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PHARMACIST MONITORING OF PATIENT HEALTH IN THE COMMUNITY

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Doctor of Philosophy

THE UNIVERSITY OF ASTON IN BIRMINGHAM

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THE UNIVERSITY OF ASTON IN BIRMINGHAM SUMMARY

PHARMACIST MONITORING OF PATIENT HEALTH IN THE COMMUNITY

Geoffrey Philip Watman Submitted for the degree of Doctor of Philosophy, 1996

The Government has established essential principles in order to make significant improvements in the health of the people and has placed an emphasis on shifting care to the primary setting.

This research has explored the potential role of the community pharmacist in health promotion in the pharmacy, and at general medical practices. The feasibility of monitoring patients' health status in the community was evaluated by intervention to assess and alter cardiovascular risk factors.

68 hypertensive patients, monitored at one surgery, had a change in mean systolic blood pressure from 158.28 to 146.55 mmHg, a reduction of 7.4 %, and a change in mean diastolic blood pressure from 90.91 to 84.85 mmHg, a reduction of 6.7%.

120 patients, from a cohort of 449 at the major practice, with an initial serum total cholesterol of 6.0+mmol/L, experienced a change in mean value from 6.79 to 6.05 mmol/L, equivalent to a reduction of 10.9%. 86% of this patient cohort showed a decrease in cholesterol concentration. Patients, placed in a high risk category according to their coronary rank score, assessed at the first health screening, showed a consistent and significant improvement in coronary score throughout the study period of two years. High risk and intermediate risk patients showed improvements in coronary score of 52% and 14% respectively. Patients in the low risk group maintained their good coronary score. In some cases, a patient's improvement was effected in liaison with the GP, after a change or addition of medication and/or dosage.

Pharmacist intervention consisted of advice on diet and lifestyle and adherence to medication regimes. It was concluded that a pharmacist can facilitate a health screening programme in the primary care setting, and provide enhanced continuity of care for the patient.

Keywords: Community pharmacists, health screening, coronary heart disease, primary health care, GP-pharmacist liaison.

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This thesis is dedicated to the memory of my parents who started my education and would have been so proud.

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ABBREVIATIONS

ACE Angiotensin Converting Enzyme

ADNFS Allied Dunbar National Fitness Score

AMA Australian Medical Association

BDA British Diabetic Association

BFHS British Family Heart Study

B & H Brent & Harrow

BG Blood Glucose

BMI Body Mass Index

BMR Basic Metabolic Rate

BP Blood Pressure

BRHS British Regional Heart Study

CHD Coronary Heart Disease

CNS Central Nervous System

COAD Chronic Obstructive Airways Disease

COM Commission for the European Community

COMA Committee on Medical Aspects of Food Policy

CR Dundee Coronary Rank

CS Dundee Coronary Risk Score

CVA Cerebrovascular Disease

CVD Cardiovascular Disease

DBP Diastolic Blood Pressure

DOH Department of Health

DRV Dietary Reference Value

EAR Estimated Average Requirement for Energy

EEC European Economic Community

FH Family History

FH CHD<60 Family History of Coronary Heart Disease before the age of 60

FHA Family Heart Association

FHS The Framingham Heart Study

FHSA Family Health Services Authority

GB Great Britain

GMP Group Medical Practice

GP General Practitioner

GSL General Sales List

HC Health Centre

HDL High Density Lipoprotein

HEA Health Education Authority

HMGCoA Hydroxymethylglutaryl coenzyme A

HRT Hormone Replacement Therapy

HTG Hypertriglyceridaemia

IDDM Insulin Dependent Diabetes Mellitus

IHD Ischaemic Heart Disease

KIP Consultative Interactive Personal

LDL Low Density Lipoprotein

LPC Local Pharmaceutical Committee

MDS Monitored Dosage System

MI Myocardial Infarction

MRFIT Multiple Risk Factor Intervention Trial

NHS National Health Service

NIDDM Non Insulin Dependent Diabetes Mellitus

NPA National Pharmaceutical Association

NSP Non Starch Polysaccharide

NZ New Zealand

OTC Over The Counter

P Pharmacy Only

PA Pharmaceutical Adviser

PACT Prescribing and Cost Analysis Data

PC Personal Computer

PCP Primary Care Pharmacist

PFM Peak Flow Monitoring

PGEC The Pharmaceutical Group of the European Community

PHCT Primary Health Care Team

PMR Patient Medication Record

POM Prescription Only Medicine

PSNC Pharmaceutical Services Negotiating Committee

P/S Polyunsaturated/Saturated Fatty Acids Ratio

RBG Random Blood Glucose

RCGP Royal College of General Practitioners

RPSGB Royal Pharmaceutical Society of Great Britain

SBP Systolic Blood Pressure

SHHS Scottish Heart Health Study

SPSS Statistics Programme for Social Scientists

STC Serum Total Cholesterol

TDM Therapeutic Drug Monitoring

TG Triglyceride

TIA Sudden Ischaemic Death

UK United Kingdom

USA United States of America

VLDL Very Low Density Lipoprotein

WHO World Health Organisation

SYNOPSIS OF THE THESIS

CHAPTER 1 The profession of pharmacy is traced to it's roots, and the author suggests the future is dependent on a patient-oriented approach. In line with the Government's policy of improving the health of the nation, cardiovascular disease was chosen as a fertile subject to explore. Developments in diagnostic testing and health screening at home and abroad are presented.

CHAPTER 2 A literature review of recent studies into the epidemiology of coronary heart disease is made with some critical evaluation.

CHAPTER 3 The operation of a cholesterol testing service in a community pharmacy, and the pharmacist's approach to giving advice on diet and nutrition is reported.

CHAPTER 4 The pharmacist's intention to work within the primary health care setting begins with a pilot study in a health centre, followed by a two-year project to monitor hypertensive patients at a general medical centre.

CHAPTER 5 A lifestyle questionnaire is sent to all patients (15-75 years) of a GMP, their cardiovascular risk factors recorded on a template at the surgery, and a random selection of 600 patients asked to attend a health screen interview.

CHAPTER 6 The results of a two-year follow-up of patients, with respect to the influence of family history, age and sex on health status is discussed. Beneficial changes in risk factor profiles, due to improvements in blood pressure and cholesterol, are shown to be statistically significant. This is a result of pharmacist intervention, establishing optimum drug therapy, reinforcing medication adherence, and providing advice on smoking cessation, exercise and diet.

CHAPTER 7 Case histories are chronicled to show benefits to individual patients, eg one who was diagnosed as diabetic.

CHAPTER 8 The views of FHSA pharmacutical advisers, on the future, possible roles of the community pharmacist, are ascertained by means of a questionnaire.

CHAPTER 9 A questionnaire is used to elicit the views of a select group of pharmacists on the future of health promotion and diagnostic testing in pharmacy.

CHAPTER 10 Developments in pharmacy practice in Europe are studied by communicating with pharmacy associations of member states of the European Union.

CHAPTER 11 Finally, proposals are made describing how pharmacy moves forward as a result of this work.

PHARMACIST MONITORING OF PATIENT HEALTH IN THE COMMUNITY

CHAPTER 1

THE EVOLUTION OF THE PROFESSION OF PHARMACY

1.1 INTRODUCTION

Community pharmacy exists as a profession throughout the developed and the developing world. Pharmacists are uniquely educated and trained in aspects of the science and practice of pharmacy.

In Britain, the basis of health care is adapting to the changing health needs of the community. Patients' needs and wishes are paramount, leading to an increased desire by Government on seamless care in the community. This shift of emphasis from primary to secondary care has led to an increasing role for all health care professionals in the primary care setting. Pharmacists working in a situation accessible to the public, with their expert knowledge of the use of medication in practice, are potentially an invaluable resource in the National Health Service (NHS). There is increasing pressure on self care as a form of treatment, leading to self-medication, which means empowerment of patients to take drugs, from an increasingly sophisticated choice, without consulting a physician. This aspect of self care is especially important to community pharmacists.

Pharmacists have increasing clinical knowledge, which is concerned with the effects of medicines on patients. The concept of clinical pharmacy has developed as a normal part of pharmaceutical services in the hospital sector, particularly in the past 20 years. Clinical pharmacy embodies the shift from product to patient orientation, and encompasses advice on the best choice and form of treatment in a given clinical situation, monitoring its effectiveness and providing the patient with relevant information on treatment to ensure their comprehension and compliance.

The aim of this research is to determine whether or not clinical aspects of pharmacy can be effectively and efficiently developed in the community setting for the benefit of the patient.

The pharmacist's role will be evaluated in association with other members of the primary health care team (PHCT), to see whether the pharmacist's knowledge can be used to improve and promote patient health, and the greater development of pharmacy practice as a dynamic, patient-orientated health service.

1.2 THE HISTORY AND DEVELOPMENT OF PHARMACY

Pharmacy began when man first employed herbs for dressing his wounds or to relieve pain. In Britain there has been a steady development from the time when the Anglo-Saxon leeches gathered herbs and compounded medicines to the present day when the practice of pharmacy can be defined as:

"concerned with the art and science of preparing from natural drugs and synthetic sources, drugs and medicines for use in the diagnosis, treatment and prevention of disease, including their proper and safe distribution, whether dispensed or sold directly to the ultimate consumer".

The forerunner of the pharmacist of today was the apothecary, and, in the 17th and 18th Centuries (until the advent of the chemist and druggist), they were engaged in the accurate preparation and dispensing of medicines as directed for the sick by a physician licensed to practise medicine.

During the Seventeenth Century, however, the families, requiring medical attention, came more and more to think of the apothecary as their "family doctor" and called in the physician only when the case was a serious one.² There was an increasing practice of medicine by the apothecary in the 18th Century, and a decision by the House of Lords confirmed that it was in the interest of the public to allow apothecaries to give advice as well as to compound and sell medicines.³

Most of the apothecaries chose to practise medicine, leading ultimately to the formation of the "general practitioner" of medicine. The preparing, compounding, dispensing and vending of drugs and medicines now became the province of the chemist and druggist, who in 1841, joined the newly formed

association of the "Pharmaceutical Society of Great Britain" and, in consequence, became the pharmaceutical chemists we know today.

1.3 COMMUNITY PHARMACY TODAY

1.3.1 Dispensing of medicines

The dispensing process which has traditionally been a core element of the work of the community pharmacist consists of:

- reviewing and confirming the prescription
- 2. filling the prescription, and
- advising the patient on the safe and effective use of the medicine dispensed.

The mechanics of this major function of accurately dispensing a prescription written by a doctor for a patient does not now extend the pharmacist's capability. The university education, training and knowledge so acquired, should realise a greater contribution to community health care. The combined effect of the availability of much more sophisticated and potent medicines, with the traditional knowledge and skills in preparing individual medicines which is no longer required, has led to the search for a change in emphasis of the role. Pharmacy as a profession has had its time-honoured base severely reduced and the mechanical aspects of dispensing of a prescription, although requiring significant elements of professional judgement, has become a technical activity. This void, created by loss of extemporaneous dispensing, due to expansion of pharmaceutical research and manufacture, came to be filled initially by an increasing demand for drug information from prescriber and patient. The pharmacist, with by far the most extensive education in drug use and effects, assumes the role of information specialist on medicines.

The advent of new substances saw the rise of more specific treatments with increasing potential for adverse and toxic effects as well as for a complex array of interactions with other medications and foods. The pharmacist is well placed to reinforce the prescriber's instructions, to provide additional therapeutic information and to monitor the patient's progress for adverse effects.

Thus, in the community, dispensing, as a fundamental feature of the pharmacist's work, can still be the focal point for an extension of his/her role, in that patient medication records and specialist drug knowledge can enable the pharmacist to provide a medical advisory service for patients, as illustrated in the reinforcement of compliance in tertiary care of asthmatics.⁴

1.3.2 The Pharmacist in Secondary Care

Consumers see pharmacists as experts on medicines willing to advise on minor ailments and more accessible than the GP. There are well-documented reports of public support for advice on over-the-counter medicines. Evidence suggests that, though an overwhelming majority of the public who ask for advice on minor ailments, find that advice useful, only approximately half the population actually use the pharmacist in this way. Responding to symptoms is an established feature of the community pharmacist's role, but, though of apparent value to the millions of consumers that enter pharmacies in Britain each day, there is no structured assessment of this service. This is in direct contrast to general medical practice, where a patient is registered and all consultations recorded so that there is a constant evaluation and re-evaluation of the patient's medical history. In the pharmacy, the patient is not registered, may be a complete stranger, and asks for advice on some health problem, in an ad hoc way; when the pharmacist, unless there is a patient medication record, has no knowledge of the background or medical history of the patient.

1.4 DEVELOPING A VISION OF PHARMACY TOWARDS 2000

The Department of Health (DOH) is clearly committed to a significant shift in the provision of health care services to patients in their own communities. ¹ Pharmacists, accessible to both patients and professional colleagues in health care teams, are ideally placed to contribute their skills to a pharmaceutical care programme that would reduce not only the cost in public resources but patient morbidity and mortality.

1.4.1 Pharmaceutical care

Pharmaceutical care has been defined as "the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve the patient's quality of life". 8

Thus, with the pharmacist's first concern being the welfare of the patient in all settings, patient orientated pharmaceutical care could mean:

- 1. Pharmacists would promote effective, rational and economic prescribing.
- 2. Pharmacists would accept responsibility for effective drug therapy of patients between one medical consultation and the next.
- 3. Pharmacists would choose the drugs, monitor the outcome, alter dosage and/or drug where necessary, and refer back to the general practitioner (GP) against a defined, patient centred protocol.
- 4. Good communications would exist between pharmacists in primary and secondary care to ensure the continuation of effective drug therapy.
- 5. Increased pharmaceutical care in the community would help to reduce the number of hospital admissions due to adverse reactions/interactions of drugs.
- Provision of domiciliary services to individual housebound patients, nursing and residential homes to ensure appropriate medication use, compliance, storage and disposal.

1.4.2 Primary health care

Pharmacists could, in this way, be usefully integrated with doctors, nurses, dieticians and other therapists in the PHCT, and contribute to clinical audit.

Preventive health care is one route the pharmacist could take to develop a structured role in the community. Health care leaflets are a useful, but passive, means of establishing the profession as a purveyor of health education in the eyes of the public, but the pharmacist needs to go further and actually get involved in an influential way with patients. According to Jepson et al, only 7% of their sample sought information or advice on keeping healthy, but that some

90% of that sample rate the pharmacist's advice at least as useful as the GPs. 6 The pharmacist could gain in profile therefore by investing more time and becoming pro-active so that the consumer perceives the role of the pharmacist at the forefront in the campaign for promoting better health and caring for people.

The community pharmacist could act as a filter, distinguishing between minor ailments that he can readily treat and those of a nature that warrant a doctor diagnosis. He could be the first port of call in diagnostic testing and the first provision for counselling on health matters and health promotion.

1.5 HEALTH SCREENING FOR HEALTH PROMOTION

Pharmacists' contribution to health promotion could be crucial at a time when the Government is concerned at the cost-effectiveness of health care. People have a ready access to pharmacies and pharmacists, readily available without the need of a prior appointment, have enormous scope for encouraging the adoption of healthier lifestyles.

1.5.1 Health

Health should be considered as a positive goal in its own right and not just freedom from disease.

Definition. Health is a state of complete physical, mental and social well-being. 9

Good health and sickness are at two ends of a continuum of health, and health promotion is intended to ensure that more individuals do have a long, full and active life.

Looking at the major causes of mortality, we ascertain that many of the diseases responsible carry recognised avoidable risk factors. Removing or minimising those risk factors reduces the chances of developing the disease.

Practical aspects of this research will examine and evaluate the role of the pharmacist in preventing Coronary Heart Disease (CHD). Referring specifically to CHD, a systematic and concerted attack on all major risk factors should now have a significant impact on the morbidity and mortality produced

by atherosclerosis, thereby bringing the epidemic of CHD under control and enhancing health in the developed world. 10

1.5.2 Health promotion

Health promotion encompasses the wider issues of health education, health protection and disease prevention. An interplay of education and related legal, environmental, economic and organisational interventions will improve health status.

1.5.2.1 Promotion of positive health

Pharmacists, armed with the knowledge of factors associated with good health, such as fitness and proper diet, can deliver this information beneficially to the public.

1.5.2.2 Prevention of ill-health

Pharmacists can identify those at risk of developing preventable illness by screening individuals in the pre-symptomatic phase, and, by encouraging them to change their behaviour and lifestyle, reduce their chances of progressing into overtill-health.

1.5.2.3 Limitation of further deterioration in health

In those with established disease, symptomatic treatment, if not cure, is possible. Health promotion, through education and monitoring by pharmacists, can ensure that treatment is optimised and hence further deterioration in health is minimised or halted.

1.5.3 The challenge for health promoters

Smoking is the single greatest cause of disease and premature death in Britain, and though a majority of smokers express a desire to give up, it is difficult for the individual to permanently succeed in turning away from health-damaging behaviour.

A fundamental objective of health promotion is to help individuals to change attitudes and develop life skills. This requires effort, conviction and motivation on the part of both the health promoter and individual.

1.5.4 The pharmacist's potential role

A Royal Pharmaceutical Society (RPSGB) working party, set up to look at the future of community pharmacy in 1991, concluded that health education, including diagnostic testing, should be a major role of the pharmacist. ¹¹ The Nuffield Inquiry published in 1986 suggested an "extended role" for the pharmacist, and concluded that there was a role for pharmacists in health education in co-operation with other health care professionals. ¹² This study will evaluate this premise.

1.6 SCREENING AND DIAGNOSTIC TESTING

The joint working party report on the future role of the community pharmaceutical services says that they received a 'considerable body of evidence' that community pharmacists should be encouraged to undertake screening and diagnostic testing. 11

Health screening by the provision of diagnostic testing services provides the necessary focus for health education. Health screening can maximise the quality, appropriateness and perceived relevance of the health promotion message.

A diagnostic test brings one into direct contact with the client, and it can be used to initiate discussion on healthy life practices coping with illness. An interactive exchange will lead to opportunities for health promotion. The test result enables an individualised approach to be made to a client, as with a cholesterol test result which will give the client information about their body or their treatment and can evoke a more positive response to dietary advice given by the health promoter. There are three issues that need to be addressed before recognising and encouraging these services.

1.6.1 The skill and training of the pharmacist

The professional and scientific background of the community pharmacist, particularly his training in physiology and biochemistry, suitably equips him to

undertake diagnostic testing. Biochemical and technological progress is such that many diagnostic tests can be performed easily in the pharmacy environment. The pharmacist's training makes him well-suited to use the instrumentation for, eg blood glucose and cholesterol testing, in a correct manner. However, it has been suggested that further education and training may be needed for the provision of specific services to patients. The pharmacist will need to be knowledgeable in the pathology and treatment of the disease processes of which the test is an indication, eg blood pressure measurement and hypertension. In this way, the pharmacist will be able to communicate more confidently with the patient and be certain not to give advice that will conflict with the GP's.

Further to this, in the interests of consistency and of safeguarding the public, blood pressure (BP) monitoring should, ideally, be done on the same equipment as that used in the patient's practice. Failing this, the equipment at the pharmacy should be calibrated with that at the surgery. The pharmacist should have training in the correct technique for measuring BP and the conventional sphygmomanometer, still favoured by GPs due to the consistency in reproducible results.

1.6.2 The consumer viewpoint

Although an extended role offers potential benefits to the public in terms of easy access to professional advice on health matters, it should not be too readily assumed that the public will use any of the services offered. Most consumers have a very positive image of the community pharmacist and would welcome extended services at the pharmacy. A small minority are not too sure about the pharmacist's medical expertise and a public relations initiative could help to inform the public and develop a further receptiveness to the extended role, particularly in relation to the role of providing advice on minor ailments and the provision of diagnostic and screening services. There are favourable reviews of a number of pharmacy-based health promotion schemes, although the uptake for the PSNC Diabetes Pilot Study was disappointingly low. The aim of this study was to provide a professional and easily accessible screening service which would raise the public's awareness of undetected diabetes, particularly in the elderly, and contribute towards identifying the estimated half a million undiagnosed diabetics in Britain who are

unaware they are at risk of long term complications. Further objectives of the study were to:

- 1. promote the pharmacy as a centre for screening;
- 2. test the feasibility of the service;
- enhance the health education role of pharmacists; and
- 4. to determine a 'bench mark' and bank of expertise for other pharmacists wishing to provide the service in the future.

Further negative feedback was highlighted by reports of the reluctance of elderly people to seek non-medical advice, and the evaluation of other members of the PHCT as being more skilled than the community pharmacist in giving advice. ¹⁴

However, there appears to be considerable support amongst the general public for the development of a range of services in community pharmacies. Research indicates that there is a need to market those services that are unfamiliar, so that the benefits to users can be explained and their uptake encouraged. There is also a need to build a closer relationship between the community pharmacist and the GP, and to demonstrate to the general public both the nature of this relationship and the complementary roles of pharmacists and GPs.

1.6.3 Payment for the service

Diagnostic services are currently provided to people who are willing to pay for them. Diagnostic tests are a way of encouraging people to take a greater responsibility for their own health, but, perhaps due to the payment factor, those having the greatest need of screening may be least likely to request these services.

Two circumstances are defined in the report as being appropriate for diagnostic testing to be undertaken in community pharmacy as part of the NHS:

1. **Doctor request.** A pharmacy could develop as a local screening centre and perform tests that are, at the moment, referred to hospital laboratories, which is usually a more time-consuming, more expensive and delaying process. Currently, this scenario is particularly appropriate with more GPs becoming

fundholders with the independence to purchase such services from pharmacist providers.

2. Local Health Commissioning Agencies. The working party suggests that it may be appropriate for FHSAs to fund the provision of testing services in community pharmacies. 11

1.6.4 History and development of diagnostic testing

Diagnostic testing has been available for some years in community pharmacy in the form of weighing scales to monitor for obesity.

- 1.6.4.1 Pregnancy testing facilities are available in 70% of pharmacies and the tests themselves are sold by most pharmacies. In the past few years, more sophisticated tests, demanding greater operational skill and resources have been introduced.
- 1.6.4.2 The taking of **blood pressure** has progressed to a level of between 12 and 15% of pharmacies offering a monitoring service. Most pharmacies overcome the skill factor by using semi-automatic machines, which need some manual operation as the cuff has to be applied around the arm and inflated over the brachial artery. A stethoscope is not required as blood pressure is measured electronically and converted to a digital readout.

The RPSGB takes the view that the community pharmacy is a suitable place for blood pressure screening. The Society says that pharmacists can detect cases of mild, symptomless hypertension and advise on lifestyle changes, or refer patients to their GP for further investigation and treatment.

Doctors, however, have reservations and the BMA disapproves of BP measurement being undertaken outside the surgery, because it feels some of the equipment may be inaccurate, leading to false readings, unnecessary referral and undue anxiety to patients.

1.6.4.3 Cholesterol screening in community pharmacy is a natural part of the extension of the pharmacist's role in illness prevention and health promotion, according to the RPSGB, provided there is adequate patient counselling.

The National Pharmaceutical Association (NPA) believes a cholesterol screening programme must be established throughout the UK if the incidence of CHD is to be drastically reduced. ¹⁷

The number of pharmacies now offering a cholesterol testing service is reputed to be around 300, according to NPA figures. In a study in the West Midlands region, 7% of pharmacies offered a blood cholesterol service and a further 13% said they were likely to introduce the service shortly. ¹⁸

Reasons for not offering the service, included perceived lack of public demand, the cost of the equipment, the fact that testing was too time consuming, and lack of space.

1.6.4.4 Blood glucose screening will increase early detection of type 2 diabetes and may reduce the cardiovascular complications of diabetes. The need for pharmacy blood glucose screening is, however, uncertain as the PSNC pilot study found fewer people requested a test than expected.

Perhaps the charge of £6 for the test was excessive, and the British Diabetic Association (BDA) felt that blood levels stipulated for a second test (8.0 mmol/L and above) were set too low and would lead to an excessive number of second testings. ¹³

Pharmacists could contribute more successfully to the identification of diabetics in the community by offering a supply of diagnostic urine dipsticks to the public; this would be cheaper, more convenient and elicit a greater response.

1.6.4.5 Peak flow monitoring is an excellent indicator of the progress of reversible obstructive airways disease, and may be used by pharmacists to contribute to the diagnosis of asthma or to follow the benefits of prophylactic or therapeutic medication.

Asthma invariably waxes and wanes throughout the year, often reflecting seasonal trigger factors, therefore it is important to maintain peak flow readings, to alert one to impending deterioration in respiratory function, enabling a continual informed adjustment in medication and dosage to be made.

Asthma follows a clinical variation of circadian rhythm, and pharmacists must appreciate that bronchial lability is greater in asthmatics at bedtime and early morning, and should advise patients to chart recordings at those times, before the use of any bronchodilator. In this way, a more accurate indication of the severity of the patient's asthma and of improvement and deterioration can be obtained than by the occasional, more haphazard, late morning measurement at a GP's surgery.

1.6.4.6 Comprehensive health checks are the logical extension of the screening services available and a range of tests could be performed to produce a 'risk analysis' for patients. Information of a patient's weight, BP and cholesterol (STC) measurements, smoking and drinking habits, and dietary style could be entered onto a computer database; the programme then analysing the patient's risk of heart disease.

A feasibility study concerned with CHD health promotion in a community pharmacy has been conducted, but was limited in its feedback as there was neither sufficient collaboration from doctors nor an extended follow-up. 19

1. 7 DIAGNOSTIC TESTING IN OTHER PARTS OF THE WORLD

1.7.1 The United States of America (USA)

Pharmacists here are actively promoting their recognition by the public as more than counters of tablets and fillers of bottles, who have been perceived as performing only a drug distribution service. They realise that recognition will only come by conscientious and dedicated effort in improving patient care.

1.7.1.1 Cholesterol screening

A study was conducted to determine if a community pharmacist could affect the STC of 51 ambulatory patients (20-60 years) with elevated cholesterol levels via a programme of education, consultation and cholesterol screening.²⁰

Pharmacist intervention included obtaining STC levels and reporting results to patients, teaching them the role of cholesterol in illness and health, explaining risk factors associated with cerebrovascular disease (CVA) and providing follow-up communication. Patients were followed-up for six months, with screenings performed two-monthly.

There was a significant decrease in mean STC concentrations between initial visit and first follow-up and initial visit and second follow-up, but no difference between first and second follow-ups. The study showed that cholesterol screening, as part of a patient education programme performed by a community pharmacist, was associated with significant STC reduction in patents with elevated STC concentrations.

The current aim in the USA is to educate the pharmacist to be a well-trained health professional, who will maintain his

proficiency, and actually use this knowledge for the health and well-being of the public.

1.7.2 New Zealand (NZ)

The health system in NZ has moved from a traditional Government-funded NHS to a more privately funded system, popularly referred to as "user pays". The position and role of community pharmacy is expected to change considerably in the next few years, and the traditional role has already changed in some pharmacies from largely dispensing to advising, counselling and dispensing.

Developments in both technology and health care provisions in NZ are rapidly changing the environment for on-site testing, and many community pharmacists are looking to expand this element of their business for a number of parameters. Dry chemistry technology means that biochemical methods used in large laboratories are now available in convenient on-the-spot systems that do not require a high level of technical expertise to perform. On-site testing technology is the focus of a number of research and development companies in NZ and a broad menu of tests is now available.

The NZ public today are far more aware of health and fitness issues than in the past and many would welcome the opportunity to establish conveniently their cholesterol, glucose and other parameters. As far as pharmacy in NZ is concerned, this "health check" would provide a major element in elevating the public's perception of the pharmacist's capability.

1.7.3 Australia

The pattern of community pharmacy in Australia is more advanced in the field of health promotion than anywhere other than in the UK. The contention in Australia is that pharmacists working more closely with the medical profession

would enhance both patient health outcome, and, with the right attitude, professional effectiveness for both doctors and pharmacists. 22

The community pharmacist is expected to promote health education in the community and provide advice on how to improve the health of consumers. This has logically extended to their offering of services such as screening tests for hyperlipidaemia, hypertension, blood glucose levels and pregnancy.

A major problem in Australia is maintaining a co-operative interface with doctors, who are generally opposed to pharmacists becoming involved in the management of major diseases, even in the support role, and are also opposed to pharmacists carrying out screening tests.

The Australian Medical Association (AMA) states that diagnosis is not the province of the pharmacist because diagnosis requires accurate history taking, examination and knowledge of differential diagnosis, for none of which the pharmacist is trained. Serious results could be caused for the patient as the community pharmacist is not in a position to evaluate the whole patient or provide adequate follow-up.

The essential pre-requisites for a community pharmacist to offer health screening are:

- Competence in the relevant pathophysiology theory, test techniques and communication involved.
- Creation of a perception of competence of you and your team.
 Currently, between 20-40% of Australian pharmacies offer BP, STC and random blood glucose (RBG) tests.

Doctors direct patients for blood analysis primarily to an independent laboratory, and secondly, tests are done on their own premises. Screening tests are paid for by the patient.

1.8 AIMS OF THE STUDY

- 1. To evaluate whether there is a role for the pharmacist in health promotion in co-operation with other professionals in the primary health care team.
- 2. To conduct an extensive, prospective study into CHD prevention in the local population.
- 3. To determine the most suitable environment for operating a health screening project.
- 4. To see whether the strategy of health promotion by a pharmacist at an individual level and as part of a community programme can facilitate the diagnosis of existing and pre-existing disease.
- 5. To determine the pharmacist's ability to influence and initiate appropriate therapy.
- 6. To assess the public's perception of the pharmacist as a credible conveyor of information relating to health matters.
- 7. To ascertain the views on the future direction of community pharmacy by analysing questionnaires sent to pharmaceutical advisers and pharmacists in the UK.
- 8. To compare the current clinical role of the pharmacist in the UK with that of his colleagues in Europe and the Rest of the World, and to evaluate future developments in Europe.
- 9. To formulate a feasible plan of action for pharmacists to carry forward to the year 2000 assuring their future engaged at the heart of health care for the public.

CHAPTER 2

CARDIOVASCULAR DISEASE: CORONARY HEART DISEASE

2.1 HISTORY

Diseases of the cardiovascular system, and in particular those falling within the definition of coronary heart disease (CHD), are together the commonest cause of death in Western society. ²³ CHD is the largest single cause of death in the UK accounting for approximately 26% of all deaths in England in 1991. ²⁴ Recent research into the detailed pathophysiology of CHD has revealed more about the links between the mechanisms and the personal and environmental factors associated with such events as myocardial infarction (MI) and sudden ischaemic death (TIA). ²³

The risk factors for CHD are generally considered to be much the same as for stroke, however it is likely that the same risk factors do not share the same importance for the two disorders. Studies suggest hyperlipidaemia is the major risk factor for CHD whereas hypertension is most important for stroke. ^{25,26}

There is now a general consensus among the public and the medical profession that this major public health problem needs to be addressed by preventive measures as well as by medical and surgical treatments.²³ There has been growing agreement that modification of those factors most closely linked to the disease is likely to produce postponement or prevention of the problem.²⁷

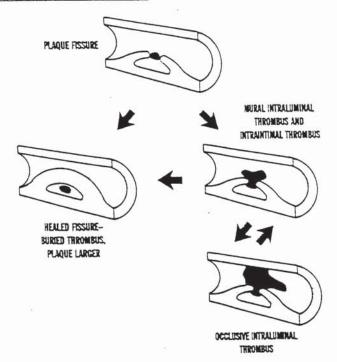
There is controversy over the question of strategy; one approach would seek to identify those at highest risk and focus attention on them; the alternative is to concentrate resources on measures directed at the whole population. The population approach would be more thorough, but more costly, therefore it should be complemented by some degree of special attention to those at highest risk of the disease.

2.2 THE NATURE OF THE PROBLEM

The term CHD covers a group of clinical syndromes that includes angina pectoris, acute MI and TIA. The common underlying pathology is atherosclerosis of the coronary arteries, which involves the formation of focal plaque. The plaque may directly encroach on the lumen in the coronary arteries producing a flow limiting stenosis, leading to stable angina.

A second facet of atherosclerosis is that one or more plaques may enter an unstable phase and be complicated by thrombus formation, a rapidly changing dynamic process, resulting in unstable angina or acute infarction. Plaque rupture leads to free communication between the lipid content of the plaque and blood in the coronary artery (Fig.2. 1). Blood from the lumen of the coronary artery dissects into the plaque, producing a large, intra-intimal thrombus rich in platelets, a process associated with crescendo angina, acute MI and sudden ischaemic death.

Figure 2.1 Evolution of a Plaque Fissure to Reseal and Stabilize or to Progress to Thrombotic Occlusion

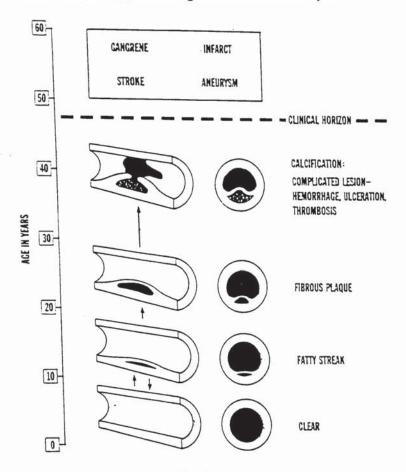


A third feature is that atherosclerotic vessels have diffuse abnormalities of vascular tonal responses which favour vasoconstriction on exercise. ²⁸

2.2.1 Pathogenesis of human atherosclerotic lesions

The larger the proportion of the total plaque volume occupied by extracellular lipid, the greater the risk of an episode of fissuring or tearing leading to a clinical manifestation (Fig. 2.2).²⁹ Lipid, particularly when it has undergone oxidation, increases inflammatory activity, monocyte infiltration and enhances vessel wall instability.³⁰

Figure 2.2 Pathogenesis of Human Atherosclerotic Lesions and their Clinical Manifestations, Showing the Natural History of Atherosclerosis

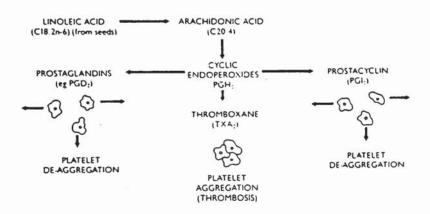


2.2.2 Biochemical cause of thrombosis

Some specialists have postulated that, if the plaque contains saturated fatty acids, then platelet contact with this extracellular lipid causes instant aggregation. By contrast, unsaturated fatty acids, such as linoleic acid, have no such aggregating action.

In Figure 2.3, Linoleic acid (a member of the omega-6-family of fatty acids) leads to both aggregation and disaggregation of blood platelets depending on the biochemical pathway.

Figure 2.3 Biochemistry of Linoleic Acid and Thrombosis



If a diet is changed from one which is very rich in omega-6 fatty acids and/or arachidonic acid (present in lean meat) to one rich in omega-3 fatty acids (present in fish oil), then the metabolic products will be a different prostaglandin and prostacylin, both of which disaggregate platelets, and a different thromboxane that has no effect on platelets, thereby preventing thrombosis.

2.3 CAUSES

Many risk factors have been found to be associated with the increased likelihood of the prevalence or incidence of CHD, although not all risk factors will have the same strength of relationship with CHD, and not all will be truly causal.

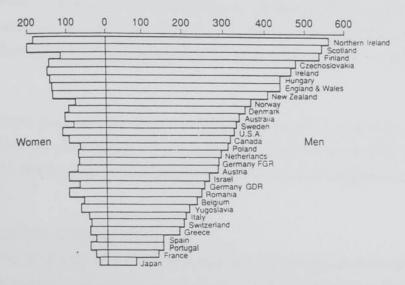
2.3.1 Criteria for causality

- 1. Strength of association in terms of relative risk and the presence of a doseresponse effect.
- 2. Consistency of the association under varying circumstances, ie when examined in different populations.
- 3. Exposure to the factor pre-dating the onset of disease.
- 4. Biological plausibility.

5. Ability to prevent the disease by avoiding exposure to the factor.

The epidemiological approach in which defined groups of people are studied to determine the factors that appear to increase the risk of the disease occurring in those populations, shows a genuine and large geographic variation in the prevalence of coronary atherosclerosis and CHD (Fig. 2.4).³¹

Figure 2.4 Age-standardized Mortality Rates for Subjects 40-69 years old for Coronary Heart Disease



2.3.2 Study approaches

- 1. Cross-sectional approaches rely on the examination of individuals in a defined population at a particular time, to determine the presence of CHD and any likely associated personal factors.
- 2. Case-control studies compare individuals with established CHD for the presence of suspected risk factors with a control group of the same age and sex and geographic/socio-economic areas as the cases.
- 3. Prospective studies in defined communities constitute a more reliable method of determining causal relationships between risk factors and disease. Here, individuals are examined both for evidence of CHD and for those factors suspected of being associated with the development of CHD.

When all the subjects have been followed for a given period of time and a number have developed new episodes of CHD (new angina, acute MI or sudden death), these 'cases' can be compared with those subjects who have not developed disease, with regard to the various measurements made on them at initial examination. The measure of the dose-response relationship of any given factor can be used to determine causal effect.

2.3.3 Analysis

Several types of analysis are possible in longitudinal studies:

- Univariate analysis refers to where one factor at a time is examined in relationship to the risk of disease, and may be of etiological significance.
 However, most factors do not exist in an independent state, eg there may be a positive correlation between body mass index (BMI) and the average level of BP.
- 2. Multivariate analysis involves a statistical procedure (multiple logistic regression) which assesses the simultaneous influence of risk factors on CHD events, illuminating which factors predominate and the independent effect of each.

2.3.4 Probability and prediction

The risk of a particular event taking place in the future, given some knowledge of the factors conditioning the outcome, may be expressed as relative risk, where the incidence in the subjects least exposed to the risk factor is used as the baseline of 1.0.

One can make a reasonable assessment of prognosis by deciding on the individual's category of risk, and approach to management will be determined by this, and secondly by personal knowledge of his physical and psychosocial characteristics. ²³

2.4 CORONARY HEART DISEASE IN POPULATIONS

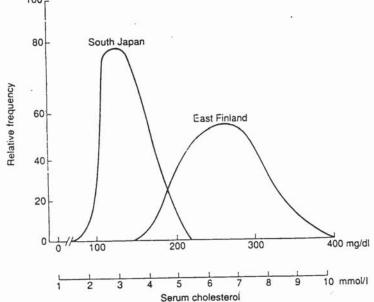
2.4.1 Concepts of population risk

From international studies, such as the Seven Countries Study, there appear to be four fundamental concepts:²⁵

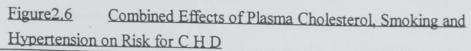
- 1. Specific susceptibility to atherosclerosis and CHD related to the mean levels of serum total cholesterol (STC) in a community.
- 2. An optimum level of STC below which CHD is not an endemic problem.
- 3. As the level of STC increases above the optimum, CHD increases progressively and then becomes endemic in the community.
- 4. The degree of endemicity depends in part on the community levels of STC and in part on the frequency of other risk factors.

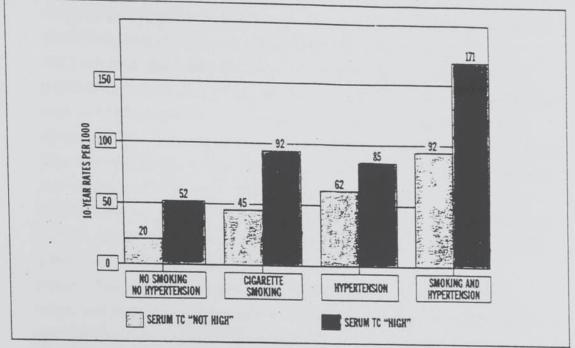
Figure 2.5, shows the blood cholesterol concentrations in two communities with very different levels of CHD - South Japan and East Finland -and illustrates this etiological model.³²

Figure 2.5 Cultural Differences in Serum Total Cholesterol Distribution



The well-established risk factors include cigarette smoking, hypertension, and raised concentrations of STC. The largest prospective study, the Multiple Risk Factor International Trial (MRFIT), of 356222 men aged 35-57 years, provided very good evidence that blood pressure, smoking, dyslipidaemia and glucose intolerance explain the majority of CHD cases. ³³ Any of these factors can act on the susceptible condition to increase both the risk of a major CHD event and atherosclerosis, but several risk factors occurring together, will act synergistically and considerably increase the risk of a major CHD event (Fig. 2.6).





The study focussed only on those men in the upper range of a risk-score distribution and who showed no evidence of CHD. Approximately half the group was randomly allocated to a special intervention programme. The other half, or 'usual care' group were given no specific advice. Over the 7-year follow-up period, CHD mortality was reduced by 22% more in the intervention group, but this was not statistically significant. The designers of the trial did not anticipate that the non-intervention group, who had been informed of their risk status, would change their lifestyle too to an extent and were, in retrospect, not a satisfactory control group.

The protective factor of greatest importance is gender, with women having considerably less CHD than men (see 2.6.2).³⁴

Physical activity is another protective factor, as long as it is sustained throughout life, frequent and fairly vigorous in relation to individual capacity (see 2.6.10).³⁵

Fundamental to the concept of susceptibility to CHD based on community levels of STC is its relationship with diet. The dietary factors most directly, and currently, implicated are a high intake of saturated fat and a low ratio of polyunsaturated to saturated fatty acids (P/S ratio). The intake of dietary cholesterol plays an additional but less consistent role. Where the presence of those factors are prolonged the less likely are their effects to be completely reversed on removal. Nevertheless, the risk of a major CHD event may still be diminished, even in the presence of considerable atherosclerosis.²⁷ The hypothesis that atherosclerosis and CHD are fundamentally nutritional problems associated with dietary fat intakes has not been proven by the various trials of CHD prevention by lowering of STC through dietary modification. Many trials have focussed on selecting individuals at high risk, but have defined high risk using levels of STC (WHO Trial of Clofibrate)³⁶ or high cholesterol and smoking (Oslo Study), 37 and only rarely has high risk been defined in a multifactorial way (MRFIT).³³ As the greatest effect of preventive measures is likely to be seen in those at highest risk of CHD, it would seem that almost all trials have limited their degree of achievement.

Finally, most of the trials have been in middle-aged or elderly men, and it seems unreasonable to expect that moderate dietary changes in middle-or old age will dramatically diminish the damage accumulated over 50 years of atherogenic experience.

Evidence, therefore, from trials lasting only 3-5 years should be regarded as less important than very strong epidemiological data.

2.5 CORONARY HEART DISEASE IN INDIVIDUALS

More convincing evidence on the causes of CHD than that from international studies, such as the Seven Countries²⁵ and the Ni-Hon-San,²⁶comes from long-term surveillance of defined populations after careful baseline evaluation of the cohort. International studies attempted to assess risk factors for CHD in geographically, socially and culturally unrelated groups. They could not explain, however, the regional and social class differences in CHD rates, in terms of differences in classic risk factors. Two prospective studies of particular significance attempted to determine the strength of association between the initial characteristics of the individuals and the emergence of CHD:

- 1. The Framingham Heart Study (FHS). This study of some 5000 men and women, aged 30-59 years, from a self-contained US community, has continued from 1948 to the present time. Multivariate regression coefficients, in a recent report, implicate the high density lipoprotein component of cholesterol (HDL-C) and systolic blood pressure (SBP) as major independent risk factors for CHD, and not cigarette smoking as reported previously. This recent analysis deals with an older sample that is highly selected; many subjects who smoke cigarettes or who are obese have died and are ineligible for inclusion in this report. Furthermore, in older age groups, competing risks from other causes of death in the course of follow-up begin to diminish the effect of risk factors on CHD, eg women smokers dying of cancer. ³⁸
- 2. The British Regional Heart Study (BRHS). This aimed to determine personal and environmental risk factors for CHD in the UK and identified quite marked differences in smoking rates and mean BP levels in keeping with both the geographical and social class differences. In this study, 7735 men, aged 40-59 years, were drawn at random from 24 towns in the UK, no attempt being made to exclude those with evidence of CHD. This overcomes the limitation of studies such as the MRFIT which exclude all men with evidence of existing CHD.²⁷

2.5.1 Incidence of heart attacks without risk factors

Among the British men in the BRHS, there was at least a two-fold independent increase in risk associated with any of the following criteria:

- 1. STC 6.0 mmol/L
- SBP 148 mm Hg, or Diastolic blood pressure (DBP) 93 mm Hg..
- 3. Currently smoking cigarettes.

Only five of the 202 cases of major CHD in the study did not meet these criteria and over two-thirds of cases fulfilled at least two of the three criteria. Of the five men not meeting these criteria, three had evidence of pre-existing CHD; also no account was taken of previous smoking, treatment for blood pressure or dietary modifications. Therefore CHD does not occur in middle-aged British men in the absence of at least one significantly increased risk factor. ³⁹

2.6 RISK FACTORS FOR CHD

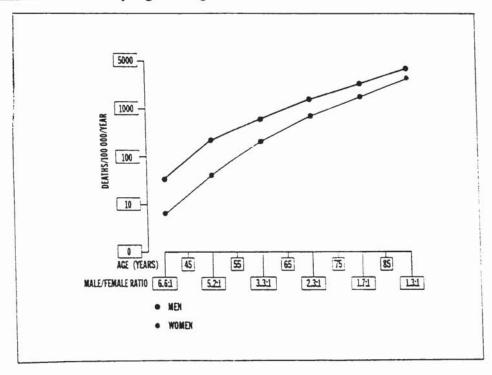
2.6.1 Age

In both men and women, the mortality rate from CHD rises steeply with increasing age - some 15 fold in men from 35-44 years to 55-64 years and some 30-fold in women over the same two decades. Ageing in its own right may have little effect on the risk of CHD, and the ageing factor is an expression of the cumulative effects of STC, raised BP, cigarette smoking and other factors over time.²³

2.6.2 Sex

There is a striking difference in mortality from CHD between the sexes, with young men (35-44 years) having a rate 5-6 times higher than women of the same age. The difference diminishes gradually with increasing age, so that men and women aged 85 years or over have almost the same mortality rate. A major reduction in the sex ratio takes place in the 45-54 year age group, with a substantial further reduction in the 55-64 year group (Figure 2.7).

Figure 2.7 Mortality Rates/100000/year from Coronary Heart Disease for Men and Women by Age in England and Wales 1984



The sex ratio is remarkably consistent in countries with very different cultures, diets and heart disease rates, suggesting an intrinsic gender-mediated difference. It seems likely therefore that women are protected to some degree by their hormonal function, and that this protection diminishes gradually during and after the menopause as oestrogen levels fall. ⁴⁰

2.6.2.1 Hormonal factors

1. Menopause

Despite uncertainty regarding the activity of specific hormones, the ability of women to menstruate constitutes an important protection against CHD. In the fifth and sixth decades of life menopausal women have a 2-3 times higher incidence of CHD than women of the same age who continue to menstruate.

2. Hormone Replacement Therapy (HRT)

In post-menopausal women, some studies have suggested that HRT reduces the risk of CHD. Oestrogens given to man, however, seem to increase the risk.

3. Oral Contraception

Oral contraceptives can raise the BP, increase blood lipid concentrations and affect blood coagulation. Although the relative risk in these women increases 3-4 fold, the absolute risk of a CHD event is still small, as the main effect is thromboembolic rather than atherosclerotic. Nevertheless, the use of oral contraceptives in the presence of cigarette smoking and hypertension constitutes a sufficient risk to consider alternative methods of contraception, especially in older women.

2.6.3 Race

No racial or ethnic group is immune to atherosclerosis and CHD, though certain uncommon genetic disorders, eg Type 11 hyperlipidaemia, may occur with greater frequency in some groups. Also, mortality from CHD and prevalence of non-insulin-dependent diabetes mellitus (NIDDM) are higher in migrants from South Asia than in the general population of the UK. Surveys have identified a pattern of metabolic disturbances associated with insulin

resistance-hyperinsulinaemia, high plasma triglyceride and low HDL-cholesterol - of which high diabetes prevalence is only one manifestation.⁴¹

Environmental factors have a powerful effect on determining rates of CHD in populations, eg the increased prevalence in the Japanese as they migrate from Japan to Hawaii to California. ²⁶

2.6.4 Diabetes mellitus

Susceptibility to arterial disease appears to rise in parallel with increasing glucose intolerance. In the developing world, where CHD is uncommon, diabetes mellitus does not produce an increased risk of CHD, suggesting that it is not a fundamental causal factor, although it may aggravate the situation. High fat, low carbohydrate diets, once commonly used in the management of diabetes in Western societies could have played an important role in increasing risk. Diabetes, like obesity, constitutes an indicator of importance in the detection of high-risk individuals.

2.6.4.1 Insulin resistance

There is now compelling evidence that many cardiovascular risk factors, either singly or in combination, are associated with high circulating insulin levels, which signify a state of insulin resistance. The high insulin levels may be causally related to some of the cardiovascular risk factors and, either independently or together with these risk factors, may also be associated with the development of atherosclerosis. A hypothesis linking hyperinsulinaemia with atherosclerosis supports prominent advice on prevention of CVD, as avoidance of obesity and regular physical exercise are both known to reduce insulin resistance and reduce high insulin levels. 42

2.6.5 Blood lipids

Body fats are a chemically varied group of substances, which include cholesterol. Cholesterol occurs in the body, both as the free substance and in the ester form, in which it is chemically bound to a fatty acid. The metabolism of cholesterol in the body is linked to that of the fatty acids and also to the triglycerides, in which fatty acids are bound to glycerol.

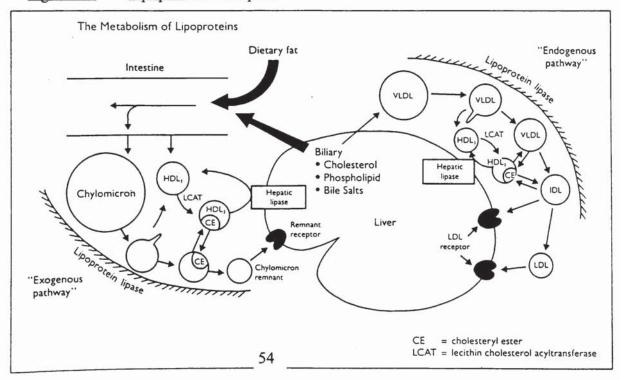
Lipids are transported in the blood in the form of lipoprotein complexes, which have a water-soluble coat of apoproteins, phospholipids and free cholesterol. There are four main types of lipoprotein particles:

- 1. Chylomicrons
- 2. very low density lipoproteins(VLDL)
- 3. low density lipoproteins (LDL), and
- 4. high density lipoproteins (HDL).

The LDL fraction, which comprises 60-70% of the STC, mediates the major atherogenic influence, while the HDL fraction of 20-25% has an inverse relationship with CHD and is generally regarded as a 'protective' cholesterol.

The current concept of the lipoprotein transport system is outlined in Figure 2.8. The major pathway for removal of LDLs is via LDL receptors on liver cells. HDLs may accept cholesterol from extrahepatic tissues and transfer it to VLDL and LDLs, facilitating the removal of free cholesterol by the liver. 43

Figure 2.8 Lipoprotein Transport

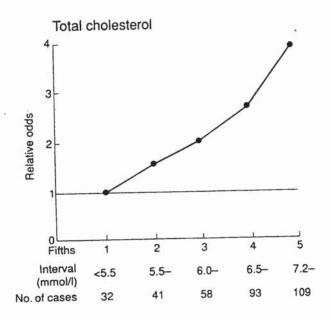


The HDL fraction is a constantly changing dynamic system, involving exchanges with other lipoproteins and interactions with special cell receptors, where they can either receive free cholesterol or deposit cholesterylester, depending on the cell's requirements.

2.6.5.1 Serum total cholesterol

There is considerable evidence that this is the most important single factor in determining the risk of CHD in individuals, as seen in the Multiple Risk Factor Intervention Trial (MRFIT). The level of risk rises progressively with increasing concentrations of STC (Fig. 2.9).³³

Figure 2.9 Relative Odds of a Major CHD Event by Fifths of the Ranked Distribution of Serum Total Cholesterol



In populations with a high average level of STC, the majority of people have levels of STC which carry increased risk of CHD. From Figure 2.9, it can be seen that the middle quintile, representing the average man in the population, has a blood cholesterol level associated with a two-fold increase in risk of a

major CHD event compared to men in the lowest quintile of the blood cholesterol distribution.

2.6.5.2 HDL-cholesterol

A number of studies have indicated that HDL-cholesterol is associated inversely with risk of CHD. However, in 6 of the 7 studies the HDL concentration difference between those developing acute major CHD and those remaining free of CHD is relatively small.²³ In the BRHS, when BMI, smoking, triglyceride and non-HDL concentration were taken into account in a multivariate analysis, no independent effect of HDL on major CHD events was noted.³⁹

As there is an inverse relationship, generally, between HDL cholesterol and VLDL triacylglycerol, low levels of the latter could be responsible for reduced atherosclerotic effect, therefore, the ratio of HDL/total plasma cholesterol could be more important than HDL levels. ⁴⁴ The findings that a low HDL and a raised LDL concentration were associated with CHD in middle aged men have implications for screening programmes. ³³

2.6.5.3 Triglycerides

In univariate analyses of data from most prospective studies, the concentration of serum triglycerides has emerged as a positive risk factor for CHD. However, there is a positive correlation with BMI, total cholesterol and LDL-cholesterol and a negative one with HDL-cholesterol. Alcohol and diabetes mellitus also exert an effect. In multivariate analysis, triglyceride concentration appears to have no independent relationship with CHD events. A French study (1986) has countered this, ⁴⁵ as has an American Consensus Conference on the treatment of hypertriglyceridaemia (HTG), concluded that raised levels can be helpful in identifying persons with increased risk of cardiovascular disease. ⁴⁶ This is because most HTG in clinical

practice is secondary to a variety of factors such as thiazide diuretics and oral contraceptives or to disorders such as diabetes and hypothyroidism, and is almost certainly involved in the complex dynamics of atherosclerosis.

2.6.5.4 Blood clotting factors

Recently, a thrombotic component in CHD has been recognised. High fibrinogen levels may predispose to thrombosis by four pathways:

- 1. atheroma
- 2. viscosity
- 3. fibrin formation, and
- platelet aggregation.

Lowering fibrinogen levels probably reduces the incidence of thrombotic episodes, indicating that high fibrinogen levels are of causal significance. In practice, the most important lifestyle change is the discontinuation or avoidance of smoking, where, although fibrinogen levels in ex-smokers do begin to fall quite soon after discontinuation, they remain above non-smoking levels for several years, as consequently does the risk of CHD itself. Fibrinogen levels are lower in men reporting continuing, strenuous exercise than in those who only mildly exercise or who do no exercise.⁴⁷

2.6.6 Dietary Factors

2.6.6.1 Dietary cholesterol

There is lack of a direct epidemiological relationship between cholesterol intake and plasma cholesterol levels, despite the correlation between dietary cholesterol and CHD which has been found between populations of different countries. This may be due to dietary cholesterol acting as an indicator of a diet high in saturated fat rather than being causative of the high incidence of CHD itself.

2.6.6.2 Dietary fat

There is remarkably consistent support for the hypothesis that populations on diets low in saturated fat and cholesterol and with a high ratio of polyunsaturated to saturated fatty acids exhibit a low incidence of CHD. The corollary is also true.In the Seven Countries Study, there is strong correlation between the 10 year CHD death rate of the 16 cohorts and the percentage of dietary calories supplied by saturated fatty acids.²⁵ When the incidence of CHD events is plotted against the P/S ratios for the seven countries, the relationship is even more striking. Some studies have shown a relationship between the diets of individuals within populations to their individual levels of STC, though this is difficult, due to the considerable variation in biological response to any stimulus. 48 Other determinants, especially genetic, play a role in the absorption, metabolism and transport of blood lipids; but, no single environmental factor has been shown to influence STC or LDLcholesterol more than diet.

Data from many studies in man and animals strongly suggests that atherosclerosis is primarily a nutritional disorder, and not an inevitable consequence of ageing. ^{33,36,49} It is to some considerable extent avoidable. To some degree, the progress of atherosclerosis may be halted and some regression may take place in certain individuals.

Randomised dietary and drug studies of primary and secondary prevention shows a convincing relationship between the percentage reduction in STC and the percentage difference in incidence of CHD between experimental and control groups. ^{23,25,43} The greater the reduction in STC by diet or by drugs, the greater the reduction in incidence of CHD. ⁵⁰

2.6.6.3 Dietary fibre

Dietary fibre comprises those fractions of complex carbohydrates which are not digested, and evidence from mortality rates from CHD for over 20 countries has shown that dietary fibre intake is inversely correlated with coronary disease. Vegetarians whose diets include dietary fibre-rich foods usually have lower levels of plasma total and LDL cholesterol and triacylglycerols than omnivores. 51

Recommendations are that those who wish to reduce their fat
intake must perforce increase their carbohydrate consumption
to maintain their energy levels. Therefore, an increase in fibre
intake is likely to be an intrinsic part of a low-fat diet.

The term 'non-starch polysaccharide' (NSP) is now recognised as more appropriate than 'dietary fibre'. A high intake of NSP may decrease the digestibility of fat, retard the absorption of glucose and decrease postprandial insulin effects, thus indirectly affecting risk of CHD.

2.6.6.4 Salt

Salt intake in the vast majority of human populations greatly exceeds physiological requirements, and epidemiological studies support the hypothesis that salt could be a critical factor in the development of hypertension. A reduction of dietary sodium intake of 20 mmol per day is associated with a population mean reduction of 2 mm Hg in blood pressure and 10% in prevalence of hypertension.

2.6.6.5 Sugar

In communities on high carbohydrate diets, obesity may be common and hypertension and diabetes prevalent while CHD remains an unusual phenomenon, contradicting some widespread views.

2.6.6.6 Alcohol

Many studies have shown that light regular drinkers have a lower rate of CHD than heavier drinkers. ⁵³ However, in several studies, including the BRHS, no significant relationship has been demonstrated between alcohol intake and the risk of CHD, and it seems that whatever personal characteristics make for light regular drinking also make for lower rates of CHD.

The connection between alcohol intake and elevated HDL has been noted in epidemiological studies and seems to be due to the stimulation of enzyme systems which increase hepatic HDL synthesis. Two other possible mechanisms for a beneficial

effect are:

- 1. reduced platelet aggregation and
- 2. increased fibrinolytic activity.

Many studies have shown an independent dose-response relationship between blood pressure and alcohol consumption, with a threshold effect before a trend for increased hypertension and stroke risk with increase intake of alcohol.⁵⁴

The mechanism may be related to changes in cardiac output, blood vessel constriction, and altered secretion of the hormones, renin, angiotensin and catecholamines.

2.6.6.7 Coffee

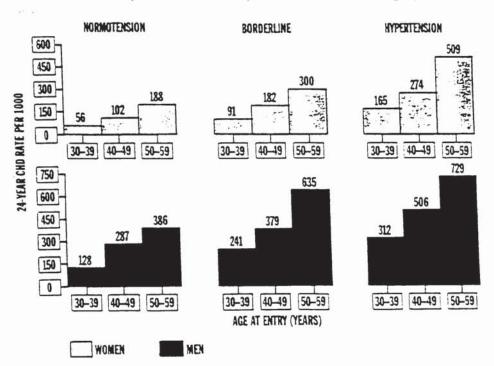
Large prospective studies have failed to incriminate coffee drinking in CHD;⁵⁵ however, a study of American doctors showed that heavy coffee consumption was associated with an increase in risk of death from CHD, after adjustments were made for initial cholesterol concentration, blood pressure and smoking habits.⁵⁶

A linear association has been shown between coffee drinking and STC, but that it was boiled, not filtered coffee, which had the hypercholesterolaemic effect; tea drinking was not associated with raised STC.⁵⁷

2.6.7 Blood pressure

Raised blood pressure levels are associated with a wide range of organic complications, including hypertensive heart disease, cerebrovascular disease, CHD and renal failure. In countries where atherosclerosis and CHD are common, raised BP is one of the most important established risk factors for CHD. The problems begin to arise when one tries to define what is 'normal' and what is 'raised' BP in the natural distribution of blood pressure. The Framingham Study took a blood pressure lower than 140/90 mm Hg as normal and higher than 160/95 mm Hg as hypertensive with a borderline group in between. Their hypertensives have a two-fold increase in risk when compared with the normotensive subjects (Fig. 2.10). 38

Figure 2.10 Framingham Study. Hypertension as a Risk Factor: 24 year Incidence of Coronary Heart Disease by Blood Pressure Category



In the BRHS a two-fold increase in risk of CHD is evident at a SBP of over 148 mm Hg, with little or no gradient of risk below this level, and the DBP of over 93 mm Hg was associated with a greater than two-fold risk of CHD.²⁷

Therefore, it seems clear that the risk of CHD is increased at levels which many clinicians would regard as acceptable and as requiring neither

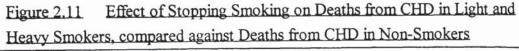
management nor monitoring. The implications for primary care are that greater efforts need to be made to identify, manage and follow-up relatively high blood pressure more effectively. The WHO definition of raised blood pressure - SBP above 160 mm Hg and DBP above 95 mm Hg - may be helpful as a practice profile recording criteria.

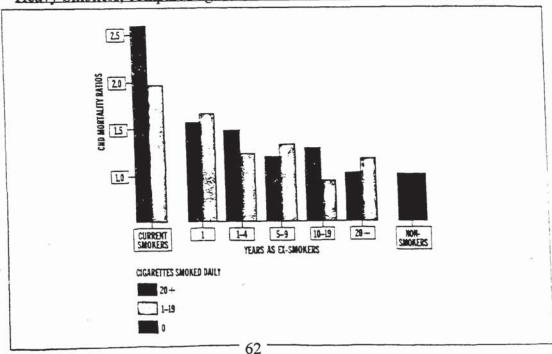
Elevated BP is an even more important risk factor for stroke.⁵⁸ There is a 15-fold increase in risk in individuals with DBPs above 100 mm Hg compared with those in whom the DBP is below 80 mm Hg. In the USA, improved treatment of high blood pressure has been credited with a greater than 50% reduction in age-adjusted stroke mortality.⁵⁹

2.6.8 Cigarette smoking

In the Framingham Study, the recorded rate of CHD in smokers was about 2-3 times that of non-smokers. No increased risk was observed in those who only smoked cigars or a pipe and were not ex-cigarette smokers.

Early studies emphasised the number of cigarettes smoked per day as a critical factor in determining the incidence of CHD. Observational studies provide evidence of a reduction in excess risk of heart attack or death from CHD in those who stop smoking compared with those who continue (Fig 2.11).⁶⁰





Data from the BRHS suggest that the benefit may be far more gradual and less complete than has been accepted, because of the increased prevalence of CHD in those who give up smoking and carry their risk with them into the early years of being an ex-smoker.

The generation of free radicals within cigarette smoke may be an important pathogenic pathway in cigarette smoke-related cell injury, both within and without the circulation. There are long-lived radicals which are associated with the tar phase of the smoke and a second category associated with the vapour phase which contains carbon and oxygen-centred radicals. There is evidence of peroxidation of LDL, causing it to be more readily taken up by macrophages, leading to fat being deposited in artery walls. ¹⁸⁹

2.6.9 Obesity

In communities in which CHD is common, overweight subjects do have a two-fold increase in risk of major CHD events. ³⁸However, obesity is closely associated with increased levels of BP, STC and triglycerides and with decreased levels of HDL-cholesterol and physical activity. Statistically, obesity cannot be shown to exert an independent effect, but an overweight person often has other relevant risk factors and it should therefore be an important focus of attention in primary health care for the patient and the doctor.

2.6.10 Physical activity

There is now considerable evidence which indicates that sustained regular physical activity affects the development of CHD. Compelling evidence has accumulated to show that physical activity can reduce the individual risk of CHD and stroke by a factor of two or more. ⁶¹Physical activity seems to be a protective factor roughly equivalent to not smoking, or with not having high blood pressure, or with not being hypercholesterolaemic. ⁴⁷

Whether this activity has to be sufficiently vigorous to improve 'cardiovascular fitness', or whether a lower level of regular activity is acceptable is not certain. In one study, moderate habitual exercise predicts low risk for CHD, independent of smoking, obesity, hypertension or parental death from heart

disease, whereas in a study in GB, vigorous exercise was seen as the critical factor affecting the incidence of CHD. 62

Additionally, exercise can modify other risk factors for CHD; it can lower BP, cause favourable changes in lipid profiles, aid weight loss and alleviate stress.⁴⁷

2.6.10.1 Mechanisms of benefit

Bradycardia may occur during resting after physical exertion (at a given exercise intensity) which may influence the risk as it decreases the work, and therefore the oxygen consumption, of the myocardium. In adults with mild to moderate hypertension, the effect is enhanced by reductions in SBP and DBP of, on average, 13 and 10 mm Hg respectively. Proliferation of capillaries in skeletal muscle on exercise accelerates the removal from the circulation of triglyceride-rich lipoproteins, increasing the synthesis of HDL. This would be consistent with improved reverse cholesterol transport, which may explain the decreased atheroma found in coronary arteries. 63

2.6.10.2 Safety of exercise

There is concern that vigorous activity which causes a marked increase in the work of the heart might precipitate an acute episode of MI. Siscovich et al (1984) concluded that the balance of risks of habitual vigorous exercise is favourable, but this study also shows that unaccustomed strenuous exercise is potentially hazardous for middle-aged or older persons. ⁶⁴

2.6.11 Family history

Cardiovascular disease, before the age of 55 in a first-degree relative, eg mother, father, brother or sister, constitutes an important risk factor for CHD and may multiply the risk 2-4 fold.²³ The aggregation of risk factors such as hypertension, diabetes mellitus and obesity in a family is also well-recognized, and high levels of STC may also cluster in families, but only a very small

proportion of these are associated with the genetically conditioned 'familial hypercholesterolaemia'. The heterozygous form of this disorder occurs in about 1 in 400-500 of the population, and the lethal homozygous form is extremely rare.⁶⁵

Most familial clusterings of risk factors and CHD are probably the result of interaction between genetic factors and environmental influences. The genetic component of CHD is probably made up of separate genetic effects on a wide variety of physiological responses. The responses to a particular stimulus will vary considerably amongst a group of individuals, usually producing a 'normal' distribution of response, some of the variation being genetic in origin.

Thus, some individuals on a high saturated fat intake will maintain a relatively low concentration of STC although, on a group basis, those with high saturated fat intakes will have higher STC concentrations than those on a low intake.

2.6.12 Psychosocial factors

Emotional stimuli may profoundly affect the cardiovascular system through their effects on autonomic nervous control. Fear, anger, love and hostility all have a considerable effect on heart rate, BP and vasomotor reactivity; these effects may have grave consequences for subjects with severely compromised coronary arteries. The 'stress hormones', noradrenaline and adrenaline, provide an instant source of energy for the ensuing flight or fight by promoting the breakdown of the body's fatty tissues so that triglycerides and free fatty acids are liberated into the bloodstream, stimulating a reflex production of more cholesterol.

The rise in plasma cholesterol does not occur in response to major upheavals, but often as a result of having to suffer the pressures of everyday life, and are of the magnitude of 10 to 35%. 66

It can be seen that the individual's whole lifestyle should be considered when counselling a patient about the need to consider the lowering of STC. It is

necessary to consider and assess the capability of a patient to respond and avoid a stress response.

In attempting to answer whether stress has a truly independent ability to damage arteries and cause CHD, Friedman and Rosenman first described a Type A behaviour pattern in the 1950's. This is characterised by aggressiveness, ambition, competitiveness, chronic impatience, was thought to roughly double the risk of developing CHD, ⁶⁷but recent results from many large studies have failed to show an independent association between Type A and risk for CHD. ³³

Psychosocial variables such as low social network, job strain and high hostility, related to a low standard of education, may be independent risk factors for CHD. Observers in the USA and UK found that the decline of age-adjusted CHD mortality, from 1960-1975, was steeper in the most compared to the least educated people, both for males and females. The lower CHD rates in the well-educated may be mediated partly by greater knowledge of and a more favourable attitude towards primary and secondary prevention of CHD. 68

2.6.13 Culture

Epidemiology is the study of the distribution and determinants of the various forms of disease in human populations. On an individual level, the notion of 'risk factors' has a predictive value, but cultural, social and psychological factors may influence much of this 'risk related behaviour'. 69 Cultural influences often shape dietary patterns, obesity or smoking. 70 Studies have examined the epidemiology of CHD, hypertension and stroke among 11900 men of Japanese ancestry living in California, Hawaii and in Japan itself. They found that there is a gradient in the occurrence of CHD between the three groups with the lowest rate in Japan, intermediate in Hawaii and highest in California. The gradient in incidence of CHD could not be explained by the presence of the usual risk factors; those who smoked similar amounts in the three groups still showed a gradient in the incidence of CHD. However, the incidence was found to be related to the degree of their adherence to the traditional Japanese culture in which they were raised. The closer their adherence to these traditional values, the lower was their incidence of CHD. Those Japanese Americans who had become most 'westernised' in outlook had higher rates than those immigrants who retained their more traditional lifestyle.71

There is a suggestion, therefore, that the culture in which an individual is raised affects his likelihood of manifesting CHD in adult life, and that this relationship of culture of upbringing to CHD 'appears to be independent of the established coronary risk factors'. In the case of the Japanese, the cultural emphasis is on group cohesion, group achievement and social stability. In this cultural group, as in other traditional societies, it is suggested that 'a stable society whose members enjoy the support of their fellows in closely knit groups may protect against the forms of social stress that may lead to CHD'.

Also, if three groups of Japanese with similar genetic backgrounds have different rates of CHD, environmental influences must somehow be implicated.

2.6.13.1 Ethnic groups in the UK

Mortality from CHD and prevalence of NIDDM are higher in migrants from South Asia than in the general population of the UK. Epidemiological studies of CHD and diabetes in South Asians provide compelling evidence for the existence of a syndrome of metabolic disturbances associated with insulin resistance and with increased risk of CHD. Some disturbance of lipoprotein metabolism, related to increased synthesis of VLDL triglyceride, is the most likely mediator of the increased CHD risk associated with insulin resistance.

High prevalence of NIDDM and other metabolic disturbances associated with insulin resistance occur in people of South Asian descent in widely different environments and persist several generations after migration; therefore it would seem that some genetic predisposition to develop insulin resistance exists in this group. ⁴¹

CHAPTER 3

THE COMMUNITY PHARMACY AS AN ACTIVE BASE FOR HEALTH PROMOTION

3.1 HEALTH ADVICE

In recent years the value of the pharmacy as a centre for health education has been increasingly recognised. As the emphasis within the NHS steadily shifts from treatment to prevention, there is considerable opportunity for the full potential of pharmacy in this field of activity to be developed for the greater benefit of the public.

Pharmacies differ from the great majority of other locations used for health promotion activity in that an estimated 4-5 million healthy people visit them daily. The an informal environment, such as community pharmacy offers, health education messages are more likely to have an impact than when the individual, possibly in an anxious state, is focused on the need for diagnosis or treatment of an illness. 5

3.1.1 The Pharmacy Health Care Scheme

1986 saw a new initiative in health education with the launch of the first national health education campaign in community pharmacies. The campaign is supported, financially, by the Health Education Council, Family Planning Association, NPA, RPSGB, and the Scottish Health Education Group. It involves the availability and distribution of printed literature on specific health related subjects, to every community pharmacy in Great Britain (GB) and Northern Ireland (NI), and is intended to be used as a springboard for existing pharmacies to become 'centres for health' providing information to assist in maintaining and improving good health.

93% of community pharmacies in GB and NI participate in this scheme and a leaflet about heart disease resulted in over 14,000 responses returned to the British Heart Foundation, requesting information on "reducing the risk of a heart attack" and "eating for a healthy heart ". This indicates a highly cost effective investment of DOH resources, and should be increased to use fully

the potential of participating community pharmacies in specific health promotion campaigns.⁷⁴

3.2 AIM OF RESEARCH

The main, initial aim of the research was to utilise the community pharmacy to encourage patients and customers to become involved in monitoring their own health status.

Achievement of this aim would be through the following proposals:

- 1. Availability and promotion of diagnostic testing, including weight measurement, blood pressure monitoring and cholesterol testing.
- 2. Monitoring the acceptability of patients and customers to take a more active involvement in their own health care.
- 3. Development of links with local general practitioners, dieticians and other health care professionals to enhance the primary health care team for the benefit of the patient.

3.2.1 Health of the Nation

"The Health of the Nation" Green Paper, published in June,1991,was a consultative document for the Government's proposals for the development of a health strategy for England.⁷⁵

3.2.1.1 A strategy for health

The aim of the strategy is to improve the span of healthy life. The key strategic policy objectives were to:

- * identify the main health problems and focus on them
- * focus on the promotion of good health and prevention of disease
- * recognize that the concerted action needed calls for greater cooperation between those involved, at national and local level
- * secure the best possible use of available resources.

This in turn would mean:

- * improving the ability to monitor the state of people's health, evaluate the health benefits of programmes, and assess the effectiveness of particular services in terms of 'health gain'.
- * ensuring everyone has the best possible information needed to understand the influences on health, and the necessary support to improve health.

The White Paper sets out a strategy for health for England in response to the Consultative Document.²⁴

The strategy selected five Key Areas for action, judged against the following criteria: 1. the area should be a major cause of premature death or avoidable ill-health in the population,

- 2. the area should be one where effective interventions are possible, offering significant scope for improvement of health,
- 3. it should be possible to monitor progress towards achievement through indicators.

3.2.1.2 Coronary heart disease and stroke

These two diseases were designated as 'Key Areas' as they are the causes of substantial, but avoidable, mortality. It was against this background, and with this encouragement, that the main part of the research project was planned by the pharmacist/author. The pharmacist, thus, focussed on CHD and stroke as a specific aim of the study, which was to assess the contribution a pharmacist can make to the reduction of risk factors associated with CHD and stroke.

3.2.1.3 Health of the Nation targets for CHD and stroke

To reduce death rates for both CHD and stroke in people under 65 by at least 40% by the year 2000 (from 58 per 100000 population in 1990 to no more than 35 per 100000 for CHD, and from 12.5/100000 population in 1990 to no more than 7.5/100000 for stroke).²⁴

3.3 DEVELOPMENT OF THE STUDY

In 1991, at the commencement of the project, the study pharmacy was already offering a weight measurement service and blood pressure monitoring.

It has been estimated that 33% of all premature deaths in the UK are caused by CHD, and there is a major Government-sponsored effort to ameliorate this problem. ⁷⁶

In the pharmacy's FHSA area CHD is the most important single cause of premature mortality and is responsible for some 500 deaths annually, in the local population. Substantial epidemiological evidence suggests that raised serum cholesterol concentrations are associated with increased risk for CHD. Evidence from primary and secondary prevention trials has established the efficiency of interventions to lower cholesterol concentrations, both dietary and pharmacological, in reducing incidence of CHD. There seems to be a consensus that a reduction in STC, if applied on a population basis, would contribute appreciably to public health. ⁷⁸

To implement the initial aim of the study, the pharmacy introduced a cholesterol screening service. In this way, the pharmacist would be provided with a focus on which to actively develop health promotion and education, consistent with the 'extended role'. ⁷⁹

3.4 CHOLESTEROL SCREENING IN THE PHARMACY

3.4.1 Requirements for an effective screening programme

The aim of any screening programme is to identify those at risk and target resources to reducing that risk.

Before implementing the cholesterol screening programme in the pharmacy, the following seven criteria were considered:

- 1. The frequency and natural history of CHD must be recognised.
- 2. The disease must be of public health importance/significance.
- 3. There must be effective diagnostic techniques to test blood cholesterol, a major risk factor, and treatment must be available.
- 4. The screening test must be simple and safe.
- 5. The screening programme must be ethical and be acceptable to the public and authorities.

- 6. The screening programme should demonstrate that the benefits outweigh the costs.
- 7. The screening test should be able to identify and separate those at low and high risk with good sensitivity and specificity. Clearly agreed and defined cut-off points and intervention targets must be established.

In order to fulfil these criteria, the pharmacist set up the following:

3.4.1.1 Training

Pharmacists must ensure that any results they provide to patients are as accurate and reliable as possible, and with this in mind, the following steps were taken:

- 1. Attendance at a technical training programme offered by the company providing the instrumentation.
- 2. Attendance at the Family Heart Association (FHA) to study their management protocol for pharmacy cholesterol testing.
- 3. Attendance at a seminar organised by the local hospital lipid consultant on blood cholesterol testing and lipid clinics.
 Further, a private consultation day spent with the lipid and diabetic consultant in her clinic, to gain essential practical experience of the size and nature of the problem.

3.4.1.2 Facilities

The test and counselling ought to be carried out in an environment separate from the main body of the shop.

Therefore, a consulting room was established to perform the analysis, having a bench with an impervious washable surface, sink and adequate lighting. The pharmacist carrying out the diagnostic test had a hepatitis B vaccination and wore latex gloves at all times when working with blood or blood-contaminated products. The latter, together with needles and lancets were disposed of with appropriate care in a sharps container, following NPA guidelines.

3.4.1.3 Principles of the test

The 'bench top' instrument used for measuring cholesterol was the Reflotron (Boehringer Mannheim) which uses a 'dry chemistry' system. All the necessary reagents are impregnated onto a porous pad on a plastic 'stick', and the addition of 30 uL of whole blood to this porous pad provides solvent to initiate the reaction.

The principle of cholesterol determination involves the quantitative analysis of free cholesterol and cholesterol esters which are released from lipoproteins by the action of surfactants. The amount of colour development is directly proportional to the concentration of cholesterol in the sample.

3.4.1.4 Accuracy of instrumentation

Independent studies have quoted a coefficient of variance, which is a measure of accuracy of results, of 3.5% for the Reflotron, equivalent in accuracy to hospital-based analytical equipment. 80

In the interests of maintaining accuracy, an internal quality assurance scheme was introduced using a suitable standard. In addition, the pharmacist participated in an external quality assurance scheme, run by the Wolfson Research Laboratories in Birmingham. They mailed three serum samples to the pharmacy on a two-monthly basis and on receipt of the results assessed the accuracy of the service being provided.

3.4.1.5 Testing procedure

An automatic pipette was used to collect a 30uL aliquot of blood sample, by capillary action, from a fingerprick, as follows:

- 1. The client was seated before the test was performed.
- 2. The patient's hand was checked for warmth, as a cold hand would inhibit the flow of blood.
- 3. The finger was swabbed with alcohol and dried with a sterile cotton gauze. This ensured cleansing of the area and also removal of any fatty material attached to the skin which could potentially affect the result.
- The finger was pierced with a suitable lancet using an Autolet apparatus. The first drop of blood was wiped with a tissue.
- A second drop of blood was allowed to form and if necessary the area was gently massaged to increase the flow, but not squeezed as this would cause trauma.

The reagent stick, plus blood sample, was then inserted into the reaction part of the instrument and incubated in the body of the instrument at 37°c for 175 seconds, after which a digital readout appeared on the screen of the STC, established by the reflectance of light from the reaction pad.

3.4.2 Cholesterol monitoring

The pharmacist initially contacted all the general medical practices within the geographical orbit of the pharmacy, informing them of the service and asking them for referral criteria for their patients' cholesterol level. A poster was then placed in the pharmacy window to advertise the service.

There was agreement that the more testing that is performed, the greater the possibility of identifying individuals who will require treatment.

A single cholesterol measurement cannot be considered to be diagnostic, but can act as a prompt for possible further action, by identifying those who are in most need for further lipid assessment.

There are also a number of variables affecting a 'one off' cholesterol measurement, some behavioural and some analytical. Clinical situations which can indicate the need for delay of measurement include:

- 1. Any patients recovering from a recent illness- delay for a month.
- 2. Any patients recovering from major surgery, myocardial infarction, or prolonged illness- delay for three months.
- 3. Pregnant patients.

A protocol was then designed for clients coming to the pharmacy for a cholesterol test. An initial charge of £7 per test was made with follow-ups charged at £5.

3.5 PROTOCOL FOR PHARMACY CHOLESTEROL SCREENING

3.5.1 Interpretation of cholesterol result

The Standing Medical Advisory Committee (1990) advised that the most important and effective way to reduce CHD is through a national food and health strategy with the aim of reducing the general level of blood cholesterol in the general population.⁷⁸

A pharmacy based cholesterol testing service can make the public more aware of the role of lipids in heart disease. In particular, the pharmacy based service provides:

1. An assured accuracy of the test method.

2. The availability of a pro-active expert counselling at the time of the test and subsequently.

The STC result, on a non fasting subject, was initially interpreted for CHD risk, according to Table 3.1, which is based on the guidelines of the International Atherosclerosis Society.

Table 3.1 C H D Risk Category for S T C Measurements

Serum Total Cholesterol mmol/L	C H D Risk Category
<5.2	Low
5.2-6.5	Slightly Increased
6.5-7.8	Moderate
>7.8	High

3.5.2 Treatment strategies

Accuracy, as confirmed by the quality control scheme, was essential, as a falsely high reading could cause needless anxiety and a falsely low one might condone the continuation of an unhealthy life-style.

Management guidelines adopted were as summarised in Table 3.2.

Table 3.2 Interventions for C H D Risk Categories

Risk Category	Intervention
Low	Healthy eating advice
Slightly Increased	Lipid lowering diet
Moderate	Lipid lowering diet and refer to dietician
High	Lipid lowering diet and refer to doctor

In the pharmacy, blood cholesterol testing formed part of a broad strategy for the control of CHD and also a focal point for health education. Thus, unlike many testing schemes, such as those conducted in health food shops, the pharmacy offers expert counselling about the results and puts the reading within the overall risk picture for CHD.

3.5.2.1 Management guidelines

- 1. The whole patient was treated, by discussing their health, diet, and lifestyle. The result reading was used as a focal point to health education.
- Cholesterol measurement is an indicative factor in heart disease screening, but there is no place for it in isolation. A family and life-style history and blood pressure reading were also recorded in all cases.

3.5.3 Advice To patients

The issues addressed systematically when giving advice to patients following a cholesterol measurement may be summarised as follows, depending upon their classification into one of four groups:

1. Low risk group (below 5.2 mmol/L)

- * Advice on principal risk factors, such as smoking, blood pressure, overweight and lack of exercise.
- * A general explanation of the necessity to eat a healthy diet, to minimise a significant rise in cholesterol level which is often associated with growing older.

2. Slightly increased risk group (cholesterol 5.2-6.5 mmol/L)

- Healthy eating, low fat diet.
- Weight reduction if necessary.
- Modify principal risk factors if possible.
- * Offer a retest within one year.

3 Moderate risk group (6.5-7.8 mmol/L)

- Controlled weight reduction if necessary.
- Healthy eating, low fat diet, but encourage a consistent diet as diet is the key to reducing cholesterol.
- Assess other risk factors and attempt to modify any.

- * Reassess after 3-6 months, as dietary modification requires at least three months to exert an adequate effect.
- * Some local GPs agreed a referral criterion by the pharmacist of 6.8-7.0 mmol/L for their patients who would be seen by them or their dietician.

4. High risk group (>7.8 mmol/L)

* Agreed referral to a patient's GP who would investigate underlying causes, such as diabetes, hypothyroidism, renal impairment, etc, and treat accordingly.

The GP should recommend:

- fasting full lipid profile
- lipid lowering diet
- reinforcement of appropriate diet and modification of other risk factors
- reassessment within 3 months

3.5.4 Principles of diet and nutrition

Diet is the cornerstone of on-going treatment and within the compass of a pharmacist to advise upon.

* As diet can reduce total blood cholesterol by up to 20%, it is often all that is required for success. 81 Each patient with a cholesterol of > 5.2 mmol/L was given a sheet indicating the low to high cholesterol-containing foods within each food category (APPENDIX 1).

Objectives for the pharmacist

For each patient:

- Assess the present dietary pattern including social and economic circumstances.
- * Ask who shops, who cooks, and whether there is access to healthy food at work.
- * Try to achieve an optimum weight by reducing energy intake and increasing exercise if appropriate.
- * Specifically reduce total fat intake to 35% of dietary energy and saturated fats to 10% of energy intake; moderately increase polyunsaturated fat to no more than 10% of dietary energy, the remaining fat intake to be monounsaturated fat.
- * Increase complex carbohydrates and fibre derived from fruit, vegetables, particularly legumes, whole grain cereals and breads.
- * Moderate the salt intake.

3.5.5 Eating and drinking habits

There is a commitment in the Health of the Nation White Paper to reduce the amount of premature death and ill-health related wholly or in part to eating and drinking habits.²⁴ An unbalanced diet often acts in combination with other elements of an unhealthy lifestyle.

The association between cholesterol and diet, provided the opportunity with the cholesterol test to inform patients of the importance and value of good nutrition in maintaining well-being. 82 Adequate and appropriate nutrition is fundamental to the maintenance of activity and growth, to the maintenance of health, and to the prevention and management of many common diseases. 82

3.5.5.1 The problem

Recent data show that the proportion of the population that is overweight has been increasing steadily in recent years: the 1991 Health Survey for England indicates that 45% of adult women are overweight, with 16% obese, and 53% of men are overweight, with 13% who are obese. 83

CHD is one of a number of diseases common in affluent societies having a nutritional basis interacting with other factors such as genetics, diabetes, smoking and lack of exercise.

3.5.5.2 The need

In Britain, fat provides about 42% of food energy, carbohydrate 45%, and protein 13%. These proportions need to be modified so that fat provides no more than 35% of energy intake with the balance being made up by an increased consumption of starchy, fibre-rich carbohydrates. Thus, if the pharmacist, as a health professional, has a good understanding of nutrition and dietary goals for health and prevention of disease, he will allow people to make informed choices about what they eat and drink, leading to a positive role in promoting good health.

In order to acquire the relevant knowledge to enable him to advise patients appropriately on nutrition, the pharmacist spent time with dieticians at a diet clinic in hospitals in Harrow and Hillingdon.

3.5.5.3 The actual targets

Between 1990 and the year 2005, the Government aim is to reduce:

- * the amount of saturates in the national diet from its current level of 16% of food energy to no more than 11% on average: a reduction of at least 35%
- * the total amount of fat in the national diet from its current level of 42% of food energy to no more than 35% on average: a reduction of at least 12% This could be done, for example, by replacing a snack of two packets of crisps and one Mars bar with one consisting of two slices of wholemeal bread, 16g of polyunsaturated margarine and 10g camembert cheese

- * the proportion of men and women aged 16-64 who are obese from current levels of 8% and 12%, respectively, to no more than 6% of men and 8% of women: reductions of 25% and 33%, respectively
- * the proportion of men drinking more than 21 units of alcohol per week and women drinking more than 14 units of alcohol per week to 18% of men and 7% of women: reductions of 30% in men and women.

3.5.6 The Pharmacy Practice Nutrition Protocol

3.5.6.1 The principles

The Committee on Medical Aspects of Food Policy (COMA) produced a report advising on intake of fat, sugar, non starch polysaccharides (NSP, or fibre), salt, vitamins and minerals. COMA expresses dietary guidelines in terms of nutrients, which need to be translated into foods and eating plans. 84

The pharmacist's aim was to help people to comprehend the information about food and nutrition and use this knowledge to provide for enjoyable, nourishing and balanced meals for themselves and the family.

3.5.6.2 The guidelines

Eight guidelines were established to help in this process:

- 1. Enjoy your food
- 2. Eat a variety of foods

Advice was based on selecting foods from each of the four main food groups. This will be discussed in more detail in Chapters 4 and 5 when dealing with the diet of patients at the two medical centres involved in the study.

3. Eat the right amount to be a healthy weight.

Most people, if they eat to appetite, are able to maintain a stable body weight over a period of time; however, a 1%-2% discrepancy can result in considerable weight gain.

There has been a general decline in physical activity by many people as a greater dependence on motor transport has increased, and there is therefore a consequent reduced need for energy. This physiological response has to contend with the social convention of eating food because it is offered rather than needed, therefore recommendations for weight loss should be coupled with advice on taking more exercise so more food can be consumed without leading to an increase in weight. Advice was given to avoid between-meal snacks and not to continue eating until full.

4. Eat plenty of foods rich in starch and fibre

The report on dietary reference values suggests that 39% of the calories we get from food should come from starch, found in cereals and root vegetables, and intrinsic milk sugars.

Starchy foods are rich in NSP (fibre) and probably help to reduce blood cholesterol concentration. Therefore, regular consumption of bread, cereal foods, beans, lentils, fruit and vegetables was recommended. Further, when advising on fibre intake, the need to take plenty of fluid, eg water, low fat milk, unsweetened fruit juice, and low sugar soft drinks, was stressed.

5. Don't eat too much fat

In addition to fulfilling nutritional requirements, providing the essential fatty acids not made in the body and the fat soluble vitamins A, D, E and K, small amounts of fat give many foods their characteristic flavour and texture. In Britain, however, most people eat too much fat, as saturates in particular.

Recommendations included: using little fat or oil in food preparations, using spreads sparingly; cutting down on fried foods; eating more fish and chicken (without the skin); trimming off all visible fat from meat; using low fat dairy products; cutting out traditional meat products, such as sausages and beefburgers, eating fewer cakes, pastries, confectionery and biscuits.

6. Don't eat sugary foods too often

Eating less sugar is a good way of cutting down on energy intake for those who need to lose weight. Extrinsic sugars are those extracted from the soluble fraction of plant foods or produced by hydrolysis of starches, eg sucrose, honey and glucose, and should be reduced from a national average of 14% of food energy to 11%. Intrinsic sugar, found within the cellular structure of unprocessed foods, such as fruit and vegetables, was recommended as a replacement.

This is equivalent to six lumps (24g) of white sugar or 16g of plain chocolate, or 30g of honey less per day.

7. Look after the vitamins and minerals in your food.

Eating a variety of fruit, salad and vegetables regularly is an important way of ensuring that certain vitamins and minerals, such as vitamin C, folate, beta-carotene and potassium, are present in the diet to a sufficient extent.

Advice was given to avoid unsatisfactory methods of preparing food and meals in order to minimise significant loss of nutrition. When foods are cooked in water, leaching can result, excessive heat can destroy or oxidise valuable nutrients.

Recommendations were to consider stir-fry, microwave use, steaming or grilling and serve cooked foods immediately to minimise losses. 8. If you drink, keep within sensible limits.

Although recent evidence has suggested that moderate alcohol consumption can actually decrease the risk of CHD, excessive intake is markedly harmful to health.⁵³ Moderation is the key to sensible drinking, with limits being set at 21 units per week for men and 14 units for women.

The British Government announced higher limits for sensible drinking in December 1995. The revised guidelines say that regular consumption of between 3 and 4 units a day for men and between 2 and 3 units for women will "not accrue significant health risk." The BMA criticised the move and stated that the beneficial effects of alcohol on heart disease are seen only in postmenopausal women and in men over 40 and can be gained from drinking between only 1 and 2 units a day. 85

Single units are designated:

- * half a pint of beer or lager
- * a glass of wine
- * a single measure of spirits
- * a small glass of sherry
- * three glasses of low alcohol wine.

Women were advised to consume lower levels of alcohol compared to men because:

- * Women experience higher peak plasma levels of alcohol, because they have more subcutaneous fat than men and lower levels of the enzyme alcohol dehydrogenase, responsible for the breakdown of alcohol.
- * The rise in blood pressure following a standard dose of alcohol/kg body weight has been shown to be higher in women than men. 86

3.5.7 Diet and lipoproteins

3.5.7.1 Cholesterol

Cholesterol is a fatty substance which is essential for the functioning of every cell. The body actually synthesises most of what it needs, mainly in the liver, but cholesterol is also present in all foods of animal origin. As well as being necessary for cell functioning, cholesterol is also required for synthesis of steroid hormones, bile salts and vitamin D.

A high intake of foods rich in saturates increase the liver synthesis of cholesterol and this cholesterol also has a slower breakdown rate under these circumstances. Consequently, blood cholesterol levels rise.

For most people, intake of dietary cholesterol has relatively little effect on blood cholesterol.⁸⁷

3.5.7.2 Saturated fatty acids

The saturated fatty acids definitely raise the plasma cholesterol level. For every 1% of the total energy intake contributed by saturated fatty acids, the STC is increased by 0.07 mmol/L, most of the increment occurring in the LDL level.⁸⁸

Saturates are found mainly in foods of animal origin and in hard margarines which have undergone a process of hydrogenation from the vegetable oils.

3.5.7.3 Monounsaturated fatty acids

The major monounsaturate, oleic acid, is neutral in its effect on STC, but when saturated fatty acids are replaced in the diet by olive oil, the rise in STC that would have been induced does not take place. 89

3.5.7.4 Polyunsaturated fatty acids

There are two types of polyunsaturates, which are provided by the diet:

- 1. The omega-3 fatty acids which include eicosopentanoic acid and docosahexanoic acid, major sources of which are mackerel, sardines, pilchards and salmon. The diet of Eskimos is rich in fish and other seafood, and, as they rarely suffer from CHD, the possibility is that fish eating may be protective against CHD. Eskimos also have long bleeding times and low platelet aggregation, therefore lowering thrombotic tendency. 89

 2. The omega-6 series, found in vegetable seed oils such as
- The omega-6 series, found in vegetable seed oils such as maize, soya bean and sunflower oils. The primary essential fatty acid in this group is linoleic acid.

A moderate intake of polyunsaturates in combination with a reduction in saturates intake has been shown to be beneficial in reducing the risk of heart disease. However, high intakes may reduce the concentration of the beneficial type of cholesterol (HDL-cholesterol) as well as LDL-cholesterol. Partly for this reason, an upper limit of 10% of calories has been placed on this type of fatty acid. Monounsaturates do not seem to affect HDL.

3.6 OBJECTIVES

This investigation had the following objectives:

- 1. To determine the feasibility of a cholesterol screening service in the pharmacy.
- 2. To determine the distribution of STC in the population visiting the pharmacy, and to equate this with that pertaining in the local area and nationally.
- 3. To evaluate the success of pharmacist intervention in the reduction of a patient's cholesterol score.

4. To assess the extent to which the pharmacist has to refer clients to their professional colleagues, such as doctors and dieticians.

3.7 RESULTS AND DISCUSSION

3.7.1 First-time cholesterol patients to the pharmacy

Hypothesis 1: The demand for cholesterol screening at a pharmacy will increase over time.

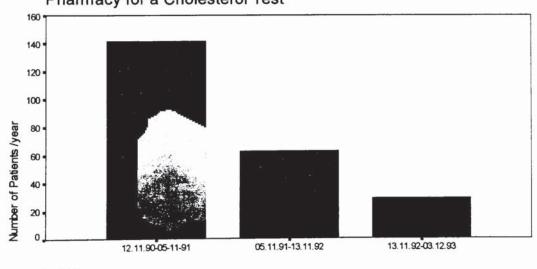
Throughout a 3-year period, 234 new patients attended the pharmacy for a cholesterol test, there being 143 in year 1, 63 in year 2 and 28 in year 3, as shown in Table 3.3 and Figure 3.1

Table 3.3 Annual Figures for Cholesterol Tests

Total Number of Patients = 234

Year Number	Patient	ts
	Count	Percentage
1	142	60.7%
2	63	26.9%
3	29	12.4%

Figure 3.1 New Patients Attending the Pharmacy for a Cholesterol Test



Date Ranges

A significant difference ($X^2 = 90.78$, df = 2, p = <0.0001) was found between years 1, 2 and 3 for attendance by patients for a cholesterol test at the pharmacy.

The demand for cholesterol screening at the study pharmacy decreased in consecutive years over a 3-year period.

This was due to:

- 1. It became fashionable to know one's cholesterol figure in 1990, but there was less perceived interest by 1993.
- 2. In any given area those that are health conscious will come during the early part of any screening programme to have a diagnostic test, leaving a greater proportion of the remaining population with less interest, or even complete disinterest.
- 3. The cost prohibited some people as they were able to have a free health screen and test at their general medical practice.

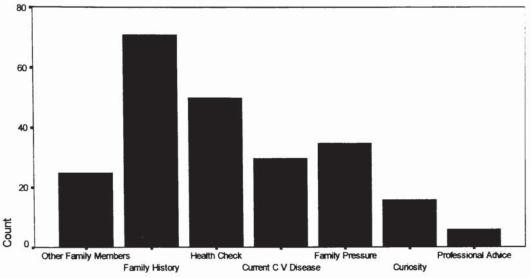
3.7.2 Reason for visit

The reason for the client's visit to the pharmacy is shown in Table 3.4 and Figure 3.2.

Table 3.4 Reason for Visit to Pharmacy for STC Test

Reason		Lents
	Count	%
Other Family Members	+	-+
with C V D	25	1 10.7%
Family History	71	1 30.3%
Health Check	50	21.4%
Current Cardiovascular	1	1
Disease	30	12.8%
Family Pressure	1 36	15.4%
Curiosity	16	6.8%
Professional Advice	1 6	2.6%

Figure 3.2 Reason for a Client's Visit



Reason for Visit

The single most important factor in stimulating a person to come for a test was a family history of CHD, and this accounted for 30% of respondents. 15% came due to family pressure and another 10% because other members of the family, not genetically related, had cardiovascular disease, and there was the belief that the family factor was significant.

3.7.3 Patient demographics

The GP practice indicating the geographical location of patients is shown in Table 3.5 and Figure 3.3, where Pinner and Hatch End and Northwood represent individual practices, and Harrow an FHSA area.

Table 3.5 Patient's GP Surgery Location

14010 010		
Surgery	Patients	
	Count	Percentage
Others	63	26.9%
Pinner 1	52	22.2%
Pinner 2	23	9.8%
Hatch End	26	11.1%
Northwood	19	8.1%
Harrow	51	21.8%

60 50 40 30 20 Others Pinner 1

Hatch End

Northwood

Harrow

Figure 3.3 Geographical Distribution of Patients

Patient's G P Practice

As 49% of patients attending for a test came from outside the geographical orbit of the main practices near the pharmacy, it was clear that the nature of the pharmacy situation was that it attracted a significant number of casual and spontaneous patients.

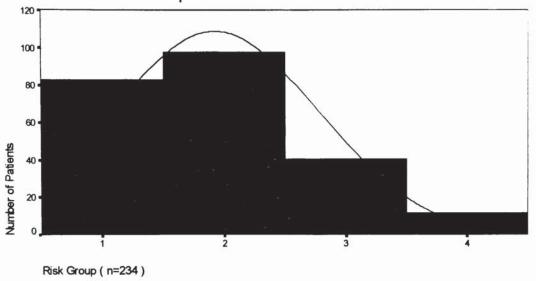
3.7.4 Cholesterol distribution

The frequency of the cholesterol readings associated with the four risk groups is shown in Table 3.6 and Figure 3.4. Figure 3.5 illustrates a more detailed STC distribution, mean value STC 5.69.

Table 3.6 Comparison of Cholesterol Distribution with Official Local Data

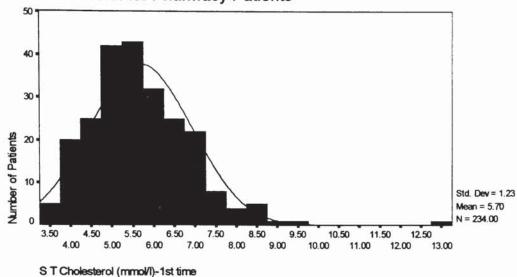
Risk	Cholesterol	sterol Percentage of Population		
Group	Level (mmol/L)	Pharmacy	Harrow	Hillingdon
1	<5.2	35	35	34
2	5.2-6.4	42	41	41
3	6.5-7.8	18	20	21
4	>7.8	5	4	4

Figure 3.4 S T C Frequency of the Four Relative Risk Groups



The normal curve in these figures is derived from the sample data using the sample mean and the variance. The variance is computed by summing the squared differences from the mean of all the observations and then dividing by one less than the number of observations. The square root of the variance is termed the standard deviation, which is expressed in the same units of measurement as the observations. A broad range of observed phenomena in nature and society is approximately normally distributed, eg cholesterol. In these histograms, the curved line indicates what the distribution of cases would be if the variable had a normal distribution with the same mean and variance.

Figure 3.5 Normal Distribution Curve of Cholesterol for Pharmacy Patients



Hypothesis 2: The distribution of cholesterol readings among the pharmacy population reflected that of the local, general population. Figures for cholesterol levels in the two nearest FHSA areas are also shown in Table 3.6. Considering the patient cohort was limited to 234, the pharmacy results closely resemble those seen in the general population and are therefore representative of the incidence. This is as would be expected as the majority of patients were from the local, resident population.

The scale of risk from high cholesterol level measurement can therefore be placed in perspective. A general practitioner with 2000 patients will have 50 patients aged 25-69 years with an STC greater than 7.8 mmol/L-1. In a group practice of 10,000 patients, 20 will have heterozygous familial hypercholesterolaemia, a genetic condition about as common as insulin dependent diabetes, in which CHD risk is increased more than 10-fold in men and 6-fold in women.

3.7.5 Change in cholesterol score

Of the 151 patients who qualified for a recall, as their STC was 5.2 mmol/L-1+, 45 actually did return at least one more time.

<u>Hypothesis 3</u>: Those patients who returned for follow-up tests and counselling showed improvement in STC readings with time. A significant reduction (t = 3.12, df = 44, p < 0.005) was found for STC between the first (mean value = 6.55 mmol/L-^1 , SD = 1.09) and the second test (6.19 mmol/L-^1 , SD=1.11).

24 of the 45 patients (>50%) had an initial STC of 6.5 mmol/L-¹+, and could be considered to have returned because of their high readings. Only four patients (<10%) had a STC of <5.2 mmol/L-¹, and could be classed as overconcerned.

A significant reduction (t = 3.33, df = 19, p < 0.005) was found for STC between the first (6.80, SD = 0.77) and the third test (6.00, SD =0.95). For the patients who returned a fourth time, no significant difference (t = 1.76, df = 5, p > 0.05) was found between the first (7.08, SD = 0.60) and the fourth test (6.67, SD = 0.92). Figure 3.6 is a graphical representation of the change in means and range of STC scores for the 19 patients who returned to the pharmacy on two occasions.

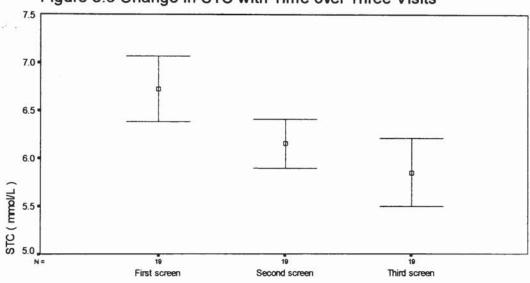


Figure 3.6 Change in STC with Time over Three Visits

Cholesterol Range for Patients at each Health Screen

The pharmacy screening service has resulted in an improvement in STC by counselling on lifestyle, diet and nutrition. Most of the actions of dietary constituents on plasma lipoprotein levels have previously been defined by, and limited to, short-term studies. These were secondary prevention trials, which targeted dietary changes more specifically than primary prevention trials which took a multifactorial approach. Subjects were well-motivated, as they had already had a heart attack, but the results, from the small number of trials undertaken, does not give a mechanistic explanation of the precise relationship between dietary fats, lipoproteins and CVD. Saturated fatty acids have been

associated with differences in incidence of CHD, but we do not know whether the prolonged ingestion of saturates may contribute to the increase in STC level that occurs with ageing. 90

3.7.6 Patients referred to a doctor

There was a total of 47 patients who were referred to either the doctor or dietician at their practice as a result of a STC reading above the criterion figure of their doctor. This was equivalent to 20% of the population tested who attended the pharmacy.

As with most self-selective screenings, it is usually the 'worried well' who present themselves for testing. Nevertheless, the results show there is a worthwhile value from this type of screening, as some 20% (47/234) of respondents were found to need referral to their doctor for further investigation.

3.8 CONCLUSIONS

- 1. As a means for enabling the pharmacist to disseminate health information to the public, a cholesterol test is an advance on the passive availability of health education leaflets. However, the results clearly indicate that the pharmacy will only see a small percentage of the population, which may actually reduce as a consequence of less national publicity. Experience of cholesterol testing shows a decreased interest from the public, and it is therefore self-limiting in its success. A regular, local advertising campaign might create more and sustained interest.
- 2. Advertising could be undertaken to generate sufficient demand to make a cholesterol testing service in the pharmacy viable. A logical and sensible approach to cholesterol testing in community pharmacy may be achieved by employing part-time dieticians. This would appear to be supported by the success of the dietary intervention. Pharmacists would have to be off the shop floor to conduct a cholesterol test and it may prove cheaper to employ a dietician than a second pharmacist, especially if a dietician was shared with other pharmacies and an appointment system operated.

- 3. The major population surveys reveal a multiplicative interaction of the major coronary risk factors.²⁷ A hypothetical connection can be made between the severity of atherosclerosis and age of onset. In the absence of other risk factors, a STC of 5.2 mmol/L may induce a critical degree of coronary sclerosis by the age of 70; with the addition of the risk factor of smoking, the critical stage is reached at 60 years of age, and, by further addition of the risk factor of hypertension, it drops to 50 years of age.⁴³ As a consequence, when planning a more comprehensive further study it was decided that it would need to encompass the evaluation, counselling and monitoring of all known risk factors.
- 4. Cholesterol levels should always be considered in terms of overall CHD risk. In isolation they are relatively meaningless, and if patients are found to have cholesterol values above 6.5 mmol/l, a full lipid profile, including plasma cholesterol, plasma triglyceride and HDL cholesterol should be obtained following an overnight fast. On the other hand, patients with cholesterol levels below this value and no history of CHD are generally at low risk of hyperlipidaemia, while patients with pre-existing CHD should be considered for a full lipid assessment whatever their cholesterol level is.
- 5. A pharmacist needs access to an individual's personal and family history in order to be effective in preventing CHD. This can ideally be done in a patient's general medical practice where his medical records are kept, so that a pharmacist working in a practice could link in with other members of the PHCT.

In the pharmacy, the pharmacist was working in isolation, and was unable to follow through with patients who had a high cholesterol, as they had to be referred to the doctor, whereupon the pharmacist normally lost contact as there is no established system for the feedback or collation of patient information. As some 20% of patients were referred to their doctor, the pharmacy study was a success in identifying a significant percentage of the population who could otherwise have developed premature vascular disease.

There is a frustration at not being involved after the initial primary care stage, and this situation stimulated him to integrate with a health centre for the next part of the research.

- 6. The marked and significant improvement in STC levels for individuals who returned to the pharmacist for lifestyle and dietary advice was a tangible factor in proving the value of the pharmacist. Further to this, the hospital dieticians admitted that patients referred to them with hyperlipidaemia were often not followed up due to limited resources; the success of the pharmacy study owed much to the conscientious monitoring and follow-up by the pharmacist.
- 7. The relationship between STC and CHD is incontrovertible, therefore the beneficial effect dietary intervention has had on STC, as seen in the Pharmacy Study, has implications for a strategy for prevention of CHD in the community. ⁹¹

CHAPTER 4

INTEGRATION OF A PHARMACIST IN A GENERAL MEDICAL PRACTICE

4.1 INTRODUCTION

During the course of the Community Pharmacy Study (Chapter 3), medical practices were contacted for their referral criteria. Some of the doctors expressed an interest in a co-operative study, the first from the nearest health centre(Surgery 1). The GP's wanted cholesterol tests done on patients opportunistically selected from the practice Hypertension and Diabetic Clinics, as well as having a free cholesterol testing service advertised to patients coming to the Health Centre. As space could only be made available at the Centre on one morning each week, the pharmacist decided to use this opportunity as a pilot study for health screening in a medical practice.

4.2 METHOD

This study took place in 1991, and was conducted weekly for a period of three months, patients arriving opportunistically. In practice, patients were booked in at reception and seen every 20 minutes, with patients filtered in from the Hypertension Clinic as convenient.

The patient's age, sex and any current illness were recorded. Their height and weight were measured using the equipment at the surgery, to calculate the body mass index (BMI). The BMI is calculated by applying the formula:

$$BMI = \underbrace{Weight(Kg)}_{Height(m)^2}$$

The BMI indicates the relative risk attached to different degrees of excess weight:

- BMI < 19.9 = underweight
- BMI 20-24.9 = acceptable
- BMI 25-29.9 = overweight
- BMI 30-40 = obese
- BMI > 40 = severely obese

The BMI allows one to show patients how much weight they need to lose to bring them into a lower health risk category.

A mercury sphygmomanometer was used to determine the patient's blood pressure, following the standardised technique illustrated by the practice nurse:

- 1. The patient should be seated for at least five minutes before their blood pressure is recorded.
- 2. The patient should not be made anxious in any way, therefore they must have an adequate explanation of the procedure, which should take place in a private area in a room which has a pleasant temperature.
- 3. Tight clothing must be removed from the patient's arm.
- 4. The cuff should be applied firmly, with the centre of the bladder over the brachial artery.
- 5. The larger size cuff (35 cm) should be used for most adult patients, to avoid "cuff hypertension".
- 6. The patient should be seated and an arm pad placed under the elbow to ensure support and relaxation of the arm and accessibility of the brachial artery.
- 7. The diaphragm of the stethoscope should be placed on the brachial artery, secured with the fingers of one hand, without pressing too hard on the bell, otherwise the artery may become distorted and produce false sounds.
- 8. Inflation should be rapid and deflation slow (2 mm Hg per second) to prevent inaccurate readings. BP varies during each beat of the heart.

The contraction of the ventricles sends a pressure wave radiating down the major arteries referred to as systolic blood pressure (SBP). When the ventricles are filling with blood the pressure in the arteries is reduced to the lowest level, diastolic blood pressure (DBP).

On deflation of the cuff to a pressure at which the SBP lightly exceeds the cuff pressure, blood will be forced through the artery at this point in the heart beat; pressure will quickly drop towards the DBP, and the artery will snap closed as

the cuff pressure again exceeds the artery pressure. The artery closing produces the Korotkoff sound, the first time representing the SBP, and on disappearance, the DBP.

9. The pressures should be recorded immediately, and the procedure repeated again from the beginning, if a pressure is missed.

The patient's STC was determined following the guidelines in Chapter 3. Questions were asked to assess the patient's smoking status, alcohol intake, exercise level and dietary habits.

The approach to smoking, drinking and exercise will be expanded upon in the major studies that follow. In this pilot project, procedures were refined for patient communication and dietary advice.

4.2.1 Patient communication

Feedback from patients during a previous Asthma Study had indicated to the pharmacist that a visit to the doctor was often a tension-inducing experience, and that much verbal information imparted was quickly forgotten. In some cases patients had not even conveyed the true reason for their visit to the GP.⁴ The pharmacist, therefore, attempted to develop an empathy with patients by engendering a relaxed, less threatening atmosphere, so that questioning, listening and explaining skills could be successfully developed.

In order to help patients remember information and advice, emphasis was given to the following:

- Speak slowly
- Avoid jargon
- Select the most important items of information, and
- Emphasise the importance of these to patient
- Repetition to reinforce the message and increase recall
- Appropriate additional written information, eg cholesterollowering diet sheet
- Check the understanding by encouraging feedback.

To gain the patient's trust, the pharmacist aimed to be warm, open and interested.

4.2.2 Dietary counselling

Patients interviewed stated that previous advice on nutrition from health professionals was confusing and based on nutrients rather than foods, eg advice was given to eat more fibre, without an indication of which foods are excellent sources of fibre. The pharmacist concentrated on the patient's motivation to choose their diet and any barriers there might be to a change, eg cost, taste, reluctance to try new foods, inadequate cooking facilities, and availability, such as limited access to shops.

His approach was to give accurate, practical, realistic and relevant advice, so that information would include practical interpretations which patients could relate and apply to their own eating patterns.

4.2.2.1 A structured approach

The following stages were used to manage dietary change:

- Screening: Although all patients could benefit from advice on healthy eating, those who had risk factors for CHD and who were overweight or obese required more specific counselling.
- Assessment: The patient's motivation to change was assessed, and an effort made to remove barriers to change.
- Negotiation: Some practical food-specific goals were discussed, eg switching to semi-skimmed milk, restricting chips to once a week, not adding sugar to drinks, eating fruit or salad instead of crisps or cakes each day.

The goals were planned as a series of realistic and achievable targets.

- Goal Setting: Patients were encouraged to take an active part in deciding and agreeing their goals, eg a slow, steady weight loss at a rate of no more than 0.5-1kg/week as the aim.
- Monitoring Progress: In the two major studies, comparison of the actual dietary changes with the action plan would be done, and measurement of such parameters as weight and cholesterol repeated to check on progress.

4.3 RESULTS AND DISCUSSION

Forty-seven patients were seen in seven sessions, 14 of whom had been directed from the GP clinics and the remainder required a cholesterol test, through the advertised facility at the health centre. Table 4.1 shows a summary of STC, DBP, SBP and BMI measurements as well as information regarding alcohol, exercise and smoking status. As this study consisted of a small cohort of patients, little meaningful information can be gleaned from the results. A t-test for independent samples of disease categories indicated a significant difference (t = 3.36, df = 45, p < 0.005) for STC values between cardiovascular patients (5.97 mmol/L-1, SD = 0.77) and all other patients (5.17, SD = 0.73). Thus, in this small sample, there was a tendency for patients with CVD to have a higher STC than the rest.

Table 4.1 Summary of Results at Surgery 1

Number of Patients = 47

Criteria	Sex of Patient		Patient
Criteria		Male	Female
Alcohol			
Intake(units/week)			
(14		- 15	29
14-21		2	
>21		1	
Body Mass Index			
<25		6	20
25-30		10	7
>30		2	2
Serum Total	<u> </u>		
Cholesterol(mmol/l)	1	-	
<5.0		5	10
5.0-5.9		8	12
6.0-6.9	25	4	7
7.0-7.9		1	
Exercise Level	-		20020
Inactive		4	6
Lightly Active		7	11
Moderately Active		4	8
Very Active		3	4
Smoking Status			
Non-smoker		8	21
Smoker		3	4
Ex-smoker	9	7	4
Diastolic Blood			
Pressure(mmHg)			
<70		2	3
70-79		2	12
80-89		2 2 5 6	8
90-99			5
>100		3	1
Systolic Blood Pressure	9 ;		
(mmHg)			_
<130		4	. 9
130-139		1	10
140-149		5	5
150-159		4	5 3
>160		4	2

4.3.1 Blood pessure and blood cholesterol

The analogy between cholesterol and blood pressure as risk factors is equally striking for CHD and for total mortality; in the MRFIT, those with levels of either STC or BP above the 85th percentile had a relative risk of CHD death about 4 times that of men in the bottom quartile. Yet, no appreciable correlation of STC and BP with each other was found. However, in other studies, hypertensive populations have been reported to have rather high levels of serum cholesterol, supporting the Northwood findings. 92

Following this indication that hypercholesterolaemia is more prevalent in hypertensive patients and significantly worsens morbidity, Ekelund *et al* set out to see whether reducing cholesterol levels has any effect on hypertension itself. They concluded that treatment with a lipid-lowering drug leading to a decrease in LDL-cholesterol strongly correlated with a reduction in the incidence of hypertension. ⁹³

4.3.2 Advantages of this pilot project plan

The facility to work with patients within a health centre environment was a considerable asset and the opportunity and experience of working with other health professionals proved invaluable.

The study plan made it possible to focus more on those patients considered at risk from CHD, and was a good rehearsal for the major studies being arranged at that time.

It was also established that 25-30 minutes would be needed for a programmed health screen interview, allowing sufficient time to take measurements and evaluate diet and lifestyle.

4.4 KING EDWARD MEDICAL CENTRE STUDY

4.4.1 Introduction

King Edward is a small, traditional general medical practice with two doctor partners and a GP trainee. The doctors have a particular interest in hypertensives and invited the pharmacist to run a cholesterol clinic on two mornings per week. Previous controlled hypertension trials showed that single factor treatment of arterial hypertension reduces CVD morbidity but, disappointingly seems to have little, if any, effect on CHD. 94 One major explanation could be a failure to reduce serum cholesterol in the hypertensive patients. As a consequence the King Edward medical practice(Surgery 2) wished to have a total risk factor profile of their hypertensive population.

The aim of the pharmacist was to identify those patients with an elevated STC and initiate effective treatment, either non-pharmacological or pharmacological.

4.4.2 Background to hypertension

Prospective epidemiological data have shown that an increased risk of CVD is predicted by increments in both systolic and diastolic blood pressure, and the increase in risk is continuous and graded. In large, controlled trials, antihypertensive drug therapy reduced strokes by 40%, virtually eliminated congestive heart failure and renal failure, but had less of an impact on myocardial infarction. 96

Trial data have shown that, if left untreated, a significant number of mild hypertensives become moderate hypertensives in a relatively short time, demonstrating the clear benefits of treatment in preventing the progression of hypertension. ⁹⁶

Essential, uncomplicated hypertension, accounting for approximately 95% of hypertensives is symptom-free and case-finding is therefore dependent on opportunistic or systematic screening.

4.4.3 Treatment of hypertension

4.4.3.1 Non-pharmacological treatment

Many subjects with elevated blood pressure at an initial reading do not need antihypertensive drugs. ¹⁰⁰ Blood pressure often falls spontaneously with repeated observation, and may respond to measures such as reductions in weight, alcohol and salt intake. Concerns regarding the uncertain benefits of the treatment of mild elevations (90 to 94 mm Hg) of BP and the risks and costs of antihypertensive drug treatment have led health professionals and patients alike to consider non-pharmacological approaches to BP reduction. Drugs are indicated only when the DBP averages 100 mm Hg or more during prolonged observation, or when complications are present. ⁹⁷

Therefore, if a pharmacist is to perform screening, it is imperative that he uses a measuring device of proven accuracy and takes three readings on separate occasions to obtain a true BP leading to an accurate diagnosis.

4.4.3.2 Antihypertensive drugs

The aim of treatment is a target DBP of <90 mm Hg, with an optimum drug regimen and freedom from side-effects. The pharmacist can play an important part by reinforcing a healthy diet and lifestyle as adjunctive therapy, encouraging patient compliance to medication, and educating patients to be aware of the risk they take in self-medicating with unproven modalities.

4.4.3.3 Choice of treatment

There are two main approaches to choosing a drug for hypertension:

The Stepped Care approach

For many years, antihypertensive drugs have been added stepwise until blood pressure is controlled, as monotherapy failed to control BP in most patients. King Edward Medical Centre have designed a treatment protocol for hypertension, as shown in Table 4.2.

Table 4.2 The Stepped Care Approach to Drug Treatment of Hypertension at Surgery 2

1. General Plan

	Step	Treatment
sod		Non-pharmacological approaches,eg weight control sodium restriction, alcohol restriction, control of other cardiovascular risk factors
	1	Thiazide or beta-blocker
37 6	2	Thiazide + beta-blocker
	3	ACE inhibitor or calcium channel blocker
	4	ACE inhibitor/thiazide or calcium channel/beta-blocker

2. Patients unable to tolerate beta-blockers and thiazides-Alternative Plan

Step	Treatment
1	Calcium channel blocker or ACE inhibitor
2	Whichever alternative is left from step 1 choice
3	Calcium channel blocker + ACE inhibitor
4	Alpha-blocker

2. The Individual Patient approach

Four classes of agents - diuretics, beta-adrenergic blockers, calcium antagonists, and angiotensin-converting enzyme inhibitors - are used as possible first-line agents, due to the doctor's emphasis on the need for a more individualised approach to treatment taking into account important patient factors, such as age, sex, race, concurrent medications, concomitant diseases and the patient's quality of life.

4.4.3.4 Drugs of first choice

There is considerable debate whether thiazides and betablockers should remain the drugs of choice or whether preference should now be given to ACE inhibitors, calcium antagonists or alpha-1 blockers. ⁹⁸It is important to review the issues that enable a pharmacist to help GPs make a rational selection of antihypertensive drugs.

1. Diuretics

In recent years, important lessons have been learnt regarding potential risks, such as the elevation of STC and, in patients with a history of IHD, sudden cardiac death, due to arrhythmia. Pharmacists should advocate the minimal effective dose of a thiazide-type diuretic as higher doses usually will not result in any additional fall in blood pressure but will expose the patient to increased risk of metabolic complications such as hypokalaemia, hypomagnesaemia, hyperglycaemia and hypercholesterolaemia. The concern about these metabolic effects and possible risks in selected patients, eg those with electrocardiographic changes prior to treatment, has led prescribers to seek alternative agents. Nonetheless, these agents are effective and inexpensive. Pharmacists should point out to their patients the need for moderate sodium restriction during diuretic therapy, as high salt intake leads to additional depletion of body potassium and an increased risk of hypokalaemic-related arrhythmia.

Beta-adrenergic blockers

These drugs can be classified according to the nature of the resultant blockade. Cardioselective agents have a relative, dose-dependent affinity for blocking cardiac beta-1 receptors in preference to beta-2 receptors involved in vasodilation, bronchodilation, and glucose homeostasis in comparison to non-selective agents. Pharmacists can use these designations to recommend therapy for patients with a history of obstructive pulmonary disease, insulin dependent diabetes mellitus prone to hypoglycaemic attacks, or peripheral vascular disease.

One problem to be considered is the tendency of beta blockers to make patients feel tired and sometimes depressed. Water-soluble agents have been promoted as being less likely to cause CNS side-effects because of less active drug entering the brain; however some patients still find the CNS effects, such as sleep disturbance and nightmares intolerable.

Calcium channel blockers

These agents vary in their cardiovascular effect according to their chemical class, their importance in the treatment of essential hypertension relates to their ability to inhibit Ca++-mediated vasoconstriction. Various vasoconstrictive stimuli including catecholamines, angiotensin, and serotonin exert their effects by activating Ca++ entry into vascular tissue with resultant vasoconstriction.

All of these agents are extensively metabolised by the liver and do not require dose adjustment in patients with renal impairment. Their relatively short half-life has led to the development of sustained-release formulations to optimise patient compliance.

Pharmacists can help in assessing the risk/benefit ratio for patients. Nifedipine and other dihydropyridines are more prone to vasodilation-related side-effects including dizziness, flushing, reflex tachycardia, and headache. Verapamil and diltiazem, due to their negative inotropic and chronotropic effects, are associated with a slight risk of precipitation of congestive heart failure and excessive bradycardia.

Angiotensin-converting enzyme inhibitors

These agents exert their pharmacological effects by inhibiting the angiotensin converting enzyme (ACE) which leads to decreased production of the potent vasoconstrictor and aldosterone angiotensin 11, leading to less sodium and water retention and less potassium excretion. ACE is also involved in the breakdown of bradykinin, a potent vasodilator, and ACE inhibition may lead to augmentation of bradykinin's effects.

ACE inhibitors appear to have comparable antihypertensive effects within their class, and clinical differences are based on their pharmacokinetic and adverse effect profiles. Class-specific adverse effects include hypotension, so that pharmacists should counsel patients to be aware of this, especially after the first dose. The most important side effect is a persistent dry cough, often paroxysmal and troublesome at night, also skin rash, taste disturbances and neutropenia, which appear to be related to the SH-group in captopril's structure.

Selective alpha-blocker

These lower blood pressure by arteriolar and venous dilation mediated by selective antagonism of alpha-1-adrenoceptors. They require dose titration, but their efficacy is similar to that of the other standard drugs, and they are said to exert a favourable effect on serum lipids, reducing STC and elevating HDL cholesterol.

4.4.3.5 Treatment considerations

Table 4.3 Drugs of Choice and Drugs to avoid in Patients with other Medical Conditions

	Concurrent	Preferred Choice	Drugs to
	Condition	of Drug	avoid
(1) =	Asthma + COAD	Calcium-channel blockers	Beta-blockers
		Diuretics	
		ACE inhibitors	
		Alpha-blockers	
	Congestive Cardiac	Diuretics	Beta-blockers
	Failure	ACE inhibitors	Verapamil
	Ischaemic Heart	Beta-blockers	
	Disease	Calcium-channel blockers	
		ACE inhibitors	
	Peripheral Vascular	Calcium-channel blockers	Beta-blockers
	Disease		
	Diabetes Mellitus	Calcium-channel blockers	Diuretics
		ACE inhibitors	Beta-blockers
	Hyperlipidaemia	ACE inhibitors	Diuretics
		Alpha-blockers	Beta-blockers
		Calcium-channel blockers	
	Hyperuricaemia		Diuretics
	Renal Artery Stenosis		ACE inhibitors
	Depression		Propranolol
			Methyldopa
	Pregnancy	Methyldopa	Diuretics
		Labetalol, Atenolol	

Perhaps the contribution pharmacists can make most often in the monitoring of hypertensives is careful attention to the patient's concomitant diseases and drugs which can lead to important drug therapy choices for the patient. Table 4.3 offers important suggestions for the pharmacist in recommending rational therapy to health care providers based on a patient having a concomitant disorder. The elderly, in particular, frequently have many concurrent disorders in addition to hypertension.

The choice of treatment will also depend on other factors including degree of blood pressure elevation, individual patient response and acceptance of a particular drug. Monotherapy will control the BP adequately in approximately 50% of patients; another 40% will normalise with the addition of a second agent from a different class. Low dose combination therapy appears to be the rational alternative in patients resistant to moderate doses of a particular agent. A small percentage of patients will have extremely resistant blood pressure which will require 3 or 4 drugs to control. 100 Newer therapies are almost always more expensive than longerestablished or traditional agents, but when justified by the clinical situation, expensive antihypertensive therapy can be cost-effective in preventing cardiovascular morbidity and mortality.

4.4.4 Method

At the time the pharmacist became actively involved as a member of the practice team, Surgery 2 were about to embark on a health screen of their 240 hypertensives. Patients were equally shared between the GP, the nurse and the pharmacist. Surgery facilities were only available to the pharmacist on two mornings per week, and patient selection was partly based on that consideration. Each patient was sent a letter inviting them to attend the surgery to see the pharmacist for the health screen (Appendix 2). Additionally, other non-hypertensive patients were referred by the GP for a complete record of

their cardiovascular profile, resulting in a total patient cohort for the pharmacist of 140. Clinics were conducted twice weekly, with an average of eight patients attending each time, so that the initial health assessment took two months.

4.4.4.1 Daily food diary

Patients, on telephoning to confirm their appointment, were asked to keep a daily food diary, comprising quantities of everything he or she ate and drank during the week before the appointment. The advantage of this technique is that it gives an overall idea of the types of food eaten and the frequency of consumption. The disadvantage is that the mere fact that food intake is being recorded is likely to modify eating habits. Confirmation of their pattern of food intake was therefore confirmed by the one-to-one interview.

4.4.4.2 Dietary assessment of patient

Calculations from the health screen interview, supplemented with information from the daily food diary, enabled the pharmacist to grade the patient's dietary status for total fat intake. An estimate of energy expended in calories per day [estimated average requirement for energy (EAR)] was made by multiplying a factor of 1.55 by the basic metabolic rate of the person (BMR). The BMR was taken from tables, relating to the sex, age and weight of the patient. Two assumptions had to be made: (a) the patient's weight remained the same, and (b) the amount of energy expended was equal to that consumed.

A Dietary Reference Value (DRV) for fat was then estimated, using the following equation:

Gm of total fat ingested daily x 9 = DRV or % energy Estimated energy expended (EAR) = from total fat

Patients were appraised as (1) low fat if their DRV was less than 26; (2) average fat with a DRV of 26-35; (3) high fat with a DRV of 36-45; and (4) very high fat with a DRV >45.

This categorisation roughly equated to the eating pattern of the cholesterol lowering, food recommendation sheet (Appendix 1), eg patients in the low fat group kept to a diet closely resembling that of the 'eat regularly' column.

This method is not ideal, but allows some form of relative appraisal, and was approved by the dieticians, who admitted that there were difficulties with interpretation of food classification and variability in an individual's record of food intake. Calculations were made following advice from Dr David Mela of the Institute of Food Research. ¹⁰¹

4.4.4.3 Health screen interview

The patients were seen in the surgery for a consultation of approximately 20 minutes, and the following information was collected:

- Age of patient.
- Sex of patient.
- Reason for attendance. The majority were from the list of hypertensives, however, the practice took the opportunity to make appointments for other patients considered 'at risk' of CHD as well as some who had attended the 'Well Man' or 'Well Woman' clinics.
- Family history of CHD, before and after 60, of hypertension, stroke and diabetes.
- The BMI of the patient.
- The SBP and DBP of the patient using the mercury sphygmomanometer used at the practice for consistent reliability.
- The STC of the patient using the Reflotron. Triglyceride (TG) levels were taken for some patients during follow-up assessments.
- The smoking status of the patient, and, if a smoker, the category and extent of smoking.

- The patient's alcohol intake, in units per week, the type of drink and the distribution throughout the week.
- The exercise level to help assess the fitness of the patient.
 Depending on the type, amount and frequency of exercise, patients were placed into four categories: inactive, lightly active, moderately active, and very active.
- The dietary status, as previously discussed, was evaluated.
- The patient's present and past illnesses.
- The patient's current medication profile.

4.4.4.4 The Dundee Coronary Risk-Disk

Evaluation of a patient's cardiovascular status, encompassing the coronary risk factors placed in perspective in relation to each other, was considered by the pharmacist an important yardstick to use when counselling on life-style modification. A simple scoring system, which could be used in general practice, would remove undue emphasis on single risk factors, seen in isolation, such as cholesterol. The score, the primary outcome variable, used in the study, was calculated with the Dundee Coronary Risk-Disk developed by Tunstall-Pedoe. This score measures continuous scales of smoking, blood pressure and cholesterol, and is based on the United Kingdom Heart Disease Prevention Project, and can be easily related to its own distribution in the general population.

The score has two elements:

1. <u>Dundee Score</u>: This is a measure of the relative risk for the three major modifiable risk factors, and not the absolute level of risk of an individual which is determined by several factors which cannot be changed such as age, sex, family history, angina, previous myocardial infarction and diabetes. Patients can be motivated to change those factors which can be modified, and are graded according to their degree of modifiable risk.

2. Dundee Rank: There was concern that the score in itself would not indicate whether the patient was at high or low risk relative to other people in that age and sex group in the general population. From the Scottish Heart Health Study (SHHS), score frequencies were expressed as percentages of the total, so that it became possible to say which score corresponds to the top 1% of the population (or 1st percentile), and which score corresponds to the 100th percentile. ¹⁰³

The percentiles were renamed Dundee Rank, which was preferable as an indicator of risk than the score, because 1 was the highest and 100 the lowest risk, and each unit represented 1% of the population. An even grading from 1 to 100 is readily understood and, when advising, can be related to a bus queue of 100 people waiting for a coronary.

Effect of Sex on Dundee Rank

When the men and women were split into 5-year age groups (SHHS), there was very little difference in the score by age for men, but the score distribution in women was different. For women there is a gradient of cholesterol and blood pressure with age, so that the score increases with age unless it is corrected. The Risk-Disk has a facility so that the score gives a uniform Rank in each age group in women.

Blood Pressure selection

The Risk-Disk gives the operator the choice of using either a systolic or diastolic blood pressure reading. For the purpose of consistency in the study, the pharmacist used the SBP scale every time when calculating the Coronary Rank (CR) and Risk Score (CS).

4.4.4.5 Patient evaluation

After the initial consultation, patients were recalled for further checks, according to the protocol outlined in Appendix 3.

4.5 OBJECTIVES

Objective 1 To determine the outcome of a pharmacist's intervention on patient BP with time.

Objective 2 To determine the outcome of a pharmacist's intervention on patient STC with time.

Objective 3 To determine the outcome of a pharmacist's intervention on patient coronary ranking with time.

Objective 4 To determine the effect of medication in achieving a reduction in STC.

Objective 5 To determine the effect of dietary modification in achieving a reduction in STC.

Objective 6 To compare the percentage change in STC of patients on medication and diet treatment with those on diet alone.

Objective 7 To determine the extent of any changes in patients' medication spectrum as a consequence of monitoring by the pharmacist.

Objective 8 To evaluate the rate of pharmacist referral to the GP, dietician or nurse for further investigation.

4.5.1 Treatment of hypercholesterolaemia: diet versus drugs

The rationale for the identification and treatment of patients with hypercholesterolaemia is based on evidence that a reduction in plasma concentrations of known atherogenic lipoproteins will lead to a slower rate of progression of atherosclerosis, the arrest of this process altogether or potentially a reversal in previously developed atherosclerotic lesions. The focus of drug treatment for patients with hypercholesterolaemia that is inadequately controlled by diet therapy alone is to reduce the plasma concentrations of low density lipoproteins (LDL) and VLDL remnants. ¹⁰⁴

The decision to begin drug therapy should be made only after the exclusion of secondary factors, such as renal or liver disease, hormonal, nutritional or

iatrogenic causes, and after an adequate trial of diet has failed to produce acceptable concentrations of plasma lipids and lipoproteins.

During the course of the initial health screens at Surgery 2, the pharmacist attended practice meetings to discuss possible treatment interventions. The doctors saw advantages of using drugs for cholesterol lowering in patients with a STC of 6.5 mmol/L-¹+, just as they did for other medical problems, such as hypertension. The pharmacist argued that a positive benefit/risk ratio for cholesterol-lowering drugs would be difficult to prove, when moderate reductions in STC levels could be achieved in most patients with dietary modification alone; this would reduce the cost of medication and avoid the problem of side-effects.

Agreement was reached that patients with a STC of between 6.5 and 7.8 mmol/L-1 would not be treated with medication, unless they had existing CHD, a family history of CHD, or diabetes. All patients with a STC of 7.8 mmol/L-1 + would receive medication. The actual drug prescribed depended on the classification of hyperlipidaemia, shown in Table 4.4. This summary is based on recommendations of the British Hyperlipidaemia Association.

Table 4.4 Drug Therapy and Hyperlipidaemia

Lipid abnormality	Plasma	LDL	Plasma	Degree of	Drug Re	egimen
	Cholest	erol 7	Triglyceride	Hyperlipio	i 1st	2nd
	- 2			-aemia	Choi	ce
Type 11a	+ N	+	N	Moderate	Resin I	Fibrate
				Severe	Statin I	Probucol
					Resin+Statir	1
Type 11b	+	+	+	Moderate	Fibrate	NA
				Severe	Resin+Fibrate	e Statin
Type 111	+	- N	+	Usually	Fibrate	Statin
				Severe		
Type 1V	- N	N	+	Moderate	Fibrate	NA
7 T				Severe	Fibrate+NA	
Type V	+	N	+	Always	Fibrate+NA	Fish
				Severe		Oil

Severe hyperlipidaemia is defined as a S T C level of 7.8 mmol/L-¹+ or a fasting triglyceride level of 4.5 mmol/L-¹+, especially if these levels occur together.

Resin = cholestyramine or colestipol

Fibrate = bezafibrate, ciprofibrate, fenofibrate or gemfibrozil

Statin = pravastatin or simvastatin

NA = nicotinic acid or derivative; N = normal

+ = raised level; _ = reduced level of plasma cholesterol

A cross-tabulation of the drug prescribed relative to the patient category is shown in Table 4.5.

Table 4.5 Patient Category at Surgery 2 and Hypolipidaemic Medication

	Count	None	Statins	Fibrates	Row
CAMECORY		.00	1.00	2.00	Total
CATEGORY Hyperten	1.00	74	9	3	86 61.4
Heart Pr	2.00 coblems	1 10	4	3	17 12.1
Smoker	3.00	1 15			15 10.7
Diabetio	4.00	1 2		i i	2 1.4
Well Mar	5.00 a/Woman	i 20	 	 	20 14.3
	Column Total	121 86.4	13 9.3	6 4.3	140 100.0

The figure indicates that hypolipidaemic medication was only prescribed for patients with previous IHD or hypertension.

4.5.2 Drug treatment of primary hypercholesterolaemia

Bile Acid Sequestrants

These have been extensively evaluated in well-conducted trials, and, in compliant patients, these drugs lower plasma concentrations of LDL-cholesterol by 20-35%. Therapy also results in a 3-8% increase in plasma concentrations of HDL-cholesterol and a small rise in plasma triglycerides. ¹⁰⁵

These drugs are insoluble ion-exchange resins which are non-systemic in that their mechanism of action is based on their ability to release chloride ions and bind bile acids in the intestinal lumen, interrupt the entero-hepatic circulation of bile acids and consequently cause an increase in the faecal excretion of steroids. The resultant compensatory increases in cholesterol biosynthesis and high affinity LDL receptors on liver cell membranes is responsible for the increased catabolism of LDL particles from plasma. ¹⁰⁶

HMGCoA Reductase Inhibitors

The recent development of specific competitive inhibitors of HMGCoA reductase, the rate-limiting enzyme in cholesterol biosynthesis, has provided a new therapeutic approach to the treatment of primary hypercholesterolaemia. There are three drugs currently licensed and prescribable for this indication: lovastatin, simvastatin and pravastatin. These drugs have been shown to reduce plasma concentrations of LDL-cholesterol in patients with heterozygous familial hypercholesterolaemia by between 20 and 45% depending on dose. Single drug therapy with each has been associated with a 20-30% decrease in plasma concentrations of triglycerides and an overall tendency for HDL-cholesterol to rise by 2-15%. ¹⁰⁷ At the cellular level, lovastatin inhibits the conversion of HMGCoA to mevalonic acid and thus the cellular synthesis of cholesterol, leading to compensatory increases in the number of high affinity LDL receptors on the cell membrane and a stimulation of LDL catabolism.

Fibrates

Several drugs in the fibric acid class have been developed. They all reduce plasma triglyceride concentrations more than they reduce total and LDL - cholesterol and concurrently raise plasma concentrations of HDL-cholesterol by 10 to 20%. The lipid lowering effects of the fibrates result from an increased activity of lipoprotein lipase, an enhanced rate of catabolism of LDL and a reduction in VLDL synthesis. ¹⁰⁴

Nicotinic Acid

Nicotinic acid exerts its action through a decrease in the hepatic synthesis of VLDL and LDL, and its long term use has been associated with a reduction in cardiovascular morbidity and mortality. Plasma concentrations of LDL-cholesterol are reduced by 20 to 33% and triglycerides by 20 to 40%, and HDL-cholesterol levels are concurrently increased by 10 to 20%. ¹⁰⁴ Unfortunately, side effects occur commonly in patients treated with nicotinic acid to the extent that it cannot be tolerated by some. Common side effects are: cutaneous flushing, nausea, abdominal discomfort and dryness of the skin.

4.5.3 Treatment policy at Surgery 2

After the initial assessment of the 140 patients, it was agreed with the doctors that 19 of them should receive medication to reduce their STC. The doctors favoured either a statin or a fibrate for treatment, 13 patients being placed on simvastatin, and 6 on bezafibrate, the latter because of raised TG levels.

4.6 RESULTS AND DISCUSSION

Of the 140 patients (78 male, 62 female) who attended the first screening visit, 86 were from the practice's hypertensive list, age under 75 years, comprising 240 individuals. The number of patients in the pharmacist's study was approximately one third of the total, partly because the doctor and nurse were already actively monitoring some hypertensives each, and partly because of the 'space and time' factor. The pharmacist could only have access to a surgery room on two mornings per week and therefore could only see patients for whom it was convenient to attend at that time. This was a research project

restraint that did not apply at Elliott Hall (Surgery 3), where the pharmacist had access to a surgery at all times (Chapters 5 and 6).

The remainder of the patients comprised:

17 with a personal history of IHD, 15 who were smokers, 2 diabetics and finally 20 attending as part of a Well Man/Well Woman clinic.

Although the pharmacist's mandate was officially to see hypertensive patients, the practice added an additional 54 patients to his appointment lists, primarily for cholesterol testing. 34 of the 54 patients had other risk factors, and the remaining 20 patients were from the Well Man/Well Woman clinic in order to complete their health status profile.

107 patients returned for a second and 67 for a third blood pressure check. 80 patients returned for a second and 44 for a third cholesterol test, patient recalls appropriating to the protocol in Appendix 3.

The prevalence of cardiovascular risk factors in the study group, related to their patient category, are shown in Table 4.6. The risk factor distribution in all men and all women is shown in Table 4.7 and 4.8.

Patient Categories and Distribution of Risk Factors for the Total Population Man/Woman 11 9254 10 10 15 13763 Well Diabetic \dashv -Patient Category Smoker 5 2 2 7007 Problems Heart 14974 113 7007 1887 24515 Hypertensiv 15 44 20 7 1 18 23 42 10 10 12 28 27 15 1 32 38 38 14 1 Ψ Number of Patients = 140 Systolic Blood Pressure Cholesterol groups Lightly Active Moderately Active 14-21 units/week B M I Categories 1-14 units/week <5.0 mmol/1
5.0-5.9 mmol/1
6.0-6.9 mmol/1
7.0-7.9 mmol/1</pre> Alcohol Groups >21 units/week Roll Your Own Fitness Level groups <130 mmHg 130-139 mmHg 140-149 mmHg 150-159 mmHg Risk Factors Very Active >8.0 mmol/1 Cigarettes Ex-smoker Giving Up >159 mmHg Inactive 20-24.9 25-29.9 30-39.9 Table 4.6 Smoker Cigar Pipe

Table 4.7 Patient Categories and Distribution of Risk Factors for the Male Population Table 4.8 Patient Categories and Distribution of Risk Factors for the Female Population

	Sex of Patient Male	Number of Pa	Number of Patients = 78				Sex of Patient Female	Number of P.	Number of Patients = 62			
			Pa	Patient Category	ry		77818		Pa	Patient Category	ıry	
	Risk Factors	Hypertensiv e	Heart Problems	Smoker	Diabetic	Well Man/Woman	Risk Factors	Hypertensiv e	Heart	Smoker	Diabetic	Well Man/Woman
	Alcohol Groups 1-14 units/week 14-21 units/week >21 units/week	24	& m	2 1 2		44	Alcohol Groups 1-14 units/week 14-21 units/week >21 units/week	27	ю	1	r .	7
	B M I Categories <20 20-24.9 25-29.9 30-39.9	1 14 24 7	80 45 60	1641	1	NΦ	B M I Categories	18 14 7	- T T T	рен н	1	1.5.5.1
121	Cholesterol groups <5.0 mmol/1 5.0-5.9 mmol/1 6.0-6.9 mmol/1 7.0-7.9 mmol/1 >8.0 mmol/1	10 19 9 6 6	© \$7 H &	ব ব ব	đ	1 5 2 3	Cholesterol groups <5.0 munol/1 5.0-5.9 mmol/1 6.0-6.9 mmol/1 7.0-7.9 mmol/1 >8.0 mmol/1 >8.0 mmol/1	2 9 18 2	2 1 1 1 1 2	1 11	п	пппп
	Fitness Level Inactive Lightly Active Moderately Active Very Active	24 10 5	. 440	∞ชหาต	ı	4 3 1	Fitness Level Inactive Lightly Active Moderately Active	20 10 2	12221	2 2	1	1 2 7 2
	Smoker No Cigarettes Ex-smoker Fipe Cigar Roll Your Own Giving Up	23 8 8 6 4 1 1 4 4 1 1 3 8 8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	9 8 1 1	3 2 1	н	vn m	Smoker No Clgarettes Ex-smoker Pipe Clgar Roll Your Own Giving Up	33 3 1	so et		H	10
	Systolic Blood Pressure groups (130 mmHg 130-139 mmHg 140-149 mmHg 150-159 mmHg >159 mmHg	1 1 14 9 21	3 1 2 3 2	224 1	1	0000	Systolic Blood Pressure groups <130 mmHg 130-139 mmHg 140-149 mmHg 150-159 mmHg	1 4 14 21	2 3	1 2	H	- 4 0 1 1

4.6.1 Alcohol intake

In this group, men were noticeably heavier drinkers than the women, 14.7% of men imbibing more than the accepted maximum limit compared to 7.3% of women. Among the hypertensive patients, the distinction was even more marked, 6.9% of women compared with 19.5% of men who drank over their limit.

4.6.2 Anthropometry

It was found that 65.4% (51/78) of men and 50% (31/62) of women were overweight (BMI 25+). This compares with the findings of the British Family Heart Study (BFHS), where 62.2% of men and 44.1% of women had a BMI >25 respectively. ¹⁰⁸ A higher proportion of men (51.3%) than women (33.9%) had a BMI of between 25 and 29, and conversely, a higher proportion of women (50%) had a BMI <25 than men (34.6%).

Overall mean BMI was 26.15 in men and 25.63 in women. Diastolic hypertension (90 + mm Hg) was found in 57.5% of patients with a BMI >25 (Table 4.9).

Table 4.9 Diastolic Blood Pressure Variation with B M I Category

B M I Categories by Diastolic B P Groups-1st time

	Count	DIASTOLIC	BP BP				
	Count Tot Pct	<70 mmHg	70-79 mm Hg 1.00	80-89 mm Hg 2.00	Hg	100+ mmH g 4.00	Row Total
BMI	1.00		3		1	1	5
<20	1.00		2.1		.7	.7	3.6
20-24.9	2.00	3 2.1	6 4.3	18 12.9	20 14.3	6 4.3	53 37.9
25-29.9	3.00	.7	3 2.1	23 16.4	28 20.0	6 4.3	61 43.6
30-39.9	4:00		4 2.9	2.9	8 5.7	2.9	20 14.3
>40	5.00					.7	.7
	Column Total	2.9	16 11.4	45 32.1	57 40.7	18 12.9	140 100.0

Number of Missing Observations: 0

4.6.3 Blood cholesterol level

The proportion of women with a STC of 6.0+ mmol/L-1 was 67.7% while in men the proportion was 42.3%, 32.3% of women and 15.4% of men had a STC of 7.0+ mmol/L-1. 8.1% of women and 5.1% of men had a STC level of 8.0 + mmol/L-1. This shows a clear trend in the direction of the women, in this group, having consistently higher levels of STC. No distinction has been made for age, as the majority of the patients were over 55 years of age, probably because only those people who were retired from work could attend the timing of the pharmacist's clinic. There was no significant difference in the age spectrum between men and women.

These findings differ, both in the proportion of individuals with an STC of 6.0+ mmol/L-1 and in the ratio of the levels in men to women, from the BFHS. However, their age range was from 40-60 years, whereas the age range at Surgery 2 was 55-75 years of age. The distribution of STC is shown in Figure 4.1. This is a Pareto cchart, which is a bar chart, sorted in descending order; the line shows the cumulative frequency across categories.

Distribution-1st Health Screen 160 140 120 100

Figure 4.1 Serum Total Cholesterol

80 50 60 40 43 20 23 23 7.0-7.9 mmol/l 6.0-6.9 mmol/l 5.0-5.9 mmol/l <5.0 mmol/l >8.0 mmol/l Cholesterol groups

The higher figures for STC in women reflects the recognised tendency for cholesterol to rise with age in women, which occurs especially after the menopause.34

There were 29 patients in the study who had a family history of CHD in a first degree relative, and 21 of these patients (72.4%) had a STC level of 6.0+ mmol/L-1, which gives a strong indication of the relationship between FHCHD and risk factors for CHD in the population. As a confirmation of this data, 12 of the 17 patients with a personal history of IHD (70.6%) had a STC level of 6.0+ mmol/L-1. Also 9 of the 20 referred from the well person clinic were seen to have a STC of 6.0+ mmol/L-1, indicating the potential benefit to the population of a broader based study.

4.6.4 Blood pressure

Systolic hypertension (160+ mm Hg) was found in 26 men (33.3%) and 24 women (38.7%). These high proportions are partly due to 86 subjects (61.4%) of the study population being treated for hypertension. In those patients, 42 (48.8%) had a SBP of 160+ mm Hg, even though 72 (83.7%) were on antihypertensive drug therapy.

The practice operates an aggressive hypertension treatment protocol and often introduces medication in patients at levels of 148 mm Hg SBP and 93 mm Hg DBP, depending on age, concurrent disease and presence of other cardiovascular risk factors. 13 patients, from the non-hypertensive group, were found to have a SBP of 150+ mm Hg. After consultation with the doctor, these patients were seen again by the practice nurse for BP measurement and 8 of them were placed on antihypertensive medication (see Table 4.2).

4.6.5 Physical activity

4.6.5.1 Contribution to individual and population risk reduction

The prevalence of the inactivity risk factor is causal and independent for CHD, and greater than the prevalence of any other risk factor, so the population risk due to inactivity is greater. ⁴⁷

The ADNFS found that an estimated 70% or more of both men and women in all age groups were below an acceptable activity level threshold that would confer significant health and functional benefits. The findings of this study closely matched this estimate: 64% of males and 69% of females were assessed to be in this category and therefore needed to increase their physical activity.

4.6.5.2 Method of assessment

Patients were asked a few relevant questions concerning their activity patterns, to provide knowledge of the frequency, intensity, time and type of activity undertaken. The intensities of activity were then divided into four categories and each patient assigned to an appropriate one.

Patient categories:

- 1. Inactive sedentary subjects, whose maximum activity is a short walk.
- 2. Light long walks (2 miles or more) at an average or slow pace, light DIY like decorating, table tennis, golf, social dancing bowls, fishing, darts, snooker, housework and non-sedentary occupations.
- 3. Moderate long walks (2 miles or more) at a brisk or fast pace, football, swimming, tennis, aerobics and cycling (if not breathless or sweating), heavy DIY (eg mixing cement), heavy gardening (eg digging), heavy housework (eg spring cleaning), active but not vigorous occupations.
- Vigorous hill-walking at a brisk pace, squash, running, football, tennis, aerobics and cycling (if breathless or sweating),

occupations involving frequent climbing, lifting or carrying heavy loads.

The activities listed above represented some of the responses categorised by the pharmacist, and, although not a validated system, it helped to establish the patient's current activity level, from which a target level could be adduced.

4.6.5.3 Appropriate interventions

The following principles were used by the pharmacist in the implementation of a policy on increasing physical activity:

- The intensity of the activity would be appropriate for the individual concerned. In practice, this meant lower target activity levels with increase in age of patient. In many cases, patients were precluded activity because of certain illnesses and symptoms:
- previously diagnosed heart trouble; in these cases a cardiac rehabilitation programme was advised.
- high blood pressure, and receiving treatment.
- angina-type pain in the chest on exertion.
- faintness, dizziness, or palpitations during exercise.
- severe disorders of the veins of the legs.
- grossly obese (>40 BMI).
- arthritis, gout, bone or joint problems
- chronic bronchitis, emphysema or regular cough.

In all cases, patients were advised to extend activity gently and build up gradually, eg, a sedentary person at present on activity level 0, was advised to walk a mile at a moderate pace twice a week, progressing to 1.5 miles after 2 weeks, and three times a week after 3 weeks.

4.6.6 Smoking status

Of the total cohort of 140 patients, 56.4% of the 78 men and 21% of the 62 women reported smoking at some time in their lives, and likewise the proportion of current smokers was 35.9% and 11.3% in men and women respectively. The incidence of smoking among hypertensive men was still 32.6% indicating that a diagnosis of high BP had not always acted as a deterrent. There were 15 patients in the smokers' group, although two were categorised as 'ex-smokers' as they had recently stopped smoking. The most promising outcome from the first consultation was that 10 patients agreed to stop smoking, four coming from the 'smokers' group, and at the end of the study, two years later, six patients had maintained their non-smoking status and four had restarted, either due to stress or excessive weight gain.

The 24 male cigarette smokers had a mean lifetime exposure to cigarette smoking of 28 pack years, whereas a figure of 20 pack years applied to the seven women.

Estimate of smoking exposure

Pack years' experience was calculated by multiplying together the reported number of years smoking cigarettes and the reported number of cigarettes per day, divided by 20.

4.7 THE INFLUENCE OF PHARMACIST COUNSELLING ON RISK FACTORS

4.7.1 Blood pressure

<u>Hypothesis 1</u>: The intervention will result in a lowering of mean BP values between the first and the final health screen.

A significant reduction (t = 5.26, df = 67, p < 0.0001) was found for SBP between the first (158.28 mm Hg, SD = 16.58) and the final test (146.55, SD = 1.12).

There was also a significant reduction (t = 4.81, df = 67, p < 0.0001) for DBP between the first (90.91 mm Hg, SD = 9.82) and the final test (84.85, SD = 6.50).

The intervention made principally by the pharmacist had influenced this improvement, as seen in Figures 4.2 and 4.3, by emphasising patient compliance and, in some instances, a recommendation for new or altered drug treatment, or a change in medication dosage.

Explanation of data in Figure 4.2 and all succeeding figures of this format Instead of plotting actual values, the boxplot displays summary statistics for the distribution. It plots the median, the 25th percentile, the lower boundary of the box, the 75th percentile, the upper boundary, and values far removed from the rest. The horizontal line inside the box represents the median. Fifty percent of the cases have values within the box. Cases with values that are between 1.5 and 3 box-lengths from the upper or lower edge of the box are called outliers and are designated with a circle. The largest and smallest observed values that aren't outliers are shown as horizontal lines, with lines drawn from the ends of the box to these values. From the median, you can determine the central tendency of the data. From the length of the box, you can determine the spread, or variability, of your observations. If the median is not in the centre of the box, you know that the observed values are skewed, positively, if the median is closer to the bottom than the top of the box. Boxplots are particularly valuable for comparing the distribution of values in several groups.

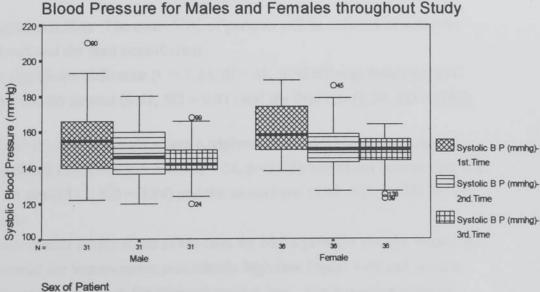
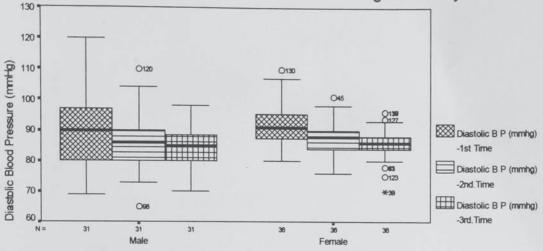


Figure 4.2 Trend in Range and Value of Systolic

Blood Pressure for Males and Females throughout Study

Figure 4.3 Trend in Range and Mean Value of Diastolic Blood Pressure for Males and Females throughout Study



Sex of Patient

4.7.2 Serum total cholesterol

<u>Hypothesis 2</u>: The mean STC of patients will be reduced between the first and the second consultation.

A significant reduction (t = 5.61, df = 79, p <0.0001) was found for STC between the first (6.83 mmol/L- 1 , SD = 1.02) and the second test (6.22, SD = 0.83).

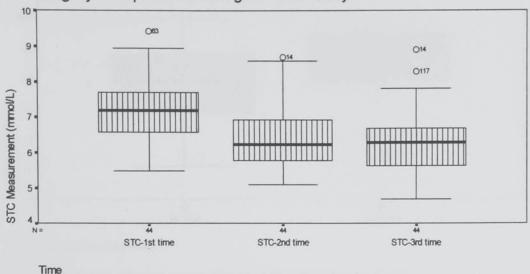
Hypothesis 2(a): The mean STC of patients will be reduced between the second and the final consultation.

No significant difference (t = 1.34, df = 42, p > 0.05) was found for STC between the second (6.41, SD = 0.81) and the final test (6.28, SD = 0.86).

However, in the patients where a triglyceride measurement was made, a significant reduction (t = 3.08, df = 14, p < 0.05) was found between the first (2.33 mmol/L- 1 , SD = 0.84) and the second test (1.98, SD = 0.76) for TG levels.

These results mirror those of the data for blood pressure change, in that the potential for improvement was initially high (see Figure 4.4) and, as time progresses, the scope for change becomes less. The important point to consider is that early improvements were consolidated and maintained throughout the study period.

Figure 4.4 Trend of STC Measurement in Surgery 2 Population throughout the Study

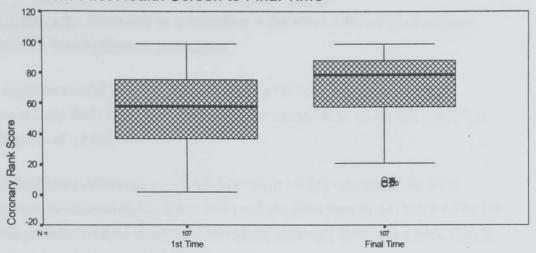


4.7.3 The Dundee Coronary Rank (CR) and Risk Score (CS)

Hypothesis 3: The mean value of CR for patients will increase between the first and the final consultation as a consequence of the intervention.

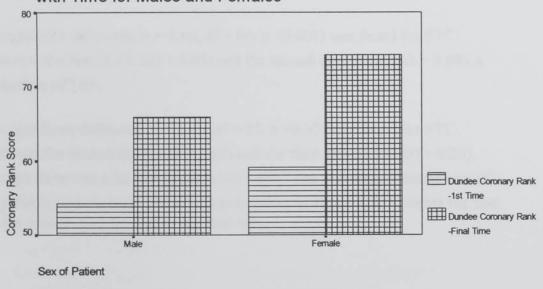
A significant increase (t = 7.77, df = 106, p < 0.0001) was found between CR at the first (mean value = 56,65, SD = 24.39) and the final time (70.03, SD = 23.98), equivalent to a percentage increase of 23.6 (see Figures 4.5 and 4.6).

Figure 4.5 Improvement of Dundee Coronary Rank from First Health Screen to Final Time



Dundee Coronary Rank

Figure 4.6 Improvement in Dundee Coronary Rank with Time for Males and Females



Males = 55

Females = 52

Hypothesis 3(a): The mean value of CS for patients will decrease from the first to the final consultation.

A significant reduction (t = 5.77, df = 106, p < 0.0001) was found between CS at the first (mean value = 6.55, SD = 4.5) and the final time (4.75, SD = 3.05), equivalent to a reduction of 27.3%.

These improvements were better than those for BP and STC, due to the fact that some patients stopped smoking.

4.7.4 Effect of medication on STC

Hypothesis 4: There will be a reduction in the mean STC value of patients placed on hypolipidaemic medication.

A significant reduction (t = 3.54, df = 18, p <0.005) was found for STC between the first (7.75, SD = 1.02) and the second time (6.74, SD = 0.99), a reduction of 12.8%.

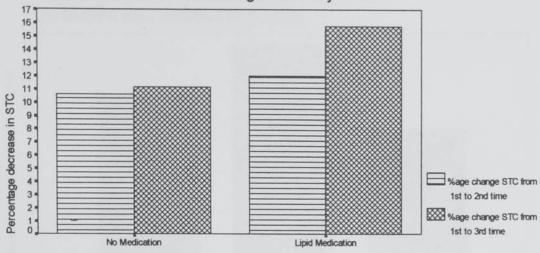
No significant difference (t = 1.67, df = 15, p > 0.05) was found for STC between the second (6.62, SD = 1.01) and the third time (6.30, SD = 1.18) for these patients on lipid-lowering medication, although there was a reduction in mean value of 4.8%.

<u>Hypothesis 5</u>: There will be a reduction in the mean STC value of patients treated with dietary modification only.

A significant difference (t = 4.64, df = 60, p < 0.001) was found for STC between the first (6.57, SD = 0.83) and the second time (6.07, SD = 0.69), a reduction of 7.6%.

No significant difference (t = 0.43, df = 27, p > 0.05) was found for STC between the second (6.26, SD = 0.65) and the third time (6.22, SD = 0.65), though there was a further reduction of 0.6%. The percentage change of STC in patients both on and off medication is shown in Figure 4.7, covering the first to the second, and the first to the final test.

Figure 4.7 Percentage Change in STC for Patients on Medication and/or Diet throughout Study



Patients' Medication Status

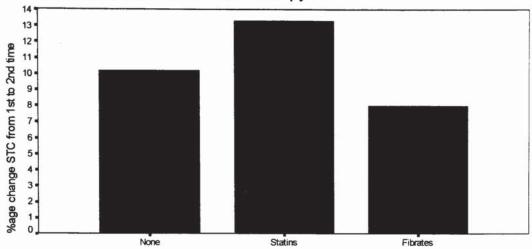
<u>Hypothesis 6</u>: The percentage reduction of STC in patients on lipid-lowering medication will be greater than that of patients on diet alone.

No significant difference (t = 1.44, df = 78, p > 0.05) was found between the two groups for percentage change of STC from the first time to the second time.

No significant difference (t = 0.92, df = 41, p > 0.05) was found between groups for percentage change of STC from the first to the final time. The lipid medication group showed a reduction of STC of 15.7%, SD = 20.01, compared to the diet only group which improved by 11.18%, SD = 12.81. The hypothesis is not confirmed.

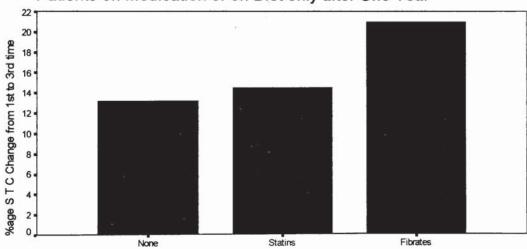
Figures 4.8 and 4.9 illustrate the comparative benefits imposed by the two drugs used, simvastatin having an initial beneficial influence of nearly 14% reduction in STC, maintained up to the final consultation, whereas bezafibrate showed little initial impact, only to aid a considerable improvement of 21% by the final stage of the study. Bezafibrate has less of an effect on STC than on TG levels, whereas statins lower STC more appreciably. Perhaps patients who are aware of their improvement in STC pay less attention to dietary advice, the bezafibrate patients becoming more conscientious in this respect when their STC showed little initial improvement. However, these effects would have to be evaluated on a larger sample.

Figure 4.8 Percentage Decrease in Cholesterol Six Months after Initiation of Therapy



Hypolipidaemic Medication

Figure 4.9 Percentage Decrease in Cholesterol for Patients on Medication or on Diet only after One Year



Hypolipidaemic Medication Status of Patients

Table 4.10 summarises the changes for CR and STC during the study, for those patients who returned to the pharmacist for a third occasion.

Table 4.10 Comparison of Parameter Changes for Patients on and off
Medication for Hyperlipidaemia

Parameter Change	Patients' Medication Status			
	No Medication	Lipid Medication		
Dundee Coronary Rank-1st time	46.38	40.84		
Dundee Coronary Rank-final time	62.63	67.79		
S T C Change from 1st to 2nd time	0.76	0.99		
S T C Change from 1st to 3rd time	1.00	1.33		
%age STC Change from 1st to 2nd time	ne 10.22	11.64		
%age STC Change from 1st to 3rd tim	e 13.18	15.78		
Number of Patients	28	16		

Figure 4.10 depicts the distribution curve of percentage change in STC which is skewed towards cholesterol lowering; however, some patients actually had an increased STC, partly due to poor compliance with diet and/or medication.

Figure 4.10 Histogram of Percentage Change in

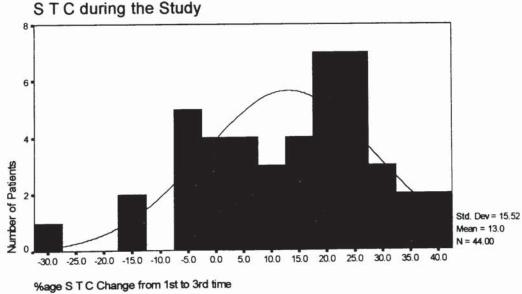
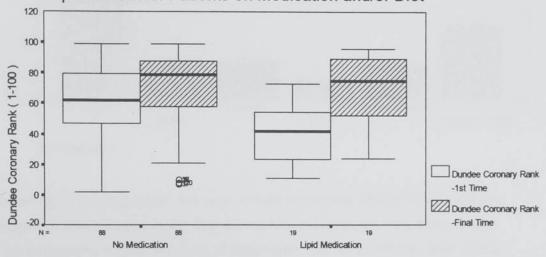


Figure 4.11 shows that the improvement in CR for patients expressed in Hypothesis 3 applied to patients both with and without medication.

Figure 4.11 Dundee Coronary Rank Score Improvement for Patients on Medication and/or Diet



Hypolipidaemic Medication Status of Patients

In this part of the study, medication has been seen to be more effective than diet, but patients in this category had a higher STC starting point and potentially a greater percentage reduction. Clinically, the results are important, as there is a 2% reduction in CHD for every 1% reduction in STC. 110

4.8 PHARMACIST INFLUENCE ON MEDICATION SPECTRUM

4.8.1 Hypertensive patients

The majority of patients when first seen by the pharmacist were on antihypertensive drugs (68 out of 86 patients) and their spectrum is shown in Figure 4.12. Although the practice protocol recommends an orderly stepwise approach (Table 4.2) to the treatment of hypertension, Figure 4.12 indicates a more random pattern. The pharmacist's aim was to ensure the patient was on the optimum drug and dosage to suit him, maintaining an acceptable BP level, with minimal side effects.

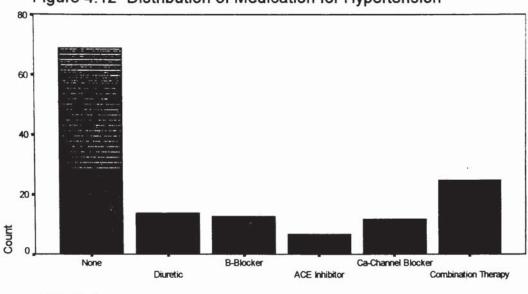
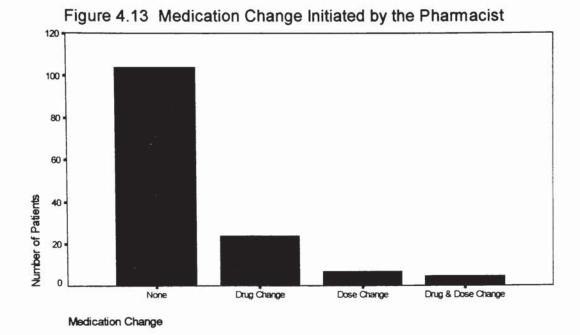


Figure 4.12 Distribution of Medication for Hypertension

B P Medication

According to a recent study, between 50 and 60 percent of new treatments are changed or discontinued in the first six months, and patients were more likely to be switched to a different class of drug rather than to a different drug within the same class. ¹¹¹ The medication change effected by the pharmacist is shown in Figure 4.13, but this includes those patients placed on hypolipidaemic medication; the number of changes exclusively related to hypertensive medication were 17, eight for newly diagnosed patients and nine from the original hypertensive group. In the surgery cohort, only 13% of the patient numbers were considered to need a different drug, compared with over 50% in the 1995 general practice studyin the UK. ¹¹¹ This may indicate the benefit of pharmacist monitoring, where patients have the actions and purposes of a prescribed drug explained, and patient compliance reinforced, in a non-threatening environment.



4.9 COMMUNICATION WITH OTHER MEMBERS OF THE PHCT

During the period of the study, information was passed to the doctors and other members of the PHCT as appropriate by the pharmacist, and reports were made at practice meetings, 52 patients (37%) being specifically referred to colleagues(Figure 4.14). The majority of these were for cholesterol (all referred to the doctor) or blood pressure (all initially referred to the nurse). This figure is almost twice that registered during the pharmacy study, but the Surgery 2 patients were mainly a selected group at high risk.

No Referral Blood Pressure Cholesterol Smoking Obesity Diabetic

Figure 4.14 Distribution of Patients Referred to other Health Care Professionals by Pharmacist

Reason for Referral to Doctor

4.10 CORRELATION OF FAMILY HISTORY TO CARDIOVASCULAR DISEASE

There was found to be no correlation in patients with a FH of hypertension or stroke with the incidence of high blood pressure (r = 0.19, p > 0.05 for FHHT and r = 0.01, p > 0.5 for FHCVA).

A significant difference (F = 5.39, p <0.005) was found between patient categories for FHCHD <60. A post hoc test revealed significant differences between patients with personal IHD and patients in the three categories of hypertension, smoking and well person.

4.11 CONCLUSION

Surgery 2 showed that, given the opportunity, the pharmacist can have an effective impact on improving the health of a practice population. At Surgery1, as in the pharmacy, he was only able to become partly involved, whereas, at Surgery 2, he was able to get a complete picture of each patient, as he had access to medical records. In this way, he was able to participate fully in the evaluation, monitoring and treatment of patients. The success of pharmacist intervention is demonstrated by the alteration of risk factor profiles, as well as by the fact that previously undiagnosed hypertensives were identified and the medication regime of some patients was altered for greater efficacy and tolerance.

CHAPTER 5

HEALTH SCREENING OF TOTAL PRACTICE POPULATION AT ELLIOTT HALL MEDICAL CENTRE (SURGERY 3)

5.1 INTRODUCTION

Patient health benefit was the main concern expressed in discussions with the doctors and other health care professionals at Surgery 3. At the time of the early dialogue, the pharmacist's idea of a health screen of a proportion of a practice population fitted in well with the plans of the medical practice, which was on the point of relocating to a new custom-built surgery. The practice were keen to have an up-to-date record of the health and lifestyle of their patients, and invited the pharmacist to organise and facilitate this, hopeful that the pharmacist input could be extended, and lead to a multi-professional development in health care.

5.2 AIMS

This investigation had the following aims:

- 1. To determine the response rate to a lifestyle questionnaire sent to patients in a practice population.
- 2. To determine the distribution of the various cardiovascular risk factors among the respondents and set up a template on the practice computer.
- 3. To set up a health screening study with a random selection of the practice population and obtain distribution figures of risk parameters and profiles of patients' personal and family history.

5.3 METHOD

All patients, aged 15-75 years, identified from a search made on the practice computer, were sent an introductory letter (Appendix 4) together with a lifestyle questionnaire (Appendix 5) designed to encompass the known risk factors for CHD. Letters were initially posted to 3941 patients, consisting of 1913 males and 2028 females, and replies were received from 1254 males (66%) and 1526 females (75%) within a two-month period.

The information from the questionnaires was entered onto the computer system at the medical practice by the pharmacist, under the classification 'Ischaemic Heart Disease Screen'.

Before agreement was reached concerning the actual protocol, suggestions for procedure moved through a number of phases. The first plan was to divide the patient cohort into three groups: one to be seen by the pharmacist, at his pharmacy; one to be seen by the practice nurse; and one, a control group, to be given health care information in the form of a leaflet distributed by the receptionist team at the practice. The use of the pharmacy setting was soon discounted, as geographically it would not be convenient for many patients to attend, and the pharmacist would not be able to access the practice computer nor check a patient's medical records. The comparison of the pharmacist with a nurse was considered invidious, especially as the main purpose of the exercise was to seek an improvement in the health status of an individual, based on education from a standard source. Advice from the Epidemiology Department at Northwick Park Hospital (NPH) stated that a group given literature by receptionists could not be considered 'true controls' as intervention had taken place.

Finally, therefore, and after many presentations at practice meetings, the pharmacist was given the freedom to control the health screen himself. A description of the research project was submitted to the Ethical Committee at NPH for approval, which was granted.

5.3.1 Patient categorisation

Patients were divided into the following categories, according to their answers to the questionnaire:

- Patients with IHD
- Patients with FH <60 CHD
- Patients with diabetes
- Patients with familial hyperlipidaemia
- Patients with high blood pressure
- Patients who smoke
- Patients with none of the above risk factors were considered as 'no risk'.

3.2 Patient selection and randomisation

600 patients were asked to attend a health screen interview, proportional to the incidence of risk factors so that a cross-section of the population would be screened. 'No risk' patients were included, as the intention of this study was to evaluate a representative sample of the practice. The 'no risk' patients would initially be treated as a 'comparison' group.

The 600 patients to be invited to a health screen were randomly selected using the facility on the computer system at the practice. In the event, only patients between 25 and 65 years of age, plus those between 16 and 25 with a family history of CHD, were chosen for the study, as this age range covered those patients considered most likely to benefit from health promotion.

The only patients excluded from the random selection were the few, at the practice, who had already been screened and perhaps treated for a high cholesterol level, as this would have introduced bias into the assessment of the value of pharmacist intervention.

5.3.2.1 Mechanics of recruitment of patients

The patients were initially assorted into groups according to their risk factor category and their sex, then again into separate 10-year age groups. They were all sent letters inviting them to attend a health screening interview (Appendix 6). These letters were posted in increments at two-weekly intervals to match the pharmacist's working programme at the practice. Appointments were made at half-hour intervals during the day, the maximum number of patients seen in any one day being 15. As the pharmacist had two days per week available, the expected projection time for seeing all patients was 20 weeks. Patients had indicated on their questionnaire, their preferred day and time for attendance, which the pharmacist endeavoured to accommodate. This resulted in the adoption of a flexible policy and attendance at the surgery by the pharmacist at various times and dates.

Experience at Surgery 2 had shown that discussion relating to diet and nutrition was time-consuming, therefore a detailed questionnaire, asking for a record of the average weekly intake of the four major food groups, complex carbohydrate, dietary fibre, protein and fat, was sent with the appointment letter (Appendix 7).

Patients were asked to bring the completed questionnaire with them to the interview.

.3.3 Health check procedure

The interview was conducted using a standard format for each patient. The following details were recorded:

- Family history of CHD <60.
- Family history of CHD >60.
- Family history of hypertension, stroke, diabetes and high cholesterol.
- Current and past illnesses.
- Current medication, for cardiovascular and other complaints.
- Patient compliance with medication, side effects and allergies experienced.
- Smoking status, both current and past.
- Alcohol intake, in units per week, and nature of drink.
- Exercise level and nature of activity.
- Confirmation of food and non-alcoholic drink intake spectrum.
 Education, work situation, marital status, interests and estimated stress.
 The following measurements were made:
- 1. Height and weight (Seca digital model 707 with telescopic measuring rod) to give the BMI.
- 2. Blood pressure (Primetest random zero sphygmomanometer). An index method was used to prevent subjective bias and give a digital read out of systolic and diastolic BP(see 5.3.3.1).
- 3. Random serum total cholesterol (Reflotron, Boehringer Mannheim, UK).
- 4. Random blood glucose (Glucometer, Bayer Diagnostics). Measurements (3) and (4) were made on a capillary blood sample. Measurement of blood glucose entailed applying a drop of blood from a finger prick to the reagent pad on a test strip. After 30 secs, the blood was removed with a tissue and the developed colour read in the meter calibrated to give a reading of RBG in mmol/L-1.
- 5. Pulse. This was done at the request of the doctors as any irregularity, indicating possible arrythmia or need for low dose aspirin medication, could be further investigated.

5.3.3.1 The Primetest sphygmomanometer

The main systematic errors that occur during indirect BP measurements are the differences in interpretation and the preference for 0 and 5 as final digits of the values.

As measurements are not made 'blind', the examiner expectations may inadvertently influence the outcome. The Primetest sphygmomanometer has been optimised for interaction between the examiner and the computer in order to eliminate this "examiner bias", so that the computer measures the pressure and the examiner recognises the heart tones, using an integrated electronic stethoscope which filters the noise and amplifies the heart tones.

The examiner notes the displayed number coincident with hearing the first and last heart tone. On entering those figures into the computer via the keyboard, the systolic and diastolic pressures are displayed. The result is a consistently objective measurement with no systematic examiner error.

5.3.3.2 Dietary information to patient

Emphasis was placed on the concept that it is the role of the whole diet and not just parts of it which is important in CHD. With this in mind, the pharmacist gave each patient a copy of the four food group guide to healthy eating (Appendix 8), and explained the appropriate quantities to eat (Appendix 9).

Each of the states of heart disease, arterial injury, atherosclerosis and thrombus formation, can be influenced by several physiological conditions, eg high blood pressure, high lipid levels and insulin resistance.

Dietary influences affect different physiological risk factors, eg high intake of saturated fatty acids increases the likelihood of both raised LDL cholesterol levels and arrythmia.

No single dietary factor should take precedence over another, and interactions between different fatty acids, NSP, alcohol, sodium and antioxidant and pro-oxidant nutrients can all determine the overall effect. Patients were therefore advised to follow the concept of the integrated diet illustrated in Appendices 8 and 9.

Additionally, specific advice to adopt the following dietary habits was given, as a result of currently reported research:

- Increase intake of vitamins C, E and beta-carotene. Highly significant correlations between low plasma concentrations of these antioxidants and risk of angina were found in a large case control study in Scotland, which investigated men aged 35-54.
- Eat a more Mediterranean-style diet, consisting of fresh fruit, vegetables and olive oil, which in practice emphasises the integrated diet discussed above. A four-year study in France has shown a greater survival rate for heart attack victims placed on a Mediterranean diet than on a conventional low fat regime. Further, a 12-year study shows that people on this diet are 30% less likely to die of heart disease. The blood of these French volunteers contained twice as much of the antioxidants luetin and alpha and beta cryptoxanthin as that of Irish volunteers. 114
- Increase bread consumption to six slices a day. The Health
 Education Authority states that bread provides fibre, relieves
 hunger, leaving less room for fatty foods and that wholemeal
 bread provides the most nourishment.
- Drinking tea is not harmful. Researchers in Holland found that four cups of tea a day could halve the risk of a heart attack. Like red wine, tea is high in flavonoids, which have a beneficial effect on blood fats and circulation. Onions, another food high in flavonoids, are further insurance against heart trouble. 115
- You may find it helpful to take garlic if you have
 hypertension. A new study has shown that garlic supplements
 taken over three months significantly reduced blood pressure in

400 patients. They had a beneficial effect on those with slightly raised blood pressure which was not severe enough to require standard drug therapy. If this BP-lowering effect can be sustained at the same level over a longer period, then stroke may be reduced by 30-40%. 116

- Eat more walnuts, almonds and hazelnuts. An American study has found that comparing a standard cholesterollowering diet with that in which 20% of the calories were derived from walnuts, the mean total cholesterol level was 12.4% lower with the walnut diet, and LDL and HDL cholesterol levels were favourably modified. 117
- Eat more soluble fibre, such as oats and pulses. Studies
 have shown that it is necessary to eat large amounts of oats
 and pulses to reduce STC. For instance volunteers who ate a
 large tin of baked beans daily for a fortnight reduced their
 cholesterol by nearly 12%. 118

5.3.4 Patient assessment

A Coronary Rank and Coronary Risk Score was calculated for each patient using the Dundee Risk-Disk (Appendix 10). As a result of their ranking, patients were divided into three groups for establishing their frequency of follow-up monitoring by the pharmacist:

Group 1: Patients with a Ranking below 60.

Group 2: Patients with a Ranking between 60 and 89.

Group 3: Patients with a Ranking of 90+.

In this way, patients were conveniently gauged as: high risk (Group 1); intermediate risk (Group 2); and low risk (Group 3).

Group 1 patients were seen 6-monthly during the two-year study period. This meant 4-5 times, depending on their progress.

Group 2 patients were seen annually, which meant 3 times, although a few, who may have regressed, were seen a fourth time.

Group 3 patients were seen twice, at first and again at the end of the study, after two years.

There were two exceptions to the exact grouping of patients according to their Rank score:

- 1. Smokers. They are inevitably given a low ranking on the Dundee System, but where their STC and BP were within normal limits, they were placed in Group 2, although their score was below 60.
- 2. Women, aged below 50 years. The Dundee System places these patients in a lower rank compared with men with similar values of STC and BP and equivalent smoking status. Again, if their STC and BP readings were good, it was not considered warranted to see these women more often than indicated by the cholesterol protocol (Appendix 3) or the practice hypertension protocol (Appendix 11). These women were therefore moved from Group 2 to Group 3.

On the other hand, there were some patients, for whom it would have been inappropriate to leave unchecked for 6 months. These included patients with a very high STC, BP or blood sugar, who were referred immediately to the doctor. Examples of this will be illustrated in Chapter 7 dealing with individual case histories.

5.3.5 Health education literature

Literature was distributed appropriately to all patients at the end of the interview to reinforce the messages conveyed verbally throughout the consultation. All leaflets were provided free by the Flora Project for Heart Disease Prevention.

'Eating for a Healthy Heart' and 'Antioxidant Vitamins' were given to all patients. The other publications, on alcohol, blood pressure, obesity, smoking, fitness and stress, were given to patients as appropriate.

3.6 Involvement of other members of the PHCT

Each doctor, in the practice in turn, took the opportunity to sit in with the pharmacist during a morning session, as did the GP trainee. Regular update meetings took place with individual doctors to discuss general progress and individual case histories, and presentations were made to practice meetings. The practice has an active Patients' Association, and the pharmacist was asked to address their meetings and contribute to their periodical.

Practice nurses were on hand to confirm a blood pressure reading if the pharmacist found it to be high. In practice, patients were asked to return one and two weeks later to the nurse for a second and third reading, before referral to the doctor.

.4 RESULTS AND DISCUSSION

5.4.1 The lifestyle questionnaire

Patient response to the questionnaire is summarised in Table 5.1. In total, 71% (2790/3941) of the questionnaires were returned within a 10-week period, and these patients were included in the study. Some replies continued to trickle through thereafter and, due to the success of the questionnaire, each doctor finding the information on the computer invaluable during surgery, all new patients to the practice were required to complete a questionnaire on registering. Response varied according to the age and sex of the patient: an overall 75% female response compared with a 66% male response: a maximum 88% response by women aged 55-65 years compared with 52% by women aged 15-25 years.

Table 5.1 Patient Categories from Questionnaire Replies

Patient Categories	All Patients	Male	Female
Total Population	3941	1913	2028
Replies	2790	1264	1526
IHD	124	69	55
FH CHD <60	528	257	271
Diabetes	50	29	21
Familial Hyperlipidaemia	15	3	12
Smoker	440	240	200
Ex-Smoker	1190	669	521
Hypertension	467	205	262
Stroke	35	16	19
B M I >25	1077	601	476
Inactive	518	230	288
Very Active	301	194	107
Alcohol > Limit	348	203	145

5.4.1.1 Coronary Heart Disease

A close family history of CHD was found in 18.9% of patients, which is somewhat less than the 25%+ of all deaths caused by CHD in the UK in 1991, ¹⁹ however, as will be seen in Section 5.4.3.1, the true level of FHCHD <60 in patients, as elicited during the interview, was 29.6%. Some 5.5% of men, in the practice, had suffered a heart attack or were suffering from angina, compared to only 3.6% of women, which reflects the national picture, the gap between the sexes closing strongly after 65 years of age, when 14.8% of men had IHD compared to 12.3% of women.

FHCHD<60: patients with a first degree relative who has had a heart attack before the age of 60 are designated a 'priority group' by the British Heart Foundation in association with the British Cardiac Society.

5.4.1.2 Diabetes

Approximately two percent of the UK population suffer from diabetes mellitus, and the practice figure of 1.8% is close to that figure. Regrettably many diabetic patients, especially those with NIDDM remain undiagnosed and, even though their disease is asymptomatic, it has the potential to precipitate long-term complications such as CHD, eye damage, vascular disease and kidney disease. It has been estimated that, in the UK, there are at least 250,000 undiagnosed cases, and with this in mind, the pharmacist suggested to the doctors that a blood glucose measurement was made at the same time as the cholesterol test, while a subject was giving blood. The doctors were in complete agreement as they felt the procedure would help identify undetected diabetic patients in the practice.

5.4.1.3 Familial hyperlipidaemia

This question caused confusion and consternation among some patients, as they had no idea what the disease was; however, the pharmacist considered that those patients with the disease would be aware of its existence. 15 patients stated that they had familial hyperlipidaemia, whereas, if figures were extrapolated nationally, only six would have been expected. During the subsequent health screen interviews it was established that five patients were inaccurate with their diagnosis and the family history was of high cholesterol.

5.4.1.4 Smoking

The targets for smoking cessation laid down in the strategy documents for the UK have implications for the possible significance of primary care intervention in achieving that change. The adult target in England is to reduce smoking prevalence in every practice population to no more than 20%, from a current 31% of men and 28% of women by the year 2000.²⁴

Surgery 3 seems to have advanced beyond that stage already, as, from Table 5.1, the percentage of men reporting as current smokers was 19% and for women only 13%. Closer examination of the figures show that, in the 15-25 age group, the incidence was highest of all, 25% of men and 22.4% of women smoking currently.

At present about 40% of all people who have ever smoked have given up. 120 At the practice, this percentage was 42.5% with 53% male ex-smokers and 34% female ex-smokers. The 'Health of the Nation' target is for a percentage of 65% of all people to stop smoking, without any new people taking up the habit. This target has already been achieved at the practice by the older males, as 65.5% of 55-65 year old men are ex-smokers.

Women in the practice have a particularly low smoking status compared to the national average. This may be due, in part, to the socioeconomic status of patients at the practice. Many of the patients, male and female, belong to the three socioeconomic groups with the lowest proportion of smokers in the population:

- Professional
- Employers and managers
- · Intermediate and junior non-manual.

5.4.1.5 High blood pressure

Hypertension figures equated well with the expected frequency, with 16.2% of men and 17.2% of women stating they had had high blood pressure at some time in their lives. ⁵⁸ The figure for women needed to be adjusted down slightly, because later investigations at the interview showed that a few of the women experienced high blood pressure in pregnancy only.

5.4.1.6 Stroke

Stroke was responsible for more than one in ten deaths in 1991, and many more suffered severe ill-health and disability. ⁵⁴ The current percentage of surviving patients at the practice who had suffered a stroke was 1.25%, and the aim of the pharmacist was to prevent any more patients, particularly the hypertensives, becoming increasingly at risk.

5.4.1.7 Body mass index

The practice population profile of the 38.6% that are considered overweight (BMI >25), compares closely with the national population average of 40%. ¹²¹ There was a distinction between the sexes, in the practice, in that 47.5% of men and only 31.2% of women were overweight, which no doubt reflects womens' greater awareness and conscientiousness in this respect, especially in the dominant socio-economic groups.

5.4.1.8 Exercise

Based on the ADNFS scoring system, 70% of the average practice population are physically too inactive. ¹⁰⁹ At Surgery 3, only 59% were in that category. However, those achieving the ideal exercise target constituted only 10.8% of the population, and among women the percentage was only 7%.

In this respect, age was not a significant factor: 37-38% in the 25-34 year and 55-64 year age groups achieved at least moderate activity status; and 47-48% of men in the 25-34 year and 55-64 year age groups did likewise.

5.4.1.9 Alcohol intake

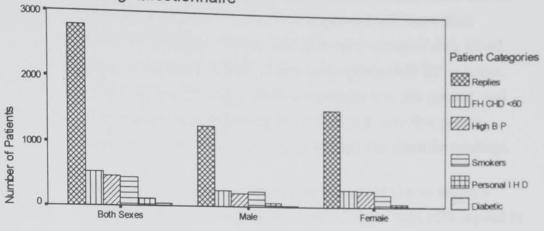
Alcohol consumption is indirectly implicated as a risk factor for CHD and directly implicated as a risk factor for stroke, due to the effect it has in raising blood pressure. 25,54

Drinking about two glasses of wine per day has been suggested to have a possible protective effect on the heart. 53,122 Any benefit from drinking alcohol is, however, outweighed by the increased risk for stroke and other diseases, involvement in accidents and antisocial behaviour. 123

The aim of the pharmacist was to optimise an individual's alcohol consumption to within sensible limits, thereby aiding any programme to reduce blood pressure and obesity. In the average practice, the number of men drinking >21 units/week is 20% and women drinking >14 units 7.5% of the population. Surgery 3 figures were: 16% for men and 9.5% for women. Only two age groups appreciably drank more than the practice average: 21.9% of men aged 25-34 years and 13% of women aged 45-54 years were the two categories concerned, which fits in with the national habits of young adult males and possibly indicates a picture of the inactive housewife whose family have left home. Many studies for male and female drinkers have shown a dose-response relationship between the level of alcohol consumed and both SBP and DBP that is independent of age, weight and smoking. 122 Other studies have revealed a U-shaped trend for increased BP and stroke risk with increasing alcohol consumption. 124

A summary of the relative incidences of the patient categories used in the study is shown in Figure 5.1.

Figure 5.1 Distribution of Risk Factors in Patients Answering Questionnaire



Sex

Patient Replies=2790. Male=1264. Female=1526

FHCHD=528. High BP=467. Smokers=440. IHD=124. Diabetic=50

5.4.1.10 General information

A majority of patients had had their BP measured in the last three years (81%), of whom 73% had had checks at the surgery (see Table 5.2). A mere 1.5% (34) had checked their BP at a pharmacy, further emphasising that the focal point for health care remains at the surgery.

Table 5.2 Previous Recording of B P and S T C of Patients

	1 aut 5.2	TTC YTC MD AND AND AND AND AND AND AND AND AND AN					
	Test	Previous Record (%)	Place of Test	Percentage Share			
			G P Surgery	73.1			
	Blood		Hospital	13.9			
	Pressure	81.2	Pharmacy	1.5			
	1105000		Work	3.5			
			Home	8.0			
	Cholesterol	26.6	G P Surgery	42.0			
			Hospital	16.0			
			Pharmacy	28.5			
			Other	13.5			

Cholesterol checks had been made in 26.5% of cases, although of these 28.5% (211) had either taken place at home with a test kit or at the pharmacy. Nearly 50% of patients still knew their cholesterol figure, whereas only 18% were aware of their blood pressure, and nearly half of these were testing their BP at home. There is therefore scope for health education in this respect, and the pharmacist subsequently discovered that very few people understood the significance of the systolic and diastolic readings.

Each patient was asked whether he/she would like to attend a health screen clinic with the pharmacist; more than 86% replied in the affirmative.

Examination of the figures showed that there was some evidence of correlation of FHCHD <60 with hypertension. 18.9% (528/2790) of patients reported a FHCHD <60, whereas the incidence of FHCHD <60 specifically among the hypertensives was 25.5% (119/467). Further, 16.7% (467/2790) of patients reported high BP, but among those with a FHCHD <60, the incidence rose to 22.5% (119/528).

Two other parameters showed an increased incidence of hypertension compared to the normal population:

- 1. 34% of diabetics had hypertension, and
- 2. 23.5% of overweight cases (BMI >25) also had hypertension.

Exercise, smoking and alcohol intake did not show any effect.

In diabetic patients, 28% had FHCHD <60 and 56% had a BMI >25, well above the incidence in the normal population of these two parameters.

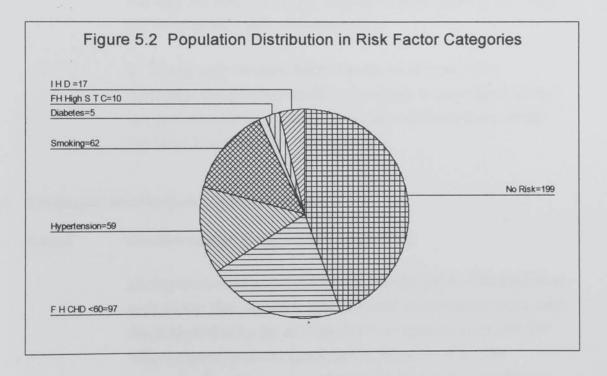
Risk Factor Category Distribution for Age and Sex of Patient Table 5.3

				Age Of Patient	ent In Years			
	15-24	15-24 years	25-34	S	35-44	years	45-54	years
	Count	Row %	Count	Row %	Count	Row %	Count	Row &
Risk Factor Category Of Patient No Risk F H CHD <60 Hypertension Smoking	13	13.4%	37 11 6 13	18.6% 11.3% 10.2% 21.0%	58 26 5 10	29.1% 26.8% 8.5% 16.1%	49 26 13	24.6% 26.8% 32.0%
Diabetes FH High Cholesterol Ischaemic Heart Disease	т	30.0%	2	20.0%	2	20.0%	1	20.08
	Age Of Patient In	ent In Years		Sex Of	Patient	The second secon		
	55-65	years	Male		Female	lle		
	Count	Row %	Count	Row %	Count	Row %		
Risk Factor Category Of Patient No Risk	55	27.6%	78	39.2%	121	60.8%		
F H CHD <60 Hypertension	21 35	59.3%	2 6 3 0	45.48	33 32	55.9%		
Diabetes FH High Cholesterol Ischaemic Heart Disease	16 1 5	100.08	10	60.08 40.08 58.88	762	40.0% 60.0% 41.2%		

5.4.2 Response to invitations to attend a health screen

2409 of the questionnaire responders indicated that they would be willing to attend a pharmacist-conducted health screen, to which the 600 patients, randomly selected, were invited. 28 of these patients had left the practice during the period between receipt of the questionnaire and sending out the health screen invitation. The attendance rate at the surgery was 78.5% (449), response rate for women being 85% (254/298) and men 71% (195/274). Table 5.3 shows the attendance figures for the various risk factor categories subdivided into sections for age and sex.

Figure 5.2 is a pie chart, whose sections represent the category distribution of risk factors, also shown in Table 5.4.



Patients were placed in the category as selected by the practice computer; there were 36 patients who had two or more risk factors, eg hypertension and smoking.

Table 5.4 Risk Factor Category of Patient

Risk Factor I	Frequency	Percentage
No Risk	199	44.3
F H C H D<60	97	21.6
Hypertension	59	13.1
Smoking	62	13.8
Diabetes	5	1.1
FH High Cholesterol	10	2.2
Ischaemic Heart Disea	ise 17	3.8

Two of the risk groups gave a low clinic attendance response:

- 1. Diabetic patients those that did not attend telephoned to say that they felt they were being 'very well looked after' by Dr J. who ran the Diabetic Clinic (8/14 patients).
- 2. Young male smokers, below the age of 44 years, who apparently thought they would be 'preached at', and therefore did not give the pharmacist the opportunity to motivate them to effect any behavioural change (9/21 patients).

1.4.3 Frequency distributions of risk parameters

5.4.3.1 Cardiovascular family history of patients

During the interview, more accurate information was obtained from each patient than may have been indicated in the questionnaire, and this is illustrated by the fact that 29.6% of patients had a FHCHD <60, compared with the questionnaire figure of 19%. The proportion for each category of family history is shown in Figure 5.3, where the definition of close and distant FHCHD <60 can be deduced from Table 5.5. Examination of the figures for close FHCHD <60 clearly indicates a greater incidence among male members of the family: 22% of FHCHD <60 was attributable to a father or brother compared to only 8% to a mother or sister. This

confirms the national trend for men to be the victims (mainly) of CHD below the age of 60 years. 125

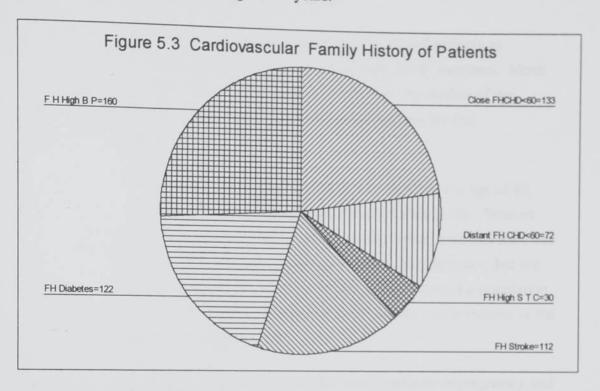


Table 5.5 Frequency Distribution of Family Members with F H CHD <60

Patient with	h Close FH CHD<60 F	requency	Percentage
	None	316	70.4
	Father	76	16.9
	Mother	32	7.1
	Brother	22	4.9
	Sister	3	0.7
Patient with	h Distant FH CHD<60		
	None	377	84.0
	Grandparent (paternal)	24	5.3
	Grandparent (maternal)		5.1
	Aunt or Uncle (paterna		3.6
	Aunt or Uncle (materna		2.0

Frequency of occurrence of a FH of CVA (stroke) was 27.4%, although, in this instance, there was no differentiation between the sexes. However, a majority of patients reported their relative as

suffering a stroke at the age of 80+ years, therefore not being associated with premature death.

High blood pressure was reported by 35.6% of patients as occurring at some time in the life of their family members. More than half (21.4%) of the cases occurred in the mother of the patient. There were two possible explanations for this phenomenon.

- 1. Many of these mothers suffered a stroke over the age of 80 years, after developing high blood pressure late in life. Women tend to live into the 80s in greater numbers than men and are more likely to have the opportunity of suffering from illnesses that are common at that age. Figures at the practice showed a population figure of 305 females compared to 171 males on the register at the age of 75 years and over.
- 2. Some women experience high blood pressure in pregnancy and label themselves as potentially hypertensive thereafter.

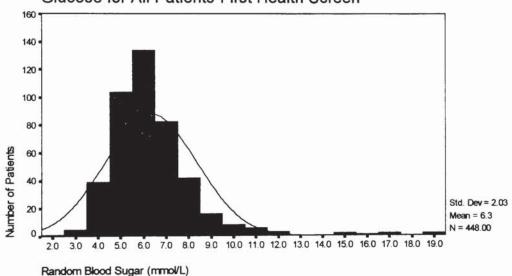
Incidence of FH of diabetes was equally as strong as FHCVA, and was present in 27.2% of the study population. The overwhelming majority of these relatives presented with diabetes after the age of 40 years, which fits in with the epidemiological evidence that maturity onset or NIDDM accounts for 75-95% of all diabetics in most populations. In the UK, diabetes affects approximately 750,000 people, of whom 600,000 have NIDDM. 126

The prevalence of insulin dependent diabetes mellitus (IDDM) is approximately 0.3% of the population in those under 30, with the greatest incidence at the time of puberty and a decline thereafter. On the other hand, the incidence of NIDDM increases with age and with increasing obesity; the prevalence for non-obese patients is 1-3% of the population, which increases sharply to 6-8% in obese patients. 127

5.4.3.2 Blood glucose

The Green Paper, in its chapter 'The NHS Role in a Strategy for Health' has laid out an extended role for the pharmacist, and one way in which this can be exploited is in the early detection of diabetes. ⁷⁵ In the Surgery3 practice study, 448 patients had a random blood sugar measurement, and the distribution is shown in Figure 5.4. 20% of patients had a RBG of 7.3+ mmol/L-1 and 10% one of 8.3+ mmol/L-1. Nineteen patients had a RBG of 10.0+ mmol/L-1 and, after consultation with the doctor in charge of the diabetic clinic at the practice, these patients were sent a letter advising them to attend hospital for investigations on a fasting blood sample (Appendix 12).

Figure 5.4 Frequency Distribution of Random Blood Glucose for All Patients-First Health Screen



Another 91 patients had their blood sugar tested in a fasting status on their second visit to the pharmacist; of these 110 patients, 100 had fasting levels below 8.0 mmol/L-¹, and ten had readings above 8.0 mmol/L-¹. Three of these ten patients, all women, were diagnosed as Type II Diabetic.

There was no correlation, however, between sex and blood glucose readings, although there was a significant difference, at the 5%

confidence level, between patients aged over 55 years and the rest of the population, emphasising the increased susceptibility of the older generation to develop diabetes.

5.4.3.3 Diabetes

Diabetes may be defined as a condition with glycosuria, raised blood sugar, and alteration in fat and protein metabolism.

Pathophysiology Insulin is synthesised in the beta-cells of the Islets of Langerhans in the form of pro-insulin. Insulin is the key hormone involved in the storage and utilisation of chemical energy available from food. Glucose is the major stimulant to insulin release, the insulin response being triggered by intake of nutrients and the release of gastro-intestinal peptide hormones. Acute deficiency of insulin leads to hepatic glycogenolysis and gluconeogenesis and a consequent increase in hepatic glucose output.

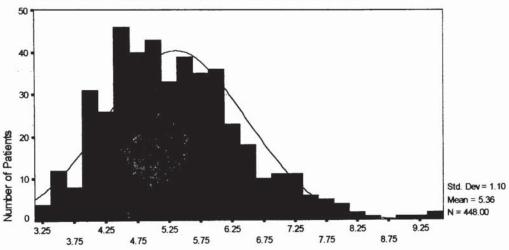
Aetiology There is a strong immunological component to IDDM and a clear association with many organ-specific auto-immune diseases. NIDDM has a much stronger genetic component than IDDM, suggesting the relative importance of inheritance over environment. Obesity, which is associated with hyperinsulinaemia, marked insulin resistance and a decrease in the number of insulin receptors, has been linked with NIDDM. 127 However, the results at Surgery 3 show no evidence of this when examining blood glucose figures related to patients' BMI, and, even among the three newly-diagnosed diabetics, two of these women had a BMI of under 25.

5.4.3.4 Serum total cholesterol distribution

The frequency curve for Surgery 3 patients (see Figure 5.5) was derived from the sample data, and the mean plasma cholesterol was 5.36 mmol/L-1. Compared to the results from the Imperial Cancer

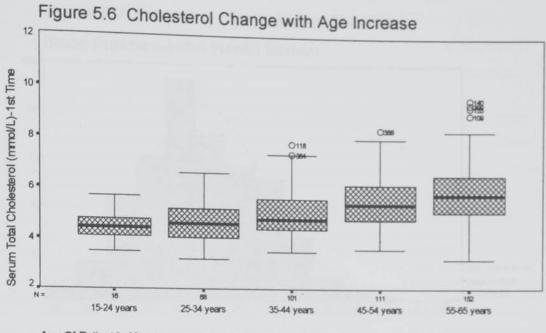
Research Fund OXCHECK Study Group, there was a bias towards a lower STC figure in the Surgery 3 Study, the mean STC for the OXCHECK Study being 5.93 mmol/L-1.128 This trend was consistent throughout the range of STC readings, there being an incidence of 3.9% for patients with an STC of 8.0+ in the OXCHECK study, compared to 2.2% in the Surgery 3 Study. Further confirmation was that only 15% of the study group had a STC of 6.5 mmol/L-1+ compared to a reported 25% from recent surveys. 129

Figure 5.5 Frequency Distribution of Serum Total Cholesterol for All Patients-First Health Screen



Serum Cholesterol (mmol/L)-1st Time

The difference may be attributable to different measurement systems in the two studies and/or lifestyle variations between the two populations. The OXCHECK Study used a conventional enzymatic laboratory wet chemistry method, which estimates cholesterol levels about 0.3 mmol/L-1 higher than the Reflotron. Figure 5.6 shows the gradual increase of STC with age, both in the mean value and the upper limit figure, which confirms results from other workers. 91 This concurred with their conclusions that a decrease of STC of 0.6 mmol/L-1 was associated with a decrease in incidence of ischaemic heart disease of 54% at age 40 years, 39% at age 50 and only 27% at 60.91

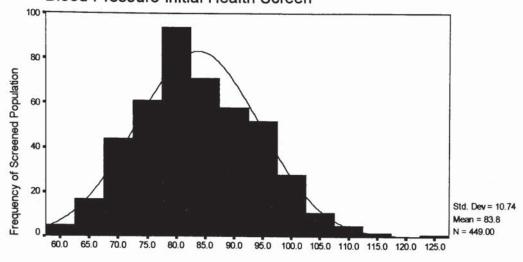


Age Of Patient In Years

5.4.3.5 Blood pressure distribution

The frequency distributions of diastolic and systolic blood pressures compared well with other recorded normal distributions (see Figure 5.7). There were 25.6% of patients in the Surgery 3 Study with a DBP > 90 mm Hg compared to 25.3% in an American study. 130 Prevalence of hypertension at the 95 mm Hg cut-off point was 14.5% in the American study and, at 8.4% at the 100 mm Hg level, compared with 11.4% and 5.6% respectively at Surgery 3.

Figure 5.7 Frequency Distribution of Diastolic Blood Pressure-Initial Health Screen



Diastolic B P (mmHg)-1st Time

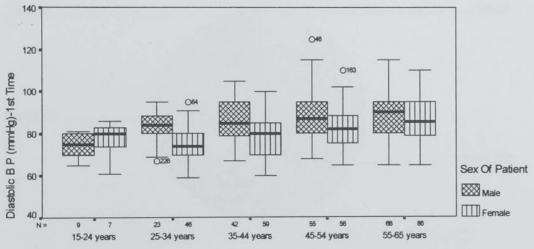
Mean systolic value at Surgery 3 was 134.6 mm Hg and the diastolic mean was 83.8 mm Hg. These were higher than those of the OXCHECK study, which were 127.6 and 76.4 mm Hg respectively; however, this latter study included patients receiving an initial health check only, whereas at Surgery 3, the patient cohort included known hypertensives. When the hypertensive category was excluded, the mean value of SBP reduced to 131.5 mm Hg and DBP to 82.1 mm Hg, closely resembling results in the Swedish study on the impact of health care advice given in primary care on cardiovascular risk. ¹³¹This study was dissimilar, however, in that most of the selected patients were men and had at least two cardiovascular risk factors.

The initial health check was successful in identifying 28 patients with either SBP of 160+ or DBP of 90+ mm Hg, who were not in the category of hypertension or ischaemic heart disease. As the practice policy is to follow patients at these BP cut-off points (see Appendix 11), these 28 patients were followed up carefully to see whether medication would be necessary. The proportion placed on medication will be discussed in the Section on medication change (see Section 6.4.16).

In the OXCHECK Study 9.8% of patients had either a SBP of 160+ or a DBP of 90+ mm Hg, compared to 7.5% of patients at Surgery 3, 11 of whom were in the original 'no risk' category.

Reflecting the expected trend in blood pressure with age, Figure 5.8 confirms that the BP readings of the Surgery 3 patient cohort gradually increased from age 25 to 65 years in both sexes. Further, the differential between males and females matched with the results from the Scottish Heart Health Study, where hypertension was considered to be prevalent in 25% of men compared to 20% of women. 132

Figure 5.8 Diastolic Blood Pressure Trend According to Sex and Age of Patient



Age Of Patient In Years

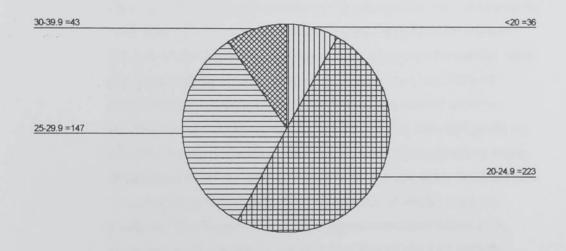
Patients in the 15-24 age group showed a higher average DBP for females than for males, but this group was a specially selected one of patients with a FHCHD <60, so were not typical of a practice population.

These findings do not reflect the general picture, where women have higher blood pressure levels, although they have higher endogenous oestrogen levels than men.³⁴

5.4.3.6 Body mass index

Health of the Nation figures indicate that approximately 40% of the average practice population have a BMI >25. At Surgery 3 the figure was 42% (189/449 patients-see Figure 5.9), with a practice mean of 24.78. Mean BMI in men was significantly greater than in women, being 25.26 for all males and 24.42 for all females. These figures agreed with the findings in the Family Heart Study, ¹⁰⁸ although the OXCHECK Study showed no differential. ¹²⁸

Figure 5.9 Pie Distribution of B M I -All Patients



There was a positive correlation with increasing age, patients in the 25-34 year age group having a mean BMI of 23.07 and the 45-54 year age group a mean BMI of 24.97. This reflected a similar pattern in the Family Heart Study. ¹⁰⁸

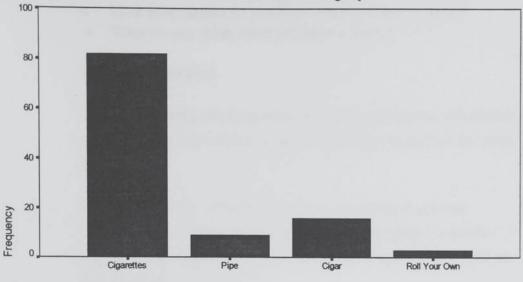
5.4.3.7 Smoking status

Anyone who stops smoking gains major and immediate health benefits. ¹³³ Data from prospective studies, such as the BRHS, indicates that smoking cessation is known to:

- decrease the ease of blood clotting within 2 weeks
- bring blood lipids back to normal within 1 month
- begin to reduce mortality and the complications associated with coronary artery disease within 1 year
- restore the risk of ischaemic stroke to normal within 5 years
- promote the resolution of peripheral vascular lesions.²⁷

In a CHD prevention programme there was, therefore, a strong armoury of evidence to convince the smokers to stop their habit. Overall, there were 110 smokers in the study (24.5%), of whom 56 were men (28.7% of the male population) and 54 were women (21.3% of the female population). This compares favourably with the 'health of the nation' figures of 31% of men and 28% of women being smokers. 19.8% of the patient cohort were exsmokers, many of whom were married couples who had given up together on the same day. The results were not as good as those determined from the questionnaire data, but the latter included 65-75 year old patients, an inordinate number of whom were exsmokers. Furthermore, interview figures are more likely to be accurate, as illustrated by the fact that five of the 199 patients responding as 'no risk' admitted to smoking. A further 43 patients, who were smokers, but not placed in the 'smoking category', had some other cardiovascular risk factor. The overwhelming majority of smokers were cigarette smokers, as shown by the distribution of smoking types in Figure 5.10.

Figure 5.10 Distribution of Smoker Category

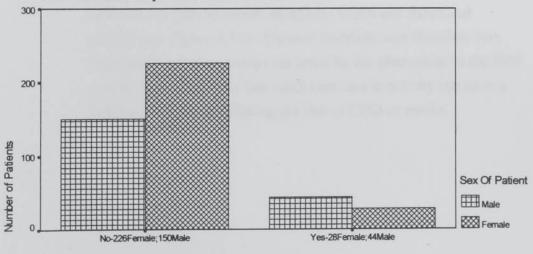


Category Of Smoker

5.4.3.8 Drinking pattern

Health of the Nation figures for England were almost replicated by the Surgery 3 Study: 28% of men and 11% of women drink more than the sensible limits in England, compared to 22.5% of men and 11% of women at Surgery 3.²⁴ The more appropriate drinking pattern of women is illustrated in Figure 5.11.

Figure 5.11 Representation of Patients who Drink over the Weekly Limit-Both Sexes



Patients Drinking Status

Assessment of alcohol consumption was made by asking:

- · On average, how many days a week do you have a drink?
- How many drinks do you have when you have a drink?
- What do you drink when you have a drink?

Practice intervention

For those patients drinking within recommended limits, affirmation of those limits, plus advice to spread drinking throughout the week was given.

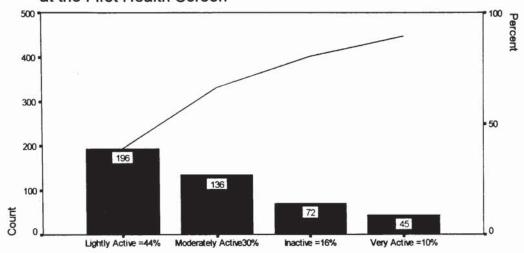
Firm, but friendly, advice to cut down was given to patients drinking above recommended limits, especially when the alcohol intake could be linked to some other presenting condition, such as hypertension.

5.4.3.9 Physical activity level

Significantly, the percentage of both men and women in all age groups who fell below an acceptable activity level threshold is greater than the percentage who smoke or who have a STC of 6.5 mmol/L-1+. The pharmacist was able to use the study at Surgery 3 to encourage physical activity in patients on a more systematic basis than the doctors were able to during conventional surgery visits.

Patient interviews confirmed that only 40% of patients took sufficient exercise to confer significant health and functional benefits (see Figure 5.12). Physical inactivity was therefore very widespread and the message imparted by the pharmacist to the 60% 'at risk' population was that small increases in activity can have a significant impact in reducing the risk of CHD or stroke.

Figure 5.12 Fitness Levels of Patients at the First Health Screen



Exercise Assessment -1st Time

5.4.3.10 Summary of results

The distribution of coronary heart disease risk by predetermined bands in men and women is shown in Tables 5.6 and 5.7. The prevalence of cardiovascular risk factors is reported for patients allocated to a 'no risk' category as well as to the 'risk' categories. Interrelations between risk factor categories and risk-evaluating parameters will be discussed in the Chapter 6.

Table 5.6 Distribution of CHD Risk Measurements by Predetermined Bands for Females

Total		22.	29 131 71 23	113 78 40 15	174	25 88 88 38 20	120 49 37 16
	Ischaemic Heart Disease	9 1	2 5	2 2	ታ ለ	חח קיח	2 2
	1 + 1	1.5	4.0	1155	мм	1 4 1	123
Of Patient	Diabetes	2	- г	N	8	11	н
Category	Smoking	25	20044	19 33	24	133 10 3	17 8 1
Risk Factor	Hypertensio n	31	3 11 12 7	100	23	2 7 113 111	m w 4+ vo
	СНD <60	46	28 13 5	23 177 2	38 15	3 18 21 10	27 12 8
	No Risk	111	14 66 35 6	62 37 15 6	392	16 477 49 9	68 24 18 6
		Patients who drink over the accepted limit. No	B M I Categories 20-24.9 25-29.9 30-39.9	Cholesterol Ranges <5.0mmol/l 5.0-5.99mmol/l 6.0-6.99mmol/l 7.0-7.99mmol/l 8.0+mmol/l	Family History of Diabetes No Yes	Diastolic Blood Pressure-Ranges <70mm Hg 70-79mm Hg 80-89mm Hg 90-99mm Hg	Systolic Blood Pressure-Ranges <130mm Hg 130-139mm Hg 140-149mm Hg

Table 5.7 Distribution of CHD Risk Measurements by Predetermined Bands for Males

Total		151	7 92 76 20	70 67 41 14	153	3.9 7.2 5.8 2.0	70 41 40 22
	Ischaemic Heart Disease	7	1 4 2 8	9 7 7	8 2	H 0 8 0 0	7 1 2 1 7
	igh	3	1 1 2	1 1 2	13	. 27	. пппп
Of Patient	pet	24	2 1	7 7	2 1	11 1	1 1
Risk Factor Category O	Smoking	20	111 111 3	4 2 8 8 4 8 8 8	27	1 13 11 2	мабле
	Hypertensio n	19	12 6	11 8 3	20	& Ø Ø	2441-6
	F H CHD <60	38	22 14 5	16 16 12 1	3.0	1 11 12 16 4	17 5 13 6 6
	No Risk	62 16	40 34 2	35 22 16 4	20	21 333 199 2	41 21 10 2 4
		Patients who drink over the accepted limit.	B M I Categories <20 20-24.9 25-29.9 30-39.9	Cholesterol Ranges <5.0mmol/1 5.0-5.99mmol/1 6.0-6.99mmol/1 7.0-7.99mmol/1 8.0+mmol/1	Family History of Diabetes	Diastolic Blood Pressure-Ranges <70mm Hg 70-79mm Hg 80-89mm Hg 90-99mm Hg	Systolic Blood Pressure-Ranges <130mm Hg 130-139mm Hg 140-149mm Hg 150-159mm Hg

5.5 CONCLUSIONS

- 1. Over 70% of patients responded to a single, mailed questionnaire on health and lifestyle first time. It was not feasible at the time to include a follow-up mailing. The response confirms the pharmacist's impression that the medical practice remains the focal point for health care in the community. A similar questionnaire survey carried out with patients directly from the Brent and Harrow Family Health Services Authority (FHSA) produced a very low response of 16.5% and the follow-up despatch increased this by only 9%.
- 2. The results show that 56% of patients at the practice have one or more major cardiovascular risk factors, and therefore any health screen programme, with limited resources in time, manpower and money, would find it more profitable to concentrate on this section of the population. Doctors at the practice commented that information from the IHD template was invaluable and time-saving when consulting patients.
- 3. Examination of the results in Tables 5.6 and 5.7 illustrates the value of the actual interview and physical assessment of the patient, as approximately 5% of patients who had thought themselves free of any risk factors had a STC of >7.0 mmol/L-1 and a further 3% had a DBP of >100 mm Hg. These figures, in conjunction with the number of individuals who are overweight and who do insufficient exercise, support those who advocate a total population health screen.

CHAPTER 6

INFLUENCE OF FAMILY HISTORY AND PHARMACIST MONITORING ON CARDIOVASCULAR STATUS

6.1 INTRODUCTION

The aims of this part of the investigation were:

- 1. To relate a patient's family history, age and sex to cardiovascular risk factors.
- 2. To examine how alterable risk factors affect each other, eg smoking and blood pressure.
- 3. To calculate a coronary rank score (CR) as an independent outcome variable for each patient.
- 4. To monitor patients for two years and evaluate their progress throughout that time.
- 5. To assess if the patients' CRs have improved as a result of pharmacist intervention.
- 6. To study the medication spectrum of patients.

6.1.1 Summary of Results of Two-year Patient Monitoring

- 1. Patients with a FH of CVD have a lower Coronary Rank Score than the rest of the practice population.
- 2. No relationship was found between FHHT and FHCVA and a patient's actual BP; nor was there any association between FH diabetes and RBG of the patient.
- 3. BP, STC, and RBG all increase with the age of the patient.
- 4. Females were found to have a lower BP than males, but there was no significant difference in values of STC or RBG.
- 5. BP and STC measurements reduced with the passage of time and pharmacist monitoring.
- 6. CR improved in the high and intermediate risk groups, and maintained it's level in the lower risk group.
- 7. SBP increased with increase of BMI, and there was a significant association between hypertension and an increase in STC.
- 8. SBP did not show any significant change with alcohol, exercise, or smoking status.

- 9. Pharmacist intervention made no impact on the average patient's BMI.
- 10. Smoking status improved, leading to less smokers and fewer cigarettes smoked.
- 11. Physical activity levels increased.
- 12. No change was effected in the practice alcohol intake.
- 13. Diet was found to be related to STC and dietary fat reduction to an improvement in STC.
- 14. HDL -Cholesterol was shown to be greater in women, lower in smokers, but unaffected by age or exercise.
- 15. TG levels were greater in men than women. TG was higher in patients with a BMI>25, and in those who habitually drink above the limits. TG increase was significantly related to HDL decrease.

6.2 METHOD

Patients were divided into three groups according to their CR. Requests to them for a 2nd, 3rd or 4th follow-up consultation were made by telephone from the surgery. Patients belonging to Groups 1 and 2 were asked to fast for 12-14 hours before arrival for their second appointment, so that a total lipid profile could be obtained, giving a truer 'equilibrium state' reading for HDL-cholesterol and triglyceride (TG) than if the patient had just partaken of a meal.

Apart from the total lipid profile, follow-up interviews were used for repeat measurements of BP and BMI, reviews of progress, reinforcement of the health message and an opportunity for further patient-counsellor interaction.

Invitations for the final health screen were sent by letter to patients in all three groups (Appendix 13). This letter was accompanied by a print-out of the individual patient's data from the most recent consultation (Appendix 14).

6.3 OBJECTIVES

6.3.1 Family history

Objective 1

To determine whether patients in the category FHCHD <60 have a lower CR or a higher CS than patients with no risk factors.

Objective 2

To determine whether there is a tendency for patients with an FH of cardiovascular disease (CHD, HT, CVA and high cholesterol) to be in Group 1 of the patient cohort.

Objective 2(a)

To determine whether patients with a close FHCHD <60, as determined during the first health screen interview, are more likely to be among Group 1 patients than either of the other two groups.

Objective 3

To determine whether patients with an FH of HT or CVA have a higher SBP or DBP than those with no such family history.

Objective 4

To determine whether patients with an FH of high cholesterol have a higher mean STC value than the rest of the practice population.

Objective 5

To determine whether patients with an FH of diabetes have a higher blood sugar level than those without a family history.

6.3.2 Risk factors

Objective 6

To determine whether patients in a 'no risk' category have a lower SBP or DBP than those with risk factors, other than hypertensive patients.

Objective 7

To determine whether patients in a 'no risk' category have a better STC than those with risk factors.

6.3.3 Age

Objective 8

To determine whether SBP, DBP, STC, or RBG increases with the increasing age of a patient.

6.3.4 Sex of the patient

Objective 9

To determine whether the sex of a patient has any influence on the value of SBP, STC, RBG, or BMI.

6.3.5 Blood pressure

Objective 10

To determine whether patients in Group 1 show a reduction in SBP or DBP with time.

Objective 10(a)

To determine whether patients with an initial DBP of 100 mm Hg+ show a consistent improvement with time.

Objective 11

To determine whether patients in Group 2 show a reduction in SBP or DBP with time.

Objective 12

To determine whether SBP increases with increase in BMI.

Objective 12(a)

To determine whether SBP is higher in individuals who drink more than the recommended limit than in those below.

Objective 12(b)

To determine whether SBP is higher in inactive than very active patients.

Objective 12(c)

To determine whether SBP is higher in individuals who smoke than in those who have never smoked.

Objective 12(d)

To determine whether SBP increases with increase in STC.

6.3.6 Serum total cholesterol

Objective 13

To determine whether patients in Group 1 and 2 show a reduction of STC with time.

6.3.7 Dundee Coronary Rank Score

Objective 14

To determine whether patients in Group 1 and 2 show a consistent improvement of CR from the first consultation through to the final interview.

Objective 14

To determine whether patients in Group 3 show any change in CR, SBP, DBP, or STC from the first to the final consultation, two years later.

6.3.8 Body mass index

Objective 15

To determine whether the BMI of the sample population reduces with counselling.

Objective 15(a)

To determine whether the BMI of patients is greater in those with risk factors than those without.

6.3.9 Smoking

Objective 16

To determine whether the smoking status of smokers in Group 1 improves as a result of pharmacist intervention.

Objective 16(a)

To determine whether the smoking status of all smokers improves as a result of pharmacist intervention.

6.3.10 Exercise

Objective 17

To determine whether the exercise level of the practice population improves with pharmacist intervention.

6.3.11 Alcohol

Objective 18

To determine whether the average alcohol intake of the practice population reduces as a result of pharmacist intervention.

6.3.12 Diet

Objective 19

To determine whether the dietary fat intake of the practice population reduces over time with counselling.

Objective 19(a)

To determine the relationship between the mean STC level of patients and their dietary assessment.

Objective 19(b)

To determine whether dietary fat reduction leads to a reduction in STC.

6.3.13 HDL-cholesterol

Low density lipoproteins (LDL's) from the liver distribute cholesterol around the body, especially to the walls of the coronary arteries, making them narrower and eventually causing blockages. High density lipoprotein removes this cholesterol and carries it back to the liver to be recycled or disposed of. The level of HDL is important as a factor in reducing the likelihood of a heart attack

Evidence suggests that there is a positive correlation between the risk of developing IHD and cholesterol levels, but a negative one with those of HDL cholesterol. Smoking, a low HDL and a raised LDL concentration were all associated with CHD in middle aged men. HDL-cholesterol has been considered a much more sensitive CHD risk determinant than STC.

Recommendations are that HDL-cholesterol should remain above 1.0 mmol/L and the ratio of STC to HDL should be below 5.2. ¹³⁵ Thus, measurement of HDL-cholesterol is the best single lipid predictor and its use avoids needlessly alarming or falsely reassuring persons at risk of CHD who have high STC values. ¹³⁶ Therefore, the STC/HDL ratio is a sensitive way to assess the risk of CHD and gives a good indication of the individual's lipid balance.

Objective 20

To determine whether HDL-cholesterol reduces with increasing age.

Objective 20(a)

To determine whether HDL levels are greater in women than men.

Objective 20(b)

To determine whether HDL varies with the risk factor category.

Objective 20(c)

To determine whether HDL is lower in smokers than non smokers.

Objective 20(d)

To determine whether HDL is greater in 'very active' than 'inactive' patients.

6.3.14 TSC/HDL Ratio

Objective 21

To determine whether the TSC/HDL ratio reflects the results found for HDL and independent risk factors.

6.3.15 Triglycerides

The role of plasma triglycerides as an independent risk factor for CHD remains controversial. Levels of triglyceride of 3-6 mmol/L-1 are often seen in obese patients and those who abuse alcohol.⁴⁵

Cholesterol from the diet enters the body with triglycerides of chylomicrons which are hydrolysed, the residual chylomicron remnants being removed rapidly by the liver. The liver likewise secretes triglyceride-rich lipoproteins called very low-density lipoprotein (VLDLs) which are degraded into smaller VLDL remnants. The latter can be removed by the liver or converted to LDL, which is the major cholesterol-carrying lipoprotein in plasma. In this way,

triglyceride-rich lipoproteins are atherogenic, and association with LDL is calculated from the equation:

Objective 22

To determine whether TG levels are greater in men than women.

Objective 22(a)

To determine whether TG levels are greater in individuals with a BMI >25 than in those with a BMI <25.

Objective 22(b)

To determine whether TG levels are greater in people who drink over the recommended limit than in those who stay below.

Objective 22(c)

To determine whether there is any correlation between HDL and TG levels.

6.4 RESULTS

As a result of the initial health screening, 71 patients were placed in the high risk Group 1, 153 in the intermediate risk Group 2 and 225 in the low risk Group 3, making 449 in total. The objectives in 6.3 were tested using the following hypotheses. A review of the statistical tests used appears in Appendix 15.

6.4.1 Family history

<u>Hypothesis 1</u>: Patients in the category FHCHD <60 have a lower CR than patients with no risk factors.

A significant difference (F = 30.20, $_{6,441}$, p < 0.0001) in CR was found between categories of patients seen at the first health screen. A Student Newman-Keuls post hoc test revealed a significant difference in value for patients in the category FHCHD < 60 (mean 72.49, SD = 24.11) than for those in the 'no risk' category (86.08, SD = 14.10).

This suggests that patients with a FHCHD <60 have a greater likelihood to develop CHD themselves than those without such a history.

Hypothesis 1(a): Patients in the category FHCHD <60 have a higher CS than those in the 'no risk' category.

A significant difference (F = 25.48, $_{6.441}$,p <0.0001) in CS was found between categories of patients at the first health screen. A post hoc test revealed a significant difference in value for patients in the category FHCHD <60 (mean = 4.49, SD = 2.84) than for those in the 'no risk' category (3.03, SD = 1.21). This shows that the relative risk of patients with a FHCHD <60 of developing CHD is greater than that of patients with no FHCHD <60. This premise holds as long as patients are free from the categorisation of hypertensive, diabetic and smoker.

Hypothesis 2: Patients with an FH of cardiovascular disease are more likely to be among Group 1 patients than either of the other two groups.

A significant association ($X^2 = 11.98$, df = 2, p <0.005) was found between coronary risk and a family history of coronary problems (Table 6.1). This was most evident in the intermediate risk group only, where there were a greater relative proportion of subjects with an FH of cardiovascular disease (42%) compared to those with no family history (28%).

Table 6.1 Patient Categorisation and FH of Cardiovascular Disease

		Risk Group		
Family History	High 1	Intermediate 2	Low 3	Row Total
None	40	75	150	265
	15%	28%	75%	59%
FH Cardiovascular	31	78	75	184
Disease	17%	42%	41%	41%
Column Total	71	153	225	449
	15.8%	34.1%	50.1%	100%

Hypothesis 2(a): Patients with a close FHCHD <60, as determined during the first health screen interview, are more likely to be among Group 1 patients than either of the other two groups.

A significant association ($X^2 = 24.99$, df = 8, p <0.0005) was found between coronary risk and a FHCHD <60 in close relatives (Table 6.2). In both the high risk and intermediate risk groups subjects with a FHCHD <60 were predominant (20% compared to 14% in Group 1 and 43% compared to 30% in Group 2), whereas in the low risk group, subjects without a FHCHD <60 prevailed (56% compared to 37%). The tendency, therefore, was for patients with an FH of cardiovascular disease to be in a higher risk category.

Table 6.2 Patient Categorisation and FH CHD<60 in Close Relatives

	R	lisk Group		
FH CHD<60	High	Intermediate	Low	Row
Close Relative	1	2	3	Total
None	45	96	175	316
	14%	30%	56%	70.4%
All Family	26	57	50	133
Members	20%	43%	37%	29.6%
Father	10	34	32	76
Mother	6	14	12	32
Brother	8	9	5	22
Sister	2	0	1	3
Column	71	153	225	449
Total	15.8%	34.1%	50.1%	100%

Hypothesis 3: Patients with an FH of HT or CVA have a higher SBP than patients with no such family history.

The t-test for independent samples showed no significant difference (t = 1.46, df = 447, p > 0.05) was found between groups for SBP. The mean value of those with an FH of HT or CVA was 136.04 mm Hg compared to 133.36 for patients with no such family history.

Hypothesis 3(a): Patients with an FH of HT or CVA have a higher DBP than patients with no such family history.

No significant difference (t = 0.85, df = 447, p > 0.05) was found between groups for DBP. Patients with FH HT or CVA had a mean value of 84.23 compared to 83.36 for patients with no such family history.

One can conclude, therefore, that a person, in this sample population, whose parent, brother or sister has high blood pressure or has had a stroke, is no more likely to have high blood pressure than any other individual in the practice population.

Hypothesis 4: Patients with an FH of high cholesterol have a higher mean STC value than the rest of the practice.

There was a significant difference ($F = 4.89,_{3,437},p < 0.005$) for STC, the post hoc test revealing a significant difference between patients with a sister or brother with high cholesterol (mean value 6.95 mmol/L- 1) and all other patients (mean value 5.34).

As there were only six patients with a sister or brother having a high cholesterol, these results may be only coincidental. Despite the relatively small group sizes, a significant difference was found, though a larger cohort would be necessary to establish this relationship. Table 6.3 reflects the distribution of patients with an FH high cholesterol in the three patient groups, and it can be seen that five of the six patients with filial high cholesterol were placed in the high or intermediate risk group.

Table 6.3 Family History of High Cholesterol and Specific Member of Family

Family	Patient Group after Initial Health Screen			
Member	High Risk	Intermediate R	lisk Low Ri	sk Row Total
None	65	136	211	412 (91.8%)
Father	1	4	4	9 (2.0%)
Mother	1	9	5	15 (3.3%)
Brother/Sister	3	2	1	6 (1.3%)
Grandparent	1	2	4	7 (1.5%)
Column Total	71	153	225	449
and about the parties of the first design of the second of	15.8	% 34.1%	50.1%	100%

Patients who had stated they had familial hyperlipidaemia did not score significantly differently from other patients in CS or CR as evidenced by the post hoc test (Hypothesis 1). There were only 10 patients in this group, and the pharmacist could not unequivocally state that all these patients had a true history of familial hyperlipidaemia.

Hypothesis 5: Patients with an FH of diabetes have a higher blood sugar level than those without a family history.

No significant difference (F = 0.64, $_{5,442}$, p > 0.05) was found between groups for blood glucose of patients with and without a FH of diabetes.

There were only five patients in the diabetic group, and no relationship was found between their diabetes and a family history of the disease.

6.4.2 Risk factors

<u>Hypothesis 6</u>: Patients in a 'no risk' category have a lower SBP than those with risk factors, excluding hypertensives. A significant difference (F = 7.64, 5,384, p <0.0001) was found between categories for SBP on the first health screen. The post hoc test revealed a significant difference in value for patients in the categories FHCHD <60 (mean value 133.31 mm Hg), personal IHD (143.82), and diabetes (165.00) compared to 'no risk' patients (128.27).

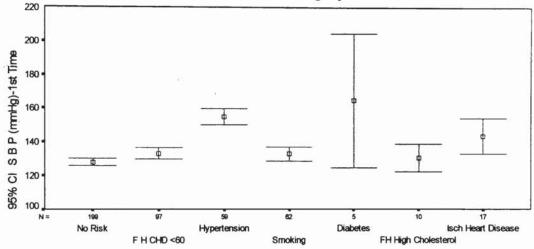
Hypothesis 6(a): Patients in a 'no risk' category have a lower DBP than those with risk factors, excluding hypertensives. A significant difference (F = 2.25, 5,384, p <0.005) was found between categories for DBP. The post hoc test revealed a significant difference between patients with FHCHD <60 (83.39) and patients with IHD (87.06) compared to 'no risk' patients (80.70).

The statistical significance was stronger for SBP than DBP in this sample, 9% of the total variation in SBP, compared to 3% in DBP, was accounted for by the risk factor category. Clinicians tend to use DBP as a predictor, and success of treatment is gauged by achievement of DBP targets. However, SBP has been shown to be a better predictor of cardiovascular mortality than DBP. 137 Figure 6.1 shows the comparison across the risk categories for SBP, and confirms that blood pressure, as well as total cholesterol concentration, tend to

be higher in individuals with cardiovascular risk factors than the rest of the population. Therefore, in any screening programme, resources would be more effectively utilised giving priority to 'at risk' individuals.

Figure 6.1 is an Error bar chart, which shows the estimated dispersion of the population from which the data has been drawn. This error bar chart shows summaries for groups of cases, and the error bars show confidence intervals for the mean. Figure 6.1 shows the 95% confidence intervals for SBP by cardiovascular risk category. A 95 % confidence interval reaches approximately two standard deviations on either side of the mean.

Figure 6.1. Systolic Blood Pressure of Patients
Related to Cardiovascular Risk Category



Risk Factor Category Of Patient

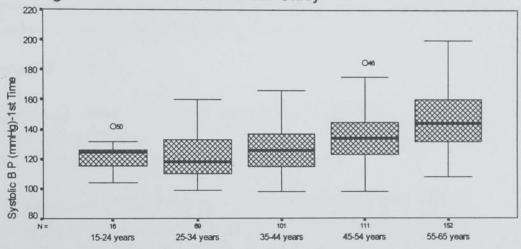
<u>Hypothesis 7</u>: Patients in a 'no risk' category have a lower mean value of STC than those with cardiovascular risk factors.

A significant difference (F = 5.12, $_{6,441}$, p < 0.0001) was found between categories for STC. A post hoc test revealed significant differences between: [1] hypertensive category patients and those in the 'no risk' category (mean value STC of 5.77 compared to 5.13 mmol/L- 1), and [2] patients with existing heart disease and those in the 'no risk' category (6.21 compared to 5.13 mmol/L- 1).

6.4.3 Age

Hypothesis 8: SBP increases with increasing age of the patient. A significant difference (F = 19.27, $_{4,392}$, $_{9} < 0.0001$) was found between groups for SBP (see Figure 6.2). A post hoc test revealed significant differences between the age group 55-64 years and all other age groups (mean range 140.23 through to 122.65 mm Hg), and between age group 45-54 and age groups 25-34 and 35-44 (mean value 132.97 compared to 123.68 and 125.73 respectively).

Figure 6.2 Systolic Blood Pressure Related to Age of Patient at the Start of the Study



Age Of Patient In Years

Hypothesis 8(a): DBP increases with increasing age of the patient. No significant difference (F = 1.25, $_{4,392}$, p >0.05) was found between groups for DBP.

Hypothesis 8(b): STC increases with increasing age of the patient. A significant difference (F = 20.09, $_{4,391}$, p < 0.0001) was found between groups for STC (see Figure 5.6). A post hoc test revealed significant differences between the 55-64 year age group (mean value 5.63 mmol/L- 1) and age groups 15-44 years (values 4.52 to 4.98), also between the 45-54 year age group (5.38 mean value) and age groups 15-44 years.

Hypothesis 8(c): RBG increases with increasing age.

A significant difference (F = 3.60, $_{4,443}$, p <0.05) was found between groups for blood glucose, the post hoc test revealing a significant difference between the 55-64 year and the 45-54 year age groups (6.82 to 6.23 mmol/L- 1).

The increase in SBP with age is as would be expected, when doctors often use the formula of 100 + age of patient to indicate the expected value of their SBP.

The increase in DBP was not so clearly defined and corroborates with the finding that DBP changes less distinctly with time than SBP.

STC increases with age, confirming the established expectation. RBG shows a significant increase as old age approaches, confirming the increasing prevalence of diabetics in the population after 55 years of age.

6.4.4 The sex of a patient

<u>Hypothesis 9</u>: The sex of a patient has no detectable influence on SBP. A significant difference (F = 5.37, p < 0.05) was found between sexes for SBP (males' mean value 137.13 mm Hg and females 132.71).

Hypothesis 9(a): The sex of a patient has no detectable influence on STC. No significant difference (F = 0.43, p > 0.05) was found between sexes for STC (males' mean value 5.42 mmol/L-¹ and females 5.32).

<u>Hypothesis 9(b)</u>: The sex of a patient has no detectable influence on RBG. No significant difference (F = 2.85, p > 0.05) was found between sexes for RBG (mean value for males 6.16 mmol/L-1 and females 6.48).

Hypothesis 9(c): The sex of a patient has no detectable influence on BMI. A significant difference(F=5.69, p<0.05)was found between the sexes for BMI (mean value for males 25.26 and females 24.42). A significant difference (F=4.54, p>0.005) was also found between age groups, BMI increasing consistently with age, independent of a patient's sex.

Examination of the analysis of variance of SBP with sex and age reveals that 25% of the total variation in SBP is accounted for by the variation in age, and a patient's sex accounts for less than 1%. Age has a much greater influence on SBP than whether a patient is male or female.

6.4.5 Blood pressure

Summary of results of SBP with time

Group 1 Pa	tients Time Per	riod Difference in SBP	Significance
	Zero to Six mon	ths 9.50	p<0.0001
	Zero to One year	r 7.19	p<0.0001
n = 68	First to Second	year 3.68	p<0.005
	Zero to Second	year 10.09	p<0.0001
Group 2 Pa	tients		
•	Zero to One year	r 1.70	p<0.05
n = 138	First to Second	year 2.13	p<0.05
	Zero to Second	year 3.11	p<0.005
Group 3 Pa	tients		
n = 192	Zero to Second	year 0.39	p>0.05

Hypothesis 10: Patients in Group 1 show a reduction in SBP with time.

A significant reduction was found (t = 4.53, df = 41, p < 0.0001) between SBP at the first test (160.43 mm Hg, SD = 19.15) and at the second test, after six months (150.93, SD = 18.18).

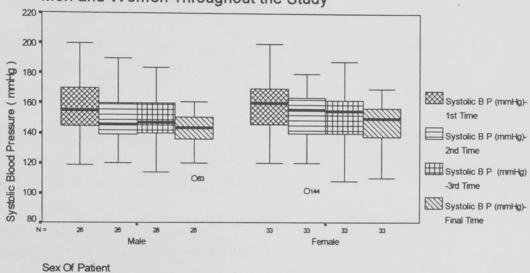
A significant reduction (t = 4.76, df = 67, p < 0.0001) was found between SBP at the first test (153.12, SD = 20.48) and the third test (145.93, SD = 18.51).

A significant reduction (t = 3.10, df = 64, p <0.005) was found between SBP at the third test (145.68, SD = 18.89) and the final test (142.00, SD = 17.10).

Finally, a significant reduction (t = 5.31, df = 66, p <0.0001) was found between SBP at the first test (151.60, SD = 21.22) and the final test (141.51, SD = 17.10).

This slight improvement in SBP throughout the study, for both males and females, is illustrated in Figure 6.3.

Figure 6.3 Systolic Blood Pressure Ranges for Men and Women Throughout the Study



Summary of results of DBP with time

Patients	Time Period	Difference in DBP	Significance
Group 1	Zero to Six months	4.62	p<0.005
n = 68	Zero to One year	2.19	p<0.05
	First to Second year	3.59	p<0.001
	Zero to Second year	5.17	p<0.0005
Group 2			
	Zero to One year	0.90	p>0.05
n = 138	First to Second year	1.28	p>0.05
	Zero to Second year	1.65	p<0.05
Group 3			
n = 192	Zero to Second year	0.36	p>0.05
Patients wi	th Initial DBP 100+		
n = 40	Zero to Second year	9.94	p<0.0001

Hypothesis 10(a): Patients in Group 1 show a reduction in DBP with time. A significant reduction (t = 2.45, df = 67, p < 0.05) was found for DBP between patients from the first test (92.31 mm Hg, SD = 11.95) to the third test (90.12, SD = 10.76)

A significant reduction (t = 3.49, df = 41, p < 0.005) was found for DBP between patients from the first test (96.55, SD = 11.45) to the second test (91.93, SD = 10.99), after six months.

A significant reduction (t = 4.02, df = 64, p <0.001) was found for DBP between patients from the third test (89.77, SD = 10.80) to the final test (86.18, SD = 10.48).

Finally, a significant reduction (t = 4.34, df = 66, p < 0.0005) was found for DBP between patients from the first test (91.16, SD = 12.34) to the final test (85.99, SD = 10.38), reflecting the results for SBP.

Hypothesis 10(b): Patients with an initial DBP of 100 mm Hg+ show a clinically significant improvement with time.

A significant difference (t = 7.25, df = 33, p < 0.0001) was found for DBP between the first (103.59, SD = 5.29) and the final test (93.65, SD = 6.55).

Figures 6.4 and 6.4a illustrate this improvement for males and females in the study.

Figure 6.4 Diastolic Blood Pressure Distribution of Patients - Initial DBP of 100+mmHg at the start of the Study

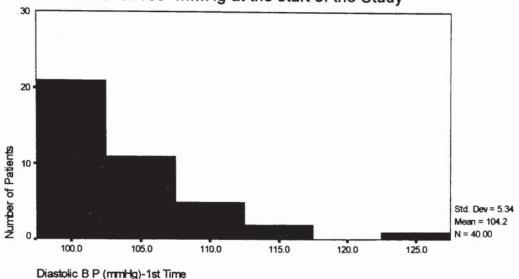
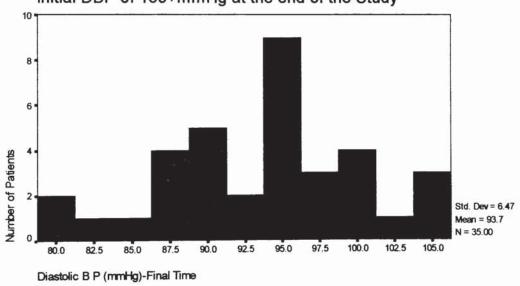


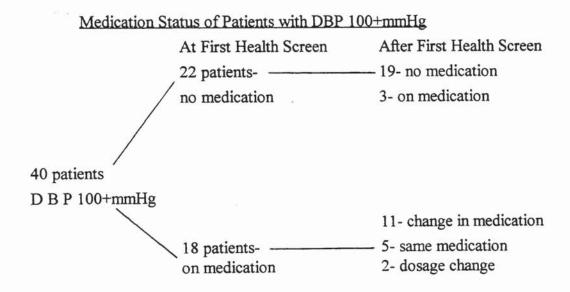
Figure 6.4a Diastolic Blood Pressure Distribution of Patients - Initial DBP of 100+mmHg at the end of the Study



The intervention by the pharmacist who gave advice on diet, lifestyle, medication adherence, and in some cases the medication spectrum and dosage, has had a significant positive effect on the blood pressure values of the patient cohort. This was apparent at each stage throughout the study, but the greatest effect was evident at the end of the two years, which indicates incremental improvements consistently over that timescale.

Following the results discussed in Hypothesis 8 and 8(a), improvement in SBP was marginally more significant than that in DBP.

The most significant improvement was obtained in those patients with initially the highest DBP. There were 40 of these patients, with a DBP of 100 mm Hg+, 22 of whom were not on medication for hypertension. Of the 18 on antihypertensive medication, 11 had a change in medication spectrum and two a dosage change, at the initiation of the pharmacist. Three of the group of 22 were placed on antihypertensive medication for the first time on the recommendation of the pharmacist, the rest showing some improvement with lifestyle changes (see diagram below).



<u>Hypothesis 11</u>: Patients in Group 2 show a reduction of SBP with time. A significant reduction (t = 1.69, df = 129, p < 0.05) was found for SBP between the first test (mean = 140.12, SD = 17.25) and the second test (138.42, SD = 15.59), one year later.

A significant reduction (t = 2.22, df = 120, p < 0.05) was found for SBP between the second test (138.45, SD = 15.61) and the final test (136.32, SD = 15.28), after two years.

A significant reduction (t = 3.06, df = 137, p < 0.005) was found for SBP between the first test (mean = 139.04, SD = 17.27) and the final test (135.93, SD = 15.59).

Hypothesis 11(a): Patients in Group 2 show a reduction of DBP with time. No significant difference (t = 1.04, df = 129, p > 0.05) was found for DBP between the first test (87.43, SD = 9.98) and the second test, after one year (86.53, SD = 11.34).

No significant difference (t = 1.51, df = 120, p > 0.05) was found for DBP between the second test (86.50, SD = 11.48) and the final test (85.22, SD = 8.60).

A significant difference (t = 2.58, df = 137, p < 0.05) was found for DBP between the first (86.46, SD = 10.04) and the final test (mean = 84.81, SD = 8.73).

As with Group 1 patients, there was an overall reduction in SBP and DBP for patients in Group 2, but not of the same magnitude, SBP reductions again being more significant than those for DBP.

Hypothesis 12: SBP increases with increase of BMI in the sample population. A significant difference (F = 13.40, 3,393, p <0.0001) was found between categories of BMI for SBP. A Student Newman-Keuls post hoc test revealed a significant difference between obese patients, BMI >30 (mean value = 143.31 mm Hg) and all other weight categories (mean range = 127.71 to 136.20). Further, a significant difference was revealed between the overweight category, BMI 25-30 (mean 136.20) and the two categories of normal and low weight (mean = 128.78 and 127.71 respectively).

Hypothesis 12(a): SBP is higher in individuals who drink more than the recommended limit than in those below.

No significant difference (t = 0.18, df = 395, p>0.05) was found for SBP between categories of alcohol intake. The mean value SBP for those drinking over the limit was 132.93, SD = 16.45, and for those drinking below, 132.53, SD = 16.30.

Hypothesis 12(b): SBP is higher in inactive than very active patients. No significant difference (F = 2.56, $_{3,392}$, $_{p} > 0.05$) was found between levels of exercise for SBP.

Hypothesis 12(c): SBP is higher in individuals who smoke than in those who have never smoked.

No significant difference (F = 0.95, $_{2,394}$, p > 0.05) was found between smokers, ex-smokers and non-smokers for SBP.

Hypothesis 12(d): SBP increases with increase in STC. A significant difference (F = 19.14, $_{4,443}$, $_{9} < 0.001$) was found between levels of STC for SBP. The Student Newman-Keuls post hoc test showed that as the value of STC increased from one level to the next, SBP increased correspondingly.

Although improvements in alcohol intake, exercise levels and smoking status may have had some influence on the reduction of SBP seen during the study period, there was no correlation between these three criteria individually and mean SBP values.

The association between hypertension and higher levels of STC confirms the interdependence of coronary risk factors evident from the Gothenburg hypertension trial: a substantial fall in CHD was confined to those participants in whom both BP and STC level decreased. 94

From the study point of view, these two variables appeared synergistic in their effect on risk, and the pharmacist's comprehensive management programme, in association with the patients' GPs was therefore likely to yield greater benefit than selective attention to one or other risk factor.

The positive correlation between hypertension and an overweight patient adds to the possibility of nutritional influences having a common adverse effect on blood pressure and plasma lipid levels.

6.4.6 Serum total cholesterol

Summary (of recu	ilts of chan	ge in STC	with time
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	Patients	Time Period	Difference in STC Significance
	Group 1	Zero to six months	0.63 p<0.0001
		Zero to one year	0.41 p<0.0001
n = 68		First to second year	r 0.25 p<0.05
		Zero to second year	or 0.64 p<0.0001
	Group 2	Zero to one year	0.22 p<0.0001
n = 138	3	First to second year	r 0.05 p>0.05
		Zero to second year	or 0.27 p<0.0001
n = 191	Group 3	Zero to second year	r +0.13 p<0.05

Figure 6.5 illustrates this improvement in STC in Group 1 patients.

Hypothesis 13: Patients in Group 1 show a reduction of STC with time. A significant reduction (t = 3.89, df = 67, p < 0.0001) for patients was found for STC between the first (mean = 6.72 mmol/L-¹, SD = 1.16) and third test, after one year (6.31, SD = 0.94). A significant reduction (t = 5.57, df = 45, p < 0.0001) was found for STC between the first (7.17, SD = 1.03) and the second test, after six months (6.54, SD = 0.86).

A significant reduction (t = 3.29, df = 64, p < 0.05) was found for STC between the third (6.31, SD = 0.94) and final test (6.06, SD = 0.74).

Finally, a significant reduction (t = 6.51, df = 66, p < 0.0001) was found for STC between the first (6.65, SD = 1.21) and the final test, after two years (6.01, SD = 0.08).

In concert with blood pressure, there was a significant improvement in cholesterol concentration for patients in the 'high risk' group throughout the study. All of these patients were seen on four or five occasions, during which

time the pharmacist was able to reinforce the original 'health message', resulting in the steady, consistent improvement in this alterable risk factor.

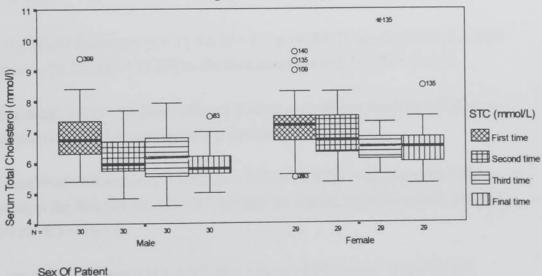
<u>Hypothesis 13(a)</u>: Patients in Group 2 show a reduction in STC with time. A significant reduction (t = 3.87, df = 128, p < 0.0001) was found for STC between the first (5.90 mmol/L-¹, SD = 0.73) and the second test (5.68, SD = 0.57).

No significant reduction (t = 1.39, df = 120, p > 0.05) was found for STC between the second (5.69, SD = 0.56) and the final test (5.64, SD = 0.61).

A significant reduction (t = 5.07, df = 137, p < 0.0001) was found for STC between the first (5.84, SD = 0.77) and the final test (5.57, SD = 0.64).

Significant improvement for STC took place in the first year only, when the greatest potential for cholesterol lowering would be expected, but monitoring by the pharmacist helped to ensure that any beneficial change was consolidated and sustained. Figure 6.5 amplifies this point, the initial sharp improvement being apparent in both sexes.

Figure 6.5 Serum Total Cholesterol Range in Men and Women Throughout the Study



6.4.7 Dundee Coronary Rank Score

Summary of Change in CR with Time

Patients	Time Period	Difference in CR	Significance
Group 1	Zero to one year	12.62	p<0.0001
n = 68	First year to second ye	ear 6.16	p<0.0001
	Zero to second year	18.09	p<0.0001
Group 2	Zero to one year	5.24	p<0.0001
n=138	First to second year	3.77	p<0.0001
	Zero to second year	9.10	p<0.0001
n=191 Group 3	Zero to second year	-0.69	p>0.05

<u>Hypothesis 14</u>: Patients in Group 1 show a consistent improvement of CR from the first consultation through to the final interview.

A significant difference (t = 7.29, df = 67, p < 0.0001) was found for CR from the first (mean value 34.44, SD = 17.22) to the third interview, after one year (47.06, SD = 21.33).

A significant difference (t = 4.67, df = 64, p < 0.0001) was found for CR from the third (46.58, SD = 21.69) to the final interview, after two years (52.74, SD = 21.54).

A significant difference (t = 11.02, df = 67, p < 0.0001) was found for CR from the first (34.19, SD = 17.29) to the final interview (52.28, SD = 21.29).

Hypothesis 14(a): Patients in Group 2 show a consistent increase of CR from the first consultation through to the final interview.

A significant difference (t = 4.46, df = 130, p < 0.0001) was found for CR between the first (64.09, SD = 17.31) and the second interview, after one year (69.33, SD = 19.17).

A significant difference (t = 4.57, df = 118, p < 0.0001) was found for CR between the second (71.08, SD = 18.19) and the final interview (74.85, SD = 17.86).

A significant difference (t = 7.94, df = 137, p < 0.0001) was found for CR between the first (66.46, SD = 16.50) and the final interview (75.56, SD = 17.32).

The main outcome variable, CR, moved in the direction of lower risk for both Group 1 and 2, confirming the trend seen in BP and STC, with the smoking element still to be evaluated. Pharmacist monitoring has affected the mean value of the CR of the 68 patients in Group 1 and the 138 patients in Group 2, who stayed with the study, away from their position on the rank scale in the direction of Rank 100. In so doing, patients' risk factors have been lowered and they have a reduced chance of developing CHD.

Hypothesis 14(b): Patients in Group 3 show no significant change in CR from the first time to the second, two years later.

No significant difference (t = 1.27, df = 190, p > 0.05) was found for CR from the first (91.85, SD = 7.43) to the final interview (91.26, SD = 7.99).

Hypothesis 14(c): Patients in Group 3 show no significant change in score parameters from the first to the final interview.

No significant difference (t = 0.49, df = 191, p > 0.05) was found for SBP from the first (127.47, SD = 14.51) to the final interview (127.08, SD = 14.48). No significant difference (t = 0.70, df = 191, p > 0.05) was found for DBP from the first (79.91, SD = 8.18) to the final interview (79.55, SD = 8.79).

A significant difference (t = 4.15, df = 190, p < 0.05) was found for STC, however, from the first (4.69, SD = 0.63) to the final interview (4.82, SD = 0.61).

In the absence of an independent control group, Group 3 acted as a comparative group, as no intervention took place for the two year period. This group showed little change in BP, although there was an overall slight increase in STC which may have reflected the relaxation in diet and exercise approaches that people adopt when they know their health status is good.

6.4.8 Body mass index

Hypothesis 15: Mean BMI of the sample population reduces with counselling.

No significant difference (t = 150, df = 66, p > 0.05) was found for BMI for Group 1 patients from the first (25.83, SD = 5.15) to the final interview (mean = 25.56, SD = 4.60).

However, a significant difference (t = 3.38, df = 137, p < 0.05) was found for BMI in Group 2 patients from the first (25.49, SD = 3.67) to the final interview (25.79, SD = 3.75).

Also, a significant difference (t = 3.38, df = 191, p < 0.05) was found for BMI in Group 3 patients from the first (24.03, SD = 3.03) to the final interview (24.29, SD = 3.06).

A significant increase in weight was recorded for patient Groups 2 and 3 during the study, which was not expected. The pharmacist found that stimulating patients to lose weight was the single most difficult objective to achieve. Group 1 patients were the only risk group to show a net average loss in weight, but this was not significant.

The absolute mean value BMI for Group 3 patients was lower than for the other two groups, which may contribute to their lower risk status.

Hypothesis 15(a): The BMI of patients will be greater in those with risk factors than those without.

A significant difference (F = 4.55, 6,442, p < 0.0005) was found between categories for BMI. A post hoc test revealed significant differences between the hypertensive category of patient (mean 26.75) and the categories of smoking (24.28) and no risk patients (24.22).

Hypertensive patients in the practice tended, therefore, to weigh more than other patients. If this effect were extrapolated on a population basis, it would mean that there would be justification in advising hypertensives to lose weight to assist the lowering of their blood pressure.

6.4.9 Smoking

Hypothesis 16: The smoking status of Group 1 patients improves as a result of pharmacist intervention.

A significant reduction (t = 3.53, df = 70, p < 0.005) was found for the number of cigarettes smoked per day from the first (mean number = 8.93, SD = 11.06) to the final interview (5.80, SD = 9.18).

Hypothesis 16(a): The smoking status of all cigarette/cigar smokers improves as a result of pharmacist intervention. A significant reduction (t = 4.57, df = 102, p <0.0001) was found for all cigarette/cigar smokers from the first (mean number smoked per day = 10.66, SD = 9.30) to the final interview (7.16, SD = 8.51).

The most conclusive evidence confirming the success of intervention relating to smokers was that, of the 110 individuals who were smokers at the start of the study, 29 had given up completely at some time during the two years. Further, some of the 81 individuals still smoking had reduced their intake, and no one, to the pharmacist's knowledge, had started smoking. Nationally, a meta-analysis of trials in 39 GP practices showed that on average an 8% cessation rate was achievable at 6 months using a simple intervention. ¹³⁸

The environment generated by the health screen interview was conducive to making appropriate approaches to individuals who smoke, within the context of discussing lifestyle changes. In contrast, personal communication from general practitioners, with whom the pharmacist worked, indicated their lack of success in motivating smokers to stop smoking during opportunistic surgery consultations. They felt that smoking was invariably divorced from the focal point of the immediate health problem and the patient was not in a receptive frame of mind for such counselling. Notwithstanding the element of health risk associated with smoking, the doctors at the practice did not deny any patient health care provision if they refused to give up smoking.

Management options The pharmacist was able to encourage smoking cessation aided either by drug treatment and/or non-drug approaches, depending on the attitude and response of the individual.

Where nicotine replacement was recommended the client's understanding about its use was checked and additional information given about potential side-effects, such as vivid dreams.

One of the doctors at the practice held a weekly smoking cessation clinic and clients were invited to enrol if they felt they could not stop smoking on their own. This was an example of teamwork in action, where the pharmacist was pivotal in referring patients to another member of the primary health care team.

Monitoring and follow-up Follow-up support was found to be an important factor in helping smokers continue cessation. When the pharmacist was seeing more than one member of a family, the issue of passive smoking became an added factor in persuading the 'smoker' in the family to stop. If any smoker lived with anyone suffering from asthma, the pharmacist was able to convey a clear message of the dangers of passive smoking. Further, while the evidence of an association between passive smoking and increased risk of lung cancer is now clear, a similar association with cardiovascular risk from prolonged exposure has now been suggested, the risk of CHD death increasing by as much as 25%. 139

6.4.10 Exercise

<u>Hypothesis 17</u>: The average fitness of the practice population improves with pharmacist intervention.

A significant difference (t = 2.82, df = 70, p < 0.005) was found for exercise level for Group 1 patients from the first (mean 1.07, SD = 0.76) to the final interview (1.28, SD = 0.72).

A significant difference (t = 3.20, df = 148, p < 0.005) was found for exercise level in Group 2 patients from the first (1.34, SD = 0.88) to the final interview (1.50, SD = 0.90).

A significant difference (t = 2.62, df = 194, p < 0.05) was found for exercise level in Group 3 patients from the first (1.40, SD = 0.88) to the final interview (1.70, SD = 1.69).

Sample means indicate a general overall success in improving the fitness level of patients counselled, which augurs well for this effect to be extended to a population policy, although not for success in every individual case.

Fitness assessment was based on research which suggests that to make any real difference, you need to exercise to the point of inducing a sweat, and patients were only placed in the 'very active' category if they confirmed that they did this for at least 20 minutes three times a week.

The study, conducted at Harvard University, followed up 17,300 Harvard graduates, aged up to 79, whose exercise patterns were recorded in the 1960's. Doctors looked at the proportion of men alive in the 1990's and found that those who undertook vigorous as opposed to gentle exercise, were, on average, 25% less likely to have died. The activity had to be a workout of sufficient intensity to raise the body's resting metabolic rate. 140

In practice, the pharmacist found that, in the majority of cases, he obtained a better response by putting across a more moderate message. Patients were recommended to exercise to make themselves warm and slightly out of breath. As long as the activity was aerobic, dynamic and of sufficient intensity for the individual, it was often more appropriate to encourage more frequent participation of a shorter duration. This enabled patients to pursue activities they enjoyed such as golf, brisk walking, dancing or even 'DIY.'

6.4.11 Alcohol

<u>Hypothesis 18</u>: The average alcohol intake of the practice population reduces as a result of pharmacist intervention.

No significant difference (t = 1.09, df = 69, p > 0.05) was found for alcohol intake for Group 1 patients from the first (8.34 units/week SD = 10.39) to the final interview (7.46, SD = 8.23).

No significant difference (t = 0.72, df = 148, p > 0.05) was found for alcohol intake for Group 2 patients from the first (7.62, SD = 9.87) to the final interview (7.42, SD = 8.78).

No significant difference (t = 1.46, df = 194, p > 0.05) was found for alcohol intake for Group 3 patients from the first (6.03, SD = 6.92) to the final interview (6.46, SD = 7.43).

The standard deviation was large relative to the mean, indicating a wide variation in the drinking habits of the practice population.

There is controversy surrounding the question of the health-giving properties of wine. Recently doctors have claimed that red wine is good for you, and the Department of Health has lifted sensible drinking limits above the present stringent levels. 85

Doctors at Bristol Royal Infirmary found that women who drank two glasses of wine a day had lower levels of HDL-Cholesterol, ¹⁴¹ and an American Study showed that the low incidence of CHD in France is partly due to the high consumption of red wine by the French. ¹⁴²

Studies suggest that flavonoids, especially one chemical found in red wine, quercetin, may be particularly potent. Flavonoids work as antioxidants, stopping oxygen binding to LDL cholesterol and also as a platelet inhibitor, suppressing the stickiness of the blood. This has a potential impact on levels, not only of heart disease, but also strokes and other circulatory diseases. 143

The pharmacist recommended that two glasses of red wine could be taken at dinner time, because of the 'blood clot busting enzyme' component, but not to go beyond this level, as alcohol's negative effects would then outweigh any positive aspects. This advice was delivered particularly to the overweight patients and was generally well received.

6.4.12 Diet

Hypothesis 19: Dietary fat intake of the practice population reduces over time with counselling.

A significant difference (t = 6.61, df = 70, p < 0.0001) was found for dietary change in Group 1 patients from the first (mean = 2.90, SD = 0.80) to the final interview (2.24, SD = 0.69).

A significant difference (t = 7.71, df = 148, p < 0.0001) was found for dietary change in Group 2 patients from the first (2.55, SD = 0.71) to the final interview (2.13, SD = 0.71).

A significant difference (t = 3.13, df = 194, p < 0.005) was found for dietary change in Group 3 patients from the first (2.03, SD = 0.72) to the final interview (1.90, SD = 0.66)

Hypothesis 19(a): The mean STC level of patients is related to their dietary assessment.

Initial STC level in the practice population was found to be significantly positively correlated with diet status (r = 0.50, n = 448, p < 0.0001), ie 25% of the variation of STC level could be accounted for by diet.

<u>Hypothesis 19(b)</u>: Dietary fat reduction leads to a reduction in STC. This association was tested by cross-tabulating the positive and negative changes in diet with the positive and negative changes in STC.

Improvement in diet was found to be significantly associated ($X^2 = 21.26$, df =1, p <0.001) with a reduction in STC. Of the people reporting positive changes in diet, 75% of them had lower cholesterol levels, compared to the 25% reporting a higher STC.

Further, 68% of those patients whose cholesterol levels worsened reported a poorer diet, compared to 32% whose cholesterol improved despite a less healthy diet.

When all patients were included in the cross-tabulation, even those where there was no dietary change, a significant association ($X^2 = 33.5$, df = 1, p <0.00001) was found between improvement in diet and reduction in STC (see Table 6.4). This table indicates that, of the people reporting positive changes in diet, nearly three-quarters of them (73%) had lower STC levels compared to 43% of them (less than half) reporting the same or a less healthy diet. Further, over half of those reporting a poorer diet showed a worsened STC compared to about a quarter of those people having an improved diet.

Table 6.4 Relationship between Improvement in Diet and Reduction in S T C

Count	Diet	Diet	Row
Row Percentage	(same or worse)	(better)	Total
Column Percentage	e		
STC	147	36	183
(same or worse)	80.3%	19.7%	46.2%
	56.8%	26.3%	
STC	112	101	213
(better)	52.6%	47.4%	53.8%
	43.2%	73.7%	
Column Total	259	137	396
	65.4%	34.6%	100%

Table 6.5 Patient Study: Dietary Fat Reduction and STC Lowering Patient. Female, age 60 years. E A R 2500 Kcals/day

Week	ly Fat Ir	ntake	0	
Before Health Screen	ning	After Health Screening		
Food Total	Fat(g)	Food To	tal Fat(g)	
Butter	140	Butter/margerine	140	
Milk	70	Milk	35	
Eggs (fried & boiled) 77	Eggs (boiled & poached)	35	
Cheese (cheddar)	60	Cheese (edam)	42	
Ham	42	Ham	42	
Bread (white)	42	Bread (wholemeal)	42	
Cakes	49	Cakes	21	
Biscuits	45	Biscuits	20	
Vegetable Oil	100	Cooking Oil	30	
Potatoes (chips &		Potatoes (roast, jacket &		
roast)	49	boiled)	21	
Chocolate	34	Chocolate	17	
Crisps & Nuts	19	Crisps & Nuts	26	
Mayonnaise Dressing	gs 45	Low-fat Sauces	11	
Cereal	5	Muesli, Porridge	8	
Bacon (lean & fat)	34	Bacon (lean, grilled)	14	
White Fish	37	Oily Fish	64	
Chicken + skin	14	Chicken	6	
Mincemeat	18	Lamb	12	
Steak (lean & fat)	12	Steak (lean,grilled)	6	
Pork	24	Turkey	7	
Meat Pie	14	Liver (+ pasta)	7	
Desserts (pies,puddir	ngs) 54	Desserts (mainly fruit)	16	
Total Weekly Fat	984	Total Weekly Fat	622	
Total Daily Fat	141	Total Daily Fat	89	
Calorie Equivalent	1265	Calorie Equivalent (Kcal)	801	
% Age Energy	50%	%Age Energy from Fat	32%	

The patient's STC reduced from 7.5 to 5.9 mmol/L-1 during the two -year period

A lipid-lowering diet, therefore, does contribute to a reduction in STC in individuals. This conclusion leads to the main question:

By how much and how quickly does reduction in STC concentration lower risk of IHD?

The Department of Environmental and Preventive Medicine at St. Bart's hospital, London analysed data from 10 prospective studies, three international studies in different communities, and 28 randomised controlled trials. The results were remarkably consistent. The cohort studies, based on half a million men, estimated that a long term reduction in STC of 0.6 mmol/L-1, which could be achieved by moderate dietary change, lowered the risk of IHD by 50% at age 40, falling to 20% at age 70.91

According to further observational studies by these researchers, there has been a systematic underestimation of association between STC and IHD, implying an even stronger correlation than previously thought. During the study, patients in Group 1 reduced their STC by an average of 0.6 mmol/L-1 (10%), which theoretically would be associated with a 27% decrease in mortality. This was achieved by lifestyle changes: exercise, weight reduction and adoption of a practicable diet, the latter not being too restrictive so that all members of the family could participate.

There have been two types of clinical trial of lipid-lowering: of the 23 that used clinical end points, most were individually affirmative; 20 or more have been subjected to several meta-analyses that have established a high level of significance of benefit and have shown clearly that the extent of benefit is related to the degree of cholesterol lowering. Thirteen trials have shown cholesterol lowering to have a favourable effect on angiographically-measured coronary or peripheral atherosclerosis, yielding retarded progression, stabilisation or regression of varying degree. ¹⁴⁵ One such trial in the UK has shown that a lipid-lowering diet can reverse coronary artery damage in men with CHD, slow coronary narrowing and, in some cases, increase artery diameter. The authors concluded that the effect is reproducible in women, is irrespective of their starting STC and may be increased by adding lipid-lowering drugs. ⁹¹

Since approximately 50% of CHD deaths occur in patients with overt preexisting CHD, the treatment of elevated lipid levels and co-existing risk factors in such patients is a potentially valuable and cost effective approach to reducing CHD in general.

While some people have suggested that trial data support the findings of epidemiological studies, others have suggested that innately low cholesterol levels may be associated with increased non-cardiovascular death rates, especially from injury. They say that lowering cholesterol may not be effective and may even be harmful in anyone other than men at high risk. ¹⁹⁰ Such associations are far from consistent and are unlikely to be cause and effect. After 20 years of research there is no persuasive evidence that reducing STC to 5.0 mmol/L-1 causes any untoward effect, and, in fact, decreased total and non-cardiovascular mortality have also been a feature of three reports of long-term follow up. ¹⁴⁵

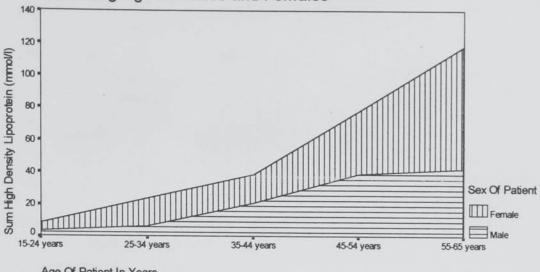
Law et al concluded, in 1994,that there is no evidence that low or reduced STC increases mortality from any cause other than haemorrhagic stroke. ¹⁴⁶

6.4.13 HDL-cholesterol

<u>Hypothesis 20</u>: HDL-cholesterol reduces with increasing age. No significant difference was found (F = 0.99, 4,216, p > 0.05) between age groups for HDL-cholesterol.

Hypothesis 20(a): HDL-cholesterol is greater in women than men. The t-test for independent samples revealed a significant difference (t = 6.48, df = 219, p < 0.0001) with females (mean = 1.34 mmol/L- 1 , SD = 0.35) having a greater HDL than males (1.06, SD = 0.29), as illustrated in Figure 6.6, where the cumulative value of females is greater than males, especially in the older age groups. Figure 6.6 is a stacked area chart with summaries for groups of cases. The category axis is the age bands; there is one point on the boundary of each area for each value of the variable. The scale axis represents the sum of the independent variable, HDL. There is one differently patterned area for each value of the sex of the patient, by which the areas are defined.

Figure 6.6 Cumulative Increase of Sum of HDL with Increasing Age for Males and Females



Age Of Patient In Years

Hypothesis 20(b): HDL does not significantly vary with the risk factor category of the patient.

A significant difference (F = 3.84, $_{6,214}$, p <0.005) was found between categories for HDL-cholesterol. A post hoc test revealed significant differences between patients in a 'no risk' category (1.35 mmol/L- 1 , SD = 0.37) and those in a smokers' category (1.10, SD = 0.29) and FHCHD <60 (1.12, SD = 0.34) category.

Hypothesis 20(c): HDL-cholesterol is lower in smokers than non smokers. A significant difference (F = 9.03, $_{2,218}$, p < 0.0005) was found between smoking status groups for HDL. A post hoc test revealed a significant increase in HDL from smokers (1.09, SD = 0.28) to lifetime non smokers (1.31, SD = 0.39). This effect is illustrated in Figure 6.7 and further amplified by Figure 6.8 which shows the HDL distribution among patients smoking more than ten cigarettes per day.

Figure 6.7 HDL-Cholesterol Distribution and Smoking Category of Male and Female Patients

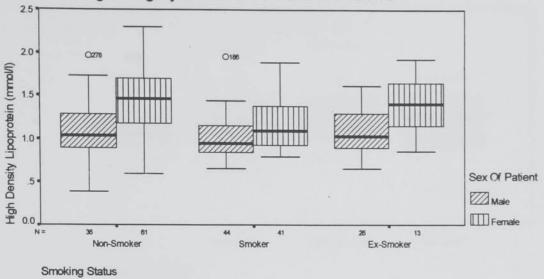
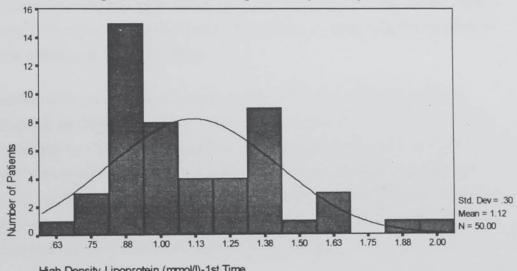


Figure 6.8 HDL-Cholesterol Distribution for Patients Smoking more than Ten Cigarettes per Day

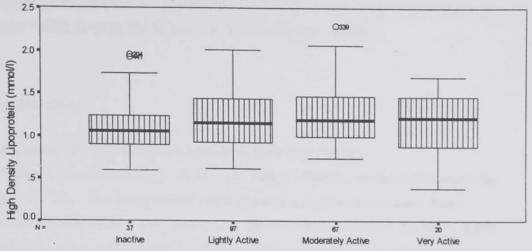


High Density Lipoprotein (mmol/l)-1st Time

Hypothesis 20(d): HDL-cholesterol is greater in 'very active' than 'inactive' patients.

No significant difference (F = 1.60, $_{3,217}$, p >0.05) was found between exercise levels for HDL-cholesterol. This lack of differentiation is seen in Figure 6.9

Figure 6.9 HDL-Cholesterol Distribution for Patients according to Level of Exercise



Exercise Assessment -1st Time

Smoking has an adverse effect on HDL-cholesterol levels, which is partially reversed in those who give up the habit. Further, there is a significantly better mean HDL value among the female than among the male population. Both of these effects are shown in Figure 6.7.

Patients with 'no risk' factors had a higher HDL than smokers, which, by accepting the beneficial role of HDL in preventing CHD, is indicative of one mechanism by which smoking adversely affects the cardiovascular system. The link between HDL and female patients may also be one mechanism for the cardio-protective effect from which women benefit, and the link between HDL and those with a FHCHD <60 confirms that this group are at higher risk of CHD and would benefit from preferential screening.

6.4.14 TSC/HDL Ratio

Hypothesis 21: Replacing the dependent variable HDL with the ratio TSC/HDL reflects the results found in Hypotheses 20, 20(a), 20(c) and 20(d).

No significant difference was found for the parameters age and exercise, as with HDL. However, no significant difference (t = 1.52, df = 179, p > 0.005) was found between smokers (mean value = 5.20, SD = 1.39) and non smokers (4.84, SD = 1.70).

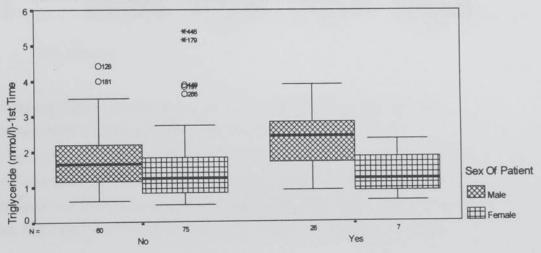
A significant difference (t = 5.58, df = 218, p < 0.0001) was found between females (4.49, SD = 1.33) and males (5.60, SD = 1.60), which is a further factor which favours the female cardiovascular risk profile.

6.4.15 Triglycerides

Hypothesis 22: TG levels are greater in men than women.

A significant difference (t = 3.36, df = 166, p <0.005) was found between the sexes for TG. The independent t-test showed a significant increase from females (mean value = 1.47 mmol/L- 1 , SD = 0.95) to males (1.95, SD = 0.89). This distinction was evident, irrespective of alcohol intake, as seen in Figure 6.10, women having the lower TG. Only in the case of women with a BMI >25 was their mean TG greater than that of the men.

Figure 6.10 Triglyceride Distribution Related to Alcohol Intake for Males and Females

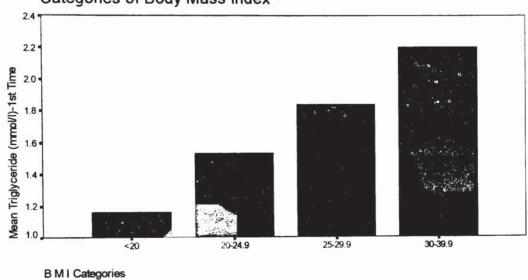


Patients who drink over the accepted limit.

Hypothesis 22(a): TG levels are greater in people with a BMI >25 than in those with a BMI <25.

A significant difference (F = 5.61, $_{3,164}$, p <0.005) was found between groups of BMI for TG. A post hoc test revealed significant differences between patients with a BMI >30 (2.20, SD = 1.02) and patients with a BMI 20-25 (1.53, SD = 0.75), and between patients with a BMI 25-30 (1.84, SD = 1.08), and those with a BMI <20 (1.16, SD = 0.59), as illustrated in Figure 6.11.

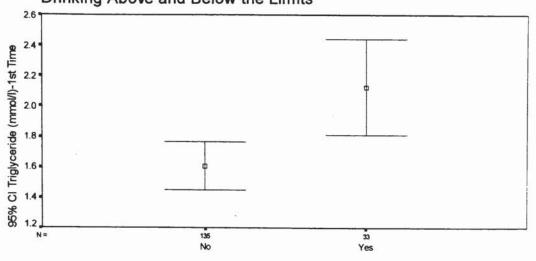
Figure 6.11 Triglyceride Levels Related to Categories of Body Mass Index



Hypothesis 22(b): TG levels are greater in people who drink over the recommended limit than in those who stay below.

A significant difference (t = 2.89, df = 166, p < 0.005) was found between alcohol groups for TG. The t-test for independent samples revealed a significant decrease from patients drinking above the limit (2.13, SD = 0.88) to those drinking below the limit (1.61, SD = 0.93), as Figure 6.12 shows.

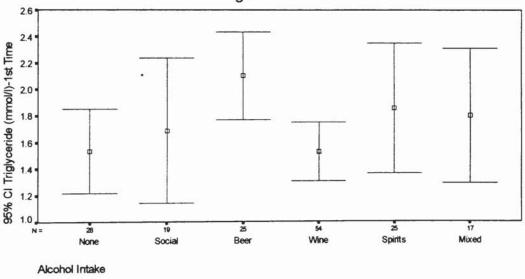
Figure 6.12 Triglyceride Levels in Patients
Drinking Above and Below the Limits



Patients who drink over the accepted limit.

Beer was found to be the alcoholic drink associated with higher TG levels and wine the best option for those who drink (Figure 6.13).

Figure 6.13 Triglyceride Levels related to the Nature of the Beverage



The British Hyperlipidaemia Association suggest that high TG levels are often seen in obese patients and in those who abuse alcohol. The results of this study are confirmatory, and women who are not obese have more favourable TG levels.

Hypothesis 22(c): As TG increases, HDL decreases. In women, a strong correlation (r = 0.44, p < 0.0001) was found between HDL (1.34 mmol/L- 1) and TG (1.47 mmol/L- 1) in the 69 pairs analysed. In men, too, there was a significant correlation (r = 0.33, p < 0.05) between HDL (1.06 mmol/L- 1) and TG (1.95 mmol/L- 1). Thus, a lowering of HDL-cholesterol is linked to an associated rise in TG. This combination of a higher HDL and lower TG in women may be further evidence of a causal link with lower CHD incidence in the female population.

6.4.16 Medication spectrum

During the course of each health screen interview, the pharmacist discussed adherence to medication whenever it was applicable. For those patients on antihypertensive medication, the spectrum of drug classes is shown in Figure 6.14, together with the various combinations of drugs prescribed.

All Patients at the Start of the Study

14

12

10

8

6

Diuretic

ACE-Inhibitor

B-Blocker

Ca-Channel Blocker

Thiazide + B-Blocker

Thiazide + ACE Inhibitor

Thiazide + ACE Inhibitor

Thiazide + ACE Inhibitor

Thiazide + ACE Inhibitor

Figure 6.14 Hypertensive Medication Spectrum for All Patients at the Start of the Study

Antihypertensive Medication

In 26 cases, new or replacement cardiovascular medication was prescribed, as a result of the pharmacist's intervention (see Table 6.6). For eight of these patients new BP medication was prescribed and for 10 patients an alteration was made to their antihypertensive therapy. In some instances, drugs were either added to or removed from the patient's prescription, or the dose was increased or decreased, or a different formulation of the drug prescribed (see

Table 6.6). Some specific cases of the influence of the pharmacist on prescribed medication will be discussed in Chapter 7.

Table 6.6 Medication Spectrum and Dose Change

	Drug Change		Dose Chang	e
	Frequency	Percentage	Frequency	Percentage
No	374	90.1	398	95.9
Yes	26	6.3	5 (formulation	on) 1.2
Increase	6	1.4	. 4	1.0
Decrease	9	2.2	8	1.9

Valid Cases = 415

6.4.17 Follow-up response

It was very encouraging to find in the study how willingly patients returned for follow-up checks, and showed confidence in the pharmacist as a health professional who they could consult about all aspects of their health care. Table 6.7 shows that 393 patients attended throughout the study, and only 26 did not attend for the final interview. These figures strongly supported the work and acceptability of a pharmacist within a general medical practice.

Table 6.7 Follow-up Response of Patients

Attendance	Frequency	Percentage
Did Not Attend	26	5.8
Attended	393	87.5
Left Practice	20	4.5
Pregnant	10	2.2

6.5 CONCLUSION

Clinical questions of importance to primary care can be answered within the primary care setting where a pharmacist has been accepted to facilitate and conduct the necessary health checks. The workload generated by health checks is daunting, the most important statistic being that 50% of patients merited follow-up for one or more independent risk factors. The pharmacist has demonstrated that he can be an invaluable, largely untapped resource in a

well-implemented strategy designed to contain the high mortality rate of CHD in a practice population.

Nothing is likely to be achieved unless there is an effective intervention to reduce the risk identified. The monitoring of patients by a pharmacist has enabled a potential risk reduction to be realised in clinical practice. Epidemiological findings show that there is a potential for reduction in overall mortality by lowering STC levels. Realising this potential depends on finding an intervention strategy which is effective and can be sustained over time. By virtue of categorising patients, and devoting energy more to interventions of proven effectiveness, such as the treatment of hypertension and provision of smoking cessation advice and support, the pharmacist was able to make optimum use of his time.

According to Rose, the population approach of the study, though labour intensive, is most beneficial.³² The case for this approach is based on three observations:

- treating only those at highest risk makes little difference to overall morbidity or mortality;
- the absolute number of people at high risk is determined by the overall distribution of risk in the population;
- achieving change in those at highest risk is largely dependent on changing cultural attitudes in the whole population.

Thus, the general practitioner should be encouraged to capitalise on the skills developed by community pharmacists in association with practice nurses and other relevant members of the PHCT, such as dieticians, in the provision of health checks in order to establish a more effective programme for the identification and management of patients with cardiovascular risk factors.

The study has shown that a population approach can achieve a substantial impact on the lifestyle of a practice.

CHAPTER 7

CASE STUDY EVALUATION

7.1 INTRODUCTION

The medical approach to understanding disease has traditionally drawn heavily on qualitative data, and in particular on case studies to illustrate important or interesting phenomena. Moreover, much of the everyday work of doctors and other health professionals still involves decisions that are qualitative rather than quantitative in nature.

This chapter will deal therefore with some typical case study evaluations of health interventions by the pharmacist that will amplify the quantitative data discussed in the previous three chapters. In this way, one can link in-depth qualitative and quantitative data by focusing on specific patients, their individual needs and implementing a process to improve their health status. The wider implications and application can follow. This can be done, for example, by looking at how the resource of medication and dietary advice successfully reduces the STC level of an individual from a potentially serious one to a level where a disease process is less likely to occur.

Method

Positive intervention approaches to various cardiovascular risk factors will be studied by reference to individual cases.

7.2 BLOOD PRESSURE

7.2.1 New diagnosis

Patient A

Male, age 40.

Family History

CHD < 60

None

CVA

Grandfather

Hypertension (HT)

Mother and Grandfather

Current Illness

None

Presenting Feature

BP 170/115

Action

Referred to practice nurse for confirmation of BP

Outcome

Patient sent by doctor to hospital for ECG and blood

tests, and placed on zestril 10mg twice daily

Measurement

BMI

30.7

STC

6.6

TG

3.0

BG

5.2

Criteria

Dietary Status

2 (normal fat)

Alcohol Intake

26 units/week

Exercise Level

0 (inactive)

Smoking

10 cigarettes per day

Result of Therapy

Monthly readings of BP for the 3 months after

medication was prescribed were: 160/110; 155/100 and 143/87 respectively,

in sequence.

7.2.2 Medication compliance

Patient B

Male, age 63

Family History

CHD < 60

None

CVA

None

HT

Brother

Current Illness

Hypertension and arthritis

Current Medication

Bendrofluazide 5mg in the morning and diclofenac

50mg twice daily

Presenting Feature

BP 176/112, previously stable at 150/95. On

questioning, the patient admitted to not complying regularly with

antihypertensive medication as he was inconvenienced by diuretic effect and

further that he had recently been suffering from nose bleeds.

Action

Patient referred to practice nurse for BP check

Outcome

After the pharmacist pointed out that NSAIDs

antagonise the hypotensive effect of diuretics, the doctor placed the patient on a calcium channel blocker.

Measurements

BMI

26.5

STC

6.2

HDL

0.93

BG

4.3

Criteria

Dietary Status

Normal fat

Alcohol Intake

6 units/week

Exercise level

Lightly active

Smoking

No

Results of Therapy

BP dropped to 130/80 and stabilised at 140/85. The

nose bleeds stopped. BP before:- 176/112; after:- 140/85.

7.2.3 Medication change

Patient C

Female, age 60

Family History

CHD < 60

None

CVA

Mother

HT

None

Current Illness

Hypertension, bronchitis and hiatus hernia

Current Medication

Enalapril 10mg in the morning, doxycycline, alupent

syrup, and gaviscon

Presenting Feature

BP at 170/98, not controlled despite medication

Action

After confirmation of BP by practice nurse, pharmacist

recommended an increase in dose or change of medication spectrum to doctor.

Outcome

Doctor doubled the dose of Enalapril to 20mg daily, and

added bendrofluazide 2.5mg in the morning to the prescription. The patient told the pharmacist that she felt 'spaced out' after taking the morning dose of

enalapril, therefore the pharmacist recommended taking enalapril at night.

Measurements

BMI

32.1

STC

5.6

TG

2.4

BG

6.3

Criteria

Dietary Status

High Fat

Alcohol Intake

None

Exercise level

Lightly active

Smoking

30 cigarettes per day

Results of Therapy

Monthly readings of BP for the 3 months after

prescription was changed were: 159/95, 145/93 and 140/90 respectively.

Further, smoking frequency dropped to 15 cigarettes per day.

7.2.4 Medication withdrawal

Patient D

Female, age 45

Family History

CHD < 60

None

CVA

None

HT

Father and twin sister

Current Illness

Hypertension and epilepsy (now latent).

Current Medication

Enalapril 2.5mg in the morning and bendrofluazide

2.5mg. daily.

Presenting Feature

BP steady at 140-150/75-85 for one year

Action Patient, in common with many others, was not keen to continue lifelong medication at her age, as initial high BP was caused by stress induced during daughter's illness. Therefore the pharmacist recommended a trial period without medication.

Outcome The doctor initiated a 24 hour BP monitor for the patient, after which she agreed to a trial period without medication, the 24 hour test showing no high peaks of BP.

Measurements	BMI	21.8
	STC	6.6
	TG	0.59
	BG	4.5

Criteria

Dietary status

High fat

Alcohol Intake

None

Exercise Level

Lightly active

Smoking

No

Result of Therapy

The patient maintained a satisfactory and steady BP

during the year following withdrawal of antihypertensive medication.

7.2.5 Medication change due to side- effects

Patient E

Female, age 45

Family History

CHD < 60

Mother and father

CVA

Mother and father

HT

Father

Current Illness

Hypertension, asthma and arthritis

Current Medication

Nifedipine SR 10mg twice daily, naproxen 250mg in the

morning, becloforte and ventolin, with prednisolone EC 5mg intermittently.

Presenting Feature

Headaches, dizziness and facial flushing, which the

pharmacist associated with the adverse effects of nifedipine.

Action

Previously, the patient had been on atenolol, which

triggered off her asthma, and bendrofluazide which was ineffective in lowering

her BP, therefore the pharmacist recommended an ACE inhibitor.

Outcome

The prescription agreed was for enalapril 10mg daily.

Measurements

BMI

23.7

STC

5.5

TG

1.39

BG

6.1

Criteria

Dietary Status

Normal fat

Exercise Level

Inactive, due to arthritis

Alcohol Intake

4 units per week

Smoking

No

Result of Therapy

Although her systolic BP remained high, at 170, as it

had with all previous medication, her diastolic BP was consistently around

70mm Hg. Naproxen was removed from the regimen to prevent interaction,

the prednisolone dose becoming constant at 2.5mg daily to control the arthritis.

7.2.6 Medication change due to metabolic effect

Patient F

Female, age 65

Family History

CHD < 60

Brothers and uncle

CVA

Mother

HT

Mother and sister

Current Illness

Oesophagitis, hypothyroidism, and previously a victim

of a myocardial infarction.

Current Medication Bendrofluazide 2.5mg in the morning, metoprolol 100mg daily, fenofibrate 100mg twice daily, aspirin e/c 300mg daily, thyroxine 100mcg daily, cisapride 10mg three times daily and omeprazole 20mg daily.

Presenting Feature A high BP of 180/115 despite medication and a high STC of 7.0mmol/L.

Action

Due to the hyperlipidaemic activity of diuretics and B-

blockers, the pharmacist recommended a change in therapy.

Outcome

The doctor prescribed enalapril 5mg daily.

Measurements

BMI

7.0

31

TG

STC

1.58

BG

8.4

Criteria

Dietary Status

High fat

Alcohol Intake

7 units per week

Exercise Level

Lightly active

Smoking

Ex-smoker

Result of Therapy Enalapril was replaced by nifedipine MR 10mg twice daily, due to the persistent cough caused. The patient's BP fluctuated between 180-190/100-110, but eventually settled for a sustained period, at 160/90.

Hypothyroidism may be linked to the hypercholesterolaemia and the STC

reduced to 5.8-6.1 after medication change. The high blood sugar was checked, and diabetes excluded.

7.2.7 Medication change due to patient's health status

Patient G

Male, age 63

Family History

CHD < 60

None

CVA

Brother

HT

None

Current Illness

Hypertension

Current Medication

Atenolol 50mg in the morning.

Presenting Feature

BP satisfactory at 148/88, but, during consultation,

patient expressed concern at urinary retention and blood in the urine.

Action

Referral to doctor for check on the patient's prostrate.

Outcome

Patient diagnosed to have Benign Prostatic Hyperplasia

and placed on Doxazosin 4mg daily.

Measurements

BMI

26.6

STC

6.1

BG

6.2

Criteria

Dietary Status

High fat

Alcohol Intake

2 units/week

Exercise Level

Lightly active

Smoking

No

Result of Therapy

The patient's urogenital symptoms subsided and high

BP remained within accepted limits, due to the alpha-adrenoceptor blocker treatment.

7.3 DIABETES

Patient H

Female, age 62

Family History

CHD < 60

Mother

CVA

Father

HT

No

Diabetes

No

Current Illness

Asthma, migraine occasionally

Current Medication

Becotide and ventolin, algicon

Presenting Feature

Random BG of 19.1

Action

Referral by doctor to the hospital for a full chemistry

and haematology analysis

Outcome

The pathology report (Appendix 16) confirmed a

diagnosis of diabetes mellitus and the patient was prescribed metformin 500mg twice daily.

Measurements

BP

162/84

STC

7.2

TG

1.93

Fasting Glucose

9.9

Criteria

Dietary Status

Very high fat

Alcohol Intake

4 units per week

Exercise Level

Inactive

Smoking

Ex-smoker

Result of Therapy The patient was extremely enthusiastic of the benefits of the health screen and very thankful that her diabetes had been diagnosed. Her diabetes necessitated an improvement, also, in dietary status and exercise level, and her blood glucose is now consistently within the normal range.

7.4 CHOLESTEROL

7.4.1 Effect of hypolipidaemic medication on patient with

hypercholesterolaemia

Patient I

Female, age 65

Family History

CHD < 60

None

CVA

None

HT

Mother

Current Illness

Hypertension, eczema

Current Medication

Atenolol 100mg and zestril 5mg in the morning; and

dermovate cream

Presenting Feature

High STC of 7.7mmol/L at first health screen

Action

Repeat STC in one month remained 7.7, therefore

patient was referred to doctor

Outcome

Patient was placed on simvastatin 10mg daily

Measurements

BMI

34.0

BP

166/87

TG

1.8

BG

5.4

Criteria

Dietary Status

Low Fat

Alcohol Intake

None

Exercise Level

Lightly Active

Smoking

No

Result of Therapy

STC readings reduced to 6.0 after 3 months, 5.4 after 6

months and 5.1mmol/L after one year. Her BP readings improved to 157/85,

155/83 and 150/75 respectively, but her BMI, despite a low fat diet, remained

at 34.

7.4.2 Effectiveness of dietary change on reducing cholesterol levels

Patient J

Female, age 58

Family History

CHD < 60

Brother

CVA

None

HT

None

Current Illness

Asthma, water retention, arthritis

Current Medication

Becotide and ventolin, moduret 25 in the morning

Presenting Feature

STC of 7.3mmol/L, also symptoms of breathlessness on

exercise the pharmacist felt were unconnected with asthma.

Action

Recommendation of 3 month trial period on cholesterol-

lowering diet, and referral to doctor for verification of angina, especially as brother has angina.

Outcome

Doctor prescribed nitrolingual spray for angina

symptoms

Measurements

BMI

28.6

BP

147/72

TG .

2.12

BG

6.8

Criteria

Dietary Status

Very high fat

Alcohol Intake

4 units per week

Exercise level

Lightly active

Smoking

Ex-smoker

Result of Therapy

The patient's STC reduced to 6.9mmol/L at 3 months,

6.1 after 6 months and remained at 6.1 after one year, a reduction of 15% due to diet alone.

7.4.3 Patient with a family history of hyperlipidaemia

Patient K

Male, age 64

Family History

CHD < 60

Father and mother

CVA

None

HT

Brother and sister

Current Illness

Haemorrhoids

Current Medication

Xyloproct suppositories

Presenting Feature

STC of 9.4mmol/L and evidence of tendon xanthomata

Action

Recommendation to place on hypolipidaemic

medication, especially as a sister has been so prescribed.

Outcome

Due to reluctance of patient to go on medication,

coupled with his age, a period of dietary modification would be tried first.

Measurements

BMI

23.3

BP

140/80

TG

1.83

BG

5.8

Criteria

Dietary Status

Normal fat

Alcohol Intake

None

Exercise Level

Lightly active

Smoking

Ex-smoker

Result of Therapy

STC measurements were 7.4mmol/L after 3 months, 7.8

after 6 months and 8.0 at one year. The patient agreed to go onto medication, and he was prescribed pravastatin 20mg each evening, recommended by the pharmacist, following the recent successful West of Scotland Coronary

Prevention Study. 148 His STC is 7.0mmol/L after a further 3 months.

7.4.4 HDL-cholesterol factor in cardiovascular risk assessment

Patient L

Female, age 41

Family History

CHD < 60

Father and mother

CVA

Father

HT

Father

Current Illness

Migraine

Current Medication

Vitamins and Mineral Supplements

Presenting Feature

High STC of 7.0mmol/L, but with an HDL of

2.0mmol/L and a STC/HDL ratio of 3.5.

Action

Recommendation to improve the balance of her diet and

to replace fatty, sugary snacks with crudites during her stressful work day as a

solicitor; also to increase physical activity.

Outcome

Agreement from doctor on a 'diet and lifestyle' policy.

Measurements

BMI

28.7

BP

132/88

TG

0.69

BG

6.8

Criteria

Dietary Status

Very high fat

Alcohol Intake

4 units per week

Exercise Level

Lightly active

Smoking

Only as a student

Result of Therapy

STC levels dropped successively to 6.7, 6.2 and finally

6.1mmol/L over a period of two years.

7.5 SMOKING

7.5.1 Successful cessation of smoking

Patient M

Male, age 45

Family History

CHD < 60

Father

CVA

None

HT

None

Current Illness

None

Current Medication

None

Presenting Feature

Smoking 20 cigarettes a day, and had consistently done

so since schooldays.

end of the study.

Action

In this case, the smoker wanted to quit for the reason of

health, finance and family considerations. The pharmacist, seeing the patient's

motivation, advised quitting immediately and prescribed a course of nicotine

replacement patches, the dose being dependent on the frequency of smoking.

The patient was also recommended to develop his favourite hobby, increase his

exercise level and eat low-calorie foods to keep him fully occupied.

Result of Therapy As all cardiovascular measurements were good, there was no recourse to the doctor, the doctors at the practice further admitted to be ineffective in applying smoking cessation methods in practice. Of crucial significance, the pharmacist monitored the patient frequently to maintain a high level of commitment, and, in this case, smoking cessation was permanent to the

7.5.2 Failure to stop patient smoking

Patient N

Female, age 33

Family History

CHD < 60

Father

CVA

None

HT

None

Current Illness

Allergic rhinitis

Current Medication

Beconase

Presenting Feature

Desire to stop smoking, currently at ten cigarettes daily.

Action

This patient had tried to stop smoking before, and

would have been successful if a stress situation had not intervened. She preferred to try without nicotine replacement therapy as previous use had in several cases affected her sleep pattern adversely.

Result of Therapy Despite encouragement and advice on nutrition, the patient was not able to quit smoking. She put on 7kg in weight in 4 months, and was convinced that smoking cessation was the cause of metabolic changes leading to this gain in weight. She was just about to embark on a new business venture and the stress involved precipitated her back to the smoking habit. She was informed of the results of a study which showed that among people in their 30s and 40s, non-fatal MI was five times more common in smokers than non-smokers, but the power of stress and unwanted weight gain prevailed. 149

7.6 ALCOHOL

7.6.1 Adverse effect of alcohol on BP

Patient O

Male, age 53

Family History

CHD < 60

None

CVA

None

HT

Father

Current Illness

Hypertension

Current Medication

Bendrofluazide 5mg and enalapril 20mg

Presenting Feature

A very high BP of 185/125, despite medication

(although adherence could not be guaranteed), and an admission that his estimation of alcohol intake of 26 units per week was untrue and that he drank 60 units of whisky alone per week.

Action

Firm advice to reduce his alcoholic intake to normal

limits and referral to the doctor.

Outcome

The patient was prescribed nifedipine MR 10mg twice

daily in addition to his other medication.

Result of Therapy BP readings came down quickly to 146/106 as a result of the medication and replacement of the whisky with red wine at an intake of 18 units weekly. BP readings sustained subsequently at 140/98 and finally remained at 140/90 on three separate occasions. At the end of the study it was agreed that he could revert to his original medication spectrum as nifedipine made him dizzy.

7.6.2 Influence of alcohol on BMI and triglyceride levels

Patient P

Male, age 54

Family History

CHD < 60

Mother, brother and sister

CVA

Grandfather

HT

Mother and sister

Current Illness

Hypertension, indigestion

Current Medication

Moducren, cimetidine

Presenting Feature

His BP was slightly high at 155/100, but his lifestyle

criteria were all poor:

Dietary Status

High fat

Alcohol Intake

40 units per week

Exercise Level

Lightly active

Smoking

30 cigarettes a day

His other measurements were:

BMI

32.6

STC

6.0

TG

3.4

BG

8.0

Action

With so many lifestyle aspects to be considered, a

priority strategy was determined. The patient's motivation was the first priority. He had recently split up from his wife and was not motivated to stop smoking. Exercise was difficult due to residual arthritis following a car accident. His eating habits were irregular, nothing at breakfast time but offset by one large meal at night. He agreed to try a more balanced redistribution during the day. Finally, his alcohol intake consisted of vodka, mainly on a

Friday night, and he was counselled to reduce this and spread his drinking throughout the week, as alcohol in excess represented extra calories.

Result of Therapy His alcohol intake dropped to 20 units per week and his TG to 2.8, but there was no change in BMI. This indicated that the reduction in TG may have arisen partly because of a lower alcohol intake, but independent of the patient's weight.

7.7 IMPROVEMENT IN DUNDEE CORONARY RANK BY CONCERTED ATTACK ON RISK FACTORS

Patient O

Male, age 64

Family History

CHD < 60

Sister

CVA

None

HT

None

Current Illness

Hypertension

Current Medication

Lacidipine 4mg daily

Presenting Feature

Due to his BP, STC and smoking, his rank score was 2,

virtually at the point of highest risk

Action

Referral to the practice nurse for confirmation of BP

and to the dietician for further advice on a healthier diet.

Outcome

Patient was kept on the same medication regime. The

doctor agreed with the pharmacist that his BP was due to non compliance and

other adverse lifestyle factors

Measurements

BMI

23.6

BP

193/120

STC

7.5

TG

1.5

Criteria

Dietary Status

High fat

Alcohol Intake

28 units per week

Exercise Level

Lightly active

Smoking

20 cigarettes per day

Result of Therapy

During the two year study period, the patient's BP

reduced steadily to a final, consistent figure of 130/80 and his STC reduced to

5.8mmol/L. His final rank score was 30, a considerable improvement, placing

him in the intermediate risk category. This was due to a concerted effort to change his lifestyle.

7.8 DISCUSSION

Individual case studies illustrate the impact and ways in which a health screening programme can contribute to patient health care and add meaning to the overall figures illustrated in Chapters 5 and 6.

One of the pharmacist's aims was to provide level of risk of CHD information to the doctor which would aid individual patient management. The CR was the main outcome variable; but the pharmacist felt that this represented an unjustifiable bias against younger women, who, in the UK, are at considerably lower risk of CHD than men. Although any rise in CR would indicate a relative lowering of risk, the pharmacist sought another method of risk assessment in order to give a clearer picture to the doctor.

The Framingham Study provides a database of statistics on which risk calculations for CHD can be based. The percentage risk of developing CHD over a selected period of time can be calculated. Pharmacist access to a Cholestech LDX Lipid Analyser enabled the calculation of the percentage risk of developing CHD within 10 years by furnishing the following determining factors: total cholesterol, HDL cholesterol ratio, sex, smoking, diabetes, personal diagnosis of CHD, age and SBP. Some following examples illustrate the use of this assessment:

1 Patients with Similar rank scores

Patient A, female, age 30, with a rank score of 16, but with a TSC/HDL of 6.0, an HDL of 0.95 and a risk percentage of 1.2.

Patient B, male, age 54, with a rank score of 13, but with a TSC/HDL of 7.8, an HDL of 0.65 and a risk percentage of 32.

The difference in risk percentage was because Patient A was a young female with a better TSC/HDL ratio.

2 Patients with similar rank scores, and same age and sex

Patient A, male, age 55, with a rank score of 72, a TSC/HDL of 5.3, an HDL of 0.92 but a risk percentage of 37.

Patient B, male, age 54, with a rank score of 67, a TSC/HDL of 4.8, an HDL of 1.11 but a risk percentage of 15.

The main reason for the difference was that Patient A had suffered a coronary.

3 Patients of similar age

Patient A, female, age 60, with a rank score of 8, a TSC/HDL of 5.3, an HDL of 1.52 but with a risk percentage of 14.

Patient B, male, age 61, with a rank score of 56, a TSC/HDL of 8.8, an HDL of 0.66 but with a risk percentage of 31.

This change in relative risk for patients A and B from one scoring system to the other was due to the difference in HDL-cholesterol of the two patients, and also that Patient A was a smoker; the Dundee system appears to weight the smoking risk more heavily than the Framingham Study.

4 Patients of different sex

Patient A, female, age 55, with a rank score of 58, a TSC/HDL of 3.6, an HDL of 1.52, but a risk percentage of 4.

Patient B, male, age 55, with a rank score of 59, a TSC/HDL of 4.0, an HDL of 1.48, but a risk percentage of 9.1.

This difference could only be explained by the Framingham Study data showing a more favourable prognosis for women.

5 Patients of same age and sex

Patient A, female, age 58, with a rank score of 48, a TSC/HDL of 5.4, an HDL of 1.13, but with a risk percentage of 12.

Patient B, female, age 58, with a rank score of 46, a TSC/HDL of 4.5, an HDL of 1.19, but with a risk percentage of 20.

This difference was due to Patient B being a diabetic.

7.9 CONCLUSION

The majority of patients registered with a doctor are seen at least once in a five-year period. As evidenced from the results in Chapters 5 and 6 and individually illustrated by the case studies in this Chapter, a systematic invitation to subjects for screening could be very successful. The Dundee score relies on three well-established risk factors, and has proved invaluable in assessing the progress of any individual. There is no doubt that prediction of the likelihood of a CHD event is improved by assessing the combined effects of several risk factors, including the presence of established evidence of CHD. The scoring system based on the Framingham Study enables one to place an individual in a group with a defined risk of a major CHD event within the next ten years, but not to predict precisely whether he will or will not have a major CHD event within this limited period of time.

The rank score and risk percentage were a useful guide, and starting point with individual patients. The pharmacist then always focused on altering dietary habits, reducing, eliminating cigarette smoking, controlling hypertension and improving fitness.

The general practice environment proved to be ideal for the passing on and reinforcement of health education, and the pharmacist found that patients were sufficiently comfortable and relaxed to raise health concerns which were not necessarily confined to CHD. This facilitated the subsequent follow up and detection of risk for many other conditions, eg cervical cancer.

CHAPTER 8

INVESTIGATION OF THE ATTITUDES OF FHSA PHARMACEUTICAL ADVISERS TO THE PHARMACIST'S EXTENDED ROLE

8.1 INTRODUCTION

Health agencies are committed to the aim of securing high quality, cost effective health care which achieves measurable health gain for the population through a professional development strategy. An essential element to this achievement is the training and development of the providers of the services, and this thesis, so far, has been concerned with demonstrating one way in which community pharmacists can positively contribute to primary care.

Primary care is the first point of contact between people and the health care system, and will in future play an increasingly important role as the foundation service of the NHS. To achieve such a strategic shift of services from secondary to primary care it is vital that primary care services are underpinned by quality assurance linked to continuing service development and improvement. Best quality provision is provided in a primary health care team with an increasingly wide range of services in a place most convenient to the patient and in an environment conducive to their requirements.

If community pharmacists are to be one of the providers in this skilled workforce, and to respond appropriately to the challenges of their extended roles, the development of their professional skills must be a continuous process. FHSA Pharmaceutical advisers are an important NHS link at the GP- pharmacist interface. A questionnaire was designed to examine the opinions of these advisers on some of the changes and options

occurring in pharmacy and primary care. The Pharmacy Practice Research Resource Centre offered assistance on the specific aspects of questionnaire design. ¹⁹¹

8.2 AIMS

The purpose of the questionnaire was:

- to determine and assess the adviser's role in community pharmacy
- to quantify the usage of computers and PMRs in British pharmacies
- to determine the adviser's viewpoint on health screening, health promotion, GP formulary development, GP- pharmacist liaison, remuneration, and the location of pharmacies
- to assess factors influencing and inhibiting the integration of the pharmacist into patient-orientated primary care services.

8.3 METHOD

8.3.1 Design of Questionnaire

The survey questionnaire (Appendix 17) was sent to 86 FHSA Pharmaceutical advisers throughout the UK, together with an accompanying letter (Appendix 18). An initial pilot questionnaire was scrutinised by the two pharmaceutical advisers at the Brent and Harrow (B&H) FHSA.

8.3.2 Equipment

The programme SPSS 6.1 for Windows on a Personal Computer was used to record results from returned questionnaires and for statistical analysis of the data.

8.4 Results

A total of 53 (61.6%) of questionnaires were returned within four weeks of issue. The survey response rate of 61.6% was considered satisfactory, and acceptable for analysis as all questionnaires were complete and usable. No second mailing was made, as the sample was considered representative.

8.4.1 Pharmaceutical adviser data

Response to Question 1 FHSA's had employed a Pharmaceutical adviser for a mean number of 3.38 years; median value 3.0, range 1 to 6 years.

Response to Question 2 The mean number of years for Pharmaceutical advisers in their post was 2.37; median value 2.50, range 6 months to 5 years.

Response to Question 3 45 advisers attended LPC meetings, two had joint meetings and six were not invited.

Question 4 Do you have an active role in advising on any of the following with community pharmacists in your area?

Table 8.1 Advice to community pharmacists

Pharmacist Role	Active Role of Pharmaceutical Adviser				
1	Number of Positive Responses	Percentage n = 53			
PMRs	32	60			
Domiciliary Visits	19	36			
Advice to Residential Homes Staff	43	81			
Supply of Medicines to Nursing Horn	nes 32	60			
Medication Disposal Arrangements	43	81			

Other advice included 8 references to prescribing advice to GPs, 4 to local pharmacy budgets, 3 to pharmacy assistant training, 2 to counselling areas, and one each to baby milk tokens, collection/delivery service, complaints, and ethnic labelling.

Question 5 Has your FHSA taken any action with regards to any of the following in Community Pharmacy?

Table 8.2 FHSA action in Community Pharmacy

Pharmacist Activity	FHSA A	Activity
	Number(53)	Percentage
Referral forms from a pharmacy to		
a GP after a diagnostic test	6	11
Referral forms from a pharmacy to		
a GP for patient's symptoms	20	38
Compliance aids for patients	17	32
Availability of disability aids to the public	9	17
Domiciliary medicine monitoring scheme	18	34
Aseptic dispensing services	0	0
Syringe/needle exchange scheme	50	94
Display of health education leaflets	50	94
Instalment dispensing arrangements	5	9

Other action in relation to community pharmacy included 6 references to health promotion, 2 to a dump campaign, and one each to a pharmacy charter, opening hours, expensive prescriptions, prepayment certificates, adverse drug reactions, and post graduate students.

8.4.2 Question 6 Computer questions

Ouestion 6.1

The mean number of pharmacies in any one FHSA area was 112.6; median 100.

Question 6.2

71% of these pharmacies kept PMRs according to the knowledge of Pharmaceutical advisers.

Question 6.3

96% of these PMRs are kept on computer.

Question 6.4

PMRs are mainly used for repeat prescription handling in 75% of cases.

Question 6.5

The mean number of GP practices in the FHSA areas was 118.3, median number 87.

Question 6.6

No GP practice has a computer connection with a community pharmacy.

8.4.3 Question 7 Health screening

Question 7.1

Pharmaceutical advisers rated the value of the pharmacist's provision of diagnostic testing as average, with a mean value of 2.7; median of 3.0, where 1 is very low and 5 is very high. Only 14 of the 53 (26%) advisers rated the pharmacist's role as high or very high.

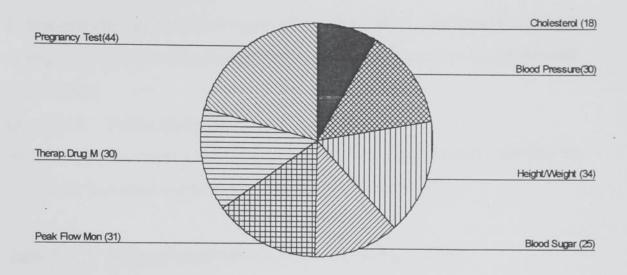
Question 7.2 As part of an integrated service by pharmacists to the public, how do you rank the following diagnostic testing services?

Table 8.3 Relative ranking of diagnostic testing services

Service	Rank Percentage	
Pregnancy Testing	83	
Height/Weight	64	
Monitoring of Pulmonary Function	59	
Therapeutic Drug Monitoring	57	
Blood Pressure	56	
Random Blood Sugar	48	
Total Serum Cholesterol	34	

Figure 8.1 shows the considered importance of one diagnostic test relative to another.

Figure 8.1 Relative Importance of Diagnostic Tests



Question 7.3 Please indicate at what charge pharmacists should provide these services to the public.

Table 8.4 Suggested charge for diagnostic services to public

Service	No	Nominal	Economic	
		Charge		
Total Serum Cholesterol	2	12	39	
Blood Pressure	8	20	25	
Height/Weight	20	20	13	
Random Blood Sugar	4	18	31	
Peak Flow Measurement	19	18	16	
Thearapeutic Drug Monitoring	11	14	28	
Pregnancy Testing	1	9	43	

Question 7.4 How many GP practices in your area offer the following tests, other than opportunistically, free of charge?

47 Pharmaceutical advisers did not know whether GPs offered cholesterol, blood sugar or pregnancy tests. Six stated that GPs in their area offered these tests opportunistically free of charge.

8.4.4 Question 8 Health promotion

Please rate the pharmacist's involvement in the following health promotion activities, on a scale of 1 to 5 where 1 is not at all involved and 5 is very involved.

Table 8.5 Rating of pharmacist's involvement in health promotion

Activity	P A Rating (p	Plus	
	Now	Future	Change(%)
Smoking Cessation	48	90	42
Alcohol Intake	19	60	41
Diet and Nutrition	33	75	42
Pregnancy	42	70	28
Exercise	22	62	40

Using the Wilcoxon matched pairs signed ranks test, a significant difference was seen (z = 5.63, p<0.00001) between the rating of smoking cessation involvement today (58% support) and in the future (92%).

A significant difference was seen (z = 5.44, p<0.0001) between the rating of alcohol intake advice today (35%) and in the future (68%).

A significant difference was seen (z = 5.71, p<0.00001) between the rating of advice on diet and nutrition today (47%) and in the future (80%).

A significant difference was seen (z = 5.16, p<0.00001) between the rating for pregnancy advice today (54%) and in the future (76%).

Finally, a significant difference was found (z = 5.37, p<0.00001) between counselling on exercise today (38%) and in the future (70%).

The practical significance of the inferential statistics is that one can be reasonably confident that the population from which the sample was drawn would generalise to a wider representation of FHSAPAs, and the significant difference between the two values indicates a greater belief in a projected future role.

8.4.5 Question 9 GP Formulary development

Question 9.1 Are any pharmacists in your area involved with GPs?

Table 8.6 Involvement of Pharmacists with GPs

Involvement	Frequ	iency	
×	Yes	No	Don't Know
1. Prescribing advice	44	6	3
2. Drug usage guidelines & treatment			
protocols development	25	19	9
3. GP practice formulary development	42	6	5

Question 9.2 A mean number of 9.63 GP practices per area are involved with pharmacists, median value 5.0, in this way.

The mean number of pharmacists involved was 5.88, median figure 4.0.

Additionally, there were other ways in which GPs collaborated with pharmacists:

1. the impact scheme, and 2. inequivalence.

Eight out of the FHSA pharmaceutical advisers were offering prescribing advice to GPs.

Question 9.3 Cost savings as a result of pharmaceutical input was found in 30% of cases, but not in 38% and 32% did not know.

Question 9.4 Can you list up to 3 examples of more appropriate prescribing due to pharmaceutical intervention?

Table 8.7 Examples of more appropriate prescribing due to pharmaceutical intervention

Intervention	Times mentioned	
Medication spectrum appraisal	29	
Generic substitution	23	
Drug delivery systems	14	
Cost -effective prescribing	14	
Reduction of range of drugs	9	
PACT data	9	
Reduction in prescriptions for anxiolitics	6	
Reduction in quantities prescribed	4	

8.4.6 Question 10 GP-Pharmacy Liaison

Question 10.1 The patient would be best served if repeat dispensing were administered by pharmacists.

There was an 85% agreement with this statement.

Question 10.2 There would be significant cost savings to the NHS if pharmacists managed the repeat prescribing for patients.

There was a 74% agreement with this statement.

Question 10.3 It would be cost-effective for the NHS to employ a pharmacist to work alongside GPs in a group practice to manage their repeat prescribing and diagnostic testing.

There was an 83% agreement with this statement .

Question 10.4 By 2000AD, the pharmacist should select the medicine and dosage within agreed protocols following medical diagnosis or assessment.

There was a 57% agreement with this statement.

The chi-square test confirmed agreement with all four statements (see Table 8.8)

Table 8.8 Summary of Statistics applied to Responses to Question 10

Question	χ^2	df	p <	
10.1	27.23	3	0.00001	
10.2	16.51	3	0.001	
10.3	28.74	3	0.0001	
10.4	17.41	4	0.005	

Figure 8.2 shows this response for all four parts of this question.

5 . 5=strongly agree--1=strongly disagree 3 • O38 Medication Selection Cost Savings To NHS Working in G M P Repeat Dispensing

Figure 8.2 GP-Pharmacy Liaison

Pharmacist Activity

n = 53

8.4.7 Question 11 Remuneration

Question 11.1 As part of pharmacists future remuneration for any new services is to be devolved locally, please rate the following list which may affect the direction of community pharmacy development (see Table 8.9).

Table 8.9 Rating of new services as part of pharmacist' future remuneration

Item	Service	Position	%age Rating
6	Domiciliary visits	1	82
4	Patient medication records	1	82
11	Advice to Nursing homes	3	79
2	Health promotion eg smoking	4	75
5	Residential homes medicine supply	5	74
9	GP Formulary development	6	72
10	Analysis of PACT data	7	70
8	Needle and syringe exchange service	8	68
7	Monitored dosage system	9	62
1	Health education leaflets	10	55
3	Health screening eg blood pressure	11	46

These results indicate the adviser's view that those services that involve direct contact between pharmacist and patient should preferentially attract remuneration.

Question 11.2 How much, as a percentage of the global sum, should be set aside for remuneration of these extra services?

The adviser's mean estimate was 25.9%, with a median figure of 20%.

Question 11.3 The two-pharmacist pharmacy is not generally an economic viability in a free market situation.

There was not a significantly distinct contention for or against this statement, 43% of advisers agreeing and 49% disagreeing with this premise $(X^2 9.55, df = 4, p>0.05)$.

8.4.8 Question 12 Location

Assuming that pharmacists' response to this new role of contributing to primary health care needs by offering a wider range of services, from which outlet do you think this can best be performed? (See Table 8.10)

Table 8.10 Type of pharmacy best suited to primary health care needs

	Type of pharmacy	Suitability (%age)	n = 53
1	Independent pharmacy outlet	70	
2	General medical practice	73	
3	Health centre	82	
4	Multiple chain chemist	52	
5	Supermarket pharmacy	29	

Question 13 Does your FHSA employ a pharmacist facilitator to co-ordinate the pharmaceutical contribution to pharmacy healthcare?

FHSAs employed pharmacist facilitators in 21 (40%) of cases and there is an intention to so do in four other areas.

Question 14 The future is for two types of pharmacy: one which provides the traditional spectrum of pharmaceutical supplies to the local community, and the other either in or near to a health centre which concentrates on dispensing and healthcare. There was no significant difference between those agreeing and those disagreeing with this statement ($X^2 = 8.04$, df = 4, p>0.05). 27/53 (51%) advisers agreed or strongly agreed with this statement.

8.4.9 Question 15 Patient-orientated health care

Please rate the influence of a list of factors which may inhibit the development of patient orientated pharmaceutical care (see Table 8.11)

Table 8.11 Rating of factors which may inhibit the development of patient-orientated pharmaceutical care

	n = 53	Factor	Percentage Score
1	Single pharma	cist pharmacies	80
2	Pharmacists no	ot accepted as a member of PHCT	68
3	Need for phar	macist to supervise dispensing etc	64
4	Pharmacist' lac	ck of access to patients' medical note	es 63
5	Pharmacists no	ot in GP practices	55
6	Historical non-	rational distribution of pharmacies	54
7	Contract limita	ation	45
8	Out of town sl	nopping malls with superstore pharm	nacies 42
9	Contractors ho	ours of opening	34
10	Freedom to or	en a pharmacy anywhere	29

8.5 DISCUSSION

8.5.1 Pharmaceutical adviser data

Most FHSAs had employed Pharmaceutical advisers (PAs) for only three years, at the time of the survey in 1994. The involvement of pharmacists alongside medical advisers has helped to confirm the relevant expertise which they have to offer to the prescribing process and to the containment of prescribing costs. Over 80% of PAs attend LPC meetings.

Advice to Community Pharmacists

PAs offer advice to pharmacists, especially with respect to new roles which involve

Health Authority initiatives and remuneration, eg PMRs. Brent and Harrow PAs have

been concentrating on: (1) medication advice to residential homes staff,

and (2) medication disposal arrangement, a focus reflected

by over 80% of PAs in the UK.

Although only 36% FHSA respondents were active in advising on provision of domiciliary services to housebound patients by pharmacists, a recent survey reported that 97% were in favour of the service being introduced immediately or in the short-medium term. ¹⁵¹This survey further indicated that 96% PAs were in favour of pharmacies acting as centres for the disposal of unwanted medicines. Community pharmacists had a convergent opinion, 89% agreeing with this recommendation. ¹⁵¹Action in Community Pharmacy

The two most active areas are:

Health education leaflets and

Syringe/needle exchange.

This is reflected in B & H where pharmacists are required to display eight health education leaflets, chosen from an extensive list selected by the FHSA, plus a pharmacy practice leaflet, in order to qualify for the practice allowance. Other leaflets can be distributed, as long as a core selection of the main categories is stocked. Pharmacists are highly receptive to the element of provision of health advice, but see leaflet distribution as passive. Their opinion is that it is the first stage in the development of activities dovetailing with the work of health promotion units, so that pharmacists would be recognised to advise individual customers on diet and lifestyle and give talks to local community groups.

B & H operate a syringe/needle exchange scheme on an independent basis through the Drug and Alcohol Centre, and successfully distribute through participating pharmacies. FHSAs widely accept this recommendation, but community pharmacists are reluctant to get involved in exchange schemes because of the stigma attached to intravenous drug users. ¹⁵² In practice, however, despite this low level of acceptance (58%) by community pharmacists, the selected pharmacies make the implementation of the service viable.

There is presently little action concerning referral documents, and pharmacists are not fully supportive of the concept, apprehensive that the completion of such forms could be time consuming and of little value. The potential is there for pharmacists and GPs to work together more closely, and the RCGP accept the concept. In fact, in one trial of a referral system, the forms were well received by patients, doctors and pharmacists. 153

Patient compliance aids is an accepted recommendation, but there is little activity, as, although 90% of community pharmacists would be willing to dispense compliance aids, only 30% would be prepared to do so if payment was not forthcoming. 154

Aids for disabled people is a concept that does not need FHSA activity. There are sufficient pharmacists interested nation-wide who are willing to offer a comprehensive provision of aids and equipment. Market forces will determine the optimum distribution of this service.

GPs, district nurses and consumers support a domiciliary medicine monitoring scheme. 155 Pharmacists would be only too pleased to supply and fill prescriptions, and counsel on the use and storage of medicines if remuneration were forthcoming.

Aseptic dispensing is not a function that is in demand in community pharmacy.

Instalment dispensing is in its infancy, and only realised in methadone supplies to addicts at present. The benefits of this activity are that:

- 1. the amount of money spent on medicine that is not needed would be reduced,
- 2 pharmacists would have more contact with patients and therefore have more time to improve their understanding of medicines,
- 3. paperwork for GPs would be reduced,
- 4. the risk of accidental poisoning in the home would be reduced with the reduction of unnecessary medicine, and
- 5. pharmacists would have the opportunity to play a more active role in the primary health care team.

A number of pilot projects to assess the value of repeat and instalment dispensing will begin in England in April 1996. 156

8.5.2 Computers

There are at least 100 pharmacies in most FHSA areas, confirming the important nature of the PA's work and responsibility.

Advisers were aware that over 70% of the pharmacies keep PMRs, of which more than 95% are computerised. This compares with returns from the Royal Pharmaceutical Society's Inspectorate in 1992, which showed that 73% of all pharmacies surveyed were using computerised PMR systems, ¹⁵⁷ and with the survey by Jepson in 1991

which showed that 77.5% of his sample were maintaining PMRs. ¹⁵⁸The estimate by the advisers, as it is more recent, would be expected to be higher than that of Jepson, but the latter's survey was limited to 293 pharmacies only, and not covering such a wide geographical area.

The figure of 75.5% for patients with regular repeat prescriptions for whom PMRs were kept, accorded with a national survey conducted by Rogers whose finding was 77.4%. 159

The mean number of GP practices approximated to the number of pharmacies, except in some City urban areas, eg London, where there is an excessive number of pharmacies compared with the number of medical practices. There is scope for a more rational distribution of pharmacies to better serve the public and enable all patients to be adequately counselled.

There is no arrangement in the UK at present for a computer connection between a GP surgery and a community pharmacy. This is something that needs to be addressed, especially if pharmacists are to become fully involved in the 'repeat prescribing process'. Pharmacists should, then, have access to comprehensive patient information data, and unnecessary duplication of records in the practice and the pharmacy would be avoided. Assuming the continued development of computer technology, a comprehensive electronic data exchange between providers of healthcare would be feasible by the year 2000. The computer would have to be sophisticated enough to allow the pharmacist access to the patient's medication history and details of relevant clinical conditions, provided confidentiality was assured. A first step could be to include a diagnosis on the prescription to match the medication prescribed.

8.5.3 Health screening

There was a neutral response to the value of the pharmacist's role in health screening by the provision of diagnostic testing services. As the pharmacy project results show (Chapter 3) extension of diagnostic testing and screening of patients is still in its infancy. Pharmacists are not certain whether this is a route along which the consumer wishes them to go, and there is uncertainty regarding the time and cost rationale. However, developments in healthcare technology will expand the applications of diagnostic tests, and pharmacists are well qualified to seize the opportunity offered by this scientific revolution, which will lead to automation and miniaturisation of these tests. Their role in preventative health care will become increasingly important, so that it is vital for pharmacists to contribute.

A recent FHSA and community pharmacist survey indicated that 78% of pharmacists appear to be keen to take on diagnostic/screening services, wheras only 45% of advisers were supportive. Surveys of GPs and district and practice nurses support the opposition of the RCGP to the provision of this service by pharmacists, arguing that the tests are arbitrary and intermittent. As the author has found, the pharmacist would be best advised to set up this service after local agreement or prior consultation with other health professionals, and this would take place ideally in the general medical practice, when the public would welcome the pharmacist involvement and interprofessional relationships would be strengthened.

As part of an integrated service, pregnancy testing, and weighing, which have been available for several decades, are still considered to be of value by the public. Blood pressure measurement and monitoring of pulmonary function both received good support. Because of the high number of prescriptions for antihypertensives and asthma medication, it was thought worthwhile to offer these services. Of the invasive techniques, TDM was well considered because of its potential, while STC and RBG testing received a vote of less than 50%. As stated, STC testing has experienced a reduction in popularity, and the response to RBG testing was a disappointment in the PSNC study.

Investment in equipment and materials was the criterion for PAs to recommend an economic charge to be made. A nominal or no charge fee structure was recommended for PFM and BMI measurement.

There is little record of what diagnostic tests are generally available at GP surgeries, and there is therefore a great potential in the pharmacist ascertaining the demand and facilitating a health screening service, particularly to fundholders.

8.5.4 Health promotion

The Government strategy document 'The Health of the Nation,' aims to 'add years to life' and 'life to years'. ²⁴ The plan to effect this aim encourages appropriate changes in people's lifestyle, focusing on smoking cessation, alcohol intake, diet and nutrition, and exercise. Health in pregnancy will benefit from action on all these behaviours, and education to expectant mothers will ensure improved health for both mothers and babies. PAs gave a neutral rating for pharmacists' involvement in these activities for the present, but are optimistic of a more active involvement in all cases in the future. It will be essential, therefore, for pharmacists to have an infrastructure for this role of supporting and encouraging people to a healthier lifestyle. Pharmacists will need some additional training to extend and develop their knowledge and communication skills.

8.5.5 GP Formulary development

Responses were encouraging about pharmacist-GP liaison, especially in relation to the giving of prescribing advice and the development of formularies. This must be tempered by the fact that approximately 10% only of GP practices and 5% of pharmacists are active in formulary collaboration. Further, in many FHSA areas, the pharmacists working on GP formularies are not practising community pharmacists but are pharmacists recruited for that purpose, according to the replies from the PAs. Future pilot studies should incorporate an input from the community pharmacist, in order to estimate the true cost benefit of such collaboration.

One project, known as the Impact (independent monitoring of prescribing costs and trends) scheme, has recently been set up and is based on the premise that the most effective way to influence GP prescribing is through one-to-one interview. ¹⁶¹ The Impact programme uses teams of specially trained community pharmacists as outreach workers who run three campaigns each year, each covering one therapeutic area; payment is now provided by the new Health Commissions.

The main example of more appropriate prescribing is the reappraisal of the medication spectrum, throughout the therapeutic classifications, leading to more rational prescribing and a reduction in the range of prescribed medication. The pharmaceutical view is that there is considerable value in the pharmacist's involvement before the prescription is written.

Attention to generic substitution is a major example, of the Government's determination to cut the NHS drug bill. However, generic prescribing should not prevent patients receiving alternative treatment, which though more expensive, may be more efficacious. Research into new drugs and the future availability of more effective remedies is dependent on a vigorous and successful pharmaceutical industry. Pharmacists can be of value to GPs in making critical, independent evaluations of recently introduced medicines.

8.5.6 GP pharmacy liaison

There was strong support for repeat dispensing to be administered by pharmacists, and over 85% of PAs agreed with this contention.

Over 73% of PAs thought that this would lead to significant cost savings to the NHS, and 83% of respondents thought that it would be cost effective for pharmacists to work alongside GPs in a general medical practice. The consensus is that there would be a positive synergistic effect if pharmacists and GPs practised alongside each other in the same workplace. The profession seems united in considering that pharmacists have a direct responsibility for managing repeat prescribing and contributing to diagnostic

testing. As confirmation that this is the direction pharmacists should take, 57% (31/53) were in agreement that pharmacists were capable of proceeding to a further stage, and should select the appropriate medication and dosage following a medical diagnosis or assessment. Suitable pilot studies should be initiated in order to test the feasibility of this activity. Inter-professional barriers would have to be overcome for this activity to become a reality. Only 18% of GPs questionned in Jepson's research (1992) had a preference for pharmacists to be in health centres. ¹⁵⁸

8.5.7 Remuneration

PMRs. Greater use of PMRs was strongly supported as part of future pharmacy remuneration packages. PMRs are now an essential, integrated component of community pharmacy, but, at present, the remuneration level is far below the cost of updates for the computer programme, notwithstanding the initial cost of equipment. Domiciliary visits were considered to be highly important. There is much work to be done in this area in order that the patient receives improved pharmaceutical care, and the pharmacist's contribution is properly compensated. Initiatives have taken place to address patient adherence and medication disposal, but, at present, domiciliary visits are commonly no more than glorified collection and delivery services. 162 Advice to Nursing homes. FHSA personnel in Brent and Harrow are concerned that the current budget is insufficient to finance pharmacist advice to nursing homes. However, many of the new nursing home enterprises belong to nation-wide networks, who have contracts for supply with one large company. This virtual monopoly effect precludes many independent pharmacists from contributing effectively. This situation could be resolved if a Health Authority limited pharmacists to have responsibility for no more than five homes.

Health promotion was also strongly recognised by the PAs, which supported the experience and data collected during this project (Chapters 3-6), that people

responded receptively to health advice on all aspects of lifestyle. The crucial issue is to translate this activity into a system of remuneration.

Medicine supplies to residential homes was strongly recognised as important. The current payment is not commensurate with the time and costs involved of a service which must do more than simply supply. Residential care homes are now insisting on the provision and use of a monitored dosage system for their patients, together with a weekly collection and delivery service. The author's experience has confirmed that, initially, such a system will cost at least £30 per patient, therefore a 60 patient home will need a £2,000 investment to set up, and due to the competition within pharmacy, the pharmacist cannot ask the home to contribute towards any of these costs. Further, the dispensing units have to be filled weekly, whereas prescriptions are normally made out for 28 days; these, too, have to be requested and collected. Therefore, in practice, one fee is obtained for every four dispensings. If pharmacists operated the repeat prescription system, they could arrange for a 7-day repeat programme and make the service viable, or change the system of remuneration.

GP formulary development was recognised as an important direction for pharmacists to fully utilise their knowledge of drugs.

PACT data analysis was also considered to be an equally important aspect for pharmacist involvement and influence on prescribing. Currently, very few pharmacists are fully cognisant with PACT, and like most doctors have insufficient time to analyse the data. Pharmacists could contribute potential savings to the NHS by cooperating with GPs. Allying PACT analysis with formulary development could make practices more efficient and profitable.

Needle/syringe exchange services are currently financed locally, and it is an essential service for the growing problem and number of addicts in the UK. In some areas there are still too few pharmacies operating this service, as there is understandable concern

that the addict may cause disruption in the pharmacy and deter other members of the public. However, the system is considered to help contain the spread of AIDS among addicts who inject and spread the disease to others. Some other European countries, such as France, have been sufficiently impressed and are now proceeding along similar lines.

Monitored dosage systems received good support. They are popular with staff at residential care homes as they remove responsibility for correct medication administration, particularly away from relief personnel, and release time for other work. Health education leaflet distribution is low on the list of priorities. Pharmacists see it as a collection service by customers, a process in which they are not normally consulted. A video presentation could be a more effective method of conveying education material. Health screening is seen as the least likely source of remuneration. There is a future for pharmacists in this field, in a GMP where diagnostic test results would be co-ordinated.

The majority of advisers thought that 20% of the global sum should be set aside for these services. The author believes that if new activities contribute to a saving in the health service budget, then pharmacists should be paid in proportion to the reductions in costs, in order to encourage them to participate. New services must attract new money, so that pilot studies must convince the new Health Authority of the relative cost savings. 12

There was a mixed feeling concerning the two-pharmacist pharmacy, 49% disagreeing, but on the grounds that at present it was not an economic viability. This is surprising as those in community pharmacy recognise that extended role activities really necessitate two pharmacists. You cannot do a cholesterol test and supervise the sale of ibuprofen at the same time. Currently, a second pharmacist is not an economic reality, other than in larger outlets where there is a more regular flow of prescriptions, adequate support staff and customers buying P medicines.

.8.5.8 Location

FHSA PAs believe that pharmacists can integrate into the PHCT most easily in a health centre (HC), or a GMP. There was less support for this to happen in a multiple chain chemist and less than 50% thought the supermarket pharmacy lent itself to PHC activities. Much of the work embodied in this thesis (Chapters 3-6) has indicated that a pharmacist can only satisfactorily effect many of these professional activities in a HC or GMP. The independent, individual chemist, by virtue of a personalised approach, is able to be more effective than those in most multiple and supermarket outlets in GP formulary development, analysis of PACT data and prescribing advice to GPs. Other extended role services, such as health promotion and nursing home advice, can be just as well done in or from the larger multiples, where they have staff specifically selected for the purpose.

A future possibility would be to have a facilitator pharmacist who could harmonise health promotion and other extended role activities. The current situation is that independent pharmacists are tied to their pharmacies and find difficulty in devoting time to new services, especially outside the pharmacy. The facilitator could orchestrate cooperation between all the pharmacies within the geographical orbit of any one GMP to harness resources for any particular service, eg a dipstick distribution from pharmacies to clients to identify any undiagnosed diabetics in an area, with an agreed protocol for reference back to the doctor.

The Future Pharmacy

Just over 50% of respondents agreed to some degree that there would be two types of pharmacy in the future. This ambivalence is no doubt due to the uncertain nature of what role the community pharmacist will play in the new NHS. It could be that some pharmacies will continue, as at present, in a commercial direction, providing an increasing spectrum of pharmaceutical supplies to the local community and enveloping

the established extra roles of health education leaflets, PMRs, MDSs, domiciliary visits, needle/syringe exchange, advice and medication to residential care and nursing homes. Individuals who are more clinically orientated will integrate with a HC or GMP and become practice pharmacists, encompassing health screening, health promotion, GP formularies, PACT analysis, prescribing advice and repeat dispensing.

8.5.9 Patient-orientated health care

The single most important factor inhibiting the integration of the pharmacist into the PHCT and making a more pro-active contribution to pharmaceutical health care is considered to be the *single pharmacist pharmacy*. The pharmacist, running a pharmacy on his own, has to prioritise his time on issues which are remunerated, such as the dispensing function, supported by the day to day operation of the business.

Contingent with this is the *need for pharmacists to supervise all dispensing* and the sale/supply of pharmacy only medicines. Even in larger pharmacies, where there is more than one pharmacist, the pressure, on supervising dispensing and monitoring pharmacy only sales, leaves little time for attention to other aspects of patient-orientated pharmaceutical care.

Pharmacists not accepted as a member of the PHCT is next as a major influence. As long as pharmacists remain closeted in their dispensaries, they will be isolated from the mainstream of community health care. Doctors see nurses more as members of the PHCT than pharmacists. Once doctors and nurses work with a pharmacist and come to appreciate his knowledge and competence, a partnership can be forged that will contribute uniquely to the PHCT. The pharmacist throughout his study, has been able to work with nurses for the mutual benefit of the practice and patients.

Lack of access to patient's medical notes follows as another factor which has an inhibiting influence on progress. Knowing the medical history of a patient enables the pharmacist to counsel more efficiently, and this can generally only be practically effected within the medical centre environment at present. If the pharmacist is to manage repeat

prescribing and do health screening, access to some aspects of medical notes will be essential. During the major part of this research project, I had authorisation to use the practice computers and was free to access patient's notes, as GPs were completely confident that I would respect confidentiality. In a recent survey, GPs were averse to pharmacists having such access, but this seemed to be because they view pharmacists as outsiders to their day to day environment. They do not consider that the dispensing pharmacist needs access to patients' notes, only, perhaps, the answer to a telephone enquiry regarding a prescription medicine. There seems to be an inadequate awareness of the current dispensing role and of a pharmacist's responsibility.

If a pharmacist were situated in a GMP, then access would no longer be a problem, and the GP would be able to benefit from the presence of another professional. GPs are keen, especially in fund-holding practices, to have a pharmacist alongside, and so shorten the lines of communication. Interviews with the GPs at the study surgeries has clearly indicated to the author the frustration and anger felt by many trying to cope with the ever-increasing burden of work thrust upon them by the NHS, especially in the policy of seamless transfer of health care from the hospital to the community. GMPs are becoming increasingly sophisticated clinical centres, offering more health care services, and the GP is central to this fast-moving treadmill. There is an opportunity, therefore, for the pharmacist to relieve some of the strain by becoming a flexible partner in patient care. Periodic visits to establish formularies and treatment protocols are not favoured by GPs, as the picture is continually changing, and someone permanently managing the drug costs and prescribing spectrum would be the preference. The dispensing function could be incorporated, as long as the pharmacist is not isolated, though there could be a conflict of interest unless pharmacist dispensing remuneration is drastically changed.

Historical non-rational distribution of pharmacies has some adverse effect. In some areas there appear to be too many pharmacies, so that some pharmacists are

underutilised. A complete restructure would be necessary to overcome this, placing some pharmacies at or near health centres to generate patient orientated pharmaceutical care and others in shopping centres with more business oriented aims.

Contract limitation is not seen as having a great influence. There are, now, too many clustered close to each other, leading to intraprofessional competition which can be counter productive. The answer might be a consortium of pharmacists with a facilitator co-ordinating the collaboration with the relevant practice.

Out of town shopping malls will not have a great influence as they concentrate on providing a rapid prescription and medicine supply. Their growing presence makes it all the more important for smaller, independent pharmacies to develop other health care functions to safeguard their financial and professional future.

Freedom to open a pharmacy anywhere is seen to have little influence on patient orientated pharmaceutical care. It would however enable pharmacists to open in locations best suited to the achievement of this aim. This could mean the demise of pharmacies in certain areas, unless they were able to relocate. In a scenario where the most suitable position attracted too many pharmacists, we would then revert to the situation of intraprofessional rivalry which would defeat the object of the exercise. Contractor hours of opening is considered by PAs to have little influence. Even with shorter opening hours the typical independent would not have more time to devote to health care activities, except domiciliary and homes visits. Most surgeries close at 6pm now, so that any service associated with them would have to take place between 9am and 6pm, and any health promotional activity would be unaffected by the hours of opening. The 'longer hours' situation developed as a result of too many pharmacies chasing too few prescriptions, and the community pharmacist created a situation where FHSAs were able to withdraw rota payments as unnecessary. The pharmacist resource could be far better utilised during normal hours in health education and prescribing advice, if the payment focus were moved away from prescriptions dispensed.

8.6 Conclusions

- FHSA pharmaceutical advisers are the link between the community

 pharmacist and Health Authority. Although there is room for improved liaison,
 advisers have been actively engaged in supporting pharmacists, particularly
 advising on services that attract payment.
- For those pharmacies not situated within the precinct of a general medical practice, a major breakthrough would be to develop computer links between GPs and community pharmacists.
- Outside of the health centre, where single tests will continue to be commanded for specific conditions, community pharmacies will respond to consumer expectations by offering a medical MOT consisting of a number of linked diagnostic tests.
- At present, GPs are more favourably disposed to pharmacists giving health promotion than doing health screening. GPs do not see a conflict of interest with reference to health promotion, whereas health screening by the pharmacist may be seen as competition for remuneration. Considerable numbers of customers pass through pharmacies every day, thus pharmacists can help to ensure the Government meets its 'Health of the Nation' targets.
- FHSA advisers feel that it is essential that pharmacists wishing to give prescribing and formulary advice to GPs do it through their auspices. In this way, pharmacy will present a united front and they will be trained in order to provide expert advice. A facilitator pharmacist could provide the necessary bond.
- There is an overwhelming consensus of opinion that pharmacists must move from the traditional picture and emphasis of a supply function to that of ultimately initiating the prescription in pharmaceutical care.
- Remuneration is a vital element to the evolution of any future role for

- pharmacy. Pharmacists should be paid in real terms for any health care service provided, and cannot continue to countenance loss making procedures such as MDS supplies to Residential Care Homes. A second pharmacist could only be justified on the basis that extra money was forthcoming for the new services provided.
- Two different classes of pharmacist may evolve, one fulfilling a clinically-orientated function, and the other continuing in a supply and medicine sales role. The clinical pharmacy role needs to develop to the extent where the pharmacist would have a greater inventory of more effective medicines to sell than is currently the case. This would mean the pharmacist would be able to successfully treat minor ailments and be in a position to refer the patient to his general medical practitioner if unable to prescribe a suitable treatment, which is not happening at present. Pharmacists would have to attend additional postgraduate courses in order to prescribe drugs in the new category.
- Pharmaceutical advisers confirmed that the 'single pharmacist pharmacy' and the 'need for pharmacists to supervise dispensing and OTC medicines sales' were the biggest factors inhibiting the development of greater patient orientated pharmaceutical care. Pharmacists, with more flexibility, and less restricted by these core activities, would then be able to demonstrate their greater value to the public and to other health care professionals. Knowledge of diagnostic information relevant to prescribed medication would accelerate the pharmacist's acceptance by GPs as a more useful contributor to the PHCT.

CHAPTER 9

QUESTIONNAIRE TO PSNC STUDY PHARMACISTS

9.1 INTRODUCTION

A pilot study was carried out by the Pharmaceutical Services Negotiating Committee(PSNC), into the feasibility of providing a cholesterol testing service from community pharmacies and the level of public demand for such a service. PSNC is the body which negotiates the remuneration system for NHS pharmaceutical services. Seven community pharmacists took part in the 12-week study, in 1989. They received training on the test procedure, how to counsel clients on the test results and on other risk factors for coronary heart disease, and when to refer clients to their general practitioner. The results indicated that pharmacy cholesterol testing was feasible and that there was a considerable demand for the service. 2171 tests were carried out during the 12-week period, which represented an average of 26 tests per pharmacy per week. The seven pharmacies taking part were from the suburban areas of Coventry, Sheffield, Nottingham and Newcastle-upon-Tyne. All of the pharmacists who participated in that study stated that they intended to continue the cholesterol measuring service. ¹⁶⁴

Two years later, a nation-wide trial was then set up to look at the role of the community pharmacist in screening for diabetes. The PSNC felt that the training and expertise of pharmacists, and the convenience of access to pharmacies by the public, would provide a professional and easily accessible screening service which could help identify some of the undiagnosed diabetics in Britain. Study objectives are listed in 1.6.2.

The three month study involved 30 pharmacies in England and Wales which offered a blood glucose testing service. The results of the trial were disappointing: 312 measurements only were made at the 30 pharmacies during a 12-week period, and only eight people were referred to their GP. 13

9.2 AIM

It was considered appropriate to ascertain the response experienced by these pharmacists to the offer of diagnostic testing, and their prediction for health screening as part of an extended role for community pharmacy. A set of questions were compiled for a questionnaire designed to collect information on:

- health screening possibilities
- · liaison by pharmacists with GPs
- relevant aspects of GP formulary development
- attitude to patient registration with a pharmacy and
- relevant audit

9.3 METHOD

9.3.1 Design of questionnaire

The survey questionnaire (Appendix 19), comprising a mix of open and closed questions, was sent to the 30 PSNC participating pharmacists, together with an accompanying letter (Appendix 20) and a reply-paid envelope.

9.3.2 Equipment

The programme SPSS 6.1 for windows was used to record results from returned questionnaires and for statistical analysis of the data.

9.4 RESULTS

A total of 20 (67%) questionnaires were returned within four weeks of issue.

9.4.1 Health screening

Question 1 Are you currently offering any diagnostic testing in your pharmacy?

All of the trial pharmacists still in practice are currently offering some diagnostic testing service in their pharmacy. The average time this occupies per week is one hour. All pharmacists are still doing pregnancy tests, but five have stopped cholesterol tests due to a waning public interest and two more pharmacists have stopped due to pressure of time (see Table 9.1).

Question 2 Which diagnostic tests do you offer, how many do you do per month and for how long have you offered them?

Question 2.1For which of these tests did you receive appropriate training?

Table 9.1 The history and uptake of the diagnostic tests

Test	Numb	er/month	Time	offered	Pharmacis	st Number
n = 20			(yea	ars) R	Receiving	Offering
	Mean	Median	Mean	Median	Training	Test
Cholesterol	1.3	1.0	2.95	3.5	15	13
Blood Pressure	4.8	2.0	5.05	6.0	9	13
Pregnancy	13.0	11.0	12.15	12	5	20
Random Blood Su	gar 0.5	0	1.2	0	12	9
Therapeutic Drug	0	0	0.3	0	3	3
Monitoring						
				-12		

Question 3 On a scale of 1 to 5 how do you rate the following diagnostic testing as part of an integrated service?

Question 3

Table 9.2 Relative ranking of diagnostic tests in an integrated service

Test	Sum of Scores
Pregnancy	83
Blood Pressure	69
Cholesterol	61
Random Blood Sugar	48
Therapeutic Drug Monitoring	42

Question 4 Which of this list of services do you think gives the pharmacist most prestige, in the eye of the public?

Question 4

Table 9.3 Percentage vote for which test gives pharmacists most prestige,

in the eve of the public.

in the eye of the paone.	
Test	Prestige %age
Cholesterol	30
Blood Pressure	10
Pregnancy	10
Random Blood Sugar	0
Therapeutic Drug Monitoring	10
Cholesterol/BP Combination	20
All Diagnostic Tests	20

Question 5 Since you have introduced the service, how have the number of BP and STC measurements you take, changed?

Question 5

Table 9.4 Change in response for BP and STC since the service was introduced.

Test	Mea	surement Freq	uency
n=16	Increased	Same	Reduced
Cholesterol	0	2	14
Blood Pressure	4	5	7

Question 6 How much do you charge, per test?

The average charge per test (to the nearest 50p) was £1 for blood pressure measurement, £8 for total serum cholesterol, £5.50 for pregnancy testing and £5.50 for blood sugar estimation.

Question 7 Do you offer a special price per person for a combination of tests?

45% of respondents stated that they offered a special price per person for a combination of tests.

Question 8 Why have you chosen to do diagnostic tests?

Table 9.5 Relative ranking for reasons to do diagnostic tests.

Reason	Ranking Score
Interest	78
Completeness of health care	71
Prestige	60
Stay ahead of competition	53
Public demand	53
Involvement with GPs	51
Extra Income	44

Question 9 Do you consider that you influenced any patients to change their lifestyle, following health screening?

85% (17/20) of pharmacists considered that they influenced some patients to change their lifestyle, following health screening, at an average estimate of 18 people per year. Smoking cessation and diet changes were the two most frequently stated aspects of health gain.

Question 10 Have you offered health screening as a paid service?

Six pharmacists have offered a health screening service to GP fund-holders and two pharmacists to a health agency or FHSA.

9.4.2 Liaison with GPs

Question 11.1

18 pharmacists (90%) informed their local GPs on first starting health screening.

Question 11.2

An average of 8 GP practices per pharmacy were informed.

Question 11.3

10 pharmacists informed GPs by letter, three by telephone and five by a visit.

Question 11.4

67% of GPs were agreeable to the inception of health screening at the pharmacy.

Ouestion 11.5

50% of pharmacists reported some small improvement in relationship with the local GPs as a result of health screening.

Question 11.6 Do you consider health screening can be best operated in the setting of a general medical centre by a practice nurse?

55% (11/20) thought a pharmacist would be best, but the practice setting was not clear, and 35% (7/20) of respondents thought that health screening would be best operated by a practice nurse in a general medical practice. The remaining two stated that collaboration between nurse and pharmacist would be best.

Reasons for a nurse to do health screening were:

- ready availability of the doctor
- free health screen within the NHS

- · hospital laboratory facilities available when necessary
- private facilities
- time element as compared to pharmacist
- GPs perception of the pharmacist
- practice nurses may be more economic

Preference for a pharmacist was because of:

- ready access to the public, without an appointment
- pharmacist's technological knowledge and expertise
- high risk people can be targeted, where a pharmacist is familiar with the person and prescribed medication
- opportunistic nature of health screening

Question 12 GP Formulary Development

Question 12.1

Table 9.6 Involvement with GPs

Do you get involved in giving GPs	Number	Percentage
1 Prescribing advice	16	80
2 PACT data advice	8	40
3 Drug usage guidelines and		
development of treatment protocols	8	40
4 GP practice formulary development	t 7	35

Question 12.2.1

Eight of the pharmacists, those giving advice on PACT data, visited the surgery to analyse the GPs prescribing.

Question 12.2.2

On average two GP practices were involved with each pharmacy.

Ouestion 12.2.3

Nine pharmacists (45%) had specific arrangements for an ongoing interprofessional service.

Ouestion 12.3

Reasons for not providing services of this nature to GPs included:

- finance
- no interest from GP
- time element
- inability to attend day-time practice meetings, as unable to leave the pharmacy
- distance of pharmacy from surgery

Ouestion 13 Prescribing Liaison

Question 13.1

There was an 85% (17/20) agreement that the pharmacist should manage a patient's repeat medication after the prescriber's initial diagnosis and prescription.

The chi-square goodness-of-fit test confirmed that a significantly greater number of respondents agreed than disagreed with this statement ($X^2=10.00$, df=3, p<0.05). This indicates that the bias in the population sample towards respondents stating a positive agreement with the premise would be repeated in the whole population from which the sample was drawn.

Question 13.2

60% (12/20) agreed to some extent that the pharmacist should recommend medication after a definitive diagnosis by the GP.

This represents the opinions of a small number of pharmacists, and was not statistically significant ($X^2=2.40$, df=3, p<0.5).

Question 13.3

For those that did not agree with this last premise, there was an equal distribution of votes for this to be accepted in 5 (6 votes), 10 (5) and 15 (5) years. Four pharmacists did not think this would ever be feasible.

Question 13.4

All agreed that pharmacists could select appropriate medication and dosage from an agreed therapeutic list.

Question 14

Table 9.7 Rating of desirability for specific involvement by a pharmacist in

speciality clinics

Clinic	Score Percentage
Asthma	78.5
Hypertension	64
Diabetes	58
Lithium	43
Family Planning	39

There was a firm support for pharmacists to become proactive in speciality clinics, particularly those where multiple medication is involved, such as asthma and hypertension. These 'trial' pharmacists commented that there is potential in other therapeutic areas, and that, if we continue to provide a supply function only, the profession is doomed.

9.4.3 Patient registration

9.3.3.1 Patient medication records (PMRs)

Question 15

Question 15.1

OTC medication information was contained on 60% (12/20) of PMRs.

Question 15.2

Not one pharmacy had a computer link with a GP practice.

Ouestion 15.3

The mean number of patients held on each of the 20 pharmacy PMR systems was 7692.

Question 15.4

Table 9.8 Pattern of PMRs in the trial pharmacies

PMRs kept	Number	Percentage
1 All patients presenting prescriptions	9	45
2 All patients over 60	17	85
3 Patients with chronic conditions	19	95
4 All patients under 12 years of age	13	65
5 All patients who have repeat prescri	iptions 19	95

Question 15.5

A very small number of patients, estimated at less than 1 in 300, did not give their permission for PMRs to be kept.

Ouestion 15.6

Five pharmacists thought GPs would be favourable to giving them access to patients' medical notes, two thought they would not be in favour, and 13 did not know or thought that some GPs might allow access.

Ouestion 15.7

'The patient's needs would be best met and the pharmacist's role consolidated if there was a formal system of patient registration with a pharmacy of the patient's choice' was a premise that was supported by 15 (75%) of the pharmacists.

9.4.4 Audit

Ouestion 16

16 pharmacists said that they intended to audit aspects of their service, three said that they had already done so and one was unwilling to do so.

Table 9.9.

Percentage interest in various model standards of professional practice.

Audit aspect	%age vote
1 The dispensing process	75
2 Written and verbal information with dispens	ed medicines to:
(a) all patients	25
(b) those taking specific medicines only	20
(c) patients in specific 'at risk 'groups only	15
3 Prescription items owing	55
4 NHS prescription items not allowed by PPA	30
5 Health promotion	55
6 Domiciliary service	45
7 Advice to residential and nursing homes	50
8 Response to symptoms	65
9 Guidance to relief pharmacists	35
10 Purchasing and stock control	55
11 Premises and equipment	35
12 Workload analysis to calculate optimum nu	ımber
of prescriptions dispensed by: (a) pharma	acist 15
(b) dispenser with pharmacist supervision	n 10

Other aspects specified were: • TV adverts

- POM to P products,
- Me-too products and
- Range of OTC medicines.

9.5 DISCUSSION

The response of 67% was considered very satisfactory, considering that four of the 10 non-respondents were no longer in practice.

9.5.1 Health screening

All 20 pharmacists were still involved in at least a pregnancy testing service. Five had dropped the cholesterol testing due to a waning public interest, and two more pharmacists had stopped due to the pressure of time, and the costly expense of maintenance and repairs to equipment. The fact that seven of these committed pharmacists no longer offer cholesterol screening is due to the limited demand and uneconomic nature of screening when full account is taken of the equipment, time and premises. It may be that the public are not aware of, or yet ready, in consistent, continuing numbers, to buy such services from community pharmacists, and do not see them as a leading source of advice on health promotion.

A majority of correspondents had received training for testing blood samples, as this was not something included in pharmaceutical education. Less than 50% had received or considered it necessary to have training in making blood pressure measurements. This may aggravate some opposition from the medical profession. B P measurements in the pharmacy are invariably made using automatic digital read out instruments, for which the pharmacist needs no additional skill, and GPs complain that the results given to patients are often misleading and too high which can result in unnecessary anxiety for the patient and time-wasting for the doctor. ¹⁶⁰ Pharmacists should liaise with their local medical practice and practice nurse and collate their instrument with the sphygmomanometer used at the surgery. Although pharmacists are not often

involved directly with family planning clinics, and despite the cost involved, pregnancy tests have, consistently, over many years, been the most frequent diagnostic test performed by pharmacists. They meet many women's need for a prompt and confidential result.

Not surprisingly, pharmacists thought that a pregnancy testing service rated highest as part of an integrated service, but also rated the value of blood pressure and cholesterol measurements at over 60%. Coincidentally, pharmaceutical advisers and pharmacists both valued pregnancy testing as an 83% rating and blood glucose measurement as 48% (Chapter 8.4.3). Only a little over a third of pharmacists were supportive of implementing a therapeutic drug monitoring service. Pharmacists are apprehensive that TDM will place a heavy burden of responsibility on them and entail specialised training. There is a need for a sustained study into the provision and benefits of such a service, its recognition and economic funding.

A distinct division appears in the pharmaceutical advisers assessment of the value of cholesterol testing (35%) and blood pressure measurement (56%) compared to that of the pharmacists, who valued cholesterol at 61% and blood pressure at 69% (Chapter 8.4.3), as summarised in Table 9.10.

Table 9.10 Assessment of the value of diagnostic tests

Diagnostic tests	Pharmaceutical advisers	Trial pharmacists
	Rating (percentage)	
	n = 53	n = 20
Cholesterol	35	61
Blood Pressure	56	69

The reasons may be due to the FHSA advisers' concern that adequate training is a prerequisite, and the lack of NHS remuneration. In its evidence to the Working Party on the Future of Community Pharmaceutical Services, PSNC recommended that community pharmacies should be included as centres for cholesterol testing and counselling, and that FHSAs should be encouraged to recommend community pharmacies for routine cholesterol and diagnostic tests. ¹⁶⁴ As consumers, in general, are not willing to pay, when many can be tested at their GP surgery at no charge, there can be little future for a comprehensive service unless it is properly funded.

Nonetheless, many pharmacists see cholesterol testing, either independently, or in combination with a blood pressure measurement, as giving the pharmacist most prestige in the eye of the public, possibly because it gives them the perception of a more clinical role. Under such circumstances they continue to offer such services as part of the wide spectrum of pharmaceutical care.

Most pharmacists reported that blood pressure measurement had reached a level of stable demand, whereas cholesterol testing had fallen away in almost every pharmacy. This reflects the author's finding in his research work (Chapter 3), and confirmed the view that initiatives involving blood cholesterol testing and treatment should attempt to control all risk factors rather than blood cholesterol alone. Pharmacists offering testing must liaise more closely with their local GPs and FHSA to ensure co-operation for the service, and the prospect that funding could ensue.

A national Scottish survey of community pharmacy services, in 1992, indicated that few of them are offering the new innovative services proposed in the official reports. The percentages of respondents (n = 903) offering cholesterol testing (1.2%), blood pressure testing (4.4%), and blood sugar testing (0.3%) was small. ¹⁶⁵ Geographical location may have some influence:

pharmacists (n = 85) questionned in a survey in Brent and Harrow, in 1994, checked cholesterol in 9.6%, blood pressure in 35.3%, and blood sugar in 18.1% of pharmacies. ¹⁶³

The trial pharmacists all charged an economic fee for the diagnostic tests offered. Higher fees were charged for cholesterol testing and monitoring of blood glucose levels, as these more sophisticated tests require a higher level of investment by the pharmacist. Nearly half the pharmacists offered a special price to those subjects requiring a combination of tests, which would also give the subject a clearer picture of their health status and should be of more value. As previously stated, these pharmacists are a special group, and their professional goals may outweigh their materialistic ones. Their interest in the completeness of healthcare ranked as the most important reason for choosing to do diagnostic tests. Additional income and staying ahead of the competition were the least important aspects recorded. If the gap between the pharmacist's interest and enthusiasm, and the demand from the public and the GPs liaison could be closed, then there would be a worthwhile future for the service. A majority of pharmacists considered that patients improved their lifestyle following health screening. This was assessed from feed-back from patients, and confirmed the potential in educating patients about lifestyle during the time waiting for diagnostic test results. Although the numbers per pharmacy per year were small, most of these patients had reported improvements in smoking, and drinking habits and in diet, after the health screening.

Most pharmacy screening services are offered on an informal basis direct to customers, but, as the results show, some community pharmacists now offer a package of diagnostic services to their local GPs. This service is provided either under contract from the district health authority or directly to a GP fund-holder.

9.5.2 Liaison with GPs

Nearly all pharmacists informed their local GPs before starting health screening, and all of these covered the practices within their immediate vicinity. 69% of GPs were agreeable to the inception of health screening in the pharmacy, a response that may have been greater if more pharmacists, than 45% (nine), had spoken directly to the GPs. 50% of the pharmacists recorded some improvement in relationship with their local GPs, but further progress in this direction may be unlikely while there is geographical separation.

In a survey of 119 GPs in the B & H area in 1994, only 26% stated that they would actually wish the pharmacist to get involved in blood pressure and cholesterol checking, though 33% were in favour of blood sugar testing. 163 This result may reflect the difference between GP innate suspicion with the reassurance from liaison by individual pharmacists. The Scottish survey (see 9.5.1) indicated that 24% of GPs (n = 266) thought that provision of diagnostic and screening services. NHS funded, by a pharmacist, was desirable. 165

FHSAs and district health authorities are in the process of merging to form unitary health authorities, who will need to commission services from varying providers. This may bring into focus the potential competition between practice nurses and community pharmacists for future services.

Some pharmacists in the study (seven) agreed that nurses would be the best option to operate a health screening service in a general medical practice setting, but more (11) thought that the pharmacy was an equally valid or better setting. Evidence from Chapters 3,4 5 and 6 indicate that the future evaluation of the patient's health status and monitoring of their progress will

become a co-operative task between the practice nurse and the practice pharmacist.

GP Formulary Development

The eight pharmacists (40%) from this small group were much more active in their involvement with GPs and PACT data compared to the FHSA adviser's estimate of 5% nationally (see 8.5.5). Jepson, in his survey on the influences on GP prescribing, in 1992, found that 3.7% of pharmacists discussed practice formularies and 2.6% discussed PACT data with GPs. 158 Bond, in her study in 1992, demonstrated that pharmacies in rural locations were more likely to be involved in formulary production. 165

Communication with doctors during the studies reported in Chapter 4 and 6 indicated that the workload in general practice is increasing to such an extent that spending time analysing prescribing data or developing a practice formulary is not a priority. Pharmacists have and can offer invaluable expertise with their special knowledge of drugs and therapeutics, and it is an opportunity the profession must take.

The main reasons given by the pharmacists for not contributing to a GP formulary and PACT data analysis revolved around the geographical separation of the pharmacy from the surgery. GPs, at the study surgeries, commented that once the non-threatening nature and the value of pharmacists in reshaping their prescribing is realised, GPs, generally, would more readily accept this function. The Scottish study (1992) indicated that 53% of GPs agreed on the desirability of pharmacists engaging in formulary development. ¹⁶⁵

Interest soon develops, when potential savings for a practice are realised, and pharmacists can overcome the problem of finance by receiving payment, either directly from a fund-holding practice or from FHSA money in their general medical services budget.

Prescribing Liaison

Both trial pharmacists and FHSA pharmaceutical advisers agreed overwhelmingly (85% rating) that the pharmacist should manage a patient's repeat medication after the GPs initial prescription. This confirms the profession's advocacy of a shift in focus from dispensing medicines to monitoring a patient's therapy. Barriers to developing such roles at the general medical practitioner interface have still to be overcome, as evidenced from the Scottish study, where 33% of GPs thought that repeat prescribing by a pharmacist was desirable. 48% of GPs rated pharmacist's reviewing medication for individual patients on a regular basis as desirable. ¹⁶⁵

A small majority of pharmacists (11/20) and advisers (30/53) agreed that pharmacists should recommend the medication after a definitive diagnosis by the GP. There was more complete agreement that pharmacists could prescribe on a limited therapeutic list (15/20). Such a suggestion is likely to be greeted with strong opposition by the majority of GPs today, as this will entail radical changes in clinical roles and responsibilities not yet acknowledged. Indeed, this particular scheme has been rejected outright by the RCGP, though work has shown that where GPs work in collaboration with pharmacists on drug choice, their prescribing is cheaper and more rational. ¹⁶⁶ GPs interviewed in the Scottish study were not favourable (7% in favour) to the pharmacist selecting the medicine and dosage, following agreed protocols. ¹⁶⁵ Pharmacists would like to work more closely with GPs, and GPs see a role for community pharmacists in advising on cost-effective prescribing. The development of a treatment protocol scheme as recommended by the working party may be more

acceptable within the framework of local liaison groups that discuss prescribing, with a flexible approach.

Encouragingly, there are now a number of initiatives to help improve GP prescribing, and the DOH has recently released £1m to fund pharmacist/GP prescribing projects in 17 FHSAs. 167 Crucially, pharmacists need to be well-prepared, and B & H, for example, are running one of the initiatives, firstly training pharmacists in drug information, PACT analysis and additional clinical knowledge of the various medicines in the BNF therapeutic classifications. 167 Speciality Clinics

Predictably, asthma management was the function receiving greatest support. 4 Asthma is a disease of varying severity that affects all ages, and airways obstruction which waxes and wanes either spontaneously or as a result of treatment is the hallmark of the condition. Patients on maintenance medications may not take their medications during periods in which they are asymptomatic, especially since many of these are young children. Furthermore, the degree of patient compliance may fall as medication requirements increase in complexity, and asthma treatment is generally based on multiple medicaments. Medication for both prophylaxis and control of this condition requires, par excellence, meticulous care in the use and maintenance of delivery systems though patients frequently have a poor grasp of the techniques required. The pharmacist is well equipped to complement the doctor by overseeing all these aspects in a clinic, and given the opportunity, could fulfil this function. Already in very many general practices, the monitoring of patients with chronic disease has become the responsibility of the practice nurse, so for the pharmacist to be seriously involved, he may only achieve this in the practice setting. A major logistical difficulty is the timing of clinics when most pharmacists cannot leave their pharmacies. This could lead to the

scenario of the pharmacist based full-time in a general medical practice, developing a range of services which could include areas like advice on formulary development and asthma clinics.

Similarly, pharmacists could play a role in patient adherence to medication and lifestyle in a diabetic and hypertension clinic, both of which received more than 50% support. In both these clinics, the pharmacist's knowledge of drugs would be vital, and he could help the patient take responsibility for medication and enable him to manage his disease process himself.

There was less support for pharmacist involvement in a lithium clinic, although initiatives in this direction have been successful in hospital-based clinics. A study (1991) at a multi-disciplinary lithium clinic has shown that pharmacists can work in an out-patient setting on an equal standing with doctors and nurses, with each professional contributing their own skills to the clinic. ¹⁶⁸ Family planning was the least popular option, pharmacists, perhaps, not seeing a clearly defined clinical function here. In fact, GPs in B & H voted 56% in favour of pharmacists offering contraceptive advice, although they are not so favourably inclined towards pharmacists working in a family planning clinic. ¹⁶³

Currently, there are other general practice clinics to which a pharmacist could make a useful contribution.

Examples are a migraine, a pain, an anticoagulant, an angina and an upper gastrointestinal tract management clinic. All these clinics involve patients on medication, and no-one in a typical practice has sufficient time to think about medicines for these patients, so that a pharmacist, who keeps up to date, clinically and therapeutically, can make a positive contribution.

9.5.3 Patient registration and PMRs

OTC medication information was contained on PMRs in those pharmacies situated in catchment areas where the majority of patients were loyal to that one pharmacy. Recording OTC medication is an ideal situation, which is of limited value if patients move from pharmacy to pharmacy. In the larger, multiple pharmacies, the customer flow purchasing P medicines is so great and so constant that it is at present a practical impossibility to record these sales on the pharmacy computer.

As indicated in the previous chapter, the stage has not yet been reached when a pharmacist has a computer link with his local GP practice. 95% of pharmacists kept PMRs for patients with chronic conditions and those on repeat prescriptions (see Table 9.8). Computerised PMRs provide patient information, such as previous medications and drug sensitivities, and can therefore help the pharmacist in checking the suitability of the patient's current medication. For these two groups of patients, a facility for monitoring drug interactions is particularly important. A smaller percentage of pharmacies kept PMRs for children under 12, as a number of these present with temporary acute illnesses only.

Less than 50% (nine) of respondents kept PMRs for all patients, but this figure is increasing. Pharmacy computers with a hard disc capacity can record every patient's entry automatically.

Accessibility to patient's medical notes is still the exception. Access to a patient's notes will become important when the pharmacist becomes involved in the prescribing process or health screening for a practice, in which case the GP will undoubtedly be co-operative.

Although the majority of patients regularly attend one pharmacy, many take their prescriptions to any number of different pharmacies, so that pharmacy which may therefore fail to reveal drug interactions, could be overcome by using centrally held patient medication records, patient held medication smart cards, or by instituting a system of patient registration at pharmacies.

Three quarters of the pharmacists thought that patients' needs would be best met if they registered with a pharmacy of their choice where their prescriptions would be dispensed. This would ensure that PMRs were reliably complete and details of deregulated pharmacy only medicines bought by patients could be included in the records, enabling safety checks to be made for possible interactions with prescribed medicines. In the Netherlands, the system has been established for a decade, and an indicator of the degree of success is that patient's compliance with medication is safeguarded, eg a patient, prescribed atenolol 100mg daily, will be contacted within a week of his expected return for a repeat prescription if it has not been collected. 170

held PMRs cannot guarantee completeness. 169 This problem of records,

9.5.4 Audit

Audit is the means by which the profession examines and evaluates its current services and alters or develops them to attain an impact, the result of which is improved and more efficient care for the patients and a health gain by the individuals.

Direct communication with the pharmacists has strongly indicated that there is a continual process of audit in their pharmacies. Presently, the consensus of opinion is that it is essential to audit the pharmacist's response to symptoms, especially following the continued criticism from the Consumers

Association. ¹⁷¹ Linking with this, audit should now concentrate on the expanding range of POM to P products and the extensive number of 'copycat' OTC medicines.

These key changes affecting the pharmacist have given him the opportunity to consolidate his position in society as the acknowledged expert on medicines. In this way, the pharmacist can fulfil a role as the gatekeeper to the nation's health by providing informed advice with medicine sales and reducing the number of patient contacts with the doctor.

9.6 Conclusions

- Health screening by diagnostic testing has an important future in community healthcare, and technological progress will increase the spectrum of disease states, potential or existing, that can be covered. There is considerable interest and a desire to offer a more complete community pharmacy health care service. Pharmacists considered that health screening was a focus during which gainful lifestyle advice could be imparted, and it is appropriate that this is established as part of pharmacy's future development.
- As more and more GP practices are becoming fund-holders, and are responsible for their prescribing budgets, pharmacists could use their expertise to synchronise the input of information to a surgery.

 Harmonisation of PACT data with a GP formulary and, further, treatment protocols, would be of immense value to GPs. At present, the busy practitioner does not have enough time to evaluate PACT data let alone benefit his prescribing with a complete picture. PACT information is limited in that there is no information on diagnosis, reasons for prescribing, or adverse drug reactions. The pharmacist could be the link that leads to a rational prescribing policy.
- Building on the foundation of prescribing advice, pharmacists are strongly in agreement with managing a patient's repeat dispensing, and, once this is established, choosing the particular drugs, and

- recommending the starting doses to the patient. The GP would explore the problem, and determine a therapeutic strategy, then the pharmacist would specify the class of drugs, initially, perhaps, from a limited therapeutic list.
- There is a role for the pharmacist in patients' drug therapy through involvement in speciality clinics. Pharmacists will then have the clinical freedom to implement protocols for a number of diseases and provide therapy in a clinical practice.
- Patient registration with a single pharmacy would facilitate the pharmacist assuming responsibility for the wider therapeutic management of patients' medication, prescribed and bought. This would enhance pharmacist-GP co-operation, and for the greater benefit and safety of the patient.
- Audit has become an essential feature with which pharmacy can ensure that its professional standards and practice are upheld.

CHAPTER 10

DEVELOPMENTS IN PHARMACY PRACTICE AMONG THE MEMBER STATES OF THE EUROPEAN UNION (PGEC)

10.1 INTRODUCTION

In 1994, the Commission for the European Community (COM) presented a report to the European Parliament of a programme of action concerning the promotion of health throughout the community, emphasising that such action should guarantee the best possible use of the resources of the member states for the health care of the public. 172 The document, translated from French, comments that attitudes towards health and sickness are constantly changing. People are becoming increasingly interested in their health and are opting for healthier lifestyles to improve it. There is greater public awareness in matters related to health; people are becoming more willing to promote and maintain good health, and to prevent and treat diseases on their own initiative. Self-care means the prevention of illness and the promotion of health, the treatment of minor ailments and injuries as well as coping with chronic disease and rehabilitation.

10.2 AIM

Growing interest in self-care makes people more aware of their responsibility for their own health and creates new and stimulating challenges for those who provide drug-related information, to help ensure the best possible treatment outcome. The aim of this part of the study is to ascertain at what stage of development European community pharmacists have reached in meeting this challenge.

10.3 OBJECTIVES

To determine:

- the extent to which community pharmacists offer diagnostic tests and blood analysis.
- 2 the extent to which deregulation has led to an extended range of medicines not restricted to prescription.
- 3 the involvement of community pharmacists in the prescribing process.
- 4 the extent to which consumers are loyal to one pharmacy.
- 5 which other activities pharmacists are pursuing to develop their role in healthcare.

10.4 METHOD

10.4.1 Design of questionnaire:

A postal questionnaire (Appendix 21) was sent to 22 pharmacy associations in 16 countries, which are members of the European Union, together with an appropriate letter of explanation (Appendix 22). In several cases, letters were translated into the relevant language (Appendix 23). Appendix 24 gives a list of the 22 pharmacy associations.

10.4.2 Equipment: The programme SPSS 6.1 for Windows was used to record results from returned questionnaires and for analysis of the data.

10.5 RESULTS

Questionnaires were sent to 22 pharmacy associations from 16 countries, and their response is summarised in Table 10.1. The **UK** were included for comparison and completion, data being provided by the NPA.

Table 10.1 Response from European Pharmacy Associations

	Countries	*	Questionnaires sent	Replies
	AUSTRIA	(A)	1	1,
	BELGIUM	(B)	1	1
i In II &	DENMARK	(Dk)	2	2
	FINLAND	(Fin)	1	1
	FRANCE	(F)	2	1
	GERMANY	(G)	1	1
	GREECE	(Gr)	1	1
	THE NETHE	RLANDS (N) 1	1
	IRELAND	(I)	2	2
	ITALY	(It)	2	2
	NORWAY	(Nor)	1	1
	PORTUGAL	(P)	2	2
	LUXEMBOU	RG (L)	1	0
	SPAIN	(Sp)	1,	1
	SWEDEN	(S)	2	2
	SWITZERLA	ND (Swi)	1	1
	UNITED KIN	NGDOM (UK	.) 1	11
	TOTAL		23	21

Response rate from the European Pharmacy Associations was 20/22 (91%).

10.5.1 Diagnostic tests

Question 1(a) Approximately what percentage of community pharmacists in your country offer the following diagnostic tests?

Urine analysis

Pregnancy

Blood Pressure Measurement

Serum Cholesterol Measurement

Blood Sugar Measurement

Therapeutic Drug Monitoring

Responses are shown in Table 10.2.

Table 10.2 Diagnostic Tests and Responses from European Countries

Estimated Percentage of Community Pharmacists offering Test Services										
	Urine	Pregnancy	BP	STC 1	RBG 7	TDM				
Country	Analysis	Test	Test Measuren							
Austria	<20	>80	60-80	<20	<20	<20				
Belgium	20-40	20-40	<20	40-60	<20	<20				
Denmark	<20	>80	20-40	20-40	<20	<20				
Finland	<20	60-80	20-40	20-40	<20	<20				
France	20-40	<20	<20	<20	<20	<20				
Germany	<20	20-40	40-60	20-40	<20	<20				
Greece	<20	>80	>80	·80 <20		<20				
Ireland	<20	<20	20-40	20-40	<20	<20				
Italy	<20	60-80	40-60	20-40	20-40	20-40				
The Netherla	nds <20	>80	20-40	<20	60-80	<20				
Norway	<20	<20	<20	<20	<20	<20				
Portugal	60-80	60-80	40-60	20-40	<20	<20				
Spain	<20	>80	>80	20-40	20-40	<20				
Sweden	<20	40-60	<20	<20	20-40	<20				
Switzerland	20-40	>80	>80	<20	<20	<20				
United Kingo	dom <20	>80	20-40	20-40	<20	<20				

Pregnancy testing is the service which is most widely offered, as distinct from other urine tests, which are still predominately done by independent laboratories and clinics, except in Portugal. BP measurement is fairly widely offered, particularly in Switzerland. In Austria, Denmark, Finland, Germany, Ireland, Italy, Netherlands, Portugal and the UK, BP monitoring is organised by individual pharmacists. In Spain, this activity is organised by the national pharmaceutical association.

There is an increasing interest in STC measurement, where tests are organised by individual pharmacists in **Denmark**, **Finland**, **Germany**, **Ireland**, **Italy**, **Netherlands**, **Portugal** and the **UK**. National pharmaceutical associations in **Belgium** and **Spain** organise cholesterol testing through the pharmacy network. A recent survey in the **UK**, in the Brent and Harrow area, showed that 90% of community pharmacies offered pregnancy testing and 25% and 12% respectively offered BP and STC measurements. ¹⁶³

Pregnancy testing is particularly well established in the **UK**, whereas the incidence of other diagnostic tests is similar to that of the other member states

incidence of other diagnostic tests is similar to that of the other member states of the PGEC. RBG measurement and TDM are both in their infancy, but could form part of the individualised pharmaceutical services community pharmacies can provide to help check on a patient's health status. In **Sweden** and **Italy**, pharmacists have been involved in national programmes to improve the awareness of diabetes and consequently there is a higher incidence of RBG measurement.

In **The Netherlands**, once a patient has been diagnosed as diabetic and needs to check his/her own blood sugar, he/she is referred by the doctor to his/her pharmacist for instruction and demonstration of the blood glucose meter. Some Dutch pharmacies do measure blood pressure and body weight, and a few offer

cholesterol screening, but most pharmacists see this as the doctor's responsibility.

Question 1(b) Is there any co-operation between pharmacists and doctors for these health screening services?

Currently there seems to be active co-operation only in **The Netherlands**, particularly for blood glucose testing. **Greece** state that there is an intention for co-operation on blood analysis. **Italy** state that, in some medium-sized towns, there are local initiatives to evaluate co-operation between pharmacists and doctors in BP measurement; and **Portugal** state there is some co-operation in BP and RBG measurement.

In the UK, in 1989, the Government proposed that health screening should be considered as an integral part of both the pharmacist's and GP's role, and that payment for such services should be initiated within the NHS, but to date the proposal has not been acted upon. ¹⁷³

10.5.2 Blood analysis

Question 2 Where do doctors direct their patients for blood analysis?

Table 10.3 summarises the responses.

Tablet 10.3 Place for Blood Analysis and Payment Agency

Country	Place	for Blood An	Pay	Payment Mechanism				
	Community	Independent	Hospital	Own	Patient	Health		
	Pharmacist	Laboratory	or Clinic	Premises	Α	uthority		
Austria	N	1	2	3	1	2		
Belgium	N	1	2	3	1	2		
Denmark	N	2	3	1	1	2		
Finland	N	. 1	3	2	2	1		
France	N	1	2	N	1	2		
Germany	N	1	3	2	2	1		
Greece	N	1	N	N	2	1		
Ireland	N	N	1	2	1	2		
Italy	N	2	1	N	1	2		
The Netherlar	nds N	2	1	N	N	1		
Norway	N	1	N	2	2	1		
Portugal	2	1	· 2	N	2	1		
Spain	N	1	N	N	1	N		
Sweden	N	3	2	1	2	1		
Switzerland	N	2	N	1	N	1		
United Kingdo	om N	2	1	N	N	1		

Key: 1 = 1st choice; 2 = 2nd choice; 3 = 3rd choice; N = Not applicable

Table 10.3 shows that doctors have a slight preference for sending patients (or their samples) to an independent laboratory for blood analysis. In **France** there is an established network of independent laboratories, to which patients, or their samples, are directed. The laboratories in **France** are sometimes operated or managed by pharmacists, though, usually there is a medical director as well as a pharmacist-member of staff.

In **Spain**, there is little near-patient testing, as, historically, patients go to independent laboratories, as in **France**.

Portugal is the only country where doctors routinely send patients to pharmacists for blood tests.

Question 3 How are these screening tests paid for?

Payment is shared between the patient and the country's health insurance scheme (see Table 10.3). There is no free service provision from a pharmacy. In **Ireland**, General Medical Service patients, who comprise 40% of the population, get a free service, whereas private patients (60%) must pay. In **France** and **Germany**, some are able to recoup their costs from private health insurance schemes.

In the UK, the NHS will cover everyone for a blood test through their medical practice, and currently, the appropriate blood samples are sent to the local hospital.

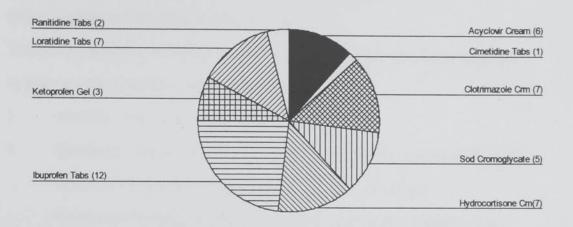
10.5.3 Deregulation of 'Prescription Only' Medicines

Ouestion 4(a) Deregulation of 'Prescription Only' Medicines

The ratio of medicines reclassified from restriction to prescription to supply by pharmacists on their own professional authority to patients or customers in the last 10 years is summarised in Figure 10.1 and Table 10.4. As far as one could ascertain, there has been no movement of medicines from POM to GSL in any

of the PGEC countries, as in the UK, where a 24-pack of ibuprofen 200mg tablets is available through drug stores.

Figure 10.1 Deregulated Pharmacy-only Medicines
Supply in European Countries



Number of Countries = 13

Table 10.4 Supply Position of Pharmacy-only Medicines in PGEC Members

Deregulated								Cou	ntry						
Medicine	A	В	Dk	F	G	Gr	Ir	It 1	N 1	Nor	P	Sp	S	Sw	UK
Ibuprofen	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y
Ketoprofen	N	N	Y	N	N	N	Y	Y	N	N	N	N	N	N	Y
Hydrocort cri	m N	N	Y	N	N	N	Y	Y	N	Y	Y	Y	Y	Y	Y
Hydrocort loz	zs N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
Clotrimazole	Y	N	Y	N	Y	N	N	Y	N	Y	N	Y	Y	Y	Y
Acyclovir	Y	N	Y	N	Y	N	Y	N	Y	N	N	N	N	Y	Y
Cimetidine	N	N	Y	N	N	N	N	N	N	N	N	N	N	N	Y
Ranitidine	N	N	Y	N	N	N	N	N	N	N	N	N	7	Y N	Y
Beclomethaso	on N	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
Sod cromogly	yc N	N	Y	N	Y	N	Y	N	Y	Y	N	N	7	Y	N Y
Butyl bromide	eN	N	N	N	N	N	N	N	N	N	N	N	N	N	Y
Loratidine	N	N	Y	N	Y	N	Y	N	Y	Y	Y	Y		Y 1	V Y

Ibuprofen may be supplied in all countries except **Greece**, where a Government decision on deregulation of medicines is awaited. **Germany**, **Italy** and **Portugal** restrict sale of ibuprofen to the 200mg strength. In all countries, where ibuprofen is sold, the sale is from pharmacies only. Other Medicines Deregulated in the Past 10 Years.

Some respondents reported other medicines that can now be sold or supplied by pharmacists to patients without prescription:

- Austria ketoconazole, as a shampoo.
- Denmark oxymetazoline, as a nasal decongestant, ketoconazole, as a shampoo and a cream, antazoline-naphazoline eye drops, dextromethorphan in a mixture or tablets, loperamide capsules, and minoxidil solution. The antihistamines, acrivastine and astemizole, have recently been deregulated.
- 3 Germany nicotine gum and patches, n-acetyl cysteine linctus, and cetirizine. Pharmacists in Germany are also allowed to sell the external NSAID preparations of piroxicam, flufenamic acid and felbinac.
- 4 Ireland deregulated a number of substances and preparations in 1993:
 - (a) mucolytics; acetylcysteine, bromhexine and carbocysteine.
 - (b) antispasmodics; cinnarizine, domperidone, and mebeverine.
 - (c) anthelmintics; levamisole, mebendazole.
 - (d) antifungals; ketoconazole, nystatin, sulconazole and tioconazole.
 - (e) external NSAIDS; diclofenac, felbinac, ketoprofen, naproxen and piroxicam.
 - (f) antihistamines; astemizole, cetirizine and terfenadine.
- 5 The Netherlands the antihistamines, terfenadine and levocabastine.
- 6 In Sweden the sale of nicotine chewing gum and patches have recently been allowed through pharmacies.

The community pharmacists of the **UK** and **Ireland** have at present the widest range of deregulated medicines, reclassified during the past 10 years, to supply at their professional discretion.

Question 4(b) Can the pharmacist on his/her own professional authority supply any of the following classes of medicines to patients/customers?

The pharmacist cannot on his/her own professional authority supply any of the following classes of medicines to patients: oral contraceptives, antihypertensives, hypolipidaemic agents, hypoglycaemics and bronchodilators. This accords with the situation in the UK. The Irish respondents report that pharmacists may supply any prescription only medicine (except controlled drugs) if a genuine emergency exists and it is impracticable for the patient to obtain a prescription from any prescriber without undue delay. The medicine has to have been previously prescribed, and the situation is equivalent to an emergency supply in the UK. There are special record keeping and labelling requirements for such medicines and in addition a maximum of only 5 days supply can be given. Exceptions are:

- a month's supply of the pill,
- a full inhaler for asthma, and
- a full course of liquid antibiotics.

Pharmacists in **Spain** are able to supply a wide range of antibiotics and the oral contraceptive tablet on their own authority without a prescription.

10.5.4 Pharmacy influence on prescribing

Question 5(a) What proportion of the community pharmacists have an accepted influence (more than the safety checking of prescription dosage, strength, interaction etc) on the prescribing pattern of medication by family doctors?

The Netherlands report an influence of 90%, Sweden of 50%, Spain of 30%, and Belgium, Austria and Greece 20%, while the others state <10%. In the UK, there is a 30% influence on prescribing, according to a recent study (Jepson 1995).¹⁷⁴

Most countries are still at the 'safety checking' stage, but **Denmark** are hopeful that their pharmacists are now progressing from 'checking upon specific items or problems concerning a prescription' to a more active role concerning all medicines.

Community pharmacists in **The Netherlands** have the greatest influence on prescribing. Some 90% of them meet their local GP groups on a regular basis to discuss a particular topic, which aims to reach agreement on the choice of medication for particular indications. The Irish respondents stated that more and more pharmacies are installing drug interaction packages on their computers so that GPs can be advised accordingly. Further, a number of community pharmacists, in Ireland, are working, part-time, in regional bodies, known as GP units, established to help GPs improve their prescribing. This is similar to several pilot schemes FHSAs are running in the **UK**. In B & H, there are 23 pharmacists, including the author, who are individually attached to a GMP to advise on rational prescribing and cost-effectiveness related to the GP practice PACT data analysis.

Swedish pharmacists participate in a programme which is known by the acronym KIP (Personal Interactive Communication), in order to promote

good professional relations with doctors whose patients are served by their pharmacies. As part of the KIP programme pharmacists regularly visit local doctors in their health centres to present news on drug therapy, newly registered and marketed medicines, and to discuss recommendations from consensus meetings on pharmacotherapy, etc. The interactive and personal involvement aspects of the KIP programme is much emphasised. Common attitudes and actions in relation to the patient's problems that the pharmacists observe are also discussed. Evaluation of this programme is presently in progress.

In **Denmark** several projects have been initiated of a similar nature to those described for the UK (see Chapter 8). Danish pharmacists are confident and optimistic that they can have a successful role in prescribing.

The Norwegian respondent states that the pharmacist's influence is increasing. A pilot project in two areas during 1994-5 was conducted, involving 10 family doctors and two community pharmacists. The two groups had five meetings on prescribing in different therapeutic groups, and the prescribing pattern of each doctor was documented and discussed. The Norwegian Pharmacy Association received encouraging feedback and intends to implement this strategy on a larger scale.

Swiss pharmacists have found that the recognition of clinical pharmacy in the hospital sector is now leading to progress with clinical pharmacy in the community.

Question 5(b) Do pharmacists have any role in regulating the number of times a prescription may be repeated?

Only Swiss pharmacists have such a role at present. They can repeat prescriptions, under a new contract arrangement, monthly, for up to one year. In Ireland too, a certain category of POM (known as SIB) can be repeated for up to six months, either in accordance with the prescriber's specific direction or at such intervals as the pharmacist deems appropriate, having due regard to the dose, and assuming the prescriber has given a direction to repeat.

Question 5(c) Do pharmacists have access to medication information from family doctor medical records?

Only **Dutch** pharmacists have formal access to medication information from GP records for their patients.

Question 5(d) Do pharmacists have access to diagnostic information from family doctor medical records?

Pharmacists do not have any formal access, although the **Austrian** respondent states that negotiations are taking place to strengthen the link between the general medical practitioners and the pharmacists.

GPs and pharmacists concerned with the same cohort of patients should meet regularly to discuss individual patients' diagnosis, and the development and modification of protocols for specific therapeutic areas. This would provide a focus to encourage teamworking and breakdown barriers, and enhance continuity of care for the patient.

10.5.5 Patient loyalty

Question 6 What proportion of patients use only one pharmacy?

The median figure is 50%, with a range from 30-90% (see Table 10.5).

Typically, Greece and Italy state that 80% of the population in country areas and peripheral points in urban areas use only one pharmacy, whereas the figure in the central, city areas is only 30%. The highest levels of loyalty (80% +) are reported by Belgium, Finland, France, Ireland and The Netherlands.

Table 10.5 Degree of Patient Loyalty and Computerisation of PMRs

Country	Percentage of Patients	Percentage of Pharmacies					
	using one Pharmacy	keeping Computerised PMRs					
Austria	50	10					
Belgium	80	40					
Denmark	50	0					
Finland	90	75					
France	80	30					
Germany	70	5					
Greece	40	10					
Ireland	85	20-95					
Italy	65	15					
The Netherlands	80	100					
Norway	75	1					
Portugal	50	0					
Spain	80	2					
Sweden	30	0					
Switzerland	90	75					
United Kingdom	60	80					

Question7(a) What proportion of pharmacies record and keep computerised PMRs?

The **Dutch** respondent stated that all their pharmacies maintain computerised PMRs (see Table 10.5). Respondents from **Switzerland** and **Finland** reported a 65 % level, followed by those from **France** and **Belgium** at 35%. The **Irish** respondent stated that, although most pharmacies are computerised, the number keeping PMRs is unknown. The **Finnish** respondent stated that prescriptions, together with additional diagnostic information, will increasingly be sent from physicians to community pharmacies via a computer modem. This means that prescribed medication will be ready by the time that the patient arrives at the pharmacy. The pharmacist will be able to optimise the time spent with each patient to ensure that patients know how to use drugs correctly and safely. Drug-related information and the follow-up of drug therapy will thus receive appropriate emphasis. PMRs, routinely checked, allow a comprehensive check on drug use, which is particularly useful in monitoring drug therapy in the elderly and in avoiding any harmful effects which might arise from drug combinations.

Greece and **Portugal** say their pharmacists still keep PMRs in 'the old fashioned way', which means a file of hand-written record cards.

Question 7(b) Do pharmacists include details of deregulated (ex-prescription only) medicines on PMRs?

Pharmacists in France, Germany, Greece, The Netherlands, Portugal and parts of Italy record these details for regular customers, with their permission. Professional confidentiality in the community pharmacy and sensitivity to a customer's privacy must be fully respected in developing and extending information systems.

Question 8(a) Is there a system for the registration of patients with a pharmacy of the patient's choice in your country?

Only pharmacists in **The Netherlands** and **Switzerland** operate such a system at present. In **The Netherlands**, every patient chooses a pharmacy, where he is registered. There, if a patient, on regular medication, does not arrive for his repeat course, he may be contacted by his pharmacy. All the patient's medication information and any contraindications or intolerances are recorded at the pharmacy.

Rural pharmacies have 10-15,000 patients, whereas city pharmacies usually have between 8-9000.

In **Switzerland**, a national sick fund is operated for individual patients through their chosen pharmacy, who keep comprehensive medication records.

Question 8(b) If no, are any such changes planned?

In Ireland a system is being discussed, for drug addicts to be registered with a particular GP and a pharmacist for methadone maintenance therapy. This is similar to the situation pertaining in the UK.

There is a pilot project to evaluate patient registration now taking place in **Norway.**

Question 8(c) Do you think a system of patient registration would contribute to making the pharmacist's role more useful for the patient?

There was an almost unanimous consensus of opinion that this would be beneficial, The **German** respondent stated that patient registration would be a positive move, but that it should remain voluntary for the patient to make their choice of pharmacy.

10.5.6 Pharmaceutical care

Question 9 Are Pharmacists actively involved in any other pharmaceutical care roles?

Austrian pharmacists are involved in a medical care project with patients on insulin therapy. The aim is to show patients how to use an instrument to measure blood glucose and co-ordinate the results with an optimum insulin formulation and dosage.

Danish respondents report the first successful TOM (Total Objective Monitoring) project, which has evaluated the pharmacist's impact on changes in asthma score, night-time symptoms, and peak flow rate in asthmatic patients. The project, involving GPs and pharmacists throughout the country, was coordinated by the Danish School of Pharmacy.

The objective of another project has been the improvement of the quality of life of the elderly by reducing and re-evaluating medicine consumption at a Danish nursing home. In **Denmark** there is no tradition for consultant pharmacists; pharmacies only deliver medicines. Patients and daily medication are taken care of by nurses and nursing aides. The major consequences are, that there is a lack of quality assurance in this work, that there is a substantial excessive use of medicine and that the medicine profiles are not reviewd regularly. The result is poor treatment at high cost. Pharmacists, working with the medical and nursing professions, and using generally accepted guidelines of rational drug therapy, effected a substantial cost reduction.

In **Finland**, pharmacists have devised a strategy programme to be fully established by 2002. Their public health care resources are not increasing at the same speed as in previous years, which places increasing pressure on

patient self-care. Pharmacists are often the only professionals consulted by customers on health matters in general, and the aim is to provide customers with sufficient information to be able to take greater responsibility for their own treatment.

In the future, community pharmacies will have separate self-care departments providing both verbal and written information as well as PC software containing an up-to-date encyclopaedia of drug actions and interactions, similar to Richardson's vadis facility. The customer will be able to watch educational videotapes on self-care, study the various dosage devices under the supervision of a pharmacist, and discuss questions relating to self-care.

The **Finnish** strategy programme states that as self-medication becomes more common, some of the safest prescription drugs suitable for self-care are expected to be made available to the consumer without a doctor's prescription. Drug-related information will be distributed more actively, both verbally and in writing, to customers seeking knowledge on the use of particular drugs. This kind of service will be made possible by placing more emphasis in education on pharmacotherapy.

In **Germany**, at present, some programmes are being developed to document pharmaceutical care projects in community pharmacy. Worldwide, health professionals are concerned that more self-medication may lead to reduced drug safety and efficacy for the patient. **German** pharmacists have developed some instruments, eg books and mutual referral forms with physicians, which could be used to optimize efficacy and to minimize the risks of self-medication. Another instrument is a patient chip card on which all diagnoses and the patient's drug therapy (Rx and OTC) can voluntarily be stored. This is helpful

for the implementation of Pharmaceutical Care, especially for the monitoring and documentation of pharmacist's activities in the field of self-therapy.

The **Greek** respondent stated that community pharmacists officially provide first aid, an expertise for which they are specially trained and funded.

Biochemical analysis is seen as a future role for the pharmacist, and there are pilot studies involving pharmacist-doctor co-operation for the treatment of diabetes.

In Italy, pharmacists are becoming increasingly involved in a multitude of health care services, eg sight and hearing testing, and weight measurement. Organisation of 'confidential' advice areas in pharmacies is occuring so that patients can discuss all health issues with pharmacists. A smart card holding all of a patient's pharmaceutical information may be implemented. Finally, community pharmacists are sometimes involved in clinical trials of drugs and co-ordinating secondary and primary care treatment of patients on admission and discharge from hospital.

Community pharmacists in **The Netherlands** already have a well defined clinical role, providing drug information for both patients and doctors. Patient information leaflets have been obligatory since 1993. Doctors are obliged to register with a local pharmacy to discuss cost-effective prescribing, rational drug use and advances in therapeutics, so that every pharmacist must keep up to date with new drug developments. These doctor-pharmacist meetings lead to agreed medication treatment protocols, and enable the pharmacist to link with their registered patients and manage their medication most effectively. and patient-orientated pharmacy.

In **Norway**, the pharmaceutical association aims to realise the potential of the community pharmacist in a health care role. In 1995, a co-operative programme between community pharmacists, child health clinics and maternity wards was launched in order to give consistent, in-depth guidance and information to parents of newly born infants.

Portuguese pharmacists are concentrating on giving more complete drug information with dispensed medicines, which includes action, mode of action, duration of therapy, side effects and interactions. Some community pharmacies, as in Austria, Greece and Sweden, are participating in a diabetes care programme. The pharmacist's role is evolving and the aim is integration in health programmes to prevent diseases, and collaboration with doctors in the early diagnosis of some diseases and the monitoring of therapeutic outcomes.

In **Sweden**, pharmacists embarked on a national and local pharmaceutical care programme in 1991. Data from the evaluation of the programmes indicate that pharmaceutical care is of benefit to the patient, stimulates staff and also increases the efficiency and profitability of pharmacies.

Swedish pharmacists feel that a well developed drug supply system must have three essential characteristics:

- · medicines should be readily available
- medicines should be efficiently and safely distributed to patients
- doctors and patients should be fully informed about the appropriate use of medicines.

Their premise is that considerable improvement can be made in respect of the third of these characteristics. Their concept of pharmaceutical care focuses on the patient's position and on the pharmacist's activity aiming at realising

maximum benefit of the chosen medication for the patient. The pharmacist must thus establish and maintain a dialogue with the physicians in matters that concern the patient and the use of medicines.

With this particular emphasis on customer's needs, **Swedish** pharmacists have devised an annual programme to focus on a special patient group with the greatest need of pharmaceutical care. Nation-wide, 1991 was the year for diabetic patients, 1992 for patients with asthma, 1993 for customers with dermatological problems and 1994 for those with senile dementia.

Another activity is the '4+ project,' where patients taking or using four or more medicines have been offered special attention and their whole medication situation reviewed by their pharmacists.

Evaluations from the diabetes year and the asthma year programmes have indicated that very large numbers of patients can be reached by messages from pharmacies. Patients with diabetes improved their knowledge and understanding of their disease and the regular use of certain diagnostic tests increased. Similarly, patients with 4+ multiple prescriptions had many medication problems that were easily resolved thereby increasing the benefit from their prescribed therapy.

10.5.7 Health Promotion

Most countries realise the importance of the pharmacist's role in health promotion, and the **Belgian** respondent stressed the need to respond to the principles of COM. ¹⁷² The major causes of mortality and morbidity in the European community are cardiovascular disease, cancer and accidents. The Commission of the European Community, under the auspices of the Council of Ministers of the European Parliament stipulates that lifestyle plays a vital role in this respect, and makes specific reference to diet, consumption of alcohol, tobacco and drugs, physical and mental health, and medicines and medication.

Community pharmacy in **Belgium** is seen as an important resource by their Government and that pharmacists have the necessary expertise to pass vital health messages to individuals in an informal atmosphere, and so encourage them to take the necessary actions.

The author considers that it is important, in the interests of all the member states, that the full potential of this important resource is utilised.

Throughout the EEC, community pharmacies are visited by millions of people each day and a great majority of these people who visit pharmacies are in good health and wish to remain so.

Activities within the framework of health promotion are already organised in Austria, Belgium, Denmark, Finland, France, Germany, Ireland, the Netherlands, Norway, Portugal, Spain and the United Kingdom.

Pharmacies in these countries display and provide leaflets for the public, covering a variety of subjects concerned with public health. The Governments in all these countries recognise the pharmacist's role by including their outlets as a source of publicity in national campaigns for health promotion. No information has been received concerning remuneration, though a system of certification of **Dutch** pharmacies, now being introduced, will relate payment to audited standards of pharmaceutical care.

Some pharmacists, in all the countries named, have accepted responsibility for health education and given talks to local schools, youth clubs and women's groups on a variety of subjects, eg 'understanding the dangers from the misuse of medicines', 'solvent abuse', and 'drug addiction'.

The association of **Finnish** Pharmacies has participated in different smoking cessation activities. During 1995, educational material concerning smoking cessation was produced and sent to every pharmacy. Smoking cessation

courses have been organised, and there have been theme days and poster displays in pharmacies.

Norwegian pharmacists have designed a project to profile the pharmacy as an important source of unbiased information and as an integral part of the local health service. Importance was placed on identifying suitable target groups of patients, where the pharmacy can influence the choice of treatment. During the project period the pharmacy was equipped with literature, video presentations and product demonstrations.

Community pharmacies in Spain have promoted a health education programme directed to the population of an area in order to increase their knowledge about health and lifestyle. The belief is that the community pharmacist, in continuous and direct contact with Society, is a suitable professional to provide this education. The purpose of this programme was to improve the pharmacist's role as a health educator and to promote the pharmacy as an open centre of consultation and advice. Subjects chosen were: drugs, medicinal plants, hypertension, skin and obesity. Information supplied was co-ordinated by the Colleges of Pharmacy, and evaluated outcomes have encouraged the organization of more activities.

Details of health promotion campaigns, organised by national pharmaceutical associations, in countries belonging to the Pharmaceutical Group of the European Union are listed in Table 10.6.

Table 10.6 Health Promotion Activities in the European Union.

Activity	Co	untry	y in w	hich	the a	ctivi	ties a	are o	rganis	ed		
	A	В	Dk	F	Fin	G	Ir	N	Nor	P	Sp	UK
Leaflet distribution	*	*	*	*	*	*		*	*	*	*	*
Poster display	*		*		*	*	*	*	*	*	*	*
Sale/supply of books	S		*		*		*	*	*	*		
Talks to local group	s	*	*	*				*		*	*	:
Talks to local schoo	ls	*	*					*		*	*	
Participation in spec	ific											
pharmacy campaigns	S	*	*	*	*	*	*	*	*	*	*	*
Participation in Gov	t.		٠									
campaigns	*	*	*	*	*	*	*	*	*	*	*	*
Participation in Heal	lth											
Authority campaigns	s *	*	*		*	*		*			*	*
Provision of services												
1. Smoking cessation		*	*			*					*	*
2. Cholesterol tests		*									*	
3. B P monitoring											*	
4. Diabetes screen			44			*			,	*		

^{* =} country participates.

In the **UK**, pharmacists, on their own initiative, have organised the supply of books providing medical information, lectures to local groups, eg the local asthma society, talks to schools, cholesterol tests, and BP and RBG measurements.

In order to ensure pharmacists are sufficiently qualified to exercise this role, pharmaceutical education in Denmark, Finland, France, The Netherlands,

Portugal, Spain and the United Kingdom has integrated health promotion into the course leading to their pharmacy degree (diploma). Post-graduate and continuing education programmes are also available to pharmacists in Belgium, Denmark, Finland, France, Germany, Ireland, Norway, Portugal, Spain and the United Kingdom.

10.6 Conclusions

In attempting to respond to objectives consistent with improving the health and the quality of life of citizens throughout the European Union, the European institutions and national governments need to utilise all the available resources. All health professionals have a role to play in order to reduce the risks of disease and encourage a healthy lifestyle. In general, the pharmacist's expertise and potential contribution has been seriously underutilised. The Pharmaceutical Group of the European Community (PGEC) welcomes favourably the opportunity to discuss with the European Commission the best way to utilise this resource to guarantee a maximum impact within the context of encouraging the population to recognise the importance of maintaining good health and avoiding diseases.

The contention of the PGEC is that the profession, building on the foundation of a role in health promotion, could move more towards a diagnostic and prescribing function, with its members using their special knowledge of pharmaceuticals to guide consumers in their appropriate use without the need for always requiring the involvement of family doctor care.

Regulatory changes introducing an extended range of pharmacy-only medicines are gathering pace in the UK, and the rest of Europe, and the developed world. There is more opportunity for people to purchase more effective and potent

products which require reliable therapeutic advice from up-to-date community pharmacists.

A system of patient registration with a pharmacy of the patient's choice is significantly acknowledged most desirable by respondents from Austria, Belgium, Denmark, France, Finland, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Sweden, Switzerland, and the UK. The respondents stated that, as the pharmaceutical and health care role continues to develop, patients would gain considerable benefit from the reliability and completeness of their pharmacy-held PMRs and the continuity of advice and treatment from their community pharmacist. In the UK, this would correlate with the benefits to patients of registration with GPs and dentists.

The RSPGB has established a forum for the pharmaceutical profession to map out a path for the future of pharmacy by launching *Pharmacy in a new age*.

This initiative in the UK has set an example, which pharmacy associations in the rest of the European Community are enthusiastically following.

CHAPTER 11

IDENTIFYING A STRATEGY FOR THE FUTURE OF PHARMACY

11.1 THE STRATEGY

The Council of the Pharmaceutical Society believes there are opportunities for pharmacy to develop as a pivotal professional service throughout health care.

The launch of "Pharmacy in the New Age" initiative marks the beginning of a process to map out a path for the future of pharmacy.

The Strategy will evaluate the overall intentions and goals of the policy to establish pharmacy as a provider unit of health care linked to Government and consumers through NHS purchasers. Maxwell suggested six dimensions of health care quality as principles of any strategy: 175

- · access to services
- relevance to need
- effectiveness
- equity
- social acceptability
- efficiency

Strategy is converted into reality by the process of implementation, which converts the strategic intention into specific objectives with defined time scales. The six dimensions could be used as a template for judging whether the strategy achieves its objectives. Community pharmacists have an advantage in that they are accessible to the public and have a platform on which to build. The aim of this research has been to implement objectives for health promotion and disease prevention, and then evaluate the impacts. Impacts refer to the results of policies, the ways in which they can change and improve the care that patients receive.

11.2 HEALTH PROMOTION

Pharmacists are seen by the general public, in descending order of importance, as advisers on OTC medicines, on symptoms of minor ailments, on prescribed medicines and finally on general health. ¹⁷⁶ Consumers are not identifying the pharmacist as a person to ask about ways of keeping healthy, partly because of a lack of private counselling facilities.

This situation was overcome during the study, and there was the time and the opportunity to be more pro-active as a health educator. The patient, able to talk to the pharmacist in private, then felt free to air his/her health worries with confidentiality. The pharmacist was either able to resolve these anxieties or evaluate them and refer to another member of the PHCT.

11.2.1 The General Practitioner viewpoint

The GPs at the medical practices involved in the study were positive in their appraisal of the benefits realised.

Impacts effected were:

- patients expressed the view that the consultation was educational and informative
- · patients were reassured on questions of health
- no patients reported as "worried well", often a criticism of community pharmacist activity
- in their function as a health care worker, pharmacists were not seen to be as threatening as doctors
- advice on smoking cessation and alcohol moderation was more readily received. Doctors find it difficult to impart health promotion advice during the course of an intensive surgery session

- doctors came to appreciate the knowledge and capability of the pharmacist. This effected a positive change in relationship with other pharmacists, thus raising their profile
- pressure from Government on GPs to impart health promotional messages to consumers could be alleviated somewhat by enlisting the help of pharmacists
- recognition of the potential for health promotion involving all the members of the community health care team.

11.3 PROSPECTIVE STUDY INTO CHD RISK FACTOR REDUCTION

The current system of payments for health promotion in British general practice requires doctors to record risk factors but places little emphasis on effective intervention or on targeting. Policy on health promotion should be based not only on the recognition of risk factors but also on evidence that they can be changed and that changing them improves health. 177 Crucial issues in health promotion are knowing how best to intervene and when to target. The Study at Surgery 3 was based on intensive individual education about the risks of cardiovascular disease. This approach has been found to be more effective then standard advice in reducing STC concentrations. 131 The apparent benefits of the strategy in the Surgery 3 Study have been the detection and improvement of several cases of raised cholesterol, high blood pressure and of glucose intolerance. Further, a quantitative identification of the health needs in the practice has been made with reference to smoking, heavy drinking, obesity and lack of exercise. Ideally, a matched practice control population would have helped to confirm the improvement in measured parameters, but this was not practical within the resources of this project.

The strategy produced an actual mean fall in cholesterol concentration in 67 patients in the high risk group of 0.65mmol/L, equivalent to 9.8%. If a 1% fall in STC concentration gives a 2% drop in risk of CHD this alone could be considered to make the study worthwhile.

Potential patient benefit was shown by the finding that, of 115 patients who had an initial STC reading of 6.0 + mmol/L-1, 99(86%) experienced a drop in STC by the final consultation. Mean values of this group had fallen from 6.79 to 6.05mmol/L-1, in the two-year time scale. These results compared favourably with a similar screening programme conducted by practice nurses and health visitors in a general practice, where 64% of their cohort of patients, STC 6.0 + mmol/L-1, showed a positive response to intervention. ¹⁷⁸ However, this programme only continued for three months.

The magnitude of the effect on STC concentration in the Surgery 3 Study was greater than the reduction of up to 4% reported in an overview of five trials of individualised advice on a reduced fat diet. ¹⁷⁹ The benefits of dietary advice are probably not fully reflected by measurements of STC. Reducing fat intake and substituting fruit and vegetables may raise serum concentrations of antioxidant vitamins and other cardioprotective factors. The Surgery 3 Study possibly benefited from the personal, dedicated involvement of the pharmacist, whereas the other studies were mostly of shorter duration, with fewer patient recalls and conducted by numerous personnel.

The most cost effective Strategy in primary care would be to target high risk groups. ¹⁸⁰ Most practices have a register of their diabetics and hypertensives, but an initial health screen would be essential in order to identify those with a FHCHD, a high STC, and those who smoke. This premise of a concerted attack on patients at high risk has recently been confirmed by the Scandinavian Simvastatin Survival Study (4S), whose cohort consisted of patients with IHD.

Simvastatin was found to reduce deaths from CHD by 42%, overall deaths by 30%, the need for bypass surgery or angioplasty by 37%, LDL by 38%, STC by 28%, and raised HDL in patients by 8%.

In a recent randomised controlled trial to assess the impact of a health check on health related behaviours and risk of CHD, feedback on risk score (CS) only had a small effect on reversible coronary risk. ¹⁸¹ The study population was predominantly middle aged male skilled manual workers, whereas, in the Surgery 3 Study, the patients were mainly an equal mix of male and female professionals and white collar workers of social classes 1 and 2. There is strong evidence of a strong relationship with social factors such as housing tenure, income and education, in that the most socially disadvantaged groups are a higher risk. ¹⁸²

11.4 SUITABLE ENVIRONMENT FOR HEALTH SCREENING

The RPSGB believes that pharmacists should make use of their skills to advise the public on maintaining a healthy lifestyle, and that they are well-equipped to conduct health screening and diagnostic testing. The SHHS found that nearly 60% of the Scottish population aged 40-59 years, have one or more risk factors for CHD. In a study in inner London, two or more risk factors for CHD were present in 25% of men and 22% of women. The Surgery 3 Study showed an incidence of 14% of patients with two or more risk factors, which means there are considerable resource and workload implications if advice on cardiovascular risk is to be given to the whole population and more intensive advice and services are to be extended to those at high risk. ¹⁸³

The pharmacist could help relieve the existing primary care workload, freeing the doctor to diagnose and manage illness. Although it may be possible for a pharmacist to provide an initial contact point for patients presenting with minor

illness, medical education, including a broad experience of clinical disease, equips a doctor to consider a range of alternative diagnoses.

There is a potential role for the pharmacist, as the demand for primary health care workers to give health promotion advice is increasing, especially as a survey has pointed out the need for improved nutritional education and training in dietary counselling for general practitioners, nurses and primary care facilitators. There are too few community dieticians to deal with this problem if we are to achieve "Health for all by the year 2000" in the UK 184,185.

The most suitable setting for the pharmacist operating a health screen would be the health centre or general medical practice, because of access to patients' medical records and availability of other members of the PHCT. A health screen could be successfully operated in the community, especially in a larger pharmacy with space to accommodate such a programme, and with the assistance of a nurse or dietician. A further possible benefit could be the attraction of the non-attenders at clinic screening programmes, who are likely to be those with higher risk factor profiles. For CHD prevention to be effective there is a need to cater for patients opportunistically. ¹⁸⁶

11.5 FACILITATION OF DIAGNOSIS OF EXISTING AND PRE-EXISTING DISEASE

One of the aims of health promotion is to encourage healthier living, by highlighting aspects of diet, weight, exercise, alcohol intake and smoking that may influence the development of disease. Health screening at Surgery 3 has been able to demonstrate potential benefits by finding an abnormal measurement that may be an element of pre-existing disease.

High Blood Pressure. At the first health screen, 25/390 (6.4%) of patients, previously not on the register of hypertensives, were found to have a BP above the outer limits prescribed by the practice protocol. 11 of the 199

- (5.5%) of the "no risk" category of patients also presented with a high BP.

 These were patients who, without identification and treatment, could have remained hypertensive. Hypertension is associated with progression of coronary atherosclerosis, congestive heart failure, and renal disease, as well as hypertensive crises.
- High Cholesterol. It is important to carry out cholesterol measurements in order to identify patients with severe hyperlipidaemia, who have a high chance of premature death without treatment. In the process, a far larger number of patients with moderate hypercholesterolaemia will be identified. They can then be treated depending on the presence of other risk factors. A total lipid profile to give an HDL cholesterol concentration will allow a more precise estimate of risk, and triglyceride measurement is required to characterise the lipoprotein abnormality. Hypertriglyceridaemia is often secondary to obesity, alcohol abuse, impaired glucose tolerance, or diabetes. ¹⁸⁷
- Blood Glucose. Health screening during the study detected some patients with a high blood glucose concentration, and identified three who were diagnosed as suffering from the existing disease of non-insulin dependent diabetes. As evidence is increasing that in some populations NIDDM shares common causal factors with CVD and in particular with CHD, screening to identify this condition remains a priority. ¹⁸⁸

11.6 INITIATION OF APPROPRIATE THERAPY

The studies at Surgery 2 and Surgery 3 provided opportunities for the pharmacist to initiate drug therapy, as illustrated in Chapter 7, where case studies illustrate the pharmacist input in the medication treatment of patients with hypertension, hypercholesterolaemia and diabetes.

There is a future for pharmacists to manage the medication for patients in speciality clinics, and act as a filter for the doctor, detecting drug interactions, side effects and inefficacious treatment.

The author's contention, supported by the FHSA pharmaceutical advisers and pharmacists, who replied to the questionnaires, is that the pharmacist's expert knowledge of drugs make him well suited to become responsible for the pharmaceutical care of the practice population.

11.6.1 Prescribing

Prescribing is the defining act of clinical intervention, marking the end of the diagnostic phase and the beginning of the therapeutic phase. The components of rational prescribing are:

- · a defensible formulation of the patient's problem
- clarity of therapeutic intention
- · access to independent data on drugs
- communication with the patient
- follow up

The pharmacist is the person trained to provide a framework of information to facilitate the third component, as follows:

- · Class, generic name, and proprietary names of drug
- therapeutic actions
- data about unwanted effects and interactions
- indications and contraindications
- recommended doses and regimes
- costs
- significant differences from previously established drugs in the same class, or drugs with an almost identical therapeutic intention
- a risk-benefit analysis

a cost-benefit analysis

The sheer size and complexity of the prescribing task may lead to doctors disaggregating the clinical task (see 9.5.2). Rational prescribing would highlight the challenge to doctors to add the efficiency of team work to their present intimate and continuing relationship with patients. The benefits of such team work, and a new co-operative relationship with pharmacists, are potentially great for doctors and nurses in the practice, and also for their patients. The pharmacists, based in practices, are known as primary care pharmacists (PCPs). Some exist already, and they oversee repeat prescriptions and manage the formulary.

The PCP's role would include:

- formulary management
- medication review
- prescription query
- pharmacokinetic assessment
- compliance assessment
- drug counselling

Some would also run speciality clinics (Chapter 9). This arrangement would mean major implications for the role and development of community pharmacists. PCPs in larger practices effect liaison with community and hospital pharmacists. Smaller practices may develop links with a number of independent pharmacies, or a pharmacist facilitator representing several pharmacies.

Whatever the configuration, there is an opportunity for pharmacists to emerge as key players in the PHCT of the future.

11.7 THE PUBLIC'S PERCEPTION OF THE PHARMACIST

As with any developments, such as those envisaged in 11.6.1, if they are seen to respond to need and to be well accepted by patients, the diffusion effect will be rapid. A questionnaire was designed to evaluate the patient's perception of the pharmacist as a health education adviser and conductor of diagnostic tests. The questions were asked verbally during the first health consultation of the 449 patients at Surgery 3. The results of the questionnaire are summarised in Table 11.1.

Table 11.1 Ouestionnaire to Patients in Surgery 3 Study

Question	Response	n = 449	
2,	Yes	No	Not Sure
1 Do you know your BP measurement?	135 (30%)	314 (70%)	
2 Do you consider health screening to be important?	411 (92%)		38 (8%)
3 Would you benefit from advice on diet and lifestyle?	395 (88%)	30 (7%)	24 (5%)
4 Do you think it's the Chemist's job to give general health advice?	289 (64%)	73 (16%)	88 (20%)
5 Would you consider going to a pharmacy offering a diagnostic testing service?	203 (45%)	182 (41%)	64 (14%)
6 Do you consider that pharmacists have been trained to conduct such tests?	221 (49%)	143 (32%)	85 (19%)

Patients were ambivalent about using the pharmacy for a diagnostic test, partly through ignorance of the education and training of a pharmacist, and partly because it would not have occurred to them.

Comments on whether the pharmacist should give health advice included: "pharmacists are: easily approachable and immediately available"

- good at giving advice on minor ailments, such as coughs and colds"
- best at identifying side-effects of medicaments"
- · wonderful. They listen and spend time"
- "pharmacists save the doctors' time"
- "we would accept health advice only from a pharmacist that is known and trusted"

The question, "What do you feel you may gain from health screening?", produced the following comments:

"It is better to be aware of a problem and do something about it before it's too late."

"It reinforces health messages and ensures continuing good health."

"It enables early detection of disease and gives peace of mind."

"Middle age is a critical time for screening, and I want to see retirement."

"It is an excellent idea, especially for those with a bad family history."

"It is very rewarding, and has galvanised me to want to lose weight."

"I am pleased to know my sugar and cholesterol levels, as the more knowledge the better."

"It sends out signals and keeps one to a healthy routine, as it is too easy to slip."

11.8 THE CLINICAL ROLE OF THE PHARMACIST IN EUROPE

The professional contribution of community pharmacists could become central to the European Community pharmaceutical supply system. If the profession moves towards a diagnostic and prescribing function, with its members using their special knowledge of pharmaceuticals to guide consumers in their appropriate use, it could offer health care consumers the option of reliable, quick and convenient therapeutic advice. This development is supported by regulatory changes introducing an extended range of pharmacy-only medicines across Europe.

11.8.1 Current philosophy for community pharmacy in Europe

A community pharmacy is a primary health care unit whose purpose is to supply drugs, often with adequate expert advice, to ensure that they are correctly used, to promote customer's health and to assist in the treatment of disease. The overriding aim is to provide community pharmacy services that consumers are satisfied with. This can only be achieved by taking into account patient's wishes and demands, and by working more closely with the rest of the health care system.

On the one hand, community pharmacies are becoming health care guidance and service units promoting health and preventing illness, and on the other hand, they are increasingly the first step in the hierarchical system of primary health care for the treatment of minor ailments, and, together with physicians, of more serious illnesses. These new activities support and supplement the traditional role of community pharmacies as dispensers of prescription drugs and providers of drug-related information.

11.9 OVERALL CONCLUSIONS

These conclusions are based on the research data in this thesis.

- Health screening and diagnostic testing can be facilitated by a pharmacist in a general medical practice, as a result of which the practice has a comprehensive record of physical and lifestyle parameters for their patients. This has provided a reference for doctors and practice nurses during subsequent surgeries.
- The initial health screen interview provided the impetus for the pharmacist to follow patients up for at least two years. This monitoring and reinforcement of health care advice led to an improvement in the coronary health status of many patients who presented with cardiovascular risk factors. Those patients with a good health profile maintained their status.
- 3 Measurable health gains were achieved for patients:
 - (a) diagnosis of possible pre-existing disease effected by detection of patients with high BP and/or STC,
 - (b) diagnosis of the existing disease of NIDDM through detection of high RBG.
- Mass population screening would be ideal, if costs and resources would allow.

 Selection of those individuals with a family history of a particular disease would, otherwise, give a greater chance of identifying those at greatest risk of developing that disease.
- Detection of abnormal physical measurements enabled the pharmacist to contribute to the prescribing process. Medication review, including drug, dosage and formulation change, was effected during the studies at the surgeries by the pharmacist, for better pharmaceutical care for the patient.

- Successful integration of the pharmacist with the PHCT was achieved during the study project. Regular contact and involvement with GPs led to their recognition of the pharmacist's expertise and value. The GP perception changed, so that he recognised the pharmacist as having an influence on prescribing.
- The costs of providing drugs and appliances to patients constitutes the largest single element of the N H S primary care budget. The acceptance of pharmacists as equal partners would enable them to be central to the management of this practice area. The profession would be enhanced, and drug selection for individual patients after initial diagnosis by the GP may become more widely accepted.
- Patients' perception of the pharmacist alters when they experience innovative services not previously associated with pharmacists. The patients' confidence in the pharmacist as a health care professional increases, and they would be amenable to pharmacists providing direct advice to them at special clinics such as asthma clinics.

11.10 PROPOSALS

- Different modes of delivering pharmaceutical care should now be considered and the potential of the primary care pharmacist should be encouraged to develop.
- 2 Links with GPs should be strengthened, creating an effective and efficient combination of doctor, nurse and pharmacist, providing a superior level of service to patients.
- Development of this new category of pharmacist should not obviate the retention of community pharmacists in their traditional high street location.

 Provision of private counselling facilities must be a priority in all pharmacies to meet the public's increasing expectations.

- 4 Health Authorities should support innovative services by appointing pharmacist facilitators to coordinate these new activities.
- Pharmacists will need continuing education to improve their clinical knowledge and ability to communicate with GPs and patients. Remuneration allocated to a student centered, multidisciplinary training alongside other primary health care team members would be particularly beneficial.

11.11 PREDICTIONS

As a consequence of the research discussed in this thesis, it is possible to consider some of the likely changes in community pharmacy as the profession moves forward towards the next millenium, in a more objective way:

- Diagnostic testing and health screening can be successfully operated by a community pharmacist in a primary care setting. In this way, a patient's health profile can be obtained and diagnosis of any existing or pre-existing disease made, which could lead to appropriate drug therapy. The research has shown that further diagnostic test results can be integrated with medication monitoring and evaluation of treatment outcomes.
- Increased recognition and utilisation of pharmacists' expertise in primary
 health care could result in an increase in demand for community-based
 pharmacists. However, there may not necessarily be a stable future for all
 independent contractors. Much dispensing is mechanical, and may be
 performed by trained dispensers. In some countries, such as Norway, a
 'prescriptionist' handles the dispensing process, releasing the pharmacist from
 the supply function. A steadily increasing number and proportion of
 prescriptions are dispensed by the larger branches of multiples and by
 supermarket pharmacies, who offer more employment for additional

- pharmacists. The independent community pharmacist will have to pursue a much more pro-active personal face to face role, in selected areas such as health promotion and prescribing, in order to survive.
- Rationalisation of pharmacies, based on geography and population movements, should take place to enable resources to be optimised and pharmacies to be located where they would be most useful. This would reduce the negative extent of intraprofessional rivalry, and could be linked with patient registration, with a pharmacy of the patient's choice. As an increasingly sophisticated range of more effective and potent drugs becomes available for patients to purchase in a self-care capacity, reliably complete PMRs become increasingly important. A formalised system of patient registration would enable the pharmacist to take proper responsibility for a patient's pharmaceutical care and enhance patient/customer safety. Other attributes would include readier seamless care between secondary and primary care, easier inter-professional liaison, especially with GPs, and facilitation of improved domiciliary care when necessary.
- Multiple chain chemists will continue to see prescriptions as a means of generating customer flow, and, with their strength in buying power, and shareholder pressure, they will continue their policy of expansion.
- Supermarket pharmacy will expand, especially if resale price maintenance on medicines is abandoned. They may contribute to health promotion through their growing customer base, especially if rationalisation as referred to in 3 above does not materialise.

The system of remuneration is of vital concern to all practising pharmacists.

For those members of the profession who are involved with formularies, prescribing advice or medication review, payment will be made by the: (a) Health Authority or Trust, (b) fundholding GP practice, or (c) GP practice staff budget.

The rates paid should be commensurate with those paid to doctors, dentists and opticians. Such investment has already been seen to effect cost savings on the drug bill, and more rational prescribing for the prime benefit of patients.

A pharmacist can make the repeat prescribing function more rational, safer and economic, and save on unskilled receptionist staff-time.

- The global sum may be redistributed to account for services other than the supply of medicine, such as advice to nursing homes. Payment for these services is now devolved locally. Practice research funding is essential to evaluate the cost-effectiveness and ensuing patient benefit.
- Leadership will be provided through the 'new age' initiative of the RPSGB, and the Community Pharmacists' Group could actively initiate the physical progress of some of the 'new age' findings. Their campaign strategy will be to promote the community pharmacist as 'A New Gatekeeper to Healthcare'. The campaign will need to define and substantiate what pharmacists can do, to promote the message to the public, the healthcare professions and ultimately the paymasters. The profession may then move forward to a more satisfying and rewarding future.

11.12 SUGGESTIONS FOR FUTURE RESEARCH

These are prompted by issues raised by the research in this thesis:

- 1. A further follow-up of patients from Surgery 3, one year later, to determine whether diagnostic information has made a continuing contribution to patient safety, health status and quality of treatment.
- A comparison of the health outcome benefit and cost of a health screening programme in a GP practice, deriving from the input of a nurse practitioner and a community pharmacist.
- A cooperative project between hospital and community pharmacists to smoothe the transition between hospital and home, with particular respect to a a patient's medication.
- 3. A project to measure the validity of health promotion in pharmacy, in terms of health gain.
- 4. An investigation by a pharmacist into the medication spectrum of patients in: (a) a nursing home, and (b) a residential care home, to determine the extent to which medication has to be reappraised to effect improved health outcomes.

A project to determine the acceptability by GPs of:

- 5. Pharmacists managing repeat prescribing
- Pharmacists choosing medication after a doctor's diagnosis
- 7. Pharmacist liaising with GPs for rational prescribing
- A computer connection from a pharmacy to a surgery, that allows the transmission of prescription data and gives pharmacists access to doctors' drug records.

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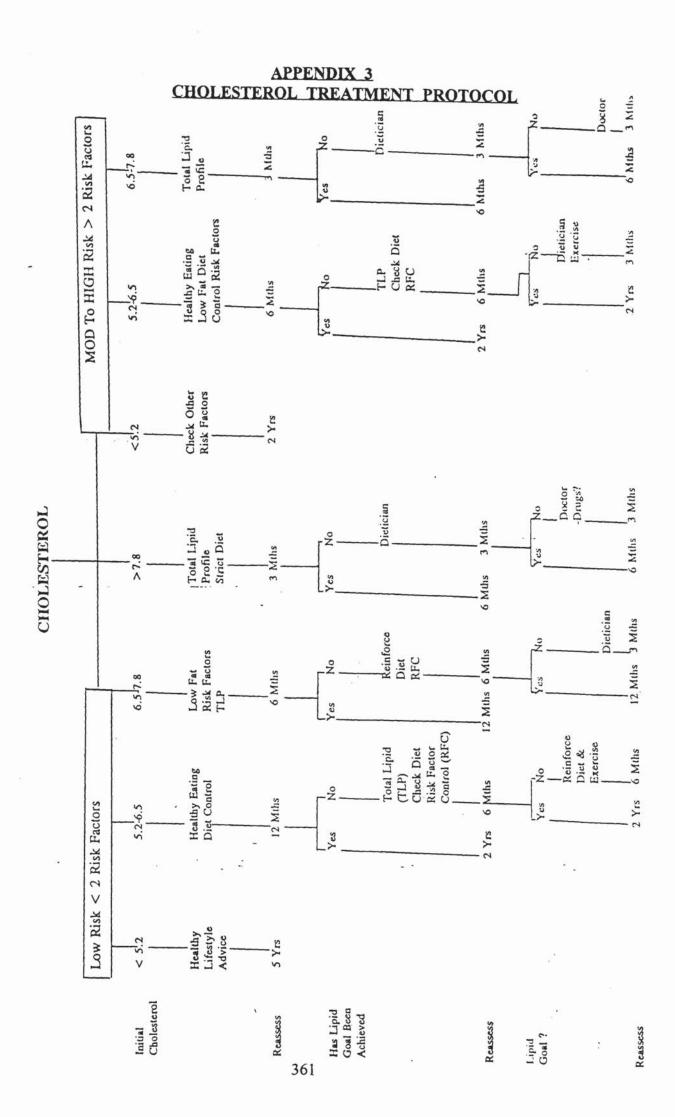
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ELLIOTT HALL MEDICAL CENTRE HEALTH SCREENING QUESTIONNAIRE

				(PLEASE AMEN LABEL DETAIL ARE INCORREC	.S
	Have you suffered fro	om any of the	e following	(please circle the appropria heart problems?	ite answer)
	a) Angina b) Heart Attack	Yes/No Yes/No	,	Bypass Heart Surgery Angioplasty	Yes/No Yes/No
	Have any of the follo before the age of 55		s suffered f	rom angina or a heart at	tack
	a) Mother b) Father	Yes/N		Brother Sister	Yes/No Yes/No
Ple	ease specify details:		/		
3.	Do you suffer from l	Diabetes?			Yes/No
3. 4. 5.	Do you suffer from Its there any hereditate Do you smoke now?	ary disease of	f Familial F	Iyperlipidaemia?	Yes/No Yes/No Yes/No
4. 5.	Is there any heredita	ary disease of	f Familial E	Iyperlipidaemia?	Yes/No
4. 5.	Is there any heredita Do you smoke now?	ary disease of	Familial F		Yes/N
4. 5.	Is there any heredita Do you smoke now? f yes, please specify:	ary disease of	"Roll You	r Own" oz p	Yes/N Yes/N
4. 5. If C	Is there any heredita Do you smoke now? f yes, please specify: Cigarettes Cigars Have you smoked r	per day per day	"Roll You Pipe Toba	r Own" oz p	Yes/N Yes/N er week er week
4. 5. If C	Is there any heredita Do you smoke now? f yes, please specify: Cigarettes Cigars Have you smoked r yes, when did you stop?	per day per day egularly in the	"Roll You Pipe Toba	r Own" oz p	Yes/Normal
4. 5. If C	Is there any heredita Do you smoke now? f yes, please specify: Cigarettes Cigars Have you smoked r yes, when did you stop? Iow long did you smoke	per day per day egularly in the	"Roll You Pipe Toba	r Own" oz p	Yes/No Yes/No er week
4. 5. If C	Is there any heredita Do you smoke now? f yes, please specify: Cigarettes Cigars Have you smoked r yes, when did you stop?	per day per day egularly in the for? nsumption?	"Roll You Pipe Toba	r Own" oz p	Yes/Normal

If yes, date of diagnosis (approx.)

Yes/No

Have you ever suffered a stroke?

What is your height?	cm.	or	Ft.	Ins.
What is your weight?	Kg.	or	St.	lbs

EXERCISE (Please be honest!!)

(a)	How many times during the <u>past 4 weeks</u> have you taken any sort of physical activity at all (including walking) that lasted <u>20 minutes or more</u> .	Number of Times :
(b)	How many of these involved continuous movement of the whole body (eg: walking, swimming, dancing, cycling, aerobics, football)	No
(c)	How many of these activities were vigorous enough to make you breathe hard or sweat.	No

10. Do you drink alcohol?

Yes/No

f Yes, specify in units	your average weekl	y consumption
Beer/Cider	Units	1 unit = ½ pint beer/cider
Sherry	Units	= 1 measure of sherry
Wine	Units	= 1 measure wine
Spirits	Units	= 1 single measure spirits

11.	Has your cholesterol be	Has your cholesterol been checked in the past 3 years?				
	If Yes, was this requeste	d by				
	a)	yourself	Yes/No			
	b)	your GP	Yes/No			
	c)	a hospital consultant	Yes/No			
	d)	other, please specify				
12.	Do you know your cho	lesterol level?	Yes/No			
13.	Has your blood pressur	re been checked in the past 3 years?	Yes/No			
	If Yes, was this	2				
	a)	at the surgery	Yes/No			
	b)	at the hospital	Yes/No			
	c)	at the chemist	Yes/No			
	d)	at work	Yes/No			
	e)	other, please specify				

14. Do you know your blood pressure reading?

Yes/No

If Yes, please specify

If you were selected for a health screening interview would you be willing to attend the Medical Centre? Yes/No

If Yes, please specify preferred day of the week and time	Day of the Week :	Time :
---	-------------------	--------



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DIET QUESTIONNAIRE TO PATIENTS

1. Are you a vegetarian? YES	
NO	
If yes, please state why:	
2. How often do you eat the following foods. Please put a tick in the box applies to you.	k that
FOOD 5 to 7 2 to 4 ONCE OCCASIONAL NE	VER
TIMES WEEKLY	
Bread, Chappatis, pitta	
Breakfast cereals, porridge	
Pasta, Rice	
Baked Beans, Lentils	
Potatoes - Jacket, Boil	
Potatoes - Roast, Chipped	
Fresh Salad/Vegetables	
Fresh Fruit	
Tinned Fruit/Vegetables	
Chicken, Turkey, Fish	
Lean Beef, Lamb, Pork	
Sausages, Meat Pies, Bacon	
Cheese	
Eggs	
Biscuits, Cakes	
Chocolates, Sweets, Crisps	
Take Away Meals	
Sauces, Ice Cream	
Soft Drinks	
Tea	

Coffee

3.	What sort of spread to you use on bread:
	Butter
	Low fat spread
	Polyunsaturated Margarine
	Soya Margarine
	Nothing
	Other, please specify:
4.	What sort of fat or oil do you use for cooking?
	Vegetable Oil
	Olive Oil
	Lard
	Butter
	Margarine
	Ghee
	Polyunsaturated Oil
	Other, please specify:
5.	Is the milk you use:
	Full fat
	Semi-skinned
	Skimmed
	Soya
	Don't drink milk
6.	What are the methods of cooking at home, in order of preference?



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APPENDIX 9 STANDARD FOOD MEASURES



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PATIENTS' INDIVIDUAL CARDIOVASCULAR SCREENING RECORD

PATIENT'S NAME

FAMILY HISTORY

- 1. Heart Disease under 60
- 2. High Blood Pressure
- 3. Stroke
- 4 Diabetes
- 5. Cholesterol

	READING	NORMAL
7 - 1 · 1 · 1 · 2 · 2 · 2 · 1 · 1 · 1 · 1 ·		
BLOOD PRESSURE		
Systolic		100-160
Diastolic		60-95
SERUM CHOLESTEROL	FC	4.0-6.5
HDL CHOLESTEROL		>1.0
TRIGLYCERIDE		0.8-1.8
BLOOD SUGAR		4.0-8.0
BMI (HEIGHT/WEIGHT)		19-25

SMOKING STATUS

EXERCISE LEVEL

STATISTICS REVIEW

Statistical tests applied to the data, measurement and categorical, in this research, have involved the estimation of one or more parameters of the distribution of scores in the population(s) from which the data were sampled and involve assumptions concerning the shape of that distribution. For example, the t-test makes use of the sample variance (S²) as an estimate of the population variance and also requires the assumption that the population from which we sampled is normal.

A Parametric Test: Tests, such as the t test, that involve either assumptions about specific parameters or their distribution are referred to as parametric tests.

1 t-test for paired samples

The set of scores that represents the difference between the subject's performance from the same population on two occasions

Example:

Chapter 6.4.5 Hypothesis 10

Systolic blood pressure at the first health screen and at

the final one.

t-tests for Paired Samples

Variable	Number pairs		2-tail Sig	Mean	SD	SE of Mean
SYSTOL1	Systolic B P	(mmHg)-1st	Time	151.5970	21.216	2.592
SYSTOL5	Systolic B P	(mmHg)-Fina	al Tim	141.5075	17.099	2.089

P	aired Diffe	rences			
Mean	SD	SE of Mean	t-value	df	2-tail Sig
10.0896	15.563	1.901	5.31	66	.000
95% CI (6.	293, 13.886)			

2 t-test for independent samples

When we are interested in testing for a difference between the mean of one population and the mean of a second population, we will be testing a null hypothesis of the form Ho: $u_1 - u_2 = 0$, because the test of this null hypothesis involves the difference between independent sample means.

Example:

Chapter 6.4.1 Hypothesis 3

Diastolic blood pressure of patients with or without a

family history of cerebrovascular disease of

hypertension.

t-tests for Independent Samples of FHHBP

Family History of H T or C V A

Variable		Number of Case:	s Mean	SD	SE of	Mean
DIASTOL1	Diastolic B P	(mmHg)-1st	Time			
No		236	83.3602	10.778		.702
Yes		213	84.2254	10.703		.733

Mean Difference = -.8652

Levene's Test for Equality of Variances: F= .032 P= .859

or TOT Dans	TICA OF M	eans		95%
t-value	df	2-Tail Sig	SE of Diff	CI for Diff
85	447	.395	1.015	(-2.860, 1.130)
85	442.92	.394	1.015	(-2.860, 1.129)
	t-value	t-value df 85 447	85 447 .395	t-value df 2-Tail Sig SE of Diff 85 447 .395 1.015

Definition of Statistical Terms

(a) Student's t distribution (t)

The sampling distribution of the t statistic, where t is the difference between a sample mean and a population mean, divided by the standard error of the mean.

(b). Degrees of freedom (df)

The number of independent pieces of information remaining after estimation of one or more parameters.

(c) p value

The probability of making a type 1 error, i e rejecting the null hypothesis when this hypothesis is true. Generally, a significant level of p < 0.05 is applied, that is, there is a less than 1 in 20 chance that the result of the statistical test could have occurred by chance. The power is the probability of correctly rejecting a false H_0 .

(d) confidence limits and confidence intervals

An interval, with limits at either end, with a specified probability of including the parameter being estimated.

(e) Homogeneity of variance

The situation in which two or more populations have equal variances.

3 Analysis of Variance (ANOVA)

A statistical technique for testing for differences in the means of several groups.

Example: Chapter 6.4.3 and 6.4.4 Hypothesis 8 and 9

Variation in systolic blood pressure accounted for by the age and the sex of a patient.

* * * ANALYSIS OF VARIANCE * * *

SYSTOL1 Systolic B P (mmHg)-lst Time SEX Sex Of Patient AGE Age Of Patient In Years by

> UNIQUE sums of squares All effects entered simultaneously

Source of Variation	Sum of Squares	DF	Mean Square	F	Sig of F
Main Effects SEX	39679.919 1051.244	5	7935.984 1051.244	28 ⁻ .755 3.809	.00
AGE	38089.224	4	9522.306	34.503	.00
2-Way Interactions SEX AGE	1640.100 1640.100	4 4	410.025 410.025	1.486	.205
Explained	46872.484	9	5208.054	18.871	.00
Residual	121158.144	439	275.987		
Total	168030.628	448	375.068		

449 cases were processed. 0 cases (.0 pct) were missing.

* * * CELL MEANS * * *

SYSTOL1 Systolic B P (mmHg)-1st Time by SEX Sex Of Patient
AGE Age Of Patient In Years

Total Population

134.63 (449)

SEX 1 137.13 132.71 (195) (254)

AGE 3 4 2 121.81 121.07 126.97 135.23 146.79 (16) (69) (101) (111) (152)

AGE 1 2 3 4 5 SEX 1 122.44 127.30 131.19 137.27 146.23 (9) (23) (42) (55) (66) 2 121.00 117.96 123.97 133.21 147.22 (7) (46) (59) (56) (86)

4 One-Way ANOVA

An analysis of variance where the groups are defined on only one independent variable.

Example: Chapter 6.4.15 Hypothesis 22 Association between TG levels and BMI in patients.

---- ONEWAY ----

Variable TRIGLYC Triglyceride (mmol/1)-1st Time By Variable BMINEW B M I Categories

Multiple Range Tests: Student-Newman-Keuls test with significance level .050

The difference between two means is significant if MEAN(J)-MEAN(I) >= .6413 * RANGE * SQRT(1/N(I) + 1/N(J)) with the following value(s) for RANGE:

Step 2 3 4 RANGE 2.81 3.35 3.67

(*) Indicates significant differences which are shown in the lower triangle

G G G G r r r r p p p p

0 1 2 3

Mean BMINEW

1.1631 Grp 0
1.5339 Grp 1
1.8402 Grp 2 *
2.2018 Grp 3 * *

---- ONEWAY ----

Variable TRIGLYC Triglyceride (mmol/1)-1st Time
By Variable BMINEW B M I Categories

Analysis of Variance

5	Source	D.F.	Sum of Squares	Mean Squares	F Ratio	F Prob.	
Between G Within G Total	•	3 164 167	13.8515 134.8771 148.7286	4.6172 .8224	5.614	.0011	
Group	Count	Mean	Standard Deviation	Standard Error	Minimum	Maximum	95 Pct Conf
Grp 0 Grp 1 Grp 2 Grp 3	13 74 53 28	1.1631 1.5339 1.8402 2.2018	.5940 .7531 1.0834 1.0222	.1647 .0875 .1468 .1932	.5100 .5000 .5000 .9200	2.7400 3.4000 5.4000 5.1500	.8041 1.3594 1.5416 1.8054
Total	168	1.7132	.9437	.0728	.5000	5.4000	1.5694

The F Statistic

F is obtained by dividing the mean square of the group by the mean square of the variance of the observations within each treatment. If H_0 is true, then both are estimating the same thing and F would be approximately 1. If the computed value of F is significantly greater than 1, then H_0 will be rejected.

B Non Parametric Tests

Inferential Statistical tests that do not rely on parameter estimation or precise distributional assumptions.

1 Chi-Square test

A statistical test often used for analysing categorical data.

Example: Chapter 6.4.1 Hypothesis 2
Association between coronary risk and family history of coronary problems

FHIST by GROUP Patient Categorisation after Initial Health Screen

		GROUP			
	Count	 High Ris k 1.00	Intermed iate Ris 2.00		Row Total
FHIST	.00	40	75	150 	265 59.0
	1.00	31	78	75 	184 41.0
	Column Total	71 15.8	153 34.1	225 50.1	449 100.0
Ch Significa	i-Square nce		Val	lue	DF
Pearson .00251		-	11.976	598	2

Number of missing observations = 0

2 Mann Whitney test

A non parametric test for comparing the central tendency of two independent samples.

3 Wilcoxon's matched pairs signed ranks test

A non parametric test for comparing the central tendency of two matched (related) samples.

Example:

Chapter 8.4.4

Rating of pharmacist's involvement in health promotion activities, now and in the future.

Crosstabulation of these five health promotion activities shown in Table 8.6 further indicate the adviser's expected trend for pharmacists involvement.

Table 8.6 Health promotion activities: A. Smoking cessation

Count	c o.o Ticuiti	promotion	delivities. 1	I. DIIIVINIE	COSSALION	
	Row Pct Col Pct	1 2.00	3.00	4.00	5.00	Row Total
Q.8.1.A	1.00		1 50.0 33.3		1 50.0 2.8	3.8
	2.00	1 5.6 100.0	1 5.6 33.3	3 16.7 25.0	13 72.2 36.1	18 34.6
	3.00		1 5.3 33.3	5 26.3 41.7	13 68.4 36.1	19 36.5
	4.00	 		3 37.5 25.0	5 62.5 13.9	8 15.4
	5.00	 		1 20.0 8.3	4 80.0 11.1	5 9.6
	Column	1	3	12	36	52
	Total	1.9	5.8	23.1	69.2	100.0

4 Correlation coefficient

Example:

Chapter 6.4.12 Hypothesis 19

Cholesterol level and significant positive correlation

with diet

- Correlation Coefficients - -

	DIET	CHOLNEW	
DIET	1.0000	.5028	
	(449)	(448)	
	P= .	P= .000	
CHOLNEW	.5028	1.0000	
	(448)	(448)	
	P= .000	P= .	

(Coefficient / (Cases) / 2-tailed Significance)

Pearsons (r) - a measure of the relationship between variables Spearmans (rs) - a correlation coefficient on ranked data.

5 Multiple correlation coefficient

Example HDL Cholesterol variable and a set of predictors.

* * * MULTIPLE REGRESSION * * * *

Listwise Deletion of Missing Data

	Mean	Std Dev	Label
HDL AGE SEX EXERCISE CIGS.DY	1.207 4.000 1.520 1.317 4.810	1.128 .501 .858	High Density Lipoprotein (mmol/l)-1st Ti Age Of Patient In Years Sex Of Patient Exercise Assessment -1st Time Amount Smoked per Day-1st Time

N of Cases = 221

Correlation, 1-tailed Sig:

	HDL	AGE	SEX	EXERCISE	CIGS.DY
HDL	1.000	.074	.401	.082	146 .015
AGE	.074	1.000	016 .406	141 .018	132 .025
SEX	.401	016 .406	1.000	026 .352	.053
EXERCISE	.082	141 .018	026 .352	1.000	069 .155
CIGS.DY	146 .015	132 .025	.053	069 .155	1.000

NORTHWICK PARK HOSPITAL REPORT FOR DIABETIC PATIENT

NORTHWICK PARK HOSPITAL DIVISION OF PATHOLOGY

(0000) но	24179	PATRICIA 62 YRS	FINAL DR A H BYERS 165-167 UXBRIDG HATCH END PINN GENERAL PRAC	GE RD ER HA5 4E	PRINTED TIME CA ADMITTED PAGE	2303 25/02/94
			CHEMISTRY			
	7.21	7-		EN DATE	25FEB94	A) - 5.5.116.
			WEEKDAY/DAY		FRI 001	
	PROCEDU	JRE :	REFERENCE RANGE	TIME UNITS	1043	
	SODIUM		(136-147)	MMOL/L	141	
	POTASSI		(3.8-5.2)	MMOL/L	4.3	
	UREA		(2.5-6.5)	MMOL/L	4.7	
	CREATIN	NINE	(45-125)	UMOL/L	85	
		E FASTING	(3.5-6.4)	MMOL/L	9.9*	
		YLATED HB	(5.6-7.6)	8	10.0*	
	CHOLES	TEROL	(4.0-6.5)	MMOL/L	7.2*	
	-			MEN DATE		9 0 90 90 91 91
			WEEKDAY/DAY			
	PROCED	URE	REFERENCE RANGE	TIME UNITS	1042	
CELL COL	JNTS					
	HB		(12.0-16.0)		14.1	
	HCT		(36.0-46.0)	8	42.6	
	WBC		(4.5-11.0)	X10^9	6.5	
	RBC		(4.50-5.90)		4.56	
	MCV		(81.0-99.0)	FL	93.4	
	MCH		(27.0-32.0)	PG %	30.9	
	MCHC	r Erm	(31.0-36.0) (150-400)	x10^9	280	
	PLATE	OCYTES	(1.3-3.0)	X10 9	2.9	
51.3		OPHILS	(2.2-7.0)	X10^9	3.0	
		OPHILS	(0.0-0.4)	X10^9	0.2	
	MONOC		(0.2-0.8)	X10^9	0.4	
	BASOP		(0.0-0.1)	X10^9	0.0	
symbols	used					

* = OUTSIDE REF RANGE

QUESTIONNAIRE TO FHSA PHARMACEUTICAL ADVISERS

Q1.	For how many years has your FHSA had a Pharmaceutical Adviser?	Yrs
Q2.	How long have you been in the post?	Yrs
Q3.	Do you attend your LPC meetings? Yes No	
	If No, please give reasons:	
Q4.	Do you have an active role in advising on any of the following with pharmacists in your area?	th community Please
	Patient Medication Records Domiciliary Visits Advice to Residential Homes Staff Supply of Medicines to Nursing Homes Medication Disposal Arrangements	Tick
	Other, please state:	
Q5.	Has your FHSA taken any action with regards to any of the follow Community Pharmacy?	wing in
Oth	Referral forms from a pharmacy to a GP after a diagnostic test Referral forms from a pharmacy to a GP for patients' symptoms Compliance aids for patients Availability of disability aids to the public Domiciliary medicine monitoring scheme Aseptic dispensing services Syringe/needle exchange scheme Display of health education leaflets Instalment dispensing arrangements ner, please state	Please Tick

Q6.	COMPUTERS
6.1	How many pharmacies are there in your FHSA area?
6.2	How many of them keep PMRs?
6.3	How many of these PMRs are kept on computer?
6.4	Are the PMRs mainly used for repeat prescription handling?
	Yes No
6.5	How many GP practices are there in your area?
6.6.	How many have a computer connection with a community pharmacist?
Q7.	HEALTH SCREENING
7.1	How do you rate the value of the pharmacist's role in health screening by the provision of diagnostic testing services? Please score your answer on a scale of 1 to 5 where 1 is very low and 5 is very high.
	The second of the very flow and one very ringin.

7.2 As part of an integrated service by pharmacists to the public, how do you rank the following diagnostic testing services? Please rank from 1 to 10, where 1 is undesirable and 10 very desirable.

SERVICE	RANK
Total Serum Cholesterol	
Blood Pressure	
Height/Weight	
Random Blood Sugar	1
Monitoring of Pulmonary Function	
Therapeutic Drug Monitoring	
Pregnancy Testing	

Others. Please name and rank:

7.3 Please indicate at what charge pharmacists should provide these services to the public.

Please Tick One

No Charge Nominal Charge

Total Serum Cholesterol

Blood Pressure

Height/Weight

Random Blood Sugar

Peak Flow Measurement

Therapeutic Drug Monitoring

Pregnancy Testing

7.4 How many GP practices in your area offer the following tests, other than opportunistically free of charge.

	Number	If Don't Know Tick
Total Serum Cholesterol		
Random Blood Sugar		
Pregnancy Testing		

8. HEALTH PROMOTION

Please rate the pharmacist's involvement in the following health promotion activities, on a scale of 1 to 5 where 1 is not at all involved and 5 is very involved.

ACTIVITY	Now	Future
Smoking Cessation		
Alcohol Intake		
Diet and Nutrition		
Pregnancy		
Exercise		

Q9. GP FORMULARY DEVELOPMENT

9.1 A	are any pharmacists in your area involved with	th GP's:		
		Yes	No	Don't Know
1. Pre	escribing advice			
2. Dr	ug usage guidelines & treatment otocols development			
3. GF	practice formulary development			
9.2 l	If Yes;		Please	e tick one
	How many GP practices are involved?			
	2. How many community pharmacists are in	volved?		
	3. Any other arrangements?			
9.3	Have you been able to record any cost savir pharmaceutical input?	ngs on p	rescribin	g as a result o
	·			res No now

9.4 Can you list up to 3 examples of more appropriate prescribing due to pharmaceutical intervention.

Would you be willing to discuss this aspect further?

Q.10 GP - PHARMACY LIAISON

10.1	"The patient would be best served if repeat dispensing pharmacists"	were administered by
	Do you:	
		Please tick one
10.2	"There would be significant cost savings to the NHS if the repeat prescribing for patients."	pharmacists managed
	Do You:	
	Strongly agree Slightly agree Neither agree nor disagree Disagree slightly Strongly disagree	Please tick one
Addit	ional comment	
10.3	"It would be cost-effective for the NHS to employ a ph alongside GPs in a group practice to manage their rep diagnostic testing."	
	Do you:	
	Strongly agree Slightly agree Neither agree nor disagree Disagree slightly Strongly disagree	Please tick one
	A I III I commont	

10.4 "By 2000AD, the pharmacist should select the medicine and dos agreed protocols following medical diagnosis or assessment"		
	Do you:	
	Strongly agree Slightly agree Neither agree nor disagree Disagree slightly Strongly disagree	Please tick one
	Additional comment	

Q11. REMUNERATION

11.1 As part of pharmacists future remuneration for any new services is to be devolved locally, please rate the following list which may affect the direction of community pharmacy development, where 1 is of no importance and 5 is of very high importance.

Item	Service	Rating	
1	Health education leaflets		
2	Health promotion, eg. smoking		
3	Health Screening, eg. blood pressure		
4	Patient medication records		
5	Residential homes medicine supply	Residential homes medicine supply	
6	Domiciliary visits		
7	Monitored dosage system		
8	Needle and syringe exchange service		
9	GP Formulary development		
10	Analysis of PACT data		
11	Advice to Nursing homes		

11.2	How much, as a percentage of the global sum, should be set aside for remuneration of these extra services?

11.3	"The two-pharmacist pharmacy is not generally an economic viability in a free market situation"
	Do you:
ė.	Strongly agree Slightly agree Neither agree nor disagree Disagree slightly Strongly disagree with this statement
Q12	LOCATION Assuming that pharmacists respond to this new role of contributing to primar health care needs by offering a wider range of services, do you think this car best be performed from:
	Please rate from 1 to 5 where 1 is least suitable and 5 the most suitable type of outlet.
	(a) an independent pharmacy outlet (b) a general medical practice (c) a health centre (d) a multiple chain chemist (e) a supermarket pharmacy
Q13.	Does your FHSA employ a pharmacist facilitator to co-ordinate the pharmaceutical contribution to the Pharmacy Health Care?
	Yes No If No, is there an intention to do so? Yes No

"The future is for two types of pharmacy: one which provides the traditional spectrum of pharmaceutical supplies to the local community, and the other either in or near to a health centre which concentrates on dispensing and health care"
riediti Care

Please

Do you:

	tick one
Strongly agree	
Slightly agree	
Neither agree nor disagree	
Disagree slightly	
Strongly disagree	

Additional comment

Q.15 Below is a list of factors which may inhibit the development of patient oriented pharmaceutical care. Please rate from 1 to 5, where 1 = very little influence and 5 = very great influence.

	Factor	Score	
1	Pharmacists not accepted as a member of PHCT		
2	Contractors hours of opening		
3	Need for pharmacist to supervise dispensing etc.		
4	Single pharmacist pharmacies		
5	Contract limitation		
6	Freedom to open a pharmacy anywhere		
7	Out of town shopping malls with superstore pharmacies		
	(distanced from GP surgeries)		
8	Pharmacists not in GP practices		
9	Pharmacists' lack of access to patients' medical notes		
10	Historical non-rational distribution of pharmacies		

Q16. Please add any other comments about your perception of the community pharmacists role in the future policy of the FHSA?

APPENDIX 18 LETTER TO FHSA PHARMACEUTICAL ADVISERS ASTON UNIVERSITY



DEPARTMENT OF PHARMACEUTICAL & BIOLOGICAL SCIENCES

Professor of Cancer Biochemistry
*M J Tisdate BSC PhO DSC
*Foressor of Pharmaceutinal Micropiolog
M R W Brown MSC PhG DSC FRPharmS
*Potessor of Pharmacolog
C 3 Ferry BPharm SSC PhO FRPharmS

* Head of Decartment this session

Dear Colleague

Community pharmacists are being encouraged to be increasingly involved with health promotion and disease prevention, although the acceptance and integration of pharmacists into the primary health care team has still to be achieved.

I am conducting research in collaboration with Dr Michael H. Jepson FRPharmS, MCPP, Head of the Pharmacy Practice Research Group at Aston. I have experience of monitoring patients for cholesterol, blood pressure and other cardiac risk factors in close association with two GP practices and recognise some of the opportunities pharmacists could develop to meet patients' needs and expectations, and therefore optimise the pharmacist's potential to contribute to Family Health Services.

The prospect of some remuneration of community pharmacy contractors being devolved through FHSAS, linked to the need to respond to 'Nuffield' and 'Pharmaceutical Care' recommendations and 'Health of the Nation' targets, provides some interesting challenges to the profession.

I would greatly appreciate your response to my questionnaire as I am very conscious of your involvement with the plans for shaping future pharmaceutical services. I thank you in anticipation for your reply, and I confirm that all responses will be treated with complete confidentiality and only used for data analysis purposes. A reply paid envelope is enclosed.

Yours faithfully

Geoffrey P. Watman MSc, MRPharmS. Pharmacy Practice Research Group

QUESTIONNAIRE TO PSNC STUDY PHARMACISTS

SECTION 1. HEALTH SCREENING

Other (please identify)

1.	Are you currently offering any dia	gnostic te	esting in your phar	macy?
	If 'Yes' how many hours per week If 'No' please give details	does the	e service occupy?	hr
2.	Which diagnostic tests do you offered and for how long have you offered Test		many do you do pe	er month Time offered
	Test	TICK	Per Month	(Years)
	Cholesterol Blood Pressure Pregnancy Random Blood Sugar Therapeutic Drug Monitoring			

2.1 For which of these tests did you receive appropriate training?

1 = Very unimportant; 5 = Ve	ry important.
Test	Score
Cholesterol Blood Pressure Pregnancy Random Blood Sugar Therapeutic Drug Monitoring Other (please identify)	
Which of this list of services in Q3 do yo most prestige, in the eye of the public?	ou think gives the pharmacist
;	
Since you have introduced the service, blood pressure measurements you take	
	increased stayed the same or reduced
Please comment	
Have the number of cholesterol tests s	ince inception -
	increased stayed the same

3.

6.	How much do you charge, per test, for:
7.	(a) Blood Pressure Measurement (b) Total Serum Cholesterol (c) Pregnancy Testing (d) Blood Glucose Estimation Do you offer a special price per person for a combination of tests?
	Yes No Please give details if you are willing to do so.

8.	Why have you chosen to do diagnostic tests? Please rank the following reasons on a scale of 1 to 5, where 1 is very unimportant and 5 very important.
	Extra income Interest Prestige Completeness of health care Involvement with GPs Stay ahead of competition Public demand Others, please identify:
9.	Do you consider that you influenced any patients to change their lifestyle, following health screening?
	Yes No
	If Yes, please estimate the number per year?

10.	Have you offered health screening as a paid se	ervice to:		
	(a) the FHSA or Commissioning HEALTH AGENCY			
	(b) GP Fund Holders?		Yes No Yes	
SECT	ION 2. LIAISON WITH GPs		No	
11.1	When you first started health screening did you inform your local GPs first?	ı	Yes No	
11.2	If Yes, how many GP practices did you inform?	,		
11.3	How did you inform the GPs	Ple	ease ti	ck
		Letter Telephone Visit Fax		
11.4	What was the percentage response in favour?			
11.5	Since inception of health screening, how has y your local GPs changed?	our relations	ship w	ith
11.6	Do you consider health screening can be best setting of a general medical centre by a practic		the	
			Yes No	3
	If Yes, please state why.		. 10	
	If No, please state why.			

The aim of questions 12, 13 & 14 is to gauge your view of the extent to which pharmacists can hope to develop their role as "experts in medicines".

12.	GP FORMULARY DEVELOPMEN	<u>NT</u>		
12.1	Do you get involved in giving GP	s:		
			Yes	No
1. Pre	scribing advice			
2. PA	CT data advice			
3. Dru	ig usage guidelines and development	of treatment protocols		
4. GP	practice formulary development			
12.2	If Yes, Please state:			
	1. Location for analysis?	SURGERY or PHARMAC	CY	
		Please underline one		
	2. Number of GP practices invo	lved?		
	3. Whether there are any arran	gements		
	for continuing follow-up	Yes		No
12.3	If you do not provide any of the please give reasons.	se services to GPs,		

13.	PRESCRIBING LIAISON						
13.1	"The pharmacist should manage a patient's repeat medication after the prescriber's initial diagnosis and prescription"						
	Do you:						
	Strongly agree Agree slightly Neither agree nor disagree Disagree slightly Strongly disagree						
	Additional comment						
13.2	"The pharmacist should recommend medication after a diagnosis by the GP."	ı defin	itive				
	Do you: Strongly agree Agree slightly Neither agree nor disagree Disagree slightly Strongly disagree						
13.3	If you do not think this is feasible at present, by what date do you think it would be?						
13.4	If you disagree, do you think pharmacists could select medicine and dosage on a limited therapeutic list?	the					
		Yes No					

14.	Do you think there is a role for specific involvement speciality clinics? Please score from 1 to 10 for the following, when 1 = poor, 5 = fair and 10 = excellent potential.		
	(a) Asthma Clinic (b) Diabetes Clinic (c) Lithium Clinic (d) Hypertension Clinic (e) Family Planning Clinic		
	Please comment, especially if you feel this is no avenue along which pharmacists should go.	t an	
15. <u>F</u>	PATIENT REGISTRATION		
15.1	Do your PMR's contain information on OTC med	dication	?
		Yes No	
15.2	Do you have a computer link with a GP practice	?	
		Yes No	
15.3	How many patients have you on your PMR sys	tem?	

15.4	Which statements ar	re most relevant to your practic	e?
			Please tick one or more
 1 ke 1 ke 1 ke 	eep PMRs for all pation eep PMRs for patient eep PMRs for all pation	ents presenting prescriptions ents over 60 s with chronic conditions ents under 12 yrs of age ents who have repeat prescript	ions
15.5	What percentage of permission for you t	patients have not given their o keep PMR's	%
15.6	Would your GP's be to patients' medical	e favourable to you having acce notes?	ess
			Yes No Don't Know
15.7	role consolidated if	s would be best met and the ph there was a formal system of poharmacy of the patient's choice	atient
	Do you:		
	*	Strongly agree Agree slightly Neither agree nor disagree Slightly disagree Strongly disagree	

AUDIT: - the development of model standards of professional praccommunity pharmacists.	tice for
Do you intend to audit aspects of your service?	
Yes	No
If Yes, please indicate those you may wish to monitor (If already doing so, please add '*'.)	Diagon tiple
й e	Please tick
The dispensing process	
Written and verbal information with dispensed medicines to:	
(a) all patients	
(b) those taking specific medicines only	
(c) patients in specific 'at risk' groups only	
Prescription items owing	
NHS prescription items not allowed by PPA	
Health promotion	
Domiciliary Service	
Advice to residential and nursing homes	
Response to symptoms	
Guidance to relief pharmacists	
Purchasing and stock control	
Premises and equipment	
Workload analysis to calculate the optimum number of prescriptions dispensed by:	
(a) dispenser with pharmacist supervision	
(b) pharmacist	
Other, please specify	
	- the development of model standards of professional practice community pharmacists. Do you intend to audit aspects of your service? Yes

17. Please add any other comments about the pharmacist's extended role and the development of more patient oriented pharmaceutical care:

Thank you very much for taking part in this survey. If you have any queries about the questionnaire or if you wish to know more about the survey, please telephone: 081 866 4577.

G.P. WATMAN MRPharmS.



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QUESTIONNAIRE TO EUROPEAN PHARMACY ASSOCIATIONS

From: The Pharmacy Practice Research Group, Aston University, Birmingham, UK, B4 7ET

 Approximately what percentage of Community Pharmacists in your country offer the following diagnostic tests.

TEST	<20%	20-40%	40-60%	60-80%	>80%
Urine analysis Pregnancy Blood Pressure Measurement Serum Cholesterol Measurement Blood Sugar Measurement Therapeutic Drug Monitoring (TDA) Others (Please identify)					

1.b)	Is there any cooperation between pharmacists and doctors
	for these health screening services.

Yes/No

If Yes, please state for which diagnostic tests?

2. Blood analysis -

Do doctors direct their patients for blood analysis to:

i) a community pharmacist?

ii) an independent laboratory?

iii) a hospital or clinic?

iv) have the tests done on their own premises?

most frequent
Yes/No
Yes/No
Yes/No
Yes/No

If you have answered 'Yes' to more than one group, please add '1' in the 'most frequent' column, then '2' etc.

3. How are	these screening tests paid for?	
		most frequent
	(a) By patient/customer(b) Health insurance scheme(c) Provided as free service by pharmacy(d) Other, please state:	Yes/No
If you have ans column, then '2	swered 'Yes' to more than one group, please add ' 2' etc.	1' in the 'most frequent'
-40 W		
4. Deregulatio	on of 'Prescription only' medicines:	
fo	Which 'prescription only' medicines have been rector supply by pharmacists on their own professional patients/customers in the last 10 years?	
	Please tic	k all that apply
	IBUPROFEN Tablets	
	KETOPROFEN Gel	
	HYDROCORTISONE Cream	
	HYDROCORTISONE Lozenges	
	CLOTRIMAZOLE Cream or Pessaries	
	ACYCLOVIR Cream	
	CIMETIDINE Tablets	
	RANITIDINE Tablets	
	BECLOMETHASONE Nasal Spray	
	SODIUM CROMOGLYCATE Eye Drops	
	BUTYL BROMIDE Tablets	
	LORATIDINE Tablets	

Others (please add)

8	(b)	Can the pharmacist on his/her own professional authority supply any of t following classes of medicines to patients/customers?						of the				
		Please Tick all that apply							oly			
			ORAL CO	ONTRA	CEPTI	VES						
			ANTIHY	PERTE	NSIVE	S						
			HYPOLII	PIDAEN	MIC AG	ENTS						
			HYPOGI	YCAE	MICS							
			BRONC	HODILA	ATORS	;]			
			Others (please	add)]			
5.	(a)	influe stren	proportion nce (more gth, intera mily docto	e than t action e	he safe	ety che	cking o	f presc	ription	dosag		
Plea	se tick	one							,	,		
			<10%	20%	30%	40%	50%	60%	70%	80%	90%	>90%
	How	is this	changing	? Plea	se give	brief c	etails?					
	(b)		harmacis nes a pre					ığ the r	number	ы		
	If Ye	es, plea	se give d	etails?							Yes/No	g _
	(c)	Do p from	pharmacis family do	ets have	e any a edical r	ccess t	o <u>medi</u> ?	cation	informa	ation	Yes/No)
	(d)	Do p	harmacis	sts have	e any a edical i	ccess f	o <u>diag</u>	nostic	informa	ation	Yes/No)

6.	What proportion of patients/customers only use one pharmacy?	
	abou	t%
7.a)	What proportion of pharmacies record and keep computerised patient medication records (PMRs)?	%
b)	Do pharmacists include details of deregulated (ex. prescription or medicines on PMRs as well as details of prescribed medicines?	ly) Yes/No
8.a)	Is there a system for the registration of patients with a pharmacy of the patient's choice in your country?	Yes/No
¥7	If 'Yes' please give brief details	
b)	If No, are any such changes planned.	Yes/No
c)	Do you think a system of patient registration would contribute to making the pharmacists role more useful for the patient?	Yes/No
9.	Are pharmacists actively involved in any other pharmaceutical care roles? eg. giving injections Others, please add	Yes/No
10.	Please add any other comments, especially about any changes in a wider healthcare role of the community pharmacist?	

Once again thank you for your co-operation.



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LETTER TO THE ITALIAN PHARMACY FEDERATION

novembre, 1995

Egregio collega,

sono farmacista comunitario praticante e sto svolgendo ricerche sulla contribuzione possibile dei farmacisti alla cura sanitaria comunitaria insieme al medici generici ed agli altri professionisti sanitari. Il mio interesse particolare e per la prevenzione della cardiopatia e monitorizzo pazienti di due studi medici generici.

Vorrei paragonare il ruolo presente e futuro del farmacista nel screening sanitario, come pure negli altri sviluppi che si svolgono nella farmacia comunitaria attraverso la Comunita Europea.

Spero che Lei riempira il questionnario breve qui accluso. Confermo che tutte le Sue risposte saranno trattate in via strettamente confidenziale e usate solamente per la raccolta dei dati.

Ho intenzione di pubblicare le mie risultanze o nel Giornale Internazionale della Pratica Farmaceutica o nel Giornale della Farmacia Sociale ed Amministrativa.

La ringrazio in anticipo per il Suo aiuto inestimabile.

Distinti saluti.

Dott.Geoffrey Watman

Per informazioni supplementari, si prega di contattare Dott.Michael Jepson al indirizzo come sopra.