NHS
Dorset
Clinical Commissioning Group

NHS Dorset Clinical Commissioning Group

Duty of Candour and Being Open Policy



Supporting people in Dorset to lead healthier lives

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PREFACE

This policy sets out the process for ensuring openness and transparency in the management of incidents, complaints, concerns or claims in the organisation.

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V2	April 2015	Updated in line with Serious Incident Framework 2015 and Duty of Candour requirements	Professional Practice Lead
V3	June 2017	Updated to reflect changes in NHS Contract, Regulation 20 of the Care Act and to reduce confusion between contractual and statutory Duty of Candour	Head of Patient Safety and Risk

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Evidence Base References	**Date**
Being Open Framework and Guidance, NHS NPSA NRLS http://www.nrls.npsa.nhs.uk/resources/collections/being-open/?entryid45=83726	2009
Serious Incident Framework, NHS England http://www.england.nhs.uk/wp-content/uploads/2015/04/serious-incidnt-framwrk-upd.pdf	2015
NHS Resolution (formerly NHS Litigation Authority) Purpose and Strategic intentions http://resolution.nhs.uk/	2017

Health and Social Care Act, Regulation 20: Duty of Candour CQC regulation 20: Duty of candour guidance for providers	2014 2015
NHS Standard Contract, Service Conditions (full length) 2016/17 NHS England https://www.england.nhs.uk/wp-content/uploads/2016/04/2-nhs-fll-length-1617-scs-apr16.pdf NHS Standard Contract, Technical Guidance 2016/17. NHS England. https://www.england.nhs.uk/wp-content/uploads/2016/04/2-nhs-contrct-tech-guid-1617.pdf	2016 2016
Seven steps to Safety. Full reference Guide. NHS England. http://www.nrls.npsa.nhs.uk/resources/collections/seven-steps-to-patient-safety/?entryid45=59787	2004

Associated Documents	**Date**
Procedure for the Management of Adverse Incidents	2015
Customer Care and Complaints policy	2016
Freedom to speak up: Raising concerns (Whistleblowing) Policy for the NHS.	2016
Risk Management Framework	2017
Procedure for the Management of Serious incidents	2015

DORSET CLINICAL COMMISSIONING GROUP

DUTY OF CANDOUR AND BEING OPEN POLICY

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Duty of Candour and Being Open

1. INTRODUCTION

1.1 The NHS Constitution was updated in 2013 to include the requirements for NHS organisations under Duty of Candour. The NHS values include respect and dignity and the need to "foster a spirit of candour and a culture of humility, openness and honesty, where staff communicate clearly and openly with patients, relatives and carers". Providers and CCGs are therefore expected to be open with individuals about any mistakes that are made during the course of their treatment or care and should:

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

1.2 It is now widely recognised that the active management of incidents (i.e. adverse events, patient safety incidents and near misses) through the timely and appropriate provision of information to those affected is an essential prerequisite to improving patient safety and the quality of health care systems.

1.3 Communicating honestly and compassionately with service users and their families when things go wrong is a vital component in dealing effectively with errors or mistakes in their care. In Being Open, NHS organisations can mitigate the trauma suffered by those affected and potentially reduce complaints or claims.

1.4 This policy is underpinned by existing Clinical Commissioning Group (CCG) policies and national guidance; The Policy and Procedure for Recording, Reporting and Managing Adverse Incidents, Customer Care and Complaints Policy, Whistleblowing Policy, Risk Management Framework, the NHS England Serious Incident Framework and the NHS Standard Contract.

2. PURPOSE

2.1 To ensure that CCG staff support the implementation of a 'Being Open' policy, it is vital that:

- Patients and their carers can be confident of the openness of the communication following a patient safety incident or complaint, including the provision of accurate information;

- Health care professionals can be assured that their employment or professional futures are not put in jeopardy by following the guidance.

2.2 The introduction of this policy will ensure the CCG's open and honest culture is extended to that of communication with patients and their carers, and communication between all health care professionals and managers within the CCG.

2.3 The policy also outlines the role and responsibility of the CCG in gaining assurance that commissioned providers are fulfilling the legal and professional requirements of the duty of candour.

2.4 Any queries in relation to the application of this policy should be directed to the Patient Safety and Risk Team.

3. DEFINITIONS AND LEGAL REQUIREMENTS

3.1 One of the key principles in the Serious Incident Framework is to be open and transparent. Both Providers and Commissioners have a statutory, contractual and professional responsibility in relation to duty of candour. The Care Act in regulation 20 clearly outlines when the duty of candour should apply and the NHS Standard Contract has been updated in 2016/17 to align with this standard.

3.2 Individual members of staff who are professionally registered are also required to the uphold the duty of candour under the regulations of their professional body (e.g. Nursing and Midwifery Council, General Medical Council, Healthcare Professions Council) and providers should have systems in place to identify and respond when a breach of these regulations is identified.

3.3 A notifiable incident is defined as any unintended or unexpected incident involving a service user during the provision of care has appeared to result in death, severe or moderate harm, or prolonged psychological harm in the service user. The death or level of harm is assessed as that of the reasonable opinion of a healthcare professional and is not attributable to the natural course of an illness or an underlying health condition in the service user. Low and no harm incidents are not notifiable to avoid excessive burdens but these incidents should still be reported to the patient if appropriate.

3.4 The Duty of Candour regulation refers to the open discussion of incidents with service users involved as soon as possible and must include an appropriate apology and information relating to the incident. The needs of those affected in the incident should be at the centre of the initial response and subsequent investigation process. Notification must also be followed up in writing and where it is not possible to contact the relevant individual a written record should be kept of the attempts made.

3.5 The following table outlines the definitions of the level of harm and the level of response required for a notifiable incident.

Grading of harm	Definition of grading	Level of response
No harm: incident	Any patient safety incident that had the potential to cause harm	These incidents are outside of the scope of the duty of

prevented	but was prevented.	candour policy. Healthcare professionals may however feel it is appropriate to inform the person involved if it is considered to be in their best interest.
No harm: incident not prevented	Any patient safety incident that occurred but no harm was caused to the person involved.	
Low harm	Any patient safety incident that led to the extra observation or minor treatment such as first aid or additional medication for the person involved.	These incidents are outside of the scope of the duty of candour policy. Being open in a discussion between staff involved and the service user and their family is usually undertaken locally.
Moderate harm	A level of harm that is not permanent but has led to a moderate increase in treatment or prolonged psychological harm of more than 28 days. For example; a return to theatre, an unplanned readmission to hospital, unexpected admission to critical care, a prolonged hospital stay or additional out patient visits.	Duty of candour is a statutory requirement (Regulation 20). Notification should be given to the person affected or their representative in person including an explanation of the incident, the process for investigation and an apology. This will be followed up in writing and on conclusion of the investigation the findings and outcome will be available to the service user of their representative.
Severe harm	Any patient safety incident that has resulted in permanent harm that is directly related to the incident and not the natural course of an illness or the underlying condition of the person affected. Examples of severe harm are; permanent lessening of bodily functions, sensory, motor, physiological or intellectual function, removal of the wrong organ or limb or brain damage.	Duty of candour is a statutory requirement – see above.
Death	Any patient safety incident that directly resulted in the death of a person and is not related to	

	their illness or underlying condition.	

3.6 It should be noted that an apology is not an admission of liability and should be offered as early as possible following identification of an incident and followed up as required throughout the investigation. The identified most appropriate member of staff should be sincere and give clear information regarding the facts of the incident.

3.7 A glossary of the terms used in this document is attached at Appendix 3.

4. PROCESS

4.1 The CCG would expect every provider organisation to ensure there is a process in place to support duty of candour in patient safety incidents where harm has occurred. This best practice will also be followed by the CCG when leading an investigation.

Identification of Incident

4.2 Notifiable incidents under duty of candour are infrequently attributable to the CCG, examples being a reportable community healthcare associated infection case (Clostridium difficile, MRSA bacteraemia) or information governance breach. The CCG will also co-ordinate the investigation of complex cases where a number of providers may be equally involved on the rare occasion that a lead organisation is not identified.

4.3 The CCG requires providers to report all serious incidents to them as specified in the standard NHS contract. The CCG will report serious incidents to the national Strategic Executive Information System on behalf of non NHS organisations with whom services are commissioned. All other expectations for these providers are in line with the NHS contract including the requirement to be open with those affected and where the duty of candour applies.

4.4 Once identified, a notifiable incident should be acknowledged to the person affected as soon possible. In those cases where the patient or their carer identifies and informs health care staff when something untoward has happened it is essential that they are taken seriously from the outset. Their concerns should be treated with compassion and understanding by all staff.

4.5 Likewise staff raising concerns and reporting incidents are to be treated without prejudice and supported appropriately during the investigation process. This may require reference to the Whistleblowing policy, access to professional advice from the relevant professional body, union, occupational health services or the Employee Assistance Programme. This right to raise a concern in the public interest is described in full in section 21 of the NHS Agenda for Change terms and conditions handbook.

Involving individuals affected by the incident

4.6 The staff involved in communicating with individuals and families should have the necessary skills and knowledge to be able to compassionately provide a full explanation of what went wrong and support the potentially distressed and bereaved through the investigation process. The most appropriate person should be decided on a case by case basis.

4.7 In the case of a Serious Incident investigation, the lead investigator will communicate with the person/s involved to arrange a meeting and agree the terms of reference of the investigation and how the report and findings will be shared at its conclusion.

4.8 All Directors and Managers have a duty to encourage an open culture between organisations, healthcare teams, staff, patients and /or carers.

When things go wrong

4.9 Being open regarding an incident should involve:

- Being told as soon as reasonably practicable by a senior member of staff;
- Acknowledgement of the distress that the incident caused;
- A sincere and compassionate apology;
- A factual explanation of what happened;
- A clear statement of what is going to happen from then onwards.

4.10 There may be specific considerations when being open and there is specific guidance regarding the management of these in the Being Open Guidance in Appendix 2. Those affected by the incident should be signposted to independent advocacy services when required (Dorset Advocacy contact details at Appendix 4).

4.11 Information about any incident must be given to those affected in a truthful and open manner by an appropriately nominated person as soon as is practicable.

4.12 The person/s affected should also be given a single point of contact for any further questions or requests and to keep them updated with the progress of the investigation. It is essential that any information is based solely on the facts known at the time. Opinions as to the cause of incidents should not be given as new information may emerge during the investigation.

4.13 Root Cause Analysis should be used to uncover the underlying causes of a serious incident. Investigations should focus on the needs of those affected and improving systems of care.

Completing the Process

4.14 Communication to the persons affected in the incident; following completion of the investigation, feedback to those involved should take the form most acceptable to them. Whatever method used the communication will include:

- reference to the chronology of clinical and other relevant facts;
- reference to details of any concerns and complaints raised;
- an apology for the harm suffered and any shortcomings in the delivery of services;
- a summary of the factors that contributed to the incident;
- information on what has been and will be done to avoid repetition;
- how these improvements will be monitored.

4.15 It is expected that in most cases there will be complete disclosure of the findings of the investigation and analysis. In some cases, information may be withheld or restricted e.g. where disclosure of information will adversely affect the health of the person; where investigations are pending coroner processes or where specific legal requirements preclude disclosure for specific purposes. In these cases, the person will be informed of the reasons for the restrictions.

5. RESPONSIBILITIES

CCG Governing Body

5.1 The CCG Governing Body is committed to implementing the principles of Being Open and the Duty of Candour. The CCG Accountable Officer is ultimately responsible and serious incidents will be brought to the attention to their attention as appropriate. The CCG Governing Body has a key responsibility for ensuring that the principles of Being Open and the Duty of Candour are embedded at a senior level within the organisation and that strategic priority and scrutiny is maintained at Governing Body level.

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

CCG Staff

5.3 Staff working in the CCG have a responsibility to openly and honestly report incidents according to the organisational adverse incident policy. Registered professionals working in the CCG must also apply the duty of candour according to their relevant professional code.

5.4 In co-ordinating a complex case it is the responsibility of the CCG to identify which organisation will apply the duty of candour at the outset of the investigation within the terms of reference. The CCG will identify which organisation will be the key contact for the individual affected for the duration of the investigation. The named person will then report to the CCG that the duty of candour requirement has been met.

5.5 Notification of an incident within the CCG will usually be reported by the individual responsible for the department.

5.6 When a breach of the contractual requirement for duty of candour is identified the CCG will take appropriate action with the provider as outlined in the NHS contract;

- request a direct written apology and explanation for the breach to the individual(s) affected from the provider's chief executive:
- publication of the fact of a breach prominently on the provider's website;
- notification to CQC by the commissioner.

Providers

5.7 Responsible managers will provide reports to the CCG as part of the contract quality review to give assurance regarding the compliance of the organisation with the legal and professional duty of candour.

Confidentiality

5.8 The principles of confidentiality and information governance should be applied to the being open process to ensure appropriate information sharing whilst protecting personal information.

5.9 Details of any incident are at all times to be considered confidential. Any disclosures beyond those staff involved should be on a strictly need to know basis e.g. as part of an investigation. Only anonymous data about incidents is disseminated beyond the healthcare professionals and investigating team. It is best practice to inform the affected person about who will be involved in the investigation and give them an opportunity to object.

Patient Safety & Risk team

5.10 In all CCG cases the Patient Safety and Risk team should be informed either by telephone, electronically or by completion of the adverse incident form depending on the severity of the incident. The Patient Safety and Risk team, together with the senior manager involved, will agree what the appropriate level of response is required.

5.11 In provider cases the team will monitor duty of candour through the serious incident review process.

5.12 NHS England will also receive anonymous notification of the incident through the National Reporting and Learning System (NRLS), which is managed locally by the Patient Safety and Risk team on notification.

General Practitioner (GP)

5.13 Consideration should be given to contacting the relevant GP at an early stage for those events that have not occurred within primary care, so that they are able to support the investigation process. Whilst it is always desirable for the purposes of continuing care to keep the GP informed, this must only be done with the consent of the person affected.

Unexpected or Untimely Death – The Coroner

5.14 All cases of untimely or unexplained death and suspected unnatural deaths need to be reported to the coroner. A coroner may request that the case not be discussed with other parties until the facts have been considered, however, this should not preclude an apology or expression of regret. In this situation, it should be made clear to the family that a full discussion of the circumstances and any residual concerns will be arranged at a date to suit both parties, after the coroner's assessment is finished.

Notification to Relevant Statutory Bodies

5.15 Health care organisations need to ensure they comply with the national notification requirements e.g. Serious Incident Framework 2015, CQC regulations, Health and Safety Executive under RIDDOR.

5.16 These requirements are monitored by the CCG as part of the contract review process.

6. DOCUMENTATION

General

6.1 The open disclosure of incidents must be properly recorded. Documentation includes a copy of relevant records, incident reports and records of the investigation and analysis process.

Incident Records

6.2 In the adverse incident file, there should be documentation of:

- the time, place, date, as well as the name and relationships of those present at the discussion;
- the plan for providing further information to the persons affected;
- questions posed by those affected and the answers provided;

- plans for follow up as discussed;
- progress notes relating to the investigation and issues explained to individual;
- copies of any statements taken in relation to the incident;
- a copy of the incident report.

6.3 Initially documentation will be held locally and copied to Patient Safety and Risk team.

6.4 At the conclusion of the investigation the documents excluding any copies of medical records will be merged and archived on the incident management database.

7. MONITORING

7.1 The CCG Serious Incident Review Group will monitor the use of being open and the duty of candour by the service providers incidents as reported in the root cause analysis paperwork submitted.

7.2 The Patient Safety and Risk team will review the reports submitted by the providers to gain assurance that in incidents of moderate harm the legal and professional requirements of duty of candour are being met. This will be a narrative report providing updates regarding the organisational policy and procedures in response to a notifiable incident.

7.3 CCG monitors the contractual duty of candour with providers as stated in the NHS standard contract through contract review meetings. Any concerns regarding compliance by providers with duty of candour requirements will be escalated via the contract quality lead to be addressed at the contract meetings.

7.4 The Patient Safety and Risk team will report compliance of both the CCG and providers with duty of candour to the CCG Quality group quarterly.

8. REVIEW

8.1 This policy will be reviewed on a bi-annual basis.

APPENDIX 1

APPENDIX 1 - REGULATION 20: DUTY OF CANDOUR. INFORMATION FOR ALL PROVIDERS: NHS BODIES, ADULT SOCIAL CARE, PRIMARY MEDICAL AND DENTAL CARE AND INDEPENDENT HEALTHCARE. CQC, MARCH 2015:

HTTPS://WWW.CQC.ORG.UK/GUIDANCE-PROVIDERS/REGULATIONS-ENFORCEMENT/REGULATION-20-DUTY-CANDOUR#FULL-REGULATION

APPENDIX 2

APPENDIX 2 - BEING OPEN GUIDANCE CAN BE ACCESSED VIA THE HYPERLINK BELOW:

HTTP://WWW.NRLS.NPSA.NHS.UK/RESOURCES/COLLECTIONS/BEING-OPEN/?ENTRYID45=83726

APPENDIX 3

GLOSSARY OF TERMS USED IN THE POLICY

Adverse incident

Any incident that resulted in unintended or unexpected harm to one or more people due to a system error or failure or a mistake (whether negligent or non-negligent) and whether by the action or omission of a healthcare worker or otherwise.

Anonymous

Information that has had removed as many patient-identifiable features as possible without making the information of no use for its purposes.

Apology

A sincere expression of regret offered for some harm sustained.

Carer/s

Family, friend or those who care for the patient and in relation to whom the patient has consented to their being informed of the patient's confidential information and their being involved in any decisions about the patient's care.

Duty of Candour

This is a legal duty to inform and apologise to patients if there have been mistakes in their care or treatment that have led to significant harm.

Harm

This is defined as 'injury (physical or psychological), suffering, disability or death'.

Health care professional

A doctor, dentist, nurse, pharmacist, optometrist, allied health care professional, or registered alternative health care practitioner.

Liability

Legal responsibility for an action or event.

NRLS - National Reporting and Learning System

The National Reporting and Learning System (NRLS) is a computer-based system designed to allow the collection and analysis of patient safety incident information. It has been developed to allow staff to provide information on adverse events that cause actual or potential harm to patients. An e-Form is the core component of the NRLS and is used to collect the information.

Patient Safety Incident

This is defined as any unintended or unexpected incident which could have or did lead to moderate of severe harm for one or more patients, receiving NHS funded healthcare and triggers the duty of candour. A notifiable death means the death of a patient where death relates to the incident rather than the natural course of the underlying condition.

Risk management

The process by which an organisation's risk (services, corporate and financial) is identified, analysed and managed to reduce to an acceptable minimum the adverse consequences for the organisation.

RCA - Root cause analysis

A systematic process whereby the factors which contributed to an incident are identified.

Other Abbreviations;

CCG – Clinical Commissioning Group

CQC – Care Quality Commission

NHS – National Health Service

RIDDOR – Reporting Injuries Diseases or Dangerous Occurrences Regulations

APPENDIX 4

DORSET ADVOCACY

Patients, their families and carers may need considerable practical and emotional help and support after experiencing a patient safety incident. The most appropriate type of support may vary among different individuals, it is therefore important to discuss their needs. Support may be provided by patients' families, social workers, religious representatives and healthcare organisations such as Independent complaints Advocacy Service (ICAS). Support for those who have no other social support and who lack full capacity is also provided through Independent Mental Capacity Advocacy (IMCAs). Dorset Advocacy is the independent provider for Dorset residents requiring ICAS or IMCAs and can be contacted at

Dorchester Office:
Unit 13-15
Jubilee Court
Paceycombe Way
Poundbury
DT1 3AE

Phone: **01305 251033**
Email:enquiries@dorsetadvocacy.co.uk
Fax: **0843 8492689**

APPENDIX 5

Title of Document: Being open POLICY (Duty of Candour)

Equality Impact Assessment Form

What are the intended outcomes of this work? *Include outline of objectives and function aims* For all staff to be aware of their responsibilities around risk management and for the CCG to have robust governance arrangements for the management of risk
Who will be affected? *e.g. staff, patients, service users etc* Staff, patients and service users

Evidence
What evidence have you considered? See list at front of policy, statutory regulations and best practice guidance.
Disability *Consider and detail (including the source of any evidence) on attitudinal, psychological and social barriers.* **Not relevant**
Sex *Consider and detail (including the source of any evidence) on men and women (potential to link to carers below).* **Not relevant**
Race *Consider and detail (including the source of any evidence) on difference ethnic groups, nationalities, Roma gypsies, Irish travellers, language barriers.* **Not relevant**
Age *Consider and detail (including the source of any evidence) across age ranges on old and younger people. This can include safeguarding, consent and child welfare.* **Not relevant**
Gender reassignment (including transgender) *Consider and detail (including the source of any evidence) on transgender and transsexual people. This can include issues such as privacy of data and harassment.* **Not relevant**
Sexual orientation *Consider and detail (including the source of any evidence) on heterosexual people as well as lesbian, gay and bi-sexual people.*

Not relevant
Religion or belief *Consider and detail (including the source of any evidence) on people with different religions, beliefs or no belief.* **Not relevant**
Pregnancy and maternity *Consider and detail (including the source of any evidence) on working arrangements, part-time working, infant caring responsibilities.* **Not relevant**
Carers *Consider and detail (including the source of any evidence) on part-time working, shift-patterns, general caring responsibilities.* **Not relevant**
Other identified groups *Consider and detail and include the source of any evidence on different socio-economic groups, area inequality, income, resident status (migrants) and other groups experiencing disadvantage and barriers to access.* **Not relevant**

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?* **Not applicable**

Addressing the impact on equalities *Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.* **None**

Name of person who carried out this assessment: **Jaydee Swarbrick, Head of Patient Safety and Risk.**
Date assessment completed: 21/6/17
Name of responsible Director: Director of Quality
Date assessment was signed: 26/6/17