Guidance on following up concerns proportionately

Contents

1. Introduction

This guidance describes in detail a framework to enable the evaluation of the level of our concern as a consequence of a worry. At the heart of the framework is an evaluation of risk to individuals, communities and public resources and assets. The framework also provides a range of proportionate options for follow up of that worry.

2. Application

This framework should be applied whenever we evaluate the level of concern in any aspect of the healthcare commission's work with healthcare organisations. It relates equally to one off events, confirmed failures and persistent poor performance.

The framework is "scalable" – it can be applied in proportion to the level of concern. At its simplest, it can be applied using the five questions in table 2 and the level of concern matrix in table 9. The rest of the framework and the complementary education available via People Development [link] are designed to enable:

- consistency in evaluation, decision making and action
- breadth of evaluation, and
- quality assurance of decision making.

Some concerns demand our immediate and urgent action. If, for example during a site visit, you were to see a patient tied to a chair, or a blocked fire escape, immediate action would be needed to ensure safety and well being. It would not be necessary to explicitly evaluate the level of concern in these cases, but having developed an understanding of the framework, you might instinctively be able to justify your reaction using it.

Our decisions about concerns are summarised in the organisational risk profile. They allow us to identify proportionate methods to follow up worries by:

- sharing and/or gathering more information,
- applying levers for improvement with internal and external partners, and
- measuring the effect of our (or others') action.

The follow up methods chosen and responsibility for their implementation are recorded in the regulatory plan.

3. Overview

Concerns arise from a variety of sources. These fall into 3 categories: measured or potential under performance, ad hoc information and clusters of information.

Our evaluation of the level of concern answers the questions:

- "What does this mean for individuals, communities and public resources and assets?" and therefore
- "How concerned are we, the regulator, about this?"

To answer the first question we use a slight modification on the common format of risk assessment:

(likelihood +/- confidence) x (severity + vulnerability) = level of concern.

The measurement of likelihood and severity reflects possible unintended or unexpected adverse impact on the:

- health and well-being of **individuals** – principally patients but also healthcare staff, carers and visitors to healthcare settings
- health and well-being of **communities** (or society as a whole) – particularly those who are at greatest risk of illness or who have poor access to healthcare
- use of **public resources and assets**, in terms of economy, efficiency and effectiveness

The likelihood of "individuals, communities or public resources and assets" being affected is largely dependent on the ability of the healthcare organisation to address the issues and ensure safety and well being. The severity of impact is greater if those affected by the concern are vulnerable e.g. as a result of disability, language barriers, dependence on service provision, age (children or older people), or mental capacity etc.

Because individuals, communities and public resources and assets are at the heart of our analysis, it provides a framework that others can relate to and therefore enables us to explain our concern to those who might help improve healthcare. In particular, this facilitates:

- healthcare organisations' understanding of our level of follow up action,
- negotiations at risk summits or case conferences with others who may have levers for improvement that would help secure effective change and
- discussions with those who can maintain pressure on implementation of healthcare organisations' action plans:
  - for NHS organisations, SHAs
  - for Foundation Trusts, Monitor
  - for independent organisations, where applicable, the Responsible Individual or Registered Provider (who monitor improvement led by the Registered Manager).

To answer the second question, "how concerned are we, the regulator, about this?", we take evaluation of level of concern and decide what action needs to be taken and by whom.

Bringing both the evaluation of level of concern and our decisions on action together our process for deciding what follow up action to take is based on **five key questions**:

1. what is **worrying** us?
2. how **likely** is it that individuals, communities and public resources and assets will be affected as a result of this?
3. how **confident** are we that the necessary improvements are being appropriately made?
4. how **severe** would the impacts on individuals, communities and public resources and assets be?
5. **what action** could be taken by whom to ensure improvement?

It is important that our evaluation and decisions are clear and consistent. The prompts and grading tables in section 5 help ensure consistency and enable quality assurance of decision-making.

4. Terminology

Words used in relation to evaluation of concern are potentially confusing. 'Worry' should therefore be used when referring to worries/sources of concern/risk framework question 1.

Worries go in and concerns come out of our evaluation!
Worries are evaluated to identify concerns and measure risks!

A full glossary is included at Annex D. Table 1 contains key definitions used throughout this document

Table 1 Key definitions

Worry (often incorrectly called a concern: see definitions below)	Our initial reaction to a piece of information or a collection of information which may illustrate potential risks to individuals, communities and/or public resources and assets. (A thing that bothers us for a reason we are not completely sure of, a suspicion or historic evidence of trouble, nothing more.) Risk framework question 1
Concern	One of four descriptions of the level of concern: business as usual, minor concern, concern, serious concern. Risk framework question 5
Concerns	Collectively, a group of minor concerns +/ concerns +/ serious concerns. Risk framework question 5
Source of concern (noun)	Sources of concern are categorised as: measured or potential under performance, ad hoc information or clusters of information. Risk framework question 1
Level of concern	An evaluation of the seriousness of potential risks to individuals, communities and/or public resources and assets. An answer to the questions: "What does this mean for individuals, communities and public resources and assets?" and "How concerned are we, the regulator, about this?" Risk framework questions 2, 3, 4 and 5

5. Processes using this evaluation

A variety of processes make use of this evaluation. In general they enable recording and sharing decisions in a risk profile:

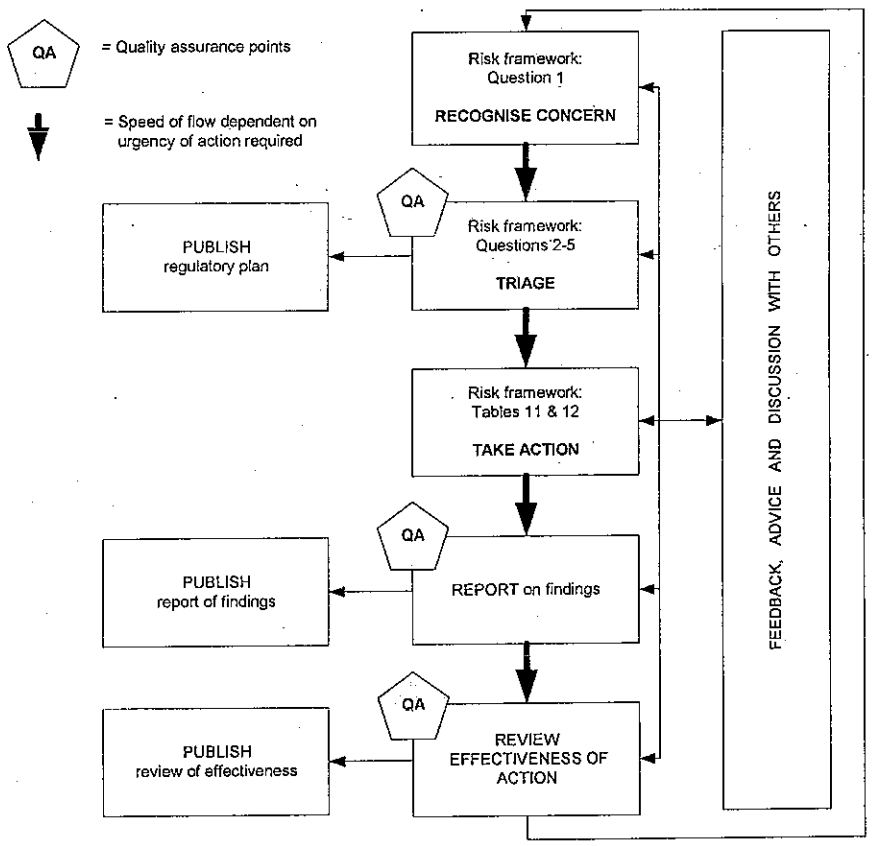
- about what to do in response to a single worry, e.g. in the IH regulatory assessment record (RAR) and other targeted workstreams (implementation increasingly in hygiene code, core standards assessments, controlled drugs, IR(ME)R, reviews & studies, investigations, interventions)
- about what to do in response to multiple or widespread worries, e.g. in the organisational risk profile (ORP)
- in preparation for a risk summit (for single or multiple/widespread worries) e.g. in the organisational risk profile (ORP)

and subsequently recording and sharing decisions in a regulatory plan to enable

- targeted information sharing, joint activity or enforcement
- quality assurance of decision making, record keeping and information flows
- publication of regulatory plans.

These processes are described separately. Generically, they follow the format in Figure 1.

Figure 1 *Generic process for following up concerns*



In many cases it is appropriate to work with Investigations/Enforcement Officers and Legal teams, to ensure that the triage, action and review stages are in line with statutory requirements.

6. What does this mean for individuals, communities and public resources and assets?

Our evaluation of the level of concern enables us to answer the question: What does this mean for individuals, communities and public resources and assets? This evaluation is based upon 5 questions. Table 2 explains the purpose of each of the questions and provides prompts to support the evaluation.

It is important that evaluations made are consistent across the healthcare commission and across all healthcare organisations. The sections following table 2 take each question in turn and contain tables to help those working with healthcare organisations evaluate a concern consistently. They also support quality assurance processes by providing a benchmark against which we can ensure that we are reacting consistently and proportionately to concerns.

The likelihood and severity tables supporting questions 2 and 4 of the risk framework are graded in line with the NPSA's guidance[1] for risk managers, clinicians and healthcare staff generally. Again, this provides a framework that others can relate to and supports consistency of analysis across healthcare organisations.

[1] "A risk matrix for risk managers" January 2008

Table 2 Tool to help consideration of level of concern

Question	The question applies equally to NHS and IH organisations and enables us to…	Prompts (NB prompts only: no need to answer each individually)
1 what is **worrying** us?	➢ identify a source of concern (see table 3); ➢ define or limit an area of concern or describe a frame of reference (e.g. Annual Health Check or Annual Self Assessment for IH organisations, organisational risk profile); ➢ identify relevant published legislation	➢ What are the **sources of concern**? ➢ Is the information **robust**? ➢ Do we have **enough** information to make a decision? ➢ How **up-to-date** is our information? ➢ What **feedback from local people** (patients, carers, visitors, staff, partners) do we have?
2 how **likely** is it that individuals, communities and public resources and assets will be affected as a result of this?	➢ establish latest measurement of **likelihood** that something will happen to individuals, communities and public resources and assets as a result of the thing we're worried about; ➢ show how different this is from the norm.	➢ How **relevant** is the concern to the population and patients served by this organisation? ➢ How **often** may incidents or complaints happen? ➢ Within the total population **how big** is the group that might be influenced (e.g. all sufferers of a particular condition)
3 how **confident** are we that the necessary improvements are being appropriately made?	➢ **modify** our **likelihood** estimate in terms of organisational capability; speed and direction of travel; ➢ establish our **confidence** in the organisation's ability to improve without our intervention; ➢ see whether or not we need to intervene, or enable others to intervene to ensure improvement.	➢ Is this a **general** failure across the whole of the healthcare organisation or restricted to a particular part of it? ➢ Is the organisation **capable** of identifying and responding to this failure appropriately? ➢ What is the organisation's **history** of compliance and response to regulatory concern? ➢ Is current management mitigating **future** problems? (e.g. deficiencies in training today may result in poorly prepared staff tomorrow) ➢ Are **other** regulators or improvement bodies already helping to overcome this concern?

4 how **severe** would the impacts on individuals, communities and public resources and assets be?	➢ judge **severity** of impact on individuals, communities and public resources and assets e.g. identify any severe risk to the safety, health or well being of a person or community. ➢ modify our severity consideration to take account of impact upon **vulnerable** people.	➢ How **long** will the impact be felt for? ➢ What **proportion** of the group identified in question 2 might be influenced (e.g. 20% of all sufferers of that condition) ➢ How much **treatment or care** will be needed to overcome the impact? ➢ How will **treatment or care costs** change in relation to the budget? ➢ What effect will this have on **human resources**, organisational development, staffing levels or staff competence? ➢ Will this impact **efficiency** of organisational or project management, or **access** to the service? ➢ Will they or we have adverse **publicity** as a result of this? ➢ Will increased **litigation** impact on the public purse? ➢ What impact will this have on the **environment** in which care is given or the environment enjoyed by the community? ➢ Are the people affected by the concern particularly **vulnerable** i.e. dependent on staff to safeguard their rights and well-being?
5 **what action** could be taken by whom to ensure improvement?	➢ conclude the **level** of the concern (business as usual, minor concern, concern or serious concern); ➢ guide our priority for action and enable appropriate follow up; ➢ justify use of public resources on this concern; ➢ identify the best lever for improvement and enable agreement to act accordingly.	➢ What is the **risk** to individuals, communities and public resources and assets and therefore what is our **level of concern**? ➢ What other regulatory plans are in place? Is it appropriate to treat this concern separately, or should we address it as part of a **cluster** of concerns? ➢ Who has the best lever for **improvement** in this situation? ➢ Do we have enough evidence to enable us (or others) to use enforcement **powers** to react effectively to this concern? ➢ Will regulatory action result in **new risks**? Do they outweigh the original risk? e.g. what happens to patients if a service closes? ➢ When do I want to **review** this plan? ➢ Are the **performance manager** and the **healthcare organisation** maintaining pressure on implementation of organisation's action plans?

Question 1: what is worrying us?

The first step in evaluating the level of a concern is establishing the source of our concern. This involves describing and evaluating the information that is causing us to worry using the prompts in table 2. The first prompt is: what are the sources of concern? Table 3 categorises sources of concern as either: measured under performance, ad hoc information or clusters of information and provides some examples of each:

Table 3 Examples of sources of concern (question 1)

e.g. measured or potential under performance*	e.g. ad hoc information*	e.g. clusters of information*
• unusual performance indicators • screening processes • single instances of non-compliance • clinical outliers • breach • offence • partner bodies' findings • surveys	• local intelligence • corporate correspondence • newspapers • the help-line • whistleblowers • information or referral from partner organisations • statutory or SUI notifications • patient intelligence ('concerning information' in IH and the equivalent in NHS) • safeguarding information • complaint analysis	• unusual trends in local intelligence • serial non-compliance (over time; within or across the same or different areas) • serial fair performance (over time; within or across the same or different areas) • geographical trends in performance • trends in performance over specific topic areas/ requirements

* This list is not exhaustive

Our evaluation of level of concern should be carried out only where observations are outside normal limits. For example, we know that deaths caused by anaesthetic errors are very rare, occurring in about 1 in 185,000 general anaesthetics given in the UK[2]. Measured performance outside of this range would be a source of concern. Some organisations do "just enough" to get through an assessment. Doing this repeatedly is a source of concern. Some organisations fail against one or two targets or have the occasional safeguarding concern. Widespread failure or a pattern of safeguarding incidents is a source of concern.

Many of the healthcare commission's information analysis systems, particularly those associated with annual assessments, are focused on identifying the risk of (sometimes undeclared) non compliance against standards and regulations. In those systems, engagement forms are analysed to identify "nuggets". These are then coded and entered into IH or NHS screening databases to provide an indicator of likelihood of non compliance against a particular standard or regulation. In this way, ad hoc information is used twice: first, on receipt to see if any individual worries are generated, and then within a screening database in support of assessment against standards and regulations. In effect, this is a form of clustering, an illustration of how we can use all of the information we hold, looking at it from different angles, giving us an early warning of potential concerns. By bringing together all of our concerns into one place, the organisational risk profile does the same thing.

[2] Risks associated with your anaesthetic - Information for Patients: The Royal College of Anaesthetists

Question 2: how likely is it that individuals, communities and public resources and assets will be affected as a result of this?

Many policies, procedures, structures and guidelines are developed to help reduce variation and reduce the likelihood that something unexpected or unintended will happen or recur. Many of our systems for measuring performance, measure the presence or effectiveness of this type of control measure. They therefore, often indicate how likely it is that something unexpected or unintended will happen or recur. For example, poor commissioning structures and processes are more likely to result in poor service provision in relation to the needs of the community or poor value for money. A history of not achieving performance requirements or performing poorly against defined indicators, suggests likely future poor performance.

Not all of our likelihood considerations are already measured. Not all worries can be mapped to standards or requirements. Some worries are based on ad hoc information. In these cases we consider the source of concern in context, to judge the likelihood that individuals, communities and public resources and assets will be affected. Table 4 helps us to grade our likelihood judgements consistently, whatever the source of concern. NB the full wording for each prompt is included in table 2. Each has been summarised or shortened to fit into this table.

Table 4 Likelihood grading (question 2)

Likelihood prompts from table 2	Rare	Unlikely	Possible	Likely	Almost certain
➢ How **relevant**	Not relevant to the affected individuals, community and/or public resources and assets	Might be relevant to a few of the affected individuals, community and/or public resources and assets	Definitely relevant to some of the affected individuals, community and/or public resources and assets Breach of legal requirement	Definitely relevant to most of the affected individuals, community and/or public resources and assets	Definitely relevant to all of the affected individuals, community and/or public resources and assets
➢ How **often**	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will probably happen/recur, possibly frequently
➢ **How big** is the group	<0.1 per cent of the total population	<0.1-1 per cent of the total population	<1-10 per cent of the total population	<10-50 per cent of the total population	>50 per cent of the total population

Question 3: how confident are we that the necessary improvements are being appropriately made?

The estimate of likelihood can be modified by consideration of our confidence in the organisation's direction of travel, history of response to regulatory concerns and engagement of other partners. In particular repeated failure to meet standards and regulations, or repeated failure to meet patient expectations would probably lead us to increase our judgement of the likelihood that individuals, communities and public resources and assets will be affected as a result of a source of concern.

There is no pre-determined formula for applying this modification – it is a judgement call as to whether the current management will affect (reduce or increase) the likelihood of an outcome or not. Table 5 provides examples to grade this judgement.

Table 5 Confidence grading (question 3)

Prompts from table 2	Not confident	Confident	Very confident
Response to concerns	Consistently causing concern. Previous concerns not responded to well	Few concerns raised and generally well responded to	Concerns rare and always well responded to
Leadership capability and capacity	Not recognising problems or evaluating them well	Recognising and evaluating problems well. Willing to modify plans to speed up or better enable improvement	Recognise own issues, evaluate them well and appropriate plans in place to address them
Partnership	Few or unsuccessful partnerships in place	Partnerships in place and improvement ongoing	Appropriate partnerships in place. All relevant partners engaged.
Governance & assurance systems	Policy written but not implemented. Poor or incomplete systems. Failures against compliance with standards	Systems implemented and improvement ongoing	Systems fully implemented and performance improvement systems in place
Patient and public involvement	Few or unsatisfactory systems in place	Systems implemented and improvement ongoing	Systems fully implemented and performance improvement systems in place

Question 4: how severe would the impacts on individuals, communities and public resources and assets be?

Lack of analysis of severity of impact is the key difference between our routine operational systems and our investigations and legal processes. Aligning these processes is essential to ensure consistency across our follow up framework.

When considering the severity of any particular outcome, we tend to focus on impacts to patients in terms of their physical or psychological well being. This is of **primary** importance but tends to ignore for example, longer term, public health and equality considerations. Table 6 is intended to trigger a wider consideration. This enables us to identify others who can help to stimulate service improvement (question 5). Our evaluation should cover all relevant impacts though we only need to record those relating to safety and the most severe to support our evaluation. Impacts on individuals, communities and public resources and assets fall into two categories:

- failure to do good or promote well being or
- detriment.

Table 6 Types of impact to consider under question 4

Failure to do good or promote well being affecting	For example...
Individuals: • patients, • carers, • staff or • visitors	Increased social isolation Increasing inequalities Decreased independence
Communities or groups of people	Increased population ill health Increased population infection rates
Public resources and assets	Missed opportunity to make savings Inappropriate opportunity costs (cost of what was not done) Increased cost as a result of delay

Detriment affecting	In terms of	For example
Individuals: • patients, • carers, • staff or • visitors	Physical or psychological well-being	Injury or illness (physical or mental) Reduced life expectancy Impaired quality of life Incapacity or disability Unexpected or unnatural death Unexpected clinical complication Compromise to a person's self esteem Distress & anxiety Healthcare acquired infection
	Dignity	Delay or omission in implementation or review of treatment Lack of assistance with basic needs e.g. feeding, washing, dressing Discomfort or embarrassment
	Rights	Breach of privacy or confidentiality Lack of engagement of family, friends and carers Lack of informed consent to care or treatment Unreasonable restraint, seclusion or detention against will without the proper legal processes and safeguards or with incorrect compliance with these processes Increased inconvenience or cost Lack of engagement in care planning
	Security of individuals and property	Physical insecurity of individuals or property Detained patients absent without leave Abduction of vulnerable person
Communities or groups of people	Public health	Contamination by hazardous material Spread of infectious disease
	Equality and equity of access to care or treatment	Lack of access to services Lack of choice Inequity of access
	Societal concerns (originating from public aversion to characteristics of the concern)	Fear of healthcare acquired infection Fear of loss of access to services Loss of confidence by society in: ➢ the provisions and arrangements in place for protecting people and; ➢ duty-holders ability to ensure well being.
Public resources and assets	Public resources and assets	Financial loss or poor value for money Poor use of fixed assets Unsustainable use of assets and resources Poor use of "recycle, reduce, reuse" opportunities
	Commissioning	Inadequate commissioning Inefficient or ineffective commissioning
	Healthcare community sustainability	Poor organisation financial standing Inappropriate satisfaction of population healthcare needs Lack of workforce planning or training provision
	Delayed impacts	Future poor clinical outcomes Future poor health Future delayed health improvement

Whether formally recorded or informally considered, we are already using severity of impact to help us decide whether or not, and how, to follow up a worry. This is probably the most judgemental element of the evaluation of level of concern. Table 7 helps ensure consistency in this judgement. NB the full wording for each prompt is included in table 2. Each has been summarised or shortened to fit into this table.

Table 7 Severity grading (question 4)

	Estimate of the severity or impact of the concern		
Prompts from table 2	Minor*	Moderate*	Major*
➢ How **long**?	Requiring time off work for <3 days Increase in length of hospital stay by 1-3 days <10% schedule slippage	Requiring time off work for 4 - 14 days Increase in length of hospital stay by 4 - 15 days 10-40% schedule slippage	Requiring time off work for >14 days Increase in length of hospital stay by >15 days >40% schedule slippage
➢ What **proportion** of the group identified might be influenced	< 10% of the group	10 – 50% of the group	>50% of the group
➢ How much **treatment or care**?	Minor injury or illness, requiring minor intervention	Moderate injury requiring professional intervention RIDDOR/agency reportable incident	Major injury leading to long term incapacity/disability or death Mismanagement of patient care with long-term effects
➢ How will **costs** change?	Loss of 0.1–0.25 per cent of organisational budget <5 per cent over project budget	Loss of 0.25–0.5 per cent of organisational budget 5–10 per cent over project budget	Uncertain delivery of key objective / Loss of >0.5 per cent of organisational budget >10 per cent over project budget Failure to meet specification Purchasers failure to pay on time/Loss of contract / payment by results
➢ What effect will this have on **human resources**?	Low staffing level that reduces the service quality	Late delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>1 day) Low staff morale Poor staff attendance at mandatory/ key training	Uncertain delivery of key objective/service due to lack of staff Unsafe staffing level or competence (>5 days) Loss of key staff No staff attendance mandatory training /key training
➢ How will this impact **efficiency or access**?	Loss/interruption of >8 hours	Loss/interruption of >1 day	Loss/interruption of >1 week
➢ Will they or we have adverse **publicity**?	Local media coverage – short-term reduction in public confidence Elements of public expectation not being met	Local media coverage – long term reduction in public confidence Low performance rating	National media coverage with >3 days service well below reasonable public expectation. MP concerned (questions in the House) Total loss of public confidence
➢ Will increased **litigation** impact on the public purse?	Claim less than £10,000	Claim(s) between £10,000 and £100,000 Breach of legal requirement	Claim(s) >£100,000
➢ Will there be any **environmental** impact?	Impact on environment restricted geographically or easily overcome	Impact on environment county-wide or challenging to overcome	National impact on environment or impossible to overcome.

* NB: our threshold for 'minor' is equivalent to the NPSA's "negligible' + 'minor' and our threshold for 'major' is equivalent to the NPSA's 'major' + 'catastrophic'. The NPSA have no definition for serious untoward incident but our threshold for 'major' would normally be considered to be equivalent.

Vulnerability modification

The healthcare commission has specific responsibilities in relation to safeguarding children and vulnerable adults. Therefore, this framework requires specific consideration of the vulnerability of the population affected by the source of concern. Again, this is not new: at it's simplest, we are often less willing to accept documentary evidence or telephone follow up where patients are in a vulnerable position (as in mental health establishments).

In every instance we need to consider whether the people whose health, well being and assets are affected by the source of the concern are in any way vulnerable e.g. as a result of disability, language barriers, dependence on service provision, age (children and older people), or mental capacity etc. If they are, our estimate of severity must be modified according to table 8:

Table 8 Vulnerability modification (question 4)

	Consider severity increase	Increase severity	Consider two levels of seventy increase
➢ Are the people affected by the concern particularly **vulnerable**?	Yes but they can express themselves clearly and/or are not totally dependent on the service	Yes but they find it difficult to express themselves clearly and/or they are partially dependent on the service	Yes and they cannot express themselves at all and/or they are fully dependent on the service

7. How concerned are we, the regulator, about this?

Having described and evaluated the potential impacts that the source of concern may have on individuals, communities and public resources and assets, the next step in our evaluation grades the level of concern. Based upon this, we can explain our response as a regulator and enable appropriate follow up. The agreed follow up is recorded in a regulatory plan.

Once the organisation has been informed of our plan of action (documented in a regulatory plan), it will be published on the healthcare commission and the concordat websites. That is, once any information gathering activity or enforcement action outside 'business as usual' is implemented (e.g. when an investigation is announced, or an improvement notice is issued) the record of the plan agreed is published.

Question 5: what action could be taken by whom to ensure improvement?

Establish the level of concern by mapping the judgements made above on likelihood (as modified by the confidence consideration) and severity (as modified by the vulnerability consideration) against on the axes of table 9. Read across and down to the point where the judgements intersect to identify the level of concern.

Table 9 *Grading the level of concern (question 5)*

Likelihood of occurrence or recurrence	Estimate of the severity or impact of the concern		
	Minor	Moderate	Major
Rare			
Unlikely	Business as usual		
Possible		Minor Concern	
Likely			Concern
Almost certain		Serious Concern	

Depending on the level of concern we are required to undertake appropriate activity or use appropriate enforcement powers or levers for improvement to follow up the concern. Table 10 defines the levels of follow up action available to us.

Table 10 *Levels of follow up action*

Level of concern	Activity	Enforcement powers and levers for improvement	What to do when concerns arise on site
Business as usual	Maintain pressure on healthcare organisation's action plan implementation	Business as usual	No concern
Minor concern	Take action to mitigate risk, normal priority: we think it will improve if we, or others recommend they take action	Level 1	Discuss & agree with line manager. Document it, include in the report with an appropriate follow up plan.
Concern	Take action to mitigate risk, high priority: we think it will improve if we, or others require healthcare organisation to take action	Level 2	Raise the issue with senior provider staff on site. Discuss & agree planned regulatory action with own line manager. Ask for confirmation that it's been addressed within a month. Document it including the follow up plan agreed on site and any further regulatory action necessary.
Serious concern	Take action to mitigate risk, urgent priority: we think we, or others need to take enforcement action to make sure it improves or close it down	Level 3	Discuss & agree action with own/available line manager while still on site. Detail concern to senior provider staff on site. Check that it's been addressed before you leave the site if it can be. Document it including the follow up plan agreed on site and any further regulatory action necessary.

The healthcare commission's legal responsibilities and responsibilities of other agencies provide different levers to enable improvement at each of these levels. Tables 11 and 12 of this guidance help us identify where it may be useful to share our evaluation of the level of concern with others:

- Table 11 identifies where others may have historical information, or may be able to obtain more information using their activities to enable us to get a fuller, more rounded picture of the concern. These activities also enable collection of evidence to support use of enforcement powers or levers for improvement.
- Table 12 identifies where others may have levers for improvement or enforcement powers that may help improve safety, well being and effective service delivery.

Table 11 Activities to enable exercise of powers by the healthcare commission and partner organisations

Gaps and alternatives to be completed at a workshop with partner organisations

Activity level	NHS			Hygiene code (NHS)	IH (registered)	IH (unregistered)	IRMER (NHS & IH)	Controlled Drugs
	General	Core standards	Targets					
Business as usual	*reviews and studies	*annual health check *inspection *engagement[3]		*inspection *engagement[3]	*annual self assessment *RAR *inspection & report *engagement[3]	*unregistered provider log *engagement[3]	*inspection *engagement[3]	*engagement[3]
Minor concern		*engagement following action planning		*engagement following recommend-ations	*engagement following requirements or concerns			
Concern	*intervention *initial consider-ations			*improvement notice	*serve a notice on a person *engagement following Reg 51		*engagement following improvement notice	
Serious concern	*investigation where worries meet investigation criteria				*evidence gathering to enable Civil and/or Criminal action	*evidence gathering to enable Civil and/or Criminal action	*evidence gathering to enable prohibition notice or prosecution	

[3] Engagement may be any form of communication

Table 12 Enforcement powers and levers for improvement available to the healthcare commission and partner organisations

Gaps and alternatives to be completed at a workshop with partner organisations

Powers level	NHS			Hygiene code (NHS)	IH (registered)	IH (unregistered)	IRMER (NHS & IH)	Controlled Drugs
	General	Core standards	Targets					
Business as usual								
Minor concern	*plan improvement process	*requirement to put in place an action plan *issue notification letter		*recommendations	*requirement to make improvements			
Concern	*'formal recommendations' following an intervention or initial consideration			*improvement notice	*reg 51 - statutory notice of requirements		*improvement notice	
Serious concern	*recommendation to SoS or to Monitor to take special measures				Civil *remove change or Impose condition on registration *cancel registration *issue simple caution Criminal *prosecution	Civil *injunction Criminal *prosecution	*prohibition notice *prosecution	

Using this framework as a basis for working with others

Throughout this document we have emphasised the necessity of ensuring that others can relate to our analysis. Using tables 11 and 12 we have identified who else may be interested in the worry and may be able to help ensure safety, well being and effective service improvement. Both risk summits (external people) and case conferences (internal people) are held as and when concerns arise which would benefit from consideration or partnership with others.

These events (meetings or teleconferences as appropriate) have a threefold purpose:

- they enable data sharing at a local level
- they enable discussion about a particular concern, or a series of particular concerns
- they enable agreement of joint regulatory plans at a local level.

Looking back to Figure 1, Risk Summits or Case Conferences provide some structure for FEEDBACK, ADVICE & DISCUSSION WITH OTHERS.

Planned risk summits, triggered risk summits and case conferences are defined in the glossary at annex D. Guidance on organising a risk summit or a case conference, and responding to invitations to attend one is given separately.

It is important to remember to apply the Information Framework and if necessary, liaise with the Information Governance team when dealing with external bodies to ensure that the commission does not breach any information law requirements.

The record of our input to either process is the organisational risk profile and the record of the agreed outcome is the regulatory record and plan (Annex C).

8. Record of consideration

We could probably identify a wide range of answers to the question "what does it mean to individuals, communities and public resources and assets?" each more or less likely to actually happen. In order to limit our consideration, we only need to identify and record:

- the highest risk along each axis of evaluation i.e.
  - the most **likely** impact of the concern and how severe that is, and
  - the most **severe** impact of the concern and how likely that is
- and any safety risks.

Record keeping requirements are often different depending on the process within the healthcare commission within which the evaluation is taking place e.g. investigations, assessment of IH organisations, issue of regulation 51 notices etc. These are normally embedded into individual workstream processes.

Unless otherwise stated, for individual concerns

- the template for consideration of level of individual concerns (Annex A) provides the record of our decision making process.
- the template regulatory plan for individual concerns (Annex B) provides the record of our regulatory plan.

In addition, all healthcare organisations will have:

- an organisational risk profile (sections B to D of Annex C or equivalent for non NHS organisations) and
- a regulatory record and plan (section E of Annex C or equivalent for non NHS organisations).

These provide the record of our decision making process across a healthcare organisation, a group of organisations or a geographical area. They enable identification of clusters of concerns and provide a record of information gathered at a risk summit or a case conference.

The amount recorded must provide an appropriate audit trail. This is not defined explicitly here. The balance between provision of detail and time constraints will be for quality assurance processes to determine. However, table 13 provides some guidelines.

Table 13 Guidance on contents of records

Question	Record	Conclusion
1 what is **worrying** us?	➢ Describe the concern or list failures, non-compliances, breaches, offences ➢ Describe briefly nature of information upon which the consideration is being made (a range from complete to patchy and current to old) ➢ Summarise local feedback	Organisational rating – weak, fair, good or excellent (NHS only at the moment)
2 how **likely** is it that individuals, communities and public resources and assets will be affected as a result of this?	➢ Describe briefly considerations in relation to the prompts in the guidance ➢ Judge what is likely to happen and grade that using the likelihood grading	Likelihood – rare, unlikely, possible, likely or almost certain
3 how **confident** are we that the necessary improvements are being appropriately made?	➢ Describe briefly considerations in relation to the prompts in the guidance ➢ Review the likelihood judgement made in question 2 and if necessary modify the grading	Confidence – not confident, confident, very confident Modified likelihood – rare, unlikely, possible, likely or almost certain
4 how **severe** would the impacts on individuals, communities and public resources and assets be?	➢ Describe briefly considerations in relation to the prompts in the guidance ➢ Specifically describe vulnerability modifier and it's effect on severity ➢ Judge the potential impacts and grade them using the severity grading	Severity – minor, moderate or major NB note also modification to reflect vulnerability of those affected
5 **what action** could be taken by whom to ensure improvement?	➢ Bring together the modified likelihood and severity judgements to grade level of concern ➢ Describe briefly considerations in relation to the prompts in the guidance	Level of concern – business as usual, minor concern, concern and serious concern Plan to ensure improvement in safety, well being and service provision

Quality control of these decisions is carried out at national risk panels and quality assurance at regional risk panels. At the root of this analysis is the question "what does it mean to individuals, communities and public resources and assets?" Therefore, it may be appropriate for patient and public representatives to be part of this quality assurance process.