adding life to days

Nottinghamshire
Hospice

POLICY/PROCEDURE INFORMATION (Policy no)	
Subject	Duty of Candour Policy *(This policy is subject to periodic review and will be amended according to service development needs)*
Applicable to	All employees and volunteers of Nottinghamshire Hospice
Target Audience	All employees and volunteers involved in the delivery of care and support and engagement with the general public in Nottinghamshire Hospice
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Lead responsible for Policy	Director of Care Services
Policy reviewed by	Director of Care Services
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CQC Standard if applicable	Regulation 20: Duty of Candour
Links to other Policies	Whistleblowing, Confidentiality, Incident Management Code of Conduct, Consent
Summary	The 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. This policy pulls together the main points of the relevant legislation to provide guidance for staff and volunteers so be able to understand their responsibilities

VERSION CONTROL		
Status	**Date**	**Due for review**
Original policy written by Jo Polkey, Director of Care and Rowena Naylor-Morell, CEO	Jan 2020	Jan 2023
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Index

Section 1 – Policy **Page No.**

1. **Statement** ………………………………………………………………………… 6

2. **Aims** ……………………………………………………………………………… 7

3. **Scope** …………………………………………………………………………….. 7

4. **Related Policies and Procedures** …………………………………………. 8

5. **Responsibilities** ……………………………………………………………….. 8

   5.1 Trust Board ………………………………………………………….... 8
   5.2 Chief Executive ………………………………………………………… 8
   5.4 Director of Care ………………………………………………. 8
   5.5 Departmental Line Managers ………………………………………… 8
   5.7 All Staff ………………………………………………………………. 9
   5.8 Investigating Officer …………………………………………………… 9

6. **Definitions** ………………………………………………………………….. 10

7. **Staff Training** ………………………………………………………………. 13

8. **Dissemination and Implementation** ………………………………………. 13

9. **Monitoring, Audit and Review** ……………………………………………… 13

Section 2 - Procedure

10. **Procedural Information** ……………………………………………………… 13

   10.1 Introduction to Being Open and Duty of Candour ………………….. 13
   10.2 Incident Identification and Reporting ………………………………… 13
   10.3 Principles of Communication and Being Open ……………………… 14
   10.4 Initial communication with the relevant person and offering an apology ………………………………………………………………. 15
   10.5 The Relevant Person cannot be contacted or declines to have further information...15
   10.6 Apology...16
   10.7 Clarity of Communication..16
   10.8 Initial meeting with the relevant person 16
   10.9 The Investigation...17

Page No.

10.10 The Notification meeting …………………………………………….. 17
10.11 Investigation Closure and Learning ………………………………… 20
10.12 Performance/Disciplinary Issues ……………………………………. 20
10.13 The potential implications of not implementing the Duty of Candour Requirements ………………………………………………………. 21
10.14 Incidents that are later uncovered or that have occurred within the care of another provider ……………………………………………… 21
10.15 Support and Advice for Staff...21

11. Appendices..23

Appendix 1 …………………………………………………………………. 23
Appendix 2 …………………………………………………………………. 26
Appendix 3 …………………………………………………………………. 27
Appendix 4 …………………………………………………………………. 28
Appendix 5 …………………………………………………………………. 29
Appendix 6 …………………………………………………………………. 30

12. References 35

13. Equality Impact Assessment 36

14. Environmental Impact Assessment 38

1. Statement

Nottinghamshire Hospice is committed to the provision of high quality care in a culture of openness and transparency for all people that access our clinical services.

Regulation 20 of The Health and Social Care Act 2008 (Regulated Activity) Regulations 2014, introducing the statutory Duty of Candour for the NHS, came into force on 27th November 2014. The introduction of Regulation 20 is a direct response to recommendation 181 of the Francis Inquiry report into Mid Staffordshire NHS Foundation Trust 2013, which recommended that a statutory Duty of Candour be imposed on healthcare providers. The regulations can be found here -:

http://www.legislation.gov.uk/uksi/2014/2936/regulation/20/made

Subsequently the Care Quality Commission (CQC) 2014 issued a guidance document addressing the Duty of Candour -:

http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

This duty is integral to the work we provide for all patients and their families who access our services. Nottinghamshire Hospice acknowledges that medical care and treatment is not harm free and mistakes do happen. If an error does occur, patients and their families will be offered an apology, truthful information and support. Learning from incidents will contribute to a culture of safety and improvement to prevent a similar incident happening to someone else.
Clinicians already have an ethical duty of candour as part of their professional registration to tell patients about errors and mistakes. This policy builds on individual professional duty and places an obligation on the organisation, not just individual healthcare professionals, to be open with patients when patient harm has been caused.

The impact and consequences of mistakes or errors can affect everyone involved and can be devastating for individual staff or teams; this policy aims to ensure there is sustained support for staff in reporting incidents and in being open.

Nottinghamshire Hospice's approach to candour underpins a commitment to providing high quality care and truthful sharing of information when an incident of patient harm occurs both at an organisational as well as an individual level and that any learning will be embedded into daily practice. The organisational values and clinical leadership aim to ensure a culture of candour by every member of staff and a continued commitment to patient safety.

This policy and procedure describes Regulation 20 and associated guidance and provides the framework for implementation into practice within Nottinghamshire Hospice.

2. Aims

This policy and procedure aims to ensure that -:

- The patient's right to openness from Nottinghamshire Hospice is clearly understood by all staff
- Candour is integrated into the everyday business of Nottinghamshire Hospice
- Duty of Candour is invoked when required
- Nottinghamshire Hospice learns from mistakes with full transparency and openness and will share learning with other healthcare providers
- Patients and their families and carers can trust us to share information with them in an open and collaborative way
- Nottinghamshire Hospice works in partnership with others to protect patients
- Hospice staff ensure appropriate support is offered to the patient/families/carers/ and colleagues
- That line managers understand an individual or team may well require support during and after an incident. Support for employees is available from Nottinghamshire Hospice's HR Team and their line manager or member of Senior Management team.

3. Scope

This policy applies to all staff including permanent and temporary staff employed by Nottinghamshire Hospice. The policy also applies to students, bank staff, contracted staff and volunteers. Every healthcare professional in Nottinghamshire Hospice must be open and honest with patients when something goes wrong with their treatment or care which causes, or has the potential to cause, harm or distress.

The Being Open Principles (National Patient Safety Agency 2009) Appendix 1 and ethical duty of openness applies to all incidents and any failure in care or treatment. The Duty of Candour (Appendix 2) applies to incidents whereby moderate harm, significant harm or death has occurred.

4. Related Policies and Procedures

Nottinghamshire Hospice :-

- Reporting of Incidents and Accidents Policy
- Complaints Policy
- Mental Capacity Act Policy
- Consent Policy
- Confidentiality Policy
- Whistleblowing Policy
- Adults and Children at Risk Safeguarding Policy

- Risk Assessment Policy
- Infection Prevention and Control

5. Responsibilities

5.1 Hospice Board of Trustees

The Board fully endorses the principles of being open and actively promotes an honest and fair culture. Nottinghamshire Hospice Board will seek assurances that the principles and processes set out in this policy work effectively to support the commitment to implementing the Duty of Candour.

Employees involved in patient safety incidents in which a patient has been harmed can be traumatised by the event. The Board will ensure that systems are in place to provide support to employees in these circumstances.

5.2 Chief Executive

The Chief Executive is responsible for ensuring there is a robust process for managing and responding to the being open and Duty of Candour process and for delegation of this role as required

5.3 Director of Care

The Director of Care is responsible for ensuring the effective implementation of this policy and procedure including:-

- Determine whether the incident is notifiable
- Reporting on the investigations arising from incidents to the Board
- Approving and signing off letters to affected patients, families and carers
- Informing regulatory bodies including Commissioners, Care Quality Commission, Health & Safety Executive and Safeguarding Teams.

5.4 Departmental Line Managers

Departmental Line Managers are responsible for:-

- Ensuring staff are aware of this duty
- Supporting staff to comply with this policy and procedure
- Managing the initial incident process

- Ensuring an apology is offered to the affected person
- Escalation of actions as appropriate
- Supporting staff members involved in the incident

5.5 All staff

All employees must comply with their relevant professional code. A joint statement on candour has been issued by the following professional healthcare regulators:

- Nursing and Midwifery Council
- Health and Care Professionals Council
- British Association of Counselling and Psychotherapy

All employees must understand their duty for being open and must demonstrate the principles of being open in their work.

All employees who become aware of an incident or near miss having occurred must follow Nottinghamshire Hospice Incident Reporting Policy and apply the principles of being open and the Duty of Candour throughout these processes.

All employees dealing with patients or relatives should abide by Nottinghamshire Hospice's complaints process and advise who patients or carers should write to if they wish to formalise a complaint.

Employees who are concerned about the non-reporting or concealment of incidents, or about on-going practices which present a serious risk to patient safety, must raise their concerns either through established governance routes or through Nottinghamshire Hospice's Board of Trustees.

5.6 Investigating Officer

An Investigating Officer must have received training in undertaking Root Cause Analysis (RCA) and be able to demonstrate competence with this skill. The Investigating Officer should be the point of contact throughout an investigation between the patient, the family and Nottinghamshire Hospice if it is agreed that this is the most appropriate approach. This communication role can be undertaken by another person such as the lead clinician or senior manager if this is more appropriate, but whoever the contact is must be recorded in the clinical notes and the incident documentation.

6. Definitions

6.1 Duty of Candour

Candour is defined in The 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."

Unlike the existing professional and ethical duty which applies to all circumstances where a patient is harmed when something goes wrong, the statutory Duty of Candour only applies to incidents where a patient suffered (or could have suffered) unintended harm resulting in moderate or severe harm or death or prolonged psychological harm.

The requirements of the **Duty of Candour** as set out by the regulations are as follows:-

As soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred a health service body must:-

(a) notify the relevant person that the incident has occurred
(b) provide reasonable support to the relevant person in relation to the incident, including when giving such notification

The notification to be given must:

(a) be given in person by one or more representatives of the health service body,
(b) provide an account, which to the best of the health service body's knowledge is true, of all the facts the health service body knows about the incident as at the date of the notification,
(c) advise the relevant person what further enquiries into the incident the health service body believes are appropriate,
(d) include an apology, and be recorded in a written record which is kept securely by the health service body
(e) The notification must be followed up in writing.

Incidents that result in no harm or low harm are not covered by the Duty of Candour. Patients should still be informed of such events in line with being open, but the emphasis for the Duty of Candour is on incidents that result in moderate harm, severe harm or death.

6.2 Being Open/Candour

Being open is described by the National Patient Safety Agency in 2009 as 'discussing patient safety incidents promptly, fully and compassionately' adding

that this 'can help patient and professionals to cope better with the after effects'. The Being Open principles are detailed in Appendix 1.

6.3 Patient Safety Incident

A notifiable patient safety incident must meet all of the following 3 critieria.

1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity regulated by the CQC.
3. In the reasonable opinion of a healthcare professional, already has, or might result in death, severe or moderate harm to the person receiving care.

You should interpret "unexpected or unintended " in relation to an incident which arises in the course of the regulated activity, not to the outcome of the incident. By "regulated activity" we mean the care or treatment provided. By "outcome" we mean the harm that occurred or could have occurred. So, if the treatment or care provided went as intended, and as expected, an incident may not qualify as a Notifiable Safety Incident, even if harm occurred.

This does not mean that known complications or side effects of treatment are always disqualified from being Notifiable Safety Incidents. In every case, the healthcare professionals involved must use their judgement to assess whether anything occurred during the provision of the care or treatment that was unexpected or unintended.

6.4 Serious Incident

A serious incident is an incident as defined by the NHS England's Serious Incident Framework (2015) is one that resulted in one or more of the following;

- Unexpected or avoidable death or severe harm of one or more patients, staff or members of the public.
- A never event - all never events are defined as serious incidents although not all never events necessarily result in severe harm or death.
- A scenario that prevents, or threatens to prevent, an organisation's ability to continue to deliver healthcare services, including data loss, property damage or incidents in population programmes like screening and immunisation where harm potentially may extend to a large population.
- Allegations, or incidents, of physical abuse and sexual assault or abuse;
- Loss of confidence in the service, adverse media coverage or public concern about healthcare or an organization.

Further guidance in relation to Serious Incidents is available in Nottinghamshire Hospice's Incident Reporting Policy. It is important to note that a Serious Incident is not necessarily the same as a Duty of Candour notifiable incident, although there will be some cases where a serious incident is also a Duty of Candour notifiable incident.

6.5 Relevant Person

The regulations use the term of the "relevant person" when describing the person who will be informed of an incident in the Duty of Candour process. This may be the

service user or patient, or the person acting on their behalf. The term “relevant person” is therefore used throughout this Trust policy.

Relevant Person
The regulations states that the “relevant person” means the service user or, in the following circumstances, a person lawfully acting on their behalf—
(a) on the death of the service user,
(b) where the service user is under 16 and not competent to make a decision in relation to their care or treatment, or
(c) where the service user is 16 or over and lacks capacity (as determined in accordance with sections 2 and 3 of the 2005 Mental Capacity Act) in relation to the matter.

6.6 Level of Harm

Level of Harm
The regulations state that the Duty of Candour applies to incidents as follows:
a) the death of the service user, where the death relates directly to the incident rather than to the natural course of the service user’s illness or underlying condition, or
(b) severe harm, moderate harm or prolonged psychological harm to the service user; “prolonged psychological harm” means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;
Moderate harm” means—
(a) harm that requires a moderate increase in treatment, and
(b) significant, but not permanent, harm;
“moderate increase in treatment” means 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);

7. Staff Training

All new clinical staff will receive training on Being Open and Duty of Candour as part of Nottinghamshire Hospice Induction Programme. This will be periodically updated as part of specific learning initiatives and as part of ongoing Hospice training.

8. Dissemination and Implementation

This policy and its associated procedural document will be available on the organisation's electronic public drive. It will be disseminated and implemented by departmental line managers

9. Monitoring, Review & Audit

This policy and procedural document will be reviewed every three years or more frequently if there are changes to legislation, practice related concerns or changes to working practice.

10. Procedure

10.1 Introduction to Being Open and Duty of Candour

All staff must understand their duty for being open and must demonstrate the principles of being open in their work.

Most clinicians will find themselves in the difficult position of having to discuss harm or potential harm with a patient at some time in their career. The following guidance provides a framework for all staff to work to.

It is recognised however that many scenarios do not always follow predetermined processes, and staff must use their own professional judgement/seek further advice in deciding, for example, when is the right time to talk to patients and families/carers.

A summary of principles of Duty of Candour are included in Appendix 2.

A summary of the stages involved in this process is provided in Appendix 3 together with a flow chart in Appendix 5.

The next section details the process for implementation of the Duty of Candour.

10.2 Incident Identification and Reporting

Firstly any actions that can be taken immediately to reduce the risk of harm to the patient or other patients must be implemented.

The initial facts of the incident should be established and an assessment of the level of harm that has happened to the patient as a result of the incident (see table below) should be undertaken.

Incident	Action
No harm *(including prevented patient safety incidents)*	o Patients are not usually contacted or involved in investigations and these types of incidents are **<u>outside</u>** the scope of the *Duty of Candour*. Openness is remains best practice, but there is no requirement to follow the Duty of Candour processes.
Low harm	o Unless there are specific indications or the patient requests it, the communication, investigation and analysis, and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. o Communication should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers'. o Reporting to the operational managers will occur through incident reporting and will be analysed centrally to detect high frequency events. o Review will occur through collated trend data and local investigation. Where the trend data indicates a pattern of related events, further investigation and analysis may be needed. Openness remains best practice, but there is no requirement to follow the Duty of Candour processes for incidents that result in this level of harm. .
Moderate harm **Severe harm or death**	o <u>The *Duty of Candour* procedure is implemented.</u> o It will be necessary to inform the Director of Care/Lead Nurse / appropriate Managers. o For Never Events the Director of Care/Lead Nurse must be informed immediately to ensure everyone who needs to know is informed. Hospice commissioners and regulators, will be informed of the incident and the management plans as a priority.

National Patient Safety Agency 2011

All incidents must be reported onto Nottinghamshire Hospice incident reporting system. The incident report must be completed as soon as possible after the incident has been discovered.

10.3 <u>Principles of Communication and Being Open</u>

There are a set of 10 principles for *Being Open,* National Patient Safety Agency 2009, (Appendix 1) that staff should refer to when communicating with the relevant person following an incident in which the patient/service user was harmed.

- Mental Capacity

  Where the patient or service user is assessed as not having the capacity to make a decision in relation to their care or treatment, or where the patient/service user is deemed not to have the necessary competency, then the most appropriate relevant person should be notified of the incident.

- Confidentiality

  Details of a patient's care and treatment should at all times be considered confidential. Where the Duty of Candour would include providing confidential information to family or carers, then the consent of the individual concerned should be sought prior to disclosing information. This consent or denial of consent to share should be recorded in the patient record and subsequent Root Cause Analysis (RCA) documentation.

  Communication with parties outside of the clinical team should be on a strictly need-to-know basis and, where practicable, records should be anonymised.

  Further information is available in Nottinghamshire Hospice's Consent Policy and Confidentiality Policy.

10.4 Initial communication with the relevant person and offering an apology

The initial 'being open' communications will vary according to the individual needs of the relevant person, the severity grading of the incident, clinical outcome and family circumstances for each specific event. The most senior clinician on the clinical shift should coordinate this initial communication, ensuring that the relevant person receives clear, unambiguous explanation of the event, and the next steps to be taken. It is also vital that staff involved in the incident receive appropriate support from the outset.

In the event a patient safety incident is identified in retrospect and/or relates to patients that are deceased the principles of Duty of Candour still apply. The nominated family member or significant other should informed or the incident and potential pending investigation. Nottinghamshire Hospice acknowledges the sensitively of such a situation and communication should be undertaken with care and using professional judgement. All decision making must be recorded in the patient record. External expert advice may be sourced to help support decision making.

10.5 The Relevant Person cannot be contacted or declines to have further information

If, after discussion, the patient says they do not want more information, then the possible consequences must be explained to them. It should be made clear that they can change their mind and have more information at any time.

All Duty of Candour conversations must be recorded in the patient record including instances when the patient has declined the offer of further information.

Where a relevant person cannot be contacted, a clear written record must be kept of the attempts made to contact or speak to the relevant person. This should evidence that every reasonable effort was made to contact the person by stating how many attempts were made, who by and when.

10.6 Apology

Where a patient safety incident has caused harm, an apology must be offered to the relevant person – a sincere expression of sorrow or regret for any possible harm and distress caused.

Guidance from the NHS Litigation Authority (2009) states:

“It is both natural and desirable for clinicians who have provided treatment which produces an adverse result, for whatever reason, to sympathise with the patient or the patient’s relatives; to express sorrow or regret at the outcome; and to apologise for shortcomings in treatment. It is most important to patients that they or their relatives receive a meaningful apology. We encourage this, and stress that apologies do not constitute an admission of liability. In addition, it is not our policy to dispute any payment, under any scheme, solely on the grounds of such an apology.”

10.7 Clarity of Communication

The individual communication needs of the relevant person, for example, linguistic or cultural needs, learning disabilities, or sensory impairments must be considered and taken into full account before any discussion takes place. This involves consideration of circumstances that can include a patient requiring additional support, such as an independent patient advisor or a translator.

10.8 Initial meeting with the relevant person

The relevant person should be initially informed of the issues surrounding the patient safety incident and its consequences in a face to face meeting.

The facts that are known should be explained. When talking to the relevant person about the incident staff must use clear, straightforward language and be honest with responses to any questions that are raised.

The relevant person should be informed that an incident analysis will be carried out and more information will become available as this progresses.

It should be made clear to the relevant person that new facts may emerge as the incident analysis proceeds.

The relevant person’s understanding of what happened should be established from the outset, as well as any questions they may have.

There should be consideration and formal noting of the relevant person’s views and concerns, and demonstration that these have been heard and taken seriously.

An explanation should be given about what will happen next in terms of the long term treatment plan for the patient as well as the incident analysis findings.

Information on likely short and long-term effects of the incident (if known) should be shared.

An offer of practical and emotional support should be made to the relevant person.

Patients, family and/or carers might be anxious, angry and frustrated, even when the discussion is conducted appropriately. It is essential that staff are not drawn into speculation, attribution of blame, denial of responsibility or the provision of conflicting information.

10.9 The Investigation

For Serious Incidents, the Investigating Officer (IO) will undertake the investigation as set out in Nottinghamshire Hospice's Incident Investigation Policy. This will be undertaken within 28 days of the incident being reported.

The IO will meet with the employee(s) directly involved in the incident to establish the facts.

Where an incident is notifiable but does not meet the criteria for a Serious Incident, then this will be classed as a 'Significant Event' and an RCA must be undertaken.

The actions above should be followed by a letter to the patient/relatives with an offer of a meeting, if this is appropriate. This should be written by the most appropriate person. This may be before the conclusion of the investigation. An example template letter is provided in Appendix 4.

The letter should advise the patient of the independent advocacy service available to support and assist them.

The Investigating Officer will keep the Director of Care and the person who is overseeing the Duty of Candour process up to date on progress with the investigation.

10.10 The Notification Meeting

A meeting with the relevant person should be arranged as soon as possible after the incident has happened to notify them of the incident. This meeting should always take place within 10 working days of the incident being discovered.

Staff identified to lead this meeting should:-

- Have a good relationship with the patient and/or their carers
- Have a good understanding of the relevant facts
- Be senior enough or have sufficient experience and expertise in relation to the type of incident to be credible to patients, carers and colleagues

- Have excellent interpersonal skills, including being able to communicate with patients and/or their carers in a way they can understand and avoiding excessive use of medical jargon
- Be willing and able to offer an apology, reassurance and feedback to patients and/or their carers
- Be able to maintain a relationship with the patient and/or their carers and to provide continued support and information
- Be culturally aware and informed about the specific needs of the patient/relatives or their carers

It may be appropriate for more than one member of staff to meet with the relevant person for support or for additional information.

At the meeting the nominated member of staff should follow the procedure below:-

- If known, explain what went wrong and where possible, why it went wrong;

- Inform the patient and/or relative(s) and others what steps are being/will be taken to prevent the incident recurring;

- Offer an apology:

- Provide opportunity for the patient and/or relatives and others to ask any questions;

- Agree with the patient and/or relatives and others any future meetings as appropriate;

- Suggest any sources of additional support and counselling and provide written information if appropriate.

- Inform the relevant person that they will receive a written summary of the incident and that they will be, if they wish, be informed of progress with the investigation. The relevant person will also receive a copy of the final investigation report.

Wherever possible a named contact should be provided who the relevant person can speak to regarding the incident. This can be a manager in the clinical team or another member of staff who has the skills and knowledge to undertaken this role. It is vitally important that whoever is named as the contact is made aware of this, agrees to the role and is furnished with all of the information they may need to ensure clear and honest communication takes place.

The senior manager/clinician for the service should be informed of the outcome of any meeting.

The communication and outcome of the notification must be clearly recorded in the clinical notes by the person who has informed the patient/family.

A letter should then be written to the relevant person setting out what was explained at the notification meeting. The letter should be drafted immediately after the notification meeting and forwarded to the Director of Care for approval prior to sending out. The letter must contain all the information that was provided at the initial notification meeting.

> The regulations state that the notification given must be followed by a written notification given or sent to the relevant person containing—
> (a) the information provided,
> (b) details of any enquiries to be undertaken,
> (c) the results of any further enquiries into the incident, and
> (d) an apology.

Any Duty of Candour letters arising out of the notification meeting must be signed off by the Director of Care and a copy kept in the clinical notes.

If, for whatever reason, the patient cannot be contacted in person or declines to speak to anyone from Nottinghamshire Hospice in relation to the incident, then the above processes do not apply but a written record must be kept of the attempts made to contact or to speak to the relevant person.

10.11 Investigation Closure and Learning

The full incident will be presented to the Quality and Safety Committee. This will include details of how the Duty of Candour has been implemented.

Once the incident is signed off for closure by the Quality and Safety Committee, a letter should be sent to the relevant person together with the anonymised investigation report and action plan. This letter will be signed off by the Chief Executive or their nominated deputy.

If the incident report or RCA is not available within the usual time frame for closure, a letter should be sent to the relevant person to provide an explanation as to when they can expect to be provided with additional details. This letter should clarify the information previously provided; reiterate key points, and record action points and future deadlines.

All learning from the incidents must be cascaded via the Incident Review Meeting and Team Meetings. This information will be relayed to Trust Board through the Director of Care Report.

The outcome of reports must also be shared with any other healthcare organisation or relevant stakeholder as appropriate to optimise learning from the incident.

10.12 Record keeping

All correspondence should be held in accordance with the Hospice Records Management Policy.

With specific relation to the Being Open/Duty of Candour the clinical records must:

- Record the sharing of any facts that are known and agreed with the relevant person;

  Record how it has been agreed that the relevant person will be kept informed of the progress and results of that investigation;

- Record, where appropriate, a full apology to the patient and their family/carers;

- Record any explanation given of the likely short and long-term effects of the incident;

- Contain copies of any letters sent to the relevant person;

- Record an offer of appropriate practical and emotional support.

10.13 Performance/Disciplinary Issues

As previously described, Nottinghamshire Hospice will strive to identify the underlying causes of patient safety incidents (i.e. systems failures or latent conditions) through RCA or incident investigation processes.

The incident decision tree –

http://www.ahrq.gov/downloads/pub/advances/vol4/meadows.pdf supports this process and provides a straightforward guidance tool to support a fair and just approach to patient safety incidents. The tool aims to support clinicians and managers in understanding when safety incidents should be attributed to systemic or organisational issues, as well as identifying the occasions when there may be individual culpability for an incident.

The purpose of the tool is to support building a just and fair safety culture that moves away from inappropriately blaming individual staff for safety incidents when these are more often the result a combination of human, organisational, technological and system factors.

Where concerns are identified about the performance of staff, Nottinghamshire Hospice's Management of Performance policy will be invoked.

This will particularly be the case in matters where safeguarding issues are identified.

The appropriate professional body (HCPC/NMC etc.) may also need to be notified.

10.14 The potential implications of not implementing the Duty of Candour requirements

As the Duty of Candour is a statutory requirement, non-compliance is a criminal offence.

Commissioners can withhold the cost of the episode of care or implement a fine of £10,000 if the cost is not known. In addition, they can do any/all of the following:

- Inform the CQC
- Require that the Chief Executive send an apology and an explanation of the breach to the patient/relatives
- Publish details of the breach on Nottinghamshire Hospice web-site.

The CQC in their guidance relating to the Duty of Candour explain the approach they will be taking to assess whether a provider is complying with the new regulation. The CQC's key lines of enquiry will be:

a. Are lessons learned and improvements made when things go wrong?
b. Are people who use services told when they are affected by something that goes wrong, given an apology and informed of any actions taken as a result?
c. How does the leadership and culture reflect the vision and values, encourage openness and transparency and promote good quality care?
d. Does the culture encourage candour, openness and honesty?

10.15 Incidents that are later uncovered or that have occurred within the care of another provider

On occasion, an incident that happened some time ago may be discovered. The incident should be reported in the usual way, and agreement reached by the senior clinician and the Director of Care as to the most appropriate action to take. A delay in discovering an incident does not mean the Duty of Candour does not apply. The processes however may require additional consideration in order that the patient is informed of the incident with care to avoid unexpected shock or distress.

Incidents that are discovered that relate to care delivered by another provider will be reported to a senior manager in that organisation, and to the commissioning body. That organisation is then responsible for implementing the Duty of Candour. Nottinghamshire Hospice will work in partnership with other providers to ensure the Duty of Candour applies as an economy wide, patient-centred policy.

10.16 Support and Advice for Staff

It is very rare for staff in healthcare to go to work with the intention of causing harm or failing to do the right thing. While we do all we can to minimise risks, it will never be possible to eliminate them fully. It should be acknowledged from the outset that many 'human factors' can increase the risk of incidents occurring such as:

- Workload
- Distractions
- Physical environment
- Physical demands
- Device/product design.

It is uncommon for any single action or ‘failure’ to be wholly responsible. The focus following an incident should always be on learning and prevention rather than individual blame.

Involvement in an incident and particularly a serious incident can have profound consequences on staff members who may experience a range of reactions. The high personal and professional standards of most clinicians and other staff may make them particularly vulnerable to these experiences. Different individuals will have differing responses to the same incident and support should always therefore be tailored to the individual. The HR Team is able to advise on resources available in Nottinghamshire Hospice,including the EAP but the support of close team members and managers is invaluable for the staff involved, and for taking forward learning from the event.

- The initial level of support is provided by line managers for employees involved in a patient safety incident.

- The second level of support is provided by appropriate Senior Managers and may include guidance from professional leads. A further level of support is provided by the Directors.
- Further Support will be available from the HR Team and Occupational Health

Teams who work in isolated services or have lone working practices may be more likely to need support. These staff also need to be able to assure their Line Managers and Nottinghamshire Hospice that they are acting in an open and candid manner with patients.

11. Appendices

Appendix 1

The 10 Principles of Being Open *- Being open* involves apologising when something has gone wrong, being open about what has happened, how and why it may have happened, and keeping the patient and their family informed as part of any subsequent review.

1. **Principle of Acknowledgement**

   All patient safety events should be acknowledged and reported as soon as they are identified. In cases where the patient, their family and carers inform healthcare employees that something has happened, their concerns must be taken seriously and should be treated with compassion and understanding by all employees. Denial of a person's concerns or defensiveness will make future open and honest communication more difficult.

2. **Principles of Truthfulness, Timeliness and Clarity of Communication**

   Information about a patient safety incident must be given in a truthful and open manner by an appropriately nominated person. Communication should be timely, informing the patient, their family and carers what has happened as soon as is practicable, based solely on the facts known at that time. It will be explained that new information may emerge as the event investigation takes place. Patients, their families and carers and appointed advocates should receive clear, unambiguous information and be given a single point of contact for any questions or requests they may have.

3. **Principle of an Apology**

   Patients, their families and carers should receive a meaningful apology - one that is a sincere expression of sorrow or regret for the harm that has resulted from a patient safety event or that the experience was poor. Both verbal and written apologies should be offered. **Saying sorry is not an admission of liability and it is the right thing to do.** Verbal apologies are essential because they allow face to face contact, where this is possible or requested. A written apology, which clearly states the organisation is sorry for the suffering and distress resulting from the patient safety event, should also be given.

4. **Principle of Recognising Patient and Carer Expectations**

   Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences, in a face to face meeting with representatives from the organisation and/or in accordance with the local resolution process where a complaint is at issue. They should be treated sympathetically, with respect and consideration. Confidentiality must be maintained at all times. Patients, their families and carers should also be provided with support in a manner to meet their needs. This may involve an independent advocate or an interpreter. Information enabling to other relevant support groups will be given as soon as possible and as appropriate.

5. Principle of Professional Support

Nottinghamshire Hospice has set out to create an environment in which all employees are encouraged to report patient safety events. Employees should feel supported throughout the patient safety event investigation process; they too may have been traumatised by the event. Resources available are referred to within the respective Hospie policies, to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the practice of individual employee Nottinghamshire Hospice's Human Resources department must be contacted for advice. Where there is reason to believe an employee has committed a punitive or criminal act, Nottinghamshire Hospice will take steps to preserve its position and advise the employee at an early stage to enable them to obtain separate legal advice and/or representation. Employees should be encouraged to seek support from relevant professional bodies. Where appropriate, a referral will also be made to the relevant Safeguarding Authority.

6. Principle of Risk Management and Systems Improvement

Root Cause Analysis (RCA) or similar techniques should be used to uncover the underlying causes of patient safety events. Investigations at any identified level will however focus on improving systems of care, which will be reviewed for their effectiveness. *Being open* is integrated into patient safety incident reporting and risk management policies and processes.

7. Principles of Multi-Disciplinary Responsibility

Being open applies to all employees who have key roles in patient care. This ensures that the *Being open* process is consistent with the philosophy that patient safety incidents usually result from system failures and rarely from actions of an individual. To ensure multi-disciplinary involvement in the *Being open* process, it is important to identify clinical and managerial leaders who will support this across the health and care agencies that may be involved. Both senior managers and senior clinicians will be asked to participate in the patient safety incident investigation and clinical risk management as set out in the respective Hospice policies and practice guidance.

8. Principles of Clinical Governance

Being open involves the support of patient safety and quality improvement through Nottinghamshire Hospice's clinical governance framework, in which patient safety incidents are investigated and analysed, to identify what can be done to prevent their recurrence. It is a system of accountability to ensure that these changes are implemented and their effectiveness reviewed. Findings are disseminated to employees so they can learn from patient safety incidents. Audits are an integral process, to monitor the implementation and effects of changes in practice following a patient safety incident.

9. Principle of Confidentiality

Details of patient safety incidents should at all times be considered confidential. The consent of the individual concerned should be sought prior to disclosing information beyond the clinicians involved in treating the patient. Nottinghamshire Hospice will anonymise any incident it publishes but still seek the agreement of those involved.

Where it is not practicable or an individual refuses consent to disclosure, disclosure may still be lawful if justified in the public interest or where those investigating the patient safety event have statutory powers for obtaining information. Communications with parties outside of those involved in the investigation will be on a strictly need to know basis. Where possible, it is good practice to inform the patient, their family and carers about who will be involved in the investigations before it takes place, and give them the opportunity to raise any objections.

10. Principle of Continuity of Care

Patients will continue to receive all usual treatment and continue to be treated with respect and compassion.

National Patient Safety Agency 2005

Appendix 2

Summary of Principles of Duty Candour

Every healthcare professional must be open and honest with patients and since November 2014, has a statutory Duty of Candour.
Candour is defined by 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 a report about that provision has been made'.

The Being Open principles and ethical duty of openness apply to all incidents and any failure in care or treatment. The Duty of Candour applies to incidents whereby moderate harm, significant harm or death has occurred.
It is a matter of judgment that needs to be exercised on a case by case basis to determine whether an incident that meets the Duty of Candour criteria has occurred. What may not appear to be such an incident at the outset may look very different once more information comes to light, and may therefore lead to an incident becoming notifiable under the Duty of Candour.

The requirements of the Duty of Candour are as follows:
As soon as reasonably practicable after becoming aware that a safety incident has occurred that falls into the moderate harm or more serious categories the healthcare professional must—
a. notify the 'relevant person' (this is usually the patient but may in some circumstances be the relative, carer or advocate) that the incident has occurred and;

b. provide reasonable support to the relevant person in relation to the incident.

The notification must:

(a) be given in person by one or more members of staff;
(b) provide an account of all the facts known about the incident to date;
(c) advise the relevant person what further enquiries into the incident will be undertaken;
(d) include an apology and/or a sincere expression of regret, and;
(e) be recorded in writing in the notes.

This notification must be followed up in writing to the relevant person.
The member of staff should be clear in the first meeting that the facts may not yet have been established, tell the relevant person only what is known and believe to be true, and answer any questions honestly and as fully as they can.

The aim of the Duty is to ensure that patients are told when harm occurs as a result of the care they receive. Where the degree of harm is not yet clear but may fall into the moderate or above categories, then the relevant person must be notified.

Appendix 3

Summary of the Stages in the Duty of Candour Process

Requirement under Duty of Candour	Responsible Person	Timeframe
For incidents where moderate harm, serious harm or death has occurred, the relevant person must be informed.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager should be made aware and if appropriate, involved.	As soon as possible after the incident has been detected and reported but always within 10 working days of the incident
Initial notification of incident must be verbal (face-to-face, where possible) unless the relevant person declines notification or cannot be contacted in person. Sincere expression of regret or sorrow must be provided verbally. This must be recorded in the patient record.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager should be made aware and if appropriate, involved.	As above.
Step-by-step explanation of the known facts must be offered to the relevant person.	As above	As above
Written notification to the relevant person. The written notification should outline the facts discussed at the notification meeting and include a sincere expression of regret or sorrow.	As above. All letters must be approved by the Director of Care or their nominated deputy.	As above (template letter available for guidance only – all letters must be personalised and tailored to the individual needs of the person receiving the letter).
Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded	As above. All follow-up letters to patients/ relatives to be approved for release by the Director of Care or their nominated deputy.	
Share incident investigation report (including action plans) with an accompanying letter.	Investigating Officer or other nominated person. Letter to be approved by Director of Care and signed off by the Chief Executive or their nominated deputy.	As soon as reasonably practicable but always within 28 working days of report being signed off as complete and incident closed.

Appendix 4

Guidance Letter Template for Initial Notification Communication Letter in Accordance with Requirements of Duty of Candour.

NB This is provided purely for guidance. All letters must be personalised and tailored to the individual needs of the person receiving the letter.

Dear Mrs/Mrs xxxxxxxxxxx

I am writing to express my sincere regret that (you/your relative XXXXX) has been involved in an incident whereby ……………(describe event here). As an organisation we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened, and what we can do to prevent such an incident occurring again in the future.

An investigation is already underway to try and establish the cause of the incident. If you would like to meet with a member of staff to discuss this, please let me know within the next two weeks, and we will arrange a mutually convenient time and place to meet.

There is an independent advocacy service available to support and assist you in this who can be contacted on XXXXXXX.

Staff member XXXXX is acting as your lead contact for the duration of the investigation. They can be contacted by email on xxxxxxxxxxxxxxx or on telephone number xxxxx xxxxxxx

Yours sincerely

Appendix 5

Duty of Candour Actions Flow Chart

As soon as incident occurs

- Provide immediate support and assistance to the patient and any staff affected by the incident.
- Record incident on Incident reporting form
- Discuss next steps with line manager/senior clinician to define Duty of Candour roles

Within 10 working days of incident being reported

Notify patient that the incident has occurred and establish whether patient consents to share information with family/carer

Notification must

- Be verbal
- Be conducted in person
- Be conducted by the department involved and include the Senior Clinician whenever possible
- Provide all facts currently known about the incident
- Include an appropriate apology
- Be supplemented by a written notification
- Be recorded in writing in the clinical notes

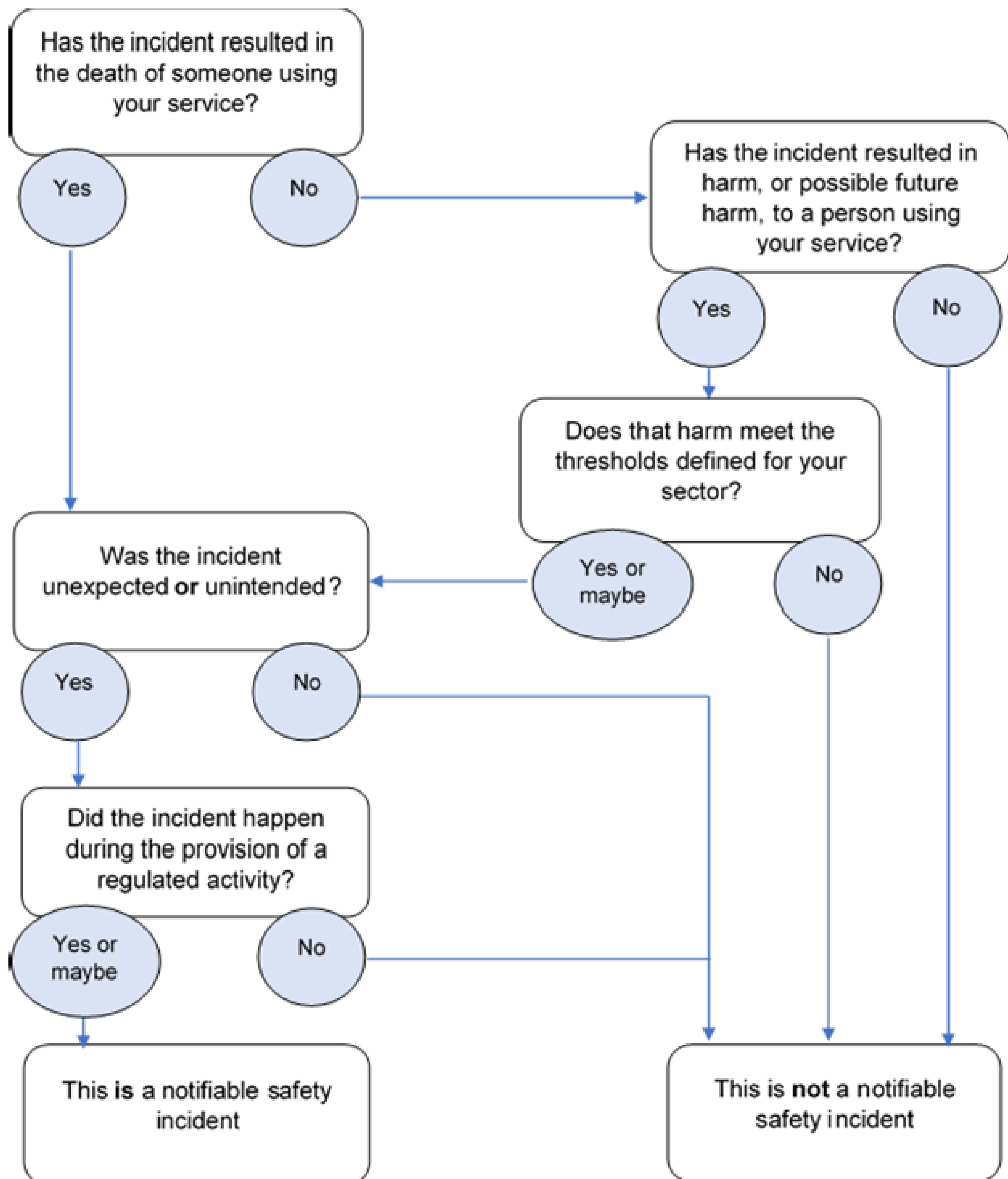
Within 28 days of the incident being reported

- Investigating Officer conducts investigation
- Offer interim update to patient/family during the course of the investigation and provide appropriate support to patient and staff.
- Maintain full written records of any meeting or other contact with the relevant person in relation to the incident
- Record any refusal by the patient/family of a meeting or other contact or information in relation to the incident

Within 10 working days of investigation

- Offer to provide the patient/next of kin with the findings of the investigation report
- Requires sign-off by Chief Executive / Deputy
- Provide copy of investigation together with letter to patient/next of kin

Appendix 6



CQC 2022

12. References

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 No. 2936 PART 3SECTION 2 Regulation 20 http://www.legislation.gov.uk/uksi/2014/2936/regulation/20/made
The Francis Enquiry 2013 http://www.midstaffspublicinquiry.com/
A promise to learn – a commitment to act: Improving the Safety of Patients in England, Berwick and the National Advisory Group on the Safety of Patients in England, 2013, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/226703/Berwick_Report.pdf.
Building a culture of candour - A review of the threshold for the duty of candour and of the incentives for care organisations to be candid http://www.rcseng.ac.uk/policy/documents/CandourreviewFinal.pdf
Human Factors in Healthcare – National Quality Board 2013 http://www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/Intervention-support/Human+Factors+How-to+Guide+v1.2.pdf
Patient Safety Incidents National Patient Safety Agency 2011 http://www.npsa.nhs.uk/nrls/reporting/what-is-a-patient-safety-incident
National Patient Safety Agency 2005 Being Open resources: http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
Mental Capacity Act 2005 – Code of Practice http://www.justice.gov.uk/protecting-the-vulnerable/mental-capacity-act
National Patient Safety Agency, Seven Steps to Patient Safety, April 2004 http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/
NHS Litigation Authority – Saying Sorry: 2013 - http://www.nhsla.com/Claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf
Care Quality Commission Provider Guidance Duty of Candour 2014 http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf
NHS England Serious Incident Framework, Supporting Learning to prevent a reoccurrence. 2015 https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2015/04/serious-incidnt-framwrk-upd2.pdf
Duty of Candor Final Report D Dalton, N Williams 2014 http://www.bing.com/search?q=daltom+and+willilams+building+a+culture+of+cnadour&src=IE-TopResult&FORM=IETR02&conversationid=

13. Equality Impact Assessment

Name of Policy/Procedure	**Being Open and Duty of Candour**
Name of Lead Director	**Rachel McCarty**
Nominated Lead	**Director of Care**
Name of Person Completing Assessment	**Rachel Hucknall / Rachel McCarty**
Date Form Completed	**March 2022**

Description and Aims of Policy/Procedure (including relevance to equalities)

This policy and procedure provides the framework for quality and consistency of communication with patients, families and carers and aims when mistakes are made and there is potential or actual patient harm It will ensure openness and transparency and where required Nottinghamshire Hospice will be complaint with the statutory Duty of Candour. It also makes provision to support staff who are involved in incidents of potential or actual patient harm

Brief Summary of Research and Relevant Data

Review of relevant guidance and legislation and cross reference to other Hospice policies and procedures.

Methods and Outcome of Consultation

Key staff will be consulted in all clinical services on this policy and procedure

Results of Initial Screening or Full Equality Impact Assessment

Equality Group	Assessment of Impact
Age	None
Gender	None
Race	None
Sexual Orientation	None
Religion or belief	None
Disability	None
Dignity and Human Rights	None
Working Patterns	None
Social Deprivation	None

Decisions and/or Recommendations (including supporting rationale)

None

Equality Action Plan (if required)
None required

Monitoring and Review Arrangements (including date of next full review)

This policy and procedure will be reviewed in three years unless there are changes to legislation or in response to learning from any incidents.

Screening Grid

Screening Grid Equality Area (Protected Characteristics)	Is this policy or service RELEVANT to this equality area? YES / NO	Assessment of Potential Impact: HIGH/MEDIUM/LOW/ NOT KNOWN		Reasons for Assessment
		positive (+)	negative (-)	
Age	NO	LOW	LOW	
Disability	NO	LOW	LOW	
Gender Reassignment	NO	LOW	LOW	
Race	NO	LOW	LOW	
Religion or Belief	NO	LOW	LOW	
Sex	NO	LOW	LOW	
Sexual Orientation	NO	LOW	LOW	
Marriage & Civil Partnership	NO	LOW	LOW	
Pregnancy & Maternity	NO	LOW	LOW	
Social Deprivation	NO	LOW	LOW	
Dignity and Human Rights	NO	HIGH	LOW	Fully supports dignity and human rights
Working Patterns	NO	LOW	LOW	

14. Environmental Impact Assessment

The purpose of an environmental impact assessment is to identify the environmental impact of policies, assess the significance of the consequences and, if required, reduce and mitigate the effect by either a) amend the policy b) implement mitigating actions.

Area of Impact	Environmental Risk/Impacts to Consider	Yes / No	Action Taken (where necessary)
Waste and Materials	• Is the policy encouraging using more materials/supplies? • Is the policy likely to increase the waste produced? • Does the policy fail to utilise opportunities for introduction/replacement of materials that can be recycled?	NO	
Soil/Land	• Is the policy likely to promote the use of substances dangerous to the land if released (egg lubricants, liquid chemicals)? • Does the policy fail to consider the need to provide adequate containment for these substances (egg bonded containers, etc.)?	NO	
Water	• Is the policy likely to result in an increase of water usage (estimate quantities)? • Is the policy likely to result in water being polluted (egg dangerous chemicals being introduced in the water)? • Does the policy fail to include a mitigating procedure (egg modify procedure to prevent water from being polluted; polluted water containment for adequate disposal)?	NO	
Air	• Is the policy likely to result in the introduction of procedures and equipment with resulting emissions to air (egg use of furnaces; combustion of fuels, emission or particles to the atmosphere)? • Does the policy fail to include a procedure to mitigate the effects? • Does the policy fail to require compliance with the limits of emission imposed by the relevant regulations?	NO	
Energy	• Does the policy result in an increase in energy consumption levels in Nottinghamshire Hospice (estimate quantities)?	NO	
Nuisances	• Would the policy result in the creation of nuisances such as noise or odour (for staff, patients, visitors, neighbours and other relevant stakeholders)?	NO	