Rheumatology Biologic Drug Monitoring Recommendations

Testing for infliximab and adalimumab drug levels and neutralising antibodies will be available from November 2017 via QEUH, Glasgow. This includes biosimilar drugs.

Indications for testing include:

- 3-6/12 after initiation of therapy to guide drug dose/infusion time interval
- Anti-TNF failure of response to determine if primary or secondary failure due to immunogenicity
- To guide dose/interval changes for patients where drug tapering is being considered (or escalation where inadequate dosing is suspected)

Practicalities of testing

- Serum sample required ideally for trough level: pre-infusion for infliximab and no earlier than 3-5 days prior to injection date for adalimumab
- No special preparation required for samples which should be sent to biochemistry at QEUH.
- TRAK request forms have been designed, but require local Board implementation
- Sample turnaround anticipated 2 weeks.

Interpretation

<table>
<thead>
<tr>
<th>Analyte</th>
<th>Lower limit of assay</th>
<th>Upper limit of measurement</th>
<th>Units</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adalimumab</td>
<td>0.4</td>
<td>14</td>
<td>ug/mL</td>
</tr>
<tr>
<td>Infliximab</td>
<td>0.3</td>
<td>14</td>
<td>ug/mL</td>
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- Levels below the lower limit suggest secondary failure of response or poor compliance. Presence of neutralising antibody may be present in the former.
- Levels above the upper limit suggest overtreatment.
Interpretation: 3-6/12 after initiation of therapy to guide drug dose/infusion time interval

Interpretation: anti-TNF failure of response

Interpretation: considering dose reduction

High/normal drug levels confer favourable likelihood of success. Undetectable drug levels with presence of antibodies suggest drug is not required for the patients remission. Consider stopping therapy.