# Diabetes Literacy. Enhancing the effectiveness of diabetes self-management education

## Final Report

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Approximately 32 million people in the EU live with type 2 diabetes, many of whom are unaware of their condition. Diabetes care takes up a significant amount of the health costs. The prevalence of diabetes set to increase. In view of these developments the capacities of the health systems in the EU Member States with regard to treatment and care must be strengthened. One of the critical success factors to address diabetes is the investment in the self-management capacity of patients.

The goal of the Diabetes Literacy project is to provide evidence to increase the effectiveness of diabetes self-management education in the EU. The outcomes will inform policy decisions on improving the care for the growing number of people with diabetes.

The Diabetes Literacy consortium consists of partners from EU Member States (Austria, Belgium, Germany, Ireland, the Netherlands, UK), non-EU countries (Israel, US, Taiwan) and collaborating partners from Denmark and South Africa. The project is conducted from November 2012 through December 2015. .

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# 1. Executive summary

About 32 million people in the EU live with type 2 diabetes. Because of ageing and changing food habits, the prevalence of diabetes will increase. Health systems need to consider cost-effective measures to fight this growing burden. Patient empowerment through self-management education is a key to the treatment of chronic disease, such as type 2 diabetes. Self-management depends on a person's health literacy, which entails people's knowledge, motivation and competences to understand and apply health information. Successful programmes address both psychosocial and health needs and encourage patient autonomy through self-management. Self-management education is widely recommended. However, questions remain with regard to its effectiveness, the best method of delivery, and the impact of patient and provider characteristics. To address key questions, the European Diabetes Literacy project was initiated, aimed at strengthening patient self-management. The project mapped existing national policies, developed a compendium of diabetes self-management education programmes in Europe; and inventoried diabetes cost applying time-driven activity based costing methodology. Main factors that have impact on effectivity were studied in an international pre-post evaluation involving more than 600 patients. At provider level, the organizational effectivity and fidelity of implementation of the interventions were researched. Improvement of diabetes education by developing accessible web-based support for patients was tested throughout Europe with more than 1.000 patients.

The Diabetes Literacy project shows that there is evidence of a growing acceptance that self-management education is a core component of diabetes care. European countries, but not yet all, incorporate self-management into their national programmes. Different types of self-management programmes exist, providing a solid foundation upon which to build in the future. No evidence was found to suggest that any one approach to self-management education involving newly diagnosed patients was significantly more effective than another. It implies that relatively cheaper forms, such as group programmes, are as effective as one-to-one education.

Strong evidence was found that diabetes self-management education is effective, although the quality can be improved. However, the project also shows that currently only 50% of the people with diabetes in Europe take part in self-management education. The implementation of cost-effective programmes should be increased to make these programmes accessible to all patients. Self-management education was effective even when providers did not strictly adhere to the programme guidelines; adaptation was sometimes associated with a greater patient improvement. On the other hand, it was also seen that programmes do not always reach the patients who are most in need. Moreover, there seems to be an under-representation of peer-led support, as well as an underdevelopment of IT-based programmes.

The cost of self-management education varied widely between countries and programmes. However, compared with the overall cost of diabetes care, self-management costs are relatively low. Diabetes self-management education can be considered a cost-effective intervention. The outcomes strongly indicate that costing of activities at the patient level using bottom-up costing methods provide the greatest opportunity to understand the relationship between cost and health outcomes. It was concluded that organizational context can impact effectivity. However, there is room for improvement to involve patients in educational approaches. Monitoring patients' progress and

evaluation of services will support organizational effectivity. A broader range of professionals should be involved, also trained in behavioural and psychosocial aspects of diabetes.

Further consideration should be given to developing web-based diabetes programmes for people with lower health literacy levels. The study showed that it is possible to develop IT-based support that engage people with lower health literacy, but are also acceptable for people with higher levels.

In order to expand, efficiency and cost-effectiveness of diabetes self-management education must be rigorously evaluated on an ongoing basis.

## 2. Project context and objectives

### 2.1 Introduction

The number of people with type 2 diabetes in the European Union (EU) Member States and worldwide is increasing at an alarming rate, which is costing the EU Member States between 5–15% of their total health expenditure. Worldwide, 1 in 11 adults have diabetes, and this will rise to 1 in 10 in 2040. Health systems need to consider cost-effective measures to fight the growing burden of diabetes and to improve the health and quality of life of people with or at risk for diabetes. A key to the treatment of chronic diseases such as type 2 diabetes, and to the prevention of complications, is patient empowerment through self-management education. Self-management depends on a patient's capacity to obtain, process and understand basic health information. The level of health literacy of a patient is a critical factor in successfully addressing diabetes and improving the outcome of treatment. As the burden of diabetes continues to grow throughout Europe, many EU Member States have put in place national diabetes plans or policy frameworks. The most successful of these frameworks addresses both psychosocial and medical needs and encourages patient autonomy through disease education and self-management. Diabetes self-management education has proven health benefits, and is widely recommended. However, questions remain with regard to its cost-effectiveness, the best method of delivery, and the impact of patient and provider characteristics on self-management education effectiveness. To gain better understanding of type 2 diabetes self-management programmes, and address some of these questions, the European Diabetes Literacy project was initiated with financial support from the European Commission under its FP7 programme.

Diabetes Literacy is a pan-European project aimed at strengthening patient self-management by exploring which programmes for diabetes self-management exist, which factors have impact on their effectiveness, and what is the potential for improvement. The project was implemented by a Consortium of research organizations from six EU Members States (Austria, Belgium, Germany, Ireland, Netherlands, United Kingdom), three non-EU countries (Israel, Taiwan and USA) and two collaborating partners (Denmark and South Africa) from November 2012 till December 2015.

The Diabetes Literacy project was structured into nine work packages. Three of the work packages were related to management, evaluation and dissemination. The remaining six work packages relate to three core tasks: Firstly, mapping existing strategies and diabetes interventions/programmes (work package 3) and diabetes cost (work package 4). Secondly, investigating factors that have impact on effectivity of diabetes education, including the type and format of the educational intervention (work package 5), the organizational context (work package 6), and the fidelity with which the intervention is implemented (work package 7). Thirdly, investigating options to improve diabetes education by developing accessible web-based support for patient self-management (work package 8).

## 2.2 Mapping strategies and interventions

Long term complications of diabetes can be minimized by maintaining an optimal glycemic control. Patients can learn skills to control their blood glucose level and reduce the risk of complications. Hence, interventions that help people to self-manage their condition is crucial for achieving improving life expectancy, better health related quality of life and reducing economic burden. The changes in attitude and increase in knowledge by educational support to diabetes patients may play a crucial role in encouraging responsibility for self-care in day to day life. Diabetes self-management education is the ongoing process of facilitating the knowledge, skill, and ability that is necessary for pre-diabetes and diabetes self-care. Various educational programmes have been developed globally, addressing different target groups and covering different topics. Education methods have evolved over the last decades from didactic presentation to patient-centered interventions based on empowerment strategies. To get an overview of the current state of the art, a first task of the Diabetes Literacy project was to map and compare the diabetes education strategies and the available diabetes self-management education programmes in Europe. This task was the main objective of work package 3. The results of this inventory provide a guideline for the further development of effective, low cost, sustainable programmes.

## 2.3 Mapping and analysis of cost of diabetes strategies and complications

Type 2 diabetes has been highlighted as one of the most significant public health issues of the 21st century. Increasing obesity, inactivity levels and the ageing population of the European region in particular will place increasing numbers of people at risk, and by consequence, place an even greater cost burden on health costs in the future. This is the reason why an important focus of the Diabetes Literacy project is on the economic aspects of diabetes. European healthcare systems have been faced with widespread calls for reform. In answering calls for greater financial management, accurate data on the cost of healthcare provision is of utmost importance. Yet despite the significance of costing in this context, it has been suggested that in practice a mixture of costing methodologies are being used, resulting in a different levels of measurement and thus incomparable data generated across providers. In order to satisfy the desired level of financial management, the Diabetes Literacy project investigated in work package 4 the costs using activity-based or patient level, costing for diabetes care.

## 2.4 Effectiveness of diabetes self-management education programmes

Diabetes education and self-management programmes are essential for providing optimal care of diabetes and other chronic disorders. Although there is evidence that diabetes self-management interventions have beneficial effects, the field is still understudied. There is sparse knowledge which specific circumstances make programmes effective, how they affect certain outcomes, or whether all programmes are equally effective across the population. Existing studies and reviews do not provide

sufficient information to answer these questions, since there is too much variety of outcome measures. The Diabetes Literacy project evaluated the effectiveness of diabetes self-management programmes in various countries, using the same instrument to measure selected outcomes. This was accomplished in work package 5, which used a pre-post evaluation design to evaluate five types of diabetes self-management programmes, differing in the format for communication they use: individual one-on-one sessions, group-based education, self-help groups (sometimes also called peer-led groups) and IT or web-based education, as well as programmes which use a mix of two or more of these modes of delivery.

## 2.5 Impact of the organization of care on programme effectiveness

Diabetes self-management programmes operate in the context of healthcare organizations. However, little is known about the organizational conditions that need to be fulfilled in order to achieve effectiveness in diabetes programmes. As such, assessing the organizational factors influencing the effectiveness of diabetes self-management education can strengthen the evidence on what constitutes effective programmes. Organizational effectiveness is the concept of how effective an organization is in achieving the outcomes the organization intends to produce, for example to which degree predetermined goals are achieved. In particular, work package 6 of the Diabetes Literacy project explored four focus areas of organizational effectiveness: the availability of easy access, availability of health care professionals with multi-disciplinary competences, availability of an efficient information system allowing patient follow-up, and evaluation of services with a view to strengthen competences and excellence as part of the organizational effectiveness of diabetes programmes.

## 2.6 Evaluation of implementation fidelity

While diabetes self-management education is generally recommended as part of diabetes strategies, the effectiveness of such programmes depends on a number of factors, which can be related to the patient (e.g., motivation), programme (e.g. content), organizational context (e.g. team composition) and the way the programme is implemented. Despite the availability of a wide variety of diabetes education self-management programmes, there is a significant lack of research about the implementation fidelity of these programmes. One of the objectives of the Diabetes Literacy project was to integrate research on implementation fidelity to other factors that influence effectivity. Implementation fidelity, or intervention integrity, is the extent to which the intervention has been delivered as planned. It implies a comparison between the implemented intervention and the original protocol. The idea underpinning the concept is that assessing the fidelity with which an intervention is implemented leads to a better understanding of what works or does not work during the programme delivery. Without this information, the absence of significant effects of an intervention may lead to a false attribution of lack of effectiveness. Moreover, evaluating the fidelity makes it also possible to identify which specific components of the intervention were adapted, and how these modifications affected the intervention outcomes. In work package 7, a novel tool for

assessing implementation fidelity was developed and applied to a selection of diabetes self-management education programmes.

## 2.7 Developing accessible web-based support for patient self-management

Health literacy is a product of the interaction between the individual and his or her environment, which includes the health care resources available to him or her. Many people have difficulty accessing face-to-face diabetes self-management education, due to barriers such as work, caring responsibilities, disability, cost, and lack of transport. These problems are more common among those with less education. Designing health care materials to be accessible and easily comprehensible can reduce the literacy burden, and address low health literacy. The rapid growth in delivery of health promotion and health care by means of digital interventions offers one possible solution to this challenge. Digital interventions can be accessed conveniently at home and have the potential for wide reach at low cost, and so could reduce health disparities. However, there is a risk that digital interventions could increase health inequalities due to a "digital divide" in both the access to the Internet and the confidence and skills of patients to use the Internet for self-management of their condition. As part of the Diabetes Literacy project, work package 8 aimed to address this gap. Previous studies of designing web-based diabetes self-management materials for people with lower levels of health literacy have had mixed results, and there are important unanswered questions about how best to meet the needs of this population. The aim of the project was to develop and trial web-based support suitable for people with varying levels of health literacy. In particular, the objective was to examine the potential for web-based materials and tools to provide enhanced support by tailoring the material to the particular needs, abilities and perspective of the user; employing engaging audio-visual presentation and quiz formats; and providing simple interactive tools to support self-management tasks.

## 2.8 Policy dialogues

Preliminary results of the Diabetes Literacy project were discussed with stakeholders at two policy dialogues. These were held during the 18th European Health Forum Gastein 2015 and the 23rd World Diabetes Congress 2015. Key research outcomes and implications of the project were presented to and discussed with stakeholders from policy, health care, and academia at the final public event "Diabetes Literacy: Strengthening Diabetes Self-Management for all in Europe" (Brussels, November 17 2015).

# 3. Main Results of the Diabetes Literacy project

The core elements of the research carried out within the Diabetes Literacy project relate to three elements: mapping the current state of national diabetes self-management education, investigating the effectiveness of different types of diabetes self-management programmes and the factors that impact on the effectiveness, and considering the potential of delivering IT-based education to improve diabetes self-management education, particularly for people with low health literacy.

A) Mapping

The Diabetes Literacy project assessed the current state of national diabetes self-management education, based on the input of multiple stakeholders (work package 3). It also developed best practice cost models for diabetes care, and assessed existing costing practices for diabetes self-management education as well as costs related to complications (work package 4).

B) Effectiveness

The effectiveness of diabetes self-management programmes that use different communication formats was assessed in work package 5 of the project. The influence of the patients' health literacy on the effectiveness of diabetes education was studied in work package 6, as well as factors in the organizational context that contribute to effectiveness. The way programmes are implemented as planned and whether this contributes to effectiveness was the focus of work package 7.

C) Improvement

The Diabetes Literacy project investigated in work package 8 whether interactive digital communication for people with low health literacy can improve their diabetes self-management, thus considering the potential of delivering IT-based education to patients with lower levels of health literacy.

In this final report, the project presents a summary of its results, using the above three headings. As these results relate to the research carried out in various work packages (3 through 8), each element will be presented by a short introduction to the topic, followed by a general description of the methodology, and a description of the main results. This section of the final report will be concluded with the summary of overall main results and their implications.

## 3A Mapping

The Diabetes Literacy project assessed the current state of national diabetes self-management education policies and programmes in work package 3 (A.1) Existing costing practices for diabetes self-management education as well as costs related to complications were assessed in work package 4 (A.2)

# 3A.1 Diabetes education strategies and existing diabetes self-management education programmes in Europe

## 3A.1.1 Introduction

Diabetes self-management education is the ongoing process of facilitating the knowledge, skill, and ability necessary for pre-diabetes and diabetes self-care. Various educational programmes have been developed globally, addressing different target groups and covering different topics. The objective of work package 3 was to map the state of art of diabetes education strategies and existing diabetes self-management education programmes in Europe. A comparative analysis was conducted of the existing mechanisms for diabetes management currently integrated into the broader health care systems in EU Member States.

## 3A.1.2 Development and methodology

To map the current state of diabetes self-management education in the EU, two strategies were used. To assess national policies in the European Member States a systematic and comparative analysis of data was conducted. Data were collected through a survey involving stakeholders, representing different groups in each European country and an expert survey involving three experts in every country. This method was supplemented by document analyses of national strategies. Existing diabetes programmes were inventoried by using an online Wiki tool and a systematic literature review of research on self-management programmes published in the last ten year.

The survey questionnaire assessing the insights of respondents concerning diabetes self-management education in their region was available online in seven languages (English, German, Spanish, French, Dutch, Mandarin and Hebrew). The response rate for the survey questionnaire varied across countries: from 0 to 95 respondents in each of the 28 EU Member States and the 4 project partner countries. The focus of the expert survey was on health policy and economical aspects regarding diabetes and consisted of an interview guide also available in several languages. Experts were identified by reviewing publications, online sources and using the networks of the project partners.

The current status of the diabetes self- management programmes was assessed from data collected via an online Wiki tool regarding existing programmes. The tool consisted of an online survey including questions describing programmes for diabetes and pre-diabetes. The Wiki tool was part of the Global Diabetes Survey, an initiative to collect data on diabetes care quality on a yearly basis. Questions were developed through an internal Delphi-like process, and were made available in seven languages with the option for participants to add, edit or delete information regarding a specific diabetes programme. The tool contains 49 questions on nine major topics, such as target group, empowerment strategy and quality management. A systematic literature review was conducted to evaluate research on diabetes self-management programmes in the last ten years, resulting in the

identification of 95 peer reviewed publications related to 154 different programmes implemented in 14 EU Member States

## 3A.1.3.1 National diabetes education policies

The priority of diabetes self-management in Europe received a rating of 6.1 on a scale of 1 to 10. The mean of the opinion on the current state of diabetes education was 5.0, also on a scale of 1 to 10. Three quarters of the respondents reported that structured diabetes education programmes for adults existed in their region, but only 37% of the respondents knew of existing programmes for peers and relatives of people with diabetes. The proportion of diabetes education programmes that were specifically designed to be accessible for people with limited literacy was limited; almost 60% of the participants had no knowledge of such programmes. Figure 1 shows an example of the way results have been presented, separately for the global and each national level.

Figure 1. A selection of two example questions from the results of the survey (global level)



**The international burden of Diabetes mellitus - estimates for 2013 [8] :**

- Diabetes international prevalence : 8.35
- Diabetes comparative prevalence : 8.26
- Incidence type 1 diabetes (0-14 years) : no data available

**Results of the survey:**

- Number of people who participated the survey: 367 (227 for Europe)
- How much is diabetes self-management prioritized in your regional community? (1: not prioritized – 10: highly prioritized) — Mean: 6.1 ± 2.5
- How satisfied are you with the current state of diabetes education in your regional community? (1: completely dissatisfied – 10: extremely satisfied) — Mean: 5.3 ± 1.9
- For which target groups do structured diabetes education programs exist in your regional community?

| Target group | % |
| --- | --- |
| children/adolescents with diabetes | 59% |
| adults with type 1 diabetes | 70% |
| adults with type 2 diabetes | 76% |
| women with gestational diabetes | 50% |
| older people | 49% |
| Peers and relatives of people with diabetes | 37% |
| other | 5% |

- Are there diabetes education programs designed to be accessible for people with limited literacy, educational attainment and language skills?

| Response | % |
| --- | --- |
| no | 28% |
| yes, for people with lower levels of literacy | 15% |
| yes, for people with lower educational attainment | 12% |
| yes, for people with lower language attainment | 12% |
| I don't know | 31% |

Three quarters of the participants also indicated that in order to be allowed to participate in a diabetes education, certain criteria must be fulfilled. These include a need assessment (25%), a recent diagnosis of T2D (18%), an ongoing basis (12%), or after disease progression (11). 27% of the respondents state that the attending physicians often actively provide self-management support to their patients, whereas 52% state they do this occasionally, and 3% never. As shown in Figure 2, 64% of children/adolescents with diabetes followed by 62% of the adults with type 1 diabetes and 58% of the women with gestational diabetes had completed or participated in a diabetes education programme at some point.

Figure 2. Participation in a diabetes education programme (global level)
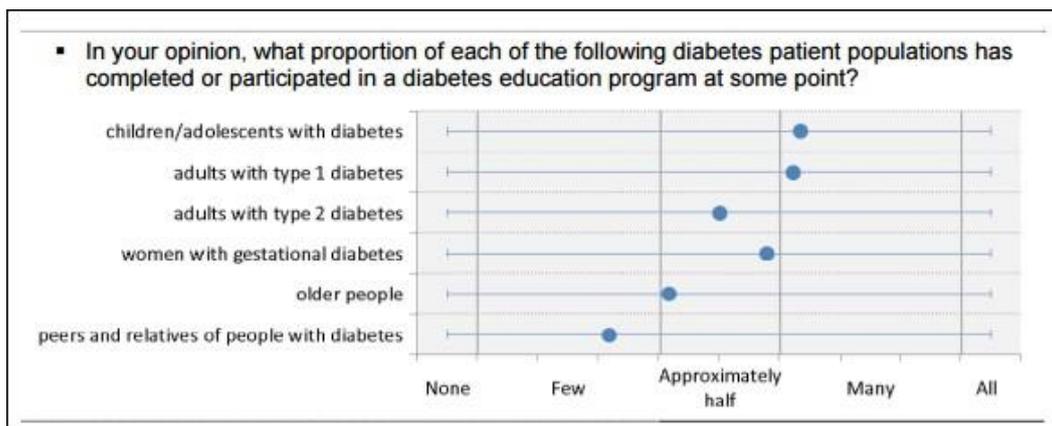


A clear majority of respondents (82%) stated that diabetes education programmes in their region promote patient empowerment and improve self-management. A similar percentage (83%) indicated that educational programmes promote a healthy lifestyle for people with diabetes. Regarding the proportion of people having adequate knowledge for managing their illness in everyday life, the respondents estimated that the general population only has sufficient knowledge about the negative impact of smoking (58%). In contrast, 27% of general population was estimated to have sufficient knowledge about the role of stress management, physical activity and nutrition for diabetes prevention (38% each category). About half of the patients with type 2 diabetes were estimated to have sufficient knowledge about general information regarding diabetes (55%), nutrition (52%), physical activity (48%), prevention and management of complications (45%), treatment with oral anti-diabetics (56%), treatment with insulin (44%), self-monitoring of blood glucose (52%) and hypoglycemia (46%). Knowledge was thought to be insufficient regarding the legal aspects of the disease (32%), coping strategies in the context of diabetes therapy (32%), and depression (29%).

## 3A.1.3.2 Existing diabetes self-management education programmes

Information about existing diabetes self-management education programmes was collected through the online Wiki and the systematic literature review. The interventions reported in the Wiki mostly (77%) were delivered in groups, with only 23% of the programmes being face to face individual sessions, and 29% using a combination of group and individual delivery strategies; only 8% of the

interventions were peer group programmes, and 7% were IT-based. The interventions identified in the literature review were also primarily (55%) delivered in groups: 18% and 19% were delivered individually and used IT, while15% followed the combined individual and group delivery strategy. The majority (77%) of the programmes described in the Wiki uses a written curriculum and 68% of the programmes provide materials such as a booklet to supplement educational sessions. Almost 20% of the studies included in the review were meant for ethnic minorities. One third of the programmes were tailored to people with low literacy levels. Three thirds of the programmes listed in the Wiki were meant for adults, as compared to only 13% and 6% targeted towards children/adolescents and older adults. This was also reflected in the literature review: 68%, 5%, and 8% of the programmes were meant for adults, children and older adults, respectively. Although support from family members can make a great difference in self-management, the Wiki tool showed that only 8% of the programmes were meant for children and parents together.

Increasing knowledge is the most commonly employed strategy for diabetes education, while psychosocial interventions (cognitive behavioral therapy) and motivational interviewing (MI)) were the least often used. Commonly used empowerment strategies in diabetes education according to both the Wiki and the literature review were increasing knowledge (77% Wiki and 30% review), changing attitudes and beliefs (65% and 10%), increasing awareness (70% and 7%), increasing self-efficacy (62% and 27%), increasing self-care skills (63% and 17%), while less used strategies include increasing social support (38 and 17%), and using psychosocial interventions (20% and 15%). "Meal planning" is the most commonly discussed topic while "dealing with depression" is the least discussed one. Teaching and learning methodologies documented in Wiki tool include lectures (49%), sharing personal experiences (59%), individual counseling (27%), group work with content development (61%), practical training (61%), behavioral training (33%), video (10%), online interactive learning (5%).

According to the Wiki data, more than 60% of the respondents think that instructors need specific diabetes related qualifications and professional training. The professional background of the educators who provided the interventions differed. According to the Wiki data, physicians (58%) and diabetes educators (59%) are most often involved in the provision of diabetes education programmes, according to the literature review the most commonly employed professional groups are diabetes specialist nurses (26%), physicians (27%) and dietitians (27. There are huge differences between countries regarding the involvement of mental health specialists in diabetes education, with the lowest involvement showing in Austria and Germany, where psychologists are involved in only 6% and 15% of programmes, and the highest in Finland, where 67% of the programmes involve a psychologist.

The findings lead to the overall conclusion that a wide variety of diabetes self-management programmes is currently available in Europe. However, the quality and effectiveness of the existing programmes can be improved by: tailoring education to the target groups; looking at conditions and components that make the programmes more effective; using opportunities for IT-based education; and improving the training of programme providers. Patient centered treatment as part of modern diabetes management encourages patients to take the responsibility of their own condition. The risk of complications is high, especially among older adults, as are cognitive impairment and diabetes related depression. As such, an optimization of self-care strategies through an individualized approach for geriatric patients should be considered. On the other hand, the incidence of type 1

diabetes in children is rapidly increasing in Europe, which makes it necessary to enhance parental involvement in self-management education. Tailoring programmes to specific needs while maintaining the core programme components can enhance self-management effectiveness in target groups. Especially for ethnic minorities tailoring to culture and health literacy level seems a prerequisite for successful programmes. With regard to the quality of existing European diabetes self-management programmes, it seems necessary to intensify and improve the training of providers, by including a greater on focus behavioural and psychosocial expertise. In some countries peer education and the involvement of professionals such as social health workers, is more common than in other countries. Other research shows that some target groups benefit from these approaches, which could be a cost-effective way to deliver diabetes education to patients who are not reached at this moment.

## 3A.2 Cost analysis of diabetes strategies in Europe

### 3A.2.1 Introduction

At least USD 147 billion was spent on diabetes healthcare in 2013 in the European region. Societal developments such as increasing obesity, inactivity levels and the ageing population of the European region will place increasing numbers of people at risk for diabetes. In practice a mixture of costing methodologies are used, which results in incomparable data across providers. In order to facilitate financial management, work package 4 of the Diabetes Literacy project investigated costing practices using activity-based or patient level, costing for diabetes.

### 3A.2.2 Development and methodology

This work package addressed three research questions: (1) investigating the existing cost sources of diabetes care; (2) investigating the cost of diabetes education per patient; and (3) exploring the costs of complications of diabetes.

Based on a literature review and archival research of sources of cost of diabetes care, the first research question was to map existing cost practices. Expert interviews focused on current accounting principles and methods used to estimate the cost of type 2 diabetes, on current uses of cost data; and on challenges and facilitators to improve current cost estimates of type 2 diabetes. The quantitative component of this study focused on the specific cost allocation methods currently used to estimate the cost of healthcare services associated with type 2 diabetes. The countries participating in this study were Ireland, the UK, Germany, Austria, Belgium, Israel and Taiwan.

The second research question focused on the cost of education per patient. A quantitative and qualitative analysis of cost of education per patient was performed, taking account also of the health outcomes achieved. A costing protocol was developed using a methodology based on the principles of time-driven activity based costing (TD-ABC). Combined with outcome data on diabetes health

literacy and quality of life health collected from patients in the pre-post evaluation study of work package 5, this information was used to demonstrate the per-patient programme cost per hour of education.

The third question was concerned with a quantitative and qualitative analysis of cost of care of type 2 diabetes and an exploration of the costs of complications of diabetes. Interviews were conducted with providers to identify the process steps and associated activities for the care pathway of the five most common types of patients with type 2 diabetes (stable glycaemic control, retinopathy, foot disease, kidney disease and myocardial infarction) across three countries, i.e., Ireland, Germany and Israel. The cost of a one year cycle of care for each of the five patient profiles was estimated from each country. A comparative cost analysis was performed to understand the reasons for significant differences in cost of care.

### 3A.2.3.1 National costing practices

Costs for the treatment of diabetes take an increasing part of national health budgets in Europe. Yet there is substantial variation in both the prevalence and range of healthcare spending on diabetes within the European region. Comparative healthcare spending estimates for diabetes both within and outside of Europe are provided in the next figure.

Figure 3: Mean diabetes-related expenditure per person with diabetes
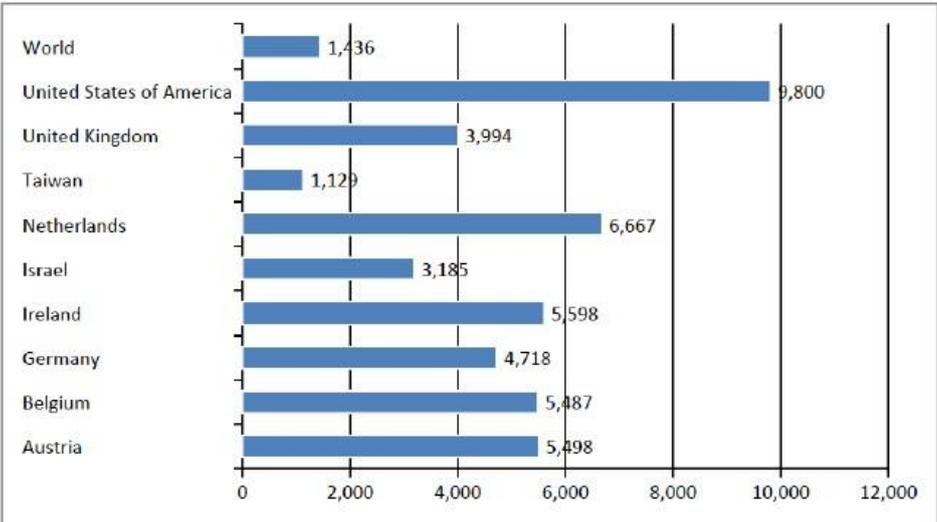


The project results about national costing practices indicate that to date costing data in the European context has, in the main, been collected using top down methods, which do not adequately indicate the actual costs incurred at the patient level in the provision of a programme of diabetes care. Systems for costing in outpatient and community settings, where much diabetes care is completed, are underdeveloped and care activity in these settings is not consistently reported. This poses a significant challenge to the determination of cost-effectiveness of diabetes care.

Costing of activities at the patient level using bottom-up costing methods provide the greatest opportunity to understand the relationship between cost and health outcomes achieved in the short, medium and long term. Throughout the interviews, respondents consistently highlighted the incomplete nature of cost and activity information in the following areas that typify diabetes care: community care activity, nursing activity, health outcomes, and costs for every patient. Key differences between jurisdictions are related to the costing methodology used to inform the reimbursement of healthcare providers; the level at which costs are reported (for example, diagnosis-related group); the presence or absence of a unique patient identifier linking episodes of care across healthcare settings (for example inpatient, outpatient and community); tracking care overtime; and the extent to which cost information is used for purposes other than price-setting and accurate reimbursement, for example, to inform service delivery and national policy and planning.

There was a consensus among the key respondents interviewed that the use of patient level data is a fundamental building block for achieving cost efficient and effective care in the future. Yet there are still a number of significant issues that need to be addressed before the potential of patient level costing in the context of type 2 diabetes can be delivered upon. Poorly integrated information systems were a frequently reported barrier. While guidelines relating to patient level costing in all of the jurisdictions included in this study exist, there remains significant variation in how they are implemented. Using a bottom-up, micro-costing approach demonstrates that the cost of healthcare associated with chronic conditions is not fixed. Thus a key challenge is convincing policy makers of the need to invest in patient level costing infrastructures, which provide information, which can be used to inform the cost-effective reform of care provision.

## 3A.2.3.2 Cost analysis of existing diabetes self-management programmes

The second objective of the costing study was to consider the costs of different types of diabetes education programmes. For this purpose, a costing study protocol was designed using a methodology based on the principles of time-driven activity based costing. Combined with outcome data collected from patients in the pre-post evaluation study, this information was used to demonstrate the per-patient programme cost relative to the clinical outcome achieved and the comparative cost analysis of the different programme types. Data were collected in a stepwise approach. Step one was to select the medical condition and/or patient population to be examined. Step two, defined the care value pathway and was completed by each partner . The next step required data collection to be completed by each project partner. In the final step the practical capacity of each resource provider was estimated; the capacity cost rate was calculated; and the total cost over each patient's cycle of care was computed.

Variations were found in cost per patient per hour of education both within and between countries. For example, within Germany the cost per patient per hour varies from $29.78 when the programme is delivered by a nutritionist to $0.74 for a peer led programme. For other countries, the costs of education programme also vary yet with lesser extremes. For instance, the UK, Israel and Ireland have similar costs per patient per hour: for the UK the costs range from $8.87 to $14.03, for Israel from $12.85 to $14.68, and for Ireland from $6.11 to $15.48. Variations in cost are related to differing modes of delivery of the programmes from individual, group, mixed and peer-led, delivered

by either one trained specialist or a mix of specialists, with differing durations and number of training hours. Some education programmes have high administrative hours and high consequent cost of delivery. A relationship was found between the type of self-management programme, the cost of delivery and health outcomes achieved, particularly for quality of life and diabetes health literacy. While some outcome data were used in this study, clinical data are needed to better evaluate the cost effectiveness of different diabetes education programmes. Clinical data should be collected before and after self-management education delivery by the national programmes as a matter of course.

### 3A.2.3.3 Comparative patient level costing

The third study regarding cost focused on the estimation of the cost of a one year cycle of care for five profiles of patients with type 2 diabetes using time-driven activity based costing applied to clinical vignettes. Data collection included 5 phases: identifying the patient categories and mapping the care pathway; obtaining activity time estimates for the provision of care; reviewing the care pathway; collecting patient level activity costs; and collecting patient-borne costs. In addition to the computation of cost data, a framework approach comprising five stages was adopted for the analysis of all activity and cost information.

Differences were found in the process of care across the three countries, as well as differences in the cost of care. Figure 4 highlights the differences in the cost of the same care pathways across the three countries in this study. Part of this variation is due to differences within the process of care for similar patient profiles. Primary and community care were identified as key factors in providing the care that is necessary to keep patients at low or even moderate risk of the above complications. However, community care for treatment in some countries remains unstructured and unstandardized, as most of the resources are invested in the treatment of severe cases of complication in the acute setting. This is particularly the case in Ireland and Germany, whereas Israel has a developed infrastructure to support patients at various stages of risk. In the other countries, a stronger investment and expertise development in the community is recommended.

Figure4: 1 year cycle cost of care per patient care pathway in three countries

| Patient Care Pathways Comparison | Costs (1 year cycle of care) International $ | | |
|---|---|---|---|
| | Ireland | Germany | Israel |
| Stable with optimum control | 1005 | 770 | 354 |
| Stable with sub-optimum control | 1610 | 1,015 | 1214 |
| Stable with sub-optimum control, retina screening | 1610 | 3,462 | 1273 |
| Stable with diabetic kidney disease | 3090 | 4,245 | 2130 |
| Active foot disease | 5685 | 16,128 | 2835 |
| Maintenance at moderate risk of active foot disease | 889 | N/A | N/A |
| Myocardial infarction | 26504 | 81,858 | 2494 |

It can be concluded that the costing methodology applied in this study created in-depth insight into the process of care for differing type 2 diabetes complications within and across countries. The methodology revealed the key cost drivers of care and showed how cost increases due to different processes of care and different levels of acuity of disease. Economic evidence was collected to support the finding that early intervention at primary and community care to prevent progression of disease and associated escalating costs. It was found that time-driven activity based costing allows a more accurate understanding of costs for low, moderate and high risk patients when top down costing methods do not reveal these costs.

## 3B. Effectiveness

The effectiveness of diabetes self-management education programmes that use different communication formats was assessed in work package 5 of the project (B.1). Work package 6 focused on the role of health literacy and on factors in the organizational context that contributes to the effectiveness of diabetes education (B.2), whereas work package 7 looked at the relation between implementation fidelity and the effectiveness of diabetes programmes (B.3).

## 3B.1 Effectiveness of different diabetes self-management education programmes

### 3B.1.1 Introduction

There is evidence that diabetes self-management interventions have beneficial effects. However there is sparse knowledge as to which specific circumstances make diabetes programmes effective, how they affect certain outcomes, or whether different types of programmes are equally effective. To answer these questions, a pre-post evaluation was performed to evaluate different kinds of diabetes self-management education programmes in various countries.

### 3B.1.2. Development and methodology

Intervention outcomes themselves are not a new research area in diabetes self-management. The most prominent endeavour was started by the American Association of Diabetes Educators (AADE). A comprehensive framework for diabetes self-management outcomes was developed with seven self-care behaviours at its core. The framework is essentially an attempt to order possible outcomes according to when they are measurable. There are immediate outcomes (e.g. acquired knowledge), intermediate (behavioural), post-intermediate (clinical) and long-term outcomes (e.g. quality of life). The assumptions include also feedback mechanisms, using the framework as a circular model. The framework focuses on the axiom that behaviour change is the core outcome. However, the other categories in the framework are not as distinctive in considering the many non-behavioural
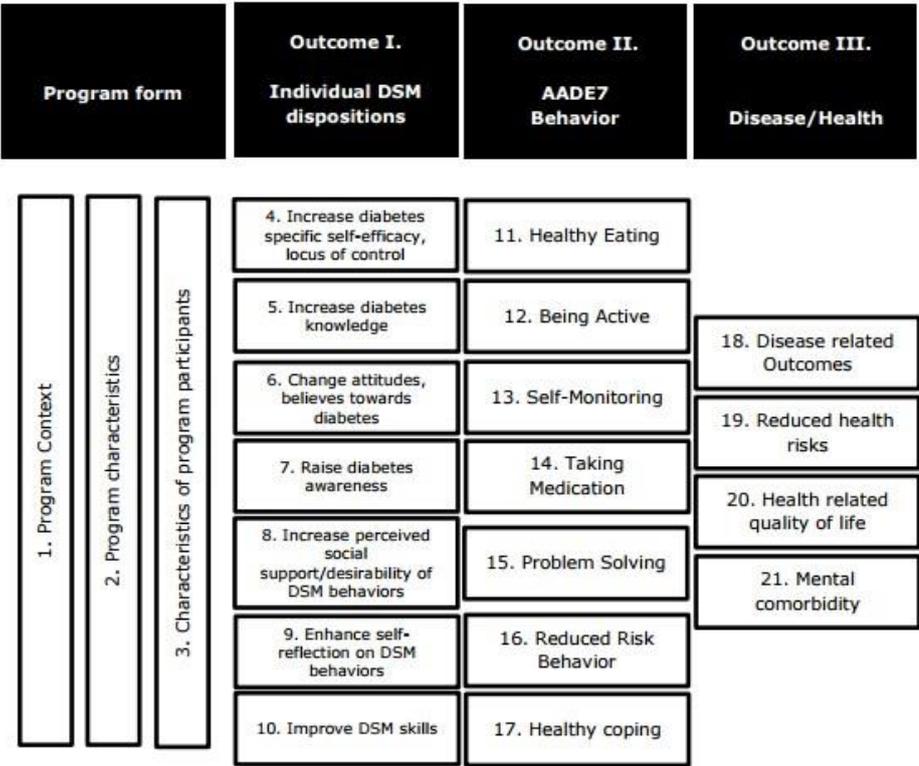
outcomes that are as well reported in evaluations of diabetes self-management programmes. Therefore, the Diabetes Literacy project further developed this model. The aim of the model development for the project was to enable a comparative pre-post evaluation study of self-management programmes. Therefore, the programme form was explicitly included. As self-management interventions are composed of multiple components, several dimensions were considered for programme form, notably: programme context and characteristics and characteristics of programme participants. Outcomes were considered at different levels. The first level comprises outcomes that are closely related to the mechanisms through which diabetes patients can be enabled for managing their condition. The second level considers specific self-management behaviours, and the third level considers disease specific and general health outcomes. The programme form and three outcome levels combined form a logical model showing the pathways for achieving health outcomes through self-management programmes. This Diabetes Self-Management Outcome Framework (DSMOF) is presented in Figure 5.

Figure 5: DSMOF logic model
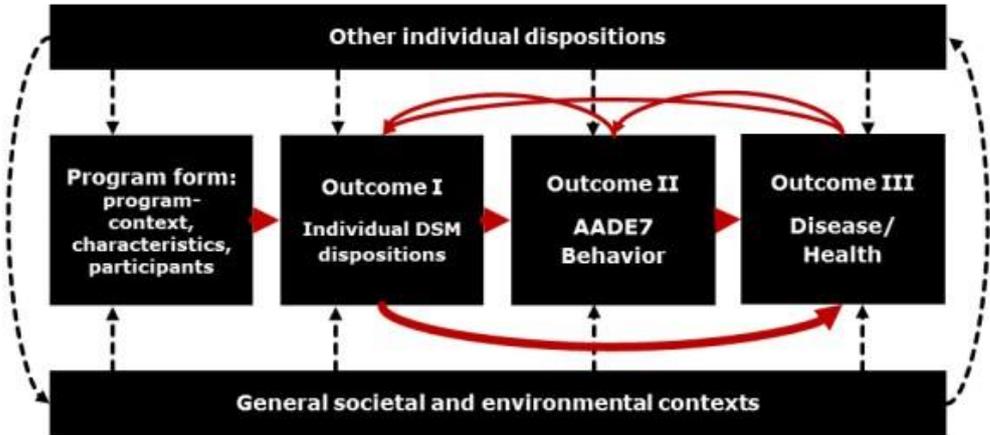


The DSMOF was used in a literature review to show that it is comprehensive enough to systemize outcomes in diabetes self-management. In Figure 6, the elements of the framework are presented. Programme form consists of three elements: programme context, programme properties and participant characteristics, which are further categorized. The first outcome elements consist of ten individual predispositions such as self-efficacy and awareness. The second outcome elements consist of the seven AADE behavioural categories. The third outcome elements are related to health, such as disease outcomes and mental comorbidity.

Figure 6: DSMOF outcome elements and sub-categories

| Program form | Outcome I.<br>Individual DSM dispositions | Outcome II.<br>AADE7 Behavior | Outcome III.<br>Disease/Health |
|---|---|---|---|
| 1. Program Context | 4. Increase diabetes specific self-efficacy, locus of control | 11. Healthy Eating | |
| 2. Program characteristics | 5. Increase diabetes knowledge | 12. Being Active | 18. Disease related Outcomes |
| 3. Characteristics of program participants | 6. Change attitudes, believes towards diabetes | 13. Self-Monitoring | 19. Reduced health risks |
| | 7. Raise diabetes awareness | 14. Taking Medication | 20. Health related quality of life |
| | 8. Increase perceived social support/desirability of DSM behaviors | 15. Problem Solving | 21. Mental comorbidity |
| | 9. Enhance self-reflection on DSM behaviors | 16. Reduced Risk Behavior | |
| | 10. Improve DSM skills | 17. Healthy coping | |

As a further basis for the study on the relative effectiveness of different formats of diabetes self-management programmes, a research protocol and survey instruments were developed. In accordance with the DSMOF model, the baseline- and follow-up-questionnaires included questions regarding socio-demographic information, diabetes self-management behaviours, disease/health indicators, and programme information. The covariates consist of a set of socio-demographic information as well as two scales for health literacy. General health literacy was measured using the 6 item short form of the HLS-EU instrument. The questionnaires were translated from English into eight languages (Arabian, Dutch, French, German, Hebrew, Mandarin, Russian, and Spanish).

Using this research protocol, a comparative study on the relative effectiveness of different formats of diabetes self-management programmes was performed. The selection of the programmes to be included in the study was based on a compendium of diabetes self-management education programmes which was produced in work package 3. Programmes were selected if they were stand-alone programmes, aimed at the improvement of self-management skills, had a written curriculum, accepted patients during the study time and were not tailored for specific target groups. Ethical approval for this research was obtained from institutional bodies contacted by the respective national partners. Patients were recruited from October 2014 to June 2015 in Austria, Belgium, Denmark, Germany, Ireland, the United Kingdom, Israel, Taiwan and California. Newly diagnosed diabetes patients who were going to start one of these programmes were asked to complete the questionnaire at the start and again after three to six months. At baseline 628 patients met the criteria and participated in the survey. Of these 628 patients, 471 also participated in the follow-up survey.

The study was designed as an observational, multicenter effectiveness study of different diabetes self-management programmes using different communication formats. The inclusion of five different kinds of programmes in nine countries results in a five arm trial, each arm of which represents a communication format. As not every country offered programmes in all five channels, the formats of programmes had to be pooled across countries. Four comparisons were made between two (combined) groups each: individual versus non-individual, group versus IT and self-help, unstructured versus structured, and mixed versus non-mixed programmes.

### 3B.1.3 Pre-post evaluation study

The pre-post evaluation study revealed an absolute total effectiveness of the programmes. A statistically significant patient improvement was found for all six the behavioural outcomes as well as for medication adherence, foot care, appraisal of diabetes, and three of the disease/health outcomes. This is a strong indication that diabetes self-management education programmes change the behaviour of newly diagnosed patient and led to behavioural and health outcomes. The largest improvement was found for foot care. Patients who participated take care of their feet over half a day more during an average week than before the diabetes programme. Participants also showed a more positive appraisal of the diabetes and better problem solving capacities. Regarding diabetes behaviour, the proportion of active participants and persons who followed the prescribed medication seven days per week is also increased. The average health related quality of life as well as the overall well-being increased and therefore mental comorbidity decreased.

With regard to the relative effectiveness of programmes, it was found that programmes with an individual component (n = 65) are more effective than other programmes (n = 301) with regard to two behavioural outcome indicators: participants who attended a diabetes education programme with an individual component take care of their feet more often and have a better attitude towards problem solving than those who attended programmes without an individual component. Group based programmes (n = 221) are significantly more effective than IT and self-help programmes combined (n = 80) for two behavioural outcome indicators: foot care and exercise at least one day a week. Patients who followed a group programme are also more likely to control their blood sugar level at least six days per week, although this effect is small. Furthermore, structured programmes (n = 299) are more effective than unstructured programmes (n = 67) when foot care is considered, but not for other outcome variables. Programmes using a mix of communication channels (n = 51) are more effective for foot care than programmes using only one channel (n = 315). None of the four comparisons however showed statistically significant differences regarding disease/health outcomes.

Thus, all types of programmes included in this study are effective in changing behaviour and improving psychological outcomes. Apart from that, diabetes specific healthy eating, diabetes specific health literacy and self-monitoring remained stable and did not decline during the intervention. These findings are consistent with previous research. The main conclusion of this study is therefore that programmes using a different communication format are equally effective, apart from some small differences regarding foot care. The findings regarding the absolute effectiveness

clearly underline the importance of diabetes self-management education. Patients definitely benefit from participation in self-management programmes. With regard to the relative programme effectiveness, the fact that largely similar results are achieved for different types of programmes opens a window of opportunity for the selection of programmes that relate to the specific needs of patients. As patients can benefit from programmes regardless of their programme format, providers can select the mode of delivery that best suits the situation, the educators and the patients concerned.

## 3B.2 Impact of organizational context on health literacy

### 3B.2.1. Introduction

Little is known about the organizational context that supports effectiveness of diabetes self-management programmes. To evaluate this issue, a tool to assess organizational effectiveness was developed and tested in an explorative study of more than 50 programmes. The results indicate strengths and weaknesses of programmes on dimensions that have impact on the programme effectiveness, such the availability of easy access, professionals with multi-disciplinary competences, information systems allowing patient follow-up, and evaluation.

### 3B.2.2 Development and methodology

A scientific literature review and expert consultations led to the design of a conceptual model, which includes thirteen indicators relevant to organizational effectiveness, including organizational structure, curriculum and guideline, target group, characteristics of the implementation team, and quality assurance. Based upon the conceptual model, a questionnaire was developed consisting of 42 items; 2-4 items per indicator. For each item a score can be computed, using one point per question, and transferred to percentages. The maximum score per domain is thus 100%. The scores on the focus areas are the mean scores of the indicators in this focus area. The mean score of the indicators reflects the overall score of the organizational effectiveness of the organisation. The questionnaire was developed in English, translated to Hebrew, Dutch, French and German. Using this questionnaire, data were collected from managers of diabetes programmes via two paths: a web-based survey, and selected programmes that were included in the pre-post evaluation study of the project. The sample yielding a total of 112 contacts to diabetes programmes in Europe and beyond. Managers of the selected programmes were contacted by email. 72 diabetes programme managers from thirteen different countries completed the questionnaire. The data analysis involved an assessment of the indicator scores for each of the organizational effectiveness indicators with particular emphasis on the four focus areas.

## 3B.2.3 Organizational effectivity

Of the 112 respondents, 94 answered the question whether the programme was integrated in a larger organization. This was the case in 41% of the programmes. In contrast, 43% of the programmes were not integrated in a larger organization, and 15 respondents (16%) did not know. The results on organizational effectiveness show a median score of 53% (39-67) on a scale of 100%. The scores on the dimensions 'evaluation of services' and 'participatory approach/ patient involvement' were comparatively low. The score on workforce development was high. The organizations mainly targeted patients with type 2 diabetes (85%), with type 1 diabetes (54%) and less often patients with pre-diabetes (29%). Many programmes (61%) did not have procedures for targeting minorities, whereas 56% had ensured that hard to reach groups could access the programme's information and individuals with low health literacy (71%) could understand the core messages. Generally, language (58%) and costs barriers (47%) were addressed to facilitate easy enrolment. In 73% of the organizations most or all staff had formal training in diabetes education. Staff mainly consisted of diabetes nurses (78%) and dieticians (56%). Host organizations were regarded as supportive (58%); seldom as hindering (5%). The programmes collaborated well with other units (56%) and with external organizations (63%). Mandatory workforce development was implemented in 71% of the organizations. Case management systems were not in place in 53%. About half of the organizations had a system to monitor the patient progress (55%) and follow-up (52%). Half of the organizations had procedures to routinely evaluate. However, this did not always lead to changes (20%). In 49% of the organizations, patients were involved; mainly in the evaluation (65%). Figure 7 shows the average score based on all included programmes as a benchmark for a specific programme.

Figure 7. Example of feedback on dimensions of organizational effectiveness
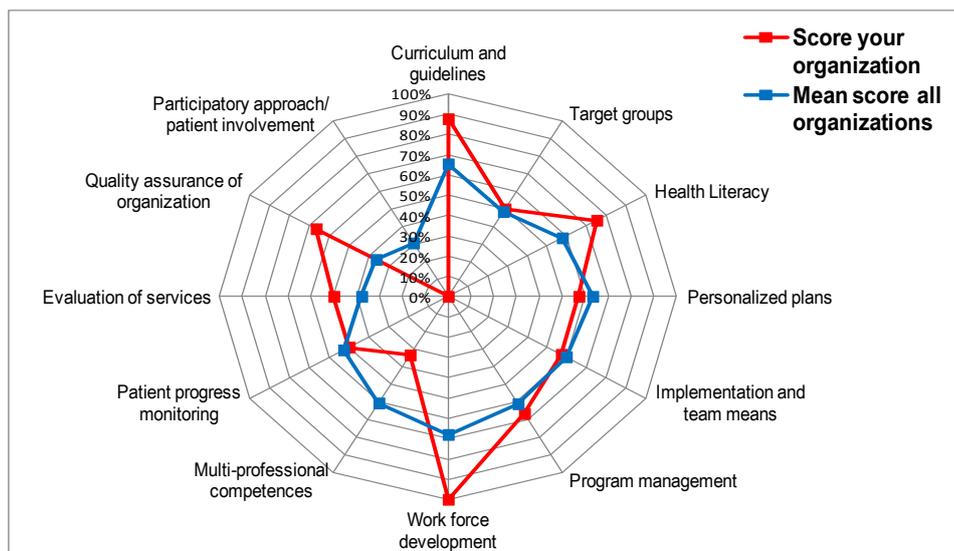
In less than half of the organizations patients were involved in the organization of the programme. Organizations are still struggling to find the best way to involve patients. Providers lack tools and methods for improving patient involvement. Although patient involvement has contributed to changes in the way services are organized (e.g., accessibility, production of patient leaflets and changes in attitudes towards patient involvement), its effect on quality and effectiveness of these services are still unknown. Furthermore, half of the organizations did not evaluate the services. The highest median scores for organizational effectiveness were found in outpatient clinics. This could be explained by their treatment of more patients with type 1 diabetes and the more complex patients with type 2 diabetes treated in outpatient clinics.

Whereas the Diabetes Literacy project is one of the first to provide an assessment of organizational effectiveness of diabetes education programmes, allowing managers of organizations offering educational interventions to identify areas in which improvements can be made, it has limitations in selection bias of participants and possible effect of social desirability in respondents. While construct validity of the tool can be assumed, the indicators of organizational effectiveness still need to be confirmed empirically. Nevertheless, the study indicates the strengths and weaknesses of existing programmes, illustrating that there is still room for improvement, especially concerning patient involvement.


### 3B.2.3 The role of health literacy in effectiveness


As part of work packages 5 and 6, the impact of general health literacy on the effectiveness of self-management programmes was assessed. To that effect, the health literacy questionnaire was added to the tool for WP5, enabling the assessment of health literacy of patients before and after they participated in the education programme. A series of repeated measures MANOVA were performed to investigate the moderating effect of health literacy on the programme effectiveness, using diabetes specific health literacy, self-management behaviours, perception of diabetes as a problem, healthy coping, perceived general health and perceived well-being as dependent variables. The results indicated that there were significant differences in patient' outcomes between the low and high health literacy group. More specifically, patients with a high level of health literacy scored higher on diabetes health literacy, coping, perceived general health, and wellbeing, whereas those with low health literacy scored higher on the perception of diabetes as a problem. However, no significant interaction effects were found between health literacy and treatment effect, indicating that (general) health literacy is not a moderator of the effectiveness of the programmes. More specifically, patients in the high health literacy group had higher scores in diabetes health literacy, coping, perceived general health, and wellbeing whereas scores of the perception of diabetes as a problem were higher in the low health literacy group. It thus shows that the two groups of health literacy differed in terms of several outcomes variables regardless of time and intervention.

Despite limitations, this research suggests that although the outcomes are higher for patients with high health literacy, patients benefit from participating in a diabetes education programme, regardless of their health literacy level. The assumption that general health literacy would play a significant role in programmes' effectiveness was not supported. Regarding this hypothesis, a detailed scrutiny of the results suggest that functional diabetes health literacy slightly improved after

the intervention for patients with low health literacy but not for those with high health literacy, and, somewhat surprisingly, that communicative diabetes health literacy slightly decreased after the intervention for patients with high health literacy but not for those with low health literacy. Overall, however, it should be concluded that other variables are more important and influential than health literacy in predicting the effectiveness of diabetes self-management programmes.

# 3B.3 Evaluation of implementation fidelity

## 3B.3.1 Introduction

Implementation fidelity, the extent to which the intervention has been delivered as planned, implies a comparison between the implemented intervention and the original. Knowledge about the implementation process leads to a better understanding of what does or does not work, and can prevent a false attribution of the effectiveness. Evaluating implementation also could indicate which core components of a programme should be delivered as planned, and modifications support the positive effects of the intervention outcomes.

## 3B.3.2 Development and methodology

To investigate the impact of implementation fidelity on diabetes education effectiveness, a systematic literature review was conducted. It confirmed that very few studies consider the provider's fidelity in implementing the original programme, and even less studies assess the impact of the provider's adherence on the effectiveness. The review also showed that implementation fidelity can be measured through three channels: direct observation, indirect observation (e.g. video recording), or via self-report measures (questionnaire or interview) with the participants or providers. Each method has its advantages and disadvantages. In addition to the different measures, there are two main approaches to assess implementation fidelity. The critical component approach considers that a programme is made of core components that are essential to reach effectiveness. In contrast, the dimensional approach holds that implementation fidelity is a multidimensional concept, whereby each dimension can be assessed separately. Three dimensions are generally used: the adherence, the exposure and the quality.

A commonly used conceptualization of implementation fidelity is a model developed by Carroll. This model follows a dimensional approach but integrates the idea of critical components in one of its dimensions. It defines implementation fidelity as the provider's adherence to the initial content, duration, frequency and coverage of the programme. The model also considers that implementation fidelity may be influenced by different contextual and individual factors: the intervention complexity; the presence of facilitating strategies; the quality of delivery; and participant responsiveness. Two

additional influencing factors were added later by others: recruitment and context. As this offers a comprehensive framework to assess implementation fidelity, it was used as a logic model in project. In the next figure this model is presented.

Figure 8. Logic model of programme implementation fidelity



(Carroll & al., 2007 ; Hasson & al., 2010)
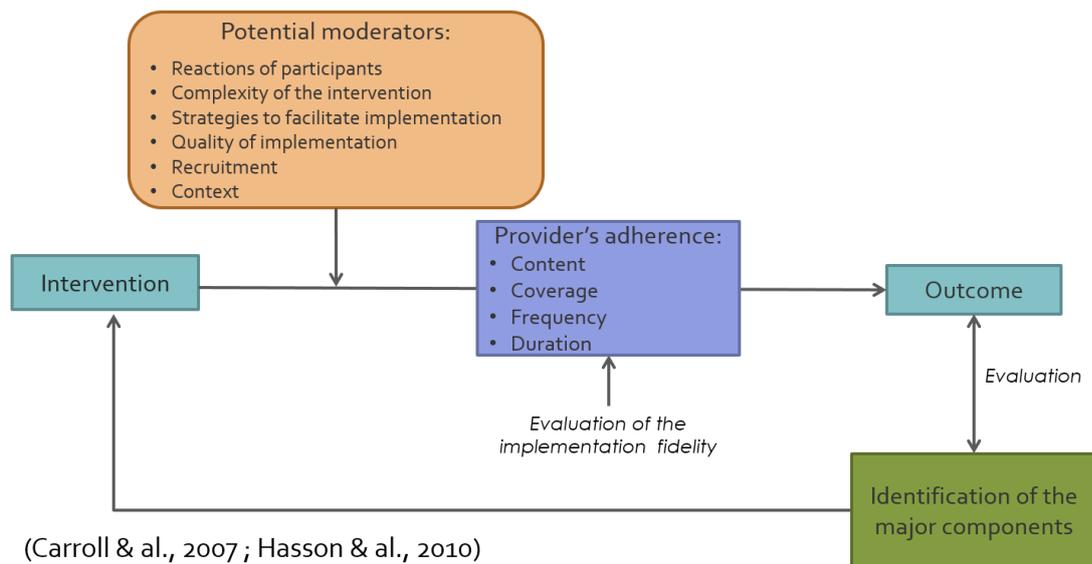
To assess the impact of implementation fidelity on the effectiveness of diabetes education programmes, data were used from the pre-post evaluation study. Self-management programmes were selected from existing programmes in Austria, Belgium, Germany, Ireland, the UK, Israel, Taiwan and the USA. As outlined earlier, patients who participated in these programmes were asked to complete the pre-assessment questionnaire, and were contacted by phone for the post-questionnaire three months later. Towards the end of the programme, providers of the selected programmes were invited to participate in a structured interview to assess implementation fidelity. The provider data were linked to those of the patients to investigate the relationship between the intervention outcomes (patient assessment level) and the implementer's adherence to the programme (provider assessment level). In total, 33 providers from 16 different programmes completed the structured interview. Their records were related to the responses of 166 diabetes patients.

Implementation fidelity was assessed using the format of a self-report questionnaire assessing the different dimensions and potential influencing factors of implementation fidelity. Respondents were asked to use a visual analogue scale to indicate the extent to which they had adhered to the content, duration, frequency, and coverage of the intervention compared to the original protocol. For each dimension, qualitative information was asked to specify what the programme was like originally, what it was like after the adaptation, and why the programme was changed. In addition, a series of items were presented to assess the different factors that may influence the intervention delivery: (a) factors related to the recipients, such as participants' responsiveness; (b) intervention complexity;

(c) the presence and the quality of facilitating strategies: i.e., training, protocol, feedback, and evaluation; (d) factors related to the provider; and (e) the favorability of the context. The questionnaire was created in French, and then translated into the different languages of the participating countries: English, German, Dutch, Hebrew, and Mandarin Chinese. Descriptive analyses of the provider data were performed on adherence to the programme content, duration, frequency and coverage, resulting in a general adherence score. Scores were also dichotomized to differentiate between providers who had adapted the programme from those who reported a total adherence. Logistic regressions were performed to test whether the potential influencing factors impacted on the provider's adherence to the programme. Analyses were performed to assess the impact of the providers' adherence (versus adaptation) on the patient outcomes, using diabetes health literacy, self-care behaviors, and general health and well-being as dependent variables. A further analysis included the providers' adherence to the content, duration, frequency and coverage.

### 3B.3.3 Implementation fidelity and intervention adaptation

Among the 33 providers, 13 reported total adherence to the programme protocol and 13 reported at least one adaptation. The providers who reported at least one adaptation provided self-management education to 49 participants involved in the study; those who reported total adherence were linked to 80 participants. The finding that more than a third of the providers reported a total adherence to the intervention is surprisingly high, as the tool that was used to assess implementation fidelity was designed to capture even small adjustments. A possible explanation for this finding may be the providers' tendency to overrate the adherence to the programme and to provide a favorable evaluation of their implementation. On the other hand, the fact that the "adapters" and "total adherers" came from different countries may reflect cultural differences in the way the instruction was given and/or the way adherence or adaptation is considered.

With regard to the reasons for adapting diabetes self-management programmes, it was assumed that the providers' likelihood to adherence to the programmes would depend on factors related to the recipients and the provider, the presence of facilitating strategies (i.e. protocol, feedback, evaluation) or the favorability of the context. The results of logistic regressions did not confirm this. A possible reason is the small number of providers involved. On the other hand, there is very little empirical research thus far that has tested the influence of the determinants of implementation fidelity. As such, the model we tested was hypothetical. The fact that we could not find support for the effect of these dimensions on programme adherence suggests that the model needs to be further refined.

The comparison between programmes with a total adherence versus adaptation did not show that implementation fidelity improved intervention effectiveness in the selected programmes. On the contrary, our research shows that some adaptations have a positive impact on some programme outcomes. More specifically, adaptations of the content or coverage of the intervention were associated with a higher improvement of critical diabetes health literacy. Adaptation of the programme duration was associated with more improvement of the participants' dieting behavior and general health. While it is not possible to fully ascertain if these differences can be attributed to the adaptation due to the different composition of the groups in terms of nationality, these findings suggest that adaptations may be positive. As such, the research supports the relevance of

distinguishing between different kinds of programme adaptations and between fidelity-consistent and fidelity-inconsistent adaptations. Fidelity-consistent modifications are defined as adaptations that do not significantly alter the core components of the intervention, while fidelity-inconsistent modifications refer to adaptations that reduce or cancel the delivery of intervention core components. Thus, it is likely that some of the reported adaptations, such as those with regard to the coverage (less participants that expected did actually participate) do not impact the effectivity of the programme, or even improve it, as it is easier to engage the participants in a smaller group.

This study shows that monitoring and evaluating the implementation of programmes sheds new light on factors that support effectiveness. Instead of focusing on total adherence to intervention protocols, adaptation of selected features to the needs of participant and/or context can be fruitful. This confirms the finding of recent studies which also indicate that programmes achieve better results when providers are allowed to make adjustments. Although this study has a number of limitations, it is the first study to assess the level of implementation fidelity of diabetes self-management education programmes in different countries using a generic instrument. Furthermore, adding to the debate between proponents of a strict implementation fidelity versus the need to adapt programmes to the needs of participants and the local context, our results tend to be in favor of fidelity-consistent modifications. Diabetes educators should pay attention to deliver the principal components of the education programmes, but they should also try to adjust the programmes to make them more suitable in a specific context. Further research is required to explore which kind of programmes can benefit from these adaptations and in which conditions

# C. Improvement

Improvement is the third main element of the Diabetes Literacy project. Work package 8 aimed to improve diabetes education by developing and testing accessible web-based support for patient self-management.

## 3C.1 Health literacy and health related digital interventions

### 3C.1.1 Introduction

The rapid growth in delivery of health promotion and health care by means of digital interventions offers one possible solution to have an alternative for the traditional face-to-face self-management education. These formats could be less accessible for people with lower health literacy levels, and have barriers such as work or caring responsibilities, cost, and lack of transport. By developing a web-based intervention 'health living with diabetes', the project aimed to address the risk that digital interventions could increase health inequalities due to a "digital divide" in both access to the Internet and confidence and skills to use the Internet for self-management of health.

## 3C.1.2 Development and methodology

In developing the 'healthy living with diabetes' web-based intervention, patient representatives and an international expert panel were involved. The web-based intervention was designed using tailoring, interactive features and audio-visual materials in order to assess how such intervention features may enhance accessibility and make it more suitable for people with lower levels of health literacy. Physical activity was identified by clinicians in the team as a priority area for managing type 2 diabetes, and therefore chosen as the focus of the intervention. The intervention was developed using LifeGuide software, a platform for developing online behaviour change interventions.

The intervention consisted of three main sections. The first was an interactive quiz intended to increase motivation to do physical activity by providing novel information about the negative consequences of inactivity and the benefits of physical activity for people with diabetes. The second section gave advice on how to increase the level of physical activity, tailored to the user's reported concerns about doing activity (e.g. dislike of exercise, lack of time or money). The third section was a physical activity planner; users were then encouraged to set a goal to slightly increase one or more of activities. In addition, the intervention contained seven 7 different audio-visual sequences that provided light-hearted accounts of how other people had increased their physical activity; six of these were tailored to age and gender. One of the intervention quiz questions was also tailored by gender, and some of the images throughout the intervention were tailored by age.

Figure 9: Visual examples of the intervention

| Example of physical activity advice / audio-visual | Example of physical activity planner |
|---|---|
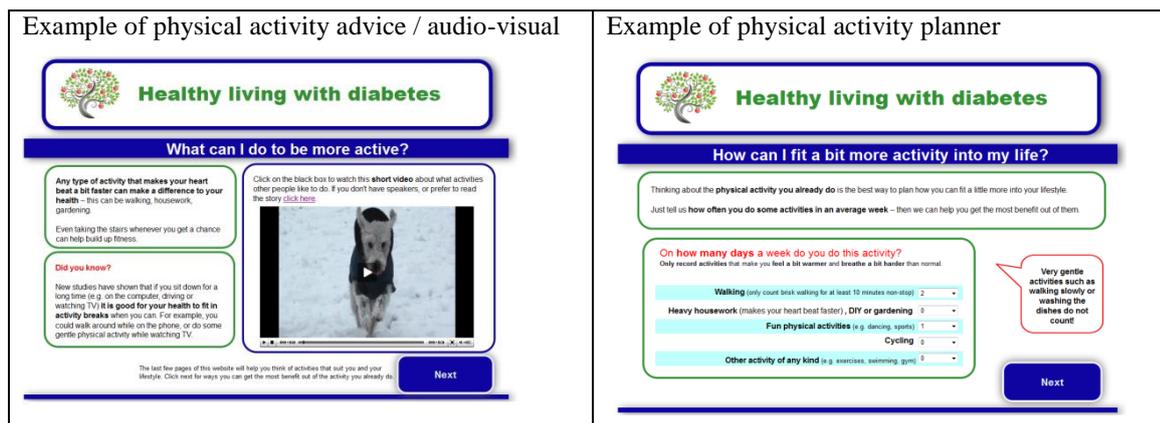


## 3C.1.3 Qualitative and quantitative research on web-based support

After initial development of the 'health living with diabetes' website, both qualitative and quantitative research was conducted. The objective of the qualitative research was to get feedback from patients from different countries who had used the materials. The objective of the quantitative research was testing the website.

The qualitative study was carried out with participants in the UK, Ireland, USA, Germany and Austria, who gave feedback on the intervention content, format, accessibility and acceptability of the 'healthy living with diabetes' intervention. The written and audio intervention content was translated. This qualitative study used observational 'think-aloud' interviews with adults of varying levels of health literacy. The 'think-aloud' interview method involves participants using the intervention as they normally would, while describing their thoughts and feelings about the intervention out loud. The analysis of the interview transcripts was carried out using inductive thematic analysis, where dominant themes were identified.  After identifying the common themes in the data, a second stage of analysis was performed to explore whether any systematic differences could be identified between specific sub-groups of participants. For this analysis a technique called 'constant comparisons' was used. 65 participants from five countries were interviewed for this study. Of these 65 participants, 38 (58%) were identified as having high health literacy, 18 (28%) as having medium health literacy, and 8 (12%) as having low health literacy.

The study revealed that the majority of the participants found the website format engaging and useful. Group comparisons between people with higher and lower levels of health literacy gave remarkably similar views. This suggests that it is possible to develop an intervention that is acceptable and accessible for people with varying levels of health literacy. It also suggests that it is possible to develop an intervention that is acceptable across several countries.

In a second study, a large-scale international quantitative experimental study was carried out in the UK, Ireland, Austria, Germany and Taiwan to compare the final interactive web-based materials to a plain text web-based version of the intervention. The plain text intervention contained the same content as the interactive version, but all tailoring, interactivity, and audio-visual features were removed. Participants completed online assessments at baseline (immediately before) and follow-up

(immediately after using the intervention materials). In total, 1045 persons participated in the quantitative study. Of these participants, 540 were randomly allocated to view the interactive intervention and 497 the plain text intervention. The comparison revealed that the interactive intervention overall did not produce better outcomes than a plain text version of the intervention. Participants in the plain text intervention group showed higher levels of engagement by completing more sections of the intervention, although this did not lead to better health literacy outcomes. Participants in both intervention groups' health literacy outcomes significantly improved as a result of looking through the web pages. These significant changes were found across all health literacy levels and all countries, with participants reporting significant changes in their beliefs and attitudes about physical activity, feeling more confident and in control of becoming more active, and a stronger intention to increase physical activity as a result of looking through either version of the web-pages. Diabetes knowledge, however, was significantly higher in the interactive group, indicating that the interactive quiz format may have been important for learning new information. Both interactive and plain text intervention groups reported high levels of enablement as a result of viewing the intervention materials, and both intervention groups were likely to recommend the intervention to friends or family with diabetes.

As the analysis by health literacy level revealed few differences, the results can be considered as an encouraging sign that the intervention design was accessible and helpful for people with low and high health literacy. Regardless of their health literacy level, participants reported high levels of enablement and said they would recommend the intervention to friends or family members with diabetes. The results of this study suggests that digital materials can be designed to improve health literacy and support self-management in people with all levels of health literacy, without increasing health inequalities. A good, clear design and person-based intervention development may be more important than interactivity and audio-visual presentations when developing accessible digital health interventions. This approach also allows intervention materials to be modified for use in different counties and cultures. In the future, well-designed digital communication materials can provide a cost-effective means of filling unmet need for support for self-management.

# 4. Key messages

Several key messages can be inferred from the work of the Diabetes Literacy project to improve the self-management education of diabetes patients.

Firstly, and most importantly, there is evidence of a growing acceptance that self-management education is a core component of diabetes care, with many European countries, but not yet all, incorporating self-management into their national programmes. Secondly, many different types of self-management education programmes already exist in Europe and in the other partner countries studied, providing a solid foundation upon which to build in the future. No evidence was found to suggest that any one approach to self-management education was significantly more effective than another, which implies that relatively cheaper forms of self-management education, such as group programmes, are as effective as one-to-one education. Thirdly, the project shows that currently only 50% of the people with diabetes in Europe take part in diabetes self-management education. Strong evidence was found that diabetes education is effective, although the quality of self-management education can still be improved. The implementation of effective and cost-effective programmes should be increased to make these programmes available and accessible to all patients in Europe.

An interesting finding was that self-management education was effective even when providers did not strictly adhere to the programme guidelines. In fact, adaptation of the programme by the trainers was sometimes associated with a greater improvement, particularly when the changes concerned the coverage rather than the content of the programme. On the other hand, it was also seen that self-education programmes do not always reach the patients who are most in need. Moreover, there seems to be an under-representation of peer-led self-management support and education, as well as an underdevelopment of IT-based programmes, suggesting that more work is needed in these areas.

The cost of diabetes self-management education varied widely between countries and between the different types of programmes operating within countries. However, compared with the overall cost of diabetes care, the cost of these programmes is relatively low. Since most programmes take at least 10 sessions to create positive health benefits, at on average a total cost of €100–150 per patient, diabetes self-management education can be considered a cost-effective intervention. The results of the project strongly indicate that costing of activities at the patient level using bottom-up costing methods provide the greatest opportunity to understand the relationship between cost and health outcomes achieved in the short, medium and long term. Using a bottom-up, micro-costing approach demonstrates that the cost of healthcare associated with chronic conditions is not fixed. Thus a key challenge is convincing policy makers of the need to invest in patient level costing infrastructures, which provide information, which can be used to inform the cost-effective reform of care provision.

Moreover, organizational context can impact effectivity. Monitoring patients' progress and evaluation of services will support organizational effectivity. There is also room for improvement to involve patients in the planning and adaptation of existing educational approaches. In addition, a broader range of professionals could be involved in self-management education, and the training of these professionals could be intensified and improved, with a greater focus on behavioural and psychosocial aspects of diabetes care. Further consideration could also be given to developing web-based diabetes education programmes for people with low health literacy levels. The study showed

that it is possible to develop IT-based programmes that engage people with lower health literacy, but are also acceptable for people with higher levels.

Finally, and crucially, the efficiency and cost-effectiveness of diabetes self-management education must be rigorously evaluated on an ongoing basis in order to expand.