Technoleg Iechyd Cymru
Health Technology Wales

Ariennir gan
Lywodraeth Cymru
Funded by
Welsh Government

Developing the Health Technology Wales (HTW) Audit Function to Assess the Adoption of HTW and NICE Guidance on Non-Medicine Technologies across Wales

Report & Recommendations

February 2020

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Executive summary

In 2014 Welsh Government conducted an inquiry into 'Access to Medical Technologies in Wales.'[1] The Chair of the inquiry noted in the report foreword: "Evidence to our inquiry suggests one overarching conclusion: Wales lacks a strategic, coordinated approach to technology evaluation and adoption."[2] A number of recommendations emerged from the inquiry aimed at improving access to medical technologies. The inquiry made two key recommendations pertaining to the establishment of Health Technology Wales, and the requirement for it to establish an audit function to monitor guidance on the adoption of non-medicine technologies across Wales.

A critical step in the adoption and spread of technological innovation is an agreed process to facilitate and monitor routine consideration, uptake, (de)commissioning and implementation of evidence-based guidance. As a result, Health Technology Wales set-up an Adoption Audit Task and Finish Group in early 2019. Since June 2019, this group has met to discuss options for optimal adoption of non-medical technologies. In addition to discussions, targeted consultation through semi-structured interviews with key stakeholders fed into the outcomes, resulting in the following recommendations:

1. The All Wales Medical Directors (AWMDs), with their remit for clinical effectiveness, should be the national peer group that oversees the HTW audit function.
2. Each local health board should extend the remit of their relevant local committee (Medicines and Therapeutic Committee/Medicines Management Committee/Medical Device Committee) to take on additional responsibilities to facilitate annual audit of the adoption and uptake of key HTW and NICE non-medicine technologies guidance.
3. Welsh Government should support utilising a range of mechanisms to encourage optimal adoption of NMTs, reduce the disparity in focus and differential adoption between medicine and non-medicine technologies within Wales, and incentivise compliance with the HTW national audit.
4. HTW should discharge its remit regarding the adoption of non-medicine technologies across Wales through provision of operational and secretariat support for the new HTW national audit function.
5. NHS boards should identify and dedicate local resources required to support the relevant health board groups to expand their remit and terms of reference. The resources required will vary depending on existing capacity, knowledge and skills within individual health boards.
6. Local Health Boards (LHBs) should identify resources to implement the new HTW audit function to ensure successful pilot, learning and full implementation.
7. That the HTW AAT&FG should be reconvened in summer and winter 2020 to evaluate the pilot introduction of the HTW audit and reflect on experience and learning to inform routine roll-out and implementation.
8. HTW should report to Welsh Government results of the implementation of the recommendations above and the pilot of the HTW audit function by the end of 2020.
9. HTW should collate the health board audit returns and prepare an annual report to the Minister for Health and Social Services, reporting on the adoption of priority HTW and NICE non-medicine technologies guidance, identifying differential adoption and the rationales provided to account for this.

Objectives and Scope of the Report

In discharging the duty of "adoption of medical technologies into practice across NHS Wales", Health Technology Wales set-up the HTW Adoption Audit Task & Finish Group (AAT&FG). This group's purpose was to review options, discuss and propose a structure and related process that will allow for effective audit of the adoption and implementation of non-medicine technologies guidance issued by both HTW and the NICE Medical Technologies Advisory Committee (MTAC) and Diagnostics Advisory Committee (DAC). This is estimated to be around 25 pieces of guidance per year. This report describes the methodology used to reach a proposal, defining the most efficient route of auditing implementation of guidance for non-medicine technologies; ultimately providing recommendations and suggested ways forward.

Background

The differences between the evidence assessment and guidance processes for medicines compared to non-medicine technologies (NMTs) are well known. NMTs encompass a wide range of interventions, including:

- devices e.g. mechanical chest compression
- diagnostic tests e.g. PET scanning
- procedures e.g. robotic surgery
- changes in organisational systems e.g. prediction tools to aid cancer assessment
- e-health and digital technologies e.g. continuous glucose monitoring.

The scale is very different with approximately 60-80 new medicines on the market annually compared to thousands of devices and other NMTs.

However, despite the scale and the regular production of NMT evidence assessment and guidance at both Wales and UK levels, Local Health Boards (LHBs) appear not to have a systematic way of managing the results to expedite equitable adoption and realise potential health gains and efficiencies across the Welsh care sector. A critical missing step in the adoption and spread of NMTs in Wales, is an agreed process to consider evidence-based guidance and information.

This contrasts with medicine products which are automatically considered by LHB Medicines and Therapeutics Committees/Medicines Management Committees who manage the process of adoption and implementation supported by mandatory guidance, funding directives and well-defined national systems e.g. AWMSG, the One Wales Interim Commissioning Process and New Treatment Fund.

In 2014 Welsh Government conducted an inquiry into 'Access to Medical Technologies in Wales.'[1] The Chair of the inquiry noted in the report foreword: "Evidence to our inquiry suggests one overarching conclusion: Wales lacks a strategic, coordinated approach to technology evaluation and adoption."[2] A number of recommendations emerged from the inquiry aimed at improving access to medical technologies. The two key recommendations pertaining to the establishment of Health Technology Wales, and the requirement for it to establish an audit function to monitor guidance on the adoption of non-medicine technologies across Wales, were as follows:

Recommendation 3 - That the Minister for Health and Social Services, within 12 months of the publication of this report, should develop options for an all-Wales medical technologies appraisal

[1] National Assembly for Wales, Health and Social Care Committee. Access to Medical Technologies in Wales. December 2014.
[2] Response to Recommendations from the Health and Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.

mechanism, to undertake a similar function in respect of medical technologies as the All Wales Medicines Strategy Group (AWMSG) does for medicines.

Recommendation 5 - That the Minister for Health and Social Services should ensure that the uptake of recommended medical technologies across Wales, including those recommended by NICE, is measured as part of a formal audit process.

Subsequently, in September 2017, Vaughan Gething, Cabinet Secretary for Health Wellbeing & Sport, wrote to all NHS Wales Chairs regarding the uptake of sacral nerve stimulation devices across the country[3], and he noted:

"…I would like to see a consistent approach across Wales, so that all Welsh patients have equitable access to services. You should be aware that, following the Inquiry into Access to Medical Technologies in Wales, the adoption of guidance across NHS Wales will be regularly audited by the newly formed, Health Technology Wales."

Health Technology Wales (HTW) was established in November 2017. HTWs purpose, as outlined in its funding award, is as follows: "…to provide a strategic, streamlined and nationally coordinated approach to the identification, appraisal and adoption of medical technologies into practice across NHS Wales."

In the two years since its inception, HTW has been focused on recruiting its core team and initiating its identification and appraisal functions, which are now fully operational. Within its grant resource, HTW has capacity to produce up to 15 rapid evidence appraisals with associated guidance for care services in Wales per annum. To date, HTW has produced twelve pieces of guidance on non-medicine technologies. Consequently, it is now timely for HTW to turn its attention to developing its national audit function and consider options to facilitate systematic routine consideration of advice on non-medicine technologies to ensure that healthcare decision makers are supported to use the best available evidence to inform their practice and that the Welsh population gain maximum benefit from their use. A glossary of key definitions is provided in Appendix 1.

A critical step in the adoption and spread of technological innovation is an agreed national process to facilitate and monitor routine consideration, uptake, (de)commissioning and implementation of evidence-based guidance in Wales. HTW set-up the Adoption Audit Task and Finish Group in June 2019, meeting to discuss options to facilitate optimal adoption of non-medical technologies.

A dominant, preferred option emerged for the HTW audit structure and received unanimous support of AAT&FG members, as follows:

A national group working alongside existing local health board groups

[3] Gething, V. Letter to all Health Board Chairs regarding funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.

Methods

An HTW Adoption Audit Task and Finish (AAT&F) Group was established to design a national audit function to effectively "audit the adoption and implementation of non-medicine technologies guidance from both Health Technology Wales (HTW) and the National Institute for Care and Clinical Excellence (NICE)". The membership and terms of reference of the AAT&FG is outlined in Appendix 2.

The AAT&FG met for the first time in June 2019 and agreed to adopt a mixed methods approach to informing the design of the HTW audit function. The key methods and stages included:

1. Agreeing the objectives, scale, scope for the HTW audit function
2. Agreeing the format, frequency and audience for the HTW audit function
3. Information gathering, nationally and internationally
4. Formulating a range of options for the design of the HTW audit function
5. Conducting a SWOT analysis and appraisal of the options proposed
6. Defining the preferred option
7. Securing support from key national peer groups for the preferred audit option
8. Targeted consultation, interviewing key stakeholders about the proposed option
9. Consultation on the draft report and recommendations.

The different stages of the process resulted in an iterative development and refinement of potential model options. The model options considered are outlined in Appendix 3. More detail on the methods and stages are outlined in the table in Appendix 4.

The outcome from Stage 6 was a specific option proposed for the All Wales Medical Directors (AWMD) to be the national peer group responsible for oversight of the HTW audit, with the existing local health board Medicine and Therapeutics Committees (MTCs)/Medicines Management Committees (MMCs)/Medical Devices Committees (MDCs), extending their remit to deliver the audit.

In order to scope feasibility and as part of Stage 8, HTW carried out semi-structured interviews with key stakeholders. Those participating in the interviews were provided with a letter of invitation, a briefing paper, a consent form and interview guide (see Appendix 8). Each interview lasted for approximately thirty minutes and analysis of these included qualitative review of emergent themes.

The results from each of the stages listed above are included in the next section of this paper.

Results

The AAT&F Group pooled expertise and considered a number of key factors in considering the design of the HTW audit function and agreed the following:

1. Objectives, scope and scale for the HTW audit function

The **objectives** of the HTW AAT&FG in designing the HTW audit function were decided:

- to make recommendations to Welsh Government to discharge recommendation 5 of the 2014 inquiry into 'Access to Medical Technologies in Wales' that requested that the Minister for Health and Social Services should 'ensure that the uptake of recommended medical

technologies across Wales, including those recommended by NICE, is measured as part of a formal audit process, and

- to design a national audit function to maximise the adoption and impact of HTW & NICE guidance by establishing an agreed 'landing zone' and a process to facilitate systematic and routine consideration of guidance on non-medicine technologies across Wales.

The **scope** of the HTW national audit function will include non-medicine technologies guidance issued by both HTW and the NICE Medical Technologies Advisory Committee (MTAC) and Diagnostics Advisory Committee (DAC).

The **scale** of the audit is expected to be up to a maximum of 25 pieces of non-medicine technologies guidance per year (15 from HTW and 10 from NICE) or around two pieces of NMT guidance per month. Only a proportion of this guidance will support adoption of the technologies appraised. The HTW audit function will, however, require review of both positive (routine or selective adoption) and negative (do not adopt) guidance recognising that the implementation of both adoption and non-adoption guidance is equally important.

2. Format, frequency and audience for the HTW audit function

The **format** of the HTW audit function will be high-level focussing on the 'Adopt or Justify' status of the guidance, reporting on two key questions:

- Has HTW and NICE non-medicine technologies guidance been adopted (i.e. a clear decision been made to either invest or divest in the technology of interest)? Yes or No?
- If HTW/NICE guidance has not been adopted, what was the justification for the decision?

An 'atlas of variation' will be included within the annual audit report to highlight any differential adoption of key non-medicine technologies across Wales, alongside consideration of any differences.

Given the broad range of technologies to be covered, the audit tools/areas to investigate are likely to vary and be dependent upon the local data available to support the audit. The proposal is to prospectively identify a small number of key indicators for each piece of guidance which will be shared with health boards to direct audit efforts and ensure that they are proportionate.

The **frequency** of the HTW audit will be annual, retrospectively auditing the adoption of HTW and NICE guidance issued in the previous calendar year. However, it is expected that the relevant local board committees will routinely discuss guidance from both HTW and NICE to prospectively consider adoption of new technologies and plan implementation and collection of data to evidence their compliance with the guidance, or otherwise, with an accompanying rationale.

Where the adoption of a technology is anticipated to be disruptive e.g. engendering significant change to the current care pathway, the audit timeline will be set for a longer period to allow services to reconfigure to accommodate adoption and implementation of the new technology.

The primary **audience** for the annual HTW audit report will be the Minister for Health and Social Services and the Chief Medical Officer, as the genesis of the request for HTW to establish a national audit function emanated from the 2014 Welsh Government inquiry. The annual audit report will also be shared with the All Wales Medical Directors (AWMDs) and the lead local health board committees as the bodies engaged in the oversight and execution of the national audit respectively.

In addition, the annual audit report will be shared with key national peer groups e.g. the Chief Executives Management Team (CEMT) and Directors of Planning (DOPs) as well as other relevant

national groups e.g. Welsh Health Specialist Services Committee (WHSSC) the NHS Wales Efficiency Board and the Regional Partnership Boards (RPBs).

These proposals will be tested during the proposed pilot of the HTW audit structure throughout 2020.

3. Information gathering nationally and internationally

Information on relevant local and national experience was gained through the expertise and experience of AAT&FG members and key informant discussions. International health system experience was obtained through a survey of members of the International Network of Agencies for Health Technology Assessment (INAHTA) that sought to identify processes that have been successful at promoting local consideration of NMT guidance produced at national levels in other healthcare systems.

The information gathered identified a lack of systematic processes for local consideration of national NMT guidance. Internationally, very few of the responding countries reported having a process to audit the adoption of national guidance on non-medicine technologies. Appendix 5 outlines the analysis of the responses received from the INAHTA survey.

During meetings, AAT&FG members also discussed and suggested a range of other potential mechanisms to encourage optimal adoption of NMTs with supportive HTW and NICE guidance and incentivise compliance with the HTW national audit, including:

- Clearly explaining the 'Adopt or Justify' status of HTW Guidance;
- Agreeing a process for the commissioning of NMTs supported by HTW guidance;
- Supplementing the supporting guidance underpinning Health Care Standard (3.3) which outlines that 'care, treatment and decision making should reflect best practice based on evidence to ensure that people receive the right care and support to meet their individual needs', to highlight HTW guidance, its status and the required annual audit return;
- Aligning the HTW audit with national and local IMTP planning processes;
- Ensuring that HTW and NICE NMT guidance, that identifies efficiency savings for NHS Wales, is included on the Finance Delivery Unit's national efficiency framework and toolkit;
- Routinely engaging the NHS Wales Improving Efficiency Board through a regular presentation to this group to make them aware of priority HTW and NICE guidance, specifically flagging those that have potential to yield cost savings for the service, and
- Considering the role of the new NHS Wales Executive in supporting the work of HTW and uptake of its national guidance.

  Depending on how the pilot of the audit progresses, the response from local health boards and the results regarding adoption of the HTW and NICE guidance, AAT&F members suggested it may be helpful to request Welsh Government issue Welsh Health Circulars to:

- Raise awareness and the profile of the HTW national audit and the requirement for LHBs to produce an annual audit return to HTW; and
- To disseminate HTW and NICE guidance e.g. quarterly.

AAT&FG members agreed to consider the requirement for Welsh Health Circular support when they reconvene to assess learnings from the pilot audit.

4. Formulating a range of options for the design of the HTW audit function

Based on the experience of AAT&FG members, and the information and intelligence gathered, an initial long-list of nine options for the HTW audit structure was formulated and is outlined below.

These options were discussed at the first AAT&FG meeting and the five shaded options were discounted due to: reluctance to establish new bodies or committees; agreement that regional structures were insufficiently mature to support a regional audit structure; feedback that the new Implementation Facilitator for Wales (NICE) did not have the capacity to lead on the audit; and agreement that continuing with the status quo was not acceptable in light of recommendation 5 from the 2014 inquiry.

Option 1: National-Level Group (new or existing)

- Option 1a: a new national group, or
- Option 1b: utilise an existing national body e.g. HTW, WHSSC or a national peer group.

Option 2: Regional-Level Group (new or existing)

- Option 2a: a new regional groups e.g. boards coming together to form a group to cover north and south Wales, or
- Option 2b: integrating the audit within an existing regional group e.g. Regional Planning Boards (RPBs)

Option 3: Local-Level Group (new or existing)

- Option 3a: establishing a new health board group, with either shared or individual Terms of References, that meet routinely to consider NMT guidance (similar to Medicine and Therapeutics Committees) or
- Option 3b: extended remit for an existing health board e.g. Medicines & Therapeutics/Medicines Management/Medical Devices Committees

Option 4: NICE Implementation Facilitator for Wales

- Build audit of key NMT guidance into the new NICE role e.g. replication use of existing NICE audit tools.

Option 5: Status Quo

- No change to the current way of working

Option 6: Combined Options

- Some combination of the above options e.g. a national oversight group working in combination with a local health board group. Specifically, the suggested option put forward was to have the All Wales Medical Directors peer group as the 'responsible body' who would take ownership of and promote the HTW audit with health board Medicine and Therapeutics Committees (MTCs) extending their remit to be the local health board group to be audited.

The options were discussed in light of the fact that, all options (except Status Quo) will:

- Be the responsible body for regularly receiving NMT Guidance from HTW & NICE.
- Agree a process to routinely consider HTW & NICE Guidance on NMTs.
- Ensure all key stakeholders are represented including industry, patients and the public.
- Ensure members have appropriate expertise on NMTs.
- Coordinate appropriate consideration and dissemination of HTW and NICE Guidance at their local level.
- Agree & disseminate 'Adopt or Justify' decisions & provide rationale underpinning those decisions.
- Coordinate an annual audit response to be submitted to HTW.
- Develop a process for considering priority NMT topics to refer to HTW for appraisal.

5. Conducting a SWOT analysis and appraisal of the options proposed

The short-list of four remaining options proposed to inform the potential design for the HTW audit function was shared with AAT&FG members in advance of their August 2019 meeting. Members were provided with a list of potential factors to consider, outlined in Appendix 6.

Members were asked to undertake a SWOT analysis of the shortlisted options and to record their key SWOT factors. Appendix 7 outlines the SWOT factors considered. Members were then asked to rank the shortlisted options based on how effective they would be a delivering against the purpose of the HTW audit.

6. Preferred option

Following extensive discussion, members unanimously coalesced around a dominant preferred option for the design of the HTW audit function, outlined below:

> **An existing national group working alongside an existing local health board group. Specifically, for the All Wales Medical Directors (AWMD) to be the national peer group overseeing the audit, with the existing health board Medicine and Therapeutic/Medicines Management/Device Committees extending their remit to be the local health board group that will undertake the annual audit return with the support of HTW.**

Given the unanimity of AAT&FG members' views, it was agreed to progress to seek support for the preferred audit structure option from key national peer and stakeholder groups.

7. Securing support from key national peer groups for the preferred audit structure

The AAT&FG shared their preferred audit structure with key national peer groups, requesting their endorsement and support. The All Wales Medical Directors (AWMDs) considered and endorsed the proposed audit structure at their July meeting (05.07.19) and agreed to be the national peer group overseeing and championing the HTW audit function. The Chief Pharmaceutical Officer (CPO) requested that the Chief Pharmacists consider the proposal at their October meeting (07.10.19). The Chief Executives Management Team (CEMT) also considered and endorsed the proposed audit structure at their October meeting (22.10.10). Finally the Directors of Planning (DoPs) considered and endorsed the proposed audit structure at their November meeting (08.11.19).

8. Targeted consultation, interviewing key stakeholders about the proposed audit option

Following endorsement from key national peer groups for the proposed HTW audit structure, HTW researchers undertook a series of semi-structured interviews with key stakeholders to gain feedback on the proposed audit structure. Specifically, interviewees were asked to consider: the strengths and weaknesses of the proposed audit structure; the main enablers and barriers to its successful implementation; and its likely feasibility and effectiveness in supporting adoption of HTW and NICE non-medicine technologies guidance.

Key informant interviews were held with a range of stakeholders, covering six of the seven Welsh health boards, and included a variety of senior healthcare professional and decision makers, including: Chairs/Vice Chairs of Medicines and Therapeutics Committees (MTCs) or alternative structures, Secretariats of MTCs, Clinical Directors of Pharmacy, senior representatives from Effective Clinical Practice, Procurement, Clinical Audit, Medical Devices Advisory Group and Welsh Government representatives.

The research instruments used to conduct the semi-structured interviews are outlined in Appendix 8, alongside a list of the job titles of the interviewees.

8.1. Emerging Themes

Thirteen semi-structured interviews were undertaken during November 2019. A thematic analysis of the transcribed interview data was undertaken, identifying and synthesising emergent themes. A detailed breakdown of the findings of these interviews can be found in Appendix 9. Of the thirteen interviews, representation was obtained from six of the seven local health boards, Welsh Government and procurement. Eight respondents held chair or secretariat functions within an MTC and two respondents held senior functions in the Medical Devices Advisory Group or Effective Clinical Practice Sub-Committees.

Seventy seven percent of the cohort suggested that HTW audit should not be undertaken by the existing MTCs, listing lack of resource and expertise as key arguments, in addition to concerns over-extending MTC remit and full agendas. Alternative suggestions included allowing each LHB to choose the most appropriate structure to undertake the HTW audit, since LHBs do not follow the same structures. Those in favour of the MTC remit extending to include non-medical devices (23%) noted that it is a clinical responsibility and it should come under the remit of clinicians. Furthermore, they noted MTC understands the structure and background of audits and MTCs have influence and membership would understand the landscape of each LHB.

The identified potential barriers of the proposed HTW audit structure revolved around three main categories, including time constraints, skill mix and expertise, and communication. All (100%) respondents acknowledged lack of time as a major barrier and eleven (85%) of the respondents felt that there is insufficient expertise and skill mix to deal with NMTs. Six (46%) of the respondents recognised effective communication and dissemination of information a barrier to ensure the running of the HTW audit.

With regards to the strengths and enablers to support the effectiveness of the proposed structure, fourteen main categories were identified. Twelve respondents highlighted that streamlining the processes to gather relevant information from already established groups and forums will be a key enabler for the function. Similarly, the importance of broader stakeholder engagement for the effectiveness of the function was acknowledged by twelve respondents. Eleven of the respondents acknowledged that access to data as well as the identification and collection of data for the HTW audit is pivotal to ensure the effectiveness of the function. This is in addition to eleven

interviewees who noted the importance of resource requirements. Furthermore, ten of the respondents recognised that having a recommended model of "best practice" of how to integrate and operate the HTW audit will be a key enabler. Additional strength and effectiveness contributors, included:

- Senior buy-in
- Financial implications
- "Adopt or Justify" Status
- Organisational Behavioural Barriers
- Target Audience
- Interactions with the Welsh Government
- HTW Work Programme
- Adherence to National Standards
- Management of Novel NMTs

Additional observations, individual opinions, recommendations as well as reasons, arguments and comments behind the central emerging themes can be found in Appendix 9.

9. Consultation on the draft report and recommendations

Drafts of this report and recommendations were shared with key internal stakeholders for comment, including: AAT&FG Members; The HTW Chair; HTW Accountable Officer; the HTW Steering Group; the HTW Appraisal Panel; The HTW Assessment Group; HTW Public Partners; and Welsh Government.

Following internal review and comment, any suggested improvements were made and then the report was shared with interview participants. The report was then placed on the HTW website.

Recommendations

The 2014 inquiry into 'Access to Medical Technologies in Wales' and the work of the HTW AAT&FG has highlighted that the current processes for considering guidance relating to the adoption of NMTs in Wales is not effective and has identified disparity in the consideration and implementation of guidance relating to medicine and non-medicine technologies in Wales with potential resultant inequities.

The HTW AAT&FG members offer the following recommendations to Welsh Government and the Minister for Health and Social Services, to discharge Recommendation 5 of the 2014 Inquiry outlined above and propose a design for the HTW national audit function that will introduce a systematic approach to facilitate routine consideration of key HTW and NICE non-medicine technologies guidance and realise their full potential in improving health and care outcomes across Wales:

1. The All Wales Medical Directors (AWMDs), with their remit for clinical effectiveness, should be the national peer group that oversees the HTW audit function.

2. Each local health board should extend the remit of their relevant local committee (Medicines and Therapeutic Committee/Medicines Management Committee/Medical Device Committee) to take on additional responsibilities to facilitate annual audit of the adoption and uptake of key HTW and NICE non-medicine technologies guidance.

It is acknowledged that there may be cross-cutting responsibilities between MTCs and other potential LHB groups. It is suggested they may wish to work in partnership and share skills and expertise as required.

Expanded responsibilities to be discharged by the relevant health board group, and considered for inclusion within their existing terms of reference, are suggested below, to ensure consistency of approach:

- Be the responsible body for regularly receiving NMT Guidance from HTW & NICE.
- Ensure members have appropriate expertise on NMTs.
- Co-opt in specialist skills as required to discuss the different types of NMTs.
- Ensure all key stakeholders are represented including industry, patients and the public.
- Agree a process to routinely consider HTW & NICE Guidance on NMTs.
- Coordinate appropriate consideration and dissemination of NMT guidance at their local level.
- Agree and disseminate their board's 'Adopt or Justify' decision regarding the adherence to HTW and NICE guidance, providing the rationale underpinning those decisions.
- Coordinate an annual audit response to be submitted to HTW.
- Develop a process for considering priority NMT topics to refer to HTW for appraisal.
- Ensure transparency in consideration of non-medicine technologies guidance.

3. Welsh Government should support utilising a range of mechanisms to encourage optimal adoption of NMTs, reduce the disparity in focus and differential adoption between medicine and non-medicine technologies within Wales, and incentivise compliance with the HTW national audit, including:

    - Defining the 'Adopt or Justify' status of HTW Guidance;
    - Consider giving the NICE MTEP (MTAC & DAC) Guidance 'Adopt or Justify' status to align it with HTW Guidance;
    - Consider the role of the new NHS Wales Executive in supporting the work of HTW and uptake of its national guidance;
    - Agreeing a process for the commissioning of NMTs supported by HTW guidance;
    - Supplementing the supporting guidance underpinning Health Care Standard (3.3) which outlines that 'care, treatment and decision making should reflect best practice based on evidence to ensure that people receive the right care and support to meet their individual needs', to highlight HTW guidance, its status and the required annual audit return.
    - Referencing the required HTW annual audit return within national and local IMTP planning processes;
    - Ensuring that HTW and NICE NMT guidance, that identifies efficiency savings for NHS Wales, is included on the Finance Delivery Unit's national efficiency framework and toolkit, and
    - HTW attendance at Efficiency Board meetings to present guidance where it is believed that Efficiency Board support is required to maximise potential efficiency savings and to deliver a system change.

4. HTW should discharge its remit regarding the adoption of non-medicine technologies across Wales through provision of operational and secretariat support for the new HTW national audit function.

5. NHS boards should identify and dedicate local resources required to support the relevant health board groups to expand their remit and terms of reference. The resources required will vary depending on existing capacity, knowledge and skills within individual health boards. Membership of the relevant existing local health board group should be supplemented to include expertise in:

    - Non-medicine technologies generally e.g. devices, diagnostics, procedures;
    - specific NMT expertise, co-opted as necessary;
    - procurement;
    - social care;
    - medtech industry, and
    - patients, carers and the public

6. Local Health Boards (LHBs) should identify resources to implement the new HTW audit function to ensure successful pilot, learning and full implementation.

7. That the HTW AAT&FG should be reconvened in summer and winter 2020 to evaluate the pilot introduction of the HTW audit and reflect on experience and learning to inform routine roll-out and implementation.

8. HTW should report to Welsh Government results of the implementation of the recommendations above and the pilot of the HTW audit function by the end of 2020.

9. HTW should collate the health board audit returns and prepare an annual report to the Minister for Health and Social Services, reporting on the adoption of priority HTW and NICE non-medicine technologies guidance, identifying differential adoption and the rationales provided to account for this.

Resources required

Additional resources will be required, at both national and local levels, to effectively pilot, evaluate, improve and fully implement the agreed HTW audit structure and associated recommendations.

- At local levels, the resources required will vary depending on existing capacity, knowledge and skills within individual health boards. Membership of the relevant existing local health board group should be supplemented to include expertise in:
    - Non-medicine technologies generally e.g. devices, diagnostics, procedures, with specific expertise co-opted as necessary
    - Procurement
    - Social care
    - Medtech industry
    - Patients, carers and the public

- At a national level, additional resources will be required to:
    - Ensure effective communication and dissemination of HTW and NICE NMT guidance to boards.
    - Ensure collaborative working between HTW and the relevant local health board committee.
    - Encourage partnership working and liaison between HTW, local health boards and the Regional Partnership Boards (RPBs) when the technologies under consideration are used in both health and social care settings.

- Develop and provide training and implementation support to the relevant local board committee on the consideration of NMT guidance.
- Provide project management and administrative support to the HTW secretariat to enable them to support health boards and discharge their national audit function.

An estimate of additional resources required to support coordination and implementation at the national level is outlined in Appendix 10. Note, while additional resource will be required to deliver the national HTW audit it should be noted that the recent HTW annual report estimated significant potential savings could result from adopting the first ten pieces of HTW guidance.

Ways forward

The AAT&FG make the following suggestions about how the recommendations can be successfully implemented:

- It is suggested that HTW should work with relevant Welsh Government colleagues to consider and agree:
    - The incentive mechanisms that can be deployed to facilitate enactment of the recommendations outlined and assist with the establishment, operation and monitoring of the HTW audit function.
    - The resources required, and their allocation, to support the extension of the relevant local health board groups' remit and operation of the HTW audit function.

- Health Technology Wales will:
    - Work with health boards to pilot the introduction of the HTW audit function.
    - Collaborate closely with the new NICE Implementation Facilitator for Wales to monitor the uptake of NICE NMT guidance.
    - Evaluate the pilot audit structure, canvassing feedback from the key stakeholders involved regarding the feasibility and effectiveness of the audit structure.
    - Reconvene the HTW Adoption Audit Task and Finish Group to consider the results of the pilot and any improvements required to support successful national implementation of the HTW audit function.
    - Raise awareness of the HTW audit function and its purpose among key health and care stakeholders across Wales.

Appendix 1: Key definitions

Non-medicine technologies (NMTs): refer to healthcare interventions other than medicines, and encompass a wide range of healthcare interventions, ranging from devices and diagnostic tests to changes in treatment pathways in health and social care.

Health Technology Wales (HTW): is a national body set up to provide assistance to care bodies when considering selected health technologies, excluding medicines. Its purpose is to "provide a strategic, streamlined and nationally coordinated approach to the identification, appraisal and adoption of medical technologies into practice across NHS Wales."[4]

HTW researches and evaluates the best available clinical and cost-effectiveness evidence about a health technology. Based on this evidence, we publish Guidance on whether the health technology should be adopted for use in Wales. The appraisal work informs commissioning by NHS Wales and care providers. HTW supports decision makers to make evidence-informed decisions on both technology investments and disinvestments. HTW works with partners across the health, care and technology sectors to ensure an all-Wales approach. HTW is funded by Welsh Government and hosted within NHS Wales, but is independent of both. The HTW Steering Group sets our strategic direction. The group ensures that we deliver against our remit that we are 'fit for purpose' and that Health Technology Guidance has national relevance for patient care in Wales. The HTW Assessment Group quality assures HTW work, ensuring methodological and scientific rigour in the Health Technology Wales processes. The HTW Appraisal Panel considers the Health Technology Wales appraisal evidence within the context of NHS Wales, and produces the Health Technology Wales guidance.

HTW Guidance: outlines in as consistent a manner as possible, the view of HTW on the clinical effectiveness, safety and cost effectiveness evidence for the technology in question in the context of Wales. HTW issues authoritative Guidance with the status us 'Adopt or Justify'. HTW Guidance does not override the individual responsibility of health professionals to make decisions. Guidance does not only includes uptake of new health technologies, but also disinvestment in current health technologies that are found to be less effective or obsolete.

National Institute for Health and Care Excellence (NICE): The National Institute for Health and Care Excellence (NICE) was formed in 1999, to create a single excellence–in-practice organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill-health. In April 2013, NICE was established in primary legislation, becoming a Non Departmental Public Body (NDPB) with statutory duties outlined in the Health and Social Care Act 2012. As a NDPB, NICE is accountable to its sponsor department, the Department of Health and Social Care, but is operationally independent of government.[5]

NICE guidance: NICE produces a range of non-medicine technology guidance through its Medical Technologies Evaluation Programme (MTEP) e.g. through its Medical Technologies Advisory Committee (MTAC) and Diagnostics Advisory Committee (DAC). Welsh Government has a service level agreement with NICE that allows Welsh care systems to utilise NICE guidance. However, this guidance has no official status in Wales and is shared 'for information' only.

[4] Response to Recommendations from the Health and Social Care Committee: Inquiry into Access to Medical Technologies in Wales. February 2015.
[5] https://www.nice.org.uk/about/who-we-are

Appendix 2: Membership of the HTW Adoption Audit Task & Finish Group (AAT&FG) and its terms of reference

Membership

The team comprised senior representatives from a range of key NHS Wales stakeholder groups, Welsh Government and NICE, supported by the HTW secretariat, including:

Susan Myles	Chair, Director Health Technology Wales
Jennifer Thomas	All Wales Medical Directors
Julie Keegan	Directors of Planning
Pete Phillips	Evidence Based Procurement Board
Andrew Smallwood	NHS Wales Shared Services Partnership
Timothy Kelland	NHS Wales Finance Delivery Unit
Karen Samuels	All Wales Therapeutics & Toxicology Centre
Andy Champion	Welsh Health Specialised Services Committee
Phil Routledge	Independent expert
Alan Meudell	Patient and Public Involvement representative
Abi Phillips	Welsh Government

In Attendance:

Julie Vile	NICE Implementation Facilitator for Wales
Heather Stephens	NICE Senior Medical Technology Implementation Manager
HTW Secretariat	Sarah McAllister

Technoleg Iechyd Cymru
Health Technology Wales

HEALTH TECHNOLOGY WALES (HTW) TERMS OF REFERENCE[1]

HTW Adoption Audit Task & Finish Group

Effective Date	13/08/2019
Approved By	
Review Date	January 2020
Lead Author	Director, Health Technology Wales
Version	Final Draft

[1] This is a living document and therefore subject to change. It will be reviewed and updated annually, or sooner if required.

Appendix 2 continued

1. BACKGROUND

In September 2017, Vaughan Gething, Cabinet Secretary for Health Wellbeing & Sport, wrote to all NHS Wales Chairs regarding the uptake of sacral nerve stimulation devices across the country. In his concluding remark he noted:

"...I would like to see a consistent approach across Wales, so that all Welsh patients have equitable access to services. You should be aware that, following the Inquiry into Access to Medical Technologies in Wales, the adoption of guidance across NHS Wales will be regularly audited by the newly formed, Health Technology Wales."

2. PURPOSE

1. To maximise the adoption & impact of HTW & NICE (National Institute of Health and Care Excellence) guidance by establishing a visible focus point or 'landing zone' & a process to facilitate routine consideration of guidance on NMTs, and

2. To focus on the 'Adopt or Justify' status of the guidance and design a process that will enable us to audit the uptake and impact of HTW & NICE Guidance.

3. SCOPE AND DUTIES

- Agree the objectives and scale of the HTW adoption audit framework.
- Establish a visible focus point and a process to facilitate routine consideration of guidance on NMTs.
- Outline a range of potential options re the design of the HTW adoption audit framework.
- Consider the pros and cons of the different options.
- Agree whether the audit should include all or selected non-medicine technologies. If the latter, propose how technologies should be selected for audit
- Consult with key stakeholders on a short list of adoption audit options.
- Agree the adoption audit monitoring and review processes.
- Agree reporting format and frequency to health boards and Welsh Government
- Reconvene to monitor progress of HTWs adoption audit system(s).

4. DELEGATED POWERS AND AUTHORITY

Health Technology Wales (HTW) was established by Ministerial recommendation to support a strategic, national approach to the identification, appraisal and adoption of non-medicine health technologies into health and care settings.

Please refer to HTW Terms of Reference and Operating Arrangements.

5. MEMBERSHIP

HTW Adoption Audit Task & Finish Group brings together strategic stakeholders with expertise and knowledge required to propose and consider a range of options to arrive at an effective design for HTWs adoption audit model.

Members:

- Director HTW (Chair)
- Senior NHS Wales representatives, including

- Director of Medicine
- Director of Planning
- EBPB representative
- Procurement representative
- Finance Delivery Unit representative
- AWTTC/AWMSG
- Welsh Health Specialised Services Committee
- Performance and Information representative
- Patient and Public Involvement representative
- HTA expert - Phil Routledge
- WHSSC representative

In Attendance:

- Welsh Government representative as HTW Sponsor
- NICE Implementation Facilitator for Wales
- HTW Secretariat

6. MEMBER APPOINTMENTS AND SUPPORT

The membership of the Adoption Audit Task & Finish Group shall be determined by the Accountable Officer, HTW Chair and HTW Director.

Members shall be appointed for a maximum four meetings, followed by a review meeting. Members are expected to commit to attend all of the meetings. During this time a member may resign or be removed by the HTW Management Team.

7. MEETINGS

Quorum

At least 50% of the members (or nominated deputies) must be present to ensure the quorum of the Group.

Frequency of meetings

It is expected that the Adoption Audit Task & Finish Group shall meet a maximum of four times.

In addition, a review meeting will be scheduled one year after completion of the task and finish group's work, after the adoption audit system has been trialled, to assess whether it is achieving its objectives and is 'fit for purpose'.

Teleconference dial-in facilities will be available for members/deputies unable to attend in person

8. RELATIONSHIP & ACCOUNTABILITIES

The Adoption Audit Task & Finish Group shall embed Velindre NHS Trusts corporate standards, priorities and requirements through the conduct of its business.

Appendix 2 continued

9. CONDUCT OF MEETINGS

The HTW secretariat will determine which items appear on the agenda in consultation with the HTW Director. Group members may also submit items for consideration. Any member wishing to have an item considered for an agenda should notify the secretariat (healthtechnology@wales.nhs.uk) at as early a date as possible.

The agenda and papers will be circulated to members at least 5 working days in advance of meetings. The order of business will normally follow the agenda but will finally be determined by the Chair. Tabled papers may be accepted with the express agreement of the Chair and only in exceptional circumstances.

No other business will be discussed at the meeting, unless permitted by the Chair.

Unconcluded items will be carried forward to next meeting or concluded electronically.

An action note from the meeting will be drawn up by the HTW secretariat, on behalf of the HTW Director.

10. REPORTING AND ASSURANCE ARRANGEMENTS

An update on the work of the Adoption Audit Task & Finish Group will be presented at forthcoming meetings of the HTW Steering Group.

11. REVIEW

These terms of reference shall be reviewed and agreed at the first meeting of the Adoption Audit Task & Finish Group.

Appendix 3: Model options and methodology

Information gathering

The first step involved gathering information and learning from experience (in local, national and international settings). Information on relevant local and national experience was gained through the expertise and experience of AAT&FG members and key informant discussions. Organisational and country experience was obtained through a survey of members of the INAHTA as well as discussions with key informants in local and national settings. An initial set of model options for the HTW audit structure was formulated based upon consideration of the information gathered.

SWOT analysis and option appraisal

A range of potential options for the design of the HTW audit function was shared with AAT&FG members for consideration, in advance of their August 2019 meeting. Members were asked to consider the strengths, weaknesses, opportunities and threats posed for each option while considering their feasibility and effectiveness. Members discussed the SWOT analysis and unanimously coalesced around a dominant preferred option. Given the unanimity of members' views it was agreed to progress by discussing the merits of this option in the stakeholder interviews.

Semi-structured interviews

The dominant preferred option emergent from AAT&FG deliberations was shared with key senior stakeholders, including chairs of the 7 health board Medicines and Therapeutics Committees/Medicines Management Committees and a variety of healthcare professionals and decision-makers. Thirteen semi-structured interviews were undertaken during November 2019. Interviewees were asked to consider the likely feasibility and effectiveness of the model prosed and for their views on the strengths and weaknesses of the audit structure proposed and the factors likely to act as enablers or barriers to its implementation. A thematic analysis of the interview data was undertaken identifying and synthesising emergent themes.

Appendix 4: Mixed methods approach to designing the HTW audit function

METHOD	ANALYSES	INPUT	TIMELINE
Aim 1: Formulate a range of options for the HTW audit function			
Formulate options	Discussion & identify examples from other areas	AAT&FG Members	June AAT&FG (11.06.19)
Review of other systems and HTA agencies	Review of INAHTA listserv responses	INAHTA agencies & HTW Researchers	June & July: INAHTA listserv query
Aim 2: Conduct a SWOT analysis and appraisal of the options proposed			
Option appraisal	SWOT analyses, rating and ranking the options	HTW Researchers; AAT&FG members; AG & AP committees	August & September: Discuss at- AG (02.07.10); AP (30.07.19); AAT&FG (13.08.19)
Aim 3: Consult on the preferred shortlisted option			
Semi-structured interviews	Thematic analysis	HTW Researchers; AAT&FG members; SG, AP & AG members; Chief Executives Management Team (CEMT); Key stakeholders	October & November: Data collection & analysis. Discuss at – AP (30.07.19); AG (06.08.19); AAT&FG (22.10.19); CEMT (22.10.19)
Aim 4: Draft report & recommendations & share with HTW SG, AG, AP & WG			
AAT&FG draft report	Narrative and Formulate & finalise recommendations	HTW Researchers; AAT&FG members; SG, AP & AG comments; Key stakeholders	November & December: Data collection & analysis; Consultation; Draft report & recommendations Discuss at – AP (26.11.19); SG (26.11.19); AG (03.12.19); AAT&FG (10.12.19)
Aim 5: General consultation			
Draft report & recommendations	Review comments on final draft report & recommendations	AAT&FG members; SG, AP & AG comments; Key stakeholders feedback session; General stakeholders	December & January: Final draft report & recommendations. Discuss at – AG (03.12.19); AAT&FG (10.12.19)
Aim 6: Finalise report post consultation with key stakeholder & agree pilot			
AAT&FG final report	Review and assimilate comments. Finalise recommendations . Agree & plan pilot.	AAT&FG members & HTW researchers	January 2020: Finalise report AAT&FG (10.12.19); AAT&FG (03.02.20) 2020 Q1:Initiate pilot

AAT&FG – Adoption Audit Task & Finish Group; **AG** - HTW Assessment Group; **AP** - HTW Appraisal Panel; **SG** – HTW Steering Group; **WG** – Welsh Government.

Appendix 5: Responses received form the International Network of Agencies for Health Technology Assessment (INAHTA)

To learn from international experience and inform the design of HTWs audit function, HTW circulated a question around the INAHTA listserv as follows:

INAHTA listserv question: Health Technology Wales is a new HTA body that provides national guidance on non-medicine technologies (any health technology other than medicines). As part of our remit, we have been asked to design an audit function to monitor the adoption of our guidance. To help inform the design of its audit function, Health Technology Wales would like to learn from systems used in other countries. We would be grateful if you could answer the question below:

What systems, mechanisms or methods are used in your country to audit the adoption of guidance on non-medicines technologies within local health systems?

Outcome: Seven agencies responded and are outlined below.

Results: Only one of the seven national HTA bodies that responded, Singapore, had a mechanism to audit the adoption of guidance on non-medicine technologies.

DEFACTUM, Denmark	In Denmark we do not have a system or guidelines on monitoring the adoption of guidance but we are discussing some of the same issues, so we would also be interested in the result of this listserv question.
HIS, Scotland, UK	we don't have anything worked up enough to share at present, but Jess Kandulu, our project officer, and copied into this email, would be very happy to have a chat with Susan some time about what she has been doing in this area.
ACE, Singapore	ACE tracks utilization of medical technologies that have been evaluated and approved for government subsidy and their impact on clinical practice and patient outcomes. In cases when an unusual pattern of utilisation is observed or there is insufficient data for utilisation tracking, ACE may conduct an Appropriateness Review (AR) to better understand the observed trend. The AR involves the review of case-level information to determine if the use of the medical technology is in line the appropriate use criteria in ACE's guidance. It will report on the percentage of cases adhering to the criteria, and provide review findings where non-adherence is observed. In instances of non-adherence, the results will be shared with the affected healthcare institution for explanation. The healthcare institution is then expected to provide recommendations on corrective and preventive actions. In instances where serious findings are reported, repeated reviews and stakeholder engagement will be conducted to ensure that the identified gaps at the affected healthcare institution are closed.
G-BA, Germany	To my knowledge, Germany does not employ such an audit system.
CDE, Taiwan, Republic of China	CDE/HTA, Taiwan does not provide national guidance on non-medicine technologies. However, for the Benefits package of National Health Insurance Administration, a regular audit operation system has been built by NHIA to tackle waste and inappropriate treatment. For example, NHIA, through the expert review, asks physicians to review the medical sampling chart. NHIA is also using

	AI to detect improper procedures as well. NHIA refuses the payments if procedures are inappropriate.
SBU, Sweden	The Swedish HTA agency, SBU, does not provide national guidance on non-medicine technologies. The National Board of Health and Welfare is responsible for this in Sweden.
INESSS, Québec, Canada (Marie-Hélène Chastenay)	I finally had a chance to ask our scientific directors and they told me we are contemplating auditing the adoption of guidance on non-medicines technologies, as an emerging practice, but for now we only do so a little bit for the implementation of norms for Transcatheter aortic valve implantation (TAVI).

A similar INAHTA query was circulated by Healthcare Improvement Scotland in 2017. Twenty national HTA agencies responded at that time: two had a structured process; six had processes in development; and twelve, the majority, reported no process existed.

Response	Yes	Somewhat	No
Countries	Republic of Lithuania, New Zealand	Wales, Northern Ireland, Australia, Finland, Brazil, Austria	England, Germany, Sweden, France, Uruguay, Canada, Colombia, Luxembourg, Switzerland, Portugal, Czech Republic, Denmark
Number of countries	2	6	12
Proportion (%)	10	30	60

New Zealand: An independent statutory body (the National Health Committee) is responsible for prioritising new and existing health technologies and making recommendations to the Ministry of Health. An implementation framework is built into each assessment. The framework ensures buy-in from all stakeholders and provides a logical and practical sequence of actions and utilises both formal and informal levers to achieve the best outcome.

Republic of Lithuania: The State Health Care Accreditation Agency (VASPVT) under the Ministry of Health is responsible for co-ordinating and implementing health technology assessments on medical devices. A committee on health technology assessments ensures appropriate dissemination within the health sector and society, and form trends of assessment, deployment and application for the technology.

Summary: Very few of the responding countries reported having a mechanisms to audit the adoption of national guidance on non-medicine technologies. HTW followed up contacts from Singapore, New Zealand and Lithuania to identify any potential learnings for Wales.

Further INAHTA Responses

A direct contact was attempted with the three identified countries representatives through INAHTA in order to obtain more information regarding the backbone/design of the audit system for the adoption of issued guidance following HTA. The built framework of the processes that were constructed around the audit function was also required from the representatives.

The contacted representative for Lithuania was Vitalija Mazgele from The State Health Care Accreditation Agency under the Ministry of Health of Lithuania (VASPVT). His response indicated

that VASPVT is responsible for organising and producing health technology assessment related to medical devices and VASPVT is no longer a member of the INAHTA organisation. VASPVT is an associated partner of EUnetHTA project and has the right to use the products created by EUnetHTA, including HTA Core Model, Methodology and the HTA Adaptation Toolkit. He indicated that at the moment there was nothing he could further help with. A further email was sent to Vitalija highlighting that VASPVT could have similar remit to HTW and that was the reason we were eager to learn more about the design of their audit function for the implementation of the appraised health technology in local health boards. Vitalija re-iterated that his work only covers the assessment of health technology and he does not have any information regarding the audit function for the implementation of such technologies. He suggested that he could redirect the query to the relevant people if he could obtain more information; however, no further response was received.

Fiona Pearce, the Deputy Director and Senior Lead Specialist of the Agency for Care Effectiveness (ACE) was contacted as the representative for Singapore. Fiona forwarded our query to Chris Foteff who runs the Medical Technology Evaluation work stream at ACE. Chris indicated that ACE measures adoption through qualitative and quantitative means. The quantitative means entail that the adoption was measured through electronic tracking utilisation with data extracted from existing databases using the ICD-10 diagnosis codes, table of surgical procedures codes and diagnostic-related groups. He indicated that in some instances manual tracking of utilisation is employed if the data is not captured electronically. In these situations this highlights interim solution to future IT enhancements. The qualitative measures of the adoption audits is conducted through chart reviews. In the case that unusual patterns of utilisation are depicted or if there is insufficient data for the utilisation review an Appropriateness Review (AR) is triggered. The AR is typically conducted as a chart review of all treated patients who received a subsidy for the technology in question. Depending on the scope and findings of the AR certain consequences arise from the AR. Some of this information was summarised in the original INAHTA listserv response.

In regard to New Zealand, the National Health Committee was identified in the INAHTA listserv to be the relevant authority to be scrutinised for the technology implementation framework. However, the National Health Committee was disestablished in March 2016 and their functions were streamlined into the Ministry of Health. After further enquiring INAHTA about the relevant person/authority that should be contacted, it was suggested that Alun Cameron from the Health Technology Reference Group (HTRG) for Australia and New Zealand was the best representative. Alun indicated that HTRG is not involved in the implementation or audit of the decisions at jurisdictional level (Australia and New Zealand) as this varies from place to place and operational matters at this level are often not widely broadcasted. He required more information regarding the original INAHTA listserv in order to follow up with more detail; however, no further response was received.

Appendix 6: Factors to consider in SWOT analysis and option appraisal

Feasibility	• ability to enable routine consideration & adoption of guidance • resources (people, time & costs) required
Stakeholder engagement	• involving all relevant stakeholders, including patients & industry • scope for public awareness & engagement • visibility & transparency
Effectiveness	• ability to enable routine consideration & adoption of guidance • need for a body(ies) with clear focus & remit • adequate expertise • reduced variation & duplication across boards
Authority	• independence of group(s) • authority to influence decision making • consistency of information & guidance
Local ownership & decision making	• flexibility for local systems • local decision making & control • local prioritization & adoption
Accountability	• coordination & organization • transparency • ease of assessment, monitoring & evaluation
Equitable access	• opportunity to obtain & use NMT information & guidance • consistency of information, guidance & adoption

Appendix 7: Factors raised during the AAT&FG members SWOT analysis of the shortlisted options

SWOT Option	Strengths (Internal)	Weaknesses (Internal)	Opportunities (External)	Threats (External)
1b Existing national group	Already established structure Authority of a national group Independence from boards National profile and voice Draw on existing expert resources Coordinated approach Ensure equity with consistent approach DU – already auditing take up of WG Alerts. Rely on current groups within health boards. Already have links into HBs and HBs understand requirement to report to DU. (It's in the name!) Fresh canvass	Lack of local ownership Less able to facilitate local adoption & implementation Possible clash with existing remit of national group Less accountability Cost and time pressures on existing staff. Social care input. More work for HB groups. Take time to develop skills etc. No local ownership Difficult to get into anyone's remit. Resourcing issues. Time to develop skills.	Raise profile of HTW Feasible Join reputational forces with HTW Coordinate activities & learning across boards Could speed up equitable adoption across the boards Visibility re stakeholder engagement Improve transparency Flexibility	Ensuring link between national & local decision making Possibly less ownership locally in boards Identifying resources required within existing budgets Resource requirement for DU? Advisory only. Governance issues; no clear authority to make decisions.
3a New health board group	Clear, new remit & focus re NMTS Maintains board autonomy Promoted local prioritisation & decision making	Onerous for boards to establish a new group Finding resources (time, people) Finding correct expertise	Local focus Clear 'landing zone' Improve local engagement re NMTs Increased visibility of HTW appraisals	Resource constraints Potential for differential decision making and potential inequity Less visibility than a national group.

	Flexibility for local systems to design their own system. Advantage that it would be specific for this role. Fresh canvass.	Potential for local variation and duplication No buy-in. Who wants to do this on top of their normal job? Extra resource. Even if set up would people turn up? (Mainly those who want to use the new technology or who want to defend their use!) Another group for Procurement to attend! Little leverage. No national component. Feasibility of getting required skills. Duplication of effort. Local differences.	Potential to engage with RPBs through local board groups. Good way to refer priority topics back to HTW. Flexibility.	Less transparent. Duplication. Disempowerment. Feasibility of getting buy in. Additional costs. Securing new funding could prove difficult. Less transparent process. Little leverage.
3b Extended remit for an existing health board group	Structure already there Local ownership Build on existing expertise Existing stakeholder engagement Combine with 1b – this is a model already in place.	Differential approaches across boards Potential lack of transparency/visibility Extending remit too big an ask Resourcing extra work Recruiting NMT expertise	Raise awareness of NMTs locally. Parity between medicine & non medicine decision making. Local prioritisation & ownership. Avoidance of duplication.	Inadequate consideration of NMTs. Lack of independence. Potential lack of authority. Potential for differential access across boards. Small pool of expertise. Dilution of expertise.

	NHS Wale governance e-manual section 3.3 “Quality Improvement, Research and Innovation“ says “Local capacity and capability is developed to support and enable teams to identify and address local improvement priorities, including participation in audit and recognised quality improvement methodologies, activities and programmes. Speed	Potential duplication of effort across boards Potential conflicts of clinical interest Which group? Medical Devices Committee or Quality and Safety Committee or MTCs? Less flexibility. Merit in adapted structure but lack of national oversight. Dilution of expertise. Less flexibility.		Link with national decision making? Governance issues. Less transparent processes.
6 National & local group Combined effort of AWMDs and MTCs	Already established structures (national & local). Authority, visibility & transparency of a national group. Independent oversight of national group of the boards. Reduction in differential approaches across boards. National & local profile & ownership. Draw on existing expertise. Coordinated approach.	Possible clash with existing remit of national & local groups. Extending remit too big of an ask. Diluted accountability. Cost and time pressures on existing staff. Resourcing extra work. Recruiting NMT expertise. Social care input.	Good visibility. Clear ‘landing zone’. Improved transparency. Improved consistency & decision making. Raise awareness of NMTs nationally & locally. Improved parity between medicine & non medicine investments &decision making.	Read across between national & local decision making. Reduced flexibility for local boards. Conflict between national and local priorities. Identifying resources required within existing budgets. Perceived lack or dilution of independence.

	Ensure equity with consistent approach. Combine national & local stakeholder engagement. Jointly agree priority topics to refer to HTW to secure national guidance. National & local ownership. Get into the mainstream. Division of labour. Avoids duplication. Existing transferable skills. No need to set up a completely new system. National involvement required to give gravitas & governance. Need local involvement to achieve delivery. Authority. Transparency & visibility. Independent oversight. One consistent agreed approach. Not being imposed. Ensure equity.	Problem is very little interest or expertise in the devices field? How to address? More bureaucracy? Staffing and funding key challenges.	Raise profile of all bodies HTW, national & local groups. Feasible. Divide and conquer. Join reputational forces. Coordinate activities & learning across boards. National & local prioritisation & ownership Reduce variation across boards. Could speed up equitable adoption across the boards. Visibility re stakeholder engagement. More leverage with NHS Wales.	Unequal leverage compared with medicines (mandatory versus advisory).

Internal factors: the *strengths* & *weaknesses* internal to the option and

External factors: the *opportunities* & *threats* presented by factors external to the option

Appendix 8: Semi-structured interviews research instruments

The research instruments used include:

- Interview Invitation Letter
- Interview Briefing Paper
- Informed Consent Form
- Interview Guide

The analysis reflected collated views from:

- Chairs/Vice Chairs of Medicines and Therapeutics Committees (MTCs) or alternative structures
- Secretariats of Medicines and Therapeutic Committees (MTCs)
- Clinical Directors of Pharmacy
- Senior representatives from Effective Clinical Practice, Procurement, Clinical Audit, Medical Devices Advisory Group, and
- Welsh Government representatives

Appendix 8 continued: Interview Invitation letter (page 1)

Technoleg Iechyd Cymru
Health Technology Wales

Date:
Reference:
Direct line:
E-mail: susan.myles@wales.nhs.uk

Dear ,

Support for the Health Technology Wales Audit Function

I am writing to invite you to participate in a brief (30 minute) interview to discuss the Medicines and Therapeutics Committees/Medicines Management Committees role in supporting the Health Technology Wales (HTW) function to audit the uptake of both HTW and NICE non-medicine technologies guidance.

The aim of the HTW audit is to maximise the adoption of non-medicine technologies across Wales that have been supported by evidence-based guidance from either HTW or NICE.

The 2014 Welsh Government inquiry into 'Access to Medical Technologies in Wales' recommended the establishment of Health Technology Wales to provide a strategic, streamlined and nationally coordinated approach to the identification, appraisal and adoption of medical technologies. Central to HTWs remit is the production of national guidance on the adoption of non-medicine technologies.

The inquiry also requested that the uptake of recommended medical technologies across Wales, including those recommended by NICE, is measured as part of a formal audit process. In September 2017, Vaughan Gething, Cabinet Secretary for Health Wellbeing & Sport, wrote to all NHS Wales Chairs noting that '*...following the Inquiry into Access to Medical Technologies in Wales, the adoption of guidance across NHS Wales will be regularly audited by the newly formed, Health Technology Wales.*"

Health Technology Wales established an Adoption Audit Task and Finish Group that formulated, considered and ranked a number of potential options to inform the design of its audit function. Further information on this is outlined in the briefing paper enclosed.

A dominant preferred option emerged from this work as follows:

- **A national group working alongside existing local health board groups.** The specific option proposed was for the All Wales Medical Directors (AWMD) to be the national peer group overseeing the audit, with the existing local health board Medicines and Therapeutics Committees/Medicines Management Committees extending their remit to be the local health board group that will undertake the audit with the support of HTW.

Appendix 8 continued: Interview Invitation letter (page 2)

Technoleg Iechyd Cymru
Health Technology Wales

The AWMDs have agreed to act as the national peer group to support the HTW audit and the Chief Pharmacists have agreed that the Health Board Medicine and Therapeutics Committees/Medicines Management Committees take on the role as the local Health Board group assisting with the HTW audit.

Please indicate if you are willing to participate in a brief interview by 4th November 2019. If you are able to participate the HTW Secretariat will contact you to arrange a convenient interview time prior to the 15th of November. A copy of the interview guide has been shared with you in advance for your consideration. If you are unable to participate in person we could alternatively arrange for the interview to be conducted by telephone. If a telephone interview is not suitable either, we would be most grateful if you could nominate another colleague to be interviewed.

Thank you in advance for your consideration and assistance.

Yours faithfully,

Dr Susan Myles
Director, HTW

Enc: Interview Invitation Letter
Interview Briefing Paper
Informed Consent Form
Interview Guide

Appendix 8 continued: Interview briefing paper (page 1)

Technoleg Iechyd Cymru
Health Technology Wales

A Proposal for Auditing the Adoption of Non-Medicines Technologies Guidance from Health Technology Wales (HTW) & the National Institute for Health & Care Excellence (NICE)

SITUATION

HTW has been asked by Welsh Government to audit the uptake of HTW and NICE Guidance on non-medicine technologies (e.g. devices, diagnostics, procedures and models of care). It is estimated that this will involve audit of up to 20 pieces of guidance per annum.

HTW has been working with key national stakeholders, considering a range of options for the design of HTWs audit function. A preferred proposed structure for the HTW audit has emerged as follows:

- The **All Wales Medical Directors** to be the national peer group overseeing the audit, with the existing health board **Medicine and Therapeutic Committees/Medicines Management Committees** extending their remit to be the local health board group that will undertake the audit with the support of HTW.

We would be most grateful if you would agree to be interviewed to feed in your thoughts on the audit structure proposed; specifically its likely feasibility and effectiveness to deliver an audit function that will support the adoption of HTW and NICE non-medicine technology guidance and assess its uptake and impact in Wales.

BACKGROUND

The differences between the evidence assessment and guidance processes for medicines compared to non-medicine technologies (NMTs) are well known. The scale is very different with approximately 60-80 new medicines on the market annually compared to thousands of devices and other NMTs.

However, despite the scale and the regular production of NMT evidence assessment and guidance at both Wales and UK levels, Health Boards appear not to have a systematic way of managing the results to expedite equitable adoption and realise potential health gains and efficiencies across the Welsh care sector. This contrasts with medicines guidance which is automatically considered by Medicines and Therapeutics Committees/Medicines Management Committees who manage the process of interpretation and implementation supported by mandatory guidance, funding directives and well-defined national systems e.g. AWMSG, the One Wales Interim Commissioning Process and New Treatment Fund.

In 2014, Welsh Government conducted an inquiry into 'Access to Medical Technologies in Wales.' [1] The Chair of the inquiry noted in the report foreword: "Evidence to our inquiry suggests one overarching conclusion: Wales lacks a strategic, coordinated approach to technology evaluation and adoption." [2] A number of recommendations emerged from the inquiry aimed at improving access to medical technologies. The two key recommendations pertaining to the establishment of Health Technology Wales, and the requirement for it to establish an audit function to monitor guidance on the adoption of non-medicine technologies across Wales, were as follows:

Appendix 8 continued: Interview briefing paper (page 2)

Recommendation 3. That the Minister for Health and Social Services, within 12 months of the publication of this report, should develop options for an **all-Wales medical technologies appraisal mechanism**, to undertake a similar function in respect of medical technologies as the All Wales Medicines Strategy Group (AWMSG) does for medicines.

Recommendation 5. That the Minister for Health and Social Services should **ensure that the uptake of recommended medical technologies across Wales, including those recommended by NICE, is measured as part of a formal audit process.**

Subsequently, In September 2017, Vaughan Gething, Cabinet Secretary for Health Wellbeing & Sport, wrote to all NHS Wales Chairs regarding the uptake of sacral nerve stimulation devices across the country. [3] In his concluding remark he noted:

"...I would like to see a consistent approach across Wales, so that all Welsh patients have equitable access to services. You should be aware that, **following the Inquiry into Access to Medical Technologies in Wales, the adoption of guidance across NHS Wales will be regularly audited by the newly formed, Health Technology Wales.**"

Health Technology Wales (HTW) was established in November 2017. HTWs purpose, as outlined in its funding award, is as follows:

"...to provide a strategic, streamlined and nationally coordinated approach to the identification, appraisal and adoption of medical technologies into practice across NHS Wales."

ASSESSMENT

A critical step in the adoption and spread of technological innovation is an agreed process to facilitate and monitor routine consideration, uptake, (de)commissioning and implementation of evidence-based guidance.

HTW has capacity to produce up to 15 rapid evidence appraisals with associated guidance for care services in Wales per annum. To date, HTW has produced ten pieces of guidance on non-medicine technologies (https://www.healthtechnology.wales/reports-guidance/). Consequently, it is now timely for HTW to turn its attention to its adoption remit generally and its required audit function specifically.

RECOMMENDATIONS

Interviewees asked to:

- Consider this briefing and the key issues outlined above.
- Participate in a brief (30 mins) semi-structured interview to inform development of the HTW audit function.

References

1. HTW Adoption Audit Task & Finish Group. June 2019.
2. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.
3. Gethin, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.


20190527_HTW ToR Adoption Audit Task

2014 WAG Report.pdf


VG_01655_17 - Letter to all HB CHairs re Fu

Appendix 8 continued: Interview Consent Form

Technoleg Iechyd Cymru
Health Technology Wales

Developing the Health Technology Wales Audit Function

Please read each statement and indicate your consent to participate in an interview by initialling each box and signing your name at the bottom.

	Initial here
I have received information about the interview (briefing note).	
I have had enough time to consider this information.	
I understand that I can choose whether or not I will take part in the interview.	
I understand that even if I decide to participate now, I can stop at any time and opt out of further processing of any information provided.	
I understand that the interview will be recorded and notes will be taken.	
I understand that any information collected during the interview will be anonymised before analysis.	
I agree to take part in the interview and give permission for my contribution to be anonymously included as part of the final report.	
I would like to receive the final report of this work.	

Health Technology Wales will not share your personal data with third parties outside of our contractual or legal obligations without your consent. Please read our Privacy Policy for complete information about how we process your personal information.

I have read the Privacy Policy and agree that Health Technology Wales can contact me.

I give consent for Health Technology Wales to share my details with relevant stakeholders who are involved in Health Technology Wales' internal processes.

Signature:	
Name:	
Date:	

Please complete and return one signed copy of this consent form.

Appendix 8 continued: Interview Questions and Prompts

Interview questions and prompts

Developing the Health Technology Wales audit function (30 minutes)
I will ask four questions, some of which we will discuss for longer than others. Our discussion will be focused on the proposed HTW audit structure provided in the briefing paper shared with you in advance.

Question 1: (10 minutes) **What do you consider to be the strengths & weaknesses of the proposed audit structure?**
Prompts: • What are the **strengths** of the proposed audit structure? Visibility, accountability, clarity, combined local/national ownership, improving equity, improving patient care? • What do you **like best** about the proposed audit structure? • What are the **weaknesses** of the proposed audit structure? Communication, resourcing, securing ownership & engagement. • What do you **like least** about the proposed audit structure? • What are the **biggest problems or challenges** associated with the proposed audit structure? • Why do you think the proposed audit structure **will, or will not**, work in Wales?
Question 2: (10 minutes) **What do you consider to be the main enablers and barriers to the successful implementation of the proposed HTW audit structure?**
Prompts: • **Enablers**: Transparency, skill mix, experience dealing with guidance, stakeholder engagement, efficiency, improving consistency & equity? • **Barriers**: Authority, ability to influence decision making, expanding ToRs, adequate expertise, capacity, resourcing issues, implementation support, meaningful stakeholder engagement, communications? • Are there any **changes or modifications** that you think could improve the effectiveness of the audit structure proposed?
Question 3: (5 minutes) **How effective do you think the proposed HTW audit structure will be in assessing the uptake of HTW and NICE non-medicine technology guidance in Wales?**
Prompts: • Facilitating adoption, clear focus & remit, adequate expertise, national/local ownership, authority, accountability, feasibility, resources (people, time costs) engagement, ownership, equity.
Question 4: (5 minutes) **Is there anything else we haven't discussed yet that you think is important for us to know about or consider as we develop the HTW audit process?**

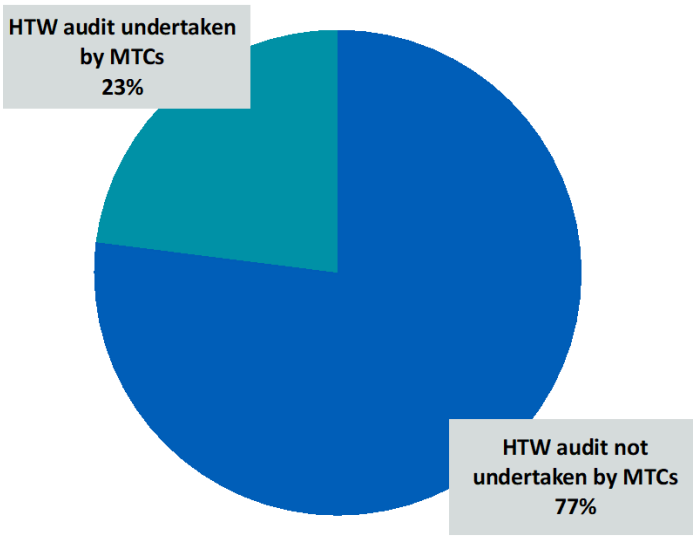
Appendix 9: Interview Analysis

1. Interviewees

A total number of thirteen interviews were conducted in November 2019. Representation was obtained from six out of the seven Local Health Boards. The analysis to date reflects collated views from:

- Chair/Vice-Chair of a Medicines and Therapeutic Committee (MTC) or alternative structure
- Clinical Director of Pharmacy
- Secretariat of MTC or alternative structure
- Clinical Audit
- Effective Clinical Practice
- Procurement
- Medical Devices Advisory Group
- Welsh Government

2. Ownership of the HTW Audit



Ten (77%) of interview respondents believed that the HTW audit **should not** be undertaken by the MTC held chair or secretariat functions within the MTC. The reasons and arguments behind the views that the HTW audit should not be undertaken by the MTCs included:

- Lack of resources to undertake additional responsibility.
- Lack of expertise to deal with non-medicine technologies (NMT).
- MTCs are large groups in terms of memberships and terms of reference (TOR).
- Extending the remit of MTC or alternative structures to undertake the HTW audit will be a weakness and it would potentially make the group lose focus.
- MTC or alternative structures have a clearly defined purpose, remit, constitution and membership for medicines only.
- The HTW audit cannot be undertaken by the MTC or alternative structure as it needs its own structure with visibility within LHBs.

Instead, these respondents suggested:

- Each LHB should choose the most appropriate structure to undertake the HTW audit since LHBs do not follow the same structures.

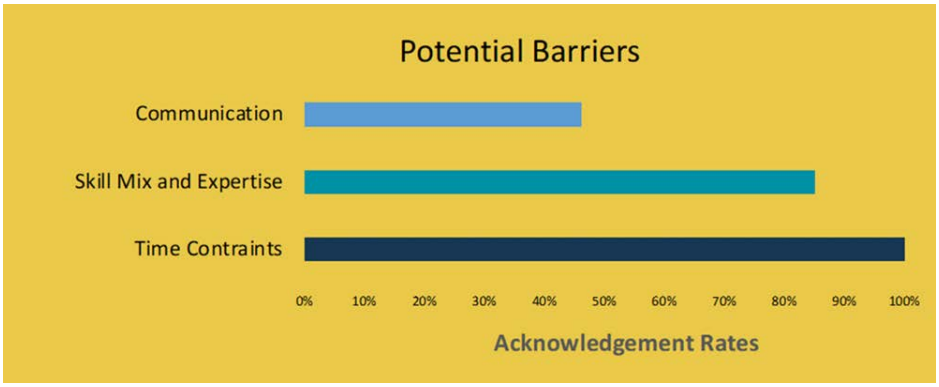
- Each LHB should choose the most appropriate structure to undertake the HTW audit since LHBs do not follow the same structures.
- Other groups might be better suited to undertake the HTW audit e.g. Clinical Procurement Group, NICE Assessment Group, NICE Advisory Group, Organisational Quality and Safety Group, Clinical Audit Function, Medical Devices Advisory Group, Clinical Governance, Effective Clinical Practice Sub-Committee, Medical Devices Governance Board.

Reasons outlined supporting (n=3; 27%) consensus that the HTW audit **should be** undertaken by the MTC included:

- It is a clinical responsibility and it should come under the remit of clinicians.
- Pre-existing infrastructure that works effectively and have robust processes.
- There is multidisciplinary involvement in the context of MTC.
- MTC understands the structure and background of audits.
- MTC has influence and understands the landscape of each LHB.

3. Potential Barriers

All (100%) of the respondents suggested that lack of current resources is a barrier for the success of the proposed audit structure.



3.1. Skill Mix and Expertise

Eleven (85%) of the respondents felt that there is a lack of the required skill mix and expertise within the MTC to ensure the running of the HTW audit. The major gaps identified include:

- Insufficient expertise to deal with NMTs.
- NMTs are broad and thus the variation of themes requires varied expertise e.g. cardiologists, surgeons, etc.
- HTW guidance is so disparate and it makes it difficult to think of a single group or forum that has the breadth to cover all relevant issues.
- MTC or alternative structures focus on medicines, the process of adopting medicines and how medicines are managed in pharmacies.
- For the MTC to undertake the HTW audit function a significant change in the remit, purpose and membership would be necessary.

3.2. Time Commitments

All (100%) respondents acknowledged lack of time as a major barrier. Reasons behind this observation include:

- Already significant agendas.
- There is a small pool of experts in Wales and thus input is constantly required from the same people.
- MTCs are already large groups in terms of membership and TOR.

- The HTW audit needs to have a simple structure with simple requirements in order to get done properly.
- MTC already struggling for the implementation of medicine guidance.
- MTC members already very busy from a clinical perspective making it difficult to maintain the meetings quorate.

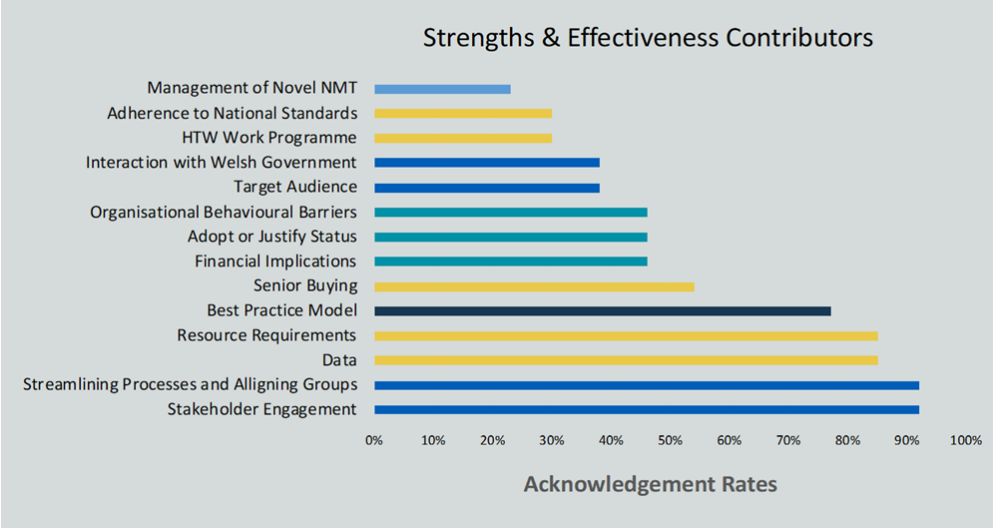
3.3. Communication

Six (46%) respondents recognised effective communication as a major barrier to ensure the running of the HTW audit. Examples included:

- Communications are often received at a very high level and it does not get cascaded to all relevant parties and stakeholders.
- A process for the communication of HTW guidance needs to be put in place, highlighting who is receiving the communication and who is it relevant for.
- An audit function is as effective as the infrastructure behind it to disseminate information and ask questions.
- The HTW audit function needs to have a clear method of communication.
- A single point of contact for the dissemination of guidance is a weakness and thus multiple recipients should be targeted to ensure the effectiveness of HTW audit.

4. Strengths and Effectiveness Contributors

Respondents considered that the HTW audit will only be effective if a couple of key aspects are considered.



4.1. Stakeholder Engagement

Twelve (92%) respondents indicated that that HTW audit will be effective only if the right stakeholder engagement is targeted. One respondent (20%) indicated that the function would be better set up in the context of another structure rather than co-opting other stakeholder onto the MTCs. Three emerging categories of stakeholders have been identified from the answers provided, including:

- **Clinical Expertise**: Assuring the correct representation of relevant clinical expertise to assess NMT (e.g. respiratory, cardiac, surgical, etc.) since not all the relevant branches are currently represented in the context of MTC or alternatives. It has been acknowledged that identifying the correct expertise has "already been a struggle." One suggestion to mitigate this barrier was to consider a "floating membership" that draws experts in for clinical input when needed.

- **Clinical Practice:** Correct representation of the stakeholders responsible for operating the NMT. Examples include doctors, nurses, community care, etc.
- **Other**: Other structures potentially involved with the NMT. Examples include procurement, clinical engineers, medical devices and equipment staff, health and safety

4.2. Best Practice Model

Ten (77%) respondents indicated that having a recommended model of "best practice" for how to integrate and operate the HTW audit will ensure the effectiveness of the function. Examples of suggestions included:

- An advisory model of best practice for how to integrate and operate HTW audit
- A process to consider guidance when received that clearly indicates whose responsibility it is to consider the NMT.
- Details of the best practice model for NMT implementation – similar to the Welsh Analytical Prescribing Support Unit (WAPSU) of the All Wales Therapeutics & Toxicology Centre (AWTTC)
- Outlining the TOR for the HTW adoption audit committee or suggesting how to expand existing TOR
- There is a good organisation for medicine guidance within organisations; however, no robust procedures for NMT.
- Best practice model should also incorporate training requirements and other potential organisational issues as well as the individuals involved in the decision-making process
- Clear audit tool kit indicating the requirements of the HTW audit, purpose, outcome and how the audit toolkits are used to improve care.

4.3. Data

Eleven (85%) respondents acknowledged that access to data as well as the identification and collection of data for the HTW audit is pivotal to ensure the effectiveness of the function. Relevant factors included:

- Access to data as well as identification and collection of data for the HTW audit is pivotal to ensure its effectiveness
- Uncertainties regarding what data will be required for the HTW audit.
- More clarity needs to be given regarding the purpose of HTW audit.
- Having a metric consisting of one or two indicators for tracking adoption would be useful.
- Uncertainties regarding the expected timeline for the implementation of HTW guidance.
- There is a need for a solution to monitor and gather data that is not a burden.

4.4. Target Audience

Five (38%) respondents indicated that knowing the target audience of the HTW annual audit report is important for the effectiveness of the audit. Participants indicated that HTW should report any governance deficit upwards to the CMO and minister; however, the audit report should be made available to the other LHBs as it could drive the implementation of guidance by public comparison.

4.5. Streamlining Processes and Aligning Groups

Twelve (92%) or respondents acknowledged the existence of already established groups and forums that undertake part of the work required for the HTW audit. Identifying and gathering the information collected by these groups will ensure that tasks are not duplicated and that mechanisms are established to feed relevant information into the HTW audit. Comments included:

- Existence of established groups and forums that undertake part of the work required for the HTW audit
- There is a lack of clarity of how different data will feed into the audit function (e.g. procurement data).
- A NICE Assessment Group exists in certain LHBs.
- There is an overlap between what is required for the audit of HTW Guidance, the audit of NICE Guidance and National Tier 1 Audits.
- There is an overlap between medicines and NMT (e.g. Free Style Libre).
- If a piece of technology is adopted multiple groups need to be involved. Examples include but are not limited to procurement, training, maintenance, disposal, storage, finance. Integration of possible uptake of technologies need to be factored into the medium-term financial plan.

4.6. Resource Requirements

Eleven (85%) respondents acknowledge the need for additional resource in order to ensure the effectiveness of the HTW audit. The suggestions highlighted the requirement for both human resources and "a system" to ensure data collection and monitor compliance. Additionally, three several of the participants suggested that LHBs should advise on the resources needed.

- Additional human resources and a "system" for data collection and monitoring compliance
- Given the variation between LHB, four (30%) of the respondents suggested that each LHB should advise on the resources needed
- AMaT – Audit Management and Tracking – will potentially be introduced and piloted in Cwm Taf next year
- Scan4Safety – for medical devices – introduced by the department of Health and Social Care – also potentially piloted next year
- Alert Tracker – medical devices – ECRI
- Datix – potential update to incorporate medical devices alerts

4.7. Interaction with Welsh Government

Five (38%) respondents acknowledged that the HTW audit should strategically align with other networks and delivery plans for health of the Welsh Government as it will influence authority. Suggestions included:

- HTW audit should strategically align with other networks and delivery plans for health in the Welsh Government as it would influence its authority
- Identify where HTW guidance fits in the health delivery plans (cardiology, respiratory, diabetes, etc.).
- HTW need to be a stakeholder in the Welsh Government for consultation when policy for delivery plans is made.
- Identify a way to tie the HTW audit to the National Integrated Medium-Term Plan (IMTP) for Wales.
- Given the experience with the New Treatment Fund, if the Welsh Government were to commission the implementation of technologies as per HTW Guidance it is necessary to know the data and evidence needed from the LHBs.

4.8. Financial Implications

Six (46%) respondents acknowledged that financial implications will influence the effectiveness of the HTW audit. Examples of concerns included:

- Financial implications will influence the effectiveness of HTW audit
- The cost of implementation of NMT highlighted in HTW guidance is a challenge.

- The cost of NMT implementation should be integrated into the planning structures in accordance to clinical needs.
- Different types of costs associated with NMT implementation given the diverse range of NMT. Examples include revenue cost, maintenance cost, etc.
- Existence of a treatment fund for drugs (New Treatment Fund) but no such thing to support NMT.
- Resource impact analyses are helpful to consider the up-take of NMT (value based healthcare).

4.9. Senior Buy-in

Seven (54%) respondents commented on the importance of senior buy-in and delivery of HTW audit, noting:

- HTW audit real strength reflected by the senior buying from All Wales Medical Directors as the national peer group overseeing the audit.
- Five (38%) respondents indicated that having a central adoption audit function for the implementation of NMT will help to ensure consistency and equity in approaches across Wales.
- HTW audit being overseen by the AWMD ensures accountability.
- Having visibility amongst AWMD is a very positive things that might help mitigate some challenges related to the implementation of NMT and ensure equity of access across Wales.

4.10. Adopt or Justify Status

Six respondents commented on the "Adopt or Justify" status of HTW Guidance, including:

- Adopt or justify is an appropriate approach but needs to be formalised as an internal process. It should not be acceptable not to do it, but it is acceptable to highlight the implementation challenges (e.g. patient safety, lack of infrastructure).
- Two respondents (16%) indicated that the HTW audit function would have been more effective and straightforward if the guidance was mandated.
- More clarity is needed on the "justify" status regarding the evidence required for the justification of HTW audit.
- Time scales need to be provided for the "adopt" status factoring in the processes required for adoption (e.g. planning, commissioning, etc.).
- More clarity regarding the level of prioritisation for HTW guidance should be provided (i.e. in comparison to NICE medicine HTAs or other guidance in general).
- HTW audit real strength reflected by the senior buying from All Wales Medical Directors as the national peer group overseeing the audit.
- Five (38%) respondents indicated that having a central adoption audit function for the implementation of NMT will help to ensure consistency and equity in approaches across Wales
- HTW audit being overseen by the AWMD ensures accountability.
- Having visibility amongst AWMD is a very positive things that might help mitigate some challenges related to the implementation of NMT and ensure equity of access across Wales.

4.11. Organisational Behavioural Barriers

Six (46%) respondents commented on potential barriers existing within organisations. Examples include:

- Organisations need to engage more in supporting skill development for new technologies and to support behavioural change for the implementation and adoption of NMT

- HTW should support an organisational behavioural change, otherwise clinicians will fight the system to implement certain NMT. Clinicians are allowed a lot of latitude in what they do as long as the ultimate goal is successfully achieved.
- The uptake of NMT will be dependent on how much clinicians are interested in specific pieces of technology. If clinicians want to adopt a change, they will create the circumstances necessary for the change to happen.
- Supporting organisational behavioural change should highlight the additional benefit that the implementation of a NMT will have.

4.12. HTW Work Programme

Four (30%) respondents commented on this area, noting:

- Sharing the HTW work programme could enable LHB to acknowledge up-coming guidance
- Therefore, required preparations as well as co-opting for relevant expertise can be targeted before the guidance is issued
- The development of a central guidance or policy regarding the process for NMT horizon scanning was also perceived as a potential enabler for the successful implementation of NMT once the guidance is issued.

4.13. Adherence to National Standards

Four (30%) respondents commented on this area, noting:

- The HTW audit function could evidence adherence to national standards of clinical practice
- Being able to evidence that national standards have been adopted could mitigate against risks, issues and accidents. Even if the HTW audit will require implementation costs it could be a spend-save option given the amount of resource (financial, staff time) currently used to generate evidence of adherence to best practice for the arising issues and accidents.
- The HTW audit could help standardise approaches in each organisation and provide evidence for adhering to national standards.
- HTW guidance and audit could provide evidence for reports where adherence to national standards is required. An example is highlighted by the reports provided to the ombudsman in case of death.
- The HTW guidance would potentially help stakeholders perceive the positive access to resources coming up with national guidance that is adopted for the benefit of patients and public.

4.14. Management of Novel NMT

Three (23%) respondents commented on this area, noting:

- Respondents indicated that active national management should be considered to identify if there is an unmet need for certain technology appraisals.
- The areas of specialty targeted for issuing NMT guidance should factor in the views of LHBs and gaps in current practice. That would allow prioritisation for the implementation of NMT that would actual reflect a real need in clinical practice.
- Approximately 20 biological therapies are on the formulary for autoimmune diseases (rheumatoid) but realistically only about ten are prescribed and used by clinicians because they do not perceive any additional benefits of the new therapies over what they already using.
- There are different technologies available for the same outcome and thus decisions for identifying the best ones should be factored in when adoption a new NMT.

5. Additional Observations

At least two (16%) of the respondents acknowledged one of the following observations:

- The HTW audit has the potential to improve patient outcomes
- Broadening the remit of MTCs will help recruit a wider range of professionals and ensure engagement
- MTCs have previous experience to deal with guidance in general
- Wales gives the perfect landscape to develop an adoption audit function due to its size
- The HTW audit will potentially enable broader data collection that can be used for various purposes (e.g. improve evidence for compliance monitoring)
- Having the guidance discussed by clinical directors of relevant departments will be an enabler for the effectiveness of HTW audit and it will account for the correct representation of the right skill mix and expertise

6. Individual Opinions and Recommendations

A series of individual opinions and points were noted during the interviews. Given the different backgrounds of the participants these observations did not necessarily form emerging themes; however, they could provide helpful insights that could aid shaping the ultimate design of the HTW audit. These are included here:

- Since a New treatment Fund exists for new drugs there is an opportunity to make a case to Welsh Government for a similar NMT fund.
- There is a Chief Pharmaceutical Officer in Wales but there is no "Chief Technology Officer"
- Each LHB has a head of procurement with a dedicated team. Procurement data is easily accessible if purchases are made through procurement services for NHS Wales as everything is done through Oracle.
- NICE guidance for medicine HTAs could be discussed at clinical team or clinical board level and the outcomes can be fed upstream to bigger committees such as the MTC or alternative structure.
- One respondent indicated that even if the HTW audit function should not come under the remit of the MTC or alternative structure, they could still have input in assisting with the audit.
- LHBs Audit Committees take responsibility to ensure that audits are correctly distributed and the relevant people are chased up. Each LHB has to have an Audit Committee; the rest of the structures are different in every LHB and there is variation between LHBs in terms of membership and TOR. Even if two committees are named the same, they might have different constitutions and remits across different LHBs.
- All LHB should have a form of Medical Devices groups. The role of the Medical Devices Group is to ensure sound governance of medical devices but not to provide guidance if a technology should be adopted or not.
- HTW audit stands a reasonable chance because HTW distributing guidance and expecting feedback in comparison to NICE that does take much interest in discovering what has been done with their advice.
- The governance structure of the MTC for the implementation of medicines could be replicated in the context of another committee that is better suited to undertake the HTW audit function for the implementation of NMT.

Appendix 10: Resources required

Additional resources will be required, at both national and local levels, to effectively implement the agreed model option and its associated recommendations.

- At local levels, the resources required will vary depending on existing capacity, skills and knowledge. Some health boards may already have existing groups in place that may be adapted to ensure appropriate representation. To ensure that NMTs can be adequately considered, member expertise should include (but not be limited to) experience in:
    - Non-medicine technologies generally e.g. devices, diagnostics, procedures, with specific expertise co-opted as necessary
    - Procurement
    - Social care
    - Medtech industry
    - Patients, carers and the public

  NHS boards may wish to engage other stakeholders as required. The local health board committee concerned should work in a transparent manner and ensure adequate engagement with key stakeholders.
- At a national level, additional resources will be required to fulfil the following responsibilities:

Responsibilities	Staff banding	Contract type & Cost	Duration
HTW Audit Manager: Work in partnership with NHS boards/RPBs and provide leadership, liaison and oversight to the establishment of the HTW audit function	One WTE band 7 staff	Permanent £48,500 p.a.	N/A

Appendix 11: Abbreviations

AAT&FG	Adoption Audit Task & Finish Group
AWMD	All Wales Medical Directors
AWMSG	All Wales Medicines Strategy Group
CEL	Chief executive letter
CEMT	Chief Executives Management Team
CPO	Chief Pharmaceutical Officer
DAC	NICE Diagnostics Advisory Committee
DOPs	Directors of Planning
EU	European Union
INAHTA	International Network of Agencies for Health Technology Assessment
LHBs	Local Health Boards
MDC	Medical Devices Committee
MHRA	Medicines and Healthcare products Regulatory Agency
MMC	Medicines Management Committee
MTA	Multiple technology appraisals
MTAC	NICE Medical Technologies Advisory Committee
MTC	Medicines and Therapeutics Committee
MTEP	Medical Technologies Evaluation Programme
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NMTs	Non-medicine technologies
RPB	Regional Partnership Board
SHTG	Scottish Health Technologies Group
SWOT analysis	Strengths, weaknesses, opportunities and threats analysis
WHC	Welsh Health Circular
WTE	Whole-time equivalent

References

1. HTW Adoption Audit Task & Finish Group. June 2019.

2. National Assembly for Wales, Health and Social Care Committee. Access to medical technologies in Wales. December 2014.

3. Gething, V. Letter to all Health Board Chairs re Funding for Sacral Nerve Stimulation in Wales. VG_01655_17. September 2017.

You can read and download this document from our website: www.healthtechnology.wales

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Health Technology Wales

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