Duty of Candour Policy

Section	OPC
Version	4
Written by	Rachel Ball
Date written	16/04/20
Approved by	Integrated Governance Committee
Date approved	July 2022
Date issued	July 2022
Reviewed	April 2024
Review date	February 2026
Associated policies	SER Policy The Complaint Process Policy The Whistleblowing Policy The Disciplinary Procedures Policy

Executive Summary: This policy clarifies the responsibilities of all employee's in relation to Duty of Candour.	
Values:	
Putting People First	x
Working Together	x
A Better Future	

VERSION CONTROL SHEET

DOCUMENT TITLE: **Duty of Candour Policy**

Version*:* 3

Version	Date	Author	Status	Comment
V0.1	2017	Dr Helen Snowden	Expired	Review and update required.
0.2	2020	Rachel Ball	Expired	Policy renewal, updated and transferred onto new OPC policy template
0.3	2022	Helen Clements	Live	Review and update complete
0.4	2024	Quality Team	Expired	Reviewed and updated

CONTENTS:

1 POLICY STATEMENT

1.1 It is the intention of OneMedical to make this duty a reality for people who come into contact with our services. We want to ensure there is clear, robust organisational support for our staff to follow their ethical and professional responsibility in being open and honest with patients. This policy is a reinforcement of OneMedical Groups commitment to a wider culture of safety, learning and improvement.

1.2 Clinicians already have an ethical duty of candour under their professional registration to inform patients about errors and mistakes. This policy builds on individual professional duty and places an obligation on the organisation - not just individual - to be open with patients when harm has occurred.
It is broadly acknowledged that healthcare treatment is not risk free. Patients, families and carers usually understand this, and want to know not only that every effort has been made to put things right, but every effort is made to prevent similar incidents happening again to somebody else**.** A critical test for patients' trust in our organisation is how we respond when things go wrong. Openness is comparatively easy when all is well, but can be far more challenging in cases of actual or possible harm.
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 unequivocal, sustained support for staff in reporting incidents and in being open and transparent.

1.3 The 'Duty of Candour' requirements reinforce the 'being open' principles by placing more emphasis on organisational responsibility. While the Duty applies to organisations, not individuals, it is clear that individuals must cooperate with it to ensure the Duty is met.

2 INTRODUCTION

2.1 The National Patient Safety Agency (NPSA) advised all NHS organisations to implement a *Being Open* Policy in September 2005. The guidance was revised in November 2009 with the publication of its best practice *Being Open Framework* (National Patient Safety Agency, 2009). Robert Francis QC's report of the Mid Staffordshire Foundation Trust Public Inquiry included 12 recommendations relating to openness, transparency and candour. Recommendation 173 states the overarching requirement:

"Every healthcare organisation and everyone working for them must be honest, open and truthful in all their dealings with patients and the public,

and organisational and personal interests must never be allowed to outweigh the duty to be honest, open and truthful".

2.2 From 2013-14 the NHS Standard Contract (NHS Commissioning Board, 2013) includes a contractual duty of candour. These requirements are covered within this policy. The Health & Social Care Act 2008 Regulations 2014 sets out the new statutory duty of candour and is one of the fundamental standards inspected by the Care Quality Commission (CQC). The statutory duty came into force on the 27th November 2014.

3 PURPOSE

3.1 The purpose of this policy is:

- To strengthen and embed a culture of openness and transparency across the organisation
- To embed learning from incidents, complaints and claims arising from notifiable
  safety incidents to improve services for service users.
- To facilitate compliance with regulation 20 requirements and in the process improve the quality and consistency of communication with service users, their families and carers when notifiable safety incidents occur.
- To ensure that service users, their families and carers, and staff all feel supported
  when notifiable safety incidents occur.

4 SCOPE

4.1 This policy is aimed at all staff working within OneMedicalGroup and sets out the infrastructure which is in place to support openness and transparency between healthcare professionals and patients, their families and carers, following a notifiable safety incident. All staff must note the limitations and exemptions that apply.

- A **notifiable safety incident** comprises of incidents that could result in, or appear to have resulted in, the **death** of a service user or **severe harm, moderate harm or prolonged psychological harm**. The trust is **not required** under the regulation to inform a service user when a „near miss" or an incident that resulted in no harm has occurred.

- **Relevant person** (Patient) – in circumstances where the patient

involved in an incident is under 16 years or over 16 years of age and not competent or lack capacity to make a decision regarding their care and treatment, or upon their death, a person acting lawfully on their behalf shall be treated as the relevant person.

- **Family members and carers –** Information should only be disclosed to them where the patient has given their expressed or implied consent; and in accordance with the Consent and Data Protection and confidentiality policies.

4.2 In the event of an incident staff are required to take immediate steps to contain the incident to minimise harm, inform the clinical manager or service delivery lead for site, withdraw and retain for examination any evidence including equipment.

4.3 Although this policy is restricted to notifiable safety incidents, all staff need to ensure that all incidents including 'near misses' are reported using the event recording (SER) system available on the OneMedical Group intranet, as soon as is practicable but with 24 hours of the incident.

5 DUTIES AND RESPONSIBILITIES

5.1 **OneMedicalGroup Board:**
The Board fully endorses the principles of being open and actively promotes an open, honest and fair culture. The 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 traumatized by the event. The Board ensures that systems are in place to provide support to employees in these circumstances.

5.2 **Chief Executive:**
The Chief Executive is ultimately responsible for the process of managing and responding to the being open/Duty of Candour process and for the delegation of this role as required.

5.3 **Executive Directors and Senior Leadership Team:**
The Executive Directors and Senior Leadership Team are responsible for actively supporting the Chief Executive with being open and the Duty of Candour principles and process.

5.4 **The Clinical Governance Team:**

The Clinical Governance Team is chaired by the Associate Director of Patient Safety and Experience. They review all Serious Incidents, notifiable incidents and SERs that are referred to ensure the quality of the investigation is of a high standard, and that associated action plans are comprehensive. They will monitor Investigation Reports to determine whether the principles of being open and the Duty of Candour have been followed appropriately in each case.

5.5 **The Associate Director of Patient Safety and Experience:**
They are responsible for ensuring the effective implementation of the Being Open and that incidents invoking Duty of Candour are reported to the Clinical Governance team and relevant members of the Senior Leadership Team.

5.6 **Clinical Service Managers/Service Coordinators:**
It is the responsibility of all clinical service managers and service coordinators to support employees to comply with this policy and to ensure members of their teams are aware of this policy.

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

> *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 the SER Reporting Policy and apply the principles of being open and the Duty of Candour throughout these processes.

All employees should abide by the organisations complaints process and inform patients or their carers of this process and provide the relevant details should 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 through the organisations Whistleblowing policy.

5.8 **Senior Clinician:**
The most senior clinician involved in the incident will determine whether the incident is notifiable. Advice can be sought from the organisations senior

leadership team.

6 DEFINITIONS

6.1 **Notifiable Safety Incident** any unintended or unexpected incident that occurred in
respect of a patient during the provision of a regulated activity that, in the reasonable
opinion of a health care professional, could result in, or appears to have resulted in:

- The death of a patient, where the death relates directly to the incident rather to the natural course of the patient's illness or underlying condition, or
- Severe harm or
- Moderate harm or
- Prolonged psychological harm to the patient.

6.2 **Relevant Person** this refers to the patient or to a person lawfully acting on their behalf in the following circumstances:

- On the death of the patient
- Where the service user is under 16 and not competent or over 16 and lacks capacity (as determined in accordance with sections 2&3 of the 2005 Act) to make a decision in relation to their care and treatment

6.3 **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 patient's illness or underlying condition.

6.4 **Moderate harm** harm that requires 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)*** AND significant but not permanent harm.

6.5 **Prolonged psychological harm** psychological harm which a patient has experienced, or is likely to experience, for a continuous period of at least 28 days

6.6 **Apology** an expression of sorrow or regret in respect of a notifiable safety incident.
Saying sorry is not an admission of liability; it is the right thing to do.

7 BEING OPEN AND DUTY OF CANDOUR PRINCIPLES AND REQUIREMENTS

7.1 This policy reflects the 'Ten Principles of Being Open' as identified in the National Patient Safety Agency's document "*Being open": communicating patient safety incidents with patients and their carers'* (NPSA, 2005).
These principles are:

- **Principle of acknowledgement**
- **Principle of truthfulness, timeliness and clarity of communication**
- **Principle of apology**
- **Principle of recognising patient and carer expectations**
- **Principle of professional support**
- **Principle of risk management and systems improvement**
- **Principle of multidisciplinary responsibility**
- **Principle of clinical governance**
- **Principle of confidentiality**
- **Principle of continuity of care**

Further detail of these principles is provided in **Appendix 1**.

7.2 To meet the statutory duty of candour requirements (Regulation 20) the organisation has to:

- Make sure it acts in an open and transparent way with relevant persons in relation to care and treatment provided to people who use services in carrying on of a regulated activity.
- Tell the relevant person in person as soon as reasonably practicable after becoming aware that a notifiable safety incident has occurred, and provide support to them in relation to the incident, including when giving the notification.
- Provide an account of the incident which, to the best of the organisation's knowledge, is true of all the facts the organisation knows about the incident as at the date of the notification.
- Advise the relevant person what further enquiries the organisation believes are appropriate.
- Offer an apology.
- Follow this up by giving the same information in writing, and providing an update on the enquiries.
- Keep a written record of all communication with the relevant person.

8 BEING OPEN AND DUTY OF CANDOUR PROCEDURES

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 in deciding, for example, when is the right time to talk to patients and families/carers. There is no substitute for clinical and professional expertise and compassionate care.
(A summary of the ***6 stages*** involved in this process is provided in **Appendix 2**)

8.1 **Stage 1**_Incident Identification and Reporting actions should be taken immediately to reduce the risk of harm to the patient. The initial facts of the incident should be established.
Level of harm should be determined
A summary of the following actions to be undertaken;

Incident	Action
No harm *(including prevented patient safety incidents)*	• Patients are not usually contacted or involved in investigations and these types of incidents. Openness remains best practice but only ***Stage 1 of the Duty of Candour process is required***.
Low harm	• Unless there are specific indications or the patient requests it, the communication & investigation, lessons learned and the implementation of changes will occur at local service delivery level with the participation of those directly involved in the incident. • If Communication is required, should take the form of an open discussion between the staff providing the patient's care and the patient and/or their carers. • Reporting to the operational managers will occur through standard SER reporting • Review will occur through local investigation

	• A recognised trend in similar incidents will be monitored and acted on by the Patient Safety Committee. • Openness remains best practice but only ***Stage 1 of the Duty of Candour process is required.***
Moderate harm **Severe harm or death**	• ***The Duty of Candour Stage 2 is implemented***. • Inform the relevant Service Delivery Lead and the Clinical Service Manager for the service. For Never Events a member of the Executive team must be informed immediately and for the most serious incidents, the Clinical Senate will also need to be contacted as quickly as possible to ensure everyone who needs to know is informed. • A decision will be made to inform the organisations insurance provider.

All incidents must be reported as a serious event (SER) in line with the SER Reporting Policy.

For any Patient Safety Incident, an incident report must be completed as soon as possible after the incident has been discovered, and always within 24 hours of detecting the incident.

8.2 **Stage 2-**_Notifying the Person and Being Open the principles for being open are provided in **Appendix 1** and staff should refer to these when communicating with the relevant person following an incident in which the patient was harmed.
The following is a guide:

- Demonstrate expression of genuine sympathy, regret and a meaningful apology for the harm that has occurred.
- Provide all current known facts about the incident
- Explain that additional information may come to light as the investigation proceeds and that substantiated developments can be communicated.
- Agree how the patient, family or carer would like to be kept informed (a meeting may be requested)
- Patients must be reassured that access to treatment and the continuity of their care will continue accordingly to their clinical needs.
- They should be informed that they have the right to continue their treatment elsewhere if they prefer.

8.3 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.

8.4 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 clinical notes.

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

8.6 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.

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

8.8 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.

8.9 **Stage 3** 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. It is most important to patients or their relatives that they receive a meaningful apology. OneMedical Group encourage this, and stress that apologies are not an admission of liability.

8.10 The following is intended as broad advice as it is recognised that the vast majority of clinical staff have extensive, highly tuned communication skills.

- 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.

- The relevant person should be fully 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 investigation will be carried out and more information will become available as this progresses.

- 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 investigation findings.

- An offer of practical and emotional support should be made.

- 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.

8.11 **Stage 4** The Investigation for Serious Incidents, the Director of Professions and the Governance, Contracting & Compliance Director will have been informed and any other relevant members of the Senior Team. A Lead for the Investigation will be established following agreement with the above parties.

All other incidents will be reported and investigated as stated in the SER Reporting Policy

A letter to the patient/relatives should be sent with an offer of a meeting, if appropriate and may be before the conclusion of the investigation. An example template letter is provided in **Appendix 3**

Progress with the investigation should be provided to the Integrated Governance Committee and/or senior managers involved in the investigation at regular intervals or as new developments come to light.

8.12 **Stage 5** A notification meeting with the relevant person should be arranged as soon as possible after a notifiable incident has happened to explain the nature of the incident. This meeting should always take place within 10 working days of the incident being discovered.
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) 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.

8.13 Wherever possible a named contact should be provided who the relevant person can speak to regarding the incident. This can be the clinical service manager 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 Clinical Services Manager for the site should be informed of the outcome of any meeting.

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

8.15 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 PSC for approval prior to sending out. The letter must contain all the information that was provided at the initial notification meeting.

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

8.17 **Stage 6** Investigation closure and learning the full Investigation report will be presented to the Clinical Senate. This will include details of how the Duty of Candour has been implemented. Once the incident is signed off for closure by the Clinical Senate, a letter should be sent to the relevant person together with the anonymised investigation report and action plan. The supporting letter should provide information in the event that the individual

wishes to pursue legal action against OneMedicalGroup. This letter will be signed off by the Director of Professions and Governance, Contracting & Compliance Director.

8.18 If the investigation report 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.

8.19_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 LESSONS LEARNT FROM INCIDENTS

10.1 All learning from the incidents will be cascaded via the Clinical Senate, PIMS and the Professions Bulletin to all service managers and clinical leads, to share with their team.
SERs will feature as a standing agenda item for PIMS and Site/Service Clinical Team Meetings.
Reports must also be shared with any other healthcare organisations or relevant stakeholders as appropriate to optimise learning from the incident.

11 DUTY OF CANDOUR COMPLIANCE/ NON-COMPLIANCE

11.1 It is essential that all staff comply with the procedures within this policy as non-compliance is an enforceable action by the CQC.
The CQC will report on the duty of candour under the safety key question in their inspection reports. The CQC would want to know whether the organisation is meeting Regulation 20: Duty of Candour. When they identify a breach of the regulation, they will assess the impact on people and decide whether or not to take regulatory action, and what action to take, in accordance with their Judgement Framework and Enforcement Policy.

12 PERFORMANCE AND DISCIPLINARY ISSUES.

12.1 OneMedicalGroup will strive to identify the underlying causes of patient safety incidents (i.e. systems failures or latent conditions) through investigative processes which support a fair and just approach to patient safety incidents.

12.2 The organisation 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.

12.3 OneMedicalGroup promote 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.

12.4 Where concerns are identified about the performance of staff, the clinical service manager will follow the organisations disciplinary procedures with support from HR team, especially where safeguarding issues are identified. The appropriate professional body (GMC/NMC etc.) may also need to be notified.

13 TRAINING

13.1 All new employees are made aware of the 'Being Open' process and Duty of Candour as part of the OneMedicalGroup induction programme.
Awareness of the being open principles will be promoted to all staff through Team Briefs, Quality Governance structures, clinical meetings and newsletters
Senior clinical staff can access further guidance and complete an e-learning module developed by the NPSA using the following link: http://www.nrls.npsa.nhs.uk/resources/collections/being-

open/

14 RATIFICATION

14.1 This policy is ratified by the Integrated Governance Committee.

15 RELEASE DETAILS

15.1 This policy will be published on the OneMedical intranet within the policies section, a copy will be distributed to all site service leads for dissemination to all staff.

16 REVIEW

16.1 This policy will be reviewed every 2 years, or at any time before this date that a significant change is identified either by regulation or otherwise.

17 PROCESS FOR MONITORING COMPLIANCE

17.1 Clinical Service Managers and Service coordinators will store local SER trackers
These shall be updated with the details and progress of any events, these trackers will be made available to the Head of Patient Safety and Quality and the Governance, Contracting & Compliance Director upon request.

17.2 Service managers will also monitor compliance within their work area, and take appropriate action when infringements of this policy are brought to their attention.

18 REFERENCES

Patient Safety Incident Response Framework 2019/20 preparing for the introduction of a new Patient Safety Incident Response Framework (PSIRF), outlining how providers should respond to patient safety incidents and how and when a patient safety investigation should be conducted. (expected 2021)
https://improvement.nhs.uk/resources/patient-safety-incident-response-framework/

NHS Standard Contract 2014/15: Updated Technical Guidance (Appendix 5: Contractual
requirements relating to Duty of Candour)
http://www.england.nhs.uk/wp-content/uploads/2014/02/tech-guide-240214.pdf

NHS National Patient Safety Agency, Being Open Framework provides guidance on
communicating about patient safety incidents with patients, families and carers
http://www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726

CQC Regulation 20: Duty of Candour; Guidance for NHS Bodies
http://www.cqc.org.uk/sites/default/files/20141120_doc_fppf_final_nhs_provider_guidance_v1-0.pdf

Care Quality Commission (Registration Requirements) Regulations 2009
http://www.legislation.gov.uk/uksi/2009/3112/made

Definitions of levels of harm included in: National Patient Safety Agency, Seven Steps to Patient Safety
http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patientsafety/?
entryid45=59787

NHS Litigation Authority, Saying Sorry
http://www.nhsla.com/claims/Documents/Saying%20Sorry%20-%20Leaflet.pdf

NHS Framework for Serious Incidents 2015
https://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf

Report of the Mid-Staffordshire NHS Foundation Trust Public Enquiry, Robert Francis
QC, February 2013, HHC 947, London: The Stationary Office.
https://www.rcgp.org.uk/policy/rcgp-policy-areas/francis-report.aspx

Technical Guidance to NHS Contract 2013-14, Annex 4, available at:
http://www.england.nhs.uk/wp-content/uploads/2013/02/contract-tech-guide

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**
   The organisation 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 Trust policies, to ensure a robust and consistent approach to patient safety event investigation. Where there are concerns about the practice of individual employee the Trust's Human Resources department must be contacted for advice. Where there is reason to believe an employee has committed a punitive or criminal act, OneMedical Group 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 Independent Safeguarding Authority.

6. **Principle of Risk Management and Systems Improvement**
   Investigations (e.g. 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 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 organisational policies and practice guidance.

8. Principles of Clinical Governance

Being open involves the support of patient safety and quality improvement through the organisations 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 a 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. OneMedical Group 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.

APPENDIX 2

	Requirement under Duty of Candour	**Responsible Person/Department**	**Timeframe**
Stage 1	No or Low harm For incidents where moderate harm, serious	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

	harm or death has occurred, the relevant person must be informed.	Inform the relevant Service Delivery Lead and the Clinical Service Manager for the service. For Never Events a member of the Executive team must be informed immediately and for the most serious incidents, the Clinical Senate will also need to be contacted as quickly as possible to ensure everyone who needs to know is informed.	Immediate notification to the responsible person/team
Stage 2	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 notes.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager and Service delivery lead should be made aware and if appropriate, involved.	As above.
Stage 3	Step-by-step explanation of the known facts must be offered to the relevant person.	Senior clinician for episode of care during which the incident occurred. The Clinical/Operational Manager and Service delivery Lead should be made aware and if appropriate, involved. for Serious Incidents, the Director of Professions and the Governance, Contracting & Compliance Director are to be informed and any other relevant members of the Senior Team. A Lead for the Investigation will be established following agreement with the above parties.	As above
Stage 4	Written notification to the relevant person. The written notification should outline the facts discussed at the notification meeting and	This letter will be signed off by the Director of Professions and Governance, Contracting & Compliance Director.	As above (template letter available for guidance only – all letters must be personalised and tailored to the

	include a sincere expression of regret or sorrow.		individual needs of the person receiving the letter).
Stage 5	Maintain full written documentation of any meetings. If meetings are offered but declined this must be recorded	Lead for the Investigation.	
Stage 6	Share incident investigation report (including action plans) with an accompanying letter.	Once the incident is signed off for closure by the Clinical Senate, a letter will be sent to the relevant person together with the anonymised investigation report and action plan. The supporting letter should provide information in the event that the individual wishes to pursue legal action against OneMedical. This letter will be signed off by the Director of Professions and Governance, Contracting & Compliance Director.	As soon as reasonably practicable but always within 25 working days of report being signed off as complete and incident closed.

APPENDIX 3

Guidance letter template for initial 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

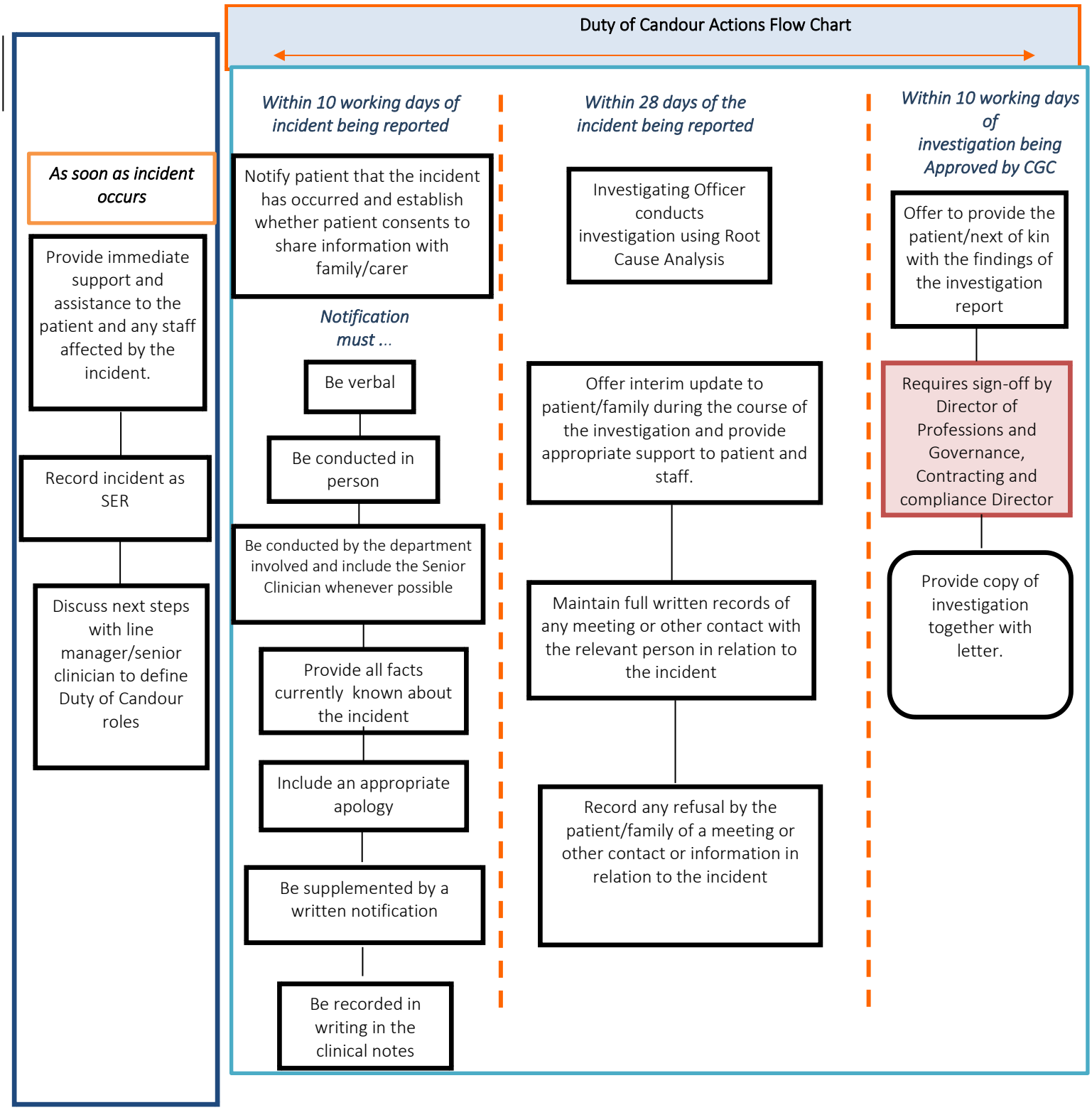
I am writing to express my sincere regret that (you/your relative XXXXX) has been involved in an incident whereby .....(describe event here). As an NHS provider we are committed to being open with patients and carers when events such as these occur so that we gain a shared understanding of what happened,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

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

Yours sincerely

APPENDIX 4


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 as SER
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 using Root Cause Analysis
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 being Approved by CGC
Offer to provide the patient/next of kin with the findings of the investigation report
Requires sign-off by Director of Professions and Governance, Contracting and compliance Director
Provide copy of investigation together with letter.

APPENDIX 5

Incident Investigation Report

Type of Incident:	
Incident Ref No:	
Date Incident Reported:	**Practice**
Registered/Walk in:	**Location:**
Residual Risk Score:	**Date of Report:**
Lead Investigator (Name/Job Title):	

Summary of Incident/

Immediate Actions Taken to Eliminate or Reduce Risk

Discussions with Patient and Relatives, Including Support Provided
.

Problem	
Contributory Factors:	
Problem	
Contributory Factors:	

Problem	
Contributory Factors:	

Good Practice
1.
2.
3.

Root Cause

Recommendations
1.
2.
3.
4.

Lessons Learned
1.
2.
3.
4.

Arrangements for Sharing Learning
Staff meetings/feedback to complainant etc

ACTION PLAN

Issue/Risk Identified	Action Required	Lead	Target Completion Date	Date Action Completed	Required Evidence/Assurance