DUTY OF CANDOUR (BEING OPEN) IN THE DEFENCE MEDICAL SERVICES

Introduction

1. The Duty of Candour was enshrined in legislation in November 2014[1] and applies to all health service bodies, including the Defence Medical Services (DMS). Promoting a culture of openness and truthfulness is prerequisite to improving patient safety and delivering high quality healthcare. The Duty of Candour is the statutory requirement of the 'Being Open' process and applies where there is a notifiable safety incident[2]. A notifiable safety incident is defined as any incident, intended or unintended, which leads to death, severe harm, moderate harm or prolonged psychological harm.

Aim

2. The aim of this leaflet is to provide policy direction on the application of the Duty of Candour across the DMS.

Scope

3. The Duty of Candour policy applies in all cases where healthcare is provided by the DMS; it also applies in situations where a patient may yet suffer moderate or severe harm as a result of something going wrong with their care. Disclosure is not required for events that do not fit the definitions provided above. Whilst the policy applies to the organisation that provides care, individual healthcare professionals also have a responsibility as directed by their regulating body[3].

4. This policy applies equally to the firm-base and whilst DMS personnel are deployed on operations. The implementation of Duty of Candour on operations will need to be incorporated into the Med Plan and included in pre-deployment training.

Background

5. The introduction of the 'Being Open' policy is a direct response to the Francis Inquiry[4] report into the Mid Staffordshire NHS Foundation Trust, which recommended that a statutory Duty of Candour be introduced for health and social care providers in order to improve patient safety.

Related policies

6. This policy is to be read in conjunction with JSP 950 Lft 5-1-4 Healthcare Governance and Assurance in the DMS.

Principles of the Duty of Candour

7. The Duty of Candour is based on the 10 principles of 'Being Open'[5]. To meet the requirement of this regulation CQC requires providers of healthcare to:

a. Ensure an open and honest culture across all levels of the organisation.

b. Tell people in a timely manner when a moderate, severe harm and death notifiable safety incident has occurred.

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[1] The Duty of Candour became a statutory duty on 27 Nov 14 as defined in the Health and Social Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.
[2] CQC use the term "notifiable safety incident", whereas the DMS prefers the use of "significant event" (SE) . For the purpose of this policy, the terms can be read as being interchangeable.
[3] The Professional Duty of Candour, Jun 2015. Accessed 28 Jun 16..
[4] Mid Staffordshire NHS Foundation Trust Public Inquiry, chaired by Robert Francis QC. Accessed 28 Jun 16.
[5] Being Open – National patient Safety Agency, Nov 2009, p. 14. Accessed 28 Jun 16.

c. Provide in writing a truthful account of the incident and an explanation about the enquiries and investigations that they will carry out.

d. Offer an apology in writing.

e. Provide reasonable support to the patient following the incident.

Implementing the Duty of Candour

8. Following a notifiable safety incident, the first priority must be prompt and corrective clinical care in order to prevent further harm. Where additional treatment is required, this should be provided when reasonably practicable, after discussion with the patient, having ensured the appropriate consent.

9. The reporting of a notifiable safety incident in the DMS is achieved by using the Automated Significant Event Reporting (ASER) system. In order to meet the Duty of Candour requirements the following actions, which are outlined in more detail at Annex A, need to be undertaken.

a. Acknowledgment of harm.

b. Submission of the significant event report (SER) on ASER.

c. Verbal notification of event and apology to patient.

d. Written notification and apology to patient (Disclosure Letter).

e. The offer of a meeting with the patient to provide a step-by step explanation of the event[6] and explanation of the Duty of Candour process.

f. Investigation of the event, to include root cause analysis.

g. Inform the patient of the investigation outcomes and lessons.

h. Ensure lessons are identified, shared and implemented.

Content of the Disclosure Letter

10. As the Letter of Disclosure is an *expression of regret* for the harm caused, it is written to the patient *prior* to the formal investigation. A suggested template for the Disclosure Letter is at Annex B and should include the following elements:

a. A truthful account of the incident (based on the facts as known).

b. An explanation about the enquiry and investigations to be carried out.

c. Acknowledgement of responsibility (if appropriate).

d. Explicit written apology.

e. An account of actions that will be taken to prevent harm to other patients under similar circumstances.

f. A commitment to provide further information at the conclusion of the investigation.

[6] The explanation is based on the known facts at the time of notification and may change following the investigation.

Principle of Apology

11. The patient should receive a sincere expression of sorrow or regret for the harm that has resulted from the incident; saying sorry is not an admission of liability. Both verbal and written apologies should be given as early as possible. The decision on which staff member should give the apology is based on seniority, relationship to the patient, as well as, experience and expertise in the type of patient SE that has occurred[7]. Although an apology should be given as soon as practicable following the incident, it is essential that the apology is planned and that the appropriate preparation is undertaken.

Special Circumstances

12. The approach to openness may need to be modified for some groups of patients. For further clarification see Annex C.

Continuity of Care

13. Patients are entitled to expect that they will continue to receive all usual treatment and that they will be treated with respect and compassion. If a patient expresses a preference for their healthcare needs to be taken over by another team/clinician, the appropriate arrangements should be made for them to receive treatment elsewhere.

Induction and Training

14. DMS personnel are to be made aware of the local Duty of Candour policy during induction and within the internal training programme, as directed by their CoC. This applies to all healthcare personnel employed in DMS facilities (military and civilian employed by the DMS) and those working at Role 4 (RCDM). Induction training for locum staff must also include information on the local policy.

Record Keeping

15. All communication with the patient (including the verbal apology) is to be recorded in the patient's electronic healthcare record. The Disclosure Letter and final investigation report are to be scanned into the healthcare record once completed.

Governance and Assurance

16. DMS facilities are to maintain a Duty of Candour register as outlined at Annex D. As the Duty of Candour register will contain personal confidential data it must be secured in accordance with the Data Protection Act[8]. The register is to be archived appropriately[9] and destroyed after 10 years.

17. Compliance will be monitored using the DMS Common Assurance Framework (CAF), ensuring that the DMS facility has a local Duty of Candour policy, that staff understand the requirement and that the policy is being effectively implemented and monitored to support improvements.

[7] If the incident involved specialist clinical services, such as Radiology, consideration should be given to include these clinicians or, at least, obtain their direction.
[8] Personal confidential data describes personal information about identified or identifiable individuals, which should be kept private or secret. 'Personal' includes the Data Protection Act 1998 (DPA) definition of personal data, but it is adapted to include dead as well as living people and 'confidential' includes both information 'given in confidence' and 'that which is owed a duty of confidence' and is adapted to include 'sensitive' as defined by the DPA.
[9] Details of the archiving procedure can be found in JSP 950 Leaflet 1-2-11 Defence Healthcare Record.

Annexes:

A. DMS Duty of Candour Actions and Timeframes.
B. Suggested Template for the Disclosure Letter.
C. Special Patient Circumstances when the approach to the Duty of Candour may require modification.
D. Duty of Candour Register Template.

DMS DUTY OF CANDOUR ACTIONS AND TIMEFRAMES

1. Whilst the following steps and timeframes are written in sequential order it should be noted that a number of the actions can be completed simultaneously. The individual responsible for maintaining the unit Duty of Candour register is also responsible for ensuring that the timeframes for reporting and recording are complied with.

Requirement under Duty of Candour	Timeframe	Comment
Step One: Acknowledgement of an incident that has caused moderate, severe harm or death. Submit a SE using the ASER system.	For severe harm and death SEs within 72 hrs; for moderate SEs as soon as practicable.	
Step Two: Notify the individual that the incident has occurred. Notification must- -be given by one or more of the DMS's representatives; -must provide an account, which to the best of DMS's knowledge is true at the date of notification; -advise the individual what further enquiries into the incident the DMS believe are appropriate; -must include an apology; -all of this must be recorded in a written record which is kept securely. This information should also be recorded by way of written record	As soon as is practicable following the incident.	See Appendix 1: Suggested template to record data from initial discussion with patient.
Step Three: Notification of SE and sincere apology must be provided in writing. This is known as the 'Disclosure Letter' and is provided **before** the investigation. It must provide (in writing): A written account, which is true to the best of DMS's knowledge, of all the facts the DMS know about the incident; Details of any enquiries which are to be made by the DMS;	As soon as is practicable following the incident.	See Annex B: Suggested 'Disclosure Letter' template to be used to write to patient formally informing them of the incident and a written apology.

The results of any further inquiries; An apology An offer of a meeting to provide an explanation of the event must be offered. Ascertain if the patient wishes to receive updates related to the event as they are identified or at the conclusion of the investigation. It should be noted that if the patient/relevant person cannot be contacted in person or declines to speak no written notification is required but a written record must be retained of all attempts to contact them/their representatives.		
Step Four: Meet with the patient following receipt of the response from the Disclosure Letter. Provide a step by step explanation of the event. (This should focus on the known events at the time and may only be an initial view pending the investigation). Ensure that the patient is provided with a point of contact in case they have any questions or concerns during the process	As soon as is practicable following the incident.	
Step Five: Complete investigation (to include a Root Cause Analysis (RCA)). Write the investigation report. Maintain full written documentation of all meetings with the patient if undertaken during the investigation period.	As soon as is practicable following the incident.	
Step Six: On conclusion of the investigation write to the patient sharing the results of the investigation findings, actions taken and lessons learned. A copy of the letter should be scanned into the patient's healthcare record.	As soon as is practicable following the incident.	See Annex B: Suggested template to write to the patient with findings of the investigation.
Step Seven: Ensure lessons from the event are shared both locally and across all levels of the organization.	As soon as is practicable following the incident.	

SUGGESTED TEMPLATE FOR INITIAL DISCUSSION WITH PATIENT

Date of Conversation:

Summary of Incident:

Who was present at this meeting/telecon?

Name of Patient:	**DOB:**
Who was informed: Patient/NOK (circle) (If discussing with NOK please ensure you have obtained consent from patient if they have capacity?)	**Service No.**
If NOK please add name/address/contact details:	
Describe a summary of what has been said to the patient or NOK ensuring an **appropriate apology** is offered:	
Does the patient/NOK wish to be informed of the findings as the investigation continues? If the answer is yes do they want to be contacted by telephone or written to?	
Does the patient want a written copy of the investigation once complete?	

Signature: **Print name:**

SUGGESTED TEMPLATE FOR THE LETTER OF DISCLOSURE

Dear *Patient, (carer or family member as appropriate),*

You (or your relative)…….. have/has been involved in a notifiable safety incident (*describe event*).

I wish to express my sincere apology that this event has occurred. The Defence Medical Services (DMS) aim to provide a quality service to *you/your (relatives as appropriate)* and to investigate promptly such adverse events and share findings with those involved. To support anyone involved in an adverse incident, the DMS has a Duty of Candour (Being Open) policy.

We would like to invite you to attend a meeting to enable us to provide you with a step-by-step explanation of the events and circumstances. I would be grateful if you would contact me in order to advise whether you would like to accept this invitation, and if so to arrange a time that would be convenient for you.

If you wish to do so, please feel free to bring along a friend or relative to offer you support during this meeting. Following this initial meeting, an investigation into the matter will be conducted and you will be provided with further information relating to the outcome of the investigation in due course.

I/ Staff member XXXXX is acting as your lead contact for the duration of the process. *I/they* can be contacted on telephone number xxxx xxxxxxx

Yours sincerely

(A copy of this letter is to be scanned into the patient's electronic healthcare record).

SPECIAL PATIENT CIRCUMSTANCES WHEN THE APPROACH TO THE DUTY OF CANDOUR MAY REQUIRE MODIFICATION

1. In some circumstances the approach to the Duty of Candour may need to be modified as outlined below. The following guidance on how to manage different categories of patient circumstances is copied from The National Patient Safety Agency.[1]

Children

2. The legal age of maturity for giving consent to treatment is 16. It is the age at which a young person acquires the full rights to make decisions about their own treatment and their right to confidentiality becomes vested in them rather than their parents or guardians. However, it is still considered good practice to encourage competent children to involve their families in decision-making.

3. The courts have stated that younger children who understand fully what is involved in the proposed procedure can also give consent. This is sometimes known as Gillick competence or the Fraser guidelines. Where a child is judged to have the cognitive ability and the emotional maturity to understand the information provided, he/she should be involved directly in the Duty of Candour process. The opportunity for parents to be involved should still be provided unless the child expresses a wish for them not to be present.

4. Where children are deemed not to have sufficient maturity or ability to understand, consideration needs to be given to whether information is provided to the parents alone or in the presence of the child. In these instances the parents' views on the issue should be sought.

Patients with mental health issues

5. Duty of Candour for relevant persons with mental health issues should follow normal procedures, unless they also have cognitive impairment (see below). The only circumstances in which it is appropriate to withhold patient safety incident information from a mentally ill person is when advised to do so by a consultant psychiatrist who feels it would cause adverse psychological harm. However, such circumstances are rare and a second opinion (by another consultant psychiatrist) would be needed to justify withholding information from the relevant person.

Patients with cognitive impairment

6. Some individuals have conditions that limit their ability to understand what is happening to them. They may have authorised a person to act on their behalf by an enduring power of attorney. In these cases steps must be taken to ensure this extends to decision-making and to the medical care and treatment of the individual. The Duty of Candour discussion would be held with the holder of the power of attorney. Where there is no such person the clinicians may act in the individual's best interest in deciding who the appropriate person is to discuss incident information with, regarding the welfare of the person as a whole and not simply their medical interests. However, where an individual has a cognitive impairment, they should, where possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to assist in the communication process.

[1].Being Open, NPSA, Nov 2009, p29. Accessed 28 Jun 16.

Individuals with learning disabilities

7. Where a relevant person has difficulties in expressing their opinion verbally, an assessment should be made about whether they are also cognitively impaired (see above). If not cognitively impaired they should be supported in the Duty of Candour process by alternative communication methods (i.e. given the opportunity to write questions down). An advocate, agreed on in consultation with the individual should be appointed. Appropriate advocates may include carers, family or friends of the patient. The advocate should assist the patient during the process, focusing on ensuring that the patient's views are considered and discussed.

DUTY OF CANDOUR REGISTER TEMPLATE

Serial	Date of SE	Patient Name	*DOB/ Service No*	Date of Verbal Notification & Apology	Within 5 days? (Y/N)	Date of Letter of Disclosure Sent	Within 10 days? (Y/N)	Date of Investigation Letter/ Report Sent	Within 20 days? (Y/N)	Lessons & Actions Identified
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										