### Ballad 1

#### Introduction
Incidence of Type II Diabetes Mellitus (T2DM) is rising; majority of T2DM is managed in primary care. NICE recommends starting Metformin as a first-line therapy. Studies have linked Metformin use with Vitamin B12 deficiency and suggest that regular monitoring of levels is warranted. The pathogenesis is not fully understood. Literature suggests that the risk of developing B12 deficiency is greatly influenced by high doses and long duration of therapy.

**Guidelines:**
- No official NICE guidelines or QOF indicators regarding the monitoring of Vitamin B12 levels in patients on Metformin
- British Society of Haematology (BSH) recommends that Vitamin B12 levels are checked, when there is a strong clinical suspicion of deficiency in patients on Metformin therapy

**Audit Methodology**
- Review records of 157 females with T2DM on Metformin
- Determine their age, dose of Metformin and duration of intake
- Determine whether their Vitamin B12 level has been checked or not
- Invite Patients for blood test if they have not had their Vitamin B12 checked
- If Vitamin B12 deficient, invite for replacement regime

### Ballad 2

#### Inclusion
Patients registered at Hucknall Road Medical Centre in Nottingham- whom have known diagnosis of T2DM and have been established on Metformin therapy. Project included – all females whom are taking Metformin 500mg tablets or 500mg Modified release tablets. N = 157

#### Phase 1 Results:
- Average age = 63.4 years
- Most common dose of Metformin = 2000mg a day
- Average duration of Metformin use = 6.4 years
- 10 out 157 patients already had Vitamin B12 deficiency and given replacement injections (6.4%)
- 6 out of 10 patients were on the highest dose of Metformin and on average had been taking the medication for 6.6 years

#### Local Haematology consultant advice:
- Review NICE guidelines on Vitamin B12 deficiency
- Vitamin B12 deficiency is not an haematology issue
- No recommendations on duration of therapy yet
- If cause is still present, it would make sense to continue replacement
- Up to GP surgery to decide the most practical management

#### Phase 2 Results:
Compliance to blood test = 72.2%
5 patients found to be Vitamin B12 deficient
3 out of 5 patients were anaemic too
Phase 1+2: 15 out of 157 were deficient = 9.6%

**Table 1:** shows details of patients with deficiency

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Dose of Metformin</th>
<th>Duration of treatment (years)</th>
<th>Vitamin B12 level</th>
<th>Folate level</th>
</tr>
</thead>
<tbody>
<tr>
<td>33</td>
<td>2000mg</td>
<td>6</td>
<td>169</td>
<td>Normal</td>
</tr>
<tr>
<td>69</td>
<td>3000mg</td>
<td>12</td>
<td>180</td>
<td>n/a</td>
</tr>
<tr>
<td>70</td>
<td>2000mg</td>
<td>5</td>
<td>179</td>
<td>Normal</td>
</tr>
<tr>
<td>64</td>
<td>1000mg</td>
<td>3</td>
<td>181</td>
<td>Normal</td>
</tr>
<tr>
<td>55</td>
<td>2000mg</td>
<td>16</td>
<td>147</td>
<td>n/a</td>
</tr>
</tbody>
</table>

#### Conclusion and Recommendation:
- Clear association of Metformin induced Vitamin B12 deficiency
- Vitamin B12 deficiency is a clinically important and treatable condition
- Vitamin B12 deficiency is associated with various systemic complications, such as neuropathy, which can be misinterpreted as Diabetic neuropathy
- The cost of checking yearly Vitamin B12 deficiency is fairly low
- Addition to the yearly recall- therefore no extra burden on the patient or appointment availability
- Patients are likely to remain on Metformin therefore oral vitamin B12 replacement should be considered for long term
- NHS- way forward is screening and prevention

Reference: