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Abstract

Quality problem

Best practice and the quality and safety of health services have become a major concern for healthcare providers, consumers and funders. One lever for improved quality and safety is formal regulation.

Intervention

In August 2008, the then healthcare regulator for England, the Healthcare Commission, introduced a new approach for risk identification, assessment, escalation.

Choice of solution

The new approach had three novel elements for a regulator. First the risk assessed was risk to the outcomes experienced by users of services rather than service or the managers of services. Second, the risk assessment was designed so that thresholds were consistent with those used in the regulated bodies and thirdly, the assessment was applied collaboratively by a group of key regulatory, inspection, audit and review bodies for healthcare.

Implementation

The new approach was rolled out across the Healthcare Commission' assessment staff with a training programme. The collaborative meetings between regulatory, inspection and review bodies were implemented on a regional basis.

Evaluation

The evaluation results provide encouraging evidence to suggest that, just six months after being launched, the new system was well accepted, visible across the Healthcare Commission and generally welcomed by staff. The system seemed to drive a sustained increase in the number of referrals for investigation and enforcement.

Lessons learned

A focus on the risk to outcomes experienced by users of services is a helpful guiding principle for regulators. As with other complex interventions, successful implementation involves a range of mechanisms (eg training, tools and effective collaborative working).

A collaborative framework for systematically handling concerns in healthcare

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Introduction

Best practice and the quality and safety of health services have become a major concern for both providers and consumers and funders [1] [2] [3] [4] [5]

This concern has led to a growing focus on health care quality and risk as a central function of health systems of care [6] [7]This focus reflects the increasing technical sophistication of modern health care, the scope for patients to be harmed by health care interventions, and the complex systems from within which health care is delivered.

One lever for improved quality and safety is formal regulation. In recent years, an international consensus on the principles of good regulation has emerged [8]. In the United Kingdom, the Better Regulation Executive has set out the principles that modern regulatory regimes should meet, namely regulation should be transparent, accountable, consistent, proportionate to risk and targeted on outcomes.

In August 2008 the then healthcare regulator for England, the Healthcare Commission introduced a new approach for risk identification, assessment, escalation and (where necessary and applicable) enforcement. This was due in part to the perception, that there was no systematic framework in place to assure the regulator, patients and healthcare professionals public that it handled all concerns about local performance consistently and proportionately.

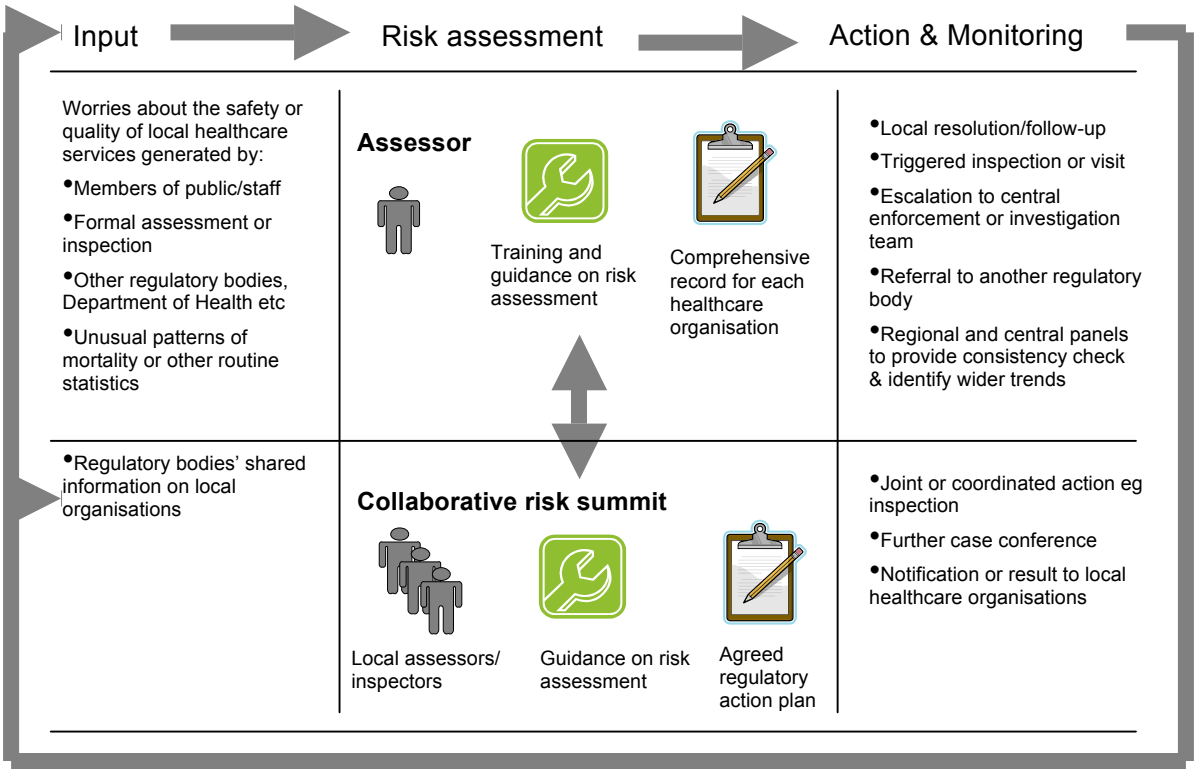
The new approach had two novel elements for a regulator. First the risk assessed was risk to the outcomes experienced by users of services, not the services or the managers of services. Second, the risk assessment was designed so that thresholds were consistent with those used in the regulated

bodies and applied so that assessments were carried out collaboratively by a group of organisations from performance managers, regulatory, audit and review bodies**.**

The Handling concerns programme

The overall aim was to help the Commission's frontline staff (assessors) evaluate and act on their concerns about local healthcare organisations in an appropriate and consistent way similarly to methods widely used in the insurance industry and which have been successfully adapted in several countries to assist staff to prioritise and classify patient safety incidents [9] [10] [11] [12]

Figure 1. Diagrammatic representation of the *Handling concerns* programme



The main elements of the programme are described below:

Training on risk assessment

Training was rolled out to all local assessors on a monthly basis from October 2008 with most assessors having completed the course by February 2009.

The training included sessions on how to carry out risk assessment using a range of scenarios and a session on when and how to escalate serious concerns to specialist enforcement and investigations teams in the Commission. The capacity of the Commission's specialist enforcement team also increased in September 2009.

Standardised method of risk assessment

Assessors were trained to evaluate risk using five key questions to underpin their analysis, elements of which were adapted from a framework developed from the NHS National Patient Safety Agency, which enables NHS risk managers in implementing an integrated system of risk assessment.

What is **worrying** you?

1. How **likely** is it that individuals, communities and/or public resources and assets will be affected as a result?
2. How **severe** would the impacts be?
3. How **confident** are you that the necessary improvements are being made?
4. **What action** could be taken by whom to ensure improvement?

Guidance was provided to assessors in the form of a series of prompts underpinning each question. Mathematical calculation was avoided as risk tolerance did not conform to a simple mathematical model, e.g. moderate * possible (2*3) was not the same as major * unlikely (3*2). The overall level of concern is decided using the following rule and table:

Level of concern = (likelihood+/- confidence) * (severity +vulnerability)

Table 1. Calculation of overall level of concern (four point scale)

Likelihood score	Severity score		
	Minor	Moderate	Major
Rare	**Business as usual**		
Unlikely			
Possible		**Minor concern**	
Likely			**Concern**
Almost certain		**Serious concern**	

Note: The likelihood score can be modified by the assessor depending on their degree of confidence that necessary improvements are being made. Likewise severity can be modified to reflect the greater risk for people in a vulnerable situation.

Assessors were provided with 'pocket guidance' in the form of a leaflet for quick reference as well as a more comprehensive set of prompts and thresholds[13].

Planned collaborative reviews

The planned collaborative reviews (also sometimes referred to as 'risk summits') involve local assessors and inspectors from various healthcare regulators and inspectorates meeting to share the information they hold about local healthcare organisations. Strategic health authority representatives also attend. The aim is to ensure that each regulator makes informed judgements about local risk and where appropriate, regulators coordinate their action to reduce unnecessary duplication of regulatory activity. A planned collaborative review was held in each strategic health authority area between November 2008 and March 2009.

Monitoring

The Commission introduced panel meetings of senior managers at regional and national level (with executive directors attending the latter) to provide challenge, accountability for risk and a consistency check.

Evaluation

The main outcomes of interest for early evaluation were:

- The extent to which Healthcare Commission assessors were aware of the new tools and guidance and used these in their work
- the impact of the new system on the consistency of assessors' judgements and actions taken
- the impact of the new system on numbers of cases referred for enforcement or further investigation
- the extent to which collaborative working resulted in a more targeted and coordinated regulatory response to concerns [14].

Methods

The programme was evaluated between November 2008 and March 2009 as it was being rolled out. There was no obvious 'control group' or baseline against which to measure the new system so a 'realistic' [15] approach was taken with multiple methods used to obtain feedback from those involved in *Handling concerns* and to identify corroborating evidence where available. The methods used to evaluate the programme included:

Face to face interviews

Semi-structured interviews were undertaken with a number of senior managers in the Healthcare Commission with responsibility for elements of *handling concerns*. A standard topic guide was used to cover managers' expectations of the system and any observed impacts.

Focus groups with local area teams

Focus groups were undertaken with four area teams (typically comprising 6-8 local assessors and the team manager) – one in each of the Healthcare Commission's four regions. Three teams were selected opportunistically ie the first agreeing to be interviewed in response to the invitation. One team was hand selected because it managed a caseload of healthcare organisations with a higher than average referral rate to the specialist enforcement team. A standardised topic guide was used covering training and confidence in undertaking risk assessment, experience and impact of the planned

collaborative reviews on ways of working, and referral to the enforcement and investigations team.

Observation

A member of the evaluation team attended a session of the training, the planned collaborative reviews and the regional panel meetings between January and March 2009.

Independent survey of risk summit attendees

An independent research consultancy was commissioned to undertake an electronic survey with all 222 attendees in February 2009. The emailed questionnaire covered attendees' perceptions of the preparation required, the experience of assessing risk collaboratively and the impact of the meetings. 115 people responded to the survey – a response rate of 52%. Respondents were representative of the whole group in terms of their employing organisation and the spread of planned collaborative reviews attended [16].

Analysis of referrals escalated for independent sector enforcement

Assessors led on triggering action in respect of non-compliance or serious safety concerns and were required to actively review the position in relation to organisations and escalating to the Healthcare Commission independent enforcement team for consideration of follow-up action.

The independent healthcare enforcement team maintained a record of all referrals received. The number of referrals was analysed before, during and after the rollout of h*andling concerns*. Referrals were expected to increase as a result of the programme

Results

Acceptability

Qualitative findings from the focus groups and interviews revealed that local assessors were familiar with the elements of the *Handling concerns* programme with which they had come into contact.

In particular, awareness of the risk assessment methodology; the process of maintaining a central record (using a standard template) and the planned collaborative review process was high and seemed to be embedded into routine ways of working by the time of the focus groups (March 2009). The pocket guidance was frequently praised and most staff thought the training was useful.

Assessors reported successfully incorporating the risk assessment into their practice (although individuals may have been reluctant in a group setting to admit having difficulties with this). However there was some discussion about how well the five questions fit with day to day situations, especially for independent healthcare sector organisations. For example, independent healthcare organisations are required to have a statement of purpose and the assessors had to check this (among other things). The link between a statement of purpose and risk to patients is not obvious but it still requires follow-up. In other words, the definition of risk needed to be specific enough to relate to real concerns but also broad enough to capture the Commission's statutory duties, if it was to work well as a single framework. Assessors seemed confident in working through these sorts of issues in practice.

The strength of the risk assessment approach was that it is generic in nature and was therefore seen to be adaptable to a wide range of regulatory situations; and based upon a conceptual framework that is familiar to both assessors and the NHS more widely (so the basis for assessors' judgements is recognised by regulated organisations).

Consistency

While assessors' self-reported confidence with the risk-assessment model tended to be high, observation of the training and planned collaborative reviews suggested that some aspects of the method were confusing. In particular people confused whether evidence should be used to support

conclusions on severity or likelihood. Also the way that judgement of risk could be 'moderated' (for example, by assessors' confidence in an organisation's understanding of and capacity to deal with the risk) was not always well understood. The evaluation found that the guidance did not provide sufficiently detailed definitions or prompts to structure decision-making in these areas.

Subjectivity was an issue raised in several of the focus groups and interviews. "*One person's concern could be another person's serious concern*" and borne out by observation at the planned collaborative reviews – where participants at times expressed different levels of concern while drawing on the same evidence. We also occasionally observed instances where the risk assessment was fitted to an assumed level of concern.

In order to address these issues, the guidance has been revised for planned collaborative reviews. [17] [18] [

The quality of staff judgements depend as much on the quality of the evidence and experience in the field as the method of risk assessment itself. While not being a 'magic bullet' for effective decision-making, the risk assessment tools provided a systematic framework for supporting, recording and validating decisions and were generally highly valued by assessors:

> "I've just completed 12 [assessments]. I lived off the pocket guidance. I'm doing [assessments] for other people. Using this I know I can justify the decision. Not just making it up." Assessor

> "It's good to get people thinking in a similar way. More detail about risk – focuses attention where it's actually needed." Central manager

Referral to specialist enforcement and investigations teams

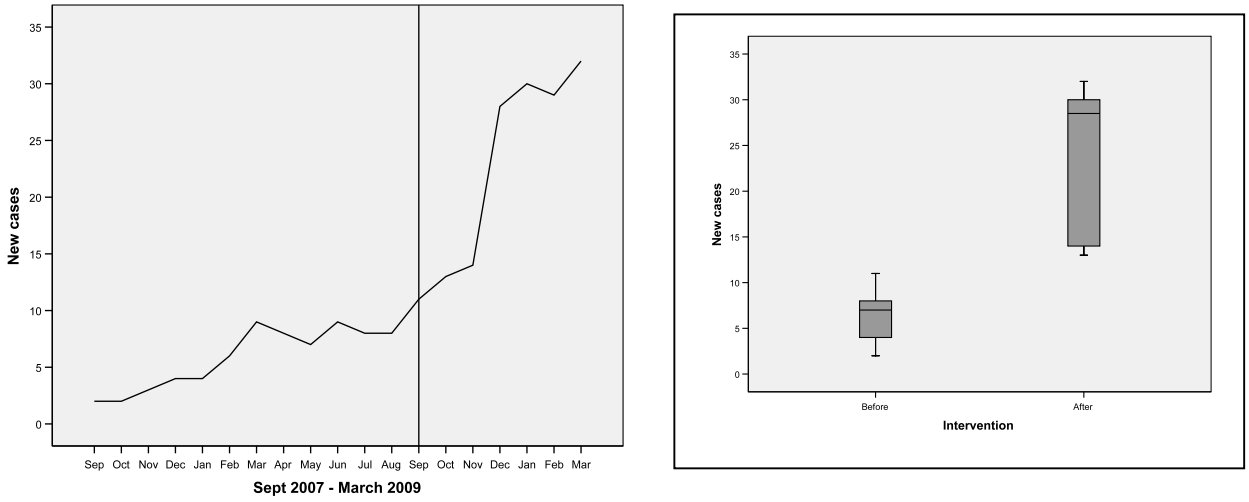
Handling concerns was designed to improve communication and referrals between the Commission's assessment staff and other specialist staff, particularly the enforcement (independent healthcare) and investigations

teams (NHS). Historically rates of referral to the enforcement team were low and the capacity of the team to deal with referrals before July 2008 was also limited.

Analysis of the number of cases managed by the enforcement team reveals a marked increase over the period in question.

In the focus group sessions, assessors reported communication and escalation to have improved, frequently citing the session on escalation as the most useful part of the training. Interviewees from these specialist teams reported that assessors were more likely to make initial contact for advice although in the case of independent healthcare enforcement team, a proportion of these queries were about issues that were inappropriate for escalation.

Figure 2. New cases accepted by the enforcement team per month



The vertical line marks the date that *Handling concerns* was launched

Figure 2 below shows the box plots of new cases pre and post intervention. These differences are significantly different (non parametric test for trend, z = 3.43 Prob > |z| = 0.001).

The impact of collaborative working

The Office of Public Management conducted an independent and anonymous survey of everyone attending the planned collaborative reviews.

Respondents felt that they had an opportunity to contribute to discussions and to question and challenge the evidence at the meetings. There was a good level of consensus about the collective judgements about risk. Over 40% of attendees described the reviews as being *very* useful for their own work.

Asked to identify the tangible impact of attending the meetings, the most frequently cited changes were better joint working and intelligence sharing between regulators. Almost a third of respondents reported undertaking some new regulatory action (eg meeting with a healthcare organisation) as a direct result of attending the summit.

Some also reported postponing or cancelling previously planned regulatory activity. While the numbers here are small (7 respondents), planned collaborative reviews would seem to have the potential to reduce unnecessary regulatory activity (a longstanding complaint from regulated organisations).

Respondents also reported improved understanding of risk assessment as a benefit. The survey also identified areas for improvement. Close to a third of respondents felt the process for submitting evidence could be improved. A number of respondents also felt their own organisations could better align their internal processes to support the meetings. Some respondents felt that the value of the meeting was dependent on the right regulatory organisations being present *and* represented by the right people. Although as reported above, respondents generally agreed with the collaborative judgements, some felt that elements of the risk assessment process could be improved, specifically: the consistency of ratings; relevance of evidence and the weighting given to different types of information.

Strengths and weaknesses

Handling concerns had a positive impact on assessors' ways of working (for example, more serious concerns were escalated to the enforcement team following its launch). However it remains difficult to quantify the effects given the lack of a clear control group. The evaluation tackled this issue by employing multiple methods to identify the likely causes of observed changes and *handling concerns* remains the most plausible trigger given its design, perceived impact and timing.

It is also difficult to identify the *relative* effects of different elements of the programme. In order to explore this issue, OPM included a question in the electronic survey of planned collaborative review attendees. This was directed only to respondents who were Healthcare Commission assessors and asked them to indicate which of a range of initiatives/experience they had found helpful - including elements of the *Handling concerns* programme. The results are shown in Table 2, with the planned collaborative reviews the element of the programme most commonly identified as helpful by this group.

Table 2. "Which of the following developments have been helpful to you in terms of handling concerns about healthcare organisations in the last six months?"

	Number agreeing	%
First-hand knowledge of the local patch	37	82
The collaborative review meetings with other regulators	36	80
The introduction of organisational risk profiles (comprehensive case history of risks and actions for each organisation)	30	67
Cumulative evidence from assessment/inspection/registration	30	67
Formal discussion within your area team (e.g.	30	67

meetings/exception reporting)		
Building up experience in assessor role	29	64
Informal advice from colleagues	29	64
The pocket guidance on handling concerns	27	60
***Handling concerns* training**	27	60
Discussion with other regulatory partners (outside risk summit meetings)	26	53
Awareness of enforcement/investigation options	24	38
Observing how others assess risk (e.g. shadowing or in risk summit)	17	36
The Commission's regional and national risk panel system	16	24
Feedback from the enforcement/ investigation teams	11	7
Not applicable	3	2
Other	1	2

Notes

Number responding: 44

Elements of the Handling concerns programme are shown in bold

Note that not all assessors will have identified any concerns serious enough for referral or escalation which will affect the numbers responding to these elements of the programme.

The evaluation was conducted at the same time as the programme was being rolled out. The 'novelty' of the programme may have influenced some of the responses (ie 'flavour of the month'). Perhaps more seriously, the lack of elapsed time made it difficult to evaluate impact using objective measures (eg an analysis of implemented actions following the collaborative reviews). We have used perceived impact instead as a proxy indicator.

Conclusion

Handling concerns involved a step change in the way the Commission's staff were asked to assess and be accountable for handling risk. The evaluation results provide encouraging evidence to suggest that, just six months after

being launched, the new system was well accepted, visible across the organisation and generally welcomed by staff.

The Healthcare Commission ceased to exist on 1 April 2009 and was replaced by a new integrated health and social care regulator, the Care Quality Commission (CQC). The CQC is continuing to support planned collaborative reviews with its regulatory partners and drew on the Healthcare Commission's Handling Concerns risk assessment process in the development of its own judgement framework for registration decisions.

While there is room for further improvement and refinement, this study shows that a relatively simple framework for setting out risk assessment and acting on concerns can work well, particularly as in this case, when staff may need to identify different types of risks in different settings and while working in partnership with other teams and organisations. Given that users of services tend to be most at risk when moving from one care provider form another the *Handling Concerns* programme provides very valuable learning.

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