Are we there yet? The never ending story of CQC regulation

Neil Grant
Partner, Ridouts LLP

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Too much or too little regulation?

There has been an endless swing of the pendulum between perceived excessive regulation and insufficient regulation (the first mainly linked to arguments about cost to business and the second to care scandals that emerge every few years).

In recent years we have had Mid Staffordshire Public Inquiry and Winterbourne View scandal.

What we need is effective regulation at the right level - is this what we now have?

The Growth of CQC Regulation

More services regulated than ever before – 40,000 services

Major new additions to regulation

- NHS providers from April 2010
- Dentists from April 2011
- GP practices from April 2013

Under a common system based on regulated activities.

Adult social care providers transitioned to the new system in October 2010.

Difficult to see it changing now that we have a market (of sorts) within the NHS and given the integration agenda

Additional strands of regulation

- Commissioners (local authorities, clinical commissioning groups, NHS England)
- Health and Safety Executive
- Profession-led regulators
- For the NHS, Monitor (for Foundation Trusts) and the NHS Trust Development Authority (for NHS Trusts)
- Local Health Watch
- Quality Surveillance Groups (local and regional)

The current CQC legislation

- Health and Social Care Act 2008
- Regulated Activities Regulations
- Registration Regulations
- The Essential Standards of Quality and Safety
- Perfectly adequate system
- Sir Robert Francis disagrees…

The New System

- New management and increased numbers of inspectors
- Chief Inspectors of Hospitals, Adult Social Care and Primary Care, operating within Directorates
- Specialist teams of inspectors
- Additional state funding
- A return to risk based inspection
- And don't forget the "Mum Test" (in relation to adult social care) and Friends and Family Test in the NHS!

The New System

- Fundamental Standards and new guidance (from April 2015)
- Fit and proper person test – to start with only the NHS (from the end of November)
- Duty of candour (key recommendation from Mid Staffordshire Inquiry) – again NHS first from the end of November

The New System

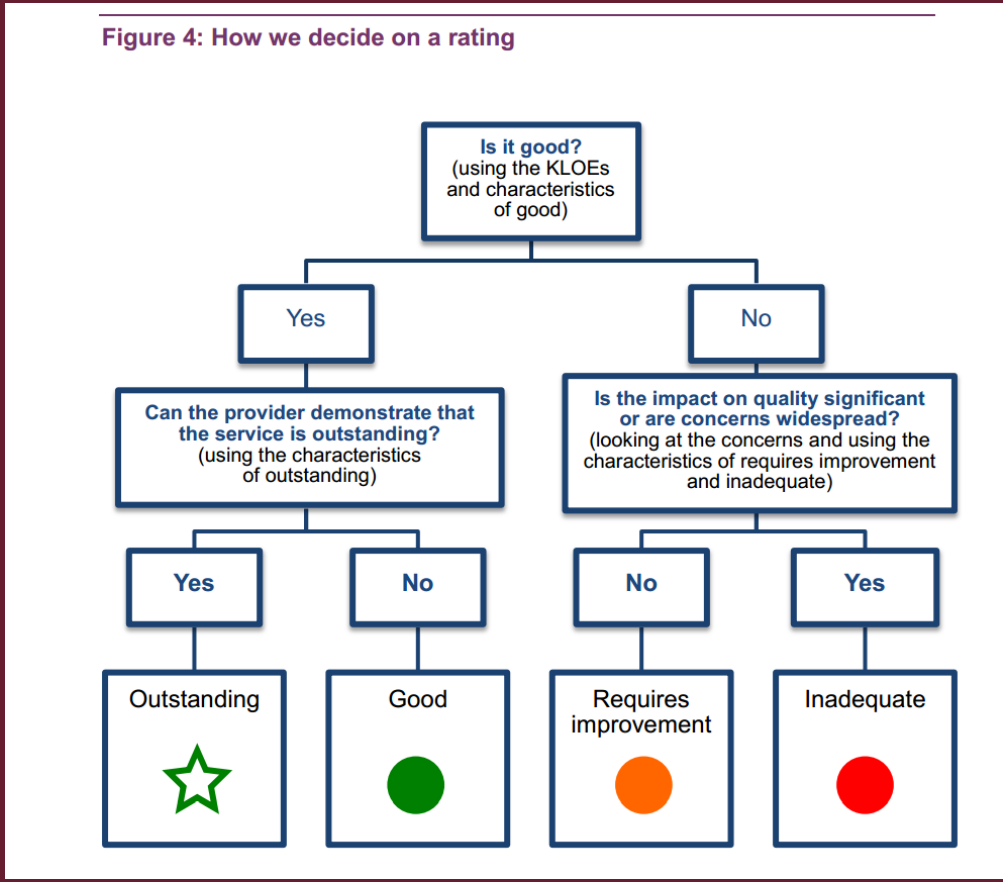
- New inspection methodology set out in the published Provider handbooks: NHS acute hospitals, GP practices, adult social care, specialist mental health services and community health services – went live this month
- Further Provider handbooks to be issued at the end of November/beginning of December for ambulance trusts and independent healthcare

The New System

- Ratings – went live this month for NHS hospitals, community health services, specialist mental health services, GP practices and adult social care
- Ratings will go live for ambulance trusts and independent hospitals in April 2015 (with shadow ratings from January to March 2015)
- Decisions yet to be made about rating dentists, private doctors and some independent ambulance services

Ratings

- CQC's starting position is Good



Ratings

- Algorithmic, rules-based approach
- Professional Judgement
- The essential elements of the judgement framework are in place
- Key Lines of Enquiry (informed by prompts and sources of information)
- Characteristics of “good”, “outstanding”, “requires improvement” and “inadequate”
- Can lead to very different and seemingly bizarre results depending on the profile of ratings

Consequences of poor ratings

- The media storm
- Special measures
- Enforcement action
- Withdrawal of business from commissioners/the public
- Careers over
- Referrals to profession-led regulators

Ratings

CQC's commissioned review of hospital ratings by the Manchester Business School and King's Fund (July 2014) acknowledges the weaknesses:

"The rating process is highly implicit, relies on professional judgement, and is probably rather variable at present with relatively low levels of interrater reliability." (page 75)

Ratings for each of 5 key questions

Is the service:

1. Safe?
2. Effective?
3. Caring?
4. Responsive?
5. Well-led?

Each question has equal weight

GP Ratings – one for each population group

The six population groups (each having equal weight):

- Older People
- Long term conditions
- Families, children & young people
- Working age people (including retired & students)
- Vulnerable people (e.g. the learning disabled)
- Poor mental health (including dementia)

Level 1 – Apply a rating to each question for each population group

Level 1: Every key question for every population group

	Safe	Effective	Caring	Responsive	Well-led
Older people	Good	Outstanding	Good	Outstanding	Good

Rules for aggregating Ratings*

Outstanding = 2 outstandings + the rest good

Requires improvement = 2 R.I. + rest good OR 1 inadequate

Inadequate = 2 or more inadequates

Good (by a process of elimination)=
1 outstanding + rest good
1 requires improvement + rest good

***When 4-8 categories are being aggregated**

Aggregating Ratings for Population Groups (Level 2)

Level 1: Every key question for every population group

	Safe	Effective	Caring	Responsive	Well-led	Overall
Older people	Good	Outstanding	Good	Outstanding	Good	★

Level 2: Aggregated rating for every population group

Overall rating (older people's service) = Outstanding

(2 outstandings and the rest goods)

Level 3: Aggregating Ratings for each key question

	Safe
Older people	Good
People with long term conditions	Good
Families, children and young people	Good
Working age people (including those recently retired and students)	Good
People whose circumstances may make them vulnerable	Good
People with poor mental health (including people with dementia)	Good
Overall	*

Overall rating ('safe') = good

(all goods)

Overall GP rating:

Level 1: Every key question for every population group

	Safe	Effective	Caring	Responsive	Well-Led	Overall
Older People	Good	Outstanding	Good	Outstanding	Good	Outstanding
People with long term conditions	Good	Inadequate	Good	Inadequate	Good	Inadequate
Families, children and young people	Good	Good	Requires Improvement	Good	Requires Improvement	Requires Improvement
Working age people (including those recently retired and students)	Good	Good	Outstanding	Good	Outstanding	Outstanding
People whose circumstances may make them vulnerable	Good	Outstanding	Good	Requires Improvement	Good	Good
People with poor mental health (including people with dementia)	Good	Good	Requires Improvement	Good	Requires Improvement	Requires Improvement

Level 2: Aggregated rating for every population group

Level 3: Aggregated rating for every key question

Overall	Good	Requires Improvement	Requires Improvement	Requires Improvement	Requires Improvement	Overall location: Requires Improvement

Level 4: Overall rating for the practice

Basic flaws in the rating system?

The aggregated population group ratings (level 2) do not directly tie into the overall key question ratings (level 3)

So you can get some strange results

And this is with oversight from a National Quality Rating Panel

Level 1: Every key question for every population group

	Safe	Effective	Caring	Responsive	Well-Led	Overall
Older People	Inadequate	Good	Good	Good	Good	Requires Improvement
People with long term conditions	Inadequate	Good	Good	Good	Good	Requires Improvement
Families, children and young people	Good	Outstanding	Outstanding	Good	Good	Outstanding
Working age people (including those recently retired and students)	Good	Good	Inadequate	Good	Good	Requires Improvement
People whose circumstances may make them vulnerable	Good	Good	Inadequate	Good	Good	Requires Improvement
People with poor mental health (including people with dementia)	Good	Good	Good	Good	Good	Good

Level 2: Aggregated rating for every population group

Level 3: Aggregated rating for every key question

Overall	Inadequate	Good	Inadequate	Good	Good	Overall location
						Inadequate

Level 4: Overall rating for the practice

Inadequate overall location although no population group is inadequate overall

Level 1: Every key question for every population group

	Safe	Effective	Caring	Responsive	Well-Led	Overall
Older People	Inadequate	Inadequate	Requires Improvement	Good	Inadequate	Inadequate
People with long term conditions	Good	Good	Requires Improvement	Requires Improvement	Good	Requires Improvement
Families, children and young people	Good	Good	Good	Good	Good	Good
Working age people (including those recently retired and students)	Good	Good	Good	Good	Good	Good
People whose circumstances may make them vulnerable	Good	Good	Good	Good	Good	Good
People with poor mental health (including people with dementia)	Good	Good	Good	Good	Good	Good

Level 2: Aggregated rating for every population group

Level 3: Aggregated rating for every key question

Overall	Requires Improvement	Requires Improvement	Requires Improvement	Good	Requires Improvement	**Overall location**
						Requires Improvement

Level 4: Overall rating for the practice

Overall inadequate older people service but overall location only requires improvement

Hospital Ratings

- Hospitals have core services rather than population groups
- Typically there are 8 core services (each of which has equal weighting) – but CQC can add additional core services e.g. Royal Surrey Hospital's regional cancer service
- Mental health trusts tend to have up to 10 or 11 core services
- There are up to 6 levels of aggregation!!

Hospital Ratings

As with each GP practice, there will be performance ratings at 4 levels for each hospital:

- Level 1: rate every core service for every key question
- Level 2: an aggregated rating for each core service
- Level 3: an aggregated rating for each key question
- Level 4: an aggregated overall rating for the location as a whole
- Which can lead to some unusual outcomes...

Level 1: Every key question for every core service provided

	Safe	Effective	Caring	Responsive	Well-led
Urgent & emergency services	Good	Good	Good	Requires improvement	Good
Medical care (including older people's care)	Good	Requires improvement	Good	Good	Good
Surgery	Good	Good	Good	Good	Good
Critical care	Good	Good	Good	Good	Good
Maternity & gynaecology	Good	Good	Good	Requires improvement	Requires improvement
Services for children & young people	Good	Good	Outstanding	Good	Good
End of life care	Good	Good	Outstanding	Outstanding	Good
Outpatients & diagnostic imaging	Requires improvement	Good	Good	Requires improvement	Inadequate

Overall
*
*
*
*
*
*
*
*

Level 2: Aggregated rating for every core service provided

Level 3: Aggregated rating for every key question

Overall	*	*	*	*	*

Overall location
*

Level 4: Overall rating for the location

Hospital Ratings

For a hospital trust, there are two additional levels (where there are multiple sites):

- Level 5: each of the key questions. This will be informed by the level 3 findings for each trust plus information on the 5 questions that is available at trust level only
- Level 6: the trust as a whole

Level 5: Each key question

	Safe	Effective	Caring	Responsive	Well-led
Trust	Good	Good	Good	Good	Requires improvement

Overall trust
*

Level 6: Overall rating for the trust

Queen Elizabeth The Queen Mother Hospital Quality Ratings

	Safe	Effective	Caring	Responsive	Well-Led	Overall
Accident and emergency	Inadequate	Not rated	Good	Inadequate	Inadequate	Inadequate
Medical care	Requires Improvement	Good	Good	Requires Improvement	Requires Improvement	Requires Improvement
Surgery	Requires Improvement	Requires Improvement	Good	Good	Inadequate	Requires Improvement
Critical care	Good	Good	Good	Good	Good	Good
Maternity and family planning	Requires Improvement	Requires Improvement	Good	Requires Improvement	Requires Improvement	Requires Improvement
Services for children and young people	Good	Inadequate	Good	Requires Improvement	Requires Improvement	Requires Improvement
End of Life Care	Requires Improvement	Requires Improvement	Good	Requires Improvement	Requires Improvement	Requires Improvement
Outpatients	Good	Not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement
Overall	Requires Improvement	Requires Improvement	Good	Requires Improvement	Inadequate	Requires Improvement

Kent & Canterbury Hospital Quality Report Ratings

	Safe	Effective	Caring	Responsive	Well-Led	Overall
Emergency care centre	Requires Improvement	Not rated	Good	Requires Improvement	Inadequate	Requires Improvement
Medical care	Requires Improvement	Good	Good	Good	Requires Improvement	Requires Improvement
Surgery	Inadequate	Good	Good	Good	Inadequate	Inadequate
Critical care	Requires Improvement	Good	Good	Good	Good	Good
Services for children and young people	Requires Improvement	Requires Improvement	Good	Good	Requires Improvement	Requires Improvement
End of life care	Requires Improvement	Requires Improvement	Good	Requires Improvement	Requires Improvement	Requires Improvement
Outpatients	Inadequate	Not rated	Good	Requires Improvement	Requires Improvement	Requires Improvement
Overall	Inadequate	Requires Improvement	Good	Requires Improvement	Inadequate	Inadequate

Care Home Ratings

By far the simplest group so far!

Based on the location, not the regulated activity

Two levels only


Level 1:
Each key question
Safe
Effective
Caring
Responsive
Well-led
Location
Good
Good
Good
Good
Requires improvement
Overall location
Good
Level 2:
Overall rating for the location

Care home rating limiters

Limiters on Well-Led:

- – No registered manager and “satisfactory steps” have not been taken to recruit one within a “reasonable timescale”
- –An additional condition of registration not being met with no good reason
- –Statutory notifications not submitted without good reason
- –PIR not returned
- –If enforcement action is being taken

can never be better than “requires improvement”

Professional judgement

Examples of scenarios where principles can be departed from:

- where the concerns identified have a very low impact on people who use the service
- where CQC has confidence in the service to address concerns or where action has already been taken
- where a single concern has been identified in a small part of a very large and wide-ranging service
- Where a core service (hospitals) is very small compared to other core services within the provider

Fundamental Standards

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014. The Fundamental Standards are set out in Regulations 9-19. They are due to come into force in their entirety in April 2015

- The majority do not give rise to direct prosecutable offences if breached including person-centred care (9), dignity and respect (10), premises and equipment (15), receiving and acting on complaints (16), good governance (17), staffing (18) and fit and proper persons employed (19)

- But they are still regulatory requirements which if breached can lead to other regulatory action

Fundamental Standards

The big change is that CQC will be able to prosecute providers for the offences detailed in the new Regulations without serving a Warning Notice

Breaches of Fundamental Standards

Regulation 22 will make it an offence for a registered person to breach the following regulations:

11 (on consent)
16(3) (supplying summaries of complaints to CQC)
17(3) (supplying reports on quality monitoring)

Breach of Regulation 11 = Fine (maximum £50,000)

Breach of Regulations 16 and 17 = Fine (maximum £2,500 but intention is for this to rise to £10,000)

Breach of Regulation 20(2)(a) and (3) (duty of candour) will also be an offence (NHS only at this stage). Again penalty is a fine (maximum £2,500 but intention is for this to rise to £10,000)

Breaches of fundamental standards

Breaches of Regulation 12 (on safe care and treatment), Regulation 13(1) to (4) (on safeguarding) and Regulation 14 (on nutritional needs) will also be an offence if the breach results in :

- avoidable harm (physical or psychological)
- a service user being exposed to a significant risk of harm or
- any loss of property by a service user (in the case of theft)

Penalty: Fine (maximum £50,000 per offence)

Defence under Regulation 22(4) to prove registered person took all reasonable steps and exercised due diligence to prevent the breach

Lead prosecutor role for CQC

From April 2015, CQC will be the lead prosecuting agency whenever a service user suffers harm in a health and social care setting e.g. scalding.

The Health and Safety at Work Act will not be used in such circumstances. CQC will instead bring prosecutions under the fundamental standards.

HSE has tended to focus on incidents leading to deaths so on Winterbourne View the police ultimately stepped in and prosecuted

The fundamental standards talk about avoidable harm – whether of a physical or psychological nature as well as exposure to a significant risk of such harm occurring

Lead prosecutor role for CQC

CQC has a broader range of enforcement powers than the HSE including penalty notices, cautions and civil remedies

The Health and Safety at Work Act will continue to apply to employees and unsafe equipment

The Department of Health is expecting CQC to prosecute far more frequently – they currently prosecute very rarely

CQC says it will generally prosecute providers for serious, multiple or persistent breaches of the fundamental standards (reflecting the HSE standard)

CQC will have to recruit additional lawyers as prosecutors

Enforcement linked to ratings

There will be a new Enforcement Policy from next April

CQC is abandoning the enforcement escalator and linking regulatory action to ratings

So if you get an inadequate rating that will almost certainly lead to intervention, whether special measures or direct enforcement action

Conclusion

Familiarise yourself with your Provider handbook in relation to the KLOEs, prompts and ratings rules generally

Give active consideration to challenging CQC on your ratings (and importantly the underlying facts and judgements) if you feel they are unfair

Ensure that you review the new Fundamental Standards and the guidance on meeting them which will be issued by CQC in due course

Train your senior staff on the reforms

Await the next set of reforms – change creates new problems leading to more change…

Neil Grant – Partner
020 7317 0347
neil@ridout-law.com

Paul Ridout – Partner
020 7317 0341
paul@ridout-law.com

www.ridout-law.com