

I completed an audit as part of my training. I chose to work with the HomeCare department - this involved assessing whether Gastroenterology patients receiving monoclonal antibodies for the treatment of IBD were adhering to a monitoring schedule stipulated within NHSL's guidelines.

I absolutely loved my project. I received lots of support from both colleagues and superiors (many kind words of encouragement!) and I am proud to say my project will have an impact on the care of these patients.

A new team of Gastro pharmacists have been recruited and have the opportunity to expand on my project.

## Nimrah Ejaz Trainee Pharmacist

It has been amazing to see all my hard work pay off. I achieved 2nd place in the West of Scotland finals and am working on getting my project published.



# Blood Monitoring in Patients With Inflammatory Bowel Disease

Nimrah Ejaz (NHS Lanarkshire)

# Inflammatory Bowel Disease (IBD)

- Umbrella term for Crohn's disease and Ulcerative Colitis (UC)
- Prevalence:
  - Crohn's → affects approximately 157 per 100,000 individuals
  - UC → affects approximately 240 per 100,000 individuals
- Conventional drug treatment can include aminosalicylates, glucocorticosteroids, azathioprine, mercaptopurine, /or methotrexate
- Biologics (including monoclonal antibodies)

# Monoclonal Antibodies (mAbs)

**mAbs in NHSL guideline are:**

Infliximab

Adalimumab

Golimumab

Ustekinumab

Vedolizumab



**Delivered via HomeCare**

# HomeCare

- Outpatient referral (occasionally inpatient referral)
- First dose IV/SC, if tolerated then SC
- Taught to self-administer
- Variable dosing
- NHSL guideline recommends to monitor FBC, U+Es, and LFTs 8-weekly → done in primary care

# Aim and Objectives

To assess adherence with blood monitoring in patients receiving monoclonal antibodies as per NHS Lanarkshire IBD guidelines

- Assess how frequently patients are being monitored
- Explore the impact of Covid-19 on the frequency of blood monitoring
- Determine if any additional factors had an impact on blood monitoring
- Review current blood monitoring guidelines

# Standards

<b>Audit Criteria</b>	<b>Standard</b>
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%

# Inclusion Criteria

- Have a diagnosis of IBD
- Be registered with the HomeCare service within NHS Lanarkshire
- Receive one of the five monoclonal antibodies stipulated in NHSL's guidelines delivered via HomeCare
  - Infliximab and vedolizumab not available SC so not available via HomeCare



# Exclusion Criteria

- Patients under the age of 16
- Patients initiated on therapy/HomeCare in July 2020 or later
- Patients who have discontinued therapy
- Not receiving a listed mAb from NHSL guidelines
- One or more apparent inpatient admissions\* lasting two days or more

\*defined as two or more consecutive bloods in an inpatient setting

Adult patients  
registered with  
HomeCare  
n = 361

27 patients excluded  
for initiating therapy  
later than July 2020  
n = 334

3 patients excluded for  
receiving tofacitinib  
n = 331

51 patients excluded  
for inpatient  
admissions  
n = 280

# Methodology – Frequency of Monitoring

- Noted bloods for each patient within time period 01/10/2019 – 30/09/2020
  - Only used if checked FBC, U+Es, and LFTs
  - Documented if patients had nil appropriate bloods
- Calculated time period between:
  - 01/10/2019 and first set of bloods
  - Each set of bloods
  - Final set of bloods and 30/09/2020

119	-43858	0	0	0	0	0	0	0	0
14	8	140	188	-44089	0	0	0	0	0
38	238	-44015	0	0	0	0	0	0	0
98	218	-44055	0	0	0	0	0	0	0
70	9	-43818	0	0	0	0	0	0	0
94	69	68	99	-44069	0	0	0	0	0
37	267	-44043	0	0	0	0	0	0	0
#VALUE!	#VALUE!	0	0	0	0	0	0	0	0
6	59	63	109	86	5	-44067	0	0	0
183	-43922	0	0	0	0	0	0	0	0
65	112	63	48	63	-44090	0	0	0	0
13	39	24	32	5	22	102	36	28	0
44	60	43	120	61	-44067	0	0	0	0
64	36	49	104	112	-44104	0	0	0	0
126	192	-44057	0	0	0	0	0	0	0
121	130	-43990	0	0	0	0	0	0	0
34	65	33	121	63	37	-44092	0	0	0
45	83	62	106	-44035	0	0	0	0	0
52	46	237	-44074	0	0	0	0	0	0
8	54	189	94	-44084	0	0	0	0	0
42	258	-44039	0	0	0	0	0	0	0
71	216	13	-44039	0	0	0	0	0	0

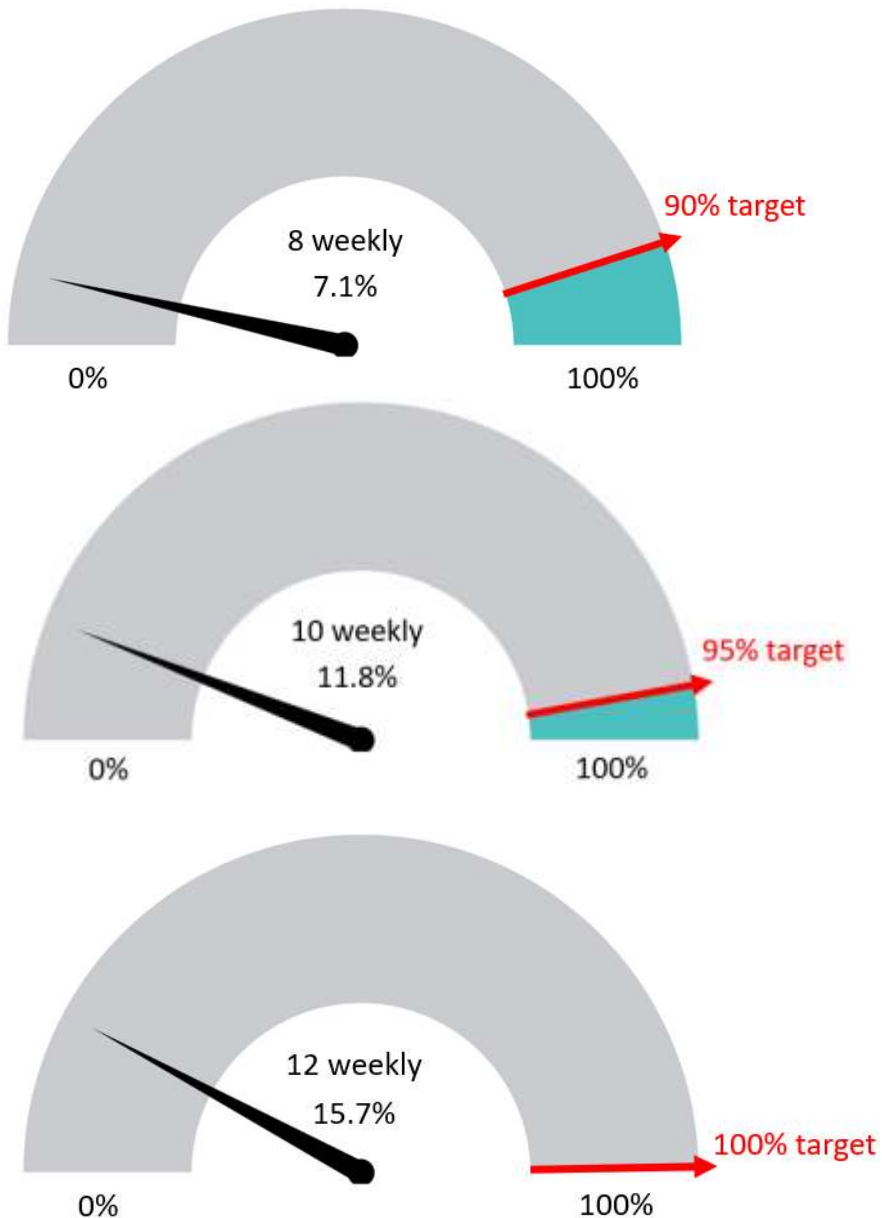
# Methodology – Covid-19

- Examined frequency of monitoring within two different time periods
  - Pre-lockdown → 01/10/2019 to 22/03/2020
  - During/post lockdown → 23/03/2020 to 30/09/2020
- For fair comparison, excluded individuals who initiated therapy after 01/10/2019
  - Excluded further 62 → n = 218

# Methodology – Other Factors

- If recently initiated on therapy, had a documented HomeCare initiation date
- Compared individuals with a documented initiation date against individuals with no documented start date

# Results – Frequency of Monitoring



Audit Criteria	Standard	Results n = 280
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%	7.1% (20 / 280)
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%	11.8% (33 / 280)
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%	15.7% (44 / 280)

Audit Criteria	Standard	Pre-lockdown	During/post lockdown
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%	16.7% (37 / 218)	4.6% (11 / 218)
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%	28.2% (62 / 218)	9.7% (22 / 218)
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%	38.4% (84 / 218)	20.4% (45 / 218)

## Results – Covid-19

n = 218

- Pre-lockdown – 25 out of 218 had nil bloods
- During/post lockdown – increased to 53 patients with nil bloods

# Results – Other Factors

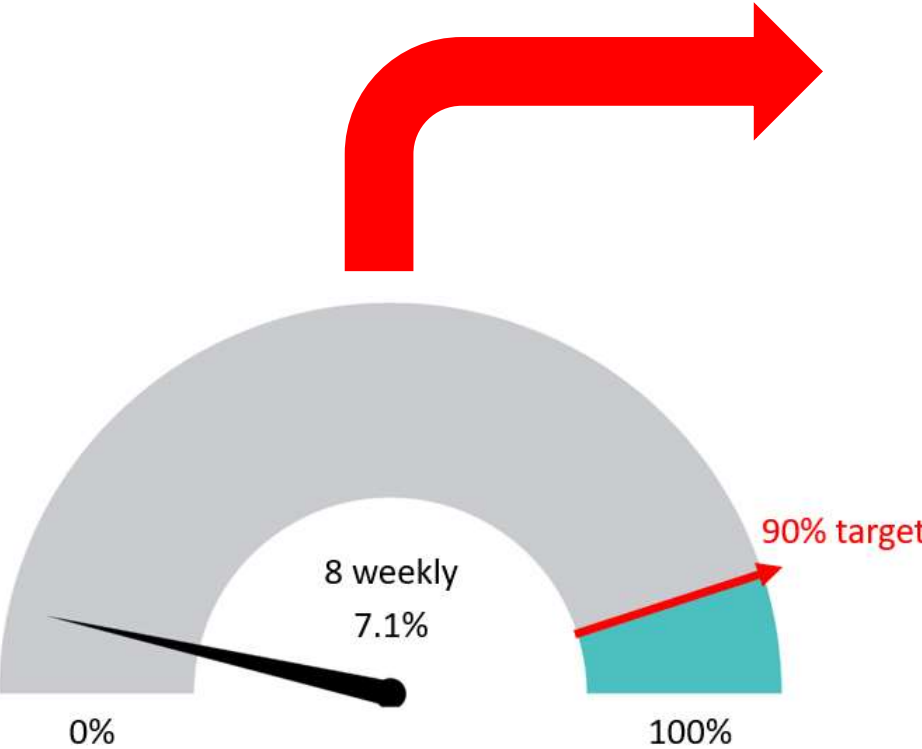
Audit Criteria	Standard	With initiation date (n = 64)	No documented initiation date (n = 216)
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%	23.4% (15 / 64)	2.3% (5 / 216)
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%	34.4% (22 / 64)	5.1% (11 / 216)
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%	40.6% (26 / 64)	8.3% (18 / 216)

# Discussion

- Is 8-weekly monitoring achievable/realistic?
  - 20 out of 280 patients (7.1%) adhered to guidelines



# Results – Frequency of Monitoring



Audit Criteria	Standard	Results n = 280
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%	7.1% (20 / 280)
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%	11.8% (33 / 280)
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%	15.7% (44 / 280)

# Discussion

- Is 8-weekly monitoring achievable/realistic?
  - 20 out of 280 patients (7.1%) adhered to guidelines
- Should Covid-19 have had an impact on blood monitoring?
  - No! – Patients stratified before lockdown started
- Patient's own responsibility to get bloods
- Risk/benefit of administering without checking bloods
  - 8-weekly recommendation not referenced
  - British Society of Rheumatology recommendation of 3-6 monthly

# Results – Other Factors

Audit Criteria	Standard	With initiation date (n = 64)	No documented initiation date (n = 216)
Blood monitoring will be performed at a minimum of 8-weekly intervals	90%	23.4% (15 / 64)	2.3% (5 / 216)
Blood monitoring will be performed at a minimum of 10-weekly intervals	95%	34.4% (22 / 64)	5.1% (11 / 216)
Blood monitoring will be performed at a minimum of 12-weekly intervals	100%	40.6% (26 / 64)	8.3% (18 / 216)

# Discussion

- Is 8-weekly monitoring achievable/realistic?
  - 20 out of 280 patients (7.1%) adhered to guidelines
- Should Covid-19 have had an impact on blood monitoring?
  - No! – Patients stratified before lockdown started
- Patient's own responsibility to get bloods
- Risk/benefit of administering without checking bloods
  - 8-weekly recommendation not referenced
  - British Society of Rheumatology recommendation of 3-6 monthly

# Proposed Actions

- Guidelines due for review January 2021 (extended to July 2021 due to Covid-19)
- Gastroenterology pharmacist
- Present findings to gastroenterology department



# Limitations

- Only one source used for data collections (LIMS)
  - Determine if inpatient admission from bloods
- Manual collection and input of data
- Not able to assess monitoring of mAbs not delivered via HomeCare

# References

- British National Formulary, Online Edition (2021). Ulcerative colitis: treatment summary. Available at <https://bnf.nice.org.uk/treatment-summary/ulcerative-colitis.html>
- British National Formulary, Online Edition (2021). Crohn's disease: treatment summary. Available at <https://bnf.nice.org.uk/treatment-summary/crohns-disease.html>
- National Institute for Health and Care Excellence (NICE) NG130. (2019). Ulcerative colitis: management. Available at <https://www.nice.org.uk/guidance/ng130/chapter/Recommendations>
- National Institute for Health and Care Excellence (NICE) NG129. (2019). Crohn's disease: management. Available at <https://www.nice.org.uk/guidance/ng129/chapter/Recommendations>
- National Institute for Health and Care Excellence (NICE) QS81. (2014). Inflammatory bowel disease: briefing paper. Available at <https://www.nice.org.uk/guidance/qs81/documents/inflammatory-bowel-disease-briefing-paper>