

# **Analysis Of The Successfully Implemented Quality Improvement Projects Concerning Cardiovascular Diseases In Family Medicine/General Practice In Europe**

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## Table of contents

I. Introduction.....	3
1. Definition and principles of Quality Improvement project.....	3
2. Epidemiology and burden of cardiovascular diseases in Europe.....	6
3. Role of primary health care in management of cardiovascular disease.....	8
4. Aims of the report.....	10
II. Methods.....	10
III. Results.....	11
1. Quality Improvement project in health promotion.....	11
A. <i>Three level strategy, Germany</i> .....	11
2. Quality Improvement project in cardiovascular disease prevention.....	13
A. <i>Heart Beat Limburg (Hartslag Limburg), Netherlands</i> .....	13
B. <i>Diabetes Support Service, Netherlands</i> .....	18
C. <i>Ketola 2000, Finland</i> .....	23
3. Quality Improvement project in cardiovascular disease diagnosis.....	25
A. <i>Verstappen 2003, Netherlands</i> .....	25
4. Quality Improvement project in cardiovascular disease treatment.....	28
A. <i>Dale 2008/2010, United Kingdom</i> .....	28
B. <i>BISOAT 2005/2006, Belgium</i> .....	31
C. <i>Wettermark 2009, Sweden</i> .....	34
5. Quality Improvement project in cardiovascular rehabilitation.....	38
6. Comprehensive Quality Improvement projects (combining different areas of FP/GPs care).....	38
A. <i>National Service Framework (NSF) for Coronary Heart Disease (CHD) and Quality and Outcomes Framework (QOF), United Kingdom</i> .....	38
B. <i>Disease management programmes in primary care, Germany (ELSID STUDY)</i> .....	52
7. A list of factors necessary for successful Quality Improvement project.....	57
IV. Conclusions.....	60
V. Summary.....	61
<i>Abbreviations</i> .....	63
VI. References.....	65
VII. Appendixes.....	71
Appendix 1. References and brief information on evaluations of other programs found on the search or in EPA report.....	71
Appendix 2. Pubmed Search.....	79

## **I. Introduction**

### **1. Definition and principles of Quality Improvement project**

In the last few decades it has been shown that despite professional training of health care professionals many patients still do not receive care they should or need or they receive unnecessary or harmful care. (Bodenheimer 1999)

The Council of Europe recommended that the governments of the member states created, where appropriate, policies and structures that support the development and implementation of "quality improvement systems". According to the definition provided by the Council of Europe quality improvement (QI) system is a set of integrated and planned activities and measures at various levels in the health care organization, aimed at continuously assuring and improving the quality of patient care. (Council of Europe 1997)

Recommendation No. R (97) 17 adopted by the Committee of Ministers of the Council of Europe described in details the development and implementation of QI systems in health care. The QI can be described as a continuous cyclic process integrated in daily work. Main activities involved in such process are:

- identification and selection of areas in need of improvement (needs assessment and problem analysis using a variety of sources)
- selecting or setting guidelines, best practices or targets for good quality patient care (consensus development, evidence-based setting of guidelines, local arrangements on care provision, identifying good practices, benchmarking, etc)
- data collection and assessment of actual quality of care (internally or externally)
- developing and carrying out a change plan related to the gaps in performance found and linked to the identified obstacles to change (by quality improvement strategies or programmes or by solving problems, evaluation of progress)
- continuous monitoring of performance. (the Council of Europe 1997)

The process should involve different aspects of patient outcomes (health status, quality of life, satisfaction, costs), process of care (patients education, clinical performance), structure of care (organization of services, access, safety procedure, equipment). (Grol 2004)

QI systems should be set up at all levels of healthcare (individual healthcare provider, health practice, hospital, other healthcare institutions, public and private) and should involve all people associated with health care (providers, patients, funders managers, authorities). (Council of Europe 1997)

The basic principles of QI include: focus on the customer, strong leadership, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision-making, and mutually beneficial supplier relationships. (Schneider 2006)

According to the abovementioned the Council of Europe's recommendation QI systems are based on the following principles:

- recognition of the different levels of development of quality policies in member States
- a preventive approach to quality
- patients' needs, opinions and experience of all aspects of their care should be regularly used as feedback
- QI should become an integral part of the daily work of all health care professionals
- systematic QI is a professional responsibility of the healthcare providers, so particular attention should be devoted to making available to them all the necessary tools for evaluation of their activities
- systematic QI must not be used in a punitive manner
- the approach to QI activities must be multiprofessional with collaboration between the various health-care professions, and between the health and social sectors
- managers at all levels are responsible for the establishment of organisational structures to ensure the incorporation of QI into daily routines and to foster the staff's commitment to and involvement in the process

- QI is based on formulation of goals, which are result of a dialogue between health care providers, patients and decision-makers
- choice of these goals should be in line with national health priorities
  
- systematic QI is a positive approach, which aims to identify the best results and use them to improve practice, however when poor outcomes are identified action should be taken to eliminate them or improve them
- activities should be based on the collection of data and information and on scientific principles and methods. (the Council of Europe 1997)

General principles of QI systems described in abovementioned recommendation include:

- systematic development of practice guidelines which are effectively disseminated and their effects are monitored
- using the results of technology assessment in decision making and health care quality improvement by applying methods of evidence based medicine
- setting up health care information systems with relevant quality indicators
- gathering information on patient's perspective (needs, priorities, experiences)
- effective mechanisms and strategies for achieving necessary changes in a planned and managed way and involving all the actors in care processes and decision making, in particular, patients. (Council of Europe 1997)

## **2. Epidemiology and burden of cardiovascular diseases in Europe**

### Cardiovascular disease (CVD) mortality

CVD is the main cause of death in most European countries, for age standardized ratios – see table. On average CVD accounts for almost half of deaths, from about 35% in some western countries to about 60% in some eastern countries. (Scholte 2006)

In all European countries cardiovascular (CV) mortality rates are lower for women than for men, however rates in Eastern Europe are higher than in Western Europe, for example in Ukraine and Republic of Moldova (8.1 per 1000 inhabitants) compared with France (1.6 per 1000), Israel (1.7 per 1000), Spain (1.9 per 1000). In the years 1980 to 2004 age standardized mortality rates were showing downward trends in Nordic, Western and Southern Europe

(except Greece), and were stable or showing upward trends in Central and Eastern European countries. (Scholte 2006)

Table 1. CV mortality rates changes between 1980 and 2004 (based on information provided in Scholte 2006).

<b>CV mortality rates and hospital discharge</b>				
Age standardized ratio per 1000 inhabitants	European Region	European Union	EU-15	Former Soviet USSR countries
CVD mortality	5.1 men; 3.4 women	3.2 men; 2.1 women		
change 1980 to 2004	From 5.5 to 4.3	From 4.4 to 2.6	From 4.3 to 2.3	From 6.7 to 8.0
CVD hospital	26.3		22.8	27.8

discharge				
Change in CVD hospital discharge	1990 to 2004 From 20.8 to 26.3		1991-1999 from 20.0 to 23.4 to 22.8 in 2004	
IHD hospital discharge	8.7		6.5	11.1
Cerebrovascular disease hospital discharge	4.9		3.8	5.8

#### CV risk factors

Smoking prevalence varies from 15% (Republic of Moldova), 16% (Sweden) to 37% (Greece, Bosnia and Herzegovina) and 39% (Albania), usually there is higher prevalence among men. Between 2000 and 2004 smoking prevalence declined in European Region from 30.2% to 29.4%. (Scholte 2006)

Obesity (BMI  $\geq 30$ ) prevalence is higher in women than in men in most countries. It is estimated that about half of adult population in the European Region is overweight (BMI  $\geq 25$ ) with average BMI 26.5 kg/m<sup>2</sup> (400 million people) and about third of the adult population is obese (130 million people). (Scholte 2006)

#### Diabetes Mellitus

It is estimated that 48 million people in the European Region suffer from DM and the prevalence is from 2% (Iceland), 3.4% (Ireland) and 3.7% (Netherlands) to 9.9% (Spain), 10.0% (Bulgaria) and 10.2% (Germany). (Scholte 2006)

## Hypertension

According to WHO MONICA study prevalence of BP  $\geq 160$  mm Hg in population 35–64 years old was below 4% in France, Spain and Belgium, while prevalence above 15% was observed in Germany and Finland. (Scholte 2006)

## Hospital discharge for CVD

About 40% of all hospital discharge in the European Region is due to CVD. Rates for hospital discharge due to CVD, ischemic heart disease and cerebrovascular disease – see table 1.

The average number of hospital discharges for IHD increased by 29% and for cerebrovascular disease – by 41% (1990-2004). (Scholte 2006)

### **3. Role of primary health care in management of cardiovascular disease**

According to the European definition of general practice/family medicine prepared by WONCA Europe in 2005 it is an academic and scientific discipline, with its own educational content, research, evidence base and clinical activity, and a clinical specialty orientated to primary care. (Allen 2005).

According to that document the characteristics of that discipline are as follows:

- normally the point of first medical contact within the health care system (open and unlimited access; all health problems regardless of the age, sex, or any other characteristic)
- efficient use of health care resources through co-ordinating care, working with other professionals in the primary care setting, and by managing the interface with other specialities
- a person-centred approach

- a unique consultation process (a relationship over time through effective communication between doctor and patient)
- responsible for the provision of longitudinal continuity of care
- a specific decision making process determined by the prevalence and incidence of illness in the community
- manages simultaneously both acute and chronic health problems of individual patients
- manages illness which presents in an undifferentiated way at an early stage in its development, which may require urgent intervention
- promotes health and well being both by appropriate and effective intervention
- has a specific responsibility for the health of the community
- deals with health problems in their physical, psychological, social, cultural and existential dimensions. (Allen 2005)

According to European guidelines on cardiovascular disease prevention in clinical practice cardiovascular risk management includes the clinical management of established CVD, prevention of CVD in patients at high risk for developing CVD, and improvement of health-related lifestyles in the population. (Fourth Joint Task Force 2007)

WONCA in their policy statement on prevention and health promotion in primary care stated that health promotion and disease prevention should represent an essential part of primary care. (WONCA 2010)

Primary care is involved in the detection, treatment and monitoring of patients with increased risk of CVD. Primary care is more than general practice/family medicine, and may include community pharmacists, practice nurses, specialized nurses, physiotherapists, dieticians, and others. Teachers, sports clubs, municipality officials and others (who are not healthcare providers) could also contribute to enhancing a healthy life style.

The GP often has an initiating, leading and co-ordinating role in CV risk management. (van Lieshout 2008)

Van Lieshout et al. described in their EPA-Cardio report that in some European countries the primary care physician has a role in preventive health education for the total population, while in other countries health education is the primary responsibility of others. In most countries the primary care physician is involved in the detection and management of patients at increased risk, particularly patients with cardiovascular conditions (e.g. hypertension, peripheral vascular diseases, etc.). In a typical general practice, a substantial proportion of the patients belongs to this category. Finally, in most countries primary care has a role in the rehabilitation and prevention of further events of patients who have had a cardiovascular event (e.g. myocardial infarction, stroke, etc.). (van Lieshout 2008) .

#### **4. Aims of the report**

General aims of this report are:

1. To gather and summarize information about QI projects
2. To identify factors necessary for successful project.

This report was created as a part of Leonardo da Vinci project “[Innovative lifelong learning of European General Physicians in Quality Improvement supported by information technology \(inGPInQI Project\)](#). It will be supportive in development of other project activities and products.

## **II. Methods**

Medical databases such as MEDLINE via PubMed and EMBASE were searched with the use of search strategies described in the Appendix. One of PubMed searches yielded 100 hits, the other 98 hits and the third one – 65 hits. EMBASE search yielded 289 hits. The searched were limited to English language publications. In addition websites of several journals were checked for relevant articles, such as: BMC Health services research, BMC Family practice,

Journal of evaluation of clinical practice, Quality and Safety in Health care, Family practice. In addition google search engine was used to search the internet.

For the description in results section the articles were selected if they described any type of QI programmes concerning CVD (hypertension, dyslipidemia, heart failure, coronary heart disease, DM) in Family Medicine/General Practice (FM/GPs) in Europe which were evaluated and were successful. If there were more than three programmes the most recent ones were selected, details of other programmes not described in details were provided in the Appendix.

Since in google search report of EPA Cardio European Project was identified describing QI programmes in CVD prevention in primary care, the programmes described there were also considered for the description and the search for most recent data on those programmes was carried out.

### **III. Results**

#### **1. Quality Improvement project in health promotion**

##### ***A. Three level strategy, Germany***

###### **General information**

Three level strategy was a community-based programme lead by GPs of the region. The project was funded by community (town administration, companies, participants of the courses) and organizations involved included sports clubs, teachers, companies, schools, town administration, GPs and local health services. (van Lieshout 2008) Three level strategy had been preceded by The German Cardiovascular Prevention study conducted 1989-1991. (Scheuermann 2000).

## **Time and size**

The project started in 1991 and is ongoing, without specified end date. The programme was implemented in the CINDI demonstration area and involved a community in the middle south of Germany (Östringen) with about 12 900 inhabitants. Since 1991 the programme has regularly performed health survey in general practices and 22 patient education groups. The pragmatic evaluation (cross-sectional study) was carried out 1992-1999 and included a 10% random sample of the population (1196 individuals). (Wiesemann 2004)

## **Aims**

The programme aimed to improve the CV risk, improve life style in the public and in the patients, improve the quality of care and the clinical performance and increase the accessibility and volume of health care. In primary prevention the project aimed to reduce hypertension, hypercholesterolemia, smoking and overweight. (van Lieshout 2008, Wiesemann 2004).

## **Interventions**

Three level strategy included (Wiesemann 2004):

1<sup>st</sup> level – activities by GP during consultation hours as usual (lifestyle counseling and “prescription” of lifestyle changing measures: e.g. educational courses) – patients failing to meet agreed goals were referred to

2<sup>nd</sup> level – activities by GP with patients groups in the practice;

3<sup>rd</sup> level – activities by GP at community level (to maintain success and prevent relapse).

Activities targeted at health professionals consisted of education on intercommunication between the coordinative practice and other GPs.

On an organisational level there was the foundation of a local working group consisting of various citizens who were interested in health care: e.g. teacher, dieticians, and physicians.

The town administration provided rooms for sports activities etc, schools, and companies. (van Lieshout 2008)

## Results

Between 1992 and 1999 (Wiesemann 2004):

- the prevalence of hypertension ( $\geq 160/95$  mm Hg) decreased from 28.4% to 9.4% ( $p < 0.001$ ),
- the prevalence of smoking decreased from 20.8% to 17.5% ( $p < 0.05$ ),
- the prevalence of obesity (BMI  $> 30$ ) did not change significantly (from 17.4% to 17.5%)
- the prevalence of cholesterol  $> 250$  mg/dl did not change significantly (from 22% on both occasions).

Health promoting activities were practiced by 67.6% of practice patients and 100% of course participants.

Barriers to health promoting activities reported by participants included: lack of time or weariness, shift work or obligations of having care for others, type of work, concomitant diseases, distance, children, occupational stress. (Wiesemann 2004)

**Limitations as described by the authors:** gender bias (more women), bias because of practice based population sample.

## **2. Quality Improvement project in cardiovascular disease prevention**

### ***A. Heart Beat Limburg (Hartslag Limburg), Netherlands***

#### **General information**

The main partners in the Heart Beat Limburg community project were the city councils of Maastricht and 4 adjacent municipalities, the Regional Public Health Institute Maastricht (RPHI), two community social work organizations, and the regional community healthcare organization, GPs (30 out of a total of about 85 working in the participating municipalities),

The Netherlands Heart Foundation (De Nederlandse Hartstichting) and The National Institute for Public Health and Environment (RIVM). (Ronda 2004)

The community-based CVD prevention program was integrated with a high-risk group approach in general practices and the local hospital cardiology department. All regional stakeholders and the National Heart Foundation (Nederlandse Hartstichting) funded the project. Also research grants were received. (van Lieshout 2008) The project was a new initiative. In January 2001, WHO selected Hartslag Limburg as one of the 12 demonstration projects based on the potential to adhere to the criteria of "Towards Unity for Health". (Ronda 2004)

The effects of community intervention were assessed in cohort study comparing intervention and reference area. (Schuit 2006)

The effect of "high risk" module was assessed in RCT with one pre-test questionnaire and two post-test questionnaires (after 4 and 18 months). Twenty five participating general practice units (each expected to include 46 patients) were randomized (after stratification for high vs low socioeconomic class of the neighborhood and high vs low GPs' preventive orientation) into 12 intervention and 13 control units (usual care). (Harting 2006)

### **Time and size**

The project was initiated in 1998 and ended in 2005 because there was no more funding. It was a large regional project (180.000 inhabitants). (van Lieshout 2008)

In the "high risk" module trial participants had to have a greater than 20% risk of incurring a CV event within 10 years according to Framingham risk-score. GPs asked high-risk patients to participate in the study either personally during consultation or by sending them an invitation letter. About half of invited patients participated (n = 1355). (Harting 2006)

## **Aims**

The aims of the project were to improve CV risk, to improve life style in the patients and in the public and to improve the quality of care and the clinical performance. (van Lieshout 2008)

## **Intervention**

From 1999 until 2003, a total number of 790 interventions (preferably evidence-based) were implemented, of which 590 were major interventions (193 diet, 361 physical activity, and 9 antismoking). Almost 50% of the interventions took place in low-income areas. Examples of activities include: computer-tailored nutrition education, nutrition education tours in supermarkets, public-private collaboration with the retail sector, television programs, food labeling, smoke-free areas, creating walking and bicycling clubs, walking and cycling campaigns, and a stop-smoking campaign, in addition to commercials on local television and radio, newspaper articles, and pamphlet distribution. (Schuit 2006)

### **'High risk project'**

A complete computerized registration of risk factors, optimization of medical treatment (according to the national practice guidelines) and health counseling on high fat consumption, smoking, physical inactivity and adherence to medical treatment (introduced as a new service in the Dutch healthcare system). Two health advisors were involved – one a specialized practice assistant and one dietician – and both were trained in behavior change and counseling

techniques. They provided personalized information as well as leaflets and booklets and if requested telephonic booster and they consulted with the GPs about their patients and included written feedback information in the patient record. Trial packages of nicotine replacement therapy and bupropion were available for smoking cessation. Patients were referred to health promotion activities in their neighborhood. (Harting 2006).

## Results

For the whole community project during the 5-year follow-up, risk factors changed unfavourably in the reference group, while there were no changes or they were less pronounced in the intervention group. Significant effect was observed on (Schuit 2006):

- BMI (adjusted difference in mean change -0.36 kg/m<sup>2</sup> in men and -0.25 kg/m<sup>2</sup> in women),
- waist circumference (-2.9 cm in men and -2.1 cm in women),
- systolic BP (-7.8 mmHg in men and -5.5 mmHg in women),
- total cholesterol (0.11 mmol/L in women)
- serum glucose (-0.23 mmol/L in women).

In the study evaluating the effect of “high risk” module (Harting 2006):

- on average the patients attended 2.31 counseling sessions (range 1–9; SD 1.38) lasting a total of 83 min (range 20– 220; SD 39.90) over a period of 53 days (range 1–322; SD 59.1)
- nutrition was at least once the primary topic of the counseling for 59% of the patients, smoking for 15% and physical activity for 23%; for 6% of the patients none of these target behaviors was the primary topic
- a telephonic booster session (an average of 10 min), was applied to 13% of the patients, and 9% of the patients were referred to local health promoting activities
- patients in the intervention group regarded the health counseling service as being of fairly high quality (8.2 on a ten-point scale), were rather satisfied with the new service and thought it a welcome addition to usual care (both 4.1 on five-point scales)
  
- the experts regarded the quality of the counseling as not entirely satisfactory (2.85 on a 4-point scale)

In intention-to-treat analyses (Harting 2006):

- a decrease in saturated fat intake of 1.3 points after 4 months (scale ranging from 7 to 30 points,  $p=0.000$ ); and 0.46 points at 18 months (B [unstandardised correlation coefficient] =  $-0.46$ , 95% CI:  $-1.06, -0.08$ ); the decrease was greater among non-smokers (B =  $-0.57$ , 95% CI:  $-1.06, -0.08$ ) and among the younger half of the sample (B =  $-1.04$ , 95% CI:  $-1.63, -0.46$ ).
- no effect for physical activity at 4 months, but in subgroup analysis for three BMI categories, intervention patients who were classified as obese at baseline (N=316) more likely to be sufficiently physically active at 18 months than control patients (OR=1.90, 95% CI: 1.09, 3.30).
- no intervention effects for smoking at 4 and 18 months.

**Limitations as described by the authors:** Shortcomings with regard to the quality and focus of the counseling component, the establishment of a computerized CV risk profile (57% of the risk profiles had been talked through by both a health advisor and a GP; reasons for not talking through the other risk profiles were lack of time [mostly] or lack of interest [sometimes] on the part of the GPs), the optimization of medical treatment and the reinforcing effect; doubts whether the multiple risk factor focus of the counseling service was the most adequate; additional follow up by phone might have been useful; the experimental condition and the content of the intervention were known to all patients before they answered the baseline questionnaire (possible that more honest answers in experimental group and more socially desirable answers in control group); baseline questionnaire may have sensitized patients in the intervention group to the approaching health counseling intervention; self-selection of the general practices and the study population; quasi-experimental study; some difference at baseline characteristics; self-reports

## ***B. Diabetes Support Service, Netherlands***

### **General information**

The Diabetes Support Service (DSS) is an activity run by a diagnostic centre (Diagnostisch Centrum Eindhoven), which is a supportive organisation for the general practice and midwives with a regional function. Income is generated by the diagnostic actions, paid for by patients or their health insurance companies. The centre is part of a holding with a strong GP participation. (van Lieshout 2008)

The effects the intervention were evaluated after 2 phases of implementation, in both cases in controlled, non-RCT study with delayed intervention in the control group (waiting list) (2001-2003). (Meulepas 2007, Meulepas 2008)

Inclusion criteria for GPs in the first phase: signed up in 1999 and at the start of the study (end 2001) had at least 10 diabetic patients registered with the DSS (intervention group) or on the waiting list (control group). (Meulepas 2007)

In the intervention group patients were included at the start of the study when they had been registered with the DSS for a minimum of 1 year and a maximum of 2 years at the start of the study. All patients in the study had had documented DM for more than 4 years at the start of the study.

In the second phase the practices which started the first phase 2 years before the pretest of the second phase and met the criteria for hiring a practice nurse (they were using an electronic patient register and had a workstation for the practice nurse) were included. Patients were included if they were called up by the DSS for a periodical laboratory test at the start of the study (beginning of 2002). (Meulepas 2008)

## **Time and size**

The DSS started in 1999. The service is an ongoing activity. It is a regional programme. In 2005 248 GPs used the facilities offered by the DSS. They had 9984 patients participating in the programme. (van Lieshout 2008)

The evaluation study after first phase was carried out among 78 GPs (n = 51 for the intervention and n = 21 for the control group) in the south of the Netherlands and 613 of their type 2 diabetic patients. Out of 449 patients in the intervention group and 164 in the control group invited to participate 353 and 129 were included in final analysis. The year before signing up with the DSS was taken for the pre-measurements and after 2 years of DSS the post-measurements took place. (Meulepas 2007)

In the second phase evaluation study was carried out among 51 general practices (n=23 for the intervention and n=28 for the control group) and 900 of their patients with DM type 2: 431 in the intervention group and 469 in the control group. (Meulepas 2008) .

## **Aims**

The aim of the programme was better metabolic control in the diabetic patients. Intermediate aims were: improving the quality of care and the clinical performance; cost containment or efficiency improvement; and logistic support in organising the care but leaving the actual provision of care in the hands of the GP. (van Lieshout 2008)

The second phase aimed to introduce patient-oriented interventions by a practice nurse in general practices which already used logistic support to improve the care processes for patients with DM. Pre-test and post-test were performed with an interval of 3 years. (Meulepas 2008)

## **Interventions**

Usual care included national guidelines available with emphasis on non-medication-based management (lifestyle modifications, especially exercise and diet). An oral antidiabetic agent

was only prescribed if insufficient results were obtained with this approach, although the emphasis still remained focused on lifestyle modifications. In the stepwise treatment approach, the dose was first increased, and then another oral agent was added. Insulin was only prescribed for the patient if the therapeutic goal had not been reached with the maximal dose of the oral agents. Patients were treated in primary care unless complications occurred; structured care was not generally offered in a general practice. (Meulepas 2008)

### First phase (Meulepas 2007)

The intervention consisted of logistic support for the GP by a DSS.

Interventions targeted at patients included providing information about the importance of the control system and the investigations done, group education for patient and their family members, arranging referrals to a dietician and help for glucose self control and starting insulin therapy (home care workers), calling patients for laboratory testing and other investigations (foot examination, fundus photography; three-monthly and annual blood test), asking patients to make an appointment in general practice to discuss results. The results of the requested tests were sent directly to the GP. This was the same procedure as for the GPs in the control group who could request regular testing by the laboratory. The actions taken by the GPs after receiving the results were not part of the intervention.

Interventions targeted at general practice included quality control for glucose testing devices and advice about this devices, help in detecting patients with DM and registration of these patients, visit of diabetes consultant for help in diabetes care and treatment advice, feedback on practice level and on patient level.

### Second phase (Meulepas 2008)

The intervention involved adding to logistic support a practice nurse with specific tasks regarding the control system (patient level) and quality surveillance (practice level). At patient level practice nurse gave information and lifestyle advice during the quarterly checkups, traced risk factors and on the basis of risk factors profile she set short-term goals and motivated the patients to make lifestyle adjustments or adjusted medications.

At the practice level, the surveillance of the control system (inclusion and follow-up of patients and supervision of the test ordering for each patient) was of importance.

In the control group, the DSS support was continued.

## Results

### First phase

Logistic support increased the number of patients with four tests a year and the content of the checkups improved. The outcome of the tests was better or less worsened in the intervention group compared to the waiting list group. (van Lieshout 2008)

After intervention (Meulepas 2007):

- more patients attending  $\geq 4$  quarterly controls (with at least testing of fasting blood glucose or HbA1c) in the intervention group while it was the same in control group (78% vs 50%; OR 2.1, 95% CI 1.2–3.7)
- more patients tested at least once a year regarding HbA1c (OR 13.4, 95% CI 1.6–114.6), cholesterol (OR 80.8, 95% CI 9.9–659.1), creatinine (OR 71.7, 95% CI 8.7–589.4), BP (OR 8.8, 95% CI 3.6–21.3), funduscopy (OR 96.5, 95% CI 20.5–215.6), foot exam (OR 7.3, 95% CI 2.0–25.9), BMI (OR 3.4, 95% CI 1.7–6.7), smoking status (OR 104.9, 95% CI 25.6–430.1), but not fasting blood glucose (OR 4.0, 95% CI 0.4–40.3)
- larger increase in the number of tests in the intervention group while it remained the same in the control group (8 vs 4)
- the HbA1c remained the same in the intervention group while there was a significant deterioration in the HbA1c in the control group (significant difference between groups)
- the percentage of patients with HbA1c  $< 7\%$  remained the same in intervention group while it decreased in control group (OR 3.8, 95% CI 2.7–7.0)
- mean fasting blood glucose, systolic BP, mean cholesterol level and mean triglyceride level improved significantly in intervention group as compared with control group
- the differences in change for diastolic BP and mean cholesterol/HDL ratio not significant

- the percentage of patients with systolic BP >150 mm Hg decreased in intervention as compared with increase in control group (OR 0.5, 95% CI 0.3–0.9); no significant difference between the groups for diastolic BP
- the percentage of patients with cholesterol >5 mmol/l decreased in intervention as compared with increase in control group (OR 0.5, 95% CI 0.3–0.8).

### Second phase

After intervention (Meulepas 2008):

- improvement of the HbA1C in the intervention group (from 7.3 to 7.1) and deterioration in the control group (from 7.2 to 7.3; significant difference in change)
- the percentage of patients with an HbA1C >8.5 decreased in intervention group (from 13 to 6%) and was the same in control group (from 16 to 14%)
- improvement in diastolic BP (significant differences in changes)
- improvement in cholesterol/HDL ratio (significant differences in changes)
- improvement in percentage of patients with diastolic BP <85 mm Hg (OR 1.4, 95% CI 1.0–2.1).
- more exercise in the intervention group as compared with the control group
- no significant differences in change: systolic BP (deteriorated in both groups) and percentage of patients with SBP <150 mm Hg, cholesterol level (improved in both groups) and percentage of patients with values <5 mmol/l, BMI (deteriorated in both groups) and percentage of patients with BMI <27 kg/m<sup>2</sup>, percentage of smokers (increase in both groups), the prescribed daily dose for oral medication (increased in both groups), the percentage of patients treated with statins (increased in both groups)
- increase in the percentage of patients treated with insulin (OR 0.5, 95% CI 0.3–0.9).

**Limitations as described by the authors:** not RCT, potential selection bias.

### *C. Ketola 2000, Finland*

#### **General information**

In Finland local authorities are responsible for providing both primary and secondary health care. Primary care is arranged through municipal health centres. The services can be provided by the local authorities or they can be bought from outside. Health centres offer both preventive and curative care. Secondary health care is mainly provided regionally. The study was a quality intervention for primary care personnel. In the studied areas 45% of population use the primary care service annually. 55% of the population does not need to use primary care or use private services (occupational health care). (Ketola 2000).

#### **Time and size**

The study was carried out in 1995–1997 in two suburban municipal health care centres with very similar populations (11 000 and 15 000 inhabitants). These populations were not overlapping and the proportion of subjects of working age was 65%. About 500 patients per health care centre per year were randomly selected. Baseline audit was carried out in May–June 1995. (Ketola 2000)

#### **Aims**

The aim of the study was to evaluate the quality of documentation of known CVD risk factors in patient records in Finnish primary care, to measure the effect of a quality improvement programme on the prevalence of the registration of measured risk factors in patient records, and to measure the effect of the programme on levels of CVD risk factors in the target population. (Ketola 2000)

#### **Intervention**

A quality improvement programme was started after the audit at the intervention station, and the other health station with seven GPs remained as a control. (Ketola 2000)

At the intervention health care centre the programme included training the personnel (five doctors, nurses, office assistants and nurses' aids) to detect high risk patients using structured CVD risk factor form which was to be filled in for every patient over 18 years of age. The intervention consisted of lectures (one on risk factors for CVD, one on the diagnosis and treatment of CVD, and two on diet counseling), participating in quality circle, development of local guidelines for CVD patients (adopted nationally recommended optimal levels and follow up schemes for BP and cholesterol and included lifestyle recommendations for diet, physical exercise, alcohol consumption and information on smoking cessation groups). The intervention health care centre received audit results and control health care centre did not receive any information during the study. (Ketola 2000).

## Results

After the quality improvement period (Ketola 2000):

- all risk factors were better recorded ( $p < 0.001$ );
- recording of family history of CVD increased in intervention group from 5% to 26% vs 6% and 9% in control group
- personal history of DM recording increased from 0.7% to 50% vs from 1.2% to 32%
- smoking habits recording increased from 6% to 39% vs from 12% to 23%
- alcohol consumption habits recording increased from 1% to 20% vs from 5% to 6%
- physical activity recording increased from 0.3% to 21% vs from 0.1% to 2%
- more patients showing high risk levels of risk factors recorded in intervention group than in control group (increased from 17% to 35% vs 22 to 29%;  $p = 0.024$  at the end of study, but no significant difference in trends)
- no change in total number of registered hypertensives (more registrations of normal BP)
- more registered hypercholesterolemic patients in the intervention healthcare centre, but the difference in time trends not significant.
- differences between the intervention and control group in the time trends for body weight (more increase in intervention healthcare centre), BMI (less increased in intervention), total

cholesterol (more decrease in intervention station), and glucose levels (more decreased in intervention station)

– the change in BP not significant in both groups.

– risk factor levels of high risk patients receiving CVD treatment decreased during the intervention.

### **3. Quality Improvement project in cardiovascular disease diagnosis**

#### ***A. Verstappen 2003, Netherlands***

##### **General information**

The effects of the intervention were evaluated in a RCT. The randomization was performed at primary care group level. Such groups involve teams of primary care physicians collaborating in a specific region. They share patient care outside office hours and they also engage in continuing medical education. Regions in the Netherlands have diagnostic centers – an institute, usually associated with a hospital, where primary care physicians can order tests without referring patients to the hospital. The study was supported by the Dutch Health Care Insurance Council. (Verstappen 2003)

##### **Time and size**

The intervention (the study) was conducted in 5 regions of the Netherlands with diagnostic centers and included 26 primary care physician groups (174 physicians) linked to one of those centers recruited from May to September 1998. The trial was conducted in the first 6 months of 1999. The baseline period for the number of tests was the last 6 months of 1998 and follow up period was the last 6 months of 1999. (Verstappen 2003).

##### **Aims**

The aim of the strategy was to achieve sustained improvements in test ordering, for example, working in line with the national, evidence-based guidelines. According to existing national, evidence-based guidelines, a decrease in the total numbers of tests ordered per clinical

problem, and of some defined inappropriate tests (as defined in the guidelines; tests inappropriate for the associated clinical problems for various reasons), is considered a quality improvement. These tests covered about 90% of all tests a primary care physician can order in a diagnostic center. For the tests used in the trial, national guidelines for optimal test ordering had to be available. (Verstappen 2003)

## **Intervention**

During the 6 months of intervention, physicians discussed 3 consecutive, personal feedback reports (received by mail, including a comparison of each physician's own data with those of colleagues) on 3 different clinical problems, in 3 small group QI meetings (about 2 weeks after postal contact; lasting 90 minutes, supervised by the medical coordinator of the diagnostic center), related them to 3 evidence based clinical guidelines developed by the Dutch College of Primary Care Physicians, and made plans for change (at individual and group level). At those meetings physicians also discussed Bayesian decision rules (to understand the probability of false-positive results in low prevalence disorders) and how to deal with the frequent requests by patients to have inappropriate tests performed. Subsequent meetings were used to evaluate whether targets had been met.

The strategy focused on specific clinical problems and the diagnostic tests used for these problems. (Verstappen 2003)

Thirteen groups of primary care physicians underwent the strategy for 3 clinical problems (arm A; CV topics, upper and lower abdominal complaints) and 13 other groups underwent the strategy for 3 other clinical problems (arm B; COPD and asthma, general complaints, degenerative joint complaints). Each arm acted as a control for the other (Verstappen 2003):

### Arm A

- CVD/hypertension; tests: Cholesterol, subfractions, potassium, sodium, creatinine, ECG (exercise); inappropriate: BUN
- upper abdominal complaints; tests: SGPT, gamma-glutamyltransferase, ultrasound scans of hepatobiliary tract; inappropriate: SGOT, LDH, amylase, bilirubin, alkaline phosphatase

– lower abdominal complaints; tests: Prostate-specific antigen, CRP, ultrasound of the kidney, IVP, double-contrast barium enema, sigmoidoscopy

#### Arm B

– COPD/asthma; tests: Allergic screening test, chest radiograph; inappropriate: immunoglobulin E

– general malaise/fatigue/vague complaints; tests: ESR, Hb with or without indices, Ht, TSH, Monospot; inappropriate: leukocyte count

– degenerative joint complaints; tests: ESR, uric acid, rheumatoid factors; inappropriate: radiographs of lumbar spine, cervical spine, shoulder, knee, hip.

## Results

For clinical problems allocated to arm A (Verstappen 2003):

– the mean total number of requested tests per 6 months per physician reduced from baseline by 12% among physicians in the arm A intervention and was unchanged in the arm B control (mean reduction of 67 more tests [95% CI 30–104] per physician per 6 months in arm A than in arm B;  $p=0.01$ )

– in a subgroup of CVD/ hypertension the mean total number of requested tests per 6 months per physician was reduced from baseline by 6% among physicians in the arm A intervention, as compared with increase by 4% in the arm B control (mean reduction of 35 more tests [95% CI 10–61] per physician per 6 months in arm A than in arm B;  $p=0.01$ ).

For clinical problems allocated to arm B (Verstappen 2003):

– the mean total number of requested tests per 6 months per physician was reduced from baseline by 8% among physicians in the arm B intervention and by 3% in the arm A control, (mean reduction of 28 more tests [95% CI –14 to 74] per physician per 6 months in arm B than in arm A;  $P=0.22$ ).

Numbers of inappropriate tests(Verstappen 2003):

- significant reduction in mean total number of inappropriate tests ordered for problems allocated to arm A (mean reduction of 16 more tests [95% CI 7–27] per physician per 6 months in arm A than in arm B;  $p = 0.01$ )
- not significant reduction inappropriate test ordered physicians in arm B for problems allocated to arm B.
- a significant reduction in the numbers of tests ordered, compared with the control group, for 4 of the tests for upper abdominal complaints: amylase, bilirubin, LDH, and alkaline phosphatase.

**Limitations as described by the authors:** Not clear if the sample of GPs representative for all Dutch GP population, it is possible that only motivated, well-functioning groups of physicians participated. The study evaluated only volume of the tests, the duration of the study was too short to determine long-term effects on test ordering.

#### **4. Quality Improvement project in cardiovascular disease treatment**

##### ***A. Dale 2008/2010, United Kingdom***

###### **General information**

The training approach reported in the publication was developed by Warwick Diabetes Care at the University of Warwick. It addresses general treatment issues in DM management and focuses on the initiation of insulin therapy in appropriate patients with DM type 2. (Dale 2008, Dale 2010)

###### **Time and size**

Between 2004 and 2006, a total of 607 practices participated in the programme. 132 healthcare professional (HCP) took part in the study, but 94 provided data after 3 (835 patients) and 6 months (475 patients). (Dale 2008) 3 year data were provided by 55 practices on 516 patients. (Dale 2010)

## **Aims**

The aim of the study was to evaluate the impact of a short training course to develop the skills of GPs and practice nurses to initiate and manage treatment with insulin. (Dale 2008)

## **Intervention**

The Warwick Diabetes Care Intensive Management of Type 2 Diabetes programme is based on a 'training the trainer' type method in which two local diabetes HCPs are trained to facilitate a training approach to GPs and practice nurses in their area. (Dale 2008)

General practice teams volunteer for the. The training approach involves presentations, small group work, case studies and practical demonstrations to provide the knowledge and skills to facilitate intensified treatment of DM type 2 in general practice and insulin initiation. The training lasted one day or two half days and included 10–14 individuals, including one GP and one practice nurse from each of a number of local practices. Practical support was provided by diabetes specialist nurse. (Dale 2008)

The course taught that (Dale 2008):

- if once daily basal insulin alone was insufficient to get HbA1c to the target agreed with the patient a small dose of short acting insulin should be given with the main meal of the day, which could then be up-titrated according to blood glucose levels after the main meal.
- if one injection of short acting insulin in addition to basal insulin was insufficient a second injection of short acting insulin should then be given with the second largest meal of the day and up-titrated
- if two injections of short acting insulin plus basal were insufficient a third dose of short acting insulin could be given.

## Results

At 6 months (Dale 2008):

- improved glycaemic control in 90% of patients following insulin initiation
- the mean HbA1c decreased from 9.6% at baseline to 8.6% at 3 months post insulin initiation and to 7.9% at 6 months.
- mean decrease of HbA1c was 1.7% (range -9% loss to +3.8% gain) with >2% reduction in 36% of patients.
- 21.9% of patients achieved HbA1c <7% and 36.4% achieved the target HbA1C <7.5%
- 71.9% patients gained weight (mean gain of 1.5 kg over six months)
- HCPs reported confidence in initiating insulin. They perceived that there was a high level of acceptability to patients

At 3 years (Dale 2010):

- no overall change in HbA1c levels
- 41% of patients for whom data were available had their HbA1c level  $\leq 7.4\%$  and 29% had HbA1c level  $\leq 7\%$ .
- the median HbA1c for patients in the audit was  $\leq 7.0\%$  for 7 (12.7%) practices, 7.1–7.5% for 14 (25.5%) practices, 7.6–8.0% for 20 (36.3%) practices, and  $>8.1\%$  for 14 (25.5%) practices (8.1–10.7%)
- 56% of patients gained weight (mean 6.45 kg), 28% lost weight (mean 4.29 kg) and 16% had no change.

**Limitations as described by the authors:** self-reported data and not validated, not all practices reported data, so generalisability could be limited; self-selected practices that may have had a greater level of knowledge and interest in DM than typical of UK general practice; the results might not be applicable to other insulin initiation courses for primary care

professionals; some critical incidents such as hypoglycaemic episodes requiring admission to hospital may have been overlooked as the log diaries did not record data on hypoglycaemic episodes experienced during dose up-titration.

## ***B. BISOAT 2005/2006, Belgium***

### **General information**

In Belgium mainly general practitioners (GPs) manage oral anticoagulation therapy. GPs for whom clinical laboratory of the Medical Centre for GPs in Tessenderlo, Belgium determines the INRs on venous blood, were invited to participate in the study. (Claes 2005)

### **Time and size**

96 GPs, regrouped in 66 GP-practices, of which 44 were single-handed, participated in the study. (Claes 2005)

Patients were included if they were treated with oral anticoagulation for at least 28 days. Those who discontinued the anticoagulation therapy for a surgical procedure during the study were excluded from analysis. (Claes 2005)

Out of 936 patients on oral anticoagulation, 834 patients (455 men and 379 women) were included in the study. (Claes 2005)

### **Aims**

The aim of the study was to improve the quality of oral anticoagulation management by GPs and to compare different models and interventions. (Claes 2005)

First part of the study was a retrospective analysis of time in range and the number of adverse events related to anticoagulation over 6 months period. In the second part (6 months) GP-practices were randomized into 4 groups. (Claes 2005)

The primary outcome measure was the quality of anticoagulation management, defined as the proportion of time that INR-values were within target range (within 0.5 and 0.75 INR-units from the chosen target INR of 2.5 or 3.5). Secondary outcomes were thromboembolic

complications and haemorrhages (according to definition of The European Atrial Fibrillation Trial Study Group). (Claes 2005).

## **Intervention**

All groups received education on oral anticoagulation, anticoagulation files (with summary of guidelines), and patient information booklets. Every 2 months, a newsletter informed the GPs on the study progress and requested them to send the anticoagulation files for control (group A intervention only).

Group B additionally received feedback on their anticoagulation performance every 2 months (compared to the entire group B and to guidelines criteria);

group C determined the international normalized ratio (INR) with a CoaguChek device in the doctor's office or at the patient's home;

group D received Dawn AC computer assisted advice for adapting oral anticoagulation. (Claes 2005)

## **Results**

INR target of 2.5 – for AF (51.5%), to prevent arterial thromboembolism (15%), for deep venous thrombosis (8%), or for pulmonary embolism (9%).

INR target of 3.5 – mechanical prosthetic heart valve (16%), the antiphospholipid syndrome (0.5%). (Claes 2005)

The risk factors for stroke and the occurrence of thromboembolic complications or bleedings were: 51% hypertension, 14.5% DM, 25% a prior stroke or transient ischaemic attack, 16% peripheral vascular disease, 27% congestive heart failure, 15% previous myocardial infarction, 31% a valve disease, 5% history of malignancy and 15% were smokers.

The median follow-up was 4.8 months. (Claes 2005)

Poor compliance of the GPs to the computer generated advice in group D was observed.

In intervention vs control group (Claes 2005) :

- a significant difference in percent of patients with at least one INR >5 (P =0.009)
- a significant decrease in percent of patients with an INR >5 after the implementation of the interventions (P = 0.019).

After the intervention (Claes 2005) :

- the percentages of time within 0.5 INR-units from target significantly increased from baseline: in group A from 55% to 63%, in group B from 49% to 60%, in group C from 46% to 57%, and group D from 44% to 55% (no significant difference among the four groups)
- the overall incidence of minor bleeding was 12.2 per 100 patient-years (no significant difference among the groups)
- the overall incidence of major bleeding was 4.9 per 100 patient-years (three were fatal; no significant difference among the groups)
- the incidence of thromboembolic events was 5.94 per 100 patient-years (14 were fatal; no significant difference among the groups)

The cost-effectiveness of the programme was also calculated. The one-time cost of multifaceted education was € 49,997 for the whole study. Monthly continuous costs per intervention ranged between € 37 and € 54 per patient. Using the CoaguChek in combination with the multifaceted education was associated with net savings and quality improvement. Sensitivity analyses showed improved cost-effectiveness with extended duration and with increased program size. (Claes 2006)

**Limitations as described by the authors:** the lack of reimbursement for postgraduate education in Belgium; Poor compliance of the GPs to the computer generated advice in group D. “Study effect” could contribute to the quality improvement.

### *C. Wettermark 2009, Sweden*

#### **General information**

In Sweden, initiatives to improve the quality of drug prescribing have been organised by drug and therapeutics committees (DTCs). These activities include decision-support systems for prescribing, educational programmes, feedback on prescribing patterns, and evidence-based guidelines for drug treatment and recently also financial incentives. (Wettermark 2009)

The provision and financing of health services in Sweden is a public sector responsibility, primarily resting with 21 county councils. Primary health care is the basis of the Swedish healthcare system but it has no gatekeeper function and therefore many healthcare providers are involved in patient management and drug prescribing. (Wettermark 2009).

#### **Time and size**

The study was performed in the county of Stockholm (1.9 million inhabitants), Sweden, with 139 (out of 154) primary healthcare centres (PHCs) participating in the project and 15 PHCs not participating. The 15 non-participating PHCs served as the 'controls'. (Wettermark 2009)

The study consisted of two parts: a observational study without a formal control group, based on quantitative data on prescribing patterns and qualitative data summarised in the 'prescribing quality reports' for 2006. (Wettermark 2009)

The time periods for quantitative analyses were October to December 2005 and October to December 2006. (Wettermark 2009)

All prescriptions issued from PHCs and dispensed at pharmacies during October to December 2005 and October to December 2006 were analysed, using adherence to the regional DTC guidelines as the main outcome measure. Adherence was assessed using the drug utilisation 90% method (focusing on drugs constituting 90% of the prescribed volume and the proportion of drugs included in the guidelines). The qualitative analysis focused on reports on the quality of drug prescribing submitted by each PHC in early 2007.

Data were collected from the Swedish National Prescription Register administered by the National Corporation of Swedish Pharmacies. (Wettermark 2009).

## **Aims**

To describe and analyse the impact of an incentives model linking payment with adherence to drug and therapeutics committee (DTC) guidelines and self-reflection of prescribing pattern in a 'prescribing quality report'. (Wettermark 2009)

## **Intervention**

Incentives linked to prescribing behaviour and adherence to guidelines were introduced in Stockholm in 2006. It included extra payments linked to the level of adherence to the DTC guidelines (measured as the proportion of the drugs prescribed included in the guidelines) and the submission of a 'prescribing quality report'. (Wettermark 2009)

Templates were issued with questions about the doctors' opinion of their adherence to DTC guidelines, goals for improvement, documentation and reporting of adverse drug reactions, contacts with the pharmaceutical industry, participation in clinical trials and continuing professional development. (Wettermark 2009)

Financial incentives were used to increase doctors' cost-consciousness and stimulating them to assess the quality of their drug prescribing and finding potential ways to improve it.

The quantitative analysis was performed with routinely collected data on dispensed prescriptions in ambulatory care patients from all PHCs participating in the programme. (Wettermark 2009)

The guidelines for comparison were the list of drugs recommended by the DTC in Stockholm in 2006. These guidelines are produced by over 20 expert groups, which include GPs, hospital specialists, pharmacists and clinical pharmacologists. They consist of diagnosis-specific evidence-based recommendations with some 200 to 240 pharmaceutical products suggested as first-line choices for outpatient treatment of common diseases.

In this study, adherence was calculated by substance regardless of which pharmaceutical product (brand or generic) was prescribed and dispensed to the patient. (Wettermark 2009)

## Results

After introduction of incentives (Oct-Dec 2006) 4.4 million prescription items were dispensed to the inhabitants of Stockholm County (2.4 prescription items per inhabitant)

The 139 PHCs participating in the programme accounted for 85% of all prescriptions issued in primary care during that period. (Wettermark 2009)

The first quality reports were submitted in early 2007 based on 2006 data. In 2006, a total of €2 million was spent on incentives to the 139 participating PHC centres, with payments per practice varying depending on their performance (for example a PHC with seven GPs and an adherence to the DTC guidelines of 87% received €18000); average adherence was 82% in October to December 2006. (Wettermark 2009).

### **During the year (Wettermark 2009):**

- a significantly higher increase (after adjustment for the ceiling effect, i.e. that the participating practices had a significantly higher adherence prior to introduction of the schemes) in mean adherence to guidelines increased among participating practices as compared with non-participating practices (by 3.3 percentage units [95% CI 2.9–3.7%] to 83% [82.6–83.7%] vs by 3.1 percentage units [95% CI 1.7–4.4%] to 78.8% [95% CI 76.7–80.9%])
- the higher adherence corresponded to savings estimated at five times greater than the cost of running the programme including the financial incentives
- the total expenditure for prescribing in primary health care was €35 million (26% of the total ambulatory care prescribing in the county)
- the number of prescriptions increased by 10% and the expenditure by 4% compared to the period before introduction of incentives

- a clear correlation was observed between high adherence and low cost per defined daily doses after the introduction of incentives. An increased adherence of 1% corresponded to €0.47 lower cost per prescription item (for a PHC of average size [6GPs], this corresponded to an approximately €21 000 lower annual drug expenditure)
- with a total of 6.4 million prescription items dispensed in 2006 at participating PHC centres, increasing adherence by 3 percentage units resulted in estimated annual savings of more than €10 million
- 58% of all PHCs reported participating in previous projects with the aim of improving prescribing quality and/or increasing the cost-effectiveness of prescribing
- over 80% of participating and non-participating practices, received support from information doctors and/or pharmacists (medical doctors or pharmacists with special training employed or financed by the DTC to disseminate guidelines and educate healthcare professionals in rational pharmacotherapy) or had guideline drugs highlighted in the electronic prescribing support system to enhance the quality and efficiency of prescribing
- 26% of PHCs had participated in clinical trials
- 22% of PHC had doctors who were members of the DTC or one of the expert groups.

Many areas for improving prescribing were identified, such as limiting the prescribing of drugs with uncertain safety profiles and documentation and reporting of adverse drug reactions. (Wettermark 2009)

The PHCs identified therapeutic areas or single drugs where a substantial improvement in adherence would be possible (increasing prescribing of recommended drugs when initiating drug therapy with new patients, or reserving certain drugs as second-line choice for more restricted indications). (Wettermark 2009)

Furthermore, many PHCs wanted to increase their knowledge of pharmacotherapy through educational activities, perform regular reviews of their prescribing patterns, and in general: 'increase knowledge about drugs and their adverse effects'. (Wettermark 2009)

**Limitations as described by the authors:** observational study, no correction for other factors influencing prescribing patterns, such as pharmaceutical company marketing activities for new and existing drugs, new indications for existing drugs and changes in regulatory policies. PHCs were not completely comparable, control PHC could have been contaminated by the intervention.

## **5. Quality Improvement project in cardiovascular rehabilitation**

The UK National Service Framework was the only project, which was found during database search and among other activities included CVD rehabilitation in primary care. The description of this project is presented below.

## **6. Comprehensive Quality Improvement projects (combining different areas of FP/GPs care)**

### ***A. National Service Framework (NSF) for Coronary Heart Disease (CHD) and Quality and Outcomes Framework (QOF), United Kingdom***

#### **General information**

The NSF for CHD programme is funded by the Department of Health, other parties involved include Primary Care Trusts, NHS staff, GPs and Primary Health Care Team. (Department of Health 2000, van Lieshout 2008)

QOF was negotiated between the British Medical Association and the National Health Service and started in 2004 incorporating 136 clinical and organizational indicators. (Roland 2004; van Lieshout 2008)

## **Time and size**

The NSF for CHD programme started in 2000 and is an ongoing nationwide programme involving not only primary care but also hospitals and specialists' care. (Department of Health 2000)

The QOF – programme of financial incentives for quality – has been initiated by the national government in 2004 and is nationwide. There is no specified end date. The indicators/targets in QOF were revised in 2006/2007. (Roland 2004; van Lieshout 2008)

## **Aims**

The aims of the NSF for CHD are to improve the CV risk, to improve the life style in patients and in the public, and to improve the quality of care and the clinical performance. The framework sets standards for the prevention, diagnosis and treatment of CHD, describes service models and explains how the standards can be delivered and how progress will be monitored. (Department of Health 2000, van Lieshout 2008)

It introduces a ten year programme to reduce premature deaths from CHD, and promote faster, fairer access to high quality services. Overall target was to reduce CHD and stroke-related deaths by 40% by March 2010. The NSF establishes 12 standards in 7 areas such as reducing heart disease in a population, preventing CHD in high risk patients in primary care, treating heart attacks and other ACS, investigating and treating stable angina, revascularization, managing HF and cardiac rehabilitation. For each of the areas appropriate interventions, service models, immediate priorities, milestones and goals marking progress in implementation, and CHD high level performance indicators are established. (Department of Health 2000)

The aim of QOF was to improve quality of care and health outcomes in a number of domains, including CVD. Financial incentives for specific areas of chronic disease management, including CHD, hypertension, DM, stroke and TIA are provided. (Roland 2004; van Lieshout 2008)

## Interventions

The description of the National Service Framework programme goals, milestones, interventions is extensive, so just a short description of areas and standards is provided. Please refer to full description of the National Service Framework for details (see References). (Department of Health 2000)

Health professionals and their organizations have to meet minimum standards for the delivery of health services in England. (Department of Health 2000)

For each area, standard – targets and goals to be met are described. (Department of Health 2000)

Clinical teams are formulated – they should meet as a team at least once every quarter to plan and discuss the results of clinical audit and, generally, to discuss clinical issues.

Primary care Groups/Primary Care Trusts and hospitals together should form a local network of cardiac care. They should have effective means for agreeing an integrated system for quality assessment and quality improvement. (Department of Health 2000)

A systematically developed and maintained practice-based CHD register, protocols and clinical audit. (Department of Health 2000)

### 1) CHD prevention (Department of Health 2000)

Standards:

- develop, implement and monitor policies that reduce the prevalence of coronary risk factors in the population, and reduce inequalities in risks of developing heart disease
- contribute to a reduction in the prevalence of smoking in the local population

Interventions described include development and implementation of a comprehensive local programme of effective policies for reducing smoking, promoting healthy eating and physical activity, and for reducing overweight and obesity.

## 2) Preventing CHD in high risk patients in primary care (Department of Health 2000)

Standards:

- identification of all people with established CVD and offering of comprehensive advice and appropriate treatment to reduce their risks (GP and primary care teams).
- identification of all people at significant risk of CVD but not having disease symptoms and offering of appropriate advice and treatment (GPs and primary care teams)

Intervention described include:

- for both populations: stop smoking advice, advice on physical activity, diet, alcohol consumption, weight and DM maintaining BP <140/85, low dose aspirin (75 mg/d), statins

and dietary advice on lowering cholesterol level <5 mmol/l (LDL < 3 mmol/l) or by 30%, scrupulous control of BP and glucose in diabetics

- additionally in people with diagnosed CHD or other occlusive arterial disease: ACEI for people with left ventricular dysfunction, beta blockers for people with a history of MI, warfarin or aspirin for people >65 years and AF.

## 3) Heart attack: AMI and other ACS (Department of Health 2000)

Standards:

- help for people with symptoms of a possible heart attack (defibrillator within 8 minutes of calling for help)

- professional assessment and aspirin if indicated for people thought to be suffering from a heart attack; thrombolysis within 60 minutes of calling for professional help
- agreed protocols/systems of care for appropriate assessment and treatment of people of people admitted to hospital with proven heart attack

Detailed interventions described for people with AMI: pre-hospital (cardio-pulmonary resuscitation and defibrillation in the event of cardiac arrest, high concentration oxygen, pain relief, aspirin  $\geq 300$ mg orally, immediate transfer to hospital), hospital, continuing care (see prevention in high risk, low dose aspirin 75 mg daily, beta-blockers for at least one year, assessment of the potential to benefit from coronary revascularization, arranging systematic individualised rehabilitation and prevention) and unstable angina (e.g. anti-thrombotics, anti-ischaemics)

#### 4) Stable angina (Department of Health 2000)

##### Standard

- appropriate investigation and treatment for people with symptoms of angina or suspected angina

Interventions described included: aetiological investigations, estimation of risk, treatment to relieve symptoms (sublingual nitrates, beta-blockers and/or nitrates and/or calcium antagonists), treatment to reduce CV risk (as in prevention in high risk patients), assessment of benefits of revascularization (referral for angiography for candidates for revascularization).

#### 5) Revascularisation (Department of Health 2000)

##### Standards:

- urgent or emergency referral to cardiologist of patients with increasing frequency or severity of symptoms of angina

- hospital-wide systems of care for patients with suspected or confirmed CHD, so they receive timely and appropriate investigation and treatment

Interventions described include angiography, quantitative assessment of urgency/risk/priority, revascularization, CABG, PTCA with or without stenting, effective secondary prevention and rehabilitation.

#### 6) HF and palliative care for people with CHD (Department of Health 2000)

##### Standards

- appropriate investigations (eg electrocardiography, echocardiography) for people with suspected HF and appropriate treatment for people with confirmed HF

Interventions described: key investigations (12 lead ECG, echocardiogram, other), clinical management (ACEI, diuretics, beta blocker, nitrates and hydralazine, digoxin, avoiding aggravating factors), continuing care (risk factor advice, advice and treatment to control BP, offering immunization against influenza annually and against pneumococcus, control of glucose level and BP in patients with DM), considering potential benefit from cardiac rehabilitation, palliative care services and palliation aids, long term social support, cardiac transplantation

#### 7) Cardiac rehabilitation (Department of Health 2000)

##### Standard:

- agreed protocols/systems of care for patients with CHD to participate in multidisciplinary programme of secondary prevention and cardiac rehabilitation, prior to leaving the hospital.

Interventions described include:

- interventions before discharge (assessment of physical, psychological and social needs for cardiac rehabilitation, written individual plan, advice on lifestyle, prescription of effective medications and education about its use, involvement of relevant informal carers, locally relevant information about cardiac rehabilitation),
- early post-discharge (comprehensive assessment of cardiac risk, needs for cardiac rehabilitation; a review of the initial plan for meeting these needs, lifestyle advice and psychological interventions from relevant trained therapists, maintain involvement of informal carers, review of involvement of cardiac support group, offering resuscitation training for family members)
- 4 weeks after acute cardiac event (as early post discharge and structured exercise sessions to meet the assessed needs of individual patients, maintain access to relevant advice and support from people trained to offer advice about exercise, relaxation, psychological interventions, health promotion and vocational advice)
- long term maintenance of changed behavior (long term follow-up in primary care, offering involvement with local cardiac support groups, referral to specialist cardiac, behavioural, e.g. exercise, smoking cessation, or psychological services as clinically indicated).

In QOF practices receive a financial ‘reward’ for achieving high scores on quality indicators. There are formal financial incentives for prevention and disease management. Family physicians can earn up to 1000 points (which translate into pounds sterling and are claimed on annual basis) for achieving the indicators. An additional 50 points are available for the provision of prompt access to services. The points are calculated on the basis of complex formula which also takes into account practice size and the prevalence of conditions assessed.

Within the framework, there are three main sections: clinical care, practice organisation and patient experience. It was not officially specified in details so implementation varied locally. (Roland 2004, van Lieshout 2008)

The clinical indicators relate to 10 chronic conditions (CHD, stroke and TIA, hypertension, hypothyroidism, DM, mental disorder, COPD, asthma, epilepsy, cancer) and relate to specific aspects of care such as regularity of monitoring. Practices earn more points if higher proportions of patients underwent “process measure” (i.e. had their BP measured) and even more points for achieving “intermediate outcomes” (risk factors managed with certain limits). The points were allocated on the basis of the workload required to provide care to the relevant standard (academic advisory group and formal scoring process by groups of family practitioners). (Roland 2004)

Practitioners can exclude patients from numerator and denominator if the patients do not attend an office visit despite three written reminders, they have newly diagnosed conditions or are newly registered, they decline the intervention or treatment, they have not tolerated a medication that is specified in the contract, they are already receiving maximal doses of a medication (e.g., for the control of cholesterol) whose effects have been suboptimal, they have a condition (e.g., an allergy or a terminal illness) for which the intervention is not clinically appropriate, or they have a supervening condition that makes treatment inappropriate. (Roland 2004)

## **Results**

### National Service Framework

The 10-years target of reducing CHD and stroke-related deaths by 40% was met after 5 years and in 2006 the reduction in circulatory mortality was 44% as compared with 1995-1997. (Department of Health 2008)

In report on progress of NSF for CHD published in 2008 and 2009 outcomes were reported as follows (Department of Health 2008, Department of Health 2009):

- the prescription rate for cholesterol-reducing statins had more than doubled (around 4 million people) over the last 3 years (the measurement and control of cholesterol is included in the QOF in the GP contract)
- number of children receiving free fruit at school increased (from 0 in 2000 to 2 million in 2006)
- smoking prevalence among adults dropped from 28% in 1998 to 21% in 2007
- increases in prescriptions of other CV products – improvements in BP levels; the prevalence of untreated hypertension decreased from 32% to 24% between 1998 and 2003
- improvement in secondary prevention (also due to the additional incentive of the QOF)
- over 70% of people with heart attack symptoms are treated with thrombolytics within 60 minutes of calling for help, compared with approximately 24% before the CHD NSF's launch.
- shortening of waiting time for heart surgery (for >3 months for heart bypass surgery 0 vs > 1,000 patients waiting over a year for surgery)
- capital programme for world-class, state-of-the-art facilities and equipment for treating patients with CHD and other heart diseases nearly completed
- increased number of cardiologists (by 61%) and cardiothoracic surgeons (by 46%)
- development of cardiac networks (advice and support to commissioners)
- cardiac rehabilitation – increasing the access, equity and uptake of cardiac rehabilitation services by improving commissioning
- HF – all aspects of HF care (e.g. the use of BNP testing in emergency admissions to speed up the diagnosis of HF, the use of telemonitoring in the community to support home management of chronic HF, and improving access to supportive and palliative care services). Support as peer support meetings, access to online resources, ongoing site visits and clinical support.
- arrhythmia service improvement work

- AF – the opportunistic screening of over 1,500 patients in a target population; 25 new cases of AF were identified and subsequently treated. Development of in-house anticoagulation services and pathways of care.
- heart attacks – development of primary angioplasty services by individual networks according to their local priorities and geography. Early results – over 40% of the population already living in areas with a 24/7 primary PCI service for heart attack.
- introduction of systematic checks for all people aged between 40 and 74 to assess and reduce individuals' risk of DM, heart disease, stroke and kidney disease
- a network of rapid access clinics that ensures that over 95% of newly referred patients are seen within two weeks
- the larger number of referrals for investigation rising from 66,000 per quarter to 110,000 per quarter.

In retrospective cohort study (Graham 2006) including patients 2 years or more after introduction

- significant reduction of in-hospital mortality (4.8% vs 3.2%;  $p = 0.02$ ) due to reduction of development of Q wave MI (40.6% vs 33.3%;  $p < 0.0001$ ) and incidence of left ventricular failure (15.9% vs 12.3%;  $p = 0.003$ )
- increased proportion of patients receiving thrombolysis (69.4% vs 84.7%;  $p < 0.0001$ ) and decreased time to receive it (percentage of patients thrombolysed within 20 minutes 12.1% vs 26.6%;  $p < 0.0001$ )
- increased percentage of patients receiving beta blockers (51.9% vs 65.8%;  $p < 0.0001$ ), ACEI (37% vs 66.4%;  $p < 0.0001$ ) and statins (55.2% vs 72.7%;  $p < 0.0001$ )
- increased percentage of patients referred for invasive investigation (18.3% vs 27%;  $p < 0.0001$ ).

In postal questionnaire used for follow-up of coronary patients who started cardiac rehabilitation programme between April 1 2001 and March 31 2004 (Evans 2005) it was observed that:

- 33% of AMI patients, 36% of CABG patients and 30% of PCI patients entered the cardiac rehabilitation programme
- 74% of patients were exercising regularly, 95% were not smoking and 79% had BMI <30 kg/m<sup>2</sup>.

In modeling study (Gemmel 2006) it was projected that:

- if lifestyle targets for primary prevention are met 73 522 (95% CI 54 117 to 95 826) CHD events would be prevented per year
- in those at high risk of developing CHD, achieving target levels for lifestyle interventions would prevent 4410 (95% CI 1 993 to 8014) CHD events and for pharmacological treatments 2008 (95% CI 790 to 3627) CHD events
- for patients with established CHD, achieving NSF targets will result in the prevention of 3067 (95% CI 1572 to 5878) CHD events through improved drug treatment and 1103 (95% CI 179 to 2097) events through lifestyle interventions.

In longitudinal cohort study 42 practices in 6 geographical areas of England were assessed according to evidence based criteria for quality of care in 1998 and 2003 (Campbell 2005). There 15 indicator assessed for CHD, 13 indicators for asthma and 22 indicators for DM. The authors collected data for up to 20 patients per condition per practice in 1998 and for 12 patients per condition per practice in 2003. For each patient they calculated quality score – a ratio of the number of chronic disease indicator for which care was provided divided by the number of indicators for which care should have been provided. It is expressed as percentage of necessary care (possible score form 0 to 100%).

Between those two periods improvement in

- quality of healthcare for CHD (maximum possible score improved from 60.5% to 78.1%; change 17.6%, 95% CI 13.9–21.4)

- quality of healthcare for asthma (from 60.1% to 70.3%; change 10.2%, 95% CI 4.6–15.8)
- quality of healthcare for DM (from 70.4% to 77.7%; change 7.3%, 95% CI 3.5–11.1)
- control of cholesterol level ( $\leq 5$  mmol/l; from 17.6% to 61.4% in CHD patients and from 21.5% to 52% in patients with DM)
- control of BP ( $\leq 150/90$  mmHg in CHD patients from 47.3% to 72.2% and  $\leq 145/85$  mmHg in diabetic patients from 21.8% to 35.8%)
- recording of frequency of angina attacks, exercise capacity and diet and weight advice and smoking advice for CHD patients
- smoking advice, recording of peak flow and symptoms in patients with asthma
- recording of creatinine, weight and HbA1c in patients with DM.

There was also non-significant improvement in glycaemic control (HbA1c  $< 7.4\%$  from 37.9% to 39.7%).

## QOF

The same longitudinal cohort study as described above measured quality of care in the same 42 practices in 2005 (Campbell 2007).

Between 2003 and 2005:

- non-significant improvement in the quality of care for CHD (from 76% to 85%;  $p=0.07$ )
- significant improvement in the quality of care for asthma (from 70% to 84%;  $p < 0.001$ ) and DM (from 70% to 81%;  $p = 0.02$ )
- significant changes for BP, cholesterol and smoking status recording and aspirin prescription or advice in CHD patients
- significant changes for symptoms and smoking recording in patients with asthma
- in patients with DM significant changes for recording of HbA1c, feet examination, peripheral neuropathy examination, retinopathy examination, weight, smoking status as well as control of BP  $\leq 140/90$  mm Hg (from 35% to 49%), serum cholesterol control (from 52% to 72.5%), HbA1c  $\leq 7.4$  (from 39.8% to 50.6%;  $p = 0.05$ )

The authors also compared the changes in the quality of care between clinical indicators for which financial incentives were provided in 2004 and those for which they were not provided. The quality of performance for indicators with incentives was higher for all conditions, but the rates did not differ significantly (study not powered to show the difference, wide CI).

Another evaluation study assessed the data extracted from clinical computing systems for 8105 family practices in England in the first year of the programme, data from UK Census and data on characteristics of individual family practices (Doran 2006). In the first year median reported achievement (proportion of patients eligible for a clinical quality indicator for whom the indicator was met) was 83.4% and estimated population achievement (proportion of the total number of patients with a medical condition for whom a quality indicator was met) was 82.9%, for CHD the numbers were 85.7% and 81.9%, for DM 80.1% and 84.8%, hypertension 81% and 91.6%, stroke 84.4% and 85.4%

In modeling study applying population impact measures to estimate cardiovascular health gains from achieving treatment targets as specified in QOF (McElduff 2004).

Numbers of events prevented in the population over 5 years in 10000 people:

- reaching cholesterol lowering targets – 15 events in people with CHD, 7 events in people with a history of stroke, 7 events in people with DM
- reaching BP lowering targets – 4 events in people with CHD, 3 events in people with a history of stroke and 3 events in people with DM and 15 in people with hypertension

Aspirin targets, ACEI targets and influenza vaccination target would have lower impact due to already high levels of care achievements.

In retrospective analysis of the data from large primary care database The Health Improvement Network (Shah 2011) the quality of care for chronic diseases among older people in care homes (n = 10 387) was compared with the community (n = 403 259).

After adjustment for age, sex, dementia and length of registration attainment of quality indicators:

- was significantly lower for care homes residents than for community residents for 14 of 16 indicators
- the largest difference was observed for CHD prescribing (beta blockers in CHD RR 0.7, 95% CI 0.65–0.75) and monitoring of DM (retinopathy screening RR 0.75, 95% CI 0.71–0.8)
- smaller differences were observed for monitoring of hypothyroidism (RR 0.93, 95% CI 0.9–0.95), BP in stroke patients (RR 0.92, 95% CI 0.9–0.95) and electrolytes for patients receiving loop diuretics (RR 0.89, 95% CI 0.87–0.92).

Patients in nursing homes were more likely to be excluded from QOF (as unsuitable or non-consenting).

**Limitations as described by the authors:** Fragmentation of care and consequent poor coordination of care, especially for patients with multiple illness; Loss of holistic approach to patient care; Reduction in quality of care for conditions not included in incentive system

Increased administrative costs; measures that require recording at the time of consultation, such as BP, may be less likely to be recorded in care homes; Quality and Outcomes Framework based indicators cannot capture fully the quality of clinical care in care homes; the absence of indicators for problems with particular relevance to people in care homes such as pain management or continence care; For pay for performance the results are based on care reported in the medical records but not necessarily on care provided; No control group could be recruited, because financial incentives were applied simultaneously across the whole of the United Kingdom; selection bias; in modeling study: some components of the proposed GP contract cannot be quantified due either to lack of effectiveness evidence or uncertainty that they will directly lead to quantifiable health gain, potential harms that may result from achievement of the quality indicators were not addressed, patient adherence to treatment was not addressed; in rehabilitation study: self-reporting of patient data, retrospective registry analysis, no control group;

## ***B. Disease management programmes in primary care, Germany (ELSID STUDY)***

### **General information**

In Germany the model for chronic care comprising of self-management, education, clinical information systems, decision support, optimal delivery design, supportive health care structures and access to community resources has been implemented by means of disease management programmes (DMP) in primary care. This programmes fit in a government strategy to strengthen the role of primary care in Germany. The Federal Ministry of Health

leads the DMPs and the programmes are funded by the sickness funds. Stakeholders are organized in Federal Joint Committee. The representatives of the following organizations are included: The Federal Association of Statutory Health Insurance Physicians, the German Hospital Organisation, The Federal Associations of Sickness Funds, and the Institute of Quality and Efficiency and Accredited Patient Organisations. This Committee generates the proposals for the (new) DMPs. These proposals have to be accredited by the Federal Insurance Office. (Joos 2005, van Lieshout 2008)

### **Time and size**

The DMPs are arranged by federal laws are nationwide. The DMP in DM started in 2003 and the DMP Coronary Heart Disease started in 2005. There is no specified end date. (Joos 2005, van Lieshout 2008)

DMP in DM is evaluated in observational ELSID study – Evaluation of a Large Scale Implementation of DMP, which is conducted in 2 federal states of Germany (Rheinland-Pfalz and Sachsen- Anhalt). It includes a total of 20,625 patients (Joos 2005).

One of the substudies compared mortality rates of patients enrolled and not enrolled into the programme (Miksch 2010). It was an observational study with overall population analysis and matched pair analysis. The study included 11,079 patients identified from routine claims data from large statutory regional healthcare fund called the Allgemeine Ortskrankenkasse (AOK). Inclusion criteria for the patients were: age > 50 years and receiving a prescription for

antidiabetic medication (oral antidiabetic drugs or insulin) in the first half-year of 2005 and in DMP group being enrolled in the program by December 31, 2005. Patients who were managing their DM by diet alone were excluded from analysis.

Patients in the non-DMP group were not enrolled in the DMP before this appointed date. In the non-DMP group, all of the patients who joined the DMP during the observational time were excluded from analysis. 2300 patients were enrolled in a DMP and 8779 received routine care.

Another substudy assessed the effectiveness of the programme with respect to the quality of life of diabetic patients with varying numbers of other medical conditions (Ose 2009; Szecsenyi 2008). The survey included a random sample of 3,546 patients taken from the ELSID population (1,532 returned questionnaires and 1399 had valid data).

Part of this study is a cluster randomized comparison of two interventions (current DMP programme and ideally implemented DMP program providing additional intervention such as for example quality circles and outreach visits) against routine care without DMP as control group, which has been only published as protocol.

By mid-2007, around 2.3 million patients with DM type 2 (around 50% of the estimated number of patients in the population) and 30,300 family practices (around 65%) were actively enrolled.

In 2010 2.7 million patients with DM type 2 were enrolled.

## **Aims**

The current DMPs focus on CVD (CHD and DM), Asthma/COPD and Breast Cancer. The DMPs on CHD and on DM have a range of aims, including improving CV risk, improving life style in patients, improving the quality of care, improving patient experiences, and lowering costs. (Joos 2005, van Lieshout 2008).

## **Intervention**

Using compulsory requirements determined on behalf of the German Ministry of Health, sickness funds arrange contracts with primary care physicians. Participation for doctors and patients is voluntary, but participating doctors are obliged to keep within the conditions of the program. (Joos 2005, van Lieshout 2008)

The laws on DMP include detailed descriptions of the requirements for patient care, which should be fulfilled to get a financial reimbursement. Individual patients with DM or CHD are included in DMP (not necessarily all patients of a practice). (Joos 2005, van Lieshout 2008)

The DMPs contain treatment standards, evidence-based guidelines, quality circles, documentation standards, regular examination appointments, reminders, referral regulations, and physician feedback reports, educational meetings, outreach visits, patient education. The physician should document a range of items on each patient to get the financial reimbursement. (Joos 2005, van Lieshout 2008)

According to the legal regulations the intervention includes consultations at 3- or 6-months intervals, when a detailed DM-specific anamnesis and physical examination including taking BP and an analysis of HbA1c are carried out. Also agreements are made concerning further treatment, e.g. target values for HbA1c and BP and participation in patient education programs for DM or hypertension. All medical findings as well as the current medications have to be documented within structured, standardized documentation sheets at each consultation. If required a referral to a specialist (e.g. ophthalmologist) is arranged. GPs get a special DM-handbook including current, evidence-based information about DM therapy. (Joos 2005, van Lieshout 2008)

DMP also includes regular recalls for patients and shared individual goal setting by the patient and the physician, with consideration of the individual circumstances and risk profiles. This shared goal setting is based on emphasizing both coordination and continuity of care and the physician's knowledge of each patient. Patients are offered lifestyle advice to enable them to achieve behavioral changes in diet and physical activity in support of their own self-management. Patients are obliged to a follow up consultation at least twice a year and to attend an educational programme. There are also financial incentives for patients.

There is no specific continuing education for health care providers or practice support to

enhance the uptake of DMP in primary care. (Joos 2005, van Lieshout 2008)

## Results

### Mortality data (Miksch 2010)

- matched pairs – death from all causes in DMP groups vs non-DMP groups: 11.3% vs 14.4% (log-rank test  $P < .01$ ). In the univariate analysis nonparticipation was associated with an increased risk of death (HR 1.3 [95% CI = 1.09, 1.55]).
- total group – death from all causes in DMP groups vs non-DMP groups: 12.8% vs 21.7% ( $P < .001$ ). The adjusted HR for nonparticipation was 1.46 (95% CI = 1.28, 1.65).

### HRQL data (Ose 2009)

HRQL was measured using EQ-5D using the value set for the European population (minimal important difference – a change in score of  $\geq 0.05$  points). On average, the patients were enrolled for 26.8 months in the DMP for DM type 2. 93% of patients in both groups had one or more other conditions, over 70% of patients in both groups had two or more conditions.

The analysis of the main effects showed that

- participation in the DMP ( $P < 0.001$ ), the number of other conditions ( $P < 0.001$ ), sex ( $P < 0.001$ ), and age ( $P < 0.001$ ) had a significant impact on the EQ-5D score
- the analysis of the interaction effect (between DMP and the number of other conditions) showed a significant impact on the EQ-5D score ( $p < 0.05$ )
- an assessment of the estimated EQ-5D score mean values showed that as the number of other conditions rose, the score decreased in both groups
- with the exception of patients with two other conditions, patients in the DMP have higher estimated mean values for all numbers of other conditions
- a minimal important difference between DMP and routine care existed for patients with four other conditions, five other conditions, and six or more other conditions.

### The Patient Assessment of Chronic Illness Care (PACIC) data (Szecsenyi 2008)

PACIC instrument is a tool to measure the quality of care according to the chronic care model (CCM) and patient motivation according to the “5A” principles (assess, advise, agree, assist, and arrange), with the PACIC-5A regarding different chronic diseases such as DM.

It addresses to what extent provided care complies with the CCM from a patient’s perspective and experience. The patients evaluate the care they received from their family practitioner over the last 6 months with regard to several topics (answers on 5-point scale from 1 to 5).

Different aspects of providing care according to the CCM are assessed: patient activation, delivery system/practice design, goal setting/tailoring, problem solving/ contextual, and follow-up/coordination.

It was observed that:

- the average overall score on the PACIC items was significantly higher for patients enrolled in the DMP as compared with patients under routine care (3.21 vs 2.86;  $p < 0.001$ )
- significant differences in the same direction were found on all five subscales of the PACIC, except for patient activation ( $P = < 0.05$ ); largest differences for follow-up/ coordination of care, goal setting/tailoring, and for the problem-solving/contextual scale.

For the 5A scales, similar differences were found for all five subscales plus the sum score (3.08 vs 2.78;  $P < 0.001$ ). The largest differences in the same direction were found for assist, advise, and assess.

**Limitations as described by the authors:** Observational design of this study does not allow to attribute a direct and causal link between enrollment in the DMP in DM and differences in mortality; no structured documentation of the causes of death; participants were all from the same regional health fund; not randomized controlled trial; groups not matched for the level of education; could be some selection bias; other confounders, such as DM durations may have confounded the results; motivation to enroll to DMP.

## **7. A list of factors necessary for successful Quality Improvement project**

Since only successful programmes were described, it was not possible to analyse the influence of facilitators and barriers that determine success or failure. The factors described by the authors of the above described studies as necessary for successful programme were as follows:

- the GP familiar with the individual problems and health resources
- counseling and reinforcing at several levels and by different professionals
- brief structured advice, continuously repeated in the general practice, and easy access to stable local health courses
- enhancing the quality of the counseling component itself, simplifying the counseling model
- long follow up, the standardized way of measuring risk factors
- health promotion methods directed at both changing health behaviors in individuals and achieving environmental, organizational, and policy changes that support healthy changes (an integrative approach)
- quality, quantity and intensity
- the patient-oriented interventions in addition to logistic support that includes the monitoring of patients (recall system)
- structuring care by practice nurse and patient's compliance to another way of living
- a multiprofessional team from the planning and start of the programme
- teaming up the professionals to solve the practical problems experienced in their own working environment
- improvements seen in audit results as motivation for the doctors
- structured follow up sheets in the patient records
- multifaceted interventions as superior to single interventions
- discussing feedback reports and guidelines (learning from each other and learning to implement new strategies)
- social influence by peer interaction

- ‘training the trainer’ approach
- multifaceted education and feedback
- active education and information booklets
- multifaceted approach of changing clinical practice by focusing on internal and external influences, small group interactive learning, evidence based guidelines with attention for the specific needs of our GPs, team building with a newsletter, and patient oriented interventions
- increased adherence through the financial incentives programme
- local ownership and learning
- close team working within practices, a combination of clinical and organisational approaches, and strategies to include the practice team, the primary care trust, and central government initiatives
- financial incentives when performance targets and rewards are aligned to the values of the staff being rewarded
- clear goals, good teamwork and effective leadership
- additional money (as in the UK)
- the telephone follow-up especially of high risk patients who fail to respond
- setting of clear, unambiguous targets contained within regularly audited guidelines
- audit, electronic records, comparing their care with others, nurses to improve the care of chronic illness.
- systems-based, multifaceted, patient-centered, and primary care-based intervention; integrating the perspectives of healthcare providers and patients within primary care settings (DMP)
- emphasis on the continuity and coordination of care in the DMP
- restructuring of chronic illness care according to models such as the chronic care model and the medical home concept (the responsibility for individual care and coordination rests with medical providers working together within a healthcare team; enrolled patients receive more

social support from their physician and doctor's assistant, who is more involved in patient care)

- structured chronic care (greater motivation and more opportunities to provide care)
- primary care-based structured and coordinated care
- in a recent systematic review the most effective interventions to improve DM care were complex and included 4 areas of care: changing of clinician behavior, changes in how practices are organized, information systems enhancement, and educational support for the patient.

The factors listed above can be categorized into several groups, such as associated with:

- health care personnel
- healthcare organization and funding (payer)
- patients and local community
- external environment.

## IV. Conclusions

The description of eleven successful QI programmes related to CVD and based in primary care in European countries, provided an overview of a variety of interventions. Since only successful programmes were described, it was not possible to analyse the influence of facilitators and barriers that determine success or failure. The authors of the studies evaluating described programmes mentioned several factors which may be necessary for a successful QI programme. Those factors included inter alia quality, quantity and intensity, brief structured advice, continuously repeated in the general practice, and easy access to stable local health courses, long follow up, the patient-oriented interventions and logistic support, a multiprofessional team from the planning and start of the programme, teaming up the professionals, audit and feedback, multifaceted interventions, social influence by peer interaction, ‘training the trainer’ approach, financial incentives, local ownership and learning, a combination of clinical and organisational approaches, clear goals, good teamwork and effective leadership, electronic records, systems-based, multifaceted, patient-centered, and primary care-based intervention, continuity and coordination of care.

The QI projects in primary care conducted in Europe and described in international journals come mainly from Western and Northern European countries. No studies evaluating results of successful QI projects conducted in Eastern European countries were found in our search. Outside the European continent, authors from USA and Australia describe their own QI projects, share their experience and promote QI in primary care.

## V. Summary

According to the Council of Europe quality improvement systems should be set up at all levels of healthcare (individual healthcare provider, health practice, hospital, other healthcare institutions, public and private) and should involve all people associated with health care (providers, patients, funders managers, authorities). Cardiovascular disease (CVD) is the main cause of death in most European countries. On average CVD accounts for almost half of deaths, from about 35% in some western countries to about 60% in some eastern countries. Primary care is involved in the detection, treatment and monitoring of patients with increased risk of CVD

The aims of the report are: to gather and summarize information about QI projects and to identify factors necessary for successful project.

Database, journal websites and google search limited to English language publications were carried out. For the description in results section the articles were selected if they described any type of QI programmes concerning CVD (hypertension, dyslipidemia, HF, CHD, DM) in Family Medicine/General Practice (FM/GPs) in Europe which were evaluated and were successful. The most recent projects were selected. Additionally information about other programmes identified in this search was provided in the Appendix.

Eleven projects were presented in details. In health promotion German Three level strategy was described, a community-based programme led by the GP. QI in CVD prevention included three projects – Heartbeat Limburg and Diabetes Support Service conducted in the Netherlands and a QI project from Finland. For QI projects in diagnosis only one project conducted in the Netherlands was found. For CVD treatment three QI projects were described – UK project on insulin therapy initiation, Belgian programme on oral anticoagulation therapy and Swedish evaluation of the programme of financial incentives for prescribing behaviour and adherence to guidelines. In comprehensive programmes chapter three projects were described – UK National Service Framework and Quality of Outcomes Framework and German Disease Management Programme for Diabetes.

The programmes described a variety of interventions. In health promotion activities included education courses and lifestyle counseling. Activities in CVD prevention included nutrition

education, TV programmes, smoke-free areas, computerized registration of risk factors, adherence to evidence based national guidelines, logistics support for GP and practice nurse, using structured CVD assessment form. In diagnostic project intervention included personal feedback and quality improvement meetings. In therapy QI programmes activities included trainings with presentations, small group work, case studies and practical demonstrations, education, feedback, device, computer assisted advice and extra payments linked to the level of adherence to the guidelines. In comprehensive programmes in UK health professionals and their organizations have to meet minimum standards for the delivery of health services in England and financial 'reward' for practices achieving high scores on quality indicators are provided. In German Disease Management Programme activities include treatment standards, evidence-based guidelines, quality circles, documentation standards, regular examination appointments, reminders, referral regulations, and physician feedback reports, educational meetings, outreach visits, patient education. The physician should document a range of items on each patient to get the financial reimbursement.

The description of eleven successful quality improvement programmes related to CVD and based in primary care in European countries, provided an overview of a variety of interventions. Since only successful programmes were described, it was not possible to analyse the influence of facilitators and barriers that determine success or failure. The authors of the studies evaluating described programmes mentioned several factors which may be necessary for a successful QI programme. Those factors included inter alia quality, quantity and intensity, brief structured advice, continuously repeated in the general practice, and easy access to stable local health courses, long follow up, the patient-oriented interventions and logistic support, a multiprofessional team from the planning and start of the programme, teaming up the professionals, audit and feedback, multifaceted interventions, social influence by peer interaction, 'training the trainer' approach, financial incentives, local ownership and learning, a combination of clinical and organisational approaches, clear goals, good teamwork and effective leadership, electronic records, systems-based, multifaceted, patient-centered, and primary care-based intervention, continuity and coordination of care.

## ***Abbreviations***

ACEI – angiotensin converting enzyme inhibitor

ACS – acute coronary syndrome

AF – atrial fibrillation

AMI – acute myocardial infarction

BMI – body mass index

BNP – brain natriuretic peptide

BP – blood pressure

BUN – blood urea nitrogen

CABG –coronary artery bypass grafting

CHD – coronary heart disease

CI – confidence interval

COPD – chronic obstructive pulmonary disease

CRP – C-reactive protein

CV – cardiovascular

CVD – cardiovascular disease

CV – cardiovascular

DM – diabetes mellitus

DMP – Disease Management Programmes

DTC – drug and therapeutics committees

ECG – electrocardiogram

EPA – European Practice Assessment

ESR – erythrocyte sedimentation rate

GP –general practitioner

HbA1c – glycated hemoglobin

HCP – health care professional

HF – heart failure

HR – hazard ratio

HRQL – health related quality of life

INR – international normalized ratio

IVP – intravenous pyelogram

LDH – lactic dehydrogenase

LDL – low density lipoprotein

NSF – National Service Framework

OR – odds ratio

PCI – percutaneous coronary intervention

PHC – primary healthcare centre

PTCA – Percutaneous Transluminal Coronary Angioplasty

RCT – randomized controlled trial

RR – relative risk

TIA – transient ischaemic attack

QI – quality improvement

QOF – Quality of Outcomes Framework

WONCA – World Organization of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians.

SGPT – serum glutamicpyruvate transaminase

SGOT – serum glutamic-oxaloacetic transaminase

TSH – thyroid-stimulating hormone

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## Results

### **1. QI project in health promotion**

#### **A. Three level strategy – Germany**

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2. Wiesemann A, Nüssel E, Scheuermann W, et al. Improving cardiovascular health in the German CINDI area: methods and results of the practice-based "Three-Level-Strategy". *Eur J Gen Pract* 1996; 2: 117-25
3. Wiesemann A, Metz J, Nuessel E, et al. Four years of practice-based and exercise-supported behavioural medicine in one community of the German CINDI area. *Int J Sports Med* 1996; 18: 308-15
4. Wiesemann A, Braunecker W, Scheidt R. Community medicine and health research in the Oestringen Model (in German: Gemeindemedizin: Gesundheitsförderung und Versorgungsforschung im Östringer Modell). *Z Allg Med* 2001; 77: 14-8
5. Scheuermann W, Razum O, Scheidt R, et al. Effectiveness of a decentralized, community-related approach to reduce cardiovascular disease risk factor levels in Germany. *Eur Heart J* 2000; 21: 1591-7
6. van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

### **2. QI project in CVD prevention**

#### **A. Netherlands– Heart Beat Limburg (Hartslag Limburg)**

1. Harting J, van Assema P, van Limpt P, et al. Cardiovascular prevention in the Hartslag Limburg project: Effects of a high-risk approach on behavioral risk factors in a general practice population. *Prev Med* 2006; 43: 372-378
2. Schuit AJ, Wendel-Vos GC, Verschuren WM, et al. Effect of 5-year community intervention Hartslag Limburg on cardiovascular risk factors. *Am J Prev Med* 2006 ; 30(3): 237-42
3. Ronckers ET, Groot W, Steenbakkens M, et al. Costs of the 'Hartslag Limburg' community heart health intervention. *BMC Public Health* 2006; 6: 51
4. Ronda G, Van Assema P, Ruland E, et al. The Dutch heart health community intervention 'Hartslag Limburg': results of an effect study at organisational level. *Public Health* 2005; 119(5): 353-60

5. Ronda G, van Assema P, Ruland E, et al. The Dutch heart health community intervention "Hartslag Limburg": design and results of a process study. *Health Educ Res* 2004; 19: 596-607

6. van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

## **B. Netherlands – Diabetes Support Service**

1. Meulepas MA, Braspenning JC, de Grauw WJ, et al. Logistic support service improves processes and outcomes of diabetes care in general practice. *Fam Pract* 2007; 24: 20-25

2. Meulepas MA, Braspenning JC, de Grauw WJ, et al. Patient-oriented intervention in addition to centrally organised checkups improves diabetic patient outcome in primary care. *Qual Saf Health Care* 2008; 17: 324-328

3. van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

## **C. Ketola 2000 Finland**

Ketola E, Sipilä R, Mäkelä M, et al. Quality improvement programme for cardiovascular disease risk factor recording in primary care *Quality in Health Care* 2000; 9: 175-180

## **3. QI project in CVD diagnosis**

Verstappen WH, van der Weijden T, Sijbrandij J, et al. Effect of a practice-based strategy on test ordering performance of primary care physicians: a randomized trial. *JAMA* 2003; 289(18): 2407-12

## **4. QI project in CVD treatment**

### **A. Dale 2008/2010 United Kingdom**

1. Dale J, Gadsby R, Shepherd J. Insulin initiation in primary care for patients with type 2 diabetes: six month follow-up audit. *British Journal of Diabetes & Vascular Disease* 2008; 8: 28

2. Dale J, Martin S, Gadsby R. Insulin initiation in primary care for patients with type 2 diabetes: 3-Year follow-up study. *Primary care diabetes* 2010; 4: 85–89

## **B. BISOAT**

1. Claes N, Buntinx F, Vijgen J, et al. The Belgian Improvement Study on Oral Anticoagulation Therapy: a randomized clinical trial. *Eur Heart J* 2005; 26:2159-65
2. Claes N, Buntinx F, Vijgen J, et al. Quality assessment of oral anticoagulation in Belgium, as practiced by a group of general practitioners. *Acta Cardiol* 2005; 60: 247-52
3. Claes N, Moeremans K, Buntinx F, et al. Estimating the Cost-Effectiveness of Quality-Improving Interventions in Oral Anticoagulation Management within General Practice. *Value in Health* 2006; 9(6): 369-376

## **C. Wettermark 2009, Sweden**

Wettermark B, Pehrsson A, Juhasz-Haverinen M, et al. Financial incentives linked to self-assessment of prescribing patterns: a new approach for quality improvement of drug prescribing in primary care. *Quality in Primary Care* 2009; 17: 179-89

## **5) QI project in CVD rehabilitation**

Please refer to UK National Service Framework below.

## **6. Comprehensive QI projects (combining the above mentioned areas)**

### **A. National Service Framework for Coronary Heart Disease and Quality and Outcomes Framework**

1. Graham JJ, Timmis A, Ramdany S, et al. Impact of the National Service Framework for coronary heart disease on treatment and outcome of patients with acute coronary syndromes. *Heart* 2006; 92: 301-6
2. Campbell S, Wilkin D. Clinical Governance in: The National Tracker Survey of Primary Care Groups and Trusts 2000/2001. Taking Responsibility? Editors: Wilkin D, Coleman A, Dowling B, Smith K. National Primary Care Research and Development Centre, University of Manchester. 2001. Available at: [www.npcrdc.ac.uk/Publications/TRACKER\\_REPORT\\_2002.pdf](http://www.npcrdc.ac.uk/Publications/TRACKER_REPORT_2002.pdf) (accessed

23.1.07).

3. McElduff P, Lyratzopoulos G, Edwards R, et al. Will changes in primary care improve health outcomes? Modelling the impact of financial incentives introduced to improve quality of care in the UK. *Qual Saf Health Care* 2004; 13: 191-7

4. Gemmell I, Heller RF, Payne F, et al. Potential population impact of the UK government strategy for reducing the burden of coronary heart disease in England: comparing primary and secondary prevention strategies. *Qual Saf Health Care* 2006; 15: 339-43

5. Evans JA, Bethel HJ, Turner SC. NSF for CHD: 3 years of 12-month follow-up audit after cardiac rehabilitation. *J Public Health (Oxf)* 2006; 28: 35-8

6. National Service Framework for Coronary Heart Disease. Modern Standards & Service Models. Department of Health, UK, March 2000

7. Department of Health Coronary Heart Disease Policy Team. The Coronary Heart Disease National Service Framework. Building on excellence, maintaining progress. Progress report for 2008, Department of Health, UK, March 2009

8. Department of Health Coronary Heart Disease Policy Team. The Coronary Heart Disease National Service Framework. Building for the future. Progress report for 2007. Department of Health, UK, February 2008

9. Boyle R. Coronary Heart Disease Ten Years On: Improving Heart Care. Available from: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_074238](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074238)

10. Roland M. Linking physicians' pay to the quality of care – a major experiment in the United Kingdom. *N Engl J Med* 2004; 351: 1448-54

11. Doran T, Fullwood C, Gravelle H, et al. Pay-for-performance in family practices in the United Kingdom. *N Engl J Med* 2006; 355: 375-84

12. Campbell SM, Roland MO, Middleton E, et al. Improvements in quality of clinical care in English general practice 1998-2003: longitudinal observational study. *BMJ* 2005; 331: 1121

13. Campbell SM, Reeves D, Kontopantelis E, et al. Improvements in clinical quality in English primary care before and after the introduction of a pay for performance scheme: longitudinal study. *N Engl J Med* 2007; 357: 181-190

14. Sheaf R, Rogers A, Pickard S, et al. A subtle governance: 'soft' medical leadership in English primary care. *Social Health Illness* 2003; 25: 408-28

15. NPCRDC Briefing: Practice-based Commissioning: theory, implementation and outcomes. The National Primary Care Research and Development Centre, UK, July 2009

16. Shah SM, Carey IM, Harris T, et al. Quality of chronic disease care for older people in care homes and the community in a primary care pay for performance system: retrospective study. *BMJ* 2011;342:d912
17. van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

## **B. Disease management programmes in primary care, Germany (ELSID STUDY)**

1. Bodenheimer T, Wagner EH, Grumbach K. Improving primary care for patients with chronic illness. *JAMA* 2002; 288: 1775-9
2. Joos SS, Rosemann TT, Heiderhoff MM, et al. ELSID-Diabetes study- Evaluation of a large scale implementation of disease management programmes for patients with type 2 diabetes. Rationale, design and conduct – a study protocol. *BMC Public Health* 2005; 5: 99.
3. Beyer M, Gensichen J, Szecsenyi J, et al. Wirksamkeit von Disease-Management-Programmen in Deutschland – Probleme der medizinischen Evaluationsforschung anhand eines Studienprotokolls. *Zeitschrift für Ärztliche Fortbildung und Qualität in Gesundheitswesen* 2006; 100: 355-64
4. Miksch A., Laux G, Ose D et al. Is There a survival benefit within a German primary care-based disease management program? *Am J Manag Care* 2010; 16(1): 49-54
5. Szecsenyi J, Rosemann T, Joos S et al. German Diabetes Disease Management Programs are appropriate for restructuring care according to the Chronic Care Model. An evaluation with the Patient Assessment of Chronic Illness Care instrument. *Diabetes Care* 2008; 31: 1150-1154
6. Ose D, Wensing M, Szecsenyi J et al. Impact of Primary Care-Based Disease Management on the Health-Related Quality of Life in patients with type 2 diabetes and comorbidity. *Diabetes Care* 2009; 32: 1594-1596
7. van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

## VII. Appendixes

### **Appendix 1. References and brief information on evaluations of other programs found on the search or in EPA report**

van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

#### **1. OI project in health promotion**

##### 1. North Karelia Project, Finland

Conducted 1972-1997 – community health promotion with activities and interventions targeted at several persons and organisations which consisted of educating of both the public and health professionals and facilitating co-operating with health organisations and with other institutions such as schools, food industry

Selected references:

Puska P, Tuomilehto J, Nissinen A, et al. The North Karelia project: 15 years of community-based prevention of coronary heart disease. *Ann Med* 1989; 21:169-173

Puska P, Tuomilehto J, Nissinen A, et al. The North Karelia Project: 20-year results and experiences. National Public Health Institute. Helsinki, 1995

Puska P The North Karelia Project: 30 years successfully preventing chronic diseases. *Diabetes Voice* 2008; 53: 26-29

Puska P. Successful prevention of non-communicable diseases: 25 year experiences with North Karelia Project in Finland. *Public Health Medicine* 2002; 4(1): 5-7

Puska P. From Framingham to North Karelia. From descriptive epidemiology to public health action. *Progress in Cardiovascular Diseases* 2010; 53: 15–20

## 2. Vorarlberg Health Monitoring & Promotion Programme, Austria

Started in 1985, education of the public, long-term tracking of risk factors

Ulmer H, Kelleher C, Diem G, Concin H. Long-term tracking of cardiovascular risk factors among men and women in a large population-based health system: the Vorarlberg Health Monitoring & Promotion Programme. *Eur Heart J.* 2003 Jun;24(11):1004-13.

Ulmer H, Kelleher C, Diem G, Concin H, Ruttman E. Estimation of seasonal variations in risk factor profiles and mortality from coronary heart disease. *Wien Klin Wochenschr.* 2004 Oct 30;116(19-20):662-8.

## 2. QI project in CVD prevention

### 1. Sondendgard 2006, Denmark

RCT of secondary prevention, conducted in 2000; multifaceted intervention according to the Audit Project Odense combining GP registrations, outreach visits and feedback, targeting secondary prevention of ischemic heart disease in general practice

Søndergaard J, Hansen DG, Aarslev P et al. A multifaceted intervention according to the Audit Project Odense method improved secondary prevention of ischemic heart disease: a randomised controlled trial. *Family Practice* 2006; 23: 198-202

### 2. Lee 2004, UK

Conducted in 1998-2002 UK; Alphabet POEM template: advice, blood pressure, cholesterol etc and CAD risk estimates at baseline vs follow up

Lee JD, Morrissey JR, Patel V. Recalculation of cardiovascular risk score as a surrogate marker of change in clinical care of diabetes patients: the Alphabet POEM project (Practice of Evidence-based Medicine. *Current Medical Research and Opinion* 2004; 20 (5): 765-772

### 3. Heart Failure Nurse 2000 UK

Heart Failure nurses run Heart Failure clinics in primary care aiming to provide optimal evidence based care. Activities consisted of education of patients as well as family members on disease process, management and control of symptoms. Also support was provided following the diagnosis of chronic heart failure. Activities targeted at health professionals were specialist training for Cardiac Nurses. Finally at the level of healthcare organisations an important activity was the forming of multidisciplinary heart failure teams)

Lloyd-Williams F, Beaton S, Goldstein P, et al. Patients and nurses' views of nurse-led heart failure clinics in general practice: a qualitative study. *Chronic Illness* 2005; 1: 39-47

Khunti K, Stone M, Paul S, et al. Disease management programme for secondary prevention of coronary heart disease and heart failure in primary care: a cluster randomised controlled trial. *Heart* 2007; 93(11): 1398-405

Riley J, Blue L. Assessing and Managing Chronic Heart Failure. *Professional Nurse* 2001; 16: 1112-5

BA Goodwin. Home cardiac rehabilitation for congestive heart failure: A nursing case management approach. *Rehabilitation Nursing* 1999; 24(4): 4143-147

#### 4. Cardiovascular risk screening in general practice: an action-research project, Belgium

Since 2003, Only description of pilot phase of the project and intermediate outcomes provided. The intervention included education of health care professionals, who were taught to use the algorithm of Boland as decision aid for cardiovascular risk management and a patient-communication guide

B. Boland, R. DeMuylder, G. Goderis et al. Cardiovascular prevention in general practice: development and validation of algorithm. *Acta Cardiol* 2004; 59(6): 598;65

R. DeMuylder, V. Lorant, D. Paulus et al. Obstacles to cardiovascular prevention in general practice. *Acta Cardiol*. 2003; 59(2): 119–125

R. DeMuylder, R. Tonglet, F. Nackers et al. Randomised evaluation of a specific training of general practitioners I cardiovascular prevention. *Acta Cardiol* 2005; 60(2):199–205

van Lieshout J, Wensing M, Grol R. Prevention of cardiovascular diseases: The role of primary care in Europe. EPA Cardio project Bertelsmann Stiftung, Germany 2008, Centre for Quality of Care Research, Radboud University Nijmegen, Netherlands 2008. available from [http://www.bertelsmann-stiftung.de/bst/en/media/xcms\\_bst\\_dms\\_27352\\_27353\\_2.pdf](http://www.bertelsmann-stiftung.de/bst/en/media/xcms_bst_dms_27352_27353_2.pdf)

#### 5. Persson 2000, Sweden

computerized journal and smoking cessation, done before 2000. The computerised journal was used to reach all diabetic smokers aged 30–75 years and to invite them to a structured smoking cessation programme. The follow-up time was 18 months

Persson L-G, Lindström K, Lingfors H. Quality improvement in primary health care using computerised journal, exemplified by a smoking cessation programme for diabetic patients. Scand J Prim Health Care 2000; 18: 252-253

#### 6. Counselling for behavioural change, Switzerland

1998, The activities of the programme were targeted at the health professionals. It consisted of education of physicians. Through education of physicians education of patients was achieved.

Cornuz J, Humair J-P, Seematter L. Efficacy of resident training in smoking cessation: a randomized, controlled trial of a program based on application of behavioral theory and practice with standardized patients. Ann Intern Med. 2002;136:429-437.

Cornuz J, Humair J-P. A New Curriculum Using Active Learning Methods and Standardized Patients to Train Residents in Smoking Cessation. J Gen Intern Med 2003; 18: 1023–1027

### **3. QI project in CVD diagnosis**

No additional projects found.

### **4. QI project in CVD treatment**

#### 1. Renders 2003 Netherlands

1992-1993, retrospective comparison of data derived from two non-randomized trials with 3.5 years of follow-up. The first programme focused on improving the skills and knowledge of GPs with regard to Type 2 diabetes,

and supported them in making organizational changes in their practice (GP care only). Centralized shared diabetes care was implemented in the second programme in which the GPs received therapy advice according to a protocol for each individual patient. The patients were also encouraged in self-management, and received structured diabetes education (Diabetes Service)

Renders CM, Valk GD, de Sonnaville JJJ et al. Quality of care for patients with Type 2 diabetes mellitus - a long-term comparison of two quality improvement programmes in the Netherlands. *Diabet Med* 2003; 20: 846-852

### 2. Wensing 2004, Germany

Large scale programme of quality circles, controlled before-after study, conducted 1996 and 1998. Intervention group – patients of primary care doctors in the region Sachsen Anhalt, who volunteered to participate. Control group included patients from a random sample of primary care doctors in the same region not participating in the quality circles. Quality circles on prescribing – 11 sessions and repeated feedback on prescribing routines. Each session focused on a specific group of drugs (among other lipid lowering, antihypertensive, antidiabetic) using clinical guidelines and other evidence-based information.

Wensing M, Broge B, Kaufmann-Kolle. Quality circles to improve prescribing patterns in primary medical care: what is their actual impact? *Journal of Evaluation in Clinical Practice* 2004; 10(3): 457-466

### 3. Quality-circle GP prescribing improvement programme, France

2001-2002, controlled before and after study conducted in three semi-rural areas of Brittany. It involved 27 GPs. The intervention involved meetings of two public health consultants with all Gps in each area every 2.5 months to provide independent information about polymedications, generic name prescribing, antibiotics, vasodilators for peripheral arterial disease, venotonic drugs, psychoactive agents, gastric protective drugs, and non-steroidal anti-inflammatory drugs. The consultants also provided feedback on prescribing patterns and cost. Quality circles met every 6 weeks. The remainder of the administrative area served as control group

Françoise Riou, Christine Piette, Gérard Durand et al. Results of a 12-month quality-circle prescribing improvement programme for GPs *British Journal of General Practice* 2007; 7: 574-576

#### 4. Peters 2008, Germany

Conducted in 2004, multifaceted intervention which aimed to implement clinical practice guidelines, assessed in RCT. Intervention: train the trainer course feedback (4 interactive education meetings) plus pharmacotherapy was compared with control group receiving standard education guideline adherence (usual lecture). It included 30 GPs and 168 patients with CHF. The groups were compared with regard to prescription rates and target dosing of ACEI, ARB, beta blockers, aldosterone antagonists at baseline and 7 months follow up.

Peters-Klimm F, Müller-Tasch T, Remppis A, et al. Improved guideline adherence to pharmacotherapy of chronic systolic heart failure in general practice – results from a cluster-randomized controlled trial of implementation of a clinical practice guideline. *Journal of Evaluation in Clinical Practice* 2008; 14: 823-829

#### 5. Montgomery 2000, UK

RCT, conducted in 1996–1998. It compared effects on hypertension of a computer based clinical decision support system plus cardiovascular risk chart and cardiovascular risk chart with usual care. It included 27 GP practices in Avon. A computer based clinical decision support system was written for most commonly used computing systems. GPs and nurses were trained to use the computer based clinical decision support system. Blood pressure and other risk factors were extracted from patients records automatically (in computer practices) or manually by the GP or nurse (in chart practice).

Montgomery AA, Fahey T, Peters TJ, et al. Evaluation of computer based clinical decision support system and risk chart for management of hypertension in primary care: randomised controlled trial. *BMJ* 2000; 320: 686-90

#### 6. Lusignan 2010, UK

Data from 8 years of the program.

Educational component – clinically relevant feedback to clinicians and statistics to health service managers and researchers. Several clinical areas involved (among other cholesterol management in ischaemic heart, atrial fibrillation, heart failure), for each separate intervention designed in cooperation with opinion leaders, locally led, half-day, data quality workshops, graphical summaries of data to each practice providing comparison of their data quality with other practices

Technical part – relevant evidence-based audit criteria identified, appropriate dataset extracted and processed to facilitate quality improvement. Inter-practice comparisons are possible and list of patients who need intervention could be produced.

de Lusignan S. An educational intervention, involving feedback of routinely collected computer data, to improve cardiovascular disease management in UK primary care. *Methods Inf Med* 2007; 46: 57-62

## **5) QI project in CVD rehabilitation**

No additional projects found

## **6. Comprehensive QI projects (combining the above mentioned areas)**

### **1. Borgermans 2009 Belgium**

diabetes RCT – regional BEFORE 2009 (Interdisciplinary diabetes care teams operating on the interface between primary and specialty care the Leuven Diabetes Project)

Borgermans L, Goderis G, Van Den Broeke C, et al. Interdisciplinary diabetes care teams operating on the interface between primary and specialty care are associated with improved outcomes of care: findings from the Leuven Diabetes Project. *BMC Health Services Research* 2009, 9: 179

### **2. Sunaert 2009/2010, Belgium**

Conducted in 2003-2007. Included a program for type 2 diabetes based on the Chronic Care Model in Belgium

Sunaert P, Bastiaens H, Feyen L, et al. Implementation of a program for type 2 diabetes based on the Chronic Care Model in a hospital-centered health care system: "the Belgian experience" *BMC Health Services Research* 2009; 9: 152

Sunaert P, Bastiaens H, Nobels F, et al. Effectiveness of the introduction of a Chronic Care Model-based program for type 2 diabetes in Belgium. *BMC Health Services Research* 2010; 10: 207

### **3. Samoutis 2008/2010, Cyprus**

Pilot conducted before 2008. Included a multifaceted quality improvement intervention model, supported by a varying degree of scientific evidence, tailored to local needs and specific country characteristics. Overall, the main components of the intervention were the development and adoption of an electronic medical record and the

introduction of clinical guidelines for the management of the targeted chronic diseases facilitated by the necessary model of organizational changes

Samoutis GA, Soteriades ES, Stoffers HE, et al. Designing a multifaceted quality improvement intervention in primary care in a country where general practice is seeking recognition: the case of Cyprus. BMC Health Services Research 2008, 8: 181

Samoutis GA, Soteriades ES, Stoffers HE, et al. A pilot quality improvement intervention in patients with diabetes and hypertension in primary care settings of Cyprus Family Practice 2010; 27: 263-270

#### 4. Hansen 2003 Denmark

Conducted in 1998. Diabetes regional project, included prospective diabetes audit circle following the principles of APO (Audit Project Odense) method

Hansen CN, Hansen DG, Kragstrup J, et al. The role of the APO methods in improving diabetes care in general practice: the results of a Danish prospective multipractice audits circle. Quality in Primary Care 2003; 11: 225-232

#### 5. Health Plan for Catalonia, Spain

Conducted in 1999-2001; The Catalan Health Department includes CVD management in the National Health Care Plan. This plan sets up health targets for several conditions. The compliance with these targets by medical professionals has financial reward. Programme interventions regarding CVD, are orientated towards risk factors management, for instance hypertension and hypercholesterolemia.

Interventions: Diagnosis, treatment and control of hypertension, hypercholesterolemia, Screening and smoking prevention, Diagnosis, treatment and control of Diabetes Mellitus)

General Directorate of Public Health. Department of Health. Evaluation of the targets of the Health Plan for Catalonia for the year 2000 1st edition General Directorate of Public Health. Department of Health, Barcelona 2005

## Appendix 2. Pubmed Search

Search History 1

Search	Most Recent Queries	Time	Result
<a href="#">#9</a>	Search <b>#6 AND#7</b> Limits: <b>English</b>	07:21:36	<a href="#">484</a>
<a href="#">#12</a>	Search <b>#9 AND #11</b> Limits: <b>English</b>	07:13:02	<a href="#">100</a>
<a href="#">#13</a>	Select <b>100</b> document(s)	07:07:46	<a href="#">100</a>
<a href="#">#11</a>	Search <b>hypertension OR dyslipidemia OR heart failure OR coronary heart disease OR cardiovascular disease OR diabetes mellitus</b> Limits: <b>English</b>	07:07:12	<a href="#">1511589</a>
<a href="#">#10</a>	Search <b>hypertension OR dyslipidemia OR hearth failure OR coronary heart disease OR cardiovascular disease OR diabetes mellitus</b> Limits: <b>English</b>	07:07:00	<a href="#">1493648</a>
<a href="#">#8</a>	Search <b>#6 AND#7</b>	07:06:00	<a href="#">530</a>
<a href="#">#7</a>	Search <b>primary care OR family medicine OR general practice OR family practice</b> [MESH]	07:05:37	<a href="#">380958</a>
<a href="#">#6</a>	Search <b>quality assurance, health care [MeSH] OR quality management [MeSH] OR quality assurance</b> [MESH]	07:04:53	<a href="#">211634</a>
<a href="#">#5</a>	Search <b>quality assurance, health care [MeSH] OR quality management [MeSH]</b>	07:04:23	<a href="#">211634</a>
<a href="#">#4</a>	Search <b>quality assurance, health care [MeSH] OR quality management"</b> [MeSH]	07:04:16	<a href="#">211634</a>
<a href="#">#3</a>	Search <b>quality assurance, health care"</b> [MeSH] OR <b>quality management"</b> [MeSH]	07:04:03	<a href="#">0</a>

## Search History 2

Search	Most Recent Queries	Time	Result
<a href="#">#13</a>	Search <b>#5 AND #7 AND #12</b> Limits: <b>English</b>	16:15:18	<a href="#">98</a>
<a href="#">#12</a>	Search <b>quality improvement programme OR quality improvement project</b> Limits: <b>English</b>	16:14:35	<a href="#">3192</a>
<a href="#">#9</a>	Search <b>#5 AND #6 AND #7</b> Limits: <b>English</b>	16:13:44	<a href="#">603</a>
<a href="#">#10</a>	Search <b>#5 AND #6 AND #7 AND Europe</b> Limits: <b>English</b>	16:12:47	<a href="#">120</a>
<a href="#">#11</a>	Select <b>120</b> document(s)	16:12:05	<a href="#">120</a>
<a href="#">#8</a>	Search <b>#5 AND #6 AND #7</b>	16:09:34	<a href="#">685</a>
<a href="#">#7</a>	Search <b>primary care OR family medicine OR general practice</b>	16:08:43	<a href="#">379246</a>
<a href="#">#6</a>	Search <b>quality improvement</b>	16:08:13	<a href="#">46914</a>
<a href="#">#5</a>	Search <b>hypertension OR dyslipidemia OR hearth failure OR coronary heart disease OR cardiovascular disease</b>	16:07:25	<a href="#">1798563</a>

## Search History 3

Search	Most Recent Queries	Time	Result
<a href="#">#23</a>	Search <b>#19 AND #20 AND #21</b> Limits: <b>English</b>	10:22:27	<a href="#">65</a>
<a href="#">#25</a>	Search <b>#24 AND #21 AND #20</b> Limits: <b>English</b>	10:21:55	<a href="#">3</a>
<a href="#">#24</a>	Search <b>quality improvement[MeSH Terms]</b> Limits: <b>English</b>	10:20:21	<a href="#">99</a>
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