



University of London

**External audit of decisions in the investigation stage
of the GMC's fitness to practise cases**

July 2007

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Executive summary

Focus of the report

This report presents the findings of an independent audit of decisions in GMC fitness to practice cases, carried out between January and June 2007 by a team from King's College London. The audit was commissioned by the GMC to check whether fitness to practice cases are being handled as intended and are dealt with in a fair, objective and transparent way.

The audit focused on three decision points in the fitness to practice procedures:

- A Initial assessment of enquiries/complaints/referrals and direction of cases (triage)
- B Responses received from NHS employers when cases are referred to local procedures (Stream 2 cases)
- C Case examiner decisions in cases where it is suggested that the doctor's fitness to practise is impaired (Stream 1 cases)

Decision point A

Audit question: Are the criteria for initial assessment applied consistently and are cases directed appropriately?

Audit findings

The guidance provided by the GMC on initial assessment of enquiries was found to be clear and easy to apply. In the sample of enquiries examined for the audit, the investigation managers had followed the guidance with a high degree of consistency and the cases had been directed in accordance with the guidance. There was concordance between the King's and GMC decisions in all but one of the 51 cases considered.

In the one exceptional case, the enquiry was handled in a way that represented a significant departure from GMC procedures. This case had also been picked up by the GMC's internal Investigations Audit Group and further action had been taken.

Decision point B

Audit questions: How long does it take to obtain a response from the NHS which results in closure of a case? What are the responses of NHS employers to the GMC when a case is referred to local procedures? What procedures and measures have been taken locally?

Audit findings

The GMC target for completing Stream 2 (local procedures) cases is eight weeks. This target was not met for more than three quarters of cases in the audit sample. Indeed, more than one third of cases had been open for seven months or longer. In some cases there were delays in the initial processing of the complaint. However, the main reason for cases remaining open so long was that the GMC was waiting for Trusts to investigate complaints and report their findings. Where the GMC had chased Trusts for responses, this appeared to have had little impact in speeding up local procedures.

Correspondence from Trusts gave some indications as to why it took so long to deal with complaints referred by the GMC. Local procedures are not only concerned to identify patient safety issues, system failures, clinical errors or substandard care, they also give high priority to satisfying the complainant. Some responses from Trusts explicitly equated 'resolution' of a complaint with satisfying the complainant. This interpretation means that it may be difficult to recognise when resolution has been achieved, except with hindsight, when it is clear that the complainant has ceased to pursue their complaint.

The audit data were used to model an approach to dealing with Stream 2 (local procedures) cases that is similar to current GMC procedures. We explored how quickly cases would close if the GMC simply accepted the Trust's assurance that there were 'no immediate concerns' about the doctor. Using this approach, 64% of cases in the sample would have been closed within the eight week target, and 84% within 12 weeks.

The content of responses from Trusts was very variable. Few included information that was likely to be useful to the GMC, beyond confirming that local investigation had taken place and assuring the GMC there were no fitness to practise concerns. Only a very few reported on remedial action that the doctor had been required to take.

Decision point C

Audit questions: Are case examiner decisions supported by reasons in a way that enables an external reviewer to understand why a decision was reached? What is the nature of the reasons recorded and are they supported by the evidence? How often, and in what circumstances, does the following occur: the guidance on criteria and thresholds suggests that an allegation should be taken as serious, suggesting impairment, but the case examiners decide not to refer the case to FTTP because they regard the allegation as insufficiently serious (rather than unsupported by the evidence)? Where this happens, is the exception justified by the case examiners in terms of the guidance?

Audit findings

Transparency of decision reasoning

All the Stream 1 cases reviewed had a clear statement of the case examiner decision and an explanation of why the decision had been reached that was easy for an

external, non-specialist reviewer to understand. Case examiner decisions made reference to the context of the case and were supported by the evidence available. Allegations were often addressed separately and systematically and arguments were clearly laid out. Although the text varied greatly in length, the detail provided was considered to be appropriate.

In a few cases the decision reasoning text did not include key information that was needed to understand why a decision had been reached. For example, we found several cases in which the case examiner decisions made sense only in the light of the doctor's history of GMC investigations, concerns raised by the doctor's employer, or knowing that there were concurrent open cases. This information was recorded elsewhere in the case record. We recognise that there is a tension between achieving complete transparency in decision making and protecting the confidentiality of those involved in a case.

Case examiner discretion

The audit explored the question of whether case examiners were following GMC guidance on making decisions about a doctor's fitness to practise. In particular, cases were scrutinised to see whether they were downplaying the seriousness of allegations that imply impairment. In cases supported by evidence in which there is a presumption of impaired fitness to practise or that the GMC will take action, case examiners were found to be following GMC guidance appropriately. Guidance is also provided to case examiners on making judgments in cases that involve serious or persistent failure to meet the standards in *Good Medical Practice*. Decisions in these cases are necessarily complex, but by exploring cases with allegations of substandard clinical care we found that case examiners appeared to be following GMC guidance in assessing the gravity of these cases.

Conclusions

The audit findings demonstrate that at key decision points in the GMC's fitness to practise procedures, cases are generally handled in a way that is transparent, consistent and appropriate in terms of the guidance and criteria provided by the GMC. The 'triage script' for initial assessment of enquiries is highly structured; it is clear and easy to apply; and investigation managers followed it with a high degree of consistency and directed cases appropriately. Procedures for dealing with Stream 2 (local procedures) cases are clearly defined by the GMC, but do not fit well with how complaints are handled locally, and it was often some months before the GMC was able to close cases. Case examiner decision reasoning in Stream 1 cases was recorded fully and clearly, with reference to the evidence and the context of the case, in a way that enabled an external reviewer to understand why the decision had been reached. We found no indication that case examiners were downplaying the seriousness of allegations that imply a doctor's fitness to practise is impaired. In cases that required case examiners to exercise discretion they did so in accordance with GMC criteria.

Impact of changed procedures

In late 2006 the GMC introduced some changes to fitness to practise procedures. The audit samples predated these changes, but we were able to use them to assess the

likely impact of three procedural changes. Our analysis indicated that the changes are appropriate and safe. They are likely to improve the efficiency of the GMC's fitness to practise procedures, in particular by reducing the volume of cases in Streams 1 and 2, with minimal risk in terms of missing fitness to practise issues.

Additional issues raised by the audit

Carrying out initial assessment of enquiries alerted us to the possibility that the way in which complaints are presented may influence whether cases are taken up by the GMC. It was also apparent that some members of the public approach the GMC expecting support for or action on complaints that it is not the GMC's role to provide.

Our analysis of Stream 1 cases with allegations of substandard clinical care highlighted that the only case in this group involving a single clinical incident that was referred to a FPHP had been supported by evidence from an independent expert. Another case involving a single clinical incident, in which the case examiners found a GP had made 'a significant clinical error', was not referred: the case examiners decided that a warning was the appropriate response. Comparison with the previous case led us to question when case examiners consider it necessary to seek an independent opinion on a doctor's performance and how this might influence the outcome of cases.

Case examiners had decided to issue warnings in three cases in the sample. In our view these decisions were consistent with GMC guidance. Two doctors did not accept the warning and in both cases the Investigation Committee did not uphold the case examiners' decision. The Investigation Committee may be presented with more information than was available to the case examiners, and the GMC's rules envisage that the Investigation Committee may reach a different decision. Nevertheless, these findings raise questions about consistency in interpreting guidance on appropriate sanctions in fitness to practise cases.

Introduction

Background

In 2004 the GMC introduced new procedures for dealing with fitness to practise cases. Criticism of the preceding system for handling complaints against doctors suggested that it was outdated, unclear and possibly biased. The new procedures are explicitly linked to the GMC's guidance on what constitutes good medical practice. The GMC has also made a commitment to ensuring that its procedures are fair, objective, transparent and free from discrimination. All points in the decision process are subject to audit by the GMC's internal Investigations Audit Group (IAG).

Since 2006 a modern IT system (Siebel) has been used to support the new fitness to practise procedures. This system not only facilitates processing of cases, it also assists GMC staff in making key decisions by linking with guidance and criteria that have been developed by the GMC on fitness to practise issues. Comprehensive data on all cases can be accessed readily and the progress of cases through the system can be tracked. It enables production of management information and internal audit by the GMC and opens up the possibility for independent, external scrutiny of GMC procedures.

In late 2006 the GMC commissioned a team from King's College London to independently audit the process for dealing with referrals and complaints about doctors, focusing on particular decision points in fitness to practise procedures. The purpose of the audit was to check whether fitness to practise cases are being handled as intended under the new procedures and that they are indeed dealt with in a fair, objective and transparent way.

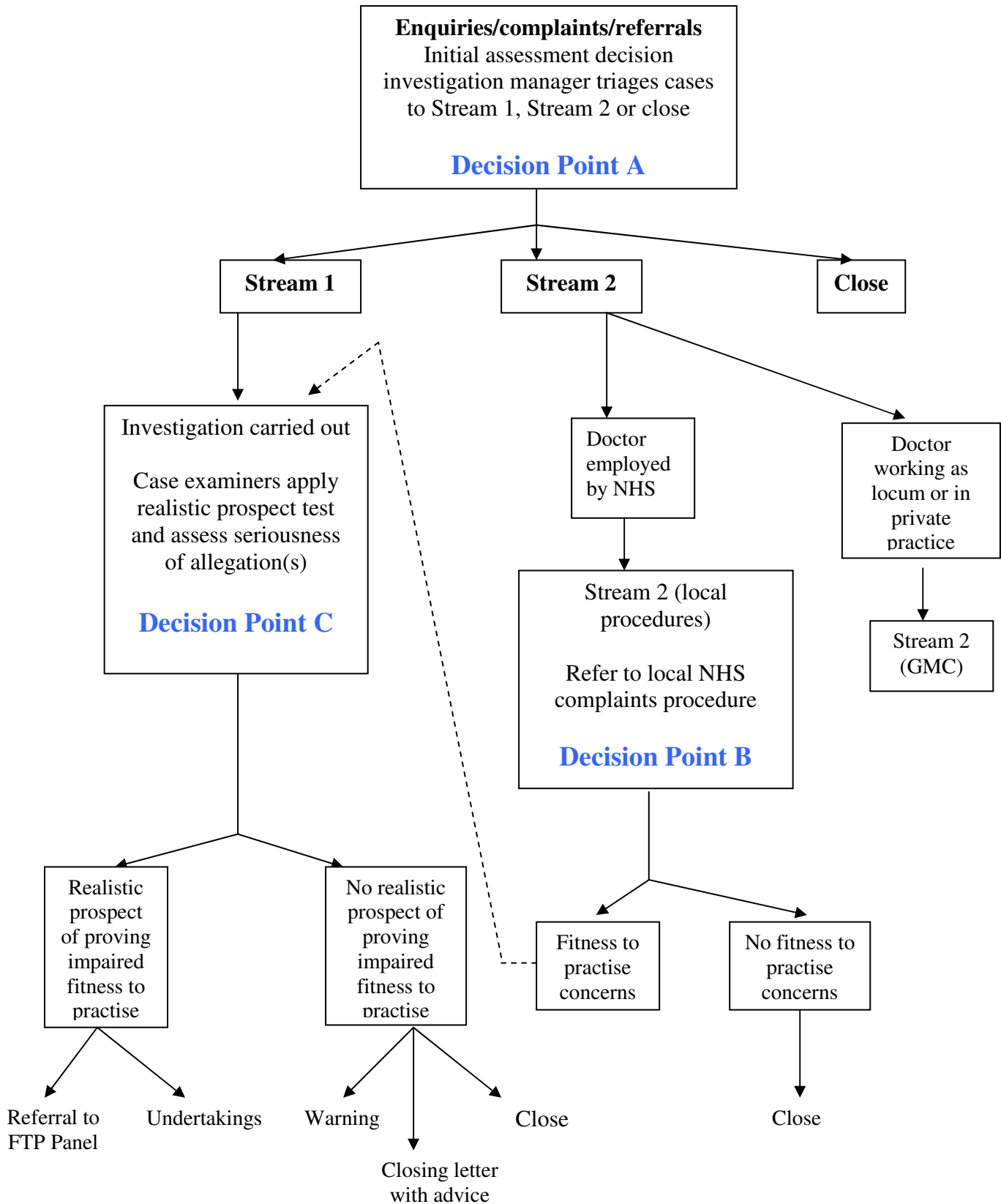
Focus

The GMC directed us to focus on three decision points in the fitness to practise procedures:

- A. Initial assessment of enquiries/complaints/referrals and direction of cases (the triage process)
- B. Responses received from NHS employers when cases are referred to local NHS procedures (Stream 2 cases)
- C. Case examiner decisions in cases where it is suggested the doctor's fitness to practise is impaired (Stream 1 cases)

These points are shown in Figure 1, which is our interpretation of the fitness to practise process at the time the audit commenced.

Figure 1: GMC decision making in fitness to practise cases



Approach

The audit was designed in consultation with staff in the GMC Fitness to Practise Directorate and conducted over a six month period between January and June 2007. During that time, we met regularly with the GMC for feedback and discussion sessions and these informal meetings also generated some supplementary questions to pursue.

In preparation for the audit, we studied:

- the *Good Medical Practice* guidance on the GMC website, which sets out expectations of GMC registered doctors;
- general information about the GMC's role in dealing with complaints, also on the website;
- the *Fitness to Practise Investigation Manual*, 6th issue (6 November 2006);
- guidance for investigation managers (the 'triage script');
- guidance for case examiners and the investigation committee ('Making decisions at the end of the investigation stage');
- and reports from two other external studies commissioned earlier by the GMC.^{1,2}

We audited each of the decision points in turn, starting with initial assessment decisions, followed by responses from local procedures (Stream 2), and finally case examiner decisions (Stream 1). Sampling and data collection were agreed with the GMC. The GMC provided lists of cases and introduced us to the Siebel database. Additional insights into the context and process of decision making were obtained through interviews conducted with three investigation managers, four case examiners (lay and medical, London and Manchester based) and the Fitness to Practise Directorate's Head of Investigation. We also attended, as observers, a meeting of the Investigations Audit Group on 30th January 2007, to hear discussion of cases and issues arising from recent internal audit.

Structure of the report

The report is divided into three sections - A, B and C - reflecting the three decision points that we examined. Each section includes an introduction to the procedures and issues involved; the specific audit questions that were addressed; the methods used; the audit findings and a summary. At the end of the report we discuss the main points raised and draw overall conclusions.

¹ York Health Economics Consortium (2006) *A Descriptive Analysis of Fitness to Practise Data (FPD) for 2005 Complaints* University of York.

² Allen I (2000) *The Handling of Complaints by the GMC: A study of decision-making and outcomes*. Policy Studies Institute, London.

A. Initial assessment decisions

A.1 Introduction

Enquiries, complaints and referrals received by the GMC are assessed by investigation managers, who are trained to follow the guidance on making decisions about whether there should be further investigation.

Decisions at this point may result in an enquiry being closed (because it is not appropriate for the GMC to pursue), being allocated to Stream 1 (because it raises questions about the doctor's fitness to practise) or to Stream 2 (because, while it does not in itself raise questions about fitness to practise, it may require action if it is part of a wider pattern of concerns). Stream 1 cases are investigated further by the GMC. Stream 2 cases are referred back to the doctor's employing NHS Hospital or Primary Care Trust to take forward under local complaints procedures, unless further concerns are raised with the GMC. If the doctor works as a locum or in private practice, the GMC contacts employers before deciding whether to conduct its own investigation.

The GMC requested an audit of initial assessment ('triage') decisions to determine whether the guidance and criteria provided (the 'triage script') are being applied fairly and consistently.

A.2 Audit question

- Are the criteria for initial assessment applied consistently, and are cases directed appropriately?

A.3 Methods

Our original plan was to draw a small sample of enquiries/complaints/referrals from the database and then replicate the triage process carried out by the GMC investigation managers, using the GMC guidance but without knowing how the enquiries in question had actually been directed by the GMC. We would then compare our decisions with those of the GMC and explore any anomalies we found. However, because we had to use the GMC's Siebel database to access enquiry information, it was not possible to be truly 'blind' to the triage outcomes. This was because the information manager's decision is recorded on the screen that comes up when information about an enquiry is accessed. Also, for a high proportion of enquiries in the audit sample, the investigation manager had requested triage advice from a case examiner.³ These exchanges often suggested how a case should be directed, and were among the documents we needed to read in order to reach our own decisions. Although not 'blind' to the actual assessment decisions, we sought to replicate the initial assessment process as closely as possible and started by looking at the letter of complaint in each case.

³ We understand that the number of requests for case examiner advice may have been unusually high in the audit sample, because at that time one of the investigation managers was new to the triage process.

The GMC provided a list of all enquiries received for the period May to September 2006 inclusive, together with the initial assessment decisions made about these enquiries. A stratified random sample of 51 enquiries was selected for audit from this list by an independent member of staff at King's. The sample comprised 17 enquiries directed by the GMC to each of the three 'streams' (close, Stream 1 and Stream 2). The size of the sample was chosen on the basis that it would be large enough to reveal any significant discrepancies. More details about sampling are in Appendix I.

For each enquiry in the sample, one member of our team read the enquiry information and, guided by the triage script, made an initial assessment decision. To check for consistency, a proportion of the inquiries (18 of the 51) were read independently by two team members, and their decisions compared. Any cases which appeared to be ambiguous or raise other issues of interest were further discussed within our team.

After completing this stage of the audit, we also interviewed two investigation managers with substantial experience of the initial assessment process, to explore their views about the process of decision making.

A.4 Applying the guidance

The guidance was easy to follow and we found it straightforward to apply to most of the enquiries. The most clear cut decisions were those that involved closing enquiries or promoting them to Stream 1. Complaints about substandard treatment were the most difficult to assess, and a few complaints from members of the public about the standard of clinical care or treatment were highlighted for discussion within the team. However, by referring to the GMC guidance, it proved possible to reach agreement on the direction of all the enquiries in the sample.

Discussion with the investigation managers confirmed that our experience was similar to theirs. As one said:

'Carrying out triage is quite straightforward. Stream 1s speak for themselves. The more tricky ones are the complaints that are either closed or Stream 2s where there can be grey areas, the lower end of the seriousness scale. I don't know whether there is a big risk there really, but when I get audited these are the ones we end up discussing – hours and hours debating, which is fine... sometimes I get frustrated that we spend a lot of time debating something that is never likely to be a GMC issue.'

A.5 Concordance between initial assessment decisions

When we compared our decisions with those of the GMC, we found a high level of concordance, as shown in Table A1.

There was only one enquiry (A20) where our decision differed from that taken by the GMC, but in this case the disagreement was significant. The enquiry had been closed by the GMC, whereas we felt it should have been promoted to Stream 1. This enquiry had come from a national medical regulatory body in another country and drew the

GMC’s attention to a case that had received a lot of publicity in that country, in which British doctors working for a charity were alleged to have used drugs past their expiry date. We were surprised that the enquiry had not been promoted, since the allegations were serious and came from a public organisation.

Table A1: Comparison of initial assessment decisions					
		GMC decision			Total
		Close	Stream 2	Stream 1	
King’s audit team decision	Close	16			16
	Stream 2		17		17
	Stream 1	1		17	18
Total		17	17	17	51

In the audit sample, public organisations were the source of 14 enquiries: nine had been promoted to Stream 1 and five closed. Enquiry A20 was unlike the other four that had been closed: two from organisations simply sharing information with the GMC; one seeking information about doctors (not UK registered) being investigated by the police abroad; and one a duplicate (opened in error) of an enquiry that had already been promoted to Stream 1.

Looking further into the documentation on this anomalous case, we found that it had also been picked up in a routine, internal GMC audit and the initial assessment decision had been questioned by the GMC audit team at that point. Although the enquiry remained closed, we understand that after the internal audit the regulatory body had been contacted again and asked to provide further information, but the GMC received no response.

A.6 Issues raised by the audit

Reading the letters of complaint to the GMC led us to wonder whether the complainant’s presentation of the issues might affect the initial assessment decision, particularly when a member of the public complains about the standard of clinical care or treatment provided. The complaints varied greatly in clarity, coherence and the amount of detail provided. Some complaints were expressed in a way that was clear cut and could be linked directly to categories in the GMC guidance, while others were more muddled and it could be difficult to ascertain who was being complained about or why. For example, enquiry A47 involved a complaint from a patient who

was dissatisfied about the care provided by a GP and a hospital specialist (who were not clearly identified). Although it was difficult to make sense of the letter, it seemed that changes to treatment had not been communicated well and the patient had been given conflicting information. The investigation manager had spoken by telephone to the complainant to try to clarify the complaint, but without success. This enquiry was closed under the ‘triage script’ reasons for closure para 2.5a.e: ‘issues cannot be identified to enable an investigation to be conducted’. We agreed that this enquiry should have been closed, since it did not appear to suggest any fitness to practise issues. However, we thought that the categorisation of the reason was not entirely satisfactory and the enquiry did not fit into any other closure categories in the triage script. Participants at the IAG meeting we attended also identified 2.5a.e as one of the categories in the triage script that was more difficult to interpret and apply.

In contrast, the audit sample also included some very well presented complaints from patients about their treatment. Two examples were discussed in our team (enquiries A25 and A31). Case examiner advice had been sought on both of these and on both occasions the advice was to close: A25 under reasons for closure para 2.5a.d: ‘disagreement with clinical judgement expressed in a medical report’ and A31 under reasons for closure para 2.5a.e (as above). Although the investigation manager had agreed with the case examiner that there appeared to be no fitness to practise issues, both these enquiries had been promoted to Stream 2. The investigation manager noted that A25 was ‘a very detailed complaint’. We agreed with the decision to direct both these enquiries to Stream 2.

For the GMC, the purpose of the triage process is to identify enquiries which indicate that a doctor’s fitness to practise may be impaired and which therefore require further investigation; and to filter out those that raise no fitness to practise issues and, as such, are not appropriate for investigation by the GMC. It was apparent from reading the letters that members of the public wanted their complaints investigated and action taken and that many had approached the GMC believing it would do this. There is clearly a tension between the two purposes, which investigation managers who carry out triage have to deal with. As one said:

‘A lot of complainants aren’t asking us to investigate under our GMC process, really they just want some sort of advice or something done. This presents us with difficulty, because Stream 2 or close doesn’t satisfy them.’

The same investigation manager also commented that:

‘Stream 2 is quite often not about fitness to practise, but about the patient being able to make a complaint and the patient feeling that there is someone listening to them. But there is no other process for dealing with them.’

A.7 Summary

The guidance provided by the GMC on initial assessment of enquiries was found to be clear and easy to apply. In the sample of enquiries examined for the audit, the investigation managers had followed the guidance with a high degree of consistency and the cases had been directed in accordance with the guidance. There was

concordance between the King's and GMC decisions in all but one of the 51 cases considered.

Issues raised by the audit of initial assessment decisions include the possibility that articulate individuals who present their complaints clearly and in detail are more likely to have their cases taken up by the GMC. It is also apparent that some members of the public want support or action on their complaints that it is not the GMC's role to provide. The triage process has been designed to segment a very wide range of enquiries and identify those requiring further investigation for fitness to practise issues; resolving complaints and satisfying individual complainants is not part of the GMC's responsibility. The investigation managers have to manage this tension between operating the triage process effectively and efficiently and public expectations of the GMC.

B. Stream 2 (local procedures) cases

B.1 Introduction

Enquiries to the GMC that are directed to Stream 2 are referred to the NHS Trust that employs the doctor. (Complaints about doctors in private practice and those who work as locums are investigated by the GMC directly.) If the employer has other concerns about the doctor, the case may be promoted to Stream 1 and investigated by the GMC, but this happens rarely. A Stream 2 case remains open until the GMC has received a ‘satisfactory’ response from the employing Trust that enables the investigation manager to close the case or, if further information is provided that calls into question the doctor’s fitness to practise, to promote it to Stream 1. Until November 2006, it was GMC policy for Stream 2 cases to remain open until local investigations or complaints procedures were complete and the GMC had been informed of the outcome. Current procedure is that a case may be closed once it has been established that the employing Trust has no other concerns about the doctor’s fitness to practise, accepts responsibility for dealing with the complaint, and agrees to inform the GMC if any fitness to practise issues are found. Another recent change is that a case may now be closed at triage rather than entering Stream 2, if it is known at that stage that the complaint has already been investigated by the employing Trust and no significant issues were identified. The GMC has a target of eight weeks for completion of Stream 2 (local procedures) cases.

The GMC requested an examination of the responses provided by NHS Trusts to Stream 2 (local procedures) cases. There were concerns about how complaints referred by the GMC are perceived by NHS Trusts; the adequacy of local procedures for handling or investigating complaints; communication with the GMC; and the length of time taken for the GMC to receive a response that allows a case to be closed.

B.2 Audit questions

- How long does it take to obtain a response from the NHS which results in closure of a case?
- What are the responses of NHS employers to the GMC when a case is referred to local procedures?
- What procedures and measures have been taken locally?

B.3 Methods

The GMC provided us with a list of all Stream 2 cases that had been opened between April and July 2006 inclusive. This period was chosen because it was thought that by the time the audit was carried out (February/March 2007) responses would have been received from the NHS to these referrals and all but a few cases would have been closed. The period chosen was before the change in GMC procedures on promoting enquiries to Stream 2 and closing Stream 2 cases as described above. A random sample of 30 local procedures cases was selected from this list by an independent member of staff at King’s. More details about sampling can be found in Appendix I.

A list of the 30 cases in the audit sample and the summary data for Stream 2 local procedures are included at Appendix II.

In discussion with the GMC, we developed a data sheet and extracted the following information on each case from the Siebel database:

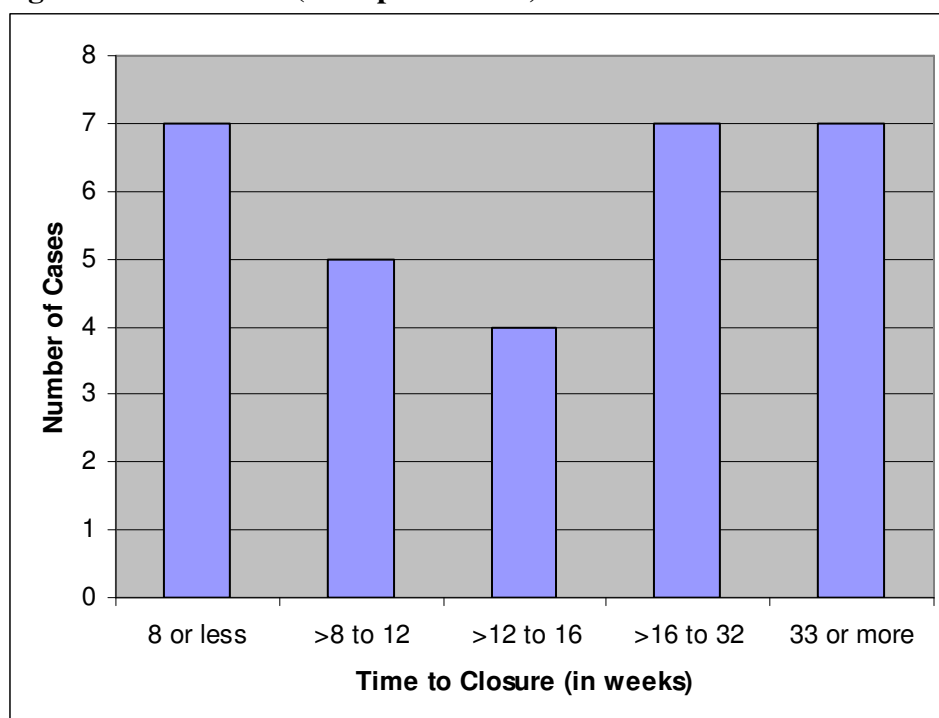
- Case ID number
- Enquiry start date
- Source and type of complaint
- Date patient consent obtained
- Date employer details obtained
- Date employer informed
- Complaint known to employer or previously investigated
- Dates GMC chased employer for response
- Employer response (actions, outcomes, who responded)
- Date case closed

The key dates listed above enabled us to calculate the time taken by a case at each stage of the process. Text from correspondence with NHS Trusts was selectively copied (and anonymised) if it included information relevant to the audit. During this stage of the audit we also interviewed the investigation manager responsible for stream 2 cases.

B.4 Time to closure

The time taken to close the 30 cases in the sample is shown in Figure B1. Only seven cases (23%) had met the eight week target for closure. Not all cases had been closed by the time the audit was carried out and five (17%) were still open on 01.03.07 (the final date of checking).

Figure B1: Stream 2 (local procedures) cases - time to closure



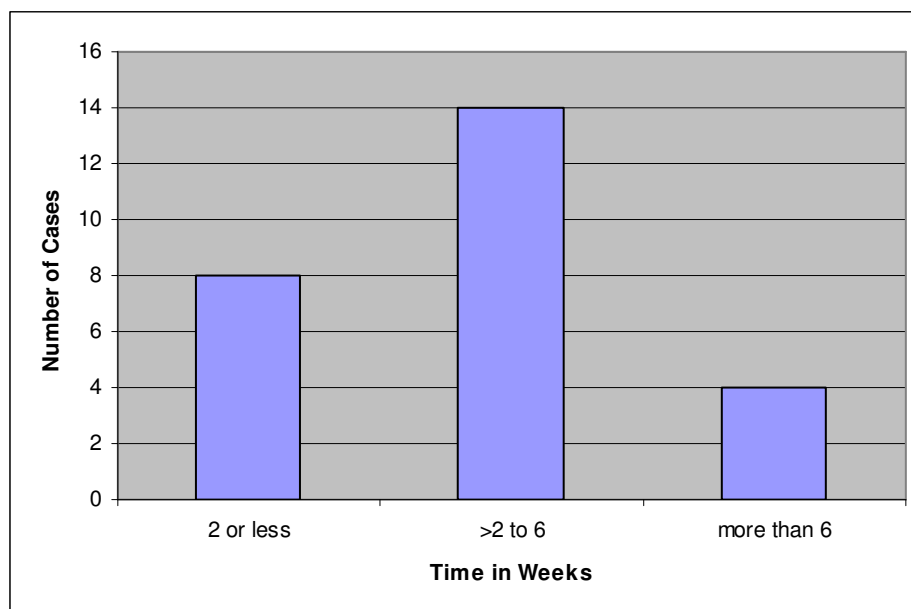
The seven cases that met the GMC closure target of eight weeks were all atypical in ways that had enabled them to be rapidly completed:

- In three cases the complainant had not consented to disclosure and the cases had been assessed as failing the public interest test (PIT)⁴
- One was a duplicate opened in error
- Three had already been investigated locally and the outcomes of the investigations were immediately available

Seven cases had remained open for more than 32 weeks. Only two of these (open for 36 weeks and 38 weeks) had been closed at the time of the audit. All seven had remained open waiting for the outcomes of local investigations to be communicated to the GMC. One was linked to concurrent Stream 1 cases involving the same doctor, who was also the subject of an investigation by NHS Counter Fraud Services.

Most cases had remained open much longer than had been anticipated, so we explored the reasons for exceeding the GMC's target for closure. The process within the GMC for handling Stream 2 (local procedures) cases includes obtaining consent from the complainant; disclosure to the doctor; identifying the employing Trust; and writing to them with details of the complaint. We calculated the time between the case being opened by the GMC and a letter being sent to the employing Trust. This information is summarised in Figure B2, which includes the 26 cases that reached this stage.

Figure B2: Stream 2 (local procedures) cases - time to employer informed



Twenty two (85%) of the cases were processed by the GMC within six weeks (eight (31%) in two weeks or less); and four cases (15%) took longer than six weeks to

⁴ The PIT is applied if the GMC does not obtain the complainant's consent to disclose the complaint to the doctor. The investigation manager considers whether it is in the public interest to proceed with the complaint without the complainant's consent. This may be necessary if there is evidence to support the allegations and they are sufficiently serious to suggest the doctor may pose a risk to patients.

process. A common factor in the cases that were processed quickly (two weeks or less) was the immediate availability or rapid receipt of correct details about the doctor's employer. Conversely, in the cases that remained with the GMC for more than six weeks there was a delay in obtaining employer details, compounded in some cases by being given wrong or misleading information and in three cases by mistakes or delays by GMC staff. The longest time taken to inform an employer was nine weeks. Delays at this initial stage thus accounted for part, but not most, of the time taken to complete the Stream 2 (local procedures) cases in this sample.

B.5 Progress chasing by the GMC

Although most of the cases audited had been open for three months or more, the majority had no or only one record of follow up by the GMC asking for an update on progress. The investigation manual indicates that the investigation officer should write to the employer asking to be kept informed of progress. If nothing is received after a month, the employer should be telephoned to discuss the situation and agree a date for providing an update. A few cases had records of several letters or phone calls, but these appeared to have had little effect in accelerating the process of obtaining information which would enable the GMC to close the case. One case (B4) stood out as having been chased at least seven times over a nine month period, to no effect. It is noteworthy that in this case the PCT's initial response to the GMC mentioned two other similar complaints about the doctor, perhaps increasing the urgency on the GMC's part to obtain further information. This case had been open for more than ten months, and remained open at 01.03.07.

B.6 Why do Trusts take so long to respond to the GMC?

Correspondence from Trusts provided an indication of some of the reasons why it took so long for them to respond in ways that allowed Stream 2 cases to be closed. Some responses indicated that complaints referred by the GMC were perhaps not given high priority. For example, one complaint (B19) previously investigated locally was reviewed by the medical director, who responded apologetically after six months:

'I am afraid that subsequently the paperwork disappeared beneath a pile of other more pressing issues. I am very sorry that this has therefore led to such a prolonged delay in responding to you.'

In other cases it appeared that the GMC's involvement was being taken seriously: the correspondence described procedures or investigations; provided details of the outcomes; and addressed questions about the doctor's performance or the standard of care provided. It was clear that following local procedures through to the point where findings can usefully be communicated to the GMC can be a complex process. For example, case B15, which was open for 36 weeks, had involved a meeting with the complainant; a separate meeting with the doctor; and formal discussions with the PCT's Decision Making Group. In a six-page letter about this case, the PCT medical director commented:

'It is also important to note that (doctor)'s failure to recognise (patient)'s chest infection did not change the diagnosis or (patient)'s subsequent

treatment. It only delayed him being seen by a specialist by a few hours, which we do not consider was clinically significant. However, we recognise that there was probably an additional worry for (complainant) and (complainant)'s nanny because of this delay. I strongly gained the opinion that (doctor) has taken this experience to heart and now has a lower threshold of suspicion for potentially serious illness in babies in general. The practice has also changed its policies in respect of children brought to a consultation other than by their parents and lowered their threshold for suspecting serious illness in these circumstances. This seems to have had a beneficial impact already. In view of (doctor)'s good past record, his regular involvement in postgraduate training, his openness in discussing this issue with his colleagues, mentor and the PCT, we considered that he is unlikely to make an error like this again. We also recognise that no clinician will ever have a career in which they have not made mistakes, but that the important thing is to learn from them. We believe that (doctor) has done this and that this learning has been shared within the practice. We therefore consider that no further action is needed in this case. We hope that (complainants) will be content with our conclusions and that (doctor) will be able to put this episode behind him while benefiting from the experience.'

In other cases, complaints that had already been dealt with were reviewed again in response to the GMC referral to see if any new issues could be identified. Case B24, an extensive complaint about all the doctors in a large group practice, was open for 21 weeks before the Director of Public Health wrote to confirm that no new issues had been raised, there were no concerns about any of the GPs and 'no further action was necessary'. In case B23, which was still open, the complaints manager wrote to say that a reconciliation meeting might be held, but warned that 'it may be some time before this complaint is resolved'.

The Trust responses indicated a concern not just to identify any patient safety or performance issues on the part of the doctor, but also to satisfy the complainant. Correspondence from Trusts quite frequently included comments about the complainant's response to attempts to resolve the complaint. Only one Trust response (B1) stated unequivocally that the process was complete and the complainant had been satisfied:

'The conciliatory meeting was successful and all points raised by the complainant were addressed and the complainant was satisfied with the outcome.'

A number of responses drew a distinction between reaching a decision about whether the doctor had been at fault and resolving the complaint to the satisfaction of the complainant. In case B28, the medical director wrote:

'This is I'm afraid an ongoing case. Certainly my own knowledge of the case is that (surgeon) gave (patient) completely appropriate advice, but (patient) has not accepted that and has ... resisted referral elsewhere. ... I, myself, remain in correspondence with (patient) In respect of (surgeon) and his engagement with (patient), I personally would regard that as closed and any

ongoing enquiries I have are related to questions posed by the patient, rather than any issue of appropriateness of (surgeon's) behaviour or advice.'

This case was closed on receipt of this letter after being open for 11 weeks. In case B29, a local investigation by the Trust medical director was well under way when the case was opened by the GMC and the Trust chief executive responded within two weeks as follows:

'I can ... confirm with a strong affirmation that there are no concerns about (doctor) which might require action by the PCT. The complaint has been dealt with by local procedures and to reassure you, the actions taken by the doctor were under the guidance of the patient's registered GP following discussion with him. There have been a number of correspondences with the patient as part of the local complaints process which is ongoing.'

The case was closed on receipt of this letter, after being open for a total of six weeks.

It is clear from the responses that there are different interpretations of what is meant by 'resolving' a complaint. The end point of the local complaints process may not always be clearly defined. If the aim is to reach a point at which the complainant is satisfied, this may often only be identifiable with hindsight, when it is apparent that the complainant is no longer pursuing the complaint. For example, if after an apology, explanatory letter or conciliation meeting the complainant does not continue to correspond with the Trust, the complaint will eventually be considered resolved. The potential for delay is well illustrated by case B12, in which the Trust wrote to say there had been a meeting with the complainant, but took a further six months to respond to the GMC as follows:

'As we received no further correspondence from the complainant following this (conciliation) meeting I assume that local resolution was achieved.'

Other Trusts apparently overcame the ambiguity around determining when a complaint was resolved to the patient's satisfaction by assuming that if the complainant was content to remain under the care of the doctor, resolution had been achieved. For example, in case B27:

'I am writing to inform you that the orthopaedic surgeon ... has ...written to (patient) asking whether he wished to remain on (surgeon)'s waiting list. (Patient) has written to say that indeed he does wish to remain on the waiting list under (surgeon)'s care. This concludes the Trust's action on this complaint.'

B.7 Did the NHS Trust already know about complaints referred by the GMC?

Of the 26 cases in the audit sample that were not closed immediately, 13 were already known to the doctor's employing NHS Trust and 13 were new, so far as could be ascertained from the information available. Of the complaints known to Trusts, six had already been investigated locally and seven were currently being dealt with. One

complainant alleged that they had complained locally, but that the Trust had failed to investigate. This was one of the cases that remained open at 01.03.07.

Of the six cases that had already been investigated locally, correspondence with the Trust indicated that four were reviewed again as a result of GMC involvement, while two were not revisited. One of the cases not reviewed again (case B22) had been investigated as a 'serious adverse event' by 'root cause analysis', resulting in a 38 page report that found 'no concerns about the doctor's competency'. In the other case (B6) the local investigation had included an appearance by the doctor before a professional performance panel which had found that no action was necessary. The case had subsequently been taken by the complainant to the Healthcare Commission, which had identified issues relating to the doctor's performance and remedial action had been proposed by the PCT.

Under current GMC procedures for initial assessment of complaints, if a local investigation has been completed and there are no concerns about the doctor, the complaint will not be considered by the GMC. The six cases described above all fall into that category.

B.8 Local procedures and measures taken by Trusts

To be confident that Trusts are using complaints as an opportunity to identify fitness to practise issues, the GMC needs to know that the Trust has taken responsibility for investigating a complaint, carried out an investigation and, if necessary, taken action. In 20 of the 26 cases in the audit sample that were not closed immediately, there was evidence of Trust activity on the complaint. In six cases there was no information, although in one of these an investigation by NHS Counter Fraud Services was underway, with which the Trust must have been cooperating. It is also possible that a Trust had investigated a complaint, but had not yet informed the GMC.

Correspondence from the Trusts varied greatly in the amount of detail it contained. Few responses included substantive information beyond confirming that local investigation had taken place and assuring the GMC that there were no fitness to practise concerns. Some correspondence provided the results of an investigation: responses varied from reporting the findings of 'root cause analysis' (case B22) to presenting the doctor's version of events. An investigation may involve seeking the views of a doctor's professional colleagues or managers. For example, in case B13 the Trust medical director states:

'I have consulted with her Clinical Director, the Divisional Director for Medicine and Associate Medical Director for Clinical Governance and Effectiveness, who all share this view. In addition there have been, and remain, no issues on her HR File.'

In six cases, some sort of conciliatory action was reported, such as holding a meeting with the patient or a letter of apology. As we described earlier, this does not necessarily satisfy the patient. In case B18, for example, the conciliatory meeting between the doctor and the patient did not satisfy the patient, who took the case to the Healthcare Commission.

Action that the doctor had been required to take was reported in only two cases. In case B6, the doctor had been required to attend a communication skills workshop and was being supported by another doctor experienced in quality improvement. The Trust stated that it would inform the GMC when the actions had been completed, adding ‘we have no immediate concerns which would require action by the GMC but would clearly report any concerns should they arise’. Similar words were used by the Trust in case B25. The doctor in this case was recommended by an independent review panel to ‘make documentation available at home visits’, ‘take better notes’ and ‘be more assiduous in his examination of patients’ and the PCT confirmed that changes had been made to practice procedures in relation to records. It also reported that the complainant was not satisfied and was taking the complaint to the Healthcare Commission and the Health Service Ombudsman.

In case B15, as quoted earlier, the Trust response cited action that had been taken at a systems level in the doctor’s general practice, including a change in practice policies regarding children brought to a consultation other than by their parents.

It was not always the Trust that investigated the complaint. In case B5 the PCT referred the complaint to the doctor’s general practice. A copy of the practice’s response to the complainant was forwarded to the GMC. Rather surprisingly in case B12, the Trust in Scotland reported it had no power to take action about a GP:

‘... our complaints department will be contacting the complainant in an attempt to achieve local resolution to the complaint. If however this fails, because (doctor) is an independent contractor then (name) NHS Trust has no further locus in this matter as we do not have the statutory powers to investigate the complaint.’

However, six months later, the same Trust wrote again saying that its complaints manager had met with the complainant, the doctor and the practice manager and it appeared that local resolution had been achieved.

In case B14, the Trust appeared to identify the patient as the problem, rather than the doctor. The Trust’s medical director wrote:

‘I am informed that (complainant) is still registered with the (name) Medical Practice and continues to collect her repeat prescriptions from there. I can only reiterate that (name) Trust has no concerns regarding (doctor) which would require action by the GMC. It may be appropriate, at this point, to mention to you that this patient tends to move from one GP practice to another and I am aware that she has made complaints against several other GPs in the past.’

B.9 At what point had cases been closed?

When the initial audit findings were fed back informally to the GMC, we were asked to explore further whether cases in the sample had been closed while the process of dealing with the complaint continued. For example, the local investigation was not complete, another body such as the Healthcare Commission was involved but had not reported, or a remedial programme for the doctor had been recommended but not

completed. Our analysis of this issue excluded four cases that were closed immediately by the GMC; five that were still open at 01.03.07; and a complaint that the Trust refused to investigate because the complainant was anonymous (case B11). It was sometimes difficult to ascertain from the correspondence whether a Trust was continuing to investigate a complaint or was still in dialogue with the complainant. Nevertheless, it was clear that the majority of cases had not been closed until the GMC had received confirmation from the Trust that its investigations into the complaint were complete, even though at this point dialogue with the complainant might still be continuing.

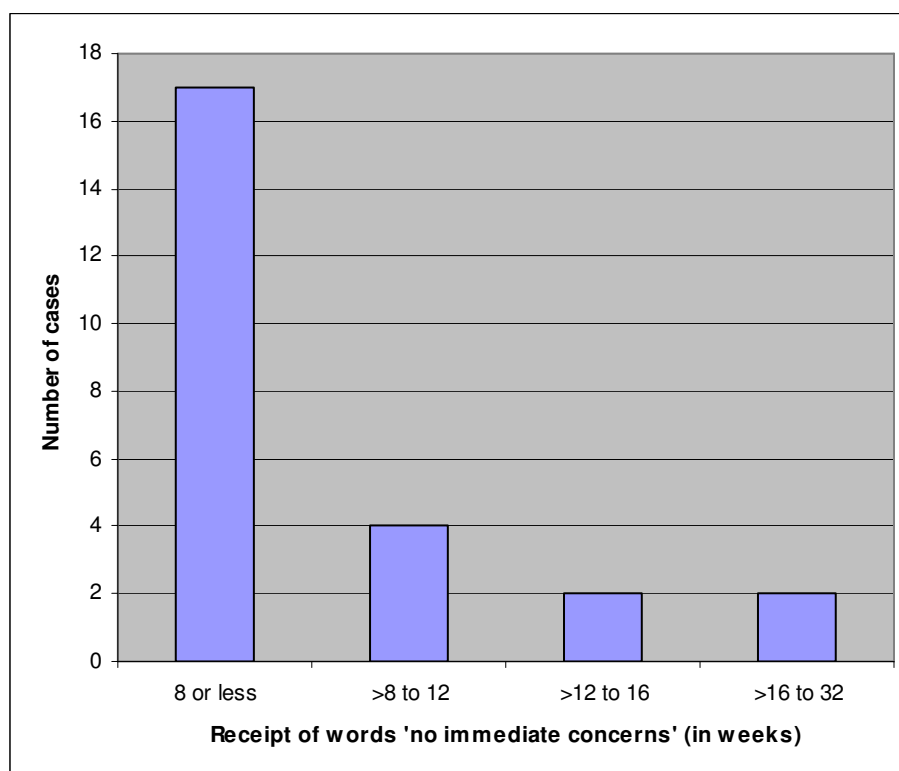
In four closed cases, correspondence from the Trust informed the GMC that the patient was not satisfied with the response and had referred their complaint to the Healthcare Commission. Three of these (B8, B10, B25) had been closed before the outcome of the Commission's investigation was known and the other (B6) had been closed after the PCT described its plan of remedial action, including support and training for the doctor, although not all these measures had yet been instituted. In contrast, case B18 remained open while it was reviewed by the Healthcare Commission. The Commission's investigation did not raise any concerns about the doctor, but the case stayed open, because the Trust reported it was to hold a meeting to review the complaint again. This case had been open for more than nine months.

B.10 Potential for earlier closure

In reviewing correspondence with Trusts, we noticed that immediate responses to the GMC letter informing a Trust about the complaint often confirmed that there were no other immediate concerns about the doctor's fitness to practise. These letters of acknowledgment were usually received very promptly. We speculated that if the GMC considered it appropriate to close a case when a Trust had agreed to deal with the complaint and provided assurance that there were 'no immediate concerns' about the doctor's fitness to practise, cases might be closed more quickly. To explore and quantify this hypothesis, we identified for each case the date at which the GMC received correspondence containing the phrase 'no immediate concerns' (or similar wording) and calculated how long the case had been open at that point.

Figure B3 summarises the results for 25 cases (we excluded three cases that had failed the Public Interest Test, one case opened in error, and one in which the doctor was being investigated for fraud). The data show that if this criterion for closing cases had been adopted, 17 (68%) of the cases would have been closed within the eight week target and 84% within 12 weeks. It is interesting to note that in all but one of the five cases that remained open at 01.03.07 the employer had already responded to say that there were 'no immediate concerns' about the doctor. The exception was the case in which the doctor was being investigated for fraud.

Figure B3: Stream 2 (local procedures) cases – time to confirmation of ‘no immediate concerns’



B.11 Summary

The GMC target for completing Stream 2 (local procedures) cases is eight weeks. This target was not met for more than three quarters of cases in the audit sample. Indeed, more than one third of cases had been open for seven months or longer. In some cases there were delays in the initial processing of the complaint. However, the main reason for cases remaining open so long was that the GMC was waiting for Trusts to investigate complaints and report their findings. Cases went into ‘limbo’ for long periods of time, with no activity recorded on Siebel. Where the GMC had chased Trusts for responses, this appeared to have had little impact in speeding up local procedures.

Correspondence from Trusts gave some indications as to why it took so long to deal with complaints referred by the GMC. Local procedures are not only concerned to identify patient safety issues, system failures, clinical errors or substandard care, they also give high priority to satisfying the complainant. Some responses from Trusts explicitly equated ‘resolution’ of a complaint with satisfying the complainant. This interpretation means that it may be difficult to recognise when resolution has been achieved, except with hindsight, when it is clear that the complainant has ceased to pursue their complaint.

The content of responses from Trusts was very variable. Few included information that was likely to be useful to the GMC, beyond confirming that local investigation

had taken place and assuring the GMC that there were no fitness to practise concerns. Only a very few reported on remedial action that the doctor had been required to take.

There was inconsistency in how the GMC dealt with Stream 2 (local procedures) cases when another body, such as the Healthcare Commission, became involved. Some cases had been closed before the results of investigations were known or had been acted on, while others had remained open.

The audit data were used to model an approach to dealing with Stream 2 (local procedures) cases that is similar to current GMC procedures. We explored how quickly cases would close if the GMC simply accepted the Trust's assurance that there were 'no immediate concerns' about the doctor. Using this approach, 64% of cases in the sample would have closed within the eight week target, and 84% within 12 weeks.

C. Stream 1 cases

C.1 Introduction

Cases allocated to Stream 1 are investigated by the GMC to obtain evidence, witness statements, expert reports, and assessments of the doctor's health or clinical performance, as necessary. When investigations are complete, the investigation manager writes a summary of the case and makes a referral to a case examiner. Each case is considered by two case examiners (one medical and one non-medical) who make a decision about whether the doctor's fitness to practise is impaired and what action should be taken. The GMC provides guidance for case examiners 'to encourage consistent and criteria based decision making'. Case examiners apply the 'realistic prospect' test⁵ to help them decide whether they will be able to establish that a doctor's fitness to practise is impaired to a degree justifying action on registration. Decision making at this point is complex and necessarily involves case examiners exercising discretion. Case examiners are required to record their decisions on the Siebel database and to explain the reasoning behind them. There is no template for structuring this information, but case examiners are expected to convey their thinking about a case, including explaining how evidence has been interpreted and making explicit why a particular course of action has been taken.

The GMC was interested in how effectively case examiners are recording the reasoning that supports their decision making. There were concerns about whether the information recorded would enable an external reviewer to assess whether GMC guidance was being applied consistently and fairly by case examiners. We were asked to investigate whether it was possible to track and understand decision making from the case records; to examine the nature of the reasons given to support case examiner decisions; and to explore whether case examiners are following GMC guidance.

C.2 Audit questions

- Are case examiner decisions supported by reasons in a way that enables an external reviewer to understand why a decision was reached?
- What is the nature of the reasons recorded and are they supported by evidence?
- How often, and in what circumstances, does the following occur: the guidance on criteria and thresholds suggests that an allegation should be taken as serious, suggesting impairment, but the case examiners decide not to refer the case because they regard the allegation as insufficiently serious (rather than unsupported by evidence)?
- Where this happens, is the exception justified by the case examiners in terms of the guidance?

⁵ This test guides case examiners in making decisions about whether to refer a case to a FTTP. See http://www.gmc-uk.org/concerns/the_investigation_process/The_Realistic_Prospect_Test.pdf

C.3 Methods

The GMC provided a list of all 57 cases that completed the case examiner decision stage in November and December 2006. We started by looking at a small number of the cases to familiarise ourselves with the case records and to determine how best to carry out the audit. Following this preliminary review, and after discussion with the GMC, it became clear that a broad cross section of cases was required to address the questions about case examiners using their discretion not to refer to a fitness to practise panel (FTPP) cases with serious allegations that are supported by evidence. We decided therefore to include in the audit all 57 cases on the list provided by the GMC.

Information from Siebel on each case was copied directly into a data sheet and anonymised. Data collected on each case included:

- GMC case number
- Allegations (by GMC category)
- Case examiner decision
- Text of referral information (case summary)
- Text of decision reasoning
- Any other relevant information to clarify the case examiners' decision

We familiarised ourselves with the 57 cases, focusing particularly on the case examiners' records of their decision reasoning. Any cases that we found complex or difficult to understand, or which appeared anomalous, were discussed with other team members. For some cases 'key documents' were accessed, but generally there was sufficient information recorded in 'referral information' and 'decision reasoning' for us to get a full picture. The data were classified and interrogated in various ways (described below) in order to address the audit questions.

We also interviewed the Fitness to Practise Directorate's Head of Investigation and four case examiners, two lay and two medical, based in London and Manchester. In the interviews we explored their views about the decision making process and the factors that influence decisions about impaired fitness to practise.

C.4 Case examiner decisions

The distribution of case examiner decisions is shown in Table C1. In 50 (88%) of the cases, the case examiners had decided there was no impaired fitness to practise and these cases had been closed. Seven cases (12%) had been referred. We understand that the distribution of case examiner decisions in the audit sample is broadly consistent with GMC statistics: we were told that about 80% of Stream 1 cases are closed at the case examiner decision stage.

Table C1: Case examiner decisions in Stream 1 cases						
	Case examiner decision					
	Close	Close with advice	Close with warning	Under-takings	FTPP	Total
Cases No (%)	39 (68)	8 (14)	3 (5)	2 (3)	5 (9)	57 (100)

More details of the audit sample are provided in Appendix III. These show the relationship between the allegations in each case and the case examiners’ decision. We have also indicated the cases that are related in various ways. The audit sample appears to reflect the breadth of Stream 1 cases and does not contain any large clusters of related cases, which could have skewed the distribution of case examiner decisions.

C.5 Transparency of case examiner decision reasoning

We found it straightforward to use Siebel to explore the reasoning behind case examiner decisions. Drilling down on the decision and reading the information recorded by the investigation manager in ‘referral information’ and by the case examiners in ‘decision reasoning’, gave us access to a summary of the case, the nature of the evidence, the findings in relation to allegations, how evidence had been interpreted and the reasoning behind the decisions that had been made.

In all cases there was a clear statement of the case examiners’ decision, supported by reference to evidence that had been gathered during the investigation.

The detail given in the decision reasoning was variable. Cases with multiple allegations, and in particular clinical care cases, tended to have very detailed and well presented decision reasoning, possibly because of the nature of the allegations and the types of evidence that had to be considered (such as information from medical records and expert reports). In the majority of cases with multiple allegations, each allegation was addressed separately in the decision reasoning. In all cases there was a summary of the evidence and the case examiners’ findings.

A few cases had as little as one or two short paragraphs of decision reasoning, stating, for example, the nature of the evidence (or lack of it) and that the realistic prospect test was not met. However, we consider the reasoning in these cases was appropriately brief. For example, in case C22, an allegation of assault that had been investigated by the police and the employing trust but did not proceed to action because there was insufficient evidence, the case examiners conclude that ‘the allegation does not meet the realistic prospect test and ... the case should therefore be

closed'. It was not only closed cases that had brief decision reasoning: decisions on two cases that resulted in undertakings were also presented without embellishment.

In some cases, we could not fully understand why a decision had been reached from the decision reasoning alone and further information had to be sought from elsewhere in the Siebel record. These cases were few, and had in common that 'something else was going on': the doctor had a history of previous GMC investigations; there were concurrent open cases; or the doctor's employer had expressed concerns about fitness to practise.

For example, case C21 concerned a GP's management of a patient who had an ectopic pregnancy. The case had been referred to a FTTP, a decision that appeared to be unusually harsh for a single clinical incident. However, the case summary revealed that the doctor had three previous GMC investigations that had been closed without action, and the employing PCT had expressed concerns about the standard of care provided. This information indicated that this case, rather than being treated as a single serious clinical incident, was being viewed by the case examiners as evidence of persistent error. We were told that information unrelated to the current case is not routinely included in the decision reasoning because this text is used in the letter that communicates the decision to the complainant and the doctor.

Initially we also found case C1 confusing. This case had arisen from a newspaper report about a doctor who had been acquitted of assault. The reason for closing the case was given as insufficient evidence. Although it seems the doctor had at some point admitted the assault, the victim would not make a complaint, the police were uncooperative and, in the case examiners' words, 'the incident had been tested in open court and found insufficient for a conviction'. However, the context of this case was that it had been opened very shortly before the doctor appeared before a FTTP for a separate incident, at which he accepted undertakings, and this seemed to have influenced the case examiners' decision. The case record also indicated that the case examiners felt that nothing would have been gained by pursuing another, possibly difficult, case:

'there appears little benefit in referring (the doctor) to a FTTP for an early review hearing, however we will need to bear in mind the need to be rigorous in our monitoring of the doctor.'

There was nothing in the case examiners' decision reasoning that enabled us to make the connection between the cases in two clusters identified as having the same complainant and being about the same episode of treatment, but concerning different doctors (see Appendix II). In cases C20, C33 and C34 different allegations had been made about the doctors, and in cases C19 and C31 the allegations were the same. We made these connections from the complainant's name and the case summaries describing the events.

However, in cases that were linked to other concurrent cases about the same doctor, we were able to track the relationship between cases from the decision reasoning. For example, cases C14 and C54 concerned the same plastic surgeon in private practice, who had been suspended by the Interim Orders Panel, but had continued to carry out some cosmetic procedures not requiring full registration. Case C14 had been closed;

case C54 had been referred to FTTP. The decision reasoning in case C14 mentioned other linked cases:

‘(doctor) is currently suspended by the IOP and faces a fitness to practise panel hearing in due course in relation to a number of serious allegations about his private clinics.’

The decision reasoning in case C54 also mentions other cases not included in the audit sample.

C.6 Cases with serious allegations, supported by evidence but not referred

To explore whether the seriousness of allegations was being taken into account appropriately by case examiners, all case examiner decisions were analysed in relation to the allegations made and the GMC guidance for case examiners.

Presumption of impaired fitness to practise

The GMC guidance for case examiners specifies that some types of allegation (sexual assault or indecency; violence; improper sexual/emotional relationships) if proven, amount to such a serious failure to meet professional standards that there is a presumption of impaired fitness to practise and an expectation that the case would be referred to a FTTP, ‘unless there are exceptional reasons for not doing so’. Six cases in the audit sample had allegations falling into these categories, as shown in Table C2.

Table C2: Cases in which there is a presumption of impaired fitness to practise	
Allegations	Case number
Violence	C1, C22
Sexual assault/indecency	C25, C57
Improper relationship	C13, C50

All these cases had been closed, except C57 which had been referred to FTTP. In this case, a doctor was alleged to have carried out a breast examination, possibly unnecessarily, and without allowing the patient privacy or providing a chaperone. The allegations had been recorded as ‘respect for patients - dignity’, but the case examiners’ assessment of the evidence led them to question the doctor’s motives and treat the complaint more seriously, as a possible sexual assault.

The other five cases had been closed because they failed the realistic prospect test; typically the alleged victim or witnesses would not cooperate with the investigation to

provide evidence. Thus we found no cases with allegations supported by evidence, in which there would be a presumption of impaired fitness to practise, that case examiners had considered insufficiently serious to refer to panel.

Presumption that the GMC will take action

The GMC guidance instructs case examiners to take seriously all allegations of dishonesty, and in cases in which the doctor's dishonesty puts patients at risk or is likely to undermine public confidence in doctors generally there should be a presumption of impaired fitness to practise. However, in more minor cases of dishonesty unrelated to professional practice, 'taking action on a doctor's registration is unlikely to be a proportionate response'. Nevertheless, all proven or admitted allegations of dishonesty 'warrant some action by the GMC' and the guidance suggests that in less serious cases the most appropriate response is a warning.

The sample included 12 cases with allegations of dishonesty: C5, C15, C28, C29, C35, C43, C45, C51, C52, C53, C54, and C55 (see Appendix III, 'probity' row in table). Of these, six cases had been closed because the allegations were unsupported by evidence. One (C15) had been closed with advice. In this case the PCT had referred the doctor with allegations of financial fraud, misreporting and poor clinical competence, but subsequently did not provide sufficient evidence to progress the case.

Two cases (C5, C29) had been closed with warnings. We identified these two as falling into the category of allegations supported by evidence, but considered by case examiners to be insufficiently serious to refer to FTTP. In case C5, the doctor had signed a form confirming pregnancy without examining the patient, who was not pregnant and had fraudulently claimed maternity pay. In case C29, the doctor had been caught cheating in a professional examination by opening the paper before the exam had started. In both cases there was unequivocal evidence to support the allegation of dishonesty. The case examiners' decision reasoning in case C5 took into account both the doctor's intention and the issue of proportionality. In case C29 the case examiner wrote:

'... the nature of the misconduct would not, of itself, be serious enough to warrant consideration of restricting or removing the doctor's registration. ... the case examiners concluded that (doctor)'s actions require a formal response and that a warning would be appropriate ...'

The decision reasoning and the decision to issue a warning in these two cases indicate that the case examiners followed GMC guidance. In case C5 the doctor accepted the warning, but in case C29 the doctor exercised the right to an oral hearing and the Investigation Committee did not uphold the warning.

The other three dishonesty cases had been referred. Case C55 concerned a doctor who had not disclosed a health problem when applying for a job. The undertakings issued included notifying prospective employers of his illness. The final two cases had been referred to FTTP, with allegations of financial fraud (case C53) and multiple allegations of poor clinical care, lack of respect for patients, and the doctor's failure to inform the patient that he was suspended from the medical register (case C54, which was linked to other cases).

In sum, we found that case examiners had exercised discretion in cases of dishonesty in a way that was entirely consistent with GMC guidance.

Serious or persistent failures

The GMC also offers guidance to case examiners on interpreting ‘serious or persistent failures’ to meet the standards in *Good Medical Practice*. The guidance implies that case examiners should consider as separate issues the seriousness of the failure and whether or not it is part of a pattern of behaviour. Evidence of persistent failure is likely to raise questions about a doctor’s fitness to practise, but isolated serious incidents or lapses in behaviour are recognised as being more difficult to assess. Separate guidance has been provided for case examiners on cases involving single clinical incidents.

Our impression from reading the case information was that case examiners routinely sought to assess whether a deficiency in a doctor’s practice or behaviour was serious and whether it was part of a pattern of behaviour. To explore this further we analysed the ‘clinical care’ cases in the sample (first row in table, Appendix III).

Thirty four cases had allegations of substandard clinical care, of which four cases had been referred to FTTP. Two of these had evidence of repeated failure to meet standards: case C54, which, as noted earlier, was linked to a number of other concurrent cases, and case C21, in which the doctor had been investigated previously by the GMC. The other two cases were single clinical incidents that the case examiners considered sufficiently serious to refer. Case C56 was a complaint from a patient about complications of eye surgery. The GMC sought an expert opinion on the case, which found that the surgeon’s practice had been ‘seriously deficient’. Case C57 was the inappropriate breast examination referred to earlier. The case examiners’ view was that ‘the seriousness of this complaint turns on (doctor)’s motivation for conducting the breast examination in the way he did’. They felt unable to resolve the conflict of evidence between doctor and patient, but had ‘sufficient doubts’ that the case was referred. At the time of writing the panel hearings had not taken place, so the outcomes of these cases were not known.

The case examiners had decided to issue a warning in only one case (C30). This case stimulated much discussion within our team. It concerned what amounted to a single clinical incident, previously investigated locally, in which there was strong evidence that the doctor made a serious clinical error by misinterpreting blood test results and failing to examine a patient who subsequently died of septicaemia. In contrast to case C56, in which expert opinion was crucial evidence, in this case the doctor was a GP and no expert opinion was sought. We were told that it is usual practice for case examiners who are GPs to rely on their own experience when assessing clinical care cases where the doctor is a GP, but to seek expert opinion on cases concerning specialised treatment. We consider this is another example of a case in which there was evidence to support the allegation of substandard clinical care, but the case examiners exercised discretion and decided it did not imply the doctor’s fitness to practise was impaired.

The evidence was laid out very clearly in the decision reasoning and the case examiners concluded that it showed that the doctor had made a ‘significant clinical error’. They argued that the doctor’s initial approach to treating the patient had been correct, as had been arranging X-rays and blood tests, but ‘if (doctor) had then considered the results of these investigations properly doubtless (doctor) would have followed a different course of treatment’. Their conclusion was:

‘Comments from (doctor)’s employers indicate that there are no general concerns about his practice and in studying (patient)’s medical notes it appears that the doctor has provided excellent care to her in the past. He has recognised that his language at the consultation was inappropriate and has apologised and there is no indication that the doctor’s manner was unusually rude. It would appear that (patient) developed an aggressive infection which progressed very quickly and although it is clear that the doctor did make a serious clinical error in failing to act on the results of the blood tests and to consider an alternative diagnosis when (patient)’s condition deteriorated it is by no means certain that admission to hospital on either 29th September or earlier on 30th September would have resulted in a different outcome. The case examiners agree that there has been a breach of ‘Good Medical Practice’ by (doctor), in that he failed to provide good clinical care to his patient which resulted in a delay in her treatment and prolonged her suffering. We therefore consider that a formal warning is appropriate in this case.’

The doctor in this case requested an oral hearing and the decision to issue a warning was not upheld by the Investigation Committee. We return to this below.

The remaining cases were closed because there was insufficient evidence to support the allegations. In many of these cases the patient had died or had suffered a seriously adverse outcome of treatment. A substantial group of cases had allegations of missed or delayed diagnosis of cancer (C8, C19, C31, C39, C40, C44, C47, C48 and C49). Typically, there may have been failure to meet standards, but no evidence of impaired fitness to practise was found. In a number of cases, poor communication with patient or colleagues was identified, and in four of the seven cases that had been closed with advice, the advice related to improving communication.

C.7 Case examiner decisions to issue a warning

In three cases in the audit sample the case examiners had decided to issue a warning. These were case C30 (described above) and the two cases in which there was evidence of dishonesty (C5 and C29, described on page 32). Looking further into these cases, we discovered that one doctor had accepted the warning (he had retired from practice before the GMC investigation took place). The other two doctors had not accepted the warning, and in neither of these cases was the case examiner decision upheld by the Investigation Committee. Both these rulings raised questions for us, since the Investigation Committee is expected to use the same guidance and criteria as case examiners when making decisions. However, the Committee may be provided with additional information to consider and under GMC rules reaches its own decision on the basis of the evidence collected during the investigation and representations made at the oral hearing. In case C30, our understanding was that the case examiners were making a decision between referring to FTTP and issuing a warning; as a

'borderline' case, with evidence that the doctor had made a serious clinical error, it seemed to us inappropriate that it was closed without any action by the GMC. In the case of proven dishonesty (C29), our assessment was that the case examiners had followed both the spirit and the letter of GMC guidance: this was a case in which there was a 'presumption that the GMC will take action' and they had appropriately issued a warning.

In our interviews with case examiners, several of them mentioned doctors not accepting warnings. One commented:

'This issue of doctors not accepting warnings is a bit of a thorny issue at the moment. The forum for resolving these disputes is the Investigation Committee and we always look very closely at whether the Investigation Committee has decided to uphold the case examiners' recommendation to give a warning or not. There is a little bit of concern as to whether they take all the issues that we've taken account of because we have given it an awful lot of thought, work, to try to make sure we are suggesting an appropriate sanction.'

C.8 Change in GMC procedures relating to single clinical incidents

The interviews with investigation managers and case examiners drew our attention to a change of procedure relating to 'single clinical incidents'. We were told that since late 2006 more of these cases had been directed to Stream 2 (local procedures), rather than to Stream 1, so that the Trust can investigate first and alert the GMC if there are any concerns about the doctor's fitness to practise. In the interviews, some case examiners expressed concern about not directly investigating cases involving single clinical incidents where there has been a serious adverse outcome for the patient. They were anxious that by passing these cases to Trusts to investigate the GMC might miss opportunities to identify doctors whose fitness to practise is impaired. As one commented:

'... I think you sometimes don't know until you dig a little bit deeper. So if you didn't investigate it and get the notes you wouldn't ascertain that they have covered something up or there is something more worrying going on. If you have got a clinical incident that results in death or adverse outcome for a patient it must warrant looking at whether the doctor's fitness to practise is affected or is worthy of concern.Sometimes it's a system failure ... or everyone's been in the wrong place at the wrong time ... and there is often a whole myriad of reasons why things have gone wrong. But in amongst them there will be a few where there is actually something seriously wrong because the doctor didn't know what he was doing.'

Another said:

'My view is that they should be in stream 1. We've got a responsibility to make sure the reputation of the profession is kept as it should be and also the

GMC's reputation as well. And we have had a lot of flack for not investigating cases properly in the past. If we were to say that we were not going to treat these certain types of cases that involve the worst possible outcome for the patient, I think it would undermine some of the work we have done up to now. Is the use of the case examiner a bit of a sledge hammer to crack a nut in these sort of cases if we are not going to refer them? ... I think in some cases it is appropriate to refer to a panel. It's really down to our judgement to make sure that we are doing our job properly and we make the appropriate decisions in the appropriate cases. I think there is a bit of a risk if we were to hive off these types of cases and close them down. If the public were aware that we were treating those cases 'less seriously', I think it might undermine confidence as well.'

These concerns prompted us to examine the audit sample (which came from the period before this change was introduced) to see which cases would no longer be in Stream 1 under the new arrangements and whether the GMC would have missed any cases in which fitness to practise issues were found.

The investigation history of the 34 cases in the audit sample with allegations of substandard clinical care is shown in Table C3.

Table C3: Investigation history of Stream 1 cases with allegations of substandard clinical care					
Investigation history		Case examiners' decision			
		Close	Close with advice	Close with warning	FTPP
Case not investigated previously*		9, 12, 19 (& 31), 23, 26, 33 (& 34), 38, 40, 41, 47 (& 48), 49	8, 10, 39, 44		
Case investigated previously**	findings critical of doctor	4, 16, 18, 52	15, 32, 36,	30	21, 57
	findings not critical of doctor	11, 17			
Doctor in private practice		3, 14			54, 56
Total number of cases = 34 * Case not previously investigated, but the GMC may have comments from employers ** Previous investigations may have been undertaken by local NHS Trust, Healthcare Commission or Health Service Ombudsman					

All the cases that had not been investigated locally were closed by case examiners. Two cases had been investigated previously by the Trust or by another body and the investigation had not resulted in any criticism of the doctor. These cases were both

closed by the case examiners. Case examiner decisions were more varied in the cases in which a previous investigation had been critical of the doctor. Two of these cases were referred to FPHP. Under the new procedure all these cases would still be directed to Stream 1 and investigated by the GMC. The four cases that concerned doctors in private practice would also be investigated by the GMC. These findings show that by applying the new procedure to the audit sample the GMC would not have missed any cases in which the doctor's fitness to practise was found to be impaired. In addition, the number of 'clinical care' cases investigated by the GMC would have been more than halved.

C.9 Summary

Transparency of decision reasoning

All the Stream 1 cases reviewed had a clear statement of the case examiner decision and an explanation of why the decision had been reached that was easy for an external, non-specialist reviewer to understand. Case examiner decisions made reference to the context of the case and were supported by the evidence available. Allegations were often addressed separately and systematically and arguments were clearly laid out. Although the text varied greatly in length, the detail provided was considered to be appropriate.

In a few cases the decision reasoning text did not include key information that was needed to understand why a decision had been reached. For example, we found several cases in which the case examiner decisions made sense only in the light of the doctor's history of GMC investigations, concerns raised by the doctor's employer, or knowing that there were concurrent open cases. This information was recorded elsewhere in the case record. We recognise that there is a tension between achieving complete transparency in decision making and protecting the confidentiality of those involved in a case.

Case examiner discretion

The audit explored the question of whether case examiners were following GMC guidance on making decisions about a doctor's fitness to practise. In particular, cases were scrutinised to see whether they were downplaying the seriousness of proven allegations that imply impairment. In cases supported by evidence in which there is a presumption of impaired fitness to practise or that the GMC will take action, case examiners were found to be following GMC guidance appropriately. Guidance is also provided to case examiners on making judgments in cases that involve serious or persistent failure to meet the standards in *Good Medical Practice*. Decisions in these cases are necessarily complex, but by exploring cases with allegations of substandard clinical care we found that case examiners appeared to be following GMC guidance in assessing the gravity of these cases. However, it is interesting to note that the only 'single clinical incident' that was referred to a FPHP was supported by evidence from an independent expert that the doctor's practice had been 'seriously deficient'.

Warnings

Case examiners had decided to issue a warning in three cases in the audit sample. Two doctors did not accept the warning and in both cases the Investigation Committee did not uphold the case examiner decision. Our view was that the case examiners had followed both the spirit and the letter of GMC guidance and made appropriate decisions in these cases. We recognise that the Investigation Committee may receive additional information to consider at the oral hearing, and GMC rules envisage that it may reach a different decision from case examiners. Nevertheless, our findings raise questions about consistency in interpreting guidance on appropriate sanctions in fitness to practise cases.

Direction of cases involving single clinical incidents

The GMC now directs cases involving single clinical incidents to Stream 2, unless they have been previously investigated locally or there are other concerns about the doctor's fitness to practise. A review of cases in the audit sample with allegations of substandard clinical care found that by applying the new procedure to these cases the GMC would not have missed any cases in which case examiners had found evidence of impaired fitness to practise. In addition, the new procedure would have more than halved the number of 'clinical care' cases investigated by the GMC.

Conclusions

The audit findings demonstrate that at key decision points in the GMC's fitness to practise procedures, cases are generally handled in a way that is transparent, consistent and appropriate in terms of the guidance and criteria provided by the GMC. The 'triage script' for initial assessment of enquiries is highly structured; it is clear and easy to apply; and investigation managers followed it with a high degree of consistency and directed cases appropriately. Procedures for dealing with Stream 2 (local procedures) cases are clearly defined by the GMC, but do not fit well with how complaints are handled locally, and it was often some months before the GMC was able to close cases. Case examiner decision reasoning in Stream 1 cases was recorded fully and clearly, with reference to the evidence and the context of the case, in a way that enabled an external reviewer to understand why the decision had been reached. We found no indication that case examiners were downplaying the seriousness of proven allegations that imply a doctor's fitness to practise is impaired. In cases that required case examiners to exercise discretion they did so in accordance with GMC criteria.

Impact of changed procedures

In late 2006 the GMC introduced some changes to fitness to practise procedures. The audit samples predated these changes, but we were able to use them to assess the likely impact of three procedural changes. Our analysis indicated that the changes are appropriate and safe. They are likely to improve the efficiency of the GMC's fitness to practise procedures, in particular by reducing the volume of cases in Streams 1 and 2, with minimal risk in terms of missing fitness to practise issues.

At triage, enquiries previously directed to Stream 2 (local procedures) are now closed if they have already been investigated by the local Trust and the findings raised no concerns about the doctor's performance. Almost a quarter of cases in the Stream 2 audit sample fell into this category. However, in the triage audit, we found it was sometimes difficult to ascertain whether the complainant had used local complaints procedures and, if so, what stage had been reached. Reduction in the volume of Stream 2 cases will depend on obtaining reliable information from the complainant at initial assessment.

Stream 2 (local procedures) cases may now be closed if the employing Trust confirms there are no immediate concerns about the doctor's fitness to practise and has agreed to investigate the complaint and inform the GMC of the findings. Our analysis showed that this approach should enable Stream 2 cases to be closed much earlier. However, to operate this procedure effectively, the GMC needs to communicate its requirements clearly to Trusts, so that the Trust officer responsible for dealing with the complaint can ensure the GMC receives appropriate and timely information. Even by streamlining procedures in this way, the audit findings suggest that it may be unrealistic to expect that a high proportion of cases could be closed within the eight week target. Moreover, it seems inappropriate to set a performance target for completing this part of the process, since it depends in large part on action by individuals in organisations outside GMC control.

More cases involving ‘single clinical incidents’, including those resulting in the death of the patient or other adverse outcomes, are now being directed to Stream 2 (local procedures) rather than to Stream 1, except where there are concerns about the doctor’s fitness to practise. Applying this approach to the sample of Stream 1 cases, we found that the GMC would not have missed any cases in which the case examiners judged there was evidence of impaired fitness to practice. In addition, the number of ‘clinical care’ cases investigated by the GMC would be substantially reduced. However, some of the case examiners we interviewed expressed reservations about not investigating cases of this type. They felt that only by investigating a case could they be reassured about the doctor’s fitness to practise. It was also suggested that there may be a risk of undermining public confidence in the GMC if it was known that cases of this type were not investigated.

Issues raised by the audit

- In the audit of triage decisions, there was one exception to complete agreement between King’s and GMC decisions on enquiry direction. We return to this not only because it was a notable disagreement, but also because the way this enquiry was handled represents a significant departure from GMC procedures. The fact that the case remained closed after being identified by the GMC audit team was also puzzling. Without knowing more details about the enquiry and any internal discussion of the decision, it remains an unexplained anomaly.
- Carrying out initial assessment of enquiries alerted us to the possibility that the way in which complaints are presented may influence whether cases are taken up by the GMC. It was also apparent that some members of the public approach the GMC expecting support for or action on complaints that it is not the GMC’s role to provide.
- Our exploration of Stream 2 (local procedures) cases raised questions about why it took so long to close these cases. Correspondence between Trusts and the GMC threw some light on why cases went into ‘limbo’ for substantial periods of time and Trusts took months rather than weeks to respond with their findings. Local complaints procedures rightly give high priority to satisfying the complainant, which may be a lengthy process. Resolving the complaint is often equated with satisfying the complainant. Thus, a Trust may not be able to confirm that the process is complete and a complaint has been resolved except with hindsight, when it is clear that the complainant has ceased to pursue their complaint. The new approach to closing Stream 2 cases should overcome this problem.
- Our analysis of stream 1 cases with allegations of substandard clinical care highlighted that the only case in this group involving a single clinical incident that was referred to a FTPP had been supported by evidence from an independent expert. Another case involving a single clinical incident, in which the case examiners found a GP had made ‘a significant clinical error’, was not referred: the case examiners decided that a warning was the appropriate response. Comparison with the previous case led us to question when case

examiners consider it necessary to seek an independent opinion on a doctor's performance and how this might influence the outcome of cases.

- Case examiners had decided to issue warnings in three cases in the sample. In our view these decisions were consistent with GMC guidance. Two doctors did not accept the warning and in both cases the Investigation Committee did not uphold the case examiners' decision. The Investigation Committee may be presented with more information than was available to the case examiners, and the GMC's rules envisage that the Investigation Committee may reach a different decision. Nevertheless, these findings raise questions about consistency in interpreting guidance on appropriate sanctions in fitness to practise cases.

Appendix I: Audit sampling procedures

Section A: Initial assessment decisions

The GMC provided Excel spreadsheets with the ID numbers of all enquiries received from May to September 2006 (inclusive), filed according to the initial assessment decision.

Enquiries received by the GMC May-Sept 2006		
Initial assessment decision	Number of enquiries	Audit sample
Closed at triage	774	17
Promoted to stream 1	581	17
Promoted to stream 2 (local procedures)	342	17
Promoted to stream 2 (GMC)	41	
Referred to other organisations	57	-
Unregistered doctor	7	-
Total	1802	51

Enquiries that were referred to other organisations or related to an unregistered doctor were excluded from the audit. An independent member of staff at King's College London created three lists of ID enquiry numbers (closed at triage; promoted to stream 1; promoted to stream 2 (local procedures and GMC combined)) and from each list selected a sample of 17 enquiries using a random number generator. (<http://www.randomnumbergenerator.com>) The three lists of 17 enquiry ID numbers were combined and resorted by ID number (effectively mixing the three sub-samples) and given to the audit team.

Section B: Stream 2 (local procedures) cases

The GMC provided a list of the ID numbers of all 268 Stream 2 cases opened from April to July 2006 (inclusive). Of these, 44 were Stream 2 (GMC) cases and these were excluded from the audit. From the 224 Stream 2 (local procedures) cases, an independent member of staff at King's College London drew a random sample of 30 cases using a random number generator (as above). A list of the ID numbers of these 30 cases was given to the King's audit team.

Appendix II: Summary data for Stream 2 (local procedures) cases

King's audit sample number	Time to closure (in weeks) + = those still open at 1.3.07	Meets 8 week target	Time to employer informed (in weeks)	Time with Trust (in weeks)	Time to employer responding with words 'no immediate concerns'
B1	17		1	16	2
B2	10		2	8	7
B3	10		2	8	9
B4	44+		2	42+	11
B5	14		6	8	14
B6	9		3	6	6
B7	6	√	Failed PIT		N/A
B8	17		2	15	2
B9	28		4	24	13
B10	18		3	15	3
B11	13		9	4	12
B12	38		2	36	3
B13	9		5	4	6
B14	16		8	8	8
B15	36		7	29	18
B16	30		4	26	6
B17	2	√			N/A Opened in error, duplicate
B18	38+		3	35+	7
B19	32		3	29	4
B20	37+		4	33+	N/A Fraud investigation currently underway
B21	2	√	Failed PIT		N/A
B22	6	√	3	3	4
B23	36+		4	32+	5
B24	21		7	14	21
B25	6	√	2	4	3
B26	3	√	Failed PIT		N/A
B27	15		5	10	7
B28	11		2	9	9
B29	6	√	3	3	4
B30	34+		3	29+	4

Appendix III: Stream 1 cases - allegations and case examiner decisions

Allegations ⁶	Case examiner decision				
	Close	Close with advice	Close with warning	Undertakings	FTPP
Good clinical care	3, 4, 9, 11, 12, 14**, 16, 17, 18, 19****, 23, 26, 31****, 33*, 34*, 38, 40, 41, 47***, 48***, 49, 52	8, 10, 15, 32, 36, 39, 44	30		21, 54**, 56, 57
Maintaining good medical practice		32			
Teaching and training	46				
Relationships with patients	9, 12, 13, 16, 18, 20*, 24, 25, 27, 33*, 34*, 47***, 48***,	8, 10, 39	30		21, 54**, 56, 57
Working with colleagues	6, 7, 19****, 26, 31****, 41	42			53
Probity	1, 22, 25, 28, 35, 43, 45, 50, 51, 52	15	5, 29	55	53, 54**
Health	37			2, 55	

Recording conventions

- Cases are numbered 1 to 57. A case number may appear more than once in the table if there are allegations in more than one category (for example, case 39 has allegations under clinical care *and* relationships with patients, so appears twice in the ‘close with advice’ decision column)
- A case may have several allegations in the same category (for example, case 2 has three allegations under health). These allegations are recorded only once (so case 2 is entered once into the table under ‘health’)
- Related cases. A number of cases are related in various ways. Four groups of cases have been linked using asterisks that indicate the following:
 - * These cases are related in that they have the same complainant but they concern different doctors, with different allegations and different decision reasoning, although they have the same outcomes (cases 20, 33 and 34).
 - ** These cases are related in that they have different complainants, but are about the same doctor, with different allegations, different decision reasoning and different outcomes (cases 14 and 54).
 - *** These cases have the same complainant, but are about different doctors, with the same allegations, decision reasoning and outcomes (cases 47 and 48).

⁶ These are based on *Good Medical Practice* (2006), paragraph 1 of which sets out the criteria for a good doctor.