Review of Patient Safety Concerns within HPB Services delivered at Aberdeen Royal Infirmary

Introduction

This review was commissioned by Mr Paul Bachoo Medical Director Acute Sector NHSG, NHSG Lead for Cancer services, Portfolio Lead for Integrated Specialist Care and NHSG Lead Realistic Medicine on behalf of NHS Grampian. The review focused on 45 separate patients whose care had been raised by two separate whistleblowers as being cause for potential concern to NHS Grampian.

Review team

The review was conducted by Professor Stephen Wigmore, Regius Chair of Clinical Surgery, University of Edinburgh and Professor Giles Toogood, Professor of HPB Surgery Leeds University. A third panel member Helen Morement, Chief Executive Officer of AMMF Cholangiocarcinoma charity was available, remotely to provide advice on patient advocacy and communication issues should these have arisen. In the event no such issues were identified and Mrs Morement was not consulted. Professors Wigmore and Toogood were issued with honorary contracts by NHS Grampian to enable them to conduct the review and were granted secure access to printed and electronic patient records.

Methodology

The review was conducted over two days in NHS Grampian facilities using secure access to the electronic patient records and paper case notes of the identified patients. Terms of reference were agreed before the review commenced and are appended (Appendix 1).
Cases were reviewed and a brief chronology agreed. Particular attention was paid to planning and preoperative investigations, perioperative care, quality of surgery, post operative complications and their management and long term care.

In all cases it was documented whether the patient experienced an adverse event or not. For the purpose of this review we used the following definitions.

- **Adverse event** is a harmful and negative outcome that happens when a patient has been provided with medical care

- **Serious Adverse Events (SAEs)** are defined as any untoward medical occurrence(s) that results in death, hospitalisation or prolongation of existing hospitalisation, persistent or significant disability/incapacity

In cases where death occurred it was documented whether death was directly related to surgery and whether death was considered avoidable using the Structured Judgement Review Method index of the avoidability of death (Appendix 2, page 9)

Each case was discussed individually and an agreed position was taken on the chronology, complication, avoidability of death and root causes.

Once all of the cases had been reviewed they were grouped into broad categories encompassing liver and pancreas surgery and an analysis of themes was conducted.

The reviewers were conscious that the cases reviewed had been those raised as potentially representing concern by whistleblowers and did not necessarily represent all of the patients who had presented to the hepatopancreatobiliary service and also did not represent all patients who had undergone liver or pancreas surgery between 2015 and 2021. This limitation should be considered by NHS Grampian in interpreting the recommendations of this review.
Further information on the overall activity and mortality of liver and pancreas surgery was obtained from presentations to the Scottish HPB Cancer Network.

Review outcomes

The review included 45 cases which represented 28 men and 17 women treated by the NHSG HPB team between 2015 and 2021. The ages of the patients ranged between 39 years and 88 years.

Of the 45 cases reviewed 31 patients have died and 14 remain alive. The review identified 19 cases where there was a serious adverse event and a further 12 cases where there was an adverse event. No adverse event was identified in 14 cases.

Of the 45 cases 31 patients have died. Nineteen of these patients were considered to have died of avoidable consequences of surgery or intervention. In 13 cases death was either unrelated to surgery or intervention or was considered to have been unavoidable. Examples of deaths that occurred related to surgery but were considered unavoidable were an individual who died of a massive pulmonary embolism in spite of all appropriate venous thomboprohylaxis measures having been employed and a different patient who suffered a fatal cerebrovascular accident in the early postoperative period following appropriate and uncomplicated surgery.

The avoidability of death was rated as described in the methods and is illustrated below. Each icon represents an individual patient.



Thematic analysis

Following individual case reviews and identification of root causes considered to have led to injury or death a thematic analysis was conducted and the results are separated into those relating to liver and pancreas surgery as shown below.

Liver Surgery

Assessment & planning

- MDT seemed reasonably well organized and provide a documentary trail of decision making
- Decision making was overly aggressive on occasions and did not appear to take the context of the patient, their comorbidity and their disease into account
- There were cases where there was clear radiological suspicion of advanced or inoperable disease that still proceeded to surgery and resulted in complications or death
- Insufficient use of CT Liver volume estimation and portal vein /hepatic vein embolization
- Overall the approach to surgery appeared rushed and patients were not adequately optimized before surgery
- There was a poor appreciation of the factors that might contribute to poor preoperative liver capacity for example age, steatosis, recent chemotherapy, alcohol use, obstructive jaundice

Anaesthetics and perioperative care

- There were occasions where major resections were overseen by non-specialist HPB anaesthetists
- Central venous pressure monitoring was not recorded frequently on anaesthetic charts and sometimes when it was recorded appeared to be excessively high. This may reflect inexperience or lack of specialist knowledge
- It is also noted that in many cases large volumes of crystalloid were given during surgery

Surgical Technique

- There are cases where there was inadequacy of surgical technique in terms of oncological principles and cancer clearance
- A recurrent theme through the cases especially those that resulted in death was high intraoperative blood loss.
- Use of haemorrhage limiting manouevres such as the Pringle Manouevre are rarely mentioned in operation notes
- There appeared to be an inappropriately high tolerance of blood loss before assistance was sought

Follow up

- No deficiency was identified in post operative follow up.

Pancreas Surgery

Assessment and planning

- There was a recurrent theme that patients were rushed to operation without adequate planning and optimization
- Failure to use biliary decompression as a risk mitigating strategy particularly in older patients
- Proceeding to surgery in patients recognized to have locally advanced disease
- Failure to use Neoadjuvant chemotherapy in patients with suspected locally advanced disease
- Failure to plan timely availability of appropriately trained individuals in cases likely to require vascular resection and reconstruction
- Acceptance of inadequate vascular reconstruction

Anaesthetics and perioperative care

- No specific deficiencies identified

Surgical Technique

- Recurrent theme of high blood loss in pancreas resectional surgery
- Suboptimal vascular resection and reconstruction with long ischemic periods and inadequate post operative flow
- Attempted vascular resections led to catastrophic situations which were difficult to rescue and led to ischemic bowel or liver failure
- No evidence of anticipation of vascular problems. Vascular expertise was only called on to attempt to rescue situations after the event, even though there was a clear likelihood of vascular compromise on preoperative imaging.

Management of complications

- Slow to identify serious complications particularly leaks from the pancreaticojejunal anastomosis which compromised patient care
- Failure to rescue through inappropriate or conservative approaches to management
- No mesenteric angiogram in patient likely to be bleeding post pancreatic resection- unclear whether this was through choice or availability

Follow up

- No deficiencies in follow up were identified

General themes

Lack of senior leadership
No clear department standards for preoperative planning
Poor decision making and aggressive strategies adopted in spite of high predicted morbidity and mortality
Preoperative anaesthetic assessment and input into the decision making around surgery at the MDT for multiple comorbid patients was inadequate or unclear.
Blood losses for resectional cases is unacceptably high throughout the period requested for review (2015-2021) for both liver and pancreas surgery.
The same mistakes around decision making, lack of planning, and technical issues with surgery were made repeatedly suggesting a lack of team learning from prior adverse events
Adequacy of interventional radiology support for preoperative preparation and management of postoperative complications- a 24 hour 365 day service should be available

Mortality rates for Liver and Pancreas surgery NHS Grampian

We have analysed available data for 2017 to 2020 for mortality associated with liver and pancreas surgery in NHS Grampian. This does not cover the entire window of cases that the review was asked to review (2015-2021) but gives indicative results of outcomes over 4 years of the 6 year period encompassed by the review.

Mortality for Liver surgery for NHS Grampian between 2017 and 2020 was very high with overall mortality for major liver resections of 12% at 30 days and 18 % at 90 days. For comparison the 30 day mortality for patients undergoing major liver resection in a cohort of 8,500 patients varied from 0.5% in non-frail patients to 2.2% in very frail patients.

Mortality for major and minor liver resections NHSG 2017-2020

	2020		2019		2018		2017		4yr (%)	
	30d	90d	30d	90d	30d	90d	30d	90d	30d	90d
Major (3+)	0/1	0/1	0/7	1/7	1/1	1/1	1/8	1/8	2/17(12)	3/17 (18)
Minor	0/17	0/17	0/27	0/27	0/13	0/13	1/17	1/17	1/ 74 (1)	1/ 74 (1)
ALPPS	-	-	0/1	0/1	-	-	0/1	0/1	0/2	0/2
Total	0/18	0/18	0/35	1/35	1/14	1/14	2/26	2/26	3/ 93(3)	4/93 (4)

Mortality for Pancreas surgery for NHS Grampian between 2017 and 2020 was very high with overall mortality for pancreatic head resection (Whipples) of 15% at 30 days and 17% at 90 days. For comparison the 30 day mortality for pancreatic head resection in the ABACUS study of almost 15,000 similar resections was 2.7% (Gleeson et al 2016)). In a larger study of 20,000 pancreas head resections the 30 day mortality was 3.7% and the 90 day mortality was 7.4% (Swanson et al 2014). The Scottish HPB Cancer network expects the upper limit of mortality for centres undertaking pancreas resection to be 5%.

Mortality for pancreas resections NHSG 2017-2020

	2020		2019		2018		2017		4yr (%)	
	30d	90d	30d	90d	30d	90d	30d	90d	30d	90d
Whipples	2/3	2/3	2/15	2/15	2/15	3/15	1/14	1/14	7/ 47(15)	8/47 (17)
Total	-	-	0/1	0/1	0/2	0/2	0/1	0/1	0/4 (0)	0/4(0)
Distal/ Other	1/7	1/7	0/11	1/11	0/5	0/5	0/9	0/9	1/32 (3)	2/32(6)
All Pancreas	*3/10*	*3/10*	*2/27*	*3/27*	*2/22*	*2/22*	*1/24*	*1/24*	*8/ 83(10)*	*10/83(12)*
Duodenal/ Biliary	0/2	0/2	1/10	1/10	1/5	1/5	0/4	0/4	2/21 (9)	2/21 (9)
Total	3/12	3/12	3/37	4/37	3/27	4/27	1/28	1/28	10/104(10)	12/104(12)

We have not specifically looked for nor identified any patterns of outcome related to individual consultant surgeons within the HPB team.

Recommendations

The review considered that the mortality for major liver surgery and pancreas resections was extremely high and that many of the deaths that were reviewed were avoidable. This review has not reviewed every major resection case undertaken by NHSG HPB team during the period rather a selection of 45 cases raised by whistleblowers. It is possible that the cases reviewed may therefore include a selection bias. The data on overall mortality for liver and pancreas surgery are however based on validated NHSG data of all activity during the cited periods and as such are a more useful metric to gauge the overall performance of the service. It is in this context that the following recommendations are made

Liver surgery recommendations

- Primary hepatocellular carcinoma- all patients should be referred to Edinburgh HPB/ Scottish Liver Transplant unit team in line with current and nationally agreed guidelines
- Cholangiocarcinoma hilar and perihilar cholangiocarcinoma- should be referred to Edinburgh HPB team in line with current and nationally agreed guidelines
- All patients who are considered to need major resections (3 or more segments) should undergo assessment of future liver remnant quality and volume
- Portal vein embolization or liver venous deprivation should be considered in any patient who has impaired liver remnant quality or volume and is planned to undergo major resection (3 or more segments).
- Measures should be put in place to minimize bleeding during surgery including further training if necessary
- Colorectal liver metastases- any patient requiring major liver resection of 3 or more segments should be transferred to a more experienced HPB unit

Pancreas Surgery recommendations

- Endoscopic UltraSound should be routinely used in potential pancreas resection candidates to ascertain positive tissue diagnosis and evaluate vascular invasion
- Patients who have very high bilirubin and are elderly or have other comorbidity should be considered for preoperative endoscopic or percutaneous biliary stenting before resectional surgery
- Any patient with tumour encroaching on superior mesenteric artery or vein or portal vein should be considered for neoadjuvant chemotherapy
- Any patient with preoperative evidence of nodal disease should also be considered for neoadjuvant chemotherapy
- Any patient in these categories who receives neoadjuvant chemotherapy or who is considered at risk of requiring vascular resection should be transferred to a unit experienced in vascular resection and reconstruction

Conclusion

This review has identified that a significant proportion of cases, which were raised by two whistleblowers as potentially showing evidence concern for quality of care, did indeed raise serious concerns for patient safety and that a number patients came to harm and died in circumstances that were avoidable as a consequence of HPB Surgery. The mortality rates for major liver surgery and head of pancreas resections in NHS Grampian lie far outside the accepted rates published in contemporary literature and which are experienced by patients receiving surgery in other Scottish and UK HPB centres. The review has identified recurring problems with lack of leadership, poor decision-making, poor preoperative planning and patient optimization and inadequate surgical technique. Consideration must be made by the board to urgently introduce

whatever measures are necessary to improve outcomes for patients served by NHS Grampian who require HPB Surgery.

References

Leigh N, Williams GA, Strasberg SM, Fields RC, Hawkins WG, Hammill CW, Sanford DE. Increased Morbidity and Mortality After Hepatectomy for Colorectal Liver Metastases in Frail Patients is Largely Driven by Worse Outcomes After Minor Hepatectomy: It's Not "Just a Wedge". Ann Surg Oncol. 2022 Sep;29(9):5476-5485. doi: 10.1245/s10434-022-11830-8. Epub 2022 May 20. PMID: 35595939.

Gleeson EM, Shaikh MF, Shewokis PA, Clarke JR, Meyers WC, Pitt HA, Bowne WB. WHipple-ABACUS, a simple, validated risk score for 30-day mortality after pancreaticoduodenectomy developed using the ACS-NSQIP database. Surgery. 2016 Nov;160(5):1279-1287. doi: 10.1016/j.surg.2016.06.040. Epub 2016 Aug 17. PMID: 27544541.

Swanson RS, Pezzi CM, Mallin K, Loomis AM, Winchester DP. The 90-day mortality after pancreatectomy for cancer is double the 30-day mortality: more than 20,000 resections from the national cancer data base. Ann Surg Oncol. 2014 Dec;21(13):4059-67. doi: 10.1245/s10434-014-4036-4. Epub 2014 Sep 5. PMID: 25190121.

Appendix 1

Terms of Reference
Review of Patient Safety Concerns
Within HPB Services delivered at Aberdeen Royal Infirmary

NHS Grampian seeks to commission a review of cases following concerns raised by 2 separate Whistle Blowers regarding patients treated within the HPB service in NHSG.

The concerns raised suggest that a poor level of patient care has caused harm and resulted in serious adverse incidents. As an initial response NHS Grampian requested an independent expert clinical opinion on a small number of randomly selected cases. This initial screening recommended a more detailed case note review be performed. For this purpose, a timely and independent review of the index cases only is being commissioned to investigate the claim.

The Review Panel is asked to establish whether there is any validity to the concern raised by the Whistle Blowers.

Commission:
This independent review is being requested on behalf of NHS Grampian (NHSG) by:
Mr Paul Bachoo, Medical Director, Acute Services, NHS Grampian

Scope:
All phases of the pathway from referral to treatment to include-

- Initial clinical assessment;
- Use of diagnostic services;
- Interpretation of information and data acquired during assessment;
- Communication and sharing of the information to:
    - Patient;
    - HPB multidisciplinary team;
    - The wider clinical term;
- Quality of the MDT process;
- Outcome of the MDT and its influence on the clinical pathway;
- Consent and consistency with prior decision making at MDT;
- Admission and initial care;
- Care during a procedure;
- Perioperative/procedure care;
- Postoperative care;
- End-of-life care (or discharge care).
- Any internal adverse event review, complaint or M and M discussion

The review team:

The review team will be comprised of 2 clinicians (SJW &GJT) and 1 lay person (HM)

Professor Stephen J Wigmore
Regius Chair of Clinical Surgery
University of Edinburgh

Professor Giles J Toogood
Professor of Hepatobiliary and Emergency General Surgery
University of Leeds

Helen Morement – CEO
AMMF – The Cholangiocarcinoma Charity

All reviewers are intimately knowledgeable of the NHS, the Specialty, Pathways and Outcomes from a range of clinical-quality and patient perspectives. The clinical experts have posts in NHS Scotland & England and remain on their relevant professional registers.

The Lead for the review will be SJW.

Clinical Governance:

This review will centre on the clinical decision making, involvement of the multidisciplinary team (MDT), adherence to MDT, clinical / specialty guidelines, clinical outcomes, quality of the governance process in place, quality of clinical incident investigations and subsequent learning.

An incident will be any unintended or unexpected event which lead to harm for a patient receiving healthcare.

A serious incident (SI) will be an act or omission in care that results in unexpected or avoidable death or serious harm.

Where a SI did occur the review team are asked to consider

- If a root cause analysis approached was used
- Whether it was performed in a clear transparent and robust manner
- Whether the output:
    - Was shared within the management structure
    - Was shared outside the team / service / management structure
    - Involved family

- Was linked to learning, reflective practise and service improvement through a thematic approach

The review team are not requested to conduct any form of interview.

Output:

With reference to the identified cases the review team are asked to form an overall judgement as to whether

- The service met the standards that would be reasonably expected
- Patients experienced a level of care that fell below the standard expected
- If the acts or omissions directly result in unexpected or avoidable death.
- The review panel are also being asked to consider if there is evidence to suggest underlying systemic failings.

A structured process to case review will be deployed to ensure consistency and thematic analysis.

The review panel are also asked to consider:

1. If there are lessons to be learned for the service or for NHS Grampian
2. If there are areas to be considered in the future model of this service
3. Instances in which duty of candour should be activated

The review team are asked to refer to the full list of patients which will be shared separately.

The Structured Judgement Review (SJR) tool is attached and request that it be considered during your process.



Paul Bachoo
Medical Director Acute Services
NHS Grampian