BMJ Open

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom

Journal:	BMJ Open
Manuscript ID:	bmjopen-2014-006687
Article Type:	Research
Date Submitted by the Author:	19-Sep-2014
Complete List of Authors:	Bourne, Tom; Imperial College London, Queen Charlottes and Chelsea Hospital Wynants, Laure; KU Leuven, Department of Electrical Engineering-ESAT Peters, Michael; British Medical Association, Doctors for Doctors Unit Audenhove, Chantal; KU Leuven, LUCAS Timmerman, Dirk; KU Leuven, Development and Regeneration Van Calster, Ben; KU Leuven, Development and Regeneration Jalmbrant, Maria; South London and Maudsley NHS Foundation Trust,
Primary Subject Heading :	Health policy
Secondary Subject Heading:	Mental health, Occupational and environmental medicine, Legal and forensic medicine
Keywords:	Anxiety disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Suicide & self-harm < PSYCHIATRY, OCCUPATIONAL & INDUSTRIAL MEDICINE, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT

SCHOLARONE™ Manuscripts

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom

Tom Bourne adjunct professor of gynaecology and consultant gynaecologist^{1,6,7}, Laure Wynants researcher in medical statistics^{2,3}, Mike Peters head of BMA Doctors for Doctors Unit ⁴, Chantal Van Audenhove professor of psychology and applied communication⁵, Dirk Timmerman professor of obstetrics and gynaecology^{6,7}, Ben van Calster professor of medical statistics⁶, Maria Jalmbrant clinical psychologist⁸

Corresponding author: Professor Tom Bourne Queen Charlotte's & Chelsea Hospital Imperial College London tbourne@imperial.ac.uk

Key words: anxiety, depression, suicide, physicians, regulation

Word count 5634

¹Queen Charlotte's & Chelsea Hospital, Imperial College, Du Cane Road, London, W12 0HS, UK

²KU Leuven Department of Electrical Engineering-ESAT, STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, Leuven, Belgium

³KU Leuven iMinds Future Health Department, Leuven, Belgium

⁴ Doctors for Doctors, British Medical Association, BMA House, Tavistock Square, London, UK

⁵LUCAS, KU Leuven, Leuven, Belgium

⁶KU Leuven Department of Development and Regeneration, Leuven, Belgium

⁷Department of Obstetrics and Gynaecology, University Hospitals Leuven, Leuven, Belgium

⁸South London and Maudsley NHS Foundation Trust, Denmark Hill, London, UK

 IMPACT study

Abstract

Objectives: the primary aim was to investigate the impact of complaints on the psychological welfare and health of doctors. The secondary aim was to assess whether doctors report exposure to a complaints process is associated with defensive medical practice.

Design: cross-sectional anonymous survey study. Participants were stratified into recent/current, past, or no complaints. Each group completed tailored versions of the survey.

Participants: 95,636 doctors were invited to participate. 10,930 (11.4%) responded. 7,926 (8.3%) completed the full survey and were included in the complete analysis.

Main outcome measures: anxiety and depression were assessed using the standardised Generalised Anxiety Disorder scale and Physical Health Questionnaire. Defensive medical practice was measured using a new measure. Single-item questions measured stress-related illnesses, complaints-related experience, attitudes towards complaints, and views on improving complaints processes.

Results: 16.9% of doctors with current/recent complaints reported moderate/severe depression (relative risk (RR) 1.77 (1.48, 21.3) compared to doctors with no complaints). 15% reported moderate/severe anxiety (RR= 2.08, 95% CI=1.61, 2.68). Distress increased with complaint severity, with highest levels after General Medical Council (GMC) referral (26.3% depression, 22.3% anxiety). Doctors with current/recent complaints were 2.08 (1.61,2.68) times more likely to report thoughts of self-harm or suicidal ideation. Most doctors reported defensive medical practice: 82-89% hedging and 46-50% avoidance. 20% reported feeling victimized after whistleblowing, 38% feeling bullied. 27% spent more than a month off work. Over 80% felt processes would improve with transparency, managerial competence, capacity to claim for lost earnings and act against vexatious complainants.

Conclusions: doctors with recent/current complaints have significant risks of moderate/severe depression, anxiety, and suicidal ideation. Morbidity was greatest in cases involving the GMC. Most doctors reported practicing defensively including avoidance of procedures and high-risk patients. Many felt victimised as whistle-blowers or bullied in relation to complaints. Factors cited to improve complaints processes included transparency and managerial competence.

Strengths and limitations of this study

Strengths

- One of the largest reported on this subject with 10,930 respondents and 7,926 completing the survey
- Respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions.

 We have obtained quantitative data on mental wellbeing using validated questionnaires.

Limitations

- The main limitation of the study was the overall response rate of 11.4%.
 Accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. On the other hand doctors were being asked to comment on their regulators, and those most traumatised by the complaints process may have avoided engaging with the survey. Doctors who have been erased from the register or changed profession would not have been contacted.
- The cross-sectional design does not enable causation to be elucidated
- We collected responses from doctors who have not experienced a complaint but observed the impact on others. This means that the "no complaints" group may have more psychological morbidity than if doctors could be isolated from complaints processes completely. This may result in relative risks in the paper being underestimated.
- Some questions involved remembering past events and the possibility of recall bias must also be considered.
- There were missing responses for a number of questions. However this was
 dealt with using multiple imputation. However we are reassured that no major
 differences between the conclusions that would be drawn using complete
 cases compared to those where data was missing and imputed were found.

Introduction

It was recently disclosed that 96 doctors have died since 2004 while involved in General Medical Council (GMC) fitness to practice proceedings, information that came to light following a freedom of information request by the group doctors4justice. In parallel to this, between 2011 and 2012 the number of doctors referred to the GMC increased by 18%¹. Most doctors referred to the GMC have their case closed at triage or have no action taken². In a recent article in the British Medical Journal (BMJ), Clare Dyer described some of the harrowing consequences for some doctors who have been through a GMC investigation³.

However the GMC represents only the tip of the iceberg in terms of the complaints system. These include both internal trust investigations, the possibility of a serious untoward incident (SUI) enquiry as well as disputes with managers and colleagues. Whilst there are some data relating to how doctors respond to GMC investigations, to our knowledge there are no studies addressing the issue of complaints procedures below this level. For many doctors, the prospect of facing a complaint or professional dispute causes them significant stress. This can manifest itself in how they perform in clinical practice and/or in their personal life, and may lead to both physical and psychological symptoms.

Clearly complaints and investigations when things go wrong are part of the checks and balances that should ensure appropriate oversight of a doctor's performance, the overall aim being to protect patients and maintain appropriate clinical standards. However the regulatory burden and stress associated with a complaints process may not lead to the outcomes that are desired.

In a previous study of surgeons surveyed in the United States (US), malpractice litigation was significantly associated with burnout, depression and suicidal ideation⁴. There are also data to suggest that medical errors are associated with burnout, depression and loss of empathy in the physician responsible⁵. None of these outcomes are likely to lead to improvements in patient care. A further study has shown suicidal ideation in over 6% of US surgeons, over twice the background rate in the population. In this study, burnout, depression, and involvement in a recent medical error were strongly and independently associated with suicidal ideation after controlling for other

personal and professional characteristics. Most surgeons in this study were reluctant to seek professional help due to concerns that there may be an impact on their career⁶.

In a study published in the BMJ, Jain and Ogden described the impact of patient complaints on general practitioners in the United Kingdom and reported an association with anger, depression and suicide⁷. It is also important to note they also described clinicians involved in complaints practicing medicine more defensively, losing confidence, offering a less appropriate service and planning to leave the profession. None of these outcomes can be considered likely to improve patient care and safety. It must be remembered that the GMC itself describes its core function as being to protect patients. So if the complaints system leads to doctors practicing overly defensive medicine, with avoidance of difficult cases and over-investigation of patients, then the entire process may lead to more harm than good in terms of patient care.

Aspects of the complaints process itself may also contribute stressors including the length of time an investigation may take and not knowing whether the case will progress. The adversarial nature of investigations and hearings is a further contributor together with a sense of isolation that many doctors feel. In addition there is uncertainty over the impact on the doctor's career and often a lack of knowledge of the process. This combination of factors may lead to physical and mental health problems. The GMC has acknowledged that there is stress associated with their procedures and commissioned the British Medical Association (BMA) Doctors for Doctors service to provide confidential emotional support to doctors going through fitness to practice proceedings.

The primary aim of this study was to investigate the psychological welfare of doctors who have observed or experienced both past and/or current complaints. The secondary aim of the study was to assess whether being involved in or witnessing a complaints process leads to doctors reporting that they practice medicine defensively.

Methods

Design

The study used a cross-sectional survey design where participants were streamed into three groups: current/recent complaint (on-going or resolved within the last 6 months), past complaint (resolved more than 6 months ago), and no complaints. Each group completed a slightly different version of the questionnaire. Participants in the current complaints and no complaints group were asked about their current mood and health whereas the past complaints group were also asked to respond about their mood and health at the time of the complaint.

Ethical approval was obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Participants

Members of the BMA in November 2012 who had pre-consented to being contacted for research purposes were invited to participate (n=95,636). They were emailed a link to an online encrypted questionnaire using Survey Monkey® and an information sheet describing the study. Participants were guaranteed that their responses were anonymous and untraceable. The survey remained open for two weeks and three reminders were sent out about the study during this time. A total of 10,930 (11.4%) participants responded to the survey. Of these, 696 (6.4%) were excluded as they only completed the demographics section, and 121 (1.1%) participants were excluded because a technical error meant that they were given the wrong sections to complete. A further 2187 (20.0%) participants completed the demographics section and indicated whether they had had a complaint and they were partially included in the analysis (sample 1). A total of 7926 (72.5%) participants completed the survey (sample 2). Of these, 1380 omitted some sections of the survey but were included in the full analysis. Demographic information in relation to both samples is shown in table 1.

In order to check that our sample was representative, we compared our study population with the total BMA membership database (see table 1). This showed that our sample was broadly representative in terms of gender (46.3% females in the BMA membership database compared to 47.5% females in both sample 1 and 2) and place of qualification (80.1% qualified in the United Kingdom in the BMA population compared to 80.7% in sample 1 and 81.2% in sample 2). Our study population consisted of more doctors in the 35-59 age range (49.8% in the BMA population compared to 74.8% in sample 1 and 73.4% in sample 2), ethnic minorities were under-represented (32.4% in the BMA population compared to 22.4% in sample 1 and 21.8% in sample 2), and consultants and GPs were over-represented (27.2% were consultants and 26% were GPs in the BMA population compared to 37.1% and 38.4% in sample 1 and 36.5% and 37.8% in sample 2) whilst junior doctors and retired doctors were underrepresented (26.4% were juniors and 8.6% were retired in the BMA population compared to 15.7% and 0.7% in sample 1 and 16.5% and 0.7% in sample 2).

Measures

A pilot of the questionnaire trialed on 20 medical doctors of varying grades and specialties and their feedback was incorporated in the questionnaire design (see details below).

Having completed 13 items obtaining demographic information (including age, specialty, gender, marital status, ethnicity, place of training, marital status, and details about their employment), participants were separated into three streams based on whether they had i) a current/recent complaint (within the past 6 months), ii) past complaint, or iii) no current or past complaints.

All participants completed the following sections (although some individual items varied in the different streams):

Experience of complaint: Participants in both complaints groups were asked 75 questions about their complaint(s) generated from Bark and colleagues⁸ and the pilot

study. This included their total number of complaints, the most significant complaint and followed by a series of questions about the most serious complaint if they had had more than one, including the reason for the complaint, the origin, the duration, the outcome, the cost (i.e. any leave taken, the estimated financial cost), and the level of support sought and obtained during the complaint. Participants who had been referred to the GMC were also asked to rate how stressful they found each aspect of the procedure. Whilst the majority of the questions used a 5-point scale, some questions were qualitative and a few were yes/no.

Attitudes towards complaints: All groups were asked ten questions using a 5-point scale generated from the pilot study about their attitudes toward complaints, the causes of complaints, and their perceived threat of future complaints. The no complaints group was asked 11 additional questions about their attitudes towards the complaints process (e.g., "I believe that complaints are reasonably dealt with") and how well they perceive that they would be supported in the event of a complaint made against them (e.g., "If I had a complaint made against me, I am confident that my management would support me").

Suggestions to improve the complaints process. All groups were asked to rate different suggestions on how to improve the complaints process on 11 5-point items. These proposals were generated from the pilot study.

Medical history: The presence of common stress-related illnesses at the time of the complaint or currently were measured using 12 items, including recurring infections, gastro-intestinal, sleep, cardio-vascular and mood problems^{9, 10}. In addition, questions were asked about self-reported drug and alcohol use, as well as life stressors at the time of both current and past complaints.

Defensive medical practice: Twenty items measuring current defensive medical practice were generated from a literature review^{10,11,12}. 12 items additional items were generated from the pilot study (5 for the no complaints group). Items were either rated on a 5-point scale or a yes/no response.

Depression: The *Physical Health Questionnaire* (*PHQ-9*¹³⁾ is a well-known standardised screening measure assessing the presence and severity of depression. It has been used across a wide range of populations and demonstrated good psychometric properties. Respondents were considered depressed if they scored 10 or more on the PHQ-9¹⁴.

Anxiety: The Generalised Anxiety Disorder scale (GAD-7)¹⁵) is a standardised screening measure assessing the presence and severity of generalized anxiety disorder. The GAD-7 is also moderately good at identifying panic disorder, social anxiety disorder, and post-traumatic stress disorder. It has been used across a wide range of populations and demonstrated good psychometric properties. Respondents were considered anxious if they scored 10 or more on the GAD-7¹⁵.

Life Satisfaction. Life satisfaction was assessed with 10 items using a 6-point scale asking about satisfaction-dissatisfaction with marriage, career, recreation/leisure, self/family, and life satisfaction/optimism.

Statistical analysis

For the purpose of this paper, we have limited ourselves to analysis of psychological welfare and health (i.e. anxiety, depression, stress-related illness), defensive practice, culture, time off work and suggestions for improving the complaints process. To summarise the fifteen items measuring defensive practice, an exploratory factor analysis was conducted which identified two underlying factors. The first involves over-investigation and overly cautious management, which we have termed "hedging" (9 items, including for example "carried out more tests than necessary", "referred patient for second opinion more than necessary" and "admitted patients to the hospital when the patient could have been discharged home safely or managed as an outpatient", Cronbach's α =0.92). The second involves avoiding difficult aspects of patient treatment, which we termed "avoidance" (3 items, "stopped doing aspects of my job", "not accepting high risk patients in order to avoid possible complications", and "avoiding a particular type of invasive procedure", Cronbach's α =0.77). Due to strongly skewed distributions, the sumscores hedging and avoidance were analysed both as dichotomous (any hedging (>0)/avoidance (>0) versus no hedging

(0)/avoidance (0)) and ordinal variables (never (0), rarely (hedging 1-12, avoidance 1-4), sometimes (hedging 13-24, avoidance 5-8) or often (hedging 25-36, avoidance 9-12) displaying hedging or avoidance behavior.)

The statistical analysis mainly consisted of descriptive analyses. Cross-tabulations of psychological welfare and defensive practice indicators have been made and relative risks were computed to investigate the relationship between complaint group and psychological welfare or defensive practice indicators. Additionally, means within the complaint groups and mean differences have been computed for continuous variables such as depression and anxiety. Asymptotic 95% confidence intervals were computed for relative risks and mean differences. Unpooled standard errors of the mean difference were used when necessary. Proportions and their 95% confidence intervals were also computed for feeling bullied during the investigation, feeling victimized because of whistle blowing and the amount of time spent off work. Proportions were computed to investigate the amount of support of respondents to various proposed actions to improve the complaints process.

As the primary aim of this study was to investigate the impact of complaints on the psychological welfare and health of doctors, a logistic regression analysis was performed to assess the relationship between moderate to severe depression and receiving a complaint, while controlling for predefined confounders (age, gender, being in a relationship, being White British, and medical specialty). Interactions of complaint with the confounders were included if necessary (α =0.001). Proportional odds logistic models were constructed to investigate whether hedging or avoidance are associated with characteristics of the complaint process (length of investigation, timing of complaint, outcome of investigation, origin of the complaint, type of the complaint). For hedging and avoidance, all two-way interactions were of interest and were included if necessary (α =0.001). We checked linearity assumptions, the presence of multi-collinearity, the presence of outliers, and the proportional odds assumption when necessary.

There was substantial item non-response. For key variables such as depression, anxiety, hedging and avoidance, non-response was approximately 20%. Missingness was addressed by performing multiple imputation using chained equations (MICE)¹⁶

with 10 iterations. Missing values were imputed 100 times, leading to 100 completed datasets. For depression, anxiety and hedging, a two-step approach to imputation was used to decrease the computational burden and make appropriate use of the available answers to separate items, first imputing the individual mean of non-missing items if at least 80% of the items of the composite scale were non-missing, followed by multiple imputation (MI) at the scale level for the remaining individuals. For avoidance, the three items were individually imputed. After MI, each completed dataset was analysed separately and results combined using standard Rubin's rules (Rubin, 1987). To assess the impact of item non-response, we performed a sensitivity analysis comparing the results of the complete case analysis to the results after MI, which assumes missingness at random. Additionally, MI assuming missingness not at random (informative missings) was considered for key variables depression, anxiety, hedging and avoidance¹⁷. Since these variables are based on responses to sensitive questions, informative missingness is plausible. As a missingness mechanism we assumed that those respondents with missingness might have been more anxious or depressed, or more likely to display hedging behavior or avoidance. More details on the MNAR analysis can be found in the supplementary file.

The data was analysed using SAS (version 9.3, SAS Institute, Cary, NC, USA). Multiple imputations were performed using IVEware (http://www.isr.umich.edu/src/smp/ive/)¹⁸.

Results

Psychological welfare and health

Overall, 16.9% of doctors with recent or ongoing complaints reported clinically significant symptoms of moderate to severe depression. Doctors in this group were at increased risk of depression compared to those with a past complaint or no personal experience of a complaint (Table 2; RR=1.77, 95% CI=1.48, 2.13). This was the case even when controlling for the effects of gender, age (cubic effect), being in a relationship (yes/no), being White British (yes/no), and medical specialty. The effect of having a recent or current complaint depends on gender. When there has been no complaint, men tend to be less likely to be depressed than women (OR=0.76, 95%

CI=0.54, 1.09), but a recent or current complaint has a higher impact on men than on women (OR women=1.72, 95% CI=1.28, 2.30; OR men=2.86, 95% CI 2.04, 4.01]. Within the PHQ-9, doctors with an ongoing or recent complaint were twice as likely as doctors with no complaints to report having thoughts of self-harm or suicidal ideation (RR=2.08, 95% CI=1.61, 2.68; see table 2). The sensitivity analysis shows that this conclusion holds under various assumed missingness mechanisms (see supplementary file 1, supplementary table 1).

Moreover, 15% of doctors in the recent complaints group reported clinically significant levels of anxiety on the GAD-7, which is twice as likely as doctors who have no complaints (see Table 2, RR= 2.08, 95% CI=1.61, 2.68). Also this conclusion holds under various assumed missingness mechanisms (see supplementary file 1, supplementary table 2).

The level of psychological distress was related to the type of complaints procedure. Doctors going through a GMC referral reported the highest levels of depression (26.3%), anxiety (22.3%) and thoughts of self-harm (15.3%) compared to SUIs (16.1%, 15.3% and 9.3% respectively), formal complaints (15.6%, 13.5% and 9.0%), and informal complaints (12%, 12% and 6.4%) (table 3).

When asked directly using a single item scale, doctors were 3.78 (95% CI=2.68, 5.32) times more likely to report the presence of suicidal thoughts whilst going through a current or recent complaint compared to doctors who had no complaints (table 4).

Doctors who have experienced either a recent or past complaint reported higher levels of health problems at the time of the complaint compared to the no complaint group. These included gastro-intestinal problems, subjective anxiety and depression, anger, other mental health problems, insomnia, relationship problems, and frequent headaches. Doctors in the current complaints group also reported higher levels of cardio-vascular problems (see table 4).

Defensive practice

Overall, 84.7% of doctors with a recent and 79.9% with a past complaint reported changing the way they practiced medicine as a result of the complaint. 72.7% of doctors with no previous complaint reported changing their practice having observed a colleague's experience of a complaint (see Table 5).

88.6% of doctors with a recent or current complaint and 82.6% of those with a past complaint displayed hedging behaviour. 81.7% of doctors with no previous complaints reported hedging. The sensitivity analysis revealed that under the MNAR assumption, the conclusion still holds that people in the recent or current complaint group display more hedging behavior than people in the no complaints group, but also people with a past complaint display considerably more hedging behavior (see supplementary file 1, supplementary table3).

49.8% or doctors with a recent or current complaint, 42.9% of doctors with a past complaint, and 46.1% of doctors with no personal experience of a complaint reported avoidance behaviour having observed a colleague's experience of a complaint. Although the results from the complete case analysis support the conclusion that mostly people in the recent and current complaint group display avoidance behaviour, the results from the analysis under the MNAR assumption suggest that it is people with a past complaint who display most avoidance behaviour (see supplementary file 1, supplementary table 4).

The multivariable proportional odds analysis indicated that the odds of more severe hedging are higher for people with a recent or ongoing complaint than for people with a past complaint (OR 1.33 95% CI=1.19, 1.49) (Table 6). The odds of hedging slightly increased with the length of time of the investigation (OR 1.01 per month, 95% CI=1.00, 1.01). Hedging was increased when retraining was imposed (OR 1.62, 95% CI=0.84, 3.13) and decreased when the doctor was suspended from practice (OR 0.56, 95% CI=0.26, 1.18). The odds of hedging also decreased when the complaint came from medical colleagues (OR 0.67, 95% CI=0.53, 0.86). There was evidence of an interaction between the type of the most serious complaint one has experienced and whether or not the complaint came from a patient (see supplementary figure 1). Hedging was higher when the complaint came from a patient, this was most clear for

IMPACT study

informal (OR=3.16, 95% CI=2.17, 4.58) and formal complaints (OR=2.18, 95% CI=1.67, 2.85). When the complaint did not come from a patient, hedging was higher for formal complaints, SUI's and GMC referrals compared to informal complaints (OR=1.52, 95% CI=1.03, 2.24, OR=2.10, 95% CI=1.31, 3.35 and OR=1.78, 95% CI=1.15, 2.71, respectively).

As with hedging, the multivariable analysis indicated that the odds of more severe avoidance increased with the length of time the investigation (OR 1.01 per month, 95% CI=1.01, 1.02), and was higher for people with a recent or current complaint than for people with a past complaint (OR 1.20, 95% CI=1.07, 1.35) (Table 7). Avoidance was also increased when the investigation resulted in imposed retraining (OR 1.79, 95% CI=1.0, 3.09). Avoidance behaviour most severely increased when the complaint came from a patient group (OR 1.71, 95% CI=1.02, 2.87) or management (OR 1.59, 95% CI=1.16, 2.16), or when the complaint was anonymous (OR 1.58, 95% CI=1.06, 2.36). The type of complaint did not meaningfully influence the odds of more severe avoidance.

Overall, as a result of their experience of the complaints process, 23% of doctors reported suggesting invasive procedures against their professional judgement, and 14% reported becoming more likely to abandon a procedure at an early stage.

Culture and time off work

20% (95% C.I. 19% to 22%) reported that they felt victimized because they had been a whistleblower for clinical or managerial dysfunction. 38% (95% C.I. 37% to 40%) of people who have had a complaint, recently or in the past, reported feeling bullied during the investigation.

60% (95% C.I. 57% to 64%) spent less than a week off work. However, 27% (95% C.I. 24% to 30%) of people with complaints spent more than a month off work.

Opinions on changes to improve the system

IMPACT study

Of those doctors that gave a response, 85% felt that for managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them mattered quite a lot or a great deal in terms of improving the process. An equal number (85%) felt that if a doctor is exonerated but has suffered financial loss during the process, then they should have the option to make a claim for recovery of lost earnings or costs and in addition that there should be complete transparency of any management communication about the subject of a complaint and that access to such communications should be given to a doctor's representatives.74% of respondents felt that it mattered quite a lot or a great deal that if a complaint from a clinical or managerial colleague was found to be vexatious then this could be investigated and possible disciplinary measures taken. The full details of responses in relation to actions that could be taken to reduce the psychological impact of complaints processes are shown in supplementary table 5.

Discussion

We have shown that doctors who responded to our questionnaire who have recently received a complaint of any kind are 77% more likely to suffer from moderate to severe depression than people who have never had a complaint. They also have double the risk of having thoughts of self-harm, and double the risk of anxiety. Welfare is lowest when the complaint involves referral to the GMC. Doctors with a recent or current complaint also reported that they suffered from an increased likelihood of cardiovascular and gastro-intestinal disorders, depression, anxiety, anger and irritability, suicidal thoughts, sleep difficulty, relationship problems, and frequent headaches than people who had not been through a complaints process. In many cases these problems persisted. We have also shown that 80% of doctors answering the survey reported changing the way they practiced as a result of either complaints against themselves, or after observing a colleague go through a complaints process. The majority (84%) of doctors reported hedging behaviour in response to a complaint (i.e. increased defensive practice) whilst many (46%) admitted avoidance. A further important finding was that many doctors who had a complaint (20%) felt they were victimised after whistle blowing. Thirty-nine percent reported that they felt bullied when they were going through the process. A large number of doctors had significant time off work as a result of a complaint with 27% spending more than a month off work.

A strength of the study is that to our knowledge it is one of the largest reported on the subject involving 10,930 respondents with 7,926 completing the survey. It is certainly the largest relating to doctors in the United Kingdom. We also think it is critical that respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions. Furthermore we have obtained quantitative data on the mental wellbeing of doctors using validated questionnaires. It is also important to note that we have collected responses from doctors who have not experienced a complaint but observed the impact on others. On the one hand this gives insight into the impact of observing a colleague going through a complaints process, however it also means that the "no complaints" group may have a higher overall level of psychological morbidity than if doctors could be isolated from complaints processes completely. Hence the relative

risks in the paper may be underestimated. A significant limitation of the study is that the response rate was 11.4%, accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. What constitutes an acceptable response rate is a subject of debate, however our response rate is clearly low¹⁹. We believe this is inevitable when asking doctors to comment on disciplinary processes and in particular on their regulator. Even if we take the view that the respondents are a selected group, they still demonstrate that a very considerable number of doctors are significantly impacted by complaints processes and practice defensively. It must also be remembered that doctors that have been most traumatised by the complaints process may have felt unable to take part in the survey and a small number are known to have committed suicide. Furthermore those no longer on the register (for example if they have changed profession or erased from the register) are unlikely to be members of the BMA and so would not have been contacted. As some questions involved remembering past events the possibility of recall bias for some answers must also be considered. For a number of questions there were missing responses. However we have considered this issue by using multiple imputation and were reassured that we found no essential differences between the conclusions that would be drawn using complete cases compared to those where missing data have been imputed.

As with any cross-sectional survey we must be careful when considering the findings, as we cannot show causation. It is possible that doctors with depression, anxiety and suicidal ideation are more likely to have complaints made against them, similarly being complained against may be the causative factor rather than the processes themselves. However this still means the information presented is important as if we take the former view, it means those going through complaints processes are a vulnerable group that need support.

It is interesting that our findings are similar to a questionnaire-based study of surgeons in the United States examining the emotional toll of malpractice lawsuits. This study found significantly more depression and burnout in surgeons who had recently been exposed to a lawsuit and highlighted the association between burnout and the likelihood of making a medical error⁴.

We found that 10% of doctors responding to the survey who have had a recent complaint have had thoughts of self-harm and are over twice as likely to have had

such thoughts compared to doctors who had not personally experienced a complaint. When referral to the GMC is looked at in isolation the number of doctors who reported suicidal ideation reached 15.3%, whilst 26.3% had moderate to severe depression and 22.3% had moderate to severe anxiety on the basis of two validated instruments. Even set against the limitations of the study we have highlighted above, these findings are concerning. In a recent feature article in the BMJ, Dyer reported on the high number of suicides associated with GMC proceedings³. Our results support the view that these proceedings have a disproportionate impact on doctors, especially as the vast majority of doctors who are referred to the GMC are found to have no significant case to answer². However the GMC is at the apex of what amounts to a "complaints pyramid" and our data show similar significant psychological morbidity for doctors when they are involved both in internal trust enquiries into complaints and in the event of a serious untoward incident investigation.

The incidence of feeling victimized following whistleblowing (20%) and bullying (38%) will be a concern to those trying to build a culture in the NHS where it is safe to speak out about clinical and managerial concerns. The Francis report highlighted the dysfunctional culture that is prevalent in many NHS organisations²⁰. Other recent reports have also highlighted serious concerns about the pressures that may be placed on hospital staff ²¹. Given the large numbers involved, our study supports the view that whistleblowing in the NHS is not always a safe action to take, that bullying is not uncommon, and that this problem is not just experienced in isolated cases.

The GMC exists to protect patients and the public. This is also the aim of other types of complaints processes with the overall purpose being to learn from mistakes and improve the performance of everyone taking part in patient care. However as with all interventions there may be unforeseen consequences. Previously Jain et al in a qualitative study reported that many general practitioners practice defensively following a complaint⁷. Our data also show the vast majority of doctors who took part in the study reported engaging in defensive practice. This involved hedging and avoidance behavior; which included carrying out more tests than necessary, over-referral, over-prescribing, avoiding procedures, not accepting high-risk patients and abandoning procedures early. These behaviors are not in the interest of patients and may cause harm, whilst they may also potentially increase cost to the wider NHS. By

far the majority of doctors who are reported to the GMC are not found to have a significant case to answer², as is probably the case with other lower level complaint investigations. It therefore does not seem unreasonable to argue that as they currently function, GMC enquiries may do more overall harm than good in terms of patient care. As the "complaints pyramid" is descended it is possible this balance may improve, although we found defensive practice across the entire spectrum of complaints processes.

Whilst we fully acknowledge the limitations associated with any study of this type, we believe our findings have implications for policy makers. Procedures must exist to enable patients to make a complaint about their care, for professionals to raise concerns about standards or practice and for untoward events to be investigated. However a system that is associated with high levels of psychological morbidity amongst those going through it is not appropriate as either the subjects of such procedures are vulnerable at the outset or are suffering such morbidity as a direct result of the investigations themselves. Most importantly, a system that leads to so many doctors practicing defensive medicine is not good for patients. The high level of suicidal ideation coupled with the recent revelations about suicide amongst doctors who have been reported to the GMC is a concern³. Recently the GMC announced a review of cases of doctor suicide associated with GMC investigations, and introduced offering emotional support to doctors going through fitness to practice procedures. A survey has also been sent out by the GMC to doctors to hear their views. These initiatives are welcome, but whether doctors will feel confident in giving critical feedback to the GMC is open to question. No such initiatives have been made to support doctors involved in other processes outside GMC proceedings, whilst our data suggest that psychological morbidity as well as hedging and avoidance behaviour is associated with the entire spectrum of complaints procedures. A further concern for patient care is the association between doctor's distress, burnout and decreased empathy with perceived medical errors²¹.

When asked how the complaints process could be improved doctors indicated that what mattered to them was that the process should be transparent and that managers responsible for complaints should be up to date and competent. There was also a clear feeling that in the event of a complaint being shown to be vexatious then there should

be disciplinary consequences if this related to managers and hospital staff, or the option for financial redress in the event it related to patients. Doctors indicated that in the event of a complaint they expected any procedure to be clear, transparent, follow due process and in the event that the complaint was shown to be vexatious, that there are consequences for those involved. Concerns about the lack of redress associated with vexatious complaints have been raised in the BMJ before²³. The logical extension of increased transparency and greater training and therefore competency amongst managers responsible for dealing with complaints would be consistency. Consistency in both the management and outcome of complaints would be valuable in restoring the sense of fairness that our results would suggest is not currently being perceived by doctors.

We have shown that doctors who responded to our questionnaire and experience or observe complaints processes exhibit high levels of psychological morbidity including severe depression and suicidal ideation. These effects are greatest when the process involves the General Medical Council. In addition the majority of these doctors exhibit hedging and avoidance, both these behaviours may be damaging to patient care and be contrary to the professed aims of these processes.

Acknowledgements

Mr. Christoph Lees (Imperial College NHS trust) and Mr. Magnus Boyd (Hill Dickinson LLP solicitors) contributed to receiving feedback on the contents and design of the questionnaire. We would like to thank all clinicians who commented on the initial versions of the survey.

Contributors

TB conceived of the original idea for the study, interpreted results, drafted the paper and is overall guarantor. MJ designed the questionnaire, interpreted results and contributed to drafts of the paper. LW and BVC carried out the statistical analysis and contributed to drafts of the papers. MP contributed to the study design, interpretation of results and commented on drafts of the paper. DT and CVA contributed to interpretation of results and commented on drafts of the paper. All authors approved the final version of the manuscript.

Funding

Tom Bourne is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. Laure Wynants is supported by a PhD grant of the Flanders' Agency for Innovation by Science and Technology (IWT Vlaanderen). Ben Van Calster is a postdoctoral fellow of the Research Foundation- Flanders (FWO).

Competing interests

All authors have completed the Unified Competing Interest form and declare: Michael Peters is head of the BMA doctors for doctors unit and so receives payment from the BMA. The BMA had no role in data collection, design of the study, data analysis, interpretation of data, or writing the report and had no influence over whether to submit the manuscript. All other authors stated that they had no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that that could appear to have influenced the submitted work

Ethical approval

Ethical approval was sought and obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Transparency declaration

The lead author (T Bourne) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no aspects of the study have been omitted in relation to the specific aspects of the study reported in this paper; and that any discrepancies from the study as planned (and, if relevant registered) have been explained.

The Licence

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors a worldwide, licence, to the Publishers and its licensees in perpetuity (subject to the Reversion of Rights set out below), in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution and convert or allow conversion into any format including without limitation audio, iii) create any other derivative work(s) based in whole or part on the Contribution, iv) to exploit all subsidiary rights that currently exist or as may exist in the future in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above.

References

- 1 White C. Complaints against doctors continue to rise. BMJ Careers 2013 Sep 30 http://careers.bmj.com/careers/advice/view-article.html?id=20014782 (accessed on 25 November 2013).
- 2 General Medical Council. Fitness to Practise Annual Statistics Report 25th September 2012 www.gmc-uk.org (accessed on 25 November 2013).
- 3 Dyer C. GMC and vulnerable doctors: too blunt an instrument? BMJ 2013;347:f6230
- 4 Balch CM, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. J Am Coll Surg 2011;**213**:657-67.
- 5 Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. Arch Surg 2011;**146**:54-62.
- 6 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;**296**:1071-78.
- 7 Jain A, Ogden J. General practitioners' experiences of patients' complaints: qualitative study. BMJ 1999; **318**:1596-99.
- 8 Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. Quality in Health Care 1997;6:7-13.
- 9 Schat AC, Kelloway EK, Desmarais, S. The Physical Health Questionnaire: construct validation of a self-report scale of somatic symptoms. J Occup Health Psychol 2005;**10**:363-81.
- 10 Studdert DM, Mello MM, Sage VM, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 2005;**293**:2609-17.

11 Nash L, Walton M, Daly M, et al. GPs' concerns about medico legal issues: How it affects their practice. Australian Fam Physician 2009;**38**:66-70.

12 Summerton N. Positive and negative factors in defensive medicine: A questionnaire study of General Practitioners. BMJ 1995;**310**:27-29.

IMPACT study

13 Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ Primary Care Study. JAMA 1999;**282**:1737-44.

14 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001;**16**:606-13.

15 Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;**166**:1092-97.

16 Raghunathan TW, Lepkowksi JM, Van Hoewyk J, et al. A multivariate technique for multiply imputing missing values using a sequence of regression models. Survey Methodology 2001;27:85–95.

17 Rubin DB. (1987). Multiple Imputation for Nonresponse in Surveys. Wiley, NY.

18 IVEware: Imputation and Variance Estimation Software.

http://www.isr.umich.edu/src/smp/ive/ (accessed on 12 August 2013).

- 19. Baruch Y. Response rate in academic studies A comparative analysis. Human relations, 1999; 52: 421-438
- 20 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013. Chaired by Robert Francis QC. http://www.midstaffspublicinquiry.com/report (accessed 25 November 2013).
- 21 Care Quality Commission recommends Essex hospital trust is put into special measures 5 November 2013. http://www.cqc.org.uk/media/care-quality-commission-

IMPACT study

<u>recommends-essex-hospital-trust-put-special-measures</u> (accessed on 25 November 2013).

- 22 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;**296**:1071-78.
- 23 Marcovitch H. GMC must recognise and deal with vexatious complaints fast. BMJ 2002;**324**:167-68.



Tables and Figures

Table 1: Demographic information relating to both sample 1 and 2 in the study

Age	Total BMA membership consented for research	Sample 1 (n=10113)	Sample 2 (n=7926)
Up to 25	17.8%	1.4%	1.4%
26-29	9.0%	5.1%	5.5%
30-34	9.6%	8.6%	8.8%
35-39	10.3%	11.0%	11.0%
40-44	10.3%	13.5%	13.1%
45-49	10.8%	16.9%	16.8%
50-54	10.3%	18.8%	18.8%
55-59	8.1%	14.6%	14.7%
60-64	5.0%	6.6%	6.4%
65-69	3.0%	2.5%	2.6%
Over 69	5.9%	1.1%	1.0%
Gender	46.3% Female	47.5% Female	47.5% Female
Place of qualification			
United Kingdom	80.1%	80.7%	81.2%
India	8.2%	6.6%	6.2%
Pakistan	2.2%	1.2%	1.2%
Ireland	0.9%	1.4%	1.4%
Nigeria	1.1%	1.2%	1.2%
Germany	0.7%	1.1%	1.2%
South Africa	0.7%	0.8%	0.8%
Other	6.2%	6.9%	6.9%
Ethnicity White British	67.6%	77.6%	78.2%
Asian or Asian British	23.3%	16.6%	15.8%
Black or Black British	3.5%	2.3%	2.3%
Chinese or Chinese British	2.9%	1.3%	1.3%
Mixed	2.7%	2.3%	2.3%
Grade:			

IMPACT study

	2.10/	1.00/	1.00/
Academics	2.1%	1.2%	1.3%
Consultants	27.2%	37.1%	36.5%
General Practice	26.0%	38.4%	37.8%
Junior Doctors	26.4%	15.7%	16.5%
SASC	5.3%	5.8%	6.11%
Retired	8.6%	0.7%	0.7%
Other or no answer	4.4%	1.0%	1.1%



Table 2. Symptoms severity and relative risk of psychological distress for each complaints group.

	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent/ current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative risk for past complaint group/ mean difference (95% CI)	Relative risk for recent complaint group / mean difference (95% CI)
Depression (PHQ-9)						
Mean (SD) a	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3 (-0.6, -0.0)	1.4 (1.1, 1.7)
Moderate to severe depression n (%)	169 (9.5%)	303 (7.8%)	381 (16.9%)	852 (10.8%)	0.81 (0.65, 1.01)	1.77 (1.48, 2.13)
Thoughts of 'self- harm' n (%)	83 (4.7%)	221 (5.7%)	218 (9.7%)	522 (6.6%)	1.22 (0.93, 1.61)	2.08 (1.61, 2.68)
Anxiety (GAD-7) Mean (SD) b	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1 (-0.4, 0.2)	1.4 (1.1, 1.7)
Moderate to severe anxiety n (%)	131 (7.3%)	234 (6.0%)	338 (15.0%)	703 (8.9%)	0.80 (0.57, 1.13)	2.08 (1.61, 2.68)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

IMPACT study

Table 3. Psychological distress within the recent / on-going complaints group by complaint that had the most impact.

the most impact.	Informal	Formal	SUI	GMC	No
					No
	complaint	Complaint	n=280	referral	complaint
	n=362	n=1196	(12.4%)	n=374	n=1780
	(16.0%)	(53.0%)		(16.6%)	(22.5%)
Depression					
(PHQ-9)					
Mean (SD) a	4.2	4.8	5.1	6.6	3.7
	(5.0)	(5.4)	(5.6)	(6.7)	(4.3)
Moderate to severe	45	190	46	100	169
depression n (%)	(12.0%)	(15.6%)	(16.1%)	(26.3%)	(9.5%)
Thoughts of 'self-	24	110	27	58	83
harm' n (%)	(6.4%)	(9.0%)	(9.3%)	(15.3%)	(4.7%)
Anxiety (GAD-7)					
Mean (SD) b	3.8	4.4	4.7	5.7	3.1
•	(4.3)	(4.7)	(5.1)	(5.7)	(3.8)
Moderate to severe	44	165	44	85	131
anxiety n (%)	(12.0%)	(13.5%)	(15.3%)	(22.3%)	(7.3%)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Table 4. Psychosomatic health for each of the complaints group. Please note that the past complaints group used retrospective information asking about worsening or onset of symptoms at the time of the complaint, whereas the no and recent complaint groups were asked about the presence of symptoms in the last twelve months.

	No complaint n=1780 (22.5%)	Recent or current complaint n=2257 (28.5%)	Past complaint n=3889 (49.1%)	RR recent or current versus no complaint.
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)	124 (7.0%)	280 (12.4%)	405 (10.4%)	1.78 (1.44-2.20)
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)	217 (12.2%)	426 (18.9%)	934 (24.0%)	1.55 (1.32-1.82)
Depression	187 (10.5%)	490 (21.7%)	1148 (29.5%)	2.07 (1.74-2.45)
Anxiety	476 (26.7%)	1108 (49.1%)	3045 (78.3%)	1.84 (1.65-2.04)
Anger and irritability	358 (20.1%)	928 (41.1%)	2406 (61.9%)	2.04 (1.77-235)
Other mental health problems	12 (0.7%)	54 (2.4%)	256 (6.6%)	3.45 (1.80-6.60)
Suicidal thoughts	44 (2.5%)	211 (9.3%)	519 (13.4%)	3.78 (2.68-5.32)
Sleep problems / insomnia	479 (26.9%)	1137 (50.4%)	288 (74.1%)	1.87 (1.67-2.10)
Relationship problems	187 (10.5%)	458 (20.3%)	911 (23.4%)	1.94 (1.63-2.30)
Frequent headaches	242 (13.6%)	432 (19.2%)	1027 (26.4%)	1.41 (1.19-1.65)
Minor colds	492 (27.6%)	509 (22.5%)	5447 (14.0%)	0.82 (0.73-0.92)
Recurring respiratory infections	77 (4.3%)	143 (6.3%)	306 (7.9%)	1.47 (1.11-1.95)

IMPACT study

Table 5 Defensive practice according to complaint group

Changed the way of practicing medicine n (%) Displayed hedging behaviour n (%) Displayed avoiding behaviour n (%) Suggested invasive procedures against	1294 (72.7%) 1454 (81.7%) 820 (46.1%)	3106 (79.9%) 3212 (82.6%) 1668 (42.9%)	1912 (84.7%) 1999 (88.6%)	6312 (79.6%) 6665 (84.1%)	1.10 (1.06,1.14) 1.01 (0.98,1.04)	(95% CI) 1.17 (1.13,1.21) 1.08
of practicing medicine n (%) Displayed hedging behaviour n (%) Displayed avoiding behaviour n (%) Suggested invasive procedures	1454 (81.7%) 820 (46.1%)	3212 (82.6%)	1999 (88.6%)	6665	1.01	(1.13,1.21)
Displayed hedging behaviour n (%) Displayed avoiding behaviour n (%) Suggested invasive procedures	820 (46.1%)	(82.6%)	(88.6%)			1.08
hedging behaviour n (%) Displayed avoiding behaviour n (%) Suggested invasive procedures	820 (46.1%)	(82.6%)	(88.6%)			
behaviour n (%) Displayed avoiding behaviour n (%) Suggested invasive procedures	820 (46.1%)	1668		,	(U.)U,1.UT	(1.05, 1.11)
Displayed avoiding behaviour n (%) Suggested invasive procedures	(46.1%)		1124			, , ,
avoiding behaviour n (%) Suggested invasive procedures	359	(42.9%)	1121	3612	0.93	1.08
Suggested invasive procedures	359	` ′	(49.8%)	(45.6%)	(0.87, 1.00)	(1.00, 1.17)
Suggested invasive procedures			, , ,	`		
invasive procedures		902	585	1846	1.15	1.29
	(20.2%)	(23.2%)	(25.9%)	(23.3%)	(1.02,1.29)	(1.13,1.46)
against			·			
professional						
judgement n (%)						
Become more	248	515	372	1136	0.95	1.18
likely to abandon	(14.0%)	(13.3%)	(16.5%)	(14.3%)	(0.80,1.13)	(1.00, 1.39)
a procedure at an						
early stage n (%)						
Become less	-	795	613		-	-
committed and		(20.5%)	(27.2%)			
worked strictly to						
job description						
n (%)						

Table 6. Factors influencing hedging behaviour.

Odds Ratio Estimates for he	dging		
Effect	Point Estimate	95% W Confidence	
Length of investigation (per month)	1.006	1.002	1.011
Recent or current complaint (versus past complaint)	1.331	1.193	1.485
Outcome of investigation			
No fault/ exonerated (yes versus no)	1.051	0.676	1.633
Retraining imposed (yes versus no)	1.622	0.913	2.885
Disciplinary action (yes versus no)	0.815	0.433	1.532
Suspended from practice (yes versus no)	0.557	0.289	1.075
Struck off from the register (yes versus no)	0.583	0.754	1.761
The process was not clearly concluded (yes versus no)	1.152	0.900	1.960
Where did the complaint come from			
Trust (yes versus no)	1.328	0.900	1.960
Medical colleagues (yes versus no)	0.672	0.526	0.860
Management (yes versus no)	0.797	0.581	1.094
Media (yes versus no)	1.084	0.467	2.515
Patient group (yes versus no)	1.495	0.906	2.464
Other health care professional (yes versus no)	1.047	0.798	1.375
Patient (yes versus no)			
For informal complaint	3.155	2.172	4.584
For formal complaint	2.180	1.670	2.846
For SUI	1.212	0.826	1.778
For GMC referral	1.670	1.207	`2.311
Anonymous (yes versus no)	1.362	0.922	2.012
Type of complaint			
Formal complaint versus informal complaint			
Complaint did not come from a patient	1.521	1.034	2,239
Complaint came from a patient	1.051	0.903	1.223
SUI versus informal complaint			
Complaint did not come from a patient	2.097	1.311	3.352
Complaint came from a patient	0.805	0.648	1.002
GMC referral versus informal complaint			
Complaint did not come from a patient	1.776	1.164	2.709
Complaint came from a patient	0.940	0.757	1.168

Table 7. Factors influencing avoidance behaviour

Odds Ratio Estimates for a	voiding		
Effect	Point Estimate	95% W Confidence	
Length of investigation (per month)	1.011	1.006	1.016
Recent or current complaint (versus past complaint)	1.201	1.069	1.350
Outcome of investigation			
No fault/ exonerated (yes versus no)	0.893	0.594	1.340
Retraining imposed (yes versus no)	1.787	1.033	3.092
Disciplinary action (yes versus no)	1.211	0.682	2.152
Suspended from practice (yes versus no)	1.066	0.566	2.008
Struck off from the register (yes versus no)	0.626	0.119	3.305
The process was not clearly concluded (yes versus no)	1.202	0.805	1.796
Where did the complaint come from			
Trust (yes versus no)	1.338	0.910	1.968
Medical colleagues (yes versus no)	1.439	1.134	1.826
Patient (yes versus no)	1.364	1.114	1.670
Management (yes versus no)	1.585	1.163	2.161
Media (yes versus no)	0.866	0.380	1.972
Patient group (yes versus no)	1.708	1.019	2.866
Other health care professional (yes versus no)	1.326	1.015	1.731
Anonymous (yes versus no)	1.580	1.057	2.360
Type of complaint			
GMC referral (versus informal complaint)	1.082	0.885	1.323
SUI (versus informal complaint)	1.112	0.904	1.368
Formal complaint (versus informal complaint)	1.036	0.893	1.203



Bourne et al

Supplementary material sensitivity analysis and supplementary tables 1-4

Sensitivity Analysis.

As a last step in the analysis, we performed a sensitivity analysis considering also missingness not at random (MNAR) for some of the key analyses. MNAR means that, even accounting for all the available observed information, the reason for observations being missing still depends on the unseen observations themselves. We performed a simple sensitivity analysis, assuming as a not ignorable missing model that depression, anxiety, hedging and avoiding are worse when the value is missing. Therefore, after multiple imputation under the MAR assumption using MICE, I increased each imputed value of depression (PHQ9) and anxiety (GAD7) by a certain number d. This number d was obtained as follows. First, a random number δ was sampled from a normal distribution with mean the estimated standard deviation of the distribution of PHQ9/GAD7, and standard deviation the square root of this value. Then $d=\max(\delta, 1)$, such that d is restricted to imply an increase in PHQ9/GAD7. Therefore, d instead of δ is added to the imputed value under missingness at random (MAR). After this, the new imputed value is rounded and bound at the maximum possible value, such that an integer number on the original scale is obtained. For hedging/avoiding, all missings were assumed to have displayed at least some hedging/avoiding behaviour. The actual score on the scale is irrelevant, because the scale is dichotomised prior to the analysis. After the imputations under MNAR are computed, analysis proceeds as usual, using Rubin's rules to combine results.

Supplementary table 1: Sensitivity analysis for PHO-9

Bourne et al

Depression	No	Past	Recent/	Total	Relative	Relative
(PHQ-9) ^a	complaint	complaint	current	n=7926	risk for	risk for
	n=1780	n=3889	complaint	(100%)	past	recent
	(22.5%)	(49.1%)	n=2257		complaint	complaint
			(28.5%)		group/	group /
					mean	mean
					difference	difference
					(95% CI)	(95% CI)
Missings	255	1144	214	1613		
	(14%)	(29%)	(9%)	(20%)		
Complete case						
Mean (SD)	3.8 (4.5)	3.4 (4.6)	5.2 (5.8)	4.1 (5.0)	-0.4	1.4
					(-0.7, 0.1)	(1.1, 1.7)
Moderate to severe	160	254	363	777	0.88	1.69
depression n (%)	(10.5%)	(9.3%)	(17.8%)	(12.3%)	(0.73, 1.06)	(1.42, 2.02)
MI MAR						
Mean (SD)	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3	1.4
					(-0.6, -0.0)	(1.1, 1.7)
Moderate to severe	169	303	381	852	0.81	1.77
depression n (%)	(9.5%)	(7.8%)	(16.9%)	(10.8%)	(0.65, 1.01)	(1.48, 2.13)
MI MNAR						
Mean (SD)	4.3 (4.6)	4.7 (4.8)	5.4 (5.7)	4.8 (5.1)	0.4	1.1
					(0.1, 0.7)	(0.8, 1.4)
Moderate to severe	238	593	432	1263	1.14	1.43
depression n (%)	(13.4%)	(15.2%)	(19.2%)	(15.9%)	(0.95, 1.35)	(1.21, 1.70)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

Bourne et al

Supplementary table 2: Sensitivity analysis for GAD-7

Supplementary table 2: Sensitivity analysis for GAD-7								
Anxiety (GAD7) b	No	Past	Recent/	Total	Relative	Relative		
	complaint	complaint	current	n=7926	risk for	risk for		
	n=1780	n=3889	complaint	(100%)	past	recent		
	(22.5%)	(49.1%)	n=2257		complaint	complaint		
			(28.5%)		group/	group /		
					mean	mean		
					difference	difference		
					(95% CI)	(95% CI)		
Missings	258	1148	201	1607		Í		
	(14%)	(30%)	(9%)	(20%)				
Complete case								
Mean (SD)	3.2 (3.9)	3.0 (4.0)	4.7 (5.0)	3.6 (4.4)	-0.2	1.5		
					(-0.4, 0.1)	(1.2, 1.8)		
Moderate to severe	123	194	330	647	0.88	1.99		
depression n (%)	(8.1%)	(7.1%)	(16.1%)	(10.2%)	(0.71, 1.09)	(1.63, 2.42)		
MI MAR								
Mean (SD)	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1	1.4		
					(-0.4, 0.2)	(1.1, 1.7)		
Moderate to severe	131	234	338	703	0.80	2.08		
depression n (%)	(7.3%)	(6.0%)	(15.0%)	(8.9%)	(0.57, 1.13)	(1.61, 2.68)		
MI MNAR								
Mean (SD)	3.7 (4.1)	4.3 (4.4)	4.9 (5.0)	4.3 (4.6)	0.5	1.2		
					(0.2, 0.9)	(0.9, 1.5)		
Moderate to severe	173	463	374	1011	1.22	1.71		
depression n (%)	(9.7%)	(11.9%)	(16.6%)	(12.75%)	(0.98, 1.51)	(1.35, 2.18)		

^b The GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Supplementary table 3: Sensitivity analysis for hedging.

Supplementary tab		ty analysis for	r hedging.			
Because of your / other's experiences with complaints, have you ever displayed	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent or current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative Risk for past complaint (95% CI)	Relative Risk for recent or current complaint (95% CI)
hedging behaviour?						
Missings	268	1241	273	1782		
Complete case	200	12.11	2.0	1702		
n (%)	1222	2135	1752	5109	1.00	1.09
	(80.8%)	(80.6%)	(88.3%)	(83.1%)	(0.97, 1.03)	(1.06,1.13)
MAR						
n (%)	1454	3212	1999	6665	1.01	1.08
	(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98, 1.04)	(1.05,
						1.11)
MI MNAR						
n (%)	1484 (83.4%)	3369 (86.6%)	2023 (89.6%)	6876 (86.8%)	1.04 (1.01,1.06)	1.08 (1.05,1.10)
			` /			, , ,

Bourne et al

Supplementary table 4: Sensitivity analysis for avoidance.

Supplementary table Because of your /	No	• •		Total	Dolotivo	Dolotivo
other's	No complaint	Past	Recent or	1 otai n=7926	Relative	Relative
	complaint n=1780	complaint	current		Risk	Risk
experiences with		n=3889	complaint	(100%)	for past	for recent
complaints, have	(22.5%)	(49.1%)	n=2257		complaint	or current
you ever			(28.5%)		(95% CI)	complaint
displayed						(95% CI)
avoiding						
behaviour?						
Missings	242	1222	257	1721		
Complete case						
n (%)	705	1137	995	2837	0.93	1.09
` '	(45.8%)	(42.6%)	(49.8%)	(45.7%)	(0.87, 1.00)	(1.01, 1.16)
MAR	,	, ,	, ,		, , ,	, , ,
n (%)	820	1668	1124	3612	0.93	1.08
11 (70)	(46.1%)	(42.9%)	(49.8%)	(45.6%)	(0.87,1.00)	(1.00,1.17)
MI MNAR	(40.170)	(42.770)	(42.070)	(43.070)	(0.67,1.00)	(1.00,1.17)
	0.47	2250	1050	4550	1 14	1.04
n (%)	947	2359	1252	4558	1.14	1.04
	(53.2%)	(60.7%)	(55.5%)	(57.5%)	(1.08,1.20)	(0.98,1.10)



Bourne et al

Supplementary table 5: How doctors ranked the importance of different actions that might be taken to improve the complaints process might be improved (note these data are not imputed).

	Not at	A	To some	Quite a	A great	missing	total
	all n (%)	little n (%)	extent n (%)	lot n (%)	deal n (%)	n	n
To allow the doctor to	245	313	2256	1524	1973	3802	10113
have more direct input into	(3.9%)	(5.0%)	(35.8%)	(24.2%)	(31.3%)	3002	10113
responses to patient	(3.770)	(3.070)	(33.070)	(21.270)	(31.370)		
complaints							
To be given a clear written	217	342	1501	1846	2400	3807	10113
protocol for any process at	(3.4%)	(5.4%)	(23.8%)	(29.3%)	(38.1%)	3007	10115
the onset	(3.170)	(0.170)	(25.070)	(2).570)	(50.170)		
To have strict adherence to	199	402	1599	1732	2379	3803	10113
a statutary timeframe for	(3.2%)	(6.4%)	(25.3%)	(27.5%)	(37.7%)	3803	10113
any complaint and	(3.270)	(0.470)	(23.370)	(27.370)	(37.770)		
investigation process							
Brief colleagues about any	261	440	1816	1972	1733	3891	10113
complaint or investigation	(4.2%)	(7.1%)	(29.2%)	(31.7%)	(27.9%)	3091	10113
to ensure unambiguous	(4.270)	(7.170)	(29.270)	(31.770)	(21.970)		
internal communications							
If a complaint from a	152	202	1202	1981	2690	3886	10113
clinical or managerial	(2.4%)	(3.2%)	(19.3%%)	(31.8)	(43.2%)	3000	10113
colleague was found to be	(2.470)	(3.270)	(19.5/0/0)	(31.6)	(43.270)		
vexatious then to have the							
option of having this							
investigated and possible							
disciplinary measures							
taken							
If a complaint from a	212	434	1296	1528	2837	3806	10113
patient was found to be	(3.4%)	(6.9%)	(20.6%)	(24.2%)	(45.0%)	3000	10115
vexatious then to have the	(3.170)	(0.570)	(20.070)	(21.270)	(13.070)		
option to take action							
against that person							
To set a limit to the time	131	260	1315	1855	2668	3884	10113
period when it is permitted	(2.1%)	(4.2%)	(21.1%)	(29.8%)	(42.8%)		
to file multiple complaints	(=11,1)	(11=74)	(====, +)	(=>,,,,)	(121070)		
relating to the same							
clinical incident or from							
the same person or persons							
If the doctor is exonerated	64	138	785	1872	3455	3799	10113
but has suffered financial	(1.0%)	(2.2%)	(12.4%)	(29.7%)	(54.7%)		
loss during the process,	, ,	, ,	,		` '		
then to have an avenue to							
make a claim for recovery							
of lost earnings or costs							
To have complete	59	102	757	1770	3559	3866	10113
transparency of any	(1.0%)	(2.2%)	(12.4%)	(28.3%)	(57.0%)		
management							
communication about the							
subject of a complaint by							
giving access to this to the							
doctor's representatives							
For all managers to	65	107	767	1744	3551	3879	10113
demonstrate a full up to	(1.0%)	(1.7%)	(12.3%)	(28.0%)	(57.0%)		
date knowledge of							
procedure in relation to							
complaints if they are							
made responsible for them							

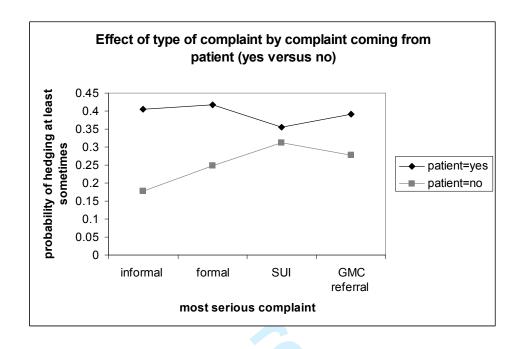
Bourne et al

The BMA and defence	186	447	1601	1465	2575	3839	10113
organisations should be	(3.0%)	(7.1%)	(25.5%)	(23.4%)	(41.0%)		
more aggressive and less							
reactive to complaints in							
general							



Supplementary online material

Supplementary figure 1: Effect of type of complaint on hedging behavior by origin of complaint.



BMJ Open

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom: a cross-sectional survey

Journal:	BMJ Open
Manuscript ID:	bmjopen-2014-006687.R1
Article Type:	Research
Date Submitted by the Author:	25-Nov-2014
Complete List of Authors:	Bourne, Tom; Imperial College London, Queen Charlottes and Chelsea Hospital Wynants, Laure; KU Leuven, Department of Electrical Engineering-ESAT Peters, Michael; British Medical Association, Doctors for Doctors Unit Audenhove, Chantal; KU Leuven, LUCAS Timmerman, Dirk; KU Leuven, Development and Regeneration Van Calster, Ben; KU Leuven, Development and Regeneration Jalmbrant, Maria; South London and Maudsley NHS Foundation Trust,
Primary Subject Heading :	Health policy
Secondary Subject Heading:	Mental health, Occupational and environmental medicine, Legal and forensic medicine
Keywords:	Anxiety disorders < PSYCHIATRY, Depression & mood disorders < PSYCHIATRY, Suicide & self-harm < PSYCHIATRY, OCCUPATIONAL & INDUSTRIAL MEDICINE, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT
Keywords:	INDUSTRIAL MEDICINE, Health policy < HEALTH SERVICES

SCHOLARONE™ Manuscripts

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom: a cross-sectional survey

Tom Bourne adjunct professor of gynaecology and consultant gynaecologist^{1,6,7}, Laure Wynants researcher in medical statistics^{2,3}, Mike Peters head of BMA Doctors for Doctors Unit ⁴, Chantal Van Audenhove professor of psychology and applied communication⁵, Dirk Timmerman professor of obstetrics and gynaecology^{6,7}, Ben van Calster professor of medical statistics⁶, Maria Jalmbrant clinical psychologist⁸

Corresponding author: Professor Tom Bourne Queen Charlotte's & Chelsea Hospital Imperial College London tbourne@imperial.ac.uk

Key words: anxiety, depression, suicide, physicians, regulation

Word count 5634

¹Queen Charlotte's & Chelsea Hospital, Imperial College, Du Cane Road, London, W12 0HS, UK

²KU Leuven Department of Electrical Engineering-ESAT, STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, Leuven, Belgium

³KU Leuven iMinds Future Health Department, Leuven, Belgium

⁴ Doctors for Doctors, British Medical Association, BMA House, Tavistock Square, London, UK

⁵LUCAS, KU Leuven, Leuven, Belgium

⁶KU Leuven Department of Development and Regeneration, Leuven, Belgium

⁷Department of Obstetrics and Gynaecology, University Hospitals Leuven, Leuven, Belgium

⁸South London and Maudsley NHS Foundation Trust, Denmark Hill, London, UK

Abstract

IMPACT study

Objectives: the primary aim was to investigate the impact of complaints on doctors psychological welfare and health. The secondary aim was to assess whether doctors report that exposure to a complaints process is associated with defensive medical practice.

Design: cross-sectional anonymous survey study. Participants were stratified into recent/current, past, no complaints. Each group completed tailored versions of the survey.

Participants: 95,636 doctors were invited to participate. 10,930 (11.4%) responded. 7,926 (8.3%) completed the full survey and were included in the complete analysis.

Main outcome measures: anxiety and depression were assessed using the standardised Generalised Anxiety Disorder scale and Physical Health Questionnaire. Defensive practice was evaluated using a new measure. Single-item questions measured stress-related illnesses, complaints-related experience, attitudes towards complaints, and views on improving complaints processes.

Results: 16.9% of doctors with current/recent complaints reported moderate/severe depression (relative risk (RR) 1.77 (95% CI=1.48, 21.3) compared to doctors with no complaints (9.5%)). 15% reported moderate/severe anxiety (RR= 2.08 (95% CI=1.61, 2.68) compared to doctors with no complaints (7.3%)). Distress increased with complaint severity, with highest levels after General Medical Council (GMC) referral (26.3% depression, 22.3% anxiety). Doctors with current/recent complaints were 2.08 (95% CI=1.61,2.68) times more likely to report thoughts of self-harm or suicidal ideation. Most doctors reported defensive practice: 82-89% hedging and 46-50% avoidance. 20% felt victimized after whistleblowing, 38% felt bullied. 27% spent over one month off work. Over 80% felt processes would improve with transparency, managerial competence, capacity to claim lost earnings and act against vexatious complainants.

Conclusions: doctors with recent/current complaints have significant risks of moderate/severe depression, anxiety, and suicidal ideation. Morbidity was greatest in cases involving the GMC. Most doctors reported practicing defensively including avoidance of procedures and high-risk patients. Many felt victimised as whistle-blowers or reported bullying. Suggestions to improve complaints processes included transparency and managerial competence.

Strengths and limitations of this study

Strengths

- One of the largest reported on this subject with 10,930 respondents and 7,926 completing the survey
- Respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions.
- We have obtained quantitative data on mental wellbeing using validated questionnaires.

Limitations

- The main limitation of the study was the overall response rate of 11.4%. Accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. On the other hand doctors were being asked to comment on their regulators, and those most traumatised by the complaints process may have avoided engaging with the survey. Doctors who have been erased from the register or changed profession would not have been contacted.
- The cross-sectional design does not enable causation to be elucidated
- We collected responses from doctors who have not experienced a complaint
 but observed the impact on others. This means that the "no complaints" group
 may have more psychological morbidity than if doctors could be isolated from
 complaints processes completely. This may result in relative risks in the paper
 being underestimated.
- Some questions involved remembering past events and the possibility of recall bias must also be considered.
- There were missing responses for a number of questions. However this was
 dealt with using multiple imputation. However we are reassured that no major
 differences between the conclusions that would be drawn using complete
 cases compared to those where data was missing and imputed were found.

Introduction

In the United Kingdom (UK), the General Medical Council (GMC) acts as the regulator and sets standards that doctors are expected follow. It has the power to warn, suspend, restrict the practice of doctors or permanently remove them from the register. These powers are established under the Medical Act (1983).

It was recently disclosed that 96 doctors have died since 2004 while involved in GMC fitness to practice proceedings. In parallel to this, between 2011 and 2012 the number of doctors referred to the GMC increased by 18%¹. Although most doctors referred to the GMC have their case closed at triage or have no action taken², there can be harrowing consequences for some doctors who go through a GMC investigation³.

However the GMC represents only the tip of the iceberg of the complaints system. These include formal and informal hospital internal enquiries, serious untoward incident (SUI) investigations and disputes with managers and colleagues. Whilst there are some data relating to how doctors respond to GMC investigations, to our knowledge there are no studies addressing the issue of complaints procedures below this level in the UK. For many doctors, the prospect of facing a complaint or professional dispute causes them significant stress. This can manifest itself in how they perform in clinical practice and/or in their personal life, and may lead to both physical and psychological symptoms.

Clearly complaints and investigations when things go wrong are part of the checks and balances that should ensure appropriate oversight of a doctor's performance, the overall aim being to protect patients and maintain appropriate clinical standards. However the regulatory burden and stress associated with a complaints process may not lead to the outcomes that are desired.

In a previous study of surgeons surveyed in the United States (US), malpractice litigation was significantly associated with burnout, depression and suicidal ideation⁴. There are also data to suggest that medical errors are associated with depression and loss of empathy in the physician responsible⁵. None of these outcomes are likely to improve patient care. A further study has shown suicidal ideation in over 6% of US surgeons, over twice the background rate in the population. In this study, burnout, depression, and involvement in a recent medical error were strongly and

IMPACT study

independently associated with suicidal ideation after controlling for other personal and professional characteristics. Most surgeons in this study were reluctant to seek professional help due to concerns that there may be an impact on their career⁶.

In a study published in the BMJ, Jain and Ogden described the impact of patient complaints on general practitioners in the United Kingdom and reported an association with anger, depression and suicide⁷. It is important to note they also described clinicians involved in complaints practicing medicine more defensively. Such practice may be broadly categorized into "hedging" and "avoidance". Hedging is when doctors are overcautious leading for example to over-prescribing, referring too many patients, or over investigation. Avoidance includes not taking on complicated patients, and avoiding certain procedures or more difficult cases.

The primary aim of this study was to investigate the psychological welfare of doctors who have observed or experienced both past and/or current complaints. The secondary aim of the study was to assess whether being involved in or witnessing a complaints process leads to doctors reporting that they practice medicine defensively.

Methods

Design

The study used a cross-sectional survey design where participants were streamed into three groups: current/recent complaint (on-going or resolved within the last 6 months), past complaint (resolved more than 6 months ago), and no complaints. Each group completed a slightly different version of the questionnaire. Participants in the current complaints and no complaints group were asked about their current mood and health whereas the past complaints group were also asked to respond about their mood and health at the time of the complaint.

Ethical approval was obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Participants

The British Medical Association (BMA) is an apolitical professional association and independent trade union that represents doctors and medical students in the UK, membership is voluntary. Members of the BMA in November 2012 who had preconsented to being contacted for research purposes were invited to participate (n=95,636). They were emailed a link to an online encrypted questionnaire using Survey Monkey® and an information sheet describing the study. Participants were guaranteed that their responses were anonymous and untraceable. The survey remained open for two weeks and three reminders were sent out about the study during this time. A total of 10,930 (11.4%) participants responded to the survey. Of these, 696 (6.4%) were excluded as they only completed the demographics section, and 121 (1.1%) participants were excluded because a technical error meant that they were given the wrong sections to complete. A further 2187 (20.0%) participants completed the demographics section and indicated whether they had had a complaint and they were partially included in the analysis (sample 1). A total of 7926 (72.5%) participants completed the survey (sample 2). Of these, 1380 omitted some sections of

the survey but were included in the full analysis. Demographic information in relation to both samples is shown in table 1.

In order to check that our sample was representative, we compared our study population with the total BMA membership database (see table 1). This showed that our sample was broadly representative in terms of gender (46.3% females in the BMA membership database compared to 47.5% females in both sample 1 and 2) and place of qualification (80.1% qualified in the United Kingdom in the BMA population compared to 80.7% in sample 1 and 81.2% in sample 2). Our study population consisted of more doctors in the 35-59 age range (49.8% in the BMA population compared to 74.8% in sample 1 and 73.4% in sample 2), ethnic minorities were under-represented (32.4% in the BMA population compared to 22.4% in sample 1 and 21.8% in sample 2), and consultants and GPs were over-represented (27.2% were consultants and 26% were GPs in the BMA population compared to 37.1% and 38.4% in sample 1 and 36.5% and 37.8% in sample 2) whilst junior doctors and retired doctors were underrepresented (26.4% were juniors and 8.6% were retired in the BMA population compared to 15.7% and 0.7% in sample 1 and 16.5% and 0.7% in sample 2).

Measures

A pilot of the questionnaire trialed on 20 medical doctors of varying grades and specialties and their feedback was incorporated in the questionnaire design (see details below). In total, 108 questions were asked to the no complaints group and 179 questions were asked to both the complaints groups. Based on filling in trial questionnaires, we estimate the time required to complete the questionnaire was approximately 30 minutes. The questionnaire is included as supplementary online information (supplementary file 1) or can be reviewed by using the following link: https://www.surveymonkey.com/s/P55KH5P

Having completed 13 items obtaining demographic information (including age, specialty, gender, marital status, ethnicity, place of training, marital status, and details about their employment), participants were separated into three streams based on

whether they had i) a current/recent complaint (within the past 6 months), ii) past complaint, or iii) no current or past complaints.

The different types of complaint or investigation that were considered in the study are outlined below:

Informal: an informal complaint usually involves a patient speaking directly to the people involved in their care in order to resolve their concerns. It can be escalated to a formal complaint if not resolved locally.

Formal: this is a written complaint usually to the chief executive or an employing organization that triggers an investigation and often requires a written response within a set time period and may lead to disciplinary action or referral to the GMC.

Serious Untoward Incident (SUI): the definition of an SUI is wide ranging and includes an unexpected death, poor clinical outcome, a hazard to public health, a trend leading to reduced standards of care, damage to reputation or confidence in a service or adverse media coverage or public concern about an organization. The aim is to prevent recurrence of the adverse event, but may lead to disciplinary action for individuals or referral to the GMC.

General Medical Council: a complaint can be made about a doctor for issues ranging from personal behavior outside work to clinical concerns about their practice. The GMC review cases and have the power to suspend doctors from practice during an investigation. This may lead to a warning or referral to a tribunal that has the power to restrict a doctor's practice, impose working under supervision, suspension from the medical register or remove a doctor from the register permanently. The GMC may also issue warnings and undertakings to doctors to change aspects of their behavior or practice.

All participants completed the following sections (although some individual items varied in the different streams):

Experience of complaint: Participants in both complaints groups were asked 75 questions about their complaint(s) generated from Bark and colleagues⁸ and the pilot study. This included their total number of complaints, the most significant complaint and followed by a series of questions about the most serious complaint if they had had

more than one, including the reason for the complaint, the origin, the duration, the outcome, the cost (i.e. any leave taken, the estimated financial cost), and the level of support sought and obtained during the complaint. Participants who had been referred to the GMC were also asked to rate how stressful they found each aspect of the procedure. Whilst the majority of the questions used a 5-point scale, some questions were qualitative and a few were yes/no.

Attitudes towards complaints: All groups were asked ten questions using a 5-point scale generated from the pilot study about their attitudes toward complaints, the causes of complaints, and their perceived threat of future complaints. The no complaints group was asked 11 additional questions about their attitudes towards the complaints process (e.g., "I believe that complaints are reasonably dealt with") and how well they perceive that they would be supported in the event of a complaint made against them (e.g., "If I had a complaint made against me, I am confident that my management would support me").

Suggestions to improve the complaints process. All groups were asked to rate different suggestions on how to improve the complaints process on 11 5-point items. These proposals were generated from the pilot study.

Medical history: The presence of common stress-related illnesses at the time of the complaint or currently were measured using 12 items, including recurring infections, gastro-intestinal, sleep, cardio-vascular and mood problems^{9, 10}. In addition, questions were asked about self-reported drug and alcohol use, as well as life stressors at the time of both current and past complaints.

Defensive medical practice: Twenty items measuring current defensive medical practice were generated from a literature review^{10,11,12}. 12 items additional items were generated from the pilot study (5 for the no complaints group). Items were either rated on a 5-point scale or a yes/no response.

Depression: The Physical Health Questionnaire (PHQ-9¹³⁾ is a well-known standardised screening measure assessing the presence and severity of depression. It has been used across a wide range of populations and demonstrated good

Page 10 of 110

 IMPACT study

psychometric properties. Respondents were considered depressed if they scored 10 or more on the PHQ-9¹⁴.

Anxiety: The Generalised Anxiety Disorder scale (GAD-7)¹⁵) is a standardised screening measure assessing the presence and severity of generalized anxiety disorder. The GAD-7 is also moderately good at identifying panic disorder, social anxiety disorder, and post-traumatic stress disorder. It has been used across a wide range of populations and demonstrated good psychometric properties. Respondents were considered anxious if they scored 10 or more on the GAD-7¹⁵.

Life Satisfaction. Life satisfaction was assessed with 10 items using a 6-point scale asking about satisfaction-dissatisfaction with marriage, career, recreation/leisure, self/family, and life satisfaction/optimism.

Statistical analysis

For the purpose of this paper, we have limited ourselves to analysis of psychological welfare and health (i.e. anxiety, depression, stress-related illness), defensive practice, culture, time off work and suggestions for improving the complaints process. To summarise the fifteen items measuring defensive practice, an exploratory factor analysis was conducted which identified two underlying factors. The first involves over-investigation and overly cautious management, which we have termed "hedging" (9 items, including for example "carried out more tests than necessary", "referred patient for second opinion more than necessary" and "admitted patients to the hospital when the patient could have been discharged home safely or managed as an outpatient", Cronbach's α =0.92). The second involves avoiding difficult aspects of patient treatment, which we termed "avoidance" (3 items, "stopped doing aspects of my job", "not accepting high risk patients in order to avoid possible complications", and "avoiding a particular type of invasive procedure", Cronbach's α =0.77). Due to strongly skewed distributions, the sumscores hedging and avoidance were analysed both as dichotomous (any hedging (>0)/avoidance (>0) versus no hedging (0)/avoidance (0)) and ordinal variables (never (0), rarely (hedging 1-12, avoidance 1-4), sometimes (hedging 13-24, avoidance 5-8) or often (hedging 25-36, avoidance 9-12) displaying hedging or avoidance behavior.)

The statistical analysis mainly consisted of descriptive analyses. Cross-tabulations of psychological welfare and defensive practice indicators have been made and relative risks were computed to investigate the relationship between complaint group and psychological welfare or defensive practice indicators. Additionally, means within the complaint groups and mean differences have been computed for continuous variables such as depression and anxiety. Asymptotic 95% confidence intervals were computed for relative risks and mean differences. Unpooled standard errors of the mean difference were used when necessary. Proportions and their 95% confidence intervals were also computed for feeling bullied during the investigation, feeling victimized because of whistle blowing and the amount of time spent off work. Proportions were computed to investigate the amount of support of respondents to various proposed actions to improve the complaints process.

As the primary aim of this study was to investigate the impact of complaints on the psychological welfare and health of doctors, a logistic regression analysis was performed to assess the relationship between moderate to severe depression and receiving a complaint, while controlling for predefined confounders (age, gender, being in a relationship, being White British, and medical specialty). Interactions of complaint with the confounders were included if necessary (α =0.001). Proportional odds logistic models were constructed to investigate whether hedging or avoidance are associated with characteristics of the complaint process (length of investigation, timing of complaint, outcome of investigation, origin of the complaint, type of the complaint). For hedging and avoidance, all two-way interactions were of interest and were included if necessary (α =0.001). We checked linearity assumptions, the presence of multi-collinearity, the presence of outliers, and the proportional odds assumption when necessary.

There was substantial item non-response. For key variables such as depression, anxiety, hedging and avoidance, non-response was approximately 20%. Missing data was addressed by performing multiple imputation¹⁶. Missing responses were replaced by 100 plausible values based on available responses to other questions, leading to 100 completed datasets that represent the uncertainty about the right value to impute. For composite scales (depression, anxiety and hedging), a two-step approach to

Page 12 of 110

IMPACT study

imputation was used to decrease the computational burden and make appropriate use of the available answers to separate items, first imputing the respondent's mean of non-missing items if at least 80% of the items of the composite scale were nonmissing, followed by multiple imputation (MI) at the scale level for the remaining individuals. For avoidance, the three items were individually imputed. Multiple imputation was performed using chained equations (MICE)¹⁶ with 10 iterations. After MI, each completed dataset was analysed separately and results combined using standard Rubin's rules (Rubin, 1987). To assess the impact of item non-response, we performed a sensitivity analysis comparing the results of the complete case analysis to the results after MI, which assumes missingness at random. Additionally, MI assuming missingness not at random (informative missings) was considered for key variables depression, anxiety, hedging and avoidance¹⁷. Since these variables are based on responses to sensitive questions, informative missingness is plausible. As a missingness mechanism we assumed that those respondents with missingness might have been more anxious or depressed, or more likely to display hedging behavior or avoidance. More details on the MNAR analysis can be found in the supplementary file.

The data was analysed using SAS (version 9.3, SAS Institute, Cary, NC, USA). Multiple imputations were performed using IVEware (http://www.isr.umich.edu/src/smp/ive/)¹⁸.

Results

Psychological welfare and health

Overall, 16.9% of doctors with recent or ongoing complaints reported clinically significant symptoms of moderate to severe depression (table 2). Doctors in this group were at increased risk of depression compared to those with a past complaint (7.8%) or no personal experience of a complaint (9.5%. RR=1.77, 95% CI=1.48, 2.13). This was the case even when controlling for the effects of gender, age (cubic effect), being in a relationship (yes/no), being White British (yes/no), and medical specialty. The effect of having a recent or current complaint depends on gender. When there has been no complaint, men tend to be less likely to be depressed than women (OR=0.76,

95% CI=0.54, 1.09), but a recent or current complaint has a higher impact on men than on women (OR women=1.72, 95% CI=1.28, 2.30; OR men=2.86, 95% CI 2.04, 4.01]. Within the PHQ-9, doctors with an ongoing or recent complaint (9.7%) were twice as likely as doctors with no complaints (4.7%) to report having thoughts of self-harm or suicidal ideation (RR=2.08, 95% CI=1.61, 2.68; see table 2). The sensitivity analysis shows that this conclusion holds under various assumed missingness mechanisms (see supplementary figure 1, supplementary table 1).

Moreover, 15% of doctors in the recent complaints group reported clinically significant levels of anxiety on the GAD-7, which is twice as likely as doctors who have no complaints (see Table 2, 7.3%, RR= 2.08, 95% CI=1.61, 2.68). Also this conclusion holds under various assumed missingness mechanisms (see supplementary file 1, supplementary table 2).

The level of psychological distress was related to the type of complaints procedure. Doctors going through a GMC referral reported the highest levels of depression (26.3%), anxiety (22.3%) and thoughts of self-harm (15.3%) compared to SUIs (16.1%, 15.3% and 9.3% respectively), formal complaints (15.6%, 13.5% and 9.0%), and informal complaints (12%, 12% and 6.4%) (table 3).

When asked directly using a single item scale, doctors were 3.78 (95% CI=2.68, 5.32) times more likely to report the presence of suicidal thoughts whilst going through a current or recent complaint compared to doctors who had no complaints (table 4).

Doctors who have experienced either a recent or past complaint reported higher levels of health problems at the time of the complaint compared to the no complaint group. These included gastro-intestinal problems, subjective anxiety and depression, anger, other mental health problems, insomnia, relationship problems, and frequent headaches. Doctors in the current complaints group also reported higher levels of cardio-vascular problems (table 4).

Defensive practice

Overall, 84.7% of doctors with a recent and 79.9% with a past complaint reported changing the way they practiced medicine as a result of the complaint. 72.7% of doctors with no previous complaint reported changing their practice having observed a colleague's experience of a complaint (table 5).

88.6% of doctors with a recent or current complaint and 82.6% of those with a past complaint displayed hedging behaviour. 81.7% of doctors with no previous complaints reported hedging. The sensitivity analysis revealed that under the MNAR assumption, the conclusion still holds that people in the recent or current complaint group display more hedging behavior than people in the no complaints group, but also people with a past complaint display considerably more hedging behavior (supplementary figure 1, supplementary table3).

49.8% or doctors with a recent or current complaint, 42.9% of doctors with a past complaint, and 46.1% of doctors with no personal experience of a complaint reported avoidance behaviour having observed a colleague's experience of a complaint. Although the results from the complete case analysis support the conclusion that mostly people in the recent and current complaint group display avoidance behaviour, the results from the analysis under the MNAR assumption suggest that it is people with a past complaint who display most avoidance behaviour (supplementary figure 1, supplementary table 4).

The multivariable proportional odds analysis indicated that the odds of more severe hedging are higher for people with a recent or ongoing complaint than for people with a past complaint (OR 1.33 95% CI=1.19, 1.49) (table 6). The odds of hedging slightly increased with the length of time of the investigation (OR 1.01 per month, 95% CI=1.00, 1.01). Hedging was increased when retraining was imposed (OR 1.62, 95% CI=0.84, 3.13) and decreased when the doctor was suspended from practice (OR 0.56, 95% CI=0.26, 1.18). The odds of hedging also decreased when the complaint came from medical colleagues (OR 0.67, 95% CI=0.53, 0.86). There was evidence of an interaction between the type of the most serious complaint one has experienced and whether or not the complaint came from a patient (supplementary figure 1). Hedging was higher when the complaint came from a patient, this was most clear for informal

(OR=3.16, 95% CI=2.17, 4.58) and formal complaints (OR=2.18, 95% CI=1.67, 2.85). When the complaint did not come from a patient, hedging was higher for formal complaints, SUI's and GMC referrals compared to informal complaints (OR=1.52, 95% CI=1.03, 2.24, OR=2.10, 95% CI=1.31, 3.35 and OR=1.78, 95% CI=1.15, 2.71, respectively).

As with hedging, the multivariable analysis indicated that the odds of more severe avoidance increased with the length of time the investigation (OR 1.01 per month, 95% CI=1.01, 1.02), and was higher for people with a recent or current complaint than for people with a past complaint (OR 1.20, 95% CI=1.07, 1.35) (table 7). Avoidance was also increased when the investigation resulted in imposed retraining (OR 1.79, 95% CI=1.0, 3.09). Avoidance behaviour most severely increased when the complaint came from a patient group (OR 1.71, 95% CI=1.02, 2.87) or management (OR 1.59, 95% CI=1.16, 2.16), or when the complaint was anonymous (OR 1.58, 95% CI=1.06, 2.36). The type of complaint did not meaningfully influence the odds of more severe avoidance.

Overall, as a result of their experience of the complaints process, 23% of doctors reported suggesting invasive procedures against their professional judgement, and 14% reported becoming more likely to abandon a procedure at an early stage.

Culture and time off work

20% (95% C.I. 19% to 22%) reported that they felt victimized because they had been a whistleblower for clinical or managerial dysfunction. 38% (95% C.I. 37% to 40%) of people who have had a complaint, recently or in the past, reported feeling bullied during the investigation.

60% (95% C.I. 57% to 64%) spent less than a week off work. However, 27% (95% C.I. 24% to 30%) of people with complaints spent more than a month off work.

Opinions on changes to improve the system

Of those doctors that gave a response, 85% felt that for managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them mattered quite a lot or a great deal in terms of improving the process. An equal number (85%) felt that if a doctor is exonerated but has suffered financial loss during the process, then they should have the option to make a claim for recovery of lost earnings or costs and in addition that there should be complete transparency of any management communication about the subject of a complaint and that access to such communications should be given to a doctor's representatives. Seventy-four percent of respondents felt that it mattered quite a lot or a great deal that if a complaint from a clinical or managerial colleague was found to be vexatious then this could be investigated and possible disciplinary measures taken. The full details of responses in relation to actions that could be taken to reduce the psychological impact of complaints processes are shown in supplementary table 5.



IMPACT study

Discussion

We have shown that doctors who responded to our questionnaire who have recently received a complaint of any kind are 77% more likely to suffer from moderate to severe depression than people who have never had a complaint. They also have double the risk of having thoughts of self-harm, and double the risk of anxiety. Welfare is lowest when the complaint involves referral to the GMC. Doctors with a recent or current complaint also reported that they suffered from an increased likelihood of cardiovascular and gastro-intestinal disorders, depression, anxiety, anger and irritability, suicidal thoughts, sleep difficulty, relationship problems, and frequent headaches than people who had not been through a complaints process. In many cases these problems persisted. We have also shown that 80% of doctors answering the survey reported changing the way they practiced as a result of either complaints against themselves, or after observing a colleague go through a complaints process. The majority (84%) of doctors reported hedging behaviour in response to a complaint (i.e. increased defensive practice) whilst many (46%) admitted avoidance. A further important finding was that many doctors who had a complaint (20%) felt they were victimised after whistle blowing, thirty-nine percent reported that they felt bullied when they were going through the process, and 27% had more than a month off work.

A strength of the study is that to our knowledge it is one of the largest reported on the subject involving 10,930 respondents with 7,926 completing the survey. It is certainly the largest relating to doctors in the UK. We think it is critical that respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions. Furthermore we have obtained quantitative data on the mental wellbeing of doctors using validated questionnaires. It is also important to note that we have collected responses from doctors who have not experienced a complaint but observed the impact on others. On the one hand this gives insight into the impact of observing a colleague going through a complaints process, however it also means that the "no complaints" group may have a higher overall level of psychological morbidity than if doctors could be isolated from complaints processes completely. Hence the relative risks in the paper may be underestimated. A significant limitation of the study is that the response rate was 11.4%, accordingly the findings must be interpreted with

caution due to the possibility of ascertainment bias. What constitutes an acceptable response rate is a subject of debate, however our response rate is clearly low¹⁹. We believe this is inevitable when asking doctors to comment on disciplinary processes and in particular on their regulator. Even if we take the view that the respondents are a selected group, they still demonstrate that a very considerable number of doctors are significantly impacted by complaints processes and practice defensively. It must also be remembered that doctors that have been most traumatised by the complaints process may have felt unable to take part in the survey and a small number are known to have committed suicide. Furthermore those no longer on the register (for example if they have changed profession or erased from the register) are unlikely to be members of the BMA and so would not have been contacted. As some questions involved remembering past events the possibility of recall bias for some answers must also be considered. For a number of questions there were missing responses. However we have considered this issue by using multiple imputation and were reassured that we found no essential differences between the conclusions that would be drawn using complete cases compared to those where missing data have been imputed.

As with any cross-sectional survey we must be careful when considering the findings, as we cannot show causation. It is possible that doctors with depression, anxiety and suicidal ideation are more likely to have complaints made against them, similarly being complained against may be the causative factor rather than the processes themselves. However this still means the information presented is important as if we take the former view, it means those going through complaints processes are a vulnerable group that need support. This was illustrated in a recent study that reported that sick doctors under investigation stated that the processes and communication style employed by the GMC were often distressing, confusing, and perceived to have impacted negatively on their mental health and ability to return to work²⁰.

It is interesting that our findings are similar to a questionnaire-based study of surgeons in the United States examining the emotional toll of malpractice lawsuits. This study found significantly more depression and burnout in surgeons who had recently been exposed to a lawsuit and highlighted the association between burnout and the likelihood of making a medical error⁴.

IMPACT study

We found that 10% of doctors responding to the survey who have had a recent complaint have had thoughts of self-harm and are over twice as likely to have had such thoughts compared to doctors who had not personally experienced a complaint. When referral to the GMC is looked at in isolation the number of doctors who reported suicidal ideation reached 15.3%, whilst 26.3% had moderate to severe depression and 22.3% had moderate to severe anxiety on the basis of two validated instruments. Even set against the limitations of the study we have highlighted above, these findings are concerning. In a recent feature article in the BMJ, Dyer reported on the high number of suicides associated with GMC proceedings³. Our results support the view that these proceedings have a disproportionate impact on doctors, especially as the vast majority of doctors who are referred to the GMC are found to have no significant case to answer². However the GMC is at the apex of what amounts to a "complaints pyramid" and our data show similar significant psychological morbidity for doctors across the entire spectrum of complaints procedures.

The incidence of feeling victimized following whistleblowing (20%) and bullying (38%) will be a concern to those trying to build a culture in the UK National Health Service (NHS) where it is safe to speak out about clinical and managerial concerns. The Francis report highlighted the dysfunctional culture that is prevalent in many NHS organisations²¹. Other reports have also highlighted serious concerns about the pressures that may be placed on hospital staff ²². Given the large numbers involved, our study supports the view that whistleblowing in the NHS is often not a safe action, that bullying is not uncommon, and that these problems are not isolated events.

The GMC exists to protect patients and the public. This is also the aim of other types of complaints processes with the overall purpose being to learn from mistakes and improve the performance of everyone taking part in patient care. However as with all interventions there may be unforeseen consequences. Previously Jain et al in a qualitative study reported that many general practitioners practice defensively following a complaint⁷. Our data also show the vast majority of doctors who took part in the study reported engaging in defensive practice. This included carrying out more tests than necessary, over-referral, over-prescribing, avoiding procedures, not accepting high-risk patients and abandoning procedures early. Nash and colleagues have also reported high levels of defensive practice²³. In their study which had a

higher response rate of 36%, 43% of doctors reported that they referred more patients, 55% ordered more tests and 11% stated they prescribed more medications than usual in response to medico-legal concerns. In a further report the same authors showed that doctors working in high- intervention areas of medicine are more likely to be the subject of medico-legal complaints²⁴. Defensive practice in such specialties may be particularly concerning.

These behaviors are not in the interest of patients and may cause harm, whilst they may also potentially increase the cost of health care provision. By far the majority of doctors who are reported to the GMC are not found to have a significant case to answer², as is probably the case with other lower level complaint investigations. It therefore does not seem unreasonable to argue that as they currently function, GMC enquiries may do more overall harm than good in terms of patient care. As the "complaints pyramid" is descended it is possible this balance may improve, although we found defensive practice across the entire spectrum of complaints processes.

Whilst we fully acknowledge the limitations associated with any study of this type, we believe our findings have implications for policy makers. Procedures must exist to enable patients to make a complaint about their care, for professionals to raise concerns about standards of practice and for serious untoward events to be investigated. However a system that is associated with high levels of psychological morbidity amongst those going through it is not appropriate as either the subjects of such procedures are vulnerable at the outset or are suffering such morbidity as a direct result of the investigations themselves. Most importantly, a system that leads to so many doctors practicing defensive medicine is not good for patients. A further concern for patient care is the association between doctor's distress, burnout and decreased empathy with perceived medical errors²⁵.

When asked how the complaints process could be improved doctors indicated that what mattered to them was that the process should be transparent and that staff responsible for investigating complaints should be up to date and competent. There was also a clear feeling that in the event of a complaint being shown to be vexatious then there should be disciplinary consequences if this related to colleagues, or the option for financial redress in the event it related to patients. Concerns about the lack of redress associated with vexatious complaints have been raised in the BMJ before²⁶.

IMPACT study

This highlights the inherent tension in the system whereby an apparent "whistleblower" may be perceived as a vexatious complainant by a colleague.

We have shown that doctors who responded to our questionnaire and experience or observe complaints processes exhibit high levels of psychological morbidity including severe depression and suicidal ideation. These effects are greatest when the process involves the General Medical Council. In addition the majority of these doctors exhibit hedging and avoidance, both these behaviours may be damaging to patient care and be contrary to the professed aims of these processes. Ind be com.

Acknowledgements

Mr. Christoph Lees (Imperial College NHS trust) and Mr. Magnus Boyd (Hill Dickinson LLP solicitors) contributed to receiving feedback on the contents and design of the questionnaire. We would like to thank all clinicians who commented on the initial versions of the survey.

Contributors

TB conceived of the original idea for the study, interpreted results, drafted the paper and is overall guarantor. MJ designed the questionnaire, obtained ethical approval, contributed to the preparation of the data set, interpreted results and contributed to drafts of the paper. LW and BVC carried out the statistical analysis and contributed to drafts of the papers. MP contributed to the study design, interpretation of results and commented on drafts of the paper. DT and CVA contributed to interpretation of results and commented on drafts of the paper. All authors approved the final version of the manuscript.

Funding

Tom Bourne is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. Laure Wynants is supported by a PhD grant of the Flanders' Agency for Innovation by Science and Technology (IWT Vlaanderen). Dirk Timmerman is a Senior Clinical Investigator of the Research Foundation- Flanders (FWO)

Competing interests

All authors have completed the Unified Competing Interest form and declare: Michael Peters is head of the BMA doctors for doctors unit and so receives payment from the BMA. The BMA had no role in data collection, design of the study, data analysis, interpretation of data, or writing the report and had no influence over whether to submit the manuscript. All other authors stated that they had no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other

relationships or activities that that could appear to have influenced the submitted work

Ethical approval

Ethical approval was sought and obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Transparency declaration

The lead author (T Bourne) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no aspects of the study have been omitted in relation to the specific aspects of the study reported in this paper; and that any discrepancies from the study as planned (and, if relevant registered) have been explained.

The Licence

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors a worldwide, licence, to the Publishers and its licensees in perpetuity (subject to the Reversion of Rights set out below), in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution and convert or allow conversion into any format including without limitation audio, iii) create any other derivative work(s) based in whole or part on the Contribution, iv) to exploit all subsidiary rights that currently exist or as may exist in the future in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above.

References

- 1 White C. Complaints against doctors continue to rise. BMJ Careers 2013 Sep 30 http://careers.bmj.com/careers/advice/view-article.html?id=20014782 (accessed on 25 November 2013).
- 2 General Medical Council. Fitness to Practise Annual Statistics Report 25th September 2012 www.gmc-uk.org (accessed on 25 November 2013).
- 3 Dyer C. GMC and vulnerable doctors: too blunt an instrument? BMJ 2013;347:f6230
- 4 Balch CM, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. J Am Coll Surg 2011;**213**:657-67.
- 5 Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. Arch Surg 2011;**146**:54-62.
- 6 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;**296**:1071-78.
- 7 Jain A, Ogden J. General practitioners' experiences of patients' complaints: qualitative study. BMJ 1999; **318**:1596-99.
- 8 Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. Quality in Health Care 1997;6:7-13.
- 9 Schat AC, Kelloway EK, Desmarais, S. The Physical Health Questionnaire: construct validation of a self-report scale of somatic symptoms. J Occup Health Psychol 2005;**10**:363-81.
- 10 Studdert DM, Mello MM, Sage VM, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 2005;**293**:2609-17.

- 11 Nash L, Walton M, Daly M, et al. GPs' concerns about medico legal issues: How it affects their practice. Australian Fam Physician 2009;**38**:66-70.
- 12 Summerton N. Positive and negative factors in defensive medicine: A questionnaire study of General Practitioners. BMJ 1995;**310**:27-29.
- 13 Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ Primary Care Study. JAMA 1999;**282**:1737-44.
- 14 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001;**16**:606-13.
- 15 Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;**166**:1092-97.
- 16 Raghunathan TW, Lepkowksi JM, Van Hoewyk J, et al. A multivariate technique for multiply imputing missing values using a sequence of regression models. Survey Methodology 2001;27:85–95.
- 17 Rubin DB. (1987). Multiple Imputation for Nonresponse in Surveys. Wiley, NY.
- 18 IVEware: Imputation and Variance Estimation Software. http://www.isr.umich.edu/src/smp/ive/ (accessed on 12 August 2013).
- 19. Baruch Y. Response rate in academic studies A comparative analysis. Human relations, 1999; 52: 421-438
- 20. Brooks SK, Del Busso L, Chalder T, Harvey SB, Hatch SL, Hotopf M, Madan I, Henderson M. 'You feel you've been bad, not ill': Sick doctors' experiences of interactions with the General Medical Council. BMJ Open. 2014 Jul 17; 4(7):e005537. doi: 10.1136/bmjopen-2014-005537.

- 21 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013. Chaired by Robert Francis QC. http://www.midstaffspublicinquiry.com/report (accessed 25 November 2013).
- 22 Care Quality Commission recommends Essex hospital trust is put into special measures 5 November 2013. http://www.cqc.org.uk/media/care-quality-commission-recommends-essex-hospital-trust-put-special-measures (accessed on 25 November 2013).
- 23 Nash LM, Walton MM, Daly MG et al. Perceived practice change in Australian doctors as a result of medicolegal concerns.

Med J Aust. 2010 Nov 15; 193(10): 579-83.

24 Nash LM, Kelly PJ, Daly MG et al. Australian doctors' involvement in medicolegal matters: a cross-sectional self-report study.

Med J Aust. 2009 Oct 19; 191(8): 436-40.

- 25 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;296:1071-78.
- 26 Marcovitch H. GMC must recognise and deal with vexatious complaints fast. BMJ 2002;324:167-68.

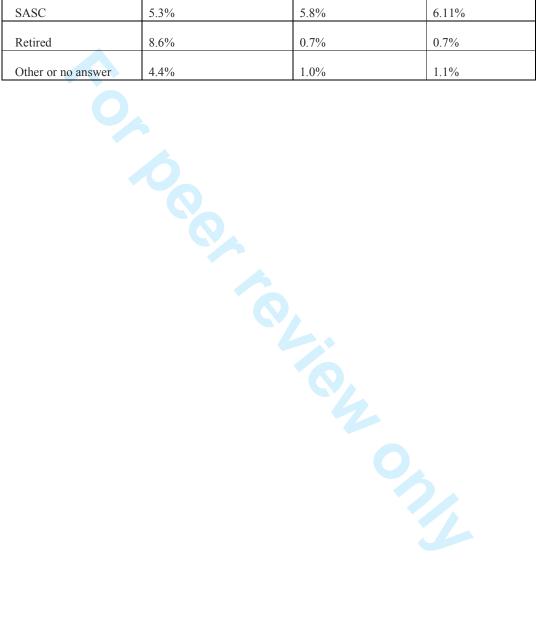
Tables and Figures

Table 1: Demographic information relating to both sample 1 and 2 in the study

Age	Total BMA membership consented for research	Sample 1 (n=10113)	Sample 2 (n=7926)
Up to 25	17.8%	1.4%	1.4%
26-29	9.0%	5.1%	5.5%
30-34	9.6%	8.6%	8.8%
35-39	10.3%	11.0%	11.0%
40-44	10.3%	13.5%	13.1%
45-49	10.8%	16.9%	16.8%
50-54	10.3%	18.8%	18.8%
55-59	8.1%	14.6%	14.7%
60-64	5.0%	6.6%	6.4%
65-69	3.0%	2.5%	2.6%
Over 69	5.9%	1.1%	1.0%
Gender	46.3% Female	47.5% Female	47.5% Female
Place of qualification			
United Kingdom	80.1%	80.7%	81.2%
India	8.2%	6.6%	6.2%
Pakistan	2.2%	1.2%	1.2%
Ireland	0.9%	1.4%	1.4%
Nigeria	1.1%	1.2%	1.2%
Germany	0.7%	1.1%	1.2%
South Africa	0.7%	0.8%	0.8%
Other	6.2%	6.9%	6.9%
Ethnicity White British	67.6%	77.6%	78.2%
Asian or Asian British	23.3%	16.6%	15.8%
Black or Black British	3.5%	2.3%	2.3%
Chinese or Chinese British	2.9%	1.3%	1.3%
Mixed	2.7%	2.3%	2.3%
Grade:			

IMPACT study

Academics	2.1%	1.2%	1.3%
Consultants	27.2%	37.1%	36.5%
General Practice	26.0%	38.4%	37.8%
Junior Doctors	26.4%	15.7%	16.5%
SASC Retired Other or no answer	5.3% 8.6% 4.4%	5.8% 0.7% 1.0%	0.7% 1.1%



IMPACT study

Table 2. Symptoms severity and relative risk of psychological distress for each complaints group.

	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent/ current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative risk for past complaint group/ mean difference (95% CI)	Relative risk for recent complaint group / mean difference (95% CI)
Depression (PHQ-9)						
Mean (SD) a	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3 (-0.6, -0.0)	1.4 (1.1, 1.7)
Moderate to severe depression n (%)	169 (9.5%)	303 (7.8%)	381 (16.9%)	852 (10.8%)	0.81 (0.65, 1.01)	1.77 (1.48, 2.13)
Thoughts of 'self- harm' n (%)	83 (4.7%)	221 (5.7%)	218 (9.7%)	522 (6.6%)	1.22 (0.93, 1.61)	2.08 (1.61, 2.68)
Anxiety (GAD-7) Mean (SD) ^b	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1 (-0.4, 0.2)	1.4 (1.1, 1.7)
Moderate to severe anxiety n (%)	131 (7.3%)	234 (6.0%)	338 (15.0%)	703 (8.9%)	0.80 (0.57, 1.13)	2.08 (1.61, 2.68)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

^b The GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Table 3. Psychological distress within the recent / on-going complaints group by complaint that had the most impact.

the most impact.	Informal	Formal	SUI	GMC	No
					No
	complaint	Complaint	n=280	referral	complaint
	n=362	n=1196	(12.4%)	n=374	n=1780
	(16.0%)	(53.0%)		(16.6%)	(22.5%)
Depression					
(PHQ-9)					
Mean (SD) a	4.2	4.8	5.1	6.6	3.7
	(5.0)	(5.4)	(5.6)	(6.7)	(4.3)
Moderate to severe	45	190	46	100	169
depression n (%)	(12.0%)	(15.6%)	(16.1%)	(26.3%)	(9.5%)
Thoughts of 'self-	24	110	27	58	83
harm' n (%)	(6.4%)	(9.0%)	(9.3%)	(15.3%)	(4.7%)
Anxiety (GAD-7)					
Mean (SD) b	3.8	4.4	4.7	5.7	3.1
•	(4.3)	(4.7)	(5.1)	(5.7)	(3.8)
Moderate to severe	44	165	44	85	131
anxiety n (%)	(12.0%)	(13.5%)	(15.3%)	(22.3%)	(7.3%)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

IMPACT study

Table 4. Psychosomatic health for each of the complaints group. Please note that the past complaints group used retrospective information asking about worsening or onset of symptoms at the time of the complaint, whereas the no and recent complaint groups were asked about the presence of symptoms in the last twelve months.

5 (10.4%) 4 (24.0%) 48 (29.5%) 45 (78.3%)	1.78 (1.44-2.20) 1.55 (1.32-1.82)
4 (24.0%) 48 (29.5%)	(1.44-2.20)
18 (29.5%)	1.55
18 (29.5%)	
	(1.52 1.02)
15 (78 30%)	2.07 (1.74-2.45)
rə (70.370)	1.84 (1.65-2.04)
06 (61.9%)	2.04 (1.77-235)
56 (6.6%)	3.45 (1.80-6.60)
9 (13.4%)	3.78 (2.68-5.32)
8 (74.1%)	1.87 (1.67-2.10)
1 (23.4%)	1.94 (1.63-2.30)
27 (26.4%)	1.41 (1.19-1.65)
47 (14.0%)	0.82 (0.73-0.92)
06 (7.9%)	1.47 (1.11-1.95)

Table 5 Defensive practice according to complaint group

Because of your/other's experiences with complaints, have you	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent or current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative Risk for past complaint (95% CI)	Relative Risk for recent or current complaint (95% CI)
Changed the way	1294	3106	1912	6312	1.10	1.17
of practicing medicine n (%)	(72.7%)	(79.9%)	(84.7%)	(79.6%)	(1.06,1.14)	(1.13,1.21)
Displayed	1454	3212	1999	6665	1.01	1.08
hedging behaviour n (%)	(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98,1.04)	(1.05,1.11)
Displayed	820	1668	1124	3612	0.93	1.08
avoiding behaviour n (%)	(46.1%)	(42.9%)	(49.8%)	(45.6%)	(0.87,1.00)	(1.00,1.17)
Suggested	359	902	585	1846	1.15	1.29
invasive procedures	(20.2%)	(23.2%)	(25.9%)	(23.3%)	(1.02,1.29)	(1.13,1.46)
against						
professional						
judgement n (%)						
Become more	248	515	372	1136	0.95	1.18
likely to abandon	(14.0%)	(13.3%)	(16.5%)	(14.3%)	(0.80,1.13)	(1.00,1.39)
a procedure at an						
early stage n (%) Become less		795	613			
committed and	-	(20.5%)	(27.2%)		_	-
worked strictly to		(20.370)	(27.270)			
job description n (%)				•		

Table 6. Factors influencing hedging behaviour.

Odds Ratio Estimates for hedging							
Effect	Point Estimate	95% Wald Confidence Limits					
Length of investigation (per month)	1.006	1.002	1.011				
Recent or current complaint (versus past complaint)	1.331	1.193	1.485				
Outcome of investigation							
No fault/ exonerated (yes versus no)	1.051	0.676	1.633				
Retraining imposed (yes versus no)	1.622	0.913	2.885				
Disciplinary action (yes versus no)	0.815	0.433	1.532				
Suspended from practice (yes versus no)	0.557	0.289	1.075				
Struck off from the register (yes versus no)	0.583	0.754	1.761				
The process was not clearly concluded (yes versus no)	1.152	0.900	1.960				
Where did the complaint come from							
Trust (yes versus no)	1.328	0.900	1.960				
Medical colleagues (yes versus no)	0.672	0.526	0.860				
Management (yes versus no)	0.797	0.581	1.094				
Media (yes versus no)	1.084	0.467	2.515				
Patient group (yes versus no)	1.495	0.906	2.464				
Other health care professional (yes versus no)	1.047	0.798	1.375				
Patient (yes versus no)							
For informal complaint	3.155	2.172	4.584				
For formal complaint	2.180	1.670	2.846				
Patient (yes versus no) For informal complaint For formal complaint For SUI For GMC referral Anonymous (yes versus no)	1.212	0.826	1.778				
For GMC referral	1.670	1.207	`2.311				
Anonymous (yes versus no)	1.362	0.922	2.012				
Type of complaint							
Formal complaint versus informal complaint							
Complaint did not come from a patient	1.521	1.034	2,239				
Complaint came from a patient	1.051	0.903	1.223				
SUI versus informal complaint							
Complaint did not come from a patient	2.097	1.311	3.352				
Complaint came from a patient	0.805	0.648	1.002				
GMC referral versus informal complaint							
Complaint did not come from a patient	1.776	1.164	2.709				
Complaint came from a patient	0.940	0.757	1.168				

Table 7. Factors influencing avoidance behaviour

Odds Ratio Estimates for avoiding							
Effect	Point Estimate	95% Wald Confidence Limits					
Length of investigation (per month)	1.011	1.006	1.016				
Recent or current complaint (versus past complaint)	1.201	1.069	1.350				
Outcome of investigation							
No fault/ exonerated (yes versus no)	0.893	0.594	1.340				
Retraining imposed (yes versus no)	1.787	1.033	3.092				
Disciplinary action (yes versus no)	1.211	0.682	2.152				
Suspended from practice (yes versus no)	1.066	0.566	2.008				
Struck off from the register (yes versus no)	0.626	0.119	3.305				
The process was not clearly concluded (yes versus no)	1.202	0.805	1.796				
Where did the complaint come from							
Trust (yes versus no)	1.338	0.910	1.968				
Medical colleagues (yes versus no)	1.439	1.134	1.826				
Patient (yes versus no)	1.364	1.114	1.670				
Management (yes versus no)	1.585	1.163	2.161				
Media (yes versus no)	0.866	0.380	1.972				
Patient group (yes versus no)	1.708	1.019	2.866				
Other health care professional (yes versus no)	1.326	1.015	1.731				
Anonymous (yes versus no)	1.580	1.057	2.360				
Type of complaint							
GMC referral (versus informal complaint)	1.082	0.885	1.323				
SUI (versus informal complaint)	1.112	0.904	1.368				
Formal complaint (versus informal complaint)	1.036	0.893	1.203				

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom: a cross-sectional survey

Tom Bourne adjunct professor of gynaecology and consultant gynaecologist^{1,6,7}, Laure Wynants researcher in medical statistics^{2,3}, Mike Peters head of BMA Doctors for Doctors Unit ⁴, Chantal Van Audenhove professor of psychology and applied communication⁵, Dirk Timmerman professor of obstetrics and gynaecology^{6,7}, Ben van Calster professor of medical statistics⁶, Maria Jalmbrant clinical psychologist⁸

Corresponding author: Professor Tom Bourne Queen Charlotte's & Chelsea Hospital Imperial College London tbourne@imperial.ac.uk

Key words: anxiety, depression, suicide, physicians, regulation

Word count 5634

¹Queen Charlotte's & Chelsea Hospital, Imperial College, Du Cane Road, London, W12 0HS, UK

²KU Leuven Department of Electrical Engineering-ESAT, STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, Leuven, Belgium

³KU Leuven iMinds Future Health Department, Leuven, Belgium

⁴ Doctors for Doctors, British Medical Association, BMA House, Tavistock Square, London, UK

⁵LUCAS, KU Leuven, Leuven, Belgium

⁶KU Leuven Department of Development and Regeneration, Leuven, Belgium

⁷Department of Obstetrics and Gynaecology, University Hospitals Leuven, Leuven, Belgium

⁸South London and Maudsley NHS Foundation Trust, Denmark Hill, London, UK

Abstract

Objectives: the primary aim was to investigate the impact of complaints on doctors the psychological welfare and health-of doctors. The secondary aim was to assess whether doctors report that exposure to a complaints process is associated with defensive medical practice.

Design: cross-sectional anonymous survey study. Participants were stratified into recent/current, past, or no complaints. Each group completed tailored versions of the survey.

Participants: 95,636 doctors were invited to participate. 10,930 (11.4%) responded. 7,926 (8.3%) completed the full survey and were included in the complete analysis.

Main outcome measures: anxiety and depression were assessed using the standardised Generalised Anxiety Disorder scale and Physical Health Questionnaire. Defensive_medical_practice was evaluatedmeasured using a new measure. Single-item questions measured stress-related illnesses, complaints-related experience, attitudes towards complaints, and views on improving complaints processes.

Results: 16.9% of doctors with current/recent complaints reported moderate/severe depression (relative risk (RR) 1.77 (95% CI=1.48, 21.3) compared to doctors with no complaints (9.5%)). 15% reported moderate/severe anxiety (RR= 2.08; (95% CI=1.61, 2.68) compared to doctors with no complaints (7.3%)). Distress increased with complaint severity, with highest levels after General Medical Council (GMC) referral (26.3% depression, 22.3% anxiety). Doctors with current/recent complaints were 2.08 (95% CI=1.61,2.68) times more likely to report thoughts of self-harm or suicidal ideation. Most doctors reported defensive medical practice: 82-89% hedging and 46-50% avoidance. 20% reported-felteling victimized after whistleblowing, 38% felteling bullied. 27% spent overmore than one a-month off work. Over 80% felt processes would improve with transparency, managerial competence, capacity to claim for lost earnings and act against vexatious complainants.

Conclusions: doctors with recent/current complaints have significant risks of moderate/severe depression, anxiety, and suicidal ideation. Morbidity was greatest in cases involving the GMC. Most doctors reported practicing defensively including avoidance of procedures and high-risk patients. Many felt victimised as whistle-blowers or reported bullbullyingied in relation to complaints. F. Suggestions toactors eited to improve complaints processes included transparency and managerial competence.

Strengths and limitations of this study

Strengths

- One of the largest reported on this subject with 10,930 respondents and 7,926 completing the survey
- Respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions.
- We have obtained quantitative data on mental wellbeing using validated questionnaires.

Limitations

- The main limitation of the study was the overall response rate of 11.4%.
 Accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. On the other hand doctors were being asked to comment on their regulators, and those most traumatised by the complaints process may have avoided engaging with the survey. Doctors who have been erased from the register or changed profession would not have been contacted.
- The cross-sectional design does not enable causation to be elucidated
- We collected responses from doctors who have not experienced a complaint but observed the impact on others. This means that the "no complaints" group may have more psychological morbidity than if doctors could be isolated from complaints processes completely. This may result in relative risks in the paper being underestimated.
- Some questions involved remembering past events and the possibility of recall bias must also be considered.
- There were missing responses for a number of questions. However this was
 dealt with using multiple imputation. However we are reassured that no major
 differences between the conclusions that would be drawn using complete
 cases compared to those where data was missing and imputed were found.

Introduction

In the United Kingdom (UK), the General Medical Council (GMC) acts as the regulator and sets standards that doctors are expected follow. It has the power to warn, suspend, restrict the practice of doctors or permanently remove them from the register. These powers are established under the Medical Act (1983).

It was recently disclosed that 96 doctors have died since 2004 while involved in General Medical Council (GMC) fitness to practice proceedings. information that came to light following a freedom of information request by the group doctors/justice. In parallel to this, between 2011 and 2012 the number of doctors referred to the GMC increased by 18%¹. Although mMost doctors referred to the GMC have their case closed at triage or have no action taken², there can be. In a recent article in the British Medical Journal (BMJ), Clare Dyer described some of the harrowing consequences for some doctors who go have been through a GMC investigation³.

However the GMC represents only the tip of the iceberg in terms of the complaints system. These include formal and informal both internal hospitaltrust internal enquiries investigations, the possibility of a serious untoward incident (SUI) investigations enquiry and well as disputes with managers and colleagues. Whilst there are some data relating to how doctors respond to GMC investigations, to our knowledge there are no studies addressing the issue of complaints procedures below this level in the UK. For many doctors, the prospect of facing a complaint or professional dispute causes them significant stress. This can manifest itself in how they perform in clinical practice and/or in their personal life, and may lead to both physical and psychological symptoms.

Clearly complaints and investigations when things go wrong are part of the checks and balances that should ensure appropriate oversight of a doctor's performance, the overall aim being to protect patients and maintain appropriate clinical standards. However the regulatory burden and stress associated with a complaints process may not lead to the outcomes that are desired.

In a previous study of surgeons surveyed in the United States (US), malpractice litigation was significantly associated with burnout, depression and suicidal ideation⁴.

There are also data to suggest that medical errors are associated with burnout, depression and loss of empathy in the physician responsible⁵. None of these outcomes are likely to lead to improvements in patient care. A further study has shown suicidal ideation in over 6% of US surgeons, over twice the background rate in the population. In this study, burnout, depression, and involvement in a recent medical error were strongly and independently associated with suicidal ideation after controlling for other personal and professional characteristics. Most surgeons in this study were reluctant to seek professional help due to concerns that there may be an impact on their career⁶.

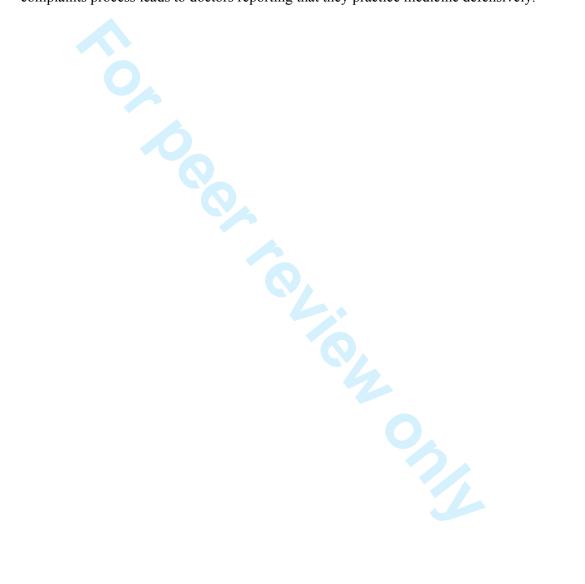
In a study published in the BMJ, Jain and Ogden described the impact of patient complaints on general practitioners in the United Kingdom and reported an association with anger, depression and suicide⁷. It is also important to note they also described clinicians involved in complaints practicing medicine more defensively...⁵ Such practice may be broadly categorized into "hedging" and "avoidance". Hedging is when doctors are overcautious leading for example to over-prescribing, referring too many patients, or over investigation. Avoidance includes not taking on complicated patients, and avoiding certain procedures or more difficult cases losing confidence, offering a less appropriate service and planning to leave the profession. None of these outcomes can be considered likely to improve patient care and safety. It must be remembered that the GMC itself describes its core function as being to protect patients. So if the complaints system leads to doctors practicing overly defensive medicine, with avoidance of difficult cases and over-investigation of patients, then the entire process may lead to more harm than good in terms of patient care.

Aspects of the complaints process itself may also contribute stressors including the length of time an investigation may take and not knowing whether the case will progress. The adversarial nature of investigations and hearings is a further contributor together with a sense of isolation that many doctors feel. In addition there is uncertainty over the impact on the doctor's career and often a lack of knowledge of the process. This combination of factors may lead to physical and mental health problems. The GMC has acknowledged that there is stress associated with their procedures and commissioned the British Medical Association (BMA) Doctors for

IMPACT study

Doctors service to provide confidential emotional support to doctors going through fitness to practice proceedings.

The primary aim of this study was to investigate the psychological welfare of doctors who have observed or experienced both past and/or current complaints. The secondary aim of the study was to assess whether being involved in or witnessing a complaints process leads to doctors reporting that they practice medicine defensively.



Methods

Design

The study used a cross-sectional survey design where participants were streamed into three groups: current/recent complaint (on-going or resolved within the last 6 months), past complaint (resolved more than 6 months ago), and no complaints. Each group completed a slightly different version of the questionnaire. Participants in the current complaints and no complaints group were asked about their current mood and health whereas the past complaints group were also asked to respond about their mood and health at the time of the complaint.

Ethical approval was obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Participants

The British Medical Association (BMA) is an apolitical professional association and independent trade union that represents doctors and medical students in the UK, membership is voluntary. Members of the BMA in November 2012 who had preconsented to being contacted for research purposes were invited to participate (n=95,636). They were emailed a link to an online encrypted questionnaire using Survey Monkey® and an information sheet describing the study. Participants were guaranteed that their responses were anonymous and untraceable. The survey remained open for two weeks and three reminders were sent out about the study during this time. A total of 10,930 (11.4%) participants responded to the survey. Of these, 696 (6.4%) were excluded as they only completed the demographics section, and 121 (1.1%) participants were excluded because a technical error meant that they were given the wrong sections to complete. A further 2187 (20.0%) participants completed the demographics section and indicated whether they had had a complaint and they were partially included in the analysis (sample 1). A total of 7926 (72.5%) participants completed the survey (sample 2). Of these, 1380 omitted some sections of

the survey but were included in the full analysis. Demographic information in relation to both samples is shown in table 1.

In order to check that our sample was representative, we compared our study population with the total BMA membership database (see table 1). This showed that our sample was broadly representative in terms of gender (46.3% females in the BMA membership database compared to 47.5% females in both sample 1 and 2) and place of qualification (80.1% qualified in the United Kingdom in the BMA population compared to 80.7% in sample 1 and 81.2% in sample 2). Our study population consisted of more doctors in the 35-59 age range (49.8% in the BMA population compared to 74.8% in sample 1 and 73.4% in sample 2), ethnic minorities were under-represented (32.4% in the BMA population compared to 22.4% in sample 1 and 21.8% in sample 2), and consultants and GPs were over-represented (27.2% were consultants and 26% were GPs in the BMA population compared to 37.1% and 38.4% in sample 1 and 36.5% and 37.8% in sample 2) whilst junior doctors and retired doctors were underrepresented (26.4% were juniors and 8.6% were retired in the BMA population compared to 15.7% and 0.7% in sample 1 and 16.5% and 0.7% in sample 2).

Measures

A pilot of the questionnaire trialed on 20 medical doctors of varying grades and specialties and their feedback was incorporated in the questionnaire design (see details below). In total, 108 questions were asked to the no complaints group and 179 questions were asked to both the complaints groups. Based on filling in trial questionnaires, we estimate the time required to complete the questionnaire was approximately 30 minutes. The questionnaire is included as supplementary online information (supplementary file 1) or can be reviewed by using the following link: https://www.surveymonkey.com/s/P55KH5P

Having completed 13 items obtaining demographic information (including age, specialty, gender, marital status, ethnicity, place of training, marital status, and details about their employment), participants were separated into three streams based on

whether they had i) a current/recent complaint (within the past 6 months), ii) past complaint, or iii) no current or past complaints.

The different types of complaint or investigation that were considered in the study are outlined below:

Informal: an informal complaint usually involves a patient speaking directly to the people involved in their care in order to resolve their concerns. It can be escalated to a formal complaint if not resolved locally.

Formal: this is a written complaint usually to the chief executive or an employing organization that triggers an investigation and often requires a written response within a set time period and may lead to disciplinary action or referral to the GMC.

Serious Untoward Incident (SUI): the definition of an SUI is wide ranging and includes an unexpected death, poor clinical outcome, a hazard to public health, a trend leading to reduced standards of care, damage to reputation or confidence in a service or adverse media coverage or public concern about an organization. The aim is to prevent recurrence of the adverse event, but may lead to disciplinary action for individuals or referral to the GMC.

General Medical Council: a complaint can be made about a doctor for issues ranging from personal behavior outside work to clinical concerns about their practice. The GMC review cases and have the power to suspend doctors from practice during an investigation. This may lead to a warning or referral to a tribunal that has the power to restrict a doctor's practice, impose working under supervision, suspension from the medical register or remove a doctor from the register permanently. The GMC may also issue warnings and undertakings to doctors to change aspects of their behavior or practice.

All participants completed the following sections (although some individual items varied in the different streams):

Experience of complaint: Participants in both complaints groups were asked 75 questions about their complaint(s) generated from Bark and colleagues⁸ and the pilot study. This included their total number of complaints, the most significant complaint and followed by a series of questions about the most serious complaint if they had had

more than one, including the reason for the complaint, the origin, the duration, the outcome, the cost (i.e. any leave taken, the estimated financial cost), and the level of support sought and obtained during the complaint. Participants who had been referred to the GMC were also asked to rate how stressful they found each aspect of the procedure. Whilst the majority of the questions used a 5-point scale, some questions were qualitative and a few were yes/no.

Attitudes towards complaints: All groups were asked ten questions using a 5-point scale generated from the pilot study about their attitudes toward complaints, the causes of complaints, and their perceived threat of future complaints. The no complaints group was asked 11 additional questions about their attitudes towards the complaints process (e.g., "I believe that complaints are reasonably dealt with") and how well they perceive that they would be supported in the event of a complaint made against them (e.g., "If I had a complaint made against me, I am confident that my management would support me").

Suggestions to improve the complaints process. All groups were asked to rate different suggestions on how to improve the complaints process on 11 5-point items. These proposals were generated from the pilot study.

Medical history: The presence of common stress-related illnesses at the time of the complaint or currently were measured using 12 items, including recurring infections, gastro-intestinal, sleep, cardio-vascular and mood problems^{9, 10}. In addition, questions were asked about self-reported drug and alcohol use, as well as life stressors at the time of both current and past complaints.

Defensive medical practice: Twenty items measuring current defensive medical practice were generated from a literature review^{10,11,12}. 12 items additional items were generated from the pilot study (5 for the no complaints group). Items were either rated on a 5-point scale or a yes/no response.

Depression: The Physical Health Questionnaire (PHQ-9¹³⁾ is a well-known standardised screening measure assessing the presence and severity of depression. It has been used across a wide range of populations and demonstrated good

psychometric properties. Respondents were considered depressed if they scored 10 or more on the PHQ-9¹⁴.

Anxiety: The Generalised Anxiety Disorder scale (GAD-7)¹⁵) is a standardised screening measure assessing the presence and severity of generalized anxiety disorder. The GAD-7 is also moderately good at identifying panic disorder, social anxiety disorder, and post-traumatic stress disorder. It has been used across a wide range of populations and demonstrated good psychometric properties. Respondents were considered anxious if they scored 10 or more on the GAD-7¹⁵.

Life Satisfaction. Life satisfaction was assessed with 10 items using a 6-point scale asking about satisfaction-dissatisfaction with marriage, career, recreation/leisure, self/family, and life satisfaction/optimism.

Statistical analysis

For the purpose of this paper, we have limited ourselves to analysis of psychological welfare and health (i.e. anxiety, depression, stress-related illness), defensive practice, culture, time off work and suggestions for improving the complaints process. To summarise the fifteen items measuring defensive practice, an exploratory factor analysis was conducted which identified two underlying factors. The first involves over-investigation and overly cautious management, which we have termed "hedging" (9 items, including for example "carried out more tests than necessary", "referred patient for second opinion more than necessary" and "admitted patients to the hospital when the patient could have been discharged home safely or managed as an outpatient", Cronbach's α =0.92). The second involves avoiding difficult aspects of patient treatment, which we termed "avoidance" (3 items, "stopped doing aspects of my job", "not accepting high risk patients in order to avoid possible complications", and "avoiding a particular type of invasive procedure", Cronbach's α =0.77). Due to strongly skewed distributions, the sumscores hedging and avoidance were analysed both as dichotomous (any hedging (>0)/avoidance (>0) versus no hedging (0)/avoidance (0)) and ordinal variables (never (0), rarely (hedging 1-12, avoidance 1-4), sometimes (hedging 13-24, avoidance 5-8) or often (hedging 25-36, avoidance 9-12) displaying hedging or avoidance behavior.)

The statistical analysis mainly consisted of descriptive analyses. Cross-tabulations of psychological welfare and defensive practice indicators have been made and relative risks were computed to investigate the relationship between complaint group and psychological welfare or defensive practice indicators. Additionally, means within the complaint groups and mean differences have been computed for continuous variables such as depression and anxiety. Asymptotic 95% confidence intervals were computed for relative risks and mean differences. Unpooled standard errors of the mean difference were used when necessary. Proportions and their 95% confidence intervals were also computed for feeling bullied during the investigation, feeling victimized because of whistle blowing and the amount of time spent off work. Proportions were computed to investigate the amount of support of respondents to various proposed actions to improve the complaints process.

As the primary aim of this study was to investigate the impact of complaints on the psychological welfare and health of doctors, a logistic regression analysis was performed to assess the relationship between moderate to severe depression and receiving a complaint, while controlling for predefined confounders (age, gender, being in a relationship, being White British, and medical specialty). Interactions of complaint with the confounders were included if necessary (α =0.001). Proportional odds logistic models were constructed to investigate whether hedging or avoidance are associated with characteristics of the complaint process (length of investigation, timing of complaint, outcome of investigation, origin of the complaint, type of the complaint). For hedging and avoidance, all two-way interactions were of interest and were included if necessary (α =0.001). We checked linearity assumptions, the presence of multi-collinearity, the presence of outliers, and the proportional odds assumption when necessary.

There was substantial item non-response. For key variables such as depression, anxiety, hedging and avoidance, non-response was approximately 20%. Missing dataness was addressed by performing multiple imputation using chained equations (MICE)¹⁶ with 10 iterations. Missing responses values were replaced imputed by 100 plausible values times, based on available responses to other questions, leading to 100 completed datasets that represent the uncertainty about the right value to impute. For

Page 48 of 110

IMPACT study

composite scales (depression, anxiety and hedging), a two-step approach to imputation was used to decrease the computational burden and make appropriate use of the available answers to separate items, first imputing the respondent's individual mean of non-missing items if at least 80% of the items of the composite scale were non-missing, followed by multiple imputation (MI) at the scale level for the remaining individuals. For avoidance, the three items were individually imputed. Multiple imputation was performed using chained equations (MICE)¹⁶ with 10 iterations. After MI, each completed dataset was analysed separately and results combined using standard Rubin's rules (Rubin, 1987). To assess the impact of item non-response, we performed a sensitivity analysis comparing the results of the complete case analysis to the results after MI, which assumes missingness at random. Additionally, MI assuming missingness not at random (informative missings) was considered for key variables depression, anxiety, hedging and avoidance¹⁷. Since these variables are based on responses to sensitive questions, informative missingness is plausible. As a missingness mechanism we assumed that those respondents with missingness might have been more anxious or depressed, or more likely to display hedging behavior or avoidance. More details on the MNAR analysis can be found in the supplementary file.

The data was analysed using SAS (version 9.3, SAS Institute, Cary, NC, USA). Multiple imputations were performed using IVEware (http://www.isr.umich.edu/src/smp/ive/)¹⁸.

Results

Psychological welfare and health

Overall, 16.9% of doctors with recent or ongoing complaints reported clinically significant symptoms of moderate to severe depression (table 2). Doctors in this group were at increased risk of depression compared to those with a past complaint (7.8%) or no personal experience of a complaint (9.5% Table 2.5 RR=1.77, 95% CI=1.48, 2.13). This was the case even when controlling for the effects of gender, age (cubic effect), being in a relationship (yes/no), being White British (yes/no), and medical specialty. The effect of having a recent or current complaint depends on gender.

When there has been no complaint, men tend to be less likely to be depressed than women (OR=0.76, 95% CI=0.54, 1.09), but a recent or current complaint has a higher impact on men than on women (OR women=1.72, 95% CI=1.28, 2.30; OR men=2.86, 95% CI 2.04, 4.01]. Within the PHQ-9, doctors with an ongoing or recent complaint (9.7%) were twice as likely as doctors with no complaints (4.7%) to report having thoughts of self-harm or suicidal ideation (RR=2.08, 95% CI=1.61, 2.68; see table 2). The sensitivity analysis shows that this conclusion holds under various assumed missingness mechanisms (see supplementary figure 1 file 1, supplementary table 1).

Moreover, 15% of doctors in the recent complaints group reported clinically significant levels of anxiety on the GAD-7, which is twice as likely as doctors who have no complaints (see Table 2, 7.3%, RR= 2.08, 95% CI=1.61, 2.68). Also this conclusion holds under various assumed missingness mechanisms (see supplementary file 1, supplementary table 2).

The level of psychological distress was related to the type of complaints procedure. Doctors going through a GMC referral reported the highest levels of depression (26.3%), anxiety (22.3%) and thoughts of self-harm (15.3%) compared to SUIs (16.1%, 15.3% and 9.3% respectively), formal complaints (15.6%, 13.5% and 9.0%), and informal complaints (12%, 12% and 6.4%) (table 3).

When asked directly using a single item scale, doctors were 3.78 (95% CI=2.68, 5.32) times more likely to report the presence of suicidal thoughts whilst going through a current or recent complaint compared to doctors who had no complaints (table 4).

Doctors who have experienced either a recent or past complaint reported higher levels of health problems at the time of the complaint compared to the no complaint group. These included gastro-intestinal problems, subjective anxiety and depression, anger, other mental health problems, insomnia, relationship problems, and frequent headaches. Doctors in the current complaints group also reported higher levels of cardio-vascular problems (see table 4).

Defensive practice

Overall, 84.7% of doctors with a recent and 79.9% with a past complaint reported changing the way they practiced medicine as a result of the complaint. 72.7% of doctors with no previous complaint reported changing their practice having observed a colleague's experience of a complaint (see <u>t</u>Table 5).

88.6% of doctors with a recent or current complaint and 82.6% of those with a past complaint displayed hedging behaviour. 81.7% of doctors with no previous complaints reported hedging. The sensitivity analysis revealed that under the MNAR assumption, the conclusion still holds that people in the recent or current complaint group display more hedging behavior than people in the no complaints group, but also people with a past complaint display considerably more hedging behavior (see supplementary figureile 14, supplementary table3).

49.8% or doctors with a recent or current complaint, 42.9% of doctors with a past complaint, and 46.1% of doctors with no personal experience of a complaint reported avoidance behaviour having observed a colleague's experience of a complaint. Although the results from the complete case analysis support the conclusion that mostly people in the recent and current complaint group display avoidance behaviour, the results from the analysis under the MNAR assumption suggest that it is people with a past complaint who display most avoidance behaviour (see supplementary figure 1 le 1, supplementary table 4).

The multivariable proportional odds analysis indicated that the odds of more severe hedging are higher for people with a recent or ongoing complaint than for people with a past complaint (OR 1.33 95% CI=1.19, 1.49) (tTable 6). The odds of hedging slightly increased with the length of time of the investigation (OR 1.01 per month, 95% CI=1.00, 1.01). Hedging was increased when retraining was imposed (OR 1.62, 95% CI=0.84, 3.13) and decreased when the doctor was suspended from practice (OR 0.56, 95% CI=0.26, 1.18). The odds of hedging also decreased when the complaint came from medical colleagues (OR 0.67, 95% CI=0.53, 0.86). There was evidence of an interaction between the type of the most serious complaint one has experienced and whether or not the complaint came from a patient (see supplementary figure 1). Hedging was higher when the complaint came from a patient, this was most clear for

informal (OR=3.16, 95% CI=2.17, 4.58) and formal complaints (OR=2.18, 95% CI=1.67, 2.85). When the complaint did not come from a patient, hedging was higher for formal complaints, SUI's and GMC referrals compared to informal complaints (OR=1.52, 95% CI=1.03, 2.24, OR=2.10, 95% CI=1.31, 3.35 and OR=1.78, 95% CI=1.15, 2.71, respectively).

As with hedging, the multivariable analysis indicated that the odds of more severe avoidance increased with the length of time the investigation (OR 1.01 per month, 95% CI=1.01, 1.02), and was higher for people with a recent or current complaint than for people with a past complaint (OR 1.20, 95% CI=1.07, 1.35) (tTable 7). Avoidance was also increased when the investigation resulted in imposed retraining (OR 1.79, 95% CI=1.0, 3.09). Avoidance behaviour most severely increased when the complaint came from a patient group (OR 1.71, 95% CI=1.02, 2.87) or management (OR 1.59, 95% CI=1.16, 2.16), or when the complaint was anonymous (OR 1.58, 95% CI=1.06, 2.36). The type of complaint did not meaningfully influence the odds of more severe avoidance.

Overall, as a result of their experience of the complaints process, 23% of doctors reported suggesting invasive procedures against their professional judgement, and 14% reported becoming more likely to abandon a procedure at an early stage.

Culture and time off work

20% (95% C.I. 19% to 22%) reported that they felt victimized because they had been a whistleblower for clinical or managerial dysfunction. 38% (95% C.I. 37% to 40%) of people who have had a complaint, recently or in the past, reported feeling bullied during the investigation.

60% (95% C.I. 57% to 64%) spent less than a week off work. However, 27% (95% C.I. 24% to 30%) of people with complaints spent more than a month off work.

Opinions on changes to improve the system

Of those doctors that gave a response, 85% felt that for managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them mattered quite a lot or a great deal in terms of improving the process. An equal number (85%) felt that if a doctor is exonerated but has suffered financial loss during the process, then they should have the option to make a claim for recovery of lost earnings or costs and in addition that there should be complete transparency of any management communication about the subject of a complaint and that access to such communications should be given to a doctor's representatives.

Seventy-four percent 74% of respondents felt that it mattered quite a lot or a great deal that if a complaint from a clinical or managerial colleague was found to be vexatious then this could be investigated and possible disciplinary measures taken. The full details of responses in relation to actions that could be taken to reduce the psychological impact of complaints processes are shown in supplementary table 5.



Discussion

We have shown that doctors who responded to our questionnaire who have recently received a complaint of any kind are 77% more likely to suffer from moderate to severe depression than people who have never had a complaint. They also have double the risk of having thoughts of self-harm, and double the risk of anxiety. Welfare is lowest when the complaint involves referral to the GMC. Doctors with a recent or current complaint also reported that they suffered from an increased likelihood of cardiovascular and gastro-intestinal disorders, depression, anxiety, anger and irritability, suicidal thoughts, sleep difficulty, relationship problems, and frequent headaches than people who had not been through a complaints process. In many cases these problems persisted. We have also shown that 80% of doctors answering the survey reported changing the way they practiced as a result of either complaints against themselves, or after observing a colleague go through a complaints process. The majority (84%) of doctors reported hedging behaviour in response to a complaint (i.e. increased defensive practice) whilst many (46%) admitted avoidance. A further important finding was that many doctors who had a complaint (20%) felt they were victimised after whistle blowing, t. Thirty-nine percent reported that they felt bullied when they were going through the process, and 27%. A large number of doctors had more than a month off worksignificant time off work as a result of a complaint. with 27% spending more than a month off work.

A strength of the study is that to our knowledge it is one of the largest reported on the subject involving 10,930 respondents with 7,926 completing the survey. It is certainly the largest relating to doctors in the UKnited Kingdom. We also think it is critical that respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions. Furthermore we have obtained quantitative data on the mental wellbeing of doctors using validated questionnaires. It is also important to note that we have collected responses from doctors who have not experienced a complaint but observed the impact on others. On the one hand this gives insight into the impact of observing a colleague going through a complaints process, however it also means that the "no complaints" group may have a higher overall level of psychological morbidity than if doctors could be isolated from complaints processes completely. Hence the relative

risks in the paper may be underestimated. A significant limitation of the study is that the response rate was 11.4%, accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. What constitutes an acceptable response rate is a subject of debate, however our response rate is clearly low¹⁹. We believe this is inevitable when asking doctors to comment on disciplinary processes and in particular on their regulator. Even if we take the view that the respondents are a selected group, they still demonstrate that a very considerable number of doctors are significantly impacted by complaints processes and practice defensively. It must also be remembered that doctors that have been most traumatised by the complaints process may have felt unable to take part in the survey and a small number are known to have committed suicide. Furthermore those no longer on the register (for example if they have changed profession or erased from the register) are unlikely to be members of the BMA and so would not have been contacted. As some questions involved remembering past events the possibility of recall bias for some answers must also be considered. For a number of questions there were missing responses. However we have considered this issue by using multiple imputation and were reassured that we found no essential differences between the conclusions that would be drawn using complete cases compared to those where missing data have been imputed.

As with any cross-sectional survey we must be careful when considering the findings, as we cannot show causation. It is possible that doctors with depression, anxiety and suicidal ideation are more likely to have complaints made against them, similarly being complained against may be the causative factor rather than the processes themselves. However this still means the information presented is important as if we take the former view, it means those going through complaints processes are a vulnerable group that need support. This was illustrated in a recent study that reported that sick doctors under investigation stated that the processes and communication style employed by the GMC were often distressing, confusing, and perceived to have impacted negatively on their mental health and ability to return to work²⁰.

It is interesting that our findings are similar to a questionnaire-based study of surgeons in the United States examining the emotional toll of malpractice lawsuits. This study found significantly more depression and burnout in surgeons who had

recently been exposed to a lawsuit and highlighted the association between burnout and the likelihood of making a medical error⁴.

We found that 10% of doctors responding to the survey who have had a recent complaint have had thoughts of self-harm and are over twice as likely to have had such thoughts compared to doctors who had not personally experienced a complaint. When referral to the GMC is looked at in isolation the number of doctors who reported suicidal ideation reached 15.3%, whilst 26.3% had moderate to severe depression and 22.3% had moderate to severe anxiety on the basis of two validated instruments. Even set against the limitations of the study we have highlighted above, these findings are concerning. In a recent feature article in the BMJ, Dyer reported on the high number of suicides associated with GMC proceedings³. Our results support the view that these proceedings have a disproportionate impact on doctors, especially as the vast majority of doctors who are referred to the GMC are found to have no significant case to answer². However the GMC is at the apex of what amounts to a "complaints pyramid" and our data show similar significant psychological morbidity for doctors across the entire spectrum of complaints procedures. when they are involved both in internal trust enquiries into complaints and in the event of a serious untoward incident investigation.

The incidence of feeling victimized following whistleblowing (20%) and bullying (38%) will be a concern to those trying to build a culture in the <u>UK National Health Service (NHS)</u> where it is safe to speak out about clinical and managerial concerns. The Francis report highlighted the dysfunctional culture that is prevalent in many NHS organisations²¹⁹. Other recent reports have also highlighted serious concerns about the pressures that may be placed on hospital staff ²²¹. Given the large numbers involved, our study supports the view that whistleblowing in the <u>NHS NHS</u>-is <u>often</u> not always a safe action to take, that bullying is not uncommon, and that these is problems are is not just experienced in isolated eventseases.

The GMC exists to protect patients and the public. This is also the aim of other types of complaints processes with the overall purpose being to learn from mistakes and improve the performance of everyone taking part in patient care. However as with all interventions there may be unforeseen consequences. Previously Jain et al in a qualitative study reported that many general practitioners practice defensively

following a complaint⁷. Our data also show the vast majority of doctors who took part in the study reported engaging in defensive practice. This <u>included involved hedging</u> and avoidance behavior; which included carrying out more tests than necessary, overreferral, over-prescribing, avoiding procedures, not accepting high-risk patients and abandoning procedures early. Nash and colleagues have also reported high levels of defensive practice²³. In their study which had a higher response rate of 36%, 43% of doctors reported that they referred more patients, 55% ordered more tests and 11% stated they prescribed more medications than usual in response to medico-legal concerns. In a further report the same authors showed that doctors working in high-intervention areas of medicine are more likely to be the subject of medico-legal complaints²⁴. Defensive practice in such specialties may be particularly concerning.

These behaviors are not in the interest of patients and may cause harm, whilst they may also potentially increase the cost of health care provision to the wider NHS. By far the majority of doctors who are reported to the GMC are not found to have a significant case to answer², as is probably the case with other lower level complaint investigations. It therefore does not seem unreasonable to argue that as they currently function, GMC enquiries may do more overall harm than good in terms of patient care. As the "complaints pyramid" is descended it is possible this balance may improve, although we found defensive practice across the entire spectrum of complaints processes.

Whilst we fully acknowledge the limitations associated with any study of this type, we believe our findings have implications for policy makers. Procedures must exist to enable patients to make a complaint about their care, for professionals to raise concerns about standards of practice and for serious untoward events to be investigated. However a system that is associated with high levels of psychological morbidity amongst those going through it is not appropriate as either the subjects of such procedures are vulnerable at the outset or are suffering such morbidity as a direct result of the investigations themselves. -Most importantly, a system that leads to so many doctors practicing defensive medicine is not good for patients. A further concern for patient care is the association between doctor's distress, burnout and decreased empathy with perceived medical errors²⁵.

The high level of suicidal ideation coupled with the recent revelations about suicide amongst doctors who have been reported to the GMC is a concern³. Recently the GMC announced a review of cases of doctor suicide associated with GMC investigations, and introduced offering emotional support to doctors going through fitness to practice procedures. A survey has also been sent out by the GMC to doctors to hear their views. These initiatives are welcome, but whether doctors will feel confident in giving critical feedback to the GMC is open to question. No such initiatives have been made to support doctors involved in other processes outside GMC proceedings, whilst our data suggest that psychological morbidity as well as hedging and avoidance behaviour is associated with the entire spectrum of complaints procedures. A further concern for patient care is the association between doctor's distress, burnout and decreased empathy with perceived medical errors²¹.

When asked how the complaints process could be improved doctors indicated that what mattered to them was that the process should be transparent and that staffmanagers responsible for investigating complaints should be up to date and competent. There was also a clear feeling that in the event of a complaint being shown to be vexatious then there should be disciplinary consequences if this related to managers and colleagues hospital staff, or the option for financial redress in the event it related to patients. Doctors indicated that in the event of a complaint they expected any procedure to be clear, transparent, follow due process and in the event that the complaint was shown to be vexatious, that there are consequences for those involved. Concerns about the lack of redress associated with vexatious complaints have been raised in the BMJ before²⁶³. This highlights the inherent tension in the system whereby an apparent "whistleblower" may be perceived as a vexatious complainant by a colleague. The logical extension of increased transparency and greater training and therefore competency amongst managers responsible for dealing with complaints would be consistency. Consistency in both the management and outcome of complaints would be valuable in restoring the sense of fairness that our results would suggest is not currently being perceived by doctors.

We have shown that doctors who responded to our questionnaire and experience or observe complaints processes exhibit high levels of psychological morbidity including severe depression and suicidal ideation. These effects are greatest when the process

involves the General Medical Council. In addition the majority of these doctors exhibit hedging and avoidance, both these behaviours may be damaging to patient care and be contrary to the professed aims of these processes.



Acknowledgements

Mr. Christoph Lees (Imperial College NHS trust) and Mr. Magnus Boyd (Hill Dickinson LLP solicitors) contributed to receiving feedback on the contents and design of the questionnaire. We would like to thank all clinicians who commented on the initial versions of the survey.

Contributors

TB conceived of the original idea for the study, interpreted results, drafted the paper and is overall guarantor. MJ designed the questionnaire, obtained ethical approval, contributed to the preparation of the data set, interpreted results and contributed to drafts of the paper. LW and BVC carried out the statistical analysis and contributed to drafts of the papers. MP contributed to the study design, interpretation of results and commented on drafts of the paper. DT and CVA contributed to interpretation of results and commented on drafts of the paper. All authors approved the final version of the manuscript.

Funding

Tom Bourne is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. Laure Wynants is supported by a PhD grant of the Flanders' Agency for Innovation by Science and Technology (IWT Vlaanderen). Dirk Timmerman is a Senior Clinical Investigator of the Research Foundation- Flanders (FWO)Ben Van Calster is a postdoctoral fellow of the Research Foundation- Flanders (FWO).

Competing interests

All authors have completed the Unified Competing Interest form and declare: Michael Peters is head of the BMA doctors for doctors unit and so receives payment from the BMA. The BMA had no role in data collection, design of the study, data analysis, interpretation of data, or writing the report and had no influence over whether to submit the manuscript. All other authors stated that they had no support from any organisation for the submitted work; no financial relationships with any organisations

Page 60 of 110

IMPACT study

that might have an interest in the submitted work in the previous three years, no other relationships or activities that that could appear to have influenced the submitted work

Ethical approval

Ethical approval was sought and obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Transparency declaration

The lead author (T Bourne) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no aspects of the study have been omitted in relation to the specific aspects of the study reported in this paper; and that any discrepancies from the study as planned (and, if relevant registered) have been explained.

The Licence

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors a worldwide, licence, to the Publishers and its licensees in perpetuity (subject to the Reversion of Rights set out below), in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution and convert or allow conversion into any format including without limitation audio, iii) create any other derivative work(s) based in whole or part on the Contribution, iv) to exploit all subsidiary rights that currently exist or as may exist in the future in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above.

IMPACT study

References

- 1 White C. Complaints against doctors continue to rise. BMJ Careers 2013 Sep 30 http://careers.bmj.com/careers/advice/view-article.html?id=20014782 (accessed on 25 November 2013).
- 2 General Medical Council. Fitness to Practise Annual Statistics Report 25th September 2012 www.gmc-uk.org (accessed on 25 November 2013).
- 3 Dyer C. GMC and vulnerable doctors: too blunt an instrument? BMJ 2013;347:f6230
- 4 Balch CM, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. J Am Coll Surg 2011;**213**:657-67.
- 5 Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. Arch Surg 2011;**146**:54-62.
- 6 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;**296**:1071-78.
- 7 Jain A, Ogden J. General practitioners' experiences of patients' complaints: qualitative study. BMJ 1999; **318**:1596-99.
- 8 Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. Quality in Health Care 1997;6:7-13.
- 9 Schat AC, Kelloway EK, Desmarais, S. The Physical Health Questionnaire: construct validation of a self-report scale of somatic symptoms. J Occup Health Psychol 2005;**10**:363-81.
- 10 Studdert DM, Mello MM, Sage VM, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 2005;**293**:2609-17.

Page 62 of 110

IMPACT study

- 11 Nash L, Walton M, Daly M, et al. GPs' concerns about medico legal issues: How it affects their practice. Australian Fam Physician 2009;**38**:66-70.
- 12 Summerton N. Positive and negative factors in defensive medicine: A questionnaire study of General Practitioners. BMJ 1995;**310**:27-29.
- 13 Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ Primary Care Study. JAMA 1999;**282**:1737-44.
- 14 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001;**16**:606-13.
- 15 Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;**166**:1092-97.
- 16 Raghunathan TW, Lepkowksi JM, Van Hoewyk J, et al. A multivariate technique for multiply imputing missing values using a sequence of regression models. Survey Methodology 2001;27:85–95.
- 17 Rubin DB. (1987). Multiple Imputation for Nonresponse in Surveys. Wiley, NY.
- 18 IVEware: Imputation and Variance Estimation Software. http://www.isr.umich.edu/src/smp/ive/ (accessed on 12 August 2013).
- 19. Baruch Y. Response rate in academic studies A comparative analysis. Human relations, 1999; 52: 421-438
- 20. Brooks SK, Del Busso L, Chalder T, Harvey SB, Hatch SL, Hotopf M, Madan I, Henderson M. 'You feel you've been bad, not ill': Sick doctors' experiences of interactions with the General Medical Council. BMJ Open. 2014 Jul 17; 4(7):e005537. doi: 10.1136/bmjopen-2014-005537.

- 21 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013. Chaired by Robert Francis QC. http://www.midstaffspublicinquiry.com/report (accessed 25 November 2013).
- 22 Care Quality Commission recommends Essex hospital trust is put into special measures 5 November 2013. http://www.cqc.org.uk/media/care-quality-commission-recommends-essex-hospital-trust-put-special-measures (accessed on 25 November 2013).
- 23 Nash LM, Walton MM, Daly MG et al. Perceived practice change in Australian doctors as a result of medicolegal concerns.

 Med J Aust. 2010 Nov 15; 193(10): 579-83.
- 24 Nash LM, Kelly PJ, Daly MG et al. Australian doctors' involvement in medicolegal matters: a cross-sectional self-report study.

 Med J Aust. 2009 Oct 19; 191(8): 436-40.
- 25 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;296:1071-78.
- 26 Marcovitch H. GMC must recognise and deal with vexatious complaints fast. BMJ 2002;324:167-68.

.

Table 1: Demographic information relating to both sample 1 and 2 in the study

Age	Total BMA membership consented for research	Sample 1 (n=10113)	Sample 2 (n=7926)
Up to 25	17.8%	1.4%	1.4%
26-29	9.0%	5.1%	5.5%
30-34	9.6%	8.6%	8.8%
35-39	10.3%	11.0%	11.0%
40-44	10.3%	13.5%	13.1%
45-49	10.8%	16.9%	16.8%
50-54	10.3%	18.8%	18.8%
55-59	8.1%	14.6%	14.7%
60-64	5.0%	6.6%	6.4%
65-69	3.0%	2.5%	2.6%
Over 69	5.9%	1.1%	1.0%
Gender	46.3% Female	47.5% Female	47.5% Female
Place of qualification			
United Kingdom	80.1%	80.7%	81.2%
India	8.2%	6.6%	6.2%
Pakistan	2.2%	1.2%	1.2%
Ireland	0.9%	1.4%	1.4%
Nigeria	1.1%	1.2%	1.2%
Germany	0.7%	1.1%	1.2%
South Africa	0.7%	0.8%	0.8%
Other	6.2%	6.9%	6.9%
Ethnicity White British	67.6%	77.6%	78.2%
Asian or Asian British	23.3%	16.6%	15.8%
Black or Black British	3.5%	2.3%	2.3%
Chinese or Chinese British	2.9%	1.3%	1.3%
Mixed	2.7%	2.3%	2.3%
Grade:			

IMPACT study

	2.10/	1.00/	1.00/
Academics	2.1%	1.2%	1.3%
Consultants	27.2%	37.1%	36.5%
General Practice	26.0%	38.4%	37.8%
Junior Doctors	26.4%	15.7%	16.5%
SASC	5.3%	5.8%	6.11%
Retired	8.6%	0.7%	0.7%
Other or no answer	4.4%	1.0%	1.1%



Table 2. Symptoms severity and relative risk of psychological distress for each complaints group.

	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent/ current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative risk for past complaint group/ mean difference (95% CI)	Relative risk for recent complaint group / mean difference (95% CI)
Depression (PHQ-9)						
Mean (SD) a	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3 (-0.6, -0.0)	1.4 (1.1, 1.7)
Moderate to severe depression n (%)	169 (9.5%)	303 (7.8%)	381 (16.9%)	852 (10.8%)	0.81 (0.65, 1.01)	1.77 (1.48, 2.13)
Thoughts of 'self- harm' n (%)	83 (4.7%)	221 (5.7%)	218 (9.7%)	522 (6.6%)	1.22 (0.93, 1.61)	2.08 (1.61, 2.68)
Anxiety (GAD-7) Mean (SD) b	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1 (-0.4, 0.2)	1.4 (1.1, 1.7)
Moderate to severe anxiety n (%)	131 (7.3%)	234 (6.0%)	338 (15.0%)	703 (8.9%)	0.80 (0.57, 1.13)	2.08 (1.61, 2.68)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

IMPACT study

Table 3. Psychological distress within the recent / on-going complaints group by complaint that had the most impact

the most impact.	ı				
	Informal	Formal	SUI	GMC	No
	complaint	Complaint	n=280	referral	complaint
	n=362	n=1196	(12.4%)	n=374	n=1780
	(16.0%)	(53.0%)		(16.6%)	(22.5%)
Depression					
(PHQ-9)					
Mean (SD) a	4.2	4.8	5.1	6.6	3.7
	(5.0)	(5.4)	(5.6)	(6.7)	(4.3)
Moderate to severe	45	190	46	100	169
depression n (%)	(12.0%)	(15.6%)	(16.1%)	(26.3%)	(9.5%)
Thoughts of 'self-	24	110	27	58	83
harm' n (%)	(6.4%)	(9.0%)	(9.3%)	(15.3%)	(4.7%)
Anxiety (GAD-7)					
Mean (SD) b	3.8	4.4	4.7	5.7	3.1
	(4.3)	(4.7)	(5.1)	(5.7)	(3.8)
Moderate to severe	44	165	44	85	131
anxiety n (%)	(12.0%)	(13.5%)	(15.3%)	(22.3%)	(7.3%)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Table 4. Psychosomatic health for each of the complaints group. Please note that the past complaints group used retrospective information asking about worsening or onset of symptoms at the time of the complaint, whereas the no and recent complaint groups were asked about the presence of symptoms in the last twelve months.

	No complaint	Recent or current complaint	Past complaint	RR recent or current versus
	n=1780 (22.5%)	n=2257 (28.5%)	n=3889 (49.1%)	no complaint.
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)	124 (7.0%)	280 (12.4%)	405 (10.4%)	1.78 (1.44-2.20)
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)	217 (12.2%)	426 (18.9%)	934 (24.0%)	1.55 (1.32-1.82)
Depression	187 (10.5%)	490 (21.7%)	1148 (29.5%)	2.07 (1.74-2.45)
Anxiety	476 (26.7%)	1108 (49.1%)	3045 (78.3%)	1.84 (1.65-2.04)
Anger and irritability	358 (20.1%)	928 (41.1%)	2406 (61.9%)	2.04 (1.77-235)
Other mental health problems	12 (0.7%)	54 (2.4%)	256 (6.6%)	3.45 (1.80-6.60)
Suicidal thoughts	44 (2.5%)	211 (9.3%)	519 (13.4%)	3.78 (2.68-5.32)
Sleep problems / insomnia	479 (26.9%)	1137 (50.4%)	288 (74.1%)	1.87 (1.67-2.10)
Relationship problems	187 (10.5%)	458 (20.3%)	911 (23.4%)	1.94 (1.63-2.30)
Frequent headaches	242 (13.6%)	432 (19.2%)	1027 (26.4%)	1.41 (1.19-1.65)
Minor colds	492 (27.6%)	509 (22.5%)	5447 (14.0%)	0.82 (0.73-0.92)
Recurring respiratory infections	77 (4.3%)	143 (6.3%)	306 (7.9%)	1.47 (1.11-1.95)

IMPACT study

Table 5 Defensive practice according to complaint group

Because of your/other's experiences with complaints, have you	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent or current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative Risk for past complaint (95% CI)	Relative Risk for recent or current complaint (95% CI)
Changed the way	1294	3106	1912	6312	1.10	1.17
of practicing	(72.7%)	(79.9%)	(84.7%)	(79.6%)	(1.06,1.14)	(1.13,1.21)
medicine n (%)	(, =,,,,,)	(1212)	(011,70)	(121273)	(-1.0,-1.1)	(,)
Displayed	1454	3212	1999	6665	1.01	1.08
hedging	(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98, 1.04)	(1.05, 1.11)
behaviour n (%)	` ′	,	, ,	,		
Displayed	820	1668	1124	3612	0.93	1.08
avoiding	(46.1%)	(42.9%)	(49.8%)	(45.6%)	(0.87,1.00)	(1.00, 1.17)
behaviour n (%)			(1 1 1 1)	()	(*****, ****)	(,,
Suggested	359	902	585	1846	1.15	1.29
invasive	(20.2%)	(23.2%)	(25.9%)	(23.3%)	(1.02,1.29)	(1.13,1.46)
procedures	`	,	, ,	,		
against						
professional						
judgement n (%)						
Become more	248	515	372	1136	0.95	1.18
likely to abandon	(14.0%)	(13.3%)	(16.5%)	(14.3%)	(0.80, 1.13)	(1.00, 1.39)
a procedure at an						
early stage n (%)						
Become less	-	795	613		-	-
committed and		(20.5%)	(27.2%)			
worked strictly to						
job description						
n (%)				_		

Table 6. Factors influencing hedging behaviour.

Odds Ratio Estimates for he	edging		
Effect	Point Estimate	95% W Confidence	
Length of investigation (per month)	1.006	1.002	1.011
Recent or current complaint (versus past complaint)	1.331	1.193	1.485
Outcome of investigation			
No fault/ exonerated (yes versus no)	1.051	0.676	1.633
Retraining imposed (yes versus no)	1.622	0.913	2.885
Disciplinary action (yes versus no)	0.815	0.433	1.532
Suspended from practice (yes versus no)	0.557	0.289	1.075
Struck off from the register (yes versus no)	0.583	0.754	1.761
The process was not clearly concluded (yes versus no)	1.152	0.900	1.960
Where did the complaint come from			
Trust (yes versus no)	1.328	0.900	1.960
Medical colleagues (yes versus no)	0.672	0.526	0.860
Management (yes versus no)	0.797	0.581	1.094
Media (yes versus no)	1.084	0.467	2.515
Patient group (yes versus no)	1.495	0.906	2.464
Other health care professional (yes versus no)	1.047	0.798	1.375
Patient (yes versus no)			
For informal complaint	3.155	2.172	4.584
For formal complaint	2.180	1.670	2.846
Patient (yes versus no) For informal complaint For SUI For GMC referral Anonymous (yes yersus no)	1.212	0.826	1.778
For GMC referral	1.670	1.207	`2.311
Anonymous (yes versus no)	1.362	0.922	2.012
Type of complaint			
Formal complaint versus informal complaint			
Complaint did not come from a patient	1.521	1.034	2,239
Complaint came from a patient	1.051	0.903	1.223
SUI versus informal complaint			
Complaint did not come from a patient	2.097	1.311	3.352
Complaint came from a patient	0.805	0.648	1.002
GMC referral versus informal complaint			
Complaint did not come from a patient	1.776	1.164	2.709
Complaint came from a patient	0.940	0.757	1.168

IMPACT study

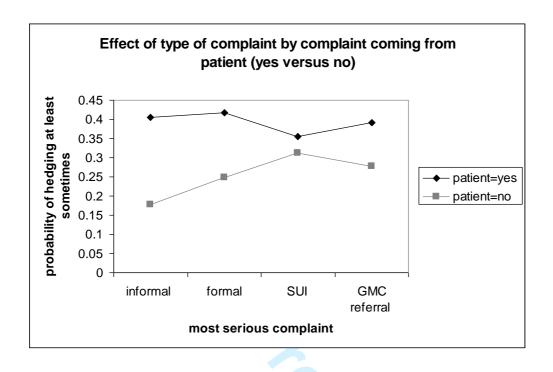
Table 7. Factors influencing avoidance behaviour

Odds Ratio Estimates for avoiding										
Effect	Point Estimate	95% Wald Confidence Limits								
Length of investigation (per month)	1.011	1.006	1.016							
Recent or current complaint (versus past complaint)	complaint) 1.201 1.069									
Outcome of investigation										
No fault/ exonerated (yes versus no)	0.893	0.594	1.340							
Retraining imposed (yes versus no)	1.787	1.033	3.092							
Disciplinary action (yes versus no)	1.211	0.682	2.152							
Suspended from practice (yes versus no)	1.066	0.566	2.008							
Struck off from the register (yes versus no)	0.626	0.119	3.305							
The process was not clearly concluded (yes versus no)	1.202	0.805	1.796							
Where did the complaint come from										
Trust (yes versus no)	1.338	0.910	1.968							
Medical colleagues (yes versus no)	1.439	1.134	1.826							
Patient (yes versus no)	1.364	1.114	1.670							
Management (yes versus no)	1.585	1.163	2.161							
Media (yes versus no)	0.866	0.380	1.972							
Patient group (yes versus no)	1.708	1.019	2.866							
Other health care professional (yes versus no)	1.326	1.015	1.731							
Anonymous (yes versus no)	1.580	1.057	2.360							
Type of complaint										
GMC referral (versus informal complaint)	1.082	0.885	1.323							
SUI (versus informal complaint)	1.112	0.904	1.368							
Formal complaint (versus informal complaint)	1.036	0.893	1.203							



Supplementary online material

Supplementary figure 1: Effect of type of complaint on hedging behavior by origin of complaint.



Supplementary material sensitivity analysis and supplementary tables 1-4

Sensitivity Analysis.

As a last step in the analysis, we performed a sensitivity analysis considering also missingness not at random (MNAR) for some of the key analyses. MNAR means that, even accounting for all the available observed information, the reason for observations being missing still depends on the unseen observations themselves. We performed a simple sensitivity analysis, assuming as a not ignorable missing model that depression, anxiety, hedging and avoiding are worse when the value is missing. Therefore, after multiple imputation under the MAR assumption using MICE, I increased each imputed value of depression (PHQ9) and anxiety (GAD7) by a certain number d. This number d was obtained as follows. First, a random number δ was sampled from a normal distribution with mean the estimated standard deviation of the distribution of PHQ9/GAD7, and standard deviation the square root of this value. Then $d=\max(\delta, 1)$, such that d is restricted to imply an increase in PHQ9/GAD7. Therefore, d instead of δ is added to the imputed value under missingness at random (MAR). After this, the new imputed value is rounded and bound at the maximum possible value, such that an integer number on the original scale is obtained. For hedging/avoiding, all missings were assumed to have displayed at least some hedging/avoiding behaviour. The actual score on the scale is irrelevant, because the scale is dichotomised prior to the analysis. After the imputations under MNAR are computed, analysis proceeds as usual, using Rubin's rules to combine results.

Bourne et al

Supplementary table 1: Sensitivity analysis for PHQ-9

Supplementary tabl				1		
Depression	No	Past	Recent/	Total	Relative	Relative
(PHQ-9) ^a	complaint	complaint	current	n=7926	risk for	risk for
	n=1780	n=3889	complaint	(100%)	past	recent
	(22.5%)	(49.1%)	n=2257		complaint	complaint
			(28.5%)		group/	group /
					mean	mean
					difference	difference
					(95% CI)	(95% CI)
Missings	255	1144	214	1613		
	(14%)	(29%)	(9%)	(20%)		
Complete case						
Mean (SD)	3.8 (4.5)	3.4 (4.6)	5.2 (5.8)	4.1 (5.0)	-0.4	1.4
					(-0.7, 0.1)	(1.1, 1.7)
Moderate to severe	160	254	363	777	0.88	1.69
depression n (%)	(10.5%)	(9.3%)	(17.8%)	(12.3%)	(0.73, 1.06)	(1.42, 2.02)
MI MAR						
Mean (SD)	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3	1.4
					(-0.6, -0.0)	(1.1, 1.7)
Moderate to severe	169	303	381	852	0.81	1.77
depression n (%)	(9.5%)	(7.8%)	(16.9%)	(10.8%)	(0.65, 1.01)	(1.48, 2.13)
MI MNAR						
Mean (SD)	4.3 (4.6)	4.7 (4.8)	5.4 (5.7)	4.8 (5.1)	0.4	1.1
·					(0.1, 0.7)	(0.8, 1.4)
Moderate to severe	238	593	432	1263	1.14	1.43
depression n (%)	(13.4%)	(15.2%)	(19.2%)	(15.9%)	(0.95, 1.35)	(1.21, 1.70)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

Bourne et al

Supplementary table 2: Sensitivity analysis for GAD-7

Supplementary tabl					I -	_
Anxiety (GAD7) b	No	Past	Recent/	Total	Relative	Relative
	complaint	complaint	current	n=7926	risk for	risk for
	n=1780	n=3889	complaint	(100%)	past	recent
	(22.5%)	(49.1%)	n=2257		complaint	complaint
			(28.5%)		group/	group /
					mean	mean
					difference	difference
					(95% CI)	(95% CI)
Missings	258	1148	201	1607		
	(14%)	(30%)	(9%)	(20%)		
Complete case						
Mean (SD)	3.2 (3.9)	3.0 (4.0)	4.7 (5.0)	3.6 (4.4)	-0.2	1.5
					(-0.4, 0.1)	(1.2, 1.8)
Moderate to severe	123	194	330	647	0.88	1.99
depression n (%)	(8.1%)	(7.1%)	(16.1%)	(10.2%)	(0.71, 1.09)	(1.63, 2.42)
MI MAR						
Mean (SD)	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1	1.4
					(-0.4, 0.2)	(1.1, 1.7)
Moderate to severe	131	234	338	703	0.80	2.08
depression n (%)	(7.3%)	(6.0%)	(15.0%)	(8.9%)	(0.57, 1.13)	(1.61, 2.68)
MI MNAR						
Mean (SD)	3.7 (4.1)	4.3 (4.4)	4.9 (5.0)	4.3 (4.6)	0.5	1.2
					(0.2, 0.9)	(0.9, 1.5)
Moderate to severe	173	463	374	1011	1.22	1.71
depression n (%)	(9.7%)	(11.9%)	(16.6%)	(12.75%)	(0.98, 1.51)	(1.35, 2.18)

b The GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Bourne et al

Supplementary table 3: Sensitivity analysis for hedging.

Supplementary tab					1	
Because of your /	No	Past	Recent or	Total	Relative	Relative
other's	complaint	complaint	current	n=7926	Risk	Risk
experiences with	n=1780	n=3889	complaint	(100%)	for past	for recent
complaints, have	(22.5%)	(49.1%)	n=2257		complaint	or current
you ever			(28.5%)		(95% CI)	complaint
displayed						(95% CI)
hedging						
behaviour?						
Missings	268	1241	273	1782		
Complete case						
n (%)	1222	2135	1752	5109	1.00	1.09
(,,,)	(80.8%)	(80.6%)	(88.3%)	(83.1%)	(0.97,1.03)	(1.06,1.13)
MAR	(00.070)	(00.070)	(00.570)	(03.170)	(0.57,1.05)	(1.00,1.13)
n (%)	1454	3212	1999	6665	1.01	1.08
11 (70)	(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98,1.04)	(1.05,
	(01./%)	(02.0%)	(00.0%)	(04.1%)	(0.90,1.04)	
MIMALAR						1.11)
MI MNAR	1404	22.60	2022	6076	1.04	1.00
n (%)	1484	3369	2023	6876	1.04	1.08
	(83.4%)	(86.6%)	(89.6%)	(86.8%)	(1.01,1.06)	(1.05, 1.10)

Bourne et al

Supplementary table 4: Sensitivity analysis for avoidance.

Because of your /	No	Past	Recent or	Total	Relative	Relative
other's	complaint	complaint	current	n=7926	Risk	Risk
experiences with	n=1780	n=3889	complaint	(100%)	for past	for recent
complaints, have	(22.5%)	(49.1%)	n=2257	(10070)	complaint	or current
you ever	(22.5 / 0)	(42.170)	(28.5%)		(95% CI)	complaint
displayed			(20.5 70)		(33 / 0 C1)	(95% CI)
avoiding						()2 /6 (21)
behaviour?						
Missings	242	1222	257	1721		
Complete case		122	207	1,21		
n (%)	705	1137	995	2837	0.93	1.09
(,,,,	(45.8%)	(42.6%)	(49.8%)	(45.7%)	(0.87,1.00)	(1.01, 1.16)
MAR		,	` /	, ,		
n (%)	820	1668	1124	3612	0.93	1.08
` ´	(46.1%)	(42.9%)	(49.8%)	(45.6%)	(0.87,1.00)	(1.00, 1.17)
MI MNAR					,	,
n (%)	947	2359	1252	4558	1.14	1.04
	(53.2%)	(60.7%)	(55.5%)	(57.5%)	(1.08,1.20)	(0.98, 1.10)

Bourne et al



Bourne et al

Supplementary table 5: How doctors ranked the importance of different actions that might be taken to improve the complaints process might be improved (note these data are not imputed).

	Not at	A	To some	Quite a	A great	missing	total
	all	little	extent	lot	deal	n	n
To all the decidence	n (%)	n (%)	n (%)	n (%)	n (%)	2002	10112
To allow the doctor to	245	313	2256	1524	1973	3802	10113
have more direct input into	(3.9%)	(5.0%)	(35.8%)	(24.2%)	(31.3%)		
responses to patient							
Complaints	217	342	1501	1846	2400	3807	10113
To be given a clear written	(3.4%)					3807	10113
protocol for any process at the onset	(3.4%)	(5.4%)	(23.8%)	(29.3%)	(38.1%)		
	100	40.	1.500				10112
To have strict adherence to	199	402	1599	1732	2379	3803	10113
a statutary timeframe for	(3.2%)	(6.4%)	(25.3%)	(27.5%)	(37.7%)		
any complaint and							
investigation process	0.61	4.40	1016	1070	1722	2001	10112
Brief colleagues about any	261	440	1816	1972	1733	3891	10113
complaint or investigation	(4.2%)	(7.1%)	(29.2%)	(31.7%)	(27.9%)		
to ensure unambiguous							
internal communications	152	202	1202	1981	2690	3886	10112
If a complaint from a			_			3880	10113
clinical or managerial colleague was found to be	(2.4%)	(3.2%)	(19.3%%)	(31.8)	(43.2%)		
vexatious then to have the							
option of having this							
investigated and possible							
disciplinary measures							
taken							
If a complaint from a	212	434	1296	1528	2837	3806	10113
patient was found to be	(3.4%)	(6.9%)	(20.6%)	(24.2%)	(45.0%)	3000	10113
vexatious then to have the	(3.470)	(0.570)	(20.070)	(24.270)	(43.070)		
option to take action							
against that person							
To set a limit to the time	131	260	1315	1855	2668	3884	10113
period when it is permitted	(2.1%)	(4.2%)	(21.1%)	(29.8%)	(42.8%)	3001	10115
to file multiple complaints	(2.170)	(/0/	(=11170)	(2)(0)()	(121070)		
relating to the same							
clinical incident or from							
the same person or persons							
If the doctor is exonerated	64	138	785	1872	3455	3799	10113
but has suffered financial	(1.0%)	(2.2%)	(12.4%)	(29.7%)	(54.7%)		=
loss during the process,				(, , , , ,			
then to have an avenue to							
make a claim for recovery							
of lost earnings or costs							
To have complete	59	102	757	1770	3559	3866	10113
transparency of any	(1.0%)	(2.2%)	(12.4%)	(28.3%)	(57.0%)		
management							
communication about the							
subject of a complaint by							
giving access to this to the							
doctor's representatives							
For all managers to	65	107	767	1744	3551	3879	10113
demonstrate a full up to	(1.0%)	(1.7%)	(12.3%)	(28.0%)	(57.0%)		
date knowledge of							
procedure in relation to							
complaints if they are							
made responsible for them							

Bourne et al

The BMA and defence	186	447	1601	1465	2575	3839	10113
organisations should be	(3.0%)	(7.1%)	(25.5%)	(23.4%)	(41.0%)		
more aggressive and less							
reactive to complaints in							
general							

1. Consent to participate in the study

This is an electronic form of consent for the study. By ticking the boxes below, you agree to take part in the study.

All information that you provide is ANONYMOUS and CONFIDENTIAL and held in strictest confidence. You will not be asked to provide any information that can be used to identify you nor can you be identified by us by filling in any part of this survey.

1. I consent to the use of my survey results to better understand the impact of complaints and investigations on doctors and their practice.

- Yes
- O No

2.

3. Demographics

This section will ask you some general questions about you and your background.

2. How old are you?



3. What is your gender?

- C Female
- Male

4. What is your Marital Status?



5. What is your Ethnic Origin?



6. In which year did you qualify?

	—
--	----------

7. If you qualified outside the UK, in which year did you come to the UK to practice medicine?

	•

8. If relevant, in which year did you complete your specialist training?

|--|

The IMPACT study
9. In which country did you complete your medical training?
10. Where is your principal workplace? (where you spend the majority of your working
time)
☐ GP surgery
☐ Elsewhere in primary care
☐ District general hospital
☐ University teaching hospital
Academic institution
Private practice clinic/hospital
Other (please specify)
11. What is your specialty?
· ·
Other (please specify)
40 In warm arranged to a st
12. Is your current post
Part time
Part time - Locum
☐ Full time
Full time - Locum
☐ Self-employed contractor
13. What is your grade?
· ·
Other (please specify)
44. Uzwalawa kawa wasanina diin wasan awasata a 240
14. How long have you worked in your current post?
4. Informal and formal complaints

 15. Have you ever been subject untoward incident? No Yes, and it is either ongoing or was resolved. Yes, and it was resolved more than 6 more than 6 more. 	ected to a	an in	form	al co		int i	E	al aa		:4 -		
Yes, and it is either ongoing or was resolv					mpia	aini,	rorm	ai Co	mpıa	int o	r ser	ious
_												
_	ved within the	past 6	6 month	s								
		, p		-								
Tes, and it was resolved more than o more	Titils ago											
. About your complaint												
16. Please enter how many of	f each of	the	follo	wing	g you	have	e had	I				
		0	1	2	3	4	5	6	7	8	9	10+
Informal complaints		0	0	0	0	0	0	0	0	0	0	0
Formal complaints		0	0	0	0	0	0	0	0	0	0	0
Serious untoward incidents		0	0	0	0	0	0	0	0	0	0	0
Referrals to the GMC		O		O	O	O	O	O	O	O	C	O
17. If applicable, which comp	laint or i	ncid	ent h	nad t	he m	ost i	mpac	t on	you?	•		
•												
Optional comments												
_	_	_	*		-	t / ref	ierra	l to tl	he Gl	MC (i	f mo	re
than one, please select the m Clinical complaint	ost serio	ous a	allega	ation	-	t / ref	ierra	l to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised	nost serio	DUS &	allega	ation	-	t / ret	ierra	I to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs	d about your p	DUS &	allega	ation	-	t / ref	ierra	l to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised	d about your p	DUS &	allega	ation	-	t / ref	ferra	I to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving,	d about your partients , fraud)	DUS &	allega	ation	-	t / ret	ferra	I to ti	he Gi	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving,	d about your pass with patients , fraud) come fro	oractice) m?	allega	ation	-	t / ret	ferra	I to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving,	d about your particular swith patients fraud) come fro	oractice) m?	allega	ation	-	t / ret	ierra	l to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving,	d about your particular swith patients, fraud) come fro	oractice) m?	allega	ation	-	t / ret	ferra	I to ti	he Gi	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving,	d about your particular swith patients fraud) come fro Yes	oractice) m?	allega	ation	-	t / ret	ferra	I to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving, 19. Where did the complaint of the complaint o	d about your pass with patients, fraud)	oractice) m?	allega	ation	-	t / ret	ierra	l to ti	he GI	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving, 19. Where did the complaint of the complaint	d about your particular swith patients fraud) come fro Yes	oractice) m? No	allega	ation	-	t / ret	ferra	l to ti	he Gi	MC (i	f mo	re
than one, please select the m Clinical complaint Clinical performance (i.e. concerns raised) Personal conduct (e.g. dishonesty, affairs) Criminal offence (e.g. dangerous driving,) 19. Where did the complaint of the complai	d about your pass with patients, fraud)	oractice) m? No	allega	ation	-	t / ret	ferra	l to ti	he Gi	MC (i	f mo	re
Clinical performance (i.e. concerns raised Personal conduct (e.g. dishonesty, affairs Criminal offence (e.g. dangerous driving, 19. Where did the complaint of Trust Medical colleagues Patient Management Media	d about your pass with patients, fraud)	oractice) m? No	allega	ation	-	t / ret	ierra	l to ti	he GI	MC (i	f mo	re

he IMPACT study								
21. How long (in months) did	the inve	estig	ation take	?				
f more than one, please sel				•				
f the investigation is ongoin	ıg, pleas	e ent	er the len	gth o	f time it l	nas ta	ken up to t	this
point								
22. If you were referred to t	ne GMC f	or a	procedure	, hov	v long die	d that	take (in m	onths)
f it is still ongoing, please s	tate how	long	ı it has tal	cen u	p to this	point		
23. How stressful did you fir	nd the fo	llowi	ng aspect	s of t	he GMC			
procedure?								
	Extremely stressful	2	Somewhat stressful	4	Not at all stressful	N/A		
The initial GMC investigation	0	0	0	0	0	0		
The decision to hold a Fitness to Practice hearing	0	0	0	0	0	0		
The Fitness to Practice hearing itself	0	0	\circ	0	\circ	0		
The appeal	0	0	0	0	0	0		
Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded Other (please specify)								
OF At any point during the in	ovootiaa	tion/						
25. At any point during the in	แงธรแนส	uon(ə <i>)</i> , uiu yol	J Yes	No			
				0	0			
Take sick leave				0	0			
Take unpaid leave				0	O			
Take sick leave Take unpaid leave Have supervised practice Have restrictions placed on your practice					© ©			
Take unpaid leave Have supervised practice				0				

The IMPACT study

- 27. Please estimate the direct financial costs (e.g. travel, legal fees, etc. in GBP) to you as a result of the investigation (if relevant)
- 28. Please estimate the indirect financial costs (e.g. loss of earnings, in GBP) to you as a result of the investigation (if relevant)
- 29. At any point of the inquiry, did you do any of the following

	Yes	No
Speak to family / friends about it	0	0
Speak to your colleagues about it	0	0
Represent yourself	0	\odot
Access support from a medical professional support organisation	0	0
Engage an independent solicitor or barrister	0	0
Were your case or the complaint published in the media (including social media)	0	0
Access support from the BMA employment advice service	0	0
Access support from the BMA counselling / other support organisation	0	0

30. As a consequence of the inquiry, to what extent do you agree/disagree with the following statements

	Strongly Agree	2	Neutral	4	Strongly Disgree	N/A
The potential consequences of the enquiry were clear to me throughout the process	0	0	0	0	0	0
I clearly understood the process	0	0	\circ	0	\circ	0
The process was transparent	0	0	\odot	0	\circ	0
Going through the process, I felt that I was assumed guilty until proven otherwise	0	0	0	0	0	0
I felt as if I had been scapegoated	0	0	\odot	0	\odot	0
I felt I had no control over what was happening to me	0	0	\odot	0	\odot	0
I felt alone in the proceedings	0	0	\odot	0	0	0
My complaint was primarily related to conflicts with colleagues	0	0	\circ	0	\circ	0
I felt well supported by my management	0	0	\odot	0	0	0
I felt well supported by my colleagues	0	0	\circ	0	0	0
I felt well supported by my medical professional support organisation	0	0	\odot	0	0	0
I felt well supported by my defence organisation	0	0	0	0	0	0
I felt that the complaint was fair	0	0	\odot	0	0	0
I felt that the complaint was reasonably dealt with	0	0	0	0	0	0
I felt that there were unnecessary delays in the process	0	0	0	0	0	0
I felt my complaint was handled competently	0	0	0	0	0	0
I was worried about the complaint escalating further	0	0	0	0	0	0
I felt that the consequences were proportionate	0	0	0	0	0	0
I felt that the nature of the process was overly punitive	O	0	\odot	0	0	0
I felt that the complaint was vexatious	0	0	0	0	0	0

31. To what extent did the following apply in relation to the process of the complaint or procedure you experienced

	Not at all	2	To some extent	4	Definitely
Normal process was not followed	0	0	0	0	0
The documentary record such as minutes produced by the investigative body was fair and accurate	O	0	0	0	0
The time scale for the investigation was needlessly protracted	0	0	0	0	0
I was kept well informed of when or if I could bring representation to meetings	0	0	0	0	0
I believe there was inappropriate or vexacious use of the hospital clinical risk process	0	O	0	O	0
I felt the complaint arose because of dysfunctional relationships within the clinical team	O	0	0	0	0
I felt victimised because I had been a whistleblower for clinical or managerial failures	0	0	O	0	0
Clinical issues were found after the initial complaint and used against me	\circ	0	O	0	\circ
I felt bullied during the investigation	0	0	0	0	0
I felt managers used the process to undermine my position	0	0	0	0	0
I felt clinical colleagues used the process to gain an advantage either financially or professionally	O	O	0	O	0
Other (please specify)					

Other (please specify)

32. During the inquiry, to what extent were you worried about the following outcomes

	A lot	2	To some extent	4	Not at all
Loss of livelihood	0	0	0	0	0
Public humiliation	0	0	0	0	\circ
Professional humiliation	0	0	0	0	0
Having aspects of your clinical practice restricted	0	0	0	0	0
Family problems	0	0	0	0	\circ
Having a marked record in the future	\circ	0	0	0	\circ
Financial costs	\odot	0	0	0	\odot

33. Currently, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- O 2
- C To some extent
- O 4
- O Not at all

34. To what extent do you agree with the following statements?

	Strongly agree	2	Neutral	4	Strongly disagree
Complaints are usually due to bad luck	0	0	O	0	0
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	O	0	O	O	O
Complaints are caused by litigatious patients	0	0	0	0	0
Doctors are hounded by the media	0	0	0	0	0
Doctors who receive complaints against them are generally unsuitable to practice medicine	O	0	O	0	O
I feel the need to please my colleagues to avoid complaints against me	O	0	O	O	O
Making a complaint is a good way of getting rid of colleagues that are "inconvenient"	О	0	О	0	O
Receiving a complaint would seriously affect my future career prospects	O	0	O	O	O
I have considered changing my career because of the high risk of receiving a complaint in my speciality	0	0	0	0	O

6. About complaints in general

35. In general, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- O 2
- C To some extent
- O 4
- O Not at all

36. To what extent do you agree with the following statements? Strongly

	Strongly agree	2	Neutral	4	Strongly disagree
Complaints are usually due to bad luck	0	0	0	0	0
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	O	O	O	O	0
Complaints are caused by litigatious patients	0	0	0	0	0
Doctors are hounded by the media	O	0	0	0	0
Doctors who receive complaints against them are generally unsuitable to practice medicine	0	0	0	0	O
I feel the need to please my colleagues to avoid complaints against me	O	0	O	O	0
Making a complaint is a good way of getting rid of colleagues that are "inconvenient"	0	0	O	0	O
Receiving a complaint would seriously affect my future career prospects	O	0	O	O	O
I have considered changing my career because of the high risk of receiving a complaint in my speciality	0	0	0	0	O

37. To what extent do you agree/disagree with the following statements?

	Strongly Agree	2	Neutral	4	Strongly Disgree
Complaints are primarily related to conflicts with colleagues	0	0	0	0	0
If I had a complaint made against me, I am confident that my management would support me	O	0	0	O	O
If I had a complaint made against me, I am confident that my colleagues would support me	O	0	O	0	O
If I had a complaint made against me, I am confident that my medical professional support organisation would support me	O	O	0	O	O
If I had a complaint made against me, I am confident that my defence organisation would support me	0	0	0	0	0
Overall, I believe that the complaints process is fair	0	0	\circ	0	\circ
Overall, I believe that complaints are reasonably dealt with	0	0	0	0	O
Overall, I believe that the complaints process is handled competently	0	0	0	0	0
Overall, I believe that the consequences are proportionate in the complaints process	O	0	0	0	0
Overall, I believe that the complaints process is vexatious	0	0	0	0	0
Overall, I believe that the complaints process is overly punitive	0	0	0	0	0

7. Medical History

ne	IMPACT study
	In the past 12 months, have you suffered from any of the following health conditions
or s	stressors (please tick all that apply)?
	Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)
	Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)
	Depression
	Anxiety
	Anger & irritability
	Other mental health problems
	Suicidal thoughts
	Sleep problems / insomnia
	Marital / relationship problems
	Frequent headaches
	Minor colds
	Recurring respiratory infections
If ye	s - please specify
39.	In the past 12 months, have you experienced any additional life stressors (e.g.
ber	eavement, accident, etc.)
0	Yes
0	No
If ye	s please specify
40.	Have you ever been aware of, or other people raised concerns, that you are drinking
too	much alcohol or taking (prescribed or non-prescribed) drugs?
	Yes, in the past (more than 6 months ago)
	Yes, currently (in the last 6 months)
	No
. Р	ossible legal consequences and professional practice
\ A	
	nin the LAST 6 MONTHS, have you ever taken the following actions which you would not have done if you were worried about possible consequences such as complaints, disciplinary actions by managers, being sued, or

publicity in the media?

he IMPACT study					
41. How often have you done any of the following?					
	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	0	0	0	0	0
Prescribed more medications than medically indicated?	0	0	\odot	0	0
Suggested invasive procedures against professional judgement?	\odot	0	0	0	0
Referred to specialists in unnecessary circumstances?	0	0	0	0	0
Conducted more investigations or made more referrals than warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	0	0	0	0
Asked for more frequent observations to be carried out on a patient than necessary?	0	0	\circ	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	0	0	0	0	0
Written more letters about a patient than is necessary to communicate about the patient's condition?	0	0	0	0	0
Referred patient for a second opinion more than necessary?	\circ	0	0	0	0
Carried out more tests than necessary?	\odot	0	0	0	\odot
Avoid a particular type of invasive procedure	0	0	0	0	0
Not accepted "high risk" patients in order to avoid possible complications	0	0	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0
Felt that you are a worse practitioner because of the above actions?	\odot	0	0	0	0

42. If you have answered "Never" to all the questions above, please omit this question. Which of the following factors are important? (please tick all boxes relevant to you)

	165	INO
Your colleagues' previous experience of complaints	0	0
Previous legal claims involving you	0	0
Previous legal claims involving your colleagues	0	0
Previous critical incident	0	0
Concerns about media interest	0	0
Other (please specify)		

43. As a result of what you know about the complaints process, have you

	Yes	No
Stayed in the specialty but stopped carrying out the area of work that are considered high risk of complaints	0	0
Changed your specialty	\circ	\circ
Become less likely to take on high-risk cases	0	0
Become more likely to abandon a procedure at an early stage	\circ	\circ
Felt that you have learnt from others' experience and improved your performance as a doctor	0	0
Other (please specify)		

44. Indicate the extent you feel that any of the following changes would improve the complaints process?

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	0	0	0	0	O
To be given a clear written protocol for any process at the onset	\circ	0	0	0	\circ
To have strict adherence to a statutary timeframe for any complaint and investigation process	0	0	0	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous internal communications	0	0	0	0	0
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and possible disciplinary measures taken	0	0	0	0	0
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	0
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	O
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	0
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	0
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	0
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	0	0	0	0	0

9. Medical History (ii)

	n the past 12 months, have you suffered from any of the following health condition
r st	ressors (please tick all that applies):
	Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)
	Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)
	Depression
	Anxiety
	Anger & irritability
	Other mental health problems
	Suicidal thoughts
	Sleep problems / insomnia
	Marital / relationship problems
	Frequent headaches
	Minor colds
	Recurring respiratory infections
f yes	please specify
	n the past 12 months, have you experienced any additional life stressors (e.g. avement, accident, etc.)
ere	
ere	avement, accident, etc.)
ere	avement, accident, etc.)
ere	avement, accident, etc.) Yes
ere	avement, accident, etc.) /es No please specify Have you ever been aware of, or other people raised concerns, that you are drinkin
f yes,	avement, accident, etc.) (es No please specify Have you ever been aware of, or other people raised concerns, that you are drinkin nuch alcohol or taking (prescribed or non-prescribed) drugs?
6 ree	avement, accident, etc.) (res No please specify Have you ever been aware of, or other people raised concerns, that you are drinkin nuch alcohol or taking (prescribed or non-prescribed) drugs? (res, in the past (more than 6 months ago)
f yes,	avement, accident, etc.) //es No please specify Have you ever been aware of, or other people raised concerns, that you are drinkin much alcohol or taking (prescribed or non-prescribed) drugs? //es, in the past (more than 6 months ago) //es, currently (in the last 6 months)
f yes,	avement, accident, etc.) (res No please specify Have you ever been aware of, or other people raised concerns, that you are drinkin nuch alcohol or taking (prescribed or non-prescribed) drugs? (res, in the past (more than 6 months ago)
ere	avement, accident, etc.) //es No please specify Have you ever been aware of, or other people raised concerns, that you are drinking much alcohol or taking (prescribed or non-prescribed) drugs? //es, in the past (more than 6 months ago) //es, currently (in the last 6 months)
O. L. Withinot w	avement, accident, etc.) (res No please specify Have you ever been aware of, or other people raised concerns, that you are drinking much alcohol or taking (prescribed or non-prescribed) drugs? (res, in the past (more than 6 months ago) (res, currently (in the last 6 months)

The	IMP	ACT	stu	dv

48. How often have you done any of the following?					
	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	0	0	0	0	0
Prescribed more medications than medically indicated?	0	\odot	\odot	0	0
Suggested invasive procedures against professional judgement?	O	\odot	0	0	0
Referred to specialists in unnecessary circumstances?	0	0	0	0	0
Conducted more investigations or made more referrals even when this is not warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	0	0	0	0
Asked for more frequent observations to be carried out on a patient than necessary?	0	\odot	0	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	0	0	0	0	0
Written more letters than is necessary to communicate about the patient's condition?	0	0	0	0	0
Referred patient for a second opinion more than necessary?	0	0	0	0	0
Carried out more tests than necessary?	0	0	0	0	0
Not accepted "high risk" patients in order to avoid possible complications?	0	0	0	0	0
Avoid a particular type of invasive procedure	0	0	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0
Felt that you are a worse practitioner because of the above actions?	0	0	0	0	O

49. If you have answered "Never" to all the questions above, please omit this question. Which of the following factors are important? (please tick all boxes relevant to you)

	165	INO
Previous experience of complaints about you	0	0
Your colleagues' previous experience of complaints	\circ	\circ
Previous legal claims involving you	0	0
Previous legal claims involving your colleagues	0	0
Previous critical incident	0	0
Concerns about media interest	0	0
Other (please specify)		

50. As a result of your experience do any of the following apply?

	Yes	No
Stayed in the specialty but stopped carrying out the area of work that led to the complaint	0	0
Changed your specialty	0	0
Less likely to take on high-risk cases	\circ	0
More likely to abandon a procedure at an early stage	0	0
Moved into a non-clinical role	0	0
You have become less committed and work strictly to your job description	0	0
You have learnt from the experience and improved your performance as a doctor	0	0
Left medicine and started a new career	0	0
The complaint or the way you were treated was related to discrimination	0	0
Retired early	0	0
Reduced your hours in the NHS to minimise your time there	0	0
Stopped working for the NHS and decided to work only in private practice or practice medicine elsewhere	0	O
Other (please specify)		

51. Indicate the extent you feel that any of the following changes would improve the process

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	O	0	0	0	0
To be given a clear written protocol for any process at the onset	0	0	0	0	0
To have strict adherence to a statutary timeframe for any complaint and investigation process	0	0	0	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous interrnal communications	0	0	0	0	O
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and with possible disciplinary measures taken	0	0	0	0	O
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	O
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	O
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	O
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	0
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	0
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	0	0	0	0	0

11. About your complaint (iii)

erious untoward incidents		0	1	2								
ormal complaints erious untoward incidents eferrals to the GMC			0	0	3	4	5	6	7	8	9	1
erious untoward incidents		0	0	0	0	0	0	0	0	0	0	
eferrals to the GMC		0	0	0	0	0	0	0	0	0	0	
		0	0	0	0	0	0	0	0	0	0	
			4.			4.			•			
I. If applicable, which com	ipiaint or i	nciae	ent n	ad ti	ne m	OST II	mpac	t on	you?			
tional comments												
tional comments												
What was the reason for	WOUL OOM	nloin	4 / ro	forr	al 4a	tha G	emc /	if m	ara 4k	on o		
 What was the reason for ease select the most serion 				IEII	ai to	uie c	JIVIC (,11 1110	ore u	iaii u	nie,	
Clinical complaint												
				II. A								
Clinical performance (i.e. concerns rai			genera	lly)								
Personal conduct (e.g. dishonesty, affa	airs with patients	s)										
Criminal offence (e.g. dangerous driving	ng, fraud)											
5. Where did the complain	t oomo fro	m2										
. Where did the complain	Yes	No										
ust												
edical colleagues												
tient												
nagement												
edia												
tient group												
her health care professional												
onymous												

the initial GMC investigation In decision to hold a Fitness to Practice hearing In the Fitness to Practice hearing itself In the appeal I
The Fitness to Practice hearing itself O O No fault / exonerated Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you Yes No alke sick leave A we restrictions placed on your practice A very restrictions placed on your practice
No fault / exonerated Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded her (please specify) I. At any point during the investigation(s), did you yes No like sick leave Size unpaid leave ave supervised practice A verification of the complaint / process No fault / exonerated Retraining imposed Retraining impos
No fault / exonerated Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you Yes No ke sick leave Retraining imposed Other (please specify) I. At any point during the investigation(s), did you Yes No Retraining imposed Other (please specify) I. At any point during the investigation(s), did you Yes No Retraining imposed Other (please specify) Other (please specify)
Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded her (please specify) I. At any point during the investigation(s), did you Yes No sike sick leave Retraining imposed One of the process was not clearly concluded The process was not clearly
Retraining imposed Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded her (please specify) I. At any point during the investigation(s), did you Yes No sike sick leave Retraining imposed One of the process was not clearly concluded The process was not clearly
Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you Yes No ake sick leave Ake unpaid leave Ave supervised practice Ave restrictions placed on your practice
Disciplinary action Suspended from practice Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you Yes No ake sick leave Ake unpaid leave Ave supervised practice Ave restrictions placed on your practice
Suspended from practice Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you yes No ake sick leave Aske unpaid leave Aske unpaid leave Aske supervised practice Aske restrictions placed on your practice
Struck off from the register The process was not clearly concluded ther (please specify) I. At any point during the investigation(s), did you Yes No ake sick leave Ake unpaid leave Ave supervised practice Ave restrictions placed on your practice
The process was not clearly concluded her (please specify) I. At any point during the investigation(s), did you Yes No like sick leave In the process was not clearly concluded the process was not clearly concluded to the process was not cle
her (please specify) I. At any point during the investigation(s), did you Yes No ake sick leave
I. At any point during the investigation(s), did you Yes No
I. At any point during the investigation(s), did you Yes No
Yes No ske sick leave C C C ave supervised practice C C C C C C C C C C C C C C C C C C C
Yes No ske sick leave C C C ave supervised practice C C C C C C C C C C C C C C C C C C C
ake sick leave C C ake unpaid leave C C ave supervised practice C C C C C C C C C C C C C C C C C C C
ave supervised practice O O ave restrictions placed on your practice O O
ave supervised practice C C ave restrictions placed on your practice C C
ave restrictions placed on your practice
ere you suspended C C
d your restrictions also include your private practice (if
2. How long were you off work in total?
<u> </u>
3. Please estimate the direct financial costs (e.g. tra
a result of the investigation (if relevant)
l. Please estimate the indirect financial costs (e.g.
sult of the investigation (if relevant)

65. At any point of the inquiry, did you

	Yes	No
Speak to family / friends about it	0	O
Speak to your colleagues about it	0	0
Represent yourself	0	0
Access support from a medical professional support organisation	0	0
Engage an independent solicitor or barrister	0	0
Were your case or the complaint published in the media (including social media)	0	0
Access support from the BMA employment advice service	0	0
Access support from the BMA counselling / other support organisation	0	0

66. As a consequence of the inquiry, to what extent do you agree/disagree with the following statements?

	Strongly agree	2	Neutral	4	Strongly disagree	N/A
The potential consequences of the enquiry were clear to me throughout the process	0	0	0	0	0	0
I clearly understood the process	\circ	0	0	0	\odot	0
The process was transparent	0	0	0	0	0	0
Going through the process, I felt that I was assumed guilty until proven otherwise	O	0	0	0	0	0
I felt as if I had been scapegoated	O	0	0	0	0	0
I felt I had no control over what was happening to me	\circ	0	0	0	\circ	0
I felt alone in the proceedings	0	0	0	0	0	0
My complaint was primarily related to conflicts with colleagues	0	0	0	0	0	0
I felt well supported by my management	\odot	0	0	0	\circ	0
I felt well supported by my colleagues	0	0	0	0	0	0
I felt well supported by my medical professional support organisation	0	0	0	0	0	0
I felt well supported by my defence organisation	0	0	0	0	0	0
I felt that the complaint was fair	0	0	0	0	0	0
I felt that the complaint was reasonably dealt with	0	0	0	0	0	0
I felt that there were unnecessary delays in the process	0	0	0	0	0	0
I felt my complaint was handled competently	0	0	0	0	0	0
I was worried about the complaint escalating further	0	0	0	0	\odot	0
I felt that the consequences were proportionate	0	0	0	0	0	0
I felt that the nature of the process was overly punitive	0	0	0	0	\odot	0
I felt that the complaint was vexatious	0	0	0	0	\circ	0

The IMPACT study

67. To what extent did the following apply in relation to the process of the complaint or procedure you experienced?

	Not at all	2	To some extent	4	Definitely
Normal process was not followed	0	0	0	0	0
The documentary record such as minutes produced by the investigative body was fair and accurate	0	0	0	0	0
The time scale for the investigation was needlessly protracted	0	0	0	0	0
I was kept well informed of when or if I could bring representation to meetings	0	0	0	0	0
I believe there was inappropriate or vexacious use of the hospital clinical risk process	0	0	0	O	0
I felt the complaint arose because of dysfunctional relationships within the clinical team	0	0	0	0	0
I felt victimised because I had been a whistleblower for clinical or managerial failures	0	0	0	0	0
Clinical issues were found after the initial complaint and used against me	0	0	0	0	0
I felt bullied during the investigation	0	0	0	0	0
I felt managers used the process to undermine my position	0	0	0	0	0
I felt clinical colleagues used the process to gain an advantage either financially or professionally	O	0	0	O	0
Other (please specify)					

Other (please specify)

68. During the inquiry, to what extent were you worried about the following outcomes?

	A lot	2	To some extent	4	Not at all
Loss of livelihood	0	0	0	0	0
Public humiliation	0	0	0	0	\circ
Professional humiliation	0	0	0	0	0
Having aspects of your clinical practice restricted	0	0	0	0	0
Family problems	0	0	0	0	\circ
Having a marked record in the future	\circ	0	0	0	\circ
Financial costs	\odot	0	0	0	\odot

69. Currently, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- C 2
- C To some extent
- O Not at all

The IMPACT study

•								
70. To what extent do you agree with the following statements?								
	Definitely agree	2	Neutral	4	Definitely disagree			
Complaints are usually due to bad luck	0	0	0	0	O			
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	0	0	0	0	0			
Complaints are caused by litigatious patients	0	0	0	0	O			
Doctors are hounded by the media	0	0	0	\circ	0			
Doctors who receive complaints against them are generally unsuitable to practice medicine	0	0	0	0	0			
I feel the need to please my colleagues to avoid complaints against me	0	0	0	0	0			
Making a complaint is a good way of getting rid of colleagues that are "inconvenient"	0	0	0	0	O			
Receiving a complaint would seriously affect my future career prospects	O	0	0	0	0			
I have considered changing my career because of the high risk of receiving a complaint in my speciality	0	0	0	0	0			

12. Medical History (iii)

71. When you were facing the investigation, did you experience any of the following?

	Improvement	No change	Onset of	Worsening of
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)	Г			
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)				
Depression				
Anxiety				
Anger & irritability				
Other mental health problems				
Suicidal thoughts				
Sleep problems / insomnia				
Relationship problems				
Frequent headaches				
Minor colds				
Recurring respiratory infections				

The IMPACT study
72. During the process, did you experience any additional life stressors (e.g.
bereavement, accident, etc.)
○ Yes
O No
If yes please specify
73. Have you ever been aware of, or other people raised concerns, that you are drinking
too much alcohol or taking (prescribed or non-prescribed) drugs?
Yes, in the past (more than 6 months ago)
Yes, currently (in the last 6 months)
Yes, during the investigation
□ No

13. Legal consequences and professional practice (iii)

Within the LAST 6 MONTHS, have you ever taken the following actions which you would not have done if you were not worried about possible consequences such as complaints, disciplinary actions by managers, being sued, or publicity in the media?

74. As a result of your experience, how often have you done any of the following?

	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	\circ	0	\circ	0	\odot
Prescribed more medications than medically indicated?	0	\circ	0	0	0
Suggested invasive procedures against professional judgement?	0	0	0	0	0
Referred to specialists in unnecessary circumstances?	0	0	0	0	0
Conducted more investigations or made more referrals than warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	O	O	0	O
Asked for more frequent observations to be carried out on a patient than necessary?	0	0	0	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	0	O	O	0	O
Written more letters about a patient than is necessary to communicate about the patient's condition?	0	0	0	0	O
Referred patient for a second opinion more than necessary?	0	0	0	0	0
Carried out more tests than necessary?	0	0	0	0	0
Not accepted "high risk" patients in order to avoid possible complications?	0	0	0	0	0
Avoid a particular type of invasive procedure	0	0	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0
Felt that you are a worse practitioner because of the above actions?	0	0	0	0	0

The IMPACT study

75. If you have answered "Never" to all the questions above, please omit this question. Which of the following factors are important? (please tick all boxes relevant to you)

	Yes	No
Previous experience of complaints about you	0	0
Your colleagues' previous experience of complaints	0	0
Previous legal claims involving you	0	0
Previous legal claims involving your colleagues	0	0
Previous critical incident	0	0
Concerns about media interest	0	0
Other (please specify)		

76. As a result of your experience do any of the following apply?

	Yes	No
Stayed in the specialty but stopped carrying out the area of work that led to the complaint	O	O
Changed your specialty	0	0
Less likely to take on high-risk cases	0	0
More likely to abandon a procedure at an early stage	0	0
Moved into a non-clinical role	0	0
You have become less committed and work strictly to your job description	0	0
You have learnt from the experience and improved your performance as a doctor	0	0
Left medicine and started a new career	0	0
The complaint or the way you were treated was related to discrimination	0	0
Retired early	0	0
Reduced your hours in the NHS to minimise your time there	0	0
Stopped working for the NHS and decided to work only in private practice or practice medicine elsewhere	0	0
Other (please specify)		

The IMPACT study

77. Indicate the extent you feel that any of the following changes would improve the process

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	0	0	0	0	\odot
To be given a clear written protocol for any process at the onset	\circ	0	0	0	0
To have strict adherence to a statutary timeframe for any complaint and investigation process	\odot	0	\circ	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous internal communications	0	0	0	0	0
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and with possible disciplinary measures taken	0	0	0	0	0
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	0
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	0
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	0
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	0
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	0
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	0	0	0	0	О

14. PHQ-9 & GAD-7

78. Over the last 2 WEEKS, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	0	0	0
Feeling down, depressed, or hopeless	0	\circ	0	\circ
Trouble falling or staying asleep, or sleeping too much	0	\odot	0	0
Feeling tired or having little energy	\circ	\circ	0	0
Poor appetite or overeating	0	0	0	0
Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	O	0	0
Trouble concentrating on things, such as reading the newspaper or watching television	О	0	О	O
Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	0	O	O
Thoughts that you would be better off dead or of hurting yourself in some way	0	0	0	0

The IMPACT study

- 79. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?
 - Not difficult at all
 - Somewhat difficult
 - Very difficult
- Extremely difficult

80. Over the last 2 WEEKS, how often have you been bothered by the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Feeling nervous, anxious or on edge	0	0	0	0
Not being able to stop or control worrying	\circ	\circ	0	\circ
Worrying too much about different things	0	0	0	0
Trouble relaxing	\circ	0	0	0
Being so restless that it is hard to sit still	0	0	0	0
Becoming easily annoyed or irritable	0	0	0	0
Feeling afraid as if something awful might happen	0	0	0	0

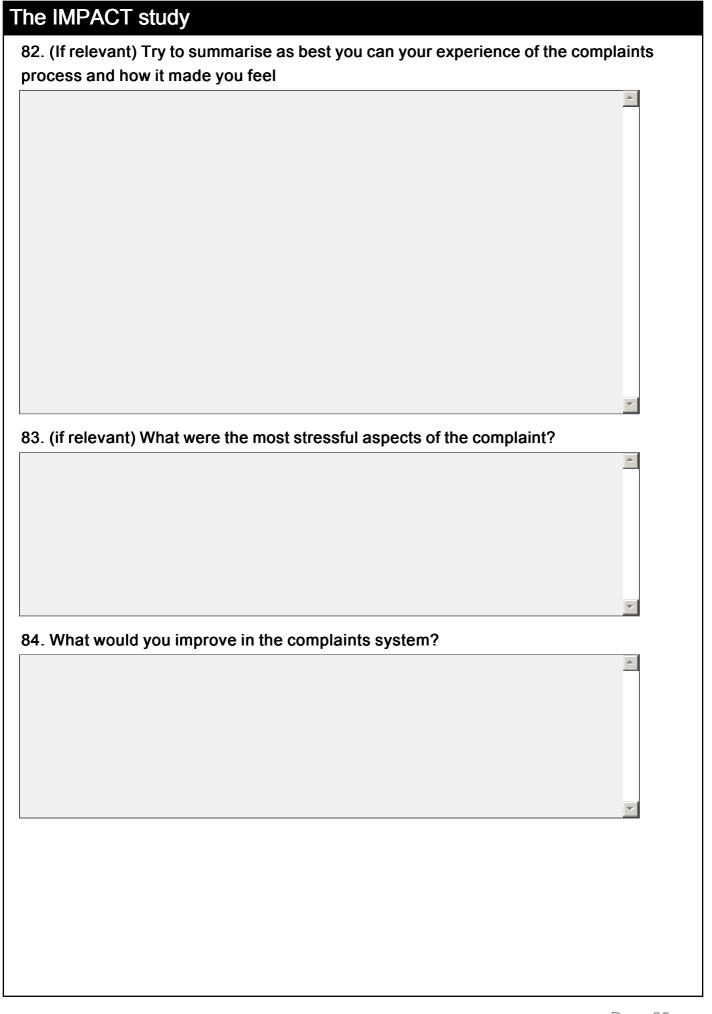
15. LDI

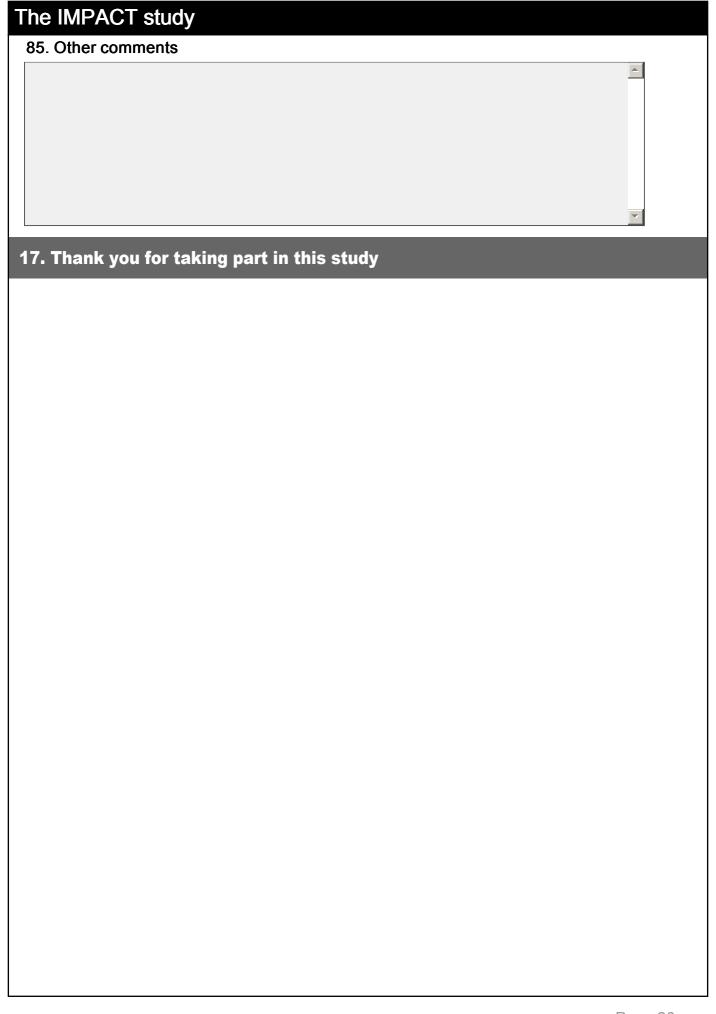
This scale is intended to estimate your current level of satisfaction with each of the eighteen areas of your life listed below. Please circle one of the numbers (1-7) beside each area. Numbers toward the left end of the seven-unit scale indicate higher levels of dissatisfaction, while numbers toward the right end of the scale indicate higher levels of satisfaction. Try to concentrate on how you currently feel about each area.

81. Please estimate your current level of satisfaction with each of the following areas of your life.

	1 Extremely dissatisfied	2	3	4	5	6 Extremely satisfied
Marriage	0	O	0	O	O	0
Relationship to spouse	O	\circ	0	0	\circ	O
Relationship to children	0	0	0	0	0	O
Financial situation	0	0	0	0	0	0
Employment	0	0	0	0	0	0
Recreation/Leisure	0	0	0	0	0	0
Social life	0	0	0	O	0	0
Physical health	0	0	0	\circ	\circ	O
Satisfaction with life	0	0	0	0	0	0
Expectations for future	0	O	O	O	0	0

16. Additional information (optional)





STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Contained in the title
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-11
Bias	9	Describe any efforts to address potential sources of bias	COMPARISON OF SAMPLE WITH SAMPLING FRAME: P 8 MISSINGNESS (AT RANDOM/NOT AT RANDOM): p 13
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-12, 13

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11-13
		(b) Describe any methods used to examine subgroups and interactions	12
		(c) Explain how missing data were addressed	12-13
		(d) If applicable, describe analytical methods taking account of sampling strategy	N A
		(e) Describe any sensitivity analyses	13
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	/
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	12; Supplementary material sensitivity analysis and supplementary tables 1-4
Outcome data	15*	Report numbers of outcome events or summary measures	Table 2 and 3
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14, 15-16
		(b) Report category boundaries when continuous variables were categorized	10, 11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14, Supplementary material sensitivity analysis and supplementary tables 1-4
Discussion			
Key results	18	Summarise key results with reference to study objectives	18
-,	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	18-19-

		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	19-20
		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	7/24
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom: a cross-sectional survey

014-006687.R2 14 m; Imperial College London, Queen Charlottes and Chelsea
14
<u> </u>
<u> </u>
n; Imperial College London, Queen Charlottes and Chelsea
aure; KU Leuven, Department of Electrical Engineering-ESAT nael; British Medical Association, Doctors for Doctors Unit , Chantal; KU Leuven, LUCAS n, Dirk; KU Leuven, Development and Regeneration , Ben; KU Leuven, Development and Regeneration Maria; South London and Maudsley NHS Foundation Trust,
су
th, Occupational and environmental medicine, Legal and edicine
orders < PSYCHIATRY, Depression & mood disorders <
9

SCHOLARONE™ Manuscripts

The impact of complaints procedures on the welfare, health and clinical practice of 7,926 doctors in the United Kingdom: a cross-sectional survey

Tom Bourne adjunct professor of gynaecology and consultant gynaecologist^{1,6,7}, Laure Wynants researcher in medical statistics^{2,3}, Mike Peters head of BMA Doctors for Doctors Unit ⁴, Chantal Van Audenhove professor of psychology and applied communication⁵, Dirk Timmerman professor of obstetrics and gynaecology^{6,7}, Ben van Calster professor of medical statistics⁶, Maria Jalmbrant clinical psychologist⁸

Corresponding author: Professor Tom Bourne Queen Charlotte's & Chelsea Hospital Imperial College London tbourne@imperial.ac.uk

Key words: anxiety, depression, suicide, physicians, regulation

Word count 5634

¹Queen Charlotte's & Chelsea Hospital, Imperial College, Du Cane Road, London, W12 0HS, UK

²KU Leuven Department of Electrical Engineering-ESAT, STADIUS Center for Dynamical Systems, Signal Processing and Data Analytics, Leuven, Belgium

³KU Leuven iMinds Future Health Department, Leuven, Belgium

⁴ Doctors for Doctors, British Medical Association, BMA House, Tavistock Square, London, UK

⁵LUCAS, KU Leuven, Leuven, Belgium

⁶KU Leuven Department of Development and Regeneration, Leuven, Belgium

⁷Department of Obstetrics and Gynaecology, University Hospitals Leuven, Leuven, Belgium

⁸South London and Maudsley NHS Foundation Trust, Denmark Hill, London, UK

IMPACT study

Abstract

Objectives: the primary aim was to investigate the impact of complaints on doctors psychological welfare and health. The secondary aim was to assess whether doctors report that exposure to a complaints process is associated with defensive medical practice.

Design: cross-sectional anonymous survey study. Participants were stratified into recent/current, past, no complaints. Each group completed tailored versions of the survey.

Participants: 95,636 doctors were invited to participate. 10,930 (11.4%) responded. 7,926 (8.3%) completed the full survey and were included in the complete analysis.

Main outcome measures: anxiety and depression were assessed using the standardised Generalised Anxiety Disorder scale and Physical Health Questionnaire. Defensive practice was evaluated using a new measure. Single-item questions measured stress-related illnesses, complaints-related experience, attitudes towards complaints, and views on improving complaints processes.

Results: 16.9% of doctors with current/recent complaints reported moderate/severe depression (relative risk (RR) 1.77 (95% CI=1.48, 21.3) compared to doctors with no complaints (9.5%)). 15% reported moderate/severe anxiety (RR= 2.08 (95% CI=1.61, 2.68) compared to doctors with no complaints (7.3%)). Distress increased with complaint severity, with highest levels after General Medical Council (GMC) referral (26.3% depression, 22.3% anxiety). Doctors with current/recent complaints were 2.08 (95% CI=1.61,2.68) times more likely to report thoughts of self-harm or suicidal ideation. Most doctors reported defensive practice: 82-89% hedging and 46-50% avoidance. 20% felt victimized after whistleblowing, 38% felt bullied. 27% spent over one month off work. Over 80% felt processes would improve with transparency, managerial competence, capacity to claim lost earnings and act against vexatious complainants.

Conclusions: doctors with recent/current complaints have significant risks of moderate/severe depression, anxiety, and suicidal ideation. Morbidity was greatest in cases involving the GMC. Most doctors reported practicing defensively including avoidance of procedures and high-risk patients. Many felt victimised as whistle-blowers or reported bullying. Suggestions to improve complaints processes included transparency and managerial competence.

Strengths and limitations of this study

Strengths

- One of the largest reported on this subject with 10,930 respondents and 7,926 completing the survey
- Respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions.
- We have obtained quantitative data on mental wellbeing using validated questionnaires.

Limitations

- The main limitation of the study was the overall response rate of 11.4%. Accordingly the findings must be interpreted with caution due to the possibility of ascertainment bias. On the other hand doctors were being asked to comment on their regulators, and those most traumatised by the complaints process may have avoided engaging with the survey. Doctors who have been erased from the register or changed profession would not have been contacted.
- The cross-sectional design does not enable causation to be elucidated
- We collected responses from doctors who have not experienced a complaint
 but observed the impact on others. This means that the "no complaints" group
 may have more psychological morbidity than if doctors could be isolated from
 complaints processes completely. This may result in relative risks in the paper
 being underestimated.
- Some questions involved remembering past events and the possibility of recall bias must also be considered.
- There were missing responses for a number of questions. However this was
 dealt with using multiple imputation. However we are reassured that no major
 differences between the conclusions that would be drawn using complete
 cases compared to those where data was missing and imputed were found.

Introduction

In the United Kingdom (UK), the General Medical Council (GMC) acts as the regulator and sets standards that doctors are expected follow. It has the power to warn, suspend, restrict the practice of doctors or permanently remove them from the register. These powers are established under the Medical Act (1983).

It was recently disclosed that 96 doctors have died since 2004 while involved in GMC fitness to practice proceedings. In parallel to this, between 2011 and 2012 the number of doctors referred to the GMC increased by 18%¹. Although most doctors referred to the GMC have their case closed at triage or have no action taken², there can be harrowing consequences for some doctors who go through a GMC investigation³.

However the GMC represents only the tip of the iceberg of the complaints system. These include formal and informal hospital internal enquiries, serious untoward incident (SUI) investigations and disputes with managers and colleagues. Whilst there are some data relating to how doctors respond to GMC investigations, to our knowledge there are no studies addressing the issue of complaints procedures below this level in the UK. For many doctors, the prospect of facing a complaint or professional dispute causes them significant stress. This can manifest itself in how they perform in clinical practice and/or in their personal life, and may lead to both physical and psychological symptoms.

Clearly complaints and investigations when things go wrong are part of the checks and balances that should ensure appropriate oversight of a doctor's performance, the overall aim being to protect patients and maintain appropriate clinical standards. However the regulatory burden and stress associated with a complaints process may not lead to the outcomes that are desired.

In a previous study of surgeons surveyed in the United States (US), malpractice litigation was significantly associated with burnout, depression and suicidal ideation⁴. There are also data to suggest that medical errors are associated with depression and loss of empathy in the physician responsible⁵. None of these outcomes are likely to improve patient care. A further study has shown suicidal ideation in over 6% of US surgeons, over twice the background rate in the population. In this study, burnout, depression, and involvement in a recent medical error were strongly and

IMPACT study

independently associated with suicidal ideation after controlling for other personal and professional characteristics. Most surgeons in this study were reluctant to seek professional help due to concerns that there may be an impact on their career⁶.

In a study published in the BMJ, Jain and Ogden described the impact of patient complaints on general practitioners in the United Kingdom and reported an association with anger, depression and suicide⁷. It is important to note they also described clinicians involved in complaints practicing medicine more defensively. Such practice may be broadly categorized into "hedging" and "avoidance". Hedging is when doctors are overcautious leading for example to over-prescribing, referring too many patients, or over investigation. Avoidance includes not taking on complicated patients, and avoiding certain procedures or more difficult cases.

The primary aim of this study was to investigate the psychological welfare of doctors who have observed or experienced both past and/or current complaints. The secondary aim of the study was to assess whether being involved in or witnessing a complaints process leads to doctors reporting that they practice medicine defensively.

Methods

Design

The study used a cross-sectional survey design where participants were streamed into three groups: current/recent complaint (on-going or resolved within the last 6 months), past complaint (resolved more than 6 months ago), and no complaints. Each group completed a slightly different version of the questionnaire. Participants in the current complaints and no complaints group were asked about their current mood and health whereas the past complaints group were also asked to respond about their mood and health at the time of the complaint.

Ethical approval was obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Participants

The British Medical Association (BMA) is an apolitical professional association and independent trade union that represents doctors and medical students in the UK, membership is voluntary. Members of the BMA in November 2012 who had preconsented to being contacted for research purposes were invited to participate (n=95,636). They were emailed a link to an online encrypted questionnaire using Survey Monkey® and an information sheet describing the study. Participants were guaranteed that their responses were anonymous and untraceable. The survey remained open for two weeks and three reminders were sent out about the study during this time. A total of 10,930 (11.4%) participants responded to the survey. Of these, 696 (6.4%) were excluded as they only completed the demographics section, and 121 (1.1%) participants were excluded because a technical error meant that they were given the wrong sections to complete. A further 2187 (20.0%) participants completed the demographics section and indicated whether they had had a complaint and they were partially included in the analysis (sample 1). A total of 7926 (72.5%) participants completed the survey (sample 2). Of these, 1380 omitted some sections of

the survey but were included in the full analysis. Demographic information in relation to both samples is shown in table 1.

In order to check that our sample was representative, we compared our study population with the total BMA membership database (see table 1). This showed that our sample was broadly representative in terms of gender (46.3% females in the BMA membership database compared to 47.5% females in both sample 1 and 2) and place of qualification (80.1% qualified in the United Kingdom in the BMA population compared to 80.7% in sample 1 and 81.2% in sample 2). Our study population consisted of more doctors in the 35-59 age range (49.8% in the BMA population compared to 74.8% in sample 1 and 73.4% in sample 2), ethnic minorities were under-represented (32.4% in the BMA population compared to 22.4% in sample 1 and 21.8% in sample 2), and consultants and GPs were over-represented (27.2% were consultants and 26% were GPs in the BMA population compared to 37.1% and 38.4% in sample 1 and 36.5% and 37.8% in sample 2) whilst junior doctors and retired doctors were underrepresented (26.4% were juniors and 8.6% were retired in the BMA population compared to 15.7% and 0.7% in sample 1 and 16.5% and 0.7% in sample 2).

Measures

A pilot of the questionnaire trialed on 20 medical doctors of varying grades and specialties and their feedback was incorporated in the questionnaire design (see details below). In total, 108 questions were asked to the no complaints group and 179 questions were asked to both the complaints groups. Based on filling in trial questionnaires, we estimate the time required to complete the questionnaire was approximately 30 minutes. The questionnaire is included as supplementary online information (supplementary file 1) or can be reviewed by using the following link: https://www.surveymonkey.com/s/P55KH5P

Having completed 13 items obtaining demographic information (including age, specialty, gender, marital status, ethnicity, place of training, marital status, and details about their employment), participants were separated into three streams based on

 IMPACT study

whether they had i) a current/recent complaint (within the past 6 months), ii) past complaint, or iii) no current or past complaints.

The different types of complaint or investigation that were considered in the study are outlined below:

Informal: an informal complaint usually involves a patient speaking directly to the people involved in their care in order to resolve their concerns. It can be escalated to a formal complaint if not resolved locally.

Formal: this is a written complaint usually to the chief executive or an employing organization that triggers an investigation and often requires a written response within a set time period and may lead to disciplinary action or referral to the GMC.

Serious Untoward Incident (SUI): the definition of an SUI is wide ranging and includes an unexpected death, poor clinical outcome, a hazard to public health, a trend leading to reduced standards of care, damage to reputation or confidence in a service or adverse media coverage or public concern about an organization. The aim is to prevent recurrence of the adverse event, but may lead to disciplinary action for individuals or referral to the GMC.

General Medical Council: a complaint can be made about a doctor for issues ranging from personal behavior outside work to clinical concerns about their practice. The GMC review cases and have the power to suspend doctors from practice during an investigation. This may lead to a warning or referral to a tribunal that has the power to restrict a doctor's practice, impose working under supervision, suspension from the medical register or remove a doctor from the register permanently. The GMC may also issue warnings and undertakings to doctors to change aspects of their behavior or practice.

All participants completed the following sections (although some individual items varied in the different streams):

Experience of complaint: Participants in both complaints groups were asked 75 questions about their complaint(s) generated from Bark and colleagues⁸ and the pilot study. This included their total number of complaints, the most significant complaint and followed by a series of questions about the most serious complaint if they had had

more than one, including the reason for the complaint, the origin, the duration, the outcome, the cost (i.e. any leave taken, the estimated financial cost), and the level of support sought and obtained during the complaint. Participants who had been referred to the GMC were also asked to rate how stressful they found each aspect of the procedure. Whilst the majority of the questions used a 5-point scale, some questions were qualitative and a few were yes/no.

Attitudes towards complaints: All groups were asked ten questions using a 5-point scale generated from the pilot study about their attitudes toward complaints, the causes of complaints, and their perceived threat of future complaints. The no complaints group was asked 11 additional questions about their attitudes towards the complaints process (e.g., "I believe that complaints are reasonably dealt with") and how well they perceive that they would be supported in the event of a complaint made against them (e.g., "If I had a complaint made against me, I am confident that my management would support me").

Suggestions to improve the complaints process. All groups were asked to rate different suggestions on how to improve the complaints process on 11 5-point items. These proposals were generated from the pilot study.

Medical history: The presence of common stress-related illnesses at the time of the complaint or currently were measured using 12 items, including recurring infections, gastro-intestinal, sleep, cardio-vascular and mood problems^{9, 10}. In addition, questions were asked about self-reported drug and alcohol use, as well as life stressors at the time of both current and past complaints.

Defensive medical practice: Twenty items measuring current defensive medical practice were generated from a literature review^{10,11,12}. 12 items additional items were generated from the pilot study (5 for the no complaints group). Items were either rated on a 5-point scale or a yes/no response.

Depression: The Physical Health Questionnaire (PHQ-9¹³⁾ is a well-known standardised screening measure assessing the presence and severity of depression. It has been used across a wide range of populations and demonstrated good

psychometric properties. Respondents were considered depressed if they scored 10 or more on the PHQ-9¹⁴.

Anxiety: The Generalised Anxiety Disorder scale (GAD-7)¹⁵) is a standardised screening measure assessing the presence and severity of generalized anxiety disorder. The GAD-7 is also moderately good at identifying panic disorder, social anxiety disorder, and post-traumatic stress disorder. It has been used across a wide range of populations and demonstrated good psychometric properties. Respondents were considered anxious if they scored 10 or more on the GAD-7¹⁵.

Life Satisfaction. Life satisfaction was assessed with 10 items using a 6-point scale asking about satisfaction-dissatisfaction with marriage, career, recreation/leisure, self/family, and life satisfaction/optimism.

Statistical analysis

For the purpose of this paper, we have limited ourselves to analysis of psychological welfare and health (i.e. anxiety, depression, stress-related illness), defensive practice, culture, time off work and suggestions for improving the complaints process. To summarise the fifteen items measuring defensive practice, an exploratory factor analysis was conducted which identified two underlying factors. The first involves over-investigation and overly cautious management, which we have termed "hedging" (9 items, including for example "carried out more tests than necessary", "referred patient for second opinion more than necessary" and "admitted patients to the hospital when the patient could have been discharged home safely or managed as an outpatient", Cronbach's α =0.92). The second involves avoiding difficult aspects of patient treatment, which we termed "avoidance" (3 items, "stopped doing aspects of my job", "not accepting high risk patients in order to avoid possible complications", and "avoiding a particular type of invasive procedure", Cronbach's α =0.77). Due to strongly skewed distributions, the sumscores hedging and avoidance were analysed both as dichotomous (any hedging (>0)/avoidance (>0) versus no hedging (0)/avoidance (0)) and ordinal variables (never (0), rarely (hedging 1-12, avoidance 1-4), sometimes (hedging 13-24, avoidance 5-8) or often (hedging 25-36, avoidance 9-12) displaying hedging or avoidance behavior.)

IMPACT study

The statistical analysis mainly consisted of descriptive analyses. Cross-tabulations of psychological welfare and defensive practice indicators have been made and relative risks were computed to investigate the relationship between complaint group and psychological welfare or defensive practice indicators. Additionally, means within the complaint groups and mean differences have been computed for continuous variables such as depression and anxiety. Asymptotic 95% confidence intervals were computed for relative risks and mean differences. Unpooled standard errors of the mean difference were used when necessary. Proportions and their 95% confidence intervals were also computed for feeling bullied during the investigation, feeling victimized because of whistle blowing and the amount of time spent off work. Proportions were computed to investigate the amount of support of respondents to various proposed actions to improve the complaints process.

As the primary aim of this study was to investigate the impact of complaints on the psychological welfare and health of doctors, a logistic regression analysis was performed to assess the relationship between moderate to severe depression and receiving a complaint, while controlling for predefined confounders (age, gender, being in a relationship, being White British, and medical specialty). Interactions of complaint with the confounders were included if necessary (α =0.001). Proportional odds logistic models were constructed to investigate whether hedging or avoidance are associated with characteristics of the complaint process (length of investigation, timing of complaint, outcome of investigation, origin of the complaint, type of the complaint). For hedging and avoidance, all two-way interactions were of interest and were included if necessary (α =0.001). We checked linearity assumptions, the presence of multi-collinearity, the presence of outliers, and the proportional odds assumption when necessary.

There was substantial item non-response. For key variables such as depression, anxiety, hedging and avoidance, non-response was approximately 20%. Missing data was addressed by performing multiple imputation¹⁶. Missing responses were replaced by 100 plausible values based on available responses to other questions, leading to 100 completed datasets that represent the uncertainty about the right value to impute. For composite scales (depression, anxiety and hedging), a two-step approach to

imputation was used to decrease the computational burden and make appropriate use of the available answers to separate items, first imputing the respondent's mean of non-missing items if at least 80% of the items of the composite scale were nonmissing, followed by multiple imputation (MI) at the scale level for the remaining individuals. For avoidance, the three items were individually imputed. Multiple imputation was performed using chained equations (MICE)¹⁶ with 10 iterations. After MI, each completed dataset was analysed separately and results combined using standard Rubin's rules (Rubin, 1987). To assess the impact of item non-response, we performed a sensitivity analysis comparing the results of the complete case analysis to the results after MI, which assumes missingness at random. Additionally, MI assuming missingness not at random (informative missings) was considered for key variables depression, anxiety, hedging and avoidance¹⁷. Since these variables are based on responses to sensitive questions, informative missingness is plausible. As a missingness mechanism we assumed that those respondents with missingness might have been more anxious or depressed, or more likely to display hedging behavior or avoidance. More details on the MNAR analysis can be found in the supplementary file.

The data was analysed using SAS (version 9.3, SAS Institute, Cary, NC, USA). Multiple imputations were performed using IVEware (http://www.isr.umich.edu/src/smp/ive/)¹⁸.

Results

Psychological welfare and health

Overall, 16.9% of doctors with recent or ongoing complaints reported clinically significant symptoms of moderate to severe depression (table 2). Doctors in this group were at increased risk of depression compared to those with a past complaint (7.8%) or no personal experience of a complaint (9.5%. RR=1.77, 95% CI=1.48, 2.13). This was the case even when controlling for the effects of gender, age (cubic effect), being in a relationship (yes/no), being White British (yes/no), and medical specialty. The effect of having a recent or current complaint depends on gender. When there has been no complaint, men tend to be less likely to be depressed than women (OR=0.76,

95% CI=0.54, 1.09), but a recent or current complaint has a higher impact on men than on women (OR women=1.72, 95% CI=1.28, 2.30; OR men=2.86, 95% CI 2.04, 4.01]. Within the PHQ-9, doctors with an ongoing or recent complaint (9.7%) were twice as likely as doctors with no complaints (4.7%) to report having thoughts of self-harm or suicidal ideation (RR=2.08, 95% CI=1.61, 2.68; see table 2). The sensitivity analysis shows that this conclusion holds under various assumed missingness mechanisms (see supplementary figure 1, supplementary table 1).

Moreover, 15% of doctors in the recent complaints group reported clinically significant levels of anxiety on the GAD-7, which is twice as likely as doctors who have no complaints (see Table 2, 7.3%, RR= 2.08, 95% CI=1.61, 2.68). Also this conclusion holds under various assumed missingness mechanisms (see supplementary file 1, supplementary table 2).

The level of psychological distress was related to the type of complaints procedure. Doctors going through a GMC referral reported the highest levels of depression (26.3%), anxiety (22.3%) and thoughts of self-harm (15.3%) compared to SUIs (16.1%, 15.3% and 9.3% respectively), formal complaints (15.6%, 13.5% and 9.0%), and informal complaints (12%, 12% and 6.4%) (table 3).

When asked directly using a single item scale, doctors were 3.78 (95% CI=2.68, 5.32) times more likely to report the presence of suicidal thoughts whilst going through a current or recent complaint compared to doctors who had no complaints (table 4).

Doctors who have experienced either a recent or past complaint reported higher levels of health problems at the time of the complaint compared to the no complaint group. These included gastro-intestinal problems, subjective anxiety and depression, anger, other mental health problems, insomnia, relationship problems, and frequent headaches. Doctors in the current complaints group also reported higher levels of cardio-vascular problems (table 4).

Defensive practice

IMPACT study

Overall, 84.7% of doctors with a recent and 79.9% with a past complaint reported changing the way they practiced medicine as a result of the complaint. 72.7% of doctors with no previous complaint reported changing their practice having observed a colleague's experience of a complaint (table 5).

88.6% of doctors with a recent or current complaint and 82.6% of those with a past complaint displayed hedging behaviour. 81.7% of doctors with no previous complaints reported hedging. The sensitivity analysis revealed that under the MNAR assumption, the conclusion still holds that people in the recent or current complaint group display more hedging behavior than people in the no complaints group, but also people with a past complaint display considerably more hedging behavior (supplementary figure 1, supplementary table3).

49.8% or doctors with a recent or current complaint, 42.9% of doctors with a past complaint, and 46.1% of doctors with no personal experience of a complaint reported avoidance behaviour having observed a colleague's experience of a complaint. Although the results from the complete case analysis support the conclusion that mostly people in the recent and current complaint group display avoidance behaviour, the results from the analysis under the MNAR assumption suggest that it is people with a past complaint who display most avoidance behaviour (supplementary figure 1, supplementary table 4).

The multivariable proportional odds analysis indicated that the odds of more severe hedging are higher for people with a recent or ongoing complaint than for people with a past complaint (OR 1.33 95% CI=1.19, 1.49) (table 6). The odds of hedging slightly increased with the length of time of the investigation (OR 1.01 per month, 95% CI=1.00, 1.01). Hedging was increased when retraining was imposed (OR 1.62, 95% CI=0.84, 3.13) and decreased when the doctor was suspended from practice (OR 0.56, 95% CI=0.26, 1.18). The odds of hedging also decreased when the complaint came from medical colleagues (OR 0.67, 95% CI=0.53, 0.86). There was evidence of an interaction between the type of the most serious complaint one has experienced and whether or not the complaint came from a patient (supplementary figure 1). Hedging was higher when the complaint came from a patient, this was most clear for informal

(OR=3.16, 95% CI=2.17, 4.58) and formal complaints (OR=2.18, 95% CI=1.67, 2.85). When the complaint did not come from a patient, hedging was higher for formal complaints, SUI's and GMC referrals compared to informal complaints (OR=1.52, 95% CI=1.03, 2.24, OR=2.10, 95% CI=1.31, 3.35 and OR=1.78, 95% CI=1.15, 2.71, respectively).

As with hedging, the multivariable analysis indicated that the odds of more severe avoidance increased with the length of time the investigation (OR 1.01 per month, 95% CI=1.01, 1.02), and was higher for people with a recent or current complaint than for people with a past complaint (OR 1.20, 95% CI=1.07, 1.35) (table 7). Avoidance was also increased when the investigation resulted in imposed retraining (OR 1.79, 95% CI=1.0, 3.09). Avoidance behaviour most severely increased when the complaint came from a patient group (OR 1.71, 95% CI=1.02, 2.87) or management (OR 1.59, 95% CI=1.16, 2.16), or when the complaint was anonymous (OR 1.58, 95% CI=1.06, 2.36). The type of complaint did not meaningfully influence the odds of more severe avoidance.

Overall, as a result of their experience of the complaints process, 23% of doctors reported suggesting invasive procedures against their professional judgement, and 14% reported becoming more likely to abandon a procedure at an early stage.

Culture and time off work

20% (95% C.I. 19% to 22%) reported that they felt victimized because they had been a whistleblower for clinical or managerial dysfunction. 38% (95% C.I. 37% to 40%) of people who have had a complaint, recently or in the past, reported feeling bullied during the investigation.

60% (95% C.I. 57% to 64%) spent less than a week off work. However, 27% (95% C.I. 24% to 30%) of people with complaints spent more than a month off work.

Opinions on changes to improve the system

Of those doctors that gave a response, 85% felt that for managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them mattered quite a lot or a great deal in terms of improving the process. An equal number (85%) felt that if a doctor is exonerated but has suffered financial loss during the process, then they should have the option to make a claim for recovery of lost earnings or costs and in addition that there should be complete transparency of any management communication about the subject of a complaint and that access to such communications should be given to a doctor's representatives. Seventy-four percent of respondents felt that it mattered quite a lot or a great deal that if a complaint from a clinical or managerial colleague was found to be vexatious then this could be investigated and possible disciplinary measures taken. The full details of responses in relation to actions that could be taken to reduce the psychological impact of complaints processes are shown in supplementary table 5.



IMPACT study

Discussion

We have shown that doctors who responded to our questionnaire who have recently received a complaint of any kind are 77% more likely to suffer from moderate to severe depression than people who have never had a complaint. They also have double the risk of having thoughts of self-harm, and double the risk of anxiety. Welfare is lowest when the complaint involves referral to the GMC. Doctors with a recent or current complaint also reported that they suffered from an increased likelihood of cardiovascular and gastro-intestinal disorders, depression, anxiety, anger and irritability, suicidal thoughts, sleep difficulty, relationship problems, and frequent headaches than people who had not been through a complaints process. In many cases these problems persisted. We have also shown that 80% of doctors answering the survey reported changing the way they practiced as a result of either complaints against themselves, or after observing a colleague go through a complaints process. The majority (84%) of doctors reported hedging behaviour in response to a complaint (i.e. increased defensive practice) whilst many (46%) admitted avoidance. A further important finding was that many doctors who had a complaint (20%) felt they were victimised after whistle blowing, thirty-nine percent reported that they felt bullied when they were going through the process, and 27% had more than a month off work.

A strength of the study is that to our knowledge it is one of the largest reported on the subject involving 10,930 respondents with 7,926 completing the survey. It is certainly the largest relating to doctors in the UK. We think it is critical that respondents were guaranteed at the outset that their responses were anonymous and untraceable, and so we think the respondents are likely to have been open about their opinions. Furthermore we have obtained quantitative data on the mental wellbeing of doctors using validated questionnaires. It is also important to note that we have collected responses from doctors who have not experienced a complaint but observed the impact on others. On the one hand this gives insight into the impact of observing a colleague going through a complaints process, however it also means that the "no complaints" group may have a higher overall level of psychological morbidity than if doctors could be isolated from complaints processes completely. Hence the relative risks in the paper may be underestimated. A significant limitation of the study is that the response rate was 11.4%, accordingly the findings must be interpreted with

caution due to the possibility of ascertainment bias. What constitutes an acceptable response rate is a subject of debate, however our response rate is clearly low¹⁹. We believe this is inevitable when asking doctors to comment on disciplinary processes and in particular on their regulator. Even if we take the view that the respondents are a selected group, they still demonstrate that a very considerable number of doctors are significantly impacted by complaints processes and practice defensively. It must also be remembered that doctors that have been most traumatised by the complaints process may have felt unable to take part in the survey and a small number are known to have committed suicide. Furthermore those no longer on the register (for example if they have changed profession or erased from the register) are unlikely to be members of the BMA and so would not have been contacted. As some questions involved remembering past events the possibility of recall bias for some answers must also be considered. For a number of questions there were missing responses. However we have considered this issue by using multiple imputation and were reassured that we found no essential differences between the conclusions that would be drawn using complete cases compared to those where missing data have been imputed.

As with any cross-sectional survey we must be careful when considering the findings, as we cannot show causation. It is possible that doctors with depression, anxiety and suicidal ideation are more likely to have complaints made against them, similarly being complained against may be the causative factor rather than the processes themselves. However this still means the information presented is important as if we take the former view, it means those going through complaints processes are a vulnerable group that need support. This was illustrated in a recent study that reported that sick doctors under investigation stated that the processes and communication style employed by the GMC were often distressing, confusing, and perceived to have impacted negatively on their mental health and ability to return to work²⁰.

It is interesting that our findings are similar to a questionnaire-based study of surgeons in the United States examining the emotional toll of malpractice lawsuits. This study found significantly more depression and burnout in surgeons who had recently been exposed to a lawsuit and highlighted the association between burnout and the likelihood of making a medical error⁴.

IMPACT study

We found that 10% of doctors responding to the survey who have had a recent complaint have had thoughts of self-harm and are over twice as likely to have had such thoughts compared to doctors who had not personally experienced a complaint. When referral to the GMC is looked at in isolation the number of doctors who reported suicidal ideation reached 15.3%, whilst 26.3% had moderate to severe depression and 22.3% had moderate to severe anxiety on the basis of two validated instruments. Even set against the limitations of the study we have highlighted above, these findings are concerning. In a recent feature article in the BMJ, Dyer reported on the high number of suicides associated with GMC proceedings³. Our results support the view that these proceedings have a disproportionate impact on doctors, especially as the vast majority of doctors who are referred to the GMC are found to have no significant case to answer². However the GMC is at the apex of what amounts to a "complaints pyramid" and our data show similar significant psychological morbidity for doctors across the entire spectrum of complaints procedures.

The incidence of feeling victimized following whistleblowing (20%) and bullying (38%) will be a concern to those trying to build a culture in the UK National Health Service (NHS) where it is safe to speak out about clinical and managerial concerns. The Francis report highlighted the dysfunctional culture that is prevalent in many NHS organisations²¹. Other reports have also highlighted serious concerns about the pressures that may be placed on hospital staff ²². Given the large numbers involved, our study supports the view that whistleblowing in the NHS is often not a safe action, that bullying is not uncommon, and that these problems are not isolated events.

The GMC exists to protect patients and the public. This is also the aim of other types of complaints processes with the overall purpose being to learn from mistakes and improve the performance of everyone taking part in patient care. However as with all interventions there may be unforeseen consequences. Previously Jain et al in a qualitative study reported that many general practitioners practice defensively following a complaint⁷. Our data also show the vast majority of doctors who took part in the study reported engaging in defensive practice. This included carrying out more tests than necessary, over-referral, over-prescribing, avoiding procedures, not accepting high-risk patients and abandoning procedures early. Nash and colleagues have also reported high levels of defensive practice²³. In their study which had a

higher response rate of 36%, 43% of doctors reported that they referred more patients, 55% ordered more tests and 11% stated they prescribed more medications than usual in response to medico-legal concerns. In a further report the same authors showed that doctors working in high- intervention areas of medicine are more likely to be the subject of medico-legal complaints²⁴. Defensive practice in such specialties may be particularly concerning.

These behaviors are not in the interest of patients and may cause harm, whilst they may also potentially increase the cost of health care provision. By far the majority of doctors who are reported to the GMC are not found to have a significant case to answer², as is probably the case with other lower level complaint investigations. It therefore does not seem unreasonable to argue that as they currently function, GMC enquiries may do more overall harm than good in terms of patient care. As the "complaints pyramid" is descended it is possible this balance may improve, although we found defensive practice across the entire spectrum of complaints processes.

Whilst we fully acknowledge the limitations associated with any study of this type, we believe our findings have implications for policy makers. Procedures must exist to enable patients to make a complaint about their care, for professionals to raise concerns about standards of practice and for serious untoward events to be investigated. However a system that is associated with high levels of psychological morbidity amongst those going through it is not appropriate as either the subjects of such procedures are vulnerable at the outset or are suffering such morbidity as a direct result of the investigations themselves. Most importantly, a system that leads to so many doctors practicing defensive medicine is not good for patients. A further concern for patient care is the association between doctor's distress, burnout and decreased empathy with perceived medical errors²⁵.

When asked how the complaints process could be improved doctors indicated that what mattered to them was that the process should be transparent and that staff responsible for investigating complaints should be up to date and competent. There was also a clear feeling that in the event of a complaint being shown to be vexatious then there should be disciplinary consequences if this related to colleagues, or the option for financial redress in the event it related to patients. Concerns about the lack of redress associated with vexatious complaints have been raised in the BMJ before²⁶.

IMPACT study

This highlights the inherent tension in the system whereby an apparent "whistleblower" may be perceived as a vexatious complainant by a colleague.

We have shown that doctors who responded to our questionnaire and experience or observe complaints processes exhibit high levels of psychological morbidity including severe depression and suicidal ideation. These effects are greatest when the process involves the General Medical Council. In addition the majority of these doctors exhibit hedging and avoidance, both these behaviours may be damaging to patient care and be contrary to the professed aims of these processes. Ind be com.

Acknowledgements

Mr. Christoph Lees (Imperial College NHS trust) and Mr. Magnus Boyd (Hill Dickinson LLP solicitors) contributed to receiving feedback on the contents and design of the questionnaire. We would like to thank all clinicians who commented on the initial versions of the survey.

Contributors

TB conceived of the original idea for the study, interpreted results, drafted the paper and is overall guarantor. MJ designed the questionnaire, obtained ethical approval, contributed to the preparation of the data set, interpreted results and contributed to drafts of the paper. LW and BVC carried out the statistical analysis and contributed to drafts of the papers. MP contributed to the study design, interpretation of results and commented on drafts of the paper. DT and CVA contributed to interpretation of results and commented on drafts of the paper. All authors approved the final version of the manuscript.

Funding

Tom Bourne is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre based at Imperial College Healthcare NHS Trust and Imperial College London. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. Laure Wynants is supported by a PhD grant of the Flanders' Agency for Innovation by Science and Technology (IWT Vlaanderen). Dirk Timmerman is a Senior Clinical Investigator of the Research Foundation- Flanders (FWO)

Competing interests

All authors have completed the Unified Competing Interest form and declare: Michael Peters is head of the BMA doctors for doctors unit and so receives payment from the BMA. The BMA had no role in data collection, design of the study, data analysis, interpretation of data, or writing the report and had no influence over whether to submit the manuscript. All other authors stated that they had no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other

relationships or activities that that could appear to have influenced the submitted work

Ethical approval

Ethical approval was sought and obtained from King's College London, Psychiatry, Nursing and Midwifery Research Ethics Subcommittee (PNM/12/13-22). All participants consented to participating in the study before they completed the questionnaire. The study was self-funded, and no external funding was sought.

Transparency declaration

The lead author (T Bourne) affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no aspects of the study have been omitted in relation to the specific aspects of the study reported in this paper; and that any discrepancies from the study as planned (and, if relevant registered) have been explained.

The Licence

The corresponding author has the right to grant on behalf of all authors and does grant on behalf of all authors a worldwide, licence, to the Publishers and its licensees in perpetuity (subject to the Reversion of Rights set out below), in all forms, formats and media (whether known now or created in the future), to i) publish, reproduce, distribute, display and store the Contribution, ii) translate the Contribution into other languages, create adaptations, reprints, include within collections and create summaries, extracts and/or, abstracts of the Contribution and convert or allow conversion into any format including without limitation audio, iii) create any other derivative work(s) based in whole or part on the Contribution, iv) to exploit all subsidiary rights that currently exist or as may exist in the future in the Contribution, v) the inclusion of electronic links from the Contribution to third party material where-ever it may be located; and, vi) licence any third party to do any or all of the above.

IMPACT study

References

- 1 White C. Complaints against doctors continue to rise. BMJ Careers 2013 Sep 30 http://careers.bmj.com/careers/advice/view-article.html?id=20014782 (accessed on 25 November 2013).
- 2 General Medical Council. Fitness to Practise Annual Statistics Report 25th September 2012 www.gmc-uk.org (accessed on 25 November 2013).
- 3 Dyer C. GMC and vulnerable doctors: too blunt an instrument? BMJ 2013;347:f6230
- 4 Balch CM, Oreskovich MR, Dyrbye LN, et al. Personal consequences of malpractice lawsuits on American surgeons. J Am Coll Surg 2011;**213**:657-67.
- 5 Shanafelt TD, Balch CM, Dyrbye L, et al. Special report: suicidal ideation among American surgeons. Arch Surg 2011;**146**:54-62.
- 6 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;**296**:1071-78.
- 7 Jain A, Ogden J. General practitioners' experiences of patients' complaints: qualitative study. BMJ 1999; **318**:1596-99.
- 8 Bark P, Vincent C, Olivieri L, et al. Impact of litigation on senior clinicians: implications for risk management. Quality in Health Care 1997;6:7-13.
- 9 Schat AC, Kelloway EK, Desmarais, S. The Physical Health Questionnaire: construct validation of a self-report scale of somatic symptoms. J Occup Health Psychol 2005;**10**:363-81.
- 10 Studdert DM, Mello MM, Sage VM, et al. Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. JAMA 2005;**293**:2609-17.

- 11 Nash L, Walton M, Daly M, et al. GPs' concerns about medico legal issues: How it affects their practice. Australian Fam Physician 2009;**38**:66-70.
- 12 Summerton N. Positive and negative factors in defensive medicine: A questionnaire study of General Practitioners. BMJ 1995;**310**:27-29.
- 13 Spitzer R, Kroenke K, Williams J. Validation and utility of a self-report version of PRIME-MD: the PHQ Primary Care Study. JAMA 1999;**282**:1737-44.
- 14 Kroenke K, Spitzer RL, Williams JBW. The PHQ-9: Validity of a brief depression severity measure. J Gen Intern Med 2001;**16**:606-13.
- 15 Spitzer RL, Kroenke K, Williams JBW, et al. A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med 2006;**166**:1092-97.
- 16 Raghunathan TW, Lepkowksi JM, Van Hoewyk J, et al. A multivariate technique for multiply imputing missing values using a sequence of regression models. Survey Methodology 2001;27:85–95.
- 17 Rubin DB. (1987). Multiple Imputation for Nonresponse in Surveys. Wiley, NY.
- 18 IVEware: Imputation and Variance Estimation Software. http://www.isr.umich.edu/src/smp/ive/ (accessed on 12 August 2013).
- 19. Baruch Y. Response rate in academic studies A comparative analysis. Human relations, 1999; 52: 421-438
- 20. Brooks SK, Del Busso L, Chalder T, Harvey SB, Hatch SL, Hotopf M, Madan I, Henderson M. 'You feel you've been bad, not ill': Sick doctors' experiences of interactions with the General Medical Council. BMJ Open. 2014 Jul 17; 4(7):e005537. doi: 10.1136/bmjopen-2014-005537.

- 21 Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry February 2013. Chaired by Robert Francis QC. http://www.midstaffspublicinquiry.com/report (accessed 25 November 2013).
- 22 Care Quality Commission recommends Essex hospital trust is put into special measures 5 November 2013. http://www.cqc.org.uk/media/care-quality-commission-recommends-essex-hospital-trust-put-special-measures (accessed on 25 November 2013).
- 23 Nash LM, Walton MM, Daly MG et al. Perceived practice change in Australian doctors as a result of medicolegal concerns.

Med J Aust. 2010 Nov 15; 193(10): 579-83.

24 Nash LM, Kelly PJ, Daly MG et al. Australian doctors' involvement in medicolegal matters: a cross-sectional self-report study.

Med J Aust. 2009 Oct 19; 191(8): 436-40.

- 25 West CP, Huschka MM, Novotny PJ, et al. Association of perceived medical errors with resident distress and empathy: a prospective longitudinal study. JAMA 2006;296:1071-78.
- 26 Marcovitch H. GMC must recognise and deal with vexatious complaints fast. BMJ 2002;324:167-68.

.

IMPACT study

Tables and Figures

Table 1: Demographic information relating to both sample 1 and 2 in the study

BMJ Open

Age	Total BMA membership consented for research	Sample 1 (n=10113)	Sample 2 (n=7926)
Up to 25	17.8%	1.4%	1.4%
26-29	9.0%	5.1%	5.5%
30-34	9.6%	8.6%	8.8%
35-39	10.3%	11.0%	11.0%
40-44	10.3%	13.5%	13.1%
45-49	10.8%	16.9%	16.8%
50-54	10.3%	18.8%	18.8%
55-59	8.1%	14.6%	14.7%
60-64	5.0%	6.6%	6.4%
65-69	3.0%	2.5%	2.6%
Over 69	5.9%	1.1%	1.0%
Gender	46.3% Female	47.5% Female	47.5% Female
Place of qualification			
United Kingdom	80.1%	80.7%	81.2%
India	8.2%	6.6%	6.2%
Pakistan	2.2%	1.2%	1.2%
Ireland	0.9%	1.4%	1.4%
Nigeria	1.1%	1.2%	1.2%
Germany	0.7%	1.1%	1.2%
South Africa	0.7%	0.8%	0.8%
Other	6.2%	6.9%	6.9%
Ethnicity White British	67.6%	77.6%	78.2%
Asian or Asian British	23.3%	16.6%	15.8%
Black or Black British	3.5%	2.3%	2.3%
Chinese or Chinese British	2.9%	1.3%	1.3%
Mixed	2.7%	2.3%	2.3%
Grade:			

Academics	2.1%	1.2%	1.3%
Consultants	27.2%	37.1%	36.5%
General Practice	26.0%	38.4%	37.8%
Junior Doctors	26.4%	15.7%	16.5%
SASC	5.3%	5.8%	6.11%
Retired	8.6%	0.7%	0.7%
Other or no answer	4.4%	1.0%	1.1%

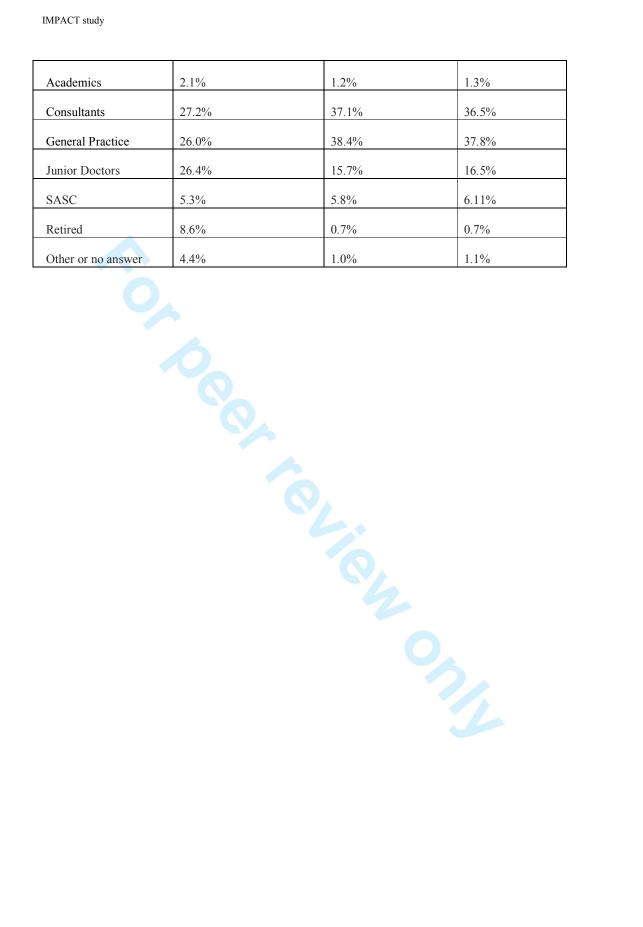


Table 2. Symptoms severity and relative risk of psychological distress for each complaints group.

	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent/ current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative risk for past complaint group/ mean difference (95% CI)	Relative risk for recent complaint group / mean difference (95% CI)
Depression (PHQ-9)						
Mean (SD) a	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3 (-0.6, -0.0)	1.4 (1.1, 1.7)
Moderate to severe depression n (%)	169 (9.5%)	303 (7.8%)	381 (16.9%)	852 (10.8%)	0.81 (0.65, 1.01)	1.77 (1.48, 2.13)
Thoughts of 'self- harm' n (%)	83 (4.7%)	221 (5.7%)	218 (9.7%)	522 (6.6%)	1.22 (0.93, 1.61)	2.08 (1.61, 2.68)
Anxiety (GAD-7) Mean (SD) ^b	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1	1.4
Moderate to severe anxiety n (%)	131 (7.3%)	234 (6.0%)	338 (15.0%)	703 (8.9%)	(-0.4, 0.2) 0.80 (0.57, 1.13)	(1.1, 1.7) 2.08 (1.61, 2.68)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression

^b The GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Table 3. Psychological distress within the recent / on-going complaints group by complaint that had the most impact.

the most impact.					
	Informal	Formal	SUI	GMC	No
	complaint	Complaint	n=280	referral	complaint
	n=362	n=1196	(12.4%)	n=374	n=1780
	(16.0%)	(53.0%)		(16.6%)	(22.5%)
Depression					
(PHQ-9)					
Mean (SD) a	4.2	4.8	5.1	6.6	3.7
	(5.0)	(5.4)	(5.6)	(6.7)	(4.3)
Moderate to severe	45	190	46	100	169
depression n (%)	(12.0%)	(15.6%)	(16.1%)	(26.3%)	(9.5%)
Thoughts of 'self-	24	110	27	58	83
harm' n (%)	(6.4%)	(9.0%)	(9.3%)	(15.3%)	(4.7%)
Anxiety (GAD-7)					
Mean (SD) b	3.8	4.4	4.7	5.7	3.1
	(4.3)	(4.7)	(5.1)	(5.7)	(3.8)
Moderate to severe	44	165	44	85	131
anxiety n (%)	(12.0%)	(13.5%)	(15.3%)	(22.3%)	(7.3%)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

^bThe GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Table 4. Psychosomatic health for each of the complaints group. Please note that the past complaints group used retrospective information asking about worsening or onset of symptoms at the time of the complaint, whereas the no and recent complaint groups were asked about the presence of symptoms in the last twelve months.

	No complaint	Recent or current complaint	Past complaint	RR recent or current versus
	n=1780 (22.5%)	n=2257 (28.5%)	n=3889 (49.1%)	no complaint.
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)	124 (7.0%)	280 (12.4%)	405 (10.4%)	1.78 (1.44-2.20)
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)	217 (12.2%)	426 (18.9%)	934 (24.0%)	1.55 (1.32-1.82)
Depression	187 (10.5%)	490 (21.7%)	1148 (29.5%)	2.07 (1.74-2.45)
Anxiety	476 (26.7%)	1108 (49.1%)	3045 (78.3%)	1.84 (1.65-2.04)
Anger and irritability	358 (20.1%)	928 (41.1%)	2406 (61.9%)	2.04 (1.77-235)
Other mental health problems	12 (0.7%)	54 (2.4%)	256 (6.6%)	3.45 (1.80-6.60)
Suicidal thoughts	44 (2.5%)	211 (9.3%)	519 (13.4%)	3.78 (2.68-5.32)
Sleep problems / insomnia	479 (26.9%)	1137 (50.4%)	288 (74.1%)	1.87 (1.67-2.10)
Relationship problems	187 (10.5%)	458 (20.3%)	911 (23.4%)	1.94 (1.63-2.30)
Frequent headaches	242 (13.6%)	432 (19.2%)	1027 (26.4%)	1.41 (1.19-1.65)
Minor colds	492 (27.6%)	509 (22.5%)	5447 (14.0%)	0.82 (0.73-0.92)
Recurring respiratory infections	77 (4.3%)	143 (6.3%)	306 (7.9%)	1.47 (1.11-1.95)

 Table 5 Defensive practice according to complaint group

Changed the way of practicing (72.7%) (79.9%) (84.7%) (79.6%) (1.06,1.14) (1.13,1.21) (1.1	Tanged the way Tang	experiences with complaints, have you	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent or current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative Risk for past complaint (95% CI)	Relative Risk for recent or current complaint (95% CI)
of practicing medicine n (%) Displayed (81.7%) (82.6%) (88.6%) (84.1%) (0.98,1.04) (1.05,1.11) Displayed (82.0 (1668 (1124 (3612 0.93 (0.87,1.00) (1.00,1.17) Displayed (46.1%) (42.9%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) Displayed (82.0 (1.02,1.29) (1.02,1.29) Displayed (82.0 (16.5%) (1.02,1.29) (1.02,1.29) Displayed (82.0 (1.02,1.29) (1.00,1.17) Displayed (82.6%) (1.02,1.29) Displayed (82.6%) (82.6%) (1.02,1.29) Displayed (1.08,1.10) Displayed (82.6%) (1.02,1.29) Displayed (82.6%) (1.02,1.29) Displayed (1.08,1.10) Displayed (82.6%) (1.02,1.29) Displayed (1.08,1.10)	Practicing edicine n (%) (79.9%) (84.7%) (79.6%) (1.06,1.14) (1.13,1.21)	Changed the way	1294	3106	1912	6312	1.10	
Displayed hedging behaviour n (%) Displayed 820	dging dging (81.7%) 1454 (82.6%) 3212 (82.6%) 1999 (88.6%) 6665 (84.1%) 1.01 (0.98,1.04) 1.08 (1.05,1.11) dging haviour n (%) asplayed oiding haviour n (%) haviour n (%) asplayed oiding haviour n (%) 820 (46.1%) 1668 (42.9%) 1124 (49.8%) 3612 (0.87,1.00) 0.93 (1.08 (0.87,1.00)) (1.00,1.17) largested vasive ocedures ainst ofessional dgement n (%) excome more tely to abandon procedure at an rely stage n (%) excome less come less excome less or mitted and orked strictly to b description (%) 372 (13.3%) 1136 (0.80,1.13) 0.95 (1.00,1.39) 1.18 (1.00,1.39) excome less of description (%) - 795 (20.5%) 613 (27.2%) -							(1.13,1.21)
Displayed hedging behaviour n (%) Displayed 820	dging dging (81.7%) 1454 (82.6%) 3212 (82.6%) 1999 (88.6%) 6665 (84.1%) 1.01 (0.98,1.04) 1.08 (1.05,1.11) dging haviour n (%) asplayed oiding haviour n (%) haviour n (%) asplayed oiding haviour n (%) 820 (46.1%) 1668 (42.9%) 1124 (49.8%) 3612 (0.87,1.00) 0.93 (1.08 (0.87,1.00)) (1.00,1.17) largested vasive ocedures ainst ofessional dgement n (%) excome more tely to abandon procedure at an rely stage n (%) excome less come less excome less or mitted and orked strictly to b description (%) 372 (13.3%) 1136 (0.80,1.13) 0.95 (1.00,1.39) 1.18 (1.00,1.39) excome less of description (%) - 795 (20.5%) 613 (27.2%) -	medicine n (%)	, , ,	, , ,	, ,	`		, , ,
Displayed 820 1668 1124 3612 0.93 1.08 (42.9%) (45.6%) (0.87,1.00) (1.00,1.17)	haviour n (%) (splayed solding (46.1%) (42.9%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (algested strictly to b description (%) (splayed (46.1%) (42.9%) (49.8%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (49.8%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (49.8%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (49.8%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (0.87,1.00) (1.00,1.17) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (0.87,1.00) (1.00,1.17) (49.8%) (20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (1.00,1.19) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (1.00,1.19) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (1.00,1.19) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (49.8%) (1.00,1.19) (49.8%		1454	3212	1999	6665	1.01	1.08
Displayed avoiding (46.1%) (42.9%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (1.	Seplayed		(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98, 1.04)	(1.05, 1.11)
Avoiding pehaviour n (%) (46.1%) (42.9%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) (1.00,1.18) (1.00,1.1	oiding haviour n (%) (46.1%) (42.9%) (49.8%) (45.6%) (0.87,1.00) (1.00,1.17) regested vasive vasive ocedures ainst ofessional degement n (%) (20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) recome more relately to abandon procedure at an rly stage n (%) (14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39) recome less remitted and orked strictly to be description (%) - 795 613 -	ehaviour n (%)						
Suggested 359 902 585 1846 1.15 1.29 (20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (20.2%) (25.9%) (23.3%) (23.3%) (1.02,1.29) (1.13,1.46) (20.2%) (25.9%) (23.3%) (haviour n (%) legested vasive vocedures ainst ofessional degement n (%) lecome more tely to abandon orrocedure at an rly stage n (%) lecome less ommitted and orked strictly to be description (%) legested (20.2%) (23.2%) (23.2%) (25.9%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (20.5%) (23.3%) (1.02,1.29) (1.13,1.46) (1.00,1.39) (1.00,1.39) (1.00,1.39) (1.00,1.39) (1.00,1.39) (1.00,1.39)	Displayed	820	1668	1124	3612	0.93	1.08
Suggested (20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (1.02,1.29) (1.13,1.29)	1.15 1.29 (20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (23.3%) (1.02,1.29) (1.13,1.46) (23.3%) (23.	voiding	(46.1%)	(42.9%)	(49.8%)	(45.6%)	(0.87, 1.00)	(1.00, 1.17)
(20.2%) (23.2%) (25.9%) (23.3%) (1.02,1.29) (1.13,1.46) (1.02,1.29) (1.13,1.29	vasive ocedures ainst offessional dgement n (%) exome more rely to abandon procedure at an rely stage n (%) exome less examples are serviced and price of the service of th	ehaviour n (%)						
rocedures gainst rofessional adgement n (%) Become more (14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39) Become less ommitted and vorked strictly to ob description (%)	ocedures ainst ofessional degement n (%) ecome more tely to abandon procedure at an orly stage n (%) ecome less ecome less emitted and orked strictly to be description (%)	uggested	359	902	585	1846	1.15	1.29
gainst rofessional adgement n (%) Become more kely to abandon procedure at an arrly stage n (%) Become less ommitted and vorked strictly to bb description (%) Second less observation (%) S	ainst ofessional degement n (%) ecome more 248 (14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39) ecome less or 795 (20.5%) (27.2%) ecome less of description (%)	nvasive	(20.2%)	(23.2%)	(25.9%)	(23.3%)	(1.02,1.29)	(1.13,1.46)
248 515 372 1136 0.95 1.18 379 379 379 379 379 379 379 379 379 380	ofessional digement n (%) ecome more	rocedures						
adgement n (%) Become more dikely to abandon procedure at an early stage n (%) Become less committed and worked strictly to ob description a (%)	degement n (%) ecome more tely to abandon procedure at an rly stage n (%) ecome less emmitted and orked strictly to b description (%) ecome strictly to b description (%) ecome more 248 515 372 1136 (0.80,1.13) (1.00,1.39) (0.80,1.13)							
Become more 248 (14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39) (1.00,	248 (14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39) (1.00,1.39) (20.5%) (27.2%)							
(14.0%) (13.3%) (16.5%) (14.3%) (0.80,1.13) (1.00,1.39	tely to abandon procedure at an rly stage n (%) ceome less							
procedure at an arly stage n (%) Become less - 795 613	procedure at an orly stage n (%) ecome less emmitted and orked strictly to be description (%)							
arly stage n (%) decome less committed and corked strictly to ob description (%) - 795 (20.5%) (27.2%)	rly stage n (%) ecome less emmitted and orked strictly to b description (%) rly stage n (%) - 795 (20.5%) (27.2%)	•	(14.0%)	(13.3%)	(16.5%)	(14.3%)	(0.80,1.13)	(1.00, 1.39)
Become less - 795 613	ecome less - 795 613							
ommitted and vorked strictly to ob description (%)	mmitted and orked strictly to b description (%)							
vorked strictly to ob description (%)	orked strictly to b description (%)		-				-	-
bb description (%)	b description (%)			(20.5%)	(27.2%)			
(%)	(%)							
		(%)						

Table 6. Factors influencing hedging behaviour.

Odds Ratio Estimates for hedging			
Effect	Point Estimate	95% W Confidence	
Length of investigation (per month)	1.006	1.002	1.011
Recent or current complaint (versus past complaint)	1.331	1.193	1.485
Outcome of investigation			
No fault/ exonerated (yes versus no)	1.051	0.676	1.633
Retraining imposed (yes versus no)	1.622	0.913	2.885
Disciplinary action (yes versus no)	0.815	0.433	1.532
Suspended from practice (yes versus no)	0.557	0.289	1.075
Struck off from the register (yes versus no)	0.583	0.754	1.761
The process was not clearly concluded (yes versus no)	1.152	0.900	1.960
Where did the complaint come from			
Trust (yes versus no)	1.328	0.900	1.960
Medical colleagues (yes versus no)	0.672	0.526	0.860
Management (yes versus no)	0.797	0.581	1.094
Media (yes versus no)	1.084	0.467	2.515
Patient group (yes versus no)	1.495	0.906	2.464
Other health care professional (yes versus no)	1.047	0.798	1.375
Patient (yes versus no)			
Patient (yes versus no) For informal complaint For formal complaint For SUI For GMC referral Anonymous (yes versus no)	3.155	2.172	4.584
For formal complaint	2.180	1.670	2.846
For SUI	1.212	0.826	1.778
For GMC referral	1.670	1.207	`2.311
Anonymous (yes versus no)	1.362	0.922	2.012
Type of complaint			
Formal complaint versus informal complaint			
Complaint did not come from a patient	1.521	1.034	2,239
Complaint came from a patient	1.051	0.903	1.223
SUI versus informal complaint			
Complaint did not come from a patient	2.097	1.311	3.352
Complaint came from a patient	0.805	0.648	1.002
GMC referral versus informal complaint			
Complaint did not come from a patient	1.776	1.164	2.709
Complaint came from a patient	0.940	0.757	1.168

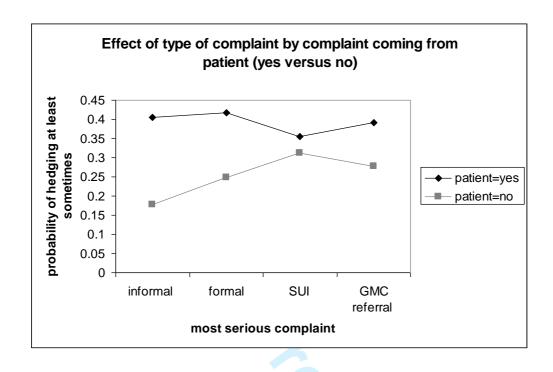
Table 7. Factors influencing avoidance behaviour

Odds Ratio Estimates for	avoiding				
Effect	Point Estimate	95% W Confidence			
Length of investigation (per month)	1.011 1.00		1.016		
Recent or current complaint (versus past complaint)	1.201	1.201 1.069			
Outcome of investigation					
No fault/ exonerated (yes versus no)	0.893	0.594	1.340		
Retraining imposed (yes versus no)	1.787	1.033	3.092		
Disciplinary action (yes versus no)	1.211	0.682	2.152		
Suspended from practice (yes versus no)	1.066	0.566	2.008		
Struck off from the register (yes versus no)	0.626	0.119	3.305		
The process was not clearly concluded (yes versus no)	1.202	0.805	1.796		
Where did the complaint come from					
Trust (yes versus no)	1.338	0.910	1.968		
Medical colleagues (yes versus no)	1.439	1.134	1.826		
Patient (yes versus no)	1.364	1.114	1.670		
Management (yes versus no)	1.585	1.163	2.161		
Media (yes versus no)	0.866	0.380	1.972		
Patient group (yes versus no)	1.708	1.019	2.866		
Other health care professional (yes versus no)	1.326	1.015	1.731		
Anonymous (yes versus no)	1.580	1.057	2.360		
Type of complaint					
GMC referral (versus informal complaint)	1.082	0.885	1.323		
SUI (versus informal complaint)	1.112	0.904	1.368		
Formal complaint (versus informal complaint)	1.036	0.893	1.203		

IMPACT study

Supplementary online material

Supplementary figure 1: Effect of type of complaint on hedging behavior by origin of complaint.



Bourne et al

Supplementary material sensitivity analysis and supplementary tables 1-4

Sensitivity Analysis.

As a last step in the analysis, we performed a sensitivity analysis considering also missingness not at random (MNAR) for some of the key analyses. MNAR means that, even accounting for all the available observed information, the reason for observations being missing still depends on the unseen observations themselves. We performed a simple sensitivity analysis, assuming as a not ignorable missing model that depression, anxiety, hedging and avoiding are worse when the value is missing. Therefore, after multiple imputation under the MAR assumption using MICE, I increased each imputed value of depression (PHQ9) and anxiety (GAD7) by a certain number d. This number d was obtained as follows. First, a random number δ was sampled from a normal distribution with mean the estimated standard deviation of the distribution of PHQ9/GAD7, and standard deviation the square root of this value. Then $d=\max(\delta, 1)$, such that d is restricted to imply an increase in PHQ9/GAD7. Therefore, d instead of δ is added to the imputed value under missingness at random (MAR). After this, the new imputed value is rounded and bound at the maximum possible value, such that an integer number on the original scale is obtained. For hedging/avoiding, all missings were assumed to have displayed at least some hedging/avoiding behaviour. The actual score on the scale is irrelevant, because the scale is dichotomised prior to the analysis. After the imputations under MNAR are computed, analysis proceeds as usual, using Rubin's rules to combine results.

Bourne et al

Supplementary table 1: Sensitivity analysis for PHQ-9

Depression	No	Past	Recent/	Total	Relative	Relative
(PHQ-9) ^a	complaint	complaint	current	n=7926	risk for	risk for
	n=1780	n=3889	complaint	(100%)	past	recent
	(22.5%)	(49.1%)	n=2257		complaint	complaint
			(28.5%)		group/	group /
					mean	mean
					difference	difference
					(95% CI)	(95% CI)
Missings	255	1144	214	1613		
	(14%)	(29%)	(9%)	(20%)		
Complete case						
Mean (SD)	3.8 (4.5)	3.4 (4.6)	5.2 (5.8)	4.1 (5.0)	-0.4	1.4
					(-0.7, 0.1)	(1.1, 1.7)
Moderate to severe	160	254	363	777	0.88	1.69
depression n (%)	(10.5%)	(9.3%)	(17.8%)	(12.3%)	(0.73, 1.06)	(1.42, 2.02)
MI MAR						
Mean (SD)	3.7 (4.3)	3.4 (4.2)	5.1 (5.6)	3.9 (4.7)	-0.3	1.4
					(-0.6, -0.0)	(1.1, 1.7)
Moderate to severe	169	303	381	852	0.81	1.77
depression n (%)	(9.5%)	(7.8%)	(16.9%)	(10.8%)	(0.65, 1.01)	(1.48, 2.13)
MI MNAR						
Mean (SD)	4.3 (4.6)	4.7 (4.8)	5.4 (5.7)	4.8 (5.1)	0.4	1.1
					(0.1, 0.7)	(0.8, 1.4)
Moderate to severe	238	593	432	1263	1.14	1.43
depression n (%)	(13.4%)	(15.2%)	(19.2%)	(15.9%)	(0.95, 1.35)	(1.21, 1.70)

^a The PHQ-9 depression scale ranges from 0 to 27. A score below five indicates absence of depression, a score between five and nine indicates mild depression, a score between ten and fourteen indicates moderate depression, a score between fifteen and nineteen indicates moderately severe depression and a score above nineteen indicates severe depression.

Bourne et al

Supplementary table 2: Sensitivity analysis for GAD-7

Anxiety (GAD7) b	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent/ current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative risk for past complaint group/	Relative risk for recent complaint group /
					mean difference (95% CI)	mean difference (95% CI)
Missings	258 (14%)	1148 (30%)	201 (9%)	1607 (20%)		
Complete case						
Mean (SD)	3.2 (3.9)	3.0 (4.0)	4.7 (5.0)	3.6 (4.4)	-0.2 (-0.4, 0.1)	1.5 (1.2, 1.8)
Moderate to severe	123	194	330	647	0.88	1.99
depression n (%)	(8.1%)	(7.1%)	(16.1%)	(10.2%)	(0.71, 1.09)	(1.63, 2.42)
MI MAR						
Mean (SD)	3.1 (3.8)	3.0 (3.8)	4.5 (4.9)	3.5 (4.2)	-0.1 (-0.4, 0.2)	1.4 (1.1, 1.7)
Moderate to severe	131	234	338	703	0.80	2.08
depression n (%)	(7.3%)	(6.0%)	(15.0%)	(8.9%)	(0.57, 1.13)	(1.61, 2.68)
MI MNAR						
Mean (SD)	3.7 (4.1)	4.3 (4.4)	4.9 (5.0)	4.3 (4.6)	0.5 (0.2, 0.9)	1.2 (0.9, 1.5)
Moderate to severe	173	463	374	1011	1.22	1.71
depression n (%)	(9.7%)	(11.9%)	(16.6%)	(12.75%)	(0.98, 1.51)	(1.35, 2.18)

^b The GAD-7 anxiety scale ranges from 0 to 21. A score below five indicates minimal anxiety, a score between five and nine indicates mild anxiety, a score between ten and fourteen indicates moderate anxiety and a score of fifteen or above indicates severe anxiety.

Bourne et al

Supplementary table 3: Sensitivity analysis for hedging.

		ty analysis for		/D 4 1	D 1 4	D 1 41
Because of your /	No	Past	Recent or	Total	Relative	Relative
other's	complaint	complaint	current	n=7926	Risk	Risk
experiences with	n=1780	n=3889	complaint	(100%)	for past	for recent
complaints, have	(22.5%)	(49.1%)	n=2257		complaint	or current
you ever			(28.5%)		(95% CI)	complaint
displayed						(95% CI)
hedging						
behaviour?						
Missings	268	1241	273	1782		
Complete case						
n (%)	1222	2135	1752	5109	1.00	1.09
11 (70)	(80.8%)	(80.6%)	(88.3%)	(83.1%)	(0.97,1.03)	(1.06,1.13)
MAR	(00.070)	(00.070)	(00.570)	(03.170)	(0.57,1.03)	(1.00,1.13)
	1454	3212	1999	6665	1.01	1.00
n (%)				6665	1.01	1.08
	(81.7%)	(82.6%)	(88.6%)	(84.1%)	(0.98,1.04)	(1.05,
						1.11)
MI MNAR						
n (%)	1484	3369	2023	6876	1.04	1.08
	(83.4%)	(86.6%)	(89.6%)	(86.8%)	(1.01, 1.06)	(1.05, 1.10)

Bourne et al

Supplementary table 4: Sensitivity analysis for avoidance.

Because of your / other's experiences with complaints, have you ever displayed avoiding behaviour?	No complaint n=1780 (22.5%)	Past complaint n=3889 (49.1%)	Recent or current complaint n=2257 (28.5%)	Total n=7926 (100%)	Relative Risk for past complaint (95% CI)	Relative Risk for recent or current complaint (95% CI)
Missings	242	1222	257	1721		
Complete case	212	1222	231	1721		
n (%)	705 (45.8%)	1137 (42.6%)	995 (49.8%)	2837 (45.7%)	0.93 (0.87,1.00)	1.09 (1.01,1.16)
MAR		,	, ,			
n (%)	820 (46.1%)	1668 (42.9%)	1124 (49.8%)	3612 (45.6%)	0.93 (0.87,1.00)	1.08 (1.00,1.17)
MI MNAR			·			
n (%)	947 (53.2%)	2359 (60.7%)	1252 (55.5%)	4558 (57.5%)	1.14 (1.08,1.20)	1.04 (0.98,1.10)



Bourne et al

Supplementary table 5: How doctors ranked the importance of different actions that might be taken to improve the complaints process might be improved (note these data are not imputed).

	Not at	A	To some	Quite a	A great	missing	total
	all	little	extent	lot	deal	n	n
To all the decidence	n (%)	n (%)	n (%)	n (%)	n (%)	2002	10112
To allow the doctor to	245	313	2256	1524	1973	3802	10113
have more direct input into responses to patient	(3.9%)	(5.0%)	(35.8%)	(24.2%)	(31.3%)		
complaints							
To be given a clear written	217	342	1501	1846	2400	3807	10113
protocol for any process at	(3.4%)	(5.4%)	(23.8%)	(29.3%)	(38.1%)	3007	10113
the onset	(3.470)	(3.470)	(23.070)	(27.570)	(30.170)		
To have strict adherence to	199	402	1599	1732	2379	3803	10113
a statutary timeframe for	(3.2%)	(6.4%)	(25.3%)	(27.5%)	(37.7%)	3803	10113
any complaint and	(3.270)	(0.4%)	(23.370)	(27.5%)	(37.770)		
investigation process							
Brief colleagues about any	261	440	1816	1972	1733	3891	10113
complaint or investigation	(4.2%)	(7.1%)	(29.2%)	(31.7%)	(27.9%)	3071	10113
to ensure unambiguous	(1.270)	(7.170)	(2).270)	(31.770)	(27.570)		
internal communications							
If a complaint from a	152	202	1202	1981	2690	3886	10113
clinical or managerial	(2.4%)	(3.2%)	(19.3%%)	(31.8)	(43.2%)		
colleague was found to be	` '		,	, ,			
vexatious then to have the							
option of having this							
investigated and possible							
disciplinary measures							
taken							
If a complaint from a	212	434	1296	1528	2837	3806	10113
patient was found to be	(3.4%)	(6.9%)	(20.6%)	(24.2%)	(45.0%)		
vexatious then to have the							
option to take action							
against that person	121	260	1215	1055	2660	2004	10112
To set a limit to the time	131	260	1315	1855	2668	3884	10113
period when it is permitted to file multiple complaints	(2.1%)	(4.2%)	(21.1%)	(29.8%)	(42.8%)		
relating to the same							
clinical incident or from							
the same person or persons							
If the doctor is exonerated	64	138	785	1872	3455	3799	10113
but has suffered financial	(1.0%)	(2.2%)	(12.4%)	(29.7%)	(54.7%)		10110
loss during the process,	(=.0,0)	\ _ /0/	\••/	(=2/0)	(2,0)		
then to have an avenue to							
make a claim for recovery							
of lost earnings or costs	<u> </u>						
To have complete	59	102	757	1770	3559	3866	10113
transparency of any	(1.0%)	(2.2%)	(12.4%)	(28.3%)	(57.0%)		
management							
communication about the							
subject of a complaint by							
giving access to this to the	1						
doctor's representatives		107	7.7	17744	2551	2070	10112
For all managers to	65	107	767	1744	3551	3879	10113
demonstrate a full up to	(1.0%)	(1.7%)	(12.3%)	(28.0%)	(57.0%)		
date knowledge of	1						
procedure in relation to							
complaints if they are made responsible for them							
made responsible for theffi	<u> </u>			<u> </u>	<u> </u>	<u> </u>	

Bourne et al

The BMA and defence	186	447	1601	1465	2575	3839	10113
organisations should be	(3.0%)	(7.1%)	(25.5%)	(23.4%)	(41.0%)		
more aggressive and less							
reactive to complaints in							
general							



1. Consent to participate in the study

This is an electronic form of consent for the study. By ticking the boxes below, you agree to take part in the study.

All information that you provide is ANONYMOUS and CONFIDENTIAL and held in strictest confidence. You will not be asked to provide any information that can be used to identify you nor can you be identified by us by filling in any part of this survey.

1. I consent to the use of my survey results to better understand the impact of complaints and investigations on doctors and their practice.

- Yes
- O No

2.

3. Demographics

This section will ask you some general questions about you and your background.

2. How old are you?



3. What is your gender?

- C Female
- Male

4. What is your Marital Status?



5. What is your Ethnic Origin?



6. In which year did you qualify?

▼

7. If you qualified outside the UK, in which year did you come to the UK to practice medicine?

	•

8. If relevant, in which year did you complete your specialist training?

	•

The IMPACT study
9. In which country did you complete your medical training?
10. Where is your principal workplace? (where you spend the majority of your working
time)
☐ GP surgery
☐ Elsewhere in primary care
☐ District general hospital
☐ University teaching hospital
☐ Academic institution
Private practice clinic/hospital
Other (please specify)
11. What is your specialty?
· ·
Other (please specify)
40 In a company to a set
12. Is your current post
Part time
Part time - Locum
☐ Full time
Full time - Locum
☐ Self-employed contractor
13. What is your grade?
·
Other (please specify)
44 Harriann harra varrusadad in resum arronnet na eta
14. How long have you worked in your current post?
4. Informal and formal complaints

he IMPACT study												
15. Have you ever been sı	ubjected to	an in	form	al co	mpla	aint, f	orm	al co	mpla	int o	r ser	ious
untoward incident?												
□ No												
Yes, and it is either ongoing or was	resolved within the	e past 6	6 month	s								
Yes, and it was resolved more than	6 months ago											
. About your complain	t											
16. Please enter how man	y of each of											
Informal complaints		0	1	2	3	4	5	6	7	8	9	10+
Formal complaints		0	0	0	0	0	0	0	0	0	0	0
Serious untoward incidents		0	0	0	0	0	0	0	0	0	0	0
Referrals to the GMC		0	0	0	0	0	0	0	0	0	0	0
Optional comments 8. What was the reason (given to you	_		_		t / ref	erra	l to ti	ne Gl	VIC (i	f mo	re
Optional comments 18. What was the reason grant complaint	given to you le most seric	ous a	alleg	ation		t / ref	erra	l to ti	ne Gl	VIC (i	f mo	re
Deptional comments 18. What was the reason grant complaint Clinical complaint Clinical performance (i.e. concerns	given to you le most serio	DUS &	alleg	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason generated the complaint	given to you le most serio raised about your affairs with patients	DUS &	alleg	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason of the content of the	given to you le most serion raised about your affairs with patients riving, fraud)	practice	alleg	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason of the property of	given to you le most serion raised about your affairs with patients riving, fraud)	practice	alleg :	ation		t / ref	erra	l to ti	he Gi	VIC (i	f mo	re
Deptional comments 18. What was the reason grant one, please select the Clinical complaint Clinical performance (i.e. concerns) Personal conduct (e.g. dishonesty, Criminal offence (e.g. dangerous decompla)	given to you ne most serion raised about your affairs with patients riving, fraud)	practice s)	alleg:	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason of than one, please select the Clinical complaint Clinical performance (i.e. concerns) Personal conduct (e.g. dishonesty, Criminal offence (e.g. dangerous decomplaint) 19. Where did the complaint	given to you e most serie raised about your affairs with patients riving, fraud) int come fro	practice s) m?	alleg:	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason grade in the concerns of the concerns of the concerns of the concerns of the complaint of the comp	given to you ne most series raised about your affairs with patients riving, fraud) int come fro	practice s) m?	alleg:	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
☐ Clinical performance (i.e. concerns ☐ Personal conduct (e.g. dishonesty,	given to you le most serie raised about your affairs with patients riving, fraud) int come fro	practices)	alleg:	ation		t / ref	erra	l to ti	he Gi	VIC (i	f mo	re
Deptional comments 18. What was the reason general complaint Clinical complaint Clinical performance (i.e. concerns) Personal conduct (e.g. dishonesty, Criminal offence (e.g. dangerous danger	given to you be most series about your affairs with patients riving, fraud) int come from Yes	practices)	e gener	ation		t / ref	erra	l to ti	he Gi	VIC (i	f mo	re
Deptional comments 18. What was the reason general complaint Clinical complaint Clinical performance (i.e. concerns) Personal conduct (e.g. dishonesty, Criminal offence (e.g. dangerous danger	given to you ne most serion raised about your affairs with patients riving, fraud) int come from Yes	practices)	allega e gener	ation		t / ref	erra	l to ti	he GI	VIC (i	f mo	re
Deptional comments 18. What was the reason of than one, please select the Clinical complaint Clinical performance (i.e. concerns) Personal conduct (e.g. dishonesty, Criminal offence (e.g. dangerous of the complation of the co	given to you be most series about your affairs with patients riving, fraud) int come from Yes	practices)	e gener	ation		t / ref	erra	l to ti	he Gi	VIC (i	f mo	re

tate how	long	orocedure it has tak	•	v lona did	
tate how	long		•	v lona did	
	_	it has tak		9 4.0	that
d the fo			cen u	p to this _l	point
d the fo					
	llowir	ng aspect	s of t	he GMC	
Extremely stressful	2	Somewhat stressful	4	Not at all stressful	N/A
C	0	O	0	©	0
0	0	0	0	0	0
-	0	-	_	6	
					0
O	O	O	O	O	O
	tion (c				
nvestiga	tion(s	s), did you		No	
			0	O	
			0	0	
			0	O	
			0	0	
			0	0	
e practice (if	applicab	le)	0	0	
	of the convestigate	o o o o o o o o o o o o o o o o o o o	o o o o of the complaint / processing the compla	o o o o o o o o o o o o o o o o o o o	the complaint / procedure? No The complaint / procedure? The stigation (s), did you Yes No O

- 27. Please estimate the direct financial costs (e.g. travel, legal fees, etc. in GBP) to you as a result of the investigation (if relevant)
- 28. Please estimate the indirect financial costs (e.g. loss of earnings, in GBP) to you as a result of the investigation (if relevant)
- 29. At any point of the inquiry, did you do any of the following

	Yes	No
Speak to family / friends about it	0	0
Speak to your colleagues about it	0	0
Represent yourself	0	0
Access support from a medical professional support organisation	0	0
Engage an independent solicitor or barrister	0	0
Were your case or the complaint published in the media (including social media)	0	0
Access support from the BMA employment advice service	0	\odot
Access support from the BMA counselling / other support organisation	0	0

30. As a consequence of the inquiry, to what extent do you agree/disagree with the following statements

	Strongly Agree	2	Neutral	4	Strongly Disgree	N/A
The potential consequences of the enquiry were clear to me throughout the process	0	0	0	0	0	0
I clearly understood the process	0	0	0	0	0	0
The process was transparent	0	0	0	0	0	0
Going through the process, I felt that I was assumed guilty until proven otherwise	0	0	O	0	0	0
I felt as if I had been scapegoated	0	0	0	0	\odot	0
I felt I had no control over what was happening to me	0	0	0	0	0	0
I felt alone in the proceedings	0	0	0	0	0	0
My complaint was primarily related to conflicts with colleagues	0	0	0	0	0	0
I felt well supported by my management	0	0	0	0	0	0
I felt well supported by my colleagues	0	0	0	0	0	0
I felt well supported by my medical professional support organisation	0	0	0	0	0	0
I felt well supported by my defence organisation	0	0	0	0	0	0
I felt that the complaint was fair	0	0	0	0	0	0
I felt that the complaint was reasonably dealt with	0	0	0	0	0	0
I felt that there were unnecessary delays in the process	0	0	0	0	0	0
I felt my complaint was handled competently	0	0	0	0	0	0
I was worried about the complaint escalating further	0	0	0	0	0	0
I felt that the consequences were proportionate	0	0	0	0	0	0
I felt that the nature of the process was overly punitive	0	0	0	0	0	0
I felt that the complaint was vexatious	0	0	0	0	0	0

31. To what extent did the following apply in relation to the process of the complaint or procedure you experienced

	Not at all	2	To some extent	4	Definitely
Normal process was not followed	0	0	0	0	0
The documentary record such as minutes produced by the investigative body was fair and accurate	0	0	0	0	O
The time scale for the investigation was needlessly protracted	0	\odot	0	0	0
I was kept well informed of when or if I could bring representation to meetings	0	0	0	0	0
I believe there was inappropriate or vexacious use of the hospital clinical risk process	0	0	0	0	0
I felt the complaint arose because of dysfunctional relationships within the clinical team	0	0	0	0	O
I felt victimised because I had been a whistleblower for clinical or managerial failures	0	0	0	0	0
Clinical issues were found after the initial complaint and used against me	0	0	\circ	0	0
I felt bullied during the investigation	0	\bigcirc	0	0	0
I felt managers used the process to undermine my position	0	0	O	0	0
I felt clinical colleagues used the process to gain an advantage either financially or professionally	O	0	0	O	0
Other (please specify)					

Other (please specify)

32. During the inquiry, to what extent were you worried about the following outcomes

	A lot	2	To some extent	4	Not at all
Loss of livelihood	0	0	0	0	0
Public humiliation	0	0	\circ	0	\circ
Professional humiliation	0	0	0	0	0
Having aspects of your clinical practice restricted	0	0	0	0	0
Family problems	0	0	0	0	\circ
Having a marked record in the future	\circ	0	0	0	\circ
Financial costs	\odot	0	0	0	\odot

33. Currently, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- O 2
- C To some extent
- O 4
- O Not at all

34. To what extent do you agree with the following statements?

	Strongly agree	2	Neutral	4	Strongly disagree
Complaints are usually due to bad luck	0	0	0	0	O
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	O	O	O	O	0
Complaints are caused by litigatious patients	0	0	0	0	0
Doctors are hounded by the media	0	0	0	0	0
Doctors who receive complaints against them are generally unsuitable to practice medicine	О	0	O	0	0
I feel the need to please my colleagues to avoid complaints against me	O	0	O	O	0
Making a complaint is a good way of getting rid of colleagues that are "inconvenient"	О	0	O	0	0
Receiving a complaint would seriously affect my future career prospects	O	0	O	0	0
I have considered changing my career because of the high risk of receiving a complaint in my speciality	0	0	O	0	O

6. About complaints in general

35. In general, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- O 2
- To some extent
- O Not at all

are "inconvenient"

receiving a complaint in my speciality

prospects

Receiving a complaint would seriously affect my future career

I have considered changing my career because of the high risk of

36. To what extent do you agree with the foll	owing sta	temen	ts?		
	Strongly agree	2	Neutral	4	Strongly disagree
Complaints are usually due to bad luck	0	0	0	0	0
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	O	O	O	0	0
Complaints are caused by litigatious patients	0	0	0	0	0
Doctors are hounded by the media	0	0	0	0	0
Doctors who receive complaints against them are generally unsuitable to practice medicine	0	0	0	0	0
I feel the need to please my colleagues to avoid complaints against me	O	0	O	0	0
Making a complaint is a good way of getting rid of colleagues that	0	0	0	\odot	0

37. To what extent do you agree/disagree with the following statements?

	Strongly Agree	2	Neutral	4	Strongly Disgree
Complaints are primarily related to conflicts with colleagues	0	0	O	0	\circ
If I had a complaint made against me, I am confident that my management would support me	O	0	0	O	0
If I had a complaint made against me, I am confident that my colleagues would support me	0	0	O	0	0
If I had a complaint made against me, I am confident that my medical professional support organisation would support me	O	0	0	O	0
If I had a complaint made against me, I am confident that my defence organisation would support me	0	0	0	0	0
Overall, I believe that the complaints process is fair	\circ	0	\circ	0	\circ
Overall, I believe that complaints are reasonably dealt with	0	0	0	0	0
Overall, I believe that the complaints process is handled competently	\circ	0	\circ	0	\circ
Overall, I believe that the consequences are proportionate in the complaints process	O	0	0	0	0
Overall, I believe that the complaints process is vexatious	0	0	0	0	0
Overall, I believe that the complaints process is overly punitive	0	0	O	0	0

7. Medical History

The IMPACT study								
38. In the past 12 months, have you suffered from any of the following health conditions								
or stressors (please tick all that apply)?								
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)								
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)								
Depression								
☐ Anxiety								
☐ Anger & irritability								
Other mental health problems								
☐ Suicidal thoughts								
□ Sleep problems / insomnia								
Marital / relationship problems								
Frequent headaches								
☐ Minor colds								
Recurring respiratory infections								
If yes - please specify								
39. In the past 12 months, have you experienced any additional life stressors (e.g. bereavement, accident, etc.) O Yes								
O No								
If yes please specify								
40. Have you ever been aware of, or other people raised concerns, that you are drinking too much alcohol or taking (prescribed or non-prescribed) drugs?								
Yes, in the past (more than 6 months ago)								
Yes, currently (in the last 6 months)								
□ No								
8. Possible legal consequences and professional practice								
Within the LAST 6 MONTHS, have you ever taken the following actions which you would not have done if you were not worried about possible consequences such as complaints, disciplinary actions by managers, being sued, or publicity in the media?								

41. How often have you done any of the following?					
	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	0	0	0	0	0
Prescribed more medications than medically indicated?	0	0	\odot	0	0
Suggested invasive procedures against professional judgement?	0	0	0	0	0
Referred to specialists in unnecessary circumstances?	\circ	0	0	0	0
Conducted more investigations or made more referrals than warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	0	O	0	0
Asked for more frequent observations to be carried out on a patient than necessary?	0	0	0	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	0	0	0	0	0
Written more letters about a patient than is necessary to communicate about the patient's condition?	0	0	0	0	0
Referred patient for a second opinion more than necessary?	0	0	0	0	0
Carried out more tests than necessary?	0	0	0	0	0
Avoid a particular type of invasive procedure	0	0	0	0	0
Not accepted "high risk" patients in order to avoid possible complications	0	0	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0

42. If you have answered "Never" to all the questions above, please omit this question. Which of the following factors are important? (please tick all boxes relevant to you)

Felt that you are a worse practitioner because of the above actions?

	Yes	No
Your colleagues' previous experience of complaints	O	0
Previous legal claims involving you	0	\circ
Previous legal claims involving your colleagues	0	\odot
Previous critical incident	0	0
Concerns about media interest	0	\odot
Other (please specify)		

43. As a result of what you know about the complaints process, have you

	168	INO
Stayed in the specialty but stopped carrying out the area of work that are considered high risk of complaints	0	0
Changed your specialty	0	0
Become less likely to take on high-risk cases	0	0
Become more likely to abandon a procedure at an early stage	O	0
Felt that you have learnt from others' experience and improved your performance as a doctor	0	0
Other (please specify)		

44. Indicate the extent you feel that any of the following changes would improve the complaints process?

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	\odot	0	0	0	\odot
To be given a clear written protocol for any process at the onset	0	0	0	0	0
To have strict adherence to a statutary timeframe for any complaint and investigation process	\odot	0	\circ	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous internal communications	0	0	0	0	0
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and possible disciplinary measures taken	0	0	0	0	0
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	0
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	0
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	0
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	0
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	0
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	0	0	0	0	0

9. Medical History (ii)

Γhe	IMPACT study
45.	In the past 12 months, have you suffered from any of the following health conditions
or s	stressors (please tick all that applies):
	Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)
	Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)
	Depression
	Anxiety
	Anger & irritability
	Other mental health problems
	Suicidal thoughts
	Sleep problems / insomnia
	Marital / relationship problems
	Frequent headaches
	Minor colds
	Recurring respiratory infections
If ye	s - please specify
	In the past 12 months, have you experienced any additional life stressors (e.g. reavement, accident, etc.)
0	No
If ye	s, please specify
	Have you ever been aware of, or other people raised concerns, that you are drinking much alcohol or taking (prescribed or non-prescribed) drugs? Yes, in the past (more than 6 months ago) Yes, currently (in the last 6 months)
10.	Legal consequences and professional practice (ii)
not	hin the LAST 6 MONTHS, have you ever taken the following actions which you would not have done if you were worried about possible consequences such as complaints, disciplinary actions by managers, being sued, or licity in the media?

The IMPACT study					
48. How often have you done any of the following?					
	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	0	0	0	0	0
Prescribed more medications than medically indicated?	0	0	0	0	0
Suggested invasive procedures against professional judgement?	0	0	O	0	0
Referred to specialists in unnecessary circumstances?	0	0	0	0	\circ
Conducted more investigations or made more referrals even when this is not warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	0	O	0	O
Asked for more frequent observations to be carried out on a patient than necessary?	0	0	0	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	0	0	0	0	O
Written more letters than is necessary to communicate about the patient's condition?	0	0	0	0	0
Referred patient for a second opinion more than necessary?	0	0	O	0	0
Carried out more tests than necessary?	0	0	0	0	0
Not accepted "high risk" patients in order to avoid possible complications?	0	0	\circ	0	\circ
Avoid a particular type of invasive procedure	0	0	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0

49. If you have answered "Never" to all the questions above, please omit this question. Which of the following factors are important? (please tick all boxes relevant to you)

Felt that you are a worse practitioner because of the above actions?

	Yes	No
Previous experience of complaints about you	\circ	O
Your colleagues' previous experience of complaints	\circ	0
Previous legal claims involving you	0	0
Previous legal claims involving your colleagues	\circ	\circ
Previous critical incident	0	0
Concerns about media interest	\circ	\circ
Other (please specify)		

The IMPACT study

50. As a result of your experience do any of the following apply?

	Yes	No
Stayed in the specialty but stopped carrying out the area of work that led to the complaint	\odot	0
Changed your specialty	0	\circ
Less likely to take on high-risk cases	\odot	0
More likely to abandon a procedure at an early stage	0	0
Moved into a non-clinical role	0	0
You have become less committed and work strictly to your job description	0	0
You have learnt from the experience and improved your performance as a doctor	\odot	0
Left medicine and started a new career	y to take on high-risk cases y to abandon a procedure at an early stage to a non-clinical role become less committed and work strictly to your job description clearnt from the experience and improved your performance as a doctor cine and started a new career cliaint or the way you were treated was related to discrimination arly your hours in the NHS to minimise your time there	
The complaint or the way you were treated was related to discrimination	\odot	0
Retired early	0	0
Reduced your hours in the NHS to minimise your time there	\odot	0
Stopped working for the NHS and decided to work only in private practice or practice medicine elsewhere	0	0
Other (please specify)		

51. Indicate the extent you feel that any of the following changes would improve the process

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	0	0	0	0	0
To be given a clear written protocol for any process at the onset	0	0	0	0	O
To have strict adherence to a statutary timeframe for any complaint and investigation process	\odot	0	0	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous interrnal communications	0	0	0	0	O
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and with possible disciplinary measures taken	0	0	0	0	0
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	O
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	O
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	O
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	O
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	O
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	0	0	0	0	O

11. About your complaint (iii)

2. Please enter how many	y of each o	f the	follo	wing	you	have	e had					
nformal complaints		0	1	2	3	4	5	6	7	8	9	10
nformal complaints		0	0	0	0	0	0	0	0	0	0	
Formal complaints Serious untoward incidents		0	0	0	0	0	0	0	0	0	0	
Referrals to the GMC		0	0	0	0	0	0	0	0	0	0	
53. If applicable, which co	mplaint or i	incid	lent l	nad t	he m	ost i	mpac	t on	you?	•		
Optional comments												
54. What was the reason fo				eferr	al to	the C	MC (if mo	ore th	nan o	ne,	
please select the most ser	ious allega	tion)	?									
Clinical complaint												
Clinical performance (i.e. concerns r	aised about your	practice	e gener	ally)								
Personal conduct (e.g. dishonesty, a	ffairs with patients	s)										
☐ Criminal offence (e.g. dangerous dri	ving fraud)											
	_	_										
55. Where did the complain	nt come fro											
Trust	Yes	No										
Medical colleagues	П	П										
Patient	П	Г										
Management												
Media												
Patient group												
Other health care professional												
Anonymous												
									_			
	r (most rec	ent)	com	pıaın	it / in	vesti	gatio	on co	nciu	aea?		
<u> </u>												
56. How long ago was you	r (most rec	ent)	com	plain	it / in	vesti	gatio	n co	nclu	ded?	•	
57. How long (in months) d	id the inves	stiga	tion	take	(if m	ore t	han d	ne,	pleas	e se	lect :	the
most serious allegation)?												
	41 0110 6			_	_						4.	
58. If you were referred to	the GMC fo	r a p	roce	:ss, h	ow le	ong c	lid th	at ta	ke (i	n mo	nths)?

The IMPACT study 59. If applicable, how stressful did you find the following aspects of the GMC process? Not at Extremely Somewhat all N/A stressful stressful stressful The initial GMC investigation The decision to hold a Fitness to Practice hearing

60. What was the outcome of the complaint / process?

No fault / exonerated
Retraining imposed

The appeal

The Fitness to Practice hearing itself

Disciplinary action	

Suspended from practice
Struck off from the register

The	process			ala anh		
rne	brocess	was	not	cieariv	CONCI	uaea

Other (please specify)

61. At any point during the investigation(s), did you

	res	NO
Take sick leave	\circ	0
Take unpaid leave	\circ	0
Have supervised practice	\odot	0
Have restrictions placed on your practice	0	0
Were you suspended	\odot	0
Did your restrictions also include your private practice (if applicable)	0	0

62. How long were you off work in total?

▼

63. Please estimate the direct financial costs (e.g. travel, legal fees, etc. in GBP) to you as a result of the investigation (if relevant)

64. Please estimate the indirect financial costs (e.g. loss of earnings in GBP) to you as a result of the investigation (if relevant)

65. At any point of the inquiry, did you		.,				
Speak to family / friends about it		Ye		No ①		
Speak to your colleagues about it				0		
Represent yourself		(0		
Access support from a medical professional support organisation				0		
		(0		
Engage an independent solicitor or barrister Were your case or the complaint published in the media (including so	cial	(0		
media)				•		
Access support from the BMA employment advice service		(0		
Access support from the BMA counselling / other support organisation		(0		
6. As a consequence of the inquiry, to wha		nt d	do yo	u		
agree/disagree with the following statement					04	
	Strongly agree	2	Neutral	4	Strongly disagree	N/A
The potential consequences of the enquiry were clear to me throughout the process	0	0	0	0	0	0
I clearly understood the process	0	0	0	0	0	0
The process was transparent	0	0	0	0	0	0
Going through the process, I felt that I was assumed guilty until proven otherwise	0	0	0	0	0	0
I felt as if I had been scapegoated	O	0	O	0	0	0
		_	_		0	0
I felt I had no control over what was happening to me	0	0	0	0	0	
	0	0	0	0	0	0
I felt alone in the proceedings						0
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues	0	0	0	0	0	
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management	0	0	0	0	0	0
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues	0 0	0 0	0 0	0	0 0	0
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation	0 0	OOOO	0 0 0	0 0 0	0 0 0	0 0
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation	© © ©	OOOOO	0 0 0	0 0 0	© © © ©	0 0 0
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation I felt that the complaint was fair	0 0 0 0 0			0 0 0 0	0 0 0 0 0	
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation I felt that the complaint was fair I felt that the complaint was reasonably dealt with						
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation I felt that the complaint was fair I felt that the complaint was reasonably dealt with I felt that there were unnecessary delays in the process						
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation I felt that the complaint was fair I felt that the complaint was reasonably dealt with I felt that there were unnecessary delays in the process I felt my complaint was handled competently						
I felt alone in the proceedings My complaint was primarily related to conflicts with colleagues I felt well supported by my management I felt well supported by my colleagues I felt well supported by my medical professional support organisation I felt well supported by my defence organisation I felt that the complaint was fair I felt that the complaint was reasonably dealt with I felt that there were unnecessary delays in the process I felt my complaint was handled competently I was worried about the complaint escalating further						
•						

The IMPACT study

67. To what extent did the following apply in relation to the process of the complaint or procedure you experienced?

	Not at all	2	To some extent	4	Definitely
Normal process was not followed	0	0	0	0	0
The documentary record such as minutes produced by the investigative body was fair and accurate	0	0	0	0	O
The time scale for the investigation was needlessly protracted	0	0	0	0	0
I was kept well informed of when or if I could bring representation to meetings	0	0	0	0	0
I believe there was inappropriate or vexacious use of the hospital clinical risk process	0	0	0	0	0
I felt the complaint arose because of dysfunctional relationships within the clinical team	O	0	0	0	0
I felt victimised because I had been a whistleblower for clinical or managerial failures	0	0	0	0	0
Clinical issues were found after the initial complaint and used against me	0	0	0	0	0
I felt bullied during the investigation	0	0	0	0	0
I felt managers used the process to undermine my position	0	0	0	0	0
I felt clinical colleagues used the process to gain an advantage either financially or professionally	O	0	0	0	0
Other (please specify)					

Other (please specify)

68. During the inquiry, to what extent were you worried about the following outcomes?

	A lot	2	To some extent	4	Not at all
Loss of livelihood	0	0	0	0	0
Public humiliation	\circ	0	\circ	0	0
Professional humiliation	0	0	0	0	0
Having aspects of your clinical practice restricted	0	0	0	0	0
Family problems	0	0	0	0	0
Having a marked record in the future	\circ	0	0	0	0
Financial costs	0	0	0	0	0

69. Currently, to what extent do you worry about complaints being made against you?

- C A great deal / nearly all the time
- O 2
- To some extent
- O 4
- Not at all

The IMPACT study					
70. To what extent do you agree with the fol	lowing sta	tement	ts?		
	Definitely agree	2	Neutral	4	Definitely disagree
Complaints are usually due to bad luck	0	0	0	0	O
A doctor who receives more complaints than other colleagues usually does so because of poor clinical performance	0	0	0	0	O
Complaints are caused by litigatious patients	0	0	0	0	0
Doctors are hounded by the media	0	0	\circ	0	0
Doctors who receive complaints against them are generally unsuitable to practice medicine	0	0	0	0	0
I feel the need to please my colleagues to avoid complaints against me	0	0	0	0	O
Making a complaint is a good way of getting rid of colleagues that are "inconvenient"	0	0	O	0	O
Receiving a complaint would seriously affect my future career prospects	O	0	0	0	0
I have considered changing my career because of the high risk of receiving a complaint in my speciality	0	0	O	0	O

12. Medical History (iii)

71. When you were facing the investigation, did you experience any of the following?

	Improvement	No change	Onset of	Worsening of
Cardio-vascular problems (e.g. high blood pressure, angina, heart attack)				
Gastro-intestinal problems (e.g. gastritis, IBS, ulcers)				
Depression				
Anxiety				
Anger & irritability				
Other mental health problems				
Suicidal thoughts				
Sleep problems / insomnia				
Relationship problems				
Frequent headaches				
Minor colds				
Recurring respiratory infections				

☐ No

The IMPACT study 72. During the process, did you experience any additional life stressors (e.g. bereavement, accident, etc.) Yes No If yes please specify 73. Have you ever been aware of, or other people raised concerns, that you are drinking too much alcohol or taking (prescribed or non-prescribed) drugs? Yes, in the past (more than 6 months ago) Yes, currently (in the last 6 months) Yes, during the investigation

13. Legal consequences and professional practice (iii)

Within the LAST 6 MONTHS, have you ever taken the following actions which you would not have done if you were not worried about possible consequences such as complaints, disciplinary actions by managers, being sued, or publicity in the media?

74. As a result of your experience, how often have you done any of the following?

	Never	2	Sometimes	4	Often
Did you change the way you practice medicine?	\circ	0	0	0	0
Prescribed more medications than medically indicated?	\circ	\odot	0	0	0
Suggested invasive procedures against professional judgement?	0	\odot	0	0	0
Referred to specialists in unnecessary circumstances?	0	0	0	0	0
Conducted more investigations or made more referrals than warranted by the patient's condition?	0	0	0	0	0
Admitted patients to hospital when the patient could have been discharged home safely or managed as an outpatient?	0	0	0	0	O
Asked for more frequent observations to be carried out on a patient than necessary?	0	\odot	O	0	0
Written in patients' records specific remarks such as "not suicidal" which you would not if you were not worried about legal/media/disciplinary consequences?	O	0	O	0	0
Written more letters about a patient than is necessary to communicate about the patient's condition?	0	0	O	0	0
Referred patient for a second opinion more than necessary?	\circ	0	0	0	0
Carried out more tests than necessary?	0	\odot	0	0	0
Not accepted "high risk" patients in order to avoid possible complications?	0	0	0	0	0
Avoid a particular type of invasive procedure	0	\odot	0	0	0
Stopped doing aspects of your job?	0	0	0	0	0
Felt that you are a worse practitioner because of the above actions?	0	0	0	O	0

75. If you have answered "Never" to a					
questions above, please omit this qu					
Vhich of the following factors are important	=				
please tick all boxes relevant to you))				
	Yes	No O			
revious experience of complaints about you	0	0			
our colleagues' previous experience of complaints					
revious legal claims involving you	0	0			
evious legal claims involving your colleagues	0	0			
evious critical incident	0	0			
oncerns about media interest	0	0			
er (please specify)					
ior (produce openity)					
Tion (please specify)					
	any of th	ne follo	wing a	apply?	,
. As a result of your experience do	_		_	Yes	No
6. As a result of your experience do	_		_	Yes	No ©
6. As a result of your experience do ayed in the specialty but stopped carrying out the area of nanged your specialty	_		_	Yes O	No ©
S. As a result of your experience do ayed in the specialty but stopped carrying out the area of nanged your specialty ass likely to take on high-risk cases	_		_	Yes O O	No O O
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of thanged your specialty ess likely to take on high-risk cases	_		_	Yes C C C	No ©
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of thanged your specialty less likely to take on high-risk cases ore likely to abandon a procedure at an early stage	_		_	Yes C C C C C	No O O O
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of thanged your specialty ess likely to take on high-risk cases ore likely to abandon a procedure at an early stage oved into a non-clinical role	of work that led	d to the com	_	Yes C C C	No O O
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of changed your specialty ess likely to take on high-risk cases fore likely to abandon a procedure at an early stage floved into a non-clinical role fou have become less committed and work strictly to your	of work that led	d to the com	_	Yes C C C C C	No O O O
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of hanged your specialty ess likely to take on high-risk cases ore likely to abandon a procedure at an early stage oved into a non-clinical role ou have become less committed and work strictly to your ou have learnt from the experience and improved your per	of work that led	d to the com	_	Yes C C C C C C C C C C C C C	No O O O O
6. As a result of your experience do sayed in the specialty but stopped carrying out the area of hanged your specialty ess likely to take on high-risk cases ore likely to abandon a procedure at an early stage oved into a non-clinical role ou have become less committed and work strictly to your ou have learnt from the experience and improved your perfet medicine and started a new career	of work that led job description erformance as	d to the com	_	Yes C C C C C C C C C C C C C C C C C C C	No
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of changed your specialty ess likely to take on high-risk cases fore likely to abandon a procedure at an early stage floved into a non-clinical role fou have become less committed and work strictly to your fou have learnt from the experience and improved your per eft medicine and started a new career the complaint or the way you were treated was related to	of work that led job description erformance as	d to the com	_	Yes C C C C C C C C C C C C C C C C C C C	No
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of hanged your specialty ess likely to take on high-risk cases lore likely to abandon a procedure at an early stage loved into a non-clinical role ou have become less committed and work strictly to your ou have learnt from the experience and improved your peter medicine and started a new career the complaint or the way you were treated was related to etired early	job description erformance as	d to the com	_	Yes C C C C C C C C C C C C C	No
Getayed in the specialty but stopped carrying out the area of Changed your specialty Less likely to take on high-risk cases More likely to abandon a procedure at an early stage Moved into a non-clinical role You have become less committed and work strictly to your You have learnt from the experience and improved your perfect medicine and started a new career The complaint or the way you were treated was related to the Retired early Reduced your hours in the NHS to minimise your time therefore elsewhere	job description erformance as	n a doctor	plaint	Yes O O O O O O O O O O O O O	No
6. As a result of your experience do tayed in the specialty but stopped carrying out the area of hanged your specialty ess likely to take on high-risk cases lore likely to abandon a procedure at an early stage loved into a non-clinical role ou have become less committed and work strictly to your ou have learnt from the experience and improved your peter medicine and started a new career the complaint or the way you were treated was related to etired early educed your hours in the NHS to minimise your time ther topped working for the NHS and decided to work only in peters.	job description erformance as	n a doctor	plaint	Yes C C C C C C C C C C C C C C C C C C C	No

The IMPACT study

77. Indicate the extent you feel that any of the following changes would improve the process

	Not at all	2	To some extent	4	A great deal
To allow the doctor to have more direct input into responses to patient complaints	0	\odot	\odot	0	0
To be given a clear written protocol for any process at the onset	0	0	\odot	0	0
To have strict adherence to a statutary timeframe for any complaint and investigation process	0	0	0	0	0
Brief colleagues about any complaint or investigation to ensure unambiguous internal communications	0	0	0	0	0
If a complaint from a clinical or managerial colleague was found to be vexatious then to have the option of having this investigated and with possible disciplinary measures taken	e O	0	0	0	0
If a complaint from a patient was found to be vexatious then to have the option to take action against that person	0	0	0	0	0
To set a limit to the time period when it is permitted to file multiple complaints relating to the same clinical incident or from the same person or persons	0	0	0	0	0
If the doctor is exonerated but has suffered financial loss during the process, then to have an avenue to make a claim for recovery of lost earnings or costs	0	0	0	0	0
To have complete transparency of any management communication about the subject of a complaint by giving access to this to the doctor's representatives	0	0	0	0	0
For all managers to demonstrate a full up to date knowledge of procedure in relation to complaints if they are made responsible for them	0	0	0	0	0
The BMA and defence organisations should be more aggressive and less reactive to complaints in general	n O	0	0	0	0

14. PHQ-9 & GAD-7

78. Over the last 2 WEEKS, how often have you been bothered by any of the following problems?

	Not at all	Several days	More than half the days	Nearly every day
Little interest or pleasure in doing things	0	0	0	0
Feeling down, depressed, or hopeless	0	0	0	\circ
Trouble falling or staying asleep, or sleeping too much	0	0	0	\odot
Feeling tired or having little energy	0	0	0	0
Poor appetite or overeating	0	0	0	0
Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	0	0	0
Trouble concentrating on things, such as reading the newspaper or watching television	0	0	О	O
Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	O	O	0	\odot
Thoughts that you would be better off dead or of hurting yourself in some way	0	0	0	0

The IMPACT study

79. If you checked off any problems, how difficult have these problems made it for
you to do your work, take care of things at home, or get along with other people?

- Not difficult at all
- Somewhat difficult
- Very difficult
- Extremely difficult

80. Over the last 2 WEEKS, how often have you been bothered by the following problems?

Not at all	Several days	More than half the days	Nearly every day
0	0	0	0
0	\circ	O	0
0	0	0	\odot
0	0	0	0
0	0	0	0
0	0	0	0
0	0	0	0
	0 0 0 0		Not at all Several days half the days C C C C C C C C C C C C C C C C C C C

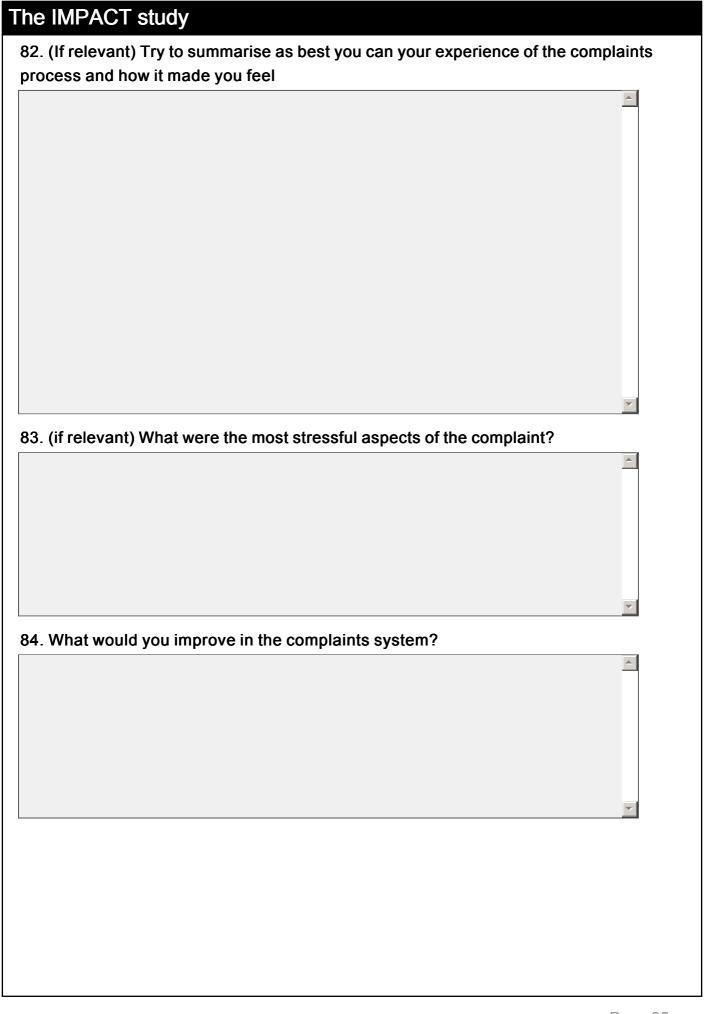
15. LDI

This scale is intended to estimate your current level of satisfaction with each of the eighteen areas of your life listed below. Please circle one of the numbers (1-7) beside each area. Numbers toward the left end of the seven-unit scale indicate higher levels of dissatisfaction, while numbers toward the right end of the scale indicate higher levels of satisfaction. Try to concentrate on how you currently feel about each area.

81. Please estimate your current level of satisfaction with each of the following areas of your life.

	1 Extremely dissatisfied	2	3	4	5	6 Extremely satisfied
Marriage	0	O	0	O	O	0
Relationship to spouse	O	\circ	0	0	\circ	O
Relationship to children	0	0	0	0	0	O
Financial situation	0	0	0	0	0	0
Employment	0	0	0	0	0	0
Recreation/Leisure	0	0	0	0	0	0
Social life	0	0	0	O	0	0
Physical health	0	0	0	\circ	\circ	0
Satisfaction with life	0	0	0	0	0	0
Expectations for future	0	O	0	O	O	0

16. Additional information (optional)





STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of cross-sectional studies

Section/Topic	Item #	Recommendation	Reported on page #
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract	Contained in the title
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4-5
Objectives	3	State specific objectives, including any prespecified hypotheses	6
Methods			
Study design	4	Present key elements of study design early in the paper	7
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	7
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants	7
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	8-11
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	8-11
Bias	9	Describe any efforts to address potential sources of bias	COMPARISON OF SAMPLE WITH SAMPLING FRAME: P 8 MISSINGNESS (AT RANDOM/NOT AT RANDOM): p 13
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	10-12, 13

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	11-13
		(b) Describe any methods used to examine subgroups and interactions	12
		(c) Explain how missing data were addressed	12-13
		(d) If applicable, describe analytical methods taking account of sampling strategy	N A
		(e) Describe any sensitivity analyses	13
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7
		(b) Give reasons for non-participation at each stage	7
		(c) Consider use of a flow diagram	/
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Table 1
		(b) Indicate number of participants with missing data for each variable of interest	12; Supplementary material sensitivity analysis and supplementary tables 1-4
Outcome data	15*	Report numbers of outcome events or summary measures	Table 2 and 3
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	13-14, 15-16
		(b) Report category boundaries when continuous variables were categorized	10, 11
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	/
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	14, Supplementary material sensitivity analysis and supplementary tables 1-4
Discussion			
Key results	18	Summarise key results with reference to study objectives	18
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and	18-19-

		magnitude of any potential bias	
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from	19-20
•		similar studies, and other relevant evidence	
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on	7/24
		which the present article is based	

^{*}Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.