Protocol

Gastroenterology Patient-Initiated Follow-Up (PIFU)

Inflammatory Bowel Disease

Version 1.0

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Background

The majority of patients with chronic health conditions such as inflammatory bowel disease (IBD) will receive regular outpatient clinic follow-up. However, whether this traditional model of outpatient care is beneficial for patients with stable disease is debatable. Providing follow-up at fixed time intervals means that these appointments are unlikely to coincide with a patient’s clinical needs. From the patient’s perspective, this may be inconvenient, resulting in unnecessary travel to the hospital and time spent waiting in clinic for routine follow-up appointments. Moreover, missed hospital appointments are a significant problem for the NHS and cost millions of pounds each year. (Whear *et al*, 2020). The need for more flexible approaches to care that more readily meet the needs of patients with chronic conditions was highlighted by a World Health Organisation report in 2002, (WHO 2002) and more recently by the Royal College of Physicians in their 2018 report *Outpatients – The Future.* (RCP 2018).Patient-initiated follow-up (PIFU) appointments may offer a solution to this problem and improve the efficiency of outpatient clinic appointment systems overall.

A Cochrane systematic review conducted in 2020 examined the effects of patient-initiated appointment systems compared with consultant-led appointment systems for patients with a range of chronic health conditions in secondary care. (Whear *et al*, 2020) The study included 17 randomised controlled trials (RCTs), involving 3584 patients, and encompassed six health conditions: cancer, rheumatoid arthritis, asthma, psoriasis, chronic obstructive pulmonary disease, and inflammatory bowel disease. The review concluded that PIFU may have little or no effect on service utilisation and that there is uncertainty regarding costs compared with consultant-led appointments. In addition, there may be little or no effect on clinical events such as relapse or patient satisfaction compared with traditional models of care. However, the quality of evidence was mostly low to very low.

RCTs examining use of PIFU in the care of patients with IBD have been conducted. One study by Williams *et al*. randomised 180 patients with inactive or mildly active but stable IBD to receive either open access follow-up or routine care. Outcomes were assessed over a 24-month period. Open access care resulted in significantly fewer hospital attendances and outpatient clinic appointments compared with routine care, but there were no differences between groups with respect to generic or disease-specific quality of life. A second multi-centre study conducted in 2004 recruited 700 patients with IBD and randomised them to receive routine care or an intervention comprising a written guide to IBD, a guided self-management strategy, and direct access to services enabling patients to self-refer (Kennedy *et al*, 2004). One year following the intervention, self-managing patients had made significantly fewer hospital visits without an increase in primary care visits, and quality of life was maintained. There was no difference with respect to patient satisfaction between the two groups.

Patient-initiated approaches to follow-up in IBD are acceptable to patients, and this approach may fit better with patients’ everyday routines, roles and responsibilities. (Rogers *et al,* 2004). However, acceptability depends on hospital personnel being responsive to patient-initiated requests for appointments. Understandably, some people may continue to prefer the fixed appointment system and respecting patient choice is key. (Rogers *et al,* 2004). A more recent study also found that patients with IBD prefer a more flexible follow-up care system. (Kemp *et al, 2013).* The authors conclude that new models of follow-up care could improve the patients' experience of care, whilst still allowing care to be targeted to those with the greatest clinical need. Such models could also offer potential cost savings with reduction in face-to-face consultations.

Development of a PIFU Service for Gastroenterology at York Hospital

It is envisaged that PIFU could be implemented to manage the long-term care and follow-up of some patients with inflammatory bowel disease (IBD) at York Hospital. IBD encompasses two conditions, namely ulcerative colitis (UC) and Crohn’s disease. There are several important clinical distinctions between these two conditions which need to be considered when planning which patients with IBD will be appropriate for PIFU.

Rather than being offered regular clinic appointments with a doctor or specialist nurse at fixed time points, PIFU patients can make their own appointment when required, for example if they are experiencing a flare-up of their disease.

PIFU offers important benefits for patients and the clinical service in gastroenterology:

* PIFU puts patients in control of their own care and provides direct access to the hospital team when needed.
* PIFU may be more convenient for patients and reduces unnecessary travel to the hospital and time spent waiting in clinic for routine follow-up appointments.
* PIFU will release clinical activity in outpatient clinics that can be used for other patients requiring regular follow-up and should reduce waiting times.
* PIFU should reduce the volume of queries received via the IBD helpline by directing certain patients with flares via a separate dedicated contact route. This should assist the IBD specialist nurses to respond to other queries more quickly, and release some time for other key clinical activities.

# Patient Selection

## Ulcerative Colitis vs Crohn’s Disease

UC is characterised by chronic inflammation affecting the colon only. No other part of the gastrointestinal tract is affected in UC. The extent of the disease may vary from involvement of the rectum only to the whole colon being affected. A substantial number of patients have disease that is confined to the rectum or the left-side of the colon only.

By contrast, Crohn’s disease is a much more heterogeneous, and often more complex, disease in which inflammation can affect any part of the gastrointestinal tract from mouth to anus. The colon and small intestine are most commonly affected. Moreover, inflammation affects the full thickness of the bowel wall, rather than being confined to the lining of the bowel as in UC. This means patients with Crohn’s disease can develop strictures (narrowing) of the bowel or fistulae (holes) between different bowel loops or the skin, including around the anal canal (perianal disease).

Due to these differences in disease phenotype, only patients with UC will be able to participate in PIFU initially. Their eligibility will also be based on additional criteria relating to disease severity and treatment as discussed below. It is important to acknowledge, however, that some patients with Crohn’s disease may have simple disease, with well-controlled symptoms. Following initial evaluation of the PIFU service, this may be expanded to include some patients with Crohn’s disease in due course.

Recommendations:

* Only patients with UC will be eligible for PIFU initially.
* Patients may have any extent of disease (proctitis, left-sided, pan-colonic) provided their symptoms are well-controlled (see below).
* It should be possible to consider some patients with Crohn’s disease for PIFU in due course; for example, patients who have had previous surgery for their disease and now require no maintenance medical therapy.

## Disease activity

In order to be eligible for PIFU, patients need to have quiescent disease. This means that they currently have no troublesome bowel symptoms to suggest active inflammation. This decision can be based on a clinical assessment of symptoms alone. Routine evaluation of faecal calprotectin or lower gastrointestinal endoscopy to assess for mucosal inflammation and disease activity prior to initiating PIFU is unnecessary. In addition, patients should not have had any disease flares requiring escalation of their treatment, including courses of steroids, within the previous 12 months.

Recommendations:

* Patients must have quiescent disease with no flares or escalation of treatment within the previous 12 months.

## Medication and Treatment

A number of different medical treatments are used to control inflammation and maintain remission in IBD. These include 5-aminosalicylates (5-ASA – mesalazine), thiopurines (azathioprine, mercaptopurine), and biologic drugs (e.g., infliximab, adalimumab, vedolizumab).

Any patient who is currently receiving biologic therapy will not be suitable for PIFU regardless of how well-controlled their disease is. This is because best practice as per NICE recommendations is that all patients receiving biologic therapy should be reviewed at least annually to determine whether biologic treatment should continue. In addition, these drugs are potent immunosuppressants, and patients who are receiving biologic drugs to control their disease will usually have had more severe disease, which has been difficult to bring into remission.

Patients with UC who are receiving monotherapy with mesalazine, either oral, topical, or in combination, will be suitable for PIFU. These drugs are the first-line medical therapy in the treatment of UC. Moreover, life-long continuation of mesalazine in UC, even for patients in remission, is usually recommended due to the potential chemoprotective effects in reducing colorectal cancer risk.

Patients who are taking thiopurines will not currently be eligible to participate in PIFU. However, patients who are well-established on the drug, and who have quiescent disease, may be included in PIFU in the future. This is because, although regular drug monitoring is required, there is an existing shared care agreement between primary and secondary care to ensure that this is managed correctly.

Recommendations:

* Patients who are taking mesalazine monotherapy are eligible for PIFU.
* Any patient receiving biologic drugs is not suitable for PIFU, even if their disease is well-controlled.
* Patients taking thiopurines may be eligible for PIFU in the future, but will not be initially.

# Other Important Clinical Considerations

## Surveillance Colonoscopy

Patient with UC are at increased risk of colorectal cancer compared with the risk in the general population. They therefore require surveillance colonoscopy. Patients should have a colonoscopy 10 years after their initial diagnosis, and this will determine timing of any subsequent surveillance. Surveillance colonoscopy can be managed independently of the PIFU service and does not require patients to have an outpatient clinic appointment. It should be arranged when patients first commence PIFU.

Recommendations:

* The treating clinician should review the timing of surveillance colonoscopy with the patient and book the procedure when the patient starts PIFU.
* Surveillance colonoscopy can be actively reviewed when patients attend for an appointment thereafter, including at their default appointment if they have not needed to contact PIFU before this time.
* The results of any surveillance colonoscopy will need to be reviewed by the responsible consultant under whom the test has been booked.
* The default clinic appointment can be arranged to fall prior to the surveillance colonoscopy if it is felt that a clinical review of fitness to proceed with the test is likely to be needed.

## Monitoring Blood Tests

Routine monitoring blood tests are not required in IBD *per se*, but are mandated for certain medical treatments. Patients taking mesalazine should have their renal function (U&Es) checked annually.

Recommendations:

* The treating clinician should review the need for monitoring blood tests with the patient and ensure these are up-to-date when the patient starts PIFU.
* The requirement for annual U&Es monitoring should be communicated to the GP when patient starts PIFU.

# Arrangements for Patients Requiring a PIFU Appointment

## Making Contact

Patients will make contact with the PIFU service using the arrangements that are already in place within the Trust.

Recommendations:

* Patients will contact PIFU by calling the IBD helpline telephone number (01904 726154).
* The IBD nurses will triage the problem and arrange appropriate follow-up.

## Provision of Clinic Appointments

Patients who contact the PIFU service for an appointment need to be reviewed within 28 days, but any review should ideally be as early as possible within this timeframe. The IBD specialist nurses can triage the problem at initial contact to ensure the patient receives an appropriate and timely review. The aim should be to initiate management of a flare promptly, including booking endoscopic assessment where required. This will therefore require PIFU appointment slots to be built into the outpatient clinic templates for the gastroenterology consultants and IBD specialist nurse clinics. It is anticipated that all the gastroenterology consultants will participate in PIFU clinic provision (Dr Adhikary, Dr Berriman, Dr Chandler, Dr Kant, Dr Robins, and Dr Turvill).

Recommendations:

* PIFU/IBD appointment slots should be built into the clinic templates for the gastroenterology consultants.
* Provision of PIFU/IBD appointment slots should be reviewed and amended based on clinical demand for these appointments.

# Arrangements for Ongoing Follow-up After a PIFU Appointment

Ongoing follow-up arrangements for patients under PIFU will be reviewed by the consultant or IBD specialist nurse when they attend their appointment. Some patients may be able to return to PIFU immediately. However, patients who have required treatment of a flare or escalation of their medical therapy will require subsequent clinical review and will not be suitable to restart PIFU straightaway. They may be able to recommence PIFU at a later date if they remain well and continue to be clinically eligible.

Recommendations:

* Ongoing follow-up arrangements for patients under PIFU will be reviewed by the gastroenterology consultant or IBD specialist nurse when they attend their appointment.

# Default Follow-up Interval

After a fixed period of time, if a patient has not needed to contact the PIFU team then they will be contacted to arrange a routine clinic appointment. It is current practice that patients with stable IBD are likely to be offered a routine clinic appointment every 12 months. Consequently, having a default follow-up interval of 1 or 2 years as is the case for Rheumatology PIFU patients would not lead to any change in the clinical service in gastroenterology. A default follow-up interval of 3 to 5 years is therefore recommended.

Recommendations:

* If a patient has not contacted the PIFU team after between 3 to 5 years they will be contacted to offer a routine follow-up appointment.
* This follow-up interval will be determined by the consultant or IBD specialist nurse when initiating PIFU.

Audit and Appraisal of PIFU in Gastroenterology

Audit and evaluation of PIFU will be needed in order to understand:

* current utilisation of the service in terms of patient numbers and clinical characteristics
* whether clinical capacity is sufficient to meet demand for PIFU appointments, and whether patients are receiving timely review
* whether the service is having a beneficial impact on clinical capacity for gastroenterology as intended
* patient satisfaction
* how the PIFU service might be developed and expanded

The following processes and key indicators are highlighted as possible targets for audit and review:

* maintaining a database of all IBD patients participating in PIFU for audit purposes
* seeking feedback regarding the service from patients
* regular audit of the number of PIFU clinic appointments utilised per month, the time from patient contact to clinic review, and whether current capacity is sufficient to meet demand
* analysis of gastroenterology outpatient clinic patient lists and waiting times, and of demand for the IBD helpline
* longer term audit of clinical outcomes among PIFU patients

Proposed Standard Operating Procedure for Implementation of PIFU in Gastroenterology

Clinic review of patient with IBD

Eligible for PIFU?

Clinic Follow-up Booked

Discuss with patient and provide written information

Patient happy for PIFU?

Book surveillance colonoscopy and arrange bloods monitoring

Patient starts PIFU and GP informed

Patient experiences flare?

If no contact within 3 to 5 years then offer routine clinic appointment

Patient contacts PIFU team

Admin team arrange PIFU clinic appointment

Consultant review and treatment plan

Remains suitable for PIFU and patient happy?

Yes

Yes

No

No

No

Yes

Yes

No

References

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Kennedy AP, *et al.* (2004) A randomised controlled trial to assess the effectiveness and cost of a patient orientated self-management approach to chronic inflammatory bowel disease. *Gut*;53:1639–1645.

Rogers A, et al. (2004) Patients’ experiences of an open access follow up arrangement in managing inflammatory bowel disease. *Qual Saf Health Care*;13:374–378.

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Williams JG, *et al*. (2000) Open access follow up for inflammatory bowel disease:

pragmatic randomised trial and cost effectiveness study. *BMJ*;320:544–8.