PREFACE

In 1995, THE ROYAL PHARMACEUTICAL SOCIETY OF GREAT BRITAIN, in partnership with **Merck Sharp & Dohme**, undertook an enquiry into what was known about the difficulties patients have in taking medicines as they are prescribed. The intention was to review what were considered to be the causes and consequences of this 'non-compliance' and to make recommendations about how to improve the taking of medicines.

In the first half of 1995, a steering group was set up in order to consult a large number of individual health care professionals and researchers known to be concerned with this issue. Seven groups, totalling 47 individuals from the hospital specialties, general practice, nursing, pharmacy, health economics, social policy analysis and others were invited to discuss their experiences and insights. Our working party was then convened, and was invited to commission additional reviews of the literature, to deliberate further and to advise.

In May 1996, we published a preliminary report in the form of a consultative document - *Partnership in Medicine Taking*. Copies were circulated to a variety of relevant organisations and individuals representing the interests of public, patients, health care professionals, managers, academics in fields related to health care and others concerned in the health and social services. In addition to the analysis of some 90 written replies commenting on our report, there followed an intensive round of consultations, including meetings with researchers and representatives of organisations concerned with particular groups of patients.

Subsequently, we commissioned seven focus groups (with patients, and with general practitioners) and met researchers currently investigating the patients' decision-taking pathways in relation to the taking of prescribed medicines*. The intention was to trawl as wide a range of informed opinion as possible, in order to test the acceptability of our preliminary assertions and conclusions, to correct errors, to draw on research and other experience not sufficiently considered in the initial report so as to modify and

strengthen the subsequent arguments.

In our earlier report we reviewed the many obstacles (technical and psycho-social) implicated in the attempt to persuade patients with serious conditions to take important and sometimes life-saving medicines in appropriate doses and over extended periods of time. Following our consultations, and not least in the light of our discussion with representatives of patient organisations, the working party arrived at much more than a modification of the views that informed its original document.

As our title indicates, the working party now advocates the concept of 'concordance'. We outline its rationale, intentions, processes and consequences. In doing so we are not simply offering an alternative, and more politically acceptable, way of talking about a technically difficult, and morally complex, problem. Rather, we wish to introduce and urge a distinct change in culture, in researching and teaching about the relationship between prescribing and medicine-taking, between patient and prescriber.

Marshall Marinker,
Chairman of Working Party
March 1997

* Reports of these meetings and focus groups will be available, on request, from the Royal Pharmaceutical Society of Great Britain.

FOREWORD

Over recent decades there have been major advances in the development of powerful medicines to treat serious diseases. Yet research strongly suggests that very many patients are, for one reason or another, unable to take medicines to best effect. This, despite prodigious efforts by researchers and practitioners, increasingly to make information about medicines more available to patients and by doctors, pharmacists, nurses and others to improve their communication skills. It was against this background that the Royal Pharmaceutical Society of Great Britain, together with Merck Sharp and Dohme, convened the working party whose report we now publish.

So complex are the challenges of modern medical treatment that teamwork is essential: the closest partnership is required between all concerned. Crucial to the achievement of such therapeutic partnerships is the inclusion of the patient as partner. These are the two major conclusions of the report that follows. First, the need for a multi-disciplinary approach to research about medicine-taking and a multi-professional approach to the processes of prescribing. Second, the need for a true partnership between patient and prescriber.

The advocacy of what the working party has called 'concordance' - a new liberal model of the relationship between prescriber and patient - has the enthusiastic support of this Society. The creation of such relationships and the extension of professional tasks that this implies, are entirely consonant with the Society's recent major policy initiatives concerned with the further development of the role of the pharmacist in a variety of health care settings.

I would like to thank the members of the working party and the many researchers, practitioners and patients' representatives who have contributed so much to the development of this project. In order to take forward the recommendations, we now seek active participation by others and further partnerships with government, the private sector and the voluntary organisations. As the report itself makes clear, its publication marks only the end of the first stage of what must become a national and sustained endeavour.

Ian Caldwell,
President, the Royal Pharmaceutical Society of Great Britain

WORKING PARTY

Dr Alison Blenkinsopp
Director of Education & Research, Department of Pharmacy Policy & Practice, University of Keele and Member of Council, Royal Pharmaceutical Society of Great Britain, London

Dr Christine Bond
Lecturer, Department of General Practice, University of Aberdeen

Dr Nicky Britten
Lecturer in Medical Sociology, Department of General Practice, United Medical & Dental School of Guy's & St Thomas' s Hospitals, London

Dr Morgan Feely
Senior Lecturer in Clinical Pharmacology & Honorary Consultant Physician, Department of Clinical Medicine, University of Leeds

Professor Charles George
Professor of Clinical Pharmacology, University of Southampton

Mr Philip Green
Deputy Secretary, Royal Pharmaceutical Society of Great Britain, London

Professor Conrad M Harris
Professor of General Practice, Division of General Practice & Public Health Medicine, University of Leeds School of Medicine

Mr Larry Hurst
Commercial Affairs Manager, Association of the British Pharmaceutical Industry, London

Professor Christopher Maggs
Professor of Nursing and Director of Research & Development, University of Staffordshire, Stafford and Mid-Staffordshire General Hospitals NHS Trust, Stafford

Professor Marshall Marinker (chairman)
Visiting Professor, Department of General Practice, United Medical & Dental School of Guy's & St Thomas' s Hospitals, London and Health Policy & Medical Education Adviser, Merck Sharp & Dohme Ltd., Hoddesdon

Dr Pauline McAvoy
Medical Director, Newcastle City Health NHS Trust

Dr Hugh McGavock
Director, Drug Utilisation Research Unit, Queen's University of Belfast

Professor Peter Noyce
Head of Department of Pharmacy and Professor of Pharmacy Practice, University of Manchester

Dr Michael Rowe
Medical Director, Bath & West Community NHS Trust, St. Martin's Hospital, Bath

Professor David Taylor
Director, GJW Government Relations, London

Ms Kate Tillet
Director of External Affairs, Merck Sharp and Dohme Ltd., Hoddesdon

Professor John Weinman
Health Psychology, United Medical & Dental School of Guy's & St Thomas' s Hospitals, London

Dr John Young
Medical Director, Merck Sharp and Dohme Ltd., Hoddesdon

SUMMARY

The terms ‘non-compliance’ and ‘non-adherence’ are used by researchers and clinicians to describe the many ways in which patients, for one reason or another, depart from the regimen of medicine taking that their doctors recommend. Many patients on short term medication depart from the recommended doses within a day or two of starting treatment. A search of the international research literature suggests that some 50% of patients who suffer from chronic diseases do not take their medication in fully therapeutic doses and so do not derive the optimum benefits of treatment. The personal cost in avoidable continuing illness and premature death and the public cost in terms of economic loss and increased health services expenditure, have been estimated as vast. This huge waste of resources has scarcely been mentioned in the course of the on-going public debate about the quality and funding of health services.

Researchers have identified many reasons for this failure to achieve the potential benefit from medication and these include failures in communication with patients, the many physical and psychological difficulties that some patients encounter (for example the problems that a patient with arthritis may experience in opening poorly designed containers, or a socially isolated elderly patient may have in remembering to take a number of different tablets at particular times of day). Researchers suggest, however, that in addition to many such important factors, the most salient and prevalent influences on medicine taking are the beliefs that people hold about their medication and about medicines in general. These beliefs are often at variance with the best evidence from medical science and consequently receive scant, if any, attention from the prescriber. Yet they are firmly rooted in the personal and family and cultural experiences of us all. For the prescriber simply to reaffirm the views of medical science, and to dismiss or ignore these beliefs, is to fail to prescribe effectively.

In so far as non-compliance has been recognised as a problem by clinicians in the past, the usual (and understandable) approach has been to attempt to persuade the patients of the error of their thinking and to communicate as clearly as possible the intentions of the prescription and the importance of sticking to the recommended regimen. Research into how this could be accomplished,

and into the long-term results of communicating with patients in this way, strongly suggests that this approach has been of limited value. If a real difference is to be made in achieving effective medicine taking, a different model of the relationship between patient and prescriber must be developed.

The pursuit of 'compliance' has hitherto suggested that the aim of prescribing was to get the patient to 'follow doctor's orders'. There was an unspoken assumption that the patient's role was to be passive and that since the prescriber's view was rational and evidence-based, it was, for these reasons, 'superior' to the beliefs and wishes of the patient. These assumptions are challenged by an alternative model of the consultation which our working party describes as 'concordance'.

Concordance is based on the notion that the work of prescriber and patient in the consultation is a negotiation between equals and that therefore the aim is a therapeutic alliance between them. This alliance may, in the end, include an agreement to differ. Its strength lies in a new assumption of respect for the patient's agenda and the creation of openness in the relationship, so that both doctor and patient together can proceed on the basis of reality and not of misunderstanding, distrust or concealment.

We recommend a nationally co-ordinated programme of further research and development, in order to gain a better understanding of the problems; to experiment with new ways of achieving more effective therapeutic alliances; to measure the consequences of this in terms of health and cost; to support training programmes for health professionals involved in prescribing, at both undergraduate and postgraduate levels; and in sequence with these research and training agendas, to implement a strategy for raising public awareness of these issues.

Such a strategy will require the active participation of organisations representing the experience and points of view of patients; the co-operation of researchers from a variety of clinical and social science disciplines; multi-agency co-operation; the involvement of health care professionals and those responsible for their education and training and the mass communications media.

To this end, we suggest that a Research and Development Committee (under the aegis of *The Royal Pharmaceutical Society of Great Britain)* be created with a remit to design and carry out a three year programme. Currently the Department of Health *Prescribing Research Initiative* is budgeted at £2.4M over four years. A comparable investment will be required in support of our recommendations and a mix of public and private funding should be sought.

INTRODUCTION

The working party began work by reviewing the evident difficulties in achieving optimum benefit from the use of appropriate modern medicines, the possible reasons for these difficulties and what experiments had been carried out to improve matters.

The consequences of failing to take medicines to best effect, as our findings revealed, can be damaging and indeed devastating for the individual patients concerned and for their families. For the National Health Service it constitutes two forms of wastage: first, a minimising of the potential benefits of drug therapy; second, the extra cost of treating the avoidable consequent morbidity.

The cost of what amounts to a massive waste of resources in the health service would, if identified as resulting from flawed policy or managerial failure, constitute a national scandal. But the problem is not one of poor policies or management. The problem arises because of pervasive failures to establish effective therapeutic partnerships between doctors and other health care workers and their patients. Yet this problem has been extensively researched and there have been many well documented and some successful, attempts to resolve it.

The evidence suggested that very many patients (some studies estimate as many as 50%) fail to comply with the terms of their prescriptions. Consequently, because of the immense personal cost to the individual patient and the financial cost to the NHS and society, the clear focus of the working party's initial concern was the achievement of more compliant medicine taking.

Almost all the explanatory models for non-compliance and the many interventions designed to overcome the patient's resistance to therapy, which we examined in our search of the literature, could all too easily be construed as describing a 'self-evident' conflict between the doctor's rational treatment and the patient's irrational resistance. It is this traditional and (from the health professional's point of view) instinctive, picture of non-compliance, that, in the course of our subsequent consultations, we have come to distrust. The attempt by social scientists to label the phenomenon 'non-adherence' rather than 'non-compliance', we came to see as a brave but inadequate attempt to find a simple semantic solution to a deep conceptual flaw in many of the previous approaches.

The traditional view of compliance can be expressed as follows:

The patient presents with a significant medical *problem* for which there is a potentially helpful treatment. What the doctor or other health care professional brings to the situation - scientific evidence and technical expertise - is classed as the *solution*. What the patient brings - 'health beliefs' based on such qualities as culture, personality, family tradition and experience - is classed by clinicians as the *impediment* to the solution. The only sensible way out of this difficulty would appear to be to bring the patient's response to the doctor's diagnosis and proposed treatment, as far as possible into line with what medical science suggests.

The working party came to see this as a misleading model of the clinical encounter. We have concluded that the task of achieving what we had described as 'taking medicines to best effect', can only come about as a consequence of a fundamental shift in the balance of power in the clinical encounter. This will require the closest attention to and genuine respect for, the validity of the patient's personal constructs and coping strategies.

We propose that in future the terms 'compliance/adherence' be reserved to signify the theoretical intention of prescription and that the term 'concordance' be adopted to signify the practical (and ethical) goal of treatment. The aim of concordance is to optimise health gain from the best use of medicines, *compatible with what the patient desires and is capable of achieving.* This restatement of the process of prescribing and taking medication is essentially a particular case, or exemplar, of a more encompassing review of the intentions of the whole clinical encounter. Concordance can be expressed as follows:

The clinical encounter is concerned with two sets of contrasted but equally cogent health beliefs - that of the patient and that of the doctor. The task of the patient is to convey her or his health beliefs to the doctor; and of the doctor, to enable this to happen. The task of the doctor or other prescriber is to convey his or her (professionally informed) health beliefs to the patient; and of the patient, to entertain these. The intention is to assist the patient to make as informed a choice as possible about the diagnosis and treatment, about benefit and risk and to take full part in a therapeutic alliance. *Although reciprocal, this is an alliance in which the most important determinations are agreed to be those that are made by the patient.*

The term 'concordance' is intended to convey respect for the health

beliefs of both doctor and patient. Furthermore, it does not predicate a resolution of the differences between them on the terms of 'superior' contemporary medical evidence. It implies a better understanding than hitherto, of the ways in which the patient perceives the illness and the treatment and then tests the appropriateness and usefulness of the doctor's picture of the illness (Horne R, 1997; Leventhal J, Diefenbach M, Leventhal E, 1992). It implies recognition of the fact that just as all prescribing is an experiment carried out by the doctor, so all medicine taking is an experiment carried out by the patient.

This proposed change in language, however, should not suggest any abandonment of the evidence from science. It is concerned, rather, to acknowledge the ethical imperatives and psycho-social determinants of the 'contract' between patient and prescriber. The tasks of patient and doctor as described above are differently weighted. That of the patient is *voluntary*: the patient has the *opportunity* to explain her beliefs and to negotiate. That of the prescriber is *obligatory*: the prescriber has the *duty* to know and present the contemporary scientific evidence and to attempt to elicit the patient's beliefs.

An acknowledgement of the likely consequences of any gap between concordance and prescription are a necessary part of the resulting agreement and a consequence of this is the doctor's duty regularly to review the concordat with the patient. We also recommend that in accordance with sound clinical practice, the content of the concordat be entered and updated in the patient's record.

Unlike the words compliance and adherence, concordance does not lend itself to one-sided negative inversion. Non-compliance can refer only to the behaviour of the patient. It identifies error and ascribes blame. The patient cannot be non-concordant since non-concordance refers not to the patient's behaviour, but rather to the outcome of the encounter between doctor and patient: it is the consultation and not the patient that is non-concordant.

Concordance describes the negotiated agreement - often an agreement to differ. Non-concordance is descriptive, not judgmental: it denotes a failure of patient and prescriber to come to an understanding and not a failure of the patient to understand.

There is an historical perspective to all this. Compliance appears to

be a legitimate goal of medical treatment in the setting of a welfare state rooted in the values and thinking of society in the 1930s. Then, the plans for future health services were driven by the values of a benign paternalism and the practice of medicine by the assumptions of a fiduciary relationship. In the 1990s these values and assumptions are changing. The media, consumer groups, health service policy makers and individual patients themselves challenge them and look for relationships between doctor and patient, public and health service, based less on trust and more on openness and respect.

The earlier values are not so much rejected as overlaid with more modern concerns for entitlements, transparency of information, accountability and contract: the autonomy of the patient assumes greater prominence than the doctor's beneficence and non-maleficence. Compliance belongs to this older world, concordance to the contemporary practice of medicine and health care provision. The price of compliance was dependency. The price of concordance is greater responsibility - of the doctor, for the quality of the diagnosis, the treatment and the explanation; of the patient, for the consequences of her or his choices.

In what follows we persist in the use of the terms 'compliance' and 'adherence' when referring to the intentions, hitherto, of researchers and clinicians and 'concordance' to signal our own key recommendation. We also recognise that the definition of 'concordance' given here is preliminary and incomplete. The processes of redefinition we take to be an important component of the further research and education that we later recommend.

As our report *From Compliance to Concordance: Achieving Shared Goals in Medicine Taking* now suggests, the concept of concordance has important implications for radical change in all the three agendas that our working party identified for action: research and development, the education and further training of health care personnel, public awareness.

Franz Kafka in *A Country Doctor* wrote "To write prescriptions is easy, but to come to an understanding with people is hard." This report is concerned with coming to such understandings.

1. BACKGROUND

1.1 The prescribing and taking of medicines is the major and growing modality of medical treatment. The effectiveness of medication depends not only on the appropriateness of the drug used, but also on the intended regimen. The failure to take the medicines as intended is likely therefore to result in relative therapeutic failure - for example some loss of the expected improvement in physical or mental function, unnecessary suffering and even premature death. There is also the potential economic cost in avoidable medical transactions (including hospital admission) and in the waste of expensive medicines misused or unused.

1.2 There are numerous examples of indisputable positive health outcomes consequent on the full and effective use of pharmaceuticals over a wide range of serious clinical conditions. These include: the use of combination oral steroidal contraceptives, the antibiotic eradication of H. pylori in peptic ulceration, the antibiotic treatment of tuberculosis, the use of lipid lowering agents in primary and secondary prevention of coronary heart disease, and of ACE Inhibitors in heart failure. As new medicines become increasingly powerful, specific and costly, the quality of decision making in prescribing and questions about the effectiveness of medication, assume ever greater importance. Research, education and policy have focused on these issues and (because of increasing pressures on the NHS budget) on the achievement of cost-benefit by prescribers. There has been far less attention paid to the part that the patient has to play - to the patient's willingness and ability to take appropriate medicines to best effect.

1.3 Although most doctors recognise that patients often fail to take their medication as prescribed, they tend to think that this is a general problem, and not particularly relevant to their own practice. Yet some of the research literature suggests that as many as one in five patients may fail to take even the first step - having the medicines dispensed at the local pharmacy. Even when the prescriptions might be thought to have been actively sought by the patients, the same problem appears: in one large study as many as 1 in 4 prescriptions for oral contraceptives were not presented to the dispensing pharmacists (Beardon 1993). In short-term illness taking the medication

in accordance with the intentions of the prescriber begins to deteriorate after the first few days of treatment.

1.4 The picture in chronic illness is more serious still. A Canadian report concluded that "...rates of compliance with different long-term medication regimens for different illnesses in different settings tend to converge to approximately 50%." (Sackett 1979) In one review of patients treated for high blood pressure, 50% were found to have dropped out of care and of those remaining in treatment only some two thirds were consuming sufficient medication to control their blood pressure (Dunbar-Jacob 1991).

1.5 Medicines are designed to be taken over a particular period of time, in recommended doses and often with attention to the period between doses; to the relationship with meal times, times of day and so on. These regimens are intended to achieve optimum tissue levels and to minimise the inconvenience or distress of unwanted effects of the medication. The pharmacological benefit relies not only on the chemical composition of the active ingredients, but also on the regimen designed to secure the optimal delivery of the drug to its site of action in the body.

1.6 For most patients illness is manifested as symptoms. Yet very frequently the medicine prescribed is aimed at the disease process and not directly at the immediate alleviation of symptoms. In the prescribing of antibiotics for an acute chest infection, for example, it is the underlying pathology and not the symptoms that are being treated - the bacteria causing the problem may be eradicated, while the cough may continue for some time after. In the management of chronic conditions (like high blood pressure) there may be no feedback in the way of evident gain in well-being to encourage the patient to continue the medication.

1.7 Sometimes (particularly in the elderly) a number of different medicines, each with a slightly different regimen, may be prescribed. Adherence to such regimens would appear to require significant effort, some disruption to the habitual patterns of daily living and something amounting to a preoccupation with the disease and its treatment. For all these reasons, strict adherence to recommended drug regimens appears to be the exception and not the rule.

1.8 Perhaps the most dramatic example of the scale and consequences of failure to take medication in accordance with the prescribed regimen, concerns immuno-suppressive medication for patients who have had organ transplants. Here it might be assumed that these patients constitute a very highly motivated group and that adherence would be high. Yet one study (Rovelli 1989) revealed that 18% of renal transplant patients were not taking their medication as prescribed. 91% of those patients who for one reason or another failed to take their medicines as prescribed, experienced organ rejection or death. This compared with only 18% organ rejection or death among those patients who adhered to the prescribed regimen. The authors of this study reported that three months after transplant "...non-compliance causes more graft loss than uncontrollable rejection in compliant patients at our centre." Such is the complexity and intractability of the problem that this report attempts to address.

2. WHAT IS COMPLIANCE OR ADHERENCE?

2.1 In much of the world literature, the term for following a recommended treatment regimen has been 'compliance'. Although this remained the most useful key word in searching the literature, the term has over the years come under attack (Stimson 1974), particularly from social scientists and healthcare ethicists. It was objected to on the ground that it failed to respect the idea of the patient's autonomy; that there were echoes of a number of familiar phrases held to betray outdated and negative attitudes to the relationship between patient and doctor. Compliance suggests that 'doctor knows best', or the expectation that the patient will 'follow doctor's orders'.

2.2 In much recent research literature the term 'adherence' is preferred and this was the term that we chose to use throughout our consultative document. It was held to be more respectful of the role that the patient can play in his or her own treatment. It suggested that the doctor is engaged in reasonable negotiation with the patient, rather than in the perfunctory issuing of instructions. However, as we have argued in the preface to this report, the dictionary scarcely distinguishes between the meanings of these two terms. Both words carry the same semantic overtones and are therefore equally unhelpful.

2.3 There is no generally recognised and accepted definition of non-compliance. Quantitative definitions may refer to the amount of medicine taken over a given period, or to compliance to the recommended *timing* of the medication, to the intended duration of the treatment, and so on. Qualitative definitions refer to such variables as intentionality, memory, health beliefs and so on. In both cases the expression 'non-compliance' needs to be qualified. Apart from failures to have prescribed medicines dispensed, most departures from compliance are partial, not total. In fact the degrees of non-compliance, the patterns of omitting or forgetting doses, the nature and frequency of so-called 'drug holidays' (when patients recurrently and abruptly halt their medication for variable periods and then, as abruptly, re-start), are all important objects of study, and can illuminate our understanding of motivation. These drug

holidays are also the potential cause of very serious damage to the patient. There can be physiological rebound effects from sudden withdrawal of some medicines and transient overdose from the sudden resumption of some medicines at full 'pre-holiday' dose. Considered together these are sources of previously unrecognised hazard and are mechanisms whereby underdosing is sometimes a source of toxicity (Urquhart 1996). For the most part in this report, we persist in employing the term non-compliance without qualification, to indicate material departures from the intended regimen likely to reduce the medicine's effectiveness.

2.4 Definitions like "...the extent to which the patient's behaviour... coincides with the clinical prescription" (Sackett 1976) fail to address the question of how much non-compliance matters in terms of the clinical outcome. This is better addressed by the definition; "the point below which the desired preventive or therapeutic result is unlikely to be achieved." (Gordis 1976) Not all drugs rely on compliance to the same extent in producing effective responses. The regimens of some drugs are much more therapeutically flexible than others and we return to this later in the report. This has suggested the need to define 'sufficient compliance' in terms specific to each particular medicine and expressed in terms of a measurable outcome (Sackett 1976, Epstein 1982).

2.5 The literature suggests that there are two sets of 'causes' of non-compliance and that most often both are present. The first concerns such aspects as the motivation and beliefs and capacities of the patient in relation to medicine taking. The second cause, the recognition of their importance by the doctor or other health care workers and the actions implied by this recognition. In constructing future models of concordance it will be essential to pay close attention to both.

3. CATEGORIES

3.1 Almost all medicines have the capacity to harm as well as to do good. The rationale of appropriate prescribing is that the probability of benefits will very greatly outweigh the possibility of disbenefits. However, all animals have inbuilt mechanisms, instincts and patterns of feeding, that protect them from ingesting harmful or poisonous substances . It seems likely that although the human animal may be intellectually aware that the medicine that the doctor has prescribed will help rather than harm, instinct may give a different sort of awareness. Non-compliance may therefore in part reflect an instinctive defence against the ingestion of potentially harmful chemicals. This may in part explain the pervasiveness of the widespread resistance to medicine taking revealed in the literature. However, to describe resistance to medicine taking as in part instinctual, does not necessarily imply that the patient's instinct may not be closely aligned with a rational analysis and resolution of risk, benefit and preference.

3.2 Researchers have found it useful to divide non-compliance into a number of categories. It is described as *primary* non-compliance when for some reason the patient fails to have the medicine dispensed, and *secondary* when the medicine is not taken as intended. Further categories relate to intentionality. Not presenting a prescription to a pharmacist in order to obtain the medicine in the first place, may be confidently categorised as *intentional* non-compliance when the patient rejects either the doctor's diagnosis or the doctor's recommended treatment. Failure to obtain the medication because the patient cannot afford the prescription charges may be classed as voluntary, but it is intentional only in a very limited sense. *Unintentional* non-compliance may be due to simple forgetfulness, or may be linked to any of a large number of demographic or social, psychological and clinical variables.

3.3 Compliance has been estimated in a variety of different ways. Patients have been asked to self report; measurements have been made by 'pill-counting' so that the number of doses remaining in a pack can be compared with what would have been expected over a given period of time; by devices which electronically record the opening of the container; by making either direct or indirect

estimates of the concentration of drug in the blood and comparing these with what would be expected from compliance to a given regimen; by clinical outcome. There are problems with the validity and reliability of all these methods. For example studies (Sackett 1976) show that patients over-estimate their own compliance compared with estimates from pill counts and urine tests. However Sackett also found that patients' self-reports of non-compliance were very accurate. The development of standardised, carefully-worded questioning protocols to obtain patients' self-reports has increased the validity and robustness of this method (Morisky 1986).

3.4 Electronic monitoring is another technique that has been used in research studies over the past 15 years (Norrel 1980, Kass 1986, Nides 1993). This technique has provided an overall picture of drug usage, including the extent and patterns of 'drug holidays', and 'white coat adherence' - the tendency of many patients to switch to regular medication in the days immediately prior to an appointment with the doctor (Feinstein 1990). Qualitative research with patients has been able to elicit further evidence of and insights into these behaviours (McGavock, Britten and Weinman 1996).

3.5 The disparity between the intentions of good prescribing practice and the actual taking of medicines, constitutes an enormous therapeutic deficit in modern medicine. There are, as we recount later, major personal costs to patients and their carers, and considerable financial penalties for the NHS and for society at large.

4. WHAT DO WE KNOW?

4.1 Previous reviews of the literature (Stockwell Morris 1992, Raynor 1992) reveal a wide variety of research approaches to the study of medicine taking. In addition, we commissioned further literature reviews from three members of our working party (McGavock, Britten and Weinman 1996). These reviews were published at the same time as our consultative document and made available to researchers on request by The Royal Pharmaceutical Society of Great Britain.

4.2 Much of the research evidence comes from work carried out in North America and as with so much behavioural science, the differences in culture, in traditions of health care, in the arrangements for social welfare and much else, make it difficult to extrapolate the findings to the United Kingdom and the National Health Service. The literature also describes many different approaches to measurement, to the definition of non-compliance and to end-point assessments. Consequently although there appears to be a consensus that non-compliance in medicine taking is an important problem, estimates of the size of the problem, the consequences for the health of individuals and the economic consequences, vary widely.

4.3 In very many studies attempts were made to determine a relationship between the patient's medicine taking and the major demographic variables (age, sex and social class), or the usual clinical variables (symptoms, diseases, classes of drugs, regimens). In fact the examination of most of these variables has shown very weak correlation with the way in which medicines are taken. By far the most important factors in predicting this appear to be the following: a) the physical and social vulnerability of the patient (for example being old, belonging to an ethnic minority, suffering from a psychotic illness); b) failures of communication (largely due to a disparity between the health beliefs of doctors and patients).

4.4 The effect of frequency of dose has also been extensively studied. There is some evidence that compliance decreases when the frequency of dose increases. There is, however, no convincing evidence of an important difference in compliance levels between once and twice daily dosing. One study (Pullar 1988) concluded that "...compliance with the once-daily regimen was best, but ...compliance with a twice-daily regimen was very similar and both were superior to

dosing three times a day." Non-compliance also increases markedly as the number of different medicines to be taken increases.

4.5 There are good reasons for suggesting that older people are more susceptible to failures of compliance. Some studies have indicated that 25% - 50% of particular groups of elderly patients do not, or cannot, take all their medications as prescribed (Shimp 1985). One reason for this is that the number of different medications prescribed increases with age (*The Royal College of Physicians* 1984; Murray 1986) often due to the presence of a number of disease processes. In relation to elderly patients, The Royal College of Physicians (1984) states that "If possible, not more than 3-4 drugs should be given each day." Another reason for failures of compliance is that the elderly are more susceptible to adverse drug reactions. The larger the number of medicines prescribed for and taken by the patient, the larger the number of adverse reactions reported (Williamson 1980). Adverse reactions discourage compliance. Finally, since cognitive and psychomotor competence are required in order to read and understand the labelling on medications and in order to be able to manipulate the containers, increasing age brings increasing problems with compliance (Murray 1986).

4.6 Much research has been conducted from a perspective which assumes that patients are being subversive or difficult if they do not 'comply'. Few of the studies we encountered tested the effect of the prescriber - we found no studies in which the comparative effectiveness of different healthcare professionals on compliance was evaluated. Nor has the influence of healthcare professionals' own health beliefs and perceptions on the patients' ability or motivation to adhere, been much considered. In most of the studies that we reviewed there was little evidence of the extent to which the patient's lifestyle was taken into account by prescribers, at the time when medicines were prescribed.

4.7 The quality of interactions between doctor and patient can have a major influence on health outcomes (Kaplan 1989). Some studies (Inui 1976, Bass 1986, Kaplan 1989 and Horder 1990), although not directly concerned with compliance, point to considerable improvements in health care outcomes consequent on achieving a richer and more co-operative interaction between doctor and patient. In UK general practice the challenge appears to be how to reach such

delicate but robust understandings in the course of consultations lasting on average some 8 minutes.

4.8 Attempts to understand patient compliance by studying demographic and other variables such as disease, symptoms, drugs and regimens have been criticised by social and behavioural scientists on the ground that they produce no predictive models and are often mutually contradictory. The models that the social and behavioural sciences seek to construct are fundamental and theoretically derived from the patient's attitudes and subjective perceptions (Kasl 1975). The sociological literature identifies the following ways of thinking about medicines and medicine taking:

- *The perceived efficacy of the medicine*. Individual patients will vary in their confidence that a given drug will alleviate their symptoms and normalise their life. Some people stop taking their drugs from time to time as a way of 'testing' their efficacy. Belief in efficacy may be tempered by a number of doubts and reservations, of which the following are the most important examples.
- *The danger of becoming 'immune' over time* (to the medicines that the doctor prescribes). This has been found in many studies (for example in patients for whom antibiotics were prescribed) and may reflect the often repeated anxiety by medical authorities that antibiotics are too frequently prescribed by general practitioners with the results that organisms become resistant.
- *The 'unnaturalness' of manufactured medicines*. A number of studies suggest that patients are anxious about the 'unnatural' nature of contemporary drugs and fear that taking them may be harmful to their body or minds. This contrasts with a wide spread willingness to trust the 'naturalness' of herbal medicines, although the picture is more complex than this.
- *The danger of addiction and dependence*. In one study (Conrad 1985) people with epilepsy believed that the medication was symbolic of the dependence created by having epilepsy and that the medication reduced their control over their own lives. Several studies have revealed fears of addiction to drugs not thought (by doctors) to induce pharmacological dependence.
- *An anti-drug attitude*. The very term 'drug' is commonly used both for medicines and for such so-called 'recreational' substances as cocaine, amphetamines, opiates and so on with their anti-social connotations and the dangers of physical, mental

and moral harm. In one study of patients on long term medication for asthma, hypertension and chronic pain, over one third of those interviewed spontaneously referred to medicines as poison (Fallsberg 1991).

- *Balancing risks and benefits*. There is some evidence that patients themselves attempt to analyse their positive and negative perceptions about the medicines and carry out their own cost-benefit analyses (Donovan 1992). This is then manifested as non-compliance.
- *Managing everyday life*. A number of studies describe the ways in which men and women use tranquillisers as a means of controlling their symptoms in relation to social stress and changing social roles brought about by separation, divorce or widowhood, problems at work and so on. Variations from the prescribed regimen reflect the wish of patients to take control over their own lives and to manage the medication in relation to the handling of everyday situations. One study of people with epilepsy (Conrad 1985) showed that patients' medication-taking behaviours were more influenced by events in their daily routine than by their doctors' advice.
- *Discrepancies between the doctor's and the patient's perceptions of risk*. A number of studies describe marked differences between the beliefs of patients and doctors about diagnosis and treatment. The patient's so-called 'unorthodox' (i.e. different from the current bio-medical) beliefs may well be unvoiced in the course of an otherwise unremarkable consultation. It is thought that these may be significant predictors of non-compliance (Britten 1996).

4.9 The sociological research has been based primarily on qualitative studies, examining people's own ideas and beliefs about medicines and medical treatments. By contrast, the psychological research has been based on the development of models to explain the ways in which such beliefs influence and determine behaviour. Although the sociological and psychological researches have had different intentions, they appear to have identified a number of common themes. These provide important insights into the contextual factors which influence behaviour and the motivational factors which determine the patient's choices. They also provide the research support for the concept of concordance.

5. POTENTIAL BENEFITS OF IMPROVING COMPLIANCE

5.1 We looked for evidence of the cost of non-compliance in terms of excessive morbidity and mortality; of inappropriate use of health care resources; and of the social and economic consequences for patients. There was a great deal of opinion in the literature about the size of the problem and in one telling phrase non-compliance is described as "America's second drug problem" (*US National Council on Patient Information and Education*, Bond 1991).

5.2 Some evidence of the likely cost of non-compliance comes from the following study (Weis 1994). In the City of New York the public health authorities saw unequivocal evidence of a rise in the prevalence of drug-resistant tuberculosis. They felt it necessary to employ a costly, cumbersome and ethically challenging method of directly observed therapy, forcing people to attend public clinics four times a week for the sole purpose of being observed to take their prescribed medicines. The result of this intervention was "...significant reductions in the frequency of primary drug resistance, acquired drug resistance, and relapse".

5.3 Although the cost of morbidity and premature mortality in most of the major diseases like asthma, arthritis, cancer, psychiatric illness and so on, is well chronicled, we have chosen one particularly dramatic and persuasive example. Research has been carried out in relation to other conditions such as epilepsy and atrial fibrillation, but we concluded that only in the study of hypertension is there a significant body of work which has addressed therapeutic outcomes (Haynes 1996). Because the economic consequences of high blood pressure and related strokes and coronary heart disease (CHD) have been so well researched and because these conditions are all amenable to treatment with drugs, we have chosen this group of conditions to illustrate the size of the potential gain from improving compliance.

5.4 Much quoted USA figures suggest that non-compliance in cardiovascular disease resulted in more than 125,000 deaths and several thousand hospitalisations a year, which represented 20 million lost work days, costing over $1.5 billion in lost earnings (Smith 1985). However, doubt has been thrown on the provenance and likelihood of these extremely high estimates (Urquhart 1996).

5.5 In the UK deaths from CHD are falling, but they remain amongst the highest rates in the world. This condition continues to be the single largest cause of death and the main single cause of premature death in the UK: provisional figures for 1993 show that this condition accounts for some 25% of all deaths. CHD accounts for some 3% of all hospital admissions and for some 10% of admissions of men aged 45-64. As many as 1 in 10 men in this age group suffer from angina and in a 12 month period 3% of men in this age group will have had a heart attack. The cost of general practice consultations, inpatient treatment, the net ingredient costs of prescriptions and chemists' dispensing has been estimated at some £1420 million. This is about 2.5% of the total NHS expenditure. Invalidity benefit costs around £858 million. The loss in industrial/commercial production attributable to CHD has been estimated as some £3 billion per annum. Strokes, strongly linked to high blood pressure, are responsible for about 11% of all deaths. Because non-fatal stroke imposes the burden of prolonged disability and rehabilitation, the cost of this morbidity accounts for as much as 4.4% of total NHS expenditure (Department of Health 1993, British Heart Foundation/ Coronary Prevention Group 1995).

5.6 There is ample evidence of the effectiveness of anti-hypertensive therapy in the reduction of strokes and that the control of high blood pressure reduces the risks of subsequent CHD. Yet failures of compliance with treatment confound attempts to control blood pressure. "The potential benefit of vigorous medical treatment for hypertension often remains out of reach, in part because the patient does not comply with treatment". (Haynes 1976)

5.7 Failures of compliance with anti-hypertensive therapy can also alter the judgement of some clinicians and researchers about the worth of embarking on treatment. "The cost effectiveness of treatment for hypertension depends not only on its efficacy in reducing blood pressure and cardiovascular risk, but also on the degree to which patients remain under medical care and adhere to prescribed regimens. Provider as well as patient behaviours bear critically upon this problem. Using evidence currently available, this analysis indicates marked deterioration of the cost-effectiveness of treatment under incomplete compliance. Particularly for mild hypertension, treatment becomes a relatively unattractive use of health care

resources" (Weinstein 1976). Yet, as a rule, little is said about compliance in much of the health education literature concerning stroke prevention. Even judgements about the cost effectiveness of screening are coloured by consideration of incomplete compliance: "The cost effectiveness of community wide screening would be improved by 30% or more... if even moderately costly and effective interventions were applied to improve compliance." (ibid)

5.8 By the same token, it has been suggested that interventions to improve compliance in hypertension (especially in higher risk patients) may be a better use of resources than interventions to improve the detection of the condition (Smith M 1985). In the United States, during the 1970s, it was estimated that half of the people being treated for hypertension dropped out of care and about one third of those remaining were not consuming sufficient medication to control their blood pressure. A review of the 1980s literature averaged the rate of compliance (in 14 studies totalling over 10,000 patients) as 64%, with a range of 38-95% (Dunbar-Jacob 1991).

5.9 In an authoritative review of antihypertensive therapy, the benefit from achieving appropriate compliance was expressed as follows: "Actual compliance with the antihypertensive therapy studied, with perhaps a reduction of about 8-10 mm in DBP (diastolic blood pressure), might reduce stroke risks by about one half and CHD by about one fifth within a few years (and the epidemiological evidence suggests that longer term therapy might eventually reduce the risk of CHD by up to one third)" (Collins 1990).

5.10 The expected benefit from the drug treatment of various cardio-vascular conditions has been calculated in terms of avoidable morbidity and mortality. In one study of 2175 patients who had sustained a myocardial infarction, those who did not adhere well to the treatment regimen (defined as taking less than 75% of prescribed medication) were two and a half times more likely than good adherers to die within a year of follow-up (Horwitz 1990). In a recent multi-disciplinary intervention study to improve compliance in patients with congestive heart failure, the results were very encouraging (Rich M 1995). Similar benefits might reasonably be anticipated in most of those conditions where effective treatments have been developed. All of these are likely to be diminished by inadequate compliance, with the potential for considerable human and economic loss.

6. SUCCESSFUL INTERVENTIONS

6.1 We looked for examples of practical interventions that had had some evidence of success. Two broad categories of interventions are described in the literature - 'educational' (primarily concerned with information-giving); and 'behavioural' (concerned with taking account of the patient's lifestyle and tailoring the medication regimen accordingly). Variants of both have been shown to enhance compliance, leading to the comment that "special treatment of any kind tended to improve medication compliance." (Rehder 1980) This suggests that, here as elsewhere, in any experimental intervention, the 'Hawthorne' effect (the introduction of any change has the potential to alter the behaviour of the individuals being studied) must be set against the observed changes.

6.2 Reviews of the literature tend to support the behavioural approach, with one reviewer stating: "patients need to know less about the pathophysiology of their disease and more about integrating new demands into their daily routine... (rather than to receive)...standard presentations of medical facts and treatment rules which all hypertensives or all diabetics or all asthmatics should know" (Mazucca SA, 1982).

6.3 In any study of medical interventions it is the achievement of positive outcomes, sometimes called 'health gain', that is of primary importance. The effect of interventions designed to improve compliance should therefore be primarily concerned with actual improvements in health rather than simply with changes in medicine taking. However, patient knowledge, levels of compliance (including proxy methods such as intervals between prescription refills or visits to the doctor) have been the main outcome measures in compliance research to date (Mazucca 1982; Dolan Mullen 1985; Raynor 1992; Stockwell Morris 1992; Devine 1995; Haynes 1996). A recent systematic review of outcome studies identified over 1700 articles, of which only 12 randomised controlled trials met the rigorous criteria of the reviewers (Haynes 1996). Other authors (Devine 1995; Dolan Mullen 1985; Stockwell Morris 1992) have similarly identified how research design needs to be made more rigorous in order to demonstrate positive outcomes. Of the few interventions which resulted in statistically significant improvements in compliance, all

showed rapid decay if the intervention (for example individual patient counselling) was not repeated regularly. No long term changes in patient compliance have yet been documented as the result of an intervention.

6.4 Another problem in assessing the relationship between interventions and outcomes concerns the definitions of the interventions under examination. The content and nature of what are commonly termed 'counselling' interventions is under-documented in published research. The terms 'education', 'teaching', 'counselling', 'information' and 'instruction' are often used interchangeably and the extent to which the patient's own agenda and concerns are addressed is rarely detailed. As a result it is difficult to assess the relative effectiveness of different designs of such interventions.

6.5 Improvements in written information in the form of printed inserts to accompany the dispensed medicines is now being pursued nationally with *The Patient Pack Initiative*. However, research suggests that patient leaflets alone, although they can improve patient satisfaction and knowledge (Gibbs 1989), generally have little effect on compliance (Raynor 1992). One evident reason for this was pointed out to us by a number of representatives of patient organisations: leaflets tend to emphasise negative attributes of the medicine such as idiosyncratic sensitivities and rare side effects, while scarcely mentioning the intended and expected benefits of use. Although they purport to be written primarily to inform the patient and facilitate choice, they are in effect medico-legally defensive. Other research (Ley 1982) has shown how critical is the type of leaflet used (format, print-size, layout, complexity of concepts and language and so on).

6.6 A number of prompts and reminders have been demonstrated to improve compliance:

- telephone or postcard reminders;
- individualised reminder charts;
- diaries;
- engaging family members and carers to provide reminders.

6.7 Attempts have also been made to modify the containers and packaging of medicines. Specially-designed multi-compartment containers (e.g. Medidos, Dosett) can enable up to a week's treatment to be pre-packaged. However, although the use of such devices has

been shown to improve compliance (Rehder 1980), they are not suitable for all patients because they require some dexterity for use (Walker 1992) and they are not suitable for all medicines. Calendar packs have been widely used although in our literature review we found little evidence of their effectiveness. The conclusion must be that such aids to compliance if they are to be effective, must be carefully targeted.

6.8 In summary, the research literature fails to reveal a coherent and clear cut account of what sort of patients are likely to adhere to advice about medication; of the parts played by doctors, nurses, and pharmacists in achieving compliance; of the relationship of compliance to particular diseases, or symptoms or situations. However, this relative failure of research to establish predominant and reliable models of non-compliance, does not diminish the importance of finding more effective and efficient approaches to medicine taking. Our consideration of the evidence has indicated quite clearly the urgent need to intensify that search now and it has suggested a way forward.

6.9 In the past successful therapy has been as much based on the logic of clinical medicine and the physician's craft as on robustly constructed models of diseases, their causes and effects. Indeed what we have learned from bio-medical, epidemiological and psycho-social research is that most diseases are multifactorial in their causes and require a multifactorial therapeutic response. Similarly we conclude that multifactorial strategies are most likely to be effective. But effective in pursuit of what goal?

6.10 As the previous sections have suggested, most interventions to date have been concerned with compliance, with enabling the patient to comply with the regime of medication intended by the doctor, and informed by clinico-pharmacological research. The goal of compliance, however, is usually acknowledged to be a proxy for the much more relevant goal of health outcome. 'Quality of care' concerns not only measures of outcome, but also the processes of that care. In the case of medication, the relationship between processes and outcome is not only pharmacological but relational and moral. All three aspects, pharmacological, relational and moral, are concerned in the goal which we describe as concordance.

7. RECOMMENDATIONS

7.1 We deem it prudent to preface our recommendations by entering some important caveats. Much of the case for improving compliance, and for achieving consequent benefits for the patient, for the health service and for society, rests on logical extrapolations from a wide ranging research literature. By far the greater part of the literature that we considered was North American, inevitably, since that is where most of the research has been undertaken. We are aware of the limitations of too readily drawing conclusions from work done in settings which are different in terms of culture and welfare provision, from those that obtain in the UK.

7.2 Although we recognise the limits of what is known, and the ethical sensitivities surrounding what we are trying to achieve, we have become convinced of the great need for further action now. Such action is essential if the true potential of modern medication is to be made available to patients and a major source of waste is to be eliminated from the health service. We have chosen to group our recommendations under three headings: *research and development, professional education and training, public awareness.*

7.3 RESEARCH AND DEVELOPMENT

7.3.1 Our overview of much of the research published in the last thirty years has suggested the need for a greater standardising of terms and units of measurement in order to move towards a coherent body of theory and a common language. Only if researchers agree on definitions and methodological standards will it be possible to compare and contrast results at national and international level. Yet at the same time the relative failure to achieve any sustained reduction in non-compliance, points to the need for a greater diversity of models and hypotheses. This reveals the paradox that we need both the creation of a greater *diversity* of models and at the same time a greater *uniformity* of definitions.

7.3.2 The development and evaluation of new explanatory and interventive models holds out such potential value to the health service, that this agenda for research and development should be given high priority by those charged with decisions about research funding. A recent rigorous review of the research evidence (Haynes 1996)

contains the following observations:

"With the astonishing advances in medical therapeutics during the past two decades one would think that studies of the nature of non-adherence and the effectiveness of strategies to help patients overcome it would flourish. On the contrary, the literature concerning interventions to improve adherence with medications is surprisingly weak."

"As low adherence affects all self-administered treatments and as the armamentarium of effective treatments continues to grow, investment in fundamental and applied adherence research is likely to pay large dividends. Indeed, because the results could be applied so broadly, effective ways to help people follow medical treatments would have far larger effects on health than any treatment itself."

7.3.3 In this document we indicate the most important research priorities as we see them and urge a nationally co-ordinated, concerted, coherent and broad approach. Given the complexity of the problems and the difficulty of producing adequate numbers, we would urge that researchers communicate and collaborate with each other, that shared definitions and criteria are agreed and that validated methods are used. In the following paragraphs, we identify key areas for further research and in relation to each of them a number of priority research questions are posed.

7.3.4 Further research is needed into the nature of the beliefs that people hold about medicines, about their motivations and reactions to information-giving and to the behaviour of health care workers, family members and friends. Most of the usual demographic variables have already been extensively investigated and we know that none of them proves to be strongly associated with compliance over time and in different clinical situations. The suggested questions are:

- What are the sources of patients' beliefs about medicines?
- What are the main general beliefs that people hold about medicines?
- What are the main specific beliefs that patients hold about their own medicines?
- How consistent are these beliefs over time and what factors influence change in beliefs?

- How do these beliefs vary within and across various cultural, socio-demographic and illness groups?
- How do these beliefs vary with the source of the medicine and its legal classification?
- What is the relation between beliefs about treatment and illness perception?
- Is it possible to develop validated instruments to measure patients' beliefs about medicines?

7.3.5 Much work has been done in developing interventions to modify medicine-taking behaviour and we would urge that this work continues. We would wish to see it firmly linked to the research agenda. We are particularly concerned to ensure the ethical soundness of this research, so that endeavours to secure appropriate medicine taking are based not on manipulation but rather on strengthening the patients' understanding and control over their own illnesses and treatments. Further light may be thrown on this by studies of medicine taking by patients who purchase over-the-counter medicines. The following questions are suggested:

- What proportion of non-adherence is intentional and what proportion is unintentional?
- In relation to both prescribed and OTC medicines, what is the relationship between payment (or not) and adherence?
- How do general and specific beliefs about medicines influence actual decisions about medicine taking?
- How might the information in Patient Information Leaflets (PILs), especially about side effects and their frequency, be better presented?
- What information do people want and need about their medicines and in what form?
- What is the influence of PILs on beliefs about medicines and decision making?
- How does the experience of side effects affect decision making about medicines?

7.3.6 New medicines may be designed to overcome the difficulties posed by non-compliance: these may include combination products (though these introduce inflexibility in tailoring the separate ingredients to the needs of the individual); modified (sustained)

release medicines; high dose, short courses; improved tolerability; design features and alternative delivery systems to oral medication. Clinical trials should include tests of compliance and statistical analyses should relate to groups of patients in terms of their compliance, as well as the doctor's intention to treat. Medicines that are currently in use should be reviewed so as to gauge their 'robustness' in terms of the relationship between dose and effect. Continuing research will be required into the effect of containers, labelling and other information giving. We suggest the following questions:

- What are the patterns of adherence in the UK, measured using validated techniques, in each of the major long-term maintenance / prophylaxis therapies?
- In relation to a limited number of common conditions and effective therapies and using credible outcome measurements, what is the minimum level of adherence necessary to succeed in the therapeutic objective (and as a corollary, below which such an objective will fail to be achieved)?
- What is the role of inanimate devices (such as dose organisers, electronic pagers, MEMS monitor system, pharmacological indicators, etc.) in the development of a partnership model?

7.3.7 The shift to a primary care led service is creating new service and case management tasks for doctors, new clinical tasks for nurses and a potentially dramatic development of the clinical role of the pharmacist in managing treatment. These developments may be so radical as to constitute the redefinition of the traditional professions. In particular, nurses are already taking on greater responsibility for, and will develop extended skills in, the management of the major chronic diseases. Pharmacists may well extend their role from dispensing to taking some of the detailed prescribing decisions about choice of alternative versions of a drug, decisions about dose, information giving, monitoring and so on. Our questions are:

- What is the pharmacist's role in a partnership model of medicine taking?
- What is the nurse's role in a partnership model of medicine taking?
- How do lay people and doctors perceive the pharmacist's and nurse's roles in relation to adherence?

- How can pharmacists best help in improving patients' knowledge of medication and their adherence?
- What changes in the training of pharmacists would facilitate pharmacists' greater contribution?

7.3.8 We also need to understand better the influence of the health beliefs of doctors, nurses and pharmacists about drugs and the nature of the gap between these health beliefs and the patient's. How do these factors affect the likelihood of the patient's compliance? Experiments with task and role and a variety of changes in the configuration and style of practice aimed at improving compliance (among other things), should be rigorously assessed in order to demonstrate a causal relationship between the changes and both compliance and health outcomes. Our questions are:

- What are the main general beliefs which the various health care professionals hold about medicines?
- What are the main specific beliefs which the various health care professionals hold about their own prescribed or OTC medicines?
- What beliefs do health professionals have about patients' medication beliefs?
- To what extent do patients and health care professionals share general and specific beliefs about medicines?

7.3.9 In order to develop policy in this area we will need a variety of economic models:

- What is the effect of the concordance model on non-presentation of prescriptions?
- What is the effect on non-presentation of prescriptions of different systems of co-payment for prescriptions?
- What are the costs and benefits of those interventions which will be advanced in order to improve medicine taking?

7.3.10 It is known that patients want more information about medicines. Compliance may be changed by giving the patient more not less control over the treatment received. The effect on compliance of giving this information is unknown. To this end we would wish to see further experimentation with patient-held records, either in the present written form of documentation, or encrypted on smart cards. We envisage developments in the use of all the current communications media (such as telephone help lines), the development of really powerful information machines on the

Internet and other interactive electronic devices. As the anticipated wide dissemination of information technology comes about, the importance of sources of information that do not involve face-to-face communication with health care professionals is likely to grow rapidly. At the other end of the spectrum we would want to support experiments to enhance the mutual self-help of groups of patients suffering from similar conditions and subject to similar treatments. Our question is:

- What are the effects of different methods of information giving?

7.3.11 The A policy of concordant partnerships between patient and prescriber suggests the following questions:

- How can concordance between patients and health care professionals be operationalised and measured?
- To what extent does a lack of concordance between patients and health care professionals affect patients' medicine taking behaviour?
- What is the evidence of health gain from concordance?
- How can a partnership model of medicine taking be developed?
- How can a partnership model of medicine taking be evaluated?

7.3.12 Crucially, we include under the rubric of research and development, the rigorous evaluation of all innovations and experiments in the delivery of health care and healthcare training, examples of which we have suggested in this document and also the wide dissemination of successful results.

7.4 PROFESSIONAL EDUCATION AND TRAINING

7.4.1 There is little evidence of current specific teaching about compliance. The Royal Pharmaceutical Society of Great Britain, for example, requires all schools of pharmacy to include it in the social and behavioural sciences component of undergraduate programmes. We also learned of national distance learning and inter-active workshops on compliance developed by the Centre for Pharmacy Postgraduate Education in England. But in response to our consultative document we received no further information about any programmes in either undergraduate or postgraduate curricula.

7.4.2 Traditionally teaching about prescribing was primarily of relevance to doctors and pharmacists in training. But with a growing role for nurses as prescribers, with wider responsibilities for commu-

nity and hospital pharmacists and with the increasing availability of powerful modern medicines without prescription over the counter of the pharmacy, prescribing becomes an increasingly required subject for a variety of health care workers.

7.4.3 This consultative document makes it clear that concordance is an integral aspect and not a detachable component, of the whole process of clinical care and hence a core subject in medical, nursing and pharmacy education. It follows that teaching about concordance should receive a high priority in the educational and training agendas of all those involved in the processes of prescribing and/or monitoring treatments. Programmes should now be instituted in the basic/undergraduate, vocational/specialist and continuing phases of education. The teaching should be both uni- and multi-disciplinary, and the learning environment both uni- and multi-professional. There is an important agenda here for Postgraduate Deans and Regional Advisors, for the academic and training leadership in medicine, nursing and pharmacy. The recently formed Regional Education Development Groups are intended to be a major force for multi-disciplinary education at both undergraduate and postgraduate levels. The task of stimulating the *multi-professional* training and clinical audits on which we place such emphasis may also be taken up by the health service Authorities and Trusts.

7.4.4 In the past decade or so the undergraduate and postgraduate curricula of healthcare professionals have seriously addressed the social, psychological and ethical dimensions of caring for patients. For example, the educational statements of the General Medical Council (*Tomorrow's Doctors* 1993) lay great emphasis on these matters. Teaching communication skills has become a salient feature in the contemporary training of doctors, nurses and pharmacists. However, most of the education and training in prescribing has concerned itself with such matters as the decision to prescribe, the choice of medication and the issues of effectiveness and efficiency. When it occurs, teaching about the psycho-social dimensions of medicine taking tends to be a part of behavioural science courses, often separated from clinical training. We believe that there is need for more so-called 'vertical integration' of such teaching so that the behavioural topics can become integrated with the teaching of pharmacology and prescribing.

7.4.5 As this report testifies, the working party has, in the course of its eighteen months of study, consultation and deliberation, moved to a much more patient-oriented understanding of the problems inherent in medicine taking, than that implied by our initial task of seeking strategies to improve compliance. The work and time required to accomplish this shift from a predominantly health care professional orientation, strongly suggests to us that no consensus yet exists about what needs to be learned by health professionals. The first task, therefore, is to discuss, negotiate, experiment with and establish such shared and explicit educational goals.

7.4.6 As part of this process it will be necessary to establish support for the future teachers of concordance, so that they are given an explanation, and can achieve a sense of ownership, of the requisite knowledge, skills and attitudes. Such support will also include developing the competencies of multi-disciplinary teaching and multi-professional learning. In pursuit of this patient-oriented agenda we believe that the concept of the patient as teacher is well worth exploring.

7.4.7 Achieving a better understanding of the patient's perspective and being better able to encourage patients to voice their ideas and concerns, appear to be of such crucial importance in the effective, efficient and humane practice of health care, that we recommend both the inclusion of appropriate education in all the phases of professional development and the concomitant assessment in the qualifying, specialist and re-accreditation exams.

7.4.8 Eventually, the standards of performance should become sufficiently agreed, unambiguous and assessable, so that the audit of concordance could be employed as a reliable marker for patient-centred care.

7.4.9 If the health care professions and their educational bodies are to implement the large and innovatory educational program which we urge, it will be mandatory to instigate a national roll-out strategy. In this regard the working party was much encouraged by the section on Professional Development set out in the Government White Paper *The National Health Service: A Service with Ambitions* (Secretary of State for Health 1996).

7.5 PUBLIC AWARENESS

7.5.1 In pursuing this agenda, care will have to be taken to focus on the key intention: not simply seeking to achieve better compliance, but rather empowering patients to take part in concordant partnerships with doctors and other health care workers, such that their decisions about medicine taking are as informed as possible by scientific evidence, but are consonant with their own perceptions and wishes. Also, a prudent course must be charted between creating uncontrolled and unfounded anxieties, on the one hand and generating a false sense of (equally groundless) security and re-assurance, on the other. Nonetheless, many of the issues associated with the problems of medicine taking ought, in our view, now to become a significant part of the larger public debate about the potential of medical treatments, the roles of health care professionals and the economics and provision of health care.

7.5.2 Perhaps our most salient observation is that the problems associated with medicine taking have been remarkably absent from almost all public discussion about the benefits and expectations of contemporary medicine. Given the vast literature on compliance, we found it surprising that the topic appears of such little concern to the majority of patients, prescribers and researchers. In almost all of the public debate about health care provision, limited resources, prioritising and rationing, the great personal and economic cost and the waste of resources consequent on our failure to ensure the best results from modern treatments, has largely been ignored. We give high priority to remedying this state of affairs.

7.5.3 However, as a preliminary step there needs to be more systematic study of different models of belief and attitudes that shape the public's views - on prescribing and taking of medicines and on the roles of medicines in health care. Campaigns of public awareness, though well intentioned, must never run ahead of the research evidence about the complicated social, psychological and ethical issues on which we have laid such emphasis in this report.

7.5.4 In the *short term* insufficient is yet known about the range and variety of health beliefs to sustain an early high-profile general public relations campaign. In the *long term* it should prove possible to mount integrated sustained public awareness campaigns using the

full range of tools and techniques available to health education and public information campaigns including drama documentaries.

7.5.5 However, in order to be in a position to mount such general public awareness campaigns, we recommend, as a matter of urgency, the setting up of a co-ordinated programme of consultations between patient representative bodies, representatives of a range of interested health care professionals, relevant researchers in the field, ethicists and mass-communication experts and organisations. Although concerned to address general awareness, we believe that any such intention will be best served by targeting materials at specific groups.

7.5.6 As far as planning is concerned, this will have to take into account the level of interest of Health Authorities and health care personnel and their willingness to participate. In particular it will be important to integrate any such programmes of (specific) patient awareness with planned action in the primary care setting. The aim is to introduce both the patients and their doctors, nurses and pharmacists, together, to the new concepts implied by 'concordance' and their consequences. Because such an integrated approach would require commitment from both the media and the primary health care team, it would particularly lend itself to locality based campaigns. This heightened 'awareness' must begin at the level of the Health Authorities who have the responsibility of developing appropriately qualified personnel to undertake the task. It will be important to evaluate any such programmes. For example, those relating to particular groups of patients may be piloted in different regions, using similar groups in other regions as controls.

7.5.7 Finally, the issue of concordance may provide a relatively sensitive and specific marker for many important aspects of the quality of the whole healthcare system, affording a window through which it would become possible to view more clearly various aspects of a patient-centred service and to judge its quality. A leading US proponent of quality assurance in health care (Berwick 1996) describes three facets of the quest for quality: *improvement, change* and *learning*. From the point of view of systems he believes that these three are "deeply united". We are concerned to bring this sense of deep unity to all the aspects of future endeavours in the pursuit of a better partnership in medicine taking and to this end propose the following policy for implementation.

8. IMPLEMENTATION

8.1 We believe that in order to implement our recommendations the following will be required:

- a research and development strategy which would seek insights from such disparate disciplines as medical sociology, health psychology, clinical pharmacology and drug utilisation research; experimentation with new configurations of health care delivery, including shifts in professional roles and tasks in relation to prescribing, new ways of informing and empowering patients including the use of information technology and the inclusion of the concordance agenda in the contracts between NHS commissioners and providers;
- the inclusion of this programme in the wider NHS R&D program, adhering to the Culyer principles and also liasing with academic bodies and individuals from the whole range of relevant disciplines, so as to integrate into clinical practice the most promising results from basic as well as applied research;
- an educational and training agenda, encompassing multi-professional co-operation, which would require support from the universities and training colleges, Postgraduate Deans and Regional Advisers, the Royal Colleges and professional societies and the new Regional Education Development Groups;
- a program to raise patient and public and professional awareness of the importance of concordance, requiring a broad range of skills and demanding the help and co-operation of patient representative groups, health care professionals, the media, the education authorities, voluntary organisations and others.

8.2 The National Health Service Executive has funded a range of experimental schemes involving community pharmacists with 'compliance' as a key area of concern. We welcome this important initiative and note the encouraging steps to be taken in this regard, outlined in the Government White Paper *Choice and Opportunity* (Secretaries of State for Health, 1996). We are conscious of the fact that if the maximum benefit is to be gained from future experimentation, the selection of projects and their evaluation needs to take place within a broad and *coherent* framework.

8.3 In order to achieve such coherence, the working party recommends a strategy designed to promote and co-ordinate the exploration and development of the concordance model and that the following steps be now taken.

8.4 A Research and Development Committee should be appointed under the aegis of a major national professional body - we suggest that *The Royal Pharmaceutical Society of Great Britain* is appropriate to take on this role. The composition of this committee would be similar to that of our working party, including experienced individuals in all the relevant fields and disciplines. Additional representation from Patient's Organisation and the Regions with special responsibility for NHS R&D and prescribing, would seem appropriate. Links to the Economic and Social Science Research Council and the Medical Council should be sought.

8.5 The terms of reference for the R&D Committee should be formulated to include:

- identifying priorities by re-iterative discussion and consultation;
- addressing these priorities;
- helping to develop the necessary academic infrastructure and encouraging multi-disciplinary approaches;
- commissioning research, educational experiments and methods of informing and involving patients and the public;
- developing a dissemination strategy including organising conferences, seminars and think tanks, in order to disseminate results and stimulate new approaches.

8.6 The pursuit of this R&D Committee's agenda would require the appointment of a full-time project co-ordinator who could be an academic in one of the related fields and, while accountable to the Council of the Society and the R&D Committee, would also be affiliated as a visiting fellow to an appropriate academic department.

8.7 We would envisage that such a committee will have accomplished its task in three years, after which the pursuit of these activities would have developed sufficient momentum not to require the special support that we believe is now essential, if the conclusions reached by our working party and documented in this report, are to be given operational expression.

8.8 We estimate that the program here outlined will require a ring-fenced R&D budget over three years. Currently the Department of Health *Prescribing Research Initiative* is budgeted at £2.4M over four years. A comparable investment will be required in support of our recommendations. The Government's commitment to 'responsiveness' in its White Paper *A Service with Ambitions* (Secretary of State for Health, 1996) seems very helpful in this regard. Substantial pump-priming might be looked for from public funds, with growing participation from the private sector. Funding from the private sector might well include support from charitable trusts and commercial organisations, including partnership with those concerned in wider community matters than health care provision.

8.9 In making these recommendations, the committee is sensitive to the many and growing demands from both public and private sources, for the support of important health care initiatives. However, the scale of the consequences of the present state of medicine taking in the treatment of patients, the huge cost in terms of patient suffering and avoidable mortality, the vast waste of scarce NHS resources, constitutes in our minds, an overwhelming argument for what is here proposed.

APPENDIX

The working party is grateful for the help of the following whom we consulted.

Professor Nick Barber, Head of Pharmacy Practice, School of Pharmacy, University of London

Professor Phil Barker, Professor of Nursing, Psychiatric Nursing Practice, Newcastle

Dr Chris Butler, Lecturer in General Practice and Principal, General Practitioner, University of Wales College of Medicine, Cardiff

Dr Dhiren Bhatt, Community Pharmacist, Suffolk LPC, Ipswich

Mr David Bolton, Secretary of Scottish Division of Royal Pharmaceutical Society, Edinburgh & Lothian Health Board

Dr Michael Chan, Director, NHS Ethnic Health Unit, Leeds

Mrs Frances Charlesworth, Director, International and Commercial Affairs, Association of British Pharmaceutical Industry, London

Professor John Cromarty, National Specialist in Clinical Pharmacy, Robert Gordon University, Aberdeen

Mr William Darling, Chairman, South of Tyne Health Authority, South Shields

Professor Arvind Deshmukh, Professor of Pharmacy Practice, University of Sunderland

Professor Robert Dingwall, Head of School of Social Studies, University of Nottingham

Dr Gordon England, Director, Medical Advisers Support Centre, Liverpool

Dr Ewing Forrester, Medical Prescribing Adviser, Glasgow

Mr Russell Foulsham, Community Pharmacist, London

Dr Peter Hill, Senior Medical Officer, Northern & Yorkshire RHA, Newcastle

Dr Rob Horne, Senior Lecturer in Clinical Pharmacy, Department of Pharmacy, University of Brighton

Dr Jill Jesson, Visiting Fellow, Department of Pharmaceutical and Biological Sciences, Aston University

Mr Clive Jones, Director of Pharmaceutical Advisory Services, Pontypridd

Dr Jim Kennedy, General Practitioner, Wolfson Unit of Clinical Pharmacology, University of Newcastle

Ms Yvonne Latawiec, Senior Assistant, NHS Ethnic Health Unit, Leeds

Mr Peter Lowe, Community Pharmacist, Newcastle

Ms Clare Mackie, Community Pharmacist, Glasgow

Professor James McElnay, Director of School, School of Pharmacy, Queen's University, Belfast

Dr Lynne Myers, Lecturer in Health Psychology and Behavioural Science, Department of Psychiatry, University College Medical School, Wolfson Building, London

Miss Rose Marie Parr, Director, Scottish Centre for Postgraduate Qualification Pharmacy Unit, University of Strathclyde

Dr Theo Raynor, Director of Pharmacy, Yorkshire Regional Pharmacy Academic Practice Unit, Leeds

Mr Ray Rowden, Director, Institute of Health Services Management, London

Dr Jim Smith, Regional Pharmaceutical Advisor, Northern Regional Drug and Therapeutic Centre, Wolfson Unit, University of Newcastle

Dr Ian Spencer, Medical Adviser, Newcastle & North Tyne Health Authority

Ms Angela Timoney, Pharmaceutical Prescribing Adviser, Glasgow

Dr Adrian Towse, Director, Office of Health Economics, London

Professor Roger Walker, Professor of Pharmacy Practice, Welsh School of Pharmacy, University of Wales, Cardiff

Professor Tom Walley, Professor of Pharmacology, Department of Pharmacology and Therapeutics, University of Liverpool

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Professor John Anderson, Postgraduate Dean and Director, Postgraduate Institute, University of London

Mrs Jean Ashcroft, Director of Public Policy and Information, Arthritis Care, London

Mr John Bauldreay, Cheshire

Mr Stephen Bazire, Pharmacy Services Director, Hellesdon Hospital, Norwich

Dr Trevor Bayley, Postgraduate Dean, Postgraduate Medical & Dental Education, Liverpool

Professor Ian Boucher CBE, Chief Scientist, The Scottish Office of Department of Health, Edinburgh

Dr Colin Bradley, Senior Lecturer, Department of General Practice, University of Birmingham

Mr Charles Butler, J R Butler Chemists, Reading

Dr Eva Celinska, Medical Director, Ciba Pharmaceuticals, West Sussex

Professor Stuart Checkley, Dean, Institute of Psychiatry, London

Professor Henry Chrystyn, Professor of Pharmacy Practice, University of Bradford

Mrs Sarah M E Cockbill, Chairman, Royal Pharmaceutical Society of Great Britain: Welsh Executive

Ms Alison Cobb, Policy Officer, MIND, London

Dr George Cowan, Dean, North Thames, Thames Postgraduate Medical & Dental Education, London

Mrs Georgina Craig, Head of Professional Development, The National Pharmaceutical Association

Mrs Jean Curtis, Chairman, Community Care Liaison Group, East Hertfordshire NHS Trust

Mr David Dickinson, Editor, Health Which, Consumer's Association, London

The Rt. Hon. Lord James Douglas-Hamilton QCMP, Minister for Home Affairs and Health, The Scottish Office, Edinburgh

Dr Jon Dowell, Research Fellow, Tayside Centre for General Practice, Dundee

Mr Mark Duman, Project Officer, King's Fund, London

Mr Mike Dunning, Project Manager, King's Fund, London

Mrs Linda Edwards, Director, National Osteoporosis Society, Bath

Mr & Mrs Philip Farmer, Haslingfield, Cambridge

Mr John Farwell, Pharmaceutical Adviser, London

Ms Christine Funnel, Director, National Eczema Society

Ms Sarah Furlong, Research Officer, King's Fund, London

Mr David Gilbert, Research Officer, King's Fund, London

Ms Christine Hancock, General Secretary, Royal College of Nursing, London

Mr Toby Harris, Director, Association of Community Health Councils for England & Wales, London

Ms Monica Hart, Communications Adviser, The Stroke Association, London

Mr Bryan Hartley, Chief Pharmaceutical Officer, Department of Health, London

Professor Ian Haslock, President, British League Against Rheumatism

Dr Jacky Hayden, Dean of Postgraduate Medical Studies, Department of Postgraduate Medicine and Dentistry, University of Manchester

Dr Shelley Heard, Postgraduate Dean, Thames Postgraduate Medical and Dental Education, London

APPENDIX

Dr Andrew Herxheimer, Clinical Pharmacologist, London

Mr Brett Hill, Senior Pharmacist, Clinical Services, Whitchurch Hospital

Miss Judith Hill, Chief Nursing Officer, Department of Health & Social Services, Belfast

Professor Steve Hudson, Professor of Pharmaceutical Care, University of Strathclyde

Dr Adrian Hunt, Senior Lecturer, University of Portsmouth

Mr Paul Hunter, Vice President, The Royal College of Ophthalmologists, London

Dr Dai John, Lecturer, Medicines Research Unit, University of Wales, Cardiff

Mr David Kennedy, Pharmacist Facilitator, Grampian Health Board

Mrs Hilary Kent, Director of Information & Training, British Epilepsy Association, Leeds

Mr Robert Lea, Regional Pharmaceutical and Prescribing Adviser, NHSE South Thames, London

Mr Neil Leadbeater, Secretary, National Pharmaceutical Advisory Committee, Scottish Office, Department of Health, Edinburgh

Mr Michael Lowe, Deputy Secretary, BMA General Medical Services Committee, London

Ms Lindsay MacHardy, Programme Manager, Health Education Board for Scotland, Edinburgh

Mr Gerald Malone MP, Parliamentary Under-Secretary of State, Department of Health, London

Professor Ian Marshall, Head of School of Pharmacy, University of Strathclyde

Ms Margaret Martin, Cambridge

Miss June McKerrow, Director, The Mental Health Foundation, London

Dr Jack McCluggage, Chief Executive/Postgraduate Dean, Northern Ireland Council for Postgraduate Medical and Dental Education, Belfast

Dr Agnes McKnight, Regional Adviser in General Practice, Northern Ireland Council for Postgraduate Medical & Dental Education

Mrs Barbara Meredith, Senior Policy and Development Manager, National Consumer Council

Miss Rosemary Mitchell, Administrator, College of Pharmacy Practice

Ms Jean Mossman, Chief Executive, BACUP (British Association of Cancer United Patients)

Ms Julie Mycroft, Principal Pharmacist, Clinical Services, The Royal Marsden NHS Trust

Mr John Myers, Morningside, Edinburgh

Professor John O'Grady, European Medical Director, Daiichi Pharmaceuticals UK Ltd, London

Mr Simon O'Neil, Diabetes Care Adviser, British Diabetic Association

Dr Elisabeth Paice, Dean/Director, Thames Postgraduate Medical & Dental Education, London

Professor Rhona Panton, Head of Department, Medicines Management, Keele University

Dr William Patterson, Regional Adviser in General Practice, South East Scotland Committee for Postgraduate Medical & Dental Education

Ms Anne Pearson, Asthma Helpline Team Leader, National Asthma Campaign, London

Professor Denis Pereira Gray, Director, Postgraduate Medical School, Institute of General Practice, University of Exeter

Mr Ronald Pitts Crick, Chairman, International Glaucoma Association, London

Dr Andrew Polmear, GP Audit Adviser, East Sussex, Brighton & Hove Medical Audit Advisory Group

Dr David Poulter, Co-Chairman, National Federation of Kidney Patient's Association

Professsor Cedric Prys Roberts, President, Royal College of Anaesthetists, London

Ms Gul Root, Pharmaceutical Adviser, East Surrey Health Authority, Surrey

Mr Tim Root, Chief Pharmacist, The Royal Marsden NHS Trust

Dr Stefan Slater, Royal College of Physicians and Surgeons of Glasgow

Dr Roger Simmons, Senior Medical Officer, The Scottish Office, Department of Health, Edinburgh

Dr James Smith, Regional Pharmaceutical Adviser/Director of Pharmacy, Department of Health, Newcastle-upon-Tyne

Miss Denise Taylor, Senior Pharmacist, Gloucester District Drug Information Service, Gloucester

Professor John Temple, Chairman, Committee of Postgraduate Medical Deans, London

Dr Jeremy St John Thomas, Secretary, Royal College of Physicians, Edinburgh

Mr Hugh Thomas, Pharmaceutical Adviser, Health Promotion Wales, Cardiff

Professor David Thompson, Director of Research and Development, School of Health, University of Hull

Mr Robert Timson, Regional Pharmaceutical Adviser, NHS Executive, Trent, Sheffield

Surgeon Captain Fred Tolley, Royal Navy, Adviser in General Practice to the Medical Director General (Navy)

Dr John Toy, Senior Medical Officer, Research and Development Department, Department of Health, London

Dr Michael Turner, Medical Director, Family Heart Association, Kidlington, Oxford

Dr Christine Tyrie, Consultant Psychiatrist, Penrith Hospital, Cumbria

Dr John Urqhart, Professor of Pharmaco-epidemiology, University of Limburg, Maastricht, The Netherlands

Ms Barbie Vaughan, Director, King's Fund, London

Mr Steven Wainwright, Lecturer in Nursing Studies, King's College, London

Miss Carwen Wynne-Howells, Chief Pharmaceutical Adviser, Welsh Office

Mrs Sonya Yates, Nursing Officer, Department of Health, Leeds

Mr Andrew Young, Executive Director, Primary & Community Care, County Durham Health Authority

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