Safety Cases – Lessons from Industry & Application in Healthcare - CQC approach

Cate Quinn, 29 March 2011

Overview

- Context: What do we mean by 'Is it safe?'
- Regulatory requirements
- How do healthcare organisations demonstrate compliance?
- How does CQC establish whether organisations are compliant?
- Other information / evidence
- Fieldwork
- Making judgements
- Plans for the future
- Feedback from healthcare organisations on the process
- Summary

Context: 'Is healthcare safe?'

- **'Safe'** in the public sphere typically means **'free from the risk of danger or harm, within 'reasonable expectations'**
- **'Reasonable expectations'** is poorly understood in the context of care.
- **CQC is often asked to give assurance** :
  - that people can continue to use the service safely in the event of a concern
  - that CQC takes responsibility for guaranteeing' safety in the future
- If our answer is:
  - **'Yes',** a single instance of poor quality care can undermine CQC's judgement.
  - **'No',** it appears we have made a judgement that this provider is unsafe. The next question is therefore, "Why haven't you shut them down?"

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What do people expect from CQC?

- Our starting point is what an average member of the public would reasonably expect from 'the regulator':
  - **Guarantee** safety in hospitals and care homes – "CQC says it's safe and it's good enough for me…"
  - **Prediction** – "CQC saw the warning signs and stepped in…"
  - **Action** – inspect, understand, and fix. "CQC saw this was wrong and put it right."
  - **Take blame** – "CQC missed the signs…"
  - **Learn lessons** and ensure 'it' never happens again. "CQC has improved its processes…"
- Expectations are growing with fewer players on the pitch

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What do we see as our role?

- We see our role as:

  -**Monitoring –** using intelligence to indicate risk of poor outcomes

  -**Mitigation** - taking action to reduce the likelihood of poor outcomes, and

  -**Dealing with failure** - responding to poor outcomes

  In the context of a legal framework that sets minimum/essential standards for care.

- CQC therefore understands **'safe care'** to be care delivered by a provider who is **compliant with our essential standards**
- Non-compliance does not necessarily mean unsafe – it means an *increasing risk* of care being unsafe. The more 'non-compliant' the greater the risk, but non-compliant is not an absolute judgement on the quality of care on offer.

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The legal framework

People can expect services to meet essential standards of quality, protect their safety and respect their dignity and rights.

Adult social care

NHS

Independent healthcare

Dentists, private ambulances (2011) & GPs (2012)

Registration

1. **Single system of registration**
2. **Single set of standards (Health and Social Care Act 2008 and regulations)**
3. **Strengthened and extended enforcement powers**

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CQC's guidance about compliance documents

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CQC's guidance about compliance: example of an OUTCOME

Plain English

People focused

Outcome based

Safeguarding people who use services from abuse

OUTCOME 7

What should people who use services experience?

People using the service:

- Are protected from abuse, or the risk of abuse, and their human rights are respected and upheld

That is because providers who are compliant with the law will:

- Take action to identify and prevent abuse from happening in a service
- Respond appropriately when it is suspected that abuse has occurred or is at risk of occurring
- Ensure that Government and local guidance about safeguarding people from abuse is accessible to all staff and put into practice
- Make sure that the use of restraint in a way that respects dignity and protects human rights, and where possible respects the preferences of people who use services
- Protect others from the negative effect of any behaviour by people who use services

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How do providers demonstrate compliance on registration?

- Providers submit registration application at level of legal entity (electronic/paper)
- Self declaration of compliance with regulations against each regulated service and location
- Supporting information identified on the application form
- Registered manager application
- Statement of purpose
- Details of accountable officer for controlled drugs
- Use guidance contained with Essential Standards of Quality and Safety and Judgement Framework
- Notification of changes during or after the application

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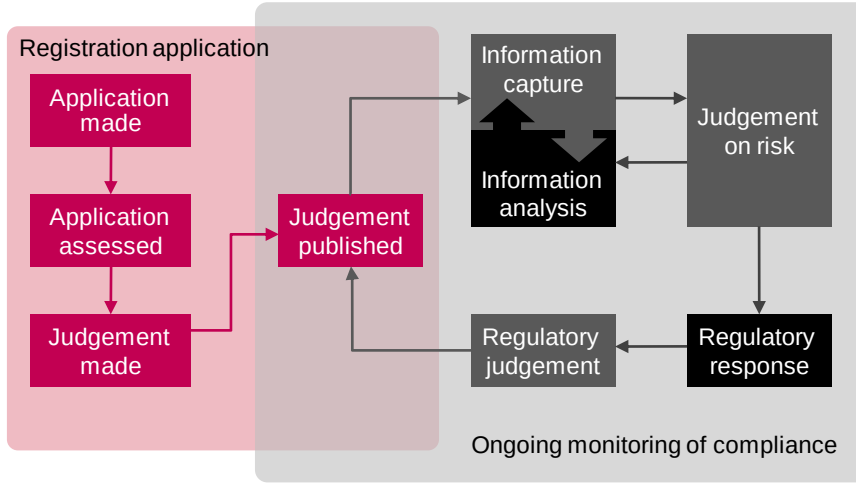
Registration and ongoing compliance: the cycle



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How does CQC assess compliance?

Responsive

A **responsive review** of compliance:

- is triggered when specific information, or a gap in information raises concern about compliance
- is not a full check of all 16 core quality and safety outcomes
- is **targeted** to the area(s) of concern
- May include a site visit
- All findings will be published

Planned

A **planned review** of compliance:

- is a scheduled check that looks across **all** regulated activities (at a location) to assess compliance with all 16 core quality and safety outcomes
- Will take place at intervals of 3 months to no less frequent than 2 years
- Will be **proportionate**, with additional activities focused on gaps on information
- May include a site visit
- All findings will be published

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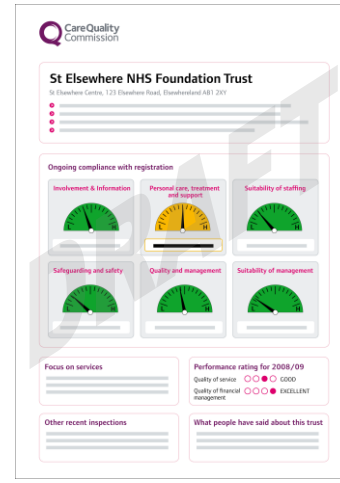
How we capture information

Quality and Risk Profiles

- We hold a quality and risk profile on each provider summarising all relevant information
- It is updated as new information arrives and inspectors are alerted to new emerging risks
- The QRP is a **prompt** not a judgement:

- Gathers all we know about an organisation
- Builds over time – never 'perfect'
- Organises information into relevant classification system (outcome areas)
- Manages flows
- Applies risk model to **calculate risk** and present findings in a way frontline staff can use



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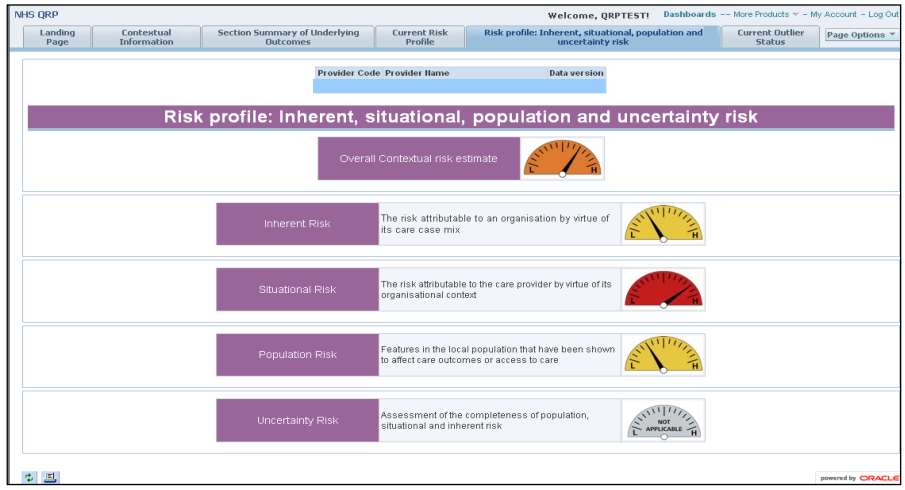
Contextual risk (to contextualise the risk displayed at outcome level)



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Item level (structured under outcomes to calculate risk):

Underlying Information for: Outcome 1 (R17) Respecting and involving people who use services

						Weighting of Items		
Item ID	Description	Data Source	Time Period Start	Time Period End	Comparison with Expected	Data Quality	Patient Experience	Strength of Outcome Mapping
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/09/2009		Negative comment	1	1	1
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/10/2009		Negative comment	1	1	1
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/10/2009		Positive comment	1	1	1
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/11/2009		Positive comment	1	1	1
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-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/11/2009		Negative comment	1	1	2
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/11/2009		Negative comment	1	1	2
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/11/2009		Positive comment	1	1	1
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/11/2009		Positive comment	1	1	1
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/12/2009		Negative comment	1	1	2
-22	Intelligence from NHS Choices -	NHS Choices, Comments from patients	01/12/2009		Positive comment	1	1	1
10141	The proportion of respondents to the adult inpatient survey who stated that a doctor or nurse did not give their family or someone close to them all the information they needed to help them recover. -	Care Quality Commission, Survey of Adult Inpatients	01/06/2009	31/08/2009	Similar to expected	2	3	3
5658	The proportion of respondents to the adult inpatient survey who stated that they were not given any information about their treatment or condition. -	Care Quality Commission, Survey of Adult Inpatients	01/06/2009	31/08/2009	Similar to expected	2	3	3
5659	The proportion of respondents to the adult inpatient survey who stated that they were not given enough privacy when being examined or treated in the em Results department. -	Care Quality Commission, Survey of Adult Inpatients	01/06/2009	31/08/2009	Similar to expected	2	3	3
5661	The proportion of respondents to the adult inpatient survey who stated that they were not given a choice of admission dates. -	Care Quality Commission, Survey of Adult Inpatients	01/06/2009	31/08/2009	Tending towards better than expected	2	3	2
5665	The proportion of respondents to the adult inpatient survey who stated that their admission date was changed by the hospital two or more times. -	Care Quality Commission, Survey of Adult Inpatients	01/06/2009	31/08/2009	Similar to expected	2	3	2

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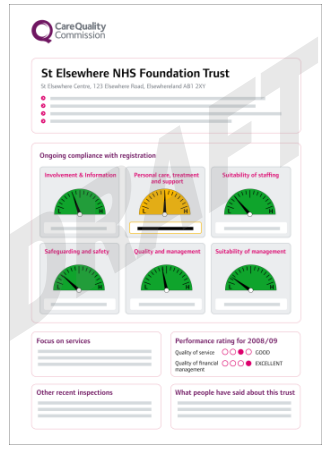
Other information

New information can come from a variety of sources:

People who use services, families and carers

Other regulatory bodies and Information Centre

Other bodies e.g.. Ombudsman, commissioners



Providers

Staff and other professionals

CQC Assessors and Inspectors

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Safety – related indicators

Example safety-related items in our Quality and Risk Profiles:

- Standardised in-hospital mortality rates
- MRSA and C. diff rates and trends
- PEAT scores
- Participation in heart disease audits
- Achievement on risk management standards
- Timeliness of submitting statutory notifications (safety incidents)
- Lack of reporting of statutory notifications
- Proportion of safety alerts acknowledged within the deadline
- Proportion of safety alerts complied with by the deadline
- Patient and staff survey data

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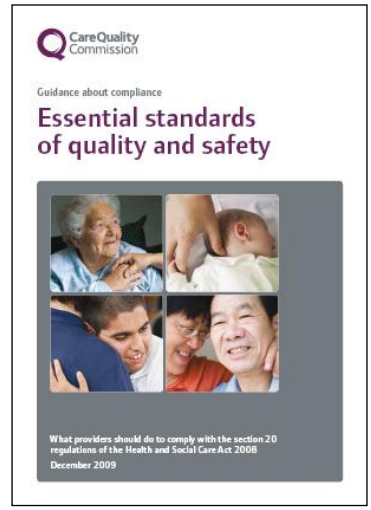
Reporting errors and incidents

Statutory notifications:

- Unexpected deaths
- Serious injuries
- Deaths and unauthorised absences of people detained or liable to be detained under the Mental Health Act 1983
- Applications to deprive a person of their liberty under the Mental Capacity Act 2005, and their outcomes

Some direct to CQC, some via NPSA



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Outliers programmes

Current programmes:

- Mortality rates
- Emergency admission rates
- Maternity indicators

Data comes from a number of different sources, such as from:

- our own data analysis or other CQC intelligence
- the Dr Foster Unit at Imperial College
- the care provider itself

Future developments:

- safety incidents
- HAI

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Site visits

- **Short, focussed unannounced site visits**, rather than set piece inspections
- Site visits will be **direct checks of compliance**
- Site visits will always include **direct observation of care** and we will **spend time with people who use the service**, their families and carers, where appropriate
- **Experts by experience** will join us on some site visits to help us engage with people who use services (social services only)
- Site visits will **take place as often as required**

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Regulatory judgement and response

Judgement framework

Stage 1: Is there enough evidence?

Stage 2: Does the evidence show compliance?

Stage 3: What is the impact on people who use services and the likelihood of this happening? Is there:

- No concern
- Minor concern
- Moderate concern
- Major concern

Stage 4: Validation

Regulatory judgement

- Judgement of compliance or concerns
- Translates minor, moderate or major concerns into regulatory judgement
- Takes account of the provider's capability to improve
- Action will be **proportionate**

Regulatory response

Maintain registration - no further action

Improvement actions:

e.g. improvement letter

Enforcement actions:

- Statutory warning notice
- Imposition or variation of conditions
- Fines
- Prosecution
- Suspension of registration
- Cancellation of registration

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Challenges

- **Notion of risk:** care is inherently risky; but there is a difference between acceptable and preventable risk.
- **Environment:** speed of change – safe to unsafe – can be very quick; so 'reasonable expectations' are in the context of a dynamic environment.
- **Scope:** CQC regulates a huge number of providers across a range of complex and dynamic sectors. There are limits to what we can achieve.
- **Capacity to tackle problems:** important to ensure people have accurate and reasonable expectations of CQC in the context of capacity and statutory functions.
- **Other players:** other bodies are responsible too (other regulators, commissioners, professionals)
- **Closure** is not an easy answer:
  - Can have major impact across a region
  - Access to suboptimal care not always worse than none
  - People with complex needs can suffer harm from being moved

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Plans for the future

New waves of registration:

- Dental services and private ambulances
- Primary medical services
- Others??

Changes to regulations

Health and Social Care Bill 2011

- Joint licensing with Monitor
- HealthWatch
- Arms Length Body Review

NQB Early Warning Systems

Operations implementation review

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Feedback from providers

- Potential confusion during structural change
- Difficulty interpreting the outcome-based requirements
- Difficulty translating generic requirements to specialist services, e.g. mental health
- Consistency in assessor/inspector judgment
- Our processes for registration could be improved
- Issues over timeliness of response/certification/variations
- Helpline services could be improved
- More help required understanding QRP and how it informs judgements

Source: NHS Confederation Member Survey: Experiences of the CQC Registration process 2010

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Is it safe? - in summary

Predicting risk
We listen, we look; and we take strong action when something goes wrong. But we don't do **prediction** – it is simply too hard to do

Minimising risk
We can hold hospitals and care homes to account so they deliver the right care to the right standards. But care carries risks. We can minimise unreasonable risks, but we cannot guarantee that any interaction with care will be safe – no-one can.

Identifying risk
When we identify risks, we review and inspect services to see what's behind them – 'risk-based regulation'

Eliminating risk
We cannot prevent risk, but we can reduce it and come down hard on those who don't do what they need to in order to provide safe care

Dealing with concerns
Where necessary, we seek improvements against clear timescales or take enforcement action (and follow up):

Enforcement action underpinned by judgement
If we believed this unit was going to put people at unacceptable risk of harm, we would have closed it in the way we shut Hill Valley Care Home in May.

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Useful references

The regulations and guidance about compliance:

http://www.cqc.org.uk/guidanceforprofessionals/nhstrusts/complyingwiththeregulations/guidanceaboutcompliance.cfm

Guidance for NHS providers on registering as a new provider:

http://www.cqc.org.uk/guidanceforprofessionals/nhstrusts/registration/registerasanewproviderormanager.cfm

Monitoring compliance and enforcement:

http://www.cqc.org.uk/guidanceforprofessionals/nhstrusts/ourmonitoringofcompliance.cfm

Making statutory notifications:

http://www.cqc.org.uk/guidanceforprofessionals/nhstrusts/registration/notifications.cfm

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Thank You

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