

Being Open and Duty of Candour Policy

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2	August 2018	Terry Vine, Deputy Chief Nurse.	Updated logo Minor spelling errors corrected Legislation added. NPSA written in full. Taken out references to NPSA as organisation doesn't exist. Reading list updated for more recent guidance.
3	October 2022	Russell Turner - Senior Quality Lead	Updated template and logo Review and rationalisation of contents Remove reference to root cause analysis investigation Change to organisation and team names Update to supporting references Minor update to narrative
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1. Introduction

The Inquiry into the Mid Staffordshire NHS Foundation Trust Hospital (The Francis Report, 2013) identified the 'system' did not put the patient first. A statutory requirement to implement Duty of Candour through Regulation 20 of the Health and Social Care Act 2008 was introduced in October 2014 and this forms part of Care Quality Commission (CQC) registration requirements. This applies to certain patient safety incidents that occur during care provided under the NHS Standard Contract and result in moderate harm, severe harm, or death (National Patient Safety Agency (NPSA) definitions).

It is recognised that a culture of openness is a prerequisite to improving patient safety and the quality of health care systems. Open and effective communication with patients should begin at the start of their care and continue throughout their time within the healthcare system. Being Open when things go wrong is key to the partnership between patients and those who provide their care and discussing what happened promptly can decrease the trauma felt and help patients cope more effectively with any after-effects of a patient safety incident. Extra costs can be incurred through litigation and further treatment following patient safety incidents but Being Open and honest can prevent such events becoming formal complaints and litigation claims.

Openness also has benefits for healthcare staff. These include satisfaction that communication with patients and/or their carers has been handled in the most appropriate way; developing a good professional reputation for handling a difficult situation properly; and improving their understanding of incidents from the perspective of the patient and/or their carers. Openness is also beneficial for the reputation of the healthcare organisations providing and commissioning services.

The Lincolnshire Integrated Care Board (LICB) and its commissioned providers are expected to be open with individuals about any mistakes that are made during the course of their treatment or care and should:

- acknowledge, apologise, and explain when things go wrong
- conduct a thorough investigation into the incident and reassure patients, their families, and carers that lessons learned will help prevent reoccurrence of the incident; and
- provide support for those involved to cope with the physical and psychological consequences of what happened.

This policy is based on guidance from the National Patient Safety Agency (NPSA), from April 2016 Care Quality Commission regulation 20 (updated July 2022), and the Patient Safety Incident Response Framework (Aug 2022) supporting guidance which promotes systematic, compassionate, and proportionate responses to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement – and with the aim of learning how to reduce risk and associated harm.

2. Purpose

The NHS Constitution for England (DoH 2021) embeds the principle of Being Open as a pledge to patients in relation to complaints and redress. It states:

The NHS also commits when mistakes happen to acknowledge them, apologise, explain what went wrong and put things right quickly and effectively

The commitment to openness extends to carers or relatives but only with the expressed consent and permission of the patient to ensure the patient's rights are advocated and confidentiality adhered to. In specific circumstances where the patient is unable to give consent, staff responsible for the care of the patient can consult directly with relatives or carers as appropriate.

The purpose of this policy is to ensure the LICB meets the regulations/statutory requirements in relation to being open and supporting providers commissioned by the LICB to be transparent and open with their service users, in relation to the care and treatment received as part of their regulated activity.

Through this work, the LICB aims to support their providers to have a patient safety focused culture, where being open and duty of candour are embedded into the incident reporting and risk management systems. To ensure individuals are supported and involved in investigations (where they wish to be) and lessons are learnt from errors.

The NPSA's document Being Open; Communicating patient safety incidents with patients their families and carers' sets out ten principles to help healthcare organisations create and embed a culture of Being Open, including the Duty of Candour:

2.1 Acknowledgement

The LICB requires that all patient safety events (and near misses) should be reported as soon as they are identified, through the incident reporting system. Where patients; their family or carers inform healthcare staff of a patient safety event, their concerns will be taken seriously and will be treated with compassion and understanding by all staff.

2.2 Truthfulness, timeliness, and clarity of communication

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred the LICB will; notify the relevant person that the incident has occurred and provide reasonable support to the relevant person in relation to the incident, when giving such notification.

The LICB acknowledges that information about patient safety incidents must be given in a truthful and open manner. A nominated senior manager will provide a single point of contact for the patient, family or carer(s) to ensure that factual, unambiguous information is provided throughout the patient safety event investigation, as well as providing a key contact to whom the patient, family or carers may direct questions and requests.

2.3 Apology

Patients, their families and/or carer(s) should receive a meaningful apology which expresses a sincere expression of sorrow and regret for the harm that has resulted from the patient safety event.

Verbal apologies are essential as they provide the opportunity for face-to-face contact with the patient, their family and/or carer(s) and the healthcare team. The verbal apology should be given as soon as staff are aware that a patient safety event has occurred.

A further written apology, clearly advising that the organisation is sorry for the suffering and distress caused will also be given, as soon as practicable after the event.

As referenced in the policy introduction, the LICB recognises that an 'apology' is not an admission of liability.

2.4 Recognising patient and carer expectations

Patients, their family and/or carer(s) as well as staff will be provided with support in a manner appropriate to their needs. Support available will include the option of an independent advocate, or interpreter, or the provision of information regarding relevant support.

It is recognised that patients, their families, and carers will expect to be fully informed of the issues surrounding a patient safety event within a face-to-face meeting with a designated representative from the Organisation.

2.5 Professional support

The LICB appreciates that staff involved in or witness to a patient safety event may feel traumatised by what has occurred and will require support throughout the investigation process.

Patient safety events vary significantly in their nature and the appropriate action to be taken in response will vary accordingly. No single one method of support is ideal for all staff members, so staff will be informed of the different types of help available to them and told how to access these readily. In terms of basic principles, the following is advocated:

- Immediate support should be provided by the Staff member's Line Manager.
- In the absence of the Line Manager an alternative Senior Manager should be identified to provide immediate support to the staff member. Thereafter necessary steps will be taken (by the alternative Senior Manager) to ensure that the staff member's Line Manager is informed of the patient safety event to enable ongoing support needs to be identified and responded to.
- There may be instances where staff may be requested to write statements or appear as witnesses as a result of being involved in or witnessing a patient safety event. In these instances, the Organisation will provide appropriate immediate and ongoing support to the staff member, as referenced within the Incident Reporting Policy.
- The Staff member may also contact their Professional Body/Union, to secure additional personal support.
- The effectiveness of the support measures provided will be assessed through management review between the Line Manager and the individual staff member.
- Patient safety incidents are almost always unintentional. If the incident is determined to be the result of criminal or unsafe practice the Director of Nursing and Quality and or Chief Clinical Officer (or their deputies) must be informed immediately.

2.6 Risk management and systems improvement

Investigations should be carried out in accordance with the LICB Incident Reporting Policy.

Line managers will grade patient safety events as soon as possible after the event. The grading will reflect the actual impact of the patient safety event and the risk to the organisation (likelihood x outcome). The level of local investigation and analysis will be dependent upon this grading.

All serious incidents, defined by the serious incident framework will automatically trigger a higher level of investigation.

2.7 Multidisciplinary responsibility

This policy applies to all staff who have a key role in the provision of patient care. Where staff are working within multi-disciplinary healthcare teams, this will be reflected in the way in which patients, their families and carers receive communication when a patient safety event has occurred.

A LICB representative will be involved in the investigation of the patient safety event, and where designated appropriate attend meetings with the patient, their family or carers.

2.8 Clinical governance

Information on learning from incidents is incorporated into the quarterly patient safety report submitted through the Operational Quality Assurance Group.

2.9 Confidentiality

Information gathered as part of the patient safety event will always remain confidential. Where disclosure of the information is required beyond the investigating team consent will be obtained from the individual concerned.

Disclosure without consent may be justified if this is deemed to be in the public interest or where those investigating the patient safety event have statutory powers to obtain the information. In these cases, advice must be sought from the Information Governance Team prior to disclosure.

To ensure that confidentiality is maintained, communication with parties outside of the clinical team must be kept on a strictly need to know basis, and where practicable, records will remain anonymous.

Furthermore, prior to the commencement of the investigation, where possible, the patient, their family and carers should be informed of who will be involved in the investigation of the patient safety incident. Patients, their family and or carers should be given an opportunity to raise any concerns or objections at this point.

2.10 Continuity of care

Patients who have been involved in a patient safety incident will continue to receive all usual treatment provided with respect and compassion. If a patient expresses a preference for their healthcare needs to be provided by another provider, appropriate arrangements will be made to ensure that care is given in accordance with their needs.

Scope

This policy applies to all permanent (clinical and non-clinical) staff, locum, agency, bank, and students working within the LICB and applies to:

Patient safety incidents that have caused:

- moderate harm
- prolonged psychological harm
- severe harm

- death
- incidents that have the potential to cause significant harm in the future

All the above require the LICB to provide a formal response which ensures all communication with patients and/or relatives and between staff/healthcare teams and, where relevant, other healthcare organisations, is open, honest and occurs as soon as reasonably practicable following an incident.

The LICB predominantly acts as commissioner of services but may provide clinical care through internal LICB teams. As a commissioner of NHS provider services and Independent Contractors in Lincolnshire the LICB has a duty of care to patients, service users and their relatives or carers to promote open discussion through the commissioning and governance processes.

The LICB manages a complaints service (refer to LICB Policy and Procedure for the Recording, Investigation and Management of Complaints, Comments, Concerns and Compliments) which on occasions may deal with a concern or complaint that will require it to be involved in a Being Open or Duty of Candour discussion with a patient / service user or their relative / carer.

All staff of the LICB should be aware of this policy and promote the principles and procedure of Being Open and Duty of Candour when commissioning services, working with colleagues from the commissioned services including Independent Contractors and the monitoring of services as part of LICB governance and assurance requirements.

3. Definitions

4.1. **Candour**

Defined in the Robert Francis report 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 a report about that provision has been made." The NHS standard contract states that this applies to 'patient safety incidents that occur during care provided under the NHS standard contract and that result in moderate harm, severe harm or death' and is a requirement to ensure that 'patients/their families are told about patient safety incidents that affect them, receive appropriate apologies, are kept informed of investigations and are supported to deal with the consequences'.

4.2. **Apology:**

An expression of sorrow or regret in respect of a notifiable patient safety incident

4.3. **Notifiable patient safety incident:**

A specific term defined in the duty of candour regulation. It should not be confused with other types of safety incidents or notifications.

A notifiable safety incident must meet all 3 of the following criteria:

- It must have been unintended or unexpected.
- It must have occurred during the provision of an activity CQC regulates.

- In the reasonable opinion of a healthcare professional, already has, or might, result in death or severe or moderate harm to the person receiving care.

A notifiable patient safety incident is also applicable if discovered when undertaking mortality reviews, or other retrospective audits. These could have happened some time ago or relate to care delivered by another provider. The provider who discovers the incident should work with others who are responsible for the incident that occurred in notifying the relevant person of the incident

4.4. Definitions of harm

These definitions of harm are aligned to CQC's notification system for reporting deaths and serious injuries and are common to all types of service.

Moderate harm

Harm that requires a moderate increase in treatment and significant, but not permanent, harm.

Severe harm

A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Moderate increase in treatment

An unplanned 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)

Prolonged pain

Pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Prolonged psychological harm

Psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

4.5. Relevant person

This is usually the person who has been affected by the patient safety incident or the person acting lawfully on their behalf

4. Roles and Responsibilities

5.1 The Chief Executive Officer for the LICB is ultimately responsible and serious incidents will be brought to the attention to the Chief Executive Officer as appropriate. The LICB Board has a key responsibility for ensuring that the principles of Being Open and the Duty of Candour are embedded at a senior level within the organisation and that strategic priority and scrutiny is maintained at LICB Board level.

The operational oversight is delegated to the Director of Nursing and Quality. The Director of Nursing and Quality will, through the Quality Team, be responsible for receiving information and analysing trends of commissioned services and will identify and act on lessons learnt ensuring that the principles of 'Being Open' is observed.

LICB Staff involved in incidents, investigation or follow-up of incidents/serious incidents/significant events and complaints are responsible for ensuring that these discussions are managed in accordance with the principles and processes outlined within this policy.

5. Implementation

There are some services provided by the LICB that may require staff to be involved in Being Open procedures for example the Complaints team or Continuing Healthcare Team, or in the event that a serious event occurs within the LICB which causes harm.

6.1. Team Discussion

- The incident should be assessed to determine the level of immediate response and the basic clinical and other facts established.
- Identify who is best placed to be responsible for leading the discussion with the patient or individual. Ideally this person should be known to and trusted by them and have a good grasp of the facts relevant to the incident. They should be able to maintain a medium to long-term relationship with the patient, their family and carers where possible, and to be able to provide continued support and information with experience and expertise in the type of patient safety incident that has occurred. It is unacceptable for junior staff to be delegated the responsibility to lead a Being Open discussion.
- The healthcare professional or LICB representative communicating information about a patient or individual safety incident should be able to nominate a colleague to assist them with the meeting. Ideally this should be someone with experience or training in communication and Being Open procedures.
- Consider each team member's communication skills; they need to be able to communicate clearly, sympathetically, and effectively.
- A debrief session for those involved should be considered as part of the process and the 'de-briefer' should be identified at this point.

6.2. Apology

- A meaningful apology should be given. This should be in the form of an appropriately worded and agreed manner of apology and should not be delayed for any reason including setting up a more formal Being Open discussion. Initially Verbally to allow face to face contact between the patient, their family and carers and the healthcare team. Followed by a written apology.

6.3. Information and Actions Ahead of the Meeting

- Information must be given to the patient or individual in a truthful and open manner by the agreed nominated person, both verbally and in writing.
- Staff should be prepared if a patient or individual does not agree with the information provided or does not wish to participate in the Being Open process. Support should be offered to the patient or individual at the earliest opportunity using available resources e.g:
 - Take into account possible patient/family/carer needs and to make all reasonable efforts to ensure the patient/family/carer experience is as stress free as possible.

- Investigate possible sources of support and counselling that you anticipate the patient may need as a result of the incident or complaint; details should be given to the patient as soon as possible.
- Consideration should be given to ensuring that support is available to the patient or their carer and that all reasonable adjustments are made to meet individual needs for example, consideration and sensitivity of all individual needs that may need to be met, such as, disability, culture, access to buildings, access to an independent advocate or utilisation of interpreting and translation services.
- The meeting should be held as soon after the incident as possible, taking into account the patient's clinical condition and the individual circumstances and social situation for those involved. Careful consideration should also be given to the venue of the meeting.
- Inform the patient or individual of the identity and role of all people attending the discussion before it takes place, allowing patient or individual to state their own preferences about which healthcare staff should be present and when and where the meeting should be held.
- 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 request should be respected and a suitable, alternative healthcare professional arranged, in agreement with the patient. Should the circumstances require, consider use of a mutually agreed mediator.

6.4. Meeting

- Introduce and explain the role of everyone present to the patient and/or their carers and ask them if they are happy with those present.
- Acknowledge what happened and apologise on behalf of the team and the organisation. Expressing regret is not an admission of liability.
- The patient or individual should be provided with a step-by-step explanation of what happened. The information should be based solely on facts known at the time and it should be explained that new information may emerge during the incident investigation that is to be undertaken and the patient or individual will be kept up to date with the progress.
- The health professional or LICB representative should:
 - Use clear, straight forward language. Provision should be made to meet the communication needs of the patient and/or their family.
 - Should ensure that the patient understands what has happened and answers any questions they might have.
 - Check the patient has understood the information given and offer to explain further should any clarification be required.
- A formal note should be made of any issues and areas of disagreement and reassurance given that they will be followed up.
- Ensure the patient or individual are fully aware of the formal complaint's procedures. It is essential that the following does not occur during the Being Open discussion – speculation; attribution of blame; denial of responsibility; provision of conflicting information from different individuals.

6.5. Follow up

- The patient or individual should be given a single point of contact for any questions or requests they may have. The lead should liaise with the Complaints Team to avoid confusion and duplication if formal procedures are instigated.
- Patient or individual should not receive conflicting information from different members of staff and the use of medical jargon should be avoided.
- The patient or individual should be informed of what steps are/will be taken to prevent a similar incident reoccurring (if known at this stage) and give an explanation about what will happen next in terms of the long-term treatment plan and the findings of the investigation.

- Being Open is not a one-off event and regular follow up meetings should be arranged by the nominated lead to ensure that the patient their relatives or carers are kept updated. This is an important step in the process and there may need to be more than one follow-up discussion.
- Full minutes of the Being Open discussion meeting, which should be signed and dated by the Chair and all members of the panel present, should be shared with the patient or individual.
- Clarify in writing the information given, reiterating key points, recording action points and confirming assigned responsibilities and deadlines. Consideration should be given to providing written information in a translated format for patients whose first language is not English.
- Health professional or LICB representatives should offer practical and emotional support to the patient, their relatives or carers and provide written information. This may involve getting help from third parties such as voluntary organisations as well as offering more direct assistance.
- Information about the patient or individual and the incident should not normally be disclosed to third parties without their consent.

6.6. Documentation

Accurate documentation must be kept during the course of the investigation process.

Including:

- The time, place, date, and names of attendees at the meetings.
- The plan for providing further information to the patient their relatives or their carers.
- Any offers of assistance and the patient, relative, carer response.
- The questions raised by the patient their family or carers or their representatives and the answers given.
- The plans for follow up as discussed and the progress noted relating to the clinical situation, and an accurate summary of all the points explained to the patient their relatives or carers.
- Any copies of letters sent to the patient or other relevant documents.
- A copy of the incident report and a summary of the discussions of the meetings which has been shared with the patient or individual.
- Details of Being Open meetings and information exchanged should be included within the final investigation report for the incident as this is required for the LICBs monitoring of performance and service improvement.
- The documentation should be kept securely and responsibility for safe storage rests with the nominated lead.

6.7. Completing the Process

After completion of any investigation, feedback to the patient or individual should take the form most acceptable to them. Whatever method is used, the communication should include:

- The chronology of clinical and other relevant facts.
- Details of the patient's or individuals concerns and complaints.
- A repeated apology for the harm suffered and any shortcomings in the delivery of care that led to the patient safety incident.
- A summary of factors that contributed to the incident.
- Information on what has been and will be done to avoid a reoccurrence of the incident and how these improvements will be monitored.

It is expected that in most cases there will be a complete discussion of the findings of the investigation. A copy of the report should be offered to the patient. However, in exceptional cases information may be withheld or restricted and the patient their relatives or carers will be informed of the reasons for this.

6.8. Continuity of Care

The LICB expects that patient or individual 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 provider. They should also be informed that they have the right to continue their treatment elsewhere if they have lost confidence in the provider involved in the incident.

6.9. Implementation

To implement Being Open successfully healthcare organisations need to have a culture that is open and fair with mechanisms in place to implement and embed the local Being Open Policy and Duty of Candour within risk management and clinical governance processes. LICB will seek to encourage open and fair reporting of incidents across the whole Lincolnshire healthcare organisation and will assist providers in the Being Open processes where support is necessary.

Information about the organisations' policies are made available to patients and public via the LICB website.

6.10. Staff responsibilities

Staff in the majority of cases do not intend to cause harm. Staff should feel supported throughout the incident investigation as they may have been affected by being involved and should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration. However, health professionals and LICB representatives are expected to be open about incidents they have been involved in, they are accountable for their actions and should feel able to talk to their colleagues and superiors about any incident and be treated fairly and supported when an incident happens. To ensure a robust and consistent approach to an investigation it is advisable to use the National Reporting and Learning System's Incident Decision Tree to determine staff actions. When there is reason for the healthcare organisation to believe a member of staff has committed a punitive or criminal act, the organisation should take steps to preserve its position and advise staff at an early stage to enable them to obtain separate legal advice and or representation.

7. Communication, Monitoring and Review

The LICB will assess the adequacy of commissioned providers policy implementation via several sources of assurances, including:

- Evidence of implementation from investigation reports.
- Assurance at Serious Incident Review Group (SIRG)
- Contract performance and quality meetings.

Should there be evidence that assurance around policy implementation or execution is not consistent with the national standards then the LICB will request assurances from providers that improvement plans have been developed and agreed at Board or partner level.

The Quality Services team will monitor the robustness of Being Open and Duty of Candour engagement carried out within provider organisations through Serious Incident investigation reviews and Serious Incident review Group. Concerns raised will be escalated via management routes and addressed on a case-by-case basis, providing support to providers if requested.

LICB Individuals who have queries regarding the contents of this policy or have difficulty understanding how this policy relates to their role, should in the first instance discuss with their Line Manager, further support can be requested through the Quality Services Team.

This policy will be disseminated through the LICB intranet and internet.

8. Staff Training

Being Open discussions require staff to be trained in the specific skills and techniques required in Being Open. Although experienced staff may hold many of these skills and some skills may be similar to those required in breaking bad news, the fundamental difference is that the patient has been harmed as a result of a patient safety incident or has made a serious complaint which forms a different context and perspective. Appropriate training from a trusted source should be provided for staff undertaking the professional Support role.

Staff should be made aware of this policy on corporate induction to the LICB. Training will be provided via incident management training to appropriate staff on request. Training is provided through the Quality Services team.

9. Equality and Diversity Statement

The ICB is committed to equality, diversity and human rights. In applying this policy and procedure, managers, employees, workers and their representatives will work in line with the Equality Act 2010, Public Sector Equality Duty and have regard to the need to:

- Eliminate unlawful discrimination, harassment, victimisation and any other conduct prohibited by the Equality Act 2010
- Advance equality of opportunity between people who share a protected characteristic and people who do not share it, and
- Foster good relations between people who share a protected characteristic and those who do not.

Managers will not discriminate in the application of this policy and procedure in respect of age, disability, race, ethnic or national origin, sex, religion and or beliefs, sexual orientation, marital/civil partnership status, social and employment status, gender identification, language, trade union membership or mental health status.

People have fundamental rights contained within the Human Rights Act 1998. Health services have positive obligations to uphold these rights and protect patients who are unable to do this for themselves. We will work to ensure that children and young people's human rights are considered in the implementation of this policy.

10. Interaction with other Policies

- 10.1. LICB Management of Complaints, Comments, Concerns and Compliments Policy
- 10.2. LICB Incident Reporting Policy

11. References

Patient Safety Incident Response Framework supporting guidance

Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.

CQC The duty of candour: guidance for providers

“Saying Sorry” leaflet NHS Resolution. publication date: 10th September 2018

“Openness and honesty when things go wrong: the professional Duty of Candour.” General Medical Council and Nursing Midwifery Council joint guidance. Updated on 15 March 2022

2022-2023 NHS Standard Contract, Technical Guidance

CQC (2014) Guidance to providers on meeting the fundamental standards and on CQCs enforcement powers. Last updated 25 August 2022

NHS Improvement (2018) Just Culture Guide



Lincolnshire
Integrated Care Board

Equality Impact Analysis Form

Project Details

Project Name:	Duty of Candour being open policy
EA Author:	Russell Turner
Team:	Nursing and Quality Team
Date completed:	05 December 2022
Version:	V3

What is the aim of the project/proposal?

To provide the Lincolnshire ICB with a comprehensive Duty of Candour being open policy. To set out the LICB commitment to open and honest communication, to give guidance on how to provide full explanations to patients and carers when harm has occurred and identify key roles and responsibilities. The primary objective is to provide a full explanation to the service user and/or carer of what has happened and the likely long and short-term consequences. Investigations into the circumstances will be objective, impartial, and open and will provide, alongside an explanation, an apology where appropriate, a description of the lessons learned and the identification of guidance/policy requiring review and/or amendment

Who will be affected by this work? e.g., staff, patients, service users, partner organisations etc.

Staff, patients, and service users of Lincolnshire

Stage 1, Scoping point

Is a full Equality Impact Analysis required for this project?

You should consider whether a full EIA is required, referring to the relevant guidance for information and guidance on making this decision.

It is important this decision is made with an open mind and correctly, advice should be sought from the EIHR team if you are unsure.

Yes	<input type="checkbox"/>	Proceed to the full Equality Impact Analysis form	No	<input checked="" type="checkbox"/>	Explain why further analysis is not required.
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If no, explain below why further Equality Impact Analysis is not required. E.g., 'This report is for information only' or 'The decision has not been made by the ICB' or 'The decision

Stage 1, Scoping point

Is a full Equality Impact Analysis required for this project?

You should consider whether a full EIA is required, referring to the relevant guidance for information and guidance on making this decision.

It is important this decision is made with an open mind and correctly, advice should be sought from the EIHR team if you are unsure.

will not have any impact on patients or staff. (Very few decisions affect all groups equally and this is not a rationale for not completing an EIA.)

This policy has undergone a regular review. The policy content has not changed but the template format has been amended to meet the LICB current requirements. Changes to organisation structure names, reporting requirements and minor amendments have also been undertaken. Whilst a full assessment is not required, we have still gone through this form to assess any potential impact on protected characteristics and other groups and included mitigating action where necessary. The policy equality statement has also been updated.

Equality Impact Analysis Form

If at an initial stage further information is needed to complete a section this should be recorded and updated in subsequent versions of the EIA. An Equality Impact Analysis is a developing document, if you need further information for any section then this should be recorded in the relevant section in the form and dated.

1. Evidence used

To demonstrate that the decision made has been informed you should include examples of the information used to determine the impact and complete the EIA.

Examples are likely to include:

- **Population Data** - e.g., demographic profile (Census),
- **Service Activity Data** e.g., profile of patients using a service
- **Consultation and Involvement findings** - e.g., any engagement with service users, local community, specific groups.
- **Research** - e.g., good practice guidelines, service evaluations, literature reviews, reports
- **Participant knowledge** - e.g., experiences of working with different or population groups, experiences of service users in other service areas / localities

2. Impact of decision

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work.

As part of these considerations, you should consider how the ICB will be meeting the requirements of the Public Sector Equality Duty

- 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.

Before completing this section, you should ensure you can suitably answer the following:

What is the equality profile of the population i.e., service users/patients and/or workforce that is intended to benefit from the activity/project?

(By collecting and analysing demographic data of protected characteristics relating to

2. Impact of decision

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work.

patients/service users and/or workforce, within the geographical area concerned, the ICB will be able to identify the groups that may be adversely affected at a greater proportion to others).

2.1 Age

Describe age-related impact and evidence. This can include safeguarding, consent, and welfare issues.

This policy is applicable across all age ranges. Consideration should be given to younger and elder service users that may have difficulty understanding the terminology and following the process. Appropriate language should be used to support service user understanding. A suitable location for in person discussion should be identified to support possible difficulties with mobility and to accommodate younger service user family support and welfare needs.

2.2 Disability

Describe disability-related impact and evidence. This can include attitudinal, physical, communication and social barriers as well as mental health/learning disabilities, cognitive impairments.

The policy is applicable to all, regardless of any disability. Due consideration should be given to the service user to ensure service user needs are taken into account throughout the investigation and during any meetings that may be undertaken, ensuring appropriate location and equipment are identified for meetings held and any sensory or neurodiversity accessible information requirements are also taken into account

2.3 Gender reassignment (including transgender)

Describe any impact and evidence in relation to transgender people. This can include issues such as privacy of data and harassment.

This policy applicable to all service users. Due regard will be given to service users' needs during the investigation and meetings. Appropriate discussions with service users who have transitioned or are going through transition to agree appropriate use of pronouns and person referencing within investigation reports and correspondence.

2.4 Marriage and civil partnership

Describe any impact and evidence in relation to marriage and civil partnership. This can include working arrangements, part time working and caring responsibilities.

<p>2. Impact of decision <i>In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work.</i></p>
<p>This policy is applicable to all service users, regardless of marital status. However due consideration should be given to family circumstances which may impact on availability during the investigation.</p>
<p>2.5 Pregnancy and maternity <i>Describe any impact and evidence in relation to Pregnancy and Maternity. This can include working arrangements, part time working and caring responsibilities.?</i></p>
<p>This policy is applicable to all service users. Due regard will be given to service users' needs during the investigation and meetings.</p>
<p>2.6 Race <i>Describe race-related impact and evidence. This can include information on different ethnic groups, Roma gypsies, Irish travellers, nationalities, cultures, and language barriers.</i></p>
<p>This policy is applicable to all service users, regardless of race. Appropriate service user requirements will be facilitated to ensure the service user can engage fully with the process. If required, the use of translators and interpreters will be undertaken to ensure full understanding by the service user of the process and outcomes.</p>
<p>2.7 Religion or belief <i>Describe any impact and evidence in relation to religion, belief or no belief on service delivery or patient experience. This can include dietary needs, consent, and end of life issues.</i></p>
<p>This policy equally applies to all regardless of religion or belief. Realistic efforts will be made to accommodate the service users' requirements to facilitate specific religious requirements or belief needs. Including timing of discussions or meetings around prayer times or ensuring appropriate or chaperones are included in the process.</p>
<p>2.8 Sex <i>Describe any impact and evidence in relation to men and women. This could include access to services and employment.</i></p>
<p>This policy equally applies to all men and women. Appropriate facilities will be made available for any individual after discussion between those involved with the process.</p>
<p>2.9 Sexual orientation <i>Describe any impact and evidence in relation to heterosexual people as well as</i></p>

2. Impact of decision

In the following boxes detail the findings and impact identified (positive or negative) within the research detailed above; this should include any identified health inequalities which exist in relation to this work.

lesbian, gay and bisexual people. This could include access to services and employment, attitudinal and social barriers.

This policy equally applies to all LGBTQ+ colleagues and service users. All service users involved with the process will be given an opportunity to request specific requirements to support their involvement and understanding with the process.

2.10 Carers

Describe any impact and evidence in relation to part-time working, shift-patterns, general caring responsibilities. (Not a legal requirement but a ICB priority and best practice)

This policy applies to carers of service users. The service users should be given an opportunity to request any specific requirements in relation to their caring responsibilities which will be supported to aid the reduction of carer pressures in the undertaking of the process.

2.11 Other disadvantaged groups

Describe any impact and evidence in relation to groups experiencing disadvantage and barriers to access and outcomes. This can include socio-economic status, resident status (migrants, asylum seekers), homeless people, looked after children, single parent households, victims of domestic abuse, victims of drug/alcohol abuse. This list is not finite. This supports the ICB in meeting its legal duties to identify and reduce health inequalities.

This policy applies to all groups experiencing disadvantage and barriers to access and outcomes. Equal consideration will be given to any service user that is involved with the process of this policy.

3. Human rights

The principles are Fairness, Respect, Equality, Dignity and Autonomy.

Will the proposal impact on human rights?	Yes	<input checked="" type="checkbox"/>	No	<input checked="" type="checkbox"/>
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Are any actions required to ensure patients' or staff human rights are protected?	Yes	<input type="checkbox"/>	No	<input checked="" type="checkbox"/>
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If so, what actions are needed? Please explain below.

3. Human rights

The principles are Fairness, Respect, Equality, Dignity and Autonomy.

4. Health Inequalities.

The Health and Social Care Act 2012 established the first specific legal duties on s ICB's to have regard to the need to reduce inequalities between patients in **access** to, and **outcomes** from, healthcare services and in securing those services are provided in an integrated way. These duties had legal effect from April 1st, 2013. The duties require that ICB's properly and seriously considers inequalities when making decisions or exercising functions, and has evidence of compliance with the duties, whilst also assessing how well commissioned providers have discharged their legal duties on health inequalities.

1. What evidence have you considered to determine what health inequalities exist in relation to your work?

This can include local and national research, surveys, reports, research interviews, focus groups, pilot activity evaluations or other Equality Analyses. If there are gaps in evidence, state what you will do to mitigate them.

(This may be different or similar to that which has informed the EIA)

2. What is the potential impact of your work on health inequalities? Can you demonstrate through evidenced based consideration how the health outcomes, experience and access to health care services differ across the population group and in different geographical locations that your work applies to?

If you feel that the project will not impact / be relevant to Health Inequalities, please give a rationale.

4. Health Inequalities.

The Health and Social Care Act 2012 established the first specific legal duties on s ICB's to have regard to the need to reduce inequalities between patients in **access** to, and **outcomes** from, healthcare services and in securing those services are provided in an integrated way. These duties had legal effect from April 1st, 2013. The duties require that ICB's properly and seriously considers inequalities when making decisions or exercising functions, and has evidence of compliance with the duties, whilst also assessing how well commissioned providers have discharged their legal duties on health inequalities.

N/A

3. How can you make sure that your work has the best chance of reducing health inequalities?

N/A

5. Engagement/consultation

What engagement is planned or has already been done to support this project?

It is expected that the ICB will have carried out a level of engagement with those affected whether formal or informal. This should be focussed to the groups most affected.

Engagement activity	With whom? <i>e.g., protected characteristic/group/community</i>	Date

Please summarise below the key finding / feedback from your engagement activity and how this will shape the policy/service decisions e.g., patient told us, so we will... (If a supporting document is available, please provide it or a link to the document)

6. Mitigations and changes

If you have identified mitigations or changes, summarise them below. E.g. restricting prescribing over the counter medication. It was identified that some patient groups require high volumes of regular prescribing of paracetamol, this needs to remain under medical supervision for patient safety, therefore an exception is provided for this group which has resolved the issue.

Are these vital to the project continuing?

N/A

7. Is further work required to complete this EIA? <i>Please state below what work is required and to what section e.g., additional consultation or engagement is required to fully understand the impact on a particular protected group (e.g. disability)</i>			
Work needed	Section	When	Date completed

8. Development of the Equality Impact Analysis <i>If the EIA has been updated from a previous version, please summarise the changes made and the rationale for the change, e.g. Additional information may have been received – examples can include consultation feedback, service Activity data</i>		
Version	Change and Rationale	Version Date
3	Update of the EIA form to support the policy	28 th Oct 2021

9. Final Sign off Completed EIA forms must be signed off by the completing manager. They will be reviewed as part of the decision-making process. Service lines should maintain an up-to-date log of all EIAs.		
Version approved:		
	Name	Date
Signature of responsible officer	LICB Clinical policy sub group	
Which committee will be considering the findings and sign off the EA?	LICB Clinical policy sub group	
Minute number <i>(to be inserted following presentation to committee)</i>		

Stage One - Quality Impact Assessment Initial Screening Tool

The QIA Initial Screening Tool is required for all projects to identify the project's impact on quality, be it positive, neutral, or adverse.

Five quality domains are thereby defined in the Initial Screening Tool, against which risks must be assessed and scored (see Appendix B for instructions on scoring).

For each quality domain in the Initial Screening Tool, highlight the proposal's impact on quality as either positive (P), neutral (N) or adverse (A). For **neutral** and **adverse** impacts, add a score for consequence (C) and likelihood (L) (Appendix B). Multiply the consequence and likelihood scores and record that number as the total score (T), then enter yes or no regarding need for a Stage 2 QIA for any domains with scores of 8 or greater. Calculate and record the total score of all domains. Complete an Equality Impact Assessment (EIA) and the EIA section on the QIA screening tool.

Quality Impact Assessment - Initial Screening Tool		Instructions:						
		<ul style="list-style-type: none"> • Answer Positive, Neutral or Adverse (P, N or A) against each quality domain • If Neutral or Adverse, insert a Consequence (C) and Likelihood (L) score, multiply the scores, and insert the total score in the Total (T) column • Add a brief description of the potential impact and mitigating actions • Insert Y (yes) indicating need for a Stage 2 QIA for any domains with scores of 8 or greater • Record the total score of all domains • Complete an Equality Impact Assessment (EIA) and the EIA section on the QIA screening tool 						
Quality Domain	Impact Question	P/ N/ A	C	L	T	Brief description of potential impact	Mitigation strategy and monitoring arrangements	Stage 2 QIA? Y/N
Duty of Quality	Could the proposal impact on any of the following? <ul style="list-style-type: none"> • The duty to safeguard children and vulnerable adults • The duty to promote equality – see https://bit.ly/3v85CNS • The functions of other services within the 	P				The Being Open and Duty of Candour Policy details the need for systematic, compassionate, and proportionate responses to patient safety incidents, anchored in the principles of openness, fair		N

	<p>organisation</p> <ul style="list-style-type: none"> • The clinical effectiveness of services • Patients' and public experiences of services • Compliance with NHS constitution's core principles - see https://bit.ly/37vzY4k <p>Any other factors related to the duty to uphold and improve quality</p>	P				<p>accountability, learning and continuous improvement – and with the aim of learning how to reduce risk and associated harm. It is recognised that on occasion mistakes are made and incidents do happen. Communication with patients and/or their carers needs to be handled appropriately</p>	
Patient Safety	<ul style="list-style-type: none"> • Avoidable harm; clinical/environmental/other • Infection prevention and control practices, systems, statutory expectations and acceptable standards • Referral to treatment times • Safeguarding Adults, Young People & Children – see https://bit.ly/3jeY3ih • Workforce levels and competencies <p>Any other risk indicators relevant to patient safety</p>	P				<p>handling a difficult situation properly with understanding from the perspective of the patient and/or their carers. Providing an apology when appropriate and conducting a fair investigation, giving an open and honest response to the investigation and looking to improve services from incidents.</p>	N
Patient / Staff Experience	<ul style="list-style-type: none"> • Informed choice, autonomy, and involvement • Access to services • Dignity, respect, compassion, and consent • Patients' satisfaction with services • Complaints and redress <p>Any other risk indicators relevant to patient experience:</p>	P					N
Clinical effectiveness	<ul style="list-style-type: none"> • Evidence based practice & standards • Clinical outcomes • Clinical leadership and engagement 	P					N



	Any other risk indicators relevant to clinical effectiveness:							
Non-clinical/operational impact	<ul style="list-style-type: none"> • Impact on cost effectiveness • Impact on infrastructure • Impact on staff satisfaction and welfare • Impact on the public perception of the organisation • Social value impact • Relationships with partner organisations 	P						N
		N/A						
		P						
		P						
		P						
		P						
		Total overall score =		0				
EQUALITY	An Equality Impact Assessment must also be undertaken							
Name of person completing the Equality Impact Assessment:	Russell Turner				Date: 5 th Jan 23		Signature: Russell Turner	
Position:	Senior quality lead							