Technoleg Iechyd Cymru
Health Technology Wales

Health Technology Wales

Adoption Audit Report 2022/2023

Executive Summary

- The Health Technology Wales (HTW) annual adoption audit was piloted in 2021/2022 and has been replicated for 2022/2023 with minor adjustments. This year, HTW has audited 11 pieces of HTW guidance and three pieces of NICE Medical Technologies Evaluation Programme (MTEP) guidance. The annual HTW adoption audit successfully discharges recommendation 5 of the 2014 inquiry into "Access to Medical Technologies in Wales" [1].

- HTW engaged with a range of stakeholders and requested returns from each of the local health boards and Welsh Health Specialised Services Committee (WHSCC). The audit response rate was encouraging with at least partial responses from six of the seven health boards and from the Welsh Health Specialised Services Committee (WHSSC). Procurement Services also provided all requested data.

- Responses from organisations where the guidance is relevant indicate that awareness of HTW guidance is high (70%), that clarity of HTW guidance recommendations is good (83%), and HTW guidance is having some form of impact in the majority of cases (72%).

- The adoption audit was able to differentiate different levels of adoption and impact of HTW guidance. In some cases, responses clearly show that HTW guidance was adopted and had a clear impact on decision-making. For guidance recommending the routine adoption of a technology, this was most evident for FreeStyle Libre (HTW guidance 004-2). For guidance not recommending routine adoption, a consistent and clear impact on decision-making was evident for the Multigrip guidance (014), which was reported to have had a moderate impact.

- There were some cases where HTW guidance appears not to have been adopted. For guidance recommending the use of a technology, this was most evident for ClearGuard™ (HTW guidance 030). This ClearGuard™ guidance was consistently reported to have had no or a minor impact. The Rapid Antigen Detection Tests (RADT) guidance (020) is a clear example of guidance not recommending routine adoption, but where the technology was implemented nonetheless. The reported impact of the RADT guidance varied between no impact and a moderate impact.

- All three pieces of NICE MTEP guidance audited recommended the use of a technology. The most impactful piece of NICE MTEP guidance was GammaCore (NICE MTG46), while the impact of ZioXT (NICE MTG52) ranged from no impact to moderate impact.

- Responses to the adoption audit identified several themes relating to awareness, clarity, intention to adopt guidance and the impact of guidance. The clarity of HTW and NICE guidance could be improved in the areas of patient selection and research recommendations. Adoption of guidance was hindered by resource limitations (positive HTW guidance is not accompanied by additional funding) and other factors such as small patient numbers, the

capabilities of existing technology and the current use of other products. The impact of guidance was affected by overlap with guidance from other agencies and the extent to which guidance concurs. Consideration by multiple bodies was suggested to lead to delays in patients accessing technologies.

- The responses provided confirm that this process is appropriate to assess the adoption of both HTW and NICE guidance. Regular monitoring of the adoption of HTW and NICE national guidance has the potential to support multiple ambitions outlined in the health and social care policy agenda for Wales, document and maximise the return on the investment in HTW, and make Wales a leader in monitoring the impact of national guidance, both in the United Kingdom and internationally.

Proposed Future Directions

- As part of the mainstreamed adoption audit, HTW should continue to engage closely with each of the local health boards, specialised commissioning and specialist trusts in order to maximise returns. HTW should consider how the process can be extended to social care and other commissioners and should develop the necessary relationships to ensure the success of future audits. HTW should seek continual suggestions for improvements in process and methodology and should act on the findings of the adoption audit to improve awareness and clarity of guidance

- HTW should mainstream the adoption audit of NICE MTEP guidance in collaboration with the Welsh NICE Health Network (WNHN). HTW should work closely with NICE to review their respective work programmes to ensure that no duplication is present and to identify opportunities for collaboration as appropriate. NICE should review the findings of the adoption audit, specifically in relation to the suggestions for improvement of research recommendations, and should consider the barriers to implementation identified.

- Local health boards, WHSCC, and the specialist trusts should continue to work with HTW to support future adoption audit reports and are encouraged to input into process and methodological improvements. HTW Health Board adoption leads should work with HTW to identify topics for appraisal and to make links with local experts who are able to provide invaluable expertise during appraisal development, which will in turn increase awareness and maximise the impact of guidance.

- Welsh Government should continue to support the HTW adoption audit as 'business as usual' and should promote participation in the HTW adoption audit to maximise the number of returns and ensure that a complete picture of adoption in Wales can be provided. Welsh Government should also consider whether there are opportunities to support the adoption of HTW and NICE MTEP guidance and to resolve barriers to adoption that have been identified.

Contents

List of abbreviations

Abbreviation	Full text
ABUHB	Aneurin Bevan University Health Board
BCUHB	Betsi Cadwaladr University Health Board
BSI	Bloodstream infection
CHG	Chlorohexidine Gluconate
COVID-19	Coronavirus Disease
CRBSI	Catheter-related bloodstream infection
CT	Computed Tomography
CTMUHB	Cwm Taf Morgannwg University Health Board
CVUHB	Cardiff & Vale University Health Board
CXL	Corneal crosslinking
FFR	Fractional flow reserve
GUI	Guidance
HDUHB	Hywel Dda University Health Board
HTW	Health Technology Wales
HUDS	Hand-held ultrasound devices
IPFR	Individual Patient Funding Request
IPG	Interventional Procedures Guidance
LHB	Local Health Board
MIB	MedTech Innovation Briefing
MTEP	Medical Technologies Evaluation Programme
NICE	National Institute for Health and Care Excellence
ONS	Occipital Nerve Stimulation
POCUS	Point-of-care ultrasound
PJI	Periprosthetic joint infection
PTHB	Powys Teaching Health Board
RADT	Rapid Antigen Detection Tests
SAVR	Surgical aortic valve replacement
SBUHB	Swansea Bay University Health Board
TAVI	Transcatheter aortic valve
THA	Total hip arthroplasty
TKA	Total knee arthroplasty
TTE	Transthoracic echocardiogram
WAST	Welsh Ambulance Services NHS Trust
WG	Welsh Government
WHSCC	Welsh Health Specialised Services Committee

1. Introduction

Health Technology Wales (HTW) was established in 2017 to provide a consistent and structured approach to assessment of non-medicine technologies in Wales as a result of a Welsh Government inquiry into "Access to Medical Technologies in Wales" [1]. The inquiry and subsequent recommendations highlighted that guidance produced by Health Technology Wales should have "Adopt or Justify" status and that the uptake of guidance should be audited to ensure equitable access to services. Health Technology Wales is well established and after refining its approaches to identification and appraisal of medical technologies, turned to considering how the adoption of its guidance could be audited and monitored.

Adoption of HTW guidance is key to ensuring that there is access to evidence-based technologies and models of care and support and that their anticipated benefits are realised for people in Wales. Further, adoption of HTW guidance ensures that technology developers and industry partners can be confident that where they have embedded the collection of supporting evidence within development and demonstrated value of their products and services, innovations will become available within the health and care system in Wales. It is therefore critical that HTW works to support adoption of guidance and audits the extent to which this has happened to assess the impact our work.

The HTW adoption audit process reports on adoption within relevant commissioning bodies and procurement services. The process was piloted in 2021/22 with a series of eight pieces of guidance, culminating in the publication of the Adoption Audit Pilot Report 2021/2022[2]. The report found that the process was feasible and acceptable for partners in Wales. The present report represents the second in a series of ongoing annual reports monitoring adoption of HTW guidance to be shared with Welsh Government and other stakeholders.

The report presents a summary of issues around adoption arising from the adoption audit and information on awareness, clarity and impact of HTW and NICE guidance on decision-making by relevant commissioning organisations. The purpose of this is to assess the extent to which HTW and NICE guidance has improved care and access for people in Wales. The adoption audit also supports NHS partners to identify variation in care and to work collaboratively to identify and design solutions.

More detailed information on responses for each of the pieces of guidance audited is also provided. A brief overview of the supporting methodology and example materials are available in Appendix I and II, respectively.

2. Summary of adoption audit findings

The 2022/2023 adoption audit replicated the adoption audit process established in the 2021/2022 pilot. In addition to auditing 11 pieces of HTW guidance, HTW have audited three pieces of NICE Medical Technologies Evaluation Programme (MTEP) guidance. The responses provided confirm that this process is appropriate to assess the adoption of both HTW and NICE guidance. The valuable information from the audit will help HTW and NICE to refine their work and can help support wider assessments of how to further support adoption in Wales.

Over the past twelve months, we have continued our work with each of the local health boards, specialised commissioning, and NHS trusts to maintain the relationships we developed as part of the 2021/2022 pilot. As a result of this work, we received at least partial responses from six of the seven health boards and from the Welsh Health Specialised Services Committee (WHSSC),

Velindre confirmed that none of the pieces of guidance included in the audit were relevant to their organisation, and while no response was received from Welsh Ambulance Services NHS Trust (WAST), the guidance is not expected to be applicable to the organisation.

In a change of approach from the pilot audit, a request for information was made of each organisation for every piece of guidance, to ensure that we target those with commissioning responsibility in each case. Respondents are then able to indicate whether the guidance is relevant to their organisation.

The audit returns indicated that there was good awareness of HTW and NICE guidance, that the recommendations are generally clear, and that guidance is having an impact on decision-making. Among those respondents who confirmed that the guidance is relevant to their organisation, 70% reported that they were aware of the guidance, 83% said the guidance was clear and 72% reported either minor, moderate or major impact on decision-making.

In some cases, responses clearly show that HTW guidance was adopted and had an impact on decision-making. For guidance recommending the routine adoption of a technology, this was most evident for FreeStyle Libre (HTW GUI004-2). It was also apparent for corneal cross-linking (CXL) (HTW GUI 002-2) although the reported impact ranged from minor to major. For guidance not recommending routine adoption, a consistent and clear impact on decision-making was evident for Multigrip (HTW GUI 014), which was reported to have had a moderate impact. Other pieces of guidance not recommending routine adoption were reported to have had a low impact, including point-of-care ultrasound (POCUS) in the diagnosis of gallstones (HTW GUI029), Synovasure (HTW GUI 008) and hand-held ultrasound devices (HUDS) (HTW GUI009) for example. This was because these technologies were not previously being used and no changes were required based on the guidance, which is a positive outcome.

There were some cases where HTW guidance appears not to have been adopted. For guidance recommending the use of a technology, this was most evident for ClearGuard™ (HTW GUI030). This guidance was consistently reported to have had no or a minor impact. RADT (HTW GUI020) is a clear example of guidance not recommending routine adoption, but where the technology was implemented nonetheless. The reported impact varied between no impact and a moderate impact.

The three pieces of NICE MTEP guidance which were selected for the audit were issued under the NHS England MedTech Funding Mandate, which requires that the recommended technology is expected to be cost saving. The most impactful piece of NICE MTEP guidance was GammaCore (NICEMTG46), while the impact of ZioXT (NICEMTG52) ranged from no impact to moderate impact.

Overall audit response rates were encouraging. However, the absence of information from one of the local health boards and partial returns for several others has limited our ability to provide a full picture on adoption of HTW and NICE guidance across Wales. HTW will continue to engage with stakeholders and work with Welsh Government to ensure that a full picture can be provided for future years.

2.1 Awareness of guidance

For each of the pieces of guidance audited, the nominated contact(s) for the relevant commissioning body was asked whether their organisation or relevant people within their organisation were aware of our guidance. Out of a total possible set of 140 responses, 97 responses (69%) across the 14 included pieces of guidance were received. 47 of these responses were organisations confirming that pieces of guidance were not relevant to their organisations. From the remaining 50 responses from organisations which confirmed that the guidance was relevant, 35 responses, (70%) indicated that there was awareness of guidance, 10 (20%) indicated that there was not awareness, three (6%) were unsure whether guidance was known of by their organisation, and one (4%) organisation had a mixed response (whereby the questionnaire was returned twice, with different responses). These numbers appear to be acceptable and indicate good awareness of HTW and NICE guidance.

Several themes were identified from the analysis of the adoption audit data relating to awareness of the guidance. In some cases, the adoption audit process itself was identified as a mechanism which increased awareness of the guidance, as respondents were sometimes unaware of the guidance prior to its circulation as part of the audit. This shows that there is a potential to harness the process to disseminate our work at an earlier stage, prior to the audit. In addition, awareness of the guidance was often linked to direct involvement in the development of HTW Evidence Appraisal Reports, for example by suggesting topics to HTW or participating in expert review.

Other mechanisms through which organisations learned of guidance included All-Wales groups, word-of-mouth discussions (including with other organisations), best practice guidance, updates from national organisations and medical sales teams.

Table 1. "Was your organisation aware of guidance on this topic?"

	ABUHB	BCUHB	CVUHB	CTMUHB	HDUHB	PTHB	SBUHB	WHSSC
GUI008 Synovasure	No response	No	Unsure	No response	No	N/A	N/A	N/A
GUI009 Handheld ultrasound devices	Yes	No response	No response	No response	Yes	N/A	Yes	N/A
GUI010 Robot-assisted thoracic surgery	N/A	No response	No response	No response	N/A	N/A	Yes	Yes
GUI013 Occipital Nerve Stimulation	Yes	N/A	Mixed (Yes/No)	No response	Yes	N/A	Yes	Yes
GUI014 Multigrip	No response	Unsure	Yes	No response	N/A	N/A	Yes	Yes
GUI020 Rapid Antigen Detecting Tests	Yes	Yes	No response	No response	Yes	N/A	Yes	N/A
GUI024 Transcatheter Aortic Valve Implantation	N/A	N/A	No response	No response	Yes	No response	Yes	Yes
GUI029 Point of care ultrasound for suspected gallstones	N/A	Unsure	No response	No response	Yes	N/A	Yes	N/A
GUI002-2 Corneal cross-linking	Yes	No answer	Yes	No response	Yes	N/A	Yes	Yes
GUI030 ClearGuard™ Antimicrobial barrier caps	Yes	No response	No response	No response	Yes	N/A	Yes	N/A
GUI004-2 FreeStyle Libre	Yes	Yes	Mixed (Yes/ Unsure)	No response	Yes	Yes	Yes	N/A
MTG32 HeartFlow	N/A	Yes	No response	No response	Yes	N/A	Yes	N/A
MTG46 GammaCore	Yes	N/A	No response	No response	Yes	N/A	Yes	N/A
MTG52 ZioXT	N/A	Yes	No response	No response	Yes	N/A	Yes	N/A

No response' indicates that the questionnaire was not returned for a piece of guidance.
No answer indicates that a return was provided but this question was not answered.
Mixed indicates that multiple responses from different individuals were returned from an organisation, with differing answers.
N/A indicates that a health board reported that a piece of guidance was not applicable to their organisation.
N.B. Velindre indicated that none of the guidance audited was relevant to their organisation, with the exception of GUI004-2, for which no confirmation was received. None of the pieces of guidance audited are expected to be relevant to WAST, but no response was received to confirm this.

2.2 Clarity of guidance

Nominated contacts were also asked whether the recommendation(s) in the guidance was clear. Out of a total possible set of 140 responses, 95 responses across the 14 pieces of guidance were received. 47 of these responses were organisations confirming that pieces of guidance were not relevant to their organisations. From the remaining 48 responses from organisations which confirmed that the guidance was relevant, 40 responses (83%) indicated that guidance was clear, six (13%) indicated that it was not clear, one (2%) was unsure and one gave a mixed response (whereby the questionnaire was returned twice, with different responses). In general, it appears that the HTW and NICE guidance audited was clear.

While the clarity of the guidance was high, several themes were identified from the analysis of the adoption audit data relating to guidance clarity. Respondents raised that clearly defined populations are crucial for interpreting guidance. This was raised for HTW guidance CXL and transcatheter aortic valve implantation (TAVI) where patient selection was noted to be unclear. Specific issues for these pieces of guidance are discussed in more detail below.

For positive guidance (recommending the use of a technology) research recommendations were felt to require better definition. Relatedly, for guidance not recommending the routine use of a technology, research recommendations were felt to be confusing following a suggestion of possible effectiveness. This valuable feedback identifies a clear area to improve upon within both HTW and NICE guidance.

For guidance not recommending the routine use of a technology, there was a suggestion that patient choice considerations raised within the guidance could lead to requests for the particular treatment or technology.

Table 2. "Was the recommendation in the guidance clear?"

	ABUHB	BCUHB	CVUHB	CTMUHB	HDUHB	PTHB	SBUHB	WHSSC
GUI008 Synovasure	No response	No answer	Yes	No response	No	N/A	N/A	N/A
GUI009 Handheld ultrasound devices	Yes	No response	No response	No response	Yes	N/A	No	N/A
GUI010 Robot-assisted thoracic surgery	N/A	No response	No response	No response	N/A	N/A	Yes	Yes
GUI013 Occipital Nerve Stimulation	Yes	N/A	Mixed (Yes, No)	No response	Yes	N/A	Yes	Yes
GUI014 Multigrip	No response	Yes	Yes	No response	N/A	N/A	Yes	Yes
GUI020 Rapid Antigen Detecting Tests	Yes	Yes	No response	No response	No	N/A	Yes	N/A
GUI024 Transcatheter Aortic Valve Implantation	N/A	N/A	No response	No response	Yes	N/A	Yes	Yes
GUI029 Point of care ultrasound for suspected gallstones	N/A	Yes	No response	No response	Yes	N/A	Yes	N/A
GUI002-2 Corneal cross-linking	Yes	No answer	Yes	No response	Yes	N/A	Yes	Yes
GUI030 ClearGuad™ Antimicrobial barrier caps	Unsure	No response	No response	No response	Yes	N/A	Yes	N/A
GUI004-2 FreeStyle Libre	No	Yes	Yes	No response	No	Yes	Yes	N/A
MTG32 HeartFlow	N/A	Yes	No response	No response	Yes	N/A	Yes	N/A
MTG46 GammaCore	Yes	N/A	No response	No response	Yes	N/A	Yes	N/A
MTG52 ZioXT	N/A	No answer	No response	No response	No	N/A	Yes	N/A

No response' indicates that the questionnaire was not returned for a piece of guidance.
No answer indicates that a return was provided but this question was not answered.
Mixed indicates that multiple responses from different individuals were returned from an organisation, with differing answers.
N/A indicates that a health board reported that a piece of guidance was not applicable to their organisation.
N.B. Velindre indicated that none of the guidance audited was relevant to their organisation, with the exception of GUI004-2, for which no confirmation was received. None of the pieces of guidance audited are expected to be relevant to WAST, but no response was received to confirm this.

2.3 Impact of guidance

Nominated contacts were asked whether they intended to adopt the guidance within their organisation. Out of a total possible set of 140 responses, 95 responses across the 14 included pieces of guidance were received. 47 of these responses were organisations confirming that pieces of guidance were not relevant to their organisations. From the remaining 48 responses from organisations which confirmed that the guidance was relevant to them, 27 (56%) intended to adopt the guidance, 11 (23%) did not intend to adopt, 7 (15%) were unsure and 3 (6%) gave a mixed response (whereby the questionnaire was returned twice, with different responses). In general, it seemed that organisations intended to adopt guidance when it was relevant to their organisation. The question seemed to be misinterpreted in several cases where guidance did not recommend the routine use of a technology, as 'did your organisation intend to adopt *this technology*' (as opposed to guidance). This could be inferred from the rest of the response. This is discussed in more detail for the relevant pieces of guidance below. HTW will improve the clarity of the question in subsequent adoption audits.

Several themes were identified from the analysis of the adoption audit data relating to organisations' intention to adopt the guidance. Where HTW or NICE issued guidance recommending that a technology should be adopted, barriers to adoption were identified such as resource implications, the current use of another product, small patient numbers (not meeting contractual volumes) and technology capabilities. In addition, positive guidance might not be adopted due to concerns about the evidence on which guidance was based. These included the lack of current standard care as a comparator and being unconvinced of the benefit. Respondents indicated that they would participate in research but that research funding was also a consideration.

Where HTW or NICE guidance recommended that a technology should be adopted and this was observed, in some cases this was already happening before the guidance was issued. In other cases guidance was adopted in theory but there were no eligible patients. Adoption was reported to be slower in primary care due to resource implications. Respondents highlighted that no funding was allocated to accompany positive HTW guidance and there should be a recognition that guidance can result in an increase in staff workload. There was an indication that flexibility in eligibility criteria within guidance was used to restrict access to prevent overwhelming of a service. This echoes a theme relating to the clarity of guidance. Where a technology is recommended, it may be that a concomitant disinvestment in the alternative is expected. There was an indication that this may not happen as expected in practice.

In some cases, HTW or NICE guidance to use a technology was adopted, but there was limited reference to ongoing evidence generation which may have formed part of the guidance. Relatedly, where HTW or NICE issued guidance not recommending the routine adoption of a technology, and yet the technology was adopted, the adoption was reported to be part of research, but detail around the nature of this research was lacking. This also relates to a theme raised in relation to the clarity of the guidance. In the case of the RADT guidance, the adoption appeared to be part of an approach supported by WG.

Table 3. "Did your organisation intend to adopt this guidance?"

	ABUHB	BCUHB	CVUHB	CTMUHB	HDUHB	PTHB	SBUHB	WHSSC
GUI008 Synovasure	No response	No	Unsure	No response	No	N/A	N/A	N/A
GUI009 Handheld ultrasound devices	Yes	No response	No response	No response	Yes	N/A	No	N/A
GUI010 Robot-assisted thoracic surgery	N/A	No response	No response	No response	N/A	N/A	Yes	Yes
GUI013 Occipital Nerve Stimulation	Yes	N/A	Mixed (Yes/No)	No response	Yes	N/A	Yes	Yes
GUI014 Multigrip	No response	Mixed (Yes/Not relevant)	Unsure	No response	N/A	N/A	Yes	Yes
GUI020 Rapid Antigen Detecting Tests	No	Unsure	No response	No response	No	N/A	Unsure	N/A
GUI024 Trancatheter Aortic Valve Implantation	N/A	N/A	No response	No response	Yes	N/A	Yes	Yes
GUI029 Point of care ultrasound for suspected gallstones	N/A	Unsure	No response	No response	Unsure	N/A	No	N/A
GUI002-2 Corneal cross-linking	Yes	No answer	Mixed (Yes/Not relevant)	No response	Yes	N/A	Yes	Yes
GUI030 ClearGuard™ Antimicrobial barrier caps	Unsure	No response	No response	No response	No	N/A	No	N/A
GUI004-2 FreeStyle Libre	Yes	Yes	Mixed (Yes/Unsure)	No response	Yes	Yes	Yes	N/A
MTG32 HeartFlow	N/A	Yes	No response	No response	No	N/A	No	N/A
MTG46 GammaCore	Yes	N/A	No response	No response	Yes	N/A	Yes	N/A
MTG52 ZioXT	N/A	No	No response	No response	No	N/A	No answer	N/A

No response' indicates that the questionnaire was not returned for a piece of guidance.
No answer indicates that a return was provided but this question was not answered.
Mixed indicates that multiple responses were returned from an organisation, with differing answers.
N/A indicates that a health board reported that a piece of guidance was not applicable to their organisation.
N.B. Velindre indicated that none of the guidance audited was relevant to their organisation, with the exception of GUI004-2, for which no confirmation was received. None of the pieces of guidance audited are expected to be relevant to WAST, but no response was received to confirm this.

Nominated contacts were also asked how much of an impact HTW guidance had within their organisation. This question was aligned with approaches for monitoring impact used in other similar initiatives. Many varied factors could affect the impact of a piece of guidance, including whether the guidance recommends the use of a technology or not, and whether or not the organisation was already using the technology. As such, a low impact may be a positive outcome in cases where HTW guidance does not recommend the use of a technology and where organisations had not implemented the technology prior to or post-publication of the guidance. Likewise a low impact may be a positive outcome where HTW guidance recommends the routine adoption of a technology, but the technology was already being used prior to publication of the guidance and this continued post-publication.

Out of a total possible set of 140 responses, 94 responses across the 14 included pieces of guidance were received. 47 of these responses were organisations confirming that pieces of guidance were not relevant to their organisations. From the remaining 47 responses from organisations which confirmed that the guidance was relevant to them, 12 (26%) reported that guidance had no impact, nine (19%) that guidance had minor impact, 19 (40%) that guidance had moderate impact, and six (13%) that guidance had a major impact. There was a mixed response from one organisation (2%).

Several themes were identified from the analysis of the adoption audit data relating to impact of the guidance. A minor impact was reported where HTW guidance was positive and where there was existing positive NICE guidance (for example CXL), while a bigger impact was reported when differences were perceived between NICE and HTW advice. Meanwhile, duplication of advice from different bodies was reported to introduce delays to implementation. HTW actively monitors the NICE forward work programme and aims not to duplicate NICE Medical Technologies Evaluation Programme (MTEP) guidance. In some cases, respondents flagged duplication of HTW guidance and different types of NICE product, such as Interventional Procedures Guidance (IPG) and Medtech Innovation Briefings (MIBs). The adoption audit responses highlight that NICE MIBs and IPGs can be perceived as guidance, while they do not consider effectiveness and cost effectiveness, which informs HTW guidance and NICE MTEP guidance. In regards to NICE MTEP guidance, a respondent reported that they would not have considered using the technology if not for the NICE guidance. Where HTW guidance was issued which did not recommend the routine adoption of a technology, a low impact was reported when health boards were already not using the technology. Guidance not recommending routine adoption could be used in the Individual Patient Funding Request (IPFR) process, where a clinician makes a request on behalf of an individual patient to a Health Board or WHSSC to fund NHS healthcare which falls outside of the range of services and treatments that a Health Board has arranged to routinely provide or commission.

Lastly, it was felt that guidance not recommending routine adoption of a technology could introduce inequity if the technology is available in other UK nations.

Table 4. "What impact did this guidance have in your organisation?"

	ABUHB	BCUHB	CVUHB	CTMUHB	HDUHB	PTHB	SBUHB	WHSSC
GUI008 Synovasure	No response	No impact	No impact	No response	No impact	N/A	N/A	N/A
GUI009 Handheld ultrasound devices	Minor impact	No response	No response	No response	Minor impact	N/A	No impact	N/A
GUI010 Robot-assisted thoracic surgery	N/A	No response	No response	No response	N/A	N/A	No impact	Moderate impact
GUI013 Occipital Nerve Stimulation	No impact	N/A	Mixed (no impact/ minor impact)	No response	No impact	N/A	No impact	Minor impact
GUI014 Multigrip	No response	Major impact	Moderate impact	No response	N/A	N/A	Moderate impact	Moderate impact
GUI020 Rapid Antigen Detecting Tests	Minor impact	Moderate impact	No response	No response	No impact	N/A	Moderate impact	N/A
GUI024 Transcatheter Aortic Valve Implantation	N/A	N/A	No response	No response	Moderate impact	N/A	Minor impact	Major impact
GUI029 Point of care ultrasound for suspected gallstones	N/A	No answer	No response	No response	Minor impact	N/A	No impact	N/A
GUI002-2 Corneal cross-linking	Major impact	No answer	Major impact	No response	Minor impact	N/A	Moderate impact	Moderate impact
GUI030 ClearGuard™ Antimicrobial barrier caps	No impact	No response	No response	No response	No answer	N/A	No answer	N/A
GUI004-2 FreeStyle Libre	Moderate impact	Moderate impact	Moderate impact	No response	Major impact	Moderate impact	Moderate impact	N/A
MTG32 HeartFlow	N/A	Major impact	No response	No response	Minor impact	N/A	Moderate impact	N/A
MTG46 GammaCore	Moderate impact	N/A	No response	No response	Moderate impact	N/A	Moderate impact	N/A
MTG52 ZioXT	N/A	Moderate impact	No response	No response	No impact	N/A	Minor impact	N/A

No response' indicates that the questionnaire was not returned for a piece of guidance
No answer indicates that a return was provided but this question was not answered.
Mixed indicates that multiple responses were returned from an organisation, with differing answers.
N/A indicates that a health board reported that a piece of guidance was not applicable to their organisation
N.B. Velindre indicated that none of the guidance audited was relevant to their organisation, with the exception of GUI004-2, for which no confirmation was received. None of the pieces of guidance audited are expected to be relevant to WAST, but no response was received to confirm this.
No impact (not considered in decision-making)

Minor impact (considered but did not inform decision-making) Moderate impact (considered and had a moderate impact on decision-making) Major impact (considered and had a major impact on decision-making)

3. Detailed information for guidance in the audit

In this section, we present a summary of the response to the adoption audit for each piece of guidance. A description of the adoption audit process and methodology is available in Appendix I, and an example of the adoption audit materials which were shared with HTW Health Board adoption leads is available in Appendix II.

3.1 Synovasure (HTW Guidance 008)

3.1.1 Background

Key details and the guidance recommendation are below:

Technology:	Synovasure Alpha Defensin test
Products:	Synovasure Alpha Defensin test (Zimmer Biomet)
Population:	People with suspected periprosthetic joint infection following total hip arthroplasty (THA) and total knee arthroplasty (TKA)
Topic Proposer:	Zimmer Biomet (product manufacturer)
Publication date:	June 2019

The use of Synovasure alpha defensin testing shows promise in the diagnosis of peri-prosthetic hip and knee infection but the evidence does not currently support routine adoption. Synovasure has the potential to further the diagnosis in patients with equivocal results from conventional testing but more convincing evidence is needed.

HTW therefore recommends further research in this group of patients to define diagnostic accuracy, clinical outcomes and cost consequences of the use of Synovasure in addition to standard investigations.

Evidence was available from a single small-scale non-randomised trial which suggested that Synovasure has high levels of sensitivity, specificity and negative predictive value. However, there was a lack of evidence on changes in management in response to testing and clinical outcomes.

Economic analyses suggested that use of Synovasure was not cost-effective if included within a package of conventional laboratory tests for all patients with suspected periprosthetic joint infection following TKA and THA. However, Synovasure may be cost-effective for people with suspected periprosthetic joint infection following TKA who have equivocal results after conventional testing. There is a high level of uncertainty within these estimates due to the limited clinical evidence base.

Please see HTW GUI008 [3] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.1.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

We received four responses to the adoption audit for this piece of guidance. The guidance is not relevant for WHSSC and Velindre. PTHB stated that the health board does not employ surgeons who undertake this kind of clinical procedure.

SBUHB, HDUHB and BCUHB were not aware of the guidance, while CVUHB were unsure. Responses were mixed on the clarity of the guidance. HDUHB found the guidance to be unclear, but reported that it was 'clear that the current evidence does not support routine adoption and that further research is required to determine clinical effectiveness'. SBUHB and CVUHB found the guidance clear.

The HTW guidance states that the evidence does not currently support routine adoption of Synovasure alpha defensin testing in the diagnosis of peri-prosthetic hip and knee infection. CVUHB were unsure whether the health board intended to adopt the guidance. Consistent with the guidance, HDUHB and SBUHB each reported that Synovasure Alpha Defensin is not used. SBUHB reported that no changes were needed. The current pathway, which preceded the guidance, is acceptable as it complies with the guidance. HDUHB reported that use of the Synovasure Alpha Defensin test has been very limited and that its use will be discouraged until further evidence is available or if the health board becomes involved in research. There was no indication in the adoption audit responses that research is currently being undertaken.

HDUHB reported no changes in service specifications or commissioning policies while CVUHB was unsure. CVUHB was neutral and HDUHB agreed that Synovasure has not been routinely adopted in their organisation as part of the suite of conventional tests for suspected peri-prosthetic joint infection after THA and TKA. Both CVUHB and HDUHB were neutral on whether Synovasure has been routinely adopted for diagnosing peri-prosthetic joint infection after THA or after TKA in people with equivocal results after conventional tests (e.g. erythrocyte sedimentation rate (ESR) PJI, serum CRP, FBC, synovial fluid white blood cell count and microscopy and culture.) In summary, both CVUHB and HDUHB felt the guidance had no impact on decision-making, as HDUHB clinicians had been unaware of the guidance prior to the circulation of the guidance as part of the adoption audit. Given that HTW guidance does not recommend routine adoption of Synovasure Alpha Defensin tests and that the technology was not previously being used routinely, a low impact is a positive outcome.

Data from Procurement Services show that low numbers of Synovasure products were procured in each health board, both before and after the publication of the guidance. We compared the period of September 2018 to April 2019 with September 2019 to April 2020. The procurement data are consistent with the lack of awareness of the guidance reported in the questionnaires and consistent with the finding that the Synovasure Alpha Defensin test has not been routinely adopted.

3.2 Handheld ultrasound devices (HTW Guidance 009)

3.2.1 Background

Key details and the guidance recommendation are below:

Technology:	Hand-held ultrasound devices
Products:	Vscan Portable Handheld Ultrasound (GE Healthcare)
Population:	People with possible systolic heart failure in community and primary care settings

Topic Proposer: Consultant Cardiologist, Cardiff & Vale University Health Board

Publication date: May 2019

Hand-held ultrasound devices (HUDs) show promise in the diagnosis of heart failure in a primary care or community setting, but the current evidence is insufficient to support routine adoption. HUDs have the potential to reduce secondary care referrals if heart failure is excluded and to facilitate earlier treatment if confirmed, but convincing evidence is needed to substantiate any clinical and system benefits.

HTW recommends further research to investigate the benefits of implementing HUDs in a primary care or community setting in Wales.

Evidence from several small-scale studies suggest that HUDs have a relatively high negative predictive value for use in excluding left ventricular systolic function as a cause of heart failure. However, no evidence examining whether decision-making based on these findings is safe and effective was identified.

Economic analyses in this context are likely to have very high uncertainties due to the limited clinical evidence. HTW modelling suggested that use of HUD would be more expensive on a per-patient basis but whether this increase would be cost-effective according to the benefits delivered was not examined.

Please see HTW GUI009 [4] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.2.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to the HTW Health Board adoption leads. We did not make a data request to procurement for this topic due to more limited information being held for services provided in primary care.

Three health boards responded to the adoption audit for this piece of guidance, while WHSSC and Velindre confirmed that the guidance is not relevant to their organisations. PTHB replied to confirm that the guidance has not been adopted, but did not respond to the more detailed questionnaire.

HDUHB and SBUHB confirmed that they were unaware of the guidance, while ABUHB were aware. ABUHB and HDUHB felt that the guidance was clear and HDUHB acknowledged that future studies may support routine use in the community. However, SBUHB felt that it was not clear whether the guidance recommended the use of this technology in this setting or not.

The HTW guidance states that the evidence does not currently support routine adoption of hand-held ultrasound devices for the diagnosis of heart failure in a primary care or community setting. HDUHB and ABUHB agreed that their health boards intended to adopt the guidance i.e. to not routinely adopt the technology. ABUHB were aware that hand-held ultrasound devices are only used by Consultant Cardiologists in hospital settings in the health board. HDUHB were prepared to participate in research and have considered future pilot studies. It therefore appears that the recommendation for further research within the guidance is being considered.

SBUHB responded that they did not intend to adopt the guidance, however this may have been interpreted as intention to adopt the technology, as SBUHB noted the lack of evidence, expertise, equipment and training for GPs. They noted that GPs would therefore be unable to confidently exclude heart failure based on their own echocardiogram interpretation.

Indeed, SBUHB and HDUHB strongly agreed and ABUHB agreed that the use of handheld ultrasound devices for assessment and diagnosis of systolic heart failure has not been routinely adopted in their organisations. SB flagged that they were aware of one doctor who does their own ECHOs.

Supporting their earlier answers, HDUHB and SBUHB confirmed that no business cases were developed and no service specifications, commissioning policy changes nor audits have occurred. ABUHB noted that the use of hand-held ultrasound devices is to be expanded in a new murmur clinic, which will be audited in 2023.

ABUHB reflected on the current service for diagnosing heart failure:

''We are fortunate we are able to perform IP TTE in a timely fashion. The HUDs are used more often at night or weekends by Consultant Cardiologists who then request a full TTE when able.''

The impact of the guidance was limited, with ABUHB and HDUHB indicating that it had a minor impact, while SBUHB reported no impact. As the guidance does not recommend the routine use of the technology and health boards were not previously using the technology, a small impact is expected.

Respondents raised possible challenges should hand-held ultrasound devices for the diagnosis of heart failure in primary care be recommended in future, citing a Swansea project with Cardiology GPs with special interest who were trained to use hand-held ultrasound devices. The project raised that the quality of images and confidence in diagnosis increases with the number of hand-held ultrasounds undertaken. The necessary numbers may be difficult to achieve in the time-pressured environments of primary care where patient numbers may be low. However, the respondent felt that there could be a future role for hand-held ultrasound if it is incorporated into teaching at medical school.

3.3 Robot-assisted thoracic surgery (HTW Guidance 010)

3.3.1 Background

Key details and the guidance recommendation are below:

Technology:	Robot surgical systems
Products:	da Vinci (Intuitive Surgical)
	Surgenius (Surgica Robotica)
	Senhance (TransEnterix)
	Freehand (Freehand 2010 Ltd)
Population:	People with lung cancer undergoing surgery
Topic Proposer:	Consultant Thoracic Surgeon, Cardiff & Vale University Health Board

Publication date: August 2019

Robot-assisted thoracic surgery shows promise for lung resection, but there is currently insufficient evidence to support routine adoption.

Further research is needed to define the possible impact of robot-assisted surgery on long term survival and disease recurrence as well as on patient experience and post-

Evidence suggests that robot-assisted thoracic surgery may improve some short-term outcomes compared with conventional surgical approaches. However, this evidence is based on non-randomised evidence and there is a lack of evidence on long-term outcomes. Robot-assisted thoracic surgery is more costly than other types of surgery and it is unclear whether these increases in cost present value for money due to the uncertainty with short and long-term outcomes.

Please see HTW GUI010 [5] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.3.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

We received two responses to the adoption audit for this piece of guidance, from SBUHB and WHSSC. HDUHB, PTHB and Velindre stated that the guidance is not relevant to their organisations.

SBUHB and WHSSC were each aware of the guidance and felt that it is clear.

WHSSC and SBUHB indicated that they intended to adopt the guidance, which stated that there is currently insufficient evidence to support routine adoption of robot-assisted thoracic surgery for lung resection. As the commissioner for adult thoracic surgery for Wales, WHSSC confirmed that robot-assisted thoracic surgery is not routinely commissioned. SBUHB strongly agreed and WHSSC agreed that robot-assisted thoracic surgery for lung resection had not been routinely adopted in their organisations.

In line with the above answers, WHSSC and SBUHB reported that no business cases had been developed nor audits undertaken and SBUHB have made no changes to service specifications or commissioning policies. WHSSC updated the published Thoracic Surgery service specification (CP144) to include a note that RATS is not routinely available.

WHSSC felt that the guidance had a moderate impact, while SBUHB reported no impact. WHSSC included the recommendation to not routinely adopt robot-assisted thoracic surgery when updating the service specification. Further, WHSSC suggested that the guidance may be used in the assessment of Individual Patient Funding Requests (IPFRs) which they felt could lead to inequity.

While there was no indication that health boards had engaged in further research, SBUHB raised that the evidence has changed since the guidance was produced. This was also evident in the response from WHSSC:

"There remains considerable pressure from the thoracic surgical services for a re-appraisal of the HTW guidance. WHSSC as the commissioner for thoracic surgical services was formally approached by the South Wales Adult Thoracic Surgical Services programme in September 2022 to ask HTW to undertake a formal reassessment of the evidence".

The Robot-assisted thoracic surgery for lung resection HTW Evidence Appraisal Report is being considered for reassessment, which will entail consideration of the emerging evidence base.

Data from Procurement Services show that Da Vinci XI Hot Shears ™ monopolar curved scissors and Da Vinci XI Prograsp™ forceps were procured both prior to and after publication of HTW guidance. However, it is not possible from these data to confirm whether robot-assisted thoracic surgery is being performed for lung resection.

3.4 ONS (HTW Guidance 013)

3.4.1 Background

Key details and the guidance recommendation are below:

Technology:	Occipital nerve stimulation
Products:	Neurostimulator devices (Abbott; Medtronic; Boston Scientific)
Population:	People with medically refractory chronic cluster headache
Topic Proposer:	Welsh Health Specialised Services Committee
Publication date:	November 2019

Occipital nerve stimulation shows promise for treating medically refractory chronic cluster headache, but the evidence is insufficient to support routine adoption.

Further research is recommended to determine the impact of occipital nerve stimulation on the frequency and severity of cluster headache attacks, quality of life and cost implications.

Evidence suggests that occipital nerve stimulation may provide benefits to patients with refractory chronic cluster headaches, particularly in terms of reducing attack frequency. However, this evidence is limited and relies on case series. There are also cases of technology failure and safety events documented in several studies. Economic evidence suggests that the initial cost of occipital nerve stimulation would be high, although there may be cost offsets relating to reductions in medication use. Findings on cost-effectiveness are uncertain and appear to be driven by duration of treatment effect.

Please see HTW GUI013 [6] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.4.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

We received responses to the adoption audit of this piece of guidance from five organisations. Velindre and PTHB indicated that the guidance was not relevant to them, however PTHB reasoned that it was not relevant as the health board had not adopted the technology. BCUHB confirmed that the technology comes under the remit of neurology, but that the health board's neurology service is delivered externally in the Walton Centre, Liverpool.

SBUHB, HDUHB, and WHSSC were aware of the guidance (the topic had been originally proposed to HTW by WHSSC), while ABUHB were not aware. We received three separate responses to the adoption audit for this piece of guidance from CVUHB, from two different individuals. Responses were mixed from the CVUHB participants on awareness of the guidance. All respondents felt the guidance was clear, with the exception of one individual from CVUHB who gave a mixed answer.

The HTW guidance stated that that the evidence was insufficient to support the routine adoption of occipital nerve stimulation for medically refractory chronic cluster headache. All respondents stated that their organisations intended to adopt the guidance, i.e. to not adopt the technology, with the exception of one CVUHB respondent who gave a mixed response and raised that there was no capacity. The same respondent felt that the guidance was unclear, so it is possible that the guidance not to routinely adopt the technology was misinterpreted. ABUHB felt that adoption was straightforward for guidance not supporting routine adoption and would welcome new high quality evidence. HDUHB noted that their Neurology service is provided by visiting Consultants from SBUHB, so decision-making remains with SBUHB and the adoption audit responses are in line with one another.

WHSSC confirmed:

''Based on HTW guidance, WHSSC has decided not to routinely commission occipital nerve stimulation for treating medically refractory chronic cluster headache. We agree that further research on the frequency and severity of cluster headache attacks, quality of life and cost (effectiveness) is needed to fully evidence the benefits before it can be considered.''

There was uncertainty on whether changes had occurred following publication of the guidance, including business cases, service specification changes and commissioning policies. WHSSC noted that it does not have a service specification or commissioning policy for the occipital nerve stimulation for treating medically refractory chronic cluster headache. However, WHSSC flagged that WHSSC IPFR panel has been informed [of the guidance], as several requests per year are received for this treatment via the IPFR process.

There was agreement from all but one respondent that occipital nerve stimulation for treating medically refractory chronic cluster headache has not been routinely adopted, which is in line with HTW guidance. The dissenting individual from CVUHB submitted two different answers. There was no indication that further research had been undertaken. All respondents indicated that the guidance had no impact, with the exception of WHSSC and one of the mixed responses from CVUHB. ABUHB clarified that HTW guidance recommending the use of a technology would be considered, but given that the HTW guidance supports the current position of not offering occipital nerve stimulation, nothing has changed. WHSSC felt the guidance had a minor impact, offering that it may impact future decision making in terms of assessing IPFR requests which could lead to inequity of provision for patients living in Wales. Respondents raised that Neurologists would consider whether their patients with cluster headaches would benefit and would likely use the IPFR route to access treatment from NHS England.

Data from Procurement Services show that neuro-stimulator devices/implantable pulse generators were procured in small numbers before and after publication of HTW guidance in

CVUHB and CTMUHB. Numbers were smaller still in ABUHB, SBUHB, BCUHB, HDUHB and PTHB, again with procurement before and after guidance publication. It is not possible to confirm whether the technology was used in cases of chronic refractory cluster headache from these data. However, the data support the finding from the questionnaire that occipital nerve stimulation has not been routinely adopted for medically refractory chronic cluster headache. The procurement data could reflect that some patients are able to access this via IPFR.

3.5 Multigrip (HTW Guidance 014)

3.5.1 Background

Key details and the guidance recommendation are below:

Technology:	Multi-grip myoelectric upper limb prosthetics
Products:	Touch Solutions (Ossur)
	Prosthetic hands (Ottobock)
	Hero Arm (Open Bionics)
Population:	People with upper limb amputation
Topic Proposer:	Welsh Health Specialised Services Committee
Publication date:	November 2019

> Multi-grip myoelectric upper limb prosthetics show promise for use by people with upper limb amputation, but the evidence is insufficient to support their routine adoption.

Evidence on the use of single-grip and multi-grip prosthetics is limited and it is difficult to make conclusions on the relative advantages and disadvantages of the technology. Due to the very limited evidence on effectiveness it was not possible to develop economic models and no other cost-effectiveness evidence was identified.

Please see HTW GUI014 [7] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.5.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

HDUHB, PTHB and Velindre stated that the guidance was not relevant to their organisations. Questionnaire responses were received from BCUHB, CVUHB, SBUHB and WHSSC.

All respondents were aware of the guidance with the exception of BCUHB, who were unsure. WHSSC and SBUHB had each been involved in the appraisal as WHSSC had initially referred the topic to HTW while the respondent from SBUHB had provided expert review on the Evidence Appraisal Report. All respondents felt the guidance was clear, with WHSSC specifying that more research is required to measure functional outcomes and quality of life.

While BCUHB had been uncertain of the organisation's awareness of the guidance, the respondent noted that Multi-grip prostheses are not available without an approved IPFR, indicating that BCUHB is compliant with HTW guidance. Few individuals within BCUHB have received Multi-grip prostheses via IPFR. SBUHB similarly responded that Multi-grip devices are not routinely provided, and also raised that the IPFR route is available if evidence is sufficient on an individual basis. The Artificial Limb and Appliance Service in Swansea has made several IPFR applications in recent years. CVUHB were unsure whether the organisation intended to adopt HTW guidance, indicating that the decision would depend on WHSSC commissioning. WHSSC confirmed that, based on HTW guidance, multi-grip myoelectric upper limb prosthetics would not be routinely commissioned. However, WHSSC informed the IPFR Panel about the guidance as several requests are received by the WHSSC Panel each year. All respondents agreed that the use of multi-grip myoelectric upper limb prosthetics for people with upper limb amputation have not been routinely adopted, in line with HTW guidance.

No business cases, service specification or commissioning policy changes were highlighted in the adoption audit responses. WHSSC indicated that work is ongoing to audit multi-grip when the QMS ISO 13485 is approved. In addition, WHSSC is working to understand the NHSE Multi Grip Hand Policy and monitor its roll-out in terms of outcomes for patients.

The respondents generally reported that the guidance had a moderate impact, while BCUHB speculated that guidance recommending against routine adoption would have had a major impact in decision-making, though awareness was limited in the health board. CVUHB indicated that the guidance would be used by WHSSC in its commissioning decisions, which is done on an all-Wales basis for prosthetics. WHSSC raised that the guidance may impact future decision-making by IPFR Panels, which they felt could lead to inequity.

Further, respondents raised that the other UK nations fund Multi-grip myoelectric hands, and indicated that HTW guidance has therefore resulted in inequity of provision. The CVUHB respondent commented:

''[I am] enthusiastic about greater adoption of multi articulating myoelectric arms and would support greater commissioning and funding from WHSSC''.

BCUHB raised some of the challenges associated with generating evidence for the benefits of multi-grip myoelectric upper limb prostheses. These include the small patient numbers, both in Wales where there are just three prosthetic centres, and in wider prosthetic research. In addition, the benefits of myoelectric prostheses may only be realised upon using the device. The respondent flagged a retrospective cohort analysis published since the publication of HTW guidance. HTW are currently updating the Evidence Appraisal Report for Multi-grip myoelectric upper limb prosthetics for use by people with upper limb amputation.

Data from Procurement Services show that Multi-grip myoelectric devices were procured in small numbers before and after publication of HTW guidance in BCUHB, SBUHB and CVUHB. It is possible that multiple components were procured for single cases, which could not be established from the data. The data support the finding from the questionnaire that multi-grip myoelectric upper limb prosthetics have not been routinely adopted for people with upper limb amputation. The procurement data could reflect that some patients are able to access this via IPFR.

3.6 Rapid Antigen Detecting Tests (HTW Guidance 020)

3.6.1 Background

Key details and the guidance recommendation are below:

Technology:	Rapid antigen detection tests
Products:	Rapid antigen detection tests (New England Biolabs; Sekisui Diagnostics)
Population:	People with sore throat in community pharmacy settings
Topic Proposer:	Chief Pharmaceutical Officer, Welsh Government
Publication date:	September 2021

> The use of rapid antigen detection tests (RADT) within the community pharmacy setting for the diagnosis and management of people with group A streptococcal infections is promising. Nonetheless, the current evidence is limited and does not support routine adoption.
>
> Further research is recommended to demonstrate the clinical effectiveness of RADT in the community pharmacy setting.

Evidence for RADT suggested it has acceptable sensitivity and specificity but there is limited evidence on the impact on patient outcomes. Economic evidence suggests that using RADT is cost-effective but there may be uncertainties due to limitations with evidence on clinical effectiveness.

Please see HTW GUI020 [8] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.6.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We did not make a data request to procurement for this topic due to more limited information being held for services provided in primary care.

We received four responses to the adoption audit for this piece of guidance, from HDUHB, SBUHB, ABUHB and BCUHB. PTHB, WHSSC and Velindre stated that the guidance is not relevant to their organisation.

SBUHB, ABUHB and BCUHB were aware of the guidance, but HDUHB were unaware. Feedback on the clarity of HTW guidance on rapid antigen detecting tests was mixed. Most respondents found the guidance clear. HDUHB, however, felt that the guidance was unclear as it suggests that there is evidence for effectiveness, but recommends further research. The respondent expects that this would be difficult to interpret in practice.

The respondents from SBUHB and BCUHB were unsure whether their organisations intended to adopt HTW guidance. The SBUHB respondent raised that the use of the RADT was a national service that was rolled out and not a specific health board initiative, and noted that 27 pharmacies are adopting the test based on national guidance. It is unclear which national guidance is referred to. BCUHB highlighted that a trial was run during the COVID-19 pandemic

which offered an equivalent service without RADT. However, a significant growth in use of antibiotics was observed. The respondent felt that removal of the RADT from the sore throat test and treat service creates a low threshold for supply of antibiotics and risks over use. BCUHB reported that RADT was subsequently reintroduced. This suggests that BCUHB and SBUHB did not adopt HTW guidance.

A similar picture was reported in HDUHB. The respondent from HDUHB was unaware of the HTW guidance and so they did not intend to adopt. They also confirmed that they are already using the OSOM test (Sekisui Diagnostics) and running a sore throat test and treat service as advised by Welsh Government.

The respondent for ABUHB provided an article from The Pharmaceutical Journal (https://pharmaceutical-journal.com/article/news/community-pharmacy-sore-throat-testing-service-to-restart-in-two-health-boards-in-wales), which cited HTW's guidance, to contextualise their decision not to adopt this HTW guidance within the community pharmacy setting. The 'Choose Pharmacy' service was intended to cover all seven health boards but was suspended due to the COVID-19 pandemic, prior to the publication of HTW guidance. The service was then resumed in two health boards, according to the article. ABUHB report that Welsh Government have encouraged further evaluation of the Sore Throat Test and Treat service, which has now been routinely adopted across the health board. The service is commissioned in 47 of 131 community pharmacies.

The article provided by the ABUHB respondent mentions that HTW guidance states that rapid antigen detecting tests show promise and that a recommendation for further research was made. It appears that ABUHB are complying with this aspect of the HTW guidance, although the specific evidence generation plans are unclear.

No business cases, service specification changes or commissioning changes were raised in the responses to the audit for this piece of guidance.

All respondents disagreed or strongly disagreed that use of rapid antigen detection tests (RADT) within the community pharmacy setting for the diagnosis and management of people with group A streptococcal infections have not been routinely adopted. ABUHB noted that the Sore Throat Test and Treat service has been firmly established in accredited pharmacies. BCUHB replied:

''The nationally commissioned Sore Throat Test and Treat element of the Clinical Community Pharmacy Service relies on RADT as a key diagnostic criteria for the supply of antibiotics and this is commissioned in pharmacies in North Wales''.

The impact of the HTW guidance was reported to range from no impact to a moderate impact. HDUHB felt that the guidance had no impact, as it was published after the pilot had been established. HDUHB felt that if the guidance had been negative, the health board would have considered it. This underlines the earlier comments from HDUHB relating to the clarity of the guidance. In conclusion, BCUHB felt that the HTW guidance should be reviewed in light of emerging evidence, citing a publication of the antibiotic prescribing rates as referenced earlier.

3.7 TAVI (HTW Guidance 024)

3.7.1 Background

Key details and the guidance recommendation are below:

Technology:	Transcatheter aortic valves
Products:	SAPIEN TAVI balloon expandable systems (Edwards Lifesciences)
	CoreValve Evolut self-expandable systems (Medtronic)
Population:	People with severe symptomatic aortic stenosis at intermediate surgical risk
Topic Proposer:	Welsh Health Specialised Services Committee
Publication date:	September 2020

Transcatheter aortic valve implantation (TAVI) is non-inferior to surgical aortic valve replacement (SAVR) in people with severe symptomatic aortic stenosis who are at intermediate surgical risk. However, the cost effectiveness evidence does not currently support the case for routine adoption.

TAVI was non-inferior to SAVR for all-cause mortality, cardiac mortality or disabling stroke, and shows similar improvements in both symptoms and quality of life. However, due to a lack of long-term data, there is uncertainty around the durability of TAVI valves and the potential need for reintervention. A cost-utility analysis developed by HTW showed that TAVI is unlikely to be cost effective in this patient group. The cost-effectiveness result was mainly driven by the cost of the TAVI valve.

Evidence from randomised studies suggests that TAVI is non-inferior to surgical aortic valve replacement for all-cause mortality, cardiac mortality, or disabling stroke. TAVI may be associated with reduced length of stay and new-onset fibrillation but also increased rates of paravalvular regurgitation. The long-term durability of TAVI devices is not established and may need more reinterventions than surgical valve replacement.

Existing economic evidence on TAVI was mixed with some studies suggesting it was cost-effective and others not. HTW developed an economic model and found that TAVI was likely to be more effective but more costly than standard care and the increase in cost did not present value.

Please see HTW GUI024 [9] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.7.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We did not make a data request to procurement for this topic as we would be unable to obtain data which focus on the use of TAVI in people with severe symptomatic aortic stenosis who are at intermediate surgical risk, which is the population of the guidance.

We received three responses to the adoption audit for this piece of guidance, from WHSSC. HDUHB and SBUHB. BCUHB, ABUHB, PTHB and Velindre responded to register that the guidance was not relevant to their organisations. Notably, no response was received from CAVUHB, one of the two centres in Wales which delivers TAVI.

WHSSC, who referred the topic to HTW, and HDUHB were aware of the guidance, while SBUHB were unaware. All respondents felt the guidance was clear, with HDUHB adding that the definition of intermediate risk is crucial in the interpretation of the guidance.

All respondents intended to adopt the guidance in their organisations. WHSSC responded that the Specialised Services Commissioning Policy CP58 for WHSSC-commissioned Trans-catheter Aortic Valve Implantation (TAVI) for Severe Symptomatic Aortic Stenosis (SSAS) remains in line with the HTW guidance. HDUHB offered that SBUHB implemented this recommendation as part of a South West Wales regional approach. HDUHB have discussed the recommendation with Morriston Cardiac centre staff. As the gatekeeper for the technology for South West Wales, SBUHB has audited the use of this technology and confirmed that the guidance is being followed. SBUHB has an active multi-disciplinary team which undertakes a patient-orientated assessment of risk, beyond simple risk scoring tools. SBUHB noted that TAVI is currently commissioned for high surgical risk cases (the WHSSC policy also covers people deemed inoperable), but that SBUHB participated in a trial looking at intermediate risk after discussion with WHSCC CEO. The respondent felt that the guidance also requires involvement of the patient and consideration of patient choice which could significantly increase requests for TAVI. This comment likely refers to the 'Appraisal Panel Considerations' section of the guidance, which states "The Appraisal Panel agreed that patient choice and shared-decision making was an important element when determining treatment for severe symptomatic AS".

SBUHB and WHSSC agreed that the use of TAVI for people with severe symptomatic aortic stenosis and intermediate surgical risk has not been routinely adopted. HDUHB reported that during the COVID-19 pandemic and since the recommendation was published, patients at intermediate surgical risk were referred for TAVI and accepted on a case by case basis. As this does not represent routine adoption, it appears that HTW guidance has been implemented.

WHSCC monitors TAVI activity and has observed an increase in procedures delivered by its commissioned providers, which mirrors national trends. WHSSC confirmed the report by HDUHB that the inclusion criteria for TAVI were broadened in the short-term during the COVID-19 pandemic to include the intermediate risk patient group. WHSSC has been assured that this temporary change to the inclusion criteria has ceased, and providers has reverted to conforming to WHSSC's substantive TAVI policy.

The impact of the guidance was reported to range from a minor impact to a major impact. The HDUHB respondent flagged that local Cardiologists had raised that further evidence is available which could support the use of TAVI in the intermediate risk patient group.

3.8 POCUS Gallstones (HTW Guidance 029)

3.8.1 Background

Key details and the guidance recommendation are below:

Technology:	Point-of-care ultrasound
Products:	Large range of devices
Population:	People with abdominal pain in acute or emergency care settings
Topic Proposer:	Consultant Gastroenterologist, Betsi Cadwaladr University Health Board
Publication date:	March 2021

> The use of portable point-of-care ultrasound (POCUS) to diagnose gallstone disease shows promise, but the current evidence is insufficient to support routine adoption.
>
> Further research is recommended to demonstrate the clinical and cost effectiveness of portable POCUS in emergency and acute care settings.

Evidence from several studies, including two comparative studies suggested that specificity was similar for point-of-care and formal ultrasound but sensitivity was higher for formal ultrasound. Economic evidence suggested that point-of-care ultrasound may cost less but also be less effective that formal ultrasound.

Please see HTW GUI029 [10] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.8.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaires to HTW Health Board adoption leads. We did not make a data request to procurement for this topic as it would not be possible to link the data to POCUS use to diagnose gallstones in the emergency and acute settings specifically.

We received responses from SBUHB, HDUHB and BCUHB for this piece of guidance. ABUHB, WHSSC, Velindre and PTHB reported that the guidance is not relevant to their organisations.

The respondents each reported that the guidance was clear. SBUHB and HDUHB were unaware of the guidance prior to its circulation as part of the adoption audit and the respondent from BCUHB was uncertain, despite BCUHB's involvement in submitting the topic to HTW. Consequently, HDUHB did not intend to adopt the guidance and SBUHB and BCUHB were unsure whether they intended to adopt the guidance. The respondent from SBUHB reported that ultrasounds are provided on a timely basis and reliably by radiology. No other changes, for example to service specifications, were reported in the adoption audit. SBUHB and HDUHB strongly agreed that the use of point-of-care ultrasound to diagnose gallstones disease for people with abdominal pain in acute or emergency settings has not been routinely adopted. This suggests that SBUHB and HDUHB are complying with HTW guidance, but that no changes were required to do so. The respondent from SBUHB noted that they would support training for physicians and surgeons if approached. There was no indication that further research is being undertaken.

SBUHB reported that the guidance had a minor impact and HDUHB reported that there was no impact, as they were unaware of the guidance and it had not impacted on decision-making.

3.9 CXL (HTW Guidance 002-2)

3.9.1 Background

Key details and the guidance recommendation are below:

Technology:	Corneal cross-linking
Products:	Riboflavin solution
Population:	Adults and children with keratoconus
Topic Proposer:	Welsh Health Specialised Services Committee
Publication date:	March 2021

> The evidence supports the routine adoption of corneal cross-linking (CXL) for children and adults with progressive keratoconus.
>
> HTW recommends the acquisition of real word data to capture long-term outcomes (including patient-reported outcomes measures) in people who have CXL for keratoconus.

Evidence from two systematic reviews of randomised controlled trials provided evidence that keratoconus progression is less likely after corneal cross-linking compared to no treatment. These sources also suggest other benefits from corneal cross-linking that ultimately may improve vision. An economic analysis developed by HTW suggested that corneal cross-linking is cost-effective if the duration of effect is 14 years or more.

Please see HTW GUI002-2 [11] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.9.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We did not make a data request to procurement for this topic as it is a procedure.

We received responses from six health boards for this piece of guidance. Velindre confirmed that the guidance is not relevant to their organisation and PTHB health board responded that it does not employ surgeons who undertake this kind of clinical procedure.

CVUHB, HDUHB, SBUHB, ABUHB and WHSSC were all aware of the guidance. Some had prior involvement with the appraisal; WHSSC had initially proposed the topic for consideration by HTW and the SBUHB respondent was aware as they had provided expert input at the HTW Appraisal Panel when the guidance was developed. HDUHB reported that the guidance was received from HTW on publication and was shared with the service.

All respondents fed back that the guidance is clear. WHSSC, however, added that the guidance was clear that corneal cross-linking should be adopted but less clear on patient selection. This would have been helpful for WHSSC in developing a commissioning policy.

CVUHB, HDUHB, SBUHB, ABUHB and WHSSC all intended to adopt the guidance that corneal cross-linking (CXL) for children and adults with progressive keratoconus should be routinely adopted. Meanwhile, the BCUHB respondent stated they intend to adopt the service for adults in the future, but that there is a delay until 2024 due to parental leave.

We received two responses to the adoption audit from the same individual at CVUHB. One response indicated that the guidance was not relevant, but later stating that a CXL service was developed after the HTW guidance and a second saying 'adopted and set up crosslinking service'. We therefore disregarded the 'not relevant' answer, and merged answers to other questions as both responses supported one another. CVUHB stated that they had adopted the guidance and established a CXL service. CVUHB confirmed that a business case was developed by the clinical director and equipment was purchased.

The WHSSC Prioritisation Panel considered the HTW guidance and Evidence Appraisal Report in 2021 and assigned CXL a 'high priority' for funding. Funding was allocated in the 2022 WHSSC Integrated Commissioning Plan. WHSSC, which has CXL commissioning responsibility for paediatric patients only, further stated that a commissioning policy (CP272) is in development which will be followed by a provider designation process. In the interim, WHSSC confirmed that requests for treatment will be funded.

ABUHB and SBUHB responded that they are already providing the service, both having developed business cases. SBUHB had already adopted CXL, following endorsement by NICE in 2013. SBUHB reported that the cost of equipment was recuperated after 20 procedures. HDUHB report that they are in the process of merging with SBUHB to form a West Wales Regional Eye Service. Currently, HDUHB makes referrals to SBUHB as a tertiary centre. SBUHB also registered that they were able to accept out of area patients where treatment is unavailable in other health boards. SBUHB regularly audit CXL activity at departmental meetings, while ABUHB said that they intend to audit the service when the number of patients grows, as the service was only established in March 2022.

All respondents except SBUHB agreed that use of corneal CXL for children with progressive keratoconus has been routinely adopted. SBUHB clarified that it has only been adopted since publication of supportive HTW Guidance. CVUHB reflected that there are currently no children on the waiting list in the health board. Similarly, ABUHB noted that the service will be provided once there are suitable patients.

In adults with progressive keratoconus, all respondents agreed or strongly agreed that CXL has been routinely adopted. This was not relevant to WHSSC, who do not have commissioning responsibility for ophthalmology services in adults. In adults, CVUHB reflected that cases have been treated, both under general and local anaesthetic.

The reported impact of the guidance ranged from a minor to major impact. In ABUHB, the guidance had a major impact as it was used in getting the business case approved to set up the service, which was subsequently set up after the HTW guidance. SBUHB and WHSSC reported a moderate impact and HDUHB felt the guidance had a minor impact, as it flagged existing NICE Interventional Procedures Guidance (IPG) for keratoconus treatment (IPG466):

"NICE guidance was already in place for Keratoconus treatment, so in reality separate guidance for Wales was not really necessary, and waiting for it has delayed implementation of the service for patients who would have benefitted from treatment at an earlier stage".

However, NICE IPGs only consider safety and efficacy whereas HTW Evidence Appraisal Reports consider effectiveness and cost effectiveness. CVUHB felt similarly that the availability of CXL was overdue in NHS Wales and SBUHB echoed that they are happy it has finally been approved.

The adoption audit responses did not register whether real world data are being captured alongside the delivery of the service.

3.10 ClearGuard™ (HTW Guidance 030)

3.10.1 Background

Key details and the guidance recommendation are below:

Technology:	Antimicrobial barrier caps
Products:	ClearGuard™ HD (ICU Medical)
Population:	People undergoing haemodialysis for chronic kidney disease
Topic Proposer:	ICU Medical (product manufacturer)
Publication date:	May 2021

> The evidence supports the routine adoption of ClearGuard HD antimicrobial barrier caps for use with haemodialysis catheter hubs.
>
> Health Technology Wales recommends the collection of real world audit data around the use of ClearGuard HD caps in Wales.

Clinical evidence shows that the use of ClearGuard™ HD caps reduce the rate of blood stream infections compared to standard caps. Economic modelling suggests that the use of ClearGuard™ HD has the potential to lead to overall cost savings.

Please see HTW GUI030 [12] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.10.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

We received responses to the adoption audit for this piece of guidance from SBUHB, HDUHB and ABUHB. WHSSC and Velindre confirmed that it is not relevant in their organisations, while PTHB Health Board reported that it does not directly provide the procedure.

All three respondents were aware of the guidance. HDUHB had involvement in the expert review of the Evidence Appraisal Report, which informs the Appraisal Panel in forming guidance. HTW guidance was also shared with the Swansea Renal Unit on several occasions. SBUHB reported that they were aware due to the HTW audit request to HDUHB.

SBUHB and HDUHB felt the guidance was clear, whereas ABUHB were unsure. Neither SBUHB nor HDUHB intended to adopt HTW guidance, and ABUHB were unsure. HDUHB raised concerns about the relevance of the guidance to their units, as the appraisal focused on evidence which did not include antimicrobial locks as a comparator, which is current standard practice. Antimicrobial locks were included as a comparator in the protocol for the appraisal, suggesting that if evidence comparing antimicrobial barrier caps with antimicrobial locks was available, it would have been included in the appraisal. HDUHB provided contextual information on the standard care in SBUHB and in the HDUHB satellite dialysis units. Based on the 2015 UKKA Clinical Practice Guideline 7.4, the units were changed from Heparin only lock (which was used in one of the included studies in the HTW guidance) to an antimicrobial lock. They observed an improvement in infection rates and time to removal of lines for infection reasons and have adopted their current practice ever since.

Similarly, SBUHB responded that the appraisal did not include relevant comparators. In their organisation, both antimicrobial dressings and antimicrobial line locks are used. It is unclear whether one regime is superior to another & whether it would be safe and or more efficacious to use the combination of dressing, lock and cap. The SBUHB respondent notes that the guidance to use antimicrobial barrier caps is useful if no antimicrobial prophylaxis was previously being used.

Further, HDUHB felt that the evidence on which the recommendation was made was not strong enough to justify that ClearGuard™ HD antimicrobial barrier caps should be routinely adopted. The HDUHB respondent raised concerns about the evidence presented in the Evidence Appraisal Report. They felt that the impact of antimicrobial barrier caps on hospital admissions and antibiotic starts were only demonstrated in one of the two included studies, but the economic analysis still considered bloodstream infection costs. The sensitivity analysis demonstrated that the results of the model are subject to change based on the assumptions made, which shows the importance of concerns including that not all bloodstream infections are catheter-related bloodstream infections and that the baseline rates of bloodstream infections vary.

As such, no business cases or service specification changes were reported in the adoption audit responses. The only change as a result of the HTW guidance was that several unit discussions on the guidance had taken place in HDUHB. HDUHB undertakes an ongoing audit of CRBSIs. The respondents disagreed or strongly disagreed that the use of ClearGuard™ HD antimicrobial barrier caps for use with haemodialysis catheter hubs had been routinely adopted. As a result, the respondents felt the guidance had either no impact or a minor impact.

The respondents raised outstanding uncertainties in the evidence base for antimicrobial barrier caps. HDUHB and SBUHB confirmed that there is no evidence comparing antimicrobial caps with standard care (antimicrobial locks). In addition there is no evidence on the use of antimicrobial caps in combination with antimicrobial locks. A further consideration is the relative benefit of Tegaderm CHG IV dressings and standard dressings. The studies in the evidence appraisal report used standard dressings, whereas the HTW economic model used the costs of Tegaderm CHG IV dressings.

The respondent also noted that there could be a possible use for antimicrobial barrier caps where antimicrobial locks are contraindicated and a higher dose of heparin is required (people with “clotty” lines).

No respondents reported that real world data have been collected, which would require that antimicrobial barrier caps were adopted. HDUHB offered that they would be happy to contribute to the design and participate in research which could address the remaining uncertainties,

although raised that funding of the research would be required due to the high cost of the antimicrobial barrier caps.

Data from Procurement Services show that low numbers of ClearGuard™ HD antimicrobial barrier caps were procured in BCUHB, CVUHB, HDUHB and SBUHB since guidance publication. As the HTW guidance was published in May 2021, we requested data from May 2020 to May 2022. However, only one Connector IV Needlefree Disinfection Cap was procured in 2021, in BCUHB. The data support the conclusion that ClearGuard™ HD antimicrobial barrier caps have not been routinely adopted.

3.11 FreeStyle Libre (HTW Guidance 004-2)

3.11.1 Background

Key details and the guidance recommendation are below:

Technology: Flash glucose monitoring

Population: People with diabetes who require treatment with insulin

Topic Proposer: Welsh Health Specialised Services Committee (WHSSC)

Publication date: August 2020

> The evidence supports the routine adoption of Freestyle Libre flash glucose monitoring to guide blood glucose regulation in people with diabetes who require treatment with insulin.

Evidence from a series of randomised controlled trials suggests that flash glucose monitoring using Freestyle Libre systems is beneficial in avoiding episodes of hypo- and hyperglycaemia. Economic evidence suggested that flash glucose monitoring is a cost-effective intervention even where conservative assumptions about effectiveness are made.

Please see HTW GUI004-2 [13] for full details of the guidance and supporting HTW Appraisal Panel discussions.

3.11.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data.

HTW received six responses to the adoption audit request for the FreeStyle Libre guidance, from BCUHB, CVUHB, HDUHB, PTHB, SBUHB and ABUHB. Velindre and WHSSC indicated that the guidance was not relevant to their organisations.

Amongst the respondents, awareness of the guidance was high. BCUHB were aware of the guidance as some members of BCUHB staff contributed to the appraisal process. The PTHB Medicine Management team were fully aware of the guidance, and HDUHB raised that they were aware of the guidance through the All Wales Diabetes Implementation Group and through word of mouth. We received two responses to the adoption audit from CVUHB from different individuals. One noted that the point-of-care team were aware but that they were unsure about awareness in diabetes teams or amongst GPs.

Responses were mixed regarding the clarity of the guidance. BCUHB, CVUHB, SBUHB and PTHB felt the guidance was clear. However, HDUHB felt that the guidance was vague around the specific scenarios where the technology may offer benefit, adding that it was "difficult to know what to do with this information particularly in relation to the HTW adopt or justify approach". This was reiterated by ABUHB, who felt that the guidance is open to individual health care professional's interpretation. Specifically, they are unsure whether it is for people with diabetes with all regimens of insulin regardless of Type 1 or Type 2 diabetes. A CVUHB respondent felt that it would have been useful to include a caution on sensor accuracy within the guidance, as the sensors are known to be less accurate in the hypoglycaemic range, and also on the first and last few days of the sensor life.

Respondents intended to adopt the guidance. HDUHB stated that the guidance had already been adopted and changes had been communicated to primary and secondary care. In addition, the formulary status was updated. Based on HTW guidance, BCUHB also made a formulary application broadening the remit for FreeStyle Libre and it is currently available in the health board. The formulary agreement advises primary care initiation for practices which are part of the Negotiated Enhanced Services, which can lead to variation in access for people with type 2 diabetes on insulin therapy. The formulary position for Continuous Glucose Monitoring is currently being updated to reflect NICE guidance.

HDUHB Diabetic Specialist Nurses and Diabetologists currently recommend and promote the use of Flash Glucose Monitoring, but some service users prefer not to use it because of limited technological awareness or ability. Conversely in ABUHB, the respondent raised that Diabetes Specialist Nursing teams in secondary care and primary care receive requests from patients for the flash glucose monitoring and most patients are also uploading their glucose data. ABUHB's Diabetes Specialist Nurses, dietitians and doctors are familiar with the Libreview platform to review glucose data, although it was raised that no additional time is allocated to review these data during consultations. ABUHB have previously audited glucose monitoring, but this has not been undertaken since the publication of HTW guidance.

ABUHB highlighted the cost and staffing implications of the guidance, flagging that no further funding was allocated. ABUHB noted that the device manufacturer supported them in providing training for patients in the community and hospitals. Hywel Dda reported that they would have liked Diabetes Specialist Nurse training from the device manufacturer, but resources did not allow. The increase in demand for the technology from patients has increased workload for Diabetes Specialist Nurses. BCUHB also reported that the services are small and planning has been insufficient to meet the current and forecasted demand for diabetes technologies, which increases waiting lists. This has led to reliance on the manufacturer (Abbott) to provide more timely access. ABUHB recommends that HTW should support health boards to increase staffing resources in view of any technology appraisals. Hywel Dda echoed the concerns about the financial and workload impact of the guidance and suggested that a toolkit for implementation would be beneficial. Similarly, BCUHB flagged the need for a forecasting model to support implementation of a Diabetes Technology Service in health boards, as current services struggle to match the growth in diabetes technologies.

PTHB responded that the health board's position was to adopt the device prior to the publication of HTW guidance. This indicates that the previous iteration of HTW guidance on FreeStyle Libre, which did not recommend routine adoption, was not adopted. They reported that a business case was developed to obtain funding in response to HTW guidance. PTHB closely monitors the issuing of Flash glucose monitors and have observed a 26% cost increase in glucose monitoring as a result of the guidance. Of note, they raised that despite the large increase in use of continuous

blood glucose monitors, only a small (10.5%) reduction in blood glucose testing strip costs has been observed. PTHB feels this merits further investigation. Echoing the response from ABUHB, CVUHB noted that initiation in primary care has resource implications. In HDUHB, primary care were initially unable to adopt the guidance but this has now been achieved. Service specification and commissioning policy changes are ongoing in CVUHB, while these changes have been observed in SBUHB.

PTHB, SBUHB, HDUHB strongly agreed and BCUHB, CVUHB and ABUHB agreed that the use of Freestyle Libre flash glucose monitoring to guide blood glucose regulation in people with diabetes who require treatment with insulin has been routinely adopted. HDUHB clarified that it was difficult to categorically confirm due to lack of audit outcomes (keeping track has not been possible due to limited resources). CVUHB raised again that implementation of the guidance has not been universal in primary care, whereas it has been routinely adopted in secondary care.

The guidance was generally reported to have had a moderate impact, implying that the guidance had been considered and had a moderate impact on decision-making. SBUHB qualified this as they were already high users of the technology, prior to the guidance publication. They felt that biggest impact was for patients with type 2 diabetes as they have used the technology routinely in type 1 diabetes for years. They noted that FreeStyle Libre 2 is popular with patients and is very helpful for clinical decision-making. Likewise, ABUHB felt that the biggest impact of the guidance was for people with Type 2 diabetes. They highlighted that collaboration with primary care diabetes teams and GP services was necessary to meet increase demands and that they had 'streamlined' the eligibility criteria within their service to prevent the service from being overwhelmed. They also flagged the beneficial impact on home bound and cared for patients, as community nurses are able to monitor the patients remotely. PTHB felt that the guidance had a moderate impact because the guidance had a positive impact on the approval of the business plan, although the Health Board had made the decision to adopt this device. BCUHB felt that the evidence appraisal report, appraisal process and guidance had strengthened the confidence in clinical decision making processes:

> *''Externally to Wales, this process is a point of reference as a robust example of reviewing the appropriateness and applicability of new health technology''.*

HDUHB reported that the guidance had a major impact, citing differences between the HTW guidance published in 2020 and the NICE MIB110 (updated in September 2017), which states that only people who have difficulties and daily multiple insulins should be considered. NICE MIBs are a type of NICE advice designed to support NHS and social care commissioners who are considering using new medical devices and other medical or diagnostic technologies. While HTW guidance and other types of NICE guidance such as MTEP guidance is based on evidence of effectiveness and cost effectiveness, MIBs do not consider effectiveness and cost effectiveness.

Some further considerations were raised during the adoption audit, including that some patients are scanning "obsessively" despite advice given and are contacting health care professionals as readings fluctuate. This could increase the burden on staff. Further, some patients experience issues with sensor failures, which can increase the costs of the technology.

Procurement data show that Freestyle Optium Neo was procured before and after publication of HTW guidance in CTMUHB, PTHB and SBUHB. A similar pattern was seen for procurement of sensors and it is noted that a new sensor is required every 14 days. This supports the conclusions based on the adoption audit questionnaires, that Freestyle Libre flash glucose monitoring was routinely adopted prior to publication of HTW guidance and that it has continued after guidance publication in PTHB and SBUHB. The procurement data supplement the qualitative data as no

questionnaire response was received from CTMUHB. The data suggest that the same trend is ongoing in CTMUHB. ABUHB and HDUHB did not appear to be represented in the procurement data.

In CVUHB and BCUHB, Freestyle Optium Neo was not procured before or after publication of HTW guidance. CVUHB reported that service specifications and commissioning changes were ongoing in the questionnaire, which could explain this finding, although they also agreed that Freestyle Libre flash glucose monitoring had been routinely adopted.

HTW was also provided with prescribing data (CASPA) which give an indication of the extent to which guidance has been adopted in primary care. The CASPA data also show that Freestyle Libre sensor kits were prescribed before and after publication of HTW guidance. These data also confirm that this is occurring in ABUHB and HDUHB.

3.12 HeartFlow (NICE MTG32)

3.12.1 Background

HTW has a mandate to audit the adoption of our guidance and that of select NICE MTGs. Key details and the guidance recommendation are below:

Technology: HeartFlow FFR_{CT}

Population: Patients with stable, recent-onset chest pain who are offered CCTA in line with the NICE guideline on chest pain [14].

Publication date: February 2017 (updated May 2021)

> The case for adopting HeartFlow FFRCT for estimating fractional flow reserve from coronary CT angiography (CCTA) is supported by the evidence. The technology is non-invasive and safe, and has a high level of diagnostic accuracy.
>
> HeartFlow FFRCT should be considered as an option for patients with stable, recent-onset chest pain who are offered CCTA in line with the NICE guideline on chest pain. Using HeartFlow FFRCT may avoid the need for invasive coronary angiography and revascularisation. For correct use, HeartFlow FFRCT requires access to 64-slice (or above) CCTA facilities.
>
> Based on the current evidence and assuming there is access to appropriate CCTA facilities, using HeartFlow FFRCT may lead to cost savings of £391 per patient **[2021]**. By adopting this technology, the NHS in England may save a minimum of £9.4 million by 2022 through avoiding invasive investigation and treatment **[2021].**

Please see NICE MTG32 [15] for full details of the guidance and supporting documentation, tools and resources.

3.12.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. In addition, we received procurement data for this topic.

We received three responses to the adoption audit questionnaire for this piece of guidance, from SBUHB, HDUHB and BCUHB. ABUHB, WHSSC and Velindre stated that the guidance was not

relevant to their organisation, and PTHB responded that the health board does not have a CT scanner.

SBUHB, HDUHB and BCUHB were all aware of NICE guidance for HeartFLow FRCT for estimating fractional flow reserve from CCTA and all respondents felt the guidance was clear. The mechanisms by which they heard about the guidance included email dissemination from a heart condition implementation group, from best practice guidance, word of mouth discussions (including with other organisations) and from medical sales team.

SBUHB and HDUHB did not intend to adopt the guidance. In SBUHB this was due to low volume of equivocal CTs, as it is unlikely that required contractual volumes (required by the company) with heart flow will be met with the patient population currently scanned. However, a review of the functional testing referral list and pathway is planned. Low volumes of equivocal CTs are coupled with developments in the evidence base for stable revascularisation. As such, SBUHB did not feel that it was suitable to adopt the guidance.

A different reason was cited by HDUHB, where the existing cardiac CT provision does not have the capability for FFRCT. HDUHB would intent to adopt the guidance in the future when the health board's CT provision improve. HDUHB also intend to embed FFRCT into training of consultants.

BCUHB indicated that they intended to adopt the guidance, however it is not currently in use. The respondent from BCUHB indicated that coronary angiograms also need to significantly increase in the health board to meet NICE recommendations, however significant investment is required. Further, BCUHB felt that the suggested cost savings do not seem easily realised as it is unlikely that angiography lists will be reduced. The respondent felt that decisions are based on cost as opposed to evidence.

No service specifications or commissioning policy changes had occurred and SBUHB and HDUHB strongly disagreed that the use of HeartFlow FFRCT to treat patients with stable, recent-onset chest pain who are offered CCTA in line with the NICE guideline on chest pain, had been routinely adopted. Nonetheless, the impact of the guidance ranged from a minor to a major impact.

HDUHB registered that cardiologists within the health board would be willing to discuss HeartFlow FFRCT in more detail.

Procurement data show some limited procurement of HeartFlow FFRCT by CT in 2022, after the publication of NICE MTG32. This supplements the adoption audit questionnaire data, as no response was received from CT. No procurement was apparent in other health boards, which supports the findings from the adoption audit questionnaires.

3.13 gammaCore (NICE MTG46)

3.13.1 Background

HTW has a mandate to audit the adoption of our guidance and that of select NICE MTGs. Key details and the guidance recommendation are below:

Technology:	gammaCore (electroCore)
Population:	People with cluster headache. Treatment with gammaCore should only continue for people whose symptoms reduce in the first 3 months
Publication date:	December 2019

Evidence supports the case for adopting gammaCore to treat cluster headache in the NHS. gammaCore reduces the frequency and intensity of cluster headache attacks and improves quality of life.

gammaCore is not effective in everyone with cluster headache. Treatment with gammaCore should only continue for people whose symptoms reduce in the first 3 months.

Cost modelling estimates that, in the first year of treatment, adding gammaCore to standard care is cost saving compared with standard care alone by an average of £450 per person. This cost saving:

- assumes that the first 3-month period of gammaCore use is offered by the company free of charge
- largely results from less use of subcutaneous sumatriptan.

Please see NICE MTG46 [16] for full details of the guidance and supporting documentation, tools and resources.

3.13.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. In addition, we received procurement data for this topic.

We received responses to the adoption audit questionnaire from SBUHB, HDUHB and ABUHB. PTHB reported that this would be delivered by a specialist in an out of county neurology clinic. BCUHB neurology service is delivered externally in the Walton Centre, Liverpool. WHSSC and Velindre indicated that the guidance was not relevant to their organisations. However, WHSSC Prioritisation Panel considered the guidance in 2020 as it was assumed they had commissioning responsibility. It was subsequently determined to be the responsibility of health boards. The WHSSC commissioning policy (PP220) was then published on behalf of the health boards.

SBUHB, HDUHB and ABUHB were all aware of the guidance. In ABUHB's case this was via the Association of British Neurologists. All respondents felt that the guidance was clear.

SBUHB, HDUHB and ABUHB intended to adopt the guidance, however respondents were unsure if service specification or commissioning policies changed (though WHSSC confirmed that a policy was published). In ABUHB, the guidance has been adopted in theory, but in practice there have been no eligible patients. HDUHB stated that SBUHB provides the neurology service via visiting consultants, and so their responses to the adoption audit are the same. SBUHB and HDUHB disagreed that Use of gammaCore to treat people with suspected cluster headache, continuing only where symptoms reduce in the first 3 months, had been routinely adopted. HDUHB noted that neurology consultants use the IPFR process on behalf of their patients who are suitable for treatment.

The NICE guidance was reported to have a moderate impact and ABUHB registered that they would not have considered using this treatment if it was not for the NICE guidance.

SBUHB and HDUHB provided a contact for a Neurology Consultant from SBUHB who would be willing to discuss gammaCore in more detail. ABUHB would also be willing to engage further.

Consistent with findings from the adoption audit questionnaires, procurement data show that GammaCore was procured once within ABUHB in 2020, after publication of NICE MTG46. ABUHB intended to adopt the guidance, but reported that patient numbers are low. No procurement activity was recorded for other health boards.

3.14 ZioXT (NICE MTG52)

3.14.1 Background

HTW has a mandate to audit the adoption of our guidance and that of select NICE MTGs. Key details and the guidance recommendation are below:

Technology: Zio XT

Population: People with suspected cardiac arrhythmias, who would benefit from ambulatory electrocardiogram (ECG) monitoring for longer than 24 hours

Publication date: December 2020

> Zio XT is recommended as an option for people with suspected cardiac arrhythmias who would benefit from ambulatory electrocardiogram (ECG) monitoring for longer than 24 hours only if NHS organisations collect information on:
>
> - resource use associated with use of Zio XT
> - longer-term clinical consequences for people who have monitoring with Zio XT (such as incidences of further stroke, transient ischaemic attack and other thromboembolisms, arrhythmia-related hospitalisations, mortality, uptake of anticoagulants or other changes in medication related to the monitoring result).
>
> Evidence shows that Zio XT is convenient and easy to wear, with an improved diagnostic yield (a measure of how many people with cardiac arrhythmia are diagnosed) compared with standard 24-hour Holter monitoring. The technology is likely to be cost neutral or cost saving compared with 24-hour Holter monitoring, but more evidence is needed.
>
> NHS organisations using Zio XT should make sure that the service complies with general data protection regulations (GDPR), and that informed consent covers how a person's data will be used.

Please see NICE MTG52 [17] for full details of the guidance and supporting documentation, tools and resources.

3.14.2 Audit Findings

To support the adoption audit for this piece of guidance, we sent a questionnaire to HTW Health Board adoption leads. We also requested procurement data for this topic, but no orders were made.

We received responses to the adoption audit questionnaire for this piece of guidance from SBUHB, HDUHB and BCUHB. ABUHB, WHSSC and Velindre confirmed that the guidance was not relevant to their organisations. The Powys Cardiac Nursing team confirmed that the

responsibility for implementing this piece of guidance would lie with a specialist out of county cardiology clinic.

SBUHB and BCUHB were aware of the guidance, but HDUHB were unaware. SBUHB said the guidance was clear, but added that the recommendation to collect resource use data was opaque. HDUHB did not find the guidance to be clear, as better definition of the long term monitoring of outcomes is required.

BCUHB and HDUHB did not intend to adopt the guidance. BCUHB, who were aware of the guidance, reported that they were using another product. They reported that no funding was available to implement the guidance, but that a business case was under development. SBUHB did not intend to adopt at present, citing the cost implications. They reported that evidence is required which demonstrates the improvement against yield for loop recorders is generated, as opposed to 24 hour tapes. SBUHB would require further economic analysis before adopting this technology. HDUHB were also unconvinced of the added benefits and required more detail on the requirement to collect data on long term outcomes.

SBUHB and HDUHB strongly disagreed and BCUHB agreed that the use of Zio XT to treat people with suspected cardiac arrhythmias, who would benefit from ambulatory electrocardiogram (ECG) monitoring for longer than 24 hours had been routinely adopted in their organisations. The impact of the guidance ranged from no impact in HDUHB to a moderate impact in BCUHB.

SBUHB and HDUHB indicated that the heads of cardiac electrophysiology departments in their organisations would be willing to discuss Zio XT in more detail.

4. Proposed Future Directions

Potential actions emerging from the 2022/2023 HTW adoption audit are outlined below according to the relevant organisation. These are based on the themes summarised in section 2 and feedback received from HTW Health Board adoption leads. Completed or updated actions from the HTW adoption audit pilot have been removed and outstanding actions are retained.

Background	Actions
For Health Technology Wales	
Methodology: Audit responses and feedback gathered during a meeting with HTW Health Board adoption leads highlighted several areas where the adoption audit methodology could be improved.	• HTW should make improvements to the current adoption audit methodology, for example: - Including an explicit question on research recommendations - Asking for further information when guidance is considered not relevant to an organisation. - Clarifying wording of the questionnaires for guidance not recommending the routine use of a technology - Adding more detailed guidance notes to help respondents fill in the questionnaire - Considering requests for CASPA data for guidance relevant to primary care
Process: Audit responses and feedback from HTW Health Board adoption leads highlighted several areas where the adoption audit process could be improved. It has been agreed to hold the meeting with HTW Health Board adoption leads annually, in advance of first-drafting of the adoption audit report. This will enable HTW to continually improve the audit process and in turn to increase the response rate. Encouragingly, the audit response rate has improved slightly. However, work remains to obtain returns from all included commissioners to facilitate All-Wales analysis and results. Since the pilot adoption audit, HTW supported the procurement of the Audit Management and Tracking (AMaT) platform. HTW and NICE guidance is uploaded to the automated system and organisations are able to respond to the audit directly. HTW has joined the AMaT user group which	• HTW should undertake the adoption audit on an alternative date (not during winter), to minimise the demands on nominated contacts and other staff during times when service pressures are high. This is likely to improve the audit response rate and timeliness of responses. • HTW should continue to engage with each of the local health boards, specialised commissioning, and specialist trusts to ensure that relationships to support the adoption audit report are further developed and maintained. • HTW should continually review adoption audit processes and ensure that the roles of nominated contacts in commissioning bodies is clear and relevant information is returned.

Background	Actions
provides a regular forum for discussion of the HTW Guidance and adoption audit.	
Alternative commissioning responsibilities: The HTW adoption audit process appears to be fit for purpose for auditing guidance on health technologies commissioned by health boards, WHSSC and WAST. We have not yet audited social care guidance and other guidance where health boards, WHSSC and WAST do not have commissioning responsibility, such as radiotherapy.	• HTW should identify nominated contacts for guidance with different commissioning responsibilities • HTW should develop a process for auditing social care guidance (in partnership with Social Care Wales).
Audit findings: Generally, there was good awareness of HTW guidance, the guidance was clear, and was having at least some impact in Wales. Despite these positive findings, there was some lack of awareness, poor clarity, or lack of impact in some cases. Since the HTW adoption audit pilot in 2021/2022, HTW has refreshed its Communications Strategy, which considers guidance dissemination. HTW has continued to develop communications strategies for individual pieces of guidance, to ensure that guidance is disseminated and there is early awareness after publication. HTW has also considered additional avenues for disseminating guidance across key national peer groups and policy leads. HTW continues to provide a brief quarterly update report to all national peer group organisations that summarises Guidance published in each period. The AMaT system also allows HTW guidance to be disseminated directly to the HTW Health Board adoption leads after publication, which will promote awareness.	• HTW should review feedback from the present adoption audit (2022/2023) and the adoption audit pilot (2021/2022) on awareness of guidance. The adoption audit process itself was raised as a mechanism for awareness of guidance. HTW should consider increasing engagement with HTW Health Board adoption leads during the earlier stages of appraisals (prior to publication of guidance) to increase awareness upfront. This could include approaching audit leads to identify relevant experts within their organisations to participate in expert review. Increasing early awareness of guidance will allow more time to implement the guidance and for the impact of the guidance to be felt. • HTW is planning an internal workshop which will review the findings of the present adoption audit (2022/2023) and the adoption audit pilot (2021/2022) on the clarity of guidance. Two pieces of guidance from the adoption audit pilot were felt not to offer sufficient clarity. In the present audit, patient selection and research recommendations were highlighted as areas for improvement. Additionally, HTW has plans to invite a medical writer to scrutinise our guidance to offer suggestions to further improve clarity. • HTW should review feedback from the present adoption audit (2022/2023) and the adoption audit pilot (2021/2022) on the impact of guidance. Impact was affected by interaction with existing advice and guidance. HTW should continue to work with

Background	Actions
	NICE on preventing overlap between the organisations and collaborating as appropriate and improving understanding of the differences between HTW guidance and the various NICE products, particularly NICE MIBs and IPGs which do not consider effectiveness and cost effectiveness.
For NICE Medical Technologies Evaluation Programme and Welsh NICE Health Network	
Process and methods: The 2022/2023 adoption audit included three pieces of NICE MTEP guidance. HTW liaised with the WNHN who selected the NICE MTEP Guidance to be included in this year's audit. The WNHN developed the adoption audit materials, which were distributed by HTW as part of the audit. HTW collected the responses and analysed results. Responses indicate that the adoption audit process and methodology is appropriate for assessing the uptake of NICE MTEP guidance.	• HTW and NICE should continue auditing NICE MTEP guidance, through a collaboration between HTW and the Welsh NICE Health Network. • HTW will engage with the WNHN on this annually and seek regular feedback to continually improve the audit process and methodology. • WHNN should consider which pieces of NICE MTEP guidance are to be included in the next audit.
Audit findings specific to NICE guidance: Generally, there was good awareness of NICE MTEP guidance, the guidance was clear, and was having a variable impact in Wales. Despite these positive findings, the adoption audit raises some areas for improvement on clarity and identified factors which may limit the impact of guidance.	• NICE should review feedback from the adoption audit on the clarity of its guidance. While guidance was generally reported to be clear, suggestions for improvement focused on research recommendations. The recommendation to collect resource use data on ZioXT was found to be 'opaque'. For the same piece of guidance, respondents felt that the long term monitoring of outcomes should be more clearly defined. • NICE should review the barriers to implementation of NICE MTEP guidance raised in the audit. Notably, funding was cited as a factor, despite the three pieces of NICE MTEP guidance selected for the audit being issued under the NHS England MedTech Funding Mandate, which requires that the recommended technology is expected to be cost saving. The NHS England MedTech Funding Mandate does not apply to Wales, and investment in implementation would be required to realise the estimated cost savings. Other factors limiting impact included low volumes of patients and limitations in existing equipment.

Background	Actions
	• NICE should consider interviewing respondents who agreed that they would be willing to discuss NICE MTEP guidance in more detail.
Audit findings (HTW guidance, relevant to NICE): The adoption audit identified that duplication of guidance can introduce delays to access. It also highlighted that different types of NICE product (such as MIBs and IPGs) can each be perceived as guidance, which can lead to the observation that there is overlap between NICE and HTW.	• NICE should continue to work with HTW on preventing overlap between the organisations and collaborating as appropriate. • NICE should raise awareness on the aims and scope of its products, clarifying which constitute guidance and which are advice.
For local health boards, specialised commissioning, and specialist trusts	
As part of the adoption audit pilot in 2021/2022, pump-priming funding provided to Local Health Boards/Trusts was successfully deployed to facilitate development of local processes to support audit of HTW and other guidance. After the audit, Local Health Boards were asked to provide a simple description of their locally agreed process. This has been partially addressed, as information was received from 6 health boards. Returns are outstanding from 1 health board. Since the pilot adoption audit, HTW supported the procurement of the Audit Management and Tracking (AMaT) platform. HTW and NICE guidance is uploaded to the automated system and organisations are able to respond to the audit directly. Six of the seven Local Health Boards utilised funding provided by HTW to procure the AMaT system and a user group was established to share intelligence. The pilot adoption audit report recommended that LHBs, WHSSC, the specialist trusts and HTW should work together to identify topics from priority areas that are likely to have strong stakeholder interest and wide support for adoption of guidance. A small number of topic suggestions were received.	• LHBs, WHSCC, the specialist trusts with support from HTW should continue to develop a community of practice (e.g. via the Welsh Audit Management and Tracking software user group) to share intelligence and continually refine and improve processes to support adoption of guidance. • HTW Health Board adoption leads should continue to engage with and strengthen their relationship with HTW, via the AMaT user group meeting and elsewhere. Adoption leads should continue an open discussion on the audit, including feeding back suggestions for improvements. It has been agreed to hold the adoption audit feedback meeting between HTW and Health Board adoption leads annually, in advance of first-drafting of the adoption audit report. • The HTW Health Board adoption leads should continue to work with HTW to identify topics from priority areas that are likely to have strong stakeholder interest, wide support for adoption and a large impact. HTW encourage topic submissions from HTW Health Board adoption leads. • HTW Health Board adoption leads should promote the implementation of HTW and NICE MTEP guidance when notified of the publication of guidance. To further the awareness of guidance, the leads should liaise with HTW during the appraisal process, prior to guidance publication, to

Background	Actions
	identify local experts who could feed into the appraisal.
For Welsh Government	
Process: The adoption audit pilot found that the process was feasible and acceptable and that the audit methods yielded valuable information to contextualise adherence to the 'Adopt of Justify' status accorded to HTW guidance. HTW and Welsh Government (WG) agreed that an annual adoption audit cycle should be included within HTW's business as usual programme, and this has since been implemented. WG and HTW agreed to an adoption audit timetable and publication framework for annual reports.	• No further actions required
Encouragingly, the audit response rate has improved slightly. However, work remains to obtain returns from all included commissioners to facilitate All-Wales analysis and results. After the adoption audit pilot in 2021/2022, WG facilitated the support of the CEO of NHS Wales, who authored a letter to audit partners to reinforce her expectation of participation in the adoption audit. In addition, HTW was able to present the 2022 adoption audit results in various key meetings, including the key national peer groups.	• WG should continue to work with HTW and other partners to discuss approaches to maximising returns for future adoption audits. This could be through a number of approaches, such as encouraging engagement through national peer groups or other ways of formalising requirements to provide returns including making reference to the adoption audit in the integrated medium term plan. • WG should continue to promote HTW's adoption audit work, such as by facilitating presentations of the results of the 2022/2023 audit at key meetings.
The 2021/2022 adoption audit pilot found that return on the investment in HTW appears to be high, but that in some cases adoption was variable across Wales or had not been achieved. The pilot adoption audit report recommended that WG should consider whether an All Wales strategy for adoption of innovative technologies would be beneficial and reduce variations in access after national guidance is published. WG is currently considering how to encourage adoption at scale of evidence based innovations. HTW is engaging in these discussions. Since the adoption audit pilot, regional and national commissioning	• WG should consider mechanisms for encouraging adoption at scale of evidence based innovations. WG should consider the findings of the 2021/2022 adoption audit pilot and the present adoption audit report relating to barriers and enablers of adoption when considering possible mechanisms to encourage adoption. In contrast to the pilot adoption audit, lack of funding was raised as a barrier to adoption. WG should consider whether adoption at scale could be encouraged using novel or existing funding mechanisms. • WG should consider whether they can help resolve barriers to adoption of HTW and

Background	Actions
approaches have been applied to HTW guidance e.g. WHSSC has prioritised Autologous Haematopoietic Stem Cell Transplant for people with highly active relapsing-remitting multiple sclerosis, and Sacral Nerve Stimulation for people with faecal incontinence.	NICE MTEP guidance identified in this report and in the pilot, for example small patient numbers. This could possibly be addressed by continuing to explore regional or national approaches to commissioning. As raised in the pilot adoption audit report, it could also include supporting the development of infrastructure. This was reiterated in the present report for NICE MTG32 on HeartFlow. • The response to the adoption audit for HTW GUI020 RADT, for which HTW issued guidance recommending against routine adoption, is indicative of the strength of impact which can be achieved through WG support of an initiative. WG should aim to submit any key areas of interest to HTW as new topics for consideration, as such topics are likely to be associated with a high impact. • Both the adoption audit pilot and the present adoption audit report flagged that consideration by multiple organisations can lead to delays in access. WG should consider whether commissioners can be encouraged to ensure that adoption is not delayed by internal processes and that duplication of decision-making in different settings is avoided as far as possible.
Other	
The present adoption audit report and the pilot report identified appeared that further research or collection of real world evidence had not been conducted where this was advised within guidance.	• HTW should continue to share its research recommendations with NIHR. HTW should continue to work with WG, Health and Care Research Wales, and others to facilitate signposting to research and evaluation funding sources where HTW has indicated that further research or collection of local 'real world evidence' is advisable.
The 2021/2022 adoption audit pilot recognised that the adoption of HTW guidance may be strengthened by engagement with additional stakeholders and that the adoption audit itself may benefit from engagement with a wider range of stakeholders. It recommended that HTW work with WG, clinical networks and others to explore how adoption could be supported by a wider range of stakeholders. Since the	• No further actions required

Background	Actions
adoption audit pilot, HTW has addressed this action by routinely sharing HTW guidance and communications plans with the HTW Stakeholder Forum, seeking suggestions for how guidance could be appropriately disseminated.	

Actively monitoring the adoption of medical technologies with supportive evidence that clearly demonstrates care system and citizen benefits has, until now, been a critical missing step in ensuring an all-Wales approach to the routine and equitable adoption of and access to clinical and cost-effective care technologies. The 2022/2023 HTW adoption audit has again evidenced that this is both feasible and acceptable and that the methodology extended well to NICE as well as HTW guidance. It firmly embeds HTW in the Welsh life science ecosystem with a central role to support innovation and investigate the value and impact that advances in medical technology offer. Further, it actively supports and reinforces multiple ambitions outlined in the health and social care policy agenda for Wales, specifically: ensuring prudent care[18]; recognising the central role of technology[1]; enhancing the wellbeing of citizens[19, 20]; demonstrating the socioeconomic duty[21]; transforming care services[22, 23]; encouraging a whole systems approach[23]; and fostering a learning health and care system[24].

HTW has previously demonstrated the significant positive impacts that adoption of its national guidance offers[25]. Squaring the circle to ensure that the high-quality guidance produced by HTW and NICE is fully utilised and adopted discharges the policy ambition to achieve this set out in the 2014 inquiry into access to medical technologies[1] and maximises the return on the investment in Health Technology Wales. Finally, it places Wales in the vanguard of these efforts both across the United Kingdom and internationally.

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Appendix I: Methodology

The HTW adoption audit process was piloted in 2022 with a series of eight pieces of guidance, culminating in the publication of the .Adoption Audit Pilot Report 2021/2022. The development of the process is described therein. HTW has refined the adoption audit process and several changes introduced to the process and methodology since the pilot are discussed below. Future adoption audits may require further developments in HTW processes, for example when auditing guidance with different commissioners for example radiotherapy guidance and social care guidance.

HTW has mainstreamed the adoption audit process and adoption audit plans, and other materials are developed prospectively by the team involved with developing the Evidence Appraisal Report and guidance. The adoption audit plans are signed off by the HTW Appraisal Panel at the time guidance is agreed.

This year, respondents were able to complete the adoption audit questionnaires (an example is available in Appendix II) either in hard copy form or via the Audit Management and Tracking system (AMaT). The use of AMaT enabled nominated contacts from each of the local health boards to disseminate the questionnaires to the relevant individuals within their organisations more easily. HTW will continue to support both methods.

HTW works with nominated contacts from each of the local health boards and other commissioning bodies. At the request of the All Wales Medical Directors Peer Group during the adoption audit pilot, these contacts were nominated by their organisations due to their work on relevant committees. In addition to the nominated contacts from local health boards, HTW disseminated questionnaires for each of the pieces of guidance to topic experts during the pilot. For the present adoption audit, HTW focused only on the nominated contacts from local health boards and other commissioning bodies, to reduce duplication and the burden on contacts of undertaking the audit.

Eleven pieces of HTW guidance and three pieces of NICE MTEP guidance were included in the 2022/2023 adoption audit. The eleven pieces of HTW guidance audited include pieces of guidance not included in the adoption audit pilot and guidance following chronologically from the pilot. The adoption audit process was extended to NICE MTEP guidance for this first time this year and so three pieces of NICE MTEP guidance issued under the NHS England MedTech Funding Mandate were prioritised by the Welsh NICE Health Network (WNHN). To carry out the audit, the WNHN developed the questionnaires for the pieces of NICE guidance. Some minor amendments were made, including removing the question on development of business cases and adding a request to provide contact details for further follow up. The adoption audit process and methodology appeared to transfer well to NICE guidance.

Some decisions were necessary during the analysis of the quantitative questionnaire data, which are documented here. Several duplicate responses were received from the same individual, either by submission of a hard copy and submission through AMaT, or where multiple submissions were made on AMaT. Where the responses were identical, the duplicates were removed. In some cases, the same individual or different individuals from the same organisation provided returns with slightly different answers. Where these answers were in conflict, this was outlined in the adoption audit report and a response of 'mixed' was designated in the tables. Where the answers conveyed supporting messages, answers were merged. In future audits, HTW should consider whether multiple submissions should be permitted within AMaT. This could be explored in future AMaT user group meetings.

As part of the adoption audit, HTW sent questionnaires to all nominated contacts from each of the local health boards and other commissioning bodies. This is a change from the pilot, when the questionnaires were sent only to the commissioners who were expected to be relevant. This change was intended to remove errors in identifying the relevant commissioner. HTW asked respondents to indicate if the guidance was not relevant to their organisation. In practice, some respondents communicated this informally, while others filled in the questionnaires either on AMaT or in hard copy and answered 'not relevant' to the question 'did your organisation intend to adopt this guidance?' For the analysis, if an organisation indicated that the guidance was not relevant we disregarded responses to other questions answered within the questionnaire, to ensure a consistent approach to the treatment of 'not relevant' in the analysis. In future audits, HTW are considering including an opportunity for organisations to expand on the rationale where an answer of 'not relevant' is provided, for example by expanding on what would happen to relevant patients within their health boards.

For the analysis of quantitative procurement data requested as part of the adoption audit, sample sizes are small and statistical analysis was not possible. As such, no consideration is made of population sizes and other factors such as the impact of COVID-19. The approach taken involves a simple comparison of procurement during a period of time before and after publication of guidance, from which it is possible to confirm only whether there was procurement before and after publication and not to identify trends nor to compare health boards. The procurement data are used to supplement the qualitative data from the questionnaires.

Overarching timelines for the HB / Trust audit return were as follows:

16/11/2023: Questionnaires sent out, deadline 03/02/2023

09/01/2023: Reminder for response sent

23/03/2023: Feedback meeting held with Adoption Audit leads

In addition to the standard reminder noted above, individual follow up was undertaken with each of the health board contacts as required

Appendix II: Full adoption audit materials for Freestyle Libre flash glucose monitoring for the management of diabetes (HTW guidance 004-2)

Adoption audit questions for nominated contacts in each local health board

As the nominated lead for the adoption audit for your organisation, we would be grateful if you could provide information for the following questions.

Where possible, we would be grateful if you could attach appropriate supporting information to your response. For example, service specification and/or commissioning policy, findings of internal audits, etc.

Awareness of guidance		
1. Was your organisation aware of this HTW guidance?	*Yes* *No* *Unsure*	*Comments:* *If relevant, please provide brief information on how your organisation was aware of guidance.*
2. Was the recommendation in the guidance clear?	*Yes* *No*	*Comments:*
3. Did your organisation intend to adopt the recommendation from this HTW guidance?	*Yes* *No* *Unsure* *Not relevant (please proceed to Q4 then Q10)*	*Comments:* *If relevant, please provide information on whether your organisation has already adopted recommendations or intends to in the future*
4. If your organisation did not intend to adopt this HTW guidance, what was the justification for this? *1.*	*Comments:*	
Response to guidance		
5. Was a business case developed to support funding in response to this HTW guidance?	*Yes* *No* *Unsure*	*Comments:* *If yes please provide details*
6. Did service specifications and/or commissioning policy change in response to this HTW guidance?	*Yes* *No* *Unsure*	*Comments:* *If yes please provide details*
7. Other than changing service specifications and commissioning policy, did your organisations take other	*Yes* *No*	*Comments:* *If yes please provide details*

actions in response to this HTW guidance?	*Unsure*	
8. Has your organisation audited use of Freestyle Libre devices in response to HTW guidance or supported further research? 2.	*Yes* *No* *Unsure*	*Comments:* *If yes please provide details*
9. To what extent would you agree with the following statement: 3. 4. Use of Freestyle Libre flash glucose monitoring to guide blood glucose regulation in people with diabetes who require treatment with insulin has been routinely adopted in your organisation. 5.	*Strongly Agree* *Agree* *Neutral* *Disagree* *Strongly disagree*	*Comments:*
Impact of guidance and feedback		
10. How much of an impact did this HTW guidance have on decision-making in your organisation?	No impact (not considered) Minor impact (considered but did not inform decision making) Moderate impact (considered and had moderate impact on decision making) Major impact (considered and had major impact on decision making)	*Comments:*
11. Do you have any other comments or reflections on this guidance?	*Comments:*	

Request for procurement data

We would be grateful if you could provide time series data for the following:

If this data is not held, please do let us know.

Technology Name:

Flash glucose monitoring

Indication and Setting:

People with diabetes receiving insulin, managed by diabetes outpatient service

Known systems or products:

Freestyle Libre 1 or 2 (Abbott)

Data items:

Monthly volume / usage by HB

Time period:

From July 2020 to July 2022 (guidance issued in July 2021)

Notes:

HTW is aware that time trends in procurement have been disrupted by the pandemic and will consider this context within any use of data. HTW is also aware that procurement trends may not give an accurate account of usage of technologies within clinical settings and receive information from other sources to try and provide a more complex picture of use.