Satellite symposium EAHP 2017

Hospira

A Pfizer Company

Case Study

Caron Underhill

Date of preparation: March 2017
PP-IFA-GLB-0556

Disclosures

- Advisory boards for Pfizer, Napp, Abbvie, Novartis, Leo and Roche.

Real life managed switching programme in IBD patients

- University Hospital, Southampton
- Motivation: potential for large drug acquisition cost savings to the health economy
  - In the UK, this accrues to CCGs
- Programme was funded through a gain share agreement with key stakeholders
- Started in April 2015

CCG, clinical commissioning group.

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Gain share agreement

- "Collaborative arrangement between healthcare commissioners and providers in working together to create incentives that achieve both better outcomes for patients and greater efficiencies in the use of medicines which are not reimbursed via national prices"
- "The principle of gain share is to distribute the cost savings between the stakeholders, which incentivises secondary care providers to make the most efficient use of high-cost drugs and re-invest the cost savings in patient care such as local IBD services"

IBD, inflammatory bowel disease.

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Gain share agreement

- All savings net of the investment in the IBD service were shared 50:50 between the hospital and the CCG
- Agreed investment included:
  - Band 7 specialist nurse post
  - 0.5 WTE clerical post
  - 0.2 WTE band 8 pharmacist
  - 0.2 WTE band 6 dietitian

WTE, whole time equivalent.

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Pharmacovigilance and practical aspects

- Trust formulary approval of biosimilar infliximab CT-P13*
- IT – Trust electronic prescribing system – brand name prescribing only
- Education of all staff on biosimilars
- Traceability system – brand name and batch number recording in patient records. Reporting to MHRA
- Brand specific biologic alert card for patients
- Prescribing of CT-P13 by pharmacist independent prescriber for at least first 3 months of the switch programme

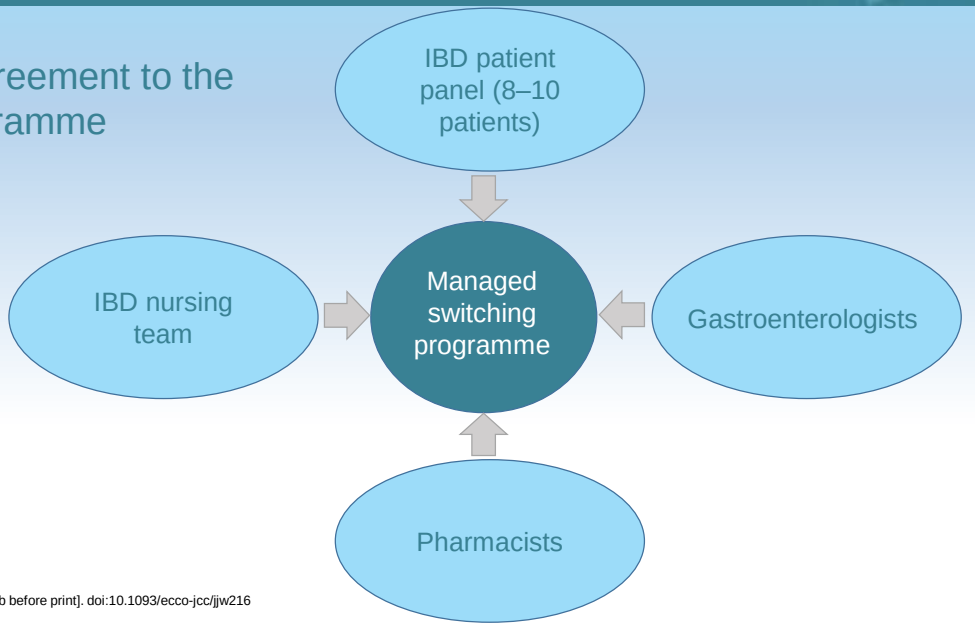
MHRA: Medicines and Healthcare products Regulatory Agency.

Information on this slide is from Caron Underhill's own experience.

*The molecule CT-P13 is marketed in different countries under different brand names, including Inflectra and Remsima.

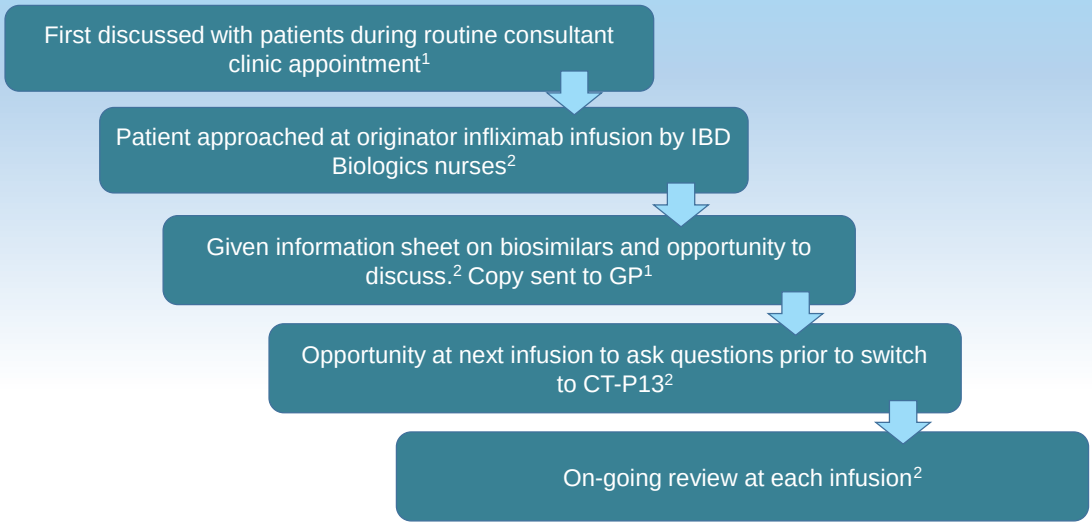
Designing the programme

- Unanimous agreement to the switching programme



Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Managed switching programme



1. Information is from Caron Underhill's own experience.
2. Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

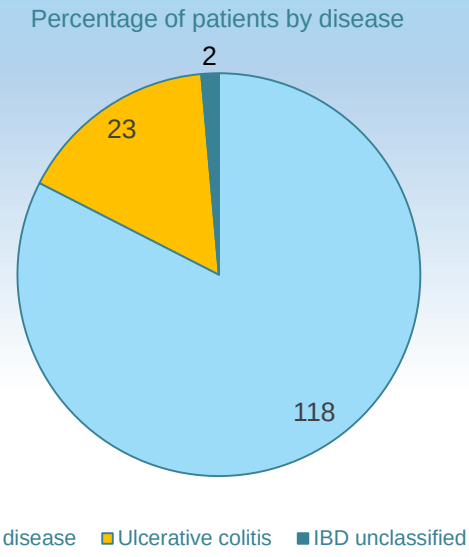
Patient information

- Patients reassured that treatment would be changed back to Remicade in unlikely event it became clinically necessary
- Patients informed to call the IBD helpline at any time if they had any concern
- Patient consent to switch recorded in medical notes
- All patients had been switched at 2 months at same dose and frequency
- Any new patients requiring infliximab initiated on CT-P13

Information on this slide is from Caron Underhill's own experience.

Demographics

- All patients (N=143) agreed to switch
- 56.6% female
- Median age = 39 years
- Median disease duration = 6 years



Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Outcomes

- IBD-control-8, IBD-control VAS, adverse events, blood laboratory measures routinely collected on database prior to switch & at each subsequent infusion post switch
- Infliximab serum trough levels, mean ADA levels – collected at 2 infusions prior to switch & prospectively at each subsequent infusion following switch

ADA, anti-drug antibodies; IBD, inflammatory bowel disease; VAS, visual analogue score.

Information on this slide is from Caron Underhill's own experience.

Efficacy

- No significant difference in IBD control
- No significant difference in biochemical markers of disease activity (CRP, albumin, platelet count, WCC, and haemoglobin) before and after the switch to CT-P13

WCC, white bloodcell count.

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

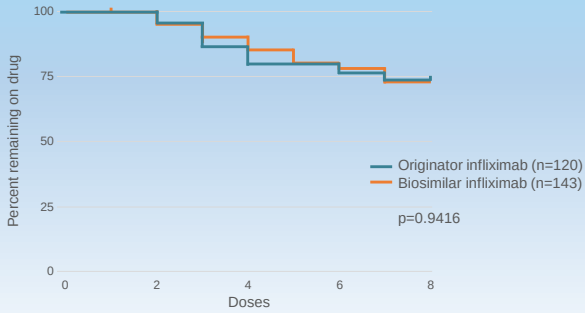
Immunogenicity & safety

- No significant difference in infliximab serum trough levels before & after the switch
- Antibody – positivity unchanged at 40% before & after switch

- No difference in safety profile before & after the switch
- Patients were more closely monitored after the switch therefore had a greater opportunity to report side effects

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Drug persistence



Dose	0	2	4	6	8
Originator IFX no (%)	120 (100)	119 (99.2)	103 (85.8)	95 (79.2)	88 (73.3)
CT-P13 no (%)	143 100	142 (99.3)	128 (89.5)	114 (79.7)	104 (72.7)

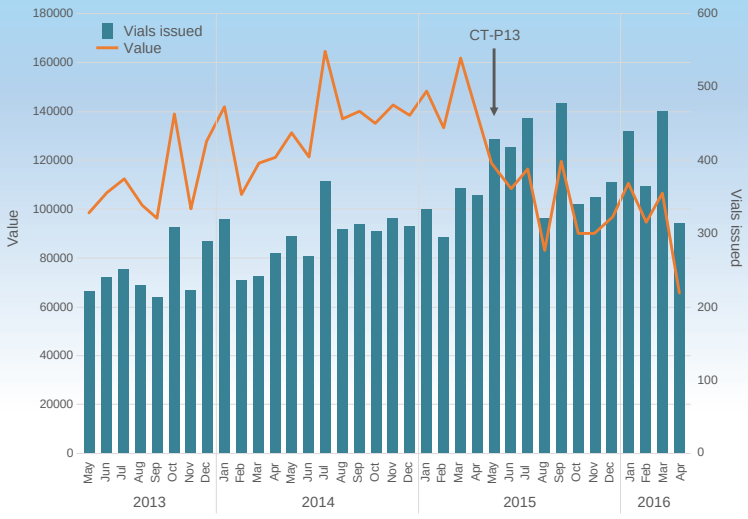
Survival curve showing percentage of patients remaining on originator and biosimilar infliximab at 1 year

- There was no statistically significant difference in drug persistence between the originator infliximab cohort and the cohort of patients switched to biosimilar infliximab CT-P13

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Drug acquisition costs and investments

- Rapid reduction in drug acquisition costs approximately £60k per month
- The total investment in IBD services was £103k yearly (12% of cost savings)



Number of vials of infliximab dispensed by the pharmacy and the drug acquisition costs billed to the clinical commissioning group (CCG)

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216

Lessons learnt

- Close collaboration between clinical speciality staff, biologics pharmacist, infusion unit staff and patients is required
- Biologic service needs to be well managed with a patient database before the biosimilar switch
- Additional time required for
  - Patient discussions
  - Patient helpline
  - Administrative work – e.g. letters
  - Education of staff
  - Pharmacovigilance – e.g. IT changes, procedures for recording batch number and brand in patient notes

Information on this slide is from Caron Underhill's own experience.

Authors' conclusions

- Successful managed switching programme to biosimilar infliximab CT-P13
- Gain share agreement ensured all stakeholders were appropriately incentivised
- Enabled service to be developed further while making significant cost savings to the healthcare system

Razanskaite V et al. *J Crohn's Colitis* 2017 [Epub before print]. doi:10.1093/ecco-jcc/jjw216