National Assembly for Wales
Health and Social Care Committee
Stroke risk reduction – follow-up inquiry

Evidence from BMS-Pfizer Alliance – SFU 6

BMS-Pfizer Alliance Response to the Health and Social Care Committee's Follow-Up Inquiry into Stroke Risk Reduction: 19th September 2013

1. Introduction

Thank you for the opportunity to contribute to this follow-up inquiry into stroke risk reduction, which follows the Committee's previous examination of the provision of stroke risk reduction services in Wales in December 2011[1].

In 2007, Bristol-Myers Squibb and Pfizer entered into a worldwide collaboration to develop and commercialise Eliquis, an investigational oral anticoagulant discovered by Bristol-Myers Squibb. This global alliance combines Bristol-Myers Squibb's long-standing strengths in cardiovascular drug development and commercialisation with Pfizer's global scale and expertise in this field.

The BMS-Pfizer Alliance supports the Committee's continued focus on stroke risk reduction in Wales. We particularly welcome the decision to review how effective the Welsh Government has been with regards to addressing the weaknesses identified by the Committee in its 2011 report, focusing specifically on the implementation of the report's recommendations. We believe it is essential that it is recognised where improvements have been made in the last two years, but also to identify where further progress is needed.

Our response to this inquiry is limited to recommendations one, four and five of the Committee's 2011 report, however we have also included some general comments on current service provision. All of our comments are focused on stroke risk reduction through the early identification of Atrial Fibrillation (AF) and the optimal treatment and management of the condition, as we believe that improvements made in these areas will be critical if the incidence of stroke is to be reduced in Wales.

We also believe that it is important to note, in specific regard to the prevention of AF-related stroke that since the Committee's previous inquiry, there has been the introduction of a new class of treatments for the prevention of AF-related stroke. Novel Oral Anticoagulants (NOACs) deliver the first and only advancement in treatment in over 50 years from warfarin, the single established treatment option for the prevention of AF-related stroke. This NOAC class therefore provides an alternative treatment option, which delivers improved patient outcomes and experience[2][3][4]. Ensuring patient access to these NICE-

[1] National Assembly for Wales Health and Social Care Committee, *Inquiry into Stroke Risk Reduction, December 2011,* Cardiff
[2] Dabigatran: http://www.nice.org.uk/nicemedia/live/13677/58470/58470.pdf Accessed: 3rd September 2013
[3] Rivaroxaban: http://www.nice.org.uk/nicemedia/live/13746/59295/59295.pdf Accessed: 3rd September 2013

approved treatments, where appropriate, will therefore need to be an essential aspect of the Welsh Government's work on stroke risk reduction going forward.

We would be delighted to have the opportunity to give evidence in person, should the Committee feel that it would be helpful to this inquiry.

2. The importance of effective diagnosis, treatment and management of AF in stroke risk reduction

AF affects 50,138 people in Wales[5]. In patients with AF, there is a fivefold increase in the risk of suffering from a stroke[6] and it has been estimated that patients with primary or secondary diagnoses of AF occupied almost 308,000 bed days in 2008, at a cost to NHS Wales of more than £100 million[7]. AF-related strokes also tend to be more severe than non-AF related strokes, with a 20% increased likelihood of death and 60% increased likelihood of disability compared to non AF-strokes[8]. They therefore not only have a potentially devastating impact on people and their families, but can also present a significant cost burden for the NHS in Wales to manage.

Anticoagulants interfere with the clotting cascade to prevent blood clots forming so easily and they can reduce the risk of stroke in patients with AF by nearly two thirds: about six in ten strokes that would have occurred in people with AF can be prevented through effective anticoagulation[9]. It is therefore clinically effective to prescribe anticoagulation to AF patients, when considered alongside a patient's stroke risk, as well as their bleeding risk.

It is essential that there is an improvement in diagnosis rates of people with AF and management of the condition to ensure that patients are initiated on anticoagulation in accordance with clinical best practice as soon as possible. We believe that there is still much that the AF community in Wales needs to work on together to reduce the risk of avoidable – and potentially fatal – stroke in patients with AF, by ensuring the delivery of safe, cost-effective and high quality care.

3. Recommendation One

We welcomed the prominence of stroke risk reduction (and AF) within the National Stroke Delivery Plan[10] published in 2012 and in particular its inclusion in the Government's vision statement. However, whilst the National Stroke Delivery Plan states that the Welsh Government will work with partners to promote better public awareness of stroke risk factors, we believe that more needs to be done in terms of

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[4] Apixaban: http://www.nice.org.uk/nicemedia/live/14086/62874/62874.pdf Accessed: 3rd September 2013

[5] The Office of Health Economics, *Estimating the direct costs of atrial fibrillation to the NHS in the constituent countries of the UK and at SHA level in England*, 2008 November 2009, London

[6] Wolf PA, Abbott RD, Kannel WB. *Atrial fibrillation as an independent risk factor for stroke: the Framingham Study*. Stroke 1991;22:983–8

[7] The Office of Health Economics, *Estimating the direct costs of atrial fibrillation to the NHS in the constituent countries of the UK and at SHA level in England*, 2008 November 2009, London

[8] Lin HJ et al., *Stroke severity in atrial fibrillation: the Framingham study.* Stroke 1996; 27:1760–4.

[9] *Patient.co.uk* http://www.patient.co.uk/health/Atrial-Fibrillation.htm Accessed: 3rd September 2013

[10] http://wales.gov.uk/docs/dhss/publications/121206nhsplanen.pdf Accessed: 4th September 2013

improving the public's specific knowledge of AF and its link to stroke risk, as current levels of awareness are low.

We noted the Public Health Wales, Community Pharmacy Wales and the Stroke Association 'Lower Your Risk of Stroke' campaign,[11] which ran across Wales throughout May 2013. However, we would like to see this type of approach to be applied more broadly and not restricted to community pharmacy. We would also be keen to gain a greater understanding of whether this campaign will be repeated, as we know that the prevalence of AF is underestimated and more needs to be done to identify those with AF who could subsequently be at risk of stroke. **We would like any future Government campaigns regarding stroke prevention to also highlight the importance of AF awareness, showcasing schemes such as 'Know Your Pulse' to raise awareness of the symptoms of AF.**

4. Recommendation Four

We agree with the Committee's recommendation that primary care has a unique role to play in stroke risk reduction in Wales, particularly around supporting people to make changes to their lifestyle. For example, our research[12] has shown that general practices are well placed to support patients wishing to stop smoking owing to GPs' relationships with patients.

However, we feel that more could be done to support primary care teams on the diagnosis, treatment and management of AF. In order to improve health outcomes for people with AF, it is imperative that more AF patients in need of anticoagulation are identified and given the preventative treatment that they are entitled to receive. There is therefore a real need for health care professionals to become better informed about how AF-related strokes can be avoided through the use of risk assessment tools, including software tools to identify AF patients at risk of stroke and to provide information on appropriate treatment options. Audit tools are a useful means by which to achieve optimal treatment and management of AF and we know that GRASP-AF has proved to be a driver for change for GPs in England and its use has been encouraged by NHS Improving Quality[13].

In Wales, Audit Plus has been developed and we believe that the Welsh Government should ensure that this is made available as soon as possible and the use of the tool should be encouraged as a Tier one target. At present, the relevant Tier one target focuses on those who have already suffered an acute stroke and we believe that more should be done to encourage stroke prevention. A new target could require all GP practices to run the Audit Plus software and act upon the results as a Tier one addition to the stroke bundle i.e. a stroke prevention bundle. It is also worth noting that Audit Plus links to the 1000 lives plus campaign through the Primary Care Quality Information Services' How to Guide for AF[14].

We also believe that there will need to be incentives put in place to overcome lack of awareness of the tool and to encourage GPs to use it. **We would like to see the Welsh Government actively promote the use of Audit Plus to ensure its widespread roll out across the country. In the absence of making this a**

[11] http://www.wales.nhs.uk/sitesplus/888/news/28550 Accessed: 6th September 2013

[12] Bevan Foundation, *Perceptions and experience of smoking cessation services in Wales*, April 2011

[13] http://www.nhsiq.nhs.uk/improvement-programmes/preventing-premature-deaths/gp-engagement.aspx Accessed: 9th September 2013

[14] http://www.wales.nhs.uk/sitesplus/888/page/59796 Accessed: 9th September 2013

Tier one target, we believe that Local Health Boards should be encouraged to put in place a Local Enhanced Service.

In addition, we believe that revisions need to be made to the Quality Outcomes Framework (QOF) to bring the AF indicators up-to-date with the 2012 European Society of Cardiology (ESC) Guidelines for the Management of Atrial Fibrillation. For example, at present, QOF awards points for treatment by anti-platelet therapy with no caveat relating to aspirin, which is not recommended by the ESC Guidelines. The Guidelines state that 'Aspirin should only be considered in patients who refuse any OAC, or cannot tolerate anticoagulants for reasons unrelated to bleeding'[15]. We also believe that consideration should be given to incorporating the use of HAS-BLED[16] into the QOF, as it is a validated bleeding risk stratification tool that has been proposed for assessing the bleeding risk of AF patients in need of anticoagulation. HAS-BLED was recently included in the consultation on the draft All Wales Risk/Benefit Assessment Tool for Oral Anticoagulant Treatment in People with Atrial Fibrillation from the All Wales Prescribing Advisory Group[17], which we welcome as a good first step. **We would like to see the Welsh Government call for revisions to the AF indicators in the QOF to reflect updated guidelines.**

In the absence of a NICE AF Quality Standard or up-to-date NICE Clinical Guidelines, guidance is still required from the Welsh Government, which sets out the roles and responsibilities for AF diagnosis and prevention of AF-related stroke (who does what and when, including taking pulse checks, prescribing anticoagulation, and providing patient information). The All Wales Medicines Strategy Group 2012 Guidance 'All Wales Advice on the Role of Oral Anticoagulants for the Prevention of Stroke and Systemic Embolism in People with Atrial Fibrillation' sets out the prescribing responsibilities but not those for diagnosis or patient information[18]. **We would like to see the development of guidance on these areas become a priority for the Welsh Government. A multi-disciplinary group could be convened to develop this guidance on behalf of the Government and the NHS in Wales.**

5. Recommendation Five

In line with the recommendation contained within the 2012 ESC Guidelines[19], we believe that commissioners should ensure that primary care clinicians undertake opportunistic screening of people aged 65 years or older by pulse palpation, followed by an ECG for those with an irregular pulse. However, we know that opportunistic screening to help identify those at risk is not currently being implemented consistently across Wales, despite the Committee's report recommendation that pulse checks are offered 'as standard'. Opportunistic screening could significantly help to identify people with

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[15] Camm AJ et al. *Guidelines for the management of Atrial Fibrillation: European Society of Cardiology (ES*). 2012

[16] Hypertension, Abnormal Liver/Renal Function, Stroke History, Bleeding Predisposition, Labile INRs, Elderly, Drugs/Alcohol Usage http://www.mdcalc.com/has-bled-score-for-major-bleeding-risk/ Accessed: 03rd September 2013

[17] AWPAG, *All Wales Risk/Benefit Assessment Tool for Oral Anticoagulant Treatment in People with Atrial Fibrillation*. August 2013

[18] http://www.awmsg.org/awmsgonline/docs/awmsg/medman/All%20Wales%20Advice%20on%20the%20Role%20of%20Oral%20Anticoagulants%20for%20the%20Prevention%20of%20Stroke%20and%20Systemic%20Embolism%20in%20People%20with%20Atrial%20Fibrillation%20(Full%20document).pdf Accessed: 9th September 2013

[19] Camm AJ et al. *Guidelines for the management of Atrial Fibrillation: European Society of Cardiology (ES*). 2012 P5 available at http://www.escardio.org/guidelines-surveys/esc guidelines/GuidelinesDocuments/Guidelines_Focused_Update_Atrial_Fib_FT.pdf

AF, whose condition might have otherwise remained undetected, and the Committee's recommendation should therefore be acted upon immediately. **The Welsh Government should actively promote the 2012 ESC Guidelines to ensure that there is routine opportunistic screening.**

As part of this, it is essential that health care professionals become better informed about the symptoms of AF and the opportunity to identify a suspected arrhythmia through opportunistic health checks. This will require access to improved education and training on AF and the prevention of AF-related stroke. **We believe that consideration should be given to developing National or Directed Enhanced Services to support Local Health Boards to deliver improved opportunistic screening.**

In relation to the fact that recommendation 5 of the Committee's report states that 'any necessary treatment which then follows (opportunistic screening) should comply with NICE Guidelines', we would like to highlight that current NICE Clinical Guidelines for AF are out of date and do not take into account newer treatments (e.g. NOACs). In addition, the All Wales Medicines Strategy Group 2012 Guidance 'All Wales Advice on the Role of Oral Anticoagulants for the Prevention of Stroke and Systemic Embolism in People with Atrial Fibrillation' is also now out of date and does not include the most recently NICE-approved NOAC. This guidance is due to be reviewed in October 2013. **We would like to see the Welsh Government actively promote the use of the 2012 ESC Guidelines, as referred to above, until NICE CG36 has been updated and the Quality Standard on AF has been published (expected in 2014).**

6. General Comments

NICE Technology Appraisals should be implemented quickly, however we know that there is often unequal access to anticoagulation options depending on geographical location. There is marked variation between local health boards in total uptake of NOACs and Wales compares unfavourably when compared to England. We believe that patients in Wales should be able to access the full range of treatment options for the prevention of AF-related strokes regardless of which local health board they fall under.

In England, a sub-group of the NICE Implementation Collaborative (NIC) is currently exploring the uptake of NOACs in England and seeking to gain a better understanding of the barriers to adoption within the system. The group is also developing solutions that promote better and more consistent access to NICE recommended treatments, medicines and technologies[20]. We understand that the All Wales Medicines Strategy Group, through the All Wales Therapeutics and Toxicology Centre, has already undertaken an initial audit on the uptake of NICE and All Wales Medicines Strategy Group Technology Appraisals earlier this year[21] and that the intention is to repeat this exercise. **We would like the implementation of Guidance on NOACs to be given priority in the further development of this audit, to ensure that there is equity in patient access to the newer treatments, where appropriate, across Wales and to ensure that unwarranted variation is identified**. This audit would be in line with the Welsh Government's commitment to minimising unnecessary risk of stroke.

Contact

[20] Nice, *Nice Implementation Collaborative Pilot 2 Update - Novel Oral Anti-coagulants,* London, July 2013

[21] http://www.awmsg.org/docs/awmsg/medman/Monitoring%20of%20Medicines%20appraised%20by%20NICE%20and%20AWMSG.pdf Accessed: 9th September 2013

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