I would very much recommend the approach outlined in this handbook. It’s not a theoretical approach. Henrietta has developed this approach of advising and supporting clinical leaders like me who are suddenly facing a serious incident with the potential to affect tens of thousands of patients. The approach outlined is properly calibrated – based on the evidence that has been collected by managing these incidents. This provides assurance to commissioners and regulators and who can acknowledge and run with a trusted process. This prevents an over-engineered solution that potentially distracts you and creates a different type of risk. You move from a: ‘What on earth do I do now?’ moment to feeling that you have a controlled process.”

Trust Medical Director
Executive Summary

Many Trusts are facing previously unidentified areas of concern which require a review of clinical care. This could be in the 18 week Referral to Treatment (RTT) pathway, the 62 or 104 day Cancer pathway or in other areas such as Maternity or in Mental Health and Learning Disability. The reason for an external clinical harm review is to give assurance to patients, patient groups, commissioners and the public as to whether any patients have been harmed as a result of the incident as well as to avoid future harm to patients. The internal clinical review process carried out by the Trust will need to interface with external stakeholders, demonstrating that duty of candour and existing quality review processes, such as investigating serious incidents, are being undertaken. Whether this is using existing quality review structures or a standalone process will depend on a number of factors including the size and scale of the underlying clinical or performance concern. This handbook will identify the factors which will make the external clinical harm panel successful including the representatives from provider, commissioner and other organisations. In addition, an example of terms of reference and agenda are included in attached annexes.

The handbook will cover who should be involved, the internal and external governance arrangements, frequency of meetings and information required, a description of the definitions of clinical harm, information about duty of candour and advice on communications and dissemination of learning.

The recommendations presented in the Handbook are as follows:

- Secure senior sponsorship from all participating organisations
- Engage relevant stakeholders early once a serious incident has been identified
- Identify a suitable chair and members of the external review panel
- Identify project support resource
- Establish whether this can be incorporated into existing clinical quality review mechanisms or a standalone process is required
- Agree the methodology, terms of reference and internal and external governance arrangements
- Agree a joint communications strategy
- Focus on quality rather than performance in panel discussions
- Agree a completion point if possible
- Write up lessons learned and individual reflections
- Share learning with neighbouring organisations
Introduction

Why a handbook?

In every industry there is a tendency to reinvent the wheel as new strategies are devised. For each organisation facing an issue requiring clinical review it is a brand new experience for the organisation. Each circumstance is unique in terms of scale, type of cases and underlying reasons. However there are many similarities in terms of key stakeholders, responsibilities of the provider and commissioning organisations and existing process for identifying and investigating harm and external quality review.

Having worked with several acute and specialised Trusts there are common themes that have been identified, things that work and others that were not helpful. A huge amount of work has been done by Trusts who have been happy to share their learning and create a community of best practice.

The NHS does not lack creativity however we are less good at sharing learning. To counteract this many industries look to a handbook, a set of written guidelines to help achieve operational and management excellence. In particular this goes for organisations spread across a wide geography. A handbook is a roadmap to implement a new process streamlining and speeding up completion of the task and identifying pitfalls as well as good practice. It is a guide, with detail but not overly prescriptive. It can be used if wished to help establish structures, governance arrangements, involve key individuals and assist with definitions of harm. A handbook works best if the individuals who actually do the work write it, with senior leadership review and sponsorship. This is a guide for establishing an External Clinical Harm review process and builds on the work done in North Central and East London.

Implementing a process for internal and external review of clinical harm can in the best circumstances achieve the following:

- Identify best practice
- Ensure resources and priorities are aligned to common goals
- Identify training needs and become part of the desired culture to develop shared values within and across the organization
- Ensure consistency of process when staff leave or join
- Best practice is replicable, high standard and not unique to a single location or manager
- Avoid waste through efficiency

It can sow the cultural seed to make improvement a sustainable part of everyday life and build relationships between commissioners and providers.

For the process to be complete it needs to involve people from every area and every level and in this way it can be a means for positive change.
External Clinical Harm Review Process

Why external?

The purpose of an External Clinical Harm review is twofold:

- Can harm be avoided by identifying patients at particular risk?
- Have any patients come to harm?

The purpose of the meetings is to give assurance about patient care although information about performance can be helpful to set the context.

Some questions are useful to ask to help develop the terms of reference of the external clinical harm review panel:

- What are the factors which will make the external clinical harm panel successful?
- Who should be involved?
- What are the governance arrangements for the panel – both internally to the provider and externally for other stakeholders?
- What is the optimum frequency of meetings?
- What information should be brought to meetings?
- What are the definitions of harm?
- What about duty of candour?
- What communications are helpful?
- How can the learning from meetings be shared?

Factors that influence the success of an external clinical harm review

The factors that can make this a successful process are no different from any other type of quality review:

- Senior sponsorship at Board level from Provider and Commissioners
- Clinical engagement – referrers and providers
- Adequate resourcing – time to undertake reviews, administration for meetings
- Good relationships between providers and commissioners
- Effective chairing focusing on quality not performance
- A common purpose – high quality patient care
- Communications – there is no such thing as over communication
Who should attend?

Chair – External Organisation Medical or Nurse Director

Provider
Senior clinical staff e.g. Medical Director/ Nurse Director or deputies
Project manager
External Chair of internal steering group *
Administrator
Operations team
Clinical Directors *
Communications lead *

Commissioner(s) Clinical Chair
Quality Lead
Contracts Lead *
Clinical representative (GP or appropriate specialist)
Communications lead *

Patient or patient group representative*
NHS Improvement*
External expert *

The people marked with an asterisk may not need to attend every meeting but may need to attend to support the panel with specific information or to develop the communications strategy. It may be helpful for the internal steering group to have an external Chair who can present the relevant information to the External Clinical Harm meeting.
Frequency of meetings

The provider needs time to analyse information between meetings. Initially the meeting frequency might be every 6-8 weeks however commissioners may wish to have more regular information sharing meetings in the intervening weeks, either face to face or as teleconferences.

Length of process

This can vary from 6-24 months plus depending on size and scale of problem and in the case of 18 week RTT the backlog trajectory. It is important that the External Clinical Review Panel members are able to commit to this at the start.

A standalone panel or existing quality review process?

This will depend on individual circumstances e.g. size and scale of problem and whether there is sufficient time for discussion during the Clinical Quality Review Group or Meeting (CQRG/CQRM). Ideally the process should revert to the existing quality review processes as soon as possible. For non-Foundation Trusts’ this will include the NHS Improvement representatives and their observations on the maturity of the CQRG process. For Foundation Trusts the process and outcomes may be reported to NHS Improvement via the Tripartite approach.

Information to be brought to meetings?

This will depend on the reason for the External Clinical Harm review and different types of review meeting will be detailed below.
Definitions of Harm

The definitions of harm developed differ for the circumstances which are being reviewed. For RTT and Cancer 62 / 104 day pathway delays differences can exist on the basis that for the latter it is less immediately clear whether or not harm has occurred. Suggested definitions for these are included below:

Definitions of Harm - RTT pathway

| Severe                                      | Irreversible progression of disease  |
|                                            | Death on the waiting list from index condition |
| Moderate                                   | Increase in symptoms                 |
|                                            | Increase in medication or treatment   |
| Low                                        | Prolongation of symptoms             |

Definitions of Harm - Cancer pathway

| Severe                                      | Delayed diagnosis                     |
|                                            | Progression of cancer                  |
|                                            | Death on the waiting list from index condition |
| Moderate                                   | Increase in symptoms                   |
|                                            | Increase in medication or treatment    |
| Low                                        | Prolongation of symptoms               |

For other types of review for example maternity, mental health or learning disability the definitions of harm will differ and part of the remit of the group can be to agree definitions which are appropriate.

For patients identified as suffering moderate harm and severe harm the duty of candour exists. For the latter group the serious incident (SI) process should also be followed.

The question of assessing psychological harm is complex as the baseline is not assessed. For example, an objective questionnaire such as PHQ-9 or HAD score is unlikely to be used at the start of a referral process and for patients not found to have cancer the investigation process can be prolonged which can have the impact of increasing anxiety.
Duty of candour

The introduction of duty of candour in November 2014 (http://www.legislation.gov.uk/ukdsi/2014/9780111117613) has put a responsibility onto providers to inform patients of severe and moderate harm. This includes moderate and severe harm which are recognised side effects of a procedure. How this is done may differ e.g. face to face in clinic, by letter but it must also be documented formally in writing.

The experience of the External Clinical Review Panels is that it is very helpful to engage the patient’s GP. This is particularly helpful if the harm was identified as part of a clinical review which may be some time after incident. The GP will know the patient and be able to liaise with the Trust regarding the best method of approach.

Duty of candour is not about blame and it is important to support staff involved including administrative, managerial and clinical.
Communications

Each organisation has its own statutory responsibilities and the provider needs to understand needs of partner organisations and vice versa. Early involvement of the communication teams from provider and commissioners can be very helpful to ensure that the situation is clearly described and the methodology for review has been agreed. For larger Trusts there may be a number of different commissioners including NHS England as commissioners of Specialised Services and it is important that there is good coordination between these organisations.

The list of stakeholders can include (but is not exhaustive):
- Patients and patient representatives
- Members of Parliament
- Chairs of Health Oversight and Scrutiny Committee
- Chair of Health and Wellbeing Boards
- Healthwatch
- Trust staff
- General Practitioners

Some Trusts have written to all patients included in a clinical harm review.

Engagement with Trust staff is vital as in some situations the underlying causes of the incident have led to breakdown in relationship between clinicians and managers. Clinical engagement is key to success as detailed above. GPs are also important as they may be seeing patients while they are on the waiting list and can flag deterioration or if the patient has had treatment elsewhere or moved abroad. Whether the communication comes straight from the Trust or via the relevant commissioner is a matter for individual organisations to consider.
Learning from meetings

Some unexpected but valuable learning which has arisen from External Clinical Harm review meetings are outlined below:

Communication across the referrer / provider interface

This has included the quality of referral letters and the route by which referrals are received by the provider (this tends to be more prescriptive in primary care than in secondary to tertiary care referrals). Regarding the flow of information to patients and GPs there is variability in the speed and content of discharge letters, appointment letters to patients may arrive after the appointment date leading to a did not attend (DNA) letter and the patient being discharged back to the GP. The value of the alert button and the dedicated email address described above should hopefully avoid excessive delays for patients as a result.

Case Study – Alert button on CCG website/ dedicated RTT email address

When a GP identifies a problem e.g. an appointment sent out after the appointment date, they are able to click an ‘alert button’ on the CCG website. Providers have also set up dedicated email addresses for GPs identifying a patient in a waiting list backlog with deteriorating health or a cancelled appointment.

For children and vulnerable adults DNA is not appropriate as these patients ‘were not brought’ to their appointments so it is important that the Access Policy and the Safeguarding Policy reflect this and that appropriate safeguards are in place including highlighting non-attendance to the referrer and the GP, for example in dental or secondary care referrals.

Case Study

Access policies need to recognise that for children and vulnerable adults there may be underlying safeguarding concerns if they are not brought to appointments.
Access policies need to reflect this when letters are sent out following a missed appointment to alert the referrer and/or the GP that a child or vulnerable adult was not brought.
18 week RTT delay

Prospective clinical triage is a fundamental requirement for all waiting lists and relies on excellent working arrangements between clinical and managerial staff. Each specialty will be aware of the risk of delay in specific conditions and can prioritise patients by clinical need over waiting time.

Weekly review of the list by the respective Clinical Director and General Manager will allow ‘tip overs’ (patients who were previously known and whose treatment has extended beyond 18 weeks) and ‘pop ons’ (patients identified through the validation process and not previously on the PTL) to be identified and given admission (TCI) dates.

The experience of over 15 000 retrospective reviews across a number of large Trusts is that they usually yield very little in terms of previously unknown findings of severe harm. This demonstrates that the existing process of recording incidents e.g. through DATIX and STEIS as they arise is effective.

Review of deaths of patients on the waiting list has similarly yielded low numbers in terms of patients dying from the condition for which they are awaiting treatment although it has raised questions some indications for which patients are listed.

Review of 62 and 104 day cancer pathway breaches

For the vast majority of Trusts cancer referrals are made via the two week wait (2WW) – thankfully the large proportion of these patients are not diagnosed with cancer. In order for the clinical review to be valuable it is advisable that the starting point is the cancer diagnosis and then a look back exercise to identify whether any breaches occurred in the patient pathway ie 62 or 104 day cancer breaches.

Case study – Abdominal Aortic Aneurysm

At a large Trust prospective review of the waiting list revealed a large backlog of patients with AAA. Clinical prioritisation of the list was undertaken and patients were reordered by the size of their aneurysm. Frequent last minute cancellations occurred at the ‘hot’ site due to emergency admissions and lack of ITU and HDU beds as cancer cases were taking priority. The Trust responded by moving AAA repair to the ‘cold’ site where the availability of ITU and HDU beds was more reliable, leading to a reduction in cancellations and a diminishing backlog of cases.
Outsourcing

To achieve performance targets some Trusts have outsourced the care of patients to alternative providers including NHS and Private organisations. It is important that the same quality review process is carried out for the patients treated elsewhere including identification of harm, duty of candour and the SI review process.

Conclusion

Facing the challenge of a serious incident requiring a clinical harm review can be daunting. By using the suggestions in this handbook and adapting it to meet the individual requirements of the system can help to engage the appropriate individuals, speed up the process, avoid pitfalls and give assurance to patients, patient groups and commissioners that a comprehensive quality review is completed.
Recommendations

The recommendations are as follows:

- Secure senior sponsorship
- Engage relevant stakeholders early once a serious incident has been identified
- Identify a suitable chair and members of the external review panel
- Identify project support resource
- Establish whether this can be incorporated into existing clinical quality review mechanisms or a standalone process is required
- Agree the methodology, terms of reference, internal and external governance arrangements
- Agree a joint communications strategy
- Focus on quality rather than performance in panel discussions
- Agree a completion point if possible
- Write up lessons learned and individual reflections
- Share learning with neighbouring organisations
Acknowledgements

I would like to thank all the individuals who have helped with the preparation of this handbook and been so generous to share their experiences. I would also like to thank the London Clinical Senate Council for their very valuable feedback and support.

If you have any questions or feedback to improve this handbook please contact me

henrietta.hughes@nhs.net

Appendix A – Suggested Agenda for 18 week RTT and Cancer 62 day pathway breach External Clinical Review panel

Appendix B – Suggested Terms of Reference for 18 week RTT and Cancer 62 day pathway breach External Clinical Review panel
Sample Agenda
External Clinical Harm Review

Date
Time
Location

Chair:

<table>
<thead>
<tr>
<th>No</th>
<th>Agenda item</th>
<th>Lead</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Introductions and apologies</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Review of minutes/actions from last meeting</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Trajectory</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Update on prospective clinical harm review</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Deaths on the PTL</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>52 week breaches</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Datix alerts/Serious incidents</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Cancer 62 day pathway breaches</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Referrer Alerts</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Any Other Business</td>
<td></td>
</tr>
</tbody>
</table>

Date and Time of Next Meeting
Appendix B

Suggested Terms of Reference
External Clinical Harm Review

**Frequency**  Monthly

**Purpose**  To give assurance to Commissioners that patients who have suffered harm have been identified and suitably followed up and that patients of greater risk of harm are prioritised by an:

- External review of the process of identifying clinical harm
- External review of the triage and escalation processes by which all patients at high risk of harm are identified and prioritised for treatment
- External review of the process of communicating to GPs, patients and external stakeholders
- Patients who might fall outside the internal clinical harm review process (including patients who died whilst awaiting treatment)

**Attendees**
External Chair
CCG Chair
CCG quality lead
GPs Leads as / when required
Chair of Trust internal clinical harm group
Trust Executives – when required
Project Manager clinical harm programme
CCG Assistant (minutes)
NHS Improvement
Communications Lead – when required

Internal governance arrangements
External governance arrangements
### Standard Agenda Items
1. Introductions and Minutes
2. Action tracker
3. Scope and trajectory
4. Clinical harm work stream milestone plan
5. Clinical Harm update – including detailed patient pathways
6. Communications
7. Lessons learnt and how these are being fed back into the organisation
8. AOB

### Inputs to meeting

<table>
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<tr>
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<th>Owner</th>
<th>Due by</th>
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</thead>
<tbody>
<tr>
<td>Internal clinical harm minutes including decisions and actions</td>
<td>Trust Project Manager</td>
<td>T-7</td>
</tr>
<tr>
<td>Internal clinical harm action log</td>
<td>Trust Project Manager</td>
<td>T-7</td>
</tr>
<tr>
<td>Trajectory</td>
<td>Trust Project Manager</td>
<td>T-7</td>
</tr>
<tr>
<td>Details of patients with harm identified</td>
<td>Internal Clinical Harm Group chair</td>
<td>T-7</td>
</tr>
<tr>
<td>Reports from SI related to RTT</td>
<td>Internal Clinical Harm Group chair</td>
<td>T-7</td>
</tr>
<tr>
<td>Report of review of deaths on PTL</td>
<td>Trust Project Manager</td>
<td>T-7</td>
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<tr>
<td>Report of cancer diagnoses with 62 day pathway breaches</td>
<td>Internal Clinical Harm Group chair</td>
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<tr>
<td>Exception report of referrer alerts</td>
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<td>CQRG minutes and relevant papers</td>
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<td>Communications update</td>
<td>Communications lead</td>
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<tr>
<td>Any internal papers around clinical harm which falls outside those specified above</td>
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Where T = date of next meeting

### Outputs
External clinical harm minutes and action log