Partneriaeth Cydwasanaethau
Gwasanaethau Archwilio a Sicrwydd
Shared Services Partnership
Audit and Assurance Services

Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

FINAL INTERIM INTERNAL AUDIT REPORT

2019/20

Swansea Bay University Health Board

Human Tissue Act: Mortuary

(SBU-1920-005)

Private and Confidential

NHS Wales Shared Services Partnership

Audit and Assurance Service

CONTENTS

Review reference:	SBU-1920-005
Report status:	Final Interim Report V1.0
Fieldwork commencement:	01/04/2019
Fieldwork / queries completion:	05/04/2019
Audit Mgt Sign-Off:	09/04/2019
Draft report issued date:	15/04/2019
Distribution:	Christine Morrell, Deputy Director of Therapies & Health Sciences Cc Chris White, Executive Director of Therapies & Health Sciences & Chief Operating Officer
Management response received:	09/05/2019
Final report issued date:	21/05/2019
Distribution:	Chris White, Executive Director of Therapies & Health Sciences & Chief Operating Officer Cc Christine Morrell, Deputy Director of Therapies & Health Sciences
Committee Chair(s):	Martin Sollis (AC), Martyn Waygood (QSC)
Proposed Receiving Committee/s:	Audit Committee, QSC
Auditor/s:	Neil Thomas

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.

Please note:
This audit report has been prepared for internal use only. Audit & Assurance Services reports are prepared, in accordance with the Service Strategy and Terms of Reference, approved by the Audit Committee. Audit reports are prepared by the staff of the NHS Wales Shared Services Partnership – Audit and Assurance Services, and addressed to Independent Members or officers including those designated as Accountable Officer. They are prepared for the sole use of the Swansea Bay University Local Health Board and no responsibility is taken by the Audit and Assurance Services Internal Auditors to any director or officer in their individual capacity, or to any third party.

1 INTRODUCTION & BACKGROUND

1.1 An internal audit review of Human Tissue Act compliance at the Health Board's mortuaries has been agreed with the Audit Committee as part of the 2019/20 internal audit plan.

The Executive Director of Therapies & Health Sciences is the Board Director with lead responsibility for Human Tissue Act compliance. This interim report has been prepared for his attention and that of his Deputy Director of Therapies & Health Sciences who oversees arrangements to ensure compliance.

1.2 The Human Tissue Act 2004 (*"The Act"*) came into force on 1st September 2006. The aim of the Act is to provide a legal framework regulating the storage and use of human tissue from the living and the removal storage and use of tissue from the deceased. It introduces regulation of other activities such as post mortem examinations, and the storage of human material for education, training and research. It is intended to achieve a balance between the rights and expectations of individuals and families, and broader considerations, such as the importance of research, education, training, pathology and public health surveillance to the population as a whole.

1.3 In response to critical reports published by the Human Tissue Authority following inspections at mortuaries managed by other organisations in NHS Wales, the Deputy Director of Therapies & Health Sciences indicated to the Health Board Quality & Safety Forum in January 2019 that an internal management review would be undertaken against the recommendations made.

1.4 Staff within the mortuaries have since compiled a self-assessment against the HTA *Post Mortem Examination: Standards & Guidance*. Whilst the mortuary management leads indicate some of the self-assessment remains to be completed, it has been provided to the Deputy Director and shared with Internal Audit to assist with planning of the audit review.

Following preliminary audit planning, including a review of the self-assessment completed to date, we propose to delay any further work but instead issue an interim report for immediate management consideration and action as appropriate.

2 ASSESSMENT OF CURRENT POSITION

2.1 The overall objective of the audit of *Human Tissue Act: Mortuary* within the Audit Plan for 2019/20 is to review arrangements in place to ensure compliance with legislation.

2.2 The self-assessment presents management's view of compliance against each of the areas in the HTA guidance as they relate to each of the sites managed by Swansea Bay UHB under the Morriston Hospital HTA licence 30015, including the mortuary it manages at Princess of Wales Hospital.

The assessment indicates that there is a limited level of management assurance currently. Whilst compliance is noted in some areas, there are several key areas of non-compliance and many more indicated as requiring improvement or further review. Some of these are in areas the HTA have considered critical or major at other establishments.

2.3 Internal Audit had been asked to consider undertaking an audit of this subject early in 2019/20. However, in view of management's own findings, we do not consider it an appropriate time for an internal audit review, but recommend that the audit be delayed until later in the year to allow mortuary management to make the improvements they have identified as required. Whilst this is the case, we have made a number of observations and recommendations for consideration by the Deputy Director in the next section of this report.

2.4 Amongst the revised (and previous) HTA requirements is the expectation for an establishment's governance arrangements to have a schedule of audits that include review of compliance with documented procedures, records (for completeness), traceability and tissues held. They require that actions to address issues arising, and the target dates for their completion, be documented.

The self-assessment indicates that such a schedule is not in place currently. Internal Audit review of the current terms of reference for the HTA Oversight Group has highlighted that they are not explicit on the requirement to receive a schedule of audits for consideration, receive the outcomes of audits undertaken, or monitor the completion of actions agreed in response to them. Our recommendations in the next section address this.

3 RECOMMENDATIONS

The completion of a management self-assessment is the first positive step to ensuring compliance with the revised guidance. The following actions are recommended to assist in making the necessary improvements at pace:

3.1 We recommend that the remaining areas of the self-assessment be completed quickly.

3.2 Actions should be agreed to address all areas for improvement. They should be prioritised so that those presenting the greatest risk of non-compliance with the Act, and/or potential for external inspection criticism and reputational damage, are targeted for early action and completion where possible. Actions should be scheduled within a documented improvement plan accordingly.

Whilst inspections elsewhere are not necessarily an indicator of all areas considered that may be considered critical at future visits within this Health Board, we would recommend that management consider those areas highlighted as *Critical* and *Major* at recent visits to Cardiff & Vale UHB and Cwm Taf UHB when assigning the prioritising tasks within Swansea Bay UHB.

3.3 Officers responsible for completing actions should be assigned. Where responsibility sits outside of the mortuary for actions, this should be communicated and agreed with senior management in those areas.

Where the Health Board is reliant upon management within another organisation eg Cwm Taf UHB, to address issues, this needs to be communicated and agreed similarly. Expectations of both organisations will need to be documented in service level agreements. The responsibility for ensuring this is achieved should be included within the action plan.

3.4 Having agreed an action plan, the Designated Individual (DI) should meet with mortuary staff regularly to monitor progress against it (we would recommend a fortnightly update). Notes be made of meetings, of actions agreed and completed – these may support assurance in respect of governance processes at a future inspection. The DI should report into the HTA Governance Group on progress against the prioritised plan, and highlight any slippage and/or issues arising.

3.5 The HTA Oversight Group should monitor progress at every meeting. The terms of reference for this group currently indicate that it meets only twice a year. This will not be adequate to ensure effective

oversight of the highest priority improvements required. Until substantial progress can be demonstrated in the highest priority areas, the meetings should be held more regularly – we would recommend monthly.

3.6 The current position and any action agreed to address it should be summarised appropriately for reporting to the Quality & Safety Forum, in order that the appropriate risks & assurances can be communicated in turn to the Quality & Safety Committee.

3.7 To ensure the ongoing operation of effective oversight, we would recommend that the terms of reference for the HTA Oversight Group be amended to include the requirements:

- To receive and agree a schedule of audits for each year that indicates the meetings at which the outcomes will be available;
- To receive the outcomes from those audits; and
- To monitor action taken to address issues arising.

The schedule should be received at each meeting in order that the group can be assured that audits are undertaken and reported as planned. The meeting action log should be used to ensure that action required following audits and assurance that it is completed is brought back to future meetings.

3.8 Lastly, we would recommend that a revised target date be agreed for the commencement of an internal audit review. In considering a suitable date, the Health Board should consider the timescales within the improvement plan, and the point at which it is anticipated management's own self-assessment will provide a substantial level of assurance regarding arrangements in place. This would be subject to independent review within the scope of the internal audit.

The Deputy Director of Therapies & Health Science has confirmed that action is being taken on these recommendations and updates will be provided to the Executive Team, Quality & Safety Forum and Quality & Safety Committee. (To that end we note that the draft version of this report was included on the agenda for the Quality & Safety Forum scheduled for 21st May 2019, though the meeting was cancelled due to operational pressures within the Health Board.)