Bayer Response to National Assembly for Wales - Health and Social Care Committee Inquiry into Stroke Risk Reduction, August 2011

Thank you for the opportunity to give Bayer's views on the consultation set out in the Health and Social Care Committee Inquiry into Stroke Risk Reduction[1].

Bayer is one of the ten largest specialty pharmaceutical companies in the world. We market our products in more than 100 countries, and generated sales of almost €11 billion in 2010[2].

Over 38,000 employees currently work for Bayer worldwide – more than 6,200 in research and development alone[2].

We aim to improve people's quality of life with our products. To achieve this, we concentrate on the research and development of innovative drugs and novel therapeutic approaches. At the same time, we are constantly improving established products. In this context, Bayer uses experience it has gained from over a century in the business.

For the purposes of this consultation we have confined our answers to discussing atrial fibrillation as a risk fa ctor for stroke in our response, as outlined in point three and four of the consultation.

- What are the particular problems in the implementation and delivery of stroke risk reduction actions?
- What evidence exists in favour of an atrial fibrillation screening programme being launched in Wales?

1. The importance of detecting and treating atrial fibrillation

Atrial fibrillation affects at least 50,688 people in Wales, with a prevalenc e of 1.69% of the population. Th e prevalenc e across Great Br itain is lower at 1.4% . (See table A below).

[1] National Assembly for Wales - Health and Social Care Committee Inquiry into Stroke Risk Reduction, August 2011
[2] Bayer HealthCare Pharmaceuticals, Corporate profile, as at 11 March 2011, http://bayerhealthcarepharmaceuticals.com/en/company/about_us/corporate_profile/index.php

Table A[3]

	Total population	AF population	% prevalence
England	54,836,561	761,965	1.39%
Scotland	5,501,944	75,036	1.36%
Wales	2,999,300	50,688	1.69%
Total GB	63,337,805	887,689	1.40%

Notes:

All AF prevalence data has been sourced from the respective country's 2009-10 QOF data

Population for England & Scotland has been sourced from the respective country's 2009-10 QOF data - this population is based on the total list sizes for all practice

Population for Wales has been sourced from ONS mid 2009 population statistics

These figures are likely to be an underestimate because the condition is often undetected.[4] Even so, each year there are more than 46,000 new cases of atrial fibrillation diagnosed in the UK [5], and the importance of recognising and treating the condition increases with age, as the incidence of resulting strokes rises from 1.5% amongst people aged 50-59 to 23.5% amongst people aged 80-89.[6]

People living with atrial fibrillation are approximately five times more likely to experience a stroke than a person without the condition[6]. When a person with atrial fibrillation has a stroke, it is often more severe due to their underlying condition[4].

In addition to the devastating and debilitating effects stroke can have on a person's life and that of their families, a recent report stated that AF is responsible for around a quarter of strokes in Wales and that associated health and social care cost in Wales could reach £46.3 million a year[7] . Strokes caused by atrial fibrillation can often lead to longer stays in hospital than required by other stroke patients[4], adding to the cost burden on the state.

2. The evidence for opportunistic screening for atrial fibrillation

[3] Data extrapolated from: Respective countries 2009-10 Atrial Fibrillation QOF data. Population of England and Scotland from respective country's 2009-2010 QOF data. Population of Wales from ONS mid 2009 population statistics

[4] NHS Improvement (2009). Commissioning for Stroke Prevention in Primary Care: The Role of Atrial Fibrillation. http://www.improvement.nhs.uk/heart/Portals/0/documents2009/AF_Commissioning_Guide_v2.pdf

[5] British Medical Journal, 330 (7485): 238-243 (2005). Iqbal, M.B., Taneja, A.K., Lip, G.Y.H. and Flather, M. Recent Developments in Atrial Fibrillation. http://www.bmj.com/cgi/reprint/330/7485/238 as at 5th August 2010

[6] Stroke, 22 (8): 983-988 (1991). Wolf P A, Abbott R D, Kannel W B. Atrial Fibrillation as an Independent Risk Factor for Stroke: The Framingham Study. http://stroke.ahajournals.org/cgi/reprint/22/8/983.pdf

[7] Keeping our finger on the pulse. Why Wales must address the personal, clinical and economic impact of atrial fibrillation, Atrial Fibrillation Association and Stroke Association Wales, August 2010 accessed at www.stroke.org.uk/document.rm?id=3221 8 September 2011

Introducing opportunistic screening, starting with including pulse checks in people's everyday interactions with the NHS would be a significant factor in identifying people with the condition, enabling those at risk to have their condition managed, saving lives and maintaining peoples' quality of life.

In England recent PCT pilots of opportunistic screening using pulse checks have proved successful with five out of seven sites reporting that pulse checks will be rolled out more widely as a result[8].

In recent times numerous NHS and Department of Health documents have cited the importance of pulse checks in detecting atrial fibrillation. These include:

- **Commissioning for Stroke Prevention in Primary Care: The Role of Atrial Fibrillation** This NHS Improvement guidance to PCTs and cardiac and stroke networks states that strokes due to atrial fibrillation are 'eminently preventable' and includes recommendations that they should prevent strokes by opportunistically screening for atrial fibrillation using manual pulse checks.[4]

- **National Service Framework for Coronary Heart Disease: Building on Excellence, Maintaining Progress: Progress Report for 2008** This Department of Health progress report on the implementation of the National Service Framework said: *"Atrial fibrillation is both under-recognised and under-treated despite evidence demonstrating that systematic screening increases the detection of new cases by approximately 60%"***.** It also notes that optimal treatment of AF in the population would reduce the overall stroke risk by 10%'. [9]

- **NICE Clinical Guideline 36 - Atrial Fibrillation: The Management of Atrial Fibrillation**[10] NICE guidance on the management of atrial fibrillation states that all patients with breathlessness, palpitations, dizziness, chest discomfort, or stroke should have their pulse checked to screen for an irregular pulse that might indicate atrial fibrillation. This should be followed by an electrocardiogram (ECG) to confirm diagnosis.

5. Problems in the implementation and delivery of stroke risk reduction actions in relation to atrial fibrillation.

[8] NHS Improvement (2009). Atrial Fibrillation in Primary Care: Making An Impact on Stroke Prevention. http://www.improvement.nhs.uk/LinkClick.aspx?fileticket=%2bLIKN1gSgOA%3d&tabid=62
[9] Department of Health (2009). National Service Framework for Coronary Heart Disease: Building on Excellence, Maintaining Progress: Progress Report for 2008 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_096555
[10] NICE (2006). Atrial Fibrillation: The Management of Atrial Fibrillation. http://www.nice.org.uk/nicemedia/live/10982/30052/30052.pdf

5.1 Awareness

A survey commissioned by The Stroke Association across Great Britain of members of the public and 1000 GPs in September 2010, found that over two thirds of the public (66%) were unable to identify the symptoms of atrial fibrillation as a possible warning sign of a future stroke.[11]

Public awareness of the signs and symptoms of AF needs to be raised in order for them to present at their doctors' surgeries. In addition, good quality patient information is required in order for patients to make informed choices about their treatment.

5.2 Detection and Treatment

Audit data suggests that current anti-coagulant management of AF is sub-optimal. NICE estimated that 46% of patients that should be treated with warfarin – the current standard of care – are not receiving it.[12]

Decisions around the correct treatment of patients with AF are based around a risk stratification tool. NHS Improvement have developed the GRASP – AF tool for GP surgeries that enables them to search through their databases of patients to detect those that may be at risk of stroke caused by atrial fibrillation. It would seem reasonable to encourage the uptake of this simple and free tool.

Once the obstacles of awareness and detection of patients with atria fibrillation are overcome, there persists a problem of under-treatment. The Stroke Association survey also found that over half of GPs (55%) believed that the problems in treatment for patients with atria fibrillation stemmed from the associated risks of using anticoagulants such as warfarin. Although 76% of GPs accurately acknowledged that stroke was a major consequence of atrial fibrillation, only 40% said they would treat patients with warfarin.[13]

Warfarin is an oral anticoagulant that, when used properly is effective; however it has a number of well documented limitations that can make it an unattractive option for doctors and patients, which reduce its effective uptake. These include:

- A narrow therapeutic index with a fine balance between decreasing the risk of thrombosis and increasing the risk of hemorrhage

[11] Stroke Association news release. Thousands at risk of stroke as Britons fail to keep their fingers on the pulse, 28 January 2011
[12] NHS Improvement Programme. Heart and Stroke Improvement. Commissioning for Stroke Prevention in Primary Care - The Role of Atrial Fibrillation. 2009. Available at: http://www.improvement.nhs.uk/heart/Portals/0/documents2009/AF_Commissioning_Guide_v2.pdf
[13] Stroke Association news release. Thousands at risk of stroke as Britons fail to keep their fingers on the pulse, 28 January 2011

- The requirement for dose adjustment using frequent, inconvenient and costly INR monitoring. The frequency of monitoring varies depending on individual patient characteristics.
- Response that is influenced by diet, concomitant medications, herbal supplements and intercurrent illness
- The need for individualised patient dosing and adjustment, often requires warfarin to be supplied in a number of different strengths. This may increase the risk of accidental overdose and requires additional patient education, especially in confused, older people.

Improved information and suppor t for patients and doctors working with warfarin is required in order to increase its effectiveness in stroke reduction.

We are in favour of the current proposed recommendations to develop the Quality and Outcomes Framework (QOF) indicators for GP's around atrial fibrillation to reward treatment with anticoagulation.[14]

We would also lik e to note that a range of oral anticoagulants are currently being developed that will offer solutions for some pat ients living with atrial fibrillation to the barriers they face under the current treatment regime.

6. Recommendations

6.1 Opportunistic screening beginning with manual pu lse checks, followed by an ECG for those people thought to be at risk should be rolled-out to identify people with atrial fibrillation at risk of st roke. Thi s could be done through systems currently in plac e such as health check services at GP surgeries and campaigns targeted at high risk groups such as the seasonal flu immunisation programme.

6.2. Greater awareness of atrial fibrillation should be supported through the continuance of programmes such as the 'Know your pulse, know your blood pressure' scheme and continued alliances with leading charities.

6.3. The suggested changes to QOF to incentivise and support appropriate anticoagulation for patients should be progressed.

6.4. GPs should be encouraged to adopt NHS Improvement's GRASP – AF tool in order to detect patients at risk of stroke.

6.5. High quality, accurate information on atrial fibrillation should be developed for doctors and patients to ensure they have the tools to make the right treatment decisions based on the latest evidence and range of treatments available.

[14] NICE: High level summary of recommendations for the NICE menu and recommendations for the retirement of indicators, August 2011 accessed at http://www.nice.org.uk/media/717/D1/QOF_Advisory_Committee_June_2011_summary_recommendations_for_menu_and_retirement.pdf