WHO Surgical Safety Checklist (Follow Up)

Draft Internal Audit Report

2020/21

Swansea Bay University Health Board

NHS Wales Shared Services Partnership

Audit and Assurance Services

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Executive sign off:	Richard Evans, Executive Medical Director
Distribution:	Aidan Byrne, Assistant Medical Director
Committee:	Audit Committee, Quality & Safety Committee

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ACKNOWLEDGEMENTS

NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

1 EXECUTIVE SUMMARY

1.1 Introduction and Background

To assist operating teams in reducing the number of adverse events, the World Health Organisation (WHO) identified a set of safety checks that could be performed in any operating room. The aim of the Surgical Safety Checklist is to reinforce accepted safety practices and foster better communication and teamwork between clinical disciplines. By following a few critical steps, health care professionals can minimise the most common and avoidable risks endangering the lives and well-being of surgical patients.

Our review of arrangements in place to ensure the effective adoption of the checklist and associated processes in 2019/20 derived a 'limited' assurance rating. Action was agreed by management to address issues raised, for implementation by November 2019.

At the point of planning for this follow up review (the start of November 2020), the status of actions recorded by management in the online tracker indicated that three medium priority recommendations have not been implemented. Two high priority, three medium priority and one low priority recommendation were recorded as complete. We therefore looked to seek evidence of implementation of these six recommendations in order to provide assurance on the progression made.

1.2 Scope and Objectives

The purpose of the 2020/21 follow up review is to confirm that the health board has implemented those recommendations made in our 2019/20 review and recorded as complete. It does not provide assurance against the full review scope and objectives of the original audit.

The 'follow up review opinion' provides an assurance level against the implementation of the actions marked by management as complete in the agreed action plan only. The recommendations made in the previous audit and an update on their status, together with any further recommendations, are set out in Appendix A. Those which were not marked as complete when we commenced our work are included at Appendix B.

Recognising other pressures on service group staff, most audit enquiries were directed towards health board staff via the Assistant Medical Director. We are grateful to his assistance with coordinating this.

1.3 Associated Risks

The overall risk considered in this follow up review is failure to implement agreed audit recommendations and therefore, continued risk that:

- Appropriate guidance may not be available for staff who are required to complete the WHO checklist;
- The checklist may not be completed for every patient undergoing a surgical procedure where required;
- Completed checklists may not be signed off by appropriate staff; and
- Non-compliance with the use of the checklist may not be identified and addressed.

2 CONCLUSION

2.1 Overall Assurance Opinion

This review has considered recommendations made previously. The report does not provide assurance against the full scope and objectives of the original audit. The 'follow-up review opinion' provides the assurance level against the implementation of the agreed action plan only, and only those actions confirmed by management as complete.

Considering the progress made against the action plan the follow-up review opinion is **Limited Assurance**.

RATING	INDICATOR	DEFINITION
Limited assurance	 - + Amber	**Follow up -** No high level recommendations implemented but progress on a majority of the medium and low recommendations.

3 FINDINGS & RECOMMENDATIONS

3.1 Summary of Audit Findings

Summary of previously agreed actions by implementation status:

Area		Priority 2019/20 audit	Direction of travel	Priority 2020/21 audit
2	WHO Checklist Exceptions	Medium	Recommendation Implemented	Closed
3	Clinical Scrutiny of Data Analysis	Medium	Remains outstanding	Medium
5a	Standardised Audit Approach	Low	Some progress made. Further work is required to reduce the risk	Low
5b	NPTH WHO Checklist Audits	Medium	Recommendation Implemented	Closed
6	Data Analysis & Observational Audit Reporting	High	Some progress made. Further work is required to reduce the risk	High
7	Corporate assurance reporting	High	Some progress made. Further work is required to reduce the risk.	High

Actions Implemented in Full	Actions Implemented in Part	Actions Not Implemented
2	3	1

The majority of actions agreed following the last audit indicated that the Executive Medical Director would write to units to address issues raised or request further data where required. We can confirm that these were communicated by letter and/or email, but while this was considered by management as complete in this respect our review of whether the actions required in correspondence were complete found that there was more to be done in most cases. We note the

beginnings of actions in some cases and recognise that the full implementation of some will have been impacted by the onset of the COVID-19 pandemic. The Theatre Performance Update Report to Performance & Finance Committee in September 2020 indicated that there was a significant reduction in theatre activity during the time of the first peak to ensure critical care nursing capacity was sufficient to meet anticipated pandemic demands – this is particularly noticeable in respect of elective activity. While this is the case, theatres have continued to deal with urgent requirements.

The key areas remaining to be addressed fully are:

- A review of Unit / Service Group Quality & Safety Groups identified that TOMS (Theatres Operating Management System) data for WHO Compliance and assurance from audit outcomes was not being received across all (though we noted reporting of audits at the quality & safety group in NPT before the onset of the pandemic).
- Additionally, reporting of unit/service group WHO Checklist assurance could not be identified within Quality & Safety Governance Group or other corporate meetings.

Additionally, analysis of TOMS data in relation to the timing of WHO Checklist sign off and sharing of this with service groups for scrutiny remains to be done. Completion of this may assist with risk-based selection of areas for checklist audits.

3.2 Summary of Recommendations

Priority ratings of the open recommendations:

	Original Audit	Current Audit
High priority	2	2
Medium priority	3	1
Low priority	1	1
Total	**6**	**4**

Audit findings and recommendations are detailed in Appendix A together with the management action plan and implementation timetable. ***In addition to these, management are aware that there are a further three recommendations outstanding for completion that were not included in the scope of this review***. These are detailed at Appendix B.

Previous Finding 2 – WHO Checklist Exceptions (Design)

Original Finding (Medium priority)

WHO Checklists were not completed in some outpatient departments, in particular Oral and Maxillofacial Outpatients and ENT outpatients.

Original Recommendation

Management should record any exceptions to the requirement to complete the WHO Checklist in SOPs / LocSSIPs for approval by the Medical Director or his nominated representative.

Original Management Response

Executive MD to write to all units to ask for assurance regarding exception reporting

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/08/2019

Current Finding 2

Fully Implemented

As indicated following the original audit (SBU-1920-021), the Executive Medical Director (EMD) issued a letter to the units within the health board highlighting the issues identified from the audit review with action points required to resolve these issues. The first issue noted was the non-completion of the WHO Checklists:

'1. WHO Checklists were not completed in some outpatient departments, in particular Oral and Maxillofacial outpatients and ENT outpatients.

Actions:

'i. Please ensure that relevant staff in all areas (not just those specified above) are all aware of the need to complete the Checklist. Please ensure that the leadership team in OMFS are aware that this issue has been highlighted in their service and that this needs to be addressed.

'ii. If there are exceptions, these should be documented in the SOPs/LocSSIPs and forwarded to me for approval of these exceptional conditions.' During the current review the Assistant Medical Director informed us that there are no exemptions to the requirement to complete the WHO checklist and that any department undertaking invasive procedures is required to complete the checklist for every patient. Within the letter issued to the Units, the EMD requested that: '*I would be grateful if you could provide me with assurance, by return, that these actions will be implemented as a matter of priority.'* The Assistant Medical Director provided replies supplied from the Singleton and Neath Port Talbot units giving assurance that the actions required by the EMD in his letter would be implemented. It was noted that the Dental Director responded with particular reference to action being taken within Oral and Maxillofacial Surgery. Correspondence within the Morriston unit indicates that the Unit Medical Director had written to ENT.

Updated Recommendation 2	**Priority Level**
No further recommendation	**N/A**

Previous Finding 3 – Clinical Scrutiny of Data Analysis (Design)
Original Finding (Medium priority) Analysis of the times recorded in TOMS for checklist sign-off highlights some occasions on which the periods between the completions of stages have been very brief and in some instances completion appears retrospective. Original Recommendation Further analysis with clinical scrutiny is recommended in these areas. Original Management Response Executive MD to request further analysis of data and sharing of information with units to ensure there is adequate scrutiny Responsible Officer – Richard Evans (Executive MD) Target Date – 01/08/2019
Current Finding 3
Not Implemented During the review, we were provided with an email sent from the Executive Medical Director to the Director of Digital requesting assistance in finding further ways to analyse the TOMS data and exploring the feasibility of providing further data to units. While there was no response recorded to this original request, the Director of Digital described to us the data currently available to units. This did not provide the further analysis required to investigate previous points raised. It was agreed that this action would be taken forward.

Updated Recommendation 3	Priority Level
Management should undertake further analysis and clinical scrutiny of TOMS data in relation to the timing of WHO Checklist completion. It may be useful to focus audits.	**Medium**

Management Response 3	Responsible Officer / Deadline
Discussion with Theatre management leads and IT have confirmed that the completion data held in TOMS is designed to be completed retrospectively rather than during the WHO checklist process to ensure staff are focussed on effective communication. This means that any timing data will not reflect actual data collection, making any analysis of this data unreliable. Discussed with Internal Audit and the limitations of TOMS data agreed. No further analysis of TOMS data planned. Compliance will be measured by in theatre audits of practice.	Completed

Previous Finding 5(a) – Standardised Audit Approach (Operating Effectiveness)
Original Finding (Low Priority) Differences in approach to audits may hinder the provision of a consistent level of assurance corporately from these reviews. Original Recommendation We would recommend that management ensure that the standard audit documentation is completed across all Theatres. Original Management Response Executive MD to write to all units to ensure staff have access to standard documentation Responsible Officer – Richard Evans (Executive MD) Target Date – 01/08/2019
Current Finding 5(a)
Implemented in Part The Executive Medical Director's letter to the Unit Medical and Service Directors requested that all staff be given access to the health board's standard audit documentation. Audit requested evidence of recently conducted observational WHO checklist audits undertaken at each unit. However only examples of audits conducted at Neath Port Talbot Hospital were provided. We were informed that since the onset of the pandemic audit activity had largely stopped. The examples provided from NPT were largely in line with the standard template, though those that related to the Wales Fertility Institute did not follow that. During the review, we were supplied with a new observational WHO checklist audit toolkit developed by the Morriston Unit. This new toolkit is being prepared to be rolled out across the health board following finalisation of the Theatre management structure.

Updated Recommendation 5(a)	Priority Level
No further recommendation noting that a new standardised audit approach is to be rolled out across all Units in the health board once the management structure is verified. The previous recommendation	**Low**

continues to apply currently: We would recommend that management ensure that the standard audit documentation is completed across all Theatres.	
Management Response 5(a)	**Responsible Officer / Deadline**
The regular audit of WHO practice will continue across all SBUHB theatres using a standard template. Results will be forwarded both to unit Q&S groups as well as the organisation's Clinical Outcomes (COEG) group.	Theatres clinical lead Theatre Senior Nurse. Outcome of audits to be received by Clinical Outcomes Group. Alastair Roeves (iDEMD; chair)

Previous Finding 5(b) – Neath Port Talbot WHO Checklist Audits (Operating Effectiveness)

Original Finding (Medium Priority)

At the time of the audit fieldwork, NPTH Theatres were not conducting WHO Checklist audits.

Original Recommendation

NPTH Management should ensure that audits of WHO Checklists are carried out in accordance with (revised) LocSSIPs.

Original Management Response

Executive MD to write to NPT Delivery Unit team and ask that they ensure audits of WHO checklists are carried out in accordance with LoCSSIPs

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/08/2019

Current Finding 5(b)

Implemented Fully

The Executive Medical Director sent an additional letter (dated 23/08/2019) to the Neath Port Talbot Service Director, requesting that if not already commenced, the unit regularly undertake audits of compliance with the WHO Checklist in accordance with the LocSSIPS.

Theatres, Recovery and Day Surgery report issued to the September 2019 meeting of the Unit's Quality, Safety and Improvement Group identified that the unit have started to undertake five WHO checklist audits per month in accordance with the LocSSIPS. Five audits undertaken between the reporting period 01/07/2019 – 31/08/2019 were reported to the group. Further audits were reported to the group in November 2019.

Due to the pandemic (covid-19) the next available Theatres, Recovery and Day Surgery report issued to the Unit's Quality, Safety and Improvement Group was July 2020. The report highlighted that due to the pandemic the theatres were closed so no audits had been undertaken.

Updated Recommendation 5(b)	Priority Level
No further recommendation	**N/A**

Previous Finding 6 – TOMS & Observational Audit Reporting (Operating Effectiveness)

Original Finding (High Priority)

TOMS checklist completion data and the outputs from observational audits were not reported within Units.

Original Recommendation

We would recommend that each Unit nominate an appropriate group to review compliance data and observational audit outcomes periodically and report assurance within its governance structure. (Any requirements of revised LocSSIPs should be considered.)

Original Management Response

Executive MD to write to all Service Directors and Unit medical Directors to ask that compliance data and observational audit outcomes are reviewed regularly at Delivery Unit Quality & Safety meetings

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/08/2019

Current Finding 6

Partially Implemented

On review of the letter issued by the Executive Medical Director to the Units it notes under action point 4:

'TOMS checklist completion data and the outputs from observational audits were not reported within Units.

'Actions:

'Please ensure that compliance data and observational audit outcomes are included as a standard item on your agenda for your Delivery Unit Quality and Safety meetings. It would also be appropriate for you to ensure that key Directorates within your Units also have audits of WHO Checklist compliance on their own Quality & Safety meeting agendas regularly.'

As part of the follow up, we reviewed the Unit Quality & Safety minutes and papers for each of the units to ensure that regular updates on TOMs data and WHO Checklist compliance audits have been issued to the groups for assurance. The following was noted:

Singleton Delivery Unit - The Unit's Quality & Safety Group papers from March 2020 to December 2020 were supplied for review. On review of the minutes and papers, no review data or WHO Checklist compliance audit outcomes were identified during this period.

Morriston Delivery Unit - Quality & Safety Unit papers for 2019/20 and 2020/21 were supplied for review. No compliance data or observational audit outcomes were identified within notes of the meetings between October 2019 and November 2020. While this was noted, it is clear that the letter from the Executive Medical Director following the previous audit report was directed by the Unit Medical Director to the unit Quality & Safety Group and clinical cabinet for discussion. Notes of the September 2019 Quality & Safety record discussion and agreement to receive a paper setting out an approval process for LocSSIPs. The subsequent January 2020 meeting received a standard operating procedure. An email from the Morriston Theatre Training & Governance lead to the Deputy Medical Director within which new audit toolkits were embedded, was forwarded to us. The email states that the unit had been undertaking audits using the new audit toolkit but this has not taken place since the beginning of the pandemic (covid-19) (no completed audits were provided).

Neath Port Talbot Delivery Unit - As noted in objective 5b, the NPT Unit have issued regular updates on WHO Checklist compliance audits to the Quality, Safety & Improvement Group. As of August 2019, the Unit started undertaking 5 WHO Checklist compliance audits per month, which was highlighted in a September 2019 Theatres report. The report also notes the compliance rate from the audits with a brief summary of the audit outcomes.

A WHO Checklist Assurance report was issued to the group in November 2019; the report holds the audits undertaken in October, with the report also giving a summary of the outcomes from each report. Due to Covid-19, the Theatres in the Unit closed resulting in no WHO Checklist audits being undertaken. This was highlighted in the Theatres report issued in July 2020.

Updated Recommendation 6	Priority Level
As indicated in the Executive Medical Director's letter, assurance regarding TOMS compliance data and observational audit outcomes should be reported periodically to service group Quality & Safety groups and discussed at appropriate Directorate meetings.	**High**
Management Response 6	**Responsible Officer / Deadline**
Unit medical directors have been reminded to ensure that the results of LocSSIPs (including the WHO) checks should be included in unit quality and safety meetings.	iDEMD Aidan Byrne (31/03/2021)

Previous Finding 7 – Corporate assurance reporting (Operating Effectiveness)

Original Finding (High Priority)

Monitoring of WHO Checklist compliance was not evident at the corporate groups.

Original Recommendation

We would recommend that the health board identify an appropriate corporate group and mechanism to receive periodic assurance on WHO Checklist compliance.

Original Management Response

WHO checklist compliance to be reviewed at Quality and Safety Forum at least biannually

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/11/2019

Current Finding 7

Partially Implemented

On completion of the previous review, the Executive Medical Director contacted the Director of Nursing & Patient Experience at the time suggesting that the checklist audit outcomes be issued to the Quality & Safety Forum (now the Quality & Safety Governance Group) on a bi-annual basis. No reports on this were evident in papers of the Quality & Safety Forum / Quality & Safety Governance Group from September 2019 – January 2021.

A paper to the QSC in February 2020 set out intended improvements to governance arrangements. These included the establishment of a Clinical Outcomes and Effectiveness Group (COEG), which would be a sub-group of the corporate Quality and Safety Governance Group. The onset of the pandemic has delayed progress on actions intended. In particular, at the outset of the review the Assistant Medical Director informed us that the COEG was still forming and not yet operating fully, so the intended route for assurance to the Quality & Safety Governance Group was not yet in place.

Updated Recommendation 7	Priority Level
We would recommend that a reporting line for corporate assurance on WHO Checklist compliance be implemented.	**High**
Management Response 7	**Responsible Officer / Deadline**
Review of LocSSIPs audits will be undertaken at COEG and organisational Q&S groups. Both groups have been informed of this requirement and have agreed to require reports.	Dr Alastair Roeves (COEG) Dr Aidan Byrne (Q&S) (Completed)

Outside Scope of Audit: Actions Recorded by Management as Outstanding for Completion

Previous Finding 1a – LocSSIPS Approval (Operating Effectiveness)

Original Finding (Medium priority)

LocSSIPs have yet to receive corporate approval

Original Recommendation

The Executive Medical Director or designated representative should agree standards corporately before wider dissemination. As part of this we would recommend that consideration be given to the clarification of responsibilities for recording data within TOMS.

Original Management Response

Executive Medical Director to establish working group to agree standards for LocSSIPs

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/11/2019

Previous Finding 1b – Units Standard Operating Procedures (Operating Effectiveness)

Original Finding (Medium priority)

The former chair of the Theatres Board indicated that Units would need to review their SOPs for specific procedures that are only commonly undertaken on their sites.

Original Recommendation

The Theatres Board should set target dates for completion of the review of SOPs by Units and monitor their completion. Executive Medical Director approval should be sought for variations to corporate standards.

Original Management Response

Theatres Board to set target dates for completion of review of SOPs and monitor completion; Exec MD to agree process for exception requests through working group

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/11/2019

Previous Finding 4 – Clinical Audits (Design)

Original Finding (Medium priority)

The LocSSIPs were not clear or consistent on the level of observational audit required and how it should be reported.

Original Recommendation

We would recommend that management review and clarify the direction within LocSSIPs in respect of the level of clinical audit expected and the groups to which it should be reported.

Original Management Response

Working group established in 1(a) to review all LocSSIPs to clarify the level of clinical audit required and how this is reported

Responsible Officer – Richard Evans (Executive MD)

Target Date – 01/11/2019

Audit Assurance Ratings

 **Substantial assurance**: **Follow up -** All recommendations implemented and operating as expected.

 **Reasonable assurance**: **Follow up** - All high level recommendations implemented and progress on the medium and low level recommendations.

 **Limited assurance: Follow up -** No high level recommendations implemented but progress on a majority of the medium and low recommendations.

 **No Assurance**: **Follow up -** No action taken to implement recommendations.

Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

Priority Level	Explanation	Management action
High	Poor key control design OR widespread non-compliance with key controls. PLUS Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in control design OR limited non-compliance with established controls. PLUS Some risk to achievement of a system objective.	Within One Month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. These are generally issues of good practice for management consideration.	Within Three Months*

** Unless a more appropriate timescale is identified/agreed at the assignment.*

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Audit

The audit was undertaken using a risk-based auditing methodology. An evaluation was undertaken in relation to priority areas established after discussion and agreement with the Health Board. Following interviews with relevant personnel and a review of key documents, files and computer data, an evaluation was made against applicable policies procedures and regulatory requirements and guidance as appropriate.

Internal control, no matter how well designed and operated, can provide only reasonable and not absolute assurance regarding the achievement of an organisation's objectives. The likelihood of achievement is affected by limitations inherent in all internal control systems. These include the possibility of poor judgement in decision-making, human error, control processes being deliberately circumvented by employees and others, management overriding controls and the occurrence of unforeseeable circumstances.

Where a control objective has not been achieved, or where it is viewed that improvements to the current internal control systems can be attained, recommendations have been made that if implemented, should ensure that the control objectives are realised/ strengthened in future.

A basic aim is to provide proactive advice, identifying good practice and any systems weaknesses for management consideration.

Responsibilities

Responsibilities of management and internal auditors:

It is management's responsibility to develop and maintain sound systems of risk management, internal control and governance and for the prevention and detection of irregularities and fraud. Internal audit work should not be seen as a substitute for management's responsibilities for the design and operation of these systems.

We plan our work so that we have a reasonable expectation of detecting significant control weaknesses and, if detected, we may carry out additional work directed towards identification of fraud or other irregularities. However, internal audit procedures alone, even when carried out with due professional care, cannot ensure fraud will be detected. The organisation's Local Counter Fraud Officer should provide support for these processes.

Office details:

SWANSEA Office
Audit and Assurance
Floor 2, Matrix House
Matrix Park
Swansea
SA6 8BX

Contact details:

Helen Higgs, Head of Internal Audit – Helen.higgs@wales.nhs.uk
Neil Thomas, Deputy Head of Internal Audit – Neil.thomas2@wales.nhs.uk
Ross Hughes, Senior Auditor – Ross.hughes@wales.nhs.uk