Consultation on proposed regulations on “duty of co-operation”

Relating to sharing information about the conduct or performance of health care workers to protect patient safety

Summary of consultation responses

DH INFORMATION READER BOX

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HR / Workforce	Commissioning
Management	IM & T
Planning /	Finance
Clinical	Social Care / Partnership Working

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For Recipient's Use	

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1. Introduction

On 5th March 2010, the Department of Health published the *Consultation on proposed regulations on "duty of co-operation"* for England (Health and Social Care Act 2008, Section 121). Having considered the responses to the consultation and for the reasons given in the section 'Department of Health reply', the Government has decided not to proceed with developing the regulations.

Section 121 of the 2008 Act gives the Secretary of State the power to make regulations in relation to England to require bodies which are designated under Part 5A of the Medical Act 1983 (in the Medical Profession (Responsible Officers) Regulation 2010) ("the Responsible Officers Regulations") and other bodies which we designate in these regulations to co-operate with one another in connection with:

- sharing information about the performance or conduct of health care workers with other designated bodies (typically, other health or social care organisations but also for instance the professional regulators) where they judge that that worker is likely to constitute a threat to the health and safety of patients;

- providing information in response to requests from other designated bodies for information about the conduct or performance of health care workers; and

- considering any issues which arise as a result of the sharing or provision of information and taking steps following such consideration.

The consultation asked a number of specific questions on the regulatory proposals presented, and also invited feedback from stakeholders on the consultation-stage impact assessment and equality impact assessment that were published as part of the consultation document. As we are not introducing the regulations, we will not be updating the impact assessment and equality impact assessment.

The consultation also focused on the purpose of introducing regulations (ie. Public safety) and asked respondents to consider among other things:

- whether the definition of "health care worker" for the purpose of these regulations, covered all individual who provide "health care";

- whether the designated bodies are appropriate;

- the role and responsibilities of the "relevant officer" on behalf of the designated body;

- the duties that the regulations would impose on a designated body;

- the safeguards to ensure that information about health care workers will be dealt with in an open and fair way;

- whether agreeing joint actions for a health care workers employed by more than one employer, presents any difficulties;

- record keeping issues;
- costs and benefits of introducing new regulations.

In addition, the consultation sought views on the findings and recommendations of the Tackling Concerns Locally – Information Management Subgroup. The Subgroup considered the information which should be available for identifying and handling concerns over the performance, conduct and health of health care workers. The report considers among other things, the information which should be available to local healthcare organisations or employers or contractors of health care workers for these purposes; the safeguards over access to such information; and the conditions under which information could be shared between designated bodies.

2. Consultation process

Due to restrictions during the pre-election period, the full public consultation on the proposed regulations on duty of co-operation ran for seventeen weeks, between 5 March and 9 July 2010 when the documents were placed on the Department of Health website. The consultation invited views on the proposed new regulations, comments on both the impact assessment and screening equality impact assessment and sought any additional views on any aspect of the consultation. Further details can be found at:

www.dh.gov.uk/en/Consultations/Closedconsultations/DH_104114

The consultation closed on 9 July 2010.

The consultation followed the 'Government Code of Practice on Consultation'. The full text of that Code of Practice is on the Better Regulation website at:

www.berr.gov.uk/whatwedo/bre/consultation-guidance/page44420.html

A full list of respondents is at **Annex A.**

We advertised the consultation in a number of other ways. For example, we emailed key organisations in the healthcare sectors to invite them to respond and to tell their members about the consultation. We arranged for information to be placed in The Week, Primary Care Newsletter, and NHS Employers intranet. We provided briefing papers for meetings between DH and external stakeholders and bodies representing healthcare workers.

3. Consultation responses

This report provides an overview of the responses received to the consultation.

The Department of Health wishes to thank all respondents for taking the time to send us their contributions to this consultation. A total of 67 responses were received to the consultation from a wide variety of stakeholders, including both individuals and organisations. The vast majority of the responses were sent in the format of the response proforma as laid out in the consultation document. A minority of responses were drafted in the format of other written communication. A breakdown of the responses by stakeholder group is shown below:

Organisation Type	Number of Respondents	% of overall response
Individual	1	1.4
NHS	25	37.3
Social Care	1	1.4
Private Health	2	17.9
Regulatory Body	12	17.9
Professional Body	16	23.8
Union	3	4.4
Social Care	1	1.4
Other	6	8.9

Overview of the Consultation responses

Particular issues around the definition of "health care worker"

Q1 Do you believe that social workers provide services which are connected to health care, as defined in paragraph 2.7? If YES, what are those services?

What you told us

Forty-three consultees offered responses to this question. Forty-seven percent of respondents believed that social workers might sometimes provide services connected with health care. The examples given of services that social workers sometimes provide that are connected with health care are Continuing Health Care, Drug and Alcohol, Care Homes, Safeguarding Children and Vulnerable Adults, diagnosis or treatment of illness, particularly those employed by Health & Social Care Partnership Trusts such as Learning Disabilities and Mental Health Services.

Comments from respondents

"Social workers overall protect and promote the welfare and well-being of children vulnerable adults and communities and therefore could be linked to document definition."

NHS Trust (anonymous)

"Health and Social workers work very closely together, in particular within learning disability services."

South Birmingham Community Health

Designated bodies (Regulation 3)

Q2 Do you agree that there is no need to designate the police in these regulations?

What you told us
Twenty-seven out of 67 respondents agreed that there is no need to designate the police in these regulations, as there are generally adequate safeguards. (See Figure 2).

Comments from respondents
"It would be unnecessary and disproportionate to involve the police in these regulations. There are already existing safeguards in place to ensure that health care workers who are suspected of having committed crimes are dealt with appropriately."

Medical Defence Union

"Professional regulators automatically receive notification about convictions and cautions of registrants via "Home Office Notifiable Occupations Circular".

Health Professions Council

"The importance of carrying out the full set of NHS Employment Checks and the potential consequences of failing to do so should be emphasised to all health bodies."

NHS Counter Fraud and Security Management Services

Education Establishments

Q3 Do you have a view on whether we should designate HEIs so that they are subject to the duties of cooperation in respect of health care workers?

What you told us
Forty-six responses were received for this question. Twenty-three of those responded were of the view that there is no need to designate Higher Education Institutions (HEIs).

Comments from respondents
"Widening the scope of regulations to cover healthcare workers who are only teaching might complicate matters. HEIs already have responsibility to share any concerns with the regulators."

Health Professions Council

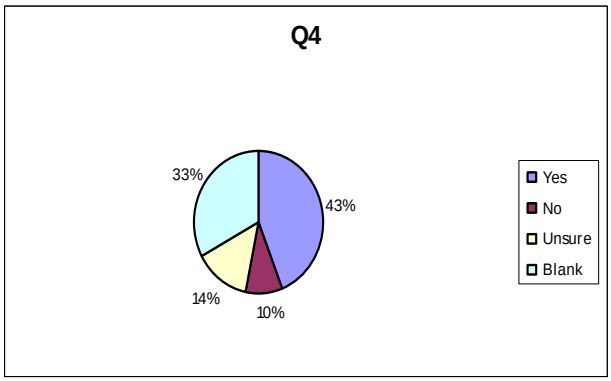
"HEIs have responsibility for training standards and competency not delivery of Health Care, therefore do not have direct role in patient safety."

Royal College of Paediatricians and Child Health

Q4	Do you agree that Regulation 3 designates all those organisations that are connected to all health care workers involved in providing health care (which are not already designated by the Responsible Officers Regulations)?

Forty-three responses were received for this question. Thirty-two per cent of respondents agreed with the proposed types of body that are designated. One respondent suggested that we consider further discussion with the proposed designated bodies to ensure the list is suitable. (See Figure 4)

Figure 4: Response to Question 4



Comments from respondents

"Regulation 3(1)(h) provides a 'catch all' provision for those bodies which do not fall into the remaining provisions of Reg 3."

Recruitment and Employment Confederation

"Regulation 3(1)(f) relies upon the 2010 regulations under the H&SCA as a way of designating 'health care organisations'. However, these regulations are not defined into healthcare and non-healthcare activities as such."

Care Quality Commission

Q5 If you answered NO to Q4, which other organisations should be designated?

Seven respondents replied "No" to Q4. The General Social Care Council (GSCC) would like to see the proposed regulations extended to apply to social workers.

Comments from respondents

"GSCC believes that they should be listed as a designated body if any social workers are to be captured by the Regulations."

General Social Care Council

"Regulation 3 is too wide. Seem to cover organisation who have no direct involvement with patient care and their employees do not have any interaction with patients themselves. Suggest to redrawn so that they relate more directly to protection the safety of patients."

Medical Defence Union

The Independent Sector

Q6 Do you have suggestions on what might usefully be included in the protocols or MoU to facilitate sharing of information about health care workers, between sectors?

Those responded to this question (34%) believe that it would be useful if a template could be provided within the guidance outlining what information should be recorded and shared with clear of what organisations need to share and when.

Comments from respondents

"Standard format for sharing and receiving information together with indication of timelines for sharing information."

Royal Pharmaceutical Society of Great Britain

"MoU needs to be kept as brief and simple as possible containing the process map and templates as appendices."

Independent Healthcare Advisory Services

"The whole system relies on the efficacy of the pre employment check process which in the NHS is subject to governance verification and is robust. This may not be the case for external organisations."

NHS Employers

Relevant Officer (Regulation 5)

Q7 What are the existing mechanisms in your organisation which the "relevant officer" should ensure are used for identifying and managing concerns about the conduct or performance of health care workers?

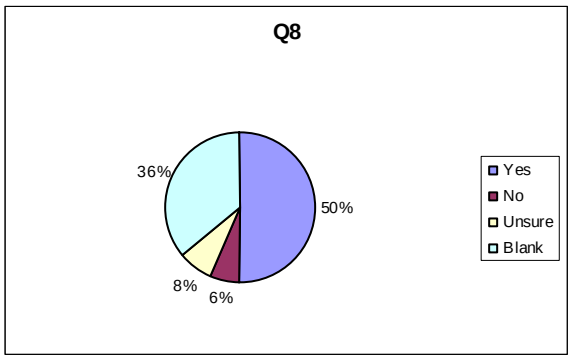
Thirty out of sixty-seven respondents commented on this question. Existing mechanisms suggested for identifying and managing concerns that "relevant officers" could use in their organisations are summarised below:

- Clinical Governance
- Informal Recorded Meetings
- SUIs and incidents
- Whistleblowing
- Patient Advisory Liaison Service (PALs)
- HR investigations process
- Line manager via personal files
- Case tracker for disciplinary and competency cases
- Complaints
- Grievances and Disciplinary Policies
- Adherence Standard Professional Referral Guidelines incl. ISA
- Appraisals
- KPI Data
- Internal and External Audits
- Bullying and Harassment Claims
- Datix Reporting (patient safety software for healthcare risk management, incident reporting software and adverse event)

Q8 Do you agree that one individual in an organisation should be given responsibility for complying with the organisation's obligations under these proposed regulations?

Forty-two responses were received to this question. Thirty-three respondents agreed that one individual in an organisation should be given responsibility for complying with the organisation's obligations under these proposed regulations. Four respondents who disagreed, believe there should be shared leadership responsibility. (See Figure 8)

Figure 8: Response to Question 8



Comments from respondents

"The range of information that would be required to co-ordinate is extensive and, for an organisation of any size, beyond the scope of any one individual. All of the companies represented by the CCA and AIMp have large number of pharmacies spread across geographical diverse areas; for the larger companies in particular it is inconceivable that a single "Relevant Officer" could cover the entire organisation; it must therefore be permissible to delegate the responsibilities of a "Relevant Officer".

Company Chemists' Association Limited

"It is important that there be consistency in the operation of the proposed regulations, and that one person at a senior level be given sole responsibility with the authority to ensure such consistency."

Royal College of Nursing

"Designated deputy would ensure that this function is always covered."

NHS Suffolk

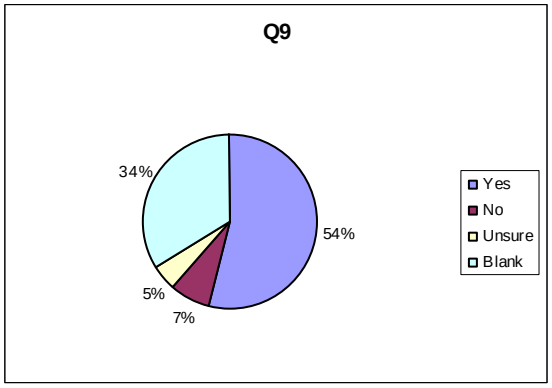
"This role could be shared as there will an interest from both HR and those with leadership roles overseeing health care workers."

University Hospitals Coventry & Warwickshire

Q9	**Do you think we should specify in guidance the minimum level of seniority a relevant officer should have? If YES, what should that minimum level of seniority be?**

There were forty-four responses to this question. Thirty-six respondents believe that it should be a member of the senior management team. (See Figure 9)

Figure 9: Response to Question 9



Comments from respondents

"CFSM has observed that at present in some trusts, relatively junior or inexperienced staff are undertaking NHS Employment Checks and they may find it difficult to challenge applicants or new employee on the validity of their documentation or may be unaware of what to look for in terms of forged or otherwise dubious docs and personal information (references, visas, incomplete employment histories). Staff may face similar issues in meeting the requirements of the proposed regulations if there is no senior individual providing direction and oversight."

Counter Fraud and Security Management

"Given the disparate types of health care organisations likely to be involved in the process, we believe that any definition of the minimum level of seniority needs to be flexible enough to deal with all the potential organisations concerned. We believe that the identified person should be a member of senior management."

Medical Protection Society

The role and responsibilities of a "relevant officer"

Q10	**How do you think the 'relevant officer' in your organisation might ensure that all the information in the organisation's possession is examined once the trigger (see flow chart at page 38) suggests a need for investigation or there is a request for information from another designated body?**

Twenty-nine respondents offered suggestions on how the "relevant officer" in his/her organisation might ensure that all the information in the organisation's possessions is examined, including:

- Through clinical governance processes
- Respond to and concerns highlighted and monitored
- Convene of a 'duty to co-operate' (or other name) meeting
- Request any relevant information from key individuals/departments/local information networks/professional bodies
- Liaise with all patients involved and keep accurate notes as evidence which will form their report and conclusion
- Collate evidence from all relevant sources and keep accurate records to enable to provide a report
- Via relevant procedures
- Appoint an investigating manager or instigate a 'case conferencing style' approach with relevant functions

Comments from respondents

"Need to design new system to facilitate this. Work closely with complaints (where appropriate) and analysing information. Need a small defined team, line manager/HR rep etc to support individual cases – depends on complexities or circumstances."

Bradford and Airedale Community Health Services

"Network with all those involved sharing information and keep accurate records as evidence which will form the investigation report and recommendations."

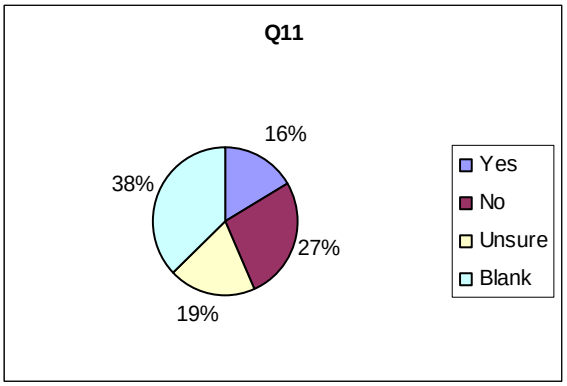
Barking and Dagenham Community Health Service

Q11 Do you think guidance should set out any other responsibilities for the 'relevant officer' role?

Eighteen respondents agreed with the responsibilities for the 'relevant officer' role set out in the consultation document. Eleven thought there are other responsibilities which could be set out in guidance and these include: (See Figure 11)

- Relevant Officers might need to consider sharing information about formal fitness to practise referrals as well as patterns of conduct (below threshold of fitness to practise) will be referred to regulator
- The role of the Relevant Officers is comprehensive and may develop other roles as it is introduced and evaluated

Figure 11: Response to Question 11

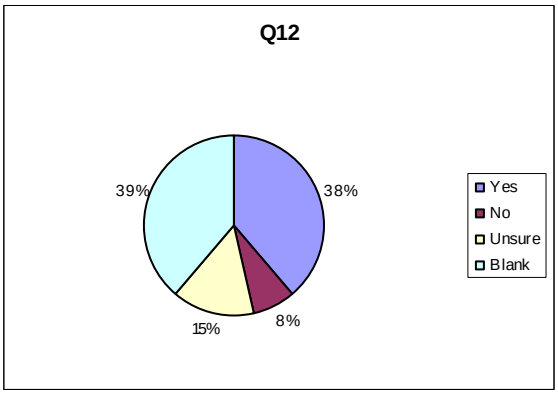


Safeguards

Q12 Do you believe the safeguarding measures will ensure that information about health care workers will be dealt with in an open and fair way? See paragraph 2.33-2.34

Forty-one responses were received for this question. More than half respondents believe the safeguarding measures referred to in paragraphs 2.33 and 2.34 will avoid unfair prejudice. (See Figure 12)

Figure 12: Response to Question 12



Comments from respondents
"As long as they are adhered to."

NHS Eastern and Coastal Kent

"FTN members would agree with the spirit of the regulations but would advise caution as to safeguards being in place to ensure only properly investigated concerns are shared and not suspicions or rumours. This should be standard good practice when undertaking any investigation."

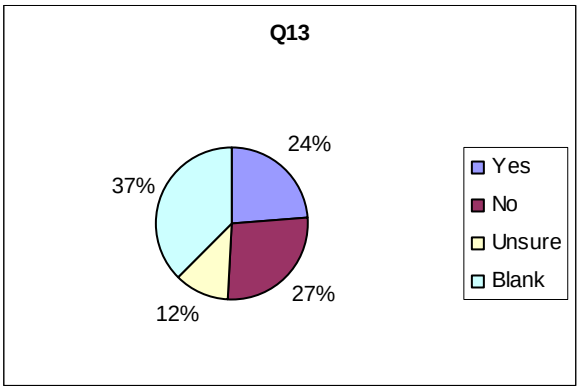
Foundation NHS Trust Network

Q13 Are there any other safeguarding measures we should include in the regulations? If YES, please specify what these are.

Sixteen respondents have identified some additional safeguarding measures that could be included in the regulations and these are listed as follows: (See Figure 13)

- Compliance with obligations under ACAS Code of Practice 1
- Duty to share information immediately where there is a risk to others and Local Authority Designated Officer (LADO) procedures
- TU/professional body
- Need to ensure links to internal Trust/NHS procedures for example if suspension/exclusion is needed
- Care must be taken not to disclose the details of the health workers, health problems - a breach of their confidentiality
- The right of individuals to know info about them is being transferred and what they are. Safeguards should be in place to protect individuals and businesses against rumour and innuendo - or personal prejudice.

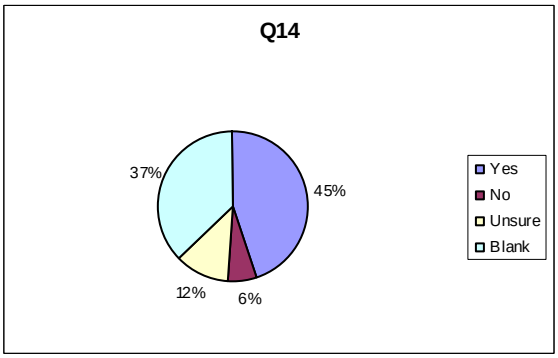
Figure 13: Response to Question 13



Q14 Do you agree that draft Regulation 6 provides a robust process for a designated body to substantiate an allegation against a health care worker before information based on it is shared with another designated body?

Forty-two respondents agreed that draft Regulation 6 provides a robust process for a designated body to substantiate an allegation against a health care worker before information based on it is shared with another designated body. (See Figure 14)

Figure 14: Response to Question 14



In the 'public interest' to protect the public

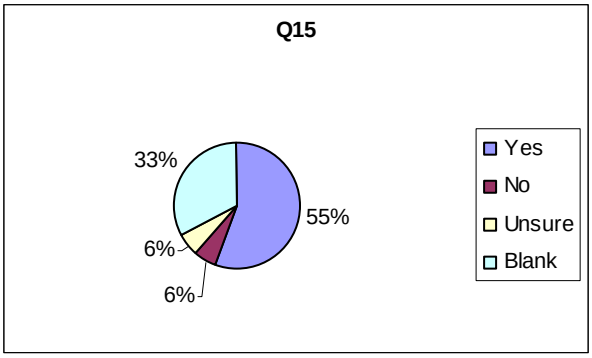
Q15 Do you agree that there is already robust guidance on how to handle confidential patient information? If No, please specify what additional clarification you need.

Fifty-five out of sixty-seven per cent respondents agreed that there is robust guidance on handling confidential information. Out of the forty-five that responded, four suggested that additional clarification on these specific aspects would be of help. (See Figure 15)

- include a specific duty to try to inform a patient even where consent is not practicable
- specify when consent may be impracticable in these circumstances and when it would be inappropriate

- highlight a duty to respect patient dissent regarding disclosures to third parties other than where statutory mandated
- sharing information could breach worker's right to confidentiality as a patient. Guidance need to these sorts of situations and concerns.

Figure 15: Response to Question 15

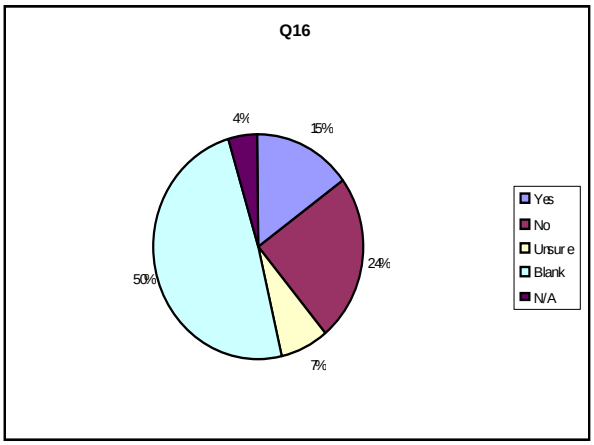


Duty to provide information on request about health care workers (Regulation 7)

Q16 When, in a recruitment process, does your organisation seek information/references about the conduct or performance of a health care worker? Does your organisation seek information from current or ex-employers prior to a request for a formal reference being made?

The majority of those who responded to this question do not seek formal references from current or last employer until job offer is made except in cases where organisations are unsure about accuracy of information provided by individuals. (See Figure 16)

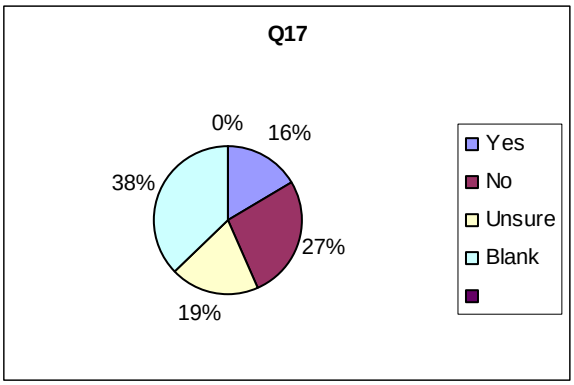
Figure 16: Response to Question 16



Q17 **Do you think regulation 7 as it stands strikes the right balance between the aims set out in paragraph 2.46? Do you think we should provide in regulation 7 that designated bodies should only provide to a recruiting designated body information about a health care worker's conduct or performance prior to the stage where references are sought, where there is an immediate threat to patient safety (with regulation 7 being complied with in full when the provision of references stage is reached)?**

Forty-one responses were received to this question. Twenty-seven respondents thought that regulation 7 is satisfactory as it stands, but suggested clear guidance should be provided in order to achieve the aim of paragraph 2.46. (See Figure 17)

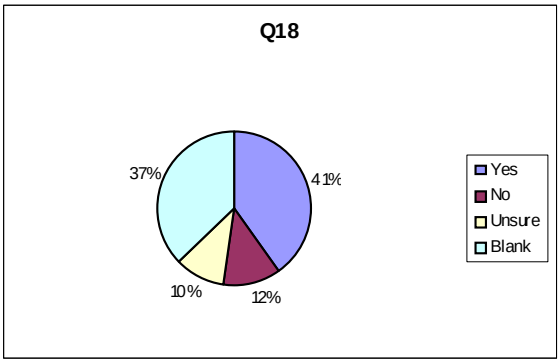
Figure 17: Response to Question 17



Q18 **If a request for information about a health care worker is made by a designated body during an appointment process, should all the relevant clinical governance information held on file by the designated body receiving the request be transferred to the requesting designated body once the appointment process has been completed?**

Twenty-seven out of forty-two respondents believed that all relevant information should be transferred to the requesting designated body once the appointment process has been completed. (See Figure 18)

Figure 18: Response to Question 18



Comments from respondents
"Could be part of the reference?"

Queen Victoria Hospital NHSFT

"Yes, as this would require as evidence of the organisation's good employment practices, especially in the event of any future investigation into the health care workers conduct or performance."

Nursing & Midwifery Council

Requirement for joint steps to be taken by designated bodies in certain circumstances (Regulation 8)

Q19 Do you foresee any difficulties with agreeing joint action where more than one designated body employs or contracts with a health care worker after one such designated body shares information under regulation 6(1) with the other designated bodies?

There were forty-five responses received to this question. Twenty-five respondents believed that difficulties will arise due to differing organisational cultures. Examples of reasons given are below. (See Figure 19)

Comments from respondents
"Different organisations have different thresholds for taking action, different approaches to concerns and there may be particular difficulties if employers are in competition with each other."

Royal Pharmaceutical Society of Great Britain

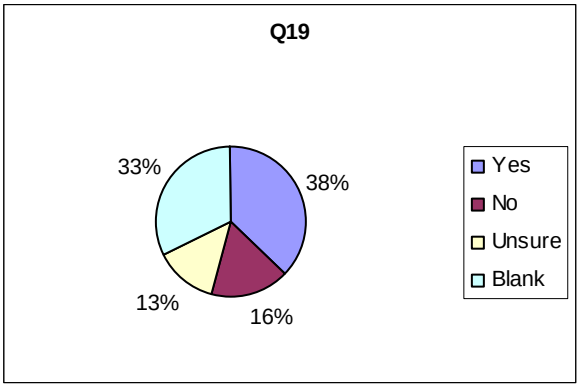
"May be different standards/thresholds/different HR processes/employment practices. Who will monitor performance?"

NHS Trust (anonymous)

"There are bound to be different approaches to problems, so guidance will have to be tight and provide a wide range of example scenarios."

British Dental Association

Figure 19: Response to Question 19



Retaining Information on concerns about health care workers

Q20 What is the current practice within your organisation about retaining information relating to verified allegations?

Twenty-five responses were received for this question. The majority of those responded stated that their organisations seemed to retain information in compliant with local governance arrangements.

Comments from respondents

"All information relating to our investigation of allegations about our registrants and the outcome of those investigations is retained indefinitely."

General Chiropractic Council

"Written warning kept on file and disregarded for disciplinary purposes after a maximum of 12 months, subject to the employee's satisfactory conduct and/or performance."

West Kent Community Health

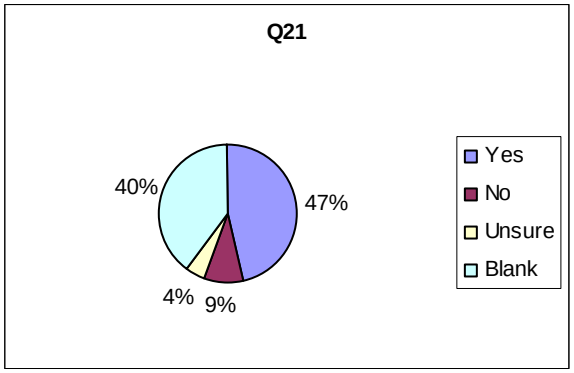
"Retain information in accordance with the records management policy (currently being reviewed) and in line with disciplinary policy - not usually for an indefinite period and in many cases not for 5 yrs."

NHS Bradford & Airedale

Q21 Do you have a view on retaining information for 5 years (or until completion of the next revalidation cycle if later) on allegations that are not possible to investigate fully or where the allegation is unfounded?

Forty consultees offered responses to this question. The majority view of those responded felt that retaining information for 5 years would be useful and some suggested to also record the outcome of the allegations. (See Figure 21)

Figure 21: Response to Question 21



Regard to Guidance (regulation 11)

Q22 Are you aware of any body, other than those listed above, whose guidance is of relevance to the proposed new regulations? If YES please specify.

Thirty-nine responses were received. Eight respondents considered that guidance from the following bodies may be of relevance.

- NHS Employers
- National Information Governance Board (NIGB) for Health and Social Care
- National Clinical Assessment Service (NCAS)
- Information Commissioner
- Information Governance Board for Health & Social Care

Q23 Are there issues on which guidance or clarification would help your organisation meet its obligations under these proposed regulations? If YES, what are those issues?

Twenty-responses were received to this question. Thirteen respondents believed guidance and clarification on issues summarised below would help their organisation comply with the proposed regulations.

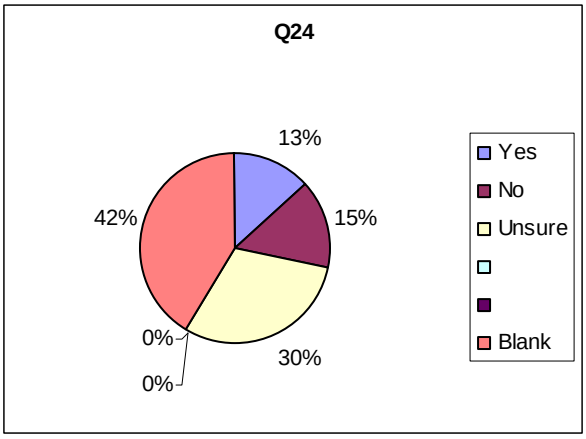
- Guidance on employment, data protection law and human Rights Act
- Guidance on possible legal matter on an ad hoc basis as they arise in each case
- Guidance on implementation, possibly communication
- Clarification of risk of grievances
- Guidance or training for relevant officers
- Guidance of the retention/transfer of information with regard to finalised regulations
- Guidance on parallel processes (e.g. other statutory responsibilities (safeguarding children), police investigations, ISA and NMC referrals)

Impact Assessment

Q24 Do you agree with our estimate of the likely costs and benefits? If not, please indicate and provide evidence, where possible, of any areas of disagreement.

There were only 39 responses to this question. Nine of the respondents agreed with the costs and benefits in the Impact Assessment, however, ten of them found the figures were not clear and do not justify the benefits which were to be gained. We tried to engage with stakeholders again because of insufficient information to questions about the impact assessment. Disappointingly there was very little additional information to a follow-up questionnaire about costings. (See Figure 24)

Figure 24: Response to Question 24



Comments from respondents

"It is not always easy to follow the figures and rationale in the impact assessment so I am still unclear about the real cost to NHS organisations. With regard to medical negligence, is there any breakdown to show how many cases are due to Doctors in training? It could be errors rather than real negligence."

Queen Victoria Hospital NHS Foundation

"We believe the regulations will incur costs due to additional time and resources required to implement locally, litigation for staff to defend themselves when aware that "learning" will be shared with other organisations for recruitment purposes. Figures for following up information seem unrealistic. References will still be required and more likely to be challenged if offers are withdrawn. Potential need to move to receiving reference prior to formal offer and delays to recruitment. Response to data protection requests".

Dudley & Walsall Mental Health Partnership NHS Trust

Q25	**According to the evidence presented in the IA, the likely cost of the preferred policy option on different organisations does not seem to be significantly related to their size. Do you agree with this proposition? If not, can you provide evidence to support your argument?**

Out of the 30 responses received, nine respondents agreed with the evidence presented in the IA that the cost does not link to the size of the organisation. However, four respondents felt that some of the large organisations envisaged an increase in their resource.

"Larger pharmacy org will employ or contract greater number of pharmacists. More likely will be incidents that require notification or collaboration. For community pharmacies burden of compliance likely to be related to size."

Pharmaceutical Services Negotiating Committee

"Larger orgs are likely to have more staff that are investigated under the regs. A linked example if looked at a PCT versus a larger Acute Trust in terms of actual number of disciplinary cases."

NHS Trust (anonymous)

"Dynamic sector - cost will depend on size of org and staff turnover."

Association of British Dispensing Opticians, Association of Optometrists, Association of Contact Lens Manufacturers, Federation of Ophthalmic & Dispensing Opticians, British Contact Lens Association

Equality Impact Assessment

Q26	**What might be the barriers (negative impact) to the proposed regulations "duty of co-operation" and good quality outcomes for everyone from the perspective of ethnicity, gender, disability, age, sexual orientation, religion/ belief, socio-economic or rural/geographical considerations? What proportionate measures could address those issues?**

Twenty respondents provided comments to this question. Nine of those responded believed that there would not be any negative impact if the proposed regulations are implemented correctly and transparently. The remaining respondents highlighted risks in terms of equality could occur as stated below.

Comments from respondents

"Employees who do not 'fit' the organisational expectations incl. prejudices of the management on basis of ethnicity/disability/gender will be at risk of being targets by trivial 'concerns' placed on the individual's file and subsequently shared."

Royal College of Paediatricians and Child Health

"Ensure employees from overseas are assessed and given additional support and training if necessary with regard to local procedures to ensure they do not suffer disadvantage."

Foundation Trust Network

Q27	**What are the positive impacts that might result from implementing this policy from the perspective of ethnicity, gender, disability, age, sexual orientation and religion/belief, socio-economic or rural/geographical considerations? What**

proportionate measures might we implement that could enhance this positive affect?

Nineteen consultees responded to this question. The most common answers in relation to the possible positive impact of the Regulations are summarised below.

- Improve public confidence in services
- Open and honest working policy
- Allow allegations to be fully investigated
- Information sharing appropriately with a rigorous audit process
- Partnership working will be enhanced between organisations
- Redress balance between formal and informal approaches where staff treatment is not always equitable
- Prospect of reducing inequalities that may already exist

Q28 Please identify how the implementation of this policy might affect the Human Rights of patients, carers, service providers or the workforce? In your opinion does this mean that this policy should not be implemented or could proportionate measures be taken to address these issues?

Twenty-three consultees offered responses to this question and their opinions and recommendations are as follows:

- Regulations should be implemented but abide by rules of natural justice, governance and information rules.
- Recommend that clear guidance and support is provided to designated bodies and staff members when under investigation
- Policy should be implemented because proposed Regulations are guided by Caldicott Principles
- Measures for protecting these groups are proportionate and anything that prevents people who present a serious safety risk to patients organisations is justified, notwithstanding the safeguards in place
- If policy implemented appropriate then may go some way to eliminating malicious accusations and therefore prevent discrimination
- Needs to be balance in the systems - includes support for employees to appeal against disclosures they think are unfair.

Types of information to be held locally

Q29 Do you have a view on the suggestion that local health care organisations should maintain a coherent and integrated set of information for all health care workers for whom the organisation which has clinical governance responsibility?

There were forty-two respondents to this question, a majority of whom shared the view that the organisation which has clinical governance responsibility should maintain a coherent and integrated set of information for a health care worker.

Comments from respondents

"As well as contributing to patient safety, this would reinforce good employment practice".

General Chiropractic Council

"This would make transparent any issues and ensure robust governance".

Royal Orthopaedic Hospital NHSF

"Would ensure the quality and safety of care given to patients by health care workers"

Barking and Dagenham Community Health Services

"This would follow best practice principles".

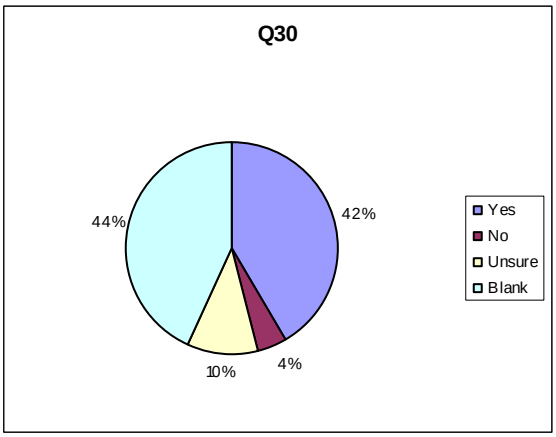
Nursing & Midwifery Council

Q30 Do you agree that these categories of information are good indicators of performance or conduct? If not, please specify what other information should be included.

There were thirty-eight responses to this question. Twenty-eight respondents agreed that the categories of information appeared to be good indicators of performance or conduct. However, we did receive suggestions of other information that might also be a good indicator of performance or conduct, including: (See figure 30)

- The use of Knowledge Skills Framework (KSF)
- References collected at the time of recruitment
- Registration information (eg.GSCC)

Figure 30: Response to Question 20



"Soft" information

Q31 What concerns do you have about sharing "soft" information?

Forty-two consultees responded to this question. The types of concerns raised about sharing "soft" information are as follows:

- Rights of health care workers
- Potential litigation by an individual who believes that their information has been shared maliciously or without due care
- Allegations are not clearly defined
- Sharing soft information from anonymous sources
- May cause great difficulty through lack of ability to agree on the significance of such information
- 'Soft' information may not be factual. Releasing this could be a risk to organisations in employment tribunal claims. Malicious allegations or poor communications
- Mischievousness, misinterpretation or confusion which may not be easy to investigate or prove
- Should be verified and substantiated otherwise could lead to damaging and prejudicial unfairness.

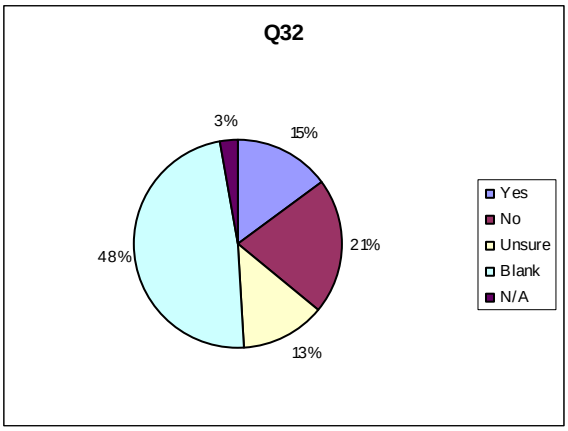
Q32 Does your organisation already share "soft" information about health care workers? If Yes, please provide details.

Out of thirty-five respondents answered this question, ten of them shared "soft" information about healthcare workers and the details are provided below: (See Figure 32)

- Internally around service issues
- Counter Fraud/Controlled Drugs Local Intelligence Network
- In context of safeguarding concerns
- Whistle blowing policy
- Specific groups and triangulated where there are already performance concerns

- GSCC will only share soft information if there is a perceived public protection risk, and this is only shared with the social worker's known current employer
- Where felt it was in the public interest to do so
- Share in a limited way with known organisations

Figure 32: Response to Question 32



Clinical negligence claims

Q33 Do you agree that contractors should notify PCTs of all negligence claims?

There were thirty-nine responses to this question of which only six disagreed that contractors should notify PCTs of all negligence claims. The reasons they gave are in their comments below. (See Figure 33)

Comments from respondents

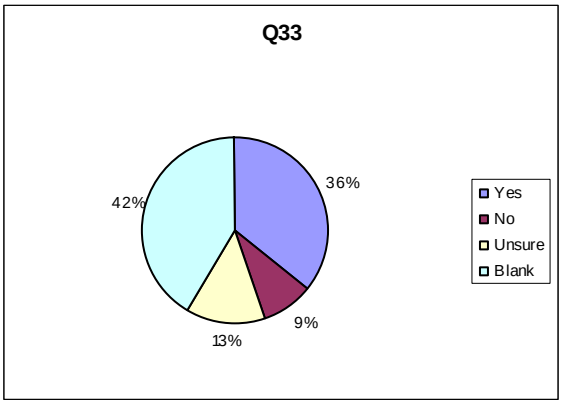
"It is generally the case that negligence claims settled out of court are subject to confidentiality provisions. While the fact that a settlement has been reached is not confidential, the details of a settlement reached on confidential terms should be not be shared, as this would constitute a breach of the confidentiality agreement. We seek clarification that information about the details of our of court settlements will not be made available under these regulations."

British Medical Council

"Negligence claims do not necessarily suggest conduct or performance is impaired. The disclosure should be to the GPhc if the pharmacy contractor believes there are conduct or performance concerns."

Pharmaceutical Services Negotiating Committee

Figure 33: Response to Question 33



Q34 Do you agree with the definition of "claims"? If NO, please explain why not?

Thirty-seven consultees offered response to this question. The majority of those responded (28) believed the definition of "claims" provided in Chapter three of the consultation document appeared reasonable. However, only two respondents do not agree with the definition and these are explained below. (See Figure 34)

Comments from respondents

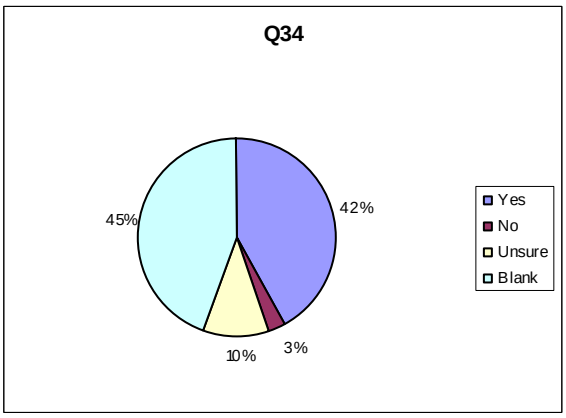
"We do not feel the definition of, "claims" properly attempts to define a 'claim', as it defines it with reference to itself. It is the BMA's views that the definition is circular and should be revisited".

British Medical Association

"A letter before action is far too early. In primary care and the independent sector around 70% of claims notified to the MDU do not progress any further. What purpose would it serve to be notified of the majority of claims that don't have sufficient merit to progress."

Medical Defence Union

Figure 34: Response to Question 34



Q35 Do you support the above approach on sharing information with patients, carers, or the public about investigations?

Thirty-eight responses were received for this question. Twenty-three were supportive of the proposed approach on sharing information with patients, carers, or the public about investigation for reasons of safety, openness, transparency and public confidence. Some respondents did however suggest when it would be appropriate to share information with patients, carers, or the public about investigations, examples of which are below. (See Figure 35)

Comments from respondents

"Yes to responding to requests to share information so long as clear what is legally and morally acceptable"

Dudley & Walsall Mental Health Partnership NHS Trust & Dudley PCT

"In general we would support the approach. However, we have particular concerns regarding health care workers with health issues. Great care must be taken not to disclose the details of the health care workers health problems through inappropriate disclosure of conditions placed on their practice which clearly relate to and identify the relevant health issue – Allowing such inadvertent disclosure to happen would be a grave disservice to health care workers, a breach of their confidentiality."

Medical Protection Society

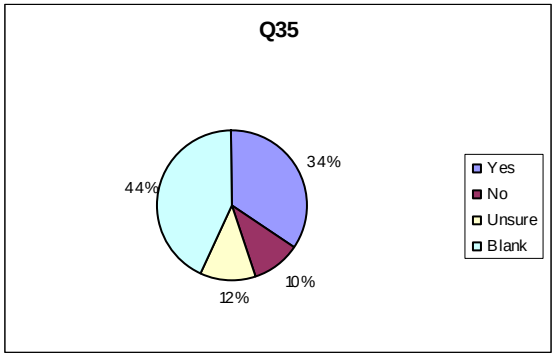
"In general yes but we do not currently disclose the fact of or details about an investigation to patients or the general public unless we take interim action to restrict or suspend a doctor's registration during that investigation. We believe that this is proportionate and provides an appropriate balance between the rights of patients to relevant information with the doctor's rights (where the allegations are at this stage unsubstantiated)."

General Medical Council

"Yes, but not as an automatic right. This should be assessed and decided on a case by case basis and share only where appropriate."

The British Dietetic Association

Figure 35: Response to Question 35

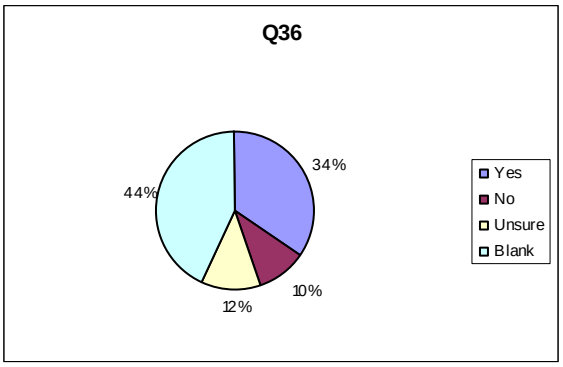


Q36 Do you support the view that the national regulator should be alerted to a pattern of conduct or performance that falls below the threshold for referrals about fitness to practise?

Out of the thirty-eight responses that were received, twenty-three respondents supported the view that the national regulator should be alerted. Those who disagreed gave the following reasons why the national regulator should not be alerted to a pattern of conduct or performance that falls below the threshold for referrals about fitness to practise. (See Figure 36)

- Needs to be balanced against the rights of the individual and substantiating the allegations
- Essential that supporting guidance makes clear the limits of these thresholds, when employers should make a referral and what information must be shared
- Consequent actions should be proportionate to the level of evidence
- Matters should be investigated prior to referral
- Provide national guidance for some local problems

Figure 36: Response to Question 36

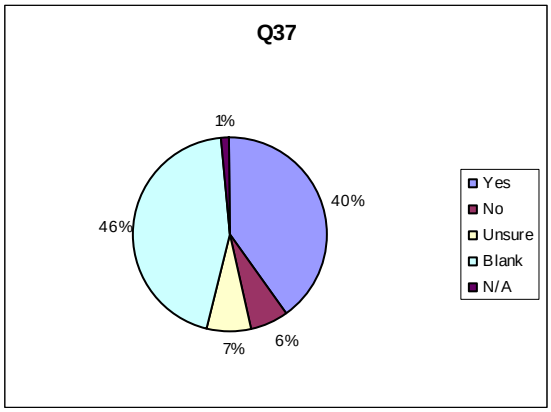


Examples of concerns there might be about a healthcare professional's performance, conduct or health

Q37 Are these examples of concerns about a health care worker's conduct or performance helpful to you when making decisions about how you would comply with the proposed regulations on duties of co-operation?

Out of the thirty-six that responded, twenty-seven found the examples of concerns about a health care worker's conduct or performance helpful when making decisions about compliance with the proposed regulations on duties of co-operation. (See Figure 37)

Figure 37: Response to Question 37



Q38 Do you have any additional comments on any aspect of this consultation

Responses were generally supportive, although few organisations did raise specific concerns. A selection of additional comments we received are given below.

"Welcome regulations. Has potential to provide clarify on when to share information and referring information to professional regulators. Welcome the fact that professional regulators are designated bodies but importantly, relies on employers to report concerns early."

Health Professions Council

"As the Govt has announced need to make substantial savings - current proposals could be scaled back."

Pharmaceutical Services Negotiating Committee

"Clarity would be needed on the use of the proposed mechanism when we employ staff who already work for another organisation who have no intention of relinquishing their role. How would we track the number of hours worked for EWTD purposes and patient safety."

South Birmingham Community Health

"In general the duty will assist GMC in performing statutory function by enabling and requiring better communication between healthcare provider orgs and regulatory bodies. The general approach is similar to the way in which GMC currently process and share information."

General Medical Practitioner

"Support Regulations - will help to improve safety and quality of patients services by making sure that employers and contractors in all health sectors and regulatory bodies share info. Would like the opportunity to carry out some further work with NHS Employers and key partners once revised regs and draft guidance has been prepared."

NHS Employers

“These regulations could pose serious implications for CQC’s statutory functions and could prove both cost and resource intensive. Strongly advise that these proposed regulations receive detailed reconsideration before progressing further.”

Care Quality Commission

“Concerned that it is intended to bring in these regulations with no coherent plan as to how they will be regulated and apparently no sanctions being available for organisations who fail to comply with them. We recommend that the power that the legislation provides to make it an offence not to comply with the regulations is used.”

Action Against Medical Accident

“Remain unconvinced that there is a compelling need for new regulations largely because mechanisms already exist which, if used correctly, should provide adequate safeguards.”

Council for Healthcare Regulatory Excellence

4. Department of Health reply

The Department of Health recognise from the mixed response to the proposed regulations for a duty of cooperation that, although all the bodies who responded to the consultation, are supportive of measures that result in improved patient safety, there are reservations about the proposed regulations. Some respondents cited the current financial pressures affecting the proposed designated bodies, but others simply remained unconvinced of the need for further legislation in this area. This latter point has been reinforced by more recent research for the [1]General Medical Council which suggested that systems to identify problems are improving and employers are giving priority to detecting and dealing with concerns.

A number of important of measures supporting the sharing of information by health care organisations have been put in place since the Health and Social Care Act 2008 commenced. Whilst there is obviously no equivalent duty on organisations to that proposed in the draft regulations, there are other, existing (or prospective) duties which require health care organisations (or health care professionals themselves), in certain circumstances, to provide information or to report specific matters. Some examples of these are given below.

The *Medical Profession (Responsible Officers) Regulation 2010 ("the Responsible Officers Regulations")* came into force on 1 January 2011 in England and Wales. These regulations make it obligatory for designated health bodies to nominate or appoint a responsible officer (usually the Medical Director in the NHS). The Responsible Officer Regulations require responsible officers to ensure that appraisals must take account of all available information relating to the doctor's fitness to practise in both work carried out for the designated body, and for any other body. We would expect that this would include information from local clinical governance systems relating to the doctor's practice. See attached link http://www.dh.gov.uk/en/Managingyourorganisation/Responsibleofficers/index.htm

The local aspect of information sharing was enhanced last year with the NHS Staff Council agreement to amend the *NHS staff Terms and Conditions of Service Handbook* to include a right and duty for employees to raise concerns in the public interest (section 21 of the handbook refers). Further information on the agreement can be accessed from the NHS Employers' website at www.nhsemployers.org

A further measure to empower staff in the NHS is the NHS Constitution. The Department of Health has consulted on reinforcing the NHS Constitution to emphasise the rights and responsibilities of NHS staff and their employers in respect of whistle-blowing. 103 responses were received in total and on 18th October Andrew Lansley, the Secretary of State for Health, announced that the NHS Constitution would be updated to include:

- an expectation, that staff should raise concerns at the earliest opportunity;
- a pledge, that NHS organisations should support staff when raising concerns; and
- clarity, around the existing legal right for staff to raise concerns about safety, malpractice or other wrong doing without suffering any detriment.

To support those staff who wish to raise concerns but are not sure how to do that or what their rights are, the Department funds a helpline giving free legal advice to callers. We

[1] Research into Fitness to Practise referrals 2011 – A report for the GMC by GfK NOP Social Research

recognise that some of the above measures will only cover health care workers employed or contracted to work by an NHS organisation. It is generally accepted that information exchange generally between the NHS and the independent health care sector, is very poor. Health care workers who are a cause of concern, sometimes go undetected, by moving between sectors before concerns are verified and acted upon. The Department has considered whether there are additional steps, short of legislating, that might be taken to strengthen safeguards in this area. With this in mind, we are developing a Memorandum of Understanding (MoU) between the NHS and the independent healthcare providers. We think the MoU should be based on employers and contractors of healthcare workers, undertaking a local risk assessment as justification for sharing and requesting information. As part of this process, and at the point of investigation, the health care worker should be asked to sign a declaration of whether they do, or do not, work for another health care provider.

The proposed MoU adopts many of the safeguards that were proposed in the draft duty of cooperation regulations to ensure a fair and transparent process whereby organisations can act quickly to safeguard patients and protect the health care worker involved from any malicious allegations. These safeguards include addressing and verifying an allegation with other relevant information, informing the health care worker and providing an opportunity to give their side of the story, and robust record keeping of information shared and provided in response to any request. A simple template to record information shared or information provided has been developed to accompany the MoU, both of which will be available on the NHS Employers' and on the Independent Health Advisory Services' websites.

Another area where information sharing about a health care worker's conduct or performance could be better is among some of the providers of agency or temporary workers. NHS Professionals' contract with workers already requires individuals to inform them about any suspension from work by another organisation. NHS Professionals also share information about suspensions with employing organisations, as well professional bodies. Similarly, suppliers of agency workers appointed on the Buying Solutions Framework agreement already require the agency worker to inform the supplier of any investigation. Information is shared with interested parties with the consent of the worker. We intend to explore with non-framework agencies whether they could adopt a similar practise.

In view of the measures that have already been introduced in this area, and having listened to views about the importance of not placing additional burdens on organisations, the Department of Health has decided not to proceed with developing the proposed duty of cooperation regulations. We will instead work with organisations to take forward measures, short of legislating, to foster better information sharing about the conduct or performance of health care workers who pose a risk to patients.

We would like to thank everyone who took the time to respond to this consultation.

Annex A: List of Respondents

The following is a list of organisations that responded to the consultation (the list does not include individual respondents):

NHS Suffolk
Westerleigh Nursing Home
General Chiropractic Council
West Kent Community Health
Health Professions Council
Royal Orthopaedic Hospital NHS Foundation Trust
Barking & Dagenham Community Health Services
North Tees & Hartlepool NHS Foundation Trust
Royal College of Midwives
Pharmaceutical Services Negotiating Committee
Barts and London NHS Trust
Medway NHS Foundation Trust
Peterborough & Stamford NHS Trust
Royal College of Psychiatrists
South Birmingham Community Health
University Hospitals Coventry and Warwickshire
Nursing Directorate of NHS Bradford & Airedale
Bradford and Airedale Community Health Services
Parliamentary and Health Service Ombudsman
Royal College of Radiologists
Royal Pharmaceutical Society of Great Britain
NHS Counter Fraud and Security Management Service
University Hospitals of Leicester NHS Trust
British Dental Association
Queen Victoria Hospital NHS Foundation Trust
Royal College of Paediatricians and Child Health
National Clinical Assessment Service
Dudley & Walsall Mental Health Partnership NHS Trust and Dudley PCT
Medical Defence Union
Independent Schools' Bursars Association and the Independent Schools Council
Company Chemists Association Limited
Council for Healthcare Regulatory Excellence
Hertfordshire PCT (Pharmacy & Medicines Management Team)
Nursing & Midwifery Council
The Association of British Dispensing Opticians
The Association of Optometrists
The Association of Contact Lens Manufacturers
The Federation of Manufacturing Opticians
Federation of Ophthalmic & Dispensing Opticians
The British Contact Lens Association
National Information Governance Board for Health and Social Care
NHS Eastern and Coastal Kent
Durham County Council
Independent Healthcare Advisory Services
Royal College of Nursing
General Social Care Council
NHS Cambridgeshire

Care Quality Commission
Medical Protection Society
Recruitment and Employment Confederation
Foundation Trust Network
Royal College of General Practitioners
Royal College of Physicians of London
General Medical Council
British Medical Association
Oxleas NHS Foundation Trust
The Medical Schools Council
The Leeds Teaching Hospital NHS Trust
NHS Employers
The Royal College of Surgeons of England
National Pharmacy Association
The British Dietetic Association
Action against Medical Accidents
The Scottish Government
Monitor
Yorks & Humber NHS Trust
Royal College of Physician of Edinburgh