” (covers pre-implementation phase of the programme including planning, organizing, training of the personnel, monitoring) and “POST START-UP period” (running the programme). The E06 questionnaire is structured respectively to these two periods and to the main steps of the programme. START-UP costs are spent only once. Countries can extend the programme without necessity to cover again the total amount of start-up costs.

To assure all necessary data for comprehensive evaluation of DE-PLAN's costs and effects (including benefits to the patients and payer) the additional forms were created:

- E03 - use of health care services (outside the DE-PLAN) filled in by participants. It was agreed that E03 will be distributed and answered by some part of patients –lately selected for the intervention (not started yet or recently started the intensive intervention). Second time this questionnaire will be provided to the same patients after one year of intervention. In GP participating practices in Krakow separate approach will be implemented: data on health care services used will be gathered for 100% of participants (including 202 subjects who have already finished the intensive intervention) using medical records of the patients (for the period before DE-PLAN) and interviewing after one year of intensive intervention.
- E08 – sub groups questionnaire. Only small group of 20 – 30 participants in every Center will be interviewed and will be asked about specific resources used and lost due to the programme (mainly for non-medical direct costs' estimation from a participant's perspective reason). In Krakow every GP is asked to complete E08 form for 20 participants.

*E07- general information questionnaire* was created for collecting data on costs (prices) of all inputs of the programme (recorded in other questionnaires).

Data collected within the Work package n° 3 are also used for socio-economic evaluation at patient level. Data are obtained from *Basic questionnaire*, *Intensive intervention questionnaire* and *I5D – evaluation of quality of life* improvements questionnaire.

Considering capacity differences among Participating Centers, it was agreed a different levels of data collection for the economic evaluation to be applied by DE-PLAN Partners: minimal, advanced and comprehensive data collection levels. Although, minimal level of data collection means that the Participating Centers are obliged to present at least data on costs of DE-PLAN realisation. Questionnaires are developed with the possibility not to answer all questions (only if not applicable for the country, or appropriate data are not available).

**II.** Two training sessions on the economic evaluation were organized during the DE-PLAN meetings in Madrid and in Cambridge. In addition, permanent reviewing, correction with detailed explanations of submitted completed forms is being provided by K. Kissimova-Skarbek (Krakow Coordinating Center).

- Data collection and economic evaluation:

Evaluation of the programme has started in parallel with clinical data collection. Results at this stage are presented in **Appendix 15** (in details for Krakow Participating Center and also summarised for 11 Centers).

Data on participants' characteristics: age, marital status, education and employment status were collected and are presented for 7 Centers (see **Appendix 15**). Krakow example is presented in details.

Resources used: the main purpose was to elicit the resources used in average by one participant (at participant's level) in every Participating Ceneter applying ingredient approach (time of personnel spent, costs of biochemical examinations, educational materials, other costs). The results are summarized separately for the first and second steps of the programme and are presented for 10 Centers (see **Appendix 15**).

- Potential savings to the societies of DE-PLAN countries

In order to assess a potential savings to the societies which may be achieved by lifestyle intervention, the burden of diabetes in the countries of DE-PLAN realisation was assessed (see **Appendix 16**)

About 30.6 bln I\$ Economic Growth was lost in DE-PLAN countries in 2006 due to diabetes mellitus (see **Appendix 16**, table 1). Even if we avoid, due to the lifestyle intervention, only 10% of a new diabetes cases, we would increase the economic growth in the DE-PLAN European countries by 3 bln I\$ and we will save the health care expenditures in these countries by at least 3.9 bln I\$ (up to 7.3 bln I\$) – in 2001 figures (see table-2, **Appendix 16**).

- **Deviations from the work programme**

Most of the DE-PLAN partners haven't transferred their collected data to the central data base in Helsinki yet. Due to that reason most of the economic evaluation calculations will be done during the next period of programme realisation.

- **Work programme planned for the following period**

Data set necessary for the economic evaluation will be collected from Local Centers and all economic analyses will be done. Results will be presented in local currency units, EUR (using current exchange rates) and International Dollars (USD ppp).

Final version of Manual complemented with country specific manuals for the economic evaluation will be prepared.

In order to support the data collection process (to assure high quality and to avoid double counting or underestimation of the costs of the DE-PLAN) Katarzyna Kissimova-Skarbek will visit Local Centers. The purpose is to collect finally all necessary data during the workshops/focuses or individual interviews with a key persons. This will also intensify the economic evaluation process.

Helsinki 9 May 2007

Jaakko Tuomilehto  
Professor, University of Helsinki  
Principal Investigator of DE-PLAN Study

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