PE1408/MM
Minister for Public Health and Sport submission of 23 May 2017

Following the meeting on 16 March 2017, the Committee asked me to provide clarification on the points of this petition, therefore I thought it might be helpful to go through the petitioners original points and answer each of them.

1. Doctors need to be made aware of the most common set of symptoms experienced and be able to think of B12 deficiency as one of the first options to explore. This is often the last thing to be checked, if it is checked at all.

The GP training curriculum includes investigation related to all types of anaemia, including pernicious anaemia and as such are expected to be able to address the signs and symptoms of a patient presenting with Pernicious Anaemia. This includes dealing with conditions that present early in the course of an illness and in a non-specific way, by selective history taking, physical examination (including a neurological examination) and investigations (including blood tests), to formulate an effective and appropriate management plan.

Healthcare professionals are expected to follow agreed local and national guidelines, in the case of pernicious anaemia this has been addressed in the publication of the British Committee for Haematology Standards (of the British Society for Haematology - BSH) guideline published in 2014. The guide features a section on clinical features for Vitamin B12 and folate deficiency.

http://www.b-s-h.org.uk/guidelines/guidelines/diagnosis-of-b12-and-folate-deficiency/

2. The diagnostic tests need to be overhauled and more reliable forms of testing used. This would include adopting a new Active –B12 Test (Axis-Shield Diagnostics) which has now recently been made available at a private clinic in the London Area. The existing options to test Homocysteine and Methylmalonic Acid (MMA) levels should also be routinely used. At the moment, these tests are rarely used.

The Committee will be aware that this is an area for experts in haematology. Therefore, it is not appropriate for Scottish Ministers or their policy officials to intervene in, or contradict the evidence based guidance produced by specialists in the field.

The BSH guideline for Vitamin B12 and folate deficiency includes a section on diagnosis and testing. Whilst the guideline notes there is no “gold standard” or definitive test/s, it includes recommendations on tests to confirm diagnosis of Vitamin B12 deficiency.

In developing the guidance the BSH included consideration of the specific tests referred to in the petition and advised that the evidence did not support the use of these routinely. Noting that:

- The Active B12 test is not completely reliable when comparisons were made with other tests and further research is required to test its effectiveness.

- The Homocysteine is a sensitive biomarker but not specific, as it is affected by folate deficiency, and levels can be elevated due a number of other conditions.

- Again the MMA test is sensitive and not specific and can be falsely increased due to a number of other conditions.

3. Some patients show no haematological signs of a deficiency but have all the advanced symptoms of one and any patient in this position should automatically be offered trial injections, regardless of apparently 'normal' blood test results. (In my own cases, there is virtually no other doctor who would have even considered treating me due to all the above tests showing normal results).

This is covered in the BSH Guidelines published in 2014, which states that treatment with cobalamin could be started whilst awaiting test results.

4. Other important levels should be checked and addressed where necessary, particularly folate and ferritin, and other coexisting conditions considered, such as hypothyroidism and adrenal insufficiency, which are very common. At the moment, most doctors are unaware of the importance of particularly folate, and are misinterpreting the British National Formulary guidance which warns against giving folic acid without first checking B12 status. Despite the presence of a folate deficiency, some doctors are wrongly withholding folic acid supplementation until the patient has had their initial course of aggressive B12 treatment and thereby vastly reducing the effectiveness of the injections which cannot be absorbed without sufficient folate. This usually leaves the patient in an even worse state of health leading to the doctor to assume the injections are not helping and even in cases withdrawing them.

This is also covered in the BSH Guidelines published in 2014.

5. Each patient should be treated symptomatically as each responds differently to the condition and its treatment, as is true of every condition. Those who need much more frequent treatment to keep stable should be given it and the option of being show how to self-inject which frees up surgery time and resources and is much more convenient for the patient."
All matters of treatment are for discussion and agreement between the individual and clinician concerned, this is not and cannot be a matter for Scottish Ministers to become involved in.

In relation to self-injecting, this is an intramuscular injection and can be a difficult to administer safely, as a result, some patients may not wish to administer it themselves, therefore this is a matter for discussion between the clinician and patient.

BSH Guidelines.

In relation to the Committee's questions regarding the BSH Guidelines and the SHS summary document. The content of the BSH Guideline were, from the outset, considered to be comprehensive and relevant for Scotland by the Scottish

Government. However, professional advisors felt that the formatting was not "user friendly" for a GP practice setting as it was very different from what GPs were used to i.e. SIGN/NICE guidelines. As a result, the Scottish Haematology Society (SHS) were approached and asked if they were willing to produce a summary document of the guideline.

This progressed until the SHS wrote to the Public Petitions Committee in March 2016, stating that they could not finish the summary document of the guideline on account of work commitments. As a result, the document has not been finalised by the professionals and cannot be published. Additionally, it is not the role of the Scottish Government to produce or publish medical documents.

The BSH guidelines have now been in circulation for three years and we are not aware of any GPs having difficulty in interpreting them.

The Committee may be interested to know that in 2015, NICE produced and published a Clinical Knowledge Summary (CKS) on Anaemia – B12 and folate deficiency: https://cks.nice.org.uk/anaemia-b12-and-folate-deficiency#!topicsummary

The Clinical Knowledge Summaries are not guidelines but described as "concise, accessible summaries of current evidence for primary care professionals".

We expect NHS clinicians in Scotland to take account of guidance produced by organisations including NICE, and any other professional bodies, in addition to agreed local guidelines in their practice.

In terms of research, within the Scottish Government, the Chief Scientist Office (CSO) has responsibility for the funding of clinical research. The CSO's research funding committees consider applications from all areas of medicine, the only stipulations being that the research is led by a Scottish-based clinician or scientist, and that it has the potential to improve the health and well-being of the people of Scotland. I can confirm that no applications in relation to pernicious anaemia have been received to date. Nevertheless, the CSO would welcome applications for research projects aimed at the diagnosis and management frequency of people with Pernicious Anaemia. These would go through the same rigorous independent review process as applications in any other clinical area.

In conclusion, we consider that the request made by the petitioner has been met. Specifically, in relation to the point raised at the committee's meeting of 16 March 2017, the NICE Clinical Knowledge Summary document meets the need identified in providing guidance in a suitable format for GPs. The NICE CKS aligns with the BHS guideline, the clinical content of which remains relevant, and addresses the questions raised by the petitioner including the frequency of vitamin B12 injections.