CHAPTER TWELVE

Clinical Governance

Introduction

12.1 I have already said in Chapter 5 that clinical governance is the means by which it is intended that NHS organisations should discharge the duty of quality imposed by the Health Act 1999. The theory of clinical governance developed from the initiative of corporate governance which originated in the early 1990s as a means of addressing unacceptably low standards in the world of business. It was heralded in the White Paper 'The New NHS', published in December 1997. At that time, there was a recognition on the part of Government that standards of care in the NHS were very variable and that this was leading not only to harm to patients, but also to loss of confidence on the part of the public. Clinical governance was to address that problem.

12.2 Clinical governance is defined by the Department of Health (DoH) as:

> **'... a framework through which National Health Service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'**.

12.3 I personally did not find that definition easy to understand and it does not seem surprising that, in the early days at least, there was a great deal of confusion and uncertainty in the medical profession about the concept of clinical governance and about what it would mean in practice. Some general practitioners (GPs) were suspicious about its purpose (believing it to be an attack on their independent contractor status) and hostile to its introduction. These feelings were heightened by the speed with which it was implemented and by the changes to the organisation of primary care which were occurring at the same time.

12.4 I hope that my own understanding of the concept of clinical governance has improved in the last few months. For those who are still unfamiliar with it, I shall attempt, not to define it, which seems to me well nigh impossible, but to describe it. Clinical governance is a system for improving the standard of clinical practice in the NHS and for protecting the public from unacceptable standards of care. The system comprises several different types of activity which should all fit together into a framework. This integrated system has replaced the previously disparate and fragmented approaches to the improvement of quality of care. The different types of activity include continuing education, the introduction and maintenance of good management systems, the promotion of clinical effectiveness, clinical audit, risk management, research and development and the fostering of an ethos of openness and accountability. Some of these activities are developmental in nature, such as continuing education and the dissemination of good practice. Risk management, by which organisations seek to analyse untoward events and learn from them, is another example of a developmental activity. Other activities are of a monitoring or supervisory nature; for example, organisations are required to collect data and information about the care being provided by their clinicians. This should enable the

organisation to detect poor performance so that it may be corrected, but data collection should also draw attention to good performance and therefore have a developmental effect. Yet other activities are designed to encourage clinicians to monitor themselves, with the intention that this should provide the opportunity and incentive to improve clinical performance. For example, clinicians are provided with data about their own performance and that of their team or group; they are also encouraged to audit their own activities and those of their colleagues.

12.5 DoH guidance published in 1999 required NHS trusts and primary care organisations (PCOs) to identify clinical governance leads (who were to be clinicians) and to set up appropriate structures for overseeing clinical governance within their organisations. Once the primary care trusts (PCTs) came into existence, they appointed their own clinical governance leads and sub-committees. Many of these clinical governance leads were local GP volunteers, who were uncertain of their precise role and lines of accountability. Some found their dual role as members of the local medical community and part of the PCT 'establishment' difficult to reconcile. Others were uncertain about how they could seek to promote good clinical governance without any 'teeth'. There were, however, many within the medical profession who welcomed the emphasis on quality that clinical governance brought and who viewed positively the opportunity of working with PCT managers to raise local standards.

Structures and Systems

12.6 At the Inquiry's seminars, Professor Aidan Halligan, Deputy Chief Medical Officer for England and Director of Clinical Governance for the NHS, emphasised that the essence of clinical governance was 'a system of accountability for care'. Delivery of clinical governance was, he said, dependent on 'architectural artifices': structures, processes, mechanisms and clear accountability arrangements.

12.7 It is, of course, evident that good governance – of whatever organisation – requires sound structures and well-designed systems. If there are no effective lines of management accountability, for example, no one will take responsibility when things go wrong. If no proper complaints system is in place, complaints will go unrecorded and potentially valuable information about poor practice or outcomes will be lost. If an organisation has no whistleblowing policy, staff may be deterred from reporting colleagues who may be guilty of dishonesty or incompetence. An absence of a system of financial checks may result in widespread fraud.

12.8 However, sound structures and systems are not, on their own, enough to secure good governance. A complaints system is of no value unless those who are intended to use it (customers, clients, patients, etc.) know of its existence and unless staff within the organisation are trained to operate it effectively. A whistleblowing policy will not be used unless staff are made aware of it and are confident that, if they voice their concerns, those concerns will be taken seriously and the organisation will deal with them fairly. It is essential to ensure that clinical governance extends to every layer of a NHS organisation so that all members of the organisation are putting into practice the systems intended to promote quality.

12.9 In the context of primary care, this means extending the systems, not only to the level of PCT staff, individual GPs and other healthcare professionals, but also to members of staff of all general practices in the area. Under the new General Medical Services (GMS) Contract, contracting practices are required to have in place an effective system of clinical governance.

The Implementation of Clinical Governance by Primary Care Trusts

12.10 At first, the term 'clinical governance' may have sounded alien; however, its translation into practical action often proved rather less daunting than had been expected. Some of the methods used were not new – for example, the monitoring of complaints against GPs, the production of data comparing the performance of one GP practice with others in the area, the encouragement of clinical audit and the monitoring of prescribing. The effect of clinical governance was to bring together these initiatives (and many others) into one coherent policy. There were, however, novel areas to be tackled, notably the implementation of the guidance contained in the new National Service Frameworks (NSFs) and issued by the National Institute for Clinical Excellence (NICE). In the early days of clinical governance, the development of strategies to monitor and improve adherence to this guidance was a major priority for the PCTs.

12.11 Recent evidence suggests that PCTs are using a wide variety of strategies to monitor and improve the quality of care locally. In this Chapter, I shall discuss a number of those in most common use. In doing so, I shall consider how (if at all) those strategies might have a beneficial effect on quality of care. I shall also consider the extent (if any) to which each of the various strategies described gives rise to meaningful information that might be of assistance to a PCT in assessing whether an individual GP is giving an acceptable standard of care to patients.

12.12 The strategies which I shall examine are:

(a) monitoring of GPs' prescribing

(b) monitoring of GPs' referrals

(c) monitoring of performance indicators and/or comparative data about the performance of general practices

(d) monitoring of data collected in connection with the new GMS Contract

(e) practice visits

(f) practice accreditation

(g) monitoring and analysis of patient complaints

(h) operation of systems for identifying and dealing with poorly performing GPs

(i) clinical audit

(j) risk management

(k) significant event review

(l) appraisal.

(a) Monitoring of General Practitioners' Prescribing

12.13 In Chapter 4, I described briefly the ePACT.net system, which is used by PCTs to monitor GPs' prescribing. This monitoring is carried out primarily in order to enable the medical and pharmaceutical advisers employed by PCTs to offer advice to GPs about the efficacy and cost-effectiveness of the drugs they prescribe. However, prescribing data might reveal defects in the quality of a doctor's prescribing. For example, it might show that s/he frequently prescribes drugs that have been replaced by better alternatives or that are inferior to newer drugs which are available. It might show that the doctor is prescribing drugs that are known to be of limited clinical value, such as nasal decongestants. The data might show that a doctor is prescribing significantly less than the average quantities of drugs used in cardiovascular disease. All these circumstances might be indicative of defects in a doctor's prescribing practice. They might also indicate a poor standard of care going beyond the issue of prescribing. For example, a doctor who persistently prescribes drugs which have been replaced by more effective alternatives may be out of date in other areas of his/her practice.

12.14 The data might even suggest the possibility of criminal activity (e.g. if a very high level of benzodiazepines were being prescribed on a regular basis). PCTs are now advised to run quarterly analyses for prescribing of opiates, benzodiazepines and amphetamines by every GP in their area. The analyses can be carried out by means of simple techniques, using the ePACT.net system. The range of drugs for which these techniques are available is expanding as new problems, involving different drugs, come to light. Of course, prescribing data can only highlight a pattern of prescribing which appears unusual. It cannot afford an explanation for the unusual pattern. The data requires interpretation in the light of local factors and of the circumstances of the individual patient(s) for whom the drugs were prescribed, before a judgement can be reached.

12.15 The monitoring of prescribing practice began primarily as a tool of financial management. However, it has now developed into a part of clinical governance. As I have said, it can raise questions about the quality of a doctor's prescribing. Those questions can lead in turn to consideration of the doctor's performance more generally. If a problem is identified, it may be capable of being remedied by the provision of advice and information. It may be more complex and require, for example, referral to the PCT's performance procedures. In either case, it can provide a valuable source of information about quality of care.

Problems with Prescribing Data

12.16 In the past, the value of prescribing data was reduced by the fact that it was available only at practice level. It was not possible to obtain data for an individual doctor, unless that doctor was a single-handed practitioner. If a doctor was a member of a large group practice, his/her prescribing pattern would have had to be very unusual indeed in order to be evident from the data relating to the practice as a whole. More often, any problems

with the quality of the prescribing of an individual member of the practice would have been obscured by the data relating to others.

12.17 Analysis of prescribing at the level of an individual prescriber is now possible. Each prescriber within a GP practice has an individual prescriber code printed on his/her prescription forms. The Prescription Pricing Authority (PPA) now produces data referable to individual prescribers. The accuracy of the data is, however, reduced if (as has been common in the past) members of a GP practice use prescription pads belonging to other members of the practice. A further problem which became evident during the course of the Stage Three seminars was that a computer generated prescription issued by one doctor might, if the computer were programmed in a certain way, carry the name of the doctor with whom the patient was registered (or, under the new GMS Contract, the patient's preferred doctor), rather than that of the doctor who had prescribed the medication. This can be prevented by adjustment of the computer but, in order for this to be done, the practice must first be aware of the problem and the need to avoid it. I have recommended in the Fourth Report that all prescribers should use only their own prescription pads, marked with their own professional registration numbers, so that all prescribing can be correctly attributed to the clinician responsible for it.

12.18 Problems also arise with repeat prescriptions. It is common for members of a GP practice to check and sign repeat prescriptions for the whole practice on a rota basis. The doctor who signs the prescription may not, therefore, be the doctor who originally prescribed the drug in question. He or she will have had no real clinical input into the choice of medication. This has the inevitable effect of rendering the prescribing data for the whole practice inaccurate. It could have the effect of obscuring an unusual pattern of prescribing by one member of a practice. Some practices, alert to this problem, have taken steps to avoid it in the past but many have not.

12.19 At the Stage Three seminars, Dr Jim Smith, Chief Pharmaceutical Officer for England, DoH, explained that a new system of dealing with repeat prescriptions had been successfully piloted in several areas and would soon be put into general operation. Under this system, a doctor who wishes to prescribe medication on a long-term basis will write a prescription to provide for periodic dispensing over a period of up to a year. The patient will leave the prescription at the pharmacy of his/her choice, will collect the drugs every few weeks and need not return to the surgery until the expiry of the prescription. The pharmacist will be responsible for reviewing the appropriateness of the continuing supplies dispensed under the prescription during its currency. Not only will this system save a great deal of time for GPs, it will also allow greater accuracy of the prescribing data because the whole quantity supplied under the prescription will be attributed to the doctor who made the original decision.

12.20 Another problem is the use by non-principals, such as locums and GP registrars (i.e. trainees), of prescription pads belonging to GP principals. These non-principals do not at present have their own individual prescriber codes. Instead, they are required to endorse their prescriptions with a red 'T' (locums) or 'D' (registrars) to differentiate themselves from the principal whose prescription pad they are using. There is no means of identifying which non-principal is the prescriber. Consequently, no individual prescribing data is

available for an individual locum and there is, therefore, no way of ascertaining whether his/her prescribing practices are in any way unusual. Furthermore, the use of their prescribing pads by others has the effect of 'blurring' the data relating to GP principals.

12.21 Steps are being taken to change these arrangements. It is hoped that, in the future, locums, deputies and other non-principals will be allocated their own unique prescriber codes. This should greatly enhance the opportunity to detect aberrant prescribing by a GP non-principal. However, it will be up to the PCT on whose list the locum is included to take responsibility for monitoring his/her prescribing and for any follow-up action which may be necessary.

12.22 Another difficulty is that the data currently available may not reveal a complete picture of an individual doctor's prescribing. If s/he issues any private prescriptions those will not be included within the data. This is a serious *lacuna* that can result in excessive or aberrant prescribing by a doctor remaining undiscovered. In my Fourth Report, I recommended that all prescriptions, whether NHS or private, should go to the PPA for processing and should be included within the prescribing data available to PCTs. This seems to me vital if PCTs are to have the information about prescribing which they need for the purposes of discharging their clinical governance responsibilities.

12.23 Current prescribing data does not necessarily reflect the prescribing practice of individual doctors and cannot, therefore, provide reliable information about the quality of practice of an individual doctor. Only if the various changes that I have described are implemented will it be possible to use it as a reliable source of information for clinical governance purposes.

(b) Monitoring of General Practitioners' Referrals

12.24 There seemed to be general agreement among witnesses and participants in the Inquiry's seminars that data about GPs' referrals to other services (in particular, hospital services) was both unreliable and difficult to interpret. It is not clear what, if any, correlation there is between referral patterns and quality of care. That being the case, the usefulness of referral data is plainly limited. Also, it is available only at practice level, so gives rise to problems similar to those already mentioned in connection with past prescribing data.

(c) Monitoring of Performance Indicators and/or Comparative Data about the Performance of General Practices

12.25 Since the mid-1990s, some PCOs have developed a range of performance indicators, compiled from the data available to them. They have compared the indicators as between practices within their own areas and practices elsewhere. They have used the results in different ways. I have previously mentioned in Chapter 5 that such indicators have sometimes been used as a trigger for investigations into the performance of certain doctors.

12.26 Many experts have doubts about the use of performance indicators as a means of assessing quality. At the Inquiry's seminars, Professor Martin Roland, Director, National Primary Care Research and Development Centre and Professor of General Practice,

University of Manchester, referred to his experiences on the Manchester Performance Panel. The Panel responded to concerns expressed about doctors, rather than (as was done elsewhere) using performance indicators to identify potential cases of poor performance. Professor Roland felt that experience had shown that the approach of the Manchester Panel was probably the right one. He pointed out that the types of problem the Panel identified (e.g. poor communication within a practice, poor teamwork, inability to work with others, poor communication with patients and poor management) were the most difficult issues to identify by means of routine data.

12.27 Dr Sarah Wilson, Director of Public Health and Medical Director, Trent Strategic Health Authority (SHA), said that, before attending the Inquiry's seminars, she had contacted the PCTs in her area to find out what clinical governance arrangements they had in place. Some had developed very sophisticated performance indicator sets, using such indicators as prescribing data, mortality rates, immunisation rates, screening uptake rates and complaints. They operate a 'traffic light' system whereby a GP who has a 'red light' (indicating that s/he is an outlier) on more than a certain number of indicators is targeted for enquiries to be made. Dr Wilson asked the clinical governance leads of the PCTs that operate this system whether there was any correlation between the incidence of a lot of 'red traffic lights' and a perception within the local health community that the performance of the doctor in question was poor. They told her that the only indicator which gave rise to such a correlation was an excess of complaints against a doctor. Dr Wilson said that there was a real concern that clinical governance leads were doing a great deal of work in developing indicator sets using data which was never intended for the purpose of determining the quality of care given by an individual doctor. Ms Fiona Freedland, Legal Director, Action against Medical Accidents (AvMA), and a non-executive director of Hackney PCT, expressed doubt, based on her own experience of the use of performance indicators, about the extent to which there was any correlation between such indicators and the competence of a GP.

12.28 Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, and Professor Richard Baker, Director, Clinical Governance Research Development Unit, University of Leicester, also referred to the limitations of the data currently available to PCTs. Such limitations exist even when the data is used to examine quality of care at practice – rather than individual doctor – level. For example, Dame Lesley mentioned problems with handling the data and with using data collected for one purpose to fulfil a different purpose. The problem becomes much more acute when an attempt is made to use the data to assess the quality of care given by an individual doctor.

12.29 Both Dame Lesley and Professor Baker pointed out that indicators and other similar data provide no information about such matters as a GP's communication skills, relationships with patients and clinical care. All these matters are vital to an assessment of quality of care.

(d) Monitoring of Data Collected in Connection with the New General Medical Services Contract

12.30 In order to discharge their responsibility for administering payments under the new GMS Contract, PCTs are obliged to collect a large quantity of data from individual GP practices.

Some of this data is similar to that collected previously in connection with targets for certain types of preventive treatment and qualification for financial incentives. According to Professor Roland, however, the new GMS Contract will 'alter radically' (by which I understand him to mean materially increase) the information available to PCTs about the quality of care being provided in practices operating under GMS Contracts. There will be the same framework of assessment for practices providing personal medical services (PMS). It is not yet clear whether individual PCTs will have the expertise or resources necessary to analyse the huge amount of data that will be available to them, and to use it to improve quality of care.

12.31 The data collected is practice-based and is not, except in the case of a single-handed practice, referable to an individual GP. At the Inquiry's seminars, Professor Roland pointed out that the GMS Contract is deliberately aimed at practice level which is, in many instances, an appropriate level at which to consider patient care. He gave the example of an individual doctor who may be poor at managing diabetes, but has a first class nurse who takes responsibility for managing diabetic patients. Those patients will get good care from the practice, notwithstanding the weakness of the individual doctor, and that is what matters. Provision of data at practice level is therefore entirely appropriate for the purposes of the GMS Contract. However, that same data cannot be used to evaluate the quality of care given by an individual doctor within the practice.

12.32 Participation in the GMS Contract's quality and outcomes framework (QOF) is voluntary, although failure to participate will mean that a practice will not qualify for additional payments under the GMS Contract. It remains to be seen whether many practices will choose not to participate in the QOF or will do so only to a limited extent. For those practices which choose this course, little or no data will be available. I suppose, however, that the very fact that a GP practice declines to participate in the QOF – or participates only to a limited extent – may in itself raise questions about the standard of care offered by that practice and may cause a PCT to subject it to closer scrutiny.

(e) Practice Visits

12.33 The clinical governance leads of many PCTs have developed a system of regular, routine practice visits. Ms Freedland spoke about the importance of these visits. First, they enable the clinical governance lead to form a relationship with GPs and to encourage a greater sense of 'ownership' of clinical governance by the profession. They have the additional benefit of enabling the clinical governance lead to observe such features as arrangements for storage of medicine and vaccinations and for infection control and the cleanliness of the surgery. They offer an opportunity to ask questions of practice staff about the procedures and policies in operation. Dr Wilson said that visiting GP practices in a systematic way is what clinical governance leads would like to do. By visiting, they can get 'a real sense of the practice'.

12.34 The form that clinical governance visits take – and, indeed, whether they take place at all – depends on the co-operation of the practice in question. Ms Freedland said that there were 'a couple of GPs' in her PCT who had denied access to the clinical governance lead. On the whole, however, the system of visiting had worked well. Dr Wilson said that, in her

area, there had been problems in the past about gaining access, but these had largely been resolved. On occasions, practice staff and practice managers had taken the initiative and arranged a visit from the PCT. Clinical governance leads (usually members of the local professional community) were conveying the message that the PCT was not there to 'beat up' GPs, but to give support and assistance. This approach appeared to have had the desired effect.

12.35 While the fact that such visits are taking place is clearly to be welcomed, it seems to me that the approach which Dr Wilson described must limit the extent to which a visiting clinical governance lead can 'challenge' members of the practice about data relating to the practice which the PCT holds or, indeed, about any other aspect of its activities. To do so would hardly be consistent with the PCT's stated role of a giver of support and assistance. This was well illustrated in the evidence of Dr Michael Taylor, Chairman of the Small Practices Association and Clinical Governance Lead, Heywood and Middleton PCT. He said that, if he visits a practice in his PCT, members of the practice know that he is never there in anything other than a supportive capacity. If he has concerns about a colleague, he has in place arrangements with neighbouring PCTs and they will carry out any necessary investigation. Nevertheless, it seems to me that there must be an intermediate stage – where no positive concerns have yet arisen but probing questions need to be asked – at which it is difficult for a PCT to maintain its wholly supportive stance. In such circumstances, the position of a clinical governance lead, usually a local GP, must be particularly difficult. At the seminars, Professor Halligan observed that clinical governance visits could have 'perverse consequences'. They could, he said, 'reinforce subversive behaviour by amplifying a culture of fear'. He said that the value of such visits had consequently been 'patchy'. He emphasised the need for a change of culture.

12.36 I am surprised and disappointed that an annual visit by officials of a PCT to a GP practice should be viewed with such suspicion – even fear – by some. It is plainly unsatisfactory that a practice should decline to permit a clinical governance visit at all. There must be a concern that those practices which are unwilling for visits to take place are the very ones where standards of care may be unacceptably low. Their failure to permit a visit has the effect of thwarting the PCT's attempts to discharge its clinical governance responsibilities.

12.37 I have already mentioned in Chapter 5 that PCTs will undertake annual reviews of the performance of all contracting practices under the arrangements for the new GMS Contract. These reviews will include a visit to the practice premises and discussions with the contractor. They will be obligatory. Practices providing PMS are already reviewed annually. Quite how these reviews will dovetail with the clinical governance visits – and whether they will, in time, replace them altogether – is not yet clear. Nor, as I have previously observed, is it clear how closely practices will be scrutinised in the course of a review.

(f) Practice Accreditation

12.38 As I have already explained in Chapter 5, practice accreditation also offers an opportunity for a practice visit and for assessment of the practice against set criteria. Under the model in use in South Yorkshire, Leicestershire and Lincolnshire, there is full involvement of the

PCT, which can use the information gained during the process of preparation for the assessment, and in the course of the assessment itself, for the purposes of clinical governance. Although the assessment is practice-based, there are, as I have explained, aspects of it which would shed light on the practice of an individual doctor.

(g) Monitoring and Analysis of Patient Complaints

12.39 At present, there are, as I have already mentioned, constraints upon the ability of PCTs to monitor and analyse complaints made about GPs and to use them effectively for clinical governance purposes. A PCT does not have a full picture of the nature and subject matter of the complaints made by patients about a doctor. A practice might 'fob off' a complaining patient or the patient might abandon his/her complaint and the PCT might never hear of it. In addition, there may be many incidents which are indicative of a poor standard of care but which are not the subject of complaints. This is particularly so under the present system, where patients may be deterred from complaining by the requirement that they should first direct their complaint to the doctor or practice concerned. (In the future, they will be able to choose whether to lodge their complaint with the practice or the PCT.) Nevertheless, it is clear that, despite the limitations upon the information available to them, PCTs find complaints a valuable indicator of the performance of a doctor and use them as a monitoring tool. Complaints by patients can, of course, provide an insight into such matters as a GP's communication skills (or lack of them), his/her relationships with patients and the quality of his/her care. These are all aspects of a doctor's practice on which performance indicators can shed no light. Moreover, many complaints can be linked clearly with an individual doctor.

12.40 I identified in Chapter 5 some of the gaps which remain in the information available to PCTs about the GPs on their list. The gaps relate to previous complaints and expressions of concern about a GP and to his/her involvement in proceedings for clinical negligence. Some of this information may be highly relevant to the quality of care being given by a doctor.

12.41 If a PCT is to have an effective system of clinical governance, it is essential that any complaint which has a bearing on quality of care is thoroughly and effectively investigated. If there has been a lapse in the quality of care, action should be taken as soon as possible to minimise or eliminate the risk that such a lapse might occur again. The present patient complaints system makes it difficult, if not impossible, for PCTs to do this.

(h) Operation of Systems for Identifying and Dealing with Poorly Performing General Practitioners

12.42 As I have explained in Chapter 5, some PCTs use data routinely collected by them in order to identify doctors who may be performing poorly. Others activate their performance procedures only in response to expressions of concern from healthcare professionals and others. Some PCTs have taken active steps (e.g. by means of distributing leaflets) to increase awareness, on the part of healthcare professionals and other staff working in primary care, of the importance of making known any concerns which they may have about the performance of GPs. PCTs should have in place effective systems for

investigating concerns when raised and for assessing performance. Remedying poor performance when identified (if necessary, by removing from practice a doctor who is providing an inadequate standard of care) is a vital part of clinical governance.

12.43 I have described in Chapter 5 the progress being made in establishing local procedures for dealing with poorly performing doctors. It is plain that the quality of local procedures (in particular, local assessments of doctors' performance) is variable at present and that further development is required in order to make them fully effective.

(i) Clinical Audit

12.44 I described in Chapter 5 the development of clinical audit in primary care. Audit is now organised by PCT sub-committees. They co-ordinate exercises, covering the whole PCT, to audit certain topics in which the PCT or local profession has a special interest. Individual practices will also carry out their own audits on subjects of particular interest to them.

12.45 Clinical audit has the potential to enable doctors to review their practices and outcomes and compare them with those of their peers. As a result, improvements can be planned and implemented and then reviewed in the same way. Audit can be a valuable tool for learning and for improving quality. The new GMS Contract makes no specific provision for audit. The thinking appears to be that the collection of data required to demonstrate quality achievement under the QOF will, in effect, amount to audit and will be rewarded by payments under the Contract.

12.46 As I have said previously, however, participation in the QOF is not obligatory. In the NHS Plan, published in 2000, the Government announced its intention of making participation in clinical audit compulsory for all doctors employed in or under contract to the NHS. This has not yet been implemented.The Inquiry understands that there are GP practices (albeit, in all probability, only a small number) which still do not undertake clinical audit.

12.47 While audit can be a means of improving quality in individual practices and can provide general information to the PCT, it is of limited, if any, use as a monitoring tool. There is no obligation on practices to share their audit results with the PCT. If they do so, it is likely that the results will be seen only by clinicians on the audit sub-committee. Any wider circulation will be on an anonymised basis, often with the results aggregated across the PCT, rather than by reference to individual practices. The audit results will usually reflect the performance of the practice as a whole and not (unless it is a single-handed practice) that of an individual doctor.

12.48 At the Inquiry's seminars, Sir Donald Irvine, former President of the General Medical Council (GMC), lamented the failure to make full use of clinical audit by employing the results to assess and improve doctors' performance. Professor Halligan agreed, saying:

> **'Sir Donald said very eloquently that 500 million** (*pounds*) **had been invested in audit, to what benefit? ... the closure did not happen. The event was carried out, the audit was carried out, the tabulation and qualification was performed but did it change anything? So people lost confidence in that process.'**

12.49 Despite these concerns, there appear to be no plans to change significantly the arrangements for clinical audit in the future. As I shall explain later in this Chapter, practice audits may form part of the evidence produced by a doctor at appraisal. However, there is no obligation on him/her to produce them. Under the present arrangements for appraisal, if an appraisee refers to an audit which his/her practice has conducted, but does not produce the audit itself, the appraiser has no power to call for it.

(j) Risk Management

12.50 The introduction of clinical governance has provided an impetus for developing systems for risk assessment and risk management within NHS organisations. In the context of secondary care, systems were initially focussed on reducing the risks of litigation resulting from adverse clinical events. There was also a move to reduce financial risk in both primary and secondary care settings. More recently, there has been greater emphasis on local risk assessment and risk management as part of the clinical governance framework.

12.51 Risk can take many forms, clinical and non-clinical, and risk can be managed in a large number of different ways. It is arguable that all initiatives which a PCT takes to improve the quality of clinical care should also have the effect of reducing risk to patients. However, a primary focus of attention within the area of risk management has been the development of mechanisms designed to ensure that adverse incidents are reported and analysed, that lessons are learned from them and that appropriate changes to practice are made in order to minimise the risk of recurrence.

12.52 The importance of such mechanisms was discussed in 'An organisation with a memory', the report of an expert group chaired by the Chief Medical Officer, which was published in 2000. The report suggested that over 850,000 adverse healthcare events (i.e. events or omissions arising during clinical care and causing physical or psychological injury) occurred annually to patients in NHS hospitals in the UK. These events were costing billions of pounds in compensation payments and additional hospital stays, quite apart from the human misery and wider economic costs associated with them. The report recognised also that some types of adverse event (sometimes the most serious) recurred over and over again, without lessons being learned from past experience. Most of the data in the report was drawn from secondary care. The authors acknowledged that little was known about the situation in primary care where incident-reporting systems appeared to be poorly developed. This was despite the fact that primary care accounted for the great majority of NHS patient contacts and that adverse events could and did occur in the primary care setting, with serious consequences for individual patients. In addition, the report noted that, in all NHS organisations, there was no systematic reporting of 'near misses'.

12.53 In 2001, the DoH publication 'Building a safer NHS for patients' set out the Government's plans for promoting patient safety. Central to those plans was the creation of a new special health authority, the National Patient Safety Agency (NPSA). It was to provide a central point for the collection of information about adverse events and near misses (known today by the collective term 'patient safety incidents') and for the analysis of the cause of the most serious incidents and of any patterns and trends which emerged. The NPSA was also

to disseminate the lessons learned from past incidents throughout NHS organisations and to have an advisory and educational role. Local systems for reporting patient safety incidents were also to be instituted. Emphasis was placed on promoting a culture of reporting and patient safety within NHS organisations. This culture was termed elsewhere in the document **'an open, no-blame reporting culture'**.

12.54 The NPSA was established in 2001 and has now started to put in place the National Reporting and Learning System (NRLS) to receive reports of patient safety incidents from NHS organisations (including PCTs) and staff, patients and carers. The NRLS is not yet fully operational and, as yet, has had little impact on primary care. It is planned that, in due course, the NRLS will also receive relevant information from other organisations (e.g. the Health and Safety Executive) which collect safety data. Reporting will be voluntary and confidential. All reports received by the NPSA will have the names of patients and staff, and other identifying data not required for the purposes of learning, removed. There will be no investigation of the individual cases reported. No data from the NPSA systems will be available for use in disciplinary actions. The sole purpose of the collection of the data is to learn from past incidents and to develop strategies for improving patient safety.

12.55 In parallel with the national system, local NHS organisations are expected to have systems in place for collecting data on patient safety incidents. The aim is to have fully integrated local and national systems to enable NHS staff and others to report incidents directly to the NPSA. SHAs already have mechanisms in place for the reporting of serious untoward incidents. Hospitals have developed systems for the reporting of patient safety incidents. Within a hospital setting, there is relatively little opportunity for incidents to go unreported. Several members of staff may be aware of them, complaints may be made to the hospital authorities, and litigation (to which the NHS trust responsible for the hospital is likely to be a party) may follow. The position is very different with primary care. GPs work in settings that are physically separate from PCTs. In general, they employ their own staff. The current system is that patient complaints are directed in the first instance to the practice and may never come to the attention of the PCT. If civil proceedings are brought against a GP, they will be dealt with by his/her medical defence organisation. Claimants will be represented by a variety of firms of solicitors. The PCT will not be a party to the litigation. There is no requirement for a GP to inform PCTs of any claim which has been intimated or brought against him/her. Thus, there is much greater potential for a PCT to remain unaware of a patient safety incident involving a GP on its list. In 1994, the PCO for Tameside did not become aware of the fact that Mrs Renate Overton had been admitted to Tameside General Hospital in an unconscious state and that the doctors at the hospital believed that her condition was attributable to a serious error made by Shipman in administering an overdose of an opiate drug. If such an incident were to occur today, it is likely that it would be reported (on an anonymous basis) to the NPSA. However, there is no system which would guarantee that the incident and the identity of the doctor would be drawn to the attention of the PCT.

12.56 The Inquiry was told that PCTs are in the process of developing systems for the reporting and analysis of patient safety incidents. At present, there is no requirement on a GP to report incidents (even serious untoward incidents) to his/her PCT or to the relevant SHA. At the Inquiry's seminars, Dr Wilson referred to her own experience of operating her SHA's

serious untoward incident reporting system. She said that the circumstances giving rise to a civil claim against a hospital doctor had almost always been reported previously to the SHA. By contrast, she could remember only one serious untoward incident being reported from the primary care sector. She said that it made her 'nervous' that she knew exactly where there was likely to be litigation in secondary care and the mental health trusts, but had no such knowledge about primary care. Ms Freedland said that she had found, when sitting on the clinical governance sub-committee of her PCT, a general ignorance of the fact that GPs were involved in adverse incidents at all. She also reported a conversation with a GP who had said:

> **' ''I sat trying to work out this week how many adverse incidents I had had in my particular practice. I sat down with a black notebook this week and I recorded 48 potential adverse incidents. I was so depressed I decided no longer to log them. When I thought about it, I am not sure what an adverse incident is or a serious untoward incident.'' '**

12.57 Ms Freedland said that a knowledge of such matters had been instilled into doctors working in the acute sector but not in general practice. She was concerned as to who was responsible for getting the message across to GPs, particularly given the PCTs' clinical governance role. Dame Lesley Southgate pointed out that many adverse incidents which occur in the context of primary care (e.g. failure to diagnose meningitis or cancer) are very serious. Yet, even when litigation has taken place, PCTs may remain unaware that these incidents have occurred.

12.58 The gathering of information about patient safety incidents (including near misses) and their cause is critical to risk management and to clinical governance. It is clear that, in the primary care setting, there is a great deal of work to do to encourage GPs, other healthcare professionals and practice staff to report relevant incidents. Even so, there may be a reluctance on the part of some to report an incident which reflects badly on their own professional performance or that of a member of their team. It is important, therefore, that PCTs are given access to information about such incidents which is available from other sources, such as patient complaints. Only if they have a full picture of incidents occurring in their areas will they be able to take appropriate steps to prevent such incidents from recurring. It will also then be possible for them to fulfil the obligation which will no doubt be placed upon them in the future to report all relevant incidents to the NPSA.

(k) Significant Event Review

12.59 Significant event review (also known as significant event audit or analysis or critical incident review, audit or analysis) is a process whereby a group of doctors (usually, but not always, from the same practice) or (less commonly) a multidisciplinary team or group discusses significant events which have occurred in the course of its practice(s) and the lessons which can be learned from those events. The event need not have been negative or had a poor outcome. It may have demonstrated good practice from which participants in the review can learn. If the event was a negative one, the participants may want to discuss whether things could have been done differently and, if so, whether a better outcome could have been achieved. In general, significant event reviews are confidential

in order to encourage participants to speak frankly. Usually, some record is made of the content of the discussion taking place at the review.

12.60 The new GMS Contract offers a financial reward to practices which have undertaken a minimum of six significant event reviews in the previous three years. A further reward is available if the practice has undertaken a minimum of 12 significant event reviews in the previous three years, which include (if these have occurred) any death occurring on the practice premises, two new cancer diagnoses, two deaths where terminal care has taken place at home, one patient complaint, one suicide and one sectioning under the Mental Health Act. Previously, there had been no financial incentive for significant event review and only about 10% of GP practices were thought to carry out significant event review. That proportion may well rise following the inclusion of incentives in the Contract.

12.61 A number of witnesses to the Inquiry spoke of the value of significant event review as a learning exercise. Dr William Reith (former chair of the Scottish Council of the Royal College of General Practitioners (RCGP)) said that the RCGP considered it such an important and helpful technique that, under the criteria for the Quality Practice Award, practices were encouraged to undertake reviews involving all members and employees. Professor Baker told the Inquiry that little formal research into the utility of significant event audit had been undertaken but those who had used the technique were positive about its impact.

12.62 At the Inquiry's seminars, Dame Lesley Southgate observed that, if Shipman had sat down with her and talked about some of the deaths of his patients, it would rapidly have become evident to her that there was something odd about them. The circumstances of many of the deaths were so very different from her own experience that this would have been immediately apparent to her. Sir Donald Irvine agreed that analysis of the deaths in discussion with a peer would have been the process most likely to have led to Shipman's discovery.

12.63 However, the value of significant event review must depend upon the amount of relevant information available to the review participants. An analysis of a death without the relevant medical records is likely to be of far less value than one where the records are available for inspection. The value of significant event review is also dependent upon the personalities of the respective participants and the extent to which they are able and willing to approach whatever information is available in an analytical manner and, if necessary, to question what they are told. As I pointed out during the evidence, the discussions between Shipman and the Form C doctors (i.e. the doctors who acted as second certifiers for the purposes of cremation) could have been viewed as 'significant event reviews' of the relevant patient's death. Yet those discussions resulted in the Form C doctors accepting unquestioningly what Shipman told them, even when there were unusual features about the deaths which should have been clearly apparent from the cremation Forms B completed by Shipman. Those discussions took place between Shipman and GP peers. Within a single-handed GP practice team, the inequality of status between the doctor and other participants in a significant event review would make it difficult for the latter to raise questions about the doctor's conduct. Certainly, it is difficult to imagine that Sister Gillian Morgan, Shipman's practice nurse, would have questioned

Shipman's conduct in the course of a review of the circumstances surrounding the death of one of his patients, or that a lay member of his staff would have felt able to do so. Some single-handed practitioners join together in groups for the purpose of significant event review. In those circumstances, other participants are dependent on the information brought to the review by the doctor whose event is being discussed. If the participants are open and honest, the review can be a valuable learning experience for all. If, however, a participant is determined to conceal his/her poor performance or criminality, it is unlikely that this would be detected.

12.64 The fact that significant event review is confidential means that, while a PCT may become aware that it is occurring, it has no access to information about the content of reviews under the new GMS Contract. PCTs will be entitled to check practices' review reports for the purpose of confirming that the relevant QOF indicators have been met. However, it seems highly unlikely that the reports will contain anything more than the bare information necessary for the purposes of confirmation.

12.65 Like clinical audit, significant event review cannot be regarded as a monitoring tool. It can be a valuable means by which individuals and teams can learn from past experience. Thus, it can assist in improving quality. However, it provides no information to the PCT about the quality of practice of an individual doctor.

(l) Appraisal

The Introduction of Compulsory Appraisal for General Practitioners

12.66 Until recently, neither GPs nor hospital consultants had been routinely required to undergo appraisal. This was in contrast to other NHS healthcare professionals, who were subject to annual appraisal. The only GPs who had had experience of appraisal were those who held posts outside general practice, e.g. in universities, where appraisal was the norm. In addition, some general practices operated their own in-house appraisal procedures.

12.67 In Chapter 5, I have described how, in the late 1990s, successive high profile cases of poor clinical performance had given rise to public concern about the arrangements then in place for identifying and eliminating incompetent and aberrant clinical practice. In addition, there was concern about the extent to which doctors were keeping their medical knowledge up to date. At that time, financial incentives were available for GPs who undertook continuing professional development. Most GPs attempted to keep abreast of new developments by attending lectures and other events. However, an individual GP's decision to attend certain educational events and not others would often be governed by such factors as geographical convenience, rather than by any coherent and structured plan to develop his/her knowledge or expertise in a particular area of practice. Choice of event would also be governed by personal preference for a topic, as opposed to remedying areas of weakness. Furthermore, those responsible for providing continuing education were not necessarily aware of the precise needs to which that education should be directed. Some groups of doctors, such as locums, found it particularly difficult to get access to continuing professional education.

12.68 In 1999, the DoH published 'Supporting doctors, protecting patients', a Consultation Paper on preventing, recognising and dealing with poor clinical performance of doctors

in the NHS in England. The paper proposed that appraisal should be made compulsory for all doctors working in the NHS, including GPs. The primary aim of appraisal was to assist in planning the individual's developmental and educational needs. However, it was also intended to assist in the recognition of poor performance. The Consultation Paper stated:

> **'It is not the primary aim of appraisal to scrutinise doctors to see if they are performing poorly but rather to help them consolidate and improve on good performance aiming towards excellence. However, it can help to recognise at an early stage developing poor performance or ill health which may be affecting practice.'**

The Consultation Paper also observed that:

> **'A comprehensive appraisal by the NHS employer** (*the Paper made it clear that this term was intended to include PCOs*) **is essential in enabling the NHS to fulfil its statutory duty of quality through clinical governance.'**

12.69 In addition, the Consultation Paper linked appraisal with the revalidation process to be introduced by the GMC. Appraisal was to provide 'a core of information' for revalidation. I shall discuss the relationship between appraisal and revalidation in Chapter 26. For the present, I shall consider appraisal solely in the context of clinical governance.

12.70 Appraisal for NHS consultants was introduced in 2001. From April 2002, participation in the appraisal scheme set up by their PCO was mandatory for all GP principals providing GMS and PMS. The vast majority of, if not all, GP principals have now been appraised at least once. A programme of appraising GP non-principals has started.

The Nature and Purpose of Appraisal

12.71 Appraisal can have a number of different aims and can be conducted in a variety of ways, depending on the purpose it is to serve. The way in which the appraisal of GPs is conducted will determine, to some extent at least, the value of the process for clinical governance purposes. It is, therefore, necessary to examine the stated purposes of GP appraisal and the way that appraisal is currently being carried out.

12.72 Appraisal usually takes place in a hierarchical employment setting. The appraiser is frequently the appraisee's line manager. The appraiser will have knowledge (often firsthand knowledge) about the appraisee's past performance. The appraisal may consist of a formal evaluation or assessment of a person's past performance, together with the setting of targets for performance in the future. Such a process could involve questioning the appraisee about aspects of his/her past performance and seeking an explanation for performance which appears to fall below the standard expected. The appraisal might identify ways in which the appraisee's performance could be improved and his/her career developed in the future. This type of appraisal has a clear performance management function.

12.73 Professor Baker described to the Inquiry his own experience of appraisal in a university setting. He said that, as an appraiser of junior members of his team, he would be familiar with their work. The purpose of the appraisal would be to look at the appraisee's plans for

the previous year and to discuss with him/her what elements had been achieved and where difficulties had arisen. If the team member had been performing inadequately or was presenting problems of any kind, Professor Baker would have been aware of this before the appraisal. He would have dealt with those issues as they arose. He would not wait for the appraisal to raise them. However, at the appraisal, he would seek to explore the appraisee's understanding of what had happened and of his/her situation because, if there was a gap between the reality of what had occurred and the appraisee's perception of it, there would be a serious management problem which he would have to address. If, on the other hand, the appraisee showed insight into his/her problems, and was working hard to improve, the focus of the appraisal would be on assisting him/her in that. Although the process described by Professor Baker was rather different from the appraisal process previously described, it was also directed at performance management.

12.74 The appraisal process described in 'Supporting doctors, protecting patients' appeared to have elements of performance management. It was described thus:

> **'The employer will wish to appraise an individual's performance in their post as well as their participation in local clinical governance activities and these two strands will tie in specifically to a health organisation's accountability to achieve high standards of quality. An employer will wish to ensure that the doctor adheres to the standards laid out in the *Duties of a doctor: good medical practice* document. However, the process will need to be strongly supported by information from external peer review so that judgements can be made about how the doctor's local practice compares to his or her peers nationally as well as to best and excellent practice.'**

12.75 The Consultation Paper made clear that the appraisal mechanisms described in it were intended to apply to independent contractor GPs, as well as to employed doctors.

12.76 When appraisal for GPs was proposed, there was considerable concern within the profession. There was a fear that appraisals would be used to 'police' doctors and that they would in reality be performance assessments which would result in judgements being made about GPs' competence. There was resistance to the use of appraisal as a management tool by the PCOs. The nature of GP appraisal, as finally agreed between the DoH and the profession, was very different from that which had been feared and, indeed, from the description set out in 'Supporting doctors, protecting patients'. It is described in DoH literature as:

> **'... a professional process of constructive dialogue, in which the doctor being appraised has a formal structured opportunity to reflect on his or her work and to consider how his or her effectiveness might be improved'**

and

> **'... a formative** (*i.e. educational*) **and a developmental process. It is about identifying development needs, not performance management.'**

12.77 As will become apparent when I come to describe the way in which GP appraisal is being conducted, it involves no objective scrutiny of past performance. It is not possible to 'fail' an appraisal. It is possible that something may occur during appraisal which causes an appraiser to have concerns about an appraisee's performance. An obvious example would be if, at the appraisal, the appraisee appeared to be under the influence of alcohol or drugs. Appraisers are instructed that, if they have serious concerns, they should suspend the appraisal. DoH guidance advises:

> **'It would be exceptional for serious concerns about performance to be first raised in an appraisal. The appraisal itself should be formative. However, both the appraiser and appraisee need to recognise that as registered medical practitioners they must protect patients when they believe that a colleague's health, conduct or performance poses a threat to patients ...'**.

12.78 In such cases, appraisers are advised to refer the matter immediately to the senior clinician/clinical governance lead and the PCT chief executive to take appropriate action. The matter should then be dealt with under the PCT's procedures for dealing with concerns about performance. The Inquiry is not aware of any appraisal which has so far resulted in serious concerns about performance being raised by an appraiser in this way.

12.79 Dr John Chisholm, Chairman of the General Practitioners Committee (GPC), British Medical Association (BMA), told the Inquiry that the character of appraisal in general practice was slightly different from that in hospital where there is 'more of an element of performance review as well as pure appraisal about the process'. He said that both the GPC and the RCGP had felt that the 'confusion' of performance review with 'pure appraisal' was 'unhelpful' and had wanted to 'maintain the purity of appraisal as a developmental tool'.

The Appraisal Process in England

12.80 Appraisal has followed a different course in England from that in other parts of the UK. In England, unlike Wales and Scotland, there has been no central system for implementing appraisal. Instead, each PCT has been left to make its own arrangements, subject to guidance issued by the DoH after negotiation with the profession. Each PCT is responsible for organising annual appraisals of all GPs, principals and non-principals, on its list.

12.81 In England, the appraisal of a GP is usually carried out by another GP from the same PCT. However, in some PCTs, appraisals have been carried out by nurses, midwives, even practice managers. The appointment of appraisers has been conducted differently from area to area. Some PCTs have selected appraisers from among the GP trainers in the area. Such appraisers will have experience of training and issues relating to professional education. They will also have attained the high standards of practice necessary for approval as GP trainers. In other areas, volunteers willing to act as appraisers have been sought and all those putting their names forward have been accepted. Some PCTs have had to 'trawl' local GPs in order to find candidates willing to act as appraisers. Others have selected appraisers from those who expressed interest in the job.

12.82 Appraisers undergo a day's (sometimes two days') initial training, during which they view a video, familiarise themselves with the relevant documentation and perform role-playing exercises. Initially, training was organised by the National Clinical Governance Support Team (NCGST) and provided by a private company. Subsequently, some PCTs have organised further training events, workshops, meetings and support groups to enable appraisers to discuss progress and any problems they may have encountered. In other areas, appraisers have received little support and only the initial training. Some PCTs have also given training to potential appraisees. Responsibility for the provision of appraiser training has now devolved to the postgraduate deaneries.

12.83 The Inquiry was told that some PCTs have allowed appraisees to choose their own appraiser from the list of appraisers in the area. Others have appointed a member of each group practice in their area as an appraiser. That appraiser has then appraised all the other members of his/her own practice. In most areas, however, appraisers have been allocated so that they are not paired with members of the same practice, or with relatives or close friends. Nevertheless, within a small professional community such as that covered by a PCT, it is inevitable that most appraisers and appraisees will at least know each other. It appears that most PCTs have operated a system whereby appraisers have been allocated to appraisees by the person appointed by the PCT to organise the appraisal process. If an appraisee objects to the appraiser allocated, the usual arrangement is that s/he can request a change. In most – but, it appears, not all – PCTs, both appraisers and appraisees are paid to participate. The rates of payment vary. In Tameside, each is paid £300, to cover preparation time as well as time spent on the appraisal itself.

12.84 Second and subsequent appraisals may or may not be carried out by the same appraiser. The Inquiry heard of several PCTs which planned to maintain, where possible, the same appraisers for a second – or even a third – year although, in the future, there was to be some rotation of appraisers to preserve the distance between appraiser and appraisee.

12.85 The appraisal process uses five standard forms which appear at Appendix D to this Report. The first two, to be completed by the appraisee, seek basic details about the appraisee (name, registered address, current posts, etc.) and information about his/her current medical activities. Form 3, entitled 'Material for Appraisal', constitutes the basis of the appraisal. It is organised under nine broad headings, namely Good Clinical Care, Maintaining Good Medical Practice, Relationships with Patients, Working with Colleagues, Teaching and Training, Probity, Management Activity, Research, Health. Seven of these headings are taken from those in the RCGP's publication 'Good Medical Practice for General Practitioners', a document which is based on the GMC publication 'Good Medical Practice'. The wording under each heading differs but, typically, Form 3 invites the appraisee to give a commentary on his/her work:

- identifying the main strengths and weaknesses in each area
- stating how his/her performance in each area has improved since the last appraisal (or over the previous year)
- giving his/her view of his/her continuing development needs

- giving a summary of factors which constrain him/her in achieving what s/he aims for.

12.86 Suggestions are made as to the documentation which an appraisee might refer to and supply in connection with his/her answers. For example, under the question relating to what the appraisee thinks are the main strengths and weaknesses of his/her clinical practice, the suggestions are:

> **'... up-to-date audit data (as appropriate); prescribing analyses (if applicable); PCT clinical governance reviews (as appropriate); relevant clinical guidelines you use; records of any significant event audits or critical incident reports; any complaints and records of their investigation; any reflective diary you keep about these events; any plaudits you have received; any ''in-house'' or personal monitoring materials you use; references or feedback from colleagues'**.

12.87 The DoH guidance which accompanies Form 3 states that the appraisee is **'invited'** to submit documents in support of what is said on the form. The appraisee is not, it is said, expected to **'prove'** his/her assertions about his/her work, but the appraiser will probably want to **'test'** some of those assertions through discussion and the documents will help both appraiser and appraisee. There is, however, no obligation to produce any particular document or class of documents. Moreover, the relevance of a document to the discussion at appraisal seems likely to be determined by the information which the appraisee chooses to include on Form 3.

12.88 The DoH guidance also advises appraisees to prepare a folder containing a set of all the documents, information, evidence and data collected for the purpose of the appraisal process. The appraisee should also prepare an outline personal development plan, setting out key development objectives and ways in which these objectives are to be addressed. This folder should be sent to the appraiser at least two weeks before the appraisal, to allow sufficient time for preparation. This can be done confidentially on-line, using the NHS Appraisal Toolkit.

12.89 The Inquiry heard that the amount of documentation provided by appraisees varies widely. According to Dr Robert Ashworth, a GP appraiser from Bradford South and West PCT (who, at the time when he gave evidence in September 2003, had conducted 21 appraisals), some GPs offer 'virtually nothing – maybe a few certificates of attendance at courses'. Others produce large amounts of information about courses attended, prescribing, referrals, significant incidents, complaints and other matters relating to their practices. Dr Ashworth had sought to encourage those who had produced little material to collect more in the future and was hoping that this would bear fruit in the second round of appraisals. However, he said that he could do no more than encourage appraisees to collect more evidence. Appraisers have no power to insist on the production of evidence.

12.90 When making the appointment for an appraisal, Dr Ashworth tells the doctors he is to appraise what they should do in preparation, i.e. complete Forms 1, 2 and 3 and gather the necessary evidence. He encourages them to deliver the forms and evidence to him well in advance of the appraisal date, so that he can read them and note any points

he wishes to raise at the appraisal. He has received the completed forms in advance in every case, but only in about half of cases did he receive any supporting evidence in advance. Again, he felt that he could not insist on this. Mrs Chris Page, Head of Service Redesign, Bebington and West Wirral PCT, who is in charge of the appraisal process for her PCT, agreed that, if a GP declined to produce documents, there was nothing that the appraiser (or, indeed, the PCT, if it became aware of the situation) could do.

12.91 Dr Chisholm explained that the wording in the DoH guidance, which 'invites' (rather than 'requires') the appraisee to provide documentation, was consciously chosen. The DoH and the GPC of the BMA had been aware during their negotiations that the profession did not view the introduction of appraisal with any enthusiasm and that, in order to get GPs to 'buy in' to the process, it was necessary to adopt a 'softly softly' approach. He hoped that a trusting relationship would develop between appraisers and appraisees which would enable appraisers to seek documentary evidence which was not at first proffered voluntarily.

12.92 The appraisal itself should be centred on the information contained within the appraisee's folder, on the contents of Form 3 and (for all but the first appraisal) on the progress which has been made on achieving the objectives set out in the appraisee's personal development plan (PDP). The appraisee should also be invited to raise any specific issues which s/he wishes to discuss. At the conclusion of the appraisal, the appraiser and appraisee should agree a summary of the appraisal discussion and of any action which it has been agreed should be taken. This should be recorded on Form 4. The appraisee then updates his/her PDP, using a standard template. It is open to an appraiser, if s/he so wishes, to complete Form 5, giving a confidential account of the appraisal interview. This is intended to inform the next appraisal. It is confidential and should be kept by the appraiser. Its completion is entirely optional.

12.93 In the vast majority of, if not all, cases, the result of appraisal will be the completion of Form 4 and the production of a PDP. The exception would be if serious concerns were identified, in which case the appraisal should be suspended and the concerns reported, as previously described. If an appraisee failed entirely to co-operate with the appraisal process, such that it was impossible to have a meaningful discussion, then, presumably, the appraiser would suspend the appraisal process and report this fact to the PCT, although the Inquiry has seen no specific guidance to deal with this situation. The more difficult problem would arise where minimal co-operation is given. It is not at all clear how limited an appraisee's co-operation must be, or how little information must be provided, before it can be said that no meaningful appraisal has taken place.

12.94 Following appraisal, it is up to individual GPs to ensure that they address the needs set out in their PDPs. DoH guidance advises that an appraiser and appraisee should make arrangements to speak or meet at least once during the course of the year following appraisal. They should spend about half an hour reviewing progress on the appraisee's agreed actions and his/her PDP. However, research has suggested that this rarely happens in practice.

Information Resulting from the Appraisal Process

12.95 The appraisal itself is confidential. Only the appraiser and appraisee are privy to what passes between them. Only the two of them see the folder prepared by the appraisee and the forms (1, 2 and 3) completed by him/her.

12.96 DoH guidance states that a copy of the completed **'appraisal summary statement'** (by which is meant Form 4) should be sent, together with the appraisee's PDP, to the senior clinician or clinical governance lead of the relevant PCT and to the PCT chief executive. In practice, this does not always happen. The Inquiry heard that, in some PCTs at least, the chief executive does not see Forms 4. Dr Ashworth's PCT does not receive copies of Form 4, just PDPs. Mrs Page reported that her PCT had agreed with local GPs that the PCT would receive only the PDP and the 'sign-off sheet' of Form 4 (i.e. the sheet containing the signed declaration that Form 4 is an accurate summary of the appraisal discussion), but not the summary itself. Sometimes, appraisers send the whole set of appraisal forms to the PCT.

12.97 If completed fully, Form 4 should give some insight at least into what passed during the appraisal. It should identify those areas where improvement or development is perceived to be needed and the action plan to address that need. The Inquiry obtained a small number of anonymised Forms 4 from the first appraisal round organised by Tameside and Glossop PCT. These contained varying amounts of detail. In one example, typical entries were (under the heading Good Clinical Care):

> **'Commentary: Good clinical care**
>
> **Action agreed: Maintain standards'**

and (under the heading Maintaining Good Medical Practice):

> **'Commentary: Good medical practice**
>
> **Action agreed: Maintain standards'**.

12.98 It may be, as one witness suggested, that those entries were made after a searching appraisal at which the appraiser had taken all necessary steps to satisfy him/herself that the appraisee was practising to a high standard. On the other hand, the appraisal may have been perfunctory and the appraiser may merely have accepted, without more, the appraisee's own assertion that s/he was performing well in the relevant areas. The completed Form 4 gives no information about what was discussed at the appraisal. At the Inquiry's seminars, Professor Halligan said that the contents of this Form 4 did not enable the PCT to make any judgement about the adequacy of the appraisal or the robustness of the process, or indeed the standard of the practitioner being appraised. He suggested that the DoH guidance may be 'too soft' and said that this would be addressed. Some of the Forms 4 supplied to the Inquiry were more detailed than the one referred to above. Even so, little indication could be gleaned from them about the quality of the appraisal which had been carried out.

12.99 Senior clinicians or clinical governance leads of PCTs are required to submit annually to the PCT chief executive an aggregated and anonymised report based on the limited

information which they receive about appraisals. This report should be discussed at board level. It should deal with emerging training and development needs and organisational service issues requiring action or investment. It should also review the operation of the appraisal process.

Information Contributing to the Appraisal Process

12.100 In an employment setting, an appraiser, who is likely to have some managerial responsibility for the appraisee, will have a background of knowledge about the appraisee and his/her performance. He or she will also have access to information from the appraisee's colleagues. The appraiser will, therefore, have hard information on which to base the discussion at appraisal. This is not the case with an appraisal conducted by a GP peer (unless, as happens in some areas, the appraiser is a member of the same practice). A GP appraiser from another practice may or may not have some general knowledge about the appraisee's practice and reputation. He or she will certainly have some knowledge about local conditions and problems affecting general practice. However, unless provided with it by a third party, s/he will have no data about the appraisee's performance, other than that which the appraisee chooses to produce. This gives an appraiser limited material on which to base the appraisal, particularly if the appraisee discloses little or no data beforehand. In those circumstances, the agenda for the appraisal will inevitably be set by the appraisee, rather than the appraiser.

12.101 The DoH guidance stated that it was **'intended that most of the documentary evidence will be supplied by the PCT as part of the regular monitoring of organisational performance undertaken by the Trust'**. The documentary evidence referred to would presumably include such information as prescribing data, data on hospital referrals, performance indicators and data about complaints and disciplinary proceedings, all of which would be within the PCT's possession. What the guidance did not make clear was whether the evidence referred to was that which would have been already supplied to the appraisee as part of the PCT's ongoing clinical governance arrangements and would (or should) be included in his/her appraisal folder, or whether it was envisaged that the PCT would supply the relevant material direct to appraisers. Sir Nigel Crisp, Permanent Secretary of the DoH and Chief Executive of the NHS in England, told the Inquiry that he would expect PCTs to provide appraisers with any information which the PCTs thought was relevant. Current guidance to GPs which accompanies the appraisal forms states, in relation to documentation: **'Your PCT may be able to help with some material'**.

12.102 It is clear that, whatever the original intention of the DoH may have been, there has been no general provision of information by PCTs to appraisers. Dr Ashworth said that, in his area, the PCT gave no information to appraisers. He said that any move to provide such information 'would ... be frowned upon by the GPs'. He pointed out that GPs are not used to being appraised and, for appraisal to develop successfully, they need to feel that it is a confidential, developmental process. If 'outside agencies' were to provide or receive information relating to the appraisal, the development of the appraisal process could, he suggested, be jeopardised. Mrs Page said that there was no routine provision of information by her PCT. However, in three cases, where there had been concerns or difficulties of which the PCT was aware and which could have impacted on the

appraisee's performance, the appraiser had been given a limited amount of information. The primary purpose of this had been to enable the appraiser to ask relevant questions and see whether any further support from the PCT was needed. Mr Julian Hartley, Chief Executive, Tameside and Glossop PCT, was also aware of one example in his PCT where the GP to be appraised had previously expressed concerns about workload and about managing the practice; the appraiser had been made aware of those concerns before the appraisal took place. Dr Robert Queenborough, Medical Director, Trafford North and Trafford South PCTs, said that no information was routinely provided by his PCTs. Indeed, there would be resistance from some appraisers to the idea of using PCT data as a basis for appraisal. He said that their attitude would be that GPs were independent contractors and that it was entirely a matter for the appraiser and the appraisee what went into appraisal.

12.103 Dr Taylor, who was in charge of appraisal for Heywood and Middleton PCT, said that he could see no difficulty in his PCT informing appraisers about such matters as the fact that an appraisee was an outlier in the prescribing of controlled drugs. However, he did not appear to believe that appraisers should be made aware of such matters as complaints or adverse disciplinary findings affecting an appraisee. Dr Linda Patterson, former Medical Director, Commission for Health Improvement (CHI), said that there was a need to discuss information about such matters as complaints at appraisal. The purpose of appraisal was to help the doctor become a better doctor so that s/he could give better care to patients. Once appraisal was viewed in that light, she thought that it became clear that such matters should be discussed. However, guidance issued by the BMA specifically prohibits discussion of complaints under investigation during the appraisal process.

12.104 Dr Chisholm told the Inquiry that he felt that the availability of information was an essential underpinning of good quality appraisal. He believed that, in accordance with the DoH guidance, to which I have already referred, PCTs should provide to both the appraiser and the appraisee information about such matters as prescribing, referrals and complaints, for use at the appraisal. Indeed, he said that he was disappointed to learn that this was not happening, since it had been intended by those involved in negotiations about the arrangements for appraisal that it should. The provision of this type of information might, he said, lead to an appraiser asking 'probing questions' during the appraisal. Sir Donald Irvine observed that the quality of the appraisal process was very largely dependent upon the quality of evidence on which it was based.

12.105 Some of the information which might usefully be discussed at appraisal (e.g. practice audits and significant event reviews, complaints logs, practice protocols) will be within the possession of the practice, and the PCT will not have access to it. An appraisee might or might not choose to produce these documents. Similarly, s/he might or might not include in his/her folder documents, such as prescribing data, which the PCT will also have. As I have already explained, there is no requirement that s/he should produce any of this documentation at the appraisal. At the conclusion of the appraisal, the PCT will have no means of knowing on what information the appraisal was based. The PCT receives no list of documents produced. Nor, even if it were aware of what documents had been available at the appraisal, would the PCT have any means of knowing which of those documents had been the subject of discussion at the appraisal meeting.

Quality Assurance of Appraisal

12.106 The Inquiry was told that quality assurance of the appraisal process was to be carried out by the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission). According to Dr Patterson, it was likely to cover such issues as whether appraisers had been trained and whether clinical outcomes data had been available and used in the course of appraisal. It was not envisaged that there would be any inspection of appraisal folders. It was difficult therefore to know how those carrying out the process would know what evidence had been available and used at appraisal. More recently, the Inquiry has been informed by the Healthcare Commission that the Commission expects to carry out periodic reviews of various aspects of the appraisal process. This will be done as part of its overall programme of themed reviews. The Commission has made clear, however, that its reviews **'could not be regarded as a comprehensive quality assurance system for the appraisal process for doctors'**.

12.107 More recently, it has been reported that the Healthcare Commission intends to consider how to assess appraisal systems as part of a general evaluation of its general review of PCTs. A consultation document is due to be produced shortly before publication of this Report.

12.108 A report by the National Association of Primary Care Educators (NAPCE), commissioned by the RCGP and published in October 2003, refers to the difficulty faced by those seeking to monitor the appraisal process:

> **'The processes involved in GP appraisal are complicated, and the status of GPs as independent practitioners in an appraisal system administered by PCTs makes observation and monitoring the system even more challenging. GP appraisal is never going to be easy to monitor.'**

12.109 The report suggests that one means of quality assurance would be to evaluate appraisals by seeking the views of appraisers and appraisees on how the appraisal went and monitoring the outcomes. Dr Malcolm Lewis, Director of Postgraduate Education, University of Wales College of Medicine, is in charge of appraisal in Wales. He told the Inquiry that the Welsh appraisal process has internal quality assurance mechanisms, including the sampling and matching of Forms 3 and 4. The opportunity of seeing and assessing the content of Form 3 (which should contain a list of the documentation brought to the appraisal by the appraisee) would give helpful information about the extent to which the appraiser had prepared for the appraisal and about the information available to the appraiser. It would not, however, provide any information about the content of any discussion which took place during the appraisal. It is difficult to see how a confidential meeting of this kind can be effectively quality assured.

Views of Appraisal

12.110 It is clear that there is an initial perception that appraisal has had some positive effects. Some GPs have pointed out that it is the first opportunity they have had to talk about themselves, their practices and their personal development needs since the end of their

training. This is particularly valuable at a time when there is concern about the isolation of and pressure upon GPs. The preparation for appraisal, if done conscientiously, compels GPs to consider their strengths and weaknesses and how they wish to develop their practices. The appraisal itself offers an opportunity to sit down in 'protected time' and have a professional dialogue about issues affecting the appraisee's practice. Many found this an enjoyable experience. The experience may well have real benefits for non-principals, especially locums, who can suffer from particular problems of isolation.

12.111 For PCTs, one benefit of appraisal is that it gives them valuable information about the training and development needs of GPs and enables them to plan for the future. It also informs the deaneries and others involved in local GP postgraduate education of the areas where educational input is required. Dr Ashworth stressed the value of this and the potential for developing training targeted at meeting the needs of local GPs, as well as at the priorities of PCTs. Mrs Page hoped that appraisal would offer an opportunity for PCTs to build up supportive relationships with GPs. Of course, much will depend upon whether the educational needs of GPs, as identified by the appraisal process, can successfully be met.

12.112 The lack of any central system for implementing appraisal has meant that there has been a corresponding lack of consistency in the arrangements made by different PCTs. There have been wide variations in the financial resources provided for appraisal and in the approaches adopted, for example, to the selection and support of GP appraisers. It seems inevitable that there will have also been wide variations in the quality of appraisals, as a result both of the differing abilities and approaches of appraisers and of the level of co-operation of appraisees. Some GPs have been very reluctant to participate.

12.113 So far, the information which has been available to appraisers has come solely from appraisees. Sometimes, very little information has been provided. The agenda for the appraisal is more or less entirely set by the appraisee. 'In a sense', as one witness put it, appraisers are 'at the mercy of the appraisee.' The School of Health and Related Research, University of Sheffield (ScHARR), which advised the DoH on the implementation of appraisal, originally suggested that PCTs might wish to nominate topics for discussion at appraisal, either with individual GPs or across the board. This appears to have happened to only a very limited extent, e.g. where specific concerns already existed about a GP to be appraised. A further difficulty is that much of the information produced by an appraisee (in common with data which is held by the PCT) is practice-based, rather than referable to the individual doctor being appraised.

12.114 I have already mentioned the failure of PCTs to provide data to appraisers for use at the appraisal meeting. Even if such data were provided, it is not clear precisely how appraisers would be expected to use it. In what detail would they be expected to read it? Would they, as Dr Chisholm suggested, be expected to study it and ask 'probing questions' about its content? Would GP appraisers be prepared to take on such a role? Would they be accountable if it subsequently became clear that they had failed to spot vital clues which should have suggested that the appraisee was harming his/her patients? Would appraisers be happy to accept such accountability? How would appraisees react to being asked 'probing questions' by their colleagues? These are questions which will

require resolution in the future if it is intended that appraisal should be based on objective data provided by the PCT.

12.115 The PCTs' position in the appraisal process highlights some of the ambiguities which they face in relation to clinical governance issues generally. The PCT organises the process and funds it. It is the PCT which has the duty of quality to discharge yet it receives a limited amount of information from the appraisal process, has little or no control over appraisers and has no means of assessing the quality of the appraisal which has taken place. There are no standards or criteria against which an appraisee's past performance is judged. A PCT can, therefore, have no confidence that an appraisee who has been 'successfully' appraised has attained a certain standard of practice. Indeed, the Inquiry heard evidence from the Medical Director of one PCT that at least one doctor who was currently being investigated by the PCT for poor performance had been appraised without any concerns being raised by the appraiser.

12.116 Professor Roland raised a different problem. He pointed out that the involvement of PCTs in the appraisal process might have the effect of preventing appraisees from being frank about any weaknesses they might have. While I can appreciate that this may be so, the same can presumably be said of any appraisal which takes place in an employment context. However, as Professor Roland and others have said, the position would be exacerbated if there were to be a direct link between appraisal and revalidation and thus between appraisal and a GP's continuing licence to practise. Witnesses have pointed out that a link between appraisal and revalidation might also be a source of concern to potential appraisers, who might be unwilling to become involved in a process that might, in theory at least, lead to a colleague losing his/her right to practise.

Future Changes to the Appraisal Process

12.117 Appraisal is in its infancy and it is too early to predict precisely how it will develop. As I have already mentioned, the RCGP has commissioned a report from the NAPCE, which contained some exploratory research on quality standards for GP appraisal. The NAPCE report makes a number of suggestions for action, including:

- the establishment of more rigorous processes for appraiser selection and training
- the provision of continuing support and development for appraisers, including a system of regional appraisal support units for appraisers
- ways to address the problem of inadequate appraisers
- the introduction of a system whereby appraisers are appraised by GPs from outside their own PCTs
- the agreement of a standard national written contract between appraisers and PCTs
- the provision of training for appraisees.

12.118 In addition, in July 2003, ScHARR reported on the arrangements for extending appraisal to non-principals, who may well experience some difficulty in accumulating evidence

for the purposes of appraisal. Recently, the NCGST and the RCGP have carried out work on drawing up a list of evidence to be produced by GPs. The results of the NCGST's work have recently been published in a document, 'Defining the evidence for Revalidation – supporting the Royal College of General Practitioners', written by the NCGST Expert Group. As its name suggests, the document is primarily concerned with revalidation and seeks to identify the minimum number of items of evidence that its authors regard as essential to allow local clinical governance certification for revalidation purposes. It seems to be envisaged that these same items of evidence (together with any others that the appraisee may wish to volunteer) may also, if the appraisee so wishes, form the basis of appraisal.

12.119 In August 2004, the RCGP published a consultation document, 'Portfolio of Evidence of Professional Standards for General Practitioners: A Tool for Continuing Professional Development, Appraisal and Revalidation'. The purpose of the document is to set out proposals for the evidence that GPs may wish to gather to demonstrate their professional standards, to use for the purpose of appraisal and to submit for assessment for the purposes of revalidation. I shall discuss the evidence identified in each of these documents in Chapter 26. Suffice it to say for the present that type of evidence set out by the NCGST Expert Group appears somewhat 'softer' than that proposed by the RCGP. An example of this is that the RCGP proposes the submission of a standardised audit conducted by an independent colleague that demonstrates the appropriate quality of the doctor's clinical records; by contrast, the NCGST Expert Group suggests that a self-reported audit of records would be acceptable. Similarly, the RCGP proposes that GPs should produce copies of all complaints involving the doctor, together with evidence that any learning needs identified have been met, whereas the NCGST document suggests that the doctor should produce only a list of complaints received and of subsequent action taken.

12.120 Recently, the DoH has commissioned further work on the progress of GP appraisal; this is shortly to be published and further guidance on the appraisal process is also expected to be published imminently. The DoH has informed the Inquiry that it will be taking steps in the future to ensure that all PCTs have sight of appraisal Form 4 in its entirety, as well as the appraisee's PDP.

12.121 As to the approach to be adopted in the future, Mr Michael Warner, former Project Director, Avon, Gloucestershire and Wiltshire SHA, stressed the need to appraise past performance and to highlight strengths and weaknesses in past performance in order to form an appropriate development plan for the future. He felt that PCTs had to work towards a more systematic and robust system of appraisal. Under such a system, the PCT would collate all the information about the GP, sit down with him/her and go through a formal appraisal process of that information. He observed that the chief executive of the PCT was ultimately accountable if poor performance led to poor service and felt that this accountability should be reflected in the appraisal process. He said that PCTs were beginning to realise that they must link past performance and future development but they were 'struggling' to make that link. He suspected that such a move would not be welcomed by the profession, although he felt that some GPs would be sympathetic. He advocated a sensitive approach, with the profession and PCTs working in partnership.

Dr Queenborough also felt that the appraisal process was likely to become more like performance management in time. Dr Patterson said that there must be some accountability for performance within the appraisal process. She spoke of her own experience of appraisal in a hospital setting which she found a very positive experience. She said that there must be an element of performance management.

12.122 I have previously referred to the fact that DoH guidance had described GP appraisal as **'formative'**. In its response to the Inquiry's Consultation Paper, however, the DoH stated that appraisal **'has both summative** (*i.e. pass/fail*) **and formative elements'**. At the Inquiry's seminars, Professor Halligan said that it should be possible to 'fail' appraisal by falling below the standards which had been accepted and received. He observed that there was no point in having a process that everyone passes. However, it was not clear whether, by 'failing', he was referring to the situation already referred to (where an appraiser has concerns serious enough to warrant suspending the appraisal) or whether he had in mind something less serious (e.g. inadequacy of documentary material, failure to comply with a PDP, or other concerns falling short of 'serious' but nevertheless requiring investigation).

12.123 Although it seems likely that many PCTs would welcome an approach which more closely resembles performance management, such a shift of emphasis would plainly be resisted by many within the profession. And, since the vast majority of appraisals will continue to be conducted by GP appraisers, it is difficult to see how such an approach could be enforced. The reality may well be that any performance management function exercised by PCTs will have to take place in a context other than appraisal, while appraisal remains aimed wholly at encouraging continuing professional development and seeking to ensure that it is occurring. The latter approach plainly has a part to play in the maintenance of standards. However, it produces little, if any, useful information about the performance and competence of individual doctors.

Monitoring of Clinical Governance Arrangements

The Commission for Health Improvement

12.124 I have already explained that, over the past few years, considerable attempts have been made within NHS organisations to establish appropriate structures and systems designed to promote good clinical governance. Those attempts have been monitored by CHI. Between 2000 and April 2004, CHI carried out a programme of local reviews of clinical governance arrangements in NHS trusts and PCTs. Each review resulted in a report which was published on CHI's website. Every review involved a visit, lasting a week, to the PCT by a team of reviewers. The team comprised about ten people, including a CHI employee (who managed the review), a doctor, a nurse, a manager, an allied healthcare professional, a representative of Social Services and a lay person. The review covered all the services provided by the PCT, including medical services. Before the visit, the PCT would be requested to submit a large amount of information (written policies, protocols, strategies, minutes of meetings and other data) to CHI. That information would be analysed in preparation for the visit.

12.125 Also before the visit took place, CHI would hold a meeting in the locality of the PCT and invite members of the public in order to get some background information about the way in which the PCT was viewed by patients, carers and other interested parties. CHI would also have access to patient surveys conducted in some areas. CHI would seek views on the PCT from such bodies as the relevant SHA, local NHS trusts and Social Services.

12.126 Reviews of PCTs were based on what Dr Patterson described as 'the seven components of clinical governance'. These were:

- patient involvement
- risk management
- clinical audit
- staffing and staff management
- education and training
- clinical effectiveness
- use of information.

12.127 Visiting teams would also look at the 'patient experience' and at the PCT's strategic capacity for developing and improving clinical governance. Dr Patterson explained that this latter element depended largely on the quality of leadership and the culture within the PCT being reviewed.

12.128 The visiting team would examine the strategies and policies which the PCT had in place under each of the seven components and would assess how they operated on the ground. Dr Patterson gave the example of risk management. A review team would want to know if the PCT had a strategy for risk management. It would then want to see how that strategy was translated into policies and procedures and, more importantly, whether it was understood by frontline staff. Where possible, staff of the PCT would be asked how they would deal with specific incidents and how they had dealt with actual incidents in the past. Thus, the CHI team would hope to discover whether the structures and systems which the PCT claimed to have in place were working effectively in practice.

12.129 In the course of the visit, the review team would spend time at the PCT offices, interviewing managers and staff and discussing the systems in operation. The team would also conduct approximately six visits to GP practices. It would attempt to choose practices of different types (e.g. urban and rural, single-handed and large group). It would look out for such obvious matters as cleanliness within the practice surgery and whether appropriate information leaflets were displayed. However, the purpose of the visit was not to look at the quality of care given by the individual practice. It was primarily to ascertain whether the PCT had an appropriate quality framework in place that was operational at practice level. The extent to which CHI was able to gather information about the way in which PCT systems and policies were working on the ground was necessarily limited by time and other factors. Its inspection would not detect poor clinical practice by individual doctors.

12.130 After the visit, a written report would be prepared, setting out CHI's assessment of the PCT's systems under each of the seven components of clinical governance. A PCT's

performance in relation to each of the seven components would be scored by the reviewing team on a four-point scale. The report would set out CHI's recommendations for future action. These recommendations were in the main directed at the setting up of new systems or the improvement of existing systems. Some recommendations related to the provision of education and training. Recommendations were not (and, indeed, were not intended to be) directed at the actual quality of clinical care being provided by GP practices. However, compliance with the recommendations might well have had the effect of improving the quality of care. An example would be a recommendation under the 'clinical effectiveness' component. This requires that PCTs should have systems in place for ensuring that treatment given is based on the best available evidence, e.g. from research, literature or local or national guidelines (including NSFs and NICE guidelines). A recommendation that a PCT should develop a system for disseminating to all GP practices new evidence about best practice might result in changes in treatment on the part of some GPs and a consequent improvement in patient care. It would not, of course, have this effect on all. The CHI report would also set out areas of notable practice by PCTs and practice from which CHI believed that the rest of the NHS could learn. Following receipt of the report, PCTs were expected to produce action plans identifying the steps they proposed to take to comply with CHI's recommendations. SHAs were then responsible for overseeing compliance with these action plans by PCTs.

12.131 The conduct of CHI reviews was extremely resource-intensive. Initially, it was intended that CHI would operate a rolling programme of inspections, returning to each organisation every few years or so. This proved impractical. Over the four years of its operation, CHI carried out 377 reviews, including 86 reviews of English and Welsh PCOs.

The Healthcare Commission

12.132 CHI's functions have now been transferred to the Healthcare Commission which is, in the short term, continuing with reviews of PCTs. In the longer term, however, it is intended that no routine clinical governance reviews should be conducted. Instead, the Healthcare Commission will carry out themed reviews of the provision of health care which will be conducted by reference to standards laid down by Government and more detailed criteria which the Healthcare Commission will itself develop. The reviews will be conducted by collecting, analysing and screening data (so-called 'intelligent information') generated by NHS bodies. The relative levels of performance of different bodies will be assessed. For those which appear to be performing less well, there will be further reviews to diagnose problems and identify any necessary remedial action. For those which appear to be performing well, there will be further reviews with a view to identifying the factors which enable them to perform well and to communicating those factors to others. There will be no comprehensive visiting programme.

12.133 So far as clinical governance is concerned, the proposed reviews will give only limited information about whether systems and policies are being implemented on the ground. Inevitably, the Healthcare Commission will be looking primarily at institutional arrangements and systems, not the practice of individual doctors.

Conclusions

12.134 Dr Patterson told the Inquiry that the reviews of PCTs by CHI completed at the time she gave evidence in September 2003 had revealed that they were 'struggling' to implement arrangements for clinical governance. As I have said, PCTs are small organisations, with a wide range of functions and a competing set of priorities. They have had little time to set up comprehensive structures and systems. Their problems have been compounded by the fact that they are not, as Dr Patterson pointed out, operating within 'a managed environment' so far as GP practices are concerned. They are not dealing with a cohesive group of employees whose behaviour they can direct. Instead, they are dealing with a number of small, geographically separate and independent organisations. Dr Patterson said that CHI had found a 'nervousness' on the part of the PCTs and a lack of clarity about what their management role was in relation to GPs. There is less of a problem with doctors working under PMS contracts. But for doctors working under the GMS Contract, there were, in Dr Patterson's view, 'some structural and cultural barriers' to implementing clinical governance arrangements across a PCT. She anticipated that this might change under the new GMS Contract.

12.135 In September 2003, the National Audit Office (NAO) published a progress report, 'Achieving Improvements through Clinical Governance', on the implementation of clinical governance by NHS trusts. The report did not deal with primary care. Given that the PCTs had been created only relatively recently, it was thought premature to report on them. Within NHS acute, mental health and ambulance trusts, the NAO found that the introduction of clinical governance had had **'many beneficial impacts'**. However, progress in its implementation was **'patchy'**, varying between trusts, within trusts and between the components of clinical governance. It seems highly likely that the implementation of clinical governance in PCTs is similarly – if not even more – patchy. This was acknowledged by Professor Halligan at the Inquiry's seminars when he said that clinical governance was not yet 'embedded' in primary care. Dame Lesley Southgate pointed out that PCTs are young organisations which are constantly changing and developing. She said that it is impossible to reach a conclusion about consistency or lack of consistency between PCTs since not enough is known about their activities. Professor Baker felt, on the basis of his own observations, that there were differences in the ways in which different PCTs had embraced clinical governance. He felt that this was largely a question of leadership and that it depended on the attitude of the clinical governance lead and chief executive of the PCT. Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, said that some PCT medical advisers interpreted governance in terms of discipline while others regarded their role as 'much more educative'. Professor Halligan also stressed the importance of leadership in the effective implementation of clinical governance arrangements. More recently, in a letter to the Inquiry dated 10th November 2004, Sir Liam Donaldson, Chief Medical Officer, has stated his belief that the culture and process of clinical governance are now **'strongly embedded in local NHS organisations'**. I do not know on what evidence that statement is based. It seems unlikely that there has been a significant advance since January 2004, when Sir Liam's colleague and other witnesses commented on the position of clinical governance in primary care.

12.136 It seems to me clear that there is indeed some way to go before clinical governance is fully implemented in primary care. I have explained also that some of the tools being used at present by PCTs in the implementation process have limitations with regard to the extent to which they can be used for clinical governance purposes. However, I do not wish to appear negative about the efforts that PCTs are currently making. Any steps taken with a view to improving the quality of patient care are to be welcomed. With time, the focussing of effort on a coherent strategy for improving quality of care must be of benefit to patients. I am merely attempting to draw attention to the difficulties currently faced by PCTs in implementing clinical governance.

12.137 In my view, the real obstacle to implementing clinical governance is that identified by Dr Patterson, namely the position of GPs as independent contractors and the consequent inability of PCTs to 'manage' them for clinical governance purposes. The tension is well illustrated by the debate over appraisal and the form which it should take. The PCTs are accountable for quality and feel the need to find ways of monitoring and assessing the quality of care being given by GPs. The profession fears 'policing' by the PCTs and consequent loss of clinical freedom. There is some confusion over accountability, particularly the accountability of clinical governance leads who, as local GPs, often have 'a foot in both camps'. Many of them have tried to adopt a 'softly softly' approach, attempting to promote a supportive climate and to encourage 'ownership' of clinical governance by the profession. The difficulty comes with those general practices which are unwilling to embrace the principles of clinical governance and where problems of poor standards of care might exist. A PCT may be virtually powerless to act if, for example, a practice will not allow a clinical governance visit to take place. It seems to me that PCTs may need to be given greater powers if they are to discharge their clinical governance responsibilities effectively and are to be accountable for discharging the duty of quality placed upon them. They will also need leadership and determination to make quality their first priority and to root out substandard practice.

12.138 Clinical governance is primarily about systems. At present, it yields little information about individual doctors. It produces even less information about such matters as a doctor's medical knowledge or consultation skills (i.e. whether s/he is skilled at eliciting the information necessary to take a history, at making a diagnosis and deciding with the patient what should be done). These are the aspects of care which matter most to patients and are absolutely fundamental to the quality and safety of medical care. It seems to me that, in primary care at least, the focus of clinical governance should move away from organisational systems and instead be directed towards the gathering and use of information about the performance of individual practices and practitioners.

12.139 In my view, if properly developed and well resourced, clinical governance could provide the most effective means of achieving two important aims. First, it could enable PCTs to detect poorly performing or dysfunctional GPs on their lists. It could also help practices to discover any problems or weaknesses among their own number. Second, it could have the beneficial effect of helping doctors who are performing satisfactorily to do even better. At the moment, I do not think it is achieving these ends, for two main reasons.

12.140 First, as I have said, the amount of information available that relates to individual doctors is very small. Most data relates to practices and not individuals. Even prescribing data

is not as sharply defined as it should be. Clinical governance will not reach its full potential until it entails the collection of data relating to individual doctors. Data relating to say six or seven practitioners may well conceal real deficiencies about an individual. Much more effort must go into the collection of data relating to individuals. This could include prescribing data, referral data and complaints. Patient satisfaction surveys should seek reactions to individual doctors and not just to the service provided by the practice. If and when mortality statistics can be analysed, they should be included. I am sure that there are other possibilities which I have not thought of.

12.141 Second, clinical governance should be given a much higher profile in the PCT. My understanding is that, at present, the clinical governance lead is usually a GP who has an interest in the subject and undertakes it on a part-time basis. I can see the value of a clinical governance lead remaining in clinical practice. However, it does not seem to me to be satisfactory that s/he should just 'pick up' what there is to be learned about clinical governance as the result of experience. There should be opportunities for clinical governance leads to share experience and to learn what more can be done and how. Also, if the experience of clinical governance leads shows that they need greater powers, they should be given them. To use a colloquial term, the process needs 'beefing up'.

12.142 I said that I would consider whether, if clinical governance had been in operation in the mid-1990s, it would have been capable of detecting Shipman's criminal activities. The short answer is that clinical governance as operated at present would not have done. If an analysis of mortality statistics could have been included, it obviously would have done; the death rates among his patients were noticeably high. I cannot think of any other clinical governance tool that would definitely have detected his crimes. Clinical audit might have done so, if the right topic had been chosen. Significant event review, focussed on a sudden death, particularly a death in the surgery, might well have done. I cannot be certain. If clinical governance were to operate in conjunction with improved death investigation and certification (as recommended in my Third Report) and improved regulation of the use of controlled drugs (as recommended in my Fourth Report) then I think the prospects of detection would be quite high. Even more important, perhaps, would be the deterrent effect of these measures.

12.143 Having said that, I do not think that clinical governance will ever be the method of choice for detecting deliberate malpractice. Those who deliberately do wrong usually take steps to cover their tracks. The usefulness of clinical governance is to be found, in my view, in what it discovers about doctors who are not performing badly on purpose and who may be quite unaware that their clinical performance is poor. Just because clinical governance would not necessarily 'catch another Shipman' does not mean that it is not thoroughly worthwhile.