IBD Registry
Biological therapy key performance indicators (KPIs) 2019-20

This document gives you the information on the KPIs that have been selected for the on-going biological therapies data collection 2016-17 through to the current year 2019-20.

The Registry biological therapies audit and quality improvement programme originated in the Royal College of Physicians (RCP) Inflammatory bowel disease (IBD) programme. This clinical audit programme was transitioned into the Registry system in 2016-17.

The goal of the Biological Therapies Audit service from the IBD Registry is to give participating teams local data to manage their biologics patients and IBD service more effectively, while patients, clinicians and the wider NHS will benefit from national audit of the safety and appropriate use of biologics and biosimilars. In time, the combined UK data will become a unique resource for real-world clinical effectiveness and health economic studies in IBD care.

The KPIs were chosen by the Transition Steering Group to focus on the findings and recommendations in the IBD biological therapies audit report published in September 2016. **(www.rcplondon.ac.uk/biologics).** The aim has been to keep the data entry required to a minimum by focusing on three key points in a patient's biologics treatment – initiation on biological therapy (including those due to switching), post- induction review and 12-month review. This data will enable the IBD Registry to fulfil the audit and quality improvement role that it has taken over from the IBD programme at the RCP and report on these key aspects of clinical safety and effectiveness.

The biological therapy KPIs:

Pre-treatment checks

- Was the patient screened before starting on a biological therapy?
- Was a formal assessment of disease activity recorded at the point the decision was made to commence a biological therapy?
- Is there a record of Registry consent being discussed with the patient?

Post-induction review (approximately 3 months after the date of the initial treatment)

- Did a post-induction review take place?
- Was a formal assessment of disease activity recorded at this time?

12-month review (approximately 12 months after the date of the initial treatment)

- Did a 12-month review take place?
- Was a formal assessment of disease activity recorded at this time?

Data Items for the KPIs

The aims for data collection are to record basic demographic and clinical data on all biologics patients and to capture information on the KPIs consistently. For each of the KPIs there are a specific set of data items that fulfil each of the KPIs. Each KPI with the relevant items are outlined below.

Pre-treatment checks

- Was the patient screened before starting on a biological therapy?
- Was a formal assessment of disease activity recorded at the point the decision was made to commence a biological therapy?
- Is there a record of Registry consent being discussed with the patient?

Data item	Data submission framework item reference
Biologics data items	
Biologics - Date of Initiation or Review Event	IBD201
Biologics Event Type	IBD202
Is the patient biologics naïve?	IBD208
Biologic Treatment type	IBD210
Date of initial treatment (first loading dose)	IBD211
Screening test items (*adult only)	
Immunity – CXR	IBD221
Immunity - HCV Serology	IBD223
Immunity - HBV Serology	IBD224
Immunity - HIV Serology *	IBD225
Immunity - TB Test	IBD226
Disease activity items - Complete one activity score (PGA is additional and optional)	
HBI Total Score	IBD237
weightedPCDAI	IBD238
SCCAI	IBD239
Modified UCDAI	IBD240
PUCAI	IBD241
Optional - Physicians Global Assessment†	IBD236
Registry consent data items	
Date consent last recorded	IBD15
Informed consent for registry	IBD16

† *Guidance from ImproveCareNow on making a Physicians' Global Assessment is attached on page 5*

Reporting outputs:

(1) Was the patient screened before starting on a biological therapy?

Denominator: All biologics naïve patients starting any biological therapy in 2016/17 or subsequent Quality Accounts period (the number recorded as having an initiation event)

Numerator: All patients who have the 5 (adult) or 4 (paediatric) selected screening tests documented as completed at the time of the initiation event.

Sub-groups: None

(2) Was a formal assessment of disease activity recorded at the point the decision was made to commence biological therapy or within the previous two weeks?

Denominator: All patients starting any biological therapy in 2016/17 or subsequent Quality Accounts period (the number recorded as having an initiation event)

Numerator: The number of those patients who had a disease activity score recorded on the date of the initiation event or in the two weeks prior to that date (PGA only does not fulfil this criterion).

Sub-groups: None

(3) Is there a record of Registry consent being discussed with the patient?

Denominator: All patients starting any biological therapy in 2016/17 or subsequent Quality Accounts period (the number recorded as having an initiation event)

Numerator: The number of those patients for whom a positive or negative response has been recorded (if full local data can be accessed e.g. in the Web Tool) or just those with a positive response recorded (if reliant on central Registry data).

Sub-groups: None

Post-induction review (approximately 3 months after the date of the initial treatment)

- Did a post induction review take place?
- Was a formal assessment of disease activity recorded at this time?

Data Item	Data Submission Framework Item Reference
Biologics data items	
Biologics - Date of Initiation or Review Event	IBD201
Biologics Event Type	IBD202
Biologic Treatment type	IBD210
Date of initial treatment (first loading dose)	IBD211
Disease activity items - Complete one activity score (PGA is additional and optional)	
HBI Total Score	IBD237
weightedPCDAI	IBD238
SCCAI	IBD239
Modified UCDAI	IBD240
PUCAI	IBD241
Optional - Physicians Global Assessment†	IBD236

† *Guidance from ImproveCareNow on making a Physicians' Global Assessment is attached on page 5*

Reporting outputs:

(4) Did a post induction review take place?

Denominator: All patients starting any biological therapy in 2016/17 or subsequent Quality Accounts period (the number recorded as having an initiation event)

Numerator: The number of these patients who have had a post-induction or ad-hoc review documented within the period of 8-16 weeks after the date of initial treatment.

Sub-groups: Above % expressed separately for each biological treatment.

(5) Was a formal assessment of disease activity recorded at this time?

Denominator: Those patients recorded as the numerator group for 4 (above)

Numerator: The number of these patients who had a disease activity score recorded at the time of review or in the two weeks prior to that review (PGA only does not fulfil this criterion).

Sub-groups: None

12-month review (approximately 12 months after the date of the initial treatment)

- Did a 12-month review take place?
- Was a formal assessment of disease activity recorded at this time?

Data Item	Data Submission Framework Item Reference
Biologics data items	
Biologics - Date of Initiation or Review Event	IBD201
Biologics Event Type	IBD202
Biologic Treatment type	IBD210
Date of initial treatment (first loading dose)	IBD211
Disease activity items - Complete one activity score (PGA is optional)	
HBI Total Score	IBD237
weightedPCDAI	IBD238
SCCAI	IBD239
Modified UCDAI	IBD240
PUCAI	IBD241
Optional - Physicians Global Assessment†	IBD236

† *Guidance from ImproveCareNow on making a Physicians' Global Assessment is attached on page 5*

Reporting outputs:

(6) Did a 12-month review take place?

Denominator: All patients starting any biological therapy in 2016/17 or subsequent Quality Accounts period (the number recorded as having an initiation event)

Numerator: The number of these patients who have had a 12-month or ad-hoc review documented within the period of 44-60 weeks after the date of initial treatment.

Sub-groups: Above % expressed separately for each biological treatment.

(7) Was a formal assessment of disease activity recorded at this time?

Denominator: Those patients recorded as the numerator group for 6 (above)

Numerator: The number of these patients who had a disease activity score recorded at the time of review or in the two weeks prior to that review (PGA only does not fulfil this criterion).

Sub-groups: None

The above are process KPIs. Where disease scores are systematically recorded the data collected will also enable reporting of outcomes in terms of the change in disease scores from initiation of treatment through to the post-induction and 12-month follow-up reviews.

ImproveCareNow Physician Global Assessment

Based on the information available, choose one category that best describes the overall disease activity

INACTIVE DISEASE	In the past week the patient has had minimal or no symptoms thought to be secondary to IBD
Abdominal pain Diarrhea, bloody stools Fatigue Activity	– Asymptomatic – Mild symptoms on one or two occasions that resolved spontaneously – Significant symptoms felt to be secondary to another disorder such as IBS or depression
Fistula	None, or a non-inflamed, indolent fistula with no or minimal drainage.
Weight loss	No unexplained wt loss
Abd mass, tenderness	None
Toxic appearance	No
Lab tests (if available)	Normal or minimal transient abnormalities

MILD DISEASE	In the past week, the patient has had mild recurring or persistent symptoms thought to be secondary to IBD
Abdominal pain	Mild abdominal pain thought to be secondary to IBD and occurring several times a week
Diarrhea, bloody stools	Mild recurrent diarrhea (without nocturnal defecation or gross inflammatory bleeding) thought to be secondary to IBD
Fatigue Activity	– Asymptomatic or mild symptoms on one or two occasions that resolved spontaneously – Significant symptoms felt to be secondary to another disorder such as IBS or depression
Fistula	Active fistula or other perianal symptoms without associated symptoms
Weight loss	No unexplained wt loss
Abd mass, tenderness	None
Toxic appearance	No
Lab tests (if available)	Persistent (and significant) laboratory abnormalities felt to be secondary to IBD with no or mild associated symptoms

MODERATE DISEASE	In the past week, the patient has had moderate (or combinations of mild and moderate) recurring or persistent symptoms thought to be due to IBD
Abdominal pain	Moderate abdominal pain thought to be secondary to IBD
Diarrhea, bloody stools	Moderate diarrhea that could include nocturnal diarrhea and gross inflammatory bleeding thought to be secondary to IBD
Fatigue	Significant fatigue thought to be secondary to IBD
Activity	Inability to maintain normal activities due to fatigue or other symptoms
Fistula	Active fistula or other perianal disease in combination with other symptoms
Weight loss	Significant unexplained weight loss
Abd mass, tenderness	Abdominal tenderness and/or small abdominal mass or fullness
Toxic appearance	No
Lab tests (if available)	Significant anemia, hypoalbuminemia, and/or elevation in inflammatory markers

SEVERE DISEASE	In the past week, the patient has had severe (or combinations of moderate and severe) recurring or persistent symptoms thought to be due to IBD
Abdominal pain	Severe abdominal pain thought to be secondary to IBD
Diarrhea, bloody stools	Significant diarrhea that could include nocturnal diarrhea and gross inflammatory bleeding thought to be secondary to IBD
Fatigue	Significant fatigue thought to be secondary to IBD
Activity	Severe impairment of normal activities due to fatigue or other symptoms
Fistula	Active fistula or other perianal disease in combination with other symptoms
Weight loss	Significant unexplained weight loss
Abd mass, tenderness	Abdominal mass and/or tenderness
Toxic appearance	Appears toxic
Lab tests (if available)	Significant anemia, hypoalbuminemia, and/or elevation in inflammatory markers