
REVIEW OF THE ALL WALES MEDICINES STRATEGY GROUP

Report
for Welsh Government

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1. INTRODUCTION

The Welsh Institute for Health and Social Care (WIHSC), University of South Wales, was commissioned by the Welsh Government to contribute to the review of the All Wales Medicines Strategy Group (AWMSG) by engaging with a range of key stakeholders.

ABOUT AWMSG

AWMSG is a Welsh Government Sponsored Advisory Body. It has a constitution¹ within which is described their 'Roles and Responsibilities' which are germane to the review:

The Committee shall advise the Welsh Ministers on strategic developments in prescribing as outlined in the AWMSG Medicines Strategy for Wales, including:

- *forecast developments in healthcare which involve the use of medicines, to advise on the potential impact for the NHS of such developments and strategically plan for their impact within the available resources. The AWTTTC will work in conjunction with the National Horizon Scanning Centre and the Pharmaceutical Industry, Research and Ethics Committees to inform the AWMSG of such developments.*
- *advise on the availability of relevant new medicines/formulations, or of existing medicines with new indications, and on the cost implications of making these medicines routinely available on the NHS. This will include making interim recommendations ahead of appraisal by NICE. The Group should complement and support the work of NICE and not in any way duplicate or conflict with its work.*
- *advise Welsh Government on the development of a consistent cost-effective medicine strategy for Wales, (with consideration to matters such as pharmaceutical developments, NICE guidance, National Service Frameworks, Welsh demography and epidemiology).*
- *advise Welsh Government on how the Health Boards and other relevant organisations might implement the advice and strategy within the financial constraints placed upon them. Monitor and review the approved strategy, responding promptly to national changes in NHS policy that will affect prescribing and medicines management locally, including NICE guidance and National Service Frameworks, and advise Welsh Government accordingly.*
- *review the roles of Medicines and Therapeutic Committees/Prescribing Advisory Groups within Local Health Boards.*
- *where appropriate, advise Welsh Government on areas where legislative changes would support the development of prescribing and medicines management initiatives.*
- *advise the Welsh Government on when medicines management policies / formularies and guidelines can be best co-ordinated.*
- *make recommendations to Welsh Government to assist in the resolution of problems relating to prescribing at the interface between primary care, acute services, specialised and tertiary services, and social care.*

¹ <http://awmsg.org/docs/awmsg/awmsgdocs/AWMSG%20Constitution.pdf>

- *receive for consideration, documents or issues referred to it by Welsh Government for Wales and other stakeholders, and advise Welsh Government accordingly.*
- *act as a focus for developing and refining local professional opinion on medicines, therapeutics and associated prescribing issues, including risk management, and to convey such opinions through appropriate mechanisms.*
- *advise Welsh Government on how consumer groups might be engaged to discuss consumer expectations and their impact on prescribing and medicines management.*
- *produce an annual report for review by Welsh Government.*
- *highlight to the Welsh Ministers, through the Chief Medical Officer or Chief Pharmaceutical Officer, issues concerning the maintenance and development of health services and health issues in Wales generally.*

TERMS OF REVIEW

The following is taken from the Welsh Government setting out the Terms of the Review:

Background

2017 marked the 15th anniversary of the All Wales Medicines Strategy Group (AWMSG) and 2018 was the 70th anniversary of the NHS. The NHS in Wales has changed dramatically over the past 15 years, as has the development of new medicines and technology to treat our population.

From January 2019 a new voluntary scheme for branded medicines pricing and access has been introduced, replacing the Pharmaceutical Price Regulation Scheme (PPRS). Under the agreement, the National Institute for Health and Care Excellence (NICE) will increase its appraisal capacity to appraise all new active substances and significant extensions to marketing authorisations by April 2020.

This clearly has implications for the future role of the AWMSG in appraising new medicines and whether there is a need for a change of focus from appraisal of medicines to supporting NHS Wales' efforts to improve medicines related outcomes

Since the AWMSG was established in 2002 there has been no formal review of the services which they provide. In comparison the National Institute of Clinical Excellence (NICE), as an arms-length body, has been subjected to a triennial review by the Department of Health and Social Care.

In the light of the significant changes in the landscape and in terms of good governance and funding process, it is, therefore, a timely opportunity to review the AWMSG.

Terms of the review

The terms of the review are to consider, review and report on:

- the role of AWMSG in supporting the future delivery of Welsh Government and NHS Wales' priorities;
- the current relationship between AWMSG and NICE in light of plans to expand NICE's appraisal role;
- the balance between various functions carried out by the AWMSG, for example between appraisal of new medicines and optimising medicine use;
- an understanding of how current funding reflects the balance of functions and whether this

reflects priorities now and for the future;

- value for money and scope for efficiencies;
- organisational governance and scrutiny, and the effectiveness of the current hosting arrangements within Cardiff and Vale UHB;
- effectiveness, outputs and benefits;
- AWMSG's capacity and capability, both in terms of staffing and leadership, to respond effectively to future demands and the changing environment.

APPROACH

Based on the eight areas above, and in the context of the current roles and responsibilities of AWMSG, we have undertaken a review of the workings of the Committee. There were two strands to this.

Firstly, the Welsh Government received 11 responses to its formal consultation process. We have reviewed these consultation responses.

Secondly, in addition to these responses, this review draws on 40 semi-structured telephone and face-to-face interviews and three group discussions that were held between March and April 2019 as described below:

Respondent category	No. of interviews	No. of group respondents	Total no. of respondents
NHS	15	-	15
AWMSG committee members	3	-	3
AWTTC staff	-	7	7
Other stakeholders ²	6	-	6
Citizens	-	6	6
Pharmaceutical industry representatives	3	-	3
TOTAL			40

The schedule of questions that was used in the interviews and discussions detailed above drew heavily on the eight issues identified under the terms of review. Each of the respondents was assured that their responses would not lead to them being identified in any way, and that their words would not be quoted directly in the report. The interviews typically lasted between 30 and

² These included a number of contributions from organisations from both inside and outside of Wales, including NICE.

45 minutes. We were also provided with supplementary written information by some interviewees, which has also been reviewed.

NOTE ON TERMS

It should be noted that there was a certain slippage in the way that terms were used throughout the interviews and discussions which has a particular relevance for two phrases:

1. **AWMSG** – it was clear that when people used the acronym AWMSG they did not all mean the same thing. The vast majority of respondents used the term to refer to both AWMSG and AWTTTC simultaneously and interchangeably. Therefore we use **AWMSG/AWTTTC** throughout this document as this is what was implied by respondents; and
2. **Medicines management** – we recognise the important difference that exists between the concept of medicines management and medicines optimisation, but again respondents used these phrases interchangeably. As such, when medicines management is used in this document, it includes both management and optimisation.

REPORT STRUCTURE

Over a short time period, this project that engaged with a broad range of people who are stakeholders or staff of AWMSG/AWTTTC. The review team³ feel that this sample of people represents a robust cross-section of opinion on the work of the organisation.

In Chapter 2 – Findings, for each item of the Terms of Reference we gathered and arranged evidence under three headings. *“What people told us”* identifies in respondents’ words the main issues they felt needed consideration. As responses came from a range of stakeholders with different interests, we analysed these and provide for the reader the range and weight of opinion under the heading *“Spectrum of Opinion”*. Finally, under *“Conclusions”* we have summarised where, on balance of the views expressed, we believe the key organisations should focus their attention.

In Chapter 3 – Areas for Further Consideration, we have done two things. First, given the range of evidence gathered in Chapter 2, we have distilled it into five strategic issues we believe the Welsh Government should deliberate upon when considering the future direction of AWMSG. Second, to provide a focus on how these issues can be taken forward into a clear plan for action we offer a set of ‘test questions’. These are designed to help work through the key decisions required to establish clarity on a future direction.

The structure of the report follows with a series of Findings structured against the eight Terms of Review. The report then proceeds to identify Areas for Further Consideration, which are borne out of our data and are written as a positive contribution to the way in which AWMSG/AWTTTC might address the issues raised in the Terms of Review, and the responses given to us in respect of these issues.

³ More on the background and experience of the team can be found at: <https://wihsc.southwales.ac.uk/team-members/>

2. FINDINGS

This chapter presents the findings of our work based on the data we have collected. What follows is a discussion of each of the eight identified Terms of Review, providing the main issues that were raised in the interviews/discussions, the spectrum of opinion offered by respondents, and a conclusion about each.

Before engaging with the detail of the findings, it is important to state that in the view of the vast majority of respondents, AWMSG/AWTTC needs to continue to play a role but needs to change in order to do this effectively. It was especially well-respected for the work that it does in respect of the Health Technology Appraisals (HTAs) that it undertakes. However, there is much to be done, as below, against the eight areas that were identified in the Terms of Review. The case for change is remarked upon by the respondents, who simultaneously value the role that it performs but who recognise that the organisation needs to develop and transform as the context within which it operates evolves.

2.1 THE ROLE OF AWMSG IN SUPPORTING THE FUTURE DELIVERY OF WELSH GOVERNMENT AND NHS WALES' PRIORITIES

What people told us

- The balance between supporting the Minister by providing an arm's length, independent strategic response to medicines access issues (e.g. through appraisals) and offering more practical operational support to the service on a range of medicines management issues including implementation and service change.
- The as yet unknown impact of proposed NICE changes on AWMSG/AWTTC's end to end appraisals process and the need to be cautious in dismantling AWMSG/AWTTC's highly valued expertise prematurely, and how transition to the new arrangements will be managed.
- The value that would be derived from using AWMSG/AWTTC's expertise in improving the service's response to commercial arrangements and the service implications of horizon scanning.
- The potential AWMSG/AWTTC role in taking their advice into the service and supporting implementation.

Spectrum of opinion

The majority value both the strategic role in supporting market access (which includes HTAs) and the more operational medicines management role and most comment positively on the quality of the work produced.

There is a division with those concerned with clinical outcomes and strategic issues such as political advice and whole systems access and those concerned with service operational aspects of implementation such as affordability and cost efficiencies and prescribing behaviour change.

It is clear that patients, manufacturers and some within the service place great value in the fact that all medicines access issues in Wales are dealt with in one place with the consistency and coherence this brings. They are also concerned that changes will result in reduced patient

access. This is not seen as such an important issue by some operational parts of the service, with others not recognising this as an issue at all.

There was significant support in the service for an expanded medicines management function which for many would include greater roles in horizon scanning and commercial arrangements (patient access schemes). There was also considerable support for continuing a centralised source of advice to ensure consistency and to avoid 'postcode prescribing'.

Conclusions

The opportunity presented by NICE expanding its HTA work is obvious and welcomed by all, but a large majority of interviewees were cautious about the scope and timing of any changes until the proposals had worked their way through and implications are clearer. There is clearly a desire in the service for more practical medicines management support and a willingness within AWMSG/AWTTTC to do more work to support the service. Some areas that were mentioned as potential future roles included, amongst others:

- Horizon scanning for new technologies including budgetary and service change implications.
- Negotiating and overseeing and managing the implementation of commercial deals and arrangements, including outcome measures.
- Advice to support implementation of HTAs.
- Policing of medicines management advice to aid performance management of HBs.
- Development of value-based prescribing guidance where there are multiple options in pathways.
- Expansion of WAPSU to measure clinical outcomes.
- Re-evaluating old technologies to recommend those now less suitable for reimbursement.
- Advice and support in changing prescribing behaviour to better implement guidelines/indicators.

This is a significant list of potential developments and the implementation of these will have significant implications for the organisation and working of AWMSG/AWTTTC.

2.2 THE CURRENT RELATIONSHIP BETWEEN AWMSG AND NICE IN LIGHT OF PLANS TO EXPAND NICE'S APPRAISAL ROLE

What people told us

- The implications for AWMSG/AWTTTC of the 2019 Voluntary Scheme for Branded Medicines and Pricing Access (VSBMPA) and the expanded role of NICE, along with new charging arrangements for appraisals are not yet clear. There is no clear understanding yet of the scope and timelines of NICE's work and what will be left for AWMSG/AWTTTC to do.
- Most agree there will still be some appraisal work necessary and that the local context is important. AWMSG/AWTTTC is perceived to offer good value for money in this work.⁴

⁴ It is important to note that this perception is based on an impression of value for money, and not on any actual data around the budget associated with AWMSG/AWTTTC that participants were aware of. We have received some information about the costs of the organisation, but this is incomplete and difficult to interpret.

- Some suggest partnership or sub-contracting with NICE on appraisals, but this has not gained much support. NICE themselves are not yet clear how the future relationship with Wales will work, but suggest there will be resources in place to fulfil their new expanded roles.
- No one yet knows (including NICE) how Wales will respond to the additional roles that NICE have been given (as part of the VSBMPA) to develop medicines management. This may include enhanced service change guidance and improved management of commercial agreements. These are not currently part of AWMSG's remit and some consider them to be desirable developments that Wales should also implement.
- The widening of the range of HTAs by NICE may mean that the decision-making process for AWMSG/AWTTC in the ones left for them to complete may have to change to bring consistency of approach.

Spectrum of opinion

Most agree that NICE expanding its role and taking on most if not all HTA work is a positive step. Most also agree that current work programmes and relationships should continue for the time being. There is considerable uncertainty about timelines and scope and no one seems to have clarity about how Wales will respond to the new roles created for NICE. Respondents were asked about charging for HTAs in Wales, but there was no clarity on what should happen.

Conclusions

It would seem that a period of watchful waiting is appropriate so that the implications of the proposed changes can be examined. In the meanwhile, it would also seem sensible to explore further with NICE and the service how AWMSG/AWTTC could fill some of the gaps created by the new VSBMPA agreement in England.

2.3 THE BALANCE BETWEEN VARIOUS FUNCTIONS CARRIED OUT BY THE AWMSG, FOR EXAMPLE BETWEEN APPRAISAL OF NEW MEDICINES AND OPTIMISING MEDICINE USE

What people told us

- There has already been a recent trend of less work on appraisals and more on medicines optimisation.⁵ This will continue with the VSBMPA changes and is welcomed by all parties. Consequently, all parties agree this review is timely.
- It is difficult to quantify the balance between these functions in the current work programme, but there is a recognition that AWMSG/AWTTC is about to approach a tipping point when for the first time there will be less HTA activity undertaken than medicines management activity.
- The question has been raised about who drives the AWMSG/AWTTC agenda and the frustration felt in some parts of the service in not being able to have an influence over the work programme.
- The value of AWMSG/AWTTC's ability and flexibility to respond to all Wales issues as they arise and to provide independent, strategic advice as and when required.

⁵ It is important to note that this was based on people's judgement about the shift in the balance of work as no figures are able to quantify this.

Spectrum of opinion

There seems to be a consensus that it is the right time to have a review of these roles and a willingness to explore how AWMSG/AWTTC can provide more operational support to the service. The main criticisms tended to come from the heads of pharmacy, who would like AWMSG/AWTTC to focus more on their day to day challenges and less on issues that affect very small numbers of patients or other stakeholders such as the wider public or manufacturers. They would like more control of the agenda. At the same time, there remains a lack of clarity about Ministerial strategic aims are translated into the work programme. Some recognised the value in maintaining a strategic arms-length body who provides advice to the Minister. This was not a consideration for many in the service.

Conclusions

The role of AWMSG/AWTTC is changing and the balance of the work it does will continue to evolve, and it may be that this evolution increases in pace. There is a tension between strategic and operational demands and the service would like more control of the agenda. This has implications for AWMSG/AWTTC's current clinical and scientific independence and its ability to balance its strategic agenda if it were to be entirely driven by shorter-term service needs.

2.4 AN UNDERSTANDING OF HOW CURRENT FUNDING REFLECTS THE BALANCE OF FUNCTIONS AND WHETHER THIS REFLECTS PRIORITIES NOW AND FOR THE FUTURE

What people told us

- Linked to objectives and performance, this was not seen by interviewees as an easy question to answer. There is uncertainty over how resources are allocated; and a lack of knowledge over what the objectives are to allow any judgement on the correct balance.
- It is very difficult to get any information on how current funding is allocated apart from the service's belief that HTA has been the political priority and the service's operational needs for prescribing guidance, pathway development have been of secondary importance.
- AWMSG/AWTTC's ability to flex their resources and be responsive as workloads and priorities shift is seen as a strategic strength.
- There is a view that whatever happens to the relationship with NICE and the balance of activities, efforts should be made to retain key staff and skills.

Spectrum of opinion

As established earlier, it is very difficult to establish the exact funding resource allocated to AWMSG (including its support from AWTTTC), and how these resources are deployed across its functions. Most people believe the priority has been towards Ministerial advice, particularly for HTAs, but have no evidence. The service believes these priorities need revisiting to enable them to benefit from more operational medicines management support. Outside of AWMSG/AWTTC, there is little consideration of the value in having a certain flexibility to how work programmes are prioritised and resourced.

Conclusions

There is broad consensus that the priority has been in completing obligatory HTAs and all other work has been fitted in around that. Resources have been allocated accordingly. The balance of work and linked resources is changing. The extent of these resources and the proportions allocated are unknown. It is also clear that the system as a whole has benefitted strategically from the flexibility AWMSG/AWTTC has had to respond to demands, though this is not always appreciated by the service. There is certainly value in making resource allocation processes and outcomes more transparent.

2.5 VALUE FOR MONEY AND SCOPE FOR EFFICIENCIES

What people told us

- There has been limited access to data which could assist in formally assessing value for money, and there are no clear objectives against which to compare outputs and outcomes. It may be that the data does not exist in such a way that would facilitate this formal assessment.
- It is acknowledged that NICE provides a “Rolls Royce” service, but it is perceived that Wales gets very good value for money compared to similar bodies across the UK (having taken account of the first bullet point above).
- It is likely there will be scope to further reduce the HTA activity over time, though there was a majority of people who felt that a reduced capacity for undertaking a number of appraisals in Wales needs to be maintained.
- There is a significant demand from the service for more medicines optimisation work to build on the work that is currently done which is valued, notably by WAPSU.
- The experts within AWTTTC are valued and it is perceived that there are enough skilled people to manage this change of focus from HTA to medicines management.

Spectrum of opinion

Most value the HTA advice, but some believe AWMSG/AWTTC resources would be better allocated on more significant matters in terms of budget and service impact as often appraisals are for very small numbers of patients. Some feel this would be better strategic value for money. There is also a consensus that if NICE do more/all appraisals this should not be duplicated in Wales. There are a number of people who question the uptake/action by HBs on the medicines management advice they are given and so questioned the performance management of HBs in taking advantage of AWMSG/AWTTC's outputs.

Conclusions

With a few exceptions most people believed that AWMSG/AWTTC's outputs were valuable and good value for money. With proposed changes expanding NICE's role in a number of different ways, there are undoubtedly opportunities to re-allocate resources. This will require a clear understanding of AWMSG/AWTTC's role and scope, particularly beyond merely providing advice, but also a close examination of how HBs influence the agenda and subsequently choose to take up advice.

2.6 ORGANISATIONAL GOVERNANCE AND SCRUTINY

What people told us

- Respondents noted that there is a lack of clarity and consistency when it comes to understanding how the governance arrangements of AWMSG/AWTTTC operate.
- It is not clear how their priorities emerge, are agreed or managed – this seems to be done informally by the Chair of AWMSG and Clinical Director of AWTTTC based on their understanding of their purpose in providing strategic advice to the Minister, requests from CPO/CMO and what resource they have available after HTAs at any one time.
- AWMSG/AWTTTC place real value on their scientific independence and their ability to respond strategically to demands placed upon them. Having said this, they do recognise they have to be responsive to service needs.
- C&V UHB and AWTTTC are comfortable in their management arrangements and the formal relationship that they have, but is not clear how they and the Welsh Government work together to set a strategic programme, agree priorities and changes or manage performance.
- As identified, there are other all Wales posts that are focused on pharmaceutical issues and are not part of the AWMSG/AWTTTC machinery. We have not explored how they might fit within the AWMSG/AWTTTC umbrella.

Spectrum of opinion

Apart from those who are at the heart of AWMSG and AWTTTC (and even here there are different views), very few people were able to offer us a clear description of the governance, performance management and accountability arrangements. There is uncertainty and a degree of frustration in the service and across other stakeholders that they do not know how the work programme is derived and feel unable to influence it.

There were a few who suggested that AWMSG/AWTTTC indicators could be built into the health boards performance management process with WG (like joint committees) so that their advice was given the right status and its implementation and performance should be managed by WG. A couple of respondents mentioned how good AWMSG/AWTTTC is in engaging clinical stakeholders in producing their guidance and that the relationship with C&V UHB's clinical networks have helped that.

Conclusions

Most respondents were unclear about this question, though a few hazarded opinions, none were confident. However, there are two important aspects to consider. The first is public accountability for the work of AWTTTC and AWMSG. It is currently difficult to explain the governance, accountability arrangements and value for money satisfactorily. Second, the role of the Welsh Government in the setting of the agenda: not only to satisfy the above question, but also to work through how NHS Wales and the WG will cover the gaps opened up by the new VSBMPA arrangements; for example, in the service implications of new medicines and patient access schemes and horizon scanning.

2.7 EFFECTIVENESS, OUTPUTS AND BENEFITS

What people told us

- As described above, the outputs of AWMSG/AWTTTC are valued by most in the service. There is a debate about the balance and how the service may be better supported in an operational sense with many examples given. An expansion of WAPSU was mentioned several times.
- It was suggested that the value of the outputs could be measured by how well they are taken up by HBs. An example given was prescribing indicators where measures showed a mixed performance and suggested they might not be an area of focus for all HBs.
- Most thought that AWMSG/AWTTTC advice is improving clinical outcomes in Wales, however it is clear that without a more sophisticated IT system this is very hard to prove.
- Focusing on medicines optimisation was noted as a key way in which the NHS could be supported to derive best value from medicines, and that AWMSG/AWTTTC could have an enhanced role in this regard.
- The role of AWMSG/AWTTTC in “policing” its own guidance was a point of discussion.

Spectrum of opinion

Although some disagreed, most valued the outputs of AWMSG/AWTTTC and thought they were beneficial. The question of balance was raised again, particularly by HB pharmacists, far less so with clinicians who mostly thought the clinical advice to be very good. There was an emphasis from HBs on the need for AWMSG/AWTTTC to provide more effective advice that would enable them to make efficiency savings. Very broadly, the clinical advice on practice variation and best practice was valued by clinicians and even without outcome measures was seen to be beneficial. On the other hand, prescribing advice that enabled reductions in prescribing volume, cost and scope to produce efficiencies was most valued by HB pharmacists. There were a small number of individuals across this broad divide who could see enhanced and substantively new roles (especially for WAPSU) that could be developed in respect of two areas. Firstly in respect of Prudent Healthcare (for example, linking the pre-existing data on use of medication with the patient pathway to provide value-based evidence on effectiveness); and secondly with regard to quality (for example, tracking low volume medication post-HTA through to the clinical outcome phase to help the service understand when medicines are providing value, and when they are not).

There was a split of opinion when respondents were asked about AWMSG/AWTTTC having more of a policing function for its guidance. Some thought it might help, others were concerned that it was out with their terms of reference and might impact upon their clinical impartiality and relationships. Some HBs did not want any outside interference in their operational roles

Conclusions

We found very few examples of where the effectiveness of AWMSG/AWTTTC outputs were being measured. This is seen as desirable but expensive and requiring better IT infrastructure. There are some limited but positive developments in WAPSU’s relationship with the NHS Wales Informatics Service (NWIS) which would permit AWMSG/AWTTTC to track the clinical outcomes of medicines (and the value-based effectiveness of them) when they are deployed within the service. AWMSG/AWTTTC sees its role as providing advice, not implementation and not

outcomes. It is obvious that the current outputs are valued, but that the service would like a greater emphasis placed on supporting them operationally. There are many suggestions for this. However, there is also a danger in being led by the service alone as some suggested that where it didn't suit them HBs did not action guidance and their performance is mixed. Although some could see a change in the AWMSG/AWTTTC role to one that included overseeing the implementation and use of its guidance this was generally resisted by HBs. Another way of improving the uptake of guidance suggested was to feed it into the joint performance management meetings between HBs and WG.

2.8 AWMSG'S CAPACITY AND CAPABILITY, BOTH IN TERMS OF STAFFING AND LEADERSHIP, TO RESPOND EFFECTIVELY TO FUTURE DEMANDS AND THE CHANGING ENVIRONMENT

What people told us

- Some in the service have referred us to how the management of strategic medicines issues works in England where NICE and NHS England play different parts, for example in affordability considerations. It is recognised that the situation in Wales is quite different with no separate NHS Board and potentially, therefore, a gap in capability and leadership.
- There are a range of potential changes on the horizon. There is also a clear willingness to review the functions of AWMSG/AWTTTC and a recognition that HTA activity will continue to decline.
- It is also clear that the knowledge, skills and experience of the AWTTTC staff who support both HTA and Medicines Optimisation work are valued.
- As identified above, the leadership structure for AWTTTC and AWMSG is not clear, particularly in relation to the governance roles of C&V UHB and the Welsh Government.
- Again, as previously discussed, the importance of AWMSG/AWTTTC having independence and flexibility to respond to strategic priorities might not sit comfortably with the service driving the agenda to support day-to-day operational issues, though it is recognised by all parties that increased responsiveness is desirable.
- Linked to this is the importance of AWMSG/AWTTTC stakeholder engagement at a strategic level. This includes patient groups, the public, manufacturers and other industrial players as well, crucially, as providing political support.
- Finally, there is the importance of whole system leadership including consistency and coherence of policy and advice. Almost all respondents valued this role and did not want a return to individual HBs deciding common medicines issues separately.

Spectrum of opinion

Most of these strategic issues were not recognised or discussed with interviewees from HBs, their focus was normally on operational support. Where they were recognised their value was noted. Most agreed there was a potential leadership gap, but couldn't put their finger on where it was or why they felt that. This was compounded by a lack of knowledge of accountabilities. Most felt that there were adequate capabilities to cope with a future agenda, provided a smooth transition in the balance between HTA and medicines management work is well managed. There was almost universal support for increasing capabilities for horizon scanning along with support

for the implications of new technologies. Also, for improved and consistent management of new commercial arrangements.

Conclusions

In arriving at conclusions about the future of AWMSG/AWTTC it is important to recognise not just the increasing demands of the service for operational support, but also the important strategic role they play. It will be necessary to consider how the changes to NICE impact on HTA capability, but also important to maintain a balance of strategic and operational advice. A bigger question again will be how much do AWMSG/AWTTC move to support the development of implementation guidance along with resources and processes to support it. Finally, there appears to be a demand to make the leadership and accountabilities clearer and more transparent along with improving the processes and opportunities to influence the agenda. Though we have noted the potential limitations of this influence if AWMSG/AWTTC is to also retain a strategic role and capability.

2.9 SUMMARY

It is clear from the findings, that many stakeholders have a broadly positive view of how AWMSG/AWTTC functions. That said, there is a clear evidence-base that change is needed to ensure that the organisation is improved and future-proofed as the world in which it operates becomes more challenging and complex. These issues are further discussed in the next chapter.

3. AREAS FOR FURTHER CONSIDERATION

In order to bring these findings together, this section outlines ‘areas for further consideration’ in five specific categories that have emerged from the evidence gathered during the study. They are offered as points for discussion and each of them is followed by a set of ‘test questions’ designed to help AWMSG/AWTTC, the Welsh Government, the NHS, C&V UHB, industry and the other key stakeholders to think about how further work and development in these areas should be focused.

Future-proofing the findings

It is important to recognise that the areas for further consideration and associated test questions below need to be considered in the context of the external environment and uncertainties in which AWMSG must operate in the future. Four strategic forces are central here, but have considerable degrees of uncertainty attached to them:

- The future needs and demands of the NHS in Wales for pharmaceuticals in the light of social, epidemiological and clinical trends that will take place in Wales
- The pharmaceutical developments that will come on stream in years to come and the clinical and cost implications of those developments.
- The resource position of the NHS in Wales (which is likely to involve low annual growth in financial resources which are less than the historic average for the NHS as a whole) and the need to finance additional pharmaceutical spending for these new products under the auspices of the VSBMPA arrangements.
- The future range and volume of activities that will be undertaken by NICE and which will impact on Wales. The uncertainty about the future activities of NICE have already been discussed in Chapter 2.

Identified areas for further consideration

We have identified a number of key areas for consideration and discussion and these need to be seen in the context of the findings of our study and the four strategic trends referred to above. These five areas are as follows:

1. Role and strategic direction
2. Working with the NHS in Wales to help drive quality improvement
3. Accountability and governance arrangements
4. Organisational arrangements and resourcing
5. Leadership and change management

3.1 ROLE AND STRATEGIC DIRECTION

Chapter 2 of our report discussed the roles of AWMSG/AWTTC and the views, from many people, that there should be change in the balance of roles with a shifting focus away from HTA work and towards other areas of activity focused on improving the quality of care which include among others, medicines management, medicines optimisation, and horizon scanning. This issue is

particularly germane given the uncertainty about the activities of NICE and the potential impact of the other three strategic forces referred to above.

However, such changes do not necessarily happen by accident but need to be planned and suitably managed. If this is not done, the organisation may drift in an unintended direction.

Test questions to be addressed

How should the balance of various roles of AWMSG/AW TTC change over time to ensure the right emphasis is placed on the quality of care?

What should be the pace of change of any shift in strategic direction by AWMSG/AW TTC?

How should AWMSG/AW TTC (and its key stakeholders) make determinations about the right balance of its functions?

In the light of the proposed changes from NICE, what represents the right balance between the strategic and more operational role of AWMSG/AW TTC?

ANNUAL PRIORITY SETTING AND MANAGEMENT

Linked to the above, and to ensure the strategic direction of the organisation is achieved, there needs to be a process of annual priority setting which shows, in a transparent manner, what the organisation aims to try and achieve over the next twelve months and how those activities align with the strategic direction. Although such a process does exist within AWMSG/AW TTC, it is not sufficiently clear to stakeholders to instil confidence in it. Hence, there is a need to develop a process which indicates, in a transparent and accountable manner, what the annual priorities of the organisation are and how delivery of these priorities is to be managed.

Test questions to be addressed

How should the process of annual priority setting by AWMSG/AW TTC be enhanced and linked to its strategic direction?

Which stakeholders/organisations should contribute to the process of annual priority setting?

What role should health boards play in setting these priorities given the pressures on their own plans, and the budgets that influence these?

How should operational activities be managed to ensure priority activities are achieved in terms of outputs and costs?

3.2 WORKING WITH THE NHS IN WALES TO HELP DRIVE QUALITY IMPROVEMENT

The findings of chapter 2 of this report were that the way in which AWMSG/AW TTC and the NHS in Wales works were, in general, seen to be quite good although improvements are always possible. However, there was a view expressed that AWMSG/AW TTC needs to help support the

drive towards value-based care, and that it can only do this if there is an improvement in the extent to which Health Boards in Wales took on board and applied the recommendations and guidance from AWMSG/AWTTTC. Various means of doing this were discussed, including the provision of statutory powers for AWMSG/AWTTTC to enforce its recommendations. However, one simpler improvement is a suggestion that AWMSG/AWTTTC should interface and communicate with Health Boards at a higher level, than has traditionally been the case, in order to “deliver the messages” at the highest managerial level. This implies a strengthened communication and engagement between AWMSG/AWTTTC staff and Board members of the Health Boards.

The purpose of such enhanced engagement would be to allow for AWMSG/AWTTTC to support the service more effectively in improving quality. There is scope for increasing the amount of work that AWMSG/AWTTTC explicitly does in respect of medicines optimisation that could help the service to understand more about the clinical outcomes being achieved, especially if WAPSU and NWIS forge closer partnership to bring extant datasets on the effectiveness of medicines together with data on the patient pathway. This closer alignment on issues of medicines optimisation and clinical outcomes could give AWMSG/AWTTTC an enhanced set of roles in using data to help drive quality improvement, and to support the service in the need to deliver more Prudent and value-based healthcare in Wales.

Test questions to be addressed

How should AWMSG/AWTTTC engage more robustly at board level with Welsh Health Boards?

What should be the dialogue and means for such engagement?

How should AWMSG/AWTTTC more effectively support the drive to improving quality across NHS Wales, and deliver more prudent and value-based healthcare?

How would AWMSG/AWTTTC organise and resource such enhanced activities?

3.3 ACCOUNTABILITY AND GOVERNANCE

In chapter 2 of our report we have reported some concerns on the existing accountability and governance arrangements of AWMSG/AWTTTC. Very few people were able to offer us a clear description of the existing governance, performance management and accountability arrangements in the organisation. Hence consideration needs to be given to having a definition of the accountability and governance arrangements of AWMSG/AWTTTC which is transparent and which has broad based support from all interested parties.

Test questions to be addressed

How should existing accountability and governance arrangements for AWMSG/AWTTTC be enhanced in order to provide clarity for all key stakeholders?

What new lines of governance and accountability need to be set?

Who should be the participants in this new accountability and governance process?

How should this new process relate to how priorities for AWMSG/AWTTC are set and managed?

3.4 ORGANISATIONAL ARRANGEMENTS AND RESOURCING

Changes made in relation to the areas described above will have implications for the ongoing organisational arrangements of AWMSG/AWTTC. It cannot just be assumed that the existing organisational arrangements will remain unchanged and changes may be needed in order to deliver the changes in strategic direction, accountability, communications etc. These implications could involve a wide range of organisational matters including:

- internal organisational structures and management reporting,
- reporting arrangements,
- deployment and management of staff resources,
- staffing numbers and skill mix,
- training and development needs, and
- operational budgets.

Test questions to be addressed

What might be the implications of changes in the “modus operandi” of AWMSG/AWTTC for its organisational arrangements?

How might changes in these organisational arrangements be made and over what timescale?

How well does the current skill mix of staff within AWMSG/AWTTC meet the requirements of the organisation as it develops?

How does the organisation re-balance its functions in order to meet the increasing demands placed upon it by the service, but also meet its strategic duties as required by the Cabinet Secretary for Health and Social Services?

AVAILABILITY OF MANAGEMENT INFORMATION

We have already referred to the paucity of management information in AWTTTC particularly around the difficulties of obtaining information on issues such as use of resources, volume of activities, outputs etc. As a consequence, we have commented that any objective assessment of matters such as efficiency, effectiveness, VFM is just not possible in the absence of such data.

Having a minimal level of robust management information is essential, not just for efficiency and value for money but for other matters such as strategic direction, operational planning, quality control, and ‘client’ satisfaction (whether this is Cardiff and Vale University Health Board as its host organisation, or the Welsh Government, as sponsoring body).

Test questions to be addressed

What management information should be routinely produced by the organisation?

By which methods is such information to be produced?

3.5 LEADERSHIP AND CHANGE MANAGEMENT

All of the above areas have change implications for the organisation. To ensure the necessary changes go smoothly some form of change management is required which is driven by having a clear leadership focus.

At the time of writing, processes are underway to make new appointments to the posts of Chair of AWMSG and Clinical Director of AWTTTC. The appointees to these posts are likely to be the ones who will lead any future change process. Hence, this provides an opportunity to appoint to these positions people who have the necessary leadership skills as well as the other skills needed.

Test questions to be addressed

What are the leadership and change management skills that will be needed in AWMSG/AWTTTC in the future?

How are these skills to be identified in possible appointments to the posts of Chair and Clinical Director?

How are these skills to be developed in other senior managers in AWTTTC?

AWMSG/AWTTTC'S INDEPENDENCE

Finally, it is important to reflect on the independence that AWMSG/AWTTTC has. As a Welsh Government Sponsored Advisory Body, it is not independent of the Welsh Government, but does act 'independently' in two key aspects. The first – that of their clinical and scientific independence – was respected and valued by all stakeholders, and one that that needs to remain as the organisation responds to the changing agenda. The second – in exercising operational independence and strategic control over their work programme – was less clear, and contested. NHS colleagues, in particular, called for more transparency in prioritisation decisions, and a greater stake in the development of AWMSG/AWTTTC's agenda. For all parties, there was a plea to be able to see how Welsh Government's priorities are translated into their annual work programme. At the moment there is a feeling that these priorities emerge and are decided by AWMSG/AWTTTC themselves rather than as part of an open and strategic planning process.

Test questions to be addressed

How do Welsh Government's priorities for service change and improvement get translated into AWMSG/AWTTTC's annual work programme?

What process should be employed in order to create greater transparency in the development of AWMSG/AWTTTC's work programme?

3.6 CONCLUSIONS

Taken together, this section represents a potential work programme for moving AWMSG/AWTTC from its current mode of operation to a new one, in line with the comments made by respondents. In doing this, we have posed a number of critical 'test questions' which, we believe, need to be addressed when considering the future role of AWMSG/AWTTC against the current AMWSG Constitution and the Roles and Responsibilities within. It may be the case that these are deemed to still be 'fit for purpose', but given the scale and scope of the feedback received in this exercise, it is likely that they will need to be amended and updated in certain respects.

The Welsh Institute for Health and Social Care (WIHSC) is part of the University of South Wales. Since 1995, WIHSC has existed to bridge gaps between academia, policy and practice.

STRATEGIC INTENT AND VISION

The strategic intent of WIHSC is to be a key player in informing and influencing the implementation of evidence-based health and care services across the statutory, voluntary and independent sectors. WIHSC has a national reputation for impact as a leading health and care policy research institute, which is built on a robust financial platform derived from the delivery of excellent academic research, evaluation and consultancy. We recognise that the following are critical factors in us delivering the strategic intent and vision:

- A **reputation** for excellence in research, evaluation and impact amongst key stakeholders – whether in government, health and care services, the media or the public
- An established **credible staff resource** including the collection of experts⁶ who can be utilised to achieved the vision
- Achieving a measure of **academic impact** in order secure the role of the institute within the relevant research frameworks of the University and beyond
- A **strong, and growing, self-financing status** based on healthy revenues

PRIORITIES

WIHSC has five priority areas reflecting our current research strengths and aspirations for new areas of work and influence.

1. Prevention of escalating need

- Understanding the nature of services and how they can offset further (more costly) interventions.

This is best demonstrated in our recent work evaluating the impact of the Integrated Care Fund 'Stay Well@Home' programme which runs across the Cwm Taf region and is designed to reduce escalating need through the front door of A+E.

*In addition our action research study for a third sector mental health charity has helped to ensure that there is now core funding for **Step by Step**, a service preventing the further escalation of issues for single homeless people presenting to the local authority with moderate mental health problems.*

2. Integration of health and care

- Analysing the ways in which the public, third and independent sectors are increasingly aligning to provide health and care services.

⁶ WIHSC enjoys the support of three Visiting Professors and two Visiting Fellows. Professor Alka Ahuja (Consultant Psychiatrist in Child and Adolescent Mental Health Services in Aneurin Bevan University Health Board) has been a part of the WIHSC team for many years. In addition, we have recently developed and appointed a WIHSC Expert Reference Group. Its members are Tony Garthwaite (Visiting Professor), Malcolm Prowle (Visiting Professor), Heulwen Blackmore (Visiting Fellow), Jeremy Felvus (Visiting Fellow) and Margaret Provis. The purpose of the ERG is to help WIHSC to realise its strategic intent and vision, and act as a critical friend and to review progress towards achieving its objectives.

Evidence of this comes from our recent study on the workforce integration of health and social care across Wales, **Working for a Shared Common Purpose**. The study was commissioned by UNISON Cymru Wales, and endorsed by the Cabinet Secretary for Health and Social Services at its launch.

Further, we supported organisations and public bodies through the **Strengthening the Connections programme** which provided networks, events and opportunities for collaborators to share experience and learn lessons about what works, where and why.

3. Co-produced care and outcomes

- Reflecting on the changes in public services brought about by user- and citizen-led services and forms of support to deliver outcomes for people.

Over many years WIHSC has run a series of citizens' juries which have provided a forum within which key issues of public policy can be discussed, debated and to some extent resolved. Most recently this focused on the crucial issue of **Antimicrobial Resistance and Stewardship** and the role of citizens.

Furthermore, our Health Foundation-funded research study to understand the impact of the **Prudent Healthcare** principles in practice focused in part of the way in which co-production has become (or has not become) integrated within the delivery of healthcare services.

4. New models of care

- Providing an evidence-base upon which new modes of 'delivery' – whether new pathways, new teams, new technology, or new medicines – will improve outcomes.

Service innovation has been at the heart of our work since WIHSC's inception. Working in partnership with the Swansea Centre for Health Economics, our UK-wide study of the impact of **Eye Clinic Liaison Officers** is one such study. We identified an evidence-base which has influenced the further implementation of this role within ophthalmology outpatient clinics.

Our study reviewing the approach to **Horizon Scanning for New Medicines** has impacted on the way in which the quartet of key stakeholders – policymakers in government, NHS organisations, the national therapeutics authority and the industry – will work together.

5. Value-based care across the whole pathway

- Detailing the impact that new models of care have for pathways and the value of those pathways, expressed in financial terms.

Understanding the ways in which the Third Sector have provided new pathways of care in many different areas across health and social care is a key part of our portfolio of projects. The **Discussion Paper** we wrote about this provides a useful insight into what is happening within the sector.

New pathways in the way services have moved from hospital to community settings is in line with principles of prudent healthcare and the approach of all the devolved administrations across the UK governments. Our work on **Community Cardiology** is noteworthy in this regard.

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