RESPONSE TO CQC CONSULTATION:

"A New Start: changes in the way the CQC regulates, inspects and monitors care"

Introduction

Action against Medical Accidents (AvMA) is the independent UK charity for patient safety and justice. We are the only patients' charity specifically focussed on these issues. Our policy priorities are informed from the experience of people who we support following things going wrong and causing harm in healthcare ("medical accidents"). We support around 3,500 people a year through our helpline and more intensive casework and inquest support service. We also work closely with the health professions, healthcare providers, regulators and government departments to improve patient safety and the way that the system responds to patients and families following a medical accident. AvMA campaigned for years for the creation of a national regulator of the NHS and for centralised collection of data and creation of solutions for patient safety. Seeing the CQC succeed is a priority for us, and thus we are pleased to respond to this consultation. We have not commented on every question, but rather have limited our comments to those areas where we feel we can add value and which about which we feel strongly.

Answers to your Questions:

General

1. What do you think about the overall changes we are making to how we regulate? What do you like about them? Do you have any concerns?

We are supportive of the overall approach in principle. However, we do have some concerns and suggestions about making the process more effective and we would reserve our final judgement until we are able to see the detail. We are happy to advise and help to make the new approach effective. We are glad that there is an appreciation that there is an urgent need for a different approach to what we have seen so far. It is not a question of 'more regulation' necessarily, but 'better regulation'. For us better regulation means the CQC being more robust in its approach; an approach that fears the worst on receipt of worrying information about provider organisations, unless and until it has satisfied itself that there is no concern about patient safety; that acts swiftly to protect patients when it is believed standards/requirements are not being adhered to and puts the protection of patient s above all else, even if this is not part of a pre agreed plan of inspections or an

existing tool for assessing risk; one that is willing and able to respond better to concerns raised by members of the public and/or staff.

One of our concerns relates to the size of the task and the capacity of the CQC to meet it. Is the CQC's energy spread too widely? Are there enough resources to do the job in the way envisaged?

We are also concerned that up to this point the culture of the CQC itself has not been right. There has been a worrying reluctance to listen to concerns of members of the board and its own staff and poor levels of meaningful engagement with and responsiveness to patients and patients groups. Moreover in the past some senior personnel in the CQC had shown themselves to lack the kind of ethical qualities that are essential for a regulator which is supposed to uphold standards. To be effective, the CQC must be an exemplar of openness, transparency and good practice itself. We believe that the CQC's new leaders recognise this and are committed to turning the ship around. However, there may be resistance from within and it will take time and demonstrable change to win back public confidence.

We think it would assist the effectiveness of the CQC and public confidence in it if it were seen to be independent of government. In terms of accountability, creating a mechanism whereby CQC reported not only to the Health Select Committee but to a 'council' of national patients' organisations should be explored.

Finally, but very importantly, we have concerns about the CQC having to rely on co-operation from other regulators such as Monitor and the NHS Trust Development Authority ultimately to take action to protect patients. This is not an adequate safeguard. CQC should be the sole regulator of fundamental standards and not have to rely on the co-operation of other regulatory bodies in order to protect patients. Prof Don Berwick's recent review suggested he agreed with Robert Francis QC that we need a simpler, seamless regulatory system which combined assessment with enforcement. It would be better to get this right first time around rather than wait for another review.

2. Do you agree with our definitions of the five questions we will ask about quality and safety (is the service safe, effective, caring,][responsive and well-led)?

All of these issues are vitally important and of course inter relate with each other. However, we are mindful of the size of the task that faces CQC and therefore do question whether some of the issues should be a responsibility of CQC to monitor and regulate. We think it is important that patient safety is the clear top priority which trumps other considerations. Recognising that no organisation is going to be 100% safe and recognising the need to encourage organisations to continually review and improve patient safety, rather than "Is the service safe?" perhaps "Does the organisation do everything possible to maintain patient safety?" would be a better question?

With two of the five questions it may be more appropriate and feasible for other organisations to take the responsibility to enable CQC to concentrate more on safety. For example: “Is the service effective?” and “Is the service responsive”. Whilst these issues are very important, we wonder whether it is too broad an agenda for CQC to monitor and regulate effectively. For example, effectiveness is an area where NICE specialises and may be better placed to make judgements. Similarly, “Responsiveness” (in terms of the example you have given; ease of access; meeting expectations re waiting times etc) is perhaps something which is better left to the commissioners of services.

We suggest that a further key question may need adding (or at the very least that it be a prominent sub question of “Is the service well led?). That is something along the lines of: “Is the service ethically run?”. See our comments on “Fundamentals of Care”.

Fundamentals of care

3. Do you think any of the areas in the draft fundamentals of care above should not be included?

No, we think these are all fundamental.

4. Do you think there are additional areas that should be fundamentals of care?

We believe that the Duty of Candour with patients/families when something is suspected or known to have gone wrong and caused harm should be part of the fundamentals of care. Expressed in a similar format to your current examples, this might be:

“If something goes wrong with my care or treatment that is suspected to have caused or may result in harm, I will be told the full facts openly and honestly at the earliest opportunity”.

As discussed under “Duty of Candour” we would also like to see something about listening to and acting upon concerns raised by staff, (and protection and support of ‘whistleblowers’, which might be:

“If staff raise a concern about safety or care of patients they will be listened to and action taken to protect patients where needed, without staff being unfairly treated.”

We think that your example of an “expected standard” of always having sufficient numbers staff of the appropriate experience and seniority available to keep patients safe should be a fundamental standard.

5. Are the fundamentals of care expressed in a way that makes it clear whether they have been broken?

Not necessarily. We think more work is needed on this.

6. Do the draft fundamentals of care feel relevant to all groups of people and settings?

Yes, we believe so.

Section 3

Intelligent monitoring of NHS acute Hospitals

7. Do you agree with the proposals for how we will organise the indicators to inform and direct our regulatory activity?
8. Do you agree with the sources we have identified for the first set of indicators?

We believe that compliance with patient safety alerts by the given deadline should be a top tier indicator. An organisation failing to comply with a centrally agreed mandatory alert designed to protect patients should always prompt action by the CQC. Please note the prominence given to the need to ensure compliance with patient safety alerts both in the Francis report and the Don Berwick report.

We agree with your sources including complaints or concerns brought to your attention by members of the public, but your systems will need to change significantly to allow this to happen.

9. Which approach should we adopt for publishing information and analysis about how we monitor each NHS trust? Should we:
−− Publish the full methodology for the indicators?
−− Share the analysis with the providers to which the analysis relates?
−− Publish our analysis once we have completed any resulting follow up and inquiries (even if we did not carry out an inspection)?

Publish everything as soon as practically possible**. Honesty, openness and timely publication are key to gaining and retaining public trust.**

Inspections

10. Do you agree with our proposals for inspecting NHS and independent acute hospitals?

We agree that your proposals are a big step in the right direction as regards the inspections themselves. However, we would urge you not to place too much emphasis on inspections at the expense of being able to monitor organisations effectively and retaining capacity to react to investigate concerns about them as and when they arise. It should not just be a question of when this can be fitted into the CQC's programme of inspections.

A key learning point from Mid Staffordshire was that the regulator must be able to pick up intelligence about organisations not only on an on-going planned basis, but when information unexpectedly comes to its attention. This might be as a result of patients or a patients' organisation contacting you with concerns, whistleblower intelligence, etc.

Another good example of how the system did not work effectively in the past was the CQC's approach to monitoring compliance with patient safety alerts. Not only did CQC not monitor compliance systematically itself, but when AvMA's research revealed large scale non-compliance by NHS Trusts and brought this to the CQC's attention, the CQC did nothing (literally) about it. The new approach must include being both willing and able to monitor and investigate issues such as this without delay and to ensure compliance. A good test of your approach would be how would you react under the new system if these circumstances were to arise again?

We welcome your intention to work with Healthwatch and to involve patients and carers in inspections. We think this should be extended to other aspects of your monitoring role. We would be interested in working with you to help make patient & public involvement in your work effective. To do so will mean building capacity and providing training and support both for Healthwatch members and other patients/carers. We would recommend that we revisit work AvMA did on developing a "Patients for Patient Safety Network" in partnership with the NPSA.

When inspections are planned, more effort should be made to contact as many users of the organisation's services as possible to invite them to give feedback. Every inspection should include looking at a sample of complaints and claims made against the organisation.

Inspections should include a 'reality check' on whether organisations are complying with fundamental and expected standards. For example, declaring compliance with patient safety alerts is one thing but inspections should look at a sample of alerts which are declared compliant and checking to see if they are in fact being complied with. Inspections should include deeper analysis of compliance with the Duty of Candour in the ways suggested below.

There should be an evaluation of the inspection process. We would like to see a clearer explanation of what CQC feels good inspection would look like, which actual inspections can be measured against.

Ratings Q's 11-16

We do not have detailed comments to make about the proposed ratings system. We feel that the greater priority should be on monitoring and retaining capacity to react quickly to investigate concerns about safety in organisations rather than creating an elaborate ratings system.

Duty of candour

17. Do you agree that a duty of candour should be introduced as a registration requirement, requiring providers to ensure their staff and clinicians are open with people and their families where there are failings in care?

Yes, we strongly agree that a Duty of Candour should be a statutory registration requirement. This is one of the biggest priorities for patients and is vital not only in respect of patients' rights but for patient safety as well. Organisations that are prepared to tolerate cover ups will not be learning organisations. We are glad that the CQC now recognises the importance of this and is prepared to give it priority. Furthermore, we believe that this requirement needs to be given the priority it deserves by incorporating it in the fundamentals of care. It should be a given that any organisation that is fit to be registered has to demonstrate that it works in an ethical, open and honest way.

The Duty of Candour should be phrased in such a way that it makes it imperative that any registered organisation does everything reasonably possible to promote openness and honesty, including providing training and support for staff and, if there is a breach, taking action against individual members of staff who breach the duty. It is important that every member of staff (or others working for the organisation) recognise that the duty is directly relevant to their individual behaviour. It should be accompanied with guidance to help and support organisations and their staff to comply.

We think a natural and complementary extension of a Duty of Candour should be ensuring appropriate support and protection for staff to raise concerns. We would like it to be a registration requirement for organisations to demonstrate that they do this and for regulatory action to be taken against any organisation who does not, or which is seen to persecute 'whistleblowers'.

18. Do you agree that we should aim to draft a duty of candour sufficiently clearly that prosecution can be brought against a health or care provider that breaches this duty?

Yes. Whilst we hope there will be full compliance the duty must be drafted carefully so that the CQC can prosecute organisations who are in breach. This will act as a powerful deterrent and incentive to improve.

19. Do you have any other comments about the introduction of a statutory duty of candour on providers of services via CQC registration requirements?

The Duty of Candour should be incorporated in the Fundamentals of Care and promoted in order to have the maximum impact. Guidance and training will need to be developed and offered to support compliance.

Care must be taken when drafting the Duty of Candour regulations that all instances of patient safety incidents suspected of causing or which may result in harm are covered by the duty. Note that Robert Francis QC used the terminology 'suspected'. This avoids the potential for organisations getting around the duty by devious interpretation of the criterion or simply to make an internal decision that no harm has been caused or can result, without reference to the patient/family. Incidents which "may result in harm" include for example incidents where the harm may take a long time to materialise and things like problems with diagnostic procedures where harm may result if an opportunity to recognise and treat a health problem is missed.

The Duty of Candour should be absolute. There should be no 'get out clauses' such as fear of, or 'prejudice' to legal proceedings..

Careful consideration needs to be given not only to how CQC reacts to and investigates reports of non-compliance with the Duty, but how it monitors and assesses compliance on an on-going basis and as part of inspections. We would like to work with CQC to develop a robust strategy to support this. There are a number of steps we would recommend such as:

- Audit random samples of complaints for evidence of compliance or non-compliance
- Scrutiny of all complaints which have been investigated by the Ombudsman and litigated cases. These are likely to throw up examples of potential breaches of the Duty
- Look for evidence that the Duty has been promoted to all staff and that training has been provided to all staff responsible for communicating with patients following incidents
- Audit random samples of patient safety incidents which registered organisations are required to report to CQC for evidence that there has been full and open communication with the patient / family

One practical step we would recommend implementing immediately is to work with providers of software supporting the reporting of incidents (eg Datix) to create a mandatory field which asks whether the patient / family have been fully informed and all information shared.

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