Early experience of switching IBD patients to biosimilar infliximab

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Clinical Lead Adult IBD service
Clinical Lead UK IBD registry

Conflicts of Interest

<table>
<thead>
<tr>
<th></th>
<th>Ad Boards</th>
<th>Speaker Fees</th>
<th>Research Collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospira</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>NAPP</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>MSD</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Abbvie</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Biogen</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Takeda</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
<td>Janssen</td>
<td>✓</td>
<td>x</td>
<td>✓</td>
</tr>
<tr>
<td>GSK</td>
<td>x</td>
<td>x</td>
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<tr>
<td>Astra Zeneca</td>
<td>x</td>
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</tbody>
</table>

Member of UK IBD Audit Biologics sub-committee
IBD Biologic Use
Southampton General Hospital
2011-2014

Cost Remicade 2013-2015 UHS
September 2014: The Biosimilar IBD IFX Challenge

1. Continue to use Remicade; await further data??
2. New starts on CT-P13
3. Switching all patients to CT-P13

Opportunity cost of new starts only

154 patients currently, 10% patients stopped/changed per year
140 infliximab patients treated for a full year
6.5 infusions with a 400mg mean dose
30-50% reduction in drug acquisition costs?
£487k-812k lost savings per year
Win, Win Win, Win?

Patients: improved quality of care, increased resources
Commissioners: Drug acquisition cost savings
Clinicians: service development
Secondary care: share of cost savings

Patient Engagement

• Patient panel: detailed discussion
  – Trust in Remicade
  – Understanding that their treatment is expensive (experience of limited access)
  – Want better IBD care and resources
• Ad Hoc discussions with clinic patients
• Development of patient material
Medical Engagement

Discussion at departmental meeting
• Biosimilar naive; Biowhat??
• Data gap in IBD; what are the risks?
• Long experience with Remicade
• Why bother?

Unanimous agreement

Managed Switching Program

Patient approached at Remicade Infusion by IBD Biologics nurses

Given information sheet on biosimilars and opportunity to discuss

Opportunity at next infusion to ask questions prior to switch to CT-P13

On-going review at each infusion
Gain Share Agreement: CCGs

Local service development (£103K PA)
- New IBD nurse post (50% biologics, 50% in-patient)
- 0.5 WTE Band 3 Clerical support
- 0.2 WTE Pharmacist
- 0.2 WTE Dietician

Risk Management

Data Collection/safety monitoring
- Data collection started pre switch
- Discussion with IBD biologics nurse at each infusion
- Disease Activity Scoring
- Adverse reactions / side effects
- IBD Control PROM
- Routine bloods
- Regular analysis and review of data
- Collection of serum samples
UHS IBD Remicade Population

- 143 patients
- 80% Crohn’s disease
- Previous doses: 10 (Range 2-50)
- Dose 350mg (range 250-850mg)
- 99% on 5mg/kg
- 79% on 8 weekly frequency

Outcome of Biosimilar Switching

- Administration of CT-P13 started 20\textsuperscript{th} April 2015
- 143 patients approached and switched
- All patients agreed
### Persistence of biosimilar infliximab

![Graph showing survival curve (percent remaining on drug) for Remicade (n=120) and Biosimilar Inflectra (n=143). The p-value is 0.3499.](image)

### Reason for withdrawing IFX

<table>
<thead>
<tr>
<th>Reasons for withdrawal</th>
<th>CT-P13 (n=27)</th>
<th>Originator infliximab (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elective withdrawal</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Primary non-response</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Secondary non-response</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Adverse Events:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Infusion reaction</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Skin</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Joints</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Immunological</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Infection</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>Other (1)</td>
<td>2</td>
<td>4</td>
</tr>
</tbody>
</table>

1 - Other: Elevated liver enzymes (1), non-compliance (3), breast malignancy (1), patient relocated (1).

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*Razanskaite et al. Submitted*
### Patient reported Side Effects

<table>
<thead>
<tr>
<th></th>
<th>Before switch</th>
<th>3rd dose of CT=P13</th>
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</thead>
<tbody>
<tr>
<td>n=93</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Joint pains</td>
<td>24 (16.8)</td>
<td>13 (9.1)</td>
</tr>
<tr>
<td>More headaches</td>
<td>21 (14.7)</td>
<td>16 (11.2)</td>
</tr>
<tr>
<td>Pins and needles/Tingling</td>
<td>12 (8.4)</td>
<td>10 (7.0)</td>
</tr>
<tr>
<td>Infusion Reaction</td>
<td>3 (2.1)</td>
<td>2 (1.4)</td>
</tr>
<tr>
<td>Breathlessness</td>
<td>4 (2.8)</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Chest pain</td>
<td>8 (5.6)</td>
<td>7 (4.9)</td>
</tr>
<tr>
<td>New rashes</td>
<td>6 (4.2)</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Infection requiring antibiotics</td>
<td>12 (8.4)</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Infection requiring no antibiotics</td>
<td>5 (3.5)</td>
<td>5 (3.5)</td>
</tr>
<tr>
<td>Other (1)</td>
<td>10 (7.0)</td>
<td>11 (7.7)</td>
</tr>
</tbody>
</table>

### Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Pre Switch (mean +/- SD)</th>
<th>Post Switch (week 16) (mean +/- SD)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>IBD Control-8</td>
<td>10.4 +/- 4.4</td>
<td>11.2 +/- 4.7</td>
<td>p=0.04</td>
</tr>
<tr>
<td>IBD Control-VAS</td>
<td>73.3 +/- 25.2</td>
<td>72.4 +/- 24.8</td>
<td>p=0.73</td>
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<tr>
<td>Albumen (g/L)</td>
<td>37.8 ± 5.0</td>
<td>37.9 ± 4.7</td>
<td>p=0.68</td>
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<tr>
<td>CRP (mg/L)</td>
<td>5.9 ± 10.1</td>
<td>5.0 ± 7.2</td>
<td>p=0.22</td>
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<tr>
<td>Platelets (10^7/L)</td>
<td>270.6 ± 78.5</td>
<td>268.9 ± 76.4 10^7/L</td>
<td>p=0.68</td>
</tr>
</tbody>
</table>
Financial outcomes

Conclusions

• No adverse clinical outcomes (but early experience)
• Gain share
  – Patient involvement and trust in clinical team
  – Collaboration and trust between commissioners and care providers
  – Clinical leadership
• £60-80,000 per month drug acquisition cost savings (143 Remicade treated patients)
Acknowledgements

West Hampshire CCG
Julia Wright (Specialist Pharmacist for Commissioning)

UHS Management
Kim Perry (Deputy Finance Director)

Southampton City CCG
Sarah Kerr (Specialist Pharmacist for Commissioning)

UHS IBD Team
Dr Ifti Ahmed
Dr Trevor Smith
Dr Mike Stroud
Dr Markus Gwiggner

GI Nurse Specialists
Maz Bettey
Louise Downey
Ann Sanderson
Sam George
Sam Sheath (Clerical support)
Caroline Davies (Clerical support)

IBD Research Team
Dr Violeta Razanskaite
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Emma Levell
Michelle Smith
Cheryl Booker (CTA)
Miranda Kean (CTA)