DUTY OF CANDOUR POLICY

Created	**August 2019**
Review Date	**August 2023**
Next Review Due	**August 2024**
Author	**Director of Quality and Governance**
Authorised By	**Chief Executive Officer**
Distribution	**All Staff**
Available to	**All Staff**

Signed……

August 2023

Signature Date …….

Change Control

Document Number	GOV – SVL0057 – Policy
Document	Duty of Candour Policy
Version	5
Owner	Director of Operations
Distribution List	All Staff
Issue Date	August 2019
Next Review Date	August 2024
File Reference	GOV – SVL0057 – Policy
Impact Assessment	Positive Impact
Author	Director of Quality and Governance

Document History

Date	Change	Authorised by
August 2019	Review and amended	LB
06/08/2019	Approved and implemented	SMT
August 2020	Review and amended	LB
August 2021	Reviewed and amended	LB
August 2022	Review and amended	LB
August 2023	Reviewed and amended	LB

Contents **Page**

1. Introduction

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 came into force on 27 November 2014. These introduced new statutory provisions regarding Duty of Candour (Regulation 20).

The regulations make it a statutory requirement that health service providers act in an open and honest way to patients and their families or carers in relation to care and treatment provided, on occasions when avoidable harm has been caused. This formalises the previously unregulated principles of Being Open, set out by the National Patient Safety Agency.

The Duty of Candour Policy is a key tenant of the organisational clinical governance framework within which patient safety events can be communicated between healthcare organisations, healthcare teams, patients, their families, or carers, as per the Duty of Candour provisions set out in the Health and Social Care Act.

Being open about what happened and discussing patient safety events promptly, fully and compassionately with patients and/or their carers can:

- Help patients and/or relatives cope better with the after-effects.
- Undertake a thorough investigation into the patient safety event and provider assurance that lessons learned will help prevent to ensure a similar type of incident does not recur.
- Provide an environment where patients and/or their Carers, healthcare professionals and managers feel supported when things go wrong.

2. Purpose

The purpose of this Policy is to ensure that patients, their families, carers, and staff feel supported when patient safety events occur, or something goes wrong.

This Policy also aims to improve the quality and consistency of communication with patients, their families or carers when patient safety events occur, so that they receive promptly the information they need to enable them to understand what happened; that a meaningful apology is offered; and they are informed of the action the Company will take to try and ensure that a similar type of patient safety event does not recur. It also aims to provide clear information to staff on what they do when they are involved and the support available to them to cope with the consequences of what happened and to communicate with patients, their families, and carers effectively.

3. Objectives

- To reinforce and support the culture of Being Open and Duty of Candour.
- To support staff and give them the confidence to act appropriately.
- To ensure the company and its staff accept professional accountability.
- To empower the Patient Experience Manager to support complainants through the process.
- To improve patient experience and satisfaction.
- To learn when things go wrong.
- To improve staff understanding of incidents from the perspective of the patient, their family, or carers.

4. Scope

This Policy is aimed at all staff.

It will apply to all incidents or complaints in the categories of moderate harm, severe harm, or death.

This Policy should be read in conjunction with the Incident Reporting Policy and Procedure, and Complaints and Compliments Policy and Procedure.

5. Equality and Human Rights Impact Statement

SVL Healthcare Services Limited (SVL) will not tolerate unlawful discrimination on the grounds of the protected characteristics of age, disability, gender reassignment, race, religion/belief, gender, sexual orientation, marriage/civil partnership, pregnancy/maternity. The Company will not tolerate unfair discrimination based on spent criminal convictions, Trade Union membership or non-membership. In addition, the Company will have due regard to advancing equality of opportunity between people from different groups and foster good relations between people from different groups.

6. Definitions

- Patient Safety – is the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum.
- Patient Safety Incident – is an event or circumstances that could have resulted, or did result, in unnecessary harm to a patient.
- Healthcare Associated Harm – is harm arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury.

7. Responsibilities

The role and responsibilities must be read and considered in conjunction with the appropriate policies relating to the Incident Reporting Policy and Procedure, and Complaints and Compliments Policy and Procedure.

7.1 **The Chief Executive** has overall accountability for the development, implementation, and application of a 'Being Open' culture and of the Duty of Candour Policy.

7.2 **The Executive Board** will promote an environment in which all staff, whether directly employed or independent contractors, are encouraged to report patient safety incidents. Staff should feel supported throughout the incident investigation process, as they too may have been traumatised by their involvement. They should not be unfairly exposed to punitive disciplinary action, increased medico-legal risk or any threat to their registration.

7.3 **The Operations Director** is required to ensure this policy and the policies and procedures that support it are developed and reviewed and to ensure complaints are dealt with as per the Company's Complaints and Compliments Policy and Procedure, with risks identified and lessons learnt to be disseminated throughout the organisation.

The Company's response to all patient safety incidents resulting in moderate or severe harm or death must ensure the principles of '**Being Open**' are observed and must ensure that identified changes to minimise risk are implemented and monitored by the Executive Board.

7.4 The **Governance Committee** is responsible for ensuring that effective risk management processes are in place to support the management of incidents and provide accurate information to patients, carers and staff in an open and timely manner.

7.5 **The Director of Quality and Governance** provides clinical oversight and advice as appropriate to any investigative process and offers clarity on clinical issues. The post holder also provides clinical support to staff involved in patient safety incidents.

7.6 **All Staff** are responsible for identifying and reporting patient safety incidents (including those that result in no harm, 'near misses') and for adopting the principles of '**Being Open'** in their communications with patients, carers, relatives, and the public.

7.7 **Investigating Officers** are responsible for ensuring that Duty of Candour is discharged in line with the Policy to the correct individual for the incidents they investigate. They are responsible for ensuring that the patient/family's and/or Carers concerns, and issues are addressed as part of the investigation.

8. Identifying the Need for Duty of Candour

Effective communication between staff who recognise an incident, and their management team is vital to ensure that the Duty of Candour process is implemented from the outset.

As soon as a patient safety event is identified where harm has occurred, the top priority is to ensure appropriate clinical care is given and action taken to prevent further harm. Whenever practicable, appropriate discussion and patient consent should be gained prior to providing any additional treatment that is required.

The following outlines the parameters for implementing Duty of Candour:

8.1 No Harm and Low Harm (including prevented patient safety incidents)

- Patients are not usually contacted or involved in these investigations and those types of incidents are outside the scope of Duty of Candour.
- Individual investigations can decide whether `No Harm/Low Harm` events are discussed with patients and or their Carers, depending on the circumstances.

8.3 Moderate Harm, Severe Harm or Death

- The Operations Director should be notified immediately and be available to provide support and advice during the process as required. The Duty of Candour Policy must be implemented.
- A higher level of response is required in these circumstances.

9. Principles

9.1 Safety incidents can have devastating emotional and physical consequences for patients, their families or carers, and staff. Being open about what happened and discussing safety incidents promptly, fully, and compassionately can help patients, carers and staff to cope better with the effects.

9.2 The principles that we use when communicating with patients, their families and/or carers, and our staff, following a safety incident in which an individual was harmed. The principles involve acknowledging, apologising, and explaining when things go wrong. This also involves conducting a thorough investigation into the incident and reassuring those involved that lessons learned will help prevent the incident recurring. At the same time, we must provide support for those involved to help cope with the physical and psychological consequences of what happened. **Appendix 1** outlines the Company's procedure for ensuring these principles are followed during management of moderate/severe harm and death related patient safety incidents.

9.3 It is important to remember that saying sorry is not an admission of liability and is the right thing to do.

9.4 All patient safety incidents must be acknowledged and reported as soon as they are identified. In cases where the patient, their family and/or carers report

something untoward, it must be taken seriously from the outset and treated with compassion.

9.5 The patient, their Carers, and families must receive clear unambiguous information by an appropriately nominated person as soon as practically possible on patient safety incidents and no more than 5 working days from the incident being identified by the Company. The information must be given in a truthful and open manner and be based purely on the facts known at the time. If new information emerges during an investigation, all concerned including staff, patients and their carers must be kept up to date. A single point of contact within the Company must be provided for any questions or requests and to avoid conflicting information being divulged from different members of the team. In addition, the Company will provide regular reports to Commissioners on all patient safety incidents involving moderate/severe harm or death.

9.7 Patients, their Carers and families will receive a sincere, meaningful apology for the harm that has resulted. Verbal apologies will be offered as soon as possible. Written apologies will be from the Chief Executive or nominated Director clearly stating regret for the suffering and distress resulting from the incident. Delays in offering apologies must be avoided as they are likely to increase the complainant's anxiety and frustration and the likelihood of them seeking medico-legal advice.

9.8 Patients, their Carers and families can reasonably expect to be fully informed of the issues surrounding a patient safety incident, and its consequences. As a minimum, the Company will offer a face-to-face meeting with Company representatives and provide a written response on the findings of their investigations. They should be treated with respect and provided support in a manner appropriate to their needs. Special circumstances should be considered, including the patient requiring additional support, such as an independent advocate. Information about support groups must be provided as soon as possible.

9.9 The Company must create a supportive environment where all staff are encouraged to report patient safety incidents. All staff involved in patient safety incidents involving moderate/severe harm or death will be provided with support by the Operations Director and/or Director of Quality and Governance. In the rare situation where it is believed that a member of staff has committed a punitive or criminal act, the Company will take steps to preserve its position and advise the member of staff at an early stage to enable them to obtain separate legal advice and/or representation. Staff will also be encouraged to seek support from relevant professional bodies.

10. Risk Management and System Improvement

10.1 Root Cause Analysis should be used to uncover underlying causes of patient safety incidents. Investigations should focus on improving systems of care, which will then be reviewed for their effectiveness.

10.2 The principles and Duty of Candour policy will be supported by the Company's patient safety and quality improvement processes through the Governance Committee.

10.3 All details of patient safety incidents will be considered confidential and will be dealt with in line with the Company's Information Governance policies and procedures.

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

11. Communicate after a Harm Event: Specific Patient Considerations

11.1 When a patient dies following an incident, it is crucial that communication is sensitive, empathetic, and open. Consideration must be given to the emotional state of the bereaved relative(s), particularly when sharing information regarding the incident. Relatives must be allowed to decide when the time is right for them to be involved. Relatives should be offered the opportunity to participate in a discussion both before, and/or after, the coroner's inquest. An apology will be issued following the patient's death together with an explanation of the coroner's process and a realistic timeframe of events.

11.2 Patients aged 16 years or over are entitled to consent to their own treatment. In broad terms patients between 16 and 18 years can agree to treatment (if they have capacity) but presently they cannot refuse treatment without support from a parent/guardian. Patients under 18 should be encouraged to involve their parents/guardians in any decision making.

In some circumstances, younger children under the age of 16 years who understand fully what is involved can also give consent **(Gillick competence)**. When this is the case, the patient should be directly involved in the Duty of Candour process. The opportunity for the child's parents/guardians to be involved should also be provided unless the child expresses a wish for them not to be present and they have competence to reach such a conclusion.

In all cases, it needs to be very carefully considered whether the information should just be provided to the guardians/parents alone or in the presence of the child. This will need to take account of the guardians/parents' wishes. In these situations, Operational staff or Managers would be wise to seek guidance from the Medical Director and/or Operations Director when dealing with children.

11.3 It is only appropriate to withhold patient safety incident information from mentally ill patients if it would be detrimental to the psychological wellbeing of the patient. This decision would need to be based upon advice received from the patient's psychiatrist. However, such circumstances are rare, and a second opinion may be needed by an independent consultant psychiatrist to justify withholding information from the patient.

While it is not appropriate to discuss patient safety incident information with a carer or relative without the express permission of the patient, there are situations when this absolute provision may be appropriately waived, where the patient lacks capacity so permitting those responsible to act in the patient's best interests which might involve carers or relatives.

11.4 Patients with cognitive impairment, should wherever possible, be involved directly in communications about what has happened. An advocate with appropriate skills should be available to the patient to assist in the communication process.

Where this is not possible and the patient has authorised a person to act on their behalf by an enduring power of attorney, it needs to be established that this extends to decision making and the medical care and treatment of the patient. In this case the Duty of Candour discussion would be held with the holder of the Power of Attorney.

11.5 If a patient has difficulty expressing their wishes verbally, an assessment should be made to decide if they are also cognitively impaired. Appropriate action and support should be taken to allow the patient to be fully involved with the investigation of any patient safety incident they have been involved.

11.6 Where required, the Company will provide advocacy services for patients. Consideration of cultural requirements will also be taken into account when planning and discussing incidents. Obtaining advice from an advocate before contact with patients and their relatives will be undertaken wherever possible to ensure such discussions are undertaken in the most beneficial way.

11.7 Some patients have communication difficulties such as hearing impairment. Plans for the meeting should fully consider their needs and be discussed prior with the person's support network.

11.8 Sometimes, despite best efforts, the relationship between the patient and/or their carers, and the healthcare professional breaks down. They may not accept the information provided or may not wish to participate in the process. In these situations, the Company will ensure these issues are dealt with as soon as they emerge. The patient will be provided with access to support services using a mutually acceptable mediator to help identify the issues and look for a mutually agreeable solution.

12. Monitoring

12.1 The Operations Director will monitor the implementation of this policy.

12.2 The Director of Quality and Governance is accountable for monitoring and reviewing the effectiveness of this policy.

12.3 Where deficiencies are identified, the Director of Quality and Governance is accountable for:

- Ensuring that such deficiencies are reflected in the Risk Register as appropriate.
- Ensuring that Managers are acting upon recommendations and implementing action plans to rectify the deficiencies.
- Ensuring that the Managers made the recommended changes in practice.
- Signing off the completed action plans for the incident log.

13. Discussion

Specific guidance is available which covers the content of the discussions with those involved, including patients, and includes what should and should not occur as follows:

What should occur:

- A verbal and/or written apology should be offered.
- Provide the known facts to date.
- Offer practical and emotional support.
- Identify the next steps for communication and keeping those involved informed.

What should not occur:

- Attributing blame.
- Speculation.
- Denial of responsibility.
- Giving conflicting information.

14. Preliminary Follow-up

14.1 The preliminary follow up should take place as soon as possible after the investigation is deemed complete with all relevant stakeholders including patients, their family or carers, and staff involved. All queries from stakeholders should be responded to in a timely manner in accordance with the relevant policies and procedures for dealing with incidents and complaints. New information emerging during an investigation or after the initial explanation must be shared with patient/family/carer within **5 working days of inclusion within any report.**

15. Process Completion and Documentation

15.1 The investigation team should ensure the following are carried out prior to the process being complete:

- Repeat the apology already given.
- Provide feedback on the findings of the investigation.
- Outline the measures taken to prevent recurrence and their on-going clinical management (if appropriate).
- Communicate the findings of the investigation to staff to share learning.
- Share the summary, where relevant, with other care providers.
- In addition to the patient safety investigation, all '**Being Open**' communications must be documented via the Incident Report Form or complaint response letter including all discussions with the patient, their carers, and staff.

16 Policy Review

This Policy will be reviewed on a yearly basis or amended in the light of new legislation and/or relevant case law, or changes to associated SVL policies.

17 Source

In compiling this Policy, reference has been made to the following sources: -

17.1 The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014 Duty of Candour (Regulation 20).

Associated Policies and procedures:

- Investigation / Near Miss / Serious Incident Policy
- Whistleblowing Policy
- Safeguarding Policy
- Complaints Policy

APPENDIX 1

PROCEDURE

1. Incident Recognition

1.1 The process begins once an incident or complaint involving **moderate/severe harm** has occurred, or a patient has died as a direct result of an incident. These incidents must be reported to the Operations Director and/or the Chief Executive Officer as a high level or serious incident as soon as possible **and as a minimum within 1 working day**.

1.2 The process should be applied for all patient safety incidents where there has been moderate/severe patient harm or death. This in practice will include serious incidents, high level incidents, formal complaints and claims dealt with by the Company.

1.3 Immediate action must be undertaken as a priority, where appropriate, to prevent further harm. All key stakeholders should be notified as soon as possible.

2. Grading of Patient Safety Incidents to Determine Level of Response

No harm/low harm: -

Patients are not usually contacted or involved in investigations resulting from this type of incident which are normally outside of the Scope of this Policy. However, there may be specific indications or requests from the patient for communication, which should be accommodated and managed at a local level following the principles.

Moderate/severe harm or death: -

The process must be applied. The Operations Director must be notified immediately to provide support and advice during the process if required to staff.

3. Preliminary Discussion

A multi-disciplinary team, including the Medical Director should meet (or if this is not practical have a telephone discussion) as soon as possible to establish:

- Basic clinical and additional facts.
- The most appropriate person to be responsible for communicating with the patient and/or their Carers.
- Who will act as single point of contact for the patient and/or their Carers and how they can be contacted?
- Immediate support requirements for healthcare staff involved, providing counselling and de-briefing sessions regarding the outcome of the investigation.

Appendix A

Equality Impact Assessment

To be completed and attached to any procedural document when submitted to the appropriate committee for consideration and approval.

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favorably than another based on:**		
	Race	No	
	Ethnic origins (including gypsies and travellers)	No	
	Nationality	No	
	Gender	No	
	Culture	No	
	Religion or belief	No	
	Sexual orientation	No	
	Age	No	
	Disability - learning disabilities, physical disability, sensory impairment, and mental health problems	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so, can the impact be avoided?**	N/A	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	N/A	
7.	**Can we reduce the impact by taking different action?**	N/A	

If you have identified a potential discriminatory impact of this procedural document, please refer it to Director of Quality and Governance, together with any suggestions as to the action required to avoid/reduce this impact.

To be completed and attached to any document which guides practice when submitted to the appropriate committee for consideration and approval.

	Title of document being reviewed:	Yes/No/ Unsure	Comments
1.	**Title**		
	Is the title clear and unambiguous?	Yes	
	Is it clear whether the document is a guideline, policy, protocol or standard?	Yes	
2.	**Rationale**		
	Are reasons for development of the document stated?	Yes	
3.	**Development Process**		
	Is the method described in brief?		
	Are people involved in the development identified?	Yes	
	Do you feel a reasonable attempt has been made to ensure relevant expertise has been used?	Yes	
	Is there evidence of consultation with stakeholders and users?	Yes	
4.	**Content**		
	Is the objective of the document clear?	Yes	
	Is the target population clear and unambiguous?	Yes	
	Are the intended outcomes described?	Yes	
	Are the statements clear and unambiguous?	Yes	
5.	**Evidence Base**		
	Is the type of evidence to support the document identified explicitly?	Yes	
	Are key references cited?	Yes	
	Are the references cited in full?	Yes	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	Are supporting documents referenced?	Yes	
6.	**Approval**		
	Does the document identify which committee/group will approve it?	Yes	
	If appropriate have the joint Human Resources/staff side committee (or equivalent) approved the document?	Yes	
7.	**Dissemination and Implementation**		
	Is there an outline/plan to identify how this will be done?	Yes	Email staff
	Does the plan include the necessary training/support to ensure compliance?	Yes	
8.	**Document Control**		
	Does the document identify where it will be held?	Yes	
	Have archiving arrangements for superseded documents been addressed?	Yes	Archived in folder store on server
9.	**Process to Monitor Compliance and Effectiveness**		
	Are there measurable standards or KPIs to support the monitoring of compliance with and effectiveness of the document?	Yes	
	Is there a plan to review or audit compliance with the document?	Yes	Internal auditor
10.	**Review Date**		
	Is the review date identified?	Yes	
	Is the frequency of review identified? If so, is it acceptable?	Yes	
11.	**Overall Responsibility for the Document**		
	Is it clear who will be responsible for co-coordinating the dissemination,	Yes	

	Title of document being reviewed:	Yes/No/ Unsure	Comments
	implementation, and review of the document?		

Individual Approval			
If you are happy to approve this document, please sign and date it and forward to the Chief Executive Officer where it will receive final approval.			
Name	Brian Wren	Date	August 2023
Signature			
SMT Approval			
If the SMT is happy to approve this document, please sign and date it and forward copies to the person with responsibility for disseminating and implementing the document and the person who is responsible for maintaining the organisation's database of approved documents.			
Name	Lee Barham	Date	August 2023
Signature