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

This document provides information about the KPIs that have been selected for the rolling biological therapies audit, which began in 2016-17 and continues to the current year, 2019-20.

The purpose of this document is to set out how the KPIs are calculated together with the data that is required to be captured for their calculations. The document is written with a clinical audience in mind.

Background

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

The KPIs were chosen by the RCP's Transition Steering Group to focus on the findings and recommendations in the IBD biological therapies audit report published in September 2016[1]. The aim is 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** (pre treatment checks), **post- induction review** and **12-month review**. This data will enable the IBD Registry to fulfil the audit and quality improvement role it has assumed from the RCP and to report on these key aspects of clinical safety and effectiveness. The KPIs do not currently including those due to switching from an originator drug to a biosimilar, but the Registry is looking to include this important element.

The biological therapy KPIs

Initiation (pre treatment screening)

- 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 (see Appendix).

[1] *(www.rcplondon.ac.uk/biologics).*

Group 1: Initiation (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?

Reporting outputs for Group 1:

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

Denominator: All patients starting any biological therapy who are recorded as biologic naïve

Numerator: All patients who have the 5 (adult) or 4 (paediatric) selected screening tests documented as completed or not indicated at the time of starting the biologic

Sub-groups: None

Notes on recording:
(1) It is critical that clinical teams positively record 'biologics naïve' - either *Yes* or *Not Indicated*, but not left blank or the KPI calculations will exclude this record
(2) All the above listed tests are required to be recorded as *Completed* or *Not Indicated* but not left blank, or the KPI calculations will exclude this record

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

Denominator: All patients starting their first recorded biological therapy

Numerator: The number of those patients who had a disease activity score recorded on the date of the treatment commenced or in the six weeks prior to that date

Sub-groups: None

Notes on recording: This KPI can calculate based on just the first biological therapy included

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

Denominator: All patients starting their first recorded biological therapy

Numerator: The number of those patients for whom a positive response has been recorded

Sub-groups: None

Group 2: 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?
- *Recommended: Has the biologic drug been stopped, if so, why?*

Reporting outputs for Group 2:

(4) Did a post induction review take place?

Denominator:	All patients starting their first recorded biological therapy who continued the drug to the time of an expected post-induction review (12 weeks))
Numerator:	The number of these patients who have had a review documented within the period of 8-16 weeks after the date of initial treatment.
Sub-groups:	

(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 within the period of 8-16 weeks after the date of initial treatment
Sub-groups:	None

Group 3: 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?
- *Recommended: Has the biologic drug been stopped, if so, why?*

Reporting outputs for Group 3:

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

Denominator:	All patients starting their first recorded biological therapy who continued the drug to the time of an expected annual review (52 weeks)
Numerator:	The number of these patients who have had a review documented within the period of 44-60 weeks after the date of initial treatment
Sub-groups:	

(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 within the period 44-60 weeks after the date of initial treatment
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.

Quality Accounts Service

Alongside the tools to capture the data for the audit, the Registry also provides an analysis and reporting service (the Biological Therapies Audit service) to give participating teams local data benchmarked against the national aggregate 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.

Methodology Revisions (2018/19)

1. As the Registry dataset enables some items to be captured in more than one 'event', the alternative data items have been added to the analysis in order to report more complete data (see Appendix)
2. To align with clinical practice 'Not Indicated' has been included as an allowable response in the pre-treatment screening KPI
3. The time-frames for recording reviews and disease scores have been adjusted to reflect clinical practice
4. Physician's Global Assessment has been included as a valid assessment of disease activity
5. *Recommended: Biologics drug stop date (if applicable) and reason drug stopped added to items captured to gather more complete description of a 'course' of biologic treatment*

Appendix – Data Items and IBD Registry Submission Framework Reference

Pre-treatment checks

Data item	Data submission framework item reference
Biologics data items	
Biologics - Date of Initiation or Review Event or Contact – Date of visit	IBD201 or IBD21
Is the patient biologics naïve?	IBD208
Biologic Treatment type or Drug - Code	IBD210 or IBD75
Date of initial treatment (first loading dose) or Drug – Start Date	IBD211 or IBD76
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	
HBI Total Score	IBD237 (Biologics item) or IBD33 (Contact item)
weightedPCDAI	IBD238 (Biologics item) or IBD35 (Contact item)
SCCAI	IBD239 (Biologics item) or IBD37 (Contact item)
Modified UCDAI	IBD240 (Biologics item) or IBD34 (Contact item)
PUCAI	IBD241 (Biologics item) or IBD36 (Contact item)
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*

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

Data Item	Data Submission Framework Item Reference
Biologics data items	
Biologics - Date of Initiation or Review Event or Contact – Date of visit	IBD201 or IBD21
Biologic Treatment type or Drug – Code	IBD210 or IBD75
Date of initial treatment (first loading dose) or Drug – Start Date	IBD211 or IBD76
Biologics Review – Treatment plan *or Drug – End Date (if applicable) **	*IBD231* *or IBD77*
Biologics Review – Reason for treatment plan *or Biologics Drug End Reason (if applicable) **	*IBD232* *or IBD82*
Disease activity items - Complete one activity score (PGA is additional and optional)	
HBI Total Score	IBD237 (Biologics item) or IBD33 (Contact item)
weightedPCDAI	IBD238 (Biologics item) or IBD35 (Contact item)
SCCAI	IBD239 (Biologics item) or IBD 37 (Contact item)
Modified UCDAI	IBD240 (Biologics item) or IBD 34 (Contact item)
PUCAI	IBD241 (Biologics item) or IBD 36 (Contact item)
Physicians Global Assessment†	IBD236

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

** *These two items added to provide biologic stop date info. They are not part of the KPI definitions*

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

Data Item	Data Submission Framework Item Reference
Biologics data items	
Biologics - Date of Initiation or Review Event or Contact – Date of visit	IBD201 or IBD21
Biologic Treatment type or Drug - Code	IBD210 or IBD75
Date of initial treatment (first loading dose) or Drug – Start Date	IBD211 or IBD76
Biologics Review – Treatment plan *or Drug – End Date (if applicable) **	*IBD231* *or IBD77*
Biologics Review – Reason for treatment plan *or Biologics Drug End Reason (if applicable) **	*IBD232* *or IBD82*
Disease activity items - Complete one activity score	
HBI Total Score	IBD237 (Biologics item) or IBD33 (Contact item)
weightedPCDAI	IBD238 (Biologics item) or IBD35 (Contact item)
SCCAI	IBD239 (Biologics item) or IBD37 (Contact item)
Modified UCDAI	IBD240 (Biologics item) or IBD34 (Contact item)
PUCAI	IBD241 (Biologics item) or IBD36 (Contact item)
Physicians Global Assessment†	IBD236

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

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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