Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks.

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Abstract	This deliverable contains a review of existing disease management strategies, including the application of information technology which can be used to support disease management strategies. This assessment contains both, a literature review of the theoretical literature and scientific evidence relating to disease management strategies and an empirical analysis of existing disease management strategies and IT support for such strategies in countries of REACTION partners. Lastly there is a review of existing predictive risk models and multi-parametric risk assessment methods, both long-term and short-term.
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1 Executive summary

The idea of integrated health care and the development towards a comprehensive and entire health care system became popular in the last decades. Disease Management (DM) in its modern form can be interpreted as integrated care for chronic diseases. The underlying aims of the Saint Vincent Declaration support the establishment of disease management programmes. Elements of Disease Management Programmes (DMP) include personal care plans, systematic patient care (regular reviews, patient education), quality improvement (such as indicators and data sharing), evidence-based clinical practice decision support, prevention strategies and pro-active care teams.

The assessment of efficiency and efficacy of disease management programmes can be conducted for the whole programme or single DMP elements. A considerable number of studies have been conducted to assess the impact of DMPs in the area of diabetes care with around one-third of these programmes demonstrating significant improvements in outcomes such as satisfaction, knowledge, adherence and some intermediate clinical outcomes. Long-term effects on mortality and quality of life are not yet known. The most successful interventions are complex and consist of several components.

For DMP programmes for chronic conditions to be successful, data needs to be collected and analysed on different levels of the health care system, by users such as health care providers, patients or decision makers. Therefore integrating information systems is necessary – on a technical level as well as on care level- for supporting the implementation of disease management programmes.
The results of the studies in this literature review show that the use of ICT within diabetes care is associated with an improvement in the quality of processes and the patient outcomes, although further research is necessary to integrate ICT in health care. Information technologies are important for the success of a DMP, but are needed across all sectors and at all levels to be able to support the aims of disease management for chronic conditions. Barriers to the adoption of information technology in diabetes care are: data privacy, insufficient financing, lack of personnel and time, fear of change. The acceptance and implementation of information technologies can be supported through user training and integration in daily practice care. Despite the lack of long-term, robust evidence, there are still high expectations of information technology for improving the quality of health care and even reducing costs.

A survey of REACTION partner countries was undertaken to establish to what extent national plans and disease management programmes concerning diabetes have been implemented. The results of the empirical analysis showed that DMP strategies and components exist in most partner countries although the exact scope and content varies considerably, as does the extent to which IT measures have been put in place to support the programmes. For many countries there is still progress to be made towards establishing agreed care plans with personal goal settings, although systematic patient care (e.g. named patient contacts, regular reminders for visits and patient education) is more established. Electronic patient data is commonly available within institutions and health care professionals within the individual institution usually have access to this. But IT systems rarely operate across sectors and institutions. Several countries have made progress in defining and measuring indicators for the quality of diabetes care. Generally the provision of diabetes information for patients and clinicians is good although there are rarely mechanisms for ensuring that decision support is actually implemented by health providers. The empirical analysis shows that some countries are much further than others as regards the establishment of DMP programmes and components. However, even among the most successful examples, IT support measures still need further developing and improving.

Diabetes complications risk factors have been intensively studied during the last decades, and these studies greatly improved the current scientific knowledge about the biological processes underlying diabetes. A principal objective in the clinical management of diabetes is the prevention of long-term vascular complications. The most common predictions for diabetes complications are cardio vascular disease, coronary heart disease and diabetic retinopathy for long term diagnosis and hyperglycaemia for short term diagnosis. In most of the studies only relatively simple statistical approaches, such as additive scores or logistic regression assuming independence between variants, have been applied.

Several studies related to diabetes have been set up for long term diagnosis. All of them had duration over 5 years and most of them had follow-up study. Some clinical measurements such as age, sex,

smoking, systolic blood pressure and glycated haemoglobin (HbA1c) are common to most of the models and are considered to be highly related to diabetes complications.
Regarding short term risk assessment models, no large, multicentre clinical study were found to be reported in the literature. While large clinical studies exist for assessing risk factors associated with long term diabetes complications, short term models are usually derived from small cohorts of patients collected in a single medical centre.

2 Introduction

2.1 Purpose, context and scope of this deliverable

The purpose of this deliverable is to describe existing disease management strategies and available risk assessment tools. We widened the remit to also include an analysis of existing information technology support that can be used to support disease management strategies. The following main aspects were considered:

- What is meant by disease management strategies and what are the elements contained within disease management strategies? What possibilities of IT support exist for DMPs?
- What is the evidence for disease management programmes, elements of disease management programmes and IT support for disease management programmes?
- What disease management programmes currently exist within Europe and in particular within REACTION partner countries? What are the main elements of these DMP programmes vis-à-vis evidence form the literature. What IT support is currently available, or planned, to implement DMP strategies? This part of the deliverable was generated on the basis of a survey of partner countries and an empirical analysis of the responses.
- Which predictive risk models and multi-parametric risk assessment methods are available for diabetes and which parameters do they contain?

2.1.1 Background

The most important initiatives for the improvement of diabetes care in Europe are described subsequently. This paper describes the out-patient care in disease management programmes.

2.1.2 The Saint Vincent Declaration

In 1989 representatives of Government Health Departments, patient organisations, diabetes experts agreed under the patronage of WHO and the International Diabetes Foundation (IDF) in St. Vincent, Italy upon the following recommendations [Regional Offices for Europe of WHO and IDF (1989)]:

It was within this meeting that implementation of the following measures for the prevention of costly complications was created:

- *“Reduce new blindness due to diabetes by one third or more.*
- *Reduce numbers of people entering end-stage diabetic renal failure by at least one third.*
- *Reduce by one half the rates of limb amputations for diabetic gangrene.*
- *Cut morbidity and mortality from coronary heart disease in the diabetic by vigorous programmes of risk factor reduction.*
- *Achieve pregnancy outcome in the diabetic woman that approximates that of the non-diabetic woman.”*

Improvement of patient education/empowerment, expert knowledge, prevention and the use of evaluated programmes and state of the art information technology for diabetes care, diagnosis, treatment and self-management were claimed. [Regional Offices for Europe of WHO and IDF (1989)], http://www.crag.scot.nhs.uk/topics/diabetes/vincent.htm].

2.1.3 The Istanbul Commitment

Following St. Vincent Declaration about 40 national diabetes action plans were elaborated and several working groups were founded. Meetings were held in Hungary (1992), Greece (1995), Portugal (1997) and Turkey (1999). Although partial results from pilot projects were discussed in these meetings, they had little impact on the overall situation.

Within the „Istanbul Commitment“ it was declared that people with diabetes still needlessly go blind, suffer from kidney failure, heart attacks, stroke and gangrene. The St. Vincent targets were reaffirmed under the assumption of sufficient existing evidence about the prevention of diabetes associated complications [Regional Offices for Europe of WHO and IDF (1999)].

The following goals were set:

- *“Individual nations review and renew their efforts to meet the St. Vincent objectives.*
- *People with diabetes are recognised as key members of the „therapeutic partnership“*
- *Modern tools and technology are used.*
- *Action is accelerated in areas of great need.”*

2.1.4 Diabetes information systems

Data are collected and analysed on different levels of the health care system, by users such as health care providers, patients or decision makers (see 3.3.2).

The DIABCARE Initiative

The DIABCARE Initiative was founded by the St. Vincent supervision team to meet the St. Vincent criteria. Therefore a standardised data set (including a paper documentation form) was developed [Piwernetz et al. (1993)].

Based on this data set a data warehouse information system was built. Its aim was to collect and analyse data on a regional level, over different health care settings (hospitals and practitioners), but only in an anonymous way. Aggregated data were sent to a server for over-regional analyses [Piwernetz (2001)].

Due to non-homogeneous implementation, a big part of the DIABCARE projects never left the status of a pilot project and ended without national implementation. Lacking user acceptance because of technical problems and the limited benefits of anonymous benchmarks were the reasons. None of the DIABCARE systems used a web based approach as a core element.

2.1.5 The requirement for national implementation

In 2003 representatives of IDF Europe stressed that the St. Vincent aims still had not been reached. “*In too many European countries we are still discussing “plans”; it is time to use our knowledge on the management of diabetes to move from Programme to Practice*.” [Hall et al. (2004)] According to a survey published in 2004 by the IDF Europe, only 55% of 32 responding countries had implemented a national diabetes programme.

In 2006 the European Union decided in the “Vienna Declaration on Diabetes” a better strategy in the treatment of Diabetes, to incorporate Disease Management Programmes and Europe-wide data collections [Austrian EU Presidency 2006 (2006)].

2.2 Integrated Care

The idea of integrated health care and the development towards a comprehensive and entire health care system became popular in the last decades. There is neither a standardised definition nor a consistent idea what integrated care means.
A definition for integrated care is given by [Kodner and Spreeuwenberg (2002)]:

> *Integration is a coherent set of methods and models on the funding, administrative, organizational, service delivery and clinical levels designed to create connectivity, alignment and collaboration within and between the cure and care sectors. The goal of these methods and models is to enhance quality of care and quality of life, consumer satisfaction and system efficiency for patients with complex, long term problems cutting across multiple services, providers and settings. The result of such multi-pronged efforts to promote integration for the benefit of these special patient groups is called integrated care.*

Disease Management in its modern form can be interpreted as integrated care for chronic diseases.

2.3 Disease Management – History and Definition

Disease management (DM) has its origin in the USA. In the early 1990 several efforts were taken to improve the inadequate treatment of patients with chronic diseases. These efforts were made by different organisations and therefore incorporated various concepts and aims. About 10 years later there were three overlapping initiatives in the chronic care landscape [Bodenheimer (2003)]:

The idea behind the Report Card Initiative was that good performance would be rewarded and patients would select organisations with better scores. The most famous report cards are those offered by the National Committee for Quality Assurance (NCQA) Health Plan Employer Data and Information Set (HEDIS). This theory turned out to be wrong and health care providers were not selected according to the results of the report cards. Nevertheless, feedback may have some impact on the performance of health care providers [Bodenheimer (2003)].

The Disease Management Industry (DMI) started in the mid 1990s. Pharmaceutical companies, insurance companies and profit-oriented start-ups offered programs for the better care of chronically ill patients and financial savings that would result from them. They calculated the patients' risk according to the resources used and patients with a high risk were treated in a very strict manner. This led to a rather acute management of complications than towards the implementation of measures to avoid them. Cost savings were achieved in the short term but these programmes remained without benefit in prevention and quality improvement in the long run [Sipkoff (2003)].

In 1999 about 200 companies were offering programmes for diabetes, asthma and congestive heart failure. The strict cost saving dogma by these companies led to the lack of well-designed trials. These trials are necessary to demonstrate reliable scientific evidence. By 2000 only few companies prospered and some Health Maintenance Organisations (HMOs) offered their own DM.

"Improving Chronic Illness Care" (ICIC): Edward Wagner developed the Chronic Care Model as a guideline for the improvement of chronic illness care [Wagner (1998)]. ICIC and disease management industry are similar in many ways, although the primary aim of the disease management industry is cost saving. In the ICIC a programme is seen as useful as soon as it improves the care of patients. Patient education is a big part of the ICIC. Programmes of the disease management industry are rarely developed by health care providers and are often disliked by practitioners. [Bodenheimer (2000)] required that the coordinating function should remain with the practitioners and that disease management programmes should support doctors in their daily practice routine. Changes made by ICIC programmes should be tangent to the facilities and the surrounding health care system. Differences in the health care systems and in the DMP concepts make it difficult to transfer the results from the USA to Europe and vice versa. In the USA, these programmes are provided by the HMOs - so they are financed and organised by „one hand" and the linkage between different care providers is given. The lack of linkage in the European health care systems needs to be addressed in the first instance. DMP are often implemented in existing health care structures without the needed reforms.

2.3.1 The Chronic Care Model

The chronic care model and the disease management industry have similar goals but realise them in different manners and therefore reveal various strengths and weaknesses. Companies in the disease management industry communicate directly with the patients, but not with participating doctors. Improvement would be achieved from changes in patients' behaviours alone. The chronic care model tries to improve the communication with the patients and doctors and tries to reorganise daily practice routine. The aim is to improve health care by systematic quality assurance for the whole population [Casalino (2005)].

Table 1: Comparison of the disease management industry with the reorganisation of care according to the chronic care model (own illustration according to [Casalino (2005)])

Disease management industry	Chronic care model (reorganisation)
Information systems extracting data from different sources, using them for prognosis models – cost efficient only due to use in a great extend.	Tight relationships to patients and knowledge about them. Could be used to improve patients' self-management
Disease management companies do not have any influence on doctors' behaviours.	Groups of doctors can organise themselves
	Improve care as a whole, not only care of certain diseases Could be tailored to the use for multimorbid patients
Communication with patients over great distance by call-centre agents, house visits through partners	Communication with patients through multidisciplinary teams

The chronic care model is interdisciplinary and multidimensional and incorporates all levels of health care and decision making. The model describes how patients (by overtaking an active role in their treatment) and practice teams improve health care results. This is achieved by the "productive interaction" between them and needs the support of organizations, the health care system and the community [Gensichen et al. (2006), Wagner et al. (1996)].

The chronic care model focuses on deficits of chronic illness care [Gensichen et al. (2006)]:

- Prevalence: the rise of prevalence of chronic diseases in relation to acute diseases. The basic care needs to be adapted to these conditions.
- Clinical care: the increasing use of diagnostic and therapeutic measures (often not evidence-based) leads to more complex decisions.
- Patients' role: the patients' role in a typical care process is most of the time passive, their needs are not taken into account (symptoms, emotions, life-style, treatment options), they are not being supported (patient education, self-management).
- Coordination: a fragmentation of care results due to lack in communication between the different care levels.
- Continuity: the focus on acute care results in a neglecting of long term treatment results.

The elements of a chronic care model are displayed in Figure 1 [Gensichen et al. (2006), Wagner et al. (1996)]:

- Self-management support: empowerment of patient's role and competences.
- Delivery system design: design and development of (new) care models, in particular through effective task allocation within the care/practice team.
- Decision support: evidence-based guidelines for doctors, decision support for patients, cooperation with experts.
- Clinical information systems: simple patient registers, therapeutic plans and reminder systems
- Informed and „activated"patients: patients with a better knowledge about their diseases are able to act as disease manager themselves and able to influence their own well-being.
- A prepared and pro-active team: a team that is familiar with chronic diseases, the documentation of treatment results and the planning of care by „one hand"(out-patient and in-patient).

- Community: communal living environment (local resources, community-based social services, self-help groups and multilevel initiatives).
- Interactions between patients and the team: treatment decision on the basis of participative decision-making
- Better clinical, functional and economic outcomes

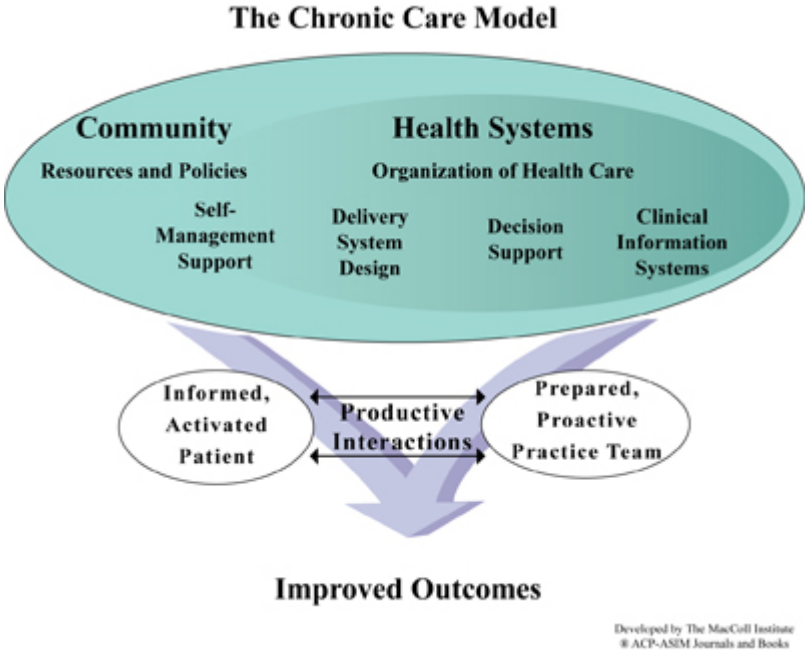

Figure 1: The Chronic Care Model [Wagner et al. (1996)][1]

A meta-analysis of chronic care models [Tsai et al. (2005)] analysed 112 studies (almost only RCTs) about asthma, heart failure, depression and diabetes. It found a positive effect on care and clinical outcomes (details see Table 6, Annex). The effects on quality of life were only positive for heart failure and depression.

2.3.2 Disease Management: Definitions and Aims

The differences in health care systems and in the development of DM led to different definitions of disease management. Newer definitions are not focused on the disease management industry but the chronic care model. [Schrijvers (2009)] gave a new definition of disease management on the basis of existing definitions. He found the following elements characterizing disease management:

- the focus on a target group
- of persons with chronic diseases

With the goal to improve

- clinical outcomes and quality
- as well as cost-effectiveness of care

By...

- the means of a systematic approach
- with preventive and curative interventions
- in which patients' self management is important and
- provided by a multidisciplinary professional team2 and

[1] Developed by the MacColl Institute ®ACP-ASIM Journals and Books, permission pending

[2] The integration of care is not explicitly mentioned, but implicitly included.

- IT technologies are used.

The concluding definition used in this paper:

> *"Disease management consists of a group of coherent interventions designed to prevent or manage one or more chronic conditions using a systematic, multidisciplinary approach and potentially employing multiple treatment modalities. The goal of disease management is to identify persons at risk for one or more chronic conditions, to promote self management by patients and to address the illnesses or conditions with maximum clinical outcome, effectiveness and efficiency regardless of treatment setting(s) or typical reimbursement patterns." [Schrijvers (2009)]*

2.4 Evidence for disease management programmes

The assessment of efficiency and efficacy of disease management programmes can be conducted for the whole programme or single DMP elements. In this sector evidence is given for whole disease management programmes.

A summarization of existing evidence is given in the systematic review by [Ofman et al. (2004)]. 102 studies addressing 11 chronic conditions were analysed by the criteria of the Cochrane EPOC group. Programmes for depression were analysed the most (41 studies) and showed the best results, 48% of the programmes showed significant improvement. 39% of programmes for coronary heart disease (CHD) (18 studies), 36% of programmes for diabetes (66 studies), 7% of programmes for hypertension (19 studies) and 25% of programmes for asthma (36 studies) showed significant improvement. Programmes for COPD (9%) or chronic pain (8%) showed the less positive effects. The summarized results of the reviews are given in Table 4.

Disease management programmes lead to an improvement of process quality of about 10% [Grimshaw et al. (2004)], they can improve patients' satisfaction, knowledge and therapy adherence, and lead to improvement of intermediate outcomes (e.g. glycated hemoglobin (HbA1c), blood pressure). Some studies show that these improvements can be remained over several years [Olivarius et al. (2001)]. Long term effects on mortality and other terminal outcomes are not yet sufficient analysed. Positive effects on different aspects of care are therefore beyond controversy. [Wagner and Groves (2002)] discovered that the most successful interventions are complex and consist of several components. They called for the broader evaluation of disease management programmes since the effectiveness of DMP interventions had been proven before under study conditions. Only few studies showed cost savings, but they are not necessarily demanded when reaching a better quality of care [Fireman et al. (2004)].

2.4.1 Evidence for DMP for diabetes mellitus

The search for reviews and meta-analyses was conducted in PubMed with the search terms `"disease management" diabetes AND (review [ti] or meta-analysis [ti])` and displayed 37 results. The search for randomized controlled trials (RCTs) was conducted in PubMed with the search terms `"disease management" diabetes` and the limitation „Randomized Controlled Trial"and led to 54 results. The titles and – if necessary – the abstracts were screened and papers eliminated that did not meet certain criteria. These criteria were: no DMPs according to the used definition in this paper, no displayed effects on process improvement, medical or economic outcomes (see Table 4), no comparable setting. Studies incorporating pharmaceutical companies were eliminated. The relevant studies are characterized below.

[Knight et al. (2005)] from the research group of Weingarten published a paper with the research question, which outcome parameters are being influenced by DMPs, independently from the used interventions. A systematic review was conducted by [Norris et al. (2002b)] about the RCTs of the "Task Force on Community Preventive Services", which developed the "Guide to Community Preventive Services" for the self-management of diabetes type 2. Only studies with entire diabetes populations were taken into account. The results could be used for managed care organizations as well as health care centres in the USA and Europe. The used definition of DMP is given in section 2.3.1.

The literature narrative by [Gillespie (2002)] gives a wide description of DM. The author is the director of the „National Pharmaceutical Council“and emphasises on the use of „pharmacy benefit management“programmes.

The study by [Cleveringa et al. (2008)] was conducted in an outpatient setting in the Netherlands (intervention group: 1.699 patients in 26 practices, control group: 1.692 patients in 29 practices).

The DMP intervention was delegated by the physician to the diabetes counsellor. The used intervention were 1) diabetes consultation with a diabetes counsellor, 2) clinical decision support system with a diagnosis and treatment algorithm according to the Dutch guidelines for type 2 diabetes, 3) recall system, 4) feedback every three months about patients reaching their treatment aims.

The RCT by [Piatt et al. (2006)] described the implementation of chronic care models in a population with low social status. The 105 patients and 24 practices were randomized in three groups: Chronic Care Model (CCM), physician-based intervention and regularly care.

[Sidorov et al. (2002)] describes quality improvement at concomitant cost savings through disease management. In a retrospective analysis over the period of two years, diabetes patients participating in a DMP in HMOs (3.118) were compared with patients treated without DMP (3.681). The interventions contained patient education, doctors' education and guidelines.

[Olivarius et al. (2001)] conducted a RCT about structured and personal care for patients with type 2 diabetes: the analysis of the influence of multifactorial, physician-based intervention on mortality and morbidity of newly diagnosed diabetes patients after six years of diagnosis, compared to those in routine care. 840 patients aged 40 plus were treated by 474 physicians (243 patients in the intervention group, 231 in the control group) in 311 practices in Denmark. The interventions consisted of regular controls, individualized time settings, supported by prompts for physicians, clinical guidelines, feedback and clinical education.

2.5 ICT for integrated care and Disease Management

In the beginning information technology was seen as relevant element of DM, especially in the USA. Interventions began with automated telephone systems for patients, registers and reminder systems for doctors. These interventions were hardly used within the care process. Through development of DM a better integration of information systems was necessary – on a technical level as well as on the care level. The transformation of the health care system towards integrated care needs the support of information and communication technology. Several aspects of integrated care and DM are being implemented through information technology [Pfeiffer (2009)]. Inappropriate information systems are a barrier for the realization of DM [Bodenheimer (1999)]. The adaptation of the health care systems should be accompanied by the implementation and integration of information systems.

The aspects of information technology in integrated care [Adaji et al. (2008), Schrijvers (2009)]:

- support changes in health care delivery
- facilitate communication between the providers in DMP
- provide doctors with data and information about individual patients and population
- integrate health data in one electronic patient record
- provide feedback to doctors and patients for decision support
- support the self-management of patients
- encourage interaction between patients and the care team
- enable care over distance through telemedicine and telemonitoring

[Glock et al. (2004)] recommend information technology for the support of medical processes in integrated care. Adequate instruments are electronic health card, electronic health record, and electronic exchange of clinical documents, electronic prescription, image documentation, data storage and illustration of clinical pathways. The main function of information technology would be the linking of health care providers. That's why communication technology plays an important role.

3 Elements of Disease Management and Information Technologies

3.1 Shifting routine practice of care providers

The aim of disease management programmes is to improve clinical outcomes, quality and cost effectiveness of care. To reach this aim, changes in daily routine of health care providers are necessary, but not easy to achieve. [Bodenheimer (1999)] postulated that insufficient changes in daily routine of physicians functions as a barrier for successful implementation of DMP. Many of the concepts and research activities contained strategies that would change daily routine of care providers.

A measure for the success of interventions in DMP is the improvement of care processes (changes in daily routine practice) according to evidence-based guidelines and the achieved improvements in patients' outcomes.

3.1.1 Implementing Evidence Based Medicine – Guideline-based decision support in Medicine

DM postulates that the medical practice varies and the variability leads to different results (there is potential for improvement) and that it is possible to implement systematic care leading to better outcomes. A shift from consensus-based medicine towards evidence-based medicine is necessary [Epstein and Sherwood (1996)].

Evidence-based medicine (EBM) is defined as the conscientious, explicit, and judicious use of current best evidence in decision making of the care of individual patients. In clinical practice evidence-based medicine means integrating individual clinical expertise with the best available external clinical evidence from systematic research, and includes the patient's individual situation and preferences [Sackett et al. (1996)].

Efforts to implement EBM have – according to [Shojania and Grimshaw (2005)] - evolved through several phases:

- First, it was assumed that clinicians would read and implement new results from the literature, systematic literature search and literature assessment was supported.
- Next, existing literature was prepared and published as guidelines, which due to certain factors were unsuccessful.
- After this, methods for quality improvement from the industry were adapted for health care, but were without success.
- Last, redesign of the existing health care systems started with the aim of optimising care to reach certain core targets. Often, IT played an essential role in this redesign.

Evidence-based clinical practice guidelines

Clinical practice guidelines developed from the try to standardise quality of patient care. They represented published consensus of expert groups. These groups were able to assess relevant literature, but their expert opinions differed and incorporated the risk of influences by financial and political agendas. Clinical guidelines that are evidence based imply that they base on published research, analyzing clinical results and that these studies are being assessed by certain criteria.

Evidence-based guidelines summarise evidence form research on a clinical useful level and show lacking of research [Gerstein and Haynes (2001)].

Evidence-based clinical guidelines are a core element of DMP for the structuring of care. The challenge is to translate these guidelines in practice and to reach their implementation. [Cabana et al.

(1999)] give some explanations why doctors do not follow clinical guidelines: 1) they do not know them, 2) they do not agree with them, 3) they do not have sufficient self-confidence for their realization, 4) they do not believe in their effectiveness, 5) they can not change their daily working practice or 5) barriers for participation are too high.

3.2 Elements of Disease Management

Disease Management is aimed at improving the quality of care. A very broad definition of the concept of „quality of medical care"is given by the American Institute of Medicine (IOM):

> *„Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." [Committee to Design a Strategy for Quality Review and Assurance in Medicare and Institute of Medicine (1990)]*

This definition of "quality of care" comprises a broad band of aspects and dimensions. It is dynamic, flexible and integrates various perspectives of different occupational groups and financiers. The formulation „increase the likelihood" shows that there is no certitude in medicine, diagnostic as well as therapeutic interventions lead with more or less likelihood to a better quality of life or a longer duration of life. That is why this definition also includes the request for adequacy [Gerlach (1998)].

As defined by this concept of quality the components of a DMP always have the aim of quality improvement ("Increasing the likelihood of desired outcomes"). A DMP therefore consists of adjusted interventions for quality improvement.

3.2.1 Interventions for quality improvement

Evidence for quality improvement strategies

[Oxman et al. (1995)] found in a systematic review of 102 studies about the effectiveness of different types of interventions in improving health that there were no "magic bullets" for improving the quality of health care.

The used taxonomy of strategies for quality improvement in physicians' practice was picked up by the Cochrane Effective Practice and Organisation of Care (EPOC) review group. This group argues that systematic reviews provide the best evidence on the effectiveness of healthcare interventions including quality improvement strategies. This group analysed systematic interventions of changes in practice and organisation of care [Grimshaw et al. (2003)]. Evidence and knowledge about quality improvement strategies have increased during the last years. [Grimshaw et al. (2001)] found that passive approaches such as emission of educational materials were generally ineffective and unlikely to result in behaviour changes. Most interventions are effective under certain circumstances, but none were generally effective. [Weingarten et al. (2002)] mentioned effect sizes for single interventions (reminder and education for physicians and patients, feedback and financial incentives).

[Grimshaw et al. (2004)] affirmed in a health technology assessment that no single intervention would overrule the other interventions and there was a variation in the observed effects. Overall, the intervention group reached an improvement of about 10% in following the target processes of care (e.g. measurement of HbA1c or foot examination). There was no sufficient evidence base to support decisions about which guideline dissemination and implementation strategies were efficient under different circumstances. In a review [Oxman et al. (1995)] found evidence that no single intervention, but combinations of interventions had some effects. The use of multi-factorial interventions is therefore recommended [Shojania and Grimshaw (2005)]. The effect of single methods for quality improvement depends partly on the clinical context and definitely on other context depending factors (such as opinion and attitude of care providers and organisational matters), which are hardly known.

Strategies for quality improvement are described below. Taxonomy and the cursive written definitions are modified according to the Cochrane EPOC [Shojania et al. (2004), Shojania et al. (2006)].

Evidence for DMP components is given in Table 5 on page 45.

Changes in the care team

Changes in the structure and organisation of the outpatient care team are defined as one of the following interventions [Shojania et al. (2004), Shojania et al. (2006)]:

- *Adding a team member or „shared care", e.g. visits with other personnel than the general practitioner (e.g. physician, diabetes nurse, pharmacist, nutritionist, chiropodist)*
- *Multidisciplinary teams, active participation of care providers from more than one discipline (e.g. medicine, care, pharmacy, nutrition) in the primary guidance of patients*
- *Expansion or changes of professional functions (e.g. nurse or pharmacist take over a more active role in the monitoring of patients or in the adaptation of medication)*

Through changes in the care team improvements in the care of diabetes and hypertension can be achieved [Shojania and Grimshaw (2005)]. In a review about the effect of quality improvement strategies on changes in blood sugar of diabetes patients, changes in the team led to a descent of HbA1c of about 0,67% and therefore represented the most successful intervention [Shojania et al. (2006)]. In the review by [Walsh et al. (2006)] changes in the team led to a reduction of blood pressure in patients with hypertension of about 9,7 / 4,2 mmHg (systolic/diastolic) and was therefore the most successful intervention. [Bodenheimer (1999)] wrote about the assignment of doctors and nurses in successful care teams. One team was responsible for 5.000 patients and the teams were responsible for the active management of the chronic disease instead of acute care. The review by [Shojania et al. (2006)] about diabetes could not identify one single and effective intervention within the care team. [Walsh et al. (2006)] showed for hypertension that in all studies a change within the teams led to a shift of responsibility from the physician towards a different care provider. Many of the studies assigned certain personnel for the management of hypertension. This was either realised by enlargement or reallocation of the team.

A review by [Renders et al. (2001a)] found that nurses were able to provide many aspects in diabetes care instead of doctors, if detailed behaviour guidelines or protocols were given and they were specially trained. Studies in which nurses (partly) overtook the diabetes care from physicians, showed positive effects on the blood sugar of patients. These results were not transferable to the management by pharmacists.

Shared Care

Shared care is a new way of cooperation between general practitioners and specialists. Theoretically this leads to the continuity of care through the general practitioners and the specialisation of care through experts. The following arrangements are possible:

- Polyclinic: a specialist visits or operates an outpatient department, the team works together on a casual basis and meets on-site.
- Basic model: specific, continuous communication system between specialist and general practitioner
- Liaison: meetings, in which specialists and basic care teams participate and the disease management is planned.
- Shared care document: collective use of information from on structured document, which is kept by the patient
- Computer-based shared care: agreed upon data set, the data is collected in specialised and basic care and analysed with shared information technology.

There is no clear evidence for shared care of diabetes and hypertension. A Cochrane Review shows no positive effects [Smith et al. (2007)].

Case Management

> *Systems for the coordination of diagnosis, treatment or management by one person or a multidisciplinary team in cooperation with or complementary to the general practitioner [Shojania et al. (2004), Shojania et al. (2006)].*

According to [Korff and Goldberg (2001)] case management comprises the following characteristics:

- responsibility for continuity of care (follow up)
- controlling of therapy adherence
- controlling of aetiopathology
- prompt reaction if patients do not stick to the evidence- and guideline-based therapy

[Gerlach et al. (2006)] mentions various reasons for case management in general practice: confidence of patients in their general practitioner and team, the use of existing structures, the co-management of all problems of chronic diseases, the completion of DMP by respecting the individual problems of patients.

Case management activities

Case management activities comprise the practice-based activities of physician assistants. Case management of diabetes leads towards a better blood sugar and better blood sugar control. Reduction of HbA1c was 0,52% [Norris et al. (2002b), Shojania and Grimshaw (2005), Shojania et al. (2006)]. In the review by [Shojania et al. (2006)] case management – besides changes in the team – was the only strategy which led in multi-factorial interventions to a significant incremental reduction of HbA1c (this means that multi-factorial interventions with this action were significantly more effective than without this action). In programmes for hypertension case management led to a better systolic blood pressure [Shojania and Grimshaw (2005)].

Patient reminder systems

> *All attempts (e.g. post cards, calls) to remind patients of appointments or relevant aspects of self-management [Shojania et al. (2004), Shojania et al. (2006)].*

The reminding of patients can either be carried out by the operating companies – normally supported by computerised systems – or by nurses or physicians (elements of case management) [Renders et al. (2001a)].

[Renders et al. (2001a)] showed an improvement of care processes, but no clear improvement of outcomes. Subsequent reviews found a better blood sugar control for diabetes (improvement of HbA1c of about 0,49%) [Shojania et al. (2006), Weingarten et al. (2002)]. In programmes for hypertension patient reminder systems led to a significant reduction of blood pressure of 3,3 mmHg (diastolic non significant) [Walsh et al. (2006)].

Patient education and self-management

> *Interventions to promote a better understanding of a target status, to educate specific prevention or care strategies, or to individual educate patients (single or team trainings with diabetes counsellors, emission of educational material).*
>
> *Provision of devices (e.g. glucose monitoring device) or access to resources (e.g. systems for electronic transmission of glucose measurements) for the promotion of self-management [Shojania et al. (2004), Shojania et al. (2006)].*

Patient education and self-management are established and guideline-recommended elements of chronic disease management [Österreichische Diabetesgesellschaft (2007)], and therefore relevant elements of DMP. There is robust evidence that patient education has positive effects. A meta-

analysis about self-management education in grown up type 2 diabetes patients found a positive effect on blood sugar [Norris et al. (2002a)].

A Cochrane Review analysed 11 studies with 1532 participants and found that patient education in groups had relevant clinical improvement of health outcomes of type 2 diabetes patients: blood sugar (HbA1c), fasting blood glucose and knowledge about diabetes after a period of 4-6 months as well as 12 months [Deakin et al. (2005)]. Self-management for patients with hypertension leads to a reduction of blood pressure. On the other hand, programmes for osteoarthritis do not seem to have the same effectiveness [Chodosh et al. (2005)].

Below there are some results from the literature about how to arrange educational and self-management programmes:

- It was stated in several studies that self-management is more than just knowledge transfer. Programmes that impart technical skills for problem solving are more effective than simple knowledge transfer [Bodenheimer (2003), Bodenheimer et al. (2002a), Norris et al. (2002a)].
- The principles “empowerment” and “participation” have shown their effectiveness [Deakin et al. (2005)] and should be applied in patient education programmes.
- Individual education and education in groups for diabetes mellitus were similarly successful, education in groups for hypertension showed significant better results [Chodosh et al. (2005)].
- The size of the group (4-6 up to 16-18 participants) had no influence on positive results, neither was there a notable positive effect of the influence of the programme’s duration [Deakin et al. (2005)].
- The review by [Norris et al. (2002a)] found that the positive effect of patient education diminished after 6-12 months. The review by [Deakin et al. (2005)] showed that additional annual units of group education could prolong the effect over a period of 2-4 years.
- Self-management programmes possibly reached their effect through better medication compliance. Outcome parameters, that could easily be influenced by pharmaceutical therapy showed the most effects [Chodosh et al. (2005)].
- According to [Deakin et al. (2005)] there is no sufficient evidence that the training has to be carried out by doctors, nurses, diabetes counsellors or nutritionists. It was shown although by [Renders et al. (2001a)] that if diabetes counsellors are the trainers in charge, then there is an improvement in the results of the care process. The doctors’ role is still important. [Norris et al. (2002a)] found out, that a longer contact with the doctor positively influences the results.

The support of self-management through information technology is described in section 3.3.3.

Electronic records

> *General electronic patient record or electronic tracking systems for patients with diabetes [Shojania et al. (2004), Shojania et al. (2006)].*

In a review by [Chaudhry et al. (2006)] about quality improvement through information technology 37% of analysed systems were electronic patient records. This review found an improvement in quality (adherence of guidelines, better monitoring, less medication mistakes), still there are only a few quantitative results and it is only possible to generalise the results to a limited extent. For diabetes there was an observed clinical relevant positive effect of electronic patient records on blood sugar level (improvement of HbA1c of about 0,43%) [Shojania et al. (2006)].

The technical details about electronic health record are given in section 3.3.5.

Clinician education

> *Interventions designed for the promotion of an increased understanding of principles guiding clinical care or awareness of specific recommendations for a target condition or patient population. Subcategories of clinician education are meetings, workshops, distribution of educational material [Shojania et al. (2004), Shojania et al. (2006)].*

Passive interventions are in general ineffective and do not lead to a behaviour modification [Grimshaw et al. (2001)]. This affects meetings in particular [Davis et al. (1995), Shojania and Grimshaw (2005)]. Printed educational material might have a positive effect on care processes, but not on patient outcomes [Farmer et al. (2008), Grimshaw et al. (2004)].

Health care providers need the skills and knowledge to improve their performance. They need to know about the importance of changes in daily routine and highly motivated. Clinician education („postgraduate education" or „provider education") showed – in combination with other strategies (reminder, audit, feedback, consensus processes, peer reviews) - moderate positive effects on care processes [Renders et al. (2001a), Weingarten et al. (2002)] and in improving the monitoring of diabetes patients (better blood glucose [Shojania and Grimshaw (2005), Weingarten et al. (2002)], HbA1c reduction of about 0,43% [Shojania et al. (2006)]). For hypertension there were no [Shojania and Grimshaw (2005)] or only little positive effects (reduction of the systolic blood pressure of about 3,3 mmHg [Walsh et al. (2006)]). The influence of clinician education is hard to assess, because it is part of many other complex interventions [Renders et al. (2001a)].

Visitations and hospitations

Visitations and hospitations, visits in doctor's practices with the aim of education can be done by specially trained experts. Visitations and hospitations had a positive effect on prescription behaviour [Grimshaw et al. (2001)] and the knowledge of care providers [Shojania and Grimshaw (2005)].

Facilitated relay of clinical information (through patients) to clinicians, patient mediated interventions

Clinical information collected by patients and relayed to clinicians by other means than the existing patient record or traditional correspondence [Shojania et al. (2004), Shojania et al. (2006)]. For example:

- *structured diabetes diaries for patients to document self-measured glucose levels*
- *web-based tools, through which patients can provide data to clinicians*
- *Point-of-care testing (e.g. HbA1c)*

[Davis et al. (1995)] called these interventions effective. [Shojania et al. (2006)] found an improvement in HbA1c of about 0,39% for diabetes patients. [Walsh et al. (2006)] found a significant lowering in blood pressure of 8 mmHg (diastolic not significant) for patients with hypertension.

To a large extend, data relay is based on IT systems or can be supported by IT systems. These systems are being discussed in section 3.3.3.

Audit und Feedback

Summarising clinical performance of care of an individual clinician or a centre over a certain period of time and giving back feedback to them (e.g. percentage of patients, who reach the HbA1c target or whose eyes are being examined on a regular basis) [Shojania et al. (2004), Shojania et al. (2006)].

According to the definition used in the Cochrane review, the summary of clinical performance can comprise data about the process of care (e.g. number of diagnostic interventions), clinical outcomes (e.g. blood pressure tests) and clinical guidelines (e.g. number of patients treated according to the guidelines). The illustration of results can be done in the following ways:

- Individual comparison of explicit quality criteria for centres.
- Benchmarking of results of other participating care providers in the programme („Peer Comparison")

- Non-open benchmarking: comparison with other (anonymous) participants or the mean results (for example the feedback reports in the German DMP) [Nolte et al. (2009)] or the DPV initiative [Grabert et al. (2002)].
- Open benchmarking: comparison with other known participants (e.g. FQSD-Ö with the Benchmarking and Reporting Service BARS) [Korsatko et al. (2007)].

In the reviews of [Grimshaw et al. (2004)] and [Jamtvedt et al. (2006)] there were no clear recommendations of how to best implement audit and feedback. There was no difference in effectiveness between „Peer Comparison"and individualised benchmarking. There is some evidence that feedback to groups is more effective than individual feedback. There exists no study comparing both groups directly.

The effects of audit and feedback on the implementation of guidelines or the improvement of care processes are little [Grimshaw et al. (2004), Jamtvedt et al. (2006)]. The effectiveness is higher the more potential for improvement exists a priori. In general the effectivity varies considerably. Most likely it depends on whether the given information is being adopted and worked with by clinicians [Bodenheimer et al. (2002b)]. The effects of audit and feedback on clinical results are not clear. Based on limited evidence these instruments seem to work better for diabetes than any other disease [Foy et al. (2005)]. Audit and feedback should therefore not be used as single instruments for the identification of quality, but in combination with other interventions to improve quality of care [Glattacker and Jäckel (2007)].

Development of indicators for audit and feedback

Quality indicators can measure all dimensions of quality. The percentage of patients getting foot examinations on a regular basis is a process indicator. Examples for intermediate and terminal outcome indicators are the percentages of patients with blood pressure under 140/90 mmHg or patients affected by retinopathy. Indicators are directly developed by evidence-based guidelines. To conduct indicators guidelines and evidence need to be interpreted. Evidence-based guidelines should therefore define clear targets [Aron and Pogach (2008), Martirosyan et al. (2008)]. After this, the indicators need to be tested for validity. To ensure that they provide adequate feedback they are chosen according to the best providers' needs [Shojania and Grimshaw (2005)].

Preparation and comparison of feedback

Risk adjustment is a first step towards the comparison of outcome indicators. Risk adjustment according to age, diabetes duration and further parameters can enable the comparability of results.

For adequately specified process indicators, risk adjustment is normally not necessary [Kiefe et al. (2001)].

The development of comparable benchmarks is the basis for process indicators. Aim is the identification of the „best of class". [Weissman et al. (1999)] presented an approach for that with „Achievable Benchmarks of Care". Benchmarks should measure performance on an objective and reproductive basis. Results of a randomised and controlled study showed a significant and relevant improvement in process of care [Kiefe et al. (2001)]. Positive effects were also shown by [Club Diabete Sicili@ (2008)].

Reminder systems and decision support systems for care provider

> *Paper-based or electronic systems, which provide diabetes-specific information to health care providers (e.g. current HbA1c) or display tasks (e.g. foot examination). In case of a simultaneous recommendation, they provide categorisation and indication for decision support [Shojania et al. (2004), Shojania et al. (2006)].*

Reminder systems for health care providers are often effective as soon as they are integrated in daily routine. Decision support systems are sometimes effective, but not in complex situations – when they would be the most desirable [Shojania and Grimshaw (2005)]. Several reviews showed an improvement in the process of care or in guideline adherence [Davis et al. (1995), Grimshaw et al. (2001), Grimshaw et al. (2004), Weingarten et al. (2002)]. A better disease monitoring as outcome

parameter was shown by [Weingarten et al. (2002)], in particular a reduction of HbA1c of 0,23% for diabetes patients[Shojania et al. (2006)] and a significant reduction of blood pressure for patients with hypertension (3,3 mmHg systolic, diastolic not significant) [Walsh et al. (2006)].

Reminder systems and decision support systems are mainly implemented by IT systems (see section 3.3.2).

Continuous quality improvement

> *Interventions using techniques of „continuous quality improvement", „total quality management", „plan-do-study-act" or another iterative process to identify quality problems, develop solutions, test their effects and then derive activities anew[Shojania et al. (2004), Shojania et al. (2006)].*

[Ellis (2006)] describes various concepts for continuous quality improvement: competitive performance benchmarking was mainly done in American programmes and by American organisations. Collaborative process benchmarking aims at improving care processes in a collaborative way to reach „best practice". A patient-orientated approach to meet the needs and expectations of patients is the so called „patient experience benchmarking". It was stated by [Shojania and Grimshaw (2005)] that the translation of industry-based quality improvement models into the health care sector were not very successful. The evidence for this intervention is not very strong. [Shojania et al. (2006)] found an improvement of HbA1c of 0,23%.

Financial, regulatory or legislative incentives

> *Positive or negative financial incentives for health care provider or patients (e.g. depending on adherence of certain care processes or target achievement by patients) or the system-wide change of reimbursement (e.g. capitation, prospective reimbursement) [Shojania et al. (2004)]*

Incentives for patients or health care providers

There is some evidence for a better achievement of therapeutic targets through incentives [Shojania and Grimshaw (2005)]. [Weingarten et al. (2002)] writes about financial incentives for patients. In general 3 out of 4 studies showed an improvement in outcome (2 for hypertension). On the contrary, [Walsh et al. (2006)] identified a study that met the inclusion criteria and led to a worsening of systolic blood pressure (13,3 mmHg). There is no sufficient evidence for diabetes [Shojania et al. (2006)]. A study by [Casalino et al. (2003)] in the USA found that external incentives encouraged the use of structured processes in care. Centres with better quality scores were rewarded financially, through better contracts or got public attention („report cards").

System-wide change in reimbursement

The system of reimbursement has certain impact on the realisation and the success of care programmes in a health care system. There was not sufficient evidence found within this research.

Check lists for documentation

In a randomised controlled study a documentation form meeting the criteria of a check list, improved process quality. The check list character of the documentation form was the only intervention [Dubey et al. (2006)].

Local opinion leaders

A Cochrane review analysed 12 RCTs about the question if presentations and meetings with local opinion leaders lead to a better performance of care providers and patient outcome. It stated that the assignment of opinion leaders is effective [Doumit et al. (2007)]. The effect size is comparable to the distribution of educational material, audit, feedback or multi-factorial interventions, although the effect is smaller than that of reminder systems.

3.2.2 Summary

Multi-factorial interventions

[Oxman et al. (1995)] found out that single interventions had poorer benefit compared to interventions with more quality improvement strategies. Passive strategies showed no benefit at all. At first, these results were proven [Grimshaw et al. (2001), Renders et al. (2001a)].

[Grimshaw et al. (2004)] relativised these findings. Multi-factorial interventions have medium-sized effects, not significantly bigger than the use of single strategies, passive distribution (e.g. of information and educational material) had little but consistent positive effects. For significant effects multi-factorial interventions are needed, but the use of single strategies shows little effects. For diabetes effects of multi-factorial interventions were better rated than single strategies, for hypertension data were not sufficient for a clear conclusion [Shojania and Grimshaw (2005)].

Effectivity of quality improvement strategies for diabetes mellitus and hypertension

The two following strategies show different effectivity of interventions for diabetes mellitus and hypertension.

Quality improvement strategies for diabetes mellitus

[Shojania et al. (2006)] analysed 66 studies and determined the effect of 11 quality improvement strategies as better control of the blood sugar level. The results are displayed in Figure 2.

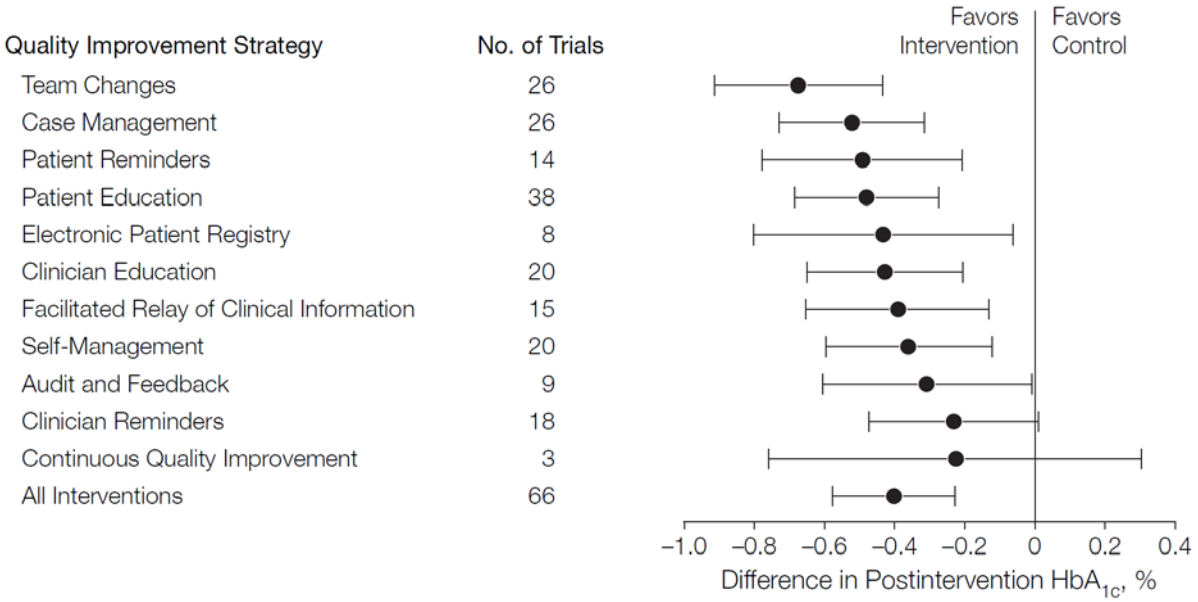

Figure 2: Differences in HbA_{1c} after the intervention and adjustment for study bias and HbA_{1c} basic value

Team changes and case management did not lead to a significant incremental reduction of the HbA1c level. This means that by implementing this measure in an already existing programme positive effects were achieved. Studies with interventions of team changes reduced the HbA1c about 0,33% (95% CI, 0,12%-0,54%; P=,004) more than those without such strategies, and interventions with case management reduced the HbA1c about 0,22% more (95% CI, 0,00%-0,44%; P=,04) than without. Successful were those interventions where case manager (nurse or pharmacists) were able to change therapy without authorisation. Reduction of HbA1c about 0.96% (95% CI, 0,52% - 1,41%) (11 Studies), compared to 0,41% (95% CI, 0,20% - 0,62%) for 15 case management studies without this character. Non-randomised studies overestimated the effect.

Quality improvement strategies for hypertension

[Walsh et al. (2006)] analysed 44 papers to examine the effects of quality improvement strategies on blood pressure reduction. The results are given in Figure 3.

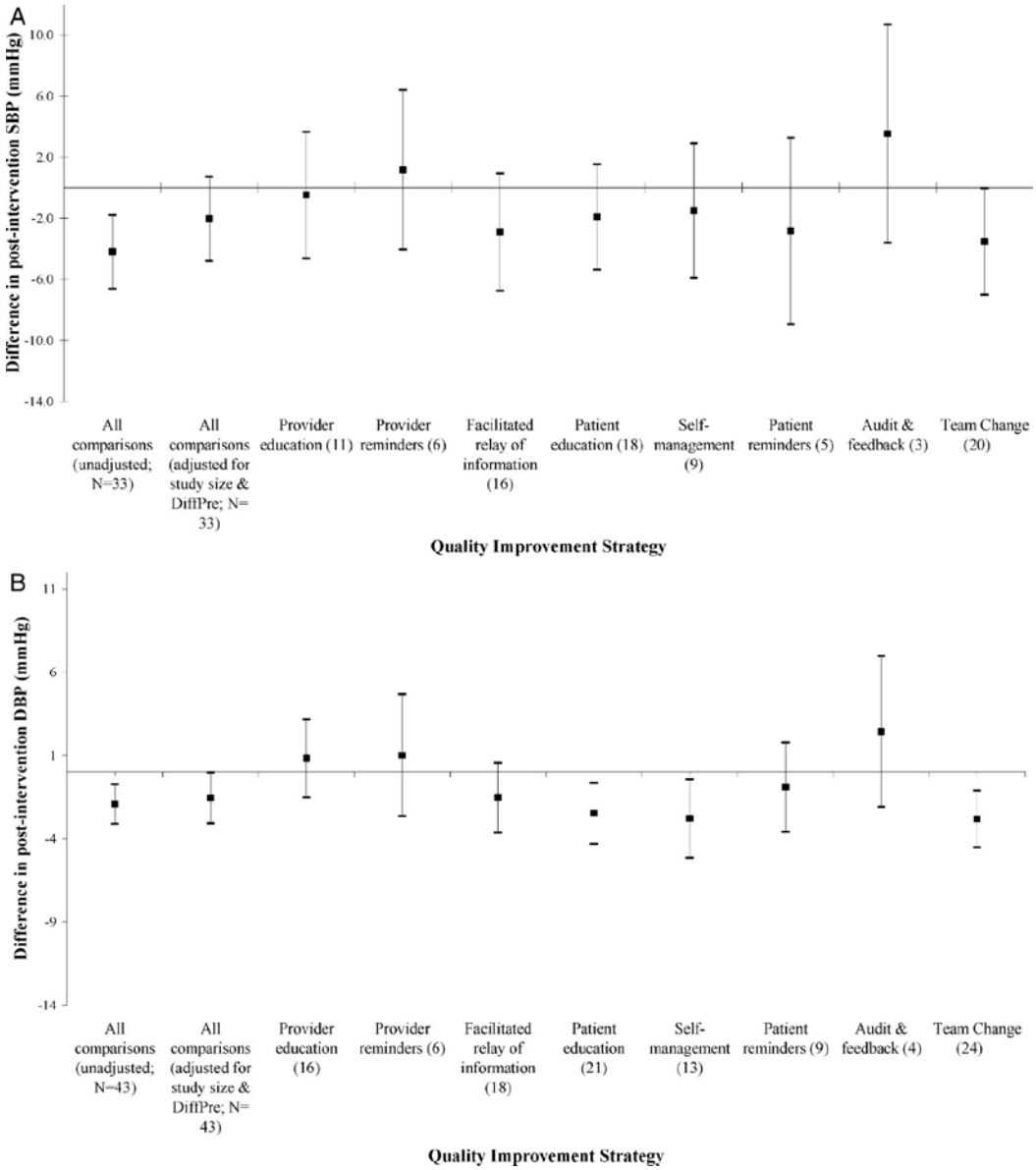

Figure 3: Changes in systolic (A) and diastolic (B) blood pressure, associated with quality improvement strategies, adjusted for study size and basic blood pressure

The blood pressure in the intervention group was reduced by an average of 4.5 mmHg compared to that of patients in the control group. The median percentage of patients reaching the blood pressure target raised about 16,2% (systolic) and 6% (diastolic). Studies with smaller sample size reached in general better reduction in blood pressure. Interventions including team changes as quality improvement strategies were associated with a better blood pressure reduction (only strategy with significant reduction of systolic and diastolic blood pressure).

3.3 Possibilities of IT support for Disease Management

Information technology can support disease management programmes on several levels. This support can be addressed towards the health care provider, the programme providers ort he patient [Bodenheimer et al. (2002b), Lester et al. (2008), Nobel and Norman (2003)].

In general, these systems can be distinguished for the following sections:

- Indices for patient identification and care provider identification
- Register with clinical data for reporting to a) health care provider or b) analyses through programme provider
- Reminder systems and decision support systems for health care providers
- Support of information, education and patient empowerment
- Tele-medical interventions and home care.

Information technologies are important for the success of a DMP, but not sufficient. For successful implementation there are more components needed, especially in outpatient care [Green et al. (2006)], where the distribution of IT tools for the support of chronic care illnesses is not given.

A paper by [Dorr et al. (2007)] analysed 112 system descriptions of information systems for the improvement of chronic illness care. The following IT elements were associated with positive effects on processes and outcomes (see Figure 4):

- Collection of therapeutic interventions („order entry“) with decision support (strong influence on prescription behaviour)
- Part of or connection with an electronic patient record
- Population management, especially population-based report or audit and feedback
- Computerised prompts (moderate)
  (The access on guidelines alone was associated with a worsening!)
- Personal health record / patient portals (moderate)
- Electronic appointment (administrative intervention) (moderate)
- Telemedicine and telemonitoring (moderate)

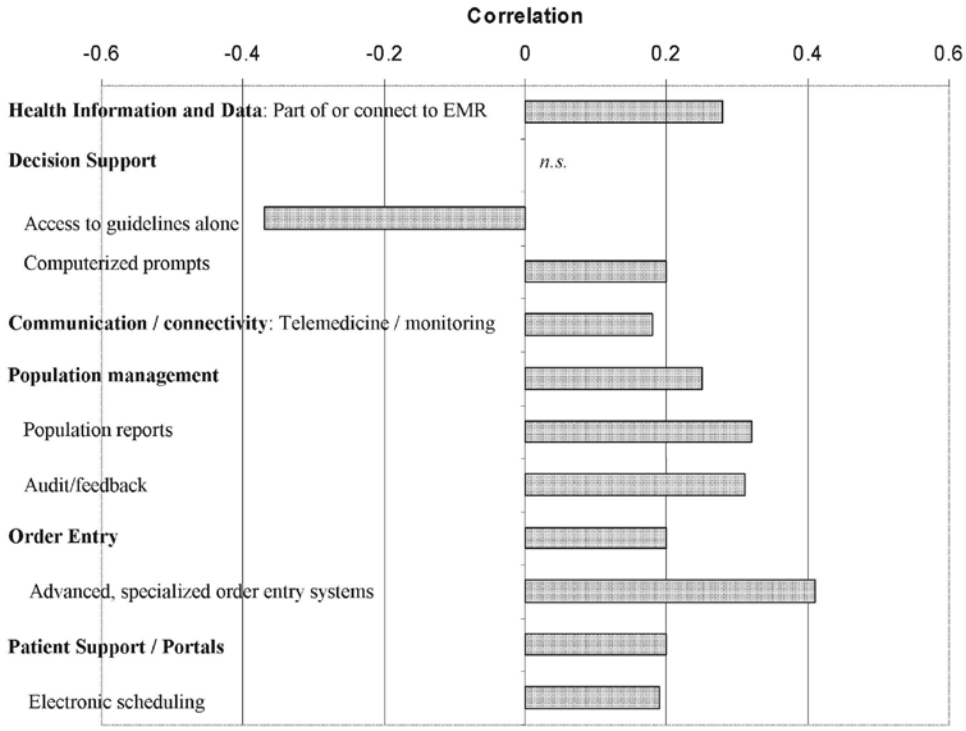

Figure 4: Correlation of existing IT components with changes in process and outcome [Dorr et al. (2007)]

Only 50 of the 112 studies were experimental and led to 67% positive results. The non-experimental results showed a strong bias (94% positive). By only taking experimental studies into account the

effects remained. It was not possible to conduct a multivariate analysis due to the small amount of studies.

The indirect effects of IT also had to be taken into account. A survey conducted in 1.040 practices in the USA showed a strong coherence between the use of information technology and the use of structured care programmes for chronic illnesses [Casalino et al. (2003)].

The following description of IT elements for the support of DMP happens according to the paper of [Bodenheimer et al. (2002b), Lester et al. (2008), Nobel and Norman (2003)].

3.3.1 Population management and administrative registers

On the contrary to disease management interventions taking place during the patient's visit (e.g. reminder or prompts) population management happens off the regular business hours. It comprises the identification of risks and relevant diseases [Lester et al. (2008)].

Panels of patients and doctors

The aim of patient and doctor panels in disease management programmes is to administer doctors and patients [Lester et al. (2008)]. It is mainly an administrative tool, important for further interventions (reminder, patient recall).

Registers

Registers comprise a summary of patient's health care data [Nobel and Norman (2003)]. They are tailored to meet the health care providers' needs, and sometimes those of the programme providers.

Identification of population

Registers enable the identification of certain diseases or problems of certain populations. This is relevant to programme providers and health care providers. It could be supported by various IT systems.

- Programme providers identify populations according to reimbursement data with diagnoses and resources used.
- Within disease management programmes programme providers can use clinical data to identify subgroups with high risks.
- Health care providers can use data from clinical documentation.

Individual and population based patient care

Registers can be used as basis for clinical decision in the planning of individual patient care [Bodenheimer et al. (2002b), Nobel and Norman (2003)], and for the support of population-based care [Bodenheimer et al. (2002b)].

Information systems enable the automatisation of registers by rule-based systems and by certain inclusion criteria in connection to the electronic health record [Lester et al. (2008)] und lead to efficiency improvement.

The use of data from different sources

Often the functions of existing registers differ. Diabetes systems of some countries already link data from different sources (record linkage). They provide clinical data to health care providers overtake tasks in decision support and provide audit and feedback [Campion et al. (2005), Joshy and Simmons (2006)]. Often these systems are web-based. Registers that are automatically filled with data reduce barriers and additional work caused by disease management programmes [Lester et al. (2008)]. An example for such a system is the „Diabetes Audit and Research in Tayside Scotland" (DARTS) Collaboration [Boyle et al. (2001)]. The aim of this project was to provide fair health care to the whole population. The system linked data from different sources. Data was extracted with special software and merged on one central place. By merging data from different sources ambiguities and mistakes

were found. Data quality was improved through feedback to care providers [Boyle and Cunningham (2002)].

Reporting and feedback (for care providers)

The evidence of the effectiveness of audit and feedback is described in section 3.2.1. Reporting is almost always supported by information technology. This support lays in data acquisition, data analyses and data visualisation. The provision of results can either be done online (synchronic, interactive access) or non synchronic via mail or download. The provision of audit and feedback on a papery basis is still favoured by general practitioners.

Data for programme providers

The systematic collection of aggregated, non-patient-related, clinical, administrative and cost-based data leads to the development of a comprehensive data warehouse [Nobel and Norman (2003)].

This data warehouse can be used to analyse various aspects of the programme and enables continuous evaluation.

- Meeting the right population,
- Development of outcome indicators,
- Changes in health care resources used by the patients
- Implementation of evidence-based processes: process quality indicators from guidelines for the illustration of process quality [Lester et al. (2008)].

Predictive Modelling

Prognosis models can be used to determine which patients can benefit the most from certain interventions and from a better care through case management. For the development of such prognosis models a broad basis of patient data (health status, behaviour, pharmaceutical therapy) needs to be merged in a data warehouse, prepared and analysed to identify certain relations [Cousins et al. (2002), Fetterolf (2006)].

Prognosis models were the core competence of the disease management industry described in section 2.3. They are still used to optimise health care resource use. Newer approaches focus on the early detection and adequate interventions for life-style modifications for high risk patients. These models are normally promoted by the eHealth and diagnostic industry [COCIR (2008)].

3.3.2 Decision support / reminder (for health care providers)

Often it is not possible to treat patients according to evidence-based guidelines. Clinical decision support systems are being implemented to support health care providers in patient treatment. It was shown that these systems were able to improve prescription practice, avoid mistakes in medication, improve preventive measures and improve therapeutic adherence [Kawamoto et al. (2005)]. Reminder can help to translate new results from research into daily routine [Balas et al. (2004)].

There is a broad spectrum of such systems for clinical decision support. They have the aim to support health care providers to meet evidence-based guidelines in their daily work [Bodenheimer et al. (2002b), Nobel and Norman (2003)]. This support can be done by additional personnel or IT systems:

- **Reminder**: provided information on the point of care [Shojania et al. (2009)].
- **Clinical Decision Support:** is the provision of “clinical knowledge and patient-related information to improve care [Purcell (2005), Shojania et al. (2009)].

There are the following ways of providing clinical decision support and reminders (depending on the level of automation and integration in information systems) [Dorr et al. (2007), Nobel and Norman (2003), Shojania et al. (2009)]:

- **Reminders and protocols – hard copy:** simple notes (on to the front page of health care records) or sophisticated pre-printed prescription forms

- **Reminders and protocols - computer-generated:** provided via hard copy or e-mail
- **Provision of guidelines**
- **Computerised prompts, generated at the point of care:** These guideline-based alerts provide relevant information during patient treatment. Pre-condition is the integration of IT systems for clinical prescriptions and patient records.

Computer-based prompts have the potential to cover several issues at the same time. That's why they are essential for quality improvement [Shojania et al. (2009)]. [Dorr et al. (2007)] found in a review that the use of special decision support through IT systems for clinical prescriptions („order entry") was successful, while the simple access to guidelines led to a worsening of care.

Core elements for effective systems

Clinical decision support systems do not always lead to an improvement in practice [Purcell (2005)]. What are the core elements for successful systems? Successful systems with specialised decision support showed the following characteristics [Dorr et al. (2007)]:

- Disease-specific check-up (e.g. consideration of preventive, diagnostic or therapeutic measures according to guidelines)
- Provision of masters for subsequent prescriptions (according to protocols for pharmaceutical treatment, consideration of contraindications)
- Support of treatment paths (e.g. patient transfers)
- Creation of orders/prescriptions not only by physicians, but also by other team members.

The review by [Kawamoto et al. (2005)] showed that computer-based prompts at the point of care were most effective. Four characteristics were described as independent predictors for effectiveness:

- automatic provision of decision support
- provision of recommendations instead of declaration
- provision of decision support „just-in-time"
- Computer-based decision support

Of 32 systems with all of the four characteristics, 30 (94%) significantly improved their clinical practice (Compared to that 68% of all 70 examined studies showed an improvement).

- Further, there were some findings for the use of the following measures:
- Continuous performance feedback
- Transmission of patients' recommendation
- Demand for documentation of reasons for lacking compliance

Reduce error sources with decision support

In a study about order entry systems [Koppel et al. (2005)] discuss some error sources that might occur by using decision support.

- User-friendliness: confusion, incomplete information, misinterpretations because of fragmented and unclear illustration.
- Organisational problems: system design not matched to organisational processes, documentation of single orders on paper outside the system, redundant functions.
- Technical reasons: wrong data because of bad data integration from different information systems and inconsistent use of the system because of system failures.

Many of these mistakes happened on a regular basis (once a week or more often). The implementation of systems for decision support therefore needs to be accompanied by the awareness of avoiding error sources.

Acceptance of reminders and decision support

Clinical information systems enable the overview of several recommendations and plans, although they can not avoid erosion effects of prompts [Dexheimer et al. (2008)]. [Saleem et al. (2005)] analysed factors for the acceptance of computerized clinical reminders:

- **Barriers**: 1) lack of coordination between nurses and providers, 2) using the reminders while not with the patient, impairing data acquisition and / or implementation of recommended actions, 3) workload, 4) lack of flexibility, 5) poor interface usability
- **Facilitators**: 1) limiting the number of reminders at a site, 2) strategic location of the computer workstations, 3) integration of reminders into workflow, 4) the ability to document system problems and receive prompt administrator feedback.

According to [Saleem et al. (2005)] some strategies might increase user acceptance. These strategies include assigning responsibility for the clinical reminders, improving visibility of positive results, creating feedback about the use of reminders and limiting the number of reminders.

To remain the autonomy of health care providers, there has to be the possibility for opting-out from reminders [Lester et al. (2008)].

Evidence for reminders and decision support

Details on the described studies can be found in Table 6. The systematic review by [Garg et al. (2005)] does not recommend a broad use of clinical decision support systems. The effects of clinical decision support on process adherence by care providers were positively rated (64% of 97 analysed studies showed improvement), although patient outcomes were not sufficient analysed and results remained inconsistent (only 13% of 52 studies about patient outcomes showed improvement). Magnitude and clinical relevance of these improvements were not assessed by this review.

[Shojania et al. (2009)] analysed the impacts of computer-based reminders, which were generated at the point of care for clinical end points. The process adherence (medication prescription, vaccination, and laboratory) improved about 4,2% (respectively about 5,6% when analysing the best outcomes of each study). The achieved improvements in the providers' behaviour were rated small to medium. In the study different sort of reminders were compared. While single studies showed strong effects, no overall characteristic leading to strong effects was identified.

Preventive measures

A paradigm change from acute care to health promotion and preventive measures can be observed in the daily practice routine of practitioners. Every patient contact can be used for primary (mammography, vaccination) or secondary preventive measures (management of diabetes and hypertension). Effects of prompts in the use of preventive care were analysed in a systematic review by [Balas et al. (2000)]. The measure for effectivity was defined as absolute increase in the rate of performed preventive measures. The review showed that an increase in this rate of about 13,1% is possible. Depending on the recommended measure increases of about 5,8% to 18,3% were possible. The effect remained – independently from the duration of the intervention. Computer-generated reminders were more successful compared to non-computer-generated reminders (13,59% to 10,08%).

An update of this work was done by [Dexheimer et al. (2008)]. 28 additional papers together with the 33 original papers were analysed. 264 interventions were analysed. The results remained the same. Computer-generated software-based reminders (13%) and computer-generated printed reminders (12%) did not dominate the hard copy reminders (14%) any more. In the majority of cases computer-generated reminders were implemented. Studies in which reminders were only sent to physicians were more effective (14%) than those settings in which the reminders were also sent to patients (10%). The best effectiveness was reached for reminders for smoking cessation (23%) and heart disease (20%). Less effectiveness was reached through reminders for preventive measures – mammography (10%), pap smear (12%) and examination for occult blood in stool (12%). Reminders for physicians are a successful approach to increase the rate of performed preventive measures. The effectivity is high [Shojania et al. (2009)], but compared to the general use of reminders still moderate [Dexheimer et al. (2008)].

Relevance in diabetes therapy due to general practitioners

The Cochrane review by [Griffin and Kinmonth (2000)] compared the examination of diabetes patients by general practitioners to these examinations conducted by specialists. According to those findings, unstructured basic care with insufficient follow-up led to a higher mortality and a worse blood glucose level than care in hospitals. By the means of a centralised, computerised recall system with prompts for patients and practitioners, at least the same level or even better standards could be achieved in short term than in hospital outpatient care.

[Balas et al. (2004)] analysed computer-based prompts in diabetes care. In a review several RCTs were analysed, in which care providers were provided with computer-generated information to influence their working practice. The adherence to recommended processes was in general 71% to 227% higher than in the control group. 6 out of 8 studies showed a significant improvement of guideline adherence.

Future perspectives

IT based reminder systems for care providers are still a promising approach for sustainable models to meet the needs for guideline-based prevention measures by simultaneously monitor the patient for acute reasons. The work by [Garg et al. (2005)] recommends the use of computerised reminders and discusses that non-computerised alternatives might be cheaper and might result in the same effects [Grimshaw et al. (2004), Ofman et al. (2004), Warsi et al. (2004)]. Despite the increasing implementation of electronic records, there is only a small amount of RCTs analysing computerised reminder systems. If multi-centred, cluster-randomised studies are needed to evaluate these interventions, then there exists no sufficient evidence yet for broad recommendations [Dexheimer et al. (2008), Garg et al. (2005)].

The fragmentation of information within the health care system leads to repeated – unnecessary – assessments of patients. With the increasing implementation of information technologies in the health care systems, information exchange and access on electronic records will be simplified in the future [Dexheimer et al. (2008)].

3.3.3 Patient Information / Patient education / Empowerment

The following section describes how information technology supports patient education and patient self-management.

Static homepages

Homepages are generally used to display information about disease management programmes and to motivate patients to participate. They play a major role as communication media for the simple distribution of information [Nobel and Norman (2003)]. This information concerns mainly organisational aspects and general medical content. Homepages are useful for publicity and to mobilise patients. There was no evidence found about relevant effects on the patients' behaviour or patients' outcomes.

Interactive application for patient communication

The described applications comprise portals for patient support and personal health records [Dorr et al. (2007)]. Their function is beyond provision of information. They have the potential to motivate patients to invest in their own self-management [Nobel and Norman (2003)].

This application has the following aims [Eng and Gustafson (1999)]:

- Transmission of information
- Enabling of informed consent
- Promote healthy life-style
- Promotion of mutual peer information and emotional support
- Promotion of self-management
- Direction of the demand for health care resources

The used elements are [Murray et al. (2005)]:

- Fun-based training of self-management
- Online access to prepared information
- Moderated discussion forums
- Interactive decision support, decision support according to collected date in the health care sector
- Computer-based communication (e.g. with diabetes counsellors)
- Use of multi-media content (video, audio, figures, animations)

The used media are mainly online portals, but also computer games and interactive CDs or DVDs.

The Cochrane review by [Murray et al. (2005)] describes the mechanism of action of this application (see Figure 5). Through information provision better knowledge evolves, gets interpreted and leads to a better motivation. The better motivation leads to life-style changes, a better well-being and improvement in clinical outcomes.

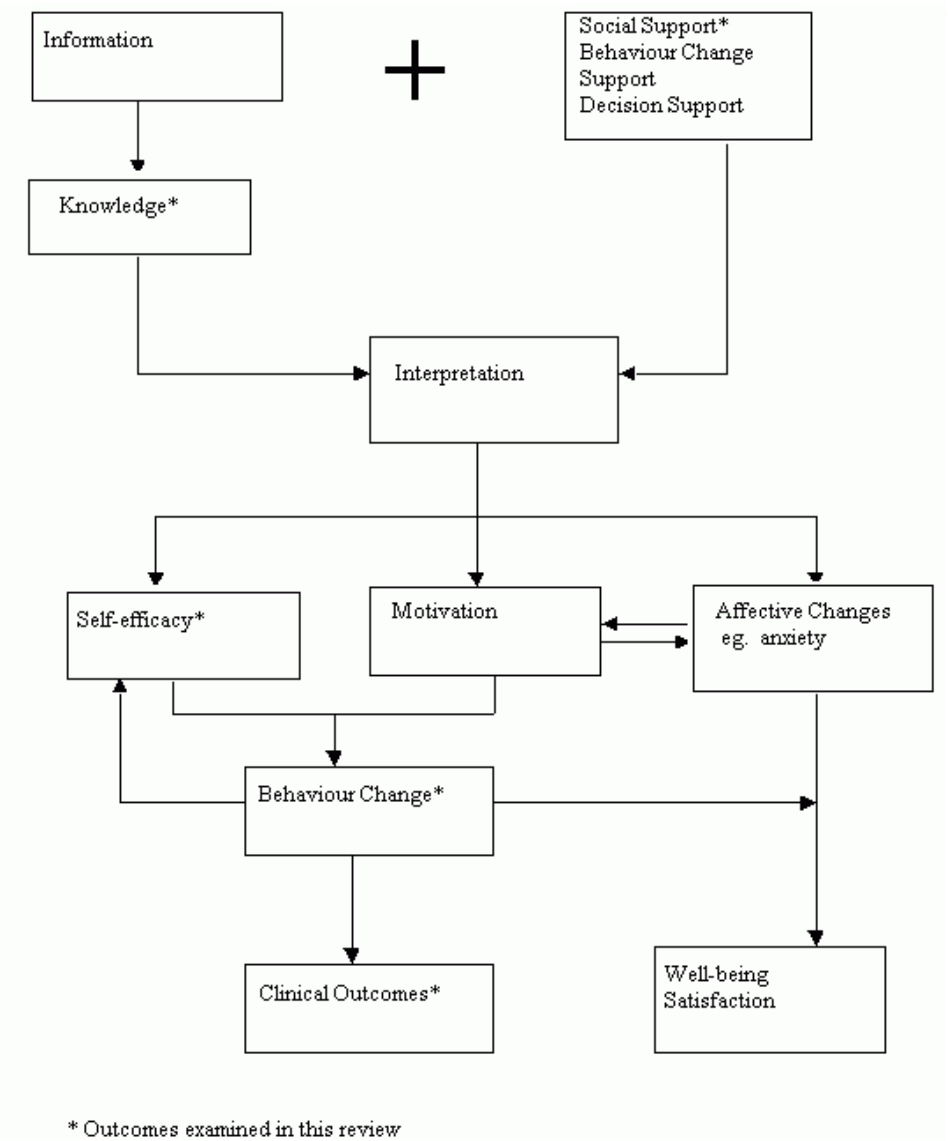

Figure 5: Postulated pathways of change [Murray et al. (2005)]

The review analysed the “Interactive Health Communication Applications (IHCAs)”, which are computer-based and web-based applications for patients. They combined the provision of health care information with at least one intervention like social support, decision support or life-style modifications.

The analysis of 24 RCTs (6 about diabetes) with 3739 participants showed significant positive effects on the knowledge of patients, the usage of social support, clinical outcomes and effectiveness.

Effects on emotional and economic outcomes were not measured. The review recommends further investment in such interactive applications for communication with patients. Unanswered remains the question for economic effects and to which extend these applications support equity in the treatment of disadvantaged groups.

The review by [Balas et al. (2004)] mainly analysed the aspects of computer-assisted education of diabetes patients. Further programs were included that contained interactive elements and displayed data from self-measurements. The review showed positive results. There were significantly better results of intermediate metabolic outcomes, especially HbA1, blood glucose measures and cholesterol.

[Jackson et al. (2006)] analysed studies for diabetes patient education and feedback via the internet and found significant improvements in HbA1c.

Personal health records (PHR)

Personal health records (PHR) are electronic applications that can be accessed by patients in a private, safe and known environment. The individual person defines access roles for practitioners and relatives and can delegate the administration of the records. The function of personal health records goes beyond data administration. The benefit lays in the combination of data, knowledge and software tools. These elements empower patients to actively participate in their own care [Tang et al. (2006), Warda (2005), Winkelman et al. (2005)].

The personal health records can either be implemented independently from other data sources, in direct connection to a patient record or in connection to more data sources (most complex version). Integration of personal health records in already existing systems of electronic patient records offer more advantages than records without such connection. Also connection to data sources such as home monitoring and telemonitoring is possible. In case of optimal adoption, these systems offer additional functions like electronic appointment, renewal of data entry and electronic communication with health care providers [Tang et al. (2006)].

Evidence of effectiveness of personal health records is limited. There are positive results concerning patient satisfaction, but confirmation of positive effects on clinical parameters or cost saving is still missing. Since evidence is not clear, there is only a ”potential” benefit for patients and health care providers [Tang et al. (2006)]. The analysis by [Kim and Johnson (2002)] about available systems showed that these systems had limited functionality.

Whether these data can be taken into account by health care providers is depending on several factors. There are reasonable demurs about data collected by patients. To avoid mistakes of diagnoses and medications, the implementation of personal health records needs to be done in connection to other sources. Data collected by patients need to be marked as such data.

Insufficient integration in regional programmes is a barrier when it comes to the use of these data by health care providers, even more when there is no reimbursement [Warda (2005)].

Data collected by patients about well-being, alimentation habits and self-management are a relevant source of information for health care providers. A case study by [Grant et al. (2006)] describes an example for collaborative care, implemented by Partners HealthCare System (Boston, MA): Data from PHR were shown to patients with a web-based application and patients could edit their own treatment and care plan. This plan was then considered by practitioners.

The acceptance of such health records depends on the underlying business model. These personal health records are often offered to individual persons or insurance companies. Private insurance companies use personal health records to achieve a competitive advantage [Tang et al. (2006)].

Barriers to the adoption of personal health records

Environmental barriers to adoption [Tang et al. (2006)]:

- Health records must interface with multiple electronic health record systems. Standards for (semantic) interoperability are therefore a condition sine qua non to realise the connection of such systems.
- Economic and market forces are obstacles to the adoption of PHR. Many stand-alone solutions have not been financially successful and therefore do no longer exist. This could possibly lead to an underestimation of personal health care record's potentials.
- Providers are careful about the legal implications of PHRs and inaccurate patient-entered information.
- A balanced level of data protection is still not found. Private health data need to be protected, but too aggressive protection measures might impede the use of personal health records.

Individual-level barriers to adoption [Lober et al. (2006), Tang et al. (2006)]:

- Patients need to accept a necessary behavioural change and the recognition of the benefit of personal health record through education and patient empowerment.
- A new understanding of roles of patients and care providers is necessary, so that the personal health record can be used as data resource.
- Lack of computer knowledge, fear of computers, cognitive and physical impairments are inhibiting factors, especially for older patients.
- Operational procedures of doctors and patients are hardly known. An understanding about how personal health records can be integrated in daily practice of individuals.
- The access to computers and networks is no problem.

Corporations outpace national health systems

Some years ago, [Warda (2005)] showed that online advertisement was not useful for health care records because of the intermixture of commercial interests with health care objects.

The content of personal health records were connected with acute health-related events and therefore their use had to be monitored.

In the meantime Google Inc. and the Microsoft Corporation picked up the subject of personal health records. Both offer their products Microsoft Health Vault (since October 2007) and Google Health (since February 2008). In particular, the fragmented health care system in the US it might be an incentive for users to administer and monitor their own health data.

These two solutions have some similarities [Kuraitis (2008), Stoltz (2008)]:

- They have the aim to organise and save data in an integrated online-environment, provide information, the search for health care providers, appointments, monitor medication and give health care providers access to data and information.
- Theses systems enable users to control and organise their own health data. They match data from different sources in one record. Users can determine which data will be recorded and who can access them.
- Both services are free of costs and web-based. They can be accessed via computer, (according to description) with the same data security as online banking.
- Both companies assure that no information will be passed on without explicit users' authorisation.
- Both offers tailored search options to match the users' needs.
- Both companies offer tools and APIs (Application Programming Interfaces) for the development of interfaces to transfer data (data import and data provision) from partners of all different provider levels (Microsoft's product seems to be a little bit more developed). [Eysenbach (2008)] welcomes this openness of web 2.0 as desirable feature. Still there is no

possibility of data export in either product. This could be because they are proprietary products and the vendors want to have provider lock-in.

- Both companies support standardised data transmission with the ASTM/HL7 Continuity of Care Document (CCD)

Microsoft Health Vault

Microsoft Health Vault is rather a personal health information platform. Only few features are developed by Microsoft, in fact, it is developed by partners and provided by them on the platform.

Core element is the search function. In the data guidelines there is written that displayed commercials are customized to the interests and preferences of the user.

Microsoft also allows the upload of data from medical devices and fitness devices (e.g. pulse watches).

Google Health

Google aims at developing a comprehensive personal health record. For partners there is the possibility to supply their service via Google Health. A big part of the functionality is developed by Google itself. Google supplies its platform to others and affirms that it is financially independent.

Google offers a search function within Google Health with no commercial ads displayed on the web page – this can not be excluded in the future. Google emphasizes that the recorded health data is not used to adopt the Google Search according to the health data.

There are several reasons why these corporations head in this direction: customer loyalty (people with a Google health record are more likely to use the Google search function), advertising revenue (Microsoft) and the value of big data collections for the development of personalised medicine.

Possible adverse effects by interactive systems for patients

In general, studies about adverse effects are hardly published. In the moment it is insecure, whether these applications have such a low risk or if adverse effects are simply not reported. [Crocco et al. (2002)]. Factors to be taken into account are equity (access and quality for the whole population), correctness of content, privacy policy and responsibility in case of errors.

3.3.4 Telemedicine, telemonitoring and telecare for patients at home

In this section technologies are discussed which enable communication, monitoring, treatment and care of patients at home, over a greater distance and with the help of telecommunication.

Two elements are relevant:

- **Patient contacts through telemedicine**: The usage of telecommunication is reduced to the role of communication medium for clinical monitoring, patient reminders or consultations by specialists (e.g. via telephone or video) [Field and Grigsby (2002), Paré et al. (2007)].
- **Home telecare / telemonitoring**: Measurements done by patients with biometric devices (e.g. scales, blood glucose measurement devices, blood pressure measurement devices) that are integrated in the system are transmitted. Computer and handhelds are used for data transmission and communication (e.g. PDAs, Smartphones) [Nobel and Norman (2003)].

Patient contacts thorough telemedicine

> *„Telemedicine is the use of telecommunications technology for medical diagnosis and patient care. " [Currell et al. (2000)]*

Adequate technologies are mainly telephone and interactive video communication, often, only videoconferences are meant when referred to telemedicine [Field and Grigsby (2002)]. Telemedicine

can cover patient care services for telepsychiatry, teleradiology, teledermatology and teleophthalmology.

Their primary aim is to enable consultations („virtual visits“) by specialists. This means that it is not per se a tool for self-management of chronic diseases [Koch (2006), Paré et al. (2007)].

[Koch (2006)] describes cultural differences concerning „virtual visits“ in North America and Europe. Virtual visits are more common in North America, whereas in Europe mainly tools for care providers with real visits are analysed. There is little evidence for the advantage of patient contacts through telemedicine. Especially the comparison between telemedicine and telephone-based consultations is insufficient analysed. [Field and Grigsby (2002)] discuss that the effectiveness of telephone-based interventions are well proven and recommend the further usage of telephone calls for the support of patient contacts through telemedicine. Current reviews question the clinical effect of telephone-based interventions: [Polisena et al. (2009a)] could not show an effect on HbA1c in patients with diabetes mellitus, and [Clark et al. (2007)] could not find evidence for reduced mortality or reduction of hospitalisation in patients with heart insufficiency. [Jackson et al. (2006)] found moderate to big improvements in HbA1c in patients with diabetes, although only 3 out of 16 studies were significant.

A review by [Verhoeven et al. (2007)] analysed studies about videoconferences with patients (13 studies + 4 studies in combination with telemonitoring). 11 out of 17 studies were uncontrolled observational studies, only 3 were RCTs. 6 studies showed improvements in HbA1c. A study about patient education via videoconference showed comparable effects like on-site education. 11 studies found a cost reduction (mainly due to reduced travel costs) – however, costs for education and equipment were not included in all analyses.

Home telecare / Telemonitoring

Home telemonitoring is a growing field since the beginning of the 1990s. Organisational and societal changes like the rising demand for patient empowerment and an ageing population are the reasons for this development [Koch (2006)].

Application areas for home telecare for chronic diseases are disease management programmes and the care of patients at home. For this usage monitoring and handhelds (e.g. PDAs, smartphones) are being applied with patient portals, described in section 3.3.3. Decision support (see 3.3.2) can be applied with home telecare. The expected benefit of this measure is better monitoring of the health status of patients and cost savings. This effect is not sufficiently analysed [Field and Grigsby (2002), Koch (2006), Verhoeven et al. (2007)].

Evidence for home telecare / telemonitoring

A Cochrane review [Currell et al. (2000)] and a systematic review [Paré et al. (2007)] found that home telecare is feasible, but there is insufficient evidence for clinical benefit. Telemonitoring remains a promising approach. Evaluation studies about the effects of home telecare are rare. This is reasoned by [Koch (2006)] with the complexity of innovation in clinical practice due to the necessity of organisational, legal and societal changes. This is why there are not sufficient evaluation systems. [Currell et al. (2000)] analysed 7 studies, 5 of which were about care and monitoring of chronic ill patients at home. [Paré et al. (2007)] analysed 65 studies about telemonitoring in different chronic diseases over the period 1990-2006. [Fursse et al. (2008)] investigated the use of telemonitoring in CHF, type 2 diabetes and essential hypertension. They stated that in a period of 12 weeks it is possible to effect a change towards a target.

The technical feasibility is given and does not need further research, the created data are precise and reliable [Currell et al. (2000), Paré et al. (2007)]. Whilst [Currell et al. (2000)] could not prove security of monitoring, a more positive appraisal was given by [Paré et al. (2007)]: Through continuous development of telecommunication technologies data can be collected and transmitted easily by patients. This helps to reduce bias and data become as reliable as data from on-site visits. It is possible to influence patients' behaviours and to empower patients. Patients had positive expectations about telemonitoring and showed high acceptance and satisfaction. The participating patients adhered to the programmes and technologies, independently from nationality, socioeconomic status and age, although compliance declined over time in some cases. The direct participation in the care process, the better knowledge and awareness about the health status lead towards an increased feeling for security and empowerment [Jaana and Paré (2007), Paré et al. (2007)]. The clinical benefit of

telemonitoring is not sufficient proven. [Paré et al. (2007)] found an improvement in the health status of patients, but with no significant effects. It was not clear, if the improvement in the studies resulted from telemonitoring or other mechanism like better consulting by care providers. None oft he studies conducted a cost-effectiveness analysis.

Home telemonitoring for diabetes mellitus

The evidence for effectiveness of home telemonitoring for diabetes has grown within the last years. The analysed studies relate predominantly on remote monitoring of glucose levels. Blood pressure monitoring is hardly linked to diabetes. Technical feasibility and acceptance are given above. Cost-effectiveness is insufficiently analysed.

[Balas et al. (2004)] detected through the usage of glucose protocols at home and computer-assisted dose adaptation of insulin a reduction in hypoglycaemias (3 out of 4 RCTs), reduction of insulin dose (3 out of 4 RCTs) and a reduction in HbA1c.

[Farmer et al. (2005)] analysed in a systematic review 26 studies (12 RCTs) about glucose telemonitoring. The studies were rather small (only 2 RCTs with >100 patients) and of short duration. The pooled results of 9 RCTs showed no effectivity of the intervention on HbA1c reduction (weighted mean difference −0,1%, 95% CI −0,4% to 0,04%). Only one study was designed to proof, if telemonitoring can substitute clinical interventions without a worsening in HbA1c.

[Jaana and Paré (2007)] analysed 17 studies about telemonitoring from the period 1991-2005 with duration of 3-15 months. 9 out of 14 studies found a significant improvement in HbA1c. 3 out of 4 studies showed improvements of various complications (reduction of hypoglycaemias, reduction of diabetic foot complication through usage of a thermometer). Statements about the resource usage were not comparable: Statements about the increased amount of work for physicians result in a reduced amount of yearly hospitalizations.

[Polisena et al. (2009a)] analysed 26 studies about telemonitoring. The effect on HbA1c was pooled out of 12 RCTs and resulted in a significant improvement (weighted mean difference -0,21; 95% CI -0,35 to -0,08). Simultaneously hospital days and hospital admissions were reduced.

[Corriveau et al. (2008)] analysed whether use of an internet-based insulin pump monitoring system improved blood glucose control in children treated with insulin pump therapy. The stated that the use of this system was associated with improvement in blood glucose control in children with type 1.

[Sutcliffe et al. (2011)] investigated whether communication technologies can be used to transfer information between healthcare professionals and young people with diabetes. Although they found positive improvement in 10 (out of 19) studies, the overall findings within the review were inconsistent of an association between improvements in HbA1c levels and increased contact.

In general, telemonitoring helps to control metabolic levels or improve them. Future research should focus on long term effects and how care can be substituted by telemonitoring.

Telemonitoring for chronic heart failure

Reviews about the usage of telemonitoring for patients with chronic heart failure confirmed their potential for the improvement of clinical outcomes. [Clark et al. (2007)] found a reduction in patients' mortality (5 RCTs, relative risk 0,62; 95% CI 0,45 to 0,85), but no significant reduction in hospital admissions. [Paré et al. (2007)] found no relevant clinical improvement for patients with heart insufficiency, but an improvement in quality of life. [Chaudhry et al. (2007)] stated that different programmes showed similar effects although the programmes' cost differed up to five times.

The evidence for telemonitoring for heart insufficiency is limited. On the basis of available data telemonitoring might be an effective strategy for disease management for high risk patients [Chaudhry et al. (2007)].

[Chaudhry et al. (2010)] found no significant differences between two groups of patients with heart failure (1653 randomized patients), who were either treated in a telemonitoring programme or in usual care.

In a review by [Inglis et al. (2010)] about structured telephone support or telemonitoring programmes for patients with chronic heart failure it was stated that structured telephone support and telemonitoring were effective in reducing the risk of all-cause mortality and CHF-related

hospitalizations in patients with CHF. They improved quality of life, reduced costs and evidence-based prescribing.

Implications for practice

[Koch (2006)] mentioned as limits for the implementation of home telecare the lack of standards in interfaces between information systems and devices as well as the lack of adequate guidelines for practical implementation. [Currell et al. (2000)] discussed that the use of telemonitoring applications led to fundamental changes in working practice. Patients and doctors need to be trained and the relationship between care provider and patient will be significantly changed.

[Paré et al. (2007)] summarised, that despite diffuse evidence on a clinical level, the potential of telemonitoring for the improvement of the health status was underlined. This justifies further research in Europe and North America.

Targets for future research

Future evaluations should base on a holistic model and a multidisciplinary approach [Koch (2006)]. The following elements were suggested by [Paré et al. (2007)]: Clinical effects, support patients' participation and motivation over time, cost-effectivity, health care providers' support, effects on health care resource use (comparison of additional effort for telemonitoring to possibly avoided complications)

Cost effectiveness of telemedicine

There is insufficient evidence that telemedicine is a cost-effective health care instrument. The mentioned studies show a positive cost effect, but their quality is insufficient to deduct general conclusions [Polisena et al. (2009b), Whitten et al. (2000), Whitten et al. (2002)].

[Whitten et al. (2002)] analysed 612 articles, only 24 of them contained cost data in sufficient quality and 20 of them were limited to simple cost comparisons. None of the studies comprised a cost-benefit analysis about therapeutic interventions. Only 7 out of 24 studies tried to identify to which extend telemedicine needs to be applied to bear up against standard care. None of the studies could answer this research question. 62,5% of these studies comprised no sensitivity analysis. An exception to that might be usage of telemedicine in special setting, in which great distances or organisational barriers exist (e.g. space programmes) and cost savings might be possible (e.g. retinopathy screening of prison inmates [Aoki et al. (2004)])

3.3.5 (Connection to) electronic records

The demand by disease management programmes to apply evidence-based clinical processes and measure processes and outcomes, leads to a strong demand for clinical information systems [Lester et al. (2008)]. There are all kinds of electronic patient records, depending on content, functions and applications. In general, electronic patient records are frequently applied. Very often they are the basis for other IT interventions (e.g. decision support, electronic orders). The review by [Dorr et al. (2007)] showed that the connection of IT systems to care of chronic diseases with electronic patient records leads to positive experimental results. This is the reason why integration of electronic health records for care improvement needs to be supported.

There are expected cost savings, shown by various cost-benefit analyses, through the use of electronic patient records (and the data exchange between health care and interoperability).

The quantified benefit prevails the (investment) costs, although the duration to break even might last up to 13 years [Shekelle et al. (2006)]. [Chaudhry et al. (2006)] proved in a systematic review of 257 studies about the influence of information and communication technologies (ICT) on health care the lack of interoperability realisation in commercial systems. The analysed systems were little multi-functional – only 3,5% of the studies evaluated multi-functional, commercial systems. Most of the systems were used for stand-alone use such as decision support for care providers (63%), electronic health records (37%) or developed as systems for electronic orders (13%).

Only 1% of the analysed systems offered the possibility to connect and interchange interoperable data.

Electronic patient record

Electronic patient records are a core element of integrated care with growing relevance. They contain information on the health status or treatment data and therefore illustrate the care process and enable the communication and cooperation between the centres.

An organisational extension in terms of shared care leads to the „Electronic Healthcare Records (EHCR)".

Data access depends on the user's profession and authorisation [Schabetsberger et al. (2006)].

The following aims and targets of electronic health records are mentioned in the literature [Glock et al. (2004)]:

- complete and structured patient record
- information source available at all times
- medical decision basis
- consistent information source
- legally accepted medical care documentation
- support of research action, education and training
- basis for reimbursement, controlling and budgeting

Standardisation, semantic interoperability

Technical standardisation and semantic interoperability are the requirements for successful communication beyond health care levels and organisation limits.

IHE (Integrating the Healthcare Enterprise)

Within the international initiative IHE, information system companies cooperate with users on the realisation of interoperability. IHE is no standard, but uses existing and accepted standards to cover all kind of health care settings. IHE provides (free accessible) recommendations on different domains in terms of profiles on how to use standards. Beyond the development of profiles IHE arranges „Connectathons", in which software developer can prove the compatibility of their products with profiles and get certificated for conformity [Integrating the Healthcare Enterprise (2009a)].

For integrated care the below mentioned profiles of the "IHE Patient Care Coordination Domain" are relevant:

Table 2 Profiles of the IHE Patient Care Coordination Domain

Cross Enterprise Sharing of Medical Summaries (XDS-MS)[*]: Transmission of clinical documents, Transfers or summaries of medical records (HL7 CDA Document, HL7 Care Record Summary or ASTM/HL7 Continuity of Care Document)
Exchange of Personal Health Record Content (XPHR) [*]: Information exchange and interoperability between the electronic patient record of care providers with the patient's personal health record.
Functional Status Assessments (FSA): Transmission of the current patients' functional status assessment during the transfer to another care facility. Documentation is made in a „Continuity of Care Document" (CCD), proper to enable long-term documentation.
Care Management (CM): Data exchange between an EHR or a medical information system and a specialised system, for example a disease management system. The profile enables the electronic dissemination of evidence-based guidelines.
Patient Plan of Care (PPOC): Documentation tool for structured and coded care documentation, kept during the whole hospitalisation and finished with discharge or transmission. The document is passed on to the next care centre in case of transmission.
Query for Existing Data (QED): Data query from an electronic record or another data storage fort he usage in clinical care, quality reporting, reimbursement, health reporting, clinical studies and the recognition of pharmacological interactions.

Request for Clinical Guidance (RCG): Integration of clinical decision support in health information systems
Immunization Content (IC): Data about vaccination, which are being transmitted between medical information systems and other systems (e.g. PHR)
Emergency Department Referral (EDR)*: Transmission of an emergency data set by an EHR system to an emergency information system
Emergency Department Encounter Summary (EDES): Summarisation of data from emergency unit visits with the current health status and all used health resources.
EMS Transfer of Care (ETC): Data transfer between emergency transport and emergency units
Antpartum Care Summary (APS): Document summarisation for pregnancies
Antepartum Record (APR): All information about pregnancies (can comprise several documents with summaries, physical examinations, lab and trainings activities)
Lab and Delivery Record (LDR): Continuance of the Antepartum Record with extensive information about mother and newborn

Source: [Integrating the Healthcare Enterprise (2009a), Integrating the Healthcare Enterprise (2009b)]

The specification of the marked profiles (*) is finalised, the other profiles are released for trial implementation.

3.3.6 Cost effectiveness of IT in Disease Management Programmes

As described previously, cost-effectiveness of IT interventions for disease management is insufficiently analysed [Jackson et al. (2006)]. [Bu et al. (2007)] analysed in a model calculation the cost saving potential of IT support within disease management. Technologies for health care providers showed the greatest saving potential: 1.016 Dollar for diabetes registers and 752 Dollar for clinical decision support, per registered patient over a period of 10 years.

Patient-centred technologies showed decent cost savings: 130 Dollar for remote monitoring, 34 Dollar for self-management, per registered patient over a decade.

[Adler-Milstein et al. (2007)] conducted a cost-benefit-analysis about the usage of IT systems in disease management programmes for various centres:

- Registers with reminders (mainly web-based): adequate measure for small to medium sized practices
- Electronic patient record with decision support: favourable tool for big practices due to high fixed costs. For big practices with already existing and implemented electronic patient records the adaptation of existing systems to the requirements of a disease management can be done more cost effective than in single-site and web-based registers.
- Remote monitoring: due to the big effort needed for remote monitoring only suitable for few patients per practice. Acquisition costs and current costs per patient are relatively high and independent from centre size.
- Platforms for self-management: cost structure analogue to that from remote monitoring with lower acquisition costs, compared to the yearly costs.

3.3.7 International implementation of IT

Despite the lack of robust evidence, there are still high expectations regarding quality improvement and cost savings possible with information technology. That is why many of the countries still support the implementation of IT in health care systems.

Often the originally calculated costs and time frames were exceeded (e.g. „Health Infoway“ in Canada, „NHS National Programme for IT“ in Great Britain) [Anderson et al. (2006)].

In the US implementation started 12 years later than in other industrialised countries [Anderson et al. (2006)]. The American Institute of Medicine requested in „Crossing the Quality Chasm“ 2004 a restructuring in health care on the basis of IT infrastructure [IOM (2004)].

The current American government works on the realisation of these recommendations and provided in the „American Recovery and Reinvestment Act of 2009“ 19 billion dollars for the establishments of information technologies in the health care system [USA (2009)].

The European Commission supports “ICT for a better Healthcare in Europe” and the “i2010-Initiative – A European Information Society for growth and employment”. It is planned that all member states develop a framework for the support of electronic health services by taking these actions: Interoperability, improvement of the infrastructure, legal and regulatory responsibilities, mobility of patients and system adaptation to the requirements [Kommission der Europäischen Gemeinschaften (2004)].

3.3.8 Aspects of IT implementation

For successful implementation of information system in health care, health care providers need to adopt these systems. According to a review by [Dorr et al. (2007)] usability has been established (16 studies with positive results, one without result and two with negative results). Also implementation of technical aspects is no impairment. The following implementation criteria are mentioned by [Lester et al. (2008)]

Respect health care provider’s workflow

- Speed
- Simplicity
- Usage of easily adoptable technology
- Respect physicians’ autonomy
- Putting clinical knowledge into action
- Getting patients involved
- Evaluation

Core elements within the system are data privacy and data integrity.

3.3.9 Summary and Discussion

The results of the above described studies show that the use of ICT within diabetes care is associated with the improvement of process and patient outcome quality [Adaji et al. (2008)]. High potential is referred to this relative young technology, but further research is necessary to integrate ICT in health care. [Jackson et al. (2006)] recommends the following study criteria: (1) RCT design (2) analysis of long-term effects of interventions (3) publication of the effects (4) representative number of ethnic minorities and underserved populations.

Barriers to the adoption of information technology in diabetes care are: data privacy, insufficient financing, lack of personnel and time, fear of change. The acceptance and implementation of information technologies can be supported through user training and integration in daily practice care.

4 Summary of evidence for DMP, components and ICT

4.1 Evidence for DMP

Table 3: Evidence for disease management programmes

Study	Effects on physician's behaviour	Effects on patient's behaviour	Patient oriented outcomes	Medical outcomes	Resource specific outcomes
[Ofman et al. (2004)] Systematic Review	**Adherence to guidelines** (14/35)[3]	**Adherence to therapeutic recommendations** (17/36) **Patient knowledge** (4/13)	**Patient satisfaction** (12/17) **Health Status / Quality of life** (5/31)	**Disease control** (33/74) **Morbidity** (7/24), **Mortality** (4/17)	**Costs** (1/7) **Emergency hospitalisations** (1/9)

Table 4: Studies on evidence for disease management programmes for diabetes mellitus

Study	Effects on physician's behaviour	Effects on patient's behaviour	Patient oriented outcomes	Medical outcomes	Resource specific outcomes
[Knight et al. (2005)] Systematic Review	Improved processes Monitoring and screening: **Retinopathy** more often **Foot examination** more often	**Foot self-control and care** more often and more adequate	Positive trends	**HbA1c** (9/24) -0,5% No statement on long-term effects. **RR systolic** (1/7) **LDL** (1/9) **HDL** (1/5)	Positive trends

[3] (x /y) … Number of studies with significant result / Number of studies with that research question

Study	Effects on physician's behaviour	Effects on patient's behaviour	Patient oriented outcomes	Medical outcomes	Resource specific outcomes
	Blood pressure control more often				
[Norris et al. (2002b)] Systematic Review	Improved processes Monitoring and screening: **HbA1c** (n=15)[4] +15,6% **Lipids** (n=9) +24% **Exe examination** (n=15) +9% **Foot examination** (n=9) +26,5%, **Proteinuria** (n=7) +9,7%	**Diabetes knowledge** improved (n=1) **Blood glucose self-testing** improved (n=1) **Self-effectiveness** (n=1) improved	**Quality of life** (n=1) improved **Patient satisfaction** (n=2) improved	Intermediate outcomes: **HbA1c** (n=19) -0,5% **Weight** (kg) (n=3) +0,2 **BMI** (kg/m^2) (n=4) +0,45 **RR** (mmHg) (n=6) systolic +0,9, diastolic -1,6 **Cholesterol** (mg/dl) (n=2) reduced	**Hospitalisations** (n=5) -31% **Number of visits** (n=4) -5,6% **Patients with yearly examination** (n=3) +7,7%
[Gillespie (2002)] Review	No statement	**Diabetes knowledge** improved (20/20) **Patient commitment** improved (9/9) **Use of medication** improved (8/14)	No statement	No statement	**Emergency admissions** reduced (2/4) **Physician visits** reduced (3/4) **Cost-effectiveness** unclear statement – more patients participating in the programme lead to less costs
[Cleveringa et al. (2008)] RCT	No statement	No statement	No statement	**HbA1c** not significantly improved, but 6,9% in both groups **10 year UKPDS Risk for CHD**	No statement

[4] (n=…) … Number of studies with details to this research question

Study	Effects on physician's behaviour	Effects on patient's behaviour	Patient oriented outcomes	Medical outcomes	Resource specific outcomes
				significantly improved **RR systolic and diastolic** significantly reduced **Total and LDL Cholesterol** significantly improved More patients reached targets: 68% **HbA1c** ≤ 7%, 53,9% **RR systolic** ≤ 140 mmHg, 53,5% **LDL Cholesterol** ≤ 2,5 mmol/l	
[Piatt et al. (2006)] RCT	No statement	**Blood glucose self-testing** +22,2% more often (compared to other groups after adjustment p=0,03) **Diabetes knowledge** improved	**Empowerment Scores** improved	**HbA1c** Improvement in CCM group -0,6% (compared to other groups after adjustment p=0,01) **Cholesterol** improved (after adjustment p=0,05)	No statement
[Sidorov et al. (2002)] Retrospective cost-analysis	Improved processes Monitoring and screening (Intervention vs. control): **HbA1c** 96,6 vs. 83,8% **Lipid testing** 91,1 vs. 77,6% **Eye examination** 79,1 vs. 74,9% **Nephropathy screening** 68,5 vs. 39,3%	No statement	No statement	**HbA1c** less patients with worse level (>9,5%)	**Costs/insured patient/month** $394,62 vs. $502.48 significantly reduced **Hospital admissions** slightly reduced **Hospital days** significantly reduced **Emergency admissions** slightly reduced **Physician visits** slightly increased

Study	Effects on physician's behaviour	Effects on patient's behaviour	Patient oriented outcomes	Medical outcomes	Resource specific outcomes
[Olivarius et al. (2001)] RCT	**Prescription performance**: Metformin more often More optimistic **aims**	No statement	Patients were more content due to the increased attention bc. of the study.	**Mortality** no differences as well as for **non fatal clinical endpoints**: Neuropathy, retinopathy, microalbuminuria, heart attack, stroke, claudication Risk factors reduced in the intervention group: **HbA1c** (8.5% vs. 9%), **RR systolic** (145 vs. 150 mmHg), **Cholesterol** (6.0 vs. 6.1 mmol/l)	**Follow-up visits at general practitioner** more often, **Visits in diabetes clinics** slightly less

4.2 Evidence for DMP components

Table 5: Evidence on DMP components, according to the Cochrane EPOC taxonomy

Intervention	Effect on Process	Effect on Outcome	Source
Patient Education	Process improvement	Outcome improvement	[Renders et al. (2001b)]
		Improved disease control Diabetes: 6/17, 0.22 (0.15 - 0.30) Hypertension: 2/2, 1.6 (0.30 - 2.9) Total: 24/55, 0.24 (0.07 - 0.40)	[Weingarten et al. (2002)]
		Diabetes: **HbA1c** reduction compared to control group 0.76% (0.34 –1.18) at immediate follow up, 0.26% (0.21% increase - 0.73% decrease) after 1-3 months and 0.26% (0.05– 0.48) after 4+ months	[Norris et al. (2002a)]

Intervention	Effect on Process	Effect on Outcome	Source
		Studies in older adults: Diabetes: **HbA1c** reduction 0,81% pooled effect size of -0.36 (95% CI, -0.52 to -0.21) **Systolic blood pressure** reduction 5 mmHg and **diastolic blood pressure** 4,3 mmHg Osteoarthritis: no clinically relevant results	[Chodosh et al. (2005)]
		Modest to large effects for some conditions and patient populations	[Shojania and Grimshaw (2005)]
		Diabetes: **Improved blood glucose control** Hypertension systolic BP improvement	[Shojania and Grimshaw (2005)]
		Diabetes: **HbA1c** reduction 0,48%;n=38 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg) systolic 8.1 (3.3–11.8); n=18 diastolic 3.8 (0.6–6.7); n=21	[Walsh et al. (2006)]
Patient group education		Diabetes: **HbA1c** reduction (significant) 1.4% (0.8 - 1.9) after 4-6 months 0.8% (0.7 - 1.0) after 12-14 months 1.0% (0.5 - 1.4) after 2 years **body weight** ↓, **diabetes knowledge** ↑ Systolic **blood pressure** -5 mmHg (1 – 10) Reduced **need for medication** (OR 11.8) **Self management** skills, **patient empowerment** ↑ Long-term effects (2 years): Improved **quality of life**, reduced **progression of**	[Deakin et al. (2005)]

Intervention	Effect on Process	Effect on Outcome	Source
		diabetic retinopathy	
Patient Self Management		Diabetes: **HbA1c** reduction 0,36%;n=20 trials	[Shojania et al. (2006)]
Patient Self Management Support	**Process of care**: 1.31 (1.00, 1.71) (Pooled Effect Size, higher is better)	**Clinical Outcome (continuous)**: −0.22 (−0.38, −0.05) (Pooled Effect Size, lower is better) **Clinical Outcome (dichotomous)**: 0.81 (0.66, 0.99) (Pooled Effect Size, lower is better) **Quality of life**: −0.03 (−0.25, 0.19) (Pooled Effect Size, higher is better)	[Tsai et al. (2005)]
Promotion of Self Management		**Blood pressure** reduction (mmHg) systolic 3.3 (2.6–10.1); n=9 diastolic 2.8 (0.4–6.7); n=13	[Walsh et al. (2006)]
Patient Reminder		Improved **disease control** Diabetes: 4/7, 0.31 (0.18 - 0.44) Total: 6/16, 0.27 (0.17 - 0.36)	[Weingarten et al. (2002)]
		Diabetes: **HbA1c** reduction 0,49%; n=14 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg) systolic 3.3 (2.3–4.5); n=5 diastolic 0.4 (-2.4–5.0); n=9	[Walsh et al. (2006)]
Patient Recall	process improvement	Outcome improvement less clear … can also improve diabetes management	[Renders et al. (2001b)]

Intervention	Effect on Process	Effect on Outcome	Source
Patient financial incentives		Improved **disease control** Hypertension: 2/2, 0.48 (0.44 - 0.53) Total: 3/4, 0.40 (0.26 - 0.54)	[Weingarten et al. (2002)]
		Some evidence for achieving target goals, but also for concerning decreases in access and conflicts of interest in physician-patient relationships	[Shojania and Grimshaw (2005)]
		Blood pressure reduction (mmHg) systolic -13.3; n=1 diastolic 0.0 (-2.0–2.5); n=3	[Walsh et al. (2006)]
Provider Education	Seemed to be effective, was always used in combination with other interventions		[Renders et al. (2001b)]
	Improved adherence to guidelines Diabetes: 1/3, 0.23 (0.1 - 0.35)[5] Hypertension: 0/4, 0 (-0.13 - 0.13) Total: 12/24, 0.44 (0.19 - 0.68)	**Improved disease control** Diabetes: 2/8, 0.21 (0.1 - 0.34) Hypertension: 2/5, 0.67 (-0.15 - 1.5) Total: 12/32 0.35 (0.19 - 0.51)	[Weingarten et al. (2002)]
		Diabetes: Improved blood glucose control Hypertension no improvement	[Shojania and Grimshaw (2005)]
		Diabetes: HbA1c reduction 0,43%;n=20 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg) systolic 3.3 (1.2–5.4); n=11 diastolic 0.6 (-0.7–3.4); n=16	[Walsh et al. (2006)]

[5] x/y, e (95% CI) … x Studies with significant result of y studies in total, effect size with CI 95%

Intervention	Effect on Process	Effect on Outcome	Source
Provider Reminders (manual or computerized decision support)	effective		[Davis et al. (1995)]
	Promising		[Grimshaw et al. (2001)]
	Reminders often effective if well integrated with workflow Decision support sometimes effective, but less so for the more complex situations in which it would be most desirable	Diabetes: Improved blood glucose control Hypertension no improvement	[Shojania and Grimshaw (2005)]
	Improved adherence to guidelines Diabetes: 1/2, 0.36 (0.02 - 0.7) Total: 6/10, 0.52 (0.35 - 0.69)	**Improved disease control** Diabetes: 2/4, 0.28 (0.12 - 0.44) Hypertension: 1/1, 0.52 (0.1 - 0.93) Total: 6/14, 0.22 (0.1 - 0.37)	[Weingarten et al. (2002)]
	Median absolute performance improvement 14,1% (14 trials)		[Grimshaw et al. (2004)]
		Diabetes: **HbA1c** reduction 0,23%;n=18 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg) systolic 1.2 (1.0–1.9); n=6 diastolic 0.3 (-0.2–1.7); n=6	[Walsh et al. (2006)]
Decision Support	**Process of care**: 1.29 (1.08, 1.54) (Pooled Effect Size, higher is better)	**Clinical Outcome (continuous)**: −0.14 (−0.33, 0.05) (Pooled Effect Size, lower is better) **Clinical Outcome (dichotomous)**: 0.87 (0.69, 1.09) (Pooled Effect Size, lower is better)	[Tsai et al. (2005)]

Intervention	Effect on Process	Effect on Outcome	Source
		Quality of life: 0.04 (−0.36, 0.45) (Pooled Effect Size, higher is better)	
Audit and feedback	Improved adherence to guidelines Diabetes: 0/2, 0.08 (-0.17 - 0.34) Total: 9/16, 0.61 (0.28 - 0.93)	Improved **disease control** Diabetes: 0/3, 0.19 (0.02 - 0.37) Hypertension: 0/1, 0.08 (-0.01 - 0.17) Total: 9/23, 0.17 (0.1 - 0.25)	[Weingarten et al. (2002)]
	Dichotomous outcomes: Adjusted risk difference of compliance with desired practice: -16% (decrease) to +70% (increase) (median 5%; inter-quartile range 3%-11%) Adjusted risk ratio 0,71 to 18,3 (median 1,08; inter-quartile range 0,99-1,30) Continuous outcomes: Adjusted percent change relative to control: -10% (absolute decrease in compliance) to 68% (increase) (median 16%; inter-quartile range 5% - 37%)		[Jamtvedt et al. (2006)]
	Median absolute performance improvement 7% (5 trials)		[Grimshaw et al. (2004)]
	Small to modest (at best) benefits		[Shojania and Grimshaw (2005)]
		Diabetes: **Improved blood glucose control** Hypertension **systolic BP improvement**	[Shojania and Grimshaw (2005)]
		Diabetes: **HbA1c** reduction 0,31%;n=9 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg)	[Walsh et al. (2006)]

Intervention	Effect on Process	Effect on Outcome	Source
		systolic 1.5 (1.2–1.7); n=3 diastolic 0.6 (0.4–1.0); n=4	
Revision of professional roles ("Changes to team or staffing")		Studies in which nurses replaced (partly) physicians in providing diabetes care generally demonstrated a **positive impact on blood glucose control**	[Renders et al. (2001b)]
		Diabetes: Improved **blood glucose control** Hypertension: **Systolic BP** improvement	[Shojania and Grimshaw (2005)]
		Diabetes: **HbA1c** reduction 0.67% (0.43%-0.91%); n=26 trials	[Shojania et al. (2006)]
		Blood pressure reduction (mmHg) systolic 9.7 (4.2–14.0); n=20 diastolic 4.2 (0.2–6.8); n=24	[Walsh et al. (2006)]
"Delivery System Design"	**Process of care**: 1.16 (1.01, 1.34) (Pooled Effect Size, higher is better)	**Clinical Outcome (continuous)**: −0.21 (−0.40, −0.02) (Pooled Effect Size, lower is better) **Clinical Outcome (dichotomous)**: 0.77 (0.62, 0.96) (Pooled Effect Size, lower is better) **Quality of life**: 0.33 (−0.10, 0.76) (Pooled Effect Size, higher is better)	[Tsai et al. (2005)]
Organizational Changes	Mostly positive results for case management and disease management programs		[Shojania and Grimshaw (2005)]

Intervention	Effect on Process	Effect on Outcome	Source
	Process of care: 0.88 (0.67, 1.16) (Pooled Effect Size, higher is better)	**Clinical Outcome (continuous)**: −0.02 (−0.33, 0.29) (Pooled Effect Size, lower is better) **Clinical Outcome (dichotomous)**: 0.82 (0.56, 1.20) (Pooled Effect Size, lower is better) **Quality of life**: −0.38 (−1.26, 0.49) (Pooled Effect Size, higher is better)	[Tsai et al. (2005)]
Printed Educational materials		Generally ineffective	[Shojania and Grimshaw (2005)]
	May have a beneficial effect on process outcomes when used alone, clinical significance is not known	No effect on patient outcomes	[Farmer et al. (2008)]
	Median absolute performance improvement 8,1% (4 trials)		[Grimshaw et al. (2004)]
	Less effective		[Davis et al. (1995)]
Conferences	Generally ineffective		[Shojania and Grimshaw (2005)]
	Relatively little impact		[Davis et al. (1995)]
Local Consensus Process			
Local opinion leaders	Overall 10% absolute decrease in non-compliance in the intervention group		[Doumit et al. (2007)]
	effective		[Davis et al. (1995)]
Facilitated Relay of Clinical Information		Diabetes: **HbA1c** reduction 0,39%;n=15 trials	[Shojania et al. (2006)]
		Hypertension: **Blood pressure** reduction	[Walsh et al. (2006)]

Intervention	Effect on Process	Effect on Outcome	Source
		(mmHg) systolic 8.0 (2.5–12.3); n=16 diastolic 1.8 (-0.1–4.5); n=18	
Patient-mediated interventions	effective		[Davis et al. (1995)]
Marketing			
Multifaceted interventions (compared to single interventions)	changes in professional performance	changes less consistent	[Oxman et al. (1995)]
	effective		[Davis et al. (1995)]
	more likely to be effective than single interventions		[Grimshaw et al. (2001)]
	can enhance the performance of health professionals in managing patients with diabetes		[Renders et al. (2001b)]
		Diabetes: Yes, better results for **blood glucose control** Hypertension insufficient data	[Shojania and Grimshaw (2005)]
Multifaceted interventions including educational outreach	Performance improvement: Cluster RCT: 11/13, median improvement 6% Controlled before after study: 2/4, median effect 7.3%		[Grimshaw et al. (2004)]
Educational outreach visits	Promising effect on prescribing		[Grimshaw et al. (2001)]
	Increased provider knowledge possible		[Shojania and Grimshaw (2005)]
	effective		[Davis et al. (1995)]

Intervention	Effect on Process	Effect on Outcome	Source
Case management		Diabetes: Improved **blood glucose control** Hypertension: Improved systolic BP	[Shojania and Grimshaw (2005)]
		Diabetes: **HbA1c** reduction 0.52%; (0.31%-0.73%); n=26 trials	[Shojania et al. (2006)]
Electronic Patient Registry (Clinical Information Systems)		Diabetes: **HbA1c** reduction 0,43%; n=8 trials	[Shojania et al. (2006)]
	Process of care: 1.08 (0.91, 1.28) (Pooled Effect Size, higher is better)	**Clinical Outcome (continuous)**: −0.06 (−0.27, 0.15) (Pooled Effect Size, lower is better) **Clinical Outcome (dichotomous)**: 0.83 (0.64, 1.07) (Pooled Effect Size, lower is better) **Quality of life**: −0.28 (−1.08, 0.51) (Pooled Effect Size, higher is better)	[Tsai et al. (2005)]
Continuous Quality Improvement		Diabetes: HbA1c reduction 0,23%; n=3 trials	[Shojania et al. (2006)]
Shared Care		No effect for diabetes and hypertension	[Smith et al. (2007)]
Informatics Systems (to promote improved care for chronic illness)	**Guideline Adherence**: -0/4/+15[6] (screening, conducting lab tests…) **Visit Frequency**: -0/5/+5 **Documentation**: -0/1/+5 **Treatment Adherence**: -0/1/+2 (primarily	**Laboratory values**: -0/5/+5 **Depression scores** (PHQ-9, Beck): -1/6/+3 **Hospitalizations**: -0/4/+3 **Quality of Life**: -0/1/+3 **Complications**: -0/1/+1	[Dorr et al. (2007)]

[6] -x/y/z … x studies with negative results, y studies with neutral result, z studies with positive results

Intervention	Effect on Process	Effect on Outcome	Source
	medication) **Referrals**: -0/2/+0 **Screening / testing**: -0/0/+2 **Cost studies**: -0/1/+10		
Community Resources		**Clinical Outcome (continuous)**: −0.11 (−0.41, 0.19) (Pooled Effect Size, lower is better)	[Tsai et al. (2005)]

4.3 Evidence for IT support of DMP

Table 6: Evidence for IT-supported DMP components

Intervention	Effect on Process	Effect on Outcome	Source
Reminders and Clinical Decision Support Point of Care computer reminders	**Median improvement in process adherence:** All reported process outcomes: 4.2% (IQR: 0.8% - 18.8%) Medication ordering: 3.3% (IQR: 0.5% - 10.6%) Vaccinations: 3.8% (IQR: 0.5% - 6.6%) Test ordering: 3.8% (IQR: 0.4% - 16.3%) **Sensitivity analysis using best outcome from each study, median improvement:** All process measures: 5.6% (IQR: 2.0% to 19.2%) Medication ordering: 6.2% (IQR: 3.0% to 28.0%)	Median absolute improvement 2.5% (IQR: 1.3% - 4.2%). Blood pressure median change: Systolic: −1.0 mmHg (IQR −2.3 to +2.0 mmHg) Diastolic: −0.2 mmHg (IQR −0.8 to +1.0 mmHg)	[Shojania et al. (2009)]
CDSS	Significant improvement of clinical practice in 68% of trials (70 trials examined).	Only 52 trials measured at least one patient outcome. Improvements were noted in only	[Kawamoto et al. (2005)]

Intervention	Effect on Process	Effect on Outcome	Source
	32 systems possessed the 4 features associated with improved practice (automatic as part of clinician workflow, recommendations rather than just assessments, at the time and location of decision making, computer based). 30 (94%) significantly improved clinical practice.	13% of these studies.	
Comparison of hospital care, GP care with/without prompting system		No difference in mortality between hospital and GP care when GPs and patients were supported through a prompting system (OR 1.06, 95% CI 0.53 - 2.11). Adverse patient outcomes without support through prompting systems.	[Griffin and Kinmonth (2000)] Five trials involving 1058 people included.
CDSS	Improved practitioner performance in 62/97 (64%) of the studies assessing this outcome. Including Diagnostic systems: 4/10 (40%) Reminder systems 16/21 (76%) Disease management systems 23/37 (62%) Drug-dosing or prescribing systems 19/29 (66%) Disease-specific results: - Cancer Screening, Vaccination, Prevention: 0/1 - Diabetes Management: 0/3 - CVD Management and Prevention: 1/12	7/52 (13%) of trials assessing 1 or more patient outcomes reported improvements. Disease-specific results: - Cancer Screening, Vaccination, Prevention: 0/1 - Diabetes Management: 0/3 - CVD Management and Prevention: 1/12	[Garg et al. (2005)] 100 randomised and non-randomised, controlled studies
CDSS	**Foot check**: 1 | 0 | 0 [7]	**HbA1c**: 2 | 1 | 1	[Adaji et al. (2008)]

[7] Number of studies with significant improvement| not significant improvement | no change

Intervention	Effect on Process	Effect on Outcome	Source
	Eye check: 0 | 1 | 1 **Physical activity advice**: 1 | 0 | 0 **Medications**: 0 | 1 | 1	**LDL-Cholesterol**: 1 | 0 | 1 **Blood pressure**: 0 |1 | 0 **Blood glucose**: 1 | 0 | 0	(Systematic review)
Physician Reminders (Prompts) to improve preventive care	Overall improvement in preventive care 13.1% (95% CI 10.5%-15.6%). Effect is dependent on recommended intervention and ranges from 5.8% to 18.3%. Improved rates of compliance with the recommended procedures for different types of reminder provision: - Computer generated (25) 13.59% (10.87-16.30)[8] - Non-computerized (8) 10.08% (1.27-18.89) - In front of chart (26) 14.01% (11.08-16.94) - Alternative delivery (7) 12.13% (5.35-18.90)		[Balas et al. (2000)] (Systematic review and meta analysis of RCTs) 33 eligible reports
Reminders (paper-based, computer-generated and computerized) for preventive care measures	Overall average increase in delivering desired preventive care measures (=effect) 12% to 14%. **Effect comparison of primary implementation reminder strategies:** Paper-based 80 (19) 14 ± 15 [-18 to 46][9] Computer-generated 136 (34) 12 ± 13 [-24 to 59] Computerized 48 (8) 13 ± 18 [-8 to 60] **Effect of prompting clinicians for preventive**		[Dexheimer et al. (2008)] (Systematic review of RCTs) 264 preventive care interventions, 4,638 clinicians and 144,605 patients

[8] Reminder method (Number of studies) Rate change% (95% CI)

[9] Number of studies (Number of interventions) Average ± Standard deviation [min, max]

Intervention	Effect on Process	Effect on Outcome	Source
	care procedures in studies with three or more interventions: Smoking cessation 6 (3) 23 ± 16 [3 to 44] Cardiac care 25 (4) 20 ± 11 [-8 to 59] Blood pressure 22 (9) 16 ± 19 [-8 to 59] Diabetes management 27 (8) 15 ± 10 [5 to 51] Vaccination 64 (24) 15 ± 14 [-15 to 50] Cholesterol 8 (6) 15 ± 17 [-1 to 54] Fecal occult blood testing 23 (16) 12 ± 13 [-11 to 37] Papanicolaou smear 36 (20) 12 ± 18 [-24 to 48] Mammogram 51 (23) 10 ± 15 [-18 to 49] **Effect comparison of clinician-only compared to clinician-patient reminders:** Clinician only 175 (44) 14 ± 16 [-18 to 60] Clinician and patient 105 (26) 10 ± 12 [-24 to 45]		
Computer-generated prompts	6/8 studies with significant improvements in guideline compliance. In a subset applying an overall adherence measure 3/4 studies showed significant improvement. Compliance with recommended processes was 71% to 227% higher than in control group.		[Balas et al. (2004)] (Review on RCTs)
Computer-assisted diabetes patient education	Improved diet	Statistically significant improvement in **metabolic indicators** (glycated haemoglobin, pre-lunch blood glucose level,	[Balas et al. (2004)] (Review on RCTs)

Intervention	Effect on Process	Effect on Outcome	Source
		and serum cholesterol)	
Web-based patient education and feedback, Diabetes		**HbA1c:** No significant change No significant changes in other clinical parameters No costs reported.	[Jackson et al. (2006)] (Systematic Review) 6 studies, 3 RCTs
Interactive Health Communication Applications		**Patient Outcomes**: **Knowledge** (SMD 0.46; 95% CI 0.22 to 0.69) **Social support** (SMD 0.35; 95% CI 0.18 to 0.52) **Clinical outcomes** (SMD 0.18; 95% CI 0.01 to 0.35) **Self-efficacy** (SMD 0.24; 95% CI 0.00 to 0.48) **Continuous behavioural outcomes** (SMD 0.20; 95% CI 0.01 to 0.40) Positive effect for **binary behavioural outcomes**, not statistically significant (OR 1.66; 95% CI 0.71 to 3.87)	[Murray et al. (2005)] (Systematic Review on RCTs)
Computer-assisted integration of clinical information		**HbA1c:** Mixed results No significant changes in other clinical parameters	[Jackson et al. (2006)] (Systematic Review) 13 studies, 7 RCTs
Self-management Support (Web-based education and peer support groups)	**Nutrition advice and changes**: 1 | 0 | 0 **Smoking cessation advice**: 1 | 0 | 0 **Physical activity advice**: 1 | 1 | 0	**HbA1c:** 6 | 1 | 1 **LDL Cholesterol:** 2 | 0 | 1 **HDL Cholesterol:** 3 | 1 | 0 **T-Cholesterol:** 4 | 0 | 0	[Adaji et al. (2008)] (Systematic Review)

Intervention	Effect on Process	Effect on Outcome	Source
		Triglycerides: 4 | 0 | 0 **Blood pressure:** 3 | 0 | 0 **Body weight:** 1 | 0 | 0 **Blood glucose:** 2 | 1 | 0	
Interactive, automated telephone calls and Telemedicine		**HbA1c**: Moderate to large declines (only 3 studies statistically significant) No significant changes in other clinical parameters	[Jackson et al. (2006)] (Systematic Review) 7 studies, 4 RCTs
Telemedicine patient encounters		No clear evidence about the effectiveness or safety of telemedicine, or that telemedicine provides equivalent care at lower cost.	[Currell et al. (2000)] (Systematic review) 7 studies, >800 patients
Structured Telephone support		**All cause admission to hospital**: Inconclusive: Relative risk 0.94 (95% CI 0.87 to 1.02) **All cause mortality:** Inconclusive: Relative risk 0.85 (95% CI 0.72 to 1.01) **Cost-effectiveness**: 3/4 reduced cost, 1 no effect	[Clark et al. (2007)] (Systematic review and meta analysis) 9 RCTs, 1 combination with telemonitoring
Telephone-based symptom monitoring, automated signs and symptoms / physiologic monitoring, Chronic Heart Failure		Beneficial effects: 6/9 studies - all-cause hospitalizations: 14%-55% reduction - heart failure hospitalizations: 29%-43% reduction - mortality: 40% to 56% reduction Telephone based symptom monitoring (5	[Chaudhry et al. (2007)] (Systematic review)

Intervention	Effect on Process	Effect on Outcome	Source
		studies): - heart failure hospitalization: reduction (3/5) - all cause hospitalization: reduction (2/5) - economic analysis: cost benefit (1/1) Automated signs and symptoms monitoring (n=1): - no effect on hospitalizations, - no economic analysis available Automated physiologic monitoring (n=1), quality ↓ - reduction in heart failure hospitalizations - intervention may be cost-beneficial Comparison of 2 or more forms of telemonitoring: - beneficial compared with usual care, different forms of telemonitoring were similarly effective - Intervention costs were 5 times higher with more complex programs ($8383 per patient per year) without additional effects on outcome	
Videoconferencing	**Improved Self care** (4/17) **Patient-caregiver interaction** (3/17)	**HbA1c** reduction (6/17) **Blood Pressure** (1/17) **Quality of Life** (3/17) **Cost reduction** (11/17)	[Verhoeven et al. (2007)] (Systematic review) 13 studies

Intervention	Effect on Process	Effect on Outcome	Source
			teleconferencing 4 studies teleconferencing in combination with telemonitoring Many observational studies
Home Telemonitoring and Videoconferencing	Studies which reported improvements:	Studies which reported improvements: Metabolic control (21/39), Cost reductions (16/39) Quality of life (6/39 studies) Transparency (5/39) Better access to care (4/39) Satisfaction with technology (26/39 studies)	[Verhoeven et al. (2007)] (Systematic review. Most of the 39 studies were observational studies!)
Home Telemonitoring (HTM) and Telephone Support (TS) for Diabetes Management		**Glycemic control (HTM):** positive effect (-0,21 95% CI -0.35 to -0.08) **Glycemic control (TS):** mixed results **Hospitalized patients:** Reduced compared to usual care (UC) **Hospitalizations:** Reduced compared to UC Quality of life: Similar or favourable to UC **Patient satisfaction**: Similar or favourable to UC	[Polisena et al. (2009a)] (Systematic review and meta analysis) 26 studies, 5069 patients (21 evaluated HTM, 5 TS)
Home Telemonitoring	**Technical / feasibility**: Consistently good level of accuracy and reliability of transmitted data, minimal	Studies limited to small samples and short durations	[Paré et al. (2007)] (Systematic review)

Intervention	Effect on Process	Effect on Outcome	Source
	technical problems	Some positive effects, but effect on reduction of number of complications remains inconsistent. **Pulmonary disease**: Identification of early changes in the condition of patients **Diabetes**: Decline in haemoglobin A1c and significant blood glucose control **Hypertension**: Reduction of systolic and diastolic blood pressure, very few reported changes in medication regimens and quality of life **Cardiac disease**: Minimal and inconclusive clinical effects, improved quality of life. **Patient attitude**: Good acceptance and compliance, but decreased compliance over time **Resources**: Reduced hospital admissions, emergency department visits, hospital length of stay significant for pulmonary and cardiac disease (inconsistent for diabetes, no evidence for hypertension) **Cost-effectiveness**: Scarce evidence	65 studies, 1990-2006 from US and Europe (pulmonary conditions, diabetes, hypertension, and cardio-vascular diseases)
Home Telemonitoring	Reduced HbA1 3/4 Reduced hypoglycaemic events and insulin doses		[Balas et al. (2004)] (Review on RCTs)

Intervention	Effect on Process	Effect on Outcome	Source
Home Telemonitoring, Diabetes	**Technical / feasibility**: Only minimal technical problems reported, errors and data quality often not reported at all	**HbA1c**: Significant reduction (9/14) **Complications**: Reduction (3/4) e.g. reduction of hypos, diabetic foot complications when using handheld infrared thermometer **Behavioural**: Good receptiveness by patients, education → patient empowerment **Resources**: Annual hospital visits 50% reduced	[Jaana and Paré (2007)] (Systematic review) 17 Studies (1991-2005), duration 3-15 months
Telemonitoring, Diabetes	**Technical / feasibility**: Electronic transfer of glucose results appears feasible in a clinical setting	**HbA1c**: Pooled results from nine studies not significant −0.1% (95% CI -0.4% to 0.04%) **Resources**: Service utilization no difference or increase for intervention group.	[Farmer et al. (2005)] (Systematic review, meta analysis) 32 papers, 26 trials (12 RCT)
Telemonitoring, Chronic Heart Failure		**Health related quality of life**: 3/6 significant benefits **All cause admission to hospital**: Inconclusive: Relative risk 0.95 (95% CI 0,89 to 1.02) **All cause mortality:** Reduced: Relative risk 0.62 (95% CI 0.45 to 0.85)	[Clark et al. (2007)] (Systematic review and meta analysis) 4 RCTs telemonitoring, 1 in combination with structured telephone support
Clinical Information Systems (Diabetes registry	**Foot check**: 3 |0 | 0 [10] **Eye check**: 1 | 0 | 0	**HbA1c:** 0 | 1 | 0 **Blood glucose**: 0 | 1 | 0	

[10] Number of studies with significant improvement| not significant improvement | no change

Intervention	Effect on Process	Effect on Outcome	Source
or EMR)	**Immunisations**: 2 | 1 | 0 **Nutrition advice**: 1 | 0 | 0 **Smoking cessation advice**: 1 | 0 | 0 **Physical activity advice**: 1 | 0 | 0		

5 DMPs in practice; empirical results

5.1 Methodology

Part of the aims of the deliverable for work package 6 was to assess existing disease management strategies. In order to generate empirical data concerning the current situation concerning disease management programmes, we devised a questionnaire (see) in which questions were asked concerning the elements of DMP programmes currently or planned to be implemented and what IT measures were in place to support the DMP elements.

Our first step was to generate the questionnaire. This was done on the basis of work by [Dorr et al. (2007), Shojania et al. (2004), Shojania et al. (2006)] and the Cochrane EPOC group (http://epoc.cochrane.org/). The results of the meta-regression analysis by [Shojania et al. (2006)] in particular were used in devising the elements of the questionnaire.

This review outlined the following quality improvement strategies, often found within DMP programmes, reported to improve the care of patients with diabetes:

- Team changes
- Case management
- Patient reminders
- Patient education
- Electronic patient registry
- Clinician education
- Facilitated relay of clinical information
- Self-management
- Audit and feedback
- Clinician reminders
- Continuous quality improvement

Following a process of internal review and revisions, the questionnaire was sent out to all REACTION partners. We received completed questionnaires from Austria, Switzerland, Spain, UK, Sweden, Hungary and Greece. Some limited, but very informative, information was able to be supplied by Denmark. In addition to completing the questionnaire, we requested respondents to send us electronic links to any important documents relating to diabetes disease management. We analysed these documents and also include details of them in the results section.

We asked respondents in the sections that follow, we describe and summarise the situation regarding the implementation of the above DMP elements and IT measures used to support these elements in the countries participating in the empirical analysis.

5.2 Results

5.2.1 National Plans for diabetes

According to the document “Overview of Diabetes Policy Frameworks in the EU Member States”, national plans for diabetes exist within the following member states (as of 2005) [FEND and IDF (2006)]:

- Austria (Austrian Diabetes Plan)
- Belgium (under the obesity plan)
- Czech Republic (2nd National Diabetes Programme), Denmark (Diabetes Action Plan)
- Estonia (Diabetes for the Family Doctors)
- Finland (Development Programme for the Prevention and Care of Diabetes, Programme for the Prevention of Type 2 Diabetes, Implementation Project of the Programme for the Prevention of Type 2 Diabetes)
- France (Plan National Diabètes)
- Germany (over 2,000 programmes running and approved by the Federal Agency for Social Insurance)
- Italy (CCM Prevention Plan: Centro Nazionale per la prevenzione e il Controllo delle malattie)
- Portugal (PNCD: National Programme of Diabetes Control; National Health Plan 2004-2010, [DGSAUDE (2004)])
- Slovakia (National Diabetes Programme)
- Sweden (part of obesity plans)
- The Netherlands (National Plan for Diabetes Care, 2005)
- United Kingdom (National Service Framework for Diabetes, [NSF (2001)])

In addition plans for a national policy are underway in Cyprus and Spain (regional plans already exist for the latter country).

5.2.2 DMP element: Agreed care plans with personal goal setting

UK

In the UK the NHS Diabetes Care Planning tool is available, which is mainly used in secondary care. Within the primary care setting, GP computer systems are less formal.

A document is available supporting care planning "Care Planning in Diabetes", Report from the joint Department of health and Diabetes UK Care Planning Working Group, 2006.

This document offers the following definition of care planning:

> *"Care planning can be defined as a process which offers people active involvement in deciding, agreeing and owning how their diabetes will be managed".*

This document details a model for effective care planning developed by the National Diabetes Care Planning Working Group. This model is based on the vision set out in the Diabetes National Service Framework and the Matrix report Good care planning for people with long term conditions[11]. Furthermore it is evidence-based in that reviews relevant to promoting patient-centred care and self management in the Cochrane Library and the Database of Reviews of Effectiveness were related to the main components of the model.

This model identifies four broad domains which form the basis for sharing and discussing information between the patient and professional. The domains are: learning about diabetes; managing diabetes; living with diabetes; other health and social issues. Following the sharing and discussing of information, there follows the action planning stage. At this stage of the consultation, the patient and professional discuss and agree upon action points; decide who will be responsible for the action points; agree when the actions will be reviewed. The outcome of the care planning consultation requires documentation, which could take the form of a care plan. A distinction is made between the care planning process and the care plan. Care planning is a dynamic process of discussion and negotiation between patient and care giver, whilst the care plan is a document whereby action points

[11] Good care planning for people with long term conditions. NHS Modernisation Agency, 2004.

and outcomes are recorded. Ideally the care plan should be available whenever a person with diabetes accesses the care system at any level, including at the in-patient level. Various sample documents are then presented in the appendix of this document which aim to support this care process, a list of which follows here:

- Diabetes care planning interim results
- Diabetes care planning summary
- Community pharmacy medicines use review & prescription intervention service

It is recommended within the document that managers and organisations put in place systems that coordinate and facilitate the care planning process. To support effective care planning consultations, the following processes have been identified:

Before the consultation

- Relevant tests should be carried out and results made available to the patient
- Sufficient information and explanation of the results should be provided to the patient
- Prompts to encourage people with diabetes to think through their thoughts and questions relating to the four domains ahead of the consultation.

During the consultation

- Review of any previous care plan
- Shared results and questions/concerns prompt sheet
- Information about local services and options for treatment/care
- Written information about risks and benefits of different treatment options ideally personalised and linked to information received during the educational programme.
- Address needs of individuals with learning disabilities and/or specific communication issues.

After the consultation

- A clear summary of the consultation (hand-held and/or electronic record) should be kept by the professional and the person with diabetes.
- Following information should be recorded in all domains, in addition to clinical data: person's issues, concerns and questions; information needs and action required; agreed priorities and goals; agreed action plan with details of how it will be measured, actions and responsibilities.

Secondary care institutions provide these plans to GP practices via email. The plans are then printed out in the surgeries and shared with patients.

The aforementioned document identifies two specific IT-related tasks for supporting the implementation of care planning:

- Establish information links and systems needed to ensure that the clinical information needed to support the care planning process is in place
- Identify how/whether the care planning record can be developed electronically

In addition the document contains a description of some examples where elements of care planning have been implemented, as follows:

In Nottingham, the Diamond diabetic register is used to store records of discussions electronically. Patients are not able to view the browser directly, however they receive print outs of any information capture forms generated after each appointment, along with an explanatory leaflet.

In Devon, a care planning process for renal patients has been developed that uses a web based tool to share information between patients and professionals. The renal patient review (RPV) provides a selected set of data from existing electronic patient records onto a website, which is accessible via an individual login. The information provided relates to results, diagnosis and selected information links according to diagnosis and treatment type. More information on this system is available at https://renalpatientview.org/index.do.

Greece

There are no agreed care plans with personal goal settings.

Hungary

There are no agreed care plans with personal goal settings.

Switzerland

Whether or not agreed care plans with personal goal settings exist, depends on the region in which patients are based.

Austria

Personal goal setting is part of the Disease Management Programme “Therapie Aktiv” which has been implemented as a pilot project in several Austrian provinces. There care plans are not electronically available but stored with the DMP physician.

Spain

Care plans are defined by the regional health authorities. There is also a national care plan entitled “Estrategia en diabetes del sistema nacional de salud”.

5.2.3 DMP element: Systematic patient care

UK

In UK there are named contacts for patients, either GPs or the lead nurse in primary care. This is supported by the electronic administration of eligible health care providers and assignment of patients. Pro-active patient care is embedded in primary care (via electronic registries in all GP practices and Primary Care Trusts) and there is a regular review of patients for retinal screening done on a call and recall basis in primary care, which is supported electronically. Structured patient education and self-management education is available either in primary care or through community diabetes teams. The expert patient programme is a self-management programme for people who are living with a chronic (long-term) condition, including diabetes. Details can be found at http://www.nhs.uk/conditions/Expert-patients-programme-/Pages/Introduction.aspx.

Courses are free and consist of six consecutive weekly sessions, with each session lasting around two-and-a half hours. Sessions are run by two tutors who both have a chronic condition. Courses are run by the EEP Community Interest Company. Patient education is also provided through the charity Diabetes UK. Case management may be conducted for complex patients for instance those with co-morbidities and other co-existing physical conditions. Some practices have implemented alert systems (e.g. home blood glucose monitoring sent electronically) and others have adopted telehealth to manage chronic diseases including diabetes. These programs are sporadic and not yet main stream. Patients are able to book appointments online, via the surgery web site. For patients that need to be referred to other specialist services they are able to use Choose & Book at http://www.chooseandbook.nhs.uk.

Greece

There is no organised systematic patient care; some centres make appointments for the regular review of patients but this is haphazard and not mandatory. There are some IT systems for patient reminders and setting appointments but they depend on the hospital and clinic and are not implemented nationally.

Hungary

There are regular visits scheduled at the GP and dialectologist, but there is no organised system for sending reminders. Basic patient education is provided following the diagnosis of diabetes. Case management is either non-existent or provided in a very basic form.

Sweden

Sweden has digitalised citizen health care contacts which mean patients can use an e-service via an internet portal. This enables them to request, cancel or reschedule appointments, refill prescriptions or ask their local medical centre to contact them (*http://www.minavardkontakter.se/C125755F00329208/p/OSAL-7PBJ24)*. A national patient register exists which contains information on all in-patients treated at public hospitals, and also at out-patient facilities. It does not cover primary care. To what extent structured patient education is offered rather depends on the region concerned, with this service being more common in the North of Sweden.

Switzerland

There are named contacts for patients at Endocrinology and Diabetologie clinics (http://www.endo-diabasel.ch/kbs_Dienstleistung/sprechstunden.htm, http://www.endokrinologie-dim.usz.ch/PatientenUndBesucher/Anmeldung/Seiten/default.aspx).

Electronic patient registries exist, based at the Endocrinology and Diabetes clinics. Structured patient education is also offered at the Endocrinology and Diabetes Clinics. Details are available at http://www.endo-diabasel.ch/kbs_Dienstleistung/sprechstdDiabetesberatung.htm and though the Daft-project. The Daft project is supported by the SGED Society for Endocrinology and Diabetology and by

the SDG Swiss Diabetes Society) and aims to establish a diabetes rehabilitation programme across Switzerland. (http://www.diafit.ch/de/20_diafit-projekt/00_diafit-projekt.htm).

There are interactive health communication applications available, such as on-line advice services, an example of which can be found at: http://www.onlineberatung.usz.ch/frage.aspx?question=63 and at the user forum for patients with diabetes, which can be accessed at http://www.diabetesclub.ch/.

Chronic disease management programmes are regionally based. The largest and most comprehensive programme, the 'Filière de soins Diabaide' has been established in Western Switzerland [Peytremann-Bridevaux and Burnand (2009)]. This programme is available to all diabetic patients in the region and is based on collaboration, information dissemination and care coordination among professions. Based within ambulatory care, multidisciplinary teams operate offering access to a network of specialists. There is patient education, support and follow-up by telephone, coordination of care, and a website offering guidelines and patient-information material.

Mibetes is a free service offered by a private company that can be used at any computer or smartphone without prior software installation. It offers the combination of diabetes management, social network and expert care. In the online diary, measurement values, activities and meals can be entered and automatic graphical and statistical displays are generated.

Austria

GPs are named contacts for patients. Patients are assigned to GPs who then sign them up for the programme. Electronic administration is in place for the registration of GPs and their patients. Lists containing patients signed up for the DMP are regularly sent to doctors. Individual patient care is to some extent pro-active; a documentation form per patient is completed annually, which forms an overview of care. Regular patient visits are part of the programme. The documentation form is electronically stored and processed either via a web browser interface, via a terminal or through submitting the paper form. The "registry" stores anonymised data only and does not allow for the searching and listing of patients or filtering by medical parameters.

Patients undergo an annual review with physicians recalling their patients individually. In addition, regular patient visits take place every three months which are part of the programme but which are not supported by reminders. The DMP programme "Therapie Aktiv" sends lists with patients who are signed up for the programme to GPs, which contain a physician reminder for the annual documentation form (due date).

A fundamental part of the DMP is group education classes with self-management education and patient empowerment. In some provinces patient education programmes were already in place before the DMP. There is a static website supporting the DMP (http://diabetes.therapie-aktiv.at/portal27/portal/diabetesportal/start/startWindow?action=2&p_menuid=64351&p_tabid=1) and a newsletter sent by email. For diabetic foot disease, specialised diabetic foot clinics have been implemented in one province (Styria) to provide structured care and case management for patients with acute foot problems (such as ulcers). In terms of IT support for case management, IT projects have been ongoing (examples of which can be found at the website of the Austrian Institute of Technology; http://www.ait.ac.at/research-services/research-services-safety-security/ehealth-ambient-assisted-living-aal/keep-in-touch-kit/) but there has been no wide-scale implementation. There are pilot projects with online portals which inform mainly patients about available care structures and services (see http://www.gesundheitsportal-steiermark.at/GesundLeben/Gesundheitszentren/Aufgaben/Seiten/default.aspx). Electronic booking provided by hospitals is starting to become available but there is no regional or national infrastructure for this.

Spain

GPs or nurses are named contacts for patients in primary care. Pro-active individual patient care is embedded in primary care and there are electronic patient registries in all GP practices. There is regular review of patients through a call and recall basis in primary care. Structured patient education is available either in primary care or through community diabetes teams. Expert patient programmes are documented at http://portal.aragon.es/portal/page/portal/INF_SANITARIA/ANEXO+V+ENFERMERIA+EN+ATENCI%

C3%93N+PRIMARIA.PDF and
http://www.guiasalud.es/GPC/GPC_429_Diabetes_2_Osteba_paciente.pdf

Case management may be performed for complex patients- there may be shared care depending on co-morbidities and physical conditions. An increasing number of hospitals in Spain have adoped e-health to manage chronic diseases including diabetes. Some relevant projects are:

- Ikono project supported by the Castilla-LaMancha government
- Red Envisad supported by the Andalucia government
- Programa tele-asistencia hospital la FE supported by the Valencia government.
- Teleasistencia for diabetes patients at San Rafael hospital, a private hospital in Madrid.

In addition, the Fuenfria hospital, Guadarrra Hospital and Virgen de Poveda Hospital all have telemedicine programmes supported by the local government of Madrid.

Patients are able to book appointments online and exchange various types of medical information. For patients that need to be referred to other specialist services, they can use the following national website to help locate a provider: http://www.060.es. In Andalucia, the following portal is available: https://ws003.juntadeandalucia.es/pls/intersas/servicios.acceso_portal.

5.2.4 DMP element: Ensuring progress

UK

The Information Centre for Health and Social Care has established the Quality and Outcomes Framework with an online GP practice results database which provides indicators for clinical care across 20 clinical areas, including diabetes. The ultimate aim is to improve standards of care by assessing and benchmarking the quality of care patients receive. The online database can be browsed to find results for the individual surgery. One can also compare local GP practices against other GP practices in the local area and the national results across England. The database is for patients and professionals to use. The Quality and Outcomes Framework (QOF) is a voluntary annual reward and incentive programme for all GP surgeries in England, detailing practice achievement results.

It contains four main components known as domains: Clinical Domain, Organisational Domain, Patient Experience Domain and Additional Services Domain. Each domain consists of a set of achievement measures which are known as indictors. Against these indicators, practices score points according to their level of achievement. The 2009/10 QOF measured achievement against 134 indicators; practices scored points on the basis of achievement against each indicator, up to a maximum of 1000 points. Practices with a higher score receive higher financial rewards. The final payment takes into account factors such as the surgery workload and the prevalence of chronic conditions within the local area.

Altogether there are 17 indicators relating to diabetes. These are shown in the following table. In terms of IT support for this element of disease management service frameworks, GPs have IT systems with the capability to analyse information from records to ensure and monitor quality of care and improvement, for instance via Contract+. Contract+ is in use at well over 1,000 sites, with strong growth in the InPractice Vision Sector and overall providing GMS analyses on over 8 million patients (http://www.frontdesk.info/default.asp). Audit+ has been installed at nearly 500 Welsh sites, analysing details on 2.7 million patients. It is also starting to be used by PCTs in England, mainly based around the need for vascular health checks.

Table 7: Diabetes Indicators in QOF, UK

Indicator	Definition
DM2	The percentage of patients with diabetes whose notes record BMI in the previous 15 months
DM5	The percentage of patients with diabetes who have a record of HbA1c or equivalent in the previous 15 months.
DM9	The percentage of patients with diabetes with a record of the presence or absence of peripheral pulses in the previous 15 months
DM 10	The percentage of patients with diabetes with a record of neuropathy testing in the previous 15 months
DM11	The percentage of patients with diabetes who have a record of the blood pressure in the previous 15 months
DM12	The percentage of patients with diabetes in whom the last blood pressure us 145/85 or less
DM13	The percentage of patients with diabetes who have a record of micro-albuminuria testing in the previous 15 months
DM 15	The percentage of patients with diabetes with a diagnosis of proteinuria or micro-albuminuria who are treated with ACE inhibitors (or A2 antagonists)
DM 16	The percentage of patients with diabetes who have a recoird of total cholesterol in the previous 15 months
DM 17	The percentage of patients with diabetes whose last measured total cholesterol within the previous 15 months is 5mmol/l or less
DM 18	The percentage of patients with diabetes who have had influenza immunisation in the preceding 1 September to 31 March
DM 19	The practice can produce a register of all patients aged 17 years and over with diabetes mellitus, which specifies whether the patient hast Type 1 or Type 2 diabetes
DM 21	The percentage of patients with diabetes who have a record of retinal screening in the previous 15 months
DM 22	The percentage of patients with diabetes who have a record of estimated glomerular filtration rate (eGFR) or serum creatinine testing in the previous 15 months
DM 23	The percentage of patients with diabetes who have a record of HbA1c or equivalent in the previous 15 months
DM 24	The percentage of patients with diabetes in whom the last HbA1c is 8 or less (or equivalent test/reference range depending on local laboratory) in the previous 15 months
DM 25	The percentage of patients with diabetes in whom the last HbA1c is 9 or

	less (or equivalent test/reference range depending on local laboratory) in the previous 15 months

The QOF system supports comparative benchmarking whereby one can compare ones performance at various levels (practice, regional, national) and, in conjunction with national and local experts, predictive modelling and analytical tools are applied.

Greece

There are no indicators on performance or quality of care and no comparisons across institutions. Physicians are responsible for monitoring the disease development and treatment adherence but there are no national targets set or systems in place as to how this should be achieved. Physicians may choose to purchase and implement diabetes-related IT systems in their practices.

Hungary

Quality indicators were collected by the Health Insurance Supervisory Authority until 2010, but the organisation ceased to exist thereafter. There indicators related to acute hospital care and none were specific to diabetes.

However there are two indicators relating to diabetes relating to primary care: the percentage of patients who had an HbA1c test and the percentage who had an eye examination (both at least once a year). This data is related to funding i.e. GPs performing better on these indicators receive greater funding. Other data is available from the National Institute for Strategic Health Research at the internet-based Hungarian Health Datawarehouse (http://hawk.eski.hu/IMEA/index.html).

However there does not seem to be a structured system for measuring or comparing institutions against performance criteria. This web facility also provides data to support funding and public health statistics including indicators relating to the incidence and prevalence of diabetes, average length of acute care stays, diabetes-related discharges from acute care, pharmaceutical sales of drugs used for diabetes and age-standardized death rates for people with diagnoses of diabetes.

Sweden

The national guidelines recommend that lipid levels should be measured at least every second year and that lipid-lowering drugs should be used if treatment goals are not reached within three to six months following changes in diet and lifestyle.

Austria

There is continuous quality improvement through evaluations performed at the programme level and feedback reports for physicians are generated based on documentation; plans are being made to discuss these results in quality circles. Anonymised data from the clinical findings sheet and administrative data are used for programme status reporting. Merging this data with reimbursement data for evaluation purposes is planned, but has not yet been carried out.

There are currently no benchmarking comparisons between regions. Medical documentation sheets are psedonymised and collected in one data pool. Anonymised data from clinical findings sheet and administrative data are used for programme status reporting.

Spain

Clinical data can be shared within primary and secondary care institutions but not between institutions. Some electronic patient registries are kept at all levels for instance primary care surgeries have all their patients on registries and, at a regional level, retinal screening is widely on registers. Information bulletings are regularly released to all health care levels.

In Andalusia, the following quality indicators are processed within the intergarted care framework:

- HbA1c examinations and levels <7% and <8%

- Eye examinations % healthy
- Feet examinations % healthy

In other parts of Spain quality indicators are also collected and processed (unfortunately since the information was only available in Spainish, it was not possible to provide a full list here of the indicators).

Denmark

The region Nordjylland has purchased an IT system for diabetes and other diseases. The purpose is the evaluation of total quality of the region's outpatient services, with automatic and systematic collating of National Indicator Project data, as shown in the following table Table 8, http://www.nip.dk/about+the+Danish+national+indicator+project

The Danish National Indicator Project (NIP) measures the quality of care provided by the hospitals to groups of patients with specific medical conditions. The aim is to create awareness in patients, families, doctors, nurses and other healthcare professionals about the extent to which the completion and outcomes of the treatment are up to the standards which is expected from a well-functioning healthcare service.

The stated aims of the project are:

- Improving the quality of prevention, diagnostics, treatment and rehabilitation
- Providing documentation for making priorities
- Information of the quality in health care for patients and consumers

The data is collected from clinical databases, medical records and central registers. When the data has been collected and analysed, the results are evaluated and interpreted nationally, regionally and locally in different units. Clinicians and managers receive continuous feedback of their results. Hospital units receive information as to whether they are below or above standard, whether they have been improving or worsening since the last feedback and whether or not they correspond to the national average.

A structured audit process is initiated in order to explain the results. Its purpose is to facilitate a specified professional interpretation and to evaluate in relation to critical incidents. The audit process is systematically organised nationally, regionally and locally. Following the audit process, the data are publicly released.

Table 8: Danish National Indicator Project

Indicator domain	Indicator	Type	Standard	Time reference
Metabolic and glycaemic regulation	Proportion of diabetics who have their HbA1c measures	process	≥95%	At last once a year
	Districation of the measured values for HbA1c	outcome	No threshold value has been determined	The most recent values
Hypertension	Proportion of diabetics who have their blood pressure measured	process	≥95%	At least once a year
	Distribution of the measured values of systolic blood pressure	outcome	No threshold value has been determined	The most recent values
	Distribution of the measured values of diastolic blood pressure	outcome	No threshold value has been determined	The most recent values
Lipid status	Proportion of diabetics for whom lipid status is checked	process	≥ 90%	At least every second year
	Distribution of the measured values of the total cholesterol	outcome	No threshold value has been determined	The most recent values
Albuminuria	Proportion of diabetics who are examined for albuminuria	process	≥95%	At least every second year
Screening for complications: eye examinations	Proportion of diabetics who have an eye examination	process	≥ 90%	At least every second year
	Proportion of diabetics who have an eye examination	process	≥95%	At least every four years

Screening for complications: foot examination	Proportion of diabetics who have their feet examined	process	≥95%	At least every second year

5.2.5 DMP element: Diabetes information

UK

Patients and professionals are able to access evidence-based information through a range of media, including NHS material (such as the Expert Patients Programme mentioned above) and charity-based information such as from Diabetes UK. In addition evidence-based guidelines are available via NICE (htttp://www.nice.org.uk; which provides written guidance for patients and professionals) and the Map of Medicine.

The Map of Medicine is a collection of evidence-based, practice-informed care maps which connect all the knowledge and services around a clinical condition. The care maps can be customised to reflect local needs and practices by commissioners looking to devise new care pathways.

Comprehensive patient information as provided by GPs and nurses to patients during consultations is also available through Patient UK (http://www.patient.co.uk). Via this website patients and professionals can access a wealth of information on diabertes including news items, information leaflets, support group information, patientplus articles written by doctors, poems/stories about the condition, online videos, guidelines and selected websites.

Digital libraries and static websites are available through OVID which anyone can access through their local hospital librarian (http://www.ovid.com).

In terms of access to their own records, hand-held records are available in some parts of the country whilst in other places patients receive copies of letters and/or results. Electronic personal health records are available via summary care records (http://www.nhscarerecords.nhs.uk). Healthcare staff will have quicker access to information about medicines patients are taking, allergies they suffer from and any bad reactions to medicines patients have had. The Summary Care Record is an electronic record which aims to give healthcare staff faster, easier access to essential information about patients, to help provide patients with safe treatment when care is needed in an emergency or when the GP practice is closed. People are able to opt in or opt out of having a Summary Care Record.

In terns if access to clinical data for professionals, this is universally available in primary care but not yet fully available in secondary care. Electronic patient records are already common in GP practices and increasingly in hospitals.

The English partner, Chorleywood Health Centre, works with the company iSOFT's (http://www.isofthealth.com) which offers fully integrated clinical, practice management and communication solutions aimed at simplifying administrative and care processes for Primary Care. Other practices use the TPP SystemOne (http://www.tpp-uk.com/GP.htm). As regards to sharing this clinical data with other institutions and settings for professionals, the SystemOne used by many PCT community settings can allow information sharing, although this would need to be agreed by all parties. As mentioned above, electronic integrated care records and registers are available in both primary and secondary care, however there is no common access by both groups.

Some electronic patient registries are kept at all levels e.g. surgeries have all their patients on registers. Regionally, retinal screening is widely maintained on registers. In terms of IT support, national read codes are available (a coded thesaurus of clinical terms) which are the basic means by which clinicians record patient findings and procedures in health and social care IT systems across primary and secondary care (e.g. GP surgeries and pathology results). The Read codes are regularly updated to reflect changes in clinical practice (www.connectingforhealth.nhs.uk/systemsandservices/data/uktc/readcodes). This website also provides information on data standards.

Greece

There are no national health service guidelines which are provided on the diagnosis and treatment of diabetes. Diabetologists are themselves responsible for keeping up-to-date with latest knowledge and international guidelines. Diabetes societies and organisations (such as the Hellenic Diabetes Society http://www.ede.gr and the North Greek Diabetes Society http://www.ngda.gr) send announcements to their members concerning evidence-based information. There are patient organisations for diabetes that offer their members information and updates as well as facilitate communication and coordinate

activities. There are some IT systems for storing and presenting the electronic health care record of a patient, but they depend on the individual hospital and clinic and are not implemented nationally. Patients do not have access to these records. Some hospitals are endeavouring to provide electronic access to clinical data for professionals within their own organisation. Every hospital stores their own (mainly hand-written) files although patients can apply to have their file moved to another hospital.

Hungary

There is only weak access to evidence-based information for patients and professionals there are websites available, mainly for patients, which contain some information about guidelines. Patients have the right to look into their health records and to obtain a copy of them although this rarely takes place in practice.

There are no electronic personal health records that patients are able to access. Professionals have access to clinical data within their own institutions – every institution or GP practice has some kind of information system via an electronic patient record which is available for use by healthcare professionals in one institution. This contains some structured fields or free text entries. Information sharing between institutions and sectors is only paper-based; the patient receives a summary or discharge letter. However there are currently pilot projects on-going in three regions testing electronic data transfer between organisations.

Switzerland

Access to evidence-based information for patients and professionals is available through various diabetes associations such as the Swiss Society for Endocrinology and Diabetes (SGED; http://www.sgedssed.ch) and the Swiss Diabetes Society (http://www.diabetesgesellschaft.ch/de/diabetes-info/ueber-diabetes) and at endocrinology and diabetes clinics, such as http://www.endokrinologie-dim.usz.ch/HealthProfessionals/Fortbildungsartikel/Seiten/default.aspx and http://endokrinologie.insel.ch/diab_prof_links.html.

Electronic patient records are used but only within endocrinology/diabetes clinics- they are not shared across health care providers from other institutions. However 2006 saw the establishment of the Swedish Strategy for eHealth and efforts are continuing to implement this, which would see the establishment of information systems and process support for the Electronic Health Record (EHR), to be available to patients and professionals.

Within some regional chronic disease management programmes (such as that in Western Switzerland), electronic medical records have been established which aim to be accessible to all healthcare professionals involved in the patient's care [Peytremann-Bridevaux and Burnand (2009)].

Austria

Guidelines for physicians are available via paper format (book), electronic (pdf) and the following website: http://www.sozialversicherung.at/mediaDB/MMDB135607_Arztinformation_300608_onlineversion_gesperrt.pdf. Patient information is available via paper (book) format, education classes (interactive group education) and newsletter (via email). Physician education is partly provided via e-learning. There are no specific Austrian digital libraries although there are two centres for evidence-based medicine in Austria.

Currently patients have no access to their own records. Some clinics provide patients with a printout following their visit with advice, for instance on how to care for diabetic foot ulcers. Patients often carry their own information on paper (diabetes diary, wound management instructions etc) which can take the form of the "Austrian Diabetes Pass" (http://www.oedg.org/diabetespass.html). This includes information about examinations, clinical findings and treatment. There is currently no electronic patient record used across sectors which patients have access to. Implementation of the electronic health record (ELGA) is planned and implementation is slowly starting. Some pilot projects have tested providing media like USB to electronically carry information, but again there has been no widespread implementation of this.

Clinical documentation is still widely kept on paper by GPs. In terms of electronic patient records used by healthcare professionals within one institution, there is a variety of EPR manufacturers however most products are specialised on administrative processes; clinical documentation is highly unstructured. The sharing of clinical data across institutions is not done electronically, although there are isolated examples of data sharing e.g. a structured paper sheet has been used to transfer eye examination results back to the main diabetes caregiver. An underlying IT infrastructure is present; each citizen has an electronic chip card (e-card). All physician surgeries and hospital clinics are equipped with reader hardware and electronic chip cards (o-card). These cards provide secure communication based on public key cryptography. This infrastructure is used for administrative processes and also fro the submission of clinical data within the DMP. However, there is no mechanism for the shared access to data. Medical findings, lab results and discharge letters are usually transmitted electronically between specialists/hospitals and GPs. However this is a directed sender-receiver communication and not a two-way communication system.

Denmark

The region Fyn established a diabetes database in 1997, allowing patients access to their own data and also information on the quality and effects of treatment. The national health portal www.sundhed.dk allows all citizens access to their own data plus access to general health-related information e.g. information on waiting times for different operations in all public hospitals.

5.2.6 DMP element: Clinical practice decision support and audit

UK

Many appraisals, guidelines and pathways are available though the Department of Health, NICE and professional organisations such as the Royal College of Nursing and the Royal College of General Practitioners. The Map of Medicine as mentioned before provides clinical pathways for diabetes. This is supported by digital libraries and static websites available in many formats. Some of these websites are open to all and others are restricted to professionals or are accessible on a fee-paying basis. Some clinical practice decision support systems have been incorporated into GP management systems e.g. through Torex Isis which provides guidelines and checklists for diabetes and other diseases.

All GP systems have some kind of pathway to check their patients against, through resources such as Map of Medicine. There is also a system of alerts, prompts and advice in most GP systems which flag up once a patient is recorded to have a specific problem.

Clinical audit is performed widely throughout PCTs as a way of benchmarking; data analysis for audit and feedback is available through a few packages which PCT staff can analyse in comparison with all practices within a locality. This can be further adjusted for use at national level. The Quality Management and Analysis System (QMAS) is a national IT system that supports the QOF payment process. QMAS was developed by NHS Connecting for Health. This new single national system ensures consistency in the calculation of quality achievement and prevalence. QMAS also gives GP practices, Primary Care Trusts and Strategic Health Authorities objective evidence and feedback on the quality of care delivered to patients. This system is available to view via the aforementioned QOF website.

Greece

There are no official guidelines to follow. Doctors receive announcements about relevant guidelines form the professional organisations, however they are not required to follow them. There are no national clinical audits.

Hungary

Textual guidelines exist and can be downloaded from http://www.drdiag.hu/kereso/iranyelvek.php?id=139. There is little or no application of care pathways at the individual patient level and no IT applications supporting this.

A growing number of organisations have ISO certification but there is no routine data analysis for audit or feedback.

Sweden

New national guidelines for the care and treatment of diabetes were published in Sweden in 1999.

Switzerland

Clinical practice decision support by way of guidelines is available through the medical professionals' organisation Swiss Society for Endocrinology and Diabetes (SGED).

Austria

Guidelines and care pathways for diabetes are available at http://www.sozialversicherung.at/mediaDB/MMDB135607_Arztinformation_300608_onlineversion_gesperrt.pdf and http://www.springerlink.com/content/3540562266364567/fulltext.pdf, although this is not supported electronically. Doctors defend their right to individual decision making and the adoption of evidence-based medicine is relatively slow. There is some interactive software supporting the application of care pathways and guidelines by context specific interfaces, prompts and alerts.

As regards clinical audit, the doctor's association has implemented a system whereby surgeries assess their own quality (although this only relates to structural issues). Data analysis (in terms of comparative risk adjusted clinical audit data for national and local use) is conducted for audit and feedback. Reports with performance feedback are distributed to physicians; the processing and report creation is computerised; report distribution to GPs is on paper. As an alternative www.healthgate.at allows documentation and data analysis online and is in place for hospitals.

Guidelines in the EU

According to the EU Overview on Diabetes Policy Frameworks in the EU member states, guidelines are also in place in the following EU member states:

- Belgium (Belgian diabetes associations, General practitioners associations and new guidelines for good medical practice of the care of people with type 2 diabetes)
- Czech Republic (set of standards of care which are updated every two years)
- Denmark (set of guidelines and recommendations from the National Board of Health)
- Estonia (Estonia Diabetes Association)
- Finland (Finish Diabetes Association for Health Professionals, Finish Scientific Society and Dehko's quality criteria for healthcare on optimal diabetes management)
- France (the AFSSAPS, ANAES, ALFEDIAM and the Société française de Cardiologie have all defined guidelines for the treatment of type 2 diabetes)
- Germany (guidelines for type 2 diabetes published jointly by the German Medical Association and the German Diabetes Expert Society)
- Ireland ("Current guidelines for diabetes care in the community" defined by the Irish College of General Practitioners)
- Latvia (Guidelines type 1 and 2)
- Lithuania (national guidelines on diagnostic and treatment methodology)
- Malta (based on the guidelines of the European Diabetes Policy Group)
- Poland (recommendations prepared by the Polish Dialectological Association)
- Portugal (general recommendations)
- Slovakia (Slovakian Diabetes Association Prevention Guidelines type 1 and 2)

- The Netherlands (Dutch Diabetes association CBO Guidelines, Dutch College of General Practitioners NHG Guidelines)

In other countries guidelines were underway at the time of the EU publication (such as in Cyprus and Slovenia)

5.2.7 DMP element: Utilisation of new technologies

UK

Technologies are implemented according to expertise and financial availability. As regards telemonitoring, home care and telecare, there is sporadic use in the UK. Most health providers are awaiting results form three large demonstrator projects which are currently in progress before making any decisions regarding utilisation (http://www.wsdactionnetwork.org.uk/). WSDAN – or the Whole System Demonstrator (LTC) Action Network – is an online resource on telecare, telehealth and the management of long-term conditions. The Network is run by The King's Fund and DH Care Networks and is funded by the Department of Health. WSDAN aims to combine research, educational and experiential learning opportunities to examine the progress and impact of telecare and telehealth in enabling long-term conditions management. In addition to the website, a key element will be to provide networking events and research and development activities. There is generally a growing shift to combine telehealth and telecare together in order to provide a more complete care package for parts of the country. Telemedicine patient encounters ("virtual visits") are often used in rural areas and are growing in popularity for application in prisons as this vastly reduces the cost of transporting prisoners for medical appointments.

There is a national process for evaluating new technologies (through NICE: National Institute for Clinical Excellence).

Greece

Pilot tele-medicine applications exist for other diseases, but not diabetes.

Hungary

With a grant from the European Regional Development Fund for IT development in healthcare, an eHealth project which aims at connecting all levels of healthcare and provide eHealth services such as an eHealth record, eConsultation and ePrescription has been started.

The European Health Telematics Association concluded in 2008 that telemedicine and the regulatory and policy framework for telemedicine are not yet implemented in Hungary. The reasons why telemedicine is not (yet) on the priority list could be that there is major structural restructuring and financing reform process going on in Hungary; there is no appropriate and ready-to-use interoperable communication infrastructure; there is no supportive legal environment; and there is only minimal awareness by local, regional and national competent authorities [Schug et al. (2008)].

Austria

There are research projects currently underway regarding telemonitoring and home care, but no widespread adoption.

Spain

New technologies are utilised, depending on the expertise and financial availability of the different regional governments. The Healthcare Technology Evaluation Agency exists to undertake health technology evaluations.

An increasing number of hospitals in Spain have adoped e-health (e.g. telemedicine, telemonitoring) to manage chronic diseases including diabetes. Example projects were listed under the Systematic Patient Care section.

5.2.8 DMP element: Prevention strategies

UK

Prevention strategies are largely conducted through national screening services and government initiatives with widespread nationwide publicity campaigns tackling topics such as obesity and alcohol awareness. Patient newsletters and websites are a growing sector; many GP practices have a news section on their websites or publish a newsletter from time to time. All NHS institutions have some kind of website available to the public. Patient recall for routine checks is widely performed throughout primary care.

Greece

Patient newsletters are provided by patient organisations to their members.

Hungary

Several websites and forums exist concerning general and diabetes-related prevention e.g. “Dr Info” health information (http://drinfo.eum.hu) which also provides telephone consultations and patient education e-learning tools.

Switzerland

Patient information concerning diabetes is available through www.diabetesgesellchaft.ch, www.diafit.ch, www.sprechzimmer.ch, http://www.endo-diabasel.ch/kbs_Dienstleistung/sprechstddiabetes.htm (the latter is an example of a clinic offering open consultation hours).

Austria

Secondary and tertiary prevention are the core aims of the DMP. Several primary prevention projects have taken place (see http://www.styriavitalis.at/download/Endbericht%20DE-Plan_Anhang.pdf) although sustaining such projects has usually proved difficult. Patient newsletter and static websites are available and the social insurance organisation can inform patients with certain risk factors or remind them of outstanding consultations.

Spain

Prevention strategies largely occur through the regional screening services. There are national government initiatives with publicity campaigns such as obesity and alcohol awareness. All Spanish regional health systems and institutions have some kind of website available to the public. Patient recall is widespread throughout primary care.

5.2.9 DMP element: Health workforce / health care system

UK

For most chronic diseases, there exist dedicated and pro-active care teams with a clear description of individual roles and responsibilities. In primary care, it is commonplace that all team members have electronic access to relevant data and this situation is improving in secondary care. Clinician education is embedded in most disciplines and E-learning is widely available to all clinicians.

In terms of planned organisation changes within the health care system, the national electronic record is still envisaged but has been delayed for various reasons; most primary care organisations have however defined their own systems for this.

Greece

Diabetologists are required to gain a certificate of expertise by a member institution of the National Center for Prevention and Treatment of Diabetes Mellitus and its Complications (http://www.hndc.gr) . Annual training for clinicians is offered in an official diabetes centre. E-learning is organised by pharmaceutical companies. There are plans to impose an electronic health record at a national level together with electronic prescriptions.

Hungary

There are no dedicated pro-active teams defined for diabetes care. As regards clinical education, there is regular mandatory training for health professions who are required to collect a certain number of credits. This can also take the form of e-learning through providers such as http://www.orvostovabbkepzes.hu.

Switzerland

Healthcare teams for diabetes are based at secondary (acute) care institutions. Clinician education is also offered at these institutions.

Austria

As yet there are no dedicated and pro-active care teams although as a first step diabetes nurses have been integrated into the DMP-Therapie Aktiv project to play a key role in diabetes education. There is no regional infrastructure for shared care. Clinical documents have to be actively sent to a receiver.

Programme-specific courses for physicians are in place and physician education is partly provided via e-learning by the doctor's association. Physician group practices have been introduced- this may lead to units with several doctors and employed nurses who form care teams with individual roles.

Spain

Dedicated and pro-active teams exist for most chronic diseases with all team members in primary care having electronic access to relevant data. This situation is improving in secondary care. Clinician education is embedded in most disciplines and e-learning is widely available to clinicians. The situation concerning national electronic records is very similar to the situation that exists in the UK; work is underway to develop and implement such a system but progress is slow.

5.2.10 General observations regarding IT measures

In the final part of the questionnaire, we invited respondents to record general observations regarding the role of IT in their health systems.

UK

Communication between primary and secondary care is still poor as IT systems are different and are not linked. Work on electronic shared records across health care sectors is continuing, but is viewed with hostility by some patients and activists who fear breaches of security/confidentiality.

Greece

There are no national IT systems in place for managing the disease; several IT systems have been funded and have either failed, been abandoned or are still undergoing construction.

5.3 Summary

National plans for diabetes are very common and exist in most countries, however the content of national plans for disease management vary enormously. For many countries there is still progress to be made towards establishing agreed care plans with personal goal setting. Systematic patient care with named patient contacts, regular reminders for visits and patient education is more established: However, IT systems for facilitating these processes are not common. Dedicated pro-active teams defined for diabetes care are more common at primary care level than at secondary care level. Electronic patient data is commonly available within instiutions and health care professionals within the individual institution usually have access to this. However IT systems rarely operate across sectors and institutions, with the result that the aims of disease management programmes (for instance coordinated care across settings with requlars quality improvement feedback) are rarely achieved.

Several countries have made progress in defining and measuring indicators for the quality of diabetes care and this report details the indicators collected in two countries: Denmark and UK.

In the UK performance in these quality indicators is connected to financial reimbursement. Perhaps the area where countries have generally been most active concerns the provision of information on diabetes. However this is often a result of initiatives from medical organisations and patient groups, rather than nationally organised initiatives. Where national guidelines have been published and disseminated, there are rarely mechanisms for ensuring the decision support is implemented. In the UK primary care organisations use IT supported evidence-based guidelines or care pathways that include a system of prompts and alerts for use at the indivual patient level; this helps ensure that such evidence-based clinical decision support actually gets put into practice.

Telemonitoring and telecare are not nationally implemented anywhere. However several countries are running research projects in these areas and results are awaited before any decisions are to be made. Patient information regarding prevention strategies is widely supported through internet sites. In some countries (UK and Spain) national public awareness campaigns regularly take place to raise awareness on issues such as obesity and alcohol. As can be seen from the analysis, some countries are much further than others as regards the general establishment of DMP elements (such as the UK) but even here IT measures supporting these elements still need further developing and improving.

6 Predictive risk models and multi-parametric risk assessment methods

6.1 Introduction

Diabetes complications risk factors have been intensively studied during the last decades, and these studies greatly improved the current scientific knowledge about the biological processes underlying diabetes. Another more practical application of risk factor studies consists in the definition of risk assessment models to be used in the clinical practice. These models consist in clinical/medical tools able to stratify diabetes patients according to their probability of developing complications or experiencing adverse events.

Several risk assessment models have been proposed in the literature; scope of this review is to provide a systematic survey of the different readily available risk assessment scores for persons with diabetes, and to compare their respective characteristics and limitations.

It can be useful, at this point, to define what we intend with the term risk assessment model, since different definitions are possible. A risk assessment model consists in any type of algorithm or mathematical formula (e.g., a set of rules, a decision tree, a weighted sum, etc.) for assessing the overall statistical probability of certain situations to occur in the future. Medical risk assessment may provide probabilistic statements as the likelihood that certain complications may occur given the present and historic health status.

We can furthermore define short and long term models. Long term models predictions span wide temporal windows (up to some years), while short term models temporal horizon is much more limited. For the present survey we decided to consider as a short time model any model predicting events within the next year at the most, and long term any other model.

Risk scores relevance in the context of clinical practice is evident: patients with high risk of complications can be treated with more targeted therapies, while low risk patients can avoid unnecessary treatments and relative side effects.

Given risk assessment models relevance, it is not surprising that these models will be used during the REACTION project for improving treatment and management of diabetes patients. In the context of the REACTION project, this survey will provide the basis for the selection of the most relevant risk score to be implemented within the REACTION platform. Moreover, published risk models will provide a guideline for devising and building new risk models upon the data collected from the REACTION project. Since we aim at including the most valuable model in the REACTION platform, we excluded from this review any work that does not fully disclose its respective risk assessment model.

The rest of this section is structure in two major subsections:

- In Section 6.2 long term models are discussed; models parameters sets are compared and the analytical approaches employed for deriving the models are discussed.
- Section 6.3 focuses on short terms models and their characteristics.

6.2 Long Term risk assessment models

Long term risk assessment models are usually built upon data collected during large scale, longitudinal clinical studies. Such type of studies typically last around a decade, involve thousands of patients in numerous health centres, and measure different aspects of patient's clinical/medical profile. Thus, it is not surprising that the data collected in each study can be employed for deriving multiple risk assessment models, differing from each other for predicted outcome, involved parameters or analytical techniques. In the following some of the principal studied that produced long term risk

assessment scores are reviewed, in conjunction with their respective models. The section categorizes the long term risk assessment models according to the study that has been used.

6.2.1 DCCT/EDIC study

A well known study of long term risk assessment related to diabetes and complications is the Diabetes Control and Complications Trial. [Control and Group (1993)] is a landmark medical study conducted by the United States National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The DCCT involved 1,441 volunteers, ages 13 to 39, with type 1 diabetes and 29 medical centres in the United States and Canada. DCCT is a multicentre, randomized clinical trial designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications. Volunteers had to have had diabetes for at least 1 year but no longer than 15 years. The study compared the effects of standard control of blood glucose versus intensive control on the complications of diabetes. Intensive control meant keeping haemoglobin A1C levels as close as possible to the normal value of 6 percent or less. Although intensive diabetes therapy was associated with a significant reduction in the incidence and progression of microvascular complications, an observed 41% relative risk reduction for macrovascular disease (95% CI −10 to 68) did not achieve statistical significance. The population studied in the DCCT was relatively young (the age range of participants was 13–39 years), and therefore their likelihood of having a significant cardiovascular event during the follow-up period was low. A new study started after the DCCT, called Epidemiology of Diabetes Interventions and Complications (EDIC). [Epidemiology of Diabetes Interventions and Complications Study Group (1999)] is a follow up study on 90% of the participants from DCCT that looked into cardiovascular disease and the effects of intensive control on quality of life and cost effectiveness. The DCCT/EDIC study provides an opportunity to explore the complex relationships among traditional CVD risk factors, glycemia, and CVD outcomes. Based on the DCCT/EDIC studies a lot of risk assessment models have been proposed for diabetes and complications. In this section we will review publications related to DCCT/EDIC studies which are focused on developing a risk assessment model for diabetes and complications.

The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study Research Group in [Nathan et al. (2005)] proposed a Cox regression model and proved that intensive therapy as compared with conventional therapy during the Diabetes Control and Complications Trial (DCCT) affected the long-term incidence of cardiovascular disease. The analysis was based on the Wilcoxon rank-sum test for quantitative variables and the chi-square test for categorical variables. The cumulative incidence of a cardiovascular event (the first of any) within groups was estimated according to the Kaplan–Meier method. Proportional-hazards models were used to assess the effects of time-dependent covariates.

[Carter et al. (2007)] proposed an ankle-to-brachial ratio index (ABI) as an indicator of atherosclerosis / occlusion in peripheral arterial disease (PAD). ABI was measured at each annual follow-up visit using an appropriately sized blood pressure cuff, a Doppler stethoscope, and acoustic gel. Participants were assessed in the supine position after resting for at least 5 min without any stressful stimuli. The order of the measurements was the right dorsalis pedis, the right posterior tibial, and the right arm pressure at the antecubital fossa. For occlusion, thresholds of <0.90 and <0.80 were considered to represent early onset and clinically relevant occlusion respectively. Calcification of peripheral arteries was defined as an ABI that exceeded 1.3 Unadjusted Cox models were constructed to examine the relationship of the DCCT treatment with each outcome separately. These models were supplemented by models that adjusted for known biological risk factors and tested for a DCCT treatment-by-sex interaction. The risk factors considered included baseline predictors of diabetes duration, sex, mild retinopathy at DCCT randomization and time-varying covariates of systolic blood pressure, A1C, LDL, and the Modification of Diet in Renal Disease Study glomular fitration rate. The type I error rate was determined to be 0.05 a priori, and no correction for multiple comparisons was applied to reported P values.

[Cleary et al. (2006)] associated CVD and CAD events with type 1 diabetes. Univariate rank correlations, partially adjusted for DCCT baseline age and sex, assessed the association between the prevalence of CAC >0 Agatston units, CAC >200 Agatston units, and the log CAC, with covariates. The cohort was the DCCT/EDIC study and Computed tomography (CT) was performed between November 2000 and March 2003 (11–20 years after enrolment into the DCCT, 7–9 years after its end) in 1,205 (86%) of the surviving 1,404 participants, with specific patient consent. CT was performed in 19 scanning sites. Clinical characteristics were compared using Wilcoxon's rank-sum test for

continuous quantitative variables and χ^2 or Fisher's exact tests for categorical variables. Analyses used the prevalence of CAC scores of >0 and >200 Agatston units; the latter has been a predictor of CVD events in other studies. The Mantel-Haenszel χ^2 test of nonzero correlation was used to test for a linear trend in proportions. The stratified adjusted Mantel-Haenszel analysis adjusted for other qualitative covariate effects on the OR or test of trend. Homogeneity of treatment effect over strata was assessed by the Breslow-Day test. Logistic regression examined the relationship between covariates and the prevalence of CAC. The entropy R^2 coefficient was used to describe the proportion of variation in risk explained by the model.

6.2.2 Qrisk study

Another large study in the field is the QRisk [Hippisley-Cox et al. (2007)]. Qrisk aims to develop a cardiovascular disease risk algorithm which will provide accurate estimates of cardiovascular risk in patients from different ethnic groups in England and Wales and to compare its performance with the modified version of Framingham score recommended by the National Institute for Health and Clinical Excellence (NICE). 2.3 million Patients aged 35-74 with 140 000 cardiovascular events participated at the QRisk study. Overall population (derivation and validation cohorts) comprised 2.22million people who were white or whose ethnic group was not recorded, 22 013 south Asian, 11 595 black African, 10 402 black Caribbean, and 19 792 from Chinese or other Asian or other ethnic groups.

Current version of the calculator is Qrisk2 [Hippisley-Cox et al. (2008)] and can be found online at (http://www.qrisk.org/). Qrisk2 uses the following parameters: age, gender, current smoker (yes/no), family history of heart disease aged <60 (yes/no), existing treatment with blood pressure agent (yes/no), postcode (postcode-related Townsend score) - an area measure of deprivation, body mass index (height and weight), systolic blood pressure (use current not pre-treatment value), total and HDL cholesterol, self-assigned ethnicity, rheumatoid arthritis, chronic kidney disease and atrial fibrillation.

Qrisk2 is built on a previous risk prediction algorithm (QRISK1) and aim to incorporate self assigned ethnicity as well as a range of other potentially relevant conditions associated with cardiovascular risk such as type 2 diabetes, treated hypertension, rheumatoid arthritis, renal disease, and atrial fibrillation. Qrisk2 uses Cox proportional hazards models in the derivation dataset to estimate the coefficients and hazard ratios associated with each potential risk factor for the first ever recorded diagnosis of cardiovascular disease for men and women separately. Qrisk2 uses fractional polynomials to model non-linear risk relations with continuous variables where appropriate and tested for interactions between each variable and age and between diabetes and deprivation. Qrisk2 compared against the original model QRisk1 and the Framingham equation and received higher values of ROC curves indicating better discrimination.

6.2.3 UKPDS study

Another online risk calculator for people with type 2 diabetes is the UKPDS risk engine (http://www.dtu.ox.ac.uk/riskengine/). The U.K. Prospective Diabetes Study [UKPDS Group (1991)] (UKPDS) is a landmark randomized controlled trial which showed that both intensive treatment of blood glucose and of blood pressure in diabetes can lower the risk of diabetes-related complications in individuals newly diagnosed with Type II diabetes. The UKPDS cohort consists of 5102 patients, followed for a median of 10.7 years. Between 1977 and 1991, general practitioners in the catchment areas of 23 participating UKPDS hospitals were asked to refer all patients aged 25 to 65 years presenting with newly diagnosed diabetes. Patients in the UKPDS had biochemical measurements, including HbA1c, blood pressures, and lipid and lipoprotein fractions, recorded at entry to the study, at randomization in the study after a three-month period of dietary therapy, and each year subsequently.

The UKPDS Risk Engine [Stevens et al. (2001)] provides risk estimates and 95% confidence intervals, in individuals with type 2 diabetes not known to have heart disease, for:

- non-fatal and fatal coronary heart disease,
- fatal coronary heart disease
- non-fatal and fatal stroke
- fatal stroke.

These can be calculated for any given duration of type 2 diabetes based on current age, sex, ethnicity, smoking status, presence or absence of atrial fibrillation and levels of HbA1c, systolic blood pressure, total cholesterol and HDL cholesterol. For the risk engine, data from 4,540 patients out of 5,102 was used. The model is approximately a proportional hazards model on discrete time. Survival analysis performed by fitting an ad hoc model. Proportional hazards assumptions have been verified with log-cumulative hazard plots. Likelihood ratio tests were made for interactions between HbA1c, systole blood pressure and lipid ratio, and for interaction between each of these and age and sex.

[Stevens et al. (2004)] using a subset of the UKPDS cohort enabled estimation of the probability of fatal coronary heart disease (CHD) and fatal stroke within the UKPDS Risk Engine or other computer models. The analysis was based on 674 cases of myocardial infarction MI (351 fatal) that occurred in 597 out of 5,102 UKPDS patients for whom covariate data were available during a median follow-up of 7 years. Multivariate logistic regression was used to compare levels of potential risk factors, within 2 years, between those with fatal MI and those with nonfatal MI and, similarly, between those with fatal stroke and those with nonfatal stroke. Similar analyses were performed for 234 strokes (48 fatal) that occurred in 199 patients. The multivariate MI model identified increased age at diagnosis of diabetes, time from diagnosis of diabetes to event, HbA1c, sBP, and urinary albumin as significant risk factors for MI case fatality at the 5% level of significance.

Another publication based on the UKPDS cohort is the [Kothari et al. (2002)]. This study propose mathematical models to estimate the risk of a first stroke using data from 4549 newly diagnosed type 2 diabetic patients enrolled in the UKPDS Study. This model forecasts the absolute risk of a first stroke in people with type 2 diabetes using variables readily available in routine clinical practice. During 30.700 person-years of follow-up, 188 first strokes (52 fatal) occurred. Model fitting was carried out by maximum likelihood estimation using the Newton-Raphson method. Diagnostic plots were used to compare survival probabilities calculated by the model with those calculated using nonparametric methods. Variables included in the final model were duration of diabetes, age, sex, smoking, systolic blood pressure, total cholesterol to high-density lipoprotein cholesterol ratio and presence of atrial fibrillation. Not included in the model were body mass index, hemoglobin A1c, ethnicity, and ex-smoking status.

[Clarke et al. (2004)] developed the UKPDS Outcomes Model for Type 2 diabetes that can be used to estimate the likely occurrence of major diabetes related complications over a lifetime. Equations for forecasting the occurrence of seven diabetes-related complications and death were estimated using data on 3642 patients from the United Kingdom Prospective Diabetes Study. The model's forecasts fell within the 95% confidence interval for the occurrence of observed events during the UKPDS follow-up period. When the model was used to simulate event history over patients' lifetimes, those treated with a regimen of conventional glucose control could expect 16.35 undiscounted quality-adjusted life years, and those receiving treatment with intensive glucose control could expect 16.62 quality-adjusted life years. Each type of diabetes-related event was modeled using one or more equations that included time-varying risk factors. In the case of diabetes-related complications, a Weibull proportional hazards regression was used to model the occurrence of a composite outcome covering both fatal and non-fatal events. The coefficients for risk factors were then estimated using maximum likelihood methods that account for censoring (e.g. due to factors such as loss of follow-up, or death). Risk factors with a p value of less than 0.05 were considered statistically significant. Separate equations were used to model diabetes-and non-diabetes-related outcomes. The outcomes were: cardiovascular disease, cerebrovascular disease, amputation, blindness, nephropathy, risk factor progression and mortality.

6.2.4 EuroDiab study

Another European diabetes study is the EURODIAB IDDM Complications Study. EuroDiab is a cross sectional study which examined 3,250 type 1 diabetic patients. Participants were aged between 15 and 60 years and recruited from 31 centres in 16 European countries. The sampling frame was all type 1 diabetes attending at least once in the last year for each centre. Patients were stratified by age (three categories), diabetes duration (three categories), and sex. Patient measurements were taken at baseline (1990–1991) and at 7 years follow-up (1997–1999).

[Vergouwe et al. (2010)] used a subset of the European Diabetes Prospective Complications Study (n = 1115) to develop and validate a clinical prediction rule that estimates the absolute risk of microalbuminuria. Patients were included in the analysis if they had a normal AER, i.e. below 20 µg/min, at baseline and a normal AER or microalbuminuria (AER between 20 and 200 µg/min) at

follow-up. The following characteristics were considered to be possibly predictive for microalbuminuria: age, sex, duration of diabetes, HbA1c, AER, fasting triacylglycerol, non-HDL- and LDL-cholesterol, WHR, BMI, pulse pressure, hypertension and smoking. Logistic regression was used to estimate multivariable regression coefficients, and odds ratios with 95% CIs for each predictor. The number of predictors was reduced with backward stepwise selection. The Akaike's information criterion for predictor selection was applied. The regression coefficients in the final model were multiplied with a shrinkage factor, which was estimated with bootstrapping. Shrinkage is applied to obtain accurate predictions for new patients. The performance of the prediction rule was assessed with calibration and discrimination (concordance statistic) measures. Finally the logistic model was transformed in a risk chart for making the risk calculation easier in real medical settings.

[Skevofilakas et al. (2010)] created a decision support system able to predict the risk of a Type 1 Diabetes Mellitus patient to develop retinopathy using the EuroDiab baseline dataset. The decision support system is a hybrid infrastructure combining a Feed forward Neural Network, a Classification and Regression Tree and a Rule Induction C5.0 classifier, with an improved Hybrid Wavelet Neural Network .A voting mechanism is utilized to merge the results from the four classification models. The risk factors used as model input that have been found as strongly correlated with the retinopathy complication by the EURODIAB Prospective Complications Study Group are: age, type 1 diabetes mellitus duration, HbA1c, cholesterol, triglycerides, hypertension and treatment duration.

6.2.5 Cleveland study

Another study related to diabetes and complications is based on the Cleveland Clinic. [Wells et al. (2008)] created a tool that predicts the risk of mortality in patients with type 2 diabetes. This study was based on a cohort of 33,067 patients with type 2 diabetes identified in the Cleveland Clinic electronic health record and were initially prescribed a single oral hypoglycemic agent between 1998 and 2006. Follow-up in the cohort ranged from 1 day to 8.2 years (median 28.6 months), and 3,661 deaths were observed. Mortality was determined in the EHR and the Social Security Death Index. A prediction tool was created using the Cox model coefficients. The tool was internally validated using repeated, random subsets of the cohort, which were not used to create the prediction model.

The following variables were included in the model: estimated glomerular filtration rate (GFR), A1C, BMI, systolic blood pressure (SBP), diastolic blood pressure (DBP), HDL and LDL cholesterol, triglycerides, history of congestive heart failure (CHF), history of coronary heart disease, smoking status, use of concomitant medications (insulin, ACE inhibitor/angiotensin receptor blocker, aspirin, clopidogrel, or lipid-lowering drug), new diabetes, sex, race, age, and oral medication class. A Cox proportional hazards regression model was created with the predictor variables and interactions with time to death as the outcome. The coefficients from the fitted Cox model were also used to develop an interactive web based calculator which available from http://www.clinicriskcalculators.org

6.2.6 Sweden study

Another independent study can be found at the Swedish National Diabetes Register [Cederholm et al. (2008)].The study is based on 11,646 female and male patients, aged 18–70 years, from the Swedish National Diabetes Register with 1,482 first incident CVD events on 58,342 person-years with mean follow-up of 5.64 years. This study presents a diabetes-specific equation for estimation of the absolute 5-year risk of first incident fatal/nonfatal cardiovascular disease (CVD) in type 2 diabetic patients. This risk equation incorporates A1C and several clinical characteristics such as: onset age of diabetes, diabetes duration, sex, BMI, smoking, systolic blood pressure, and antihypertensive and lipid-reducing drugs. All predictors included were associated with the outcome ($P < 0.0001$, except for BMI $P = 0.0016$) with Cox regression analysis. Calibration was excellent when assessed by comparing observed and predicted risk. Discrimination was sufficient, with a receiver operator curve statistic of 0.70. Mean 5-year risk of CVD in all patients was 12.0±7.5%, whereas 54% of the patients had a 5-year risk >=10%.

6.2.7 An overview

A principal objective in the clinical management of diabetes is the prevention of long-term vascular complications. The most common predictions for diabetes complications are cardio vascular disease, coronary heart disease and diabetic retinopathy for long term diagnosis and hyperglycemia for short

term diagnosis. In most of the studies only relatively simple statistical approaches, such as additive scores or logistic regression assuming independence between variants, have been applied.

The following tables (Table 9, Table 10 and Explanation of Table 10: √ indicates that the model takes into account the attribute. The attributes as numbered at the table are: 1 Age, 2 Race, 3 sex, 4 Smoking, 5 Waist / hip ratio,6 BMI, 7 Duration of diagnosed biabetes, 8 Systolic Blood Pressure, 9 Diastolic blood pressure, 10 A1C, 11 Changes in A1C, 12 Total Cholesterol / HDL, 13 Total cholesterol, 14 HDL cholesterol, 15 LDL cholesterol, 16 Triglycerides, 17 Albuminuria, 18 Microalbuminuria, 19 Insuline, 20 Blood glucose, 21 White blood cell count, 22 Glomerural filtration rate, 23 Glycosylated Hemoglobin Value, 24 Time to event, 25 History of previous adverse event, 26 Myocardial infarction in parents , 27 Atrial Fibrillation, 28 Hypertension, 29 Heart Failure, 30 Heart Diseases, 31 Presence of renal disease, 32 Rheumatoid arthritis, 33 Neuropathy, 34 Retinopathy, 35 Type of treatment, 36 Treatment duration, 37 Antyperthensive medication, 38 Use of other concomitant medications

Table 11) give an overview of the long term risk assessment studies and models. Table 9 gives an overview of the selected studies. Table 10 summarizes the attributes used for every risk assessment model and the outcome, and Explanation of Table 10: √ indicates that the model takes into account the attribute. The attributes as numbered at the table are: 1 Age, 2 Race, 3 sex, 4 Smoking, 5 Waist / hip ratio,6 BMI, 7 Duration of diagnosed biabetes, 8 Systolic Blood Pressure, 9 Diastolic blood pressure, 10 A1C, 11 Changes in A1C, 12 Total Cholesterol / HDL, 13 Total cholesterol, 14 HDL cholesterol, 15 LDL cholesterol, 16 Triglycerides, 17 Albuminuria, 18 Microalbuminuria, 19 Insuline, 20 Blood glucose, 21 White blood cell count, 22 Glomerural filtration rate, 23 Glycosylated Hemoglobin Value, 24 Time to event, 25 History of previous adverse event, 26 Myocardial infarction in parents , 27 Atrial Fibrillation, 28 Hypertension, 29 Heart Failure, 30 Heart Diseases, 31 Presence of renal disease, 32 Rheumatoid arthritis, 33 Neuropathy, 34 Retinopathy, 35 Type of treatment, 36 Treatment duration, 37 Antyperthensive medication, 38 Use of other concomitant medications

Table 11 gives a short description of the analysis performed and the type of risk assessment model produced. Note that Table 9 reports one line for each study, while Table 10 and Explanation of Table 10: √ indicates that the model takes into account the attribute. The attributes as numbered at the table are: 1 Age, 2 Race, 3 sex, 4 Smoking, 5 Waist / hip ratio,6 BMI, 7 Duration of diagnosed biabetes, 8 Systolic Blood Pressure, 9 Diastolic blood pressure, 10 A1C, 11 Changes in A1C, 12 Total Cholesterol / HDL, 13 Total cholesterol, 14 HDL cholesterol, 15 LDL cholesterol, 16 Triglycerides, 17 Albuminuria, 18 Microalbuminuria, 19 Insuline, 20 Blood glucose, 21 White blood cell count, 22 Glomerural filtration rate, 23 Glycosylated Hemoglobin Value, 24 Time to event, 25 History of previous adverse event, 26 Myocardial infarction in parents , 27 Atrial Fibrillation, 28 Hypertension, 29 Heart Failure, 30 Heart Diseases, 31 Presence of renal disease, 32 Rheumatoid arthritis, 33 Neuropathy, 34 Retinopathy, 35 Type of treatment, 36 Treatment duration, 37 Antyperthensive medication, 38 Use of other concomitant medications

Table 11 report one line for each model (and each line of Table 10 corresponds to one line in Explanation of Table 10: √ indicates that the model takes into account the attribute. The attributes as numbered at the table are: 1 Age, 2 Race, 3 sex, 4 Smoking, 5 Waist / hip ratio,6 BMI, 7 Duration of diagnosed biabetes, 8 Systolic Blood Pressure, 9 Diastolic blood pressure, 10 A1C, 11 Changes in A1C, 12 Total Cholesterol / HDL, 13 Total cholesterol, 14 HDL cholesterol, 15 LDL cholesterol, 16 Triglycerides, 17 Albuminuria, 18 Microalbuminuria, 19 Insuline, 20 Blood glucose, 21 White blood cell count, 22 Glomerural filtration rate, 23 Glycosylated Hemoglobin Value, 24 Time to event, 25 History of previous adverse event, 26 Myocardial infarction in parents , 27 Atrial Fibrillation, 28 Hypertension, 29 Heart Failure, 30 Heart Diseases, 31 Presence of renal disease, 32 Rheumatoid arthritis, 33 Neuropathy, 34 Retinopathy, 35 Type of treatment, 36 Treatment duration, 37 Antyperthensive medication, 38 Use of other concomitant medications

Table 11).

As we can see from Table 9 several studies related to diabetes have been set up for long term diagnosis. All of them had duration over 5 years and most of them had follow-up study.

Table 10 summarizes the predicting outcome and the attributes used at the Long term risk assessment models. As we can see from Table 10 some clinical measurements such as age, sex,

smoking, systolic blood pressure and glycosylated hemoglobin (A1C) are common to most of the models and are considered to be highly related to diabetes complications.

Risk assessment models were mainly derived by using Cox regression algorithms or some type of proportional hazard model (models 1, 5, 8 – 14). Models 2 – 4 employed logistic functions, while model 7 was built by using a set of different parametric survival models. Model 6 is the only one that employs “data mining” algorithms for creating a classifier.

It is interesting to examine whether any approach for dealing with censored data was take into consideration. Censorship arises when a patient does not experience adverse events before the end of the study, or if the patients leave the study for external causes. In these cases the time to event remains unknown, and special technique must be utilized for taking in account the loss of information. Survival regression methods were originally devised for dealing with censored data; thus models 1, 5, 6, 8 – 14 were built taking in account the presence of censorship. The remaining models were all fitted with some procedure that are not able to deal with censored data, nevertheless no strategy for accounting censorship are explicitly stated in their respective papers, and no information are provided about the effective presence of censored data in the analyzed samples.

Another relevant aspect of the process related to the construction of a predictive model is the validations of the generality of the model, i.e., its ability of correctly estimate the risk for new subjects. Ideally, model generality should be tested on a large sample that has never been used during the training phase; however, some techniques (e.g., cross validation) allow evaluating a model performance even though a limited sample size is available. Among the models we selected, models 13 and 14 subdivided their samples in training (derivation) and validation cohort, where the derivation cohort was used for training the model and the validation cohort for testing the model. Study related to models 1, 6 and 8 employed a cross validation technique for evaluate model generality. Cross validation consists in training repetitively a model by excluding a different subset of the cohort each time. The excluded subset is then tested for evaluating the model. For model 9, the researchers selected from the initial samples two randomly selected subgroups, A and B, with 5,823 patients in each subgroup. A model was generated in subgroup A, according to the procedure used for deriving the global model. This equation was subsequently used in subgroup B to estimate predicted survival rate for comparison with observed rate. Model 7 predictions were instead compared with baseline predictions provided by life table methods. Finally, the remaining studies did not perform any type of model validation.

Table 9: Summary of the selected studies for long term risk assessment models.

Study name (acronym)	Ref	year	Diabetes Type	Location	Number of patients	Sampling methodology	Repeated measurements	Follow up duration	Short rationale of the study	Data availability
DCCT	1,2,3,4,5	1993	Type I	USA	1441	Randomized clinical trial	Yes	Mean follow up: 17 years	A multicenter, randomized clinical trial designed to compare intensive with conventional diabetes therapy with regard to their effects on the development and progression of the early vascular and neurologic complications of IDDM.	Data Available upon request www.niddkrepository.org
QRISK	6,7	2007	Type II	UK	1.28 million	i.i.d.	Yes	Median follow up: 6.5 years	QRISK is likely to provide more appropriate estimates of cardiovascular disease risk in contemporary UK populations and better discriminate those at high risk on the basis of their age, sex, and social deprivation as well as existing antihypertensive treatment.	Data Available upon request www.qresearch.org
UKPDS	8,9,10,11,12	1977 - 1991	Type II	U.K.	4540	Landmark randomized controlled trial	yes	Median follow up: 10.7 years	Studying diabetes related complication in individuals newly diagnosed with Type II diabetes	No data available for external researchers
EURODIAB	13,14	1989 - 1996	Type I	Europe (16 cuntries)	3250 (follw up only for 1172)	Stratified selection	No	Mean follow up: 7.3 ± 0.6 years	To assess the prevalence of and risk factors for neuropathy in type I diabetes patients	No data available for external researchers
Cleveland	15	1998 - 2006	Type II	Cleveland, Ohio, USA	33067	i.i.d.	No	Median follow up: 28.6 months	Creating a tool that predicts the risk of mortality in patients with type 2 diabetes	No data available for external researchers
Sweden	16	1998 - 2003	Type II	Sweden	11646	i.i.d.	Yes	Mean follow up: 5.64 years	Creating a diabetes-specific equation for estimation of the absolute 5-year risk of first incident fatal/nonfatal cardiovascular disease (CVD)	No data available for external researchers

Table 9 shows the year and the location of the study, the number of patients, the sampling methodology, follow up duration and a short description of the rationale of every study.

Table 10: Summary of the predicting outcome and the attributes used at the Long term risk assessment models.

#	Outcome	Study	Ref	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38
1	Coronary Heart Disease	UKPDS	9	√	√	√	√				√		√		√																										
2	Microalbunimuria	EURODIAB	13				√	√	√				√																												
3	Myocardial Infarction Case Fatality	UKPDS	10	√							√		√							√						√														
4	Stroke Case Fatality	UKPDS	10			√					√		√											√			√													
5	Stroke	UKPDS	11	√		√	√			√	√				√														√											
6	Diabetic retinopathy	EURODIAB	14	√						√			√			√			√											√										
7	Several outcomes	UKPDS	12	√	√	√	√		√	√	√			√	√											√	√		√										
8	Mortality	Cleveland	15	√	√	√	√		√	√	√	√	√		√	√			√						√							√	√				√			√
9	Cardio Vascular Disease	Sweden	16	√		√	√		√	√	√		√																										√	√
10	Cardio Vascular Disease	DCCT	3	√			√										√	√		√	√					√							√							
11	Cardio Vascular Disease	DCCT	4			√	√						√					√							√										√					
12	Cardio Vascular Disease	DCCT	5	√		√	√	√		√			√			√	√	√		√										√										
13	Cardio Vascular Disease	QRISK	6	√		√	√		√		√						√	√										√												
14	Cardio Vascular Disease	QRISK	7	√	√	√	√		√		√						√	√										√						√		√				

Explanation of Table 10: √ indicates that the model takes into account the attribute. The attributes as numbered at the table are: 1 Age, 2 Race, 3 sex, 4 Smoking, 5 Waist / hip ratio,6 BMI, 7 Duration of diagnosed biabetes, 8 Systolic Blood Pressure, 9 Diastolic blood pressure, 10 A1C, 11 Changes in A1C, 12 Total Cholesterol / HDL, 13 Total cholesterol, 14 HDL cholesterol, 15 LDL cholesterol, 16 Triglycerides, 17 Albuminuria, 18 Microalbuminuria, 19 Insuline, 20 Blood glucose, 21 White blood cell count, 22 Glomerural filtration rate, 23 Glycosylated Hemoglobin Value, 24 Time to event, 25 History of previous adverse event, 26 Myocardial infarction in parents , 27 Atrial Fibrillation, 28 Hypertension, 29 Heart Failure, 30 Heart Diseases, 31 Presence of renal disease, 32 Rheumatoid arthritis, 33 Neuropathy, 34 Retinopathy, 35 Type of treatment, 36 Treatment duration, 37 Antyperthensive medication, 38 Use of other concomitant medications

Table 11: Type of risk assessment models produced by the study for the Long term risk assessment models.

Model number	Study name (acronym)	Ref	Performed analysis	Risk assessment model
1	**UKPDS**	9	Survival analysis performed by fitting an ad hoc model	The model is approximately a proportional hazards model on discrete time
2	**EURODIAB**	13	Multivariate logistic regression with a backward feature selection procedure	The logistic model was transformed in a risk chart for making the risk calculation easier in real medical settings
3	**UKPDS**	10	Multivariate logistic regression	Logistic function
4	**UKPDS**	10	Multivariate logistic regression	Logistic function
5	**UKPDS**	11	Survival analysis performed by fitting an ad hoc model	The model is approximately a proportional hazards model on discrete time
6	**EURODIAB**	14	A combined classifier was trained by using a cross validation approach and the Area Under the Curve metric for evaluating the results.	Combined model composed by a Feedforward Neural Network, a Classification and Regression Tree a Rule Induction C5.0 classifier, and an improved Hybrid Wavelet Neural Network
7	**UKPDS**	12	Parametric survival models were used for estimating adverse events probability. Multi level models were employed for modeling risk factors evolution.	A set of equations providing risk scores for different outcomes
8	**Cleveland**	15	Cox survival model evaluated with a 10 fold cross validation	Cox regression model
9	**Sweden**	16	Cox regression in conjunction with different featrure selection methods	Cox regression model
10	**DCCT**	3	Cox regression analysis	Cox regression model
11	**DCCT**	4	Proportional-hazards models were used to assess the effects of time-dependent covariates	Cox regression model

12	**DCCT**	5	Tobit-censored regression models assessed covariate effects on the observed CAC score	Tobit survival regression models
13	**QRISK**	6	Cox regression analysis.	Cox regression model
14	**QRISK**	7	Qrisk2 algorithm is built on its previous version (QRISK1) and incorporates self assigned ethnicity and other parameters such as type 2 diabetes, treated hypertension, rheumatoid arthritis, renal disease, and atrial fibrillation. Cox regression analysis was again used for deriving the model.	Cox regression model

Table 11 gives a short description of the analysis performed and the type of risk assessment model produced by the study for the Long term risk assessment models.

6.3 Short term risk assessment models

Hyperglycaemia and hypoglycaemia respectively denote a condition in which an excessive or insufficient amount of glucose circulates in the blood plasma. Both conditions can lead to serious outcomes, like diabetic coma or ketoacidosis, or even death.

Not surprising, the objective of short term risk assessment models for diabetic patients usually consists in predicting hyper or hypo glycaemic events. In particular, diabetes short time risk assessment model can be classified as following:

1. **Blood glucose control algorithms**

   These algorithms try to predict blood glucose level in a very short temporal range, typically spanning from some minutes to few hours. These models are employed in the context of intensive insulin therapy, a relatively new therapeutic approach that attempts to dynamically control blood glucose level, by injecting small amount of insulin several times a day. In synthesis, blood glucose control algorithms employ control system theory concepts and methods for identifying the correct number and timing of insulin injections to be performed in order to maintain euglycaemia (see for example [Eren-Oruklu et al. (2009), Ståhl and Johansson (2009)]). This problem became even more challenging after the introduction of insulin pump, that are small wearable medical devices able to measure the level of glucose and inject small quantities of insulin through an hypodermic needle. Intuitively, a robust and effective blood glucose control algorithm in conjunction with insulin pomp devices might be employed for making the glucose control process fully automatic.

2. **Short time risk assessment models for adverse events.**

   This second class of models attempt to predict the risk of adverse events in a relatively long time window, e.g. few weeks. Predicted outcomes usually consist in hypoglycaemic events, even though models for other adverse events exist as well. These models differ from the previous ones since they can be employed for stratifying diabetes patients among different classes of risk, but not for planning injections schedule for intensive insulinotherapy.

Blood glucose control algorithms are not proper risk assessment model, since their main focus is to suggest the best action in order to avoid a possible adverse event, rather than evaluating the risk of a complication. Thus we excluded blood glucose control algorithms from this review.

Regarding short time risk assessment models, at the best of our knowledge no large, multicenter clinical study is reported in the literature. While large clinical studies exist for assessing long term diabetes complications risk factors, short term models are usually derived from small cohort of patients collected in a single medical centre. Moreover, the amount of literature for short time models seems to be considerable poorer than the literature for long time models. Relevant examples found during this review are reported in the following.

6.3.1 Predicting Hypoglycemia events

An example of risk assessment model for predicting hypoglycaemia event is reported in [Murata et al. (2004)]. In this work the authors aim at developing a method for evaluating hypoglycaemia risk in type II diabetes patients that are insulin-treated. During the study 195 subjects self monitored their own blood glucose level four times a day for a period of 8 weeks. The patients were successively followed for one year, for assessing the presence of hypoglycaemia events. Logistic regression was used for linking the mean value and the standard deviation of blood glucose measurements taken during the 8 weeks period with the occurrence of hypoglycaemia events. The analysis demonstrated that these two simple parameters (blood glucose mean level and blood glucose level standard deviation) can be employed for building a risk assessment model with about 0.75 Area under the Curve performance measured on a validation set.

A hypoglycaemia risk assessment model for type I diabetes patients' is reported in [Mühlhauser et al. (1998)]. In this study, 684 patients underwent a first baseline assessment, comprehensive of socio demographic and disease related variables, hypoglycaemia awareness, diabetes management, and attitudes and behavioural aspects as expressed by the patients. Occurrence of severe hypoglycaemia events was ten monitored for a mean period of 19 ± 6 months. Multivariate survival Cox regression models were used to assess the relevant factors, namely occurrence of a severe hypoglycaemia event

during the preceding year, any history of severe hypoglycaemia, C-peptide negativity, social status, and patients' determination to reach euglycaemia. Interestingly, social and motivational factors appear to be relevant for avoid the onset of adverse events, indicating that the lower the social status and the higher the patients' determination to reach euglycaemia, the higher the risk of severe hypoglycaemia.

6.3.2 Predicting other adverse events

The work reported in [Efstathiou et al. (2002)] focus on building a risk assessment model for predicting mortality during diabetes ketoacidosis events. A total of 154 patients were retrospectively included in the study, and a set of clinical and laboratory variables were analyzed via a multivariate approach. Logistic regression identified a total of six relevant variables: severe coexisting diseases and pH < 7 at admission; units of regular insulin required in the first 12 h > 50 and serum glucose > 16.7 mmo/l (in the first 12 h); depressed mental state and fever after 24 h. The risk score was then evaluated through a comparison with an already established mortality risk score, the APACHE III [Knaus et al. (1991)].

7 Literature

[Adaji et al. (2008)] Akuh Adaji, Peter Schattner, and Kay Jones. The use of information technology to enhance diabetes management in primary care: a literature review. *Inform Prim Care*, 16 (3): 229–237, 2008.

[Adler-Milstein et al. (2007)] Julia Adler-Milstein, Davis Bu, Eric Pan, Janice Walker, David Kendrick, Julie M Hook, David W Bates, and Blackford Middleton. The cost of information technology-enabled diabetes management. *Dis Manag*, 10 (3): 115–128, Jun 2007. doi: 10.1089/dis.2007.103640. URL http://dx.doi.org/-10.1089/dis.2007.103640.

[Anderson et al. (2006)] Gerard F Anderson, Bianca K Frogner, Roger A Johns, and Uwe E Reinhardt. Health care spending and use of information technology in OECD countries. *Health Aff (Millwood)*, 25 (3): 819–831, 2006. doi: 10.1377/hlthaff.25.3.819.

[Aoki et al. (2004)] Noriaki Aoki, Kim Dunn, Tsuguya Fukui, J. Robert Beck, William J Schull, and Helen K Li. Cost-effectiveness analysis of telemedicine to evaluate diabetic retinopathy in a prison population. *Diabetes Care*, 27 (5): 1095–1101, May 2004.

[Aron and Pogach (2008)] David Aron and Leonard Pogach. Quality indicators for diabetes mellitus in the ambulatory setting: using the Delphi method to inform performance measurement development. *Qual Saf Health Care*, 17 (5): 315–317, Oct 2008. doi: 10.1136/qshc.2007.026161. URL http://dx.doi.org/10.1136/-qshc.2007.026161.

[Austrian EU Presidency 2006 (2006)] Austrian EU Presidency 2006. Vienna Declaration on Diabetes. In *EU Presidency Conference on the Prevention of Type 2 Diabetes*, 2006.

[Balas et al. (2000)] E. A. Balas, S. Weingarten, C. T. Garb, D. Blumenthal, S. A. Boren, and G. D. Brown. Improving preventive care by prompting physicians. *Arch Intern Med*, 160 (3): 301–308, Feb 2000.

[Balas et al. (2004)] E. Andrew Balas, Santosh Krishna, Rainer A Kretschmer, Thomas R Cheek, David F Lobach, and Suzanne Austin Boren. Computerized knowledge management in diabetes care. *Med Care*, 42 (6): 610–621, Jun 2004.

[Bodenheimer (1999)] T. Bodenheimer. Disease management–promises and pitfalls. *N Engl J Med*, 340 (15): 1202–1205, Apr 1999.

[Bodenheimer (2000)] T. Bodenheimer. Disease management in the American market. *BMJ*, 320 (7234): 563–566, Feb 2000.

[Bodenheimer (2003)] Thomas Bodenheimer. Interventions to improve chronic illness care: evaluating their effectiveness. *Dis Manag*, 6 (2): 63–71, 2003. doi: 10.1089/109350703321908441. URL http://dx.doi.org/-10.1089/109350703321908441.

[Bodenheimer et al. (2002a)] Thomas Bodenheimer, Kate Lorig, Halsted Holman, and Kevin Grumbach. Patient self-management of chronic disease in primary care. *JAMA*, 288 (19): 2469–2475, Nov 2002.

[Bodenheimer et al. (2002b)] Thomas Bodenheimer, Edward H Wagner, and Kevin Grumbach. Improving primary care for patients with chronic illness. *JAMA*, 288 (14): 1775–1779, Oct 2002.

[Boyle et al. (2001)] D. I. Boyle, S. Cunningham, F. M. Sullivan, and A. Morris. Technology integration for the provision of population-based equitable patient care: The Tayside Regional Diabetes Network–a brief description. *Diabetes Nutr Metab*, 14 (2): 100–103, Apr 2001.

[Boyle and Cunningham (2002)] D.I.R. Boyle and S.G. Cunningham. Resolving fundamental quality issues in linked datasets for clinical care. *Health Informatics Journal*, 8 (2): 73–77, 2002. URL http://jhi.sagepub.com/-cgi/content/abstract/8/2/73.

[Bu et al. (2007)] Davis Bu, Eric Pan, Janice Walker, Julia Adler-Milstein, David Kendrick, Julie M Hook, Caitlin M Cusack, David W Bates, and Blackford Middleton. Benefits of information technology-enabled diabetes management. *Diabetes Care*, 30 (5): 1137–1142, May 2007. doi: 10.2337/dc06-2101. URL http://dx.doi.org/-10.2337/dc06-2101.

[Cabana et al. (1999)] M. D. Cabana, C. S. Rand, N. R. Powe, A. W. Wu, M. H. Wilson, P. A. Abboud, and H. R. Rubin. Why don't physicians follow clinical practice guidelines? A framework for improvement. *JAMA*, 282 (15): 1458–1465, Oct 1999.

[Campion et al. (2005)] Francis X Campion, George L Tully, Jo-Ann Barrett, Paulo Andre, and Ann Sweeney. Improving quality of care using a diabetes registry and disease management services in an integrated delivery network. *Dis Manag*, 8 (4): 245–252, Aug 2005. doi: 10.1089/dis.2005.8.245. URL http://dx.doi.org/10.1089/-dis.2005.8.245.

[Carter et al. (2007)] Rickey E Carter, Daniel T Lackland, Patricia A Cleary, Eunsil Yim, Maria F Lopes-Virella, Gregory E Gilbert, Trevor J Orchard, Diabetes Control, Complications Trial/Epidemiology of Diabetes Interventions, and Complications (DCCT/EDIC) Study Research Group. Intensive treatment of

diabetes is associated with a reduced rate of peripheral arterial calcification in the diabetes control and complications trial. *Diabetes Care*, 30 (10): 2646–2648, Oct 2007.

[Casalino et al. (2003)] Lawrence Casalino, Robin R Gillies, Stephen M Shortell, Julie A Schmittdiel, Thomas Bodenheimer, James C Robinson, Thomas Rundall, Nancy Oswald, Helen Schauffler, and Margaret C Wang. External incentives, information technology, and organized processes to improve health care quality for patients with chronic diseases. *JAMA*, 289 (4): 434–441, 2003.

[Casalino (2005)] Lawrence P Casalino. Disease management and the organization of physician practice. *JAMA*, 293 (4): 485–488, Jan 2005. doi: 10.1001/jama.293.4.485. URL http://dx.doi.org/10.1001/jama.293.4.485.

[Cederholm et al. (2008)] Jan Cederholm, Katarina Eeg-Olofsson, Björn Eliasson, Björn Zethelius, Peter M Nilsson, Soffia Gudbjörnsdottir, and Swedish National Diabetes Register. Risk prediction of cardiovascular disease in type 2 diabetes: a risk equation from the Swedish National Diabetes Register. *Diabetes Care*, 31 (10): 2038–2043, Oct 2008.

[Chaudhry et al. (2006)] Basit Chaudhry, Jerome Wang, Shinyi Wu, Margaret Maglione, Walter Mojica, Elizabeth Roth, Sally C Morton, and Paul G Shekelle. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. *Ann Intern Med*, 144 (10): 742–752, May 2006.

[Chaudhry et al. (2007)] Sarwat I Chaudhry, Christopher O Phillips, Simon S Stewart, Barbara Riegel, Jennifer A Mattera, Anthony F Jerant, and Harlan M Krumholz. Telemonitoring for patients with chronic heart failure: a systematic review. *J Card Fail*, 13 (1): 56–62, Feb 2007. doi: 10.1016/j.cardfail.2006.09.001. URL http://dx.doi.org/10.1016/j.cardfail.2006.09.001.

[Chaudhry et al. (2010)] Sarwat I Chaudhry, Jennifer A Mattera, Jeptha P Curtis, John A Spertus, Jeph Herrin, Zhenqiu Lin, Christopher O Phillips, Beth V Hodshon, Lawton S Cooper, and Harlan M Krumholz. Telemonitoring in patients with heart failure. *N Engl J Med*, 363 (24): 2301–2309, Dec 2010. doi: 10.1056/NEJMoa1010029. URL http://dx.doi.org/10.1056/NEJMoa1010029.

[Chodosh et al. (2005)] Joshua Chodosh, Sally C Morton, Walter Mojica, Margaret Maglione, Marika J Suttorp, Lara Hilton, Shannon Rhodes, and Paul Shekelle. Meta-analysis: chronic disease self-management programs for older adults. *Ann Intern Med*, 143 (6): 427–438, Sep 2005.

[Clark et al. (2007)] Robyn A Clark, Sally C Inglis, Finlay A McAlister, John G F Cleland, and Simon Stewart. Telemonitoring or structured telephone support programmes for patients with chronic heart failure: systematic review and meta-analysis. *BMJ*, 334 (7600): 942, May 2007. doi: 10.1136/bmj.39156.536968.55. URL http://dx.doi.org/10.1136/bmj.39156.536968.55.

[Clarke et al. (2004)] P. M. Clarke, A. M. Gray, A. Briggs, A. J. Farmer, P. Fenn, R. J. Stevens, D. R. Matthews, I. M. Stratton, R. R. Holman, and U. K. Prospective Diabetes Study (UKDPS) Group. A model to estimate the lifetime health outcomes of patients with type 2 diabetes: the United Kingdom Prospective Diabetes Study (UKPDS) Outcomes Model (UKPDS no. 68). *Diabetologia*, 47 (10): 1747–1759, Oct 2004.

[Cleary et al. (2006)] Patricia A Cleary, Trevor J Orchard, Saul Genuth, Nathan D Wong, Robert Detrano, Jye-Yu C Backlund, Bernard Zinman, Alan Jacobson, Wanjie Sun, John M Lachin, David M Nathan, and D. C. C. T/E. D. I. C. Research Group. The effect of intensive glycemic treatment on coronary artery calcification in type 1 diabetic participants of the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications (DCCT/EDIC) Study. *Diabetes*, 55 (12): 3556–3565, Dec 2006.

[Cleveringa et al. (2008)] Frits G W Cleveringa, Kees J Gorter, Maureen van den Donk, and Guy E H M Rutten. Combined task delegation, computerized decision support, and feedback improve cardiovascular risk for type 2 diabetic patients: a cluster randomized trial in primary care. *Diabetes Care*, 31 (12): 2273–2275, Dec 2008. doi: 10.2337/dc08-0312. URL http://dx.doi.org/10.2337/dc08-0312.

[Club Diabete Sicili@ (2008)] Club Diabete Sicili@. Five-year impact of a continuous quality improvement effort implemented by a network of diabetes outpatient clinics. *Diabetes Care*, 31 (1): 57–62, Jan 2008.

[COCIR (2008)] COCIR. COCIR White Paper - Towards a sustainable healthcare model. Technical report, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, 2008. URL http://www.cocir.org/uploads/documents/-34-cocir_wp_on_sustainable_hc_-_released_on_19_nov._2008.pdf.

[Committee to Design a Strategy for Quality Review and Assurance in Medicare and Institute of Medicine (1990)] Committee to Design a Strategy for Quality Review and Assurance in Medicare and Institute of Medicine. *Medicare: A Strategy for Quality Assurance : Sources and Methods Volume II*. National Academies Press, 1990. ISBN 0309042380.

[Control and Group (1993)]The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group. *N Engl J Med*, 329 (14): 977–986, Sep 1993.

[Corriveau et al. (2008)] Erin A Corriveau, Peter J Durso, Ellen D Kaufman, Betty J Skipper, Louise A Laskaratos, and Kimberly B Heintzman. Effect of Carelink, an internet-based insulin pump monitoring system, on glycemic control in rural and urban children with type 1 diabetes mellitus. *Pediatr Diabetes*, 9 (4 Pt 2): 360–

366, Aug 2008. doi: 10.1111/j.1399-5448.2008.00363.x. URL http://dx.doi.org/10.1111/j.1399-5448.2008.00363.x.

[Cousins et al. (2002)] Michael S. Cousins, Lisa M. Shickle, and John A Bander. An Introduction to Predictive Modeling for Disease Management Risk Stratification. *Disease Management*, 3 (5): 157–167, September 2002.

[Crocco et al. (2002)] Anthony G Crocco, Miguel Villasis-Keever, and Alejandro R Jadad. Analysis of cases of harm associated with use of health information on the internet. *JAMA*, 287 (21): 2869–2871, Jun 2002.

[Currell et al. (2000)] R. Currell, C. Urquhart, P. Wainwright, and R. Lewis. Telemedicine versus face to face patient care: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, 2 (2): CD002098, 2000. doi: 10.1002/14651858.CD002098.

[Davis et al. (1995)] D. A. Davis, M. A. Thomson, A. D. Oxman, and R. B. Haynes. Changing physician performance. A systematic review of the effect of continuing medical education strategies. *JAMA*, 274 (9): 700–705, Sep 1995.

[Deakin et al. (2005)] T. Deakin, C. E. McShane, J. E. Cade, and R. D R R Williams. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*, 2: CD003417, 2005. doi: 10.1002/14651858.CD003417.pub2. URL http://dx.doi.org/10.1002/-14651858.CD003417.pub2.

[Dexheimer et al. (2008)] Judith W Dexheimer, Thomas R Talbot, David L Sanders, S. Trent Rosenbloom, and Dominik Aronsky. Prompting clinicians about preventive care measures: a systematic review of randomized controlled trials. *J Am Med Inform Assoc*, 15 (3): 311–320, 2008. doi: 10.1197/jamia.M2555. URL http://-dx.doi.org/10.1197/jamia.M2555.

[DGSAUDE (2004)] DGSAUDE. National Health Plan 2004-2010. Ministry of Health, June 2004.

[Dorr et al. (2007)] David Dorr, Laura M Bonner, Amy N Cohen, Rebecca S Shoai, Ruth Perrin, Edmund Chaney, and Alexander S Young. Informatics systems to promote improved care for chronic illness: a literature review. *J Am Med Inform Assoc*, 14 (2): 156–163, 2007. doi: 10.1197/jamia.M2255. URL http://-dx.doi.org/10.1197/jamia.M2255.

[Doumit et al. (2007)] G. Doumit, M. Gattellari, J. Grimshaw, and Ma O'brien. Local opinion leaders: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, 1: CD000125, 2007. doi: 10.1002/14651858.CD000125.pub3. URL http://dx.doi.org/10.1002/14651858.CD000125.pub3.

[Dubey et al. (2006)] Vinita Dubey, Roy Mathew, Karl Iglar, Rahim Moineddin, and Richard Glazier. Improving preventive service delivery at adult complete health check-ups: the Preventive health Evidence-based Recommendation Form (PERFORM) cluster randomized controlled trial. *BMC Fam Pract*, 7: 44, 2006. doi: 10.1186/1471-2296-7-44. URL http://dx.doi.org/10.1186/1471-2296-7-44.

[Efstathiou et al. (2002)] Stamatis P Efstathiou, Aphrodite G Tsiakou, Dimitrios I Tsioulos, Ioannis D Zacharos, Athanasios G Mitromaras, Stylianos E Mastorantonakis, Themistoklis N Panagiotou, and Theodore D Mountokalakis. A mortality prediction model in diabetic ketoacidosis. *Clin Endocrinol (Oxf)*, 57 (5): 595–601, Nov 2002.

[Ellis (2006)] Judith Ellis. All inclusive benchmarking. *J Nurs Manag*, 14 (5): 377–383, Jul 2006. doi: 10.1111/j.1365-2934.2006.00596.x. URL http://dx.doi.org/10.1111/j.1365-2934.2006.00596.x.

[Eng and Gustafson (1999)] TR Eng and DH Gustafson, editors. *Wired for Health and Well-Being: the Emergence of Interactive Health Communication*. US Department of Health and Human Services, U.S. Government Printing Office, Washington, DC, April 1999.

[Epidemiology of Diabetes Interventions and Complications Study Group (1999)] Epidemiology of Diabetes Interventions and Complications Study Group. Epidemiology of Diabetes Interventions and Complications (EDIC). Design, implementation, and preliminary results of a long-term follow-up of the Diabetes Control and Complications Trial cohort. *Diabetes Care*, 22 (1): 99–111, Jan 1999.

[Epstein and Sherwood (1996)] R. S. Epstein and L. M. Sherwood. From outcomes research to disease management: a guide for the perplexed. *Ann Intern Med*, 124 (9): 832–837, May 1996.

[Eren-Oruklu et al. (2009)] Meriyan Eren-Oruklu, Ali Cinar, Lauretta Quinn, and Donald Smith. Estimation of future glucose concentrations with subject-specific recursive linear models. *Diabetes Technol Ther*, 11 (4): 243–253, Apr 2009. doi: 10.1089/dia.2008.0065. URL http://dx.doi.org/10.1089/dia.2008.0065.

[Eysenbach (2008)] Gunther Eysenbach. Medicine 2.0: social networking, collaboration, participation, apomediation, and openness. *J Med Internet Res*, 10 (3): e22, 2008. doi: 10.2196/jmir.1030. URL http://-dx.doi.org/10.2196/jmir.1030.

[Farmer et al. (2005)] A. Farmer, O. J. Gibson, L. Tarassenko, and A. Neil. A systematic review of telemedicine interventions to support blood glucose self-monitoring in diabetes. *Diabet Med*, 22 (10): 1372–1378, Oct 2005. doi: 10.1111/j.1464-5491.2005.01627.x. URL http://dx.doi.org/10.1111/j.1464-5491.2005.01627.x.

[Farmer et al. (2008)] Anna P Farmer, France Légaré, Lucile Turcot, Jeremy Grimshaw, Emma Harvey, Jessie L McGowan, and Fredric Wolf. Printed educational materials: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, (3): CD004398, 2008. doi: 10.1002/14651858.CD004398.pub2. URL http://dx.doi.org/10.1002/14651858.CD004398.pub2.

[FEND and IDF (2006)] FEND and IDF. Diabetes, The Policy Puzzle: Towards Benchmarking in the EU 25, 2006.

[Fetterolf (2006)] Donald Fetterolf. Notes from the field: the economic value chain in disease management organizations. *Dis Manag*, 9 (6): 316–327, Dec 2006. doi: 10.1089/dis.2006.9.316. URL http://dx.doi.org/-10.1089/dis.2006.9.316.

[Field and Grigsby (2002)] Marilyn J Field and Jim Grigsby. Telemedicine and remote patient monitoring. *JAMA*, 288 (4): 423–425, 2002.

[Fireman et al. (2004)] Bruce Fireman, Joan Bartlett, and Joe Selby. Can disease management reduce health care costs by improving quality? *Health Aff (Millwood)*, 23 (6): 63–75, 2004.

[Foy et al. (2005)] R. Foy, M. P. Eccles, G. Jamtvedt, J. Young, J. M. Grimshaw, and R. Baker. What do we know about how to do audit and feedback? Pitfalls in applying evidence from a systematic review. *BMC Health Serv Res*, 5: 50, 2005. doi: 10.1186/1472-6963-5-50. URL http://dx.doi.org/10.1186/1472-6963-5-50.

[Fursse et al. (2008)] Joanna Fursse, Malcolm Clarke, Russell Jones, Sneh Khemka, and Genevieve Findlay. Early experience in using telemonitoring for the management of chronic disease in primary care. *J Telemed Telecare*, 14 (3): 122–124, 2008. doi: 10.1258/jtt.2008.003005. URL http://dx.doi.org/10.1258/-jtt.2008.003005.

[Garg et al. (2005)] Amit X Garg, Neill K J Adhikari, Heather McDonald, M. Patricia Rosas-Arellano, P. J. Devereaux, Joseph Beyene, Justina Sam, and R. Brian Haynes. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes: a systematic review. *JAMA*, 293 (10): 1223–1238, Mar 2005. doi: 10.1001/jama.293.10.1223. URL http://dx.doi.org/10.1001/jama.293.10.1223.

[Gensichen et al. (2006)] Jochen Gensichen, Christiane Muth, Martin Butzlaff, Thomas Rosemann, Heiner Raspe, Gabriele Müller de Cornejo, Martin Beyer, Martin Härter, Ulrich A Müller, Christiane E Angermann, Ferdinand M Gerlach, and Ed Wagner. [The future is chronic: German primary care and the Chronic Care Model–The comprehensive principles in the proactive treatment of the chronically ill]. *Z Arztl Fortbild Qualitatssich*, 100 (5): 365–374, 2006.

[Gerlach (1998)] F. M. Gerlach. Qualitätsmanagement in der Medizin - Definition und Ziele. *Z Rheumatol*, 57 (5): 335–339, Oct 1998.

[Gerlach et al. (2006)] Ferdinand M Gerlach, Martin Beyer, Kristina Saal, Monika Peitz, and Jochen Gensichen. [New perspectives in the primary care of the chronically ill–against the "tyranny of the urgent". Part 2: The chronic care model und case management as the basis of a forward-looking approach to primary care]. *Z Arztl Fortbild Qualitatssich*, 100 (5): 345–352, 2006.

[Gerstein and Haynes (2001)] Hertzel C. Gerstein and R. Brian Haynes. *Evidence-Based Diabetes Care*. B.C. Decker Inc, April 2001. ISBN 1550091247.

[Gillespie (2002)] Jeann Lee Gillespie. The Value of Disease Management - Part 2: Balancing Cost and Quality in the Treatment of Diabetes Mellitus: An Annotated Bibliography of Studies on the Benefits of Disease Management Services for the Treatment of Diabetes Mellitus. *Dis Manag*, 5 (1): 37–50, Mar 2002.

[Glattacker and Jäckel (2007)] M. Glattacker and W. H. Jäckel. Evaluation der Qualitätssicherung – aktuelle Datenlage und Konsequenzen für die Forschung. *Gesundheitswesen*, 69 (5): 277–283, May 2007. doi: 10.1055/s-2007-981460. URL http://dx.doi.org/10.1055/s-2007-981460.

[Glock et al. (2004)] Gerhard Glock, Stefan Sohn, and Oliver Schöffski. *IT-Unterstützung für den medizinischen Prozess in der integrierten Versorgung*. Health Economics Research Zentrum, 1 edition, December 2004. ISBN 3936863040.

[Grabert et al. (2002)] Matthias Grabert, Franz Schweiggert, and Reinhard W Holl. A framework for diabetes documentation and quality management in Germany: 10 years of experience with DPV. *Comput Methods Programs Biomed*, 69 (2): 115–121, Aug 2002.

[Grant et al. (2006)] Richard W Grant, Jonathan S Wald, Eric G Poon, Jeffrey L Schnipper, Tejal K Gandhi, Lynn A Volk, and Blackford Middleton. Design and implementation of a web-based patient portal linked to an ambulatory care electronic health record: patient gateway for diabetes collaborative care. *Diabetes Technol Ther*, 8 (5): 576–586, Oct 2006. doi: 10.1089/dia.2006.8.576. URL http://dx.doi.org/10.1089/dia.2006.8.576.

[Green et al. (2006)] Carolyn J Green, Patricia Fortin, Malcolm Maclure, Art Macgregor, and Sylvia Robinson. Information system support as a critical success factor for chronic disease management: Necessary but not sufficient. *Int J Med Inform*, 75 (12): 818–828, Dec 2006. doi: 10.1016/j.ijmedinf.2006.05.042. URL http://dx.doi.org/10.1016/j.ijmedinf.2006.05.042.

[Griffin and Kinmonth (2000)] S. Griffin and A. L. Kinmonth. Diabetes care: the effectiveness of systems for routine surveillance for people with diabetes. *Cochrane Database Syst Rev*, 2: CD000541, 2000.

[Grimshaw et al. (2003)] J. Grimshaw, L. M. McAuley, L. A. Bero, R. Grilli, A. D. Oxman, C. Ramsay, L. Vale, and M. Zwarenstein. Systematic reviews of the effectiveness of quality improvement strategies and programmes. *Qual Saf Health Care*, 12 (4): 298–303, Aug 2003.

[Grimshaw et al. (2001)] J. M. Grimshaw, L. Shirran, R. Thomas, G. Mowatt, C. Fraser, L. Bero, R. Grilli, E. Harvey, A. Oxman, and M. A. O'Brien. Changing provider behavior: an overview of systematic reviews of interventions. *Med Care*, 39 (8 Suppl 2): II2–I45, Aug 2001.

[Grimshaw et al. (2004)] J. M. Grimshaw, R. E. Thomas, G. MacLennan, C. Fraser, C. R. Ramsay, L. Vale, P. Whitty, M. P. Eccles, L. Matowe, L. Shirran, M. Wensing, R. Dijkstra, and C. Donaldson. Effectiveness and efficiency of guideline dissemination and implementation strategies. *Health Technol Assess*, 8 (6): iii–iv, 1–72, Feb 2004.

[Hall et al. (2004)] Michael Hall, Itamar Raz, and Lex Herrebrugh. Re-awakening the Saint Vincent Movement. IDF Homepage, 2004. URL http://www.idf.org/webdata/docs/RevivalofSVMapril2004%20textMichael.doc. Zugriff am 8. August 2009.

[Hippisley-Cox et al. (2007)] Julia Hippisley-Cox, Carol Coupland, Yana Vinogradova, John Robson, Margaret May, and Peter Brindle. Derivation and validation of QRISK, a new cardiovascular disease risk score for the United Kingdom: prospective open cohort study. *BMJ*, 335 (7611): 136, Jul 2007. doi: 10.1136/bmj.39261.471806.55. URL http://dx.doi.org/10.1136/bmj.39261.471806.55.

[Hippisley-Cox et al. (2008)] Julia Hippisley-Cox, Carol Coupland, Yana Vinogradova, John Robson, Rubin Minhas, Aziz Sheikh, and Peter Brindle. Predicting cardiovascular risk in England and Wales: prospective derivation and validation of QRISK2. *BMJ*, 336 (7659): 1475–1482, Jun 2008. doi: 10.1136/bmj.39609.449676.25. URL http://dx.doi.org/10.1136/bmj.39609.449676.25.

[Inglis et al. (2010)] Sally C Inglis, Robyn A Clark, Finlay A McAlister, Jocasta Ball, Christian Lewinter, Damien Cullington, Simon Stewart, and John Gf Cleland. Structured telephone support or telemonitoring programmes for patients with chronic heart failure. *Cochrane Database Syst Rev*, (8): CD007228, 2010. doi: 10.1002/14651858.CD007228.pub2. URL http://dx.doi.org/10.1002/14651858.CD007228.pub2.

[Integrating the Healthcare Enterprise (2009a)] Integrating the Healthcare Enterprise. IHE.net Home, 2009. URL http://www.ihe.net/. (last checked 29.11.2009).

[Integrating the Healthcare Enterprise (2009b)] Integrating the Healthcare Enterprise. IHE Patient Care Coordination (PCC) Technical Framework Volume I. Technical Report Revision 5.0, August 2009.

[IOM (2004)] IOM. *Crossing the Quality Chasm - A New Health System for the 21st Century*. NATIONAL ACADEMY PRESS, 2101 Constitution Avenue, N.W., Washington, DC 20418, 2004. ISBN ISBN 0-309-07280-8. URL http://www.nap.edu/catalog.php?record_id=10027.

[Jaana and Paré (2007)] Mirou Jaana and Guy Paré. Home telemonitoring of patients with diabetes: a systematic assessment of observed effects. *J Eval Clin Pract*, 13 (2): 242–253, Apr 2007. doi: 10.1111/j.1365-2753.2006.00686.x. URL http://dx.doi.org/10.1111/j.1365-2753.2006.00686.x.

[Jackson et al. (2006)] Chandra L Jackson, Shari Bolen, Frederick L Brancati, Marian L Batts-Turner, and Tiffany L Gary. A systematic review of interactive computer-assisted technology in diabetes care. Interactive information technology in diabetes care. *J Gen Intern Med*, 21 (2): 105–110, Feb 2006. doi: 10.1111/j.1525-1497.2005.00310.x. URL http://dx.doi.org/10.1111/j.1525-1497.2005.00310.x.

[Jamtvedt et al. (2006)] G. Jamtvedt, J. M. Young, D. T. Kristoffersen, M. A. O'Brien, and A. D. Oxman. Audit and feedback: effects on professional practice and health care outcomes. *Cochrane Database Syst Rev*, 2: CD000259, 2006. doi: 10.1002/14651858.CD000259.pub2. URL http://dx.doi.org/10.1002/-14651858.CD000259.pub2.

[Joshy and Simmons (2006)] Grace Joshy and David Simmons. Diabetes information systems: a rapidly emerging support for diabetes surveillance and care. *Diabetes Technol Ther*, 8 (5): 587–597, Oct 2006. doi: 10.1089/dia.2006.8.587. URL http://dx.doi.org/10.1089/dia.2006.8.587.

[Kawamoto et al. (2005)] Kensaku Kawamoto, Caitlin A Houlihan, E. Andrew Balas, and David F Lobach. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ*, 330 (7494): 765, Apr 2005. doi: 10.1136/bmj.38398.500764.8F. URL http://-dx.doi.org/10.1136/bmj.38398.500764.8F.

[Kiefe et al. (2001)] C. I. Kiefe, J. J. Allison, O. D. Williams, S. D. Person, M. T. Weaver, and N. W. Weissman. Improving quality improvement using achievable benchmarks for physician feedback: a randomized controlled trial. *JAMA*, 285 (22): 2871–2879, Jun 2001.

[Kim and Johnson (2002)] Matthew I Kim and Kevin B Johnson. Personal health records: evaluation of functionality and utility. *J Am Med Inform Assoc*, 9 (2): 171–180, 2002.

[Knaus et al. (1991)] W. A. Knaus, D. P. Wagner, E. A. Draper, J. E. Zimmerman, M. Bergner, P. G. Bastos, C. A. Sirio, D. J. Murphy, T. Lotring, and A. Damiano. The APACHE III prognostic system. Risk prediction of hospital mortality for critically ill hospitalized adults. *Chest*, 100 (6): 1619–1636, Dec 1991.

[Knight et al. (2005)] Kevin Knight, Enkhe Badamgarav, James M Henning, Vic Hasselblad, Anacleto D Gano, Joshua J Ofman, and Scott R Weingarten. A systematic review of diabetes disease management programs. *Am J Manag Care*, 11 (4): 242–250, Apr 2005.

[Koch (2006)] Sabine Koch. Home telehealth–current state and future trends. *Int J Med Inform*, 75 (8): 565–576, Aug 2006. doi: 10.1016/j.ijmedinf.2005.09.002. URL http://dx.doi.org/10.1016/j.ijmedinf.2005.09.002.

[Kodner and Spreeuwenberg (2002)] Dennis L Kodner and Cor Spreeuwenberg. Integrated care: meaning, logic, applications, and implications–a discussion paper. *Int J Integr Care*, 2: e12, 2002.

[Kommission der Europäischen Gemeinschaften (2004)] Kommission der Europäischen Gemeinschaften. Mitteilung der Kommission an den Rat, das Europäische Parlament, den Europäischen Wirtschafts- und Sozialausschuss und den Ausschuss der Regionen. Elektronische Gesundheitsdienste – eine bessere Gesundheitsfürsorge für Europas Bürger: Aktionsplan für einen europäischen Raum der elektronischen Gesundheitsdienste, 30. April 2004. (last checked 29.11.2009).

[Koppel et al. (2005)] Ross Koppel, Joshua P Metlay, Abigail Cohen, Brian Abaluck, A. Russell Localio, Stephen E Kimmel, and Brian L Strom. Role of computerized physician order entry systems in facilitating medication errors. *JAMA*, 293 (10): 1197–1203, Mar 2005. doi: 10.1001/jama.293.10.1197. URL http://-dx.doi.org/10.1001/jama.293.10.1197.

[Korff and Goldberg (2001)] M. Von Korff and D. Goldberg. Improving outcomes in depression. *BMJ*, 323 (7319): 948–949, Oct 2001.

[Korsatko et al. (2007)] Stefan Korsatko, Wolfgang Habacher, Ivo Rakovac, Johannes Plank, Sabine Seereiner, Peter Beck, Robert Gfrerer, Peter Mrak, Bernd Bauer, Manfred Grossschädl, and Thomas R Pieber. Evaluation of a teaching and treatment program in over 4,000 type 2 diabetic patients after introduction of reimbursement policy for physicians. *Diabetes Care*, 30 (6): 1584–1586, Jun 2007. doi: 10.2337/dc06-2095.

[Kothari et al. (2002)] Viti Kothari, Richard J Stevens, Amanda I Adler, Irene M Stratton, Susan E Manley, H. Andrew Neil, and Rudy R Holman. UKPDS 60: risk of stroke in type 2 diabetes estimated by the UK Prospective Diabetes Study risk engine. *Stroke*, 33 (7): 1776–1781, Jul 2002.

[Kuraitis (2008)] Vince Kuraitis. A First Comparison of Google Health and MS HealthVault, March 3 2008. URL http://e-caremanagement.com/a-first-comparison-of-google-health-and-ms-healthvault/. (last checked 24.11.2009).

[Lester et al. (2008)] William T Lester, Adrian H Zai, Richard W Grant, and Henry C Chueh. Designing healthcare information technology to catalyse change in clinical care. *Inform Prim Care*, 16 (1): 9–19, 2008.

[Lober et al. (2006)] W. B. Lober, B. Zierler, A. Herbaugh, S. E. Shinstrom, A. Stolyar, E. H. Kim, and Y. Kim. Barriers to the use of a personal health record by an elderly population. *AMIA Annu Symp Proc*, pages 514–518, 2006.

[Martirosyan et al. (2008)] L. Martirosyan, J. Braspenning, P. Denig, W. J C de Grauw, M. Bouma, F. Storms, and F. M. Haaijer-Ruskamp. Prescribing quality indicators of type 2 diabetes mellitus ambulatory care. *Qual Saf Health Care*, 17 (5): 318–323, Oct 2008. doi: 10.1136/qshc.2007.024224. URL http://dx.doi.org/10.1136/-qshc.2007.024224.

[Mühlhauser et al. (1998)] I. Mühlhauser, H. Overmann, R. Bender, U. Bott, and M. Berger. Risk factors of severe hypoglycaemia in adult patients with Type I diabetes–a prospective population based study. *Diabetologia*, 41 (11): 1274–1282, Nov 1998. doi: 10.1007/s001250051065. URL http://dx.doi.org/10.1007/s001250051065.

[Murata et al. (2004)] Glen H Murata, Richard M Hoffman, Jayendra H Shah, Christopher S Wendel, and William C Duckworth. A probabilistic model for predicting hypoglycemia in type 2 diabetes mellitus: The Diabetes Outcomes in Veterans Study (DOVES). *Arch Intern Med*, 164 (13): 1445–1450, Jul 2004. doi: 10.1001/archinte.164.13.1445. URL http://dx.doi.org/10.1001/archinte.164.13.1445.

[Murray et al. (2005)] E. Murray, J. Burns, Tai S See, R. Lai, and I. Nazareth. Interactive Health Communication Applications for people with chronic disease. *Cochrane Database Syst Rev*, 4: CD004274, 2005. doi: 10.1002/14651858.CD004274.pub4. URL http://dx.doi.org/10.1002/14651858.CD004274.pub4.

[Nathan et al. (2005)] David M Nathan, Patricia A Cleary, Jye-Yu C Backlund, Saul M Genuth, John M Lachin, Trevor J Orchard, Philip Raskin, Bernard Zinman, Diabetes Control, Complications Trial/Epidemiology of Diabetes Interventions, and Complications (DCCT/EDIC) Study Research Group. Intensive diabetes treatment and cardiovascular disease in patients with type 1 diabetes. *N Engl J Med*, 353 (25): 2643–2653, Dec 2005.

[Nobel and Norman (2003)] Jeremy J Nobel and Gordon K Norman. Emerging information management technologies and the future of disease management. *Dis Manag*, 6 (4): 219–231, 2003. doi: 10.1089/109350703322682531. URL http://dx.doi.org/10.1089/109350703322682531.

[Nolte et al. (2009)] Ellen Nolte, Cecile Knai, and Martin McKee, editors. *Managing Chronic Conditions: Experience in Eight Countries*. World Health Organisation, May 2009. ISBN 928904294X.

[Norris et al. (2002a)] Susan L Norris, Joseph Lau, S. Jay Smith, Christopher H Schmid, and Michael M Engelgau. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care*, 25 (7): 1159–1171, Jul 2002.

[Norris et al. (2002b)] Susan L Norris, Phyllis J Nichols, Carl J Caspersen, Russell E Glasgow, Michael M Engelgau, Leonard Jack, George Isham, Susan R Snyder, Vilma G Carande-Kulis, Sanford Garfield, Peter Briss, and David McCulloch. The effectiveness of disease and case management for people with diabetes. A systematic review. *Am J Prev Med*, 22 (4 Suppl): 15–38, May 2002.

[NSF (2001)] NSF. National Service Framework - Modern Standards and Service Models - Diabetes. Department of Health, 2001.

[Ofman et al. (2004)] Joshua J Ofman, Enkhe Badamgarav, James M Henning, Kevin Knight, Anacleto D Gano, Rebecka K Levan, Shoval Gur-Arie, Margaret S Richards, Vic Hasselblad, and Scott R Weingarten. Does disease management improve clinical and economic outcomes in patients with chronic diseases? A systematic review. *Am J Med*, 117 (3): 182–192, Aug 2004.

[Olivarius et al. (2001)] N. F. Olivarius, H. Beck-Nielsen, A. H. Andreasen, M. Hørder, and P. A. Pedersen. Randomised controlled trial of structured personal care of type 2 diabetes mellitus. *BMJ*, 323 (7319): 970–975, Oct 2001.

[Oxman et al. (1995)] A. D. Oxman, M. A. Thomson, D. A. Davis, and R. B. Haynes. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *CMAJ*, 153 (10): 1423–1431, Nov 1995.

[Paré et al. (2007)] Guy Paré, Mirou Jaana, and Claude Sicotte. Systematic review of home telemonitoring for chronic diseases: the evidence base. *J Am Med Inform Assoc*, 14 (3): 269–277, 2007. doi: 10.1197/jamia.M2270. URL http://dx.doi.org/10.1197/jamia.M2270.

[Peytremann-Bridevaux and Burnand (2009)] Isabelle Peytremann-Bridevaux and Bernard Burnand. Inventory and perspectives of chronic disease management programs in Switzerland: an exploratory survey. *Int J Integr Care*, 9: e93, 2009.

[Pfeiffer (2009)] K. P. Pfeiffer. Future development of medical informatics from the viewpoint of health telematics. *Methods Inf Med*, 48 (1): 55–61, 2009.

[Piatt et al. (2006)] Gretchen A Piatt, Trevor J Orchard, Sharlene Emerson, David Simmons, Thomas J Songer, Maria M Brooks, Mary Korytkowski, Linda M Siminerio, Usman Ahmad, and Janice C Zgibor. Translating the chronic care model into the community: results from a randomized controlled trial of a multifaceted diabetes care intervention. *Diabetes Care*, 29 (4): 811–817, Apr 2006.

[Piwernetz (2001)] K. Piwernetz. DIABCARE Quality Network in Europe–a model for quality management in chronic diseases. *Int Clin Psychopharmacol*, 16 Suppl 3: S5–13, Apr 2001.

[Piwernetz et al. (1993)] K. Piwernetz, P. D. Home, O. Snorgaard, M. Antsiferov, K. Staehr-Johansen, and M. Krans. Monitoring the targets of the St Vincent Declaration and the implementation of quality management in diabetes care: the DIABCARE initiative. The DIABCARE Monitoring Group of the St Vincent Declaration Steering Committee. *Diabet Med*, 10 (4): 371–377, May 1993.

[Polisena et al. (2009a)] J. Polisena, K. Tran, K. Cimon, B. Hutton, S. McGill, and K. Palmer. Home telehealth for diabetes management: a systematic review and meta-analysis. *Diabetes Obes Metab*, 11 (10): 913–930, Oct 2009. doi: 10.1111/j.1463-1326.2009.01057.x. URL http://dx.doi.org/10.1111/j.1463-1326.2009.01057.x.

[Polisena et al. (2009b)] Julie Polisena, Doug Coyle, Kathryn Coyle, and Sarah McGill. Home telehealth for chronic disease management: a systematic review and an analysis of economic evaluations. *Int J Technol Assess Health Care*, 25 (3): 339–349, Jul 2009. doi: 10.1017/S0266462309990201. URL http://dx.doi.org/-10.1017/S0266462309990201.

[Purcell (2005)] Gretchen P Purcell. What makes a good clinical decision support system. *BMJ*, 330 (7494): 740–741, Apr 2005. doi: 10.1136/bmj.330.7494.740. URL http://dx.doi.org/10.1136/bmj.330.7494.740.

[Regional Offices for Europe of WHO and IDF (1989)] Regional Offices for Europe of WHO and IDF. Diabetesfürsorge und -forschung in Europa - Die St. Vincent Deklaration. In *Diabetes mellitus in Europa: Ein Problem in jedem Lebensalter und in allen Ländern - Ein Modell zur Prävention und Selbstbetreuung*, St. Vincent (Italien), October 1989.

[Regional Offices for Europe of WHO and IDF (1999)] Regional Offices for Europe of WHO and IDF. Istanbul Commitment. In *10th Anniversary Meeting of The St. Vincent Declaration Diabetes Action Programme*, Istanbul (Turkey), October 1999.

[Renders et al. (2001a)] C. M. Renders, G. D. Valk, S. Griffin, E. H. Wagner, J. T. Eijk, and W. J. Assendelft. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev*, 1: CD001481, 2001.

[Renders et al. (2001b)] C. M. Renders, G. D. Valk, S. J. Griffin, E. H. Wagner, J. T. Eijk Van, and W. J. Assendelft. Interventions to improve the management of diabetes in primary care, outpatient, and community settings: a systematic review. *Diabetes Care*, 24 (10): 1821–1833, Oct 2001.

[Sackett et al. (1996)] D. L. Sackett, W. M. Rosenberg, J. A. Gray, R. B. Haynes, and W. S. Richardson. Evidence based medicine: what it is and what it isn't. *BMJ*, 312 (7023): 71–72, Jan 1996.

[Saleem et al. (2005)] Jason J Saleem, Emily S Patterson, Laura Militello, Marta L Render, Greg Orshansky, and Steven M Asch. Exploring barriers and facilitators to the use of computerized clinical reminders. *J Am Med Inform Assoc*, 12 (4): 438–447, 2005. doi: 10.1197/jamia.M1777. URL http://dx.doi.org/10.1197/-jamia.M1777.

[Schabetsberger et al. (2006)] Thomas Schabetsberger, Elske Ammenwerth, Ruth Breu, Alexander Hoerbst, Georg Goebel, Robert Penz, Klaus Schindelwig, Herlinde Toth, Raimund Vogl, and Florian Wozak. E-health approach to link-up actors in the health care system of Austria. *Stud Health Technol Inform*, 124: 415–420, 2006.

[Schrijvers (2009)] Guus Schrijvers. Disease management: a proposal for a new definition. *Int J Integr Care*, 9: e06, 2009.

[Schug et al. (2008)] Stephan H. Schug, Chris Flim, and Jelle Attema. Sustainable Telemedicine: paradigms for future-proof healthcare - A briefing Paper. Technical report, European Health Telematics Association (EHTEL), February 2008.

[Shekelle et al. (2006)] P.G. Shekelle, S.C. Morton, and E.B. Keeler. Costs and benefits of health information technology. Technical Report Evidence Report/Technology Assessment No. 132, Agency for Healthcare Research and Quality (AHRQ), Rockville, MD, April 2006. URL http://www.mrw.interscience.wiley.com/-cochrane/clhta/articles/HTA-20060285/frame.html.

[Shojania and Grimshaw (2005)] Kaveh G Shojania and Jeremy M Grimshaw. Evidence-based quality improvement: the state of the science. *Health Aff (Millwood)*, 24 (1): 138–150, 2005. doi: 10.1377/hlthaff.24.1.138. URL http://dx.doi.org/10.1377/hlthaff.24.1.138.

[Shojania et al. (2004)] Kaveh G. Shojania, Kathryn M. McDonald, Robert M. Wachter, and Douglas K. Owens. Closing The Quality Gap: A Critical Analysis of Quality Improvement Strategies, Volume 1—Series Overview and Methodology. Technical Report Technical Review 9 (Contract No. 290-02-0017 to the Stanford University–UCSF Evidence-based Practice Center). AHRQ Publication No. 04-0051-1., Agency for Healthcare Research and Quality, Rockville, MD, August 2004.

[Shojania et al. (2006)] Kaveh G Shojania, Sumant R Ranji, Kathryn M McDonald, Jeremy M Grimshaw, Vandana Sundaram, Robert J Rushakoff, and Douglas K Owens. Effects of quality improvement strategies for type 2 diabetes on glycemic control: a meta-regression analysis. *JAMA*, 296 (4): 427–440, Jul 2006. doi: 10.1001/jama.296.4.427. URL http://dx.doi.org/10.1001/jama.296.4.427.

[Shojania et al. (2009)] Kaveh G Shojania, Alison Jennings, Alain Mayhew, Craig R Ramsay, Martin P Eccles, and Jeremy Grimshaw. The effects of on-screen, point of care computer reminders on processes and outcomes of care. *Cochrane Database Syst Rev*, (3): CD001096, 2009. doi: 10.1002/14651858.CD001096.pub2. URL http://dx.doi.org/10.1002/14651858.CD001096.pub2.

[Sidorov et al. (2002)] Jaan Sidorov, Robert Shull, Janet Tomcavage, Sabrina Girolami, Nadine Lawton, and Ronald Harris. Does diabetes disease management save money and improve outcomes? A report of simultaneous short-term savings and quality improvement associated with a health maintenance organization-sponsored disease management program among patients fulfilling health employer data and information set criteria. *Diabetes Care*, 25 (4): 684–689, Apr 2002.

[Sipkoff (2003)] Martin Sipkoff. Health plans begin to address chronic care management. *Manag Care*, 12 (12): 24–5, 29–31, Dec 2003.

[Skevofilakas et al. (2010)] Marios Skevofilakas, Konstantia Zarkogianni, Basil G Karamanos, and Konstantina S Nikita. A hybrid Decision Support System for the risk assessment of retinopathy development as a long term complication of Type 1 Diabetes Mellitus. *Conf Proc IEEE Eng Med Biol Soc*, 2010: 6713–6716, 2010. doi: 10.1109/IEMBS.2010.5626245. URL http://dx.doi.org/10.1109/IEMBS.2010.5626245.

[Smith et al. (2007)] Sm Smith, S. Allwright, and T. O'dowd. Effectiveness of shared care across the interface between primary and specialty care in chronic disease management. *Cochrane Database Syst Rev*, - (3): CD004910, 2007. doi: 10.1002/14651858.CD004910.pub2. URL http://dx.doi.org/10.1002/-14651858.CD004910.pub2.

[Österreichische Diabetesgesellschaft (2007)] Österreichische Diabetesgesellschaft. Diabetes mellitus – Leitlinien für die Praxis, überarbeitete und erweiterte Fassung 2007. *Wien Klin Wochenschr*, 119 (15-16 Suppl 2): 5–64, 2007. doi: 10.1007/s00508-007-0832-1.

[Stevens et al. (2001)] R. J. Stevens, V. Kothari, A. I. Adler, I. M. Stratton, and United Kingdom Prospective Diabetes Study (UKPDS) Group. The UKPDS risk engine: a model for the risk of coronary heart disease in Type II diabetes (UKPDS 56). *Clin Sci (Lond)*, 101 (6): 671–679, Dec 2001.

[Stevens et al. (2004)] Richard J Stevens, Ruth L Coleman, Amanda I Adler, Irene M Stratton, David R Matthews, and Rury R Holman. Risk factors for myocardial infarction case fatality and stroke case fatality in type 2 diabetes: UKPDS 66. *Diabetes Care*, 27 (1): 201–207, Jan 2004.

[Ståhl and Johansson (2009)] F. Ståhl and R. Johansson. Diabetes mellitus modeling and short-term prediction based on blood glucose measurements. *Math Biosci*, 217 (2): 101–117, Feb 2009. doi: 10.1016/j.mbs.2008.10.008. URL http://dx.doi.org/10.1016/j.mbs.2008.10.008.

[Stoltz (2008)] Craig Stoltz. Microsoft Health vs.Google Health, March 11 2008. URL http://-www.washingtonpost.com/wp-dyn/content/article/2008/03/10/AR2008031001532.html. (last checked 24.11.2009).

[Sutcliffe et al. (2011)] Paul Sutcliffe, Steven Martin, Jackie Sturt, John Powell, Frances Griffiths, Ann Adams, and Jeremy Dale. Systematic review of communication technologies to promote access and engagement of young people with diabetes into healthcare. *BMC Endocr Disord*, 11: 1, 2011. doi: 10.1186/1472-6823-11-1. URL http://dx.doi.org/10.1186/1472-6823-11-1.

[Tang et al. (2006)] Paul C Tang, Joan S Ash, David W Bates, J. Marc Overhage, and Daniel Z Sands. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. *J Am Med Inform Assoc*, 13 (2): 121–126, 2006. doi: 10.1197/jamia.M2025. URL http://dx.doi.org/10.1197/jamia.M2025.

[Tsai et al. (2005)] Alexander C Tsai, Sally C Morton, Carol M Mangione, and Emmett B Keeler. A meta-analysis of interventions to improve care for chronic illnesses. *Am J Manag Care*, 11 (8): 478–488, Aug 2005.

[UKPDS Group (1991)] UKPDS Group. UK Prospective Diabetes Study (UKPDS). VIII. Study design, progress and performance. *Diabetologia*, 34 (12): 877–890, Dec 1991.

[USA (2009)] USA. American Recovery and Reinvestment Act of 2009, February 2009. URL http://-en.wikipedia.org/wiki/American_Recovery_and_Reinvestment_Act_of_2009#Healthcare. (last checked 30.11.2009).

[Vergouwe et al. (2010)] Y. Vergouwe, S. S. Soedamah-Muthu, J. Zgibor, N. Chaturvedi, C. Forsblom, J. K. Snell-Bergeon, D. M. Maahs, P-H. Groop, M. Rewers, T. J. Orchard, J. H. Fuller, and K. G M Moons. Progression to microalbuminuria in type 1 diabetes: development and validation of a prediction rule. *Diabetologia*, 53 (2): 254–262, Feb 2010. doi: 10.1007/s00125-009-1585-3. URL http://dx.doi.org/10.1007/-s00125-009-1585-3.

[Verhoeven et al. (2007)] Fenne Verhoeven, Lisette van Gemert-Pijnen, Karin Dijkstra, Nicol Nijland, Erwin Seydel, and Michaël Steehouder. The contribution of teleconsultation and videoconferencing to diabetes care: a systematic literature review. *J Med Internet Res*, 9 (5): e37, 2007. doi: 10.2196/jmir.9.5.e37. URL http://-dx.doi.org/10.2196/jmir.9.5.e37.

[Wagner (1998)] E. H. Wagner. Chronic disease management: what will it take to improve care for chronic illness? *Eff Clin Pract*, 1 (1): 2–4, 1998.

[Wagner et al. (1996)] E. H. Wagner, B. T. Austin, and M. Von Korff. Organizing care for patients with chronic illness. *Milbank Q*, 74 (4): 511–544, 1996.

[Wagner and Groves (2002)] Edward H Wagner and Trish Groves. Care for chronic diseases. *BMJ*, 325 (7370): 913–914, Oct 2002.

[Walsh et al. (2006)] Judith M E Walsh, Kathryn M McDonald, Kaveh G Shojania, Vandana Sundaram, Smita Nayak, Robyn Lewis, Douglas K Owens, and Mary Kane Goldstein. Quality improvement strategies for hypertension management: a systematic review. *Med Care*, 44 (7): 646–657, Jul 2006. doi: 10.1097/01.mlr.0000220260.30768.32. URL http://dx.doi.org/10.1097/01.mlr.0000220260.30768.32.

[Warda (2005)] Frank Warda. *Elektronische Gesundheitsakten, Möglichkeiten für Patienten, Ärzte und Industrie, Aktueller Stand der Entwicklung in Deutschland*. Rheinware, August 2005. ISBN 3-938975-00-8.

[Warsi et al. (2004)] Asra Warsi, Philip S Wang, Michael P LaValley, Jerry Avorn, and Daniel H Solomon. Self-management education programs in chronic disease: a systematic review and methodological critique of the literature. *Arch Intern Med*, 164 (15): 1641–1649, 2004. doi: 10.1001/archinte.164.15.1641. URL http://-dx.doi.org/10.1001/archinte.164.15.1641.

[Weingarten et al. (2002)] Scott R Weingarten, James M Henning, Enkhe Badamgarav, Kevin Knight, Vic Hasselblad, Anacleto Gano, and Joshua J Ofman. Interventions used in disease management programmes for patients with chronic illness-which ones work? Meta-analysis of published reports. *BMJ*, 325 (7370): 925, Oct 2002.

[Weissman et al. (1999)] N. W. Weissman, J. J. Allison, C. I. Kiefe, R. M. Farmer, M. T. Weaver, O. D. Williams, I. G. Child, J. H. Pemberton, K. C. Brown, and C. S. Baker. Achievable benchmarks of care: the ABCs of benchmarking. *J Eval Clin Pract*, 5 (3): 269–281, Aug 1999.

[Wells et al. (2008)] Brian J Wells, Anil Jain, Susana Arrigain, Changhong Yu, Wayne A Rosenkrans, and Michael W Kattan. Predicting 6-year mortality risk in patients with type 2 diabetes. *Diabetes Care*, 31 (12): 2301–2306, Dec 2008. doi: 10.2337/dc08-1047. URL http://dx.doi.org/10.2337/dc08-1047.

[Whitten et al. (2000)] P. Whitten, C. Kingsley, and J. Grigsby. Results of a meta-analysis of cost-benefit research: is this a question worth asking? *J Telemed Telecare*, 6 Suppl 1: S4–S6, 2000.

[Whitten et al. (2002)] Pamela S Whitten, Frances S Mair, Alan Haycox, Carl R May, Tracy L Williams, and Seth Hellmich. Systematic review of cost effectiveness studies of telemedicine interventions. *BMJ*, 324 (7351): 1434–1437, Jun 2002.

[Winkelman et al. (2005)] Warren J Winkelman, Kevin J Leonard, and Peter G Rossos. Patient-perceived usefulness of online electronic medical records: employing grounded theory in the development of information and communication technologies for use by patients living with chronic illness. *J Am Med Inform Assoc*, 12 (3): 306–314, 2005. doi: 10.1197/jamia.M1712. URL http://dx.doi.org/10.1197/jamia.M1712.

8 Annex: Questionnaire

REACTION
Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks

Disease Management Strategy Questionnaire

Dear Reaction-Partners,

We are writing to you today to kindly request your assistance in Workpackage 6 (Assessment of existing disease management strategies and available risk assessment tools).

In order to carry out this deliverable, we would like to find out whether, in the countries of our project partners, there are any (a) disease management strategies, targets or recommendations concerning care for patients with diabetes and/or (b) IT or e-Health measures in place to support the content, delivery or monitoring of health care for patients with diabetes. We are interested in all strategies and measures whether at the local, regional or national level and at all care levels (primary and secondary/acute care).

Disease management strategies

Our definition of disease management strategies is broad. We include here any *strategies, guidance* or *recommendations/targets* in place for the content, delivery/organisation and monitoring of health care services for patients with diabetes in both acute (secondary care) and non-acute (primary care) settings. In particular we would like to consider:

(i) strategies in the form of care pathways that include recommendations for diagnosis and management, such as the UK Map of Medicine
(ii) national targets such as the UK National Service Framework with recommendations for service content and delivery. (Standards, Delivery Strategy) or the Austrian Diabetes Plan (Link)

Please send us any relevant information for your country by way of documents or web links.

IT measures/e-health support

Our second request relates to information concerning IT measures or e-health support in place for the diagnosis, treatment and monitoring of diabetes (for instance the generation of electronic patient reminders).

On the basis of a review of published literature on IT measures/e-health support for health care, we have devised the attached questionnaire that lists potential measures. We would kindly ask you to indicate on this questionnaire whether any of these measures are in place in your country. Please also let us know whether any additional IT measures are in place, which do not appear on this list, by using the space provided at the end of the questionnaire.

If you do not personally have access to information on strategies/targets or IT measures, please pass this request on to the relevant expert for your country. Please do not forget to send us the contact details of any experts you pass this request on to, so that we can follow-up the request.

Thank you in advance for your assistance. We look forward to hearing from you.
Please send your response by December 20th, 2010 to louise.schmidt@joanneum.at.

If you have any questions, please do not hesitate to contact us.

Best wishes

The Team from Joanneum Research

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REACTION
Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks

Disease Management Strategy Questionnaire

Country: _____ **Provided by (name, institution, external expert):** _____

Disease management service framework elements	Status in your country *) please provide Info and Links	Potential IT support for disease management	Status in your country *) please provide Info and Links
Agreed Care Plan with personal goal setting			
		Make individual care plan electronically available to patients and professionals	
Systematic patient care			
Named contact for patients		Patient and physician panels: Electronic administration of eligible health care providers and assignment of patients	
Pro-active individual patient care (based on overviews of patient care)		Electronic patient registries	
Regular review of patients, patient reminders		Call and re-call systems for professionals → regular review	
Structured patient education / self management education, empowerment		Interactive health communication applications	
Case Management		Alert systems e.g. home blood glucose monitoring sent electronically	
		Information about available health services, electronic booking	
Ensuring progress			
Continuous quality improvement: quality indicators for clinical audit		Analyse information from records to ensure and monitor quality of care and improvement.	
Performance indicators: Comparative benchmarking on regional level		Electronic collection, analysis and comparison of performance indicators	
Comprehensive data pool (e.g. to support public health and planning etc.)		Provide data management and analysis. Application of predictive modelling and analytic tools.	
Diabetes information			
Access to evidence based information for patients and professionals throgh a range of media		Digital Libraries, Static websites	
Patient access to their own records, Facilitated relay of clinical information from patients to professionals (e.g. patient carries own record)		Electronic Personal Health Record / Diabetes Record (access for patients to their records)	
Access to clinical data for professionals (in their own settings)		Electronic Patient Record (used by healthcare professionals in one institution)	
Access to clinical data by other institutions and settings for professionals		Electronic Integrated Care Records and Registers (common standards, nationally agreed datasets)	

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REACTION
Remote Accessibility to Diabetes Management and Therapy in Operational healthcare Networks

Disease Management Strategy Questionnaire

Disease management service framework elements	Status in your country *) please provide Info and Links	Potential IT support for disease management	Status in your country *) please provide Info and Links
• Agreed information sharing protocols (e.g. access for dieticians or podiatrists have access to care plan) • Common dataset (common "language" for diabetes through a wider dataset)		(registers for primary care as well as registers for long term complications)	
		Electronic patient registries (possible at different levels: surgery, regional, national)	
National infrastructure for accurate and timely flow of information (shared across institutional boundaries and health care settings, including social services where appropriate)		National Electronic Health Record Infrastructure	
		Security and confidentiality frameworks	
Clinical and practice decision support and audit			
Availability of appraisals, guidelines and care pathways		Digital Libraries, Static websites	
Application of care pathways at individual patient level, decision support		Electronic care record systems in primary care: Interactive software supporting application of care pathways and guidelines by context specific interfaces, prompts and alerts Clinical decision support systems	
Clinical audit		Data analysis for audit and feedback (comparative risk adjusted clinical audit data for national and local use)	
Utilization of new technologies			
		Telemonitoring, Home Care	
		Telemedicine patient encounters ("virtual visits")	
Prevention strategies			
		Patient Newsletters, Websites	
		Patient Recall for routine checks	
Health workforce / Health care system			
Dedicated and pro-active care teams with clear description of individual roles and responsibilities		All team members have electronic access to relevant data	
Clinician education		E-Learning	
Plans for, or recent changes to, care delivery systems, not just related to diabetes			

Please add here information related to other IT measures in place in your country: _____

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