

Enhancing the Effectiveness of Diabetes Self-Management Education: The Diabetes Literacy Project

Authors

S. Van den Broucke¹, G. Van der Zanden¹, P. Chang², G. Doyle³, D. Levin⁴, J. Pelikan⁵, D. Schillinger⁶, P. Schwarz⁷, K. Sørensen⁸, L. Yardley⁹, H. Riemenschneider⁷

Affiliations

Affiliation addresses are listed at the end of the article

Key words

- type 2 diabetes
- diabetes self-management
- health literacy
- implementation fidelity
- patient level costs of T2D

Abstract

Patient empowerment through self-management education is central to improving the quality of diabetes care and preventing Type 2 Diabetes. Although national programs exist, there is no EU-wide strategy for diabetes self-management education, and patients with limited literacy face barriers to effective self-management. The Diabetes Literacy project, initiated with the support of the European Commission, aims to fill this gap. The project investigates the effectiveness of diabetes self-management education, targeting people with or at risk of Type 2 Diabetes in the 28 EU Member States, as part of a comprehensive EU-wide diabetes strategy. National diabetes strategies in the EU, US, Taiwan, and Israel are compared, and diabetes self-management programs inventorized. The costs of the diabetes

care pathway are assessed on a per person basis at national level. A comparison is made of the (cost)-effectiveness of different methods for diabetes self-management support, and the moderating role of health literacy, organization of the health services, and implementation fidelity of education programs are considered. Web-based materials are developed and evaluated by randomized trials to evaluate if interactive internet delivery can enhance self-management support for people with lower levels of health literacy. The 3-year project started in December 2012. Several literature reviews have been produced and protocol development and research design are in the final stages. Primary and secondary data collection and analysis take place in 2014. The results will inform policy decisions on improving the prevention, treatment, and care for persons with diabetes across literacy levels.

received 02.05.2014
accepted 20.08.2014

Bibliography

DOI <http://dx.doi.org/10.1055/s-0034-1389952>
Published online: 2014
Horm Metab Res
© Georg Thieme Verlag KG
Stuttgart · New York
ISSN 0018-5043

Correspondence

Prof. S. Van den Broucke
Institut de Recherche en
Sciences Psychologiques
Université catholique de
Louvain
Place Cardinal Mercier 10
1348 Louvain-la-Neuve
Belgium
Tel.: +32/10/479 046
Fax: +32/10/473 774
stephan.vandenbroucke@uclouvain.be

Introduction

Diabetes mellitus is the fourth largest cause of death in the European Union (EU). Approximately 32 million people in the EU live with Type 2 Diabetes, many of whom are unaware of their condition. Across Europe, 300 000 people die from diabetes and related complications each year. As the treatment of diabetes is costly, diabetes care takes up a significant amount of the health costs, with a share varying between 5 and 15% of the total health expenditure depending on the country [1]. Type 2 Diabetes (T2D) is strongly associated with being overweight and obese, the prevalence of which is rapidly increasing in the EU and worldwide both in adults and children [2]. It has been established that even childhood obesity is associated with features of the metabolic syndrome, including insulin resistance and disturbed glucose metabolism [3]. In conjunction with the demographic evolution towards an age-

ing population and changing food environments, the prevalence of T2D is set to increase in the years to come [4]. In consequence, diabetes care will represent an even larger proportion of the healthcare expenditure across the EU and elsewhere.

In view of these developments, actions to improve the quality of treatment and care of diabetes as well as further preventive measures are called for [5–10]. This implies that the capacities of the health systems in the EU Member States (EU MS) with regard to treatment and care for diabetes must be strengthened. Presently, 18 of the 28 EU MS have introduced national diabetes plans or policy frameworks. The most successful of these pay attention to psychosocial as well as medical factors, by promoting quality of care and services as well as the enhancement of the autonomy of the patients through therapeutic education [11]. Other crucial success factors include an investment in primary prevention of

obesity and of lifestyle related diseases, early detection of diabetes, efficient systems for patient follow-up, multidisciplinary competences of health care professionals, and access to educational information and to high quality care services.

One of the critical success factors to address diabetes is the investment in the self-management capacity of patients. Because diabetes requires extensive self-care, the capacities of patients to manage their own illness and care process are considered a key determinant of treatment outcomes. To enhance these capacities, education of persons with diabetes is widely recommended. However, whereas an investment in diabetes self-management education (DSME) would seem an effective way to increase effectiveness and reduce the cost of diabetes, several questions must be addressed before the large scale implementation of such education can be recommended as part of a comprehensive diabetes strategy.

First, while DSME and lifestyle modification for people with diabetes has been shown to have positive outcomes [12,13], the cost-effectiveness of these interventions is not sufficiently substantiated. Previous research suggests that there is a lack of individual cost information at the level of the provider, which makes comparisons at a provider, national and EU level difficult. Second, while the effectiveness of DSME education could be enhanced by methods using information technology (IT) or the involvement of self-help groups, the relative effectiveness of these approaches has not been well researched. Third, the success of a diabetes education program depends on the quality of its implementation, which in the case of diabetes self-management (DSM) has hardly been researched at all. As such, the enhancement of the implementation fidelity (IF), or the degree to which a program is delivered as intended [14], could optimize the conditions under which DSME is provided, and thus contribute to the effectiveness of these programs. Fourth, the effectiveness of DSME also depends on various patient characteristics. Apart from age, sex and ethnicity, the level of health literacy plays a key role [15]. Low health literacy has been linked to poor health outcomes for a number of conditions, including diabetes. However, while low literacy is likely to impede self-management, its moderating role in improving self-management behaviors in persons with diabetes, especially via internet-based programs, has not yet been systematically investigated. Providing patients with literacy-appropriate diabetes education materials may therefore be an effective strategy for imparting skills necessary for DSM [16]. Finally, the (cost-) effectiveness of DSME also depends on the organization of the health services. Key elements that determine the quality of the health system with regard to treatment and care for diabetes include easy access to care, the availability of professionals with multidisciplinary competences, an efficient information system allowing patient follow-up, and continuous evaluation of care.

The Diabetes Literacy (DL) Project aims to investigate these issues with a view to make evidence-based recommendations to increase the effectiveness of DSME, as part of a comprehensive diabetes strategy at EU level. By collecting and analyzing evidence regarding patient education programs targeting people with T2D or at risk of T2D in the EU and 3 selected non-EU countries, it builds an evidence base to inform policy decisions on improving the prevention, treatment and care for persons with diabetes across literacy levels. The specific objectives of the project are to (1) perform a comparative analysis of national diabetes strategies across the 28 EU MS and 3 non-EU nations; (2) compile a compendium of DSME programs in the 28 EU MS; (3)

document the existing costing practices for T2D at the national level; (4) develop an appropriate patient level costing methodology for T2D and estimate the comparative cost of T2D education per patient; (5) compare the relative effectiveness and cost-effectiveness of existing individual, group, and IT-based DSME and self-help programs; (6) assess the moderating impact of low health literacy on the effectiveness of DSME programs, differentiating between individual, group, IT-based, and self-help programs; (7) assess the role of multidisciplinary competent professionals, patient follow-up systems, and evaluation of services as conditions for DSME effectiveness; (8) assess the role of implementation fidelity for the effectiveness of DSME programs; (9) determine whether interactive and audiovisual features of internet delivery-based DSME education materials can improve engagement and health literacy; and (10) make recommendations for the development of best practice models for DSME as part of a comprehensive diabetes strategy at EU level.

Methods



Structure and general method of the project

The Diabetes Literacy consortium (DL Consortium) involves partners from 6 EU MS (Belgium, Germany, Ireland, Austria, Netherlands, and the UK) and 3 non-EU countries (USA, Israel, and Taiwan). Collaborating partners from Denmark and South Africa also participate in the project (www.diabetesliteracy.eu). The Consortium represents expertise in the fields of diabetology, health services research, public health, health economics, health care costing, health psychology, sociology, health communication, health education and promotion, and health literacy. Formal meetings of the Consortium are organized twice per year. The project is organized into 9 work packages (WPs) (● Fig. 1). The first 2 WP are concerned with the management of the project, with WP1 focusing on the overall management and WP2 on the internal evaluation of the project tasks, to avoid risks and ensure that the objectives will be reached. The other WP are concerned with primary and secondary data collection and analyses to meet the project objectives. WP3 focuses on the analysis of national diabetes strategies and on the inventory of DSME programs. A sample of programs in the inventory will be selected for the other WPs. WP4 develops a patient level costing method for T2D and evaluates the costs of diabetes education at a national level. WP5 compares the (cost-) effectiveness of individual, group, and IT-based DSME programs. WP6 considers the conditions for program effectiveness and the impact of health literacy on program outcomes, while WP7 will analyze the impact of implementation fidelity on DSME programs. WP8 will pilot literacy-appropriate IT-based self-management materials. Finally, WP9 will integrate the results of the different WPs and formulate recommendations for best practice models for DSME and disseminate these to stakeholders at national and EU level.

Comparative analysis of national diabetes strategies and programs

To assess diabetes strategies in the 28 European MS, the project undertakes a comparative analysis involving different diabetes-related stakeholder groups, with a view to making an annotated compendium of DSME programs in the EU. The variation of DSME programs across the EU helps to identify gaps and barriers in diabetes education management. The comparative analysis is based on information collected by the Diabetes Literacy Survey

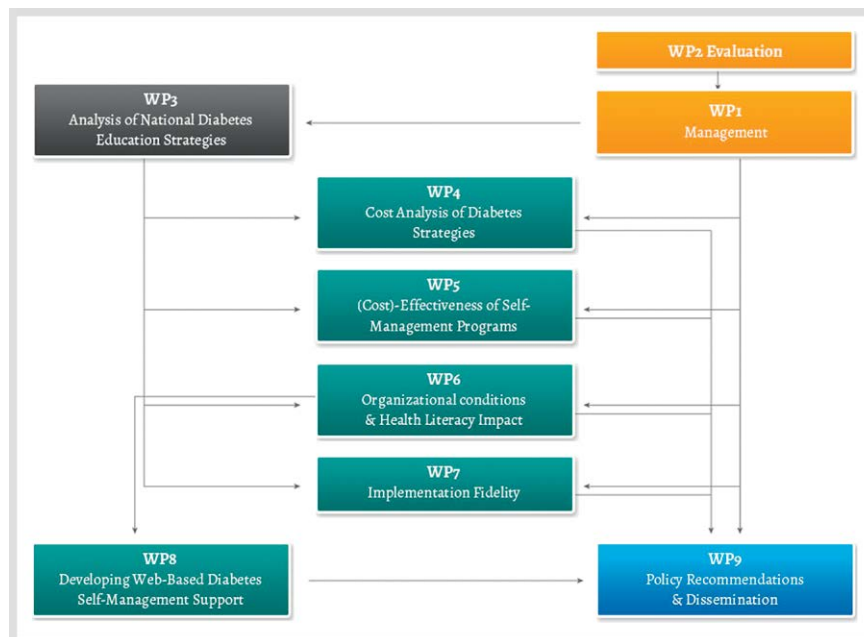


Fig. 1 Structure of the Diabetes Literacy Project (color figure available online only).

(DLS), which consists of 2 online instruments in several languages, built consensually by a multiple Delphi process carried out within the consortium. The first instrument is a questionnaire to determine the diabetes education conditions in the EU; the second is an online wiki tool to collect data on existing educational programs for diabetes and pre-diabetes prevention.

The survey is conducted in partnership with the Global Diabetes Survey (GDS), which is an initiative to collect data on diabetes care quality on a yearly basis carried out on the initiative of one of the Consortium partners (TU Dresden) [17]. Previous GDS members and the large networks of the DL Consortium are invited through online networking, personal contacts, and public calls to register and complete the DLS online on <http://www.globaldiabetessurvey.com/>. The aim is to obtain a participation rate of 1 per 100 000 people with diabetes. The target group are all those who are directly or indirectly involved in the care of people with T2D or people at risk of T2D, T2D patients and their families, health professionals and researchers as well as patient organizations. Experiences and insights of the respondents concerning the state of DSME in their region are assessed.

The wiki tool serves to collect data on DSME programs from more than one person or organization. Titles of DSME programs are selected from the survey, and participants have the possibility to add, edit, or delete information about a specific program. After completion of the survey, data regarding the survey and wiki will be made anonymous. For country-specific analyses, results will be averaged, since the point of view of the individual actors regarding the care process can differ according to the type of group they belong (patients, care providers, other stakeholders). The training programs recorded on the wiki will be made publicly available to enable searching.

Parallel to the survey, a literature search is performed using a wide range of sources to trace DSME programs that have not been evaluated or for which results have not been published. As a next step, experts from the countries that report DSME programs will be invited to validate the information via personal interviews, and the author or main user of the DSME program will be identified and interviewed. This information will then be compiled in the form of a compendium.

Cost analysis of diabetes strategies

In economic and health terms, diabetes is costly to both the individual and the health care system. The Code-2 study involving 8 EU MS estimated direct diabetes-related healthcare costs at €2834 per person, per annum [18]. According to the recent IDF Atlas, which estimates the mean diabetes-related expenditures per person with diabetes at world level, expenditures of countries participating in the DL Project range from USD 1129 (Taiwan) to USD 9800 (US), and for the EU MS involved in the project between USD 3994 (UK) and USD 6667 (Netherlands) [19]. Contrary to diabetes-related expenditure, the cost-effectiveness of DSME and lifestyle modification for people with diabetes has not been sufficiently substantiated. Moreover, the lack of individual patient cost information at provider and national level makes comparisons at national or EU level difficult. To date, cost accounting across the EU has mostly employed a top-down method, whereas bottom up costing methods, in particular activity based costing (ABC), produce higher quality data. ABC is a cost calculation system that allocates costs to activities and resources based on consumption, which can be gathered at the patient level over a full cycle of care [20–22]. Current costing methodologies seek to relate the patient level costs with the health outcomes for the patient.

To understand differences in approaches to costing health care and within and across health systems, the DL Project focuses specifically on the patient level (micro) costs of T2D care in Europe. As a first step, a thematic literature review has been carried out of the ABC methodology as applied to health care services and the derivation of patient level costs. In the second step, existing cost practices across each health system in the 6 EU countries and 3 non-EU countries participating in the DL Project are documented using a mixed methods approach involving qualitative expert interviews of national costing practices and survey data collection of cost allocation methods in clinical settings. In order to collect cost allocation information in a uniform way, we will administer an online survey of cost allocation methods which is comparable to the Materiality and Quality Score (MAQS) of the UK based Healthcare Financial Management Association (HFMA) [23]. Based on step 1, we propose an appropriate patient level costing method for T2D underpinned

by activity based costing principles. This method is in the first instance applied in Ireland, whereby a cost analysis of the existing T2D care pathways is currently being conducted in the diabetes clinics of an acute care setting and a community care setting. Differences in care-related activity, time, resource consumption, and cost of care provision will be shown between exemplar clinical cases of T2D patients who illustrate different levels of acuity. In a final step, we will apply this costing method in selected countries of the project Consortium. Following the application and further model refinement, we will then propose a best-practice patient-level costing model for T2D.

Effectiveness of DSME programs

An important objective of the DL Project is to evaluate DSME programs with regard to their effectiveness and cost-effectiveness. This will be accomplished by a pre-post evaluation study of 4 different kinds of programs, distinct by their mode of delivery: (a) individual education in one-on-one sessions, (b) group-based education, (c) self-help groups, and (d) IT and web-based education. An assessment of the literature shows that existing studies do not allow to conclude whether certain channels for T2D DSME interventions are more effective than others. This is mainly due to the large disparity of outcome measures used, along with a wide range of psychological, social, behavioral, clinical and wellbeing outcomes.

To achieve more consistency, the current project developed a Diabetes Self-Management Outcome Framework (DSMOF). This framework incorporates the 7 health care behaviors that are at the core of the AADE7 framework developed by the American Association of Diabetes Educators (AADE) [24], which is essentially an attempt to order possible DSM outcomes according to when they are measurable. However, as other categories in the AADE framework are not as distinctive to assess the nonbehavioral outcomes that are often reported in evaluations of diabetes interventions, the DSMOF takes a broader approach and considers elements at 4 levels: (a) *program form*, such as program content and other characteristics; (b) *first-order outcomes*, which refer to strategies that are related to the change process of individuals and individual DSM dispositions; (c) *behavioral outcomes*, referring to the AADE7 behaviors; and (d) *clinical and psychological outcomes*, as a more distal outcome level.

Using this framework, outcomes indicators have been selected for inclusion in a controlled pre-post evaluation study that will assess and compare the impact of different delivery modes of DSM programs (individual, group-based, self-help, IT-based) in terms of different outcomes. Data will be collected in different programs across countries, whereby sites will be pooled for the analysis. As the success of the trial also depends on external circumstances such as the existence and access to eligible programs, a more general aim is to compare interventions that involve individual education with interventions that do not.

The role of health literacy

An important element in evaluation of effectiveness of DSM programs will be health literacy. Health literacy is linked to literacy and entails people's knowledge, and competences to access, understand, appraise, and apply health information in order to make judgments and take decisions in everyday life concerning healthcare, disease prevention and health promotion to maintain or improve quality of life during the life course [25]. There is a growing body of research linking poor health literacy to increased use of services, poor adherence to medical instruc-

tions, poorer health status, and higher mortality [26]. As such, inadequate health literacy contributes to the disproportionate burden of diabetes-related problems among those affected [27]. Persons with diabetes and with limited health literacy are also less likely to access internet-based patient information [28], which means that those most at risk will fall further behind if health systems increasingly rely on nontailored internet-based services.

To assess the impact of low health literacy on program outcomes, the project will use the Short Form of the European Health Literacy Survey Questionnaire (HLS-EU-Q) [29] to measure the level of health literacy of the patients participating in the programs selected for the pre-post evaluation study, and relate it to the outcome measures.

Organization of diabetes care

At program level, the conditions for effectiveness in the organization of diabetes care will also be studied. Of particular interest is the role of multi-disciplinarily among staff, patient follow-up and the design of the DSME services. To complement the results of the DLS and wiki, an in-depth analysis will be performed of selected programs that seem to perform well on a number of indicators. Qualitative semi-structured interviews will be used with a focus on particular enabling and hindering organizational factors influencing conditions for program effectiveness.

Implementation fidelity of DSME

The success of a DSME program not only depends on the strategy that is used, but also on the quality with which it is implemented. A key element of implementation quality is its fidelity, or the degree to which the intervention is delivered as intended [14]. The principal component of IF is adherence, the degree to which the active ingredients of the intervention have been delivered to the participants with the planned frequency, duration and intensity. The level of IF is moderated by interrelated variables. Important variables are (a) intervention complexity, (b) facilitation strategies, (c) provider characteristics, (d) participant responsiveness, (e) participant recruitment; and (f) the cultural and organizational context [30].

Existing reviews of studies of DSME indicate that program guidelines are often poorly implemented, and that studies seldom provide sufficient detail of the implementation to consider replication [31]. As such, having information about the IF can help to understand why the intervention was successful or not. In addition, it can help to identify which components have been adapted and how these adaptations have influenced the outcomes [32]. Therefore, the DL project will develop an assessment tool to operationalize relevant IF dimensions for DSME programs, using documentation complemented by information deriving from telephone interviews with key informants. The results in terms of adherence, exposure, program delivery, participant responsiveness, recruitment and context will be related to the effectiveness of the programs concerned.

Web-based support for DSME

Access to and use of the internet via PC or mobile phone is becoming very common, even among relatively disadvantaged groups. However, previous studies of web-based DSM 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. As it is expected that in the future IT-based DSME interventions will increase,

one of the objectives of the DL Project is to determine how to make internet-delivered support accessible and engaging for people with lower levels of health literacy. In particular, the project will examine the potential for web-based materials and tools to provide enhanced support by (a) tailoring the material to the particular needs, abilities and perspective of the user; (b) employing engaging audio-visual presentation and quiz formats; and (c) providing simple interactive tools to support self-management tasks.

As a first step, core components of web-based patient self-management resources to increase motivation and confidence to increase physical activity have been selected, based on the input of an expert panel of members of the DL Consortium, clinicians, and patient representatives from the participating countries in the project. In a second task, web-based materials that can be accessed by PC are being developed in English and German, using the LifeGuide software which permits rapid duplication and modification of web-based interventions without the requirement for extensive programming [33].

To gain an in-depth understanding of users' views and usage of the materials and tools, a series of qualitative analyses will be undertaken, including observational think-aloud studies. The study will explore how people with varying levels of health literacy experience different online formats of delivering health information. Think aloud procedures allow the researchers to identify problems and barriers the user might experience while using the website [34]. To ensure a sufficient range of views, the sample of patients with diabetes from different countries will include a varied profile of participants including different times since diagnosis of T2D and different levels of health literacy. The finalized materials (website) will be evaluated in a series of small randomized trials, assessing if the interactive and audio-visual features of internet delivery improve engagement and health literacy, particularly in people with lower levels of health literacy. Persons with T2D from primary and specialty care and self-help group web-sites will be recruited, over-sampling from deprived areas to ensure adequate representation of people with low health literacy levels. The control group will receive the same information, but without any interactivity or audiovisual content. This will be a proof-of-concept study that will seek to demonstrate immediate effects on user engagement and changes in known predictors of behavior.

Conclusions

Diabetes requires extensive self-care, and the self-management capacity of patients is considered critical for successful diabetes management. To improve the effectiveness of diabetes management education, the DL Project will perform a comparative analysis of diabetes strategies in the EU, assess patient level costs of T2D care using the principles of activity based costing, conduct an evaluation study to assess whether certain DSME formats are more effective than others, and consider organizational conditions and implementation quality on program effectiveness. As patients with limited health literacy have been shown to struggle with diabetes self-management, the project will also consider the impact of health literacy on program effectiveness and examine the potential for web-based materials to be used in DSME programs for people with lower levels of health literacy. The findings of the project will be translated into recommendations for policies, through policy dialogues, a conference, and

discussions with national and EU stakeholders from practice, policy and research. By contributing to the evidence base to increase the effectiveness of diabetes self-management education in the EU Member States, the results of the project will give input for policy decisions on improving the treatment and care of different patient groups as well as the prevention of diabetes. The results will be used to formulate recommendations for the development of best practice models for DSME that can be used in the development of a comprehensive diabetes strategy at EU level for patients of varying literacy levels. Improving diabetes literacy through diabetes self-management education must be a focus to effectively fight the consequences of the growing number of people suffering with diabetes and to increase the quality of care of diabetes while maintaining costs.

Since the role of self-management is not only of great significance for patients with diabetes but extends to other chronic diseases as well, the recommendations and focus on patient education and health literacy in the DL Project can also be extended and applied to other chronic diseases. Therefore, the results of this project will be actively disseminated to scientists, health professionals, patient organizations, policy makers, and other stakeholders.

Acknowledgements

This article is a deliverable of the Diabetes Literacy project supported by grant FP7-Health-2012-Innovation-1/306186 of the European Commission. The authors would like to thank the partners of the Diabetes Literacy Consortium for contributing to the content of this article.

The Diabetes Literacy Consortium consists of the following members:

- Université Catholique de Louvain, Belgium: Stephan Van den Broucke Ph.D.; Gerard Van der Zanden MA; Marie Housiaux Ph.D.; Louise Schinckus MA; Loveness Dube MA MPH.
- Technische Universität Dresden, Medical Faculty, Germany: Peter Schwarz M.D., Ph.D.; Henna Riemenschneider MA MPH; Gabriele Mueller MPH; Caroline Lang MPH; Antje Linder; Thoralf Stange.
- University College Dublin, Quin School of Business, Ireland: Gerardine Doyle Ph.D.; Sarah Gibney Ph.D.
- Ludwig Boltzmann Institute for Health Promotion Research, Austria: Jürgen Pelikan Ph.D.; Florian Röthling M.Sc.; Kristin Ganahl.
- Maastricht University, Department of International Health, The Netherlands: Helmut Brand M.D., Ph.D.; Kristine Sørensen Ph.D.; Timo Clemens MPH.
- University of Southampton, UK: Lucy Yardley Ph.D.; Don Nutbeam Ph.D., Paul Little Ph.D., Ingrid Muller Ph.D.; Ali Rowsell.
- CLALIT Health Services, Israel: Diane Levin Ph.D.; Ziv Har-Gil MPH.
- University of California at San Francisco, USA: Dean Schillinger M.D., Ph.D.; Courtney Lyles Ph.D.
- Taipei Medical University, Taiwan: Peter Chang M.D., Ph.D., Duong Van Tuyen, Alice Lin, Candy Kuo, Jenny Jao.

Conflict of Interest

The authors declare that they have no conflict of interest in the authorship or publication of this contribution.

Affiliations

- ¹ Université catholique de Louvain, Louvain-La-Neuve, Belgium
- ² Taipei Medical University, Taipei Hospital, MOHW, Taipei, Taiwan
- ³ University College Dublin, Dublin, Ireland
- ⁴ Clalit Health Services & University of Haifa, Tel Aviv, Israel
- ⁵ Ludwig Boltzman Institute of Health Promotion Research, Vienna, Austria
- ⁶ University of San California at San Francisco, San Francisco, USA
- ⁷ Technical University Dresden, Dresden, Germany
- ⁸ Maastricht University, Maastricht, The Netherlands
- ⁹ University of Southampton, Southampton, UK

References

- 1 Health Service Executive. National Service Plan. 2011
- 2 Hjartaker A, Langseth H, Weiderpass E. Obesity and diabetes epidemics: cancer repercussions. *Adv Exp Med Biol* 2008; 630: 72–93
- 3 Blüher S, Molz E, Wiegand S, Otto KP, Sergeev E, Tuschy S, l'Allemand-Jander D, Kiess W, Holl R for the APV initiative and the German Competence Net Obesity. Body Mass Index, waist circumference, and waist-to-height ratio as predictors of cardiometabolic risk in childhood obesity depending on pubertal development. *J Clin Endocrinol Metab* 2013; 98: 3384–3393
- 4 The diabetes pandemic. *Lancet* 2011; 378: 99
- 5 Schwarz PE, Lindstrom J, Kissimova-Scarbeck K, Szybinski Z, Barengo NC, Peltonen M, Tuomilehto J. The European perspective of type 2 diabetes prevention: diabetes in Europe – prevention using lifestyle, physical activity and nutritional intervention (DE-PLAN) project. *Exp Clin Endocrinol Diabetes* 2008; 116: 167–172
- 6 Schwarz PE, Muylle F, Valensi P, Hall M. The European perspective of diabetes prevention. *Horm Metab Res* 2008; 40: 511–514
- 7 Pajunen P, Landgraf R, Muylle F, Neumann A, Lindström J, Schwarz PE, Peltonen M on behalf of the IMAGE Study Group. Quality indicators for the prevention of type 2 diabetes in Europe – IMAGE. *Horm Metab Res* 2010; 42 (Suppl 1): S56–S63
- 8 Lindstrom J, Neumann A, Sheppard KE, Gilis-Januszewska A, Greaves CJ, Handke U, Pajunen P, Puhl S, Pölönen A, Rissanen A, Roden M, Stemper T, Telle-Hjellset V, Tuomilehto J, Velickiene D, Schwarz PE, on behalf of the IMAGE Study Group. Take action to prevent diabetes – the IMAGE toolkit for the prevention of type 2 diabetes in Europe. *Horm Metab Res* 2010; 42 (Suppl 1): S37–S55
- 9 Paulweber B, Valensi P, Lindstrom J, Lalic NM, Greaves CJ, McKee M, Kissimova-Skarbek K, Liatis S, Cosson E, Szendroedi J, Sheppard KE, Charlesworth K, Felton A-M, Hall M, Rissanen A, Tuomilehto J, Schwarz PE, Roden M on behalf of the IMAGE Study Group. A European evidence-based guideline for the prevention of type 2 diabetes. *Horm Metab Res* 2010; 42 (Suppl 1): S3–S36
- 10 Schwarz PE, Greaves CJ, Lindstrom J, Yates T, Davies MJ. Nonpharmacological interventions for the prevention of type 2 diabetes mellitus. *Nat Rev Endocrinol* 2012; 8: 363–373
- 11 Fond-Harmant L. Diabetes plans in six European countries and in Canada. *Sante Publique* 2011; 23: 41–53
- 12 Boren SA, Fitzner KA, Panhalkar PS, Specker JE. Costs and benefits associated with diabetes education: a review of the literature. *Diabetes Educ* 2009; 35: 72–96
- 13 Minet L, Moller S, Vach W, Wagner L, Henriksen JE. Mediating the effect of self-care management intervention in type 2 diabetes: a meta-analysis of 47 randomised controlled trials. *Patient Educ Couns* 2010; 80: 29–41
- 14 Carroll C, Patterson M, Wood S, Booth A, Rick J, Balain S. A conceptual framework for implementation fidelity. *Implement Sci* 2007; 2: 40
- 15 Boren SA. A review of health literacy and diabetes: opportunities for technology. *J Diabetes Sci Technol* 2009; 3: 202–209
- 16 Wallace AS, Seligman HK, Davis TC, Schillinger D, Arnold CL, Bryant-Shilliday B, Freburger JK, DeWalt DA. Literacy-appropriate educational materials and brief counseling improve diabetes self-management. *Patient Educ Couns* 2009; 75: 328–333
- 17 Schwarz PEH, Gallein G, Ebermann D, Müller A, Lindner A, Rothe U, Tibor Nebel I, Müller G. Global Diabetes Survey – An annual report on quality of diabetes care. *Diabetes Res Clin Pract* 2013; 100: 11–18
- 18 Massi-Benedetti M. The cost of diabetes Type II in Europe: the CODE-2 Study. *Diabetologia* 2002; 45: S1–S4
- 19 International Diabetes Federation. Diabetes Atlas. 6th edition. International Diabetes Federation, 2013
- 20 Anderson W. Managing costs and cost structure throughout the value chain: research on strategic cost management. *Handbooks of Management Accounting Research* 2006; 2: 481–506
- 21 Kaplan RS, Porter ME. How to solve the cost crisis in health care. *Harvard Business Review* 2011; 89: 46–52
- 22 Chapman CS, Kern A, Laguerre A, Angele-Halgand N, Angert A, Campanale C, Cinquini L, Doyle G, Garrot T, Hansen A, Hartmann F, Hinz V, Mateus C, Perego P, Sikkut R, Tenucci A, Quentin Q. International approaches to clinical costing. *Healthcare Financial Management Association*. London: 2013
- 23 Healthcare Financial Management Association. Acute health clinical costing standards 2012/13. London: 2012
- 24 AADE7. Self-Care Behaviors. *Diabetes Educ* 2008; 34: 445–449
- 25 Sorensen K, Van den Broucke S, Fullam J, Doyle G, Pelikan J, Slonska Z, Brand H for the European Health Literacy Consortium. Health literacy and public health: a systematic review and integration of definitions and models. *BMC Public Health* 2012; 12: 80
- 26 Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. *Ann Intern Med* 2011; 155: 97–107
- 27 Schillinger D, Grumbach K, Piette J, Wang F, Osmond D, Daher C, Palacios J, Diaz Sullivan G, Bindman AB. Association of health literacy with diabetes outcomes. *JAMA* 2002; 288: 475–482
- 28 Sarkar U, Schillinger D, Lopez A, Sudore R. Validation of self-reported health literacy questions among diverse English and Spanish-speaking populations. *J Gen Intern Med* 2011; 26: 265–271
- 29 HLS-EU Consortium. Comparative report of health literacy in eight EU Member States. The European Health Literacy Survey HLS-EU. <http://www.health-literacy.eu.2012> (22 June 2014 last accessed)
- 30 Hasson H. Systematic evaluation of implementation fidelity of complex interventions in health and social care. *Implement Sci* 2010; 5: 67
- 31 Norris SL, Engelgau MM, Venkat-Narayan KM. Effectiveness of self-management training in type 2 diabetes. A systematic review of randomized controlled trials. *Diabetes Care* 2001; 24: 561–587
- 32 Schinckus L, Van den Broucke S, Housiaux M. Assessment of implementation fidelity in diabetes self-management education programs: A systematic review. *Patient Educ Couns* 2014; 96: 13–21
- 33 Morrison L, Joseph J, Andreou P, Yardley L. Application of the lifeGuide: a think-aloud study of users' experiences of the 'internet doctor'. In 5th International Conference on e-Social Science, Cologne, Germany, 24–26 Jun 2009; 2010: 4
- 34 Charters E. The use of Think-aloud Methods in Qualitative Research An Introduction to Think-aloud Methods. *Brock Education* 2003; 12: 68–82