



**CYFARFOD MEWNOL PWYLLGOR BWRDD PRIFYSGOL IECHYD
UNIVERSITY HEALTH BOARD MEETING**

DYDDIAD Y CYFARFOD: DATE OF MEETING:	30 September 2021
TEITL YR ADRODDIAD: TITLE OF REPORT:	An External Review of the Llwynhendy Tuberculosis Outbreak
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Phil Kloer, Medical Director & Deputy Chief Executive
SWYDDOG ADRODD: REPORTING OFFICER:	Phil Kloer, Medical Director & Deputy Chief Executive

Pwrpas yr Adroddiad (dewiswch fel yn addas)

Purpose of the Report (select as appropriate)

Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA

SBAR REPORT

Sefyllfa / Situation

The purpose of this paper is twofold. First, to provide an update on the commissioning, jointly with Public Health Wales (PHW), of an external review of the management of the Llwynhendy Tuberculosis Outbreak incident. Second, to seek the Board's approval of the Terms of Reference, the timelines and governance arrangements for the review. This item is also being reported to the September 2021 PHW Public Board meeting.

Cefndir / Background

On 9th November 2010, an outbreak investigation was initiated into a cluster of active Tuberculosis (TB) cases with the same genotype profile, occurring in the Llwynhendy area of Carmarthenshire. By the end of 2018, 29 (twenty-nine) cases (in 28 individuals) of active TB disease were linked to the outbreak. In the intervening years, the outbreak investigation was re-opened and closed twice. In November 2018 the outbreak investigation was re-opened for the fourth time in response to new cases of TB. The outbreak control team was re-established and wider contact screening was carried out in the local community. At the time of writing, in September 2021, there are now 31 cases associated with this outbreak.

In 2019, a rapid internal review was carried out by PHW, to identify immediate actions and to make recommendations for the ongoing management of the outbreak.

The findings of the internal review were presented to an In-Committee Board meeting in November 2019. One of the key recommendations of the review was to commission, jointly with PHW, an external review of the outbreak and its management, to inform the approach to the management of TB disease in Wales. The Board agreed to proceed with the external review.

In response to the COVID-19 pandemic, a decision was taken early in 2020 to pause the review. In June 2021, following a meeting with PHW, the Chief Executives of HDdUHB and PHW agreed that the external review should be resumed at the earliest opportunity. It has

been agreed in principle to resume the process to initiate the external review. This report provides an update on the current situation and seeks approval of the Terms of Reference for the review.

Asesiad / Assessment

The Terms of Reference for the review are attached as Appendix A.

Professor Mike Morgan has been appointed as the chair of the external review panel and has been formally commissioned, on 16th August 2021, to oversee the review.

The purpose of the Review is to examine:

- Whether the management of the outbreak since 2010 overall, and at each stage, was conducted in accordance with best practice guidance in place at the time of each phase of the outbreak (with reference to national strategies, plans, guidelines and organisational protocols and procedures);
- The effectiveness of the respective involvement of Public Health Wales and Hywel Dda University Health Board in the control of the outbreak and treatment of latent or active TB cases at each stage (including the current phase) including the people and financial resources provided by both organisations in response to the outbreak to prevent disease transmission and treat identified TB disease;
- The governance arrangements (including reporting and escalation) for informing Teams and Boards of the outbreak and providing assurance to the Boards of each organisation;
- A review of any reported cases of: 1. People identified over the course of the outbreak who have died where the death certificate identified that TB contributed to or caused the death, and 2. People that have developed active TB;
- The effectiveness of any policy(ies) relevant to TB disease prevention, treatment and control including the management of outbreaks applicable in Wales in each phase of the outbreak and the reporting arrangements within Wales since the outbreak was first declared in 2010;
- The effectiveness of external expert advice sought and obtained including liaison with other organisations, for example, Public Health England (and UK Health Security Agency from October 2021) or the British Thoracic Society.

The review will be undertaken as part of the legal duty of candour for Public Health Wales and Hywel Dda University Health Board and accordingly, the communication and dissemination of the findings will adopt an open and transparent approach.

The Executive Medical Director at Public Health Wales and the Executive Medical Director at Hywel Dda University Health Board will be the joint Executive sponsors of the review and are accountable to their Boards for the delivery of the Reviewers' report(s).

A Project team will be established to support the review panel. The Project team will be led by a Project manager and will include administrative support, Communications and Information and Communications Technology. The Chair of the Review Panel will work closely with the Project Team to ensure adequate support to the review and review panel members.

Board members will note that a final report will be submitted to and presented at the respective Boards no later than May 2022, with an expectation of a report to QSEC by the end of March 2022.

3.1 Ongoing outbreak management

An outbreak control team (OCT) continues to meet to oversee the coordination, investigation and management of the outbreak. All relevant stakeholders are involved in the OCT on an ongoing basis.

3.2 Well-being of Future Generations (Wales) Act 2015

This paper is written with due consideration of the five ways of working, as defined within the sustainable development principle in the Act, in the following ways:



Hirdymor

Long Term

Even though Wales has a low prevalence of TB, a long-term commitment is necessary to minimise the threat from the infection.



Atal

Prevention

Prevention is important to minimise the risk of transmission. Measures include surveillance and screening supported by strategic plans and policies.



Integreiddio

Integration

The response to this outbreak demonstrates the need for a joined up health protection system in Wales that includes national and local clinical and public health services. This will be met through the development of the Health Protection response system for Wales.



Cydweithio

Collaboration

Effective prevention and treatment of TB requires close collaboration between public health protection services, local health board TB clinical services and local authority public protection services.



Cynnwys

Involvement

The follow up to this paper will involve senior health protection and microbiology staff together with staff from the local health board and Welsh Government. An external review will involve senior public health and respiratory medicine experts commissioned from outside Public Health Wales and the health board.

Timeline of the Review

An External Review of the Llwynhendy Tuberculosis Outbreak Timeline

Project Start

First Milestone/ Stage Reporting for Project

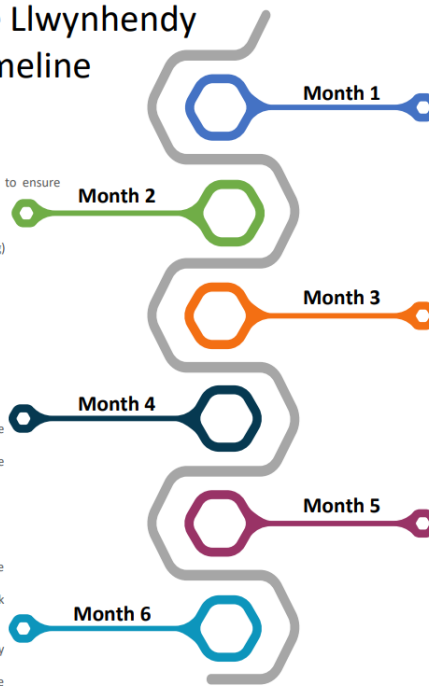
- Project monitoring
- Highlight reporting to Project Lead
- Escalation policy within the project documentation to be reviewed to ensure access to information for reviewers.
- Appropriate stage milestones i.e. update on current reviews
- Stakeholder profiles for any identified character interviews
- Implementation of communication management (meetings scheduling)
- Monitoring and updating of benefits profiling
- Review PID to ensure the scope of the project is still relevant.

Third Milestone/ Stage Reporting

- Dependencies will include:
- Highlight reporting
 - Stakeholder engagement between the different stakeholder groups
 - Highlight and update all relevant risks/ benefits of the project to gauge whether any benefits have already been realised.
 - Reporting on Project progress versus Project Mandate and review the PID to ensure the scope remains relevant.

End of TB review Project

- Referring back to initial mandate and ensuring the SRO is happy for the project to close
- Recognise the learning opportunities and initiate the post project work and documentation
- Communicate the post project learning with the stakeholders
- Establish the key findings with each organisation and outline the key recommendations.
- Undertake Lessons Learned exercise following the confirmation the project is eligible to be signed off.



- Project Commencement
- Identified risks and issues confirmed with project lead and reviewers with a view to outline any mitigating actions.
- First tranche of materials distributed to reviewers
- Quality & Assurance Management arrangements
- Establishment of KPI's
- Project Manager oversight to enable patient documentation is available to reviewers.

Second Milestone/ Stage Reporting

- The midpoint of the project will seek to inform each board on the progress of the work through highlight reporting
- Regular reporting to continue to each board with regular Project lead support from the Project Manager.
- Key Performance Indicator Review and update of Benefits profiles
- Update of Risk and Issue Management i.e. have there been any further identification of issues/ are there any opportunities or threats to project?
- Review of PID to ensure the document remains relevant to the delivery of the project.

Fourth Milestone/ Stage reporting

- Is the project in a fit place to close after the project end date?
- Have any improvement opportunities been realised/ put in place already?
- Does the work now adhere to any outstanding quality assurance mechanisms
- Review of Governance documentation and any key issues relating to Project.
- Highlight reporting
- Review of risks and issues to scope whether any mitigating actions are required following the final stage.

Argymhelliad / Recommendation

The Board is asked to:

- Note the joint arrangements with Public Health Wales to undertake an independent external review.
- Note that the review is being undertaken as part of the legal duty of candour for Public Health Wales and Hywel Dda University Health Board and accordingly, the communication and dissemination of the findings will adopt an open and transparent approach.
- Approve the terms of reference, timeline for the project, and the proposed governance arrangements.

Amcanion: (rhaid cwblhau)

Objectives: (must be completed)

Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:
Datix Risk Register Reference and Score:

Not applicable.

Safon(au) Gofal ac Iechyd: Health and Care Standard(s): Hyperlink to NHS Wales Health & Care Standards	1.1 Health Promotion, Protection and Improvement 2.4 Infection Prevention and Control (IPC) and Decontamination
Amcanion Strategol y BIP: UHB Strategic Objectives: Hyperlink to HDdUHB Strategic Objectives	All Strategic Objectives are applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Statement	Improve Population Health through prevention and early intervention

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	Detailed in previous reports and throughout paper.
Rhestr Termau: Glossary of Terms:	Contained within the body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Cyfarfod Bwrdd Iechyd Prifysgol: Parties / Committees consulted prior to University Health Board:	Members of the Outbreak Control Team.

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Funding for TB Screening has been approved and all costs and resource requirements associated with the management of this outbreak are being tracked and monitored.
Ansawdd / Gofal Claf: Quality / Patient Care:	Preventing TB transmission and possible associated deaths in the population.
Gweithlu: Workforce:	Workforce time associated with the management of the TB outbreak.
Risg: Risk:	Preventing TB transmission and possible associated deaths in the population.
Cyfreithiol: Legal:	Preventing TB transmission and possible associated deaths in the population.
Enw Da: Reputational:	Preventing TB transmission and possible associated deaths in the population. A communication plan has been developed to support the management of the TB screening and approved by the Outbreak Control Team.
Gyfrinachedd: Privacy:	Not applicable.
Cydraddoldeb: Equality:	Preventing TB transmission and possible associated deaths in the population.

An External Review of the Llwynhendy Tuberculosis Outbreak

Terms of Reference

1. Scope

- 1.1 An outbreak of *M. tuberculosis* (TB) centred on the Llwynhendy electoral ward in Carmarthenshire, West Wales was first declared in November 2010. Since then an outbreak control team (OCT) has been convened and stood down three times. In November 2018 an OCT was reconvened for the fourth time. This is now delivering a staged approach to community screening that it is hoped will conclude by the end of September 2019.
- 1.2 The Boards of Public Health Wales and Hywel Dda University Health Board wish to examine whether the outbreak has been managed optimally including whether contact tracing should have been extended at an earlier stage, and whether the clinical care provided to cases was optimal, and if these affected the extent and impact of the outbreak.
- 1.3 Public Health Wales and Hywel Dda University Health Board have agreed to jointly commission an independent external review to examine these questions as well as to identify the lessons learned from the response to this outbreak and to provide assurance of the current arrangements.
- 1.4 The review will cover the management of the outbreak from November 2010, when first declared, until the present time (August 2021), to identify the actions that have been taken in response to lessons identified.

2. Purpose

- 2.1 The purpose of the Review is to examine:
 - Whether the management of the outbreak since 2010 overall, and at each stage, was conducted in accordance with best practice guidance in place at the time of each phase of the outbreak (with reference to national strategies, plans, guidelines and organisational protocols and procedures);
 - The effectiveness of the respective involvement of Public Health Wales and Hywel Dda University Health Board in the control of the outbreak and treatment of latent or active TB cases at each stage (including the current phase) including the people and financial resources provided by both organisations in response to the outbreak to prevent disease transmission and treat identified TB disease;
 - The governance arrangements (including reporting and escalation) for informing Teams and Boards of the outbreak and providing assurance to the Boards of each organisation;
 - A review of any reported cases of: 1. People identified over the course of the outbreak who have died where the death certificate identified

that TB contributed to or caused the death, and 2. People that have developed active TB;

- The effectiveness of any policy(ies) relevant to TB disease prevention, treatment and control including the management of outbreaks applicable in Wales in each phase of the outbreak and the reporting arrangements within Wales since the outbreak was first declared in 2010;
- The effectiveness of external expert advice sought and obtained including liaison with other organisations, for example, Public Health England (and UK Health Security Agency from October 2021) or the British Thoracic Society.

2.2 The review should identify lessons learned and make recommendations to Public Health Wales and Hywel Dda University Health Board for improvement. There may also be recommendations for other key stakeholders.

3. Reporting and Accountability

3.1 The Executive Medical Director at Public Health Wales and the Executive Medical Director at Hywel Dda University Health Board will be the joint Executive sponsors of the review and are accountable to their Boards for the delivery of the Reviewers' report(s).

3.2 The priority of both organisations at the present time is to continue to manage the outbreak and not distract attention or divert resources from that objective.

3.3 The sponsors would like the review to proceed at pace and are therefore looking to receive an interim Reviewers' report(s) by the end of February 2022 (indicative) with the view to have a preliminary discussion with the Chairs of the Boards and Chief Executives of both organisations prior to a final report being submitted to and presented at the respective Boards no later than May 2022, with an expectation of a report to QSIAC by the end of March.

3.4 The Executive sponsors will prepare a joint SBAR for the respective Boards to support the review panel's final report.

3.5 The Reviewer(s) may wish to establish short duration task and finish groups on specific matters of enquiry as and when necessary, for example, a mortality review group and both organisations will give reasonable consideration to requests for any associated necessary resources.

3.6 The Review Project team will report regularly (monthly) on progress of the review to the Executive Sponsor and Executive Team in each organisation.

3.7 If, in the course of the Review, matters are identified that require immediate and urgent action on grounds of public health or quality and safety of clinical care, then these will be raised, in the first instance, with the Executive Sponsors of the Review to determine whether urgent actions are required.

4. Membership of the review team

4.1 The Reviewers are expected to include:

- A senior public health specialist with expertise in health protection including outbreak control and ideally with demonstrable knowledge of tuberculosis as a public health issue.
- A senior respiratory medicine specialist with expertise in tuberculosis disease.
- A respiratory nurse specialist with expertise in tuberculosis disease.
- A senior microbiologist with expertise in TB diagnosis and expertise in public health microbiology.
- Lay Member: An independent lay representative from a national organisation that has an interest in the treatment and control of tuberculosis and patient outcomes.

The review panel will be chaired by Professor Mike Morgan, previously NHS England's National Clinical Director for Respiratory Disease.

5. Resources to support the review

The commissioning organisations will agree a reasonable request from the reviewers for the resources, human and otherwise, needed to deliver the review. It is expected that this will include access to relevant premises and facilities to conduct necessary activities (meetings etc.); administrative support to assist document retrieval and management, arranging interviews, and the preparation of (a) report(s); retrieval and preparation of case records to support a mortality review; and project management to deliver the review.

A Project team will be established to support the review panel. The Project team will be led by a Project manager and will include administrative support, Communications and Information and Communications Technology. The Chair of the Review Panel will work closely with the Project Team to ensure adequate support to the review and review panel members.

6. Communications and publication of review findings

- 6.1 The review is undertaken as part of the legal duty of candour for Public Health Wales and Hywel Dda University Health Board and accordingly, the communication and dissemination of the findings will adopt an open and transparent approach.
- 6.2 A joint Communications Strategy will be agreed by both Public Health Wales and Hywel Dda University Health Board, that will define the end-

to-end process from the initiation of the review to the publication of the findings.

- 6.3 The Communication Strategy will include consideration of the needs of key stakeholders, including members of the public, individuals and families directly affected, Welsh Government, Health Boards, Community Health Councils and Local Authorities.
- 6.4 A joint Communications Plan will include details on plans for publication, including indicative timelines for public meetings and meetings with those directly affected. Where required, earlier contact will be made with individuals and families affected.

Meng Khaw
Philip Kloer

13 August 2021