CQC Learning from Deaths Monitoring and Inspection Tool – Long Guide (Interim Guidance draft 5 September 2017)

| Well-led 8: are there robust systems and processes for learning, continuous improvement and innovation? |
| Well-led 8.3 How effective is participation in and learning from internal and external reviews, including those related to mortality or the death of a person using the service? Is learning shared effectively and used to make improvements? |

**Background**

This tool is designed to provide a systematic way to assess how providers learn from reviews and investigation of deaths. The method builds on CQC’s thematic review “Learning, candour and accountability” published in December 2016 (http://www.cqc.org.uk/publications/themed-work/learning-candour-and-accountability). This found that “many carers and families do not experience the NHS as being open and transparent and opportunities are missed to learn across the system from deaths that may have been prevented.”

It should be applied to services provided by NHS acute, community and mental health trusts. It excludes services such as those that are NHS funded but provided by independent providers. This is the same scope as the CQC thematic review.

The approach tests the progress NHS trusts have made in meeting national guidance on Learning from Deaths, that sets out what families and carers should expect, and will highlight any good practices. The national guidance issued on March 2017 (https://www.england.nhs.uk/wp-content/uploads/2017/03/nqb-national-guidance-learning-from-deaths.pdf) focusses on NHS acute care, with later national guidance expected on NHS provided mental health services and NHS provided community health services. This is the start of a development journey for NHS trusts and CQC is not expecting trusts to have implemented all the requirements in the short period since March, especially as some guidance has still to be issued. So we are looking at where NHS trusts have got on their development journey.

This guidance uses a set of good practice principles that have been developed by the NHSI Safety Team and the Healthcare Safety Investigation Branch. The method has been piloted in the summer 2017 at three NHS trusts, two acute and a mental health provider, and through public comment through the CQC website and electronic community, with around 100 responses which have helped shape the approach.

An overview of the review process is given in the flowchart below. Further detail on the approach is in the Long Guide to Learning from Deaths, published alongside this document.
Flowchart of Method for Assessing Provider’s Learning from Deaths

**Monitoring: analysis of intelligence on risk & recurrent problems:**
- Family, carer & other concerns
- Individual investigation findings (e.g. PHSO, Coroners)
- Intelligence from partner organisations (e.g. CCGs & GPs)
- Intelligence from the provider (e.g. PALS, bereavement services, Duty of Candour)
- Review of NHS trust policy against 5 principles* & national guidance (for each trust by September 2017)

**Monitoring: Case Review** - if raised risk - obtain list of recent reviews and investigations of deaths, inspection team select at random up to 4 cases including, where possible, deaths of person with learning disability and mental health problem. Give families & carers opportunity to feedback on their experiences. Assess cases against 5 principles* and good practice

*Five NHSI/HSIB principles:*
1. Strategic
2. People focussed
3. Preventative
4. Expert led/credible
5. Collaborative

**Well-led inspection triggered**

Set up trust interviews: Non – Exec lead, Exec lead, Head of Quality & Safety, 1 or 2 investigators, family liaison persons – add questions to any existing/new interview

Summary of findings by 5 principles* using interview grid

Corroborate with other information on learning from incidents e.g. complaints, Duty of Candour reporting, Coroners reports, PHSO investigations findings

Report under Well-led KLOE 8.3 with a paragraph on findings

Report main findings back to central team
Monitoring: reviewing intelligence relevant to providers learning from deaths

Intelligence for monitoring and relationship management includes:

This includes gaining insight from gathering the views of families, carers and others on learning from deaths. Families and carers will have the greatest knowledge of the person who has died and see the whole pathway that their relative experienced. When we consulted on this approach there was a clear message from families and carers who responded that they be given the opportunity to be asked directly about the positives and negatives of their experiences of how their relative death was reviewed and investigated. CQC needs to have a range of methods to directly communicate with families and carers about their experiences such as on-line forms, telephone interviews, talking to existing family support groups, individual or group interviews. Also it is proposed that families and carers are given the opportunity to be asked and to answer the same questions about their relatives death in the individual case reviews – see Annex B for suggested questions for a telephone interview or to put in an e-mail to gather experience of families and carers.

- Local Clinical Commissioning Groups should be contacted prior to inspections and asked to highlight any issues they have heard from GPs and others about the quality of reviews and investigations carried out by the provider. Commissioners are responsible for conducting quality assurance reviews of all investigation reports and are required to do this within 20 calendar days – see page 44 of the Serious Incident Framework: https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf.

- Collecting and analysing the mortality data for individual NHS trusts that they must collect on Deaths. This should not be used for comparisons between trusts – as it can be counted differently in different trusts and is not straightforward to interpret as the reasons for differences between organisations have not been fully explained. However it can be used to check on the progress made in collecting the data and how Boards and local leaders are using it as a source of learning. The information NHS trusts must collect, from April 2017 on a quarterly basis, includes:
  - The total number of deaths of people in their care (including the Trust’s in-patient deaths, which includes Emergency Department deaths for acute trusts) – deaths for people with a learning disability are recorded separately
  - The total number of those deaths the Trust has subjected to case record review – shown separately for those assessed by the Royal College of Physicians methodology and the LeDeR methodology
  - Of these deaths subject to case record review, estimates of how many deaths were judged more likely than not to have been due to problems in care – recorded separately for people with a learning disability
  - Accompanied by relevant qualitative information and interpretation.

- The new CQC Provider Information Returns includes information to review on:
  - PHSO upheld/partially upheld investigation complaints cases and action plans
  - regulation 28 Coroners reports to follow-up to see what action has taken place
Monitoring: Analysing up to four reviews and investigations of recent deaths

The trigger as to whether to carry out this analysis is where there are concerns raised by a family or carer or from other sources of evidence that recurrent problems are occurring in terms of learning from deaths.

The analysis is part of monitoring in order to spread the activity across the year, it can be done to respond to concerns, there is the opportunity to apply a standard approach, can be combined with other monitoring activity such as Duty of Candour (?), can be used to focus the on-site inspection work.

This activity is seen as the most valuable by families & carers and health professionals, based on CQC website responses to the approach. Benefits of the case review are that it is a way to test:

- The extent to which the trust’s policy is implemented in reviews and investigations of individual deaths
- The engagement with families and carers for instance through the tone, stage and content of communication
- Whether the investigation of the deaths of people who are vulnerable through their circumstances, such as having a learning disability, are treated the same as other people who have died

The resources involved are within a range of 3 to 4 hours of the time of a medical director special advisor and 4 to 5 hours of a specialist inspector.

A list of recent deaths in the last year (to consider cases after the national guidance was issued in March 2017) needs to be provided by the trust, rather than focus on investigations, to test how all deaths are reviewed rather than those selected for investigation. From this list the inspection team should select at random a sample of four cases. This should include the death of a person with a learning disability and a death of a person with mental health needs (for acute and community trusts only, in mental health trusts it is assumed that all patients will meet this criteria)). Asking whether the provider can identify people who have died with these characteristics will help to test the ability of the provider to record disabilities in NHS records so care can be managed appropriately. If possible, the cases selected might include at least one case that has been concluded, so as to demonstrate the whole investigation process.

The trust should be asked for each case file which has details of correspondence. It should be explained that CQC needs this information to assess the processes of the trust and will not disclose information about the individual cases.
A framework for analysing the individual cases is at Annex B. There is benefit in comparing the findings from the investigations of these deaths with the analysis of serious incident investigations and complaints – to see if there are common themes around the extent that the provider learns from deaths.

**Monitoring: Reviewing the trusts policy on responding to deaths**

The National Guidance expects that this should set out how the trust will respond to and learn from deaths of patients who die under its management and care. Each trust should publish an updated policy by September 2017 including:

- “How its processes respond to the death of someone with a learning disability, or mental health needs, to an infant or child death, to a stillbirth or to a maternal death”
- “The Trust’s approach to undertaking case record reviews.” Acute trusts should use an evidence-based methodology for reviewing the quality of care provided to those patients who die. This could include the Structured Judgement Framework (SJR) of the Royal College of Physicians or the PRISM methodology. Methods for mental health and community trusts are not developed but the SJR can be used as a starting point and adapted by these providers to reflect their individual service users and clinical circumstances. The case records review of deaths of people with learning disabilities by acute, mental health and community trusts should adopt the methodology developed by the Learning Disabilities Mortality Review (LeDeR) programme in those regions were the programme is available.
- “Categories and selection of deaths in scope for case record review: As a minimum and from the outset, Trusts should focus reviews on in-patient deaths.....In particular contexts, and as these processes become more established, Trusts should include cases of people who had been an in-patient but had died within 30 days of leaving hospital. Mental Health Trusts and Community Trusts will want to carefully consider which categories of outpatient and/or community patients are within scope for review taking a proportionate approach. The rationale for the scope selected by Trusts will need to be published and open to scrutiny.”
- “Providers should have a clear policy for engagement with bereaved families and carers, including giving them the opportunity to raise questions or share concerns in relation to the quality of care received by loved ones.”
- Annex A includes a more detailed checklist of key points from the National Guidance
Regulatory planning meeting for provider level well-led inspection

At the Regulatory Planning Meeting, for the provider level well-led assessment, the following decisions need to be taken:

Setting up the interviews for the on-site inspection for Provider level well-led assessment

1. Review the intelligence from monitoring and any case review to adapt interview questions.
2. Review the information published by the trust in the Quality Accounts or Board reports relating to learning from deaths
3. Set up the interviews with:
   a. Lead non-executive interviews – who is the designated Board lead on deaths, what Board discussion is there, progress have they made and plans, etc. – could a few questions be included in the Non Executives Directors?
   b. Executive lead on learning from deaths – you have already included this in the meeting with the Medical Director or Nursing Director.
   c. Head or Lead on safety and quality – ask about organisation of reviews and investigations into deaths and what is done with the learning - would these questions fit in the other related meetings with groups that monitor and manage quality of care.
   d. Investigators - talking to one or two staff who have carried out investigations (might be those who worked on the four cases reviewed in depth) to test how they were selected, independence, trained and supported, how learning spread, etc.
   e. Services in the trust that support families and carers such as bereavement counsellors, PALs, family liaison officers, Chaplins or others. Ensure that at least people in one of these support roles are interviewed.

Ensuring there is the necessary expertise on the inspection team from either/or:

- Special advisor medical director to provide clinical knowledge to
  o asking the additional questions to be added to existing or extra interviews
  o understand the results from the reviewing the four death cases – understanding the practical applications of root cause analysis methods in clinical environments and whether the necessary learning has taken place

- Specialist inspector with some of the following attributes
  o Experience of the Deaths Thematic Review so understands the key issues and broad methods
  o Understands the requirements of the national guidance on learning from deaths
  o Received training from material housed in the CQC Academy including guidance developed by NHSE and NHSI (videos, guides etc. available)?
- Participates in CQC experience sharing workshops and a CQC learning community
- Able to support the reviewing of the four death cases – understanding the practical applications of robust root cause analysis in clinical environments
Questions to ask during the on-site inspection

These questions are structured around a set of principles developed by the NHS Improvement Safety Team and the Healthcare Safety Investigation Branch. You can print this table and use it during interviews to record findings.

<table>
<thead>
<tr>
<th>Key principle (NHSI/HSIB)</th>
<th>Element</th>
<th>Question asked</th>
<th>Possible evidence sources</th>
<th>Main findings</th>
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<tbody>
<tr>
<td>Strategic – the focus is on quality of output and not just quantity of reporting; resources are invested in identifying cases and investigated work to support good quality outputs.</td>
<td>Fewer better/quality not quantity - Strategy, policy, rationale and process</td>
<td>What policy and process do you have/are developing to identify deaths for review and investigation to meet the national guidance on learning from deaths? (National Guidance expects each NHS trust should publish an updated policy by September 2017)</td>
<td>Analysis of investigation of deaths selected by CQC inspection team (plus findings from Serious Incident investigations done by others on the team). Interviews with medical director, directorate teams. Interview with clinical outcome manager who developed the information system for learning from deaths. Interview with Director who leads on services for people with a learning disability. Review written policy setting up the system.</td>
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<td>What progress has been made on publishing quarterly data on deaths? (National Guidance expects the publication of the data and learning points from it by the end of December 2017)</td>
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<td>What work is done with partners to explore learning across care settings and pathways?</td>
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<td>Resourced</td>
<td>How are reviews and investigations of deaths resourced?</td>
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| Board support/Governance | Who is the Board lead on deaths?  
What board discussion is there?  
How is learning from deaths, incident investigations, complaints, coroners reports, etc. co-ordinated?  
What progress has been made – are there specific examples?  
What further plans are there?  
How do you ensure that actions are delivered?  
Are there any examples were the Board has challenged the activities? | Interviews with non-execs group, medical director, directorate teams.  
Review agenda, minutes and action plans of any mortality or similar group |
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| People focussed – patients, families, carers and staff are active and supported participants. | Involvement of families and carers in investigations                     | How do you engage with families and carers? (with example questions below)  
  - how does the trust seek feedback from families and carers after every death? (as this should help drive which deaths are reviewed)  
  - where appropriate, how did the trust ensure the family and/or carers received an early and genuine apology? (as required under Duty of Candour Regulation 20 for a notifiable safety incident)  
  - Did they help set the terms of reference? | Analysis of individual death investigations including where a person had a learning difficulty  
  Analysis of correspondence of a particular case that was an investigation of a death, a complaints and an investigation.  
  Interview bereavement services and check bereavement pack to see whether opportunity for the family and carers to raise concerns about care. |
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<th>Question</th>
<th>Method</th>
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<td>- how can they raise concerns during the process?</td>
<td>Interview with PALs or similar team who liaise with families</td>
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<td>- what support is provided to families?</td>
<td>Interview with complaints team</td>
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<td>- how does the trust handle communication with families who do not engage?</td>
<td>Cross-check with findings from analysis of sample of complaints cases – are there similar themes?</td>
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<td>- who handles the liaison (a single named person)?</td>
<td>Cross-check with findings from analysis of serious incidents</td>
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<td>- how are they kept informed about timescales and findings?</td>
<td>Cross-check with any other Duty of Candour findings</td>
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<td>- what monitoring is done to ensure family wants are delivered?</td>
<td>Visits to any wards when question asked (of ward sisters) about how people raise concerns and what action takes place</td>
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<td>- what feedback do you have from families on how well they are engaged?</td>
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<td>- have families been involved in improving the process?</td>
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<tr>
<td>Key principle (NHSI/HSIB)</td>
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<td>Preventative (investigations for learning) – all investigations identify and act on deep-seated causal factors to prevent or measurably and</td>
<td>Do you have evidence of any examples of good learning where previous recurrent incidents being reduced or prevented following implementation of improvements from</td>
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sustainability reduce recurrence. They do not seek to determine liability, attribution or cause of death.

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<tr>
<th>Review and investigation of deaths of people with a learning disability or severe mental health problem</th>
<th>How do you review and investigate a death of a person with a learning disability or severe mental health problem? Can the trust identify those people who have died who have a learning disability?</th>
<th>Interview with trust lead on people with a learning disability</th>
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<tr>
<td>investigations into deaths? What are the key features of the trust’s review and investigation process?</td>
<td>The review and investigation process should have features that establish: the facts, what happened (effect), to whom, when, where, how and why (root cause/human factors) - identified the patient’s needs and risks at the time of death - whether failing in care or treatment - look for improvements rather than blame - how occurrence may be reduced or eliminated - make recommendations and an action plan</td>
<td>Provide a report or record of investigation process and outcome - provide a means to share learning - identify routes to share learning</td>
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<tr>
<td>Key principle (NHSI/HSIB)</td>
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| Expertly led/credible - led by experts; open, honest and transparent; objective; planned; timely and responsive; systematically and system-based; trustworthy; fair and just. | Process to review and investigate deaths | Can you talk me through the process you use to review and investigate deaths?  
- System-based approach (e.g. Working with partners such as GPs)?  
- Training, support and expertise available (e.g. safety investigation, human factors, improvement science)? | Review Investigation policy and templates used  
Interview Head of Quality & Safety, Clinical Outcomes Manager who developed any mortality system.  
Case review of individual reviews and investigations of deaths – look at case files not just the investigation report to understand whether the policy is translated into practice. |
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<tr>
<th>Question</th>
<th>Methodology</th>
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<tr>
<td>Resources available (e.g. dedicated time)</td>
<td>Interview investigators – talk through carrying out an investigation</td>
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<td>Proportionate to incident and risk?</td>
<td>Interview PALs or equivalent</td>
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<td>Clear terms of reference?</td>
<td>Interview with departmental triumvirates</td>
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<td>Clear what evidence used?</td>
<td>Annual NHS staff survey – staff who felt incident reporting procedures fair and effective</td>
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<td>Did families receive the information they needed (under Duty of Candour)?</td>
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<td>Are investigators independent of the care provided?</td>
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<td>Bespoke plan for each investigation?</td>
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<td>Responsive at start, timely in completion (e.g. within 60 days)?</td>
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<td>Seek to report the truth accurately e.g. accounts of staff and families?</td>
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<td>Fair and just (e.g. promotes a safe and open culture)</td>
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<td>Collect feedback from families and carers?</td>
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<td>Was the report clearly written and easy to read?</td>
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<tr>
<td>Key principle (NHSI/HSIB)</td>
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<tr>
<td>Collaborative – supports system-wide investigation (cross pathway/boundary issues); enables information sharing and action across systems; facilitates</td>
<td>Involves other provider organisations in cross pathway/boundary deaths</td>
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collaboration where multiple investigations are ongoing.

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<tr>
<th>Actions which are evidenced to measurably prevent or reduce recurrence are shared widely</th>
<th>What mechanisms does the trust use to identify which improvements are effective?</th>
<th>What mechanisms does the trust use to share with partner organisations improvements made?</th>
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<th>What are the challenges and achievements?</th>
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**What is good practice**

We asked in our consultation on the CQC website and CQC’s electronic community what good practice looks like. The answer given by the around 100 responses was - being open and honest with families and carers; putting effort and thought into compassionate day to day communication with families and carers; having independent, robust and professional investigations; and having a means to share learning and stop repeating the mistakes.

The elements of good practice, with those suggested the most listed first, were:

- Transparent, open and honest communication with families and carers (24 mentions)
- A Compassionate, sympathetic and supportive approach to the bereaved family & carers (13 mentions)
- Keeping the family engaged and informed (12 mentions)
- Independent, unbiased & honest investigations (9 mentions),
- Robust & thorough investigation, using root cause analysis, consistent, well-done, expert, detailed (9 mentions)
- Engage and feedback to front-line staff on findings (7 mentions)
• Clear identification of improvements needed, monitoring to ensure the changes are embedded into daily routine and same problems do not re-occur (7 mentions).
• Report that is timely (5 mentions)
• Findings that do not seek to blame individuals but focuses on training and development (4 mentions)
• Single key worker from NHS to deal with (3 mentions)
• Sharing of good practice (2 mentions)
• Family satisfied with outcome, triage deaths reviewed and investigated to maximise learning (1 mention each)

Reporting findings for the Well-led Inspection Report

It is suggested that a single summary section is drafted for the inspection report under the heading ‘Learning from Deaths’ under Key Lines of Enquiry.

Well-led 8: are there robust systems and processes for learning, continuous improvement and innovation?

Well-led 8.3 How effective is participation in and learning from internal and external reviews, including those related to mortality or the death of a person using the service? Is learning shared effectively and used to make improvements?

The key elements to cover are:

1. Progress made on setting up a method of reviewing and investigating deaths to meet the national guidelines
2. Whether deaths of people with a learning disability are reviewed and investigated to the same good standard as other deaths
3. Family and carer involvement
4. Evidence that the reviews and investigations reduce reoccurring problems
5. Evidence that common themes across complaints cases, serious incidents and deaths are brought together and addressed
6. Board oversight and challenge to ensure that the reviews and investigations stop reoccurring problems

We want to use these paragraphs on findings to analyse for a follow-up national report on what our inspections have found. Also to provide further details could you, at the end of the inspection, please complete the proforma at Annex D and return to [Insert Address]. Thank you.

Service level inspections
Service level inspections provide an opportunity to follow up issues to test whether there are examples of learning from deaths claimed in the well-led assessment in front-line services.


- CQC’s review of front-line practice in 12 NHS trusts “Learning, candour and accountability” found that “many carers and families do not experience the NHS as being open and transparent and that opportunities are missed to learn across the system from deaths that may have been prevented.”
- In response the Secretary of State for Health and the National Quality Board has developed national guidance (add link) that sets out what families and carers should expect from NHS organisation. As part of CQC’s response to the Death Review it has developed this tool to support local CQC teams involved in its new approach to monitoring and inspection.
- The new National Guidance¹ expects NHS trusts to:
  - “Ensure their governance arrangements and processes include, facilitate and give due focus to the review, investigation and reporting of deaths, including those deaths that are determined, more likely than not to have resulted from problems in care.”
  - “Ensure that they share and act upon any learning derived from these processes.”
  - “The standards expected of Trust boards including having an existing executive director take responsibility for the learning from deaths agenda and an existing non-executive director take responsibility for oversight of progress.”
  - “Review and, if necessary, enhance skills and training to support this agenda. Providers need to ensure that staff reporting deaths have appropriate skills through specialist training and protected time under their contracted hours to review and investigate deaths to a high standard.”
  - “Providers have a clear policy for engagement with bereaved families and carers, including giving them the opportunity to raise questions or share concerns in relation to the quality of care received by their loved one. Providers should make it a priority to work more closely with bereaved families and carers and ensure a consistent level of timely, meaningful and compassionate support and engagement is delivered and assured at every stage, from notification of the death to an investigation report and its lessons learned and actions taken.”
  - As a minimum each NHS trust “should publish an updated policy by September 2017 on how it responds to, and learns from, deaths of patients who die under its management and care, including:

¹ National Guidance on Learning from Deaths, Executive Summary, First Edition March 2017, National Quality Board
- How its processes respond to the death of an individual with a learning disability or mental health needs, an infant or child death and a stillbirth or maternal death
- “The Trust’s approach to undertaking case record reviews.” Trusts should use an evidence-based methodology including the Structured Judgement Review for acute trusts and the Learning Disabilities Mortality Review (LeDeR) for case reviews of deaths of people with learning disabilities. “As a minimum and from the outset, Trusts should focus reviews on inpatient deaths.”

  - From April 2017, Trusts will be required to collect and publish on a quarterly basis specified information on deaths. This should be through a paper and agenda item to a public board meeting in each quarter to set out the Trust’s policy and approach (by the end of Quarter 2 – end of September 2017) and the publication of the data and learning points (from Quarter 3 onwards – end of December 2017). “The data will be summarised in their Quality Accounts from June 2018, including evidence of learning and action.”
  - The data on deaths should include:
    - “The total number of the Trust’s inpatient deaths (including Emergency Department deaths for acute Trusts)”
    - “those deaths that the Trust has subject to case record review”
    - “of these deaths subject to review, Trusts will need to provide estimates of how many deaths were judged more likely than not to have been due to problems in care.”
    - “accompanied by relevant qualitative information and interpretation”

Trust Policy for Responding to Deaths – Key Points (from National Guidance Annex C)

“Trusts should have a policy in place that sets out how they respond to the deaths of patients who die under their management and care.

POLICY FOR RESPONDING TO DEATHS - KEY POINTS

The policy should include how providers:

- **determine which patients are considered to be under their care and included for case record review if they die** (it should also state which patients are specifically excluded);

- **report the death within the organisation and to other organisations who may have an interest** (including the deceased person’s GP), including how they determine which other organisations should be informed;
• respond to the death of an individual with a learning disability (Annex D) or mental health needs (Annex E), an infant or child death (Annex F) and a stillbirth or maternal death (Annex G) and the provider’s processes to support such deaths;

• review the care provided to patients who they do not consider to have been under their care at the time of death but where another organisation suggests that the Trust should review the care provided to the patient in the past;

• review the care provided to patients whose death may have been expected, for example those receiving end of life care;

• record the outcome of their decision whether or not to review or investigate the death, which should have been informed by the views of bereaved families and carers;

• engage meaningfully and compassionately with bereaved families and carers - this should include informing the family/carers if the provider intends to review or investigate the care provided to the patient. In the case of an investigation, this should include details of how families/carers will be involved to the extent that they wish to be involved. Initial contact with families/carers are often managed by the clinicians responsible for the care of the patient. Given that providers must offer families/carers the opportunity to express concerns about the care given to patients who have died, then the involvement of clinicians who cared for the patient may be considered a barrier to raising concerns. Providers should therefore offer other routes for doing this;

• offer guidance, where appropriate, on obtaining legal advice for families, carers or staff. This should include clear expectations that the reasons, purpose and involvement of any lawyers by providers will be communicated clearly from the outset, preferably by the clinical team, so families and carers understand the reasons and are also offered an opportunity to have their own advocates.”
Annex B – Framework to analyse individual deaths

This framework provides a method to assess the process for reviewing and investigating individual deaths in order to test:

- The extent to which the trust’s policy is implemented in reviews and investigations of individual deaths
- The engagement with families and carers for instance through the tone, stage and content of communication
- Whether the investigation of the deaths of people who are vulnerable through their circumstances, such as having a learning disability, are treated the same as other people who have died

The structure follows the process of conducting a review and investigation.

The method should be applied to the case notes, not just the Root cause Analysis findings, in order to understand engagement with family and carers, staff involved in the care, partner organisations, etc.

Also it is proposed that families and carers are given the opportunity to be asked and to answer similar questions about their relatives death in the individual case reviews - see the suggested questions that could be used for a telephone interview or be e-mailed.

<table>
<thead>
<tr>
<th>What to look for</th>
<th>Criteria</th>
<th>Findings</th>
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<tbody>
<tr>
<td>1. Are the basic facts accurately recorded?</td>
<td>Demographic information e.g. age, gender Details of next of kin/family members Length of admission/time using services Date and time of death Location of death e.g. inpatient, community setting Stated cause of death</td>
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<td>Does the incident report reflect that further information was reviewed e.g. care records?</td>
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<td>2. Is the initial review done in an effective and timely way?</td>
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<tr>
<td>What information was used</td>
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<td>What criteria was used, were they noted</td>
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<td>72 hour maximum for the initial review</td>
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<td>As soon as possible following awareness of death to report incident</td>
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<td>Are any delays in meeting reporting and reviewing times clearly explained</td>
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<td>3. People focussed – how is the family and carers engaged?</td>
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<td>Did they receive a genuine apology?</td>
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<td>How could they raise concerns during the process?</td>
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<td>What support was provided?</td>
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<td>Was there a single named person who liaised with the family?</td>
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<td>Did they help set the terms of reference?</td>
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<td>How were they kept informed about timescales and findings?</td>
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<tr>
<td>What monitoring was there that family wants were delivered?</td>
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<tr>
<td>Was there feedback sought from families?</td>
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<tr>
<td>How were staff involved in care engaged? What support was given to them?</td>
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<td>4. Was the review and investigation focussed on learning?</td>
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<td>Did the review and investigation process establish:</td>
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<tr>
<td>- the facts, what happened (effect), to whom, when, where, how and why (root cause)</td>
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<tr>
<td>- identified the patient’s needs and risks at the time of death</td>
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<tr>
<td>- whether failing in care or treatment</td>
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<tr>
<td>- look for improvements rather than blame</td>
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<td>5. Was the review and investigation expertly led and credible?</td>
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<tr>
<td>- Training, support and expertise available (e.g. safety investigation, human factors, improvement science)?</td>
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<td>- Resources available (e.g. dedicated time)</td>
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<tr>
<td>- Proportionate to incident and risk?</td>
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<tr>
<td>- Clear terms of reference?</td>
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<tr>
<td>- Clear what evidence used?</td>
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<tr>
<td>- Did families receive the information they needed (Duty of Candour)?</td>
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<tr>
<td>- Independence of investigators?</td>
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<tr>
<td>- Bespoke plan for each investigation?</td>
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<tr>
<td>- Responsive at start, timely in completion (e.g. within 60 days)?</td>
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<tr>
<td>- Seek to report the truth accurately e.g. accounts of staff and families?</td>
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<tr>
<td>- Fair and just e.g. promotes a safe and open culture</td>
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<tr>
<td>- Collected feedback from families and carers?</td>
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<tr>
<td>- Was the report clearly written and easy to read?</td>
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<tr>
<td>- Clear what improvements in care were needed?</td>
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<tr>
<td>- Clear who needed to take action?</td>
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<table>
<thead>
<tr>
<th>6. Was the review and investigation done in a collaborative way across the care system?</th>
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<tbody>
<tr>
<td>- System-based approach taken (e.g. work with partners such as GPs)?</td>
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</table>
Telephone interview or form to e-mail to gather experience of families and carers

CQC is carrying out an assessment of the care provided at your local NHS trust. As part of that work we want to understand how the trust learns from the death of patients so that any problems in care do not re-occur. The activity includes Care Quality Commission (CQC) inspectors looking at a sample of deaths to understand how they were reviewed and investigated. We have selected the sample and this includes the death of your loved one.

We would like to ask you some questions so you have an opportunity to share your experiences with us but you do not have to do this if you do not want. The questions are below and we would value any comments you might want to make. These comments will be kept confidential to CQC and will only be used to draw out more general points about the trust.

Thanks you for taking the time to give comments and help in CQC’s work.

If you want to contact CQC about this work please ring xxxxxxx or e-mail yyyyyy.

<table>
<thead>
<tr>
<th>Main question</th>
<th>Issues might cover</th>
<th>Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Please can you explain what happened in the death of your loved one? What</td>
<td>Understand circumstances, was the patient respected and cared for.</td>
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<tr>
<td>kind of needs did they have? Was the death expected? What do you feel about</td>
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<tr>
<td>the quality of care they received?</td>
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<tr>
<td>2. How were the family involved in any review or investigation?</td>
<td>Did you receive a genuine apology?</td>
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<td></td>
<td>Did you raise concerns?</td>
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<td></td>
<td>What support was provided?</td>
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<td>26</td>
<td>3. Did someone review what had happened soon after the death?</td>
<td>4. Was the review or investigation well-led?</td>
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<tr>
<td>Was there a single named person who liaised with the family?</td>
<td>What information was used</td>
<td>- Training, support and expertise available (e.g. safety investigation, human factors, improvement science)?</td>
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<tr>
<td>Did the family and carers help set the terms of reference?</td>
<td>What criteria was used, were they noted</td>
<td>- Resources available (e.g. dedicated time)</td>
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<tr>
<td>How were you kept informed about timescales and findings?</td>
<td>72 hour maximum for the initial review</td>
<td>- Proportionate to incident and risk?</td>
</tr>
<tr>
<td>Did you feel your questions were answered honestly?</td>
<td>As soon as possible following awareness of death to report incident</td>
<td>- Clear terms of reference?</td>
</tr>
<tr>
<td>What monitoring was there that your questions were answered?</td>
<td>Are any delays in meeting reporting and reviewing times clearly explained</td>
<td>- Clear what evidence used?</td>
</tr>
<tr>
<td>Was there feedback sought from the family and carers?</td>
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<td>- Did families receive the information they needed (Duty of Candour)?</td>
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<td>How were staff involved in care engaged? What support was given to them?</td>
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<td>- Independence of investigators?</td>
</tr>
</tbody>
</table>
- Bespoke plan for each investigation?
- Responsive at start, timely in completion (e.g. within 60 days)?
- Seek to report the truth accurately e.g. reflected accounts by staff and families?
- Fair and just e.g. promotes a safe and open culture
- Collected feedback from families and carers?
- Was the report clearly written and easy to read?
- Clear what improvements in care were needed?
- Clear who needed to take action?

Did the review and investigation process establish:

- the facts, what happened (effect), to whom, when, where, how and why (root cause)
- identified the patient’s needs and risks at the time of death
- whether failing in care or treatment
- looked for improvements rather than blame
- how reoccurrence may be reduced or eliminated
- make recommendations and an action plan
- provide a report or record of investigation process and outcome
- provide a means and routes to share learning

5. Did the review or investigation involve other organisations who provided care?

- Did others involved in the care of your loved one, such as GPs and other hospitals, part of the review and investigation?
- How were transfers in care between different providers included?
- Is it clear how lessons were shared with partner organisations?
6. Do you believe that any mistakes made would happen again? Why is this?

7. What was good about the review or investigation? What could have been done better?

**Annex C – What is important to families, carers and others in how NHS providers learn from deaths - summary of responses received from the families & carers, health professionals and the CQC electronic community in June & July 2017.**

**Summary of public engagement on CQC proposed method on assessing NHS providers learning from deaths**

**Background**

During June and July 2017 CQC asked the public for comments as part of piloting its proposed approach to strengthening its monitoring and inspection approach to assess how NHS providers learn from deaths.

The recommendation for CQC made in the national thematic report “Learning, Candour and Accountability” was:

**Recommendation 8: Strengthening CQC’s assessment of learning from deaths in our monitoring and inspections** to cover the process by which providers identify patients who have died and decide which reviews or investigations are needed, with particular emphasis on:

- how trusts have involved families and carers in reviews and investigations
- patients with a learning disability or mental health problem
- the quality of investigations carried out by trusts
- reports to trust boards on learning from deaths
- action taken in response to learning from deaths
We asked similar questions of two groups in June and July 2017 about our proposed approach:

- The public through the CQC website between – with a notice sent to families and carers who had been involved in the CQC thematic review “Learning, Candour and Accountability”. We received 34 responses – including 14 from relatives of people who had died and 12 health professionals.
- The CQC’s on-line community from who we received 67 responses.

The proposed approach on which people were asked for comment

Initially this approach will be applied to providers of NHS funded acute care, community health care, mental health services and learning disability services. A later phase in 2018 proposes to develop an approach for GP practices, adult social care services, independent healthcare providers, ambulance NHS trusts.

The aim of this approach is to:

- support NHS trusts to move towards a culture where learning from deaths is an accepted part of practice that provides answers for families on What happened? What went wrong/could have been done better? What went right/was done well?
- identify any immediate actions needed to protect people
- provide CQC with more systematic methods to monitor and inspect
- provide a baseline to help providers understand what they are good at as well as where they need to improve
- link to guidance and support provided by partner organisations such as NHS Improvement.

The principles used are based on asking a similar set of questions to those asked when we produced our national report – How are families and carers involved? How are cases identified for review? What is the process to investigate cases? What investment is made in training and support for investigations? What governance arrangements are in place to ensure learning takes place and care is improved?

This approach will form part of our new assessments of how well-led is an NHS service, which will be carried out in every NHS trust from this Autumn 2017 until March 2019 and then after that annually. There are three main parts to our proposed approach.
1. **Monitoring and relationship management.** As part of how CQC monitors services we want to gather intelligence from families and carers. Possible sources include local Healthwatch, PHSO investigation findings, Patient Liaison Services (PALS), Clinical Commissioning Groups, Bereavement Services, NHS trust meetings. Also we will gather information that NHS trusts are now required to collect on the numbers of deaths of (in)patients, those that have been reviewed thoroughly and estimates of how many deaths were judged more likely than not to have been due to problems in care. We want your views on whether these are the important sources or whether we should be picking up other information to understand the experience of families and carers.

2. **Risk-based review of individual investigations of deaths.** Where there are concerns raised by families or carers or from other information, we will review a sample of up to four cases of deaths that have been investigated selected randomly by the inspection team. These will include, where these have occurred in the trust, a person with a learning disability and person with a mental health need. We want your views on how this activity should be triggered.

3. **Inspection interviews.** At all providers we will review trust policies and procedures; as well as interview the board member and executive who leads on learning from deaths, the operational lead on quality and safety and some of those who investigate cases. We need to capture the views of families and carers and need to know how best to do this.

We will assess findings against a new key line of enquiry which is now part of the well-led assessment and rating:

> How effective is participation in and learning from internal and external reviews, including those related to mortality or the death of a service user?
> Is learning shared effectively and used to make improvements?

**What comments did people make?**

The main issues and challenges for the CQC approach include:

- **On monitoring and relationship management:** CQC needs to follow-up to see what action has happened following Coroners investigations, PHSO investigations, Duty of Candour reporting; CQC needs to have a range of methods to directly communicate with families and carers about their experiences such as on-line forms, telephone interviews, talking to existing family support groups, individual or group interviews; talk to local GPs; CQC needs the capability to analyse mortality data to spot unusual and repeated patterns of unexpected deaths, including people with a learning disability, suicides; safeguarding issues raised; monitor staffing levels.

- **On the risk-based review of individual investigations of deaths:** this activity is seen as the most valuable by website responses from families & carers and health professionals; CQC needs to select the cases from a list of recent deaths, rather than investigations, to test how all deaths are reviewed as well as those investigated; test ability of providers to record disabilities in NHS records so care can be managed appropriately (tested
when CQC asks for a case of a death of a person with a learning disability); as well as concerns raised by families and carers need to include concerns raised by others such as GPs or other visitors; need to have methods that provide families with opportunity to discuss their experiences of the selected cases; take account of transfers in care between different providers; test for communication and engagement of families – how responded to their concerns; test independence, robustness, thoroughness of investigations;

- **On-site inspections**: focus on actions taken after a review or investigation; need to link with findings from analysis of complaints and serious incidents; talk to families and carers who have experienced deaths and front-line staff involved, investigators, Boards about oversight, CEO, medical director, nursing director, head of serious incident management, mortality lead, externally GPs, those who liaise with families; test questions to ask against proposed list and cover any gaps.

**Detailed analysis**

More detail on the responses to the individual questions is below.

1. **Comments on the overall approach**

Most responses rated the approach as meeting or partially meeting the recommendations in the CQC thematic report – “Learning, Candour and Accountability” published in December 2017. There was agreement with the principles, that they sought to address the main issues, asked the right questions, gave more prominence to family and carer concerns and might bring improvements. However there was general scepticism about whether CQC can make a difference given people’s previous largely negative experiences, comments included the need for clarity on how to engage with families and carers, the need to highlight good practice to get progress.

2. **Which element of the approach is the most valuable?**

The website responses rated the review of individual deaths selected by CQC as the most valuable, because it could test the involvement of families and carers and the standard of reviews and investigations carried out. The on-line community rated the value of the three parts of the approach equally – monitoring, risk-based case review and inspection interviews.

Other comments on particular issues:

- On monitoring and relationship management – “need to interview families and carers direct” perhaps by “a phonecall from an empathic individual?”, “important to look at concerns and suggestions from the families but also at the positive comments”, “CQC could try ‘mystery..."
shopping”, need to consider also “coroners reports and action plans from previous deaths and homicides”, “audit of local press reports about concerns of families at Coroner’s Courts cross referenced with an audit ....about how the matter was dealt with and investigated and reported to the Board”,

- On risk-based review of individual investigations of deaths – need to go beyond concerns raised by families and carers to include “any concern raised. It could be a visitor of a nearby bed, a visiting teacher, the GP, etc.” CQC needs to include reviewing “cases not investigated to be assured that all deaths are reviewed appropriately”.
- How to take account of the continuity of care when patients are transferred between services – “a trust who transfers patients who have died within a month should be involved in the investigation of the death as well as the ‘receiving’ hospital”
- Health staff also mentioned the need to recognise and tackle practical barriers to improvement – recognising what factors where in the control of local staff and which were not, having the time to implement the changes needed by new national guidance on learning from deaths, pressures on services that affected the ability to meet standards of care, difficulties of obtaining information from carers, the need to create an open culture where frontline and other staff feel that they can speak up.

3. **What do you think should be the most important information we should be monitoring?**

In terms of comments from the CQC website relative and carer’s comments on monitoring focussed on:

- Mortality data – how many expected deaths, how many could have been prevented, similarity of issues with other serious incidents not involving a death
- ability to record disabilities in NHS records so care can be managed appropriately
- assess quality of investigations into deaths – how families are dealt with and the communication handled, compare the case notes to the serious incident investigation, assess the quality of the notes and care plan – do they show insight into the patient’s condition and attempt to pass on/communicate concerns
- use other intelligence sources to check recommendations are implemented from Coroners, PHSO complaints upheld and not upheld,
- feeds into newspaper reports about inquests of cases where families have raised concerns, use intelligence from concerns from staff and ex-staff, etc.
- records of board meetings reporting death investigations and the extent of audit being undertaken

Comments on the CQC website from health professionals focussed on:
• Quality of investigations – root cause analysis, specificity of recommendations, identifying trends and themes, understanding the stories as well as the numbers
• Actions taken as a result of learning from investigations
• Involvement of families and carers, how the trust responded to the concerns they raised, how carry out duty of candour
• Complaints
• Broader drivers of quality of care - Staffing levels and ratios, caseload, recruitment and retention.

4. **During the inspection who should CQC talk to?**

From the CQC websites relatives and carers comments on monitoring focussed on CQC talking to:

• Families and carers of those who have experienced the avoidable deaths of their loved ones
• Front-line healthcare staff who deal with patients, families and carers
• Other professionals not employed by the organisation – GPs, social workers, agency staff

From the CQC websites health professionals comments focussed on involving a range of people reflecting the chain of command in the trust including:

• Investigators – do they understand the processes and have the relevant skills
• Board – do they have oversight and understand the issues
• CEO, Medical director, chief nurse, family liaison officers, head of serious incident management, mortality lead, frontline medical and nursing staff
• Families and carers

The CQC electronic community believed that:

• A Strong consensus around asking families, staff directly involved in care, GPs, and a wide range of other staff including those across different organisations.
• CQC should choose which relatives to talk to not the provider
• Suggestions on how to approach families. Directly in a one-to-one relaxed meeting where what said is confidential. Indirectly – through webform or paper form people can complete. (Challenge – how will CQC offer to talk to families – current proposal is to look at case file on the death only? Put question to family group & implementation group?)
• Need to ensure confidentiality of information given by staff (to CQC) is protected so staff can be open and not punished.
• (Challenge on what separating what best can cover in CQC case review and what best done in the provider investigation)
• (Challenge of developing & supporting inspectors to do effective case reviews)

What questions should CQC ask?

There were a large number of suggested issues and questions that CQC should ask. Mostly these were already covered in the proposed approach but there were a few issues where we adapted the questions CQC will ask, such as in the review of individual deaths the question to ask families about their experiences.

5. How should CQC capture the experiences of families and carers?

The CQC electronic community suggested a range of approaches (Challenge: how could we incorporate into CQC monitoring & inspection methods?):

• Reinforce proposed methods – ask for good and bad, Review all correspondence with the family, select a random set of cases,
• Others can talk to - hospital chaplains and others who have contact with patients and families
• New proposals – offer a range of options to families and carers including:
  ▪ Face-to-face – telephone surveys direct to families, discussion panels of families (less intimidating than solo face-to-face interview), attending support groups, Record interviews with families along the lines of The Listening Project on Radio 4(?)
  ▪ On-line – questionnaires – set up a website and blog which could be advertised in the hospitals and on the NHS website where people can send comments, e-mail directly families
  ▪ By post - address, like PO Box, where people can write about their experiences
  ▪ General communication – raise public awareness of CQC as a place people can report concerns, allow time (a month) for families to grieve and reflect
  ▪ Organisations to contact - Seek feedback from support organisations such as SENDIASS, the Community Support Advisory Service of charities such as the National Autistic Society.
6. **How should we decide which are the trusts where CQC needs to review individual deaths?**

From the CQC website relatives and carers comments on monitoring suggested that CQC focussed on deaths that have already attracted press headlines or attention from PHSO and other organisations.

From the CQC websites health professionals comments focussed on:

- Need to look at cases not investigated as well as those investigated (so pick from list of deaths not a list of investigations)
- Trusts that are outliers on mortality data – either very low or very high mortality rates, persistent high suicide rates, high rates of deaths of people with learning difficulties
- Trusts with issues from Coroner regulations 28 cases, PHSO investigations of deaths and other complaints.

The CQC electronic community suggestions (with those suggested most listed first) included:

- Statistical analysis of unusual pattern or higher number of unexpected deaths that is repeated, comparisons with similar trusts (12 mentions) [CQC need mortality data analysis & interpretation expertise to deliver this activity]
- Reports from GPs (5 mentions), social services
- Reports from doctors and nurses (5 mentions)
- Complaints about care concerns by public or carers (4 mentions)
- Coroner’s reports findings (2 mentions)
- Safeguarding issues raised (2 mentions)
- Research local newspaper reports expressing concerns over treatment and deaths; social media
- Test whether trust has a system capable of spotting poor care
- Consistently poor complaint handling by an organisation
- CQC have a system whereby relatives can flag bad treatment (is this not covered by “Tell us about your care” on CQC website reporting of bad care? good care?)?
- Check staffing levels
- CQC choose a sample of cases to review
- CQC test whether providers look for common themes in reviews and investigations
7. **What else should CQC consider when assessing whether a trust has an open and learning culture?**
   - From the CQC websites relatives and carers focused on:
     - Checking newspapers and media to see if same problems reoccur around investigations of deaths
     - Check to see if investigations are co-produced with families and relatives – talk to local family and carer groups
     - Look for examples of feedback and learning from investigations from clinicians
   - From the CQC websites health professionals comments focused on:
     - Check family & carer feedback, Duty of Candour reporting
     - Check with front-line clinicians and middle managers about examples of learning from investigations
     - Extent of involvement of families and carers

8. **What does good practice look like?**

The focus of all the different groups was the same - being open and honest with families and carers; putting effort and thought into compassionate day to day communication with families and carers; having independent, robust and professional investigations; and having a means to share learning and stop repeating the mistakes.

The elements of good practice, with those suggested most listed first, were:

- Transparency & open, honest communication with families and carers (24 mentions)
- Compassionate, sympathetic and supportive approach to the bereaved family & carers (13 mentions)
- Keeping the family engaged and informed (12 mentions)
- Independent & unbiased & honest investigations (9 mentions)
- Robust & thorough investigation, root cause analysis, consistent, well-done, expert, detailed (9 mentions)
- Engage and feedback to front-line staff on findings (7 mentions)
- Clear identification of improvements needed, monitoring to ensure the changes are embedded into daily routine and same problems do not re-occur (7 mentions)
- Report that is timely (5 mentions)
- Findings that do not seek to blame individuals but focused on training and development (3 mentions)
- Single key worker from NHS to deal with (3 mentions)
- Sharing of good practice (2 mentions)
- Family satisfied with outcome, triage deaths reviewed and investigated to maximise learning, Mediator service available (1 mention each)

We have used this analysis of these responses to further develop our monitoring and inspection approach to how we assess NHS providers learning from deaths.

Annex D – feedback of findings to the central support team

Please complete the form below, providing whatever details you believe appropriate, and return to

<table>
<thead>
<tr>
<th>Principle</th>
<th>Good practice</th>
<th>Requiring further development</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Strategic – the focus is on quality of output and not just quantity of reporting; resources are invested in identifying cases and investigated work to support good quality outputs.</td>
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<tr>
<td>2. People focussed – patients, families, carers and staff are active and supported participants.</td>
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<tr>
<td>3. Preventative (investigations for learning) – all investigations identify and act on deep-seated causal factors to prevent or measurably and sustainability reduce recurrence. They do not seek to determine liability, attribution or cause of death.</td>
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<tr>
<td>4. Expertly led/credible - led by experts; open, honest and transparent; objective; planned; timely and responsive; systematically and system-based; trustworthy; fair and just.</td>
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<tr>
<td>5. Collaborative – supports system-wide investigation (cross pathway/boundary issues); enables information</td>
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</table>
sharing and action across systems; facilitates collaboration where multiple investigations are ongoing.

Details of good practice examples: