Leicestershire Partnership NHS Trust

A Culture of Candour Policy (Incorporating 'Being Open' and 'Duty of Candour)

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Contents

Version Control and Summary of Changes

Version number	Date	Comments (description change and amendments)
Version 5	October – November 2019	Policy completely reviewed & updated to reflect current National NHS & LPT processes; future strategy and direction of services and serious incident/patient safety management. Provide appendices that include staff guides.
Version 6	November/ December 2020	Post 'Duty of Candour' 360 Assurance Review - Updated to reflect feedback. Title altered to reflect the national direction of patient safety incident investigations 'Culture of Candour'. Flow chart realigned Feedback from staff (DMH) to include an example of final sharing letter
Version 10	Oct 2021	Post CQC inspection to review and make actions clearer and responsibility for Directorates
Version 10a V10.1 Ext agreed at Dec Quality Forum	Jan 2022	Reviewed by Kerry O'Reardon – Risk and Assurance Lead

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Equality Statement

Leicestershire Partnership NHS Trust (LPT) aims to design and implement policy documents that meet the diverse needs of our service, population and workforce, ensuring that none

are placed at a disadvantage over others.

It takes into account the provisions of the Equality Act 2010 and advances equal opportunities for all.

This document has been assessed to ensure that no one receives less favorable treatment on the protected characteristics of their age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

In carrying out its functions, LPT must have due regard to the different needs of different protected equality groups in their area.

This applies to all the activities for which LPT is responsible, including policy development, review and implementation.

Due Regard

The Trust's commitment to equality means that this policy has been screened in relation to paying due regard to the general duty of the Equality Act 2010 to eliminate unlawful discrimination, harassment and victimisation; advance equality of opportunity and foster good relations. Information about due regard can be found on the Equality page on e-source and/or by contacting the LPT Equalities Team.

This is evidenced by the provision of information to patients/carers or families in a format appropriate to them and the sensitivity of the situation. Use of translation services will be considered and requested in appropriate cases.

In addition to the examples highlighted above, equality monitoring of all relevant protected characteristics to which the policy applies will be undertaken. Robust actions to reduce, mitigate and where possible remove any adverse impact will be agreed and effectively monitored.

This policy will be continually reviewed to ensure any inequality of opportunity for service users, patients, carers and staff is eliminated wherever possible.

The Due regard assessment template is Appendix 10 of this document

Definitions that apply to this Policy

Approved	Formal confirmation by relevant Committee that the document meets the required standards and may be sent to the Patient Safety Improvement Group (PSIG)
Duty of Candour (DoC)	DUTY OF CANDOUR is a statutory (legal) duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England.
Being Open	Discussing and communicating openly, promptly, fully, effectively and compassionate with those involved in incidents, complaints or claims. It is about being open and transparent with service users about their care and treatment, including when it goes wrong.
Transparency	Allowing information about the truth about performance and outcomes to be shared with staff, patients, the public and regulators
Apology	An 'apology' is an expression of sorrow or regret in respect of a notifiable safety incident. It is not an admission of guilt. Saying 'Sorry' is always best practice
Severe Harm	Permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage related directly to the incident (and not a natural cause of the patient/service user's illness or underlying condition)
Moderate Harm	A moderate increase in treatment (i.e. "*a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care)"); and* *(b) significant, but not permanent, harm, or* *(c) prolonged psychological harm/prolonged pain persisting for over 28 days*
Relevant Person	This may be the patient or service user, or the person acting lawfully on their behalf in the following circumstances: on the death of the patient, or where the patient is under 16 and not competent to make a decision in relation to their care or treatment, or where the patient is 16 or over and lacks the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.
Stakeholders	Staff, Patients/Service Users/Families/carers.
Policy	A policy is principles and rules formulated or adopted by an organisation to reach its long term goals. Policies will be prescriptive by nature. They will state the Trusts expectations for action in a specific subject area and set the parameters within which individuals will operate.

Due Regard	Having due regard for advancing equality involves: • Removing or minimising disadvantages suffered by people due to their protected characteristics. • Taking steps to meet the needs of people from protected groups where these are different from the needs of other people. • Encouraging people from protected groups to participate in public life or in other activities where their participation is disproportionately low.

1.0 Summary

Duty of Candour can make an important contribution to creating a culture of openness, transparency and honesty which always places the safety and the needs of the patient and family above the reputation of the organisation.

What is needed is a culture of openness and honesty, stimulated by a duty of candour, which is wholeheartedly adopted by organisations and individuals. This will enable our patients to be reassured that when things go wrong, we will learn, and we will improve. (Dalton Review 2014)

The commitment to candour has to be about values and it has to be routed in genuine engagement of staff building on their own professional duties and their personnel commitments to their patients.

Appendix 2 describes a summary of this policy, to be used in conjunction with the flowchart (section 5), to provide a 'quick' guide of the process of Culture of Candour in LPT.

2.0 Introduction

This policy seeks to describe the Trusts commitment to openness and transparency at all times.

This policy also describes the requirements under the Health & Social Care Act (2008) Regulation 20: Duty of Candour in particular:

- Inform and apologise by saying 'sorry' to the patient/family as soon as possible following an incident being identified as meeting the requirement
- Follow this up with an explanation of the investigation and a formal written apology using the word 'sorry'
- When the investigation is complete. Share the findings of the investigation and a further written apology specific to the findings of the investigation

Following the occurrence of a notifiable patient safety incident of moderate harm, severe harm or death, we are required to fulfil responsibilities under CQC Regulation 20 of the Health and Social Care Act 2008, Duty of Candour, (introduced in 2014 as a direct response to Recommendation 181 of the Francis Inquiry report into the Mid Staffordshire NHS Foundation Trust). This means that staff have a responsibility to make contact with the patient (and their family and carers) to make them aware of the incident, offer an apology and support. This policy will guide staff to appropriately fulfil this duty.

'Candour' is defined by Sir Robert Francis as 'the volunteering of all relevant information to persons who have or may have been harmed by the provision of services, whether or not the information has been requested and whether or not a complaint or report about that provision has been made'.

This policy has been developed, reviewed, and updated with changes in national standards from the NPSA "Being Open – Saying Sorry When Things go Wrong" document to provide guidance for best practice, and was developed to support the introduction of the Health and Care Social Act 2008 regulations (2014) relating to Duty of Candour and CQC Regulation 20 Duty of Candour.

In April 2015 this became law for all providers registered with the CQC to achieve a verbal Duty of Candour for moderate harm and above. This should be followed up with a written Duty of Candour in a suitable timeframe.
The Standard NHS contract had previously stated that 10 working days is reasonable

In March 2017, the National Quality Board set out to initiate a standardised approach to learning from deaths, central to which was improving engagement with families and carers in that process.

In addition, NHS Resolution (2017) describe that 'saying sorry' meaningfully when things go wrong is vital for everyone involved in an incident, including the patient, their family, carers, and the staff that care for them. 'Saying sorry' is **always** the right thing to do and is not an admission of liability and acknowledges that something could have gone better. This supports the first step to learning from what happened and preventing it recurring

Who does this policy affect?
This policy is aimed at any healthcare staff responsible for ensuring support of the process of openness between healthcare professionals and patients, service users, families and/or their carers following an incident. It gives advice on the 'dos and don'ts of communicating with patients and/or their carers following harm.

'Being Open' is a fundamental process affecting integrated governance throughout the Trust. This document is integrated with the incident, Serious Incident and Complaints processes and clinical quality governance framework. A culture of transparency is fundamental to learning from error.

This document provides a framework for:

- Open, accurate and timely communication, apology and support to patients, relatives, cases - staff
- Staff to be encouraged to admit shortcomings and mistakes learn from errors and be supported.
- Thorough and effective investigation and learning to occur systematically.

All moderate, severe harm and death incidents must have documented evidence of the 'Being Open' process. This is referred to as the 'Duty of Candour' and is a contractual requirement reflecting the Francis Report (2013) following the Mid Staffordshire Enquiry.

3.0 Scope of the Policy

The Trust's Policy for the reporting and management of incidents encourages staff to report all patient safety incidents, including those where there was 'no harm' or it was a prevented patient safety incident (near miss). This policy only relates to incidents graded with a consequence of 'Moderate', 'Severe' or 'Catastrophic' using the Framework/Compulsory Guidance from 'NHS Improvement Serious Incident Framework 2015' and this is unlikely to change in the foreseeable future.

Incidents graded as 'No Harm' or 'Low' in general, do not have to be managed under Duty of Candour using this policy. However, there may be circumstances in which 'Low' and 'No harm' incidents would be appropriate to be communicated to the patient and/or their carer; 'being open' following these incidents is the 'right thing to do'. An example would be where the incident could have resulted in severe harm or death but through luck did not (near miss).

4.0 Benefits

'Being Open' was facilitated by the 7 Steps to Patient Safety (NPSA, 2003) initiative which described a methodical approach to developing a patient safety culture in healthcare organisations. However, it is recognised that more recent public facing enquiries such as the Francis Enquiry (2013) and the Morecambe Bay Investigation (2015) have influenced and changed the culture within healthcare organisations strongly influenced by statutory monitoring by the CQC of 'Being Open' and enacting 'Duty of Candour'.

It is well recognised that patients, service users, families/carers value healthcare professionals being open and honest about the care and when things may have gone wrong.

5.0 Duty of Candour (DOC) flow diagram

Where incidents cause 'Moderate' and ''Severe Harm' or 'Death' '**Duty of Candour'** applies

For all other incidents even if they are no harm/low harm an apology **/ 'BEING OPEN'** should be given to the patient or relevant person and details of the event should be shared.

BEING OPEN: Discussion with patient/relevant person within 48hrs of incident occurring or in case of delayed identification, as soon as possible after identification. Record and agree the disclosure/discussion with patient/or relatives in records & Ulysses incident

DOC: ideally face to face, as a minimum by phone must take place **& then followed up in writing within 10 days** of escalated incident by agreed lead professional (staff level of Registrar/Consultant/Team Leader Band 7 or above). **The sharing of the 'AVMA' leaflet forms part of the written response**

COMMUNICATION: Agreed professional will give information, support and outline the investigation process/timescale to patient/family. Identify if and when they would like to meet and anything they may wish to be included as part of the investigation. Agree method/frequency of communication.

DOCUMENTATION: Record decision/communication in patient's records & on Ulysses DoC Tab. (CPST will send DoC Assurance template & completion instructions). Record date, time, those present, issues raised, that an apology was given (say 'sorry'), the plan for further communication, right of reply at the draft report stage and sharing final report following sign off by Commissioners will be shared with patient/relatives/carers i.e. at agreed meeting, sent by post/email with agreed follow up contact when they have had an opportunity to read the report.

FINAL Duty of Candour: When the final report is shared with patient/family a final 'Duty of Candour' letter of apology should also be sent/given to the patient/family. The letter should always describe that we are sorry for the distress/impact of the incident and a description of actions as a result inviting them to feedback to LPT. This letter comes from the Director or an appropriate member of the Executive Team

6.0 Duties/Responsibilities within the organisation

6.1 Chief Executive
The Chief Executive is responsible for ensuring that there are effective arrangements for Being Open and Duty of Candour within LPT.

6.2 Director of Nursing/Allied Health Professionals & Quality
To promote the Being Open/Duty of Candour culture and ensure overall implementation of this document supported, where appropriate, by the Medical Director. To ensure that the corporate patient safety team has effective systems in place for monitoring assurance purposes.

6.3 Medical Director
Has Caldicott Guardian responsibilities and will support Consultant colleagues with the principles and execution of 'Being Open' and compliance with the 'Duty of Candour'.

6.4 Clinical Service Director
The Clinical Service Director is responsible for ensuring that the principles of this policy are applied consistently across their Directorate. To ensure that patient s and or their families have been informed when it is considered that there may have been harm caused and any communication is compassionate. There is also a responsibility to support open communication between staff, patients, families and carers. The Director is responsible for leading the Duty of Candour policy.

6.5 Clinical Quality and Governance Leads
The Clinical Governance Leads, along with heads of service/service managers support the Corporate Patient Safety Team/Patient Experience Team in discovering the circumstances of an incident and ensure that appropriate discussions with patient/carers have taken or will take place and are recorded appropriately.
Through the clinical areas they will promote the Duty of Candour policy to all grades of staff and ensure that they access relevant training.
Additional responsibilities:

- Monitoring completion of the Duty of Candour process using the relevant section of the Trust incident reporting system Ulysses.
- Oversee the timely review of incidents in their Directorate to ensure that all incidents that meet the requirement for DOC are identified in a timely manner
- Escalation to the Clinical Director or Head of Nursing of any instance where the Duty of Candour process has not been adhered to
- Ensure there is governance oversight of this compliance.

6.6 Heads of Service/Service Managers/Matrons
They must be informed of all incidents that result in moderate, severe harm or death, and that patients/families/carers have been informed; 'being open'. May also be the persons who enact the full Duty of Candour.

6.7 Head of Patient Experience/Corporate Patient Safety Team
The Head of Patient Experience and Corporate Patient Safety Team will undertake assurance in respect of becoming aware of a complaint that meets the criteria for serious incident. A designated member of the corporate patient safety team, with the support of the Trust's Legal Facilitator, will be the lead point of communication with H M Coroner and other interested external stakeholders (e.g., commissioners, Police) where required.

6.8 Lead Clinician Responsible for Care of Patient
The lead clinician responsible for the care of the patient involved in any event may be involved in 'Being Open/Duty of Candour' practice or will participate fully with the lead responsible for communicating with the person involved in the event.

6.9 Patient and Family Liaison Lead (Corporate Patient Safety Team)
The Patient and Family Liaison Lead will provide support to the clinical leads and managers in ensuring that the Trust satisfies its obligations under CQC Regulation 20: Duty of Candour in the initial notification of a qualifying patient safety incident. The Patient and Family Liaison Lead will ensure a consistent level of timely, meaningful and compassionate engagement throughout the investigation and feedback process. They are also a point of contact for staff in relation to Being Open/Duty of Candour. It is not the role of the Patient and Family Liaison Lead to undertake Duty of Candour on behalf of clinical teams.

6.10 All Staff
All staff, including temporary staff, have a responsibility to participate with the requirements of this policy and the need to report, inform and discuss adverse events with the patients, families/carers, in line with this policy. In addition, all staff are required to inform their manager immediately if an event occurs as Being Open will apply and Duty of Candour where moderate harm or above has occurred?

NB all registered staff have a professional Duty of Candour

Any member of staff, who believes that a colleague is not following this policy after an incident, should discuss this with their line-manager. Failure to follow this policy could lead to action being taken in accordance with the Trust's Disciplinary Policy and may also result in referral to the relevant profession's regulatory body.

6.11 The Person Responsible for the Being Open/Duty of Candour
For the initial notification that an incident has occurred; this will be undertaken by the most appropriate person; usually a manager/supervisor; it could also be a member of staff who already has an established relationship with the affected patient, their family and/or carers and any relevant others. This will be agreed locally and is likely to be a member of staff that works in a role that directly involves them with the patient. Details of this contact should be retained. It is the responsibility of this person to complete the information on the DOC assurance template/Ulysses the Trust's incident management system.

6.12 Ward/Team Managers
Following any local incident, the Ward/Team Manager has the responsibility to check that the event has been locally investigated and for appropriate cases that the patient and relevant others have been informed of the event. A record of this conversation must be recorded within the Ulysses incident record by the reviewer/manager. If it has been identified that the patient and relevant others have not been informed, the Ward/Team Manager will take appropriate steps to ensure the appropriate communication has taken place.
The Ward/Team Manager will inform the Senior Manager/Head of Service of the requirement for the Being Open/Duty of Candour processes according to the grading of

the incident and will provide assurance of any communications for which they have responsibility for.

6.13 Serious Incident (SI) Investigators should:

- Ensure that they follow and enact the 'Being Open and Duty of Candour' Seek assurance that 'Being Open/Duty of Candour' communication has occurred with the patient/family or carers as an early priority
- Always make contact with patient/family where possible assuming that a person has the capacity to make 'particular decisions when it needs to be made' unless you have evidence they do not (according the statutory principles of the Mental Capacity Act 2005). Or in cases where it is known they do not, invite the relevant person to contribute to the SI Investigation and reflect their contribution in the final report. Patients/family, who are proven to lack capacity, should always, where possible, be present during discussion/any decision making.
- Refer to the Being Open/Duty of Candour discussions recorded in the health records/incident record and included in the 72 hour Report in their investigation.
- Alert the Commissioning Manager/ Governance Manager/Corporate Patient Safety Team of any cases where there is difficulty in the Being Open/Duty of Candour process.
- Ensure that an accurate record is maintained on Ulysses

7.0 Key Benefits of 'Being Open and the Culture of Candour'

Openness about what appears to have happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects. Patient safety incidents can also lead to further treatment and ultimately litigation; openness and honesty can help prevent such events becoming formal complaints and litigation claims.

For healthcare staff, Being Open has several benefits, including:

- Satisfaction that communication with patients and/or their carers following a patient safety incident has been handled in the most appropriate way.
- Improving the understanding of incidents from the perspective of the patient and/or their carers
- The knowledge that lessons learned from incidents will help prevent them happening again.
- Having a good professional reputation for handling a difficult situation well and earning respect among peers and colleagues.

By being open and transparent, staff can decrease the trauma and disappointment often reported by many patients/families when care has not gone according to plan.

8.0 Communication with Patients, Service Users, Families/Carers

CQC Regulation 20: Duty of Candour is a direct response to recommendation 181 of the Francis Inquiry Report (2013) and requires that communication should be with **'the relevant person'** – this may be the patient/service user, or the person acting lawfully on their behalf in the following circumstances: on the death of the patient, or where the patient is under 16 and not competent to make a decision in relation to their care or

treatment, or where the patient is 16 or over and is proven to lack the mental capacity in relation to the matter in accordance with the Mental Capacity Act 2005.

Patients/carers/families should receive a sincere expression of apology for events that result in harm or have the potential to do so. Consideration must be made in relation to the following points:

- Offer appropriate sources of support to the patient or family, chaplaincy services, bereavement support agencies, where relevant or advocacy agency contact details.
- Offer a 'Being Open/Duty of Candour' meeting as soon as possible after the incident/event, with consideration made as to the availability of the patient/family/carer, availability of any relevant key staff members and location of the meeting.
- Choose the most appropriate staff member to be the main point of contact for the patient, their family and/or carers. For Serious Incidents, Clinical Reviews, Complaints or claims investigations, this person will generally be the lead investigator. It is expected however, that the initial 'Being Open/Duty of Candour' conversation /meeting relating to the incident itself, rather than the notification of the investigation, will have already have been completed by the manager of the responsible clinical area or suitable delegate as soon as was reasonably possible.
- The content of the 'Being Open/Duty of Candour' conversation/meeting must be truthful and factual, explained in clear terms to the patient/carer/family, ensuring they understand and allowing questions to be asked.
- All communication in relation to the initial 'Being Open/Duty of Candour' discussions, including at clinical level, must be documented fully in Ulysses to include the date and the member of staff who has made contact. This will also be recorded in the clinical records.
- Where attempts to contact have been unsuccessful, a record/detail/method of attempts should be kept and noted in records and Ulysses.
- Complaints communications will be recorded by the lead investigator and covered in response letters or complaints files for verbal resolutions. Details of complaints MUST not be entered into the clinical record.
- Follow-up after a 'Being Open/Duty of Candour' conversation/meeting should be offered to allow the patient/carer/family an opportunity to ask further questions and to be kept updated.
- Where an incident that caused(s) 'moderate harm and above' has occurred, and where it is reasonable to suspect that this was owing to an act or omission by LPT staff, a formal duty of candour follow up letter **MUST** also be sent following the initial incident notification. This letter should contain an apology, (using the word 'sorry' is best practice) that the incident has occurred, an explanation of the facts known so far and what, at that time, is the expected follow up. **LPT 'Duty of Candour' letter Template can be used (Appendix 3),** a '**AVMA: The Duty of Candour' leaflet should** also be sent at this time which offers written patient information.
- All communication with patients/families must be timely, using clear language. Contact with the relevant person should be made through all possible means.
- Being Open meetings must allow sufficient time for discussion and questions.
- Staff must demonstrate that they are approachable through written communications, the way they speak and their body language.

- Openness is promoted by staff showing they are caring and sympathetic,and providing several opportunities for patients/relatives to ask questions and gain information.
- Duty of Candour is a mandatory terms of reference for all SI's and a mandatory action point on each Action Plan.
- Disclosing to the patient that an incident has occurred, which they may be unaware of, has to occur **as soon as possible** (and within **10** working days of identifying the incident) by a member of staff with understanding and experience/support as part of a planned process.
- It is usual to share the findings of investigations with the patient/family afterwards in a letter and a meeting. Patients/families are asked how they would prefer this to occur.

9.0 Response following a death in care

When recording a death on Ulysses, questions are asked regarding Duty of Candour. It is important to understand that these questions relate to the fact that an incident has occurred and a patient has died, rather than the death itself. Therefore the contact, apology offered and support offered under Duty of Candour should be in respect of the incident, rather than just informing the next of kin regarding a death; which will have often been undertaken by the Police or Ambulance services for community based deaths. This will of course not be the case in the event that a patient dies whilst under the 24/7 care of LPT, where the manager will also be informing the family of the death itself.

If LPT are notified or become aware of a death please liaise with your line manager as to whether contact by/from LPT is appropriate. Should the decision be made that contact is not appropriate; the rationale for this should be noted in the Duty of Candour free text point on Ulysses.

The National Quality Board, National Guidance on Learning from Deaths (2017) has determined the following principles for all NHS Trusts to follow in engaging meaningfully and compassionately with bereaved families and carers in relation to all stages of responding to a death:

- Bereaved families and carers should be treated as equal partners following bereavement.
- Bereaved families and carers must always receive a clear, honest, compassionate and sensitive response in a sympathetic environment.
- Bereaved families and carers should receive a high standard of bereavement care which respects confidentiality, values, culture and beliefs, including being offered appropriate support. This includes providing, offering or directing people to specialist suicide bereavement support.
- Bereaved families and carers should be informed of their right to raise concerns about the quality of care provided to their loved one.
- Bereaved families and carers views should help to inform decisions about whether a review or investigation is needed.
- Bereaved families and carers should receive timely, responsive contact and support in all aspects of an investigation process, with a single point of contact and liaison.
- Bereaved families and carers should be partners in an investigation to the extent, and at whichever stages, that they wish to be involved, as they offer a unique and equally valid source of information and evidence that can better inform investigations.

- Bereaved families and carers who have experienced the investigation process should be supported to work in partnership with Trusts in delivering training for staff in supporting family and carer involvement where they want to.

9.1 In the event that the death has occurred within another organisation (e.g. secondary care)
Whoever first identifies, or is made aware that a patient safety incident has occurred must also notify the Corporate Patient Safety Team via Ulysses and identify as to whether contact with the family is appropriate. A review of the care provided by LPT prior to the patient's death may still be appropriate and therefore Duty of Candour still applies.

If there has been a significant delay in notification (e.g. notification has come via the Coroner's Court or GP a number of months later) a Ulysses incident should still be raised. However, in these circumstances the Duty of Candour processes may require additional consideration in order that the carers/families are informed of the suspected incident carefully to avoid unexpected shock or distress.

9.2 Inquests and Other Interested External Stakeholders
It is important that Being Open/Duty of Candour is applied in relation to assisting HM Coroner in investigations for inquest purposes. The Corporate Patient Safety Manager will share copies of Serious Incident and Clinical Review investigation reports, including statements and associated documentation with Her Majesty's Coroner for those incidents which are subject to inquest. Information will also be shared as part of 'Being Open/Duty of Candour' to other appropriate interested external stakeholders e.g. Health and Safety Executive, Police, CQC, Parliamentary and Health Service Ombudsman etc. Usually, the Being Open /Duty of Candour discussion and any investigation occur before the coroner's inquest. However, in certain circumstances, the Trust may consider it appropriate to wait for the coroner's inquest before holding the discussion with the bereaved families/carers as the coroner's report may help to complete the picture of events leading up to the patient/service user's death. In any event an apology should be issued as soon as possible after the patient/service user's death, together with an explanation that the coroner's process has been initiated and a realistic timeframe of when the family/ carers will be provided with more information

9.3 Breaches of confidentiality
In cases where there is a confirmed breach of confidential personal data, it is best practice guidance that the organisation legally responsible for the data, should notify the relevant data subject of this breach. This best practice guidance is supported further by the General Data Protection Regulation (GDPR). This regulation makes it a legal requirement to inform data subjects of a breach of their data rights when the risk to the data subject is considered high.

Risk exists when the data breach could lead to physical, material or non-material damage to the data subject. Any breach of sensitive personal data as defined by the Data Protection Act 98 or of the special categories of personal data as defined by the General Data Protection Regulation should be considered likely to cause damage. Notification to the data subject should include a full explanation of the cause of the breach with the remedial action being undertaken and an apology.
The Information Governance Team will provide specialist advice to the Investigating Manager on request. For each breach of confidentiality the Duty of Candour

communication will also need to be approved by the Senior Information Risk Owner for the Trust.
Where there is uncertainty as to whether a data breach has taken place, the decision to notify the data subject should be made by assessing the following factors:

- The likelihood that a breach occurred
- The possibility of damage
- The need of the data subject to take precautionary action e.g. change bank details.

9.4 Criminal or intentional unsafe act

Patient safety incidents are almost always unintentional. However, if at any stage following an incident it is determined that harm may have been the result of a criminal or intentional unsafe act, the Director of Nursing. AHP & Quality should be notified immediately. This also applies to independent contractors operating within primary care.

10.0 Special Circumstances

There are instances where the approach to 'Being Open/Duty of Candour' may need to be modified according to the patient/service user and their circumstances, particularly with regard to mental capacity:

10.1 Children

The legal age of maturity and acquisition of the full rights to make decisions regarding treatment and for giving of consent is 16 years of age
By virtue of section 8 of the Family Law Reform Act 1969, people aged 16 or 17 are presumed to be capable of consenting to their own medical treatment, and any ancillary procedures involved in that treatment, such as an anaesthetic.
At this time the individual's right to confidentiality becomes vested in them rather than parents/guardians. However, it is still considered good practice to encourage competent children to involve their families in any decision-making. Previous legal rulings have determined that children under 16, who fully understand what is involved in any planned treatment/care or a decision process, can also give consent (also known as Gillick competence based on Fraser Guidelines as detailed in Gillick v West Norfolk & Wisbeck Area Health Authority [1986] AC 112 House of Lords.). Where a child is involved in a patient safety incident and is judged to have the cognitive ability and emotional maturity to understand the information provided, she/he should be directly involved the 'Being Open/Duty of Candour' process. The patents should still be involved unless the child expresses a wish for them not to be present.
Where a child is deemed not to have sufficient maturity or the ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child and the views of the parents should be sought first. In addition, one has to assume a 16–18-year-old is competent until proven otherwise,
In order to establish whether a young person aged 16 or 17 has the requisite capacity to consent to the proposed intervention, the same criteria as for adults should be used. If a young person lacks capacity to consent because of an impairment of, or a disturbance in the functioning of, the mind or brain then the Mental Capacity Act 2005 will apply in the same way as it does to those who are 18 and over (see chapter 2).

10.2 Patients/Service users under the care of a mental health team

Usual procedure around Being Open/Duty of Candour should be followed unless the service user also has a cognitive impairment (see below). The only circumstance where it is appropriate to withhold patient safety incident information from a service user under the care of a mental health team is when it would cause adverse psychological harm to disclose the information. This decision should be made by their responsible medical clinician and supported by a second opinion. Apart from exceptional circumstances, it is never appropriate to discuss patient safety incident information with a carer or relative without the express permission of the service user. To do so is an infringement of the patient's confidentiality and human rights.

10.3 Patients/Service users with cognitive impairment
Where an individual has a condition which limit their ability to understand what is happening to them, they may have an authorised person able to act on their behalf under a lasting/enduring Power of Attorney. After confirming this Power of Attorney extends to decision making and medical care/treatment of the patient the Being Open/Duty of Candour discussion would be held with the holder of the Power of Attorney. Where a Power of Attorney has not been appointed, the clinicians may act in the service user's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the service user as a whole and not simply their medical interests. However, the service user with a cognitive impairment should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

10.4 Patients/Service users with reduced intellectual ability and difficulty with everyday activities (learning disabilities)
Where a service user has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If not cognitively impaired they should be supported in the 'Being Open/Duty of Candour' process by alternative communication methods (i.e., communication support following personalised communication guidelines).

On agreement and consultation with the patient, family/carer, an advocate should be appointed; appropriate advocates may include carers, family or friends of the service user. The advocate should assist the patient during the 'Being Open/Duty of Candour process', focusing on ensuring that their views are considered and discussed.

10.5 Complaint received from Patient/Family
If a service receives a formal complaint during the SI Investigation process the Patient Involvement Team must be informed of the ongoing SI and all relevant information shared: the complaint response will be 'on hold' and patient/family informed until the SI investigation or internal investigation process is completed. Where possible it may be acceptable to incorporate the patients/families concerns into the SI investigation with mutual negotiation.

11.0 'Being Open /Duty of Candour' Initial Processes

11.1 Incident Detection or Recognition

The 'Being Open/Duty of Candour' process begins with the recognition that a patient has suffered moderate or severe harm, has died, as a result of an incident. Formal 'Duty of Candour' requires the patient/relatives to be informed verbally as soon as possible

following identification of the incident. This should be followed up with written details, and **must be completed by 10 working days after identifying that the incident occurred or was reported. The CPST will provide support with the time requirements.**

A patient safety incident may be identified by:

- Staff at the time of the incident
- Staff retrospectively when an unexpected outcome is detected
- Patient, family/carers who expresses concern or dissatisfaction with their or patient's healthcare either at the time of the incident or retrospectively
- Incident detection systems such as incident reporting or medical records review
- Other sources such as detection by other patients, visitors or non-clinical staff

As soon as a patient safety incident is identified ensure that prompt and appropriate clinical care and prevention of further harm is in place. Where additional treatment is required, this should occur whenever reasonably practicable after a discussion with the patient and with appropriate consent. Where the degree of harm is not yet clear but may fall into the above categories in future, the relevant person must be informed of the notifiable safety incident in line with the requirements of the regulation.

All Patient Safety Incidents should be reported in line with the Incident/Serious Incident Reporting Policy

11.2 Initiating the Being Open/Duty of Candour Process

Staff must report the incident via the electronic incident reporting system and to senior staff immediately
Face to face discussion is best or a telephone conversation if the patient/service user is not in hospital. Verbal communication should always occur before a letter is sent. It is useful to identify an appropriate senior staff member to be a single Trust point of contact.

Make Initial Disclosure and Apology with the Patient/Family as Soon As Possible and Within 10 Working Days of identifying the Incident
Delay in disclosure must be avoided. The initial communication must occur even if details are not yet clear. This communication can occur by any appropriate means – face-to-face is best, but it can be a telephone call or invitation to a meeting. Reference should be made to the investigation which may provide different or further information.

This initial communication must be recorded in the health records with a heading "Duty of Candour meeting" – Date, time, people present (including patient and family names), apology, what was discussed, concerns raised by the family, arrangements for further communication/support etc.

The communication is to disclose that an incident has occurred, offering apology and sympathetic support. It is important to avoid giving too much detail about the incident until the incident investigation has been completed. The patient/family can be told they will be invited to a meeting to discuss details either during or after the investigation, as preferred by the patient/family. Patient/family concerns, preferences etc. should be recorded and considered in the investigation.

An offer to meet is made to the family. This is usually at the end of the investigation so the findings can be shared and discussed, but may also occur before the investigation starts or during the process. The approach is agreed with the patient/family. The patient/family may require meetings at any stage during the investigation.

This is recorded on the DOC assurance template

11.3 Initial assessment to determine level of response and preliminary team discussion may be required where it is not clear
It is best practice that the multidisciplinary team (MDT), including the most senior health professional involved meet as soon as possible after the event to:

- Establish basic clinical and other facts
- Assess the incident and determine the level of immediate response
- Identify who will be responsible for discussion with the patient, family/carers
- Consider the appropriateness of engaging patient support at this early stage:
    - This includes the use of a facilitator, a patient advocate or a healthcare
    - professional who will be responsible for identifying the patient's needs and
    - communicating them back to the healthcare team
- Identify immediate support needs for the healthcare staff involved
- Ensure a consistent approach by all team members around discussions with the patient and family/carers
- Inform Corporate Patient Safety Team and local Head of Service of any potential serious incident by email LPT-PatientSafety@leicspart.nhs.uk

11.4 Levels of 'harm'

Low (minimal harm)
Unless there are specific indications or the patient requests it, the communication, investigation, analysis and the implementation of changes will occur at local service level. Communication should take include recorded open discussion, including an apology, between the staff providing the patient's care and the patient and family/carers. Reporting remains through Ulysses with feedback into local governance processes.

Moderate, Severe and Death

Harm Level	Definition
Death	The **death relates directly to the incident** rather than the natural course of the patient's illness or underlying condition
Severe Harm	A **permanent** lessening of bodily, sensory, motor, physiological or intellectual functions **related directly to the incident** rather than the natural course of the patient's illness or underlying condition
Moderate Harm	Harm that requires a **moderate increase in treatment** e.g. unplanned surgery, unplanned readmission, prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, transfer to another treatment area (e.g. acute trust for surgery) **Significant but not permanent harm**
Prolonged Psychological Harm	A patient has experienced, or is likely to experience for at least 28 consecutive days
Prolonged Pain	A patient has experienced, or is likely to experience for at least 28

	consecutive days

11.5 Timing of initial 'Being Open'/Duty of Candour' discussion

The initial 'Being Open/Duty of Candour' discussion with the patient, family/carers should occur as soon as possible after recognition of the incident. Factors to consider when timing this discussion should include:

- Clinical condition of the patient. Some patients may require more than one meeting to ensure that all the information has been communicated to and understood by them
- Availability of the patient's family and/or carers
- Availability of support staff, for example a translator or independent advocate, if required
- Patient preference (in terms of when and where the meeting takes place and who leads the discussion)
    - Duty of Candour initial disclosure must take place within 10 days of incident or incident recognition; **any delay and details must be recorded on Ulysses**

11.6 The healthcare professional who informs the patient and/or their carers about a patient safety incident

This should be the most senior person responsible for the patient's care and/or someone with experience and expertise in the type of incident that has occurred. This could either be the patient's Consultant, Ward Manager/Matron.

They should:

- Ideally be known to, and trusted by, the patient, family/carer (Relevant person)
- Be able to relay the facts relevant to the incident
- Offer an apology, reassurance and feedback to patient, family/carers
- Provide information about available impartial advocacy and support services, their local, i.e. Healthwatch and other relevant support groups, for example Cruse Bereavement Care and Action against Medical Accidents (AvMA), to help them with emotional support/counselling
- Provide support to access the complaints procedure if requested

11.6.1 Assistance with the initial 'Being Open/Duty of Candour' discussion

The healthcare professional communicating information about an incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience of Being Open procedures.

11.6.2 Consultation with the patient regarding the healthcare professional leading the 'Being Open/Duty of Candour' discussion

If for any reason it becomes clear during the initial discussion that the patient would prefer to speak to a different healthcare professional, the patient's wishes should be respected. A substitute, with whom the patient is satisfied, should be provided.

11.6.3 Responsibilities of junior healthcare professionals

Junior staff or those in training should not lead the Being Open/Duty of Candour process

except when all the following criteria have been considered:

- The incident resulted in low harm
- They have expressed a wish to be involved in the discussion with the patient, family/carers
- The senior healthcare professional responsible for the care is present for support

11.6.4 Patient safety incidents related to the environment of care

In such cases a senior manager of the relevant service will be responsible for communication. A senior member of the MDT, where possible, should be present to assist at the initial 'Being Open/Duty of Candour' discussion. The healthcare professional responsible for treating the injury should also be present to assist in providing information on what will happen next and the likely effects of the injury.

11.6.5 Involving healthcare staff who made mistakes

Some patient safety incidents that resulted in moderate harm, major harm or death will result from errors made by healthcare staff while caring for the patient. In these circumstances the member(s) of staff involved may or may not wish to participate in the 'Being Open/Duty of Candour' discussion with the patient and/or their carers.

11.6.6 Content of the initial 'Being Open/Duty of Candour' discussion with the patient and/or their carers

With the patient's agreement, carers and those close to the patient can be included in the discussions and decision making. If the patient is unable to participate or has died, then the carers or people closely involved with the patient may be provided with limited information in order to make decisions. This should be done with regard to confidentiality and any patient instructions.

Useful points to consider:

- Patients, families/carers are likely to be anxious, angry and frustrated
- There should be an expression of genuine sympathy, regret and an apology for the incident and any harm that has occurred; ensuring the word 'sorry' is used.
- The patient, family/carers should be informed that an incident investigation is being carried out to understanding what has happened which will allow more information sharing once investigation is complete.
- It should be made clear to the patient and/or their carers that new facts may emerge as the incident investigation proceeds
- The patient's and/or carers understanding of what happened should be taken into consideration, as well as any questions they may have and would like considered as part of the ongoing investigation.
- Appropriate language/terminology should be used when speaking to patients, families/carers. For example, using the terms 'patient safety incident' or 'adverse event' may be at best meaningless and at worst insulting to a patient and/or their carers. If a patient's and/or their carers first language is not English, or they have other communication difficulties, their language needs should be addressed as well as providing information in both verbal and written formats. The use of a translator should always be considered.
- An explanation should be given about what will happen next in terms of the long-

term treatment plan and incident analysis findings, in which the patient will have the opportunity to be involved
- Information on likely short- and long-term effects of the incident (if known) should be shared. The latter may have to be delayed to a subsequent meeting when the situation becomes clearer. Some patients may not wish to know every detail of an incident. They should be reassured that if they change their minds, this information will be made available to them
- An offer of practical and emotional support should be made. This may involve giving information on third parties such as charities and voluntary organisations, as well as offering more direct assistance. Information about the patient and the incident should not normally be disclosed to third parties without the patient's consent.
- The patient, family/carer should be given the contact details of one member of staff who will be their contact point for them.
- Explain that they are entitled to continue to receive all usual treatment and be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team, the appropriate arrangements should be made for them to receive treatment elsewhere

It is essential that the following **does not occur:**
- Speculation
- Attribution of blame
- Denial of responsibility
- Provision of conflicting information

The initial 'Being Open/Duty of Candour' discussion is the first part of an ongoing communication process. There should be repeated opportunities for the patient and/or carer to obtain information about the incident by contact with and from investigators.

Formal Duty of Candour **must be undertaken for all 'moderate and above' incidents**. This is a statutory requirement and should be undertaken by Band 7 and above Nursing/AHP staff and medical staff of Registrar and above.
Once this meeting has taken place its record must be detailed in a formal letter – see **appendix 4** to guide the context of the letter.

12.0 Completing the Formal Statutory 'Duty of Candour' process after initial 'Being Open/Duty of Candour'

12.1 Communication with the patient and/or their carers following completed and closed serious investigation report must be offered to be shared within 10 working days

After completion of the incident investigation, a request to meet should be offered to feedback findings if the requested method to meet by the patient/family/carer is written only then the letter should include the following:
- A sincere and meaningful apology including the use of the word 'sorry' that the incident occurred
- The chronology of clinical and other relevant facts
- Details of the patient's, families/carers concerns and questions
- A summary of the factors that contributed to the incident
- Information on what has been and will be done to avoid recurrence of the incident

and how these improvements will be monitored
- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident
- Letter to be signed by the appropriate Director or Executive sign off following Head of Nursing approval.

13.0 Special Circumstances
It is expected that in most cases there will be a complete discussion of the findings of the investigation and analysis. In some cases, information may be withheld or restricted, for example: where communicating information will adversely affect the health of the patient; where investigations are pending coronial processes; where specific legal requirements preclude disclosure for specific purposes. In these cases, the patient will be informed of the reasons for the restrictions.

13.1 Continuity of care
When a patient has been harmed during the course of treatment and requires further therapeutic management or rehabilitation, they should be informed, in an accessible way, of the ongoing clinical management plan. This may be encompassed in discharge planning policies addressed to designated individuals, such as the referring GP, when the patient safety incident has not occurred within the Trust.

Patients and/or their carers should be reassured that they will continue to be treated according to their clinical needs even in circumstances where there is a dispute between them and the healthcare team.
They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the healthcare team involved in the patient safety incident.

14.0 Monitoring Compliance and Effectiveness

The Incident Oversight Group (IOG) will monitor compliance and effectiveness of this policy. Any reported issues regarding compliance will be escalated to the Quality Forum. This policy will be reviewed at the time specified for review. Evidence from serious incident reports will be collected to monitor use of the Duty of Candour Policy.
The CPST will monitor the timeliness of communication monthly (based on the best practice timescales previously identified in the NHS standard Contract of 10 days) and will review the quality of the communication on an ad hoc basis monthly and formally yearly in November. (starting 2022)

Clinical directorates will ensure oversight at DMT

For information on how this policy will be monitored please refer to the monitoring table in Appendix 6.

14.1 Identification of a statutory Breach

Should the Directorate or the CPST believe a statutory breach has occurred this will be escalated and discussed at Strategic Executive Board (SEB) and if confirmed a statutory notification will be made

14.2 What are the consequences of breaching the duty?

When CQC identifies a breach of Regulation 20, it will assess the impact and decide whether it needs to take regulatory action. CQC have indicated however:

- We expect to mainly use the new regulations on candour to confirm or encourage good practice through the ratings we give, rather than to enforce them directly.
- Criminal sanctions have a role to play, but by themselves are unlikely to be the strongest driver for promoting a culture of openness in providers.

- We will develop the processes that our inspectors will use to inspect and enforce the duty of candour, and ensure that our approach is proportionate, for example taking account the degree of harm.

- We will not shy away from using the full weight of our powers, but we anticipate that this will be in cases where there is evidence of deliberate withholding or manipulation of information.

Overall whilst doctors and nurses will not be personally liable in terms of any criminal sanctions; where CQC identifies a breach, it is open to it to prosecute that organisation should it feel that the breach is serious enough. Consequently, it is entirely possible for an organisation to be prosecuted for failing to meet the statutory requirements of Regulation 20.

It was the case that where an organisation failed to meet the requirements of a Regulation, a warning notice was issued with a timescale for compliance. If that organisation then failed to comply, CQC may decide to bring a prosecution. If the organisation did comply, then no prosecution could be brought. This has now changed with the implementation of Regulation 20 so that if an organisation is not meeting its obligations in terms of its statutory duty of candour, it is open to the CQC to immediately prosecute. Clearly this is only likely to happen in the most serious of cases (ie where there are a lack of systems for example), but it is something to bear in mind.

In addition, it is also worth noting that in terms of personal liability a Director or Senior Manager can also be prosecuted, with criminal sanctions imposed if the organisation's serious failure to meet statutory requirements of the duty of candour stem from actions done with consent, or as a result of neglect, or the failure should have been reasonably known, for example.

15.0 Training Needs

There is a need for training identified within this policy. In accordance with the classification of training outlined in the Trust Learning and Development Strategy there is a Duty of Candour e-learning package available to all staff.
The CPST will also provide face to face training on request

There is no ‘being open’ specific training package

16.0 Standards/Performance Indicators

TARGET/STANDARDS: CQC	**KEY PERFORMANCE INDICATOR**
Regulation 10: Dignity and Respect	Annual Audit of completion of Duty of Candour as part of the SI process
Regulation 12: Safe Care and Treatment	Annual Audit of completion of Duty of Candour as part of the SI process
Regulation 20: Duty of Candour	Statutory Requirement via key lines of enquiry

17.0 Useful Links, Reference and Bibliography

AvMA	Action against Medical Accidents	http://www.avma.org.uk/
Cruse	Bereavement Care	www.crusebereavementcare.org.uk
GMC	General Medical Council	http://www.gmc-uk.org/
HCPC	Health and Care Professions Council	http://www.hcpc-uk.co.uk/
MDU	Medical Defence Union	http://www.the-mdu.com/
MPS	Medical Protection Society	http://www.medicalprotection.org/uk
NMC	Nursing and Midwifery Council	http://www.nmc-uk.org/
RCN	Royal College of Nursing	www.rcn.org.uk
RCGP	Royal College of General Practitioners	http://www.rcgp.org.uk
RCP	Royal College of Physicians	www.rcplondon.ac.uk
NHS Resolution		https://resolution.nhs.uk/

Care Quality Commission https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour

Francis Enquiry: Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry: Executive Summary. Francis, R. (2013).
http://www.midstaffspublicinquiry.com/report

The Report of the Morecambe Bay Investigation Dr Bill Kirkup CBE March 2015
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/408480/47487_MBI_Accessible_v0.1.pdf

Guidance on the professional duty of candour: Joint guidance with the General Medical Council on the duty of candour. https://www.nmc.org.uk/standards/guidance/the-professional-duty-of-candour/

'**Saying Sorry when things go wrong: being Open: Communicating patient safety incidents with patients, their families and carers**'. NPSA November 2009 – available online

NHS Improvement Serious Incident Framework 2015

'Examining new options and opportunities for providers of NHS care' 'The Dalton Review' 2014.
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/384126/Dalton_Review.pdf

Appendix 1

A GUIDE TO APPLYING THE DUTY OF CANDOUR

The Duty of Candour refers to saying sorry when things have 'gone wrong'. Whether anything has 'gone wrong' may not be known until any investigation or Coroner's inquest process has completed; by which time any opportunities to engage with and involve patients and/or families may be lost.

The complex realities of delivering healthcare can mean that identifying a patient safety incident that leads to harm is not always straightforward *(Building a Culture of Candour 2014)* The majority of harm that occurs is not always a simple case of one error leading to obvious identifiable harm. Most harm is a consequence of multiple instances of sub-optimal care that are not necessarily obvious to those involved in the delivery of care.

Deciding Whether the Duty of Candour Applies

The Duty of Candour is a legal and contractual duty to inform patients and families when there has been a mistake in their care which has caused harm. The Duty of Candour only applies where a 'notifiable safety incident' has occurred during the delivery of a regulated activity and:

1. The incident was an **unintended** or **unexpected** outcome of the care planned for the patient **AND**

2. The incident **could** have or **appears** to have resulted in the level of harm described in the table below

Harm Level	Definition
Death	The **death relates directly to the incident** rather than the natural course of the patient's illness or underlying condition
Severe Harm	A **permanent** lessening of bodily, sensory, motor, physiological or intellectual functions **related directly to the incident** rather than the natural course of the patient's illness or underlying condition
Moderate Harm	Harm that requires a **moderate increase in treatment** e.g. unplanned surgery, unplanned readmission, prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, transfer to another treatment area (e.g. acute trust for surgery) **Significant but not permanent harm**
Prolonged Psychological Harm	A patient has experienced, or is likely to experience for at least 28 consecutive days
Prolonged Pain	A patient has experienced, or is likely to experience for at least 28 consecutive days

Where the degree of harm is not immediately clear but **may** fall into the above self-harm categories in future, the relevant person must be informed of the incident in line with the requirements of the regulation. In all such cases, the decision and rationale for not implementing Duty of Candour should be clearly documented in the patient clinical notes.

Mental Health Examples

In-Patient Self-Harm

NICE guidance defines self-harm as:

'[…] any act of non-fatal self-poisoning or self-injury carried out by a person, irrespective of their motivation. This commonly involves self-poisoning with medication or self-injury by cutting. Self-harm is not used to refer to harm arising from overeating, body piercing, body tattooing, excessive consumption of alcohol or recreational drugs, starvation arising from anorexia nervosa or accidental harm to oneself.'

Patients who present self-harming behaviours must have a meaningful risk assessment, safety care plan and wherever practicable, an advance statement in place which have been developed in collaboration with the patient. However, it is recognised that self-harm is complex and in spite of these being in place, self-injurious behaviour may still occur.

Where it is clear that a patient who has self-harmed has done so as a result of an omission, an error or deviation from a risk management plan, these events will trigger the Duty of Candour process. However, where it is clear that a patient has self-harmed and this was not as a direct result of any potential failures by staff in the delivery of care, such events are not liable to the Duty of Candour.

Therefore:
A patient detained under the Mental Health Act, known to be at risk of self-harm, had to be transferred by ambulance to neighbouring acute hospital for surgery to close self-inflicted wounds. A review of observation records found gaps and it could not be evidenced that the patient had received the agreed levels of observation to control known risks. **The Duty of Candour applies**.

Died by Suicide
A patient on a mental health inpatient ward or in the community has apparently died by suicide. This is an example where the incident resulted in death. **The Duty of Candour applies**.

Restraint Injury
A patient's arm was broken during a restraint which resulted in surgery and/or wearing a cast for several weeks. This is an example where an incident resulted in moderate/severe harm. **The Duty of Candour applies**.

Patient Assault
There is an altercation between two patients which results in one patient suffering severe bruising and injuries which require requires surgery or significant treatment in A & E. This is an example where an incident resulted in moderate harm. **The Duty of Candour applies** (relating to the victim)

Suspected death by Suicide in Community Forensic Services
A person was arrested and detained at a local Police Station on suspicion of carrying out an offence. When the person came into police custody he reported no concerns to the custody staff but was upset at the allegations made against him. Because of this, the Community Liaison and Diversion Team were asked to offer the detainee an assessment of his mental health and wellbeing, which they did. The detainee declined this and also the offer of an opt-in letter and crisis contact information, stating that he was ok. He was subsequently released under investigation by the police and no further contact received from anyone until the team were notified about his death by the police. **The Duty of Candour does not apply**

General Health Community Examples

Pressure Ulcers
A patient who is on the case load of a community nursing team is being cared for at home. The patient was very frail, had poor mobility and often spent a significant time in bed. The patient had been assessed and an appropriate care plan was in place which was implemented however they developed a grade 4 acquired pressure ulcer. **The Duty of Candour applies**.

Fall from a Hoist
A patient in the community falls from a hoist whilst being cared for by Trust staff and fractures their femur requiring admission to an acute trust and surgery. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and also prolonged pain. **The Duty of Candour applies**.

Medication Error
A patient in the community was assessed as needing full staff support in the management of their insulin. A nurse visits to give their morning dose and finds the patient unconscious, calls 999 and they get admitted to an acute trust. It was later identified that the nurse who administered the evening medication had misread the medicine chart and had given the patient too much insulin. The patient fully recovered and returned home. This is an example of moderate harm resulting in an unplanned admission. **The Duty of Candour applies**.

This is an example of where the policy may not be followed immediately as the patient may not have been unconscious because they had been harmed. This policy would be followed when the medication error became apparent.

General Health and Mental Health Examples
In-Patient Fall (1)

A confused elderly patient who, *should have been supervised* but wasn't; falls and sustains a fracture that requires surgery and/or extra time in hospital. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and also prolonged pain. In this case it is clear at the outset that care was not delivered as planned. **The Duty of Candour applies**.

In-Patient Fall (2)
A confused elderly patient on a ward falls and sustains a fracture that requires surgery and/or extra time in hospital. This would be classified as moderate/ severe harm requiring an unplanned increase in treatment and also prolonged pain. Although in this case it is not known

at the time of the fall whether there were any problems in the care delivered, this policy should be followed as to wait for the outcome of an investigation which may identify issues in the care is too late to apologise for the harm and suffering caused. **The Duty of Candour applies**.

Sudden death of an in-patient

A patient dies suddenly on an in-patient ward and the cause is not known, but it could be natural causes (e.g., a stroke). At this stage it is not known whether any problems in care may have contributed to the death; however, this policy should be followed as to wait for the outcome of an investigation which may identify issues in the care is too late to apologise to the family for their loss. **The Duty of Candour applies**. Until the outcome of the investigation and if there is no 'incident' being open would then apply

Offender Health Examples

Violence against a prisoner

If the only contact a patient had had with healthcare was due to a minor healthcare problem, e.g., verruca on his foot being removed and he was then stabbed to death by another prisoner who had not had any contact with healthcare then the **Duty of Candour does not apply.**

Mental health contact
A patient had been referred to the mental health team due to being high risk of attempting to end his/her life on admission but had not been seen within the first two weeks by anyone from the mental health team, had not been put on an assessment, care in custody and teamwork process in prison (ACCT) and then died by suicide. **The Duty of Candour applies**.

Community Forensic Examples

Suspected death by suicide in Community Forensic Services
A person was arrested and detained at a local Police Station on suspicion of carrying out an offence. When the person came into police custody, he reported no concerns to the custody staff but was upset at the allegations made against him. Because of this, the Community Liaison and Diversion Team were asked to offer the detainee an assessment of his mental health and wellbeing, which they did. The detainee declined this and also the offer of an opt-in letter and crisis contact information, stating that he was ok. He was subsequently released under investigation by the police and no further contact received from anyone until the team were notified about his death by the police. **The Duty of Candour does not apply**

Information Governance Breach
Member of staff went to their car in the morning and found that their laptop, camera and all cables had been stolen from their work bag that had been left in the boot of the car. The laptop was encrypted and there was no patient or staff identifiable information stored directly on the laptop as it was all on the shared drive. There was no paperwork with patient identifiable information in the bag that could have been stolen. However, the camera contained photos of pressure ulcers and skin damage on patients with their patient record labels attached which included patient identifiable information. **The Duty of Candour applies**

Appendix 2

Being Open/Duty of Candour Summary
Includes communication, documentation, and meeting requirements

1. Communication

Open and effective communication with the patient and family is likely to include the following aspects:

- Early on identify and seek to meet patient's practical and emotional needs e.g., the names of people who can provide assistance and support to the patient (patient's consent would be required before information can be given).
- Any special restrictions on openness that the patient would like the healthcare team to respect.
- Identifying whether the patient wants to know every aspect of what went wrong. If they do not, respect their wishes and reassure them that this information will be made available later on should they change their mind.
- Provide repeated opportunities for the patient and family to ask for information about the incident.
- Provide information in written and verbal form, even if they **DECLINE** to be involved in investigation/feedback.
- Provide assurance that an ongoing care plan will be formulated with the patient.
- Facilitate inclusion of the patient's family in discussions if the patient wishes.
- Information may need to be given more than once and at different times to allow the patient and family to understand.
- Ensure the patient's account of events leading up to the incident is fed into the incident investigation.
- Provide information on how improvements will be made as a result of learning from the incident. Record your conversations

2. Before meeting with patient/family/carer

- Preliminary multi-disciplinary team discussion is often useful and should be held as soon as possible after the event, including the most senior health professional involved.
- Basic plans should be made about who does what and how patient 's needs will be met.
- The timing of the 'Being Open' meeting/communication should be actioned as soon as possible after the incident.
- An appropriate staff member should be chosen to communicate with patients/carers and inform them about the incident. This is often the most senior person responsible for the patients care and/or someone with appropriate experience and expertise.
- The healthcare professional meeting patient/family/carer may consider an additional colleague to be present.
- Normally, junior health care professionals should not lead the 'Being Open' process. If they ask to be involved, they should be accompanied and supported by a senior team member (band 7 & above or Medical Doctor at Registrar & above).
- Where possible the meeting should include a senior member of the multidisciplinary team and the healthcare professional responsible for treating the patient
- Incidents arising from errors by healthcare staff, the involvement of the staff involved should be considered balancing the needs of the patient/family/carers with those of the healthcare professional concerned
- The incident must always be reported via the Trust incident reporting system.

3. The initial meeting

The 'Being Open' initial discussion should include:

- Expressions of sympathy or regret/and/or apologies. Best practice is to use the word 'sorry'.
- Handling the facts and when disagreement about them occurs.
- Understanding and noting the views of patients, family and carers.
- Appropriate language and terminology.
- Explaining what happens next in terms of treatment plan and incident analysis findings.
- Information on effects of the incident.
- Offering practical and emotional support.
- Recognising that patients/carers may be angry or frustrated.
- Avoiding speculation, attribution of blame, denial of responsibility and conflicting information.
- Arrangements for subsequent discussions.
- Copy of investigation report should be offered once available.

4. Documentation

All staff managing Duty of Candour meetings must be aware of the following documentation requirements:

- Have a copy of incident report or complaint and SI investigation report.
- A written record of Duty of Candour discussions/meetings is made in health records: that includes Date, time, place, date and name and relationships of all attendees
- Plan for providing further information to patient and family
- Offers of assistance and the patient's and family's response
- Questions raised by the patient and family/issues for consideration in the investigation are documented
- Progress notes relating to the clinical situation and an accurate summary of all the points explained to the patient and family
- Written record of the discussions (a summary should be shared with the patient/family/relevant person)

The above information also needs to be completed in Ulysses as part of the incident investigation process

5. Preliminary Follow-Up

Follow-up discussions should be planned, carried out and recorded. These should occur at the earliest practicable opportunity.

6. Completing the Process when investigation is complete

- Feedback – this should be given in a form acceptable to the patient or family/nominated person after completion of the incident investigation, usually through discussion.
- Communication should include a chronology, details of concerns and complaints, apology and any shortcomings, factors that contributed and what has been and will be done to prevent recurrence, with monitoring arrangements.
- Arrangements for continuity of care need to be made and information given to patients on their clinical management plan.
- Reassurance should be given that the dispute will not affect their care and their right to continue their treatment elsewhere.
- Changes as a result of learning must be communicated with staff. This is a vital step to prevent recurrence.

Appendix 3

Leicester Partnership NHS Trust

Incident Investigation 'Being Open/Duty of Candour' Assurance Form – stored in Ulysses

Ulysses Number:			
StEIS Number:			
Incident Type:			
Does the incident meet threshold of formal Duty of Candour?	**If no – describe why?**		
INFORMING PATIENT / SERVICE USER/FAMILY/CARER OF INCIDENT **Please note* even if Duty of Candour not required – 'Being Open' is always required and contact should be recorded**			
Date:		**Time:**	
Name **Address** **Telephone** **Email** **Preferred Method of contact (i.e. phone, letter, email)**			
Staff Name/Role Completing initial Duty of Candour/Being Open			
Confirmation of apology & saying sorry:			
Details of patient/family/carer request to be involved in the investigation including issues they may wish to be included and how they wish to receive feedback:			
Investigation Feedback to patient/family/carer following closure of the report: (Include details of who was the feedback was given to)			

Date feedback given to patient / family / carer: Method of Contact i.e. Telephone / face to face / post (please also give dates and times of attempted contact by telephone and dates letters or emails were sent – please embed a copy of the letter / email)	
Who gave feedback (name and role):	
Summary of Information Provided:	
Additional actions identified by patient / family / carer following feedback:	
Feedback process for additional actions:	
Confirmation additional actions completed:	
Form Completed By:	
Date:	

Leicestershire Partnership NHS
NHS Trust

PLEASE NOTE THE ATTACHED COMMENTS IN THE APPENDICES ARE FOR STAFF REFERENCE AND NEED TO BE REMOVED PRIOR TO LETTERS BEING SENT

Address of CH

Appendix 4: Example of Duty of Candour Initial – must always be on headed paper **Letter**

Tel: 0116 ext. TBC

Email: xxxx.xxxx@leicspart.nhs.uk

Ref:

Secretary Tel: 0116….. ext. TBC

www.leicspart.nhs.uk

Date:

Private & Confidential

Name

Address

Dear Name

Regarding: Name, Date of Birth, Hospital number, Address

I am writing further to our conversation on date. Please let me offer again my sincere apologies for what has happened and I am sorry for the distress this might have caused.

When we spoke I explained that we believed errors or omissions had occurred during your/ name's time in our hospital/ under our community service; we believe these might have been avoided. In our conversation I described that the following had occurred: please briefly describe the facts of the events as discussed with the patient/ relevant person.

We take events such as these very seriously and class them as a serious patient safety incident. This means an investigation will be undertaken to explore what has happened, we will provide you with an explanation of why it happened, and make changes that we hope will prevent future similar events. We will be open and honest with you during this process and we have a statutory duty of candour to you.

The investigation will be undertaken by the Trust and can take up to three months to complete. This is to ensure an in-depth review of the circumstances of the incident takes place and to allow time for investigators to speak with all relevant members of staff. We appreciate that three months might seem like a long time for an investigation, but we want you to feel confident that our investigation has been thorough.

Commented [AS1]: **Please ensure that text highlighted in red is edited/removed**
Tracked/comment boxes are removed and all font in black/Arial size 12 before sending out

Commented [AS2]: To relevant person.

"Relevant person" means the patient or, in the following circumstances, a person lawfully acting on their behalf:

-on the death of the service user.
-where the patient is under 16 and not competent to make a decision in relation to their care/ treatment.
-where the patient is 16 or over and is proven to lack capacity in relation to the matter.

Commented [AS3]: Please add here sincere condolences if there has been a death. For example: May I also offer my sincere condolences on the death of XXXX.

Commented [AS4]: Delete/ edit as appropriate.

Commented [AS5]: Please describe the facts of the events as discussed with the patient/relevant person.

This should be fact based without speculation. Include any answers to questions already asked by the family if they can be answered.

Commented [AS6]: Remove if not a Serious Incident or not yet declared a Serious Incident (as declared by the Corporate Patient Safety Team).

As part of the investigation we would like to hear your experience of what happened. If you feel we did not give you an opportunity to do this when we spoke before, or if there are things you would like to add or questions you would like to ask, please get in touch with the named person below/ me (via details at the top of this letter).

Commented [AS7]: Delete as appropriate and complete details. This is the primary contact point for the patient or relevant person during the investigation.

The named person for any correspondence related to this is:

- Name:
- Job title:
- Contact telephone:
- Email:

Commented [AS8]: May be the same as author of the letter, in which case you can remove this section.

I will update you fortnightly/ monthly about the progress of the investigation and the timeframe for its completion. Once the investigation is complete, we will ensure we share the findings with you by a method of your choice.

Commented [AS9]: State a frequency/ timeframe here that is realistic e.g. fortnightly/monthly or as agreed

If you do not wish us to contact you about the outcome of the investigation, or if you would prefer us to contact a relative or carer on your behalf, please let us know.

I have enclosed a copy of the charity AvMA's leaflet on Duty of Candour. This describes what you can expect from the Trust in relation to us being open and honest with you. It also provides you with details of an organisation who you can contact for support. You might like to talk to your GP about what has happened. Your GP will be able to direct you to other forms of support, e.g. counselling.

Commented [AS10]: Ensure a copy of the .pdf below is included. This can be accessed here:

AvMA Duty of Candour leaflet.pdf

Support is also available through.

Commented [AS11]: Insert if there is specific or any other support is available to the patient/ family e.g. named bereavement nurse

If there is anything in this letter that we have not explained clearly enough, or there is anything else I can help with, please contact me. My contact details are at the top of this letter. Please allow me to again express my apologies for what has happened.

Yours sincerely

Name

Job Title

This document can be provided in different languages and formats. For more information please contact: ……

Leicestershire Partnership NHS
NHS Trust

Address of service

Appendix 5: Example of Duty of Candour Final Letter – must always be on headed paper

Tel: 0116 ext. TBC

Email: xxxx.xxxx@leicspart.nhs.uk

Secretary Tel: 0116….. ext. TBC

www.leicspart.nhs.uk

Ref:

Date:

Private & Confidential

Name

Address

Dear Name

Regarding: Name, Date of Birth, Hospital number, Address

I am writing further to our conversation on date. Please let me offer again my sincere apologies for what has happened and am sorry for the distress this might have caused.

We have now completed our investigation into your/ name's time in our hospital/ under our service; to establish what had led to this XXXXXXX. In our initial conversation I described that the following had occurred: please describe the facts of the events as discussed with the patient/ relevant person.

The investigation has now concluded and we would like to share our findings with you…….. .

As part of the sharing of the investigation report we would like to hear your feedback and have an opportunity to explain the report to you & XXXXX .

If you do not wish us to contact you about the outcome of the investigation, or if you would prefer us to contact a relative or carer on your behalf, please let us know.

If there is anything in this letter that we have not explained clearly enough, or there is anything

Commented [AS12]: Please ensure that text highlighted in red is edited/removed
Tracked/comment boxes are removed and all font in black/Arial or Comic Sans

Commented [AS13]: To relevant person.

"Relevant person" means the patient or, in the following circumstances, a person lawfully acting on their behalf:

-on the death of the service user.
-where the patient is under 16 and not competent to make a decision in relation to their care/ treatment.
-where the patient is 16 or over and is proven to lack capacity in relation to the matter.

Commented [AS14]: Please add here sincere condolences if there has been a death. For example: May I also offer my sincere condolences on the death of XXXX.

Commented [AS15]: Delete/ edit as appropriate.

Commented [AS16]: Brief description of what occurred

else I can help with, please contact me. My contact details are at the top of this letter. Again I am sorry for the distress the investigation may have caused ……..and for what has happened.

Commented [AS17]: Adjust as required but please say sorry

Yours sincerely

Name

Job Title

Appendix 6
AVMA: Duty of Candour Leaflet

AvMA Duty of Candour Leaflet.pdf

Appendix 7

Duties outlined in this Policy will be evidenced through monitoring of the other minimum requirements
Where monitoring identifies any shortfall in compliance the group responsible for the Policy (as identified on the policy cover) shall be responsible for developing and monitoring any action plans to ensure future compliance

Reference	Minimum requirements to be monitored	Evidence for Self-	Process for monitoring	Responsible Individual / Group	Frequency of monitoring
	a) how communication between healthcare organisations, healthcare teams, staff, patients, their relatives and carers is encouraged	Section 8	Compliance with Duty of Candour is monitored monthly by the incident oversight group monthly nd compliance status shared with Quality Forum and Trust Board A yearly audit of the quality of this will be undertaken in a peer review style	Clinical Audit Team with Corporate Patient Safety Team Supporting	Monthly Annual (in November)
	b) how staff acknowledge, apologise and explain when things go wrong	Section 8	Monthly directorate reports detailing the Duty of Candour compliance of all incidents meeting the criteria	Incident Oversight Group (IOG)	monthly

Appendix 8

Training Requirements

Training Needs Analysis

Training topic:	Duty of Candour
Type of training: (see study leave policy)	☐ Mandatory (must be on mandatory training register) ☐✓ Role specific ☐ Personal development
Division(s) to which the training is applicable:	☐✓Adult Mental Health & Learning Disability Services ☐✓Community Health Services ☐✓Enabling Services ☐✓Families Young People Children ☐✓ Hosted Services
Staff groups who require the training:	Completion of the Duty of Candour training module (via elearning) is role required for all clinical staff (doctors, nurses and AHPs), patient facing administrative staff or those handling patient identifiable data.
Regularity of Update requirement:	As part of initial induction for all healthcare professionals and bi-annually as short update or if there are significant changes to the standard Ad hoc training sessions based on an individual's training needs as defined within their annual appraisal or job description. Being Open/Duty of Candour will be incorporated into training delivered covering incidents, complaints and claims management. Investigation training that is mandatory will cover the requirement of Being Open.
Who is responsible for delivery of this training?	• Training and Development Team - ELearning package • Additional face to face support on Duty of Candour will be given at team/departmental meetings as required or identified by monitoring.
Have resources been identified?	Yes: all staff Bespoke: Doctors: online video https://www.themdu.com/guidance-and-advice/guides/duty-of-candour
Has a training plan been agreed?	No

Where will completion of this training be recorded?	☐✓ULearn ☐ Other (please specify)
How is this training going to be monitored?	Training and Development Reports

Appendix 9

NHS Constitution

The NHS will provide a universal service for all based on clinical need, not ability to pay. The NHS will provide a comprehensive range of services

Shape its services around the needs and preferences of individual patients, their families and their carers	☐✓
Respond to different needs of different sectors of the population	☐✓
Work continuously to improve quality services and to minimise errors	☐✓
Support and value its staff	☐✓
Work together with others to ensure a seamless service for patients	☐✓
Help keep people healthy and work to reduce health inequalities	☐✓
Respect the confidentiality of individual patients and provide open access to information about services, treatment and performance	☐✓

Appendix 10

Due Regard Screening Template

Section 1	
Name of activity/proposal	Duty of Candour Policy
Date Screening commenced	08/10/2019
Directorate / Service carrying out the Assessment	Corporate Patient Safety Team
Name and role of person undertaking this Due Regard (Equality Analysis)	Susan Arnold - Corporate Patient Safety Team Lead Nurse
Give an overview of the aims, objectives and purpose of the proposal:	
AIMS: The aim of the policy is to ensure communication is open, honest and occurs as soon as possible following an incident. It encompasses communication between healthcare organisations, healthcare teams and patients, service users, families and/or their carers.	
OBJECTIVES: This document describes how the Trust implements the	

Section 2	
Protected Characteristic	**If the proposal/s have a positive or negative impact please give brief details**
Age	No negative impacts identified.
Disability	No negative impacts identified.
Gender reassignment	No negative impacts identified.
Marriage & Civil Partnership	No negative impacts identified.
Pregnancy & Maternity	No negative impacts identified.
Race	No negative impacts identified.
Religion and Belief	No negative impacts identified.
Sex	No negative impacts identified.
Sexual Orientation	No negative impacts identified.
Other equality groups?	No negative impacts identified.

Section 3			
Does this activity propose major changes in terms of scale or significance for LPT? For example, is there a clear indication that, although the proposal is minor it is likely to have a major affect for people from an equality group/s? Please <u>tick</u> appropriate box below.			
Yes		No ✓	
High risk: Complete a full EIA starting click here to proceed to Part B		Low risk: Go to Section 4.	✓

Section 4			
If this proposal is low risk please give evidence or justification for how you reached this decision:			
No negative impacts were identified with regards to the protected characteristics.			
Signed by reviewer/assessor	Susan Arnold	**Date**	08/10/2019
Sign off that this proposal is low risk and does not require a full Equality Analysis			
Head of Service Signed		**Date**	

Appendix 11 - DATA PRIVACY IMPACT ASSESSMENT SCREENING

Data Privacy impact assessment (DPIAs) are a tool which can help organisations identify the most effective way to comply with their data protection obligations and meet Individual's expectations of privacy.
The following screening questions will help the Trust determine if there are any privacy issues associated with the implementation of the Policy. Answering 'yes' to any of these questions is an indication that a DPIA may be a useful exercise. An explanation for the answers will assist with the determination as to whether a full DPIA is required which will require senior management support, at this stage the Head of Data Privacy must be involved.

Name of Document:	**Duty of Candour (incorporating 'Being Open') Policy**	
Completed by:	**Susan Arnold**	
Job title	**Lead Nurse – Corporate Patient Safety Team**	**Date 22/01/2020**

Screening Questions	**Yes / No**	**Explanatory Note**
1. Will the process described in the document involve the collection of new information about individuals? This is information in excess of what is required to carry out the process described within the document.	No	
2. Will the process described in the document compel individuals to provide information about them? This is information in excess of what is required to carry out the process described within the document.	No	
3. Will information about individuals be disclosed to organisations or people who have not previously had routine access to the information as part of the process described in this document?	No	
4. Are you using information about individuals for a purpose it is not currently used for, or in a way it is not currently used?	No	
5. Does the process outlined in this document involve the use of new technology which might be perceived as being privacy intrusive? For example, the use of biometrics.	No	
6. Will the process outlined in this document result in decisions being made or action taken against individuals in ways which can have a significant impact on them?	No	
7. As part of the process outlined in this document, is the information about individuals of a kind particularly likely to raise privacy concerns or expectations? For examples, health records, criminal records or other information that people would consider to be particularly private.	No	
8. Will the process require you to contact individuals in ways which they may find intrusive?	No	

If the answer to any of these questions is 'Yes' please contact the Data Privacy Team via Lpt-dataprivacy@leicspart.secure.nhs.uk
In this case, ratification of a procedural document will not take place until review by the Head of Data Privacy.

Data Privacy approval name:	
Date of approval	

Acknowledgement: This is based on the work of Princess Alexandra Hospital NHS Trust

Appendix 12

CONTRIBUTION LIST

Key individuals involved in developing the document

Name	Designation
Susan Arnold (Reviewer)	Corporate Patient Safety Team Lead Nurse
Jo Nicholls	Patient Safety Manager (Initial)
Tracy Ward	Head of Patient Safety

Circulated to the following individuals for comments

Name	Designation	Version
Tracy Ward	Head of Patient Safety	2020
Members of Patient Safety Group (PSIG) November /Dec 2019	Includes Governance Leads for Directorates, Head of Nursing, Allied Health professional,	
Julie Quincey	Interim Lead Nurse for Safeguarding	
360 assurance		
Kate Dyer		
Michelle Churchard		
Heather Darlow		
IOG		