Heartwatch

The National Heartwatch Programme

The National Programme in General Practice for the Secondary Prevention of Cardiovascular Disease in Ireland

Heartwatch Clinical Report

March 2003 to December 2005 – Second Report

June 2006

The Heartwatch National Programme Centre (NPC)
The Independent National Data Centre (INDC)

Heartwatch is a partnership between the Department of Health and Children, the Health Service Executive, the Irish College of General Practitioners and the Irish Heart Foundation.

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DEPARTMENT OF HEALTH AND CHILDREN
AN ROINN SLÁINTE AGUS LEANAÍ

Irish College of General Practitioners

IRISH HEART FOUNDATION

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

The Heartwatch National Programme Centre (NPC)
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Foreword

Professor John Feely

The Heartwatch Programme was one of the main recommendations in *Building Healthier Hearts* launched by the Taoiseach in 1999. The Health Strategy recognised the pivotal role of general practice in preventing and treating cardiovascular disease. There is now sufficient information available after two years to analyse the impact of this Programme on some 4,000 participants.

The results are very clear – there were significant improvements in the management of cardiovascular risk factors such as high cholesterol, high blood pressure and smoking, the main drivers of heart disease and it is estimated that 81 lives were saved and many further heart attacks and strokes prevented.

This Programme is unique in other respects. It provides a template for the effective delivery of chronic disease management in primary care at a modest cost. It allowed for independent assessment of the use of resources and outcomes and it has proved 'cost effective'. It has also dealt with 'teething problems' of collection and electronic transmission of a large amount of data in general practice. With the enthusiastic co-operation of patients, it shows how collaboration between those charged with the delivery of care – practitioners and nurses, project directors and unit managers with planners can deliver a national health strategy in a seamless manner. The next challenge is the extension of the Heartwatch Programme to all eligible patients in general practice.

The report herein is based on an independent statistical evaluation of the available data. I would like to commend the Department of Health and Children, the Health Service Executive, Irish College of General Practitioners, Irish Medical Organisation and the Irish Heart Foundation for enabling this unique collaborative effort.

Professor John Feely
Chairman, Initial Implementation Phase

Acknowledgements

The Heartwatch Programme is being undertaken by The Department of Health and Children and the Health Service Executive (formerly the Health Boards) in partnership with the Irish College of General Practitioners and the Irish Heart Foundation.

We wish to thank the members of the National Steering Committee and the Data Management Committee who oversee the programme at a national level.

The National Programme Centre and Independent National Data Centre, Mr John Leahy, National Programme Manager and staff are to be thanked for their commitment to the task. We are indebted to Mr Fionán Ó Cuinneagáin, CEO of ICGP and Dr Michael Boland, Director PRC, ICGP and all the GP coordinators and GP IT tutors.

All of the Health Boards have enthusiastically supported the programme and special thanks to the Nurse Facilitators, Cardiovascular Project Directors, Primary Care Unit Managers and other Health Service Executive team members.

The analysis of our data is crucial to the success of the programme and we thank those involved – Dr Kathleen Bennett, Department of Pharmacology and Therapeutics,Trinity Centre for Health Sciences, St James's Hospital, Dublin with assistance from Dr Zubair Kabir, Department of Pharmacology and Therapeutics, Trinity Centre and Dr Claire Collins, Irish College of General Practitioners.

Thanks also to the HSE Shared Services – Primary Care Reimbursement Service (formerly GMS Payments Board), the office of the Data Protection Commissioner and the Health Informatics Association for their continuing support and advice.

The most important people in a programme such as this are the patients and we are grateful to the general practitioners and their practice nurses who have identified and recruited these patients and have persevered with the tremendous change management required to establish a national programme such as this.

Finally, a special word of thanks to Mr Chris Fitzgerald, Mr Brian Mullins, Dr Emer Shelley and the staff of the Health Promotion Unit of the Department of Health and Children.

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Executive Summary

This evaluation relates to the first phase of Heartwatch, a structured programme of secondary prevention of cardiovascular disease in general practice in Ireland.

The overall aim of Heartwatch is to reduce morbidity and mortality due to cardiovascular disease.

This report, requested by the National Steering Committee of the Heartwatch programme, summarises the results to December 2005. The data in this report are for the first 33 months of the programme. In total 12,800 patients were recruited into the Heartwatch programme during this period.

A total of 7,099 individuals had complete data at one year, and 4,011 at one and two years.

The main elements of the analysis were to:

- Examine changes in risk factor and treatment uptake levels over the first two years of the programme, and GP variations in treatment uptake
- Compare uptake of preventive therapies in GMS patients in the Heartwatch programme with all GMS patients registered with Heartwatch and non-Heartwatch GPs and
- Model the data to estimate the lives and life years gained from the programme, and associated cost-effectiveness.

Registration details demonstrate that:

- Three-quarters of patients are male (76%)
- Less than one-fifth are aged under 55 years (14%)
- Almost three-quarters of patients (71%) had a GMS medical card.

Changes in risk factors and treatments

Patients who had valid data at visit 1 and one year showed significant improvements in the control of a number of risk factors (as evidenced by a reduction in the proportion outside target measurements) including:

- Systolic and diastolic blood pressure
- Total and LDL cholesterol
- Smoking.

Improvements in risk factor levels continued to two years, with only:

- 34% outside target for systolic BP and 8% for diastolic BP
- 16% outside target for total cholesterol and 17% for LDL cholesterol
- 10% remaining smokers at two years, from a baseline 14%.

There were little or no improvements for body mass index, waist circumference and exercise levels from baseline. There were 215 (3%) new cases of diabetes by one year in the cohort with one year follow-up, increasing the overall prevalence to 17%. In the two year cohort there were 170 (4%) new diabetes cases over the two years, bringing the overall prevalence to 19%.

There were significant improvements in the prescribing of secondary preventive therapies with an absolute increase of:

- 7% in ACE inhibitors
- 4% in beta-blockers
- 11% in statin therapy at two years.

By two years into the programme 90% of all patients were receiving statin therapy. The majority of patients were on aspirin (87%) by one and two years.

In patients with diabetes, 91% were prescribed statin therapy at two years, a 13% increase on baseline levels. Aspirin prescribing increased by 1% to 85% and ACE inhibitors by 5% to 66%.

There were large variations in the prescribing of secondary preventive therapies between GPs at baseline, for example, a two fold variation in statin prescribing, but this reduced considerably over the two years of the programme to 1.4 fold, providing evidence for improvements in the quality of care provided.

Comparison with all GMS patients

GMS patients in the Heartwatch programme had higher prescribing rates of secondary preventive therapies when compared with all GMS coronary heart disease (CHD) patients registered with the Heartwatch GP. Patients in the Heartwatch programme were almost three times more likely to receive statin therapy than all GMS patients with CHD.

Cost-effectiveness analysis

Epidemiology modelling of the two year cohort estimated that 81 deaths were prevented or postponed, and 522 life years gained over the two years of the Heartwatch programme. Additional drug costs, due to initiating secondary preventive therapies throughout the two years of the programme, were estimated at €656,473. The total additional cost of the Heartwatch programme was estimated at €4,169,023, including the cost of all the GP visits and administration costs.

The incremental cost-effectiveness ratio (ICER) was estimated at €51,469 per life saved, and €7,987 per life year gained. ICERs less than €20,000 per life year gained would be considered very cost-effective.

Summary

In summary, the Heartwatch structured care programme has shown:

- Significant improvements in reducing the levels of the three main risk factors (smoking, cholesterol and blood pressure)
- Increased uptake of evidence-based secondary preventive therapies
- Improved screening and treatment uptake in those with diabetes
- To be very cost-effective and is associated with improvements in the quality of care provided by GPs in the programme.

Key Findings

Risk Factor	Outcome
Systolic BP	21% Improvement *(See Section 4)*
Diastolic BP	45% Improvement *(See Section 4)*
Total Cholesterol	53% Improvement *(See Section 4)*
LDL Cholesterol	51% Improvement *(See Section 4)*
Smoking	26% Improvement *(See Section 4)*
Body Mass Index	1% Improvement *(See Section 4)*
Waist Circumference	0.3% Improvement *(See Section 4)*
Exercise	1% Improvement *(See Section 4)*
Treatment Uptake Levels	Significant Improvements *(See Section 4)*
GP Variation in Prescribing	26% Improvement *(See Section 8)*
Monitoring & Screening Diabetes	29% Improvement *(See Section 4)*
Mortality	81 Deaths Prevented or Postponed *(See Section 7)*
Morbidity	522 Life Years Gained *(See Section 7)*
Cost Effectiveness	€7,987 per LYG – Very Cost Effective *(See Section 7)*

Introduction & Background

Introduction and Background to the Heartwatch Programme

The Heartwatch Programme is now in it's fourth year of operation and the Heartwatch National Steering Committee has commissioned a sub-group *(See Appendix 1)* to coordinate and oversee an in-depth independent analysis report on the programme's progress to date.

The independent analysis in this report includes information patient outcomes and projections on reductions in morbidity and mortality using modelling. These results may be extrapolated to the total population eligible for secondary prevention (and possibly beyond this).

The calculated number of deaths prevented or postponed and life years gained by enrolment in Heartwatch are presented, based on analyses of the Heartwatch database up to end of November 2005, as well as an economic analysis of patient care using defined indicators.

The following sections in Part 1 of the report provide a brief overview of the background, infrastructures and operational developments to date. Please refer to the *Heartwatch Report (2004)*[1] for a more detailed description of structures.

Background

As is the case within the international community, it is well established that morbidity and mortality from cardiovascular disease is one of the greatest challenges facing the Irish Health Service. "Vascular diseases, of which cardiovascular disease is the most common, account for over 40% of all deaths and 37% of deaths under 65 years in Ireland. Within cardiovascular disease, ischaemic heart disease (IHD) is by far the most common. It alone accounts for approximately 25% of all deaths." [1, 2]

The European Heart Survey Programme, Euroaspire II, concluded "Considerable potential to raise the standard of preventive cardiology exists throughout Europe in order to reduce coronary morbidity and mortality".[3]

The rationale for an active approach to the prevention of cardiovascular disease (CVD) is firmly based on five observations:[4]

- CVD is the major cause of premature death in most European populations; it is an important source of disability and contributes in large part to the escalating costs of healthcare
- The underlying pathology is usually atherosclerosis, which develops insidiously over many years and is usually advanced by the time symptoms occur
- Death, myocardial infarction and stroke frequently occur suddenly and before medical care is available, and many therapeutic interventions are therefore inapplicable or palliative
- The mass occurrence of CVD relates strongly to lifestyles and modifiable physiological factors
- Risk factor modifications have been unequivocally shown to reduce mortality and morbidity, especially in people with either unrecognised or recognised CVD.

Implementing the National Cardiovascular Strategy

The Heartwatch Programme has been agreed by the Department of Health and Children, the Health Boards, (now the Health Service Executive) and the Irish College of General Practitioners in collaboration with the Irish Heart Foundation and is the culmination of several years of preparatory work.

The initial implementation phase focuses on secondary prevention amongst those with significant proven cardiovascular disease. This is implementing the recommendations of the report of the Cardiovascular Strategy Group, *'Building Healthier Hearts'*[5] which recommends (R6.21) that secondary prevention for most patients with cardiovascular disease should be provided in the general practice setting and goes on to state (Implementation 16.3) "the Department of Health and Children, the Irish College of General Practitioners and other relevant organisations should agree and implement a scheme for secondary prevention in patients with cardiovascular disease or diabetes."

The Heartwatch Programme sets out to tackle the

problem of cardiovascular disease in Ireland by establishing a strategic national approach to the implementation of internationally recognised cardiovascular prevention guidelines.[6]

The overall aim of Heartwatch is to reduce the morbidity and mortality of patients of the programme.

The interim objectives of the programme are:

- To examine the baseline levels of risk factors and therapeutic interventions relevant to secondary prevention and their trends over time
- To examine the processes involved in implementing the programme including the referral process and patient retention
- To record the incidence of cardiovascular events in patients participating in the programme.

The setup of Heartwatch commenced in September 2002 and the first patients were seen in March 2003. It is currently funded for 20% of the population and involves 480 General Practitioners throughout Ireland.

The programme implements continuing care, including secondary prevention, of patients who have had a myocardial infarction (MI), coronary artery bypass graft (CABG) or percutaneous transluminal coronary angioplasty (PTCA). Diabetes patients from the HSE – Midland Area Diabetes Structured Care Programme are also included under the Heartwatch Programme.

The Heartwatch Programme

Heartwatch provides a protocol for the continuing care of eligible patients including a schedule of up to four general practice consultations per annum initially, and details of the risk factors to be measured with target levels of control to be achieved.

The aim of continuing care is:

- To encourage the patient to lead as full and active a life as possible
- To record the current status of the patient in respect of the key risk factors of smoking, blood pressure, lipids, BMI and waist circumference
- To review the other lifestyle issues of diet and exercise
- To record the adequacy of diabetic control where appropriate
- To review current medication, compliance and the need to prescribe
- To intervene as appropriate or arrange referral for intervention by other specialist services based in the practice, the hospital or the community.

Data on 90% of patients and quarterly continuing care visits is sent electronically from the practice to the Independent National Data Centre which was established in 2003 specifically for the Programme (10% of practices return data via paper returns which is then input electronically).

A National Programme Centre and regional infrastructures and processes have been established to implement and manage the Heartwatch Programme.

Independent National Data Centre (INDC)

The Independent National Data Centre (INDC) is located at South Cumberland Street, Dublin with the main system server located at a secure co-location facility based at Parkwest, Dublin.

The INDC receives the data from the participant Heartwatch GP practices and is responsible for the data management aspects of the programme including the production and dissemination of anonymised relevant data and data reports as may be approved by the Data Management Committee, which oversees the activities of the INDC. Protocols and systems are in place to ensure that patient and GP confidentiality is maintained.

The development of Phase 2 of the INDC data system was completed in 2005 and features:

- Full automation of data processing
- Additional query functionality
- Additional on-line facilities for Heartwatch participants and INDC administration
- Financial reports
- Standard GP and national clinical reports
- Customised GP and national clinical reports.

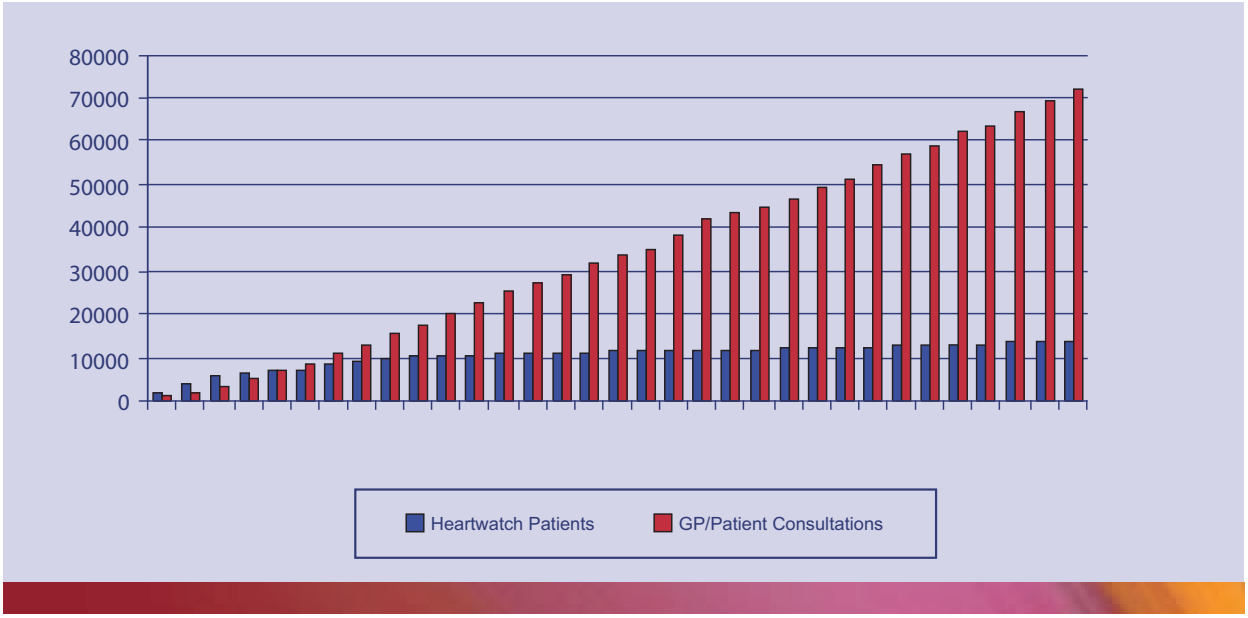
One of the most important and innovative of these developments is that GPs/practice users can now access Heartwatch demographic and clinical data for their own patients as well as regional and national information automatically, online through the INDC system.

Data on Patient Care

Heartwatch has now established the largest database on cardiovascular disease within Primary Care in Ireland, with over 13,000 patients now registered to the Programme and data collected on over 80,000 GP/patient consultations.

A number of academic and medical research organisations have been successfully approved by the Data Management Committee to access this rich source of data and are currently conducting a number of research projects.

Figure 1



Clinical Data Analysis

Section 1: Methodology

Exclusions to the analysis were:

- Patients without a valid visit 1 or any valid data beyond visit 1
- MHB patients with diabetes (but no diagnosed coronary heart disease) as their qualifying criterion.

To be included in the following analysis each patient had to have a valid visit 1 (baseline) and a one year follow-up visit. In addition, a subset of these with a valid two year follow-up visit were also considered. Each patient was assigned as having a valid one year and two year follow-up visit in the following way:

The difference in days was calculated between visit 1 and all other subsequent visits. The visit date closest (in days) to 365 days (one year cohort) and 730 days (two year cohort) was assigned as the one year or two year follow-up visit if such a visit existed.

Each follow-up visit had to be within two months of the 365 (one year) and 730 (two year) days to be included. In addition, for two year cohort only, individuals were also required to have data available at one year.

For the one year cohort there were 7,099 individuals with valid data with age and gender recorded. This is 88% of the total of 8,067 who had completed four visits by December 2005.

For the two year cohort there were 4,011 individuals with valid data at one and two years.

Demographic data for all individuals in the original file (11,542) and those included in the one year and two year follow-up cohorts are presented in *Tables 1-5* in the results section.

Early enrolees were those individuals recruited into the programme (visit 1) from February to August 2003 (inclusive). Late enrolees were any individuals recruited from September 2003 onwards.

Statistical methods

Paired t-tests were used to compare mean changes in risk factors between visits for continuous data and McNemar's test for paired dichotomous data. Two-sided significance is assumed throughout at $p<0.05$. SAS statistical software (SAS Institute Inc V9) was used for analysis purposes.

Risk factor data

Risk factor data for all patients at visit 1 and at the one year and two year follow-up visits was considered.

Means (standard deviations, SD) at visit 1 and at the one year and two year follow–up visits were calculated for the following risk factors:

- Systolic BP, Diastolic BP, Total Cholesterol, LDL cholesterol, Body mass index, weight, fasting glucose (for non-diabetics at both visits), HbA1c (for diabetics at both visits), waist circumference.

In addition the percentage smoking prevalence was calculated based on an individual have any of the following recorded: smoker of one or more cigarettes per day, cigar or pipe smoker. Absolute change in risk factors, between visit 1 and one or two year follow-up visit, was calculated.

The percentage of patients outside the targets (as recommended by *Second Joint Task Force report*[6]) at visit 1 and the one or two year follow-up visits were calculated and included exercise and physical activity. Relative change between the visits was calculated, relative to visit 1.

Recommendations made in the more recent *Third Joint Task Force document*[4], published in 2003, were compared with the earlier *Second Joint Task Force report*[6] (published 1998).

Two risk factor measures that had changed were total and LDL cholesterol. Total cholesterol recommendations were <5mmol/l, but more recently (Third Joint Task Force) changed to <4.5mmol/l. LDL cholesterol recommendations were <3mmol/l, but more recently changed to <2.5mmol/l.

The percentage of patients outside these two sets of targets, for total cholesterol and LDL cholesterol, at visit 1 and the one and two year follow-up visits was compared.

Treatment data

Percentage uptake of treatments, including aspirin, statins, beta blockers, ACE inhibitors, diuretics, calcium channel blockers, other lipid lowering agents, anti-hypertensive and oral hypoglycaemic agents was examined at visit 1 and at the one year and two year follow-up visits.

For the purpose of categorising patients as having received or not having received such treatments the following were combined: 'Decreased dose', 'Increased dose', 'Maintained' and 'New' as receiving treatment; 'Not prescribed' and 'Discontinued' as not receiving treatment.

Any changes in medication were noted as an increase or decrease in dose of the existing treatment, a discontinuation of the treatment or newly initiating the treatment. The percentage of these changes out of all those having received treatment is given.

In addition, aspirin, statin and ACE inhibitor prescribing was examined in the subset of patients with diabetes at both visit 1 and at either the one or two year follow-up visit.

Section 2: Patient Recruitment and Demographics

A total of 11,542 individual patients were available in the Heartwatch database, after excluding those from the MHB with diabetes only. The number with a valid age and gender is given in *Table 1a*. The majority of patients were men (75.6%) and the largest age category was 55-74 years (65.2%).

Table 1a: Demographic data – age category and gender

Age category	Males	Females	Total
<55	1,358 (15.7%)	250 (8.9%)	1,608 (14.0%)
55-64	2,587 (29.8%)	590 (21.1%)	3,177 (27.7%)
65-74	3,235 (37.3%)	1,066 (38.1%)	4,301 (37.5%)
75+	1,497 (17.5%)	894 (21.1%)	2,391 (20.8%)
Total with age & sex	8,677 (75.6%)	2,800 (24.4%)	11,477

More women were GMS eligible (81.6%) than men (68.1%) in the Heartwatch programme, which was not surprising given that more women are GMS eligible generally.

The majority of GMS eligible patients were 65 years and over and 96% of the over 75 year olds had medical cards *(Table 1b)*.

Table 1b: Age category by GMS eligibility

Age category	Not GMS eligible	GMS eligible	Total
<55	822	786 (48.9%)	1,608
55-64	1,482	1,695 (53.4%)	3,177
65-74	881	3,418 (79.5%)	4,299
75+	102	2,287 (95.7%)	2,389
Total <70 years	3,074	3,796 (55.2%)	6,917
Total in file	3,287	8,186 (71.4%)	11,473

The distribution of enrolees by health board area is given in *Table 2* below. The distribution of GPs both within Heartwatch and nationally appear similar, except for the NEA health board, where recruitment started early.

Table 2: Participation by health boards and HSE areas

	N patients	%	N (%) GPs	N (%) GPs (%) nationally[a]
HSE Dublin North East				
NA	934	8.1	43 (9.4)	240 (10.9)
NEA	2,056	17.8	66 (14.5)	163 (7.4)
Total	2,990	25.9	109 (23.9)	403 (18.3)
HSE Dublin Mid Leinster				
ECA	847	7.3	38 (8.3)	209 (9.5)
SWA	1,056	9.2	53 (11.6)	300 (13.6)
MA	834	7.2	25 (5.5)	123 (5.6)
Total	2,737	23.7	116 (25.4)	632 (28.7)
HSE West				
MWA	922	8.0	36 (7.9)	204 (9.2)
WA	1,122	9.7	49 (10.7)	256 (11.6)
NWA	968	8.4	32 (7.0)	131 (5.9)
Total	3,012	26.1	117 (25.6)	591 (26.7)
HSE South				
SA	1,598	13.9	68 (14.9)	372 (16.8)
SEA	1,205	10.4	46 (10.1)	212 (9.6)
Total	2,803	24.3	114 (25.0)	584 (26.4)
National Total	**11,542**	**100%**	**456 (20.6)**	**2,210**

[a] from GMS annual report 2004. Includes all GMS GPs and 226 GPs who do not have agreements under the scheme, but provide services under childhood immunisation, HAA, Heartwatch, Palliative care, Methadone treatment scheme

In *Table 3* the total number of patient visits completed is given. The majority of second visits (90%) were completed to December 2005, and almost 80% of third visits. The average number of days to the fourth visit was 360, close to the one year follow-up expected. Similarly, the average number of days to the eighth visit was 721, close to an expected two year follow-up of 730 days.

Table 3: Patient visits completed to Dec 2005

Visit	N	Mean days to visit
1	11,542	
2	10,129	131.8
3	9,018	248.4
4	7,990	358.0
5	7,020	462.8
6	5,986	559.6
7	4,793	646.5
8	3,522	721.3
9	2,326	790.1

One year follow-up cohort

All individuals having valid data at visit 1 and one year were included in this analysis. The total number was 7,099 and the closest visit to one year is given in *Table 4a*. The data from this visit was used in subsequent analysis of risk factors and medications.

The distribution of age and gender in this cohort is given in *Table 4b* and is similar to that of the original sample. The percentage of women and men who are GMS eligible is 83% and 71% respectively. There were slightly more GMS eligible patients in this cohort across all age categories than for the total sample *(Table 4c)*.

Table 4a: Visit closest to one year follow-up

Visit	N
2	190 (2.7%)
3	893 (12.6%)
4	2,734 (38.5%)
5	3,257 (45.9%)
6	25 (0.35%)
Total	**7,099**

Table 4b: Age and gender distribution of one year cohort

Age category	Males	Females	Total
<55	817	144 (15.0%)	961
55-64	1,617	360 (18.2%)	1,977
65-74	2,071	690 (25.0%)	2,761
75+	859	532 (38.3%)	11,391
Total with age & sex	5,364	1,726 (24.3%)	7,090

Table 4c: Age category by GMS status

Age category	Not GMS eligible	GMS eligible	Total
<55	462	499 (51.9%)	961
55-64	857	1,120 (56.7%)	1,977
65-74	514	2,246 (81.4%)	2,760
75+	45	1,344 (96.8%)	1,389
Total <70 yrs	1,783	2,482 (58.2%)	4,265
Total in file	1,878	5,209 (73.5%)	7,087

Two year follow-up cohort

All individuals having valid data at visit 1 and at one and two years were included in this analysis. The total number was 4,011 and the closest visit to two years is given in *Table 5a*. The data from this visit was used in subsequent analysis of risk factors and medications

The distribution of age and gender in this cohort is given in *Table 5b* and is similar to that of the original sample. The percentage of women and men who are GMS eligible is 85.7% and 72.2% respectively.

There were slightly more GMS eligible patients in this cohort across all age categories than for the total sample *(Table 5c)*.

Table 5a: Visit closest to two year follow-up

Visit	N
3	6 (0.2%)
4	47 (1.2%)
5	169 (4.2%)
6	438 (10.9%)
7	891 (22.2%)
8	1,265 (31.5%)
9	1,161 (29.0%)
10	34 (0.85%)
Total	**4,011**

Table 5b: Age and gender distribution of two year cohort

Age category	Males	Females	Total
<55	427	72 (14.4%)	499 (12.5%)
55-64	921	191 (17.2%)	1,112 (27.7%)
65-74	1,185	419 (26.1%)	1,604 (40.0%)
75+	492	301 (38.0%)	793 (19.8%)
Total with age & sex	3,025 (75.5%)	983 (24.5%)	4,008

Table 5c: Age group by GMS status in two year cohort

Age category	Not GMS eligible	GMS eligible	Total
<55	239	260 (52.1%)	499
55-64	447	665 (59.8%)	1,112
65-74	276	1,327 (82.8%)	1,603
75+	14	777 (98.2%)	791
Total <70 years	931	1,447 (60.9%)	2,378
Total in file	976	3,029 (75.6%)	4,005

Section 3: One year follow-up cohort

Risk factor data

There were substantial declines in several of the risk factors from visit 1 to the one year follow-up time point. *Table 6* gives the details of the actual levels in all patients at visit 1 and again at one year. In addition the difference between these is given, a negative value indicating a decline in the risk factor.

There are statistically significant declines for systolic and diastolic blood pressure, total and LDL cholesterol, body mass index and smoking prevalence. There was a significant decrease in HbA1c levels for those with diabetes at both visits.

There were an additional 215 (3.0%) new cases of diabetes diagnosed by one year, increasing the overall prevalence to 17.1%. By one year the majority had type 2 diabetes (1,001, 82.3%), followed by type 1 diabetes (110, 9.0%), and IGT (105, 8.6%). More women (19.4%) compared with men (16.4%) had diabetes, with little difference across age (<55 14.2%; 55-64 18.8%; 65-74 17.3%; 75+ 16.6%).

The percentage of patients within recommended targets had improved by one year, with only 35.5% outside target at one year for systolic blood pressure and 9.3% for diastolic blood pressure *(Table 7)*. Only 21.3% were outside range for total cholesterol and 22.5% for LDL cholesterol, and 12% remained smokers at one year.

Although the percentages outside target had improved for body mass index, waist circumference and exercise levels, the percentages remained high *(Table 7)*. The lack of improvement in exercise levels may explain the small change in BMI over time.

Many of the risk factor target levels were based on the recommendations of the Second Joint Task Force of European and other Societies on Coronary Prevention[6]. However, the Third Joint Task Force published their updated recommendations in 2003[4] and the targets for total and LDL cholesterol were compared.

For the Second Joint Task force these were <5mmol/l and <3mmol/l for total and LDL cholesterol respectively, and for the Third Task Force these had reduced to <4.5mmol/l and <2.5mmol/l for total and LDL cholesterol.

For comparison *Table 8* gives the percentage outside targets for the one year cohort using both sets of recommendations. There are improvements in all targets, but less so, as anticipated, when applying the Third Joint Task Force recommendations.

Table 6: Risk factor data on those in one year follow-up cohort (N = 7,099)

Variable	N with data at both visits	Baseline (visit 1) (means±SD except for smoking)	One (means±SD except for smoking)	Diff. between 1 yr and visit 1 (p value)[&]
Systolic BP	7,041	134.8±19.2	132.6±17.6	-2.2 (p<0.0001)
Diastolic BP	7,045	77.8 ±9.9	76.3±9.5	-1.5 (p<0.0001)
Total cholesterol	7,037	4.6±1.0	4.4±0.9	-0.26 (p<0.0001)
LDL cholesterol	7,023	2.7±0.9	2.5±0.8	-0.2 (p<0.0001)
Body mass index	6,733	28.1±4.1	28.0±4.1	-0.05 (p=0.009)
Fasting glucose[#]	4,138	5.4±2.0	6.0±4.3	+0.6 (p<0.0001)
HbA1c[$]	817	7.3±1.4	7.1±1.3	-0.2 (p=0.0005)
Waist circumference	6,336	95.6±12.4	95.6±11.9	-0.05 (p=0.66)
Smoking (%)	7,097	14.8%	12.0%	-2.8% (p<0.0001)

[#] Data based on non-diabetic patients at both visit one and one year; [$] Data based on diabetic patients at both visit one and one year.
[&] Mean change presented except for smoking. Paired t-test used for comparing mean difference, and McNemar's test for change in smoking %

Table 7: Percentage of patients outside target at one year for cohort of patients with data at one year

Variable	N with data at both visits	% outside target at visit 1	% outside target at 1 yr	% change (relative to visit 1)
Systolic BP	7,041	42.2	35.5	-15.9**
Diastolic BP	7,045	13.8	9.3	-32.6**
Total cholesterol	7,037	34.1	21.3	-37.5**
LDL cholesterol	7,023	33.1	22.5	-32.0**
Body mass index	6,733	76.7	76.1	-0.8
Fasting glucose	4,138	29.6	34.1	+15.2*
HbA1c	817	64.4	63.2	-1.9
Waist circumference[$]	6,336	71.1	70.6	-0.7
Smoking (%)	7,097	14.8	12.0	-18.9**
Exercise (%)	6,870	65.6	64.0	-2.4*

** p < 0.05*
*** p < 0.001 (McNemar's test)*
[$] different targets for men and women: < 94cm (M) and < 80cm (W)

Table 8: Percentage of patients outside target at one year for cohort of patients with data at one year – LDL and total cholesterol only using second and third joint task force recommendations

Variable	N with data at both visits	% outside target at visit 1	% outside target at 1 yr	% change (relative to visit 1)
LDL cholesterol <3mmol (2nd Taskforce)	7,023	33.1	22.5	-32.0
LDL cholesterol <2.5mmol (3rd Taskforce)	7,023	58.1	49.0	-15.7
Total cholesterol <5mmol (2nd Taskforce)	7,037	34.1	21.3	-37.5
Total cholesterol <4.5mmol (3rd Taskforce)	7,037	55.0	44.2	-19.6

Medications – one year follow-up cohort

There were substantial increases in medication usage between visit 1 and one year.

The largest increases in prescribing were for statins (at 7.0% absolute, or 8.8% relative increase), ACE inhibitors at 4.8% absolute increase, beta blockers with an increase of 2.5% and diuretics and ATII inhibitors at an increase of 2.1% and 1.5% respectively.

Table 9a gives details of the actual medication uptake levels in all patients at visit one and again one year later. In addition, the difference between these is given, with a positive value indicating a greater uptake in use of the medication.

There will be a proportion of those in whom the treatments are contraindicated (eg. 10%-15% for aspirin), and therefore it is likely that the maximum number of patients who can be treated are treated.

The percentage of changes to medication, including decreasing or increasing dose, discontinuation or initiating therapy at any visit up to one year, are given in the final column and *Figure 2*. In most cases there was only one change to medication.

For diabetic patients there were large increases in prescribing for aspirin, statin therapy and ACE inhibitors *(see Table 9b)* at one year follow-up.

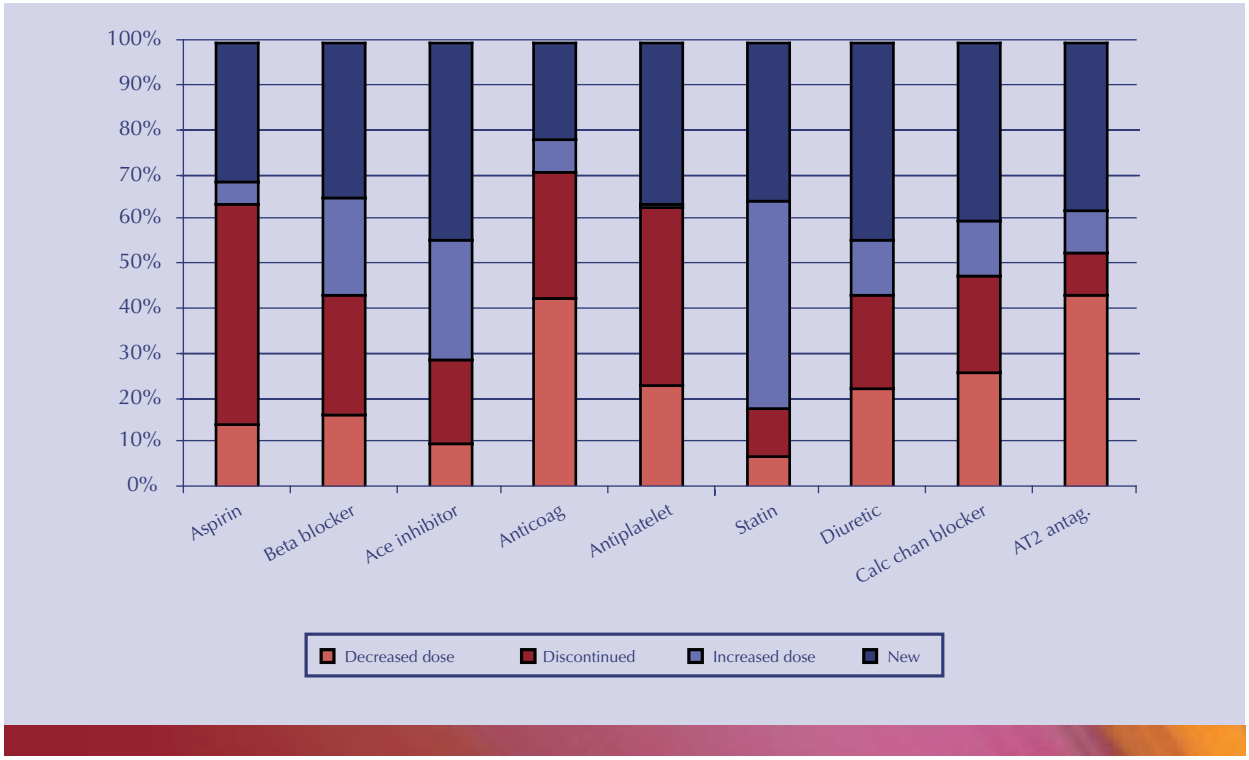
Table 9a: Medication usage at visit one and one year

Medication	Baseline (visit 1) % uptake	1 yr % uptake	Diff. between 1 yr & visit 1	Medication change % (% of those with only 1 change)
Sulphonylureas	6.7	6.8	+0.1	32.1 (85.4)
Biguanides	7.3	7.9	+0.6	33.2 (84.0)
Glucosidase	1.3	0.7	-0.6	44.0 (93.0)
Other hypoglycaemic agents	1.3	1.1	-0.2	46.2 (92.0)
Aspirin	87.0	87.0	0.0	4.6 (90.2)
Beta blocker	59.8	62.3	+2.5	13.7 (86.6)
Ace inhibitors	44.4	49.2	+4.8	20.1 (86.4)
Anticoagulants	10.7	10.7	0.0	26.4 (83.8)
Antiplatelets	17.2	17.4	+0.2	29.4 (91.3)
Statins	79.2	86.2	+7.0	17.7 (85.5)
Fibrate	2.7	2.3	-0.4	65.0 (89.6)
Other Lipid lowering	4.0	4.0	0.0	72.0 (92.3)
Diuretic	25.0	27.1	+2.1	22.5 (88.6)
Ca channel blocker	19.4	19.4	0.0	20.4 (89.6)
ATII inhibitor	8.7	10.2	+1.5	33.5 (89.4)
Other antihypertensive	12.4	11.4	-1.0	33.5 (100)

Table 9b: Medication usage among diabetic patients at visit one and one year. (at both visits, N = 1,216)

Treatment	Baseline (visit 1) % uptake	1 yr % uptake	Diff. between 1 yr & visit 1	Medication change (any of decreased, increased dose, discont., new
Aspirin	85.9	87.0	+1.1	7.8
Statin	78.6	85.3	+6.7	23.3
ACE inhibitor	58.2	63.5	+5.3	23.4

Figure 2: Changes in medication from visit one to one year follow-up visit for all patients with any change recorded



Section 4: Two year follow-up cohort

Risk factor data

There were substantial declines in several of the risk factors from visit 1 to the two year follow-up time point. *Table 10* gives the details of the actual levels in all patients at visit 1 and again at two years. In addition the difference between these is given, a negative value indicating a decline in the risk factor, etc. There are statistically significant declines for systolic and diastolic blood pressure, total and LDL cholesterol, body mass index and smoking prevalence. All levels had declined even further than at one year, suggesting that continued improvements beyond the initial year were possible. There was a slight decrease in HbA1c levels for those with diabetes at both visits, but the percentage outside target did not change significantly. In addition, the percentage of patients with diabetes having HbA1c levels ≥7.5% was 34.5% at visit 1, 30.2% at one year and 29.7% at two years, suggesting some improvement in those in the highest band. Age-adjustment (for two year period) made no difference to the results.

By two years there was an additional 170 (4.2%) new cases of diabetes from visit 1, increasing the overall prevalence of diabetes to 18.7% at two years.

The percentage of patients within recommended targets had improved by two years, and only 34.2% were outside target at two years for systolic blood pressure and 7.6% for diastolic blood pressure *(Table 11)*. Only 16.4% were outside the range for total cholesterol and 16.6% for LDL cholesterol, and 10.1% remained smokers at two years.

Although the percentages outside target were improved for body mass index, waist circumference and exercise levels, the percentages still remained relatively high. In addition the changes from visit 1 to one year within this cohort are also given for comparison with data from the earlier one year only follow-up cohort.

For comparison of Second and Third Joint Task Force recommendations for total and LDL cholesterol, *Table 12* gives the percentages outside target for the two year cohort. There are improvements in all targets, but less so, as anticipated, when applying the Third Joint Task Force recommendations.

Table 10: Risk factor data on those in two-year follow-up cohort, who also have data at one year (N = 4,011)

Variable	N with data at visit	Baseline (visit 1) (means ±SD except smoking)	1 yr (means ±SD except smoking)	2 yr (means ±SD except smoking)	Diff. visit 1 and 2 yr follow-up (p value) &
Systolic BP	4,011	135.2±18.8	132.5±17.4	132.5±17.2	-2.7 (p<0.0001)
Diastolic BP	4,011	77.9 ±9.8	76.3±9.4	75.6±9.0	-2.3 (p<0.0001)
Total cholesterol	4,009	4.7±0.9	4.4±0.9	4.3±0.9	-0.4 (p<0.0001)
LDL cholesterol	4,008	2.7±0.8	2.5±0.7	2.4±0.7	-0.3 (p<0.0001)
Body mass index	3,908	28.1±4.1	28.0±4.1	28.0±4.1	-0.1 (p<0.0001)
Fasting glucose#	2,442	5.3±1.7	5.3±1.7	5.3±1.7	0.0 (p=0.031)
HbA1c$	501	7.2±1.5	7.0±1.2	7.1±1.2	-0.1 (p=0.08)
Waist circumfer.	3,550	95.7±12.2	95.6±12.0	95.5±11.6	-0.2 (p=0.35)
Smoking (%)	4,011	13.7%	11.3%	10.1%	-3.6% (p<0.0001)

 # Data based on non-diabetic patients at both visit 1 and 1 year; $ Data based on diabetic patients at visit 1, 1 and 2 years – the percentage of those with Hba1c ≥7.5% was 34.5% at visit 1, 30.2% at 1 year and 29.7% at 2 years.

& Means change presented except for smoking. Paired t-test used for comparing mean difference, and McNemar's test for change in smoking %.

Table 11: Percentage of patients outside target at two years for cohort of patients with data at one and two years

Variable	N with data at visit	% outside target at visit 1	% outside target at 1 yr	% outside target at 2 yrs	% change relative to visit 1 (1 yr improvement)
Systolic BP	4,011	43.4	35.6	34.2	-21.2** [-18]
Diastolic BP	4,011	13.9	9.4	7.6	-45.3** [-32.4]
Total cholesterol	4,009	34.7	21.7	16.4	-52.7** [-37.5]
LDL cholesterol	4,008	33.5	22.8	16.6	-50.5** [-31.9]
Body mass index	3,908	75.7	75.2	74.9	-1.1 [-0.7]
Fasting glucose	2,442	28.1	31.2	28.2	+0.4 [+11]
HbA1c$	501	66.3	64.5	67.1	+1.2 [-2.7]
Waist circumfer.#	3,550	70.7	70.9	70. 5	-0.3 [+0.3]
Smoking (%)	4,011	13.7	11.3	10.1	-26.3** [-17.5]
Exercise	3,980	62.5	61.8	61.7	-1.3 [-1.1]

*** p < 0.001 (McNemar's test)*

$ Data based on diabetic patients at visit 1, 1 and 2 years – the percentage of those with HbA1c ≥ 7.5% was 34.5% at visit 1, 30.2% at 1 year and 29.7% at 2 years.

 # Different targets for men and women: < 94cm (M) and < 80cm (W)

Table 12: Percentage of patients outside target at two years for the cohort of patients with data at one and two years – LDL and total cholesterol only using second and third taskforce results

Variable	N with data at both visits	% outside target at visit 1	% outside target at 2 yrs	% change (relative to visit 1)
LDL cholesterol <3mmol (2nd Taskforce)	4,008	33.5	16.6	-50.5
LDL cholesterol <2.5mmol (3rd Taskforce)	4,008	59.1	42.7	-27.7
Total cholesterol <5mmol (2nd Taskforce)	4,009	34.7	16.4	-52.7
Total cholesterol <4.5mmol (3rd Taskforce)	4,009	56.1	36.9	-34.2

Medications – two year follow-up cohort

There were substantial increases in medication usage between visit 1 and two years. The largest increases in prescribing were for statins (at 11.4% absolute, or 14.5% relative increase), ACE inhibitors at 7.3% absolute increase, beta blockers with an increase of 4.2% and diuretics and ATII inhibitors at an increase of 3.6% and 2.9% respectively.

Table 13a gives details of the medication uptake levels in all patients at visit 1 and two years later. In addition the difference between these is given, with a positive value indicating an increase in the uptake of the medication. The percentage of changes to medication are given in the final column, including decreasing or increasing dose, discontinuation or initiating therapy at any visit up to two years, are given in the final column and *Figure 3*. In most cases there was only one change to medication.

The trends in prescribing of secondary preventive therapies continued, and by two years, 91% of diabetic patients were receiving statin therapy *(Table 13b)*.

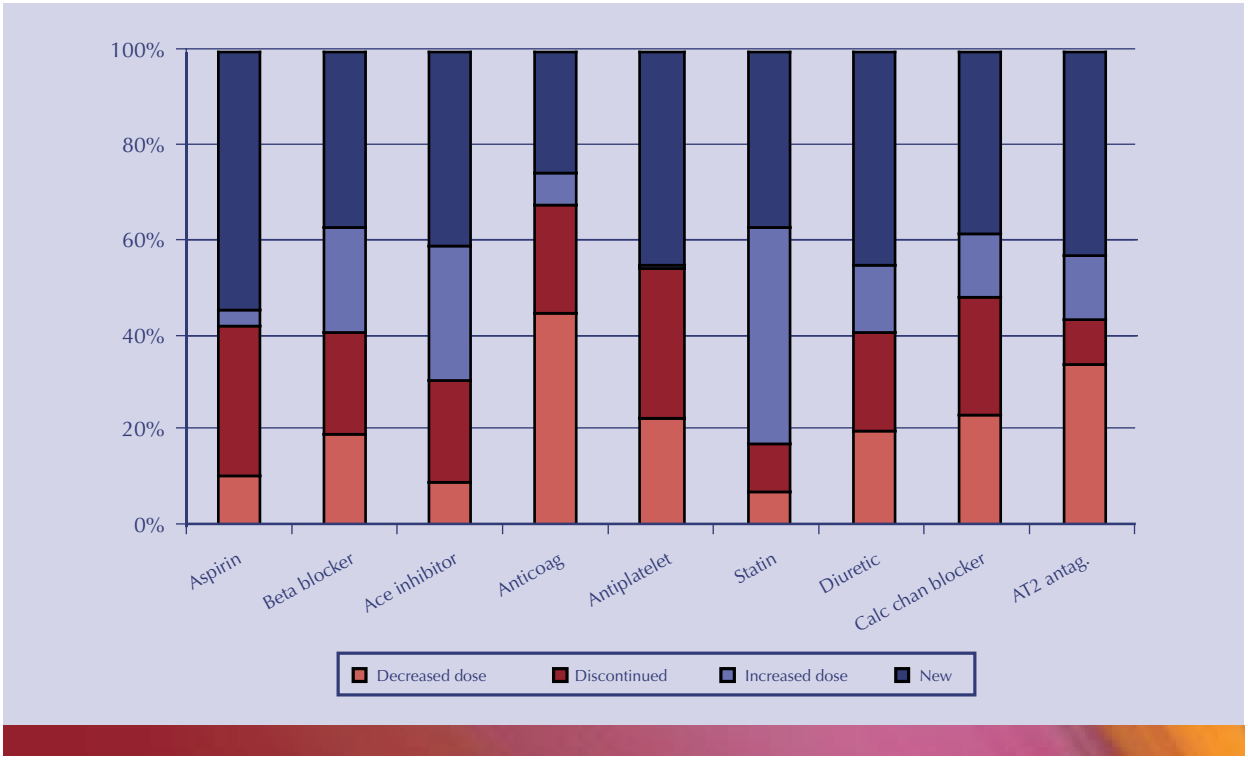
Table 13a: Medication usage at visit 1 and 2 years

Medication	Baseline (visit 1) % uptake	2 yr % uptake	Diff. between 2 yrs & visit 1	Medication change % (% of these with only 1 change)
Sulphonylureas	7.0	7.3	+0.3	43.4 (72.6)
Biguanides	7.2	8.6	+1.4	46.7 (72.9)
Glucosidase	1.4	0.6	-0.8	48.5 (94.0)
Other hypoglycaemic agents	1.3	1.25	-0.05	59.0 (78.3)
Aspirin	87.2	86.8	-0.4	8.2 (100)
Beta blocker	59.2	63.4	+4.2	23.2 (75.4)
Ace inhibitors	43.5	50.8	+7.3	32.1 (74.9)
Anticoagulants	10.3	10.0	-0.3	41.5 (75.2)
Antiplatelets	14.1	16.0	+1.9	45.1 (82.3)
Statins	78.5	89.9	+11.4	31.0 (73.0)
Fibrate	2.5	1.8	-0.7	63.3 (83.3)
Other Lipid lowering	3.9	4.9	+1.0	76.9 (82.2)
Diuretic	25.3	28.9	+3.6	35.3 (75.6)
Ca channel blocker	20.7	21.0	+0.3	33.9 (82.1)
ATII inhibitor	8.9	11.8	+2.9	52.4 (80.4)
Other antihypertensive	12.5	11.1	-1.4	37.6 (80.4)

Table 13b: Medication usage in those with diabetes at visit 1 and two years (at both visits, N = 582)

Treatment	Baseline (visit 1) % uptake	2 yr % uptake	Diff. between 2 yr & visit 1	Medication change (any of decreased, increased dose, discont., new
Aspirin	84.0	85.1	+1.1	11.6%
Statin	77.7	90.7	+13.0	33.6%
ACE inhibitor	61.0	66.0	+5.0	27.4%

Figure 3: Changes in medication from visit 1 to two year follow-up visit for all patients with any change recorded



Section 5: Events during Heartwatch programme

A total of 2,499 events were recorded up to December 2005, experienced by 1,762 individuals (or 15.3% of all patients).

Of those with an event, almost 30% experienced more than one event *(Table 14a)*.

Table 14a: Patient visits completed to Dec 2005

	No of patients with an event	% of patients
1 event	1,265	71.8
2 events	342	19.4
3 events	103	5.8
4 or more events	52	3.0
Total	**1,762**	**100.0**

Table 14b shows the frequency of each event, appointment and admission recorded to Dec 2005. Approximately 13.4% of all patients required a hospital admission, and 5% of patients attended a cardiology outpatient department.

Table 14b: Frequency of type of events

	N of events	% of all events
Hospital admission	1,546	61.9
A & E admission	187	7.5
Cardiology OPD	568	22.7
PCI/PTCA	301	12.0
CABG	150	6.0
Cardiac arrest	106	4.2
MI	231	9.2
TIA	79	3.2
CVA	105	4.2
PVD	75	3.0
Intermittent claudication	34	1.4
Arrhythmia	227	9.1
Heart Failure	221	8.8
Angina pectoris	603	24.1
Conductive Disorders	61	2.4
Adverse Drug Reaction	69	2.8
Deaths	272	10.9

Section 6: GMS prescribing data analysis

Prescribing data from the GMS payments board (now HSE – Primary Care Reimbursement Services, PCRS) pharmacy claims database was used to compare cardiovascular disease prescribing patterns between:

- GMS patients within the Heartwatch programme and all GMS coronary heart disease (CHD) patients under the Heartwatch GP and
- Heartwatch and non-Heartwatch GPs before and during the Heartwatch programme (years 2002 and 2004).

A list of GMS doctor numbers (DNUMs) in the Heartwatch programme was provided by the INDC. This list was merged with the GMS prescribing database for years 2002 and 2004 to identify Heartwatch and non-Heartwatch GPs.

The HSE-PCRS scheme is a means-tested scheme providing free medical care for all those eligible and covers approximately 31% of the total population (approximately 1.2 million).

Prescriptions are dispensed through community pharmacies operating within the scheme, and a computer system processes pharmacists' claims which, in addition to providing details on prescription items, also contain (unlike Prescription Analysis and Cost (PACT) data) demographic data on patients, such as age and sex.

No information on diagnosis is recorded. All prescription items are coded according to the World Health Organization (WHO) Anatomical Therapeutic Chemical (ATC) classification system.

National data for all those aged 25 years and over were included. The following treatments (ATC codes) were considered:

- Nitrate therapy (C01DA)
- Aspirin (B01AC06)
- Anticoagulants (B01AA/B)
- All antiplatelets (B01AC)
- Diuretics (C03)
- Beta blockers (C07)
- Calcium channel blockers (C08)
- ACE inhibitors (C09)
- Statins (C10AA)
- All lipid lowering drugs (C10).

As Heartwatch is a secondary preventive programme, interest is mainly in those with established CHD, therefore only those patients who had received either a nitrate or aspirin prescription during the year in question were considered to have CHD. Prescribing rates of secondary preventive therapies are considered in this group alone.

Logistic regression analysis was used to examine the likelihood of receiving preventive therapies in Heartwatch compared with non-Heartwatch GPs.

As many of the patients registered with Heartwatch GPs may not have been included in the Heartwatch Programme, the results probably dilute the effect of Heartwatch Programme.

Table 15 gives the total number of GMS eligible patients with CHD (as defined by prescribing of any nitrate or aspirin) during 2002, by age and gender. It shows the increasing trend in CHD with age, and in men compared with women.

Table 15: Age-specific prevalence of CHD in the GMS eligible population (2002 data)

	GMS eligible population		
	>25 yrs with CHD	**All GMS eligible patients**	**Rate per 1,000 GMS eligible pop**
GMS population	177,224	809,882	218.8
Male patients	84,004	347,624	241.7
Female patients	93,220	462,258	201.7
Age			
25-34 yrs	1,528	100,813	15.2
35-44 yrs	3,348	103,703	32.3
45-54 yrs	10,552	108,527	97.2
55-64 yrs	23,923	113,774	210.3
65-74 yrs	58,375	175,148	333.3
75+ years	79,498	207,917	382.4

Table 16 compares the CHD patient populations between participating Heartwatch GMS GPs in the GMS prescribing database, and the Heartwatch database. There are large differences in the age and gender distributions of those individuals in the Heartwatch programme and those in the GMS CHD population. This is likely to have an effect on prescribing of secondary preventive therapies within each group and is adjusted for in subsequent analyses.

Table 16: Heartwatch GMS GPs only: Study population characteristics in (1) Heartwatch GMS patients in the programme and (2) All GMS CHD patients from the GMS database

Heartwatch GMS GPs only	**All GMS CHD patients in programme (1)**		**All GMS CHD patients from GMS database (2)**	
	N	**%**	**N**	**%**
Number of GPs	452		452	
GMS population >25 yrs with CHD	8,200		50,667	28.6
Male patients	5,915	72.1	23,946	47.3
Female patients	2,285	27.9	26,721	52.7
Age				
<55 yrs	786	9.6	4,616	9.1
55-64 yrs	1,695	20.7	6,893	13.6
65-74 yrs	3,418	41.8	16,250	32.1
75+ years	2,287	27.9	22,908	45.2

Table 17 gives the percentage prescribing of secondary preventive therapies for all GMS patients in Heartwatch and all GMS patients, from the prescribing database, registered with Heartwatch GPs only. The results show that there was higher prescribing rates for most secondary preventive therapies (except calcium channel blockers and diuretics) for GMS CHD patients in the Heartwatch Programme compared with all GMS CHD patients registered with Heartwatch GPs.

Table 17: Secondary preventive therapies at visit 1 for those with one year follow-up and all HW GMS patients compared with GMS data for Heartwatch GPs only

Secondary preventive therapies	Heartwatch GPs – all GMS CHD patients in programme (1) (% prescribed)	Heartwatch GPs – all GMS CHD patients from GMS database (2) (% prescribed)	Odds ratio[1] (95% CI) for secondary preventive therapies in (1) vs (2)
Beta blockers	59.7	38.8	2.1 (1.96, 2.20)
Any ACE inhibitors	45.7	37.1	1.3 (1.23, 1.38)
Statins	77.4	50.1	2.9 (2.68, 3.07)
Calcium channel blockers	20.8	23.6	0.8 (0.78, 0.90)
Diuretics	28.7	40.8	0.7 (0.67, 0.76)

[1] *Adjusted for gender and age of patients*

Tables 18 and 19 give the percentage prescribing of secondary preventive therapies in the GMS prescribing database for 2004 and 2002 among those individuals with established CHD (ie. already in receipt of a nitrate or aspirin prescription).

The results show that while rates of prescribing of secondary preventive therapies were similar for Heartwatch and non-Heartwatch GPs in 2002, they did increase slightly in Heartwatch GPs compared with non-Heartwatch GPs by 2004.

However, the overall GMS prescribing rates still remained much lower than those observed in the individuals in the Heartwatch Programme. This may be for a number of reasons.

Firstly, the distribution of age and gender is not the same between the Heartwatch enrollees and those within the GMS database. There is a preponderance of men in the Heartwatch programme (72.1%) compared with the GMS prescribing database (47.3%), and the elderly are over-represented in the GMS population compared with Heartwatch (twice the rate of those over 75 years, and almost half the rate of 45-64 year olds in GMS compared with Heartwatch). This is likely to have a great impact on prescribing patterns and has been adjusted for in the analysis.

Secondly, the GMS database contains all GMS eligible patients who were dispensed a prescription, irrespective of whether or not they were enrolled in the Heartwatch programme.

A Heartwatch GP may have enrolled only a fraction of their CHD patients into the Programme, and thus the effects of the Heartwatch Programme are likely to have been diluted by inclusion of all patients.

Finally, in this analysis we only examine GMS eligible patients, and therefore if the GP enrolled non-GMS patients, these will not be identified in this analysis.

Table 18: Secondary preventive prescribing in the CHD population (those already prescribed nitrate and/or aspirin) in 2004 [baseline uptake in Heartwatch programme with one year follow-up]

Secondary preventive therapies	Heartwatch GPs (% prescribed)	Not Heartwatch GPs (% prescribed)	Odds ratio for prescribing in Heartwatch vs non-Heartwatch GPs[1]
Beta blockers	39.7 [56.9]	39.3	1.02 (1.00,1.04)
Any ACE inhibitors	38.0 [44.4]	37.2	1.04 (1.02,1.06)
Statins	50.9 [77.3]	49.2	1.08 (1.06,1.10)
Calcium channel blockers	24.4 [19.0]	23.9	1.03 (1.01,1.06)
Diuretics	42.4 [24.8]	41.8	1.03 (1.01,1.05)

[1] *Adjusted for gender and age of patients*

Table 19: Secondary preventive prescribing in the Higher Risk CHD population (those already prescribed nitrate and/or aspirin) in 2002 [baseline uptake in Heartwatch programme with one year follow-up]

Secondary preventive therapies	Heartwatch GPs (% prescribed)	Not Heartwatch GPs (% prescribed)	Odds ratio for prescribing in Heartwatch vs non-Heartwatch GPs[1]
Beta blockers	35.6 [56.9]	35.8	0.99 (0.97,1.01)
Any ACE inhibitors	34.1 [44.4]	33.4	1.04 (1.01,1.06)
Statins	35.8 [77.3]	35.3	1.03 (1.00,1.05)
Calcium channel blockers	25.2 [19.0]	25.1	1.00 (0.98,1.03)
Diuretics	43.5 [24.8]	43.6	1.0 (0.98,1.02)

[1] *Adjusted for gender and age of patients*

Differences in prescribing between Heartwatch enrollees and those included in the GMS prescription database likely to be due to differences observed in age and gender between the two study samples (see Table 1).

Section 7: Heartwatch impact modelling – two year follow-up

Methods

The cell-based mortality model in Microsoft Excel has been described in detail elsewhere.[7] In brief, the number of CHD deaths prevented or postponed by each specific secondary preventive treatment and by each risk factor change was calculated for the Heartwatch cohort (those having follow-up visit data at one and two years) using epidemiological modelling.

The total number of eligible patients at visit 1 was calculated as the number of eligible patients in the two year follow-up cohort (3,937 under 85 years of age) plus the number who died before reaching the two year follow-up (191), giving a total of 4,128.

The observed death rate over two years, therefore, was 4.6%. From this the expected number of CHD deaths was calculated for the 4,128 eligible population based on case fatality rates in those having had a myocardial infarction or coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI). The expected number of CHD deaths in this eligible population of 4,128 was 298 (7.2%), a 50% increase on the observed rate.

We identified and incorporated data for men and women aged 25 to 84 years in the Heartwatch Programme cohort, stratified by age and sex, detailing:

- Use of specific medical treatments
- Trends in major cardiovascular risk factors (smoking, total cholesterol, hypertension) over two years
- Effectiveness of specific cardiology treatments
- Effectiveness of specific risk factor reductions.

Data on the effectiveness of therapeutic interventions post-MI and the mortality reduction from specific population cardiovascular risk factor changes came from published randomised controlled trials, meta-analyses and cohort studies.[8-12]

The mortality reduction for each treatment was calculated using the relative mortality reduction reported in published meta-analyses and trials. Further details on this are given in the *Table* below. A high compliance rate (90%) was assumed for taking all medications.

Results

The results from the IMPACT model are given below *(Table 20a)* for CHD deaths prevented or postponed due to treatments and management of risk factors within the Heartwatch programme.

Estimating costs of the Heartwatch Programme

In order to examine the additional costs associated with the Heartwatch programme, the costs of all 'new' secondary preventive therapies (including aspirin, statins, ACE inhibitors and beta blockers) initiated and continued during the programme were calculated. Drug costs were based on a weighted average of the common drugs prescribed within the GMS scheme during 2004 (including pharmacy fee).

Risk factor and goal	Relative risk reduction: CHD death	Source of evidence	Relative risk reduction: Recurrent MI
Platelet function – Aspirin	15%	ATC[8]	34%
Beta blocker post-MI	23%	Freemantle et al 1999[9]	26% [13]
Ace inhibitor post-MI	23%	Garg et al[10]	22% [14]
Cardiac rehabilitation	27%	Taylor 2002[11]	-
LDL, total cholesterol lowering, statin	23%	Wilt et al 2004[12]	38% [15]

In addition to the drug costs, costs for the additional Heartwatch visits (€50 per visit) and administration costs, which include IT, rental of premises, staff in regional teams, consumables, overheads, hardware and software (estimated at €1,000,000 per annum) were included. As the follow-up is for two years, no discounting on costs or life years gained have been made. The perspective for the health economic evaluation is primary care provider and does not include costs of hospitalisation, etc.

Table 20b gives the additional costs over the first year of the programme and *Table 20c* over the two years of the programme, in the two year cohort. Most of the additional costs are associated with the fee paid for the GP visits and administration.

Table 20d gives the incremental cost-effectiveness ratio (ICER) per death prevented or postponed and life years gained and indicates that the Heartwatch programme provides value for money. An ICER < €20,000 per life year gained would be considered very cost-effective and therapeutic interventions with ICERs < €58,000 are frequently considered cost-effective. For example, an analysis of the cost-effectiveness of simvastatin for secondary prevention using the 4S Study found the cost per life year saved was £5,502 (€7,975), well within the range for cost-effectiveness.[16]

Table 20a: CHD deaths prevented or postponed as a result of increases in treatment uptake levels and risk factor changes in Heartwatch

Medical treatments	**Total eligible***	**Deaths prevented/ postponed**
Secondary prevention Post myocardial Infarction	2,064	16
Secondary prevention Post-revascularisation (CABG/Angioplasty)	2,064	9
Total Treatment Effects	**4,128**	**25**
Risk Factors	**Relative changes In risk factor (%)**	**CHD deaths prevented or postponed**
Smoking	-26%	8
Cholesterol	-8%	40
Diastolic BP	-9%	8
Total Risk Factor Effects		**56**
Total from treatments and risk factors		**81**

** Number at visit 1 with one and two year follow-up data*

Table 20b: Additional costs over the first year of the programme (in two year cohort)

		Total incremental expenditure due to Heartwatch Programme (€)	Incremental expenditure per patient over 1 yr (€)
Secondary prevention therapies	Aspirin[a]	4,661	1.18
	Statin[b]	164,354	42.0
	Beta blocker[c]	14,329	3.6
	ACE inhibitors[d]	37,187	9.4
	Total	220,531	56.0
Cost of GP visits		868,600	220.6
Administration costs		1,000,000	254.0
Total		**2,089,131**	**530.6**

[a] Assumed cost €0.21 per day; [b]€1.49 per day; [c]€0.38 per day; [d]€0.65 per day based on weighted costs from GMS prescribing database.

Table 20c: Additional costs over the two years of the programme (in two year cohort)

		Total incremental expenditure due to Heartwatch Programme (€)	Incremental expenditure per patient over 2 yrs (€)
Secondary prevention therapies	Aspirin[a]	13,804	3.50
	Statin[b]	477,920	121.4
	Beta blocker[c]	47,141	12.0
	ACE inhibitors[d]	117,608	29.9
	Total	656,473	166.7
Cost of GP visits		1,512,550	384.2
Administration costs		2,000,000	508.0
Total		**4,169,023**	**1,059.0**

[a] Assumed cost €0.21 per day; [b]€1.49 per day; [c]€0.38 per day; [d]€0.65 per day based on weighted costs from GMS prescribing database.

Table 20d: Cost-effectiveness of Heartwatch Programme over the two years of the Programme (in two year cohort)

	Total incremental expenditure (€)	Total deaths prevented or postponed	Incremental cost per death prevented or postponed	Incremental cost per life year gained (€)[1]
Total secondary preventive therapies	656,473	81	8,105	1,258
Drug costs with cost of all GP visits and administration costs	4,169,023	81	51,469	7,987

Costs based on additional costs incurred as a result of the Programme. [1] There were 522 estimated life years gained from the Programme.

Section 8: Heartwatch GP variations in patient demographics and secondary preventive therapies prescribed

The figures in this section show the distribution of the numbers of patients and patient characteristics by GP, for all 11,542 patients in the Heartwatch Programme.

Table 21 gives the 10th and 90th centiles for these distributions and indicates wide variation for numbers of patients recruited, and percentage male and GMS eligible. The variation in mean age was less evident.

Table 21: Variation in number of patients recruited, mean age of patient, % males and % GMS eligible by GP

	10th Centile	90th Centile	Ratio 90th/10th	Min, Max
Number of patients	15	44	2.9	1, 213
Mean age	62.2	70.7	1.1	40.6, 81.7
% male	57.9	90.0	1.6	0, 100
% GMS eligible	50.0	93.3	1.9	0, 100

Variation in secondary preventive therapies

For the two year follow-up cohort, standardised prescribing ratios (SPRs),[17] similar to standardised mortality ratios, were calculated for each GP based on standardising for their total age/gender population recruited within the Heartwatch Programme. The expected numbers were calculated from the total secondary preventive prescribing of all heartwatch GPs. *Table 22* gives the 10th and 90th centiles of the GP SPRs for secondary preventive therapies and the ratio (as a measure of variation) of these values.

The trend is towards less variability over time for all therapies, although there has been little change in the variation of aspirin prescribing over time. The greatest change was observed in the prescribing of statins, with increased prescribing over time and reduced variability. Reduced variability indicates better quality of care for the patients, as there is greater consensus amongst the GPs.

Table 22: Variation in SPRs for GP prescribing of aspirin, beta blockers, ACE inhibitors and statins at baseline, one year and two years

Treatment		10th Centile	90th Centile	Ratio
Aspirin	Baseline	81.6	116.1	1.4
	One year	82.0	116.5	1.4
	Two years	78.1	117.1	1.5
Beta blockers	Baseline	59.9	147.8	2.5
	One year	65.3	148.8	2.3
	Two years	63.9	147.8	2.3
ACE inhibitors	Baseline	57.2	169.5	3.0
	One year	60.6	159.9	2.6
	Two years	57.0	154.1	2.7
Statins	Baseline	67.3	128.2	1.9
	One year	77.7	116.7	1.5
	Two years	80.7	112.3	1.4

Discussion

Discussion

Background

As is the case within the international community, it is well established that morbidity and mortality from cardiovascular disease is one of the greatest challenges facing the Irish Health Service.

The Heartwatch Programme, now in it's fourth year of operation, sets out to tackle the problem of cardiovascular disease in Ireland by establishing a strategic national approach to the implementation of internationally recognised cardiovascular prevention guidelines.

The implementation of the national programme has been undertaken in a spirit of partnership between all of the parties including the Department of Health and Children, the Health Boards (now the Health Services Executive), the Irish Heart Foundation and the Irish College of General Practitioners as the Heartwatch Programme is the main focus of delivery of the Cardiovascular strategy in the primary care setting.

Ireland is now leading the way in Europe, as such an innovative and comprehensive national approach to the prevention of cardiovascular disease has not been previously adopted.

Heartwatch has now established the largest database on cardiovascular disease within Primary Care in Ireland, with over 13,000 patients now registered to the programme and data collected on over 80,000 GP/patient consultations.

The independent analysis in this report includes information on patient outcomes and projections on reductions in morbidity and mortality using modelling. These results may be extrapolated to the total population eligible for secondary prevention (and possibly beyond this).

The calculated number of deaths prevented or postponed and life years gained by enrolment in Heartwatch are presented, based on analyses of the Heartwatch database up to end of November 2005, as well as an economic analysis of patient care using defined indicators.

Clinical findings

Patients involved in the Heartwatch Programme have shown significant improvements in the control of certain risk factors including systolic blood pressure, diastolic blood pressure, total cholesterol, LDL cholesterol and smoking.

These are the three main risk factors which have been shown to account for approximately 60% of the decline in coronary heart disease mortality in Ireland as elsewhere.[7]

However, little or no improvements were shown for BMI, waist circumference or exercise, but internationally it has also been difficult to achieve changes in BMI, exercise etc.[3] Changes in these risk factors may require a more direct intervention to modify lifestyle, which might include both individually tailored advice on diet and exercise regimes, as well as a more team based approach.

Treatment uptake levels have increased considerably, particularly in relation to statin therapy, with 90% of participants receiving this therapy at two years. The programme had shown significant increases in evidence-based prescribing across several secondary preventive therapies, in some cases to the optimal level achievable.

There have been improvements in the monitoring and screening for diabetes, with an additional 4.2% of diabetes patients identified at two years, which represents a 29% improvement in detection rate and increases in prescribing of secondary preventive therapies in this high risk population, with nine out of 10 patients now receiving statin therapy.

Given the increasing prevalence of diabetes in the population, improvements in this area are essential.

A reduction in the GP variability for prescribing of secondary preventive therapies was found over the one and two years of the Programme, in particular for statin therapy, where the variability was reduced from 1.9 to 1.4 fold. This represents a 26% improvement on the variation between GPs prescribing and demonstrates the improvements in the quality and consistency of care provided by GPs within the Programme.

Key Findings

Risk Factor	Outcome
Systolic BP	21.2% Improvement *(See Section 4)*
Diastolic BP	45.3% Improvement *(See Section 4)*
Total Cholesterol	52.7% Improvement *(See Section 4)*
LDL Cholesterol	50.5% Improvement *(See Section 4)*
Smoking	26.3% Improvement *(See Section 4)*
Body Mass Index	1.1% Improvement *(See Section 4)*
Waist Circumference	0.3% Improvement *(See Section 4)*
Exercise	1.3% Improvement *(See Section 4)*
Treatment Uptake levels	Significant Improvements *(See Section 4)*
GP Variation in prescribing	26% Improvement *(See Section 8)*
Monitoring & Screening Diabetes	29% Improvement *(See Section 4)*
Mortality	81 Deaths Prevented or Postponed *(See Section 7)*
Morbidity	522 Life Years Gained *(See Section 7)*
Cost Effectiveness	€7,987 per LYG – Very Cost Effective *(See Section 7)*

Heartwatch GMS patients were more likely to receive statin therapy, ACE inhibitors and beta blockers, when compared with all coronary heart disease GMS patients under the care of the Heartwatch GP, but less likely to receive diuretics or calcium channel blockers.

Therefore, it appears that although a GP may be involved in the Heartwatch Programme, not all patients with CHD under their care may receive the same secondary preventive therapies. This is an area that may require further evaluation.

The Heartwatch Programme has been shown to be both effective and cost-effective. It has been shown to increase lives saved and life years gained, and with the incremental cost per life year gained at €7987, is a very cost-effective programme.

This is similar to other studies, such as the cost-effectiveness of simvastatin for secondary prevention using the 4S Study, which found the cost per life year saved was £5,502 (€7,975), well within the range for cost-effectiveness.[16] Incremental cost effectiveness ratios (ICERs) less than €20,000 per life year gained are considered to be very cost effective.

Using epidemiology modelling 81 deaths are estimated to have been prevented or postponed and 522 life years gained over the two years of the Heartwatch Programme.

Future progress

The national Heartwatch programme is the first national structured programme to examine coronary heart disease in Ireland.

It has demonstrated the feasibility of delivering a structured care programme to a large proportion of the population, with improvements in quality and access to healthcare.

Unlike randomised controlled trials, the Heartwatch Programme has captured 'real-life' healthcare in a representative group of general practitioners nationally.

This makes it more generalisable to a wider population than a randomised controlled trial.[18]

The Heartwatch Programme has provided valuable data on heart disease in primary care in Ireland. It is the largest database on cardiovascular disease within primary care in Ireland and constitutes a valuable data resource for secondary analysis.

The anonymous database is available, on application and subject to approval, to academic and medical research organisations for this purpose.

The Heartwatch Programme sets the standard of care that should be achieved in all such patients, by showing significant improvements in outcomes as well as being very cost-effective. Given the success of the programme, which involved over 460 general practitioners, it could be seen as a suitable template for the future management of chronic illness in primary care.

Following the independent review of the data from Heartwatch patients who have attended and completed one or two year follow-up visits, the benefits to be achieved in the programme are evident. There is an urgency to address the need to extend this programme to the whole population and ensure that equity and access to this service is available to all patients and practices.

References & Appendix

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Appendix 1

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Appendix II

Early versus later enrollers

It had been suggested that those patients enrolled into the study earlier on may have differed in terms whether they were prevalent or incident (new) cases. In order to examine any differences between these groups, demographics, risk factor changes and uptake of treatments, were compared.

Age and GMS eligibility differed significantly between the early and late enrollers who had a one year follow-up visit, with slightly more elderly individuals and more GMS eligible in the early compared with the later enrollees *(Table 23)*. There was no difference in gender distribution.

Table 23: Demographic data for early versus late enrollers – one year follow up

	Early enrollers (Feb-Aug 2003) n = 5,177	Later enrollers (Sept 2003 onwards)	p-value for difference
Females	1,284 (24.8%)	442 (23%)	0.11
Age <55	664 (12.8%)	297 (15.5%)	
55-64	1,410 (27.3%)	567 (29.6%)	
65-74	2,042 (39.5%)	719 (37.5%)	
75+	1,055 (20.4%)	336 (17.5%)	0.001
GMS card holders	3,940 (76.2%)	1,276 (66.4%)	<0.0001

Table 24 gives the adjusted mean difference in risk factors between visit 1 and one year for the early and late enrollees (-ve value indicates a decline in the risk factor from visit 1). This shows that changes in systolic BP were significantly greater in the early compared with late enrollees, but that reductions in total and LDL cholesterol were greater in the late enrollees. There was a larger change in fasting glucose for early enrollees.

Table 25 gives shows that, for the two year cohort, the demographics between early and late enrollees were very similar, with only GMS eligibility higher in the early enrollees.

Table 24: Proportion of patients on medications and change in medication

	Early enrollers (Feb-Aug 2003) N = 5,177		Late enrollers (Sept 2003 onwards) N = 1,922		p-value for difference between early vs late[a]
	Baseline (visit 1)	Difference at 1 yr	Baseline (visit 1)	Difference at 1 yr	
Systolic BP	135.5	-2.9	135.6	-1.7	0.03
Diastolic BP	77.8	-1.3	78.3	-1.9	0.04
Total cholesterol	4.7	-0.2	4.6	-0.3	0.04
LDL cholesterol	2.7	-0.2	2.7	-0.2	0.02
Body mass index	28.0	-0.1	28.0	-0.1	0.5
Fasting glucose[&]	5.3	+1.0	5.3	+0.3	<0.0001
HbA1c[#]	7.3	-0.2	7.2	-0.2	0.99
Waist circumference	93.2	-0.1	93.5	-0.2	0.97
Smoking (%)	14.1%	2.5% decrease	15.6%	3.6% decrease	

[&] non diabetics at both visits; [#] diabetics at both visits; [a] adjusted for age, gender and GMS eligibility

Table 25: Demographic data for early versus late enrollers – two year follow up

	Early enrollers (Feb-Aug 2003) N = 3,678	Later enrollers (Sept 2003 onwards)) N = 333	p-value for difference
Female	908 (24.7%)	75 (22.5%)	0.4
Age <55	454 (12.3)	47 (14.1)	
55-64	1,014 (27.6)	98 (29.4)	
65-74	1,475 (40.1)	130 (39.0)	
75+	735 (20.0)	58 (17.4)	0.5
GMS card holder	2,796 (76.1)	236 (70.9)	0.03

Table 26 gives the adjusted mean difference in risk factors between visit 1 and two years for the early and late enrollees (-ve value indicates a decline in the risk factor from visit 1). This shows that changes in HbA1c and waist circumference were significantly greater in the late compared with early enrollees.

Overall we find few differences between early and late enrollees, which suggests that GPs were not selecting particular types of patients (prevalent or incident cases) into the Programme

Table 26: Adjusted[a] means (except smoking) for difference in risk factor values at two years from visit 1 between early and late enrollers

	Early enrollers (Feb-Aug 2003) N = 3,678			Late enrollers (Sept 2003 onwards) N = 333			p-value for change in risk factors at 2 yrs
	Visit 1	Diff. at 1 yr	Diff. at 2 yrs	Visit 1	Diff. at 1 yr	Diff. at 2 yrs	
Systolic BP	135.7	-2.9	-2.9	137.5	-3.4	-3.6	0.5
Diastolic BP	78.0	-1.4	-2.3	79.3	-2.8	-2.8	0.4
Total cholesterol	4.7	-0.2	-0.4	4.8	-0.3	-0.4	0.8
LDL cholesterol	2.7	-0.2	-0.3	2.7	-0.2	-0.3	0.9
Body mass index	28.0	-0.1	-0.1	28.1	-0.1	-0.2	0.6
Fasting glucose[&]	5.3	+1.3	+0.006	5.2	+0.8	+0.007	0.8
HbA1c[#]	7.2	-0.2	-0.1	7.1	-0.3	-0.4	0.1
Waist circumfer.	93.8	-0.4	-0.5	93.0	-0.3	+1.0	0.01
Smoking (%)	13.3%	2.2% decrease	3.4% decrease	17.4%	3.6% decrease	5.4% decrease	0.5

[&] non diabetics at both visits; [#] diabetics at both visits; [a] adjusted for age, gender and GMS eligibility

Table 27 gives the percentage of medications that individuals received at baseline and the change by one year. The pattern of uptake by one year is fairly similar in the early versus late enrollees, except a slight increased use of aspirin, and decreased use of ACE inhibitors and diuretics in the late enrollees.

Table 27: Medication usage at visit 1 and one year follow-up in early versus late enrollees

Treatment	Early enrollees		Late enrollees	
	BASELINE (visit 1) % uptake	Change at 1 yr	BASELINE (visit 1) % uptake	Change at 1 yr
Sulphonylureas	6.8%	+2.5%	4.8%	+0.2%
Biguanides	6.9%	+1.0%	6.3%	+0.5%
Glucosidase	0.8%	0.0%	0.6%	0.0%
Other hypoglycaemic agents	0.9%	+0.1%	0.9%	+0.5%
Aspirin	86.5%	+0.2%	88.6%	+0.2%
Beta blocker	57.7%	+2.7%	65.4%	+2.1%
Ace inhibitors	43.8%	+5.6%	46.2%	+3.6%
Anticoagulants	10.9%	0.0%	10.2%	0.0%
Antiplatelets	14.1%	+1.5%	25.5%	-3.5%
Statins	77.8%	+7.4%	83.0%	+6.1%
Fibrate	2.9%	-0.5%	2.4%	-0.4%
Other Lipid lowering	4.2%	-0.5%	3.5%	+1.1%
Diuretic	25.6%	+2.3%	23.3%	+1.5%
Ca channel blocker	20.6%	+0.3%	16.1%	+1.3%
ATII inhibitor	8.8%	+1.5%	8.5%	+1.5%
Other antihypertensive	13.1%	-1.2%	10.9%	-1.1%

Table 28 gives similar results for changes in medication use by two years. There is a significant increased use of aspirin and calcium channel blocker in the late enrollees, but significantly less use of beta blockers and ACE inhibitors at two years.

Although some differences between early and late enrolees were found early on in the programme (at one year follow-up) these differences were less evident at two years.

Table 28: Medication usage at visit 1, and change by one and two years in early versus late enrolees

Treatment	Early enrollees		Late enrollees	
	BASELINE (visit 1) % uptake	% Change at 2 yrs	BASELINE (visit 1) % uptake	% Change at 2 yrs
Sulphonylureas	6.5%	+0.5	5.1%	+0.6
Biguanides	6.7%	+1.4	4.5%	+1.8
Glucosidase	0.9%	+0.2	0.6%	-0.3
Other hypoglycaemic agents	0.9%	+0.3	0.9%	+0.3
Aspirin	86.5%	+0.4	89.5%	+0.6
Beta blocker	58.6%	+4.6	65.5%	0.0
Ace inhibitors	43.1%	+7.6	47.4%	+4.9
Anticoagulants	10.5%	-0.3	8.4%	+0.6
Antiplatelets	13.6%	+2.3	19.2%	+2.1
Statins	78.4%	+11.4	79.9%	+11.1
Fibrate	2.6%	-0.7	1.8%	-0.9
Other Lipid lowering	4.0%	+1.0	3.0%	+0.6
Diuretic	25.2%	+3.6	26.1%	+3.3
Ca channel blocker	20.9%	0.0	18.0%	+3.9
ATII inhibitor	9.0%	+3.0	7.8%	+1.5
Other antihypertensive	12.5%	-1.5	12.9%	+0.3

Notes

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