

ORIGINAL ARTICLE

Cardiovascular risk factors in primary care: methods and baseline prevalence rates – the DETECT program

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Key words: Cardiovascular disease – Coronary heart disease – Diabetes – Hypertension – Lipid disorders – Prevalence – Risk factors

ABSTRACT

Objectives: DETECT is an epidemiological study in primary care to examine (a) the prevalence rates and comorbidity of diabetes mellitus, hypertension, hyperlipidaemia and coronary heart disease (CHD), and associated conditions; (b) the frequency of behavioural and clinical risk factors for onset and progression; (c) the 12-month course and outcome; and (d) the met and unmet needs for these patients.

Methods: Three-stage, cross-sectional clinical-epidemiological study with a prospective-longitudinal component in a nationally representative sample of $N = 3795$ primary care

settings [response rate (RR): 60.2%] and $N = 55518$ patients (RR: 95.5%). Patients completed a standardized assessment, including questionnaires for patients and the physician and diagnostic screening measures (i.e. blood pressure, heart rate, body mass index and waist circumference assessments). A subsample of patients ($N = 7519$) also completed a standardized laboratory screening program and was followed-up after 12 months. Data were weighted to adjust for non-response, regional distribution and attrition.

Results: (1) Doctors and patients sample can be regarded as representative for primary care

settings in Germany. (2) The clinician-rated point prevalence of hypertension is highest (35.5%), followed by hyperlipidaemia (29.1%), diabetes (14.1%) and CHD (12.1%); prevalence rates of each disorder as well as their co-incidence rates increase markedly with age. (3) The vast majority (78%) of all patients revealed multiple (3+) behavioural and clinical risk factors.

Conclusion: The findings of DETECT underline the considerable burden for primary care doctors in managing a highly morbid patient population, with predominantly complex risk factor constellations, in routine care. Our data provide, in unprecedented detail, a basis for calculating age-, gender- and risk-group-adjusted risk-factor profiles in routine care.

Introduction

Numerous clinical and community studies have described the key behavioural and clinical risk factors for onset and progression of cardiovascular disease (CVD), primarily coronary heart disease (CHD), other atherosclerotic conditions and diabetes mellitus¹⁻¹¹. Improved recognition and diagnosis and treatment of CVD-associated high risk constellations such as hyperlipidaemia, hypertension, diabetes mellitus – rank among the top priorities in all health care systems. Several national and international initiatives and programs have been launched to increase awareness and rates of detection, treatment and effective control of single and combined risk factors in the population^{8,9,12} in addition to a wealth of clinical studies¹³⁻¹⁵. These intensive efforts have had so far only limited general impact^{7,16}. There is unequivocal evidence that still a substantial proportion of subjects in the population remain unrecognized, poorly treated and largely uncontrolled^{1,8,17,18}.

Among others^{17,19,20}, Böhler *et al.*¹⁴ recently reviewed and discussed this situation in greater detail from various perspectives. They highlighted among other issues the need for (a) a better understanding of the mechanisms involved in illness progression, particularly with regard to pattern of comorbidity, (b) a better understanding of the complex interrelationship of behavioural and clinical risk factors for CHD, including the derivation of valid risk factor scores and markers and (c) clinical epidemiological studies in primary care settings and routine care. Ninety per cent of the adult population in developed countries see their primary care physician at least once a year and undoubtedly primary care physicians have a core gatekeeper function for diagnosis, prevention and treatment²¹. Yet, in contrast to the core role of primary care, surprisingly few large-scale studies in primary care which are sufficiently representative, are available to provide detailed information about the prevalence of risk factors in primary care and specifically among high risk subgroups.

Aims

In response to these needs, we initiated DETECT ('Diabetes Cardiovascular Risk-Evaluation: Targets and

Essential Data for Commitment of Treatment'), a large-scale, nationally representative epidemiological study. The primary aims of the overall study are to determine in primary care: (1) the prevalence of CHD and CHD risk factors such as smoking, BMI, diabetes, hypertension and hyperlipidaemia, and associated conditions (2) the age- and gender-specific frequency and combination of behavioural, clinical and laboratory risk factors among primary care patients in general as well as in subgroups of patients (by disease, stage and risk status), (3) treatment goals and drug and non-drug interventions as well as the degree of met and unmet needs from the patients and doctors perspective and (4) 12-month course and outcome in order to identify characteristics of patients and predictors associated with an unfavourable course. Secondary goals refer to examination of the predictive utility of various existing aggregated risk factor scores, the role of psychological factors and depression in particular for course and outcome.

This paper is the first publication from this program, presenting in greater detail the design and methods of DETECT as well as core baseline findings with regard to the prevalence rates of selected clinical diagnoses and the frequency of selected lifestyle and clinical risk factors.

Methods

Design

DETECT is a 3-stage epidemiological study (see Figure 1), consisting of:

1. A *provider (pre-study) survey* in a nationally representative sample of primary care doctors in Germany. Participating doctors completed a questionnaire regarding personal and structural characteristics of their offices and regarding qualifications and attitudes related to recognition, diagnosis and care of patients with CVD, hypertension, diabetes and other high risk groups. This pre-study information also served as an independent assessment of potentially relevant predictors.
2. A cross-sectional *point prevalence study* (main, second stage study) of unselected consecutive patients attending these primary care settings. This main study consisted of a target (half-) day

assessment of unselected consecutive patients attending the doctor's office in the predetermined study period on this day. Patients were informed by posters and leaflets about participation of the respective offices in the study and that they were free to decline participation. All patients had to sign an informed consent form, to complete a self-report *patient's* questionnaire, followed by a structured *doctor's* clinical interview and examination by the doctor, including weight, height, waist-hip ratio, blood pressure and heart rate measurements and a documentation of laboratory findings from the patients records. Further, a random subsample participated in addition in a broad *standardized laboratory* screening work up (see below).

3. A *prospective-longitudinal cohort study* in the *random laboratory subsample* of stage 2 patients. The follow-up assessment was identical to stage 2, including the standardized laboratory screening work up, and was supplemented by a broader range of outcome variables (not dealt with here). In addition, a follow-up tracking assessment was installed to reduce attrition rates (Figure 1).

Sampling of primary care doctors for DETECT

The doctors' sample is based on a nation-wide sample of doctors with primary care functions (medical

practitioners, general practitioners, general internists). Sampling was based on 1060 regional segments (according to the criteria of the Institute for Medical Statistics, Frankfurt am Main, Germany), clustered into 128 geographical areas for which primary care doctor addresses were available. From this nationwide database a random sample of 7053 doctors was drawn. A total of 468 study monitors was responsible for recruiting the doctors into the study in their target area assigned. Assisted by a recruitment package, monitors were requested to inform doctors about the study aims and procedures, to recruit up to eight doctors, strictly following the order on the list provided and to code, for each doctor, willingness to enrol as well as reasons not to participate. All participating doctors signed the study enrolment form and were offered a compensation of 6 Euro for each patient documented in the main study and an additional 5 Euro for participating in the laboratory component. Upon recruitment, all participating doctors also completed the pre-study doctor's questionnaire. Participating doctors were trained by the study monitors regarding study procedures and were instructed to screen all patients presenting in their practice alternatively on the forenoon of either the 16th or 18th of September 2003 with the study instruments. The protocol specifically demanded inclusion of all attendees and prohibited any systematic choice of patients except for the following exclusion criteria: age below 18 years, acute medical condition rendering the screening procedure unacceptable on

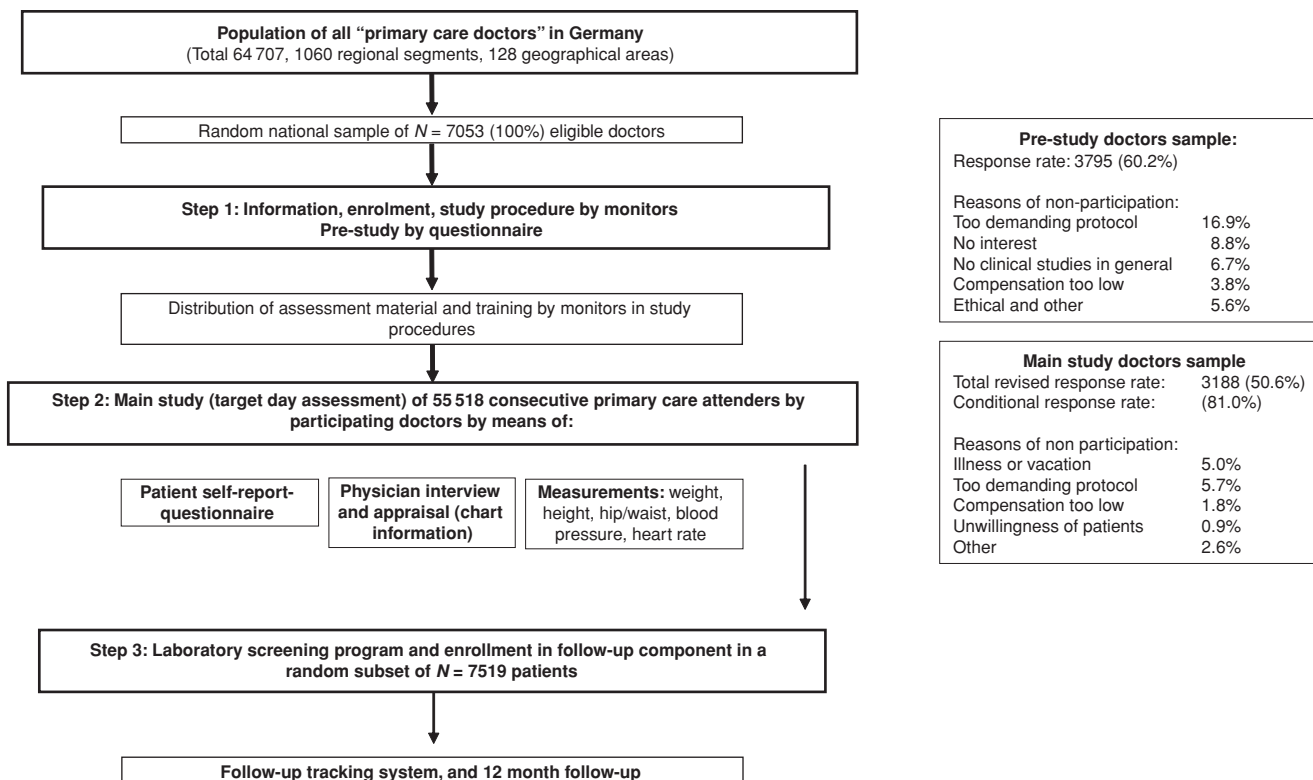


Figure 1. Design and sample of the DETECT study

ethical grounds, dementia or other cognitive or sensory deficits that would make it unlikely that the self-reported measures could be completed or would provide meaningful information. Monitors also cautioned doctors to neither change their routine practice behaviours nor to selectively invite patients for participation on the target day, in order to provide a typical picture of their everyday practice and to avoid major selection effects.

Study participation of doctors

Pre-study

Out of a total of initially $N = 7053$ (100%) eligible primary care physicians, $N = 3795$ doctors were successfully recruited, meeting the recruitment criteria, namely enrolment from signature, completion of pre-study questionnaire, willingness to adhere to the complex laboratory and follow-up procedures. This constitutes a total initial response rate of 60.2%. Most frequent reasons for non-participation were: 'protocol too demanding for routine care' (16.9%), no interest (8.8%), not enrolling in clinical studies in general (6.7%), financial compensation not sufficiently high (3.8%), and other reasons (5.3%) such as ethical concerns, lack of time, or unavailability due to vacation.

Cross-sectional main study

In the period between the pre-study and the main study (5 months) a further $N = 607$ doctors withdrew their initial consent to participate in the main study, reducing the main study sample to $N = 3188$. $N = 188$ (5.0%) dropped out because of illness or vacation, 218 (5.7%) because protocol was too demanding, 68 (1.8%) because the honorarium appeared too low, 35 (0.9%) because of assumed general unwillingness of patients to participate and 98 (2.6%) because of other reasons. This constitutes a conditional main study response rate of 81% and an overall response rate, as compared to the initial base sample of 50.6%.

Sample for laboratory screening and longitudinal cohort study (12-month follow-up)

One thousand doctors of the main study were randomly selected for participation in the laboratory and follow-up component of DETECT. Participating doctors in this component were requested to participate additionally in: (a) an additional laboratory program, to be conducted in at least 12 patients randomly selected and (b) to enrol these patients for a 12-month follow-up investigation involving the same standardized study procedures including laboratory testing. For this subset of laboratory/follow-up-doctors a conditional drop out rate of 14.3% ($N = 149$) was observed.

Doctors sample non-response adjustment

Because the number of non-participation of doctors might have affected the sample, representativeness was examined (a) by comparing the geographic distribution in the pre- and main-study sample with the distribution in the population of all doctors in Germany. Although no substantial differences were observed, some notable differences were apparent. Since we cannot exclude the possibility that willingness to participate might be systematically influenced by regionally different practice patterns or intervention preferences that might affect the findings, we adjusted for regional distribution by using a weighting scheme for both the pre-study as well as the main-study sample. We further examined using the pre-study questionnaire (b), whether doctors refusing participation or dropping out differed from those participating in the main study. In none of the variables examined (number of patients, region, specialization, preference of patients with specific diagnoses, frequency of interventions) were significant differences found (table available on request). Thus, based on the findings of the pre-study questionnaire, the study sample of doctors can be regarded as nationally representative in terms of regional distribution, age, years of experience, specialty orientation, and patient load per day.

Cross-sectional part: patient sample and participation

In the predetermined half-day recruitment period, an estimated total of 89 742 patients attended the 3188 participating primary care settings; the mean number of patients per doctor/half day was 28.2. Figure 2 reports the patients' response rate and the most frequent reason for drop-out/non-participation of patients.

Of these patients, 1.6% were rated as meeting the exclusion criteria and were thus not assessed. The most frequent reason was that patients were unable to read the instructions, because they forgot to bring their glasses. Almost one third of these patients could not be examined due to logistical and time constraints that prohibited dealing with more than a few patients at a time. Since on average 28 patients attended the doctor during the half day assessment period, on average only 18 patients could be approached. The informed consent and instruction procedure for the patient to fill out the questionnaire required at least about 5 min, in addition to an average of 15 min–20 min for the interview by the doctors and coding of the doctors assessment form and the time for the blood sampling. The total number of eligible patients to which questionnaires were distributed was $N = 59\,403$. $N = 3607$ patients refused participation (6.1%), for an additional 278 patients

Main study and laboratory sample

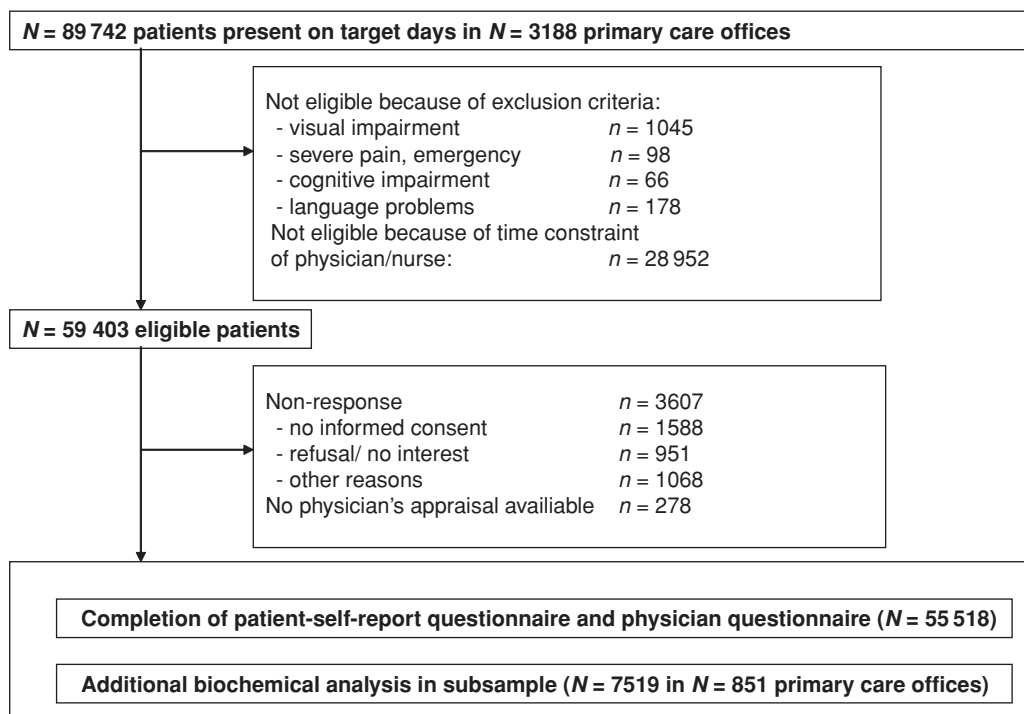


Figure 2. Data on study participation

no corresponding doctor assessment was performed (0.5%), leaving a total number of $N = 55\,518$ patients (response rate 93.5%) for the subsequent analyses.

For $N = 7521$ patients the laboratory screening program was completed, valid laboratory data were obtained for a total of $N = 7519$ patients by 851 doctors; these cases also entered the follow-up stage of DETECT.

Instruments and measures

The *pre-study questionnaire* served to collect background information on the participating physician's profile (qualification and specialization), nature of the practice setting, and physician's attitude and perceptions towards guidelines and programs for diabetes, hypertension, and cardiovascular risk management. Further, the frequency of laboratory and diagnostic measures as well as treatment targets for these various patient groups along with a description of preferred treatments were assessed. The *patient's questionnaire* was used to collect data on a variety of variables including biosocial characteristics, lifestyle and behavioural risk factors, generic health status, and details on patient's illness history and treatment (if applicable). This questionnaire included standardized instruments, like the EQ-5D as an assessment of quality of life^{22,23}, the Life-Orientation-Test²⁴ (LOT-R) as an assessment of dispositional optimism as well as the Depression-Screening Questionnaire²⁵

(DSQ) and a patient's rated stroke-risk-index. The *doctor's clinical examination* covered a total of 28 items evaluating the presence and severity of coronary risk factors, presence of comorbid conditions as well as information about treatment, current and past and family history, compliance and long term management. Information on blood pressure and selected laboratory parameters from the record as well as the doctor's assessment of lipids, diabetes and hypertension control was also collected. In addition the protocol required a standardized assessment of: (a) patients' current heart rate, (b) measured weight and height (body mass index, BMI), (c) measured waist and hip circumference, (d) systolic and diastolic blood pressure (measured by indirect cuff sphygmomanometry after several minutes of rest in a sitting position as recommended).

Laboratory screening program

For each patient sampled for laboratory and follow-up component, blood samples were collected and shipped by courier within 24h to the central laboratory at the Medical University of Graz (Austria). Clinical chemical parameters (creatine kinase [CK], creatine kinase MB [CK-MB] if CK was elevated, aspartate amino transferase [ASAT], alanine amino transferase [ALAT], gamma glutamyl transferase [GGT], alkaline phosphatase [AP], total bilirubin, creatinine, urea, uric acid, glucose) as well as albumin, 'high sensitive' CRP, cholesterol, triglycerides,

and lipoprotein [Lp(a)] were determined on a Roche Modular automatic analyser. Blood cell count was performed on a Sysmex XE 2100 analysing system. For the determination of the lipoprotein subclasses (HDL, LDL, VLDL) the HELENA SAS-3/SAS-4 was used. Haemoglobin (Hb) A1c was determined on an ADAMS HA 8160 analysing system. For all parameters, reagents and secondary standard were used as recommended by the manufacturers. Inter-assay coefficients of variation of these methods are provided in Table 1.

Diagnostic and variable conventions and definitions

All prevalence estimates reported in this paper are based exclusively on doctors' clinical diagnosis rated as being 'definite' in the standardized assessment. The risk factors considered were defined in accordance with the ESC definitions and criteria¹³ namely: (i) poor physical activity (defined in this study by patients self-report data: duration of any physical activity less than 2 h/week), (ii) elevated blood pressure BP \geq 140 mmHg and/or \geq 90 mmHg, (iii) BMI \geq 25, (iv) increased abdominal fat (men $>$ 102 cm, females $>$ 88 cm), (v) total plasma cholesterol $>$ 190 mg/dL, (vi) LDL cholesterol $>$ 115 mg/dL, (vii) HbA1c $>$ 6.1%, (viii) current smoker (defined as used any tobacco product in the past 4 weeks) and (ix) family history of myocardial infarction prior age of 60 years.

Statistical analyses

The prevalence estimates derived from the study are based on the assessment of all unselected consecutive primary care attendees in the participating settings on the study day and are thus point prevalence estimates. The prevalence estimates were adjusted for non-response and attrition that occurred during the sampling process. To reveal the effect

of weighting, we report the weighted and unweighted findings in this paper. Using cross tables, frequency distributions and descriptive statistics, we compared the distributions of variables among all categories. The investigated units (patients) are clustered into primary sampling units (primary care practices) in cross-sectional studies²⁶. That means that our observations of primary care patients might be correlated with primary care practices. This fact has consequences for the quantification of the statistical uncertainty, for example, for the calculation of confidence intervals. A widely accepted method for clustered samples is the Huber-White-Sandwich Matrix²⁷. All statistical analyses were conducted with the software package STATA 8²⁸ to adjust standard errors and confidence intervals for clustering of observations.

Results

Sociodemographic characteristics of the study sample

Table 2 demonstrates that the total sample of $N = 55\,518$ subjects and the laboratory sample of $N = 7\,519$ patients are similar in terms of the sociodemographic variables. The comparison between the weighted and unweighted data further reveals mostly marginal differences, indicating that the design effects are relatively weak. One third of the DETECT study sample is older than 65 years, whereas subjects below the age of 33 years constitute roughly 15%. Consistent with this age distribution over 40% of the sample is not in the work force anymore.

Baseline clinical characteristics of the study sample

Table 3 shows the clinical baseline characteristics of the main study sample and the laboratory subsample.

Table 1. Analytical variance of all quantitative measures in the laboratory screening program

Parameter	Coefficient of variation (%)	Parameter	Coefficient of variation (%)
Creatine kinase	1.4	Mean corpuscular haemoglobin concentration	0.9
Aspartate amino transferase	3.2	Platelets	1.5
Aalanine amino transferase	3.2	Mean platelet volume	1.2
Gamma glutamyl transferase	1.3	Albumin	3.9
Alkaline phosphatase	0.67	High-sensitive C-reactive protein	1.9
Total bilirubin	1.9	Cholesterol	1.71
Creatinine	2.3	Triglycerides	2.7
Urea	3.4	Lipoprotein (a)	1.7
Uric acid	1.7	High density lipoprotein cholesterol	1.8
White blood cells	2.7	Very low density lipoprotein cholesterol	5.6
Red blood cells	1.5	Low density lipoprotein cholesterol	6.4
Haemoglobin	1.0	Glycated haemoglobin A1c	13.4
Haematocrit	1.0		

Similar to sociodemographic characteristics both samples do not differ with regard to clinical characteristics considered.

Point prevalence of hypertension, hyperlipidaemia, diabetes and CHD

Tables 4(a) and (b) reports by age group and gender the unweighted and weighted point prevalence rates of the

four target diagnoses, hypertension, hyperlipidaemia, diabetes and CVD, as diagnosed by the doctor on the target day. Despite some minor differences (of less than 2%), the comparison of findings in Tables 4(a) and (b) reveals that the weighted prevalence distribution of the four target diagnoses in the total and the laboratory sample are by and large very similar. In both samples hypertension was diagnosed most frequently (35.5%), followed by hyperlipidaemia (29.5%), diabetes

Table 2. Sociodemographic baseline characteristics of the DETECT participants in the main study and the laboratory subsample, weighted (*w*) and unweighted (*uw*)

	Main study (N = 55 518)		Laboratory sample (N = 7519)	
	uw	w	uw	W
Gender				
Male (%)	40.8	40.8	41.0	41.0
Female (%)	59.2	59.2	59.0	59.0
Age, mean (SD)	53.9 (17.3)	53.8 (17.4)	57.7 (14.4)	56.5 (14.6)
18–34 (%)	15.7	16.0	4.3	5.1
35–44 (%)	15.9	16.0	17.0	19.0
45–54 (%)	16.8	16.6	20.2	21.1
55–64 (%)	19.1	19.0	21.7	20.9
65–74 (%)	20.8	20.6	24.3	22.4
75+ (%)	11.7	11.9	12.5	11.5
Marital status				
Single (%)	17.9	18.1	9.8	10.6
Married (%)	63.0	62.7	69.7	69.7
Divorced/widowed (%)	19.2	19.1	20.4	19.7
Total valid observation (%)	100.00	100.00	100.00	100.00
Professional status				
Employed (%)	40.9	41.3	39.7	42.8
Unemployed (%)	6.9	6.4	5.7	5.7
Housewife (%)	7.9	8.6	7.7	7.7
Retired (%)	40.2	39.7	45.1	41.8
Other (%)	4.1	4.0	1.9	2.0
Total valid observation (%)	100.00	100.00	100.00	100.00

Table 3. Clinical baseline characteristics of the DETECT participants in the main study and the laboratory subsample (weighted)

	Main study (N = 55 518)		Laboratory sample (N = 7519)	
	%	Mean (SD)	%	Mean (SD)
BMI		26.8 (5.3)		26.9 (4.8)
Underweight (%)	1.7		1.3	
Normal weight (%)	38.5		36.9	
Overweight (%)	37.3		39.5	
Obesity (%)	22.5		22.4	
Waist circumference		93.6 (15.6)		94 (14.8)
WHR		0.9 (0.1)		0.9 (0.1)
HbA1c (%)		6.5 (1.2)		5.5 (0.8)
Fasting glucose (mg/dl)		98.6 (33.2)		100.3 (33.8)
LDL-cholesterol (mg/dl)		132.8 (40.0)		126.4 (33.6)
HDL-cholesterol (mg/dl)		58.8 (35.2)		54.9 (18.7)
Plasma cholesterol (mg/dl)		213.8 (44.1)		221.7 (42.7)
Triglycerides (mg/dl)		157.9 (100.3)		149.0 (122.2)
Systolic BP (mmHg)		131.7 (18.4)		131.4 (18.4)
Diastolic BP (mmHg)		79.8 (9.9)		79.8 (9.9)
Family history of MI (%)	15.1		15.5	

Table 4. Prevalence of clinical diagnosis in (a) the main study and (b) the laboratory sample: weighted (w) and unweighted (uw) data

(a) Main study (N = 55 518): clinicians' diagnosis*												
Age range	Hypertension (N = 20 164)			Hyperlipidaemia (N = 16 178)			Diabetes (N = 8094)			CHD (N = 6895)		
	N	%w	%uw	N	%w	%uw	N	%w	%uw	N	%w	%uw
All												
18–34	326	3.7	3.6	292	3.4	3.5	121	1.4	1.4	49	0.6	0.6
35–44	1085	12.3	11.6	1202	13.6	13.8	297	3.4	3.2	133	1.5	1.5
45–54	2736	29.3	28.4	2434	26.1	26.5	897	9.6	9.1	486	5.2	5.1
55–64	4966	46.8	45.7	4207	39.7	40.3	1942	18.3	17.9	1397	13.2	12.9
65–74	6941	60.1	59.4	5366	46.4	47.1	3051	26.4	25.6	2736	23.7	23.1
75+	4110	63.5	62.6	2677	41.4	42.0	1786	27.6	26.7	2094	32.4	31.2
Total	20 164	36.3	35.5	16 178	29.1	29.5	8094	14.6	14.1	6895	12.4	12.1
Male												
18–34	159	4.9	4.7	115	3.6	3.7	48	1.5	1.4	15	0.5	0.5
35–44	517	15.5	14.6	647	19.4	19.6	149	4.5	4.3	78	2.3	2.3
45–54	1292	34.2	33.4	1292	34.2	34.4	502	13.3	12.5	323	8.5	8.3
55–64	2282	48.4	47.2	2013	42.7	42.9	1027	21.8	21.1	931	19.7	19.3
65–74	3119	60.1	59.6	2309	44.5	44.9	1531	29.5	28.6	1624	31.3	30.8
75+	1495	61.9	61.2	935	38.7	39.4	682	28.2	27.5	998	41.3	40.6
Total	8864	39.1	38.3	7311	32.2	32.4	3939	17.4	16.7	3969	17.5	17.2
Female												
18–34	167	3.1	2.9	177	3.2	3.4	73	1.3	1.3	34	0.6	0.6
35–44	568	10.3	9.8	555	10.1	10.3	148	2.7	2.6	55	1.0	1.0
45–54	1444	26.1	25.0	1142	20.6	21.1	395	7.1	6.9	163	2.9	2.9
55–64	2684	45.6	44.5	2194	37.2	38.1	915	15.5	15.2	466	7.9	7.7
65–74	3822	60.0	59.2	3057	48.0	48.9	1520	23.9	23.2	1112	17.5	16.8
75+	2615	64.5	63.3	1742	42.9	43.6	1104	27.2	26.2	1096	27.0	25.6
Total	11 300	34.4	33.6	8867	27.0	27.5	4155	12.7	12.3	2926	8.9	8.6
(b) Laboratory sample (N = 7519): clinicians' diagnosis*												
Age range	Hypertension (N = 3078)			Hyperlipidaemia (N = 2629)			Diabetes (N = 1299)			CHD (N = 1039)		
	N	%w	%uw	N	%w	%uw	N	%w	%uw	N	%w	%uw
All												
18–34	17	5.2	4.1	23	7.1	5.2	7	2.2	1.6	1	0.3	0.2
35–44	154	12.1	9.7	199	15.6	11.9	49	3.8	2.9	23	1.8	1.5
45–54	397	26.1	22.1	399	26.3	21.1	136	9.0	7.0	79	5.2	4.3
55–64	761	46.7	42.0	698	42.8	37.7	311	19.1	16.0	210	12.9	11.5
65–74	1124	61.5	57.4	889	48.7	44.4	514	28.1	24.8	405	22.2	21.0
75+	625	66.4	62.4	421	44.7	41.1	282	30.0	26.3	321	34.1	32.7
Total	3078	40.9	35.5	2629	35.0	29.5	1299	17.3	14.0	1039	13.8	12.1
Male												
18–34	8	7.6	6.3	13	12.4	9.5	3	2.9	2.3	0	0.0	0.0
35–44	70	16.2	13.3	94	21.7	17.0	21	4.9	3.8	19	4.4	3.7
45–54	191	31.7	27.4	195	32.4	27.1	77	12.8	10.3	48	8.0	6.9
55–64	375	49.7	44.9	345	45.8	40.8	184	24.4	20.8	147	19.5	17.6
65–74	509	61.4	57.2	396	47.8	44.0	262	31.6	28.3	249	30.0	28.7
75+	226	63.1	58.8	158	44.1	40.9	110	30.7	27.2	157	43.9	42.4
Total	1379	44.8	39.5	1201	39.0	33.9	657	21.3	17.9	620	20.1	18.1
Female												
18–34	9	4.1	3.1	10	4.5	3.2	4	1.8	1.4	1	0.5	0.3
35–44	84	10.0	7.9	105	12.5	9.4	28	3.3	2.5	4	0.5	0.4
45–54	206	22.5	18.8	204	22.3	17.4	59	6.4	4.9	31	3.4	2.8
55–64	386	44.0	39.5	353	40.3	35.1	127	14.5	12.0	63	7.2	6.4
65–74	615	61.6	57.6	493	49.4	44.7	252	25.3	22.0	156	15.6	14.6
75+	399	68.4	64.7	263	45.1	41.2	172	29.5	25.7	164	28.1	26.7
Total	1699	38.3	32.8	1428	32.2	26.6	642	14.5	11.5	419	9.4	8.1

*Diagnostic status is exclusively based on the clinicians' diagnosis coded as 'definite' in the assessment form. 'Probable' or 'questionable' diagnoses are not included

(14.1%, respectively 14.0% in the laboratory sample) and CHD (12.1%). The table also reveals for both sexes considerable age-related increases for all diagnoses as well as generally higher morbidity rates for males.

Prevalence of clinical and behavioural risk factors

Figure 3 reports the weighted point prevalence rates of the risk factors examined in the total sample and the laboratory-follow-up cohort. In both samples the most prevalent risk factors were: increased BMI, increased total plasma cholesterol, increased abdominal fat, and blood pressure. The least frequent factors were increased HbA1c and indications for a positive family history of MI. When applying the definitions of the European Society of Cardiology (ESC) for hypertension in patients with type 2 diabetes (< 130/< 80 mmHg), the hypertension prevalence increased to 44.9 % in the main study and to 47.1 % in the laboratory sample, respectively. Only 3%–5% of patients in both samples reveal no risk factor, however, almost 20% five or more. The figure further reveals (a) considerably higher LDL and total plasma cholesterol findings in the laboratory sample as compared to the total sample and (b) a slightly higher mean number of risk factors.

Discussion

The DETECT study is among the few epidemiological studies aiming at determining the prevalence of risk factors as well as the degree of met and unmet needs directly in primary and routine care respectively^{1,17}. As a naturalistic nationwide cross-sectional study with an embedded laboratory and follow-up cohort in over 3000 primary care settings and over 55 000 unselected consecutive primary care patients, one core aim of this paper was to present the methods, response rates as well as some baseline prevalence findings. As a prerequisite for interpreting and generalizing findings particularly from the more detailed laboratory and follow-up cohort, initial emphasis was laid upon establishing the representativeness of both samples, highlighting potential limitations.

Sample representativeness

As compared to previous nationwide studies with random sampling schemes in primary care^{17,29} in Germany, DETECT reveals a slightly lower overall response rate of 60.2% of all eligible primary care doctors. The non-participation rate is largely due to the recruitment process. All eligible doctors were initially asked to eventually also

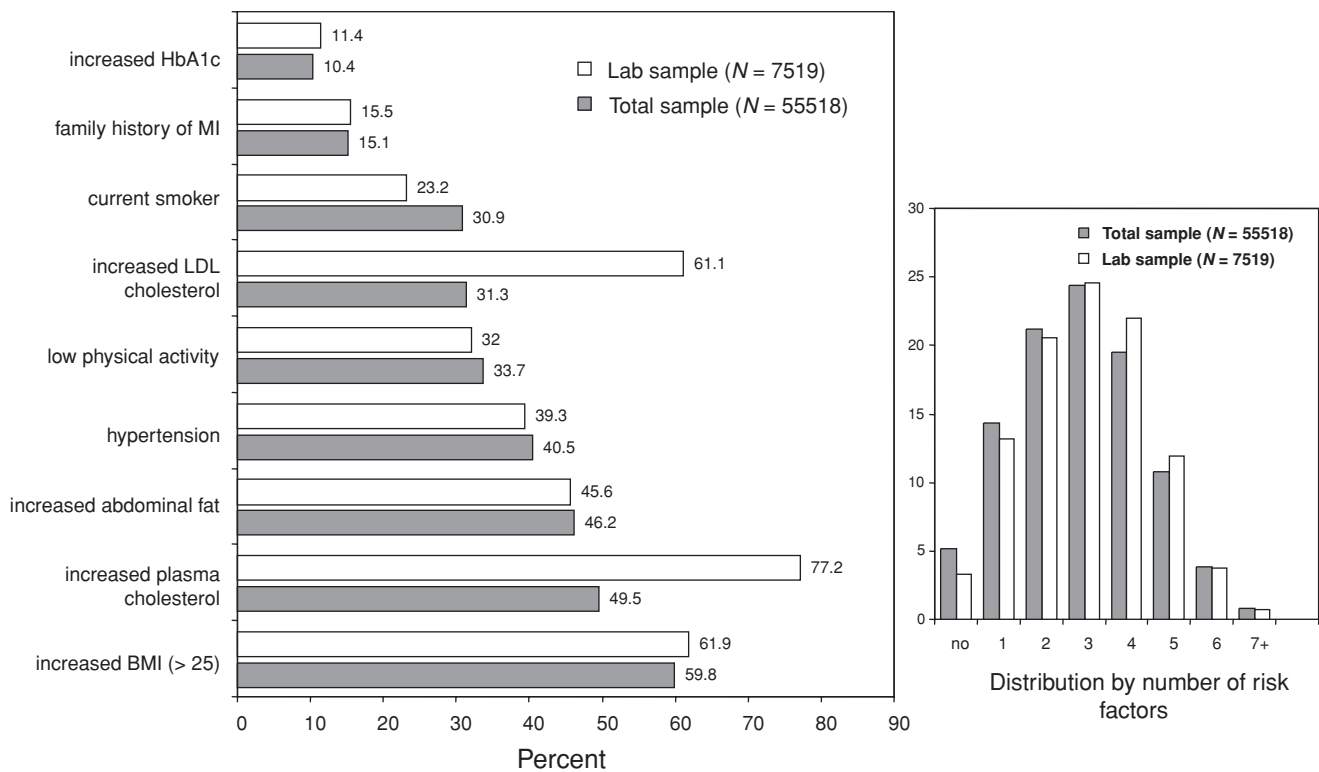


Figure 3. Distribution of risk factors in the DETECT main and laboratory sample

participate in the much more complex laboratory and follow-up component as well. As indicated by the non-participation and drop-out protocols the demanding protocol characteristics involved in the laboratory substudy and follow-up cohort were the most frequent reasons for declining. However, in comparison with registry data (IMS) as well as comparisons with a study using a similar sampling strategy¹⁷ we did not identify any indications for selective drop-out or refusal by region or type of primary care setting (data available on request). In contrast to apparently lower doctor response rates, the patient response rate was excellent with a response rate of over 90% of patients eligible. This high response rate in a sample of consecutive patients in primary care could be regarded as a particular strength of the study.

Comparisons between the total sample and the laboratory cohort revealed almost no remarkable differences with regard to any of the sociodemographic or clinical diagnostic variables considered. This indicates that, by and large, the study protocol requirement to recruit patients randomly without selection bias into both the laboratory and the follow-up cohort has been followed. The only noticeable exception is that the laboratory sample risk profile reveals much higher proportions of patients with increased LDL and total cholesterol levels. Although we are unable at this point to explain this finding entirely, our most likely explanation is that laboratory sample doctors received feedback about the actual laboratory and lipid values for each patient as part of the standardized laboratory procedures. In contrast, doctors not participating in the laboratory cohort relied entirely on their routine findings. We cannot entirely exclude the possibility that the laboratory cohort doctors recruited higher proportions of high risk patients with comorbidity and multiple risk factors into the study. However, beyond the increased rates of hyperlipidaemia no indication for this hypothesis was found.

Prevalence of disorders and risk factors

In accordance with our earlier HYDRA findings^{1,17,30} the present study confirms the high prevalence of hypertension (35.0%) dyslipidaemia (29.5%), diabetes (14.6%), and CHD (12.1%) in primary care patients and in particular among the elderly. Thus, the findings also underline indirectly the enormous quantitative burden caused by these conditions in primary care. However, it should be noted as a limitation that these preliminary baseline data are at this point exclusively based on the treating physician's diagnoses. Based on previous evidence from Sharma¹, we expect, at least with regard to hypertension, a considerable underestimation of the true prevalence^{31,32}. Upon availability of the laboratory data and the clinical appraisal of these findings in the follow-up study, the DETECT data will allow us to estimate more precisely the true prevalence rates of

each of these conditions. This will enable us to determine the degree of underdiagnosis and undertreatment as well as predictors for both in greater detail. Further biomarkers are currently under investigation. These include NT-pro-brain natriuretic peptide, testosterone, and thyroid stimulating hormone. The latter might be of particular interest as hypothyroidism is one of the major causes of secondary hypercholesterolemia.

In addition to the substantial burden created by the mere numbers of patients with these target conditions, the DETECT findings on the prevalence and co-occurrence of core behavioural and clinical risk factors are noteworthy. Despite the fact that most of the patients have been seen and treated by the primary care doctor for many years on average, the vast majority has multiple, i.e. more than four, risk factors. The high proportion of patients in primary care with multiple risk factors in combination with the high prevalence rate of illnesses is noteworthy and needs careful further analyses by examining the data by age and risk strata. Particularly in the light of the current strive to implement more effectively preventive measures for CVD, diabetes and other diseases, such data can be regarded as essential for planning effective intervention programs e.g. by mapping the risk profiles by age and gender as well as various high risk constellations. Because of the significant beneficial effects of more aggressive and early treatment of high risk constellations on the further development and course of complications³³⁻³⁵ as well as the overall costs of health care^{36,37} such age group, gender and high risk group adjusted data might be particularly helpful. They might help to set priorities with regard to efforts for improved recognition and management of patients in various stages of disease progression and thus contribute to better levels of recognition and control of cardiovascular risk constellations.

Acknowledgements

DETECT (Diabetes Cardiovascular Risk-Evaluation: Targets and Essential Data for Commitment of Treatment) is a cross-sectional and prospective-longitudinal, nationwide clinical epidemiological study. DETECT is supported by an unrestricted educational grant of Pfizer GmbH, Karlsruhe, Germany.

Members of the DETECT-Study group include: *Principal investigator*: Professor Dr. H.-U. Wittchen; *Staff members*: Dr. H. Glaesmer, E. Katze, Dipl.-Math. J. Klotsche, Dipl.-Psych. A. Bayer, Dipl.-Psych. A. Neumann. *Steering Committee*: Professor Dr. H. Lehnert (Magdeburg), Professor Dr. G. Stalla (München), Professor Dr. M. A. Zeiher (Frankfurt); *Advisory Board*: Professor Dr. W. März (Graz), Professor Dr. S. Silber (München), Professor Dr. U. Koch (Hamburg), Dr. D. Pittrow (München/Dresden).

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Paper CMRO-2883_3, Accepted for publication: 21 February 2005
Published Online: 01 April 2005
doi:10.1185/030079905X38187