PE1408/OO

Petitioner – Mrs Andrea MacArthur of 28 August 2017

Since my last submission in February 2017, I have received a response from the Scottish Minister for Health. All her replies referred to my original petition document in 2011 and the situation has evolved since then. The most obvious development has been the updated British Society of Haematology (BSH) guidelines in 2014[1], and it is certain elements of these that I am now also challenging. However, no mention was made of my long-term concerns, namely, the fate of those patients who do not manage on the standard maintenance treatment, and the guidelines themselves admit that: *'Although there is little evidence that more frequent dosing is harmful, specific objective studies demonstrating clinical benefit are absent, and the GWG[2] cannot make specific recommendations.'* These patients are therefore left to deteriorate despite there being no justifiable reason why they can't receive whatever level of treatment controls their symptoms. Again, there was also no response to my repeated comments on the relevance of Parietal Cell antibodies (PCABs). When is someone going to address both these issues?

Worryingly, a third major concern has recently come to light, and this is that an increasing number of GP surgeries are sending almost identical letters to all their patients on B12 injections, claiming that they don't have Pernicious Anemia (PA) if they test negative for Intrinsic Factor antibodies (IFABs). In some cases, treatment will be withdrawn for no other reason than their B12 level is within the normal range, which is inevitable once on maintenance therapy and the BSH Guidelines confirms that, once on treatment, *'No further testing of cobalamin levels is required.'* Below is replicated the text of one such letter received by a patient in the Lothian area but this is being replicated across the UK.

Dear,

We are conducting a review of B12 injections in the practice. We are going to request a test for something called "Intrinsic Factor" on your next visit. If this test is positive then it means you definitely have Pernicious Anaemia and you will need to continue with your injections every 3 months.

If you[r] test is negative it means we can review the need for the injections and it is likely that you do not need more. (The initial 5 loading doses are usually all that is needed for long lasting protection) We would then simply check your blood once a year to make sure your levels of B12 have not fallen.

Please ask the nurse next time you are in.

Dr

Medical Practice

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[1] http://onlinelibrary.wiley.com/doi/10.1111/bjh.12959/fu

[2] Guidelines Working Group

This course of action seems to have sprung up from nowhere and I appeal to the parliament to investigate its origin as the author urgently needs to be re-educated on their understanding of PA. Not only should it be six loading doses that patients are to be given, but the letter also directly contradicts the 2014 Guidelines, which specifically say:

'IFAB is positive in 40–60% of cases, i.e., low sensitivity, and the finding of a negative IFAB assay does not therefore rule out pernicious anaemia. In addition, the positivity rate increases with age . . . Patients negative for IFAB, with no other causes of deficiency, may still have pernicious anaemia and should be treated as anti-IFAB-negative pernicious anaemia. Lifelong therapy should be continued in the presence of an objective clinical response' 1

Indeed, the Health Minster referred to these guidelines in her response: '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.' However, the evidence I have provided clearly shows that not only are doctors disregarding the current guidance but are also giving a spurious reason, which directly contravenes it, in order to withdraw vital and lifelong treatment. I was so dismayed at hearing from yet another patient who had received such a letter that I 'phoned her GP practice and was told that the doctors decided on this action themselves, after 'extensive research', which clearly was not true. The following day the Pernicious Anaemia Society also contacted the practice and the patient subsequently received an apology and had her injections reinstated.

I am involved with what is presently the largest online support group for this condition, with over 16,000 members, and I conducted a short survey of UK patient experience. I realise that the medical profession will instantly dismiss it as irrelevant but the findings are what I expected and are a sorry indictment of the way PA patients are being treated. Of the many UK members that completed the survey:

- 91% of them had, at some point, received an official diagnosis of PA or B12 Deficiency. Diagnoses were based on various clinical findings. However, 43% of all patients later had their diagnosis withdrawn.

- 47% had to fight to be given injections following evidence of PA.

- 51% were not given the full course of loading injections, and some were not given any at all.

- 39% waited between 4 and 9 years for a diagnosis, and a further 27% waited over 10 years.

- 14% were refused treatment altogether, despite their diagnosis.

- 62% of patients had to directly ask their doctor to test their B12 level and some doctors refused to do so. A number of patients were only tested after

seeing a different doctor or consultant. Some doctors even refused to follow the advice of a consultant to start the patient on injections.

- 89% say they do not do well on their current maintenance injection level. The remainder are those who either self-inject or have persuaded their GP to let them have whatever injection frequency keeps them stable. There were 0% of patients managing on a 3-monthly maintenance injection frequency, which is the current recommendation for most patients.

- Of the 75% who requested more frequent maintenance injections, only 9% of these were successful, but rarely to a level that controlled their symptoms.

- 17% were offered oral B12. Of those who tried it, 95% did not respond to it, but it inevitably raised their B12 serum level, making it appear that they were B12 replete and was often used as an excuse to deny them injections.

- A staggering 93% say they are unhappy with their current level of treatment as it is not sufficient to manage their symptoms and prevent continued deterioration. Quite a few self-inject at home to top up what they can access from their GP. Most though are afraid to admit to this in case they are refused any further injections from their GP, and this does actually happen.

After seeing the above statistics, how can anyone say this condition is being well managed?

In a separate poll, with 539 respondents, 352 of them had taken the decision to self-inject, 324 of these without their doctor's cooperation or knowledge. The remaining 28 patients had their GP's approval, however, only 16 of them were provided with the B12 and equipment. The other 12 were forced to purchase it themselves from mainland Europe, despite their doctors agreeing it was helping them. This is shocking that people are forced into this in order to try and manage a medical condition that the NHS is refusing to treat in many cases, and which would cost very little if they would allow patients to self-inject at home.

GPs are giving the impression that there is perhaps an increasing incidence of B12 Deficiency and, if so, I can accept that GP surgeries could possibly become overwhelmed with the amount of appointment time needed to administer maintenance injections, but solving that problem by withdrawing treatment altogether is appalling and would not be tolerated for any other lifelong medical condition.

I've suggested before that injectable B12 be additionally licenced for subcutaneous use, as certain brands of hydroxocobalamin already are, and patients can then be taught how to self-inject at home in the same manner as diabetic patients. Indeed, as already mentioned, many of them have already been forced to adopt this practice using supplies they purchase online or in other EU countries, such as France, Spain and Germany, where it is freely available in pharmacies. Again, I ask that this be seriously considered since there is no known danger of toxicity, and since diabetic patients are trusted to administer their own insulin, which has definite danger of overdose, then why can't PA patients be trusted to do the same with innocuous B12? I had to self-inject three

times a week for five years, with my GP's full cooperation, and it was what kept me alive until, by chance, I found the actual reason for my extreme deficiency which, fortunately, was one of the very few causes which can be resolved with the appropriate medicine. However, I am also proof that such frequent dosing is not at all harmful.

Lastly, the Health Minister says, *'In conclusion, we consider that the request made by the petitioner has been met.'* A similar response was received from the Short Life Working Group (SLWG) in their letter of 20th July: *'Accordingly, we consider that the request made by the petitioner has been met.'*
None of my requests have been met and the subject of parietal cells has not even been acknowledged any time I've mentioned it. An extract from a respected medical source[3] confirms what I have been saying all along:

'This study provides evidence that testing for gastric parietal cell antibodies is an appropriate screening test for pernicious anaemia, with intrinsic factor antibodies reserved for confirmatory testing'

The current guidelines prefer to rely exclusively on the IFAb test and ignore the PCAb one so they can't both be right. This is why the medical profession have to address the issues that I have repeatedly brought before them because real people are suffering greatly as a result of it. I am an example of how effectively a patient can be managed without it placing a burden on the GP practice. It is surely a far greater cost to the NHS to have to treat PA patients' progressively worsening health problems than it ever would be to effectively treat their PA when first discovered, restoring them to health before permanent neurological damage occurs.

I again request that I am permitted to speak directly to those whose responsibility it is to monitor and improve the way this condition is treated, and to be permitted to attend a future petitions committee meeting. Surely, after almost six years, my request is not unreasonable,

[3] https://www.ncbi.nlm.nih.gov/pubmed/19398595