GIRFT, RCS and BAETS

Best practice for Thyroidectomy Documentation

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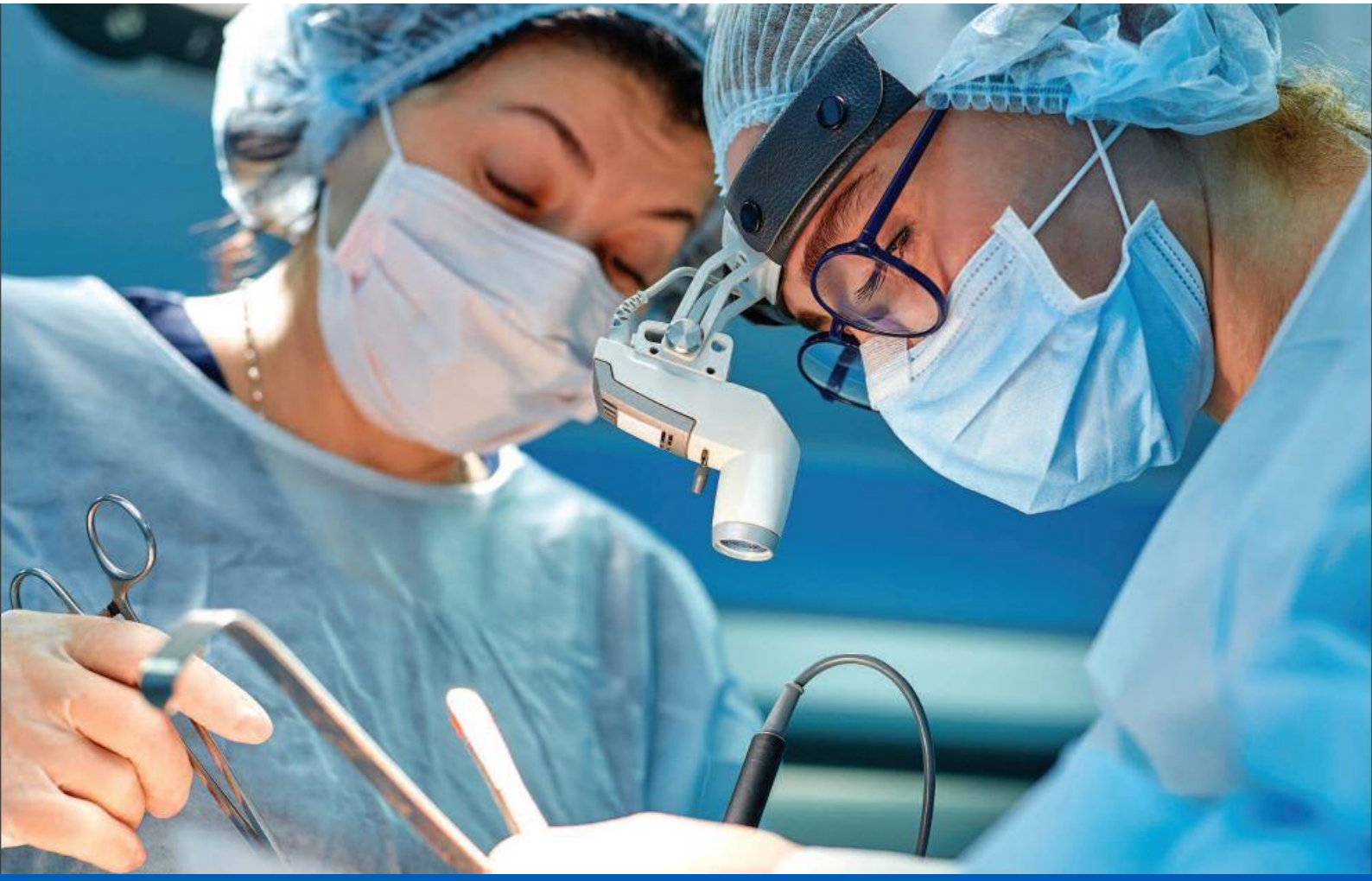

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1. Background and Justification

This guidance has been produced by GIRFT in partnership with the Royal College of Surgeons (RCS) and British Association of Endocrine & Thyroid Surgeons (BAETS). It is aimed to provide advice on various aspects of surgery which should be available and clearly documented in a thyroidectomy operation record. The document is not a comprehensive guide to this surgical procedure, however it is hoped that surgeons will find the advice it offers helpful.

This document was developed from the analysis of existing guidance, medical negligence claims notified to NHS Resolution by NHS trusts, feedback from NHS panel firm lawyers and expert witnesses. It has been established that poor operative documentation has made the investigation of incidents leading to claims difficult and has prevented the defence of good clinical practice. This guidance seeks to provide (non-mandatory) recommendations of what would reasonably be expected to be documented to support both good clinical communication with colleagues and potential review of operations in response to a patient complaint.

It is expected that the standards listed would be included within the documentation of patient care and although the majority will be included in the operation note, the information could be contained elsewhere in the patient record including assessment in A&E, ward round entries, a separate WHO Surgical Safety Checklist and drug charts. It is preferable where possible that the operation record is typed. The documentation where appropriate may be made by other members of the surgical team apart from the operating surgeon. However, it is the operating surgeon’s responsibility to ensure that appropriate documentation has occurred. The operating record should accompany the patient into recovery and to the ward.

The guidance includes case vignettes which provide useful context and should be read in parallel with the recommendations.

2. Recommendations for documentation of practice in all patients undergoing thyroidectomy:

1. The indications for the operation and the evidence both in terms of serological markers, imaging, presenting complaint and clinical examination that has led to the recommendation to perform this operation. If appropriate, record the outcomes of any MDT meetings used to discuss complex cases including the agreed actions.
2. Documentation of the informed consent process including the risks of not operating should be available. The likelihood of a blood transfusion or the need to proceed with any other additional procedures as relevant should be recorded along with the associated risks. It should be clearly documented if the patient does not consent to any of these relevant procedures including transfusion.
3. Safety briefing, sign in, time out, and sign out as part of WHO Surgical Safety Checklist[1]. Presence of required surgical equipment should be confirmed[2].
4. Record names of all surgeons including name/grade of lead surgeon and assistants.
5. Record the date and time of the procedure.
6. Record names and grade of anaesthetist(s) and type(s) of anaesthetic used.
7. If used, record the use of an intraoperative nerve monitoring and whether it is intermittent or continuous. Any additional monitoring beyond recurrent laryngeal nerve monitoring and whether the nerve was stimulated at 1mA/designated current post-procedure e.g., for operations including neck dissection this should be highlighted.
8. Record drugs given pre-operatively and during surgery including the local anaesthetic (+/- adrenaline) drug name, volume and concentrations.
9. Record patient position and skin preparation.
10. Describe or draw the location of the incisions made with reference to anatomical landmarks and previous surgical wounds.
11. Record keys steps of the approach including whether and on which side the strap muscles were divided for access.
12. Documentation of identification and protection of key structures including superior and inferior parathyroids, recurrent laryngeal nerve and external superior laryngeal nerve. Document if additional technology is used to aid parathyroid identification: Fluoptics +/- indocyanine green to assess gland viability. It must be documented if parathyroid transplantation takes place, which gland and at which site did transplantation take place. A suggested table is illustrated below:

	Left			Right		
Structure	**Identified?**	**Preserved?**	**Stimulating at end of procedure?**	**Identified?**	**Preserved?**	**Stimulating end of procedure?**
External laryngeal	Yes/No	Yes/No	Yes/No @ __mA	Yes/No	Yes/No	Yes/No @ __mA
Recurrent laryngeal	Yes/No	Yes/No	Yes/No @ __mA	Yes/No	Yes/No	Yes/No @ __mA
			Site of auto-transplantation			**Site of auto-transplantation**
Superior parathyroid	Yes/No	Yes/No		Yes/No	Yes/No	
Inferior parathyroid	Yes/No	Yes/No		Yes/No	Yes/No	

13. Record the removal of the thyroid, whether any of the thyroid was retained and any intra-operative findings including any abnormal anatomy.
14. Document whether histology specimens were sent including sites and type.
15. Record that haemostasis was achieved before beginning closure. Document if any adjunctive haemostatic agents have been used or systemic agents such as TXA.
16. Record all details of intra-operative concerns or complications e.g., recurrent laryngeal nerve section, parathyroid damage, significant haemorrhage. Include what remedial action was taken where appropriate detailing any additional procedures performed and the rationale for them.
17. Document sequential method of wound closure, whether any drains were used and what dressing was applied.
18. The post-operative monitoring for bleeding, stridor, haematoma +/- drain output should be documented.
19. The post-operative plan for:
    a. Planned post-operative inpatient blood tests e.g., parathyroid hormone (PTH) and calcium levels including exact times should be documented
    b. Medications including antibiotics, analgesia, calcium supplementation, thyroxine dose;
    c. Frequency of clinical observations in the post-operative period;
    d. VTE thromboprophylaxis (including risk assessment and deviations from local protocol) should be documented as appropriate;
    e. When the patient should eat and drink;
    f. Plans for drain removal if used;
    g. Plans for discharge;
    h. Removal of sutures where required; and
    i. Any follow up with a plan to check any relevant pathology results.
20. Operation details should be uploaded to the *United Kingdom Registry of Endocrine and Thyroid Surgery.*

21. Signature of the first surgeon alongside their name and grade to confirm the record is complete and accurate.

3. Duty of Candour

It is important that appropriate duty of candour is exercised informing the patient of any events or perioperative complications which could cause harm or compromise their outcome, at the earliest opportunity following detection and as deemed appropriate by the treating team. This should be carried out in accordance with local policy and should include a clear apology, an offer of an appropriate remedy (if possible) and/or support. The communication should detail the short and long-term effects of what has happened to the patient.[3]

4. Case Vignettes

Case vignette 1

Alleged Nerve Injury

A patient underwent laryngectomy and left hemi-thyroidectomy due to a laryngeal tumour. Whilst the operation was a success, the patient unfortunately suffered a hypoglossal nerve injury, which affected speech and ability to swallow. Detailed operative records showed no evidence of negligence and the claim, subsequently brought for clinical negligence, was successfully defended at trial.

Message

Sometimes events occur which are not expected, are rare and cannot be explained. Depending upon the circumstances of the case, wholly unexpected events are not negligent. Whilst this case was, rightly, defended with the benefit of impressive witness evidence, this would have not been possible without the detailed operative notes that clearly identified the key structures that had been appropriately protected.

After the case was closed, clinical staff took time to reflect on what else could be done in future to reduce variation and guarantee high standards of documentation for all such surgery so that similar legal cases could be avoided or defended effectively. Having clear criteria about what should be recorded (e.g., as set out in this guide) is a key part of delivering this high standard.

Case vignette 2

Inadequate Incision

The case concerned a thyroidectomy and left neck dissection. The expert evidence from an ENT surgeon was highly critical, highlighting that the incision was totally inadequate to gain the requisite access. The claimant alleges that he sustained injury to his phrenic and accessory nerves, brachial plexus and stenosis of the subclavian artery. Furthermore, there was a sub-standard operation note. The expert said:

1. It should have contained the indication for surgery and should have had the findings clearly outlined and described.
2. Details of the procedure should then have followed in a series of steps discussing type of incision and its extent/the areas within the neck that were accessed and how all the relevant structures to be preserved were identified.
3. There should then have been a list or a diagram of the surgical specimens.
4. In the neck it is possible to identify and confirm ongoing function of significant nerves using a nerve monitor, and this should have been carried out and the results recorded.

Following a conference with experts and the treating surgeons, the critical expert backed down and agreed that the incision may have been reasonable given the experience of the operating surgeons, and the only known injury (damaged subclavian artery) could have been caused by non-negligent means. The case is still active, but it is hoped that the claimant will drop the claim against the Trust when the co-defendant GP serves their defence which is expected to contain admissions.

No damages paid yet as the case is still active. We do not expect damages to be excessive in this case as in the case conference it has been accepted that the incision might be satisfactory for an experienced surgeon. However, the subclavian artery remains definitely injured and so there will be damages and costs due.

Message

Clear documentation of a procedure including how relevant structures were protected is essential to defend good clinical practice. Evidence of discussion of the duty of candour with the patient regarding the injury that occurred or perceived injuries would have been helpful and may have prevented the claim.

Case vignette 3

Bruising of parathyroid glands during total thyroidectomy and failure to treat low parathyroid hormone post-operatively.

A patient was referred to hospital for investigation of a lump in her throat with a family history of thyroid cancer. Test results showed a benign cyst. A CT scan showed some early narrowing of the trachea on the left and the left thyroid lobe appeared larger. The possibility of surgery (left hemi-thyroidectomy or total thyroidectomy) was discussed and the claimant elected to proceed with a total thyroidectomy. The consent form stated that the intended benefits were to relieve compressive symptoms and the risks were noted as scarring, bleeding, infection, hypocalcaemia, the need for hormone supplements, hoarse voice, loss of voice, airway compromise, tracheostomy. A total thyroidectomy was performed.

Allegations were raised that there was a failure to obtain informed consent, that a partial thyroidectomy should have been performed and that there was a failure to monitor hypoparathyroidism post-operatively. The patient claimed that had she been consented properly she would have opted for a partial thyroidectomy and if her condition had been monitored appropriately, she would have avoided severe hypocalcaemia and tetanic muscular spasms.

Damages were agreed in the sum of £25,000 and the claimant's legal costs were settled at £50,000.

Message

Permanent hypoparathyroidism is a recognised risk although there was no definite evidence that the patient had permanent hypoparathyroidism. However, areas of vulnerability identified for the trust were in relation to bruising of the parathyroid glands during the thyroidectomy, and that the low parathyroid hormone was not treated promptly post-operatively with calcium supplementation and repeat monitoring prior to any discharge. It was recognised that this failure caused issues with breathing and carpopedal spasm. The case highlights the importance of documented inpatient PTH and calcium levels before discharge.

5. Acknowledgements and References

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[1] WHO Surgical safety checklist, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/
[2] National safety standards for invasive procedures, https://improvement.nhs.uk/resources/national-safety-standards-invasive-procedures/
[3] Openness and honesty when things go wrong: the professional duty of candour, https://www.gmc-uk.org/-/media/documents/DoC_guidance_englsih.pdf_61618688.pdf