Stratification of inflammatory bowel disease outpatients by disease activity and risk of complications to guide out-of-hospital monitoring: a patient-centred quality improvement project

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ABSTRACT

Background Inflammatory bowel disease (IBD) is a chronic relapsing-remitting condition affecting 600,000 people in the UK. Traditionally, patients attend outpatient clinics for monitoring regardless of their symptoms or risk of developing complications. This can lead to a mismatch between need and access: patients in remission given elective appointments displace those in need of urgent specialist attention. Novel initiatives implemented in the UK to improve outpatient monitoring have often required a well-maintained patient registry, empowered patients and significant information technology support.

Design and strategy In this large-scale quality improvement project at St Mark’s Hospital, a tertiary centre for IBD, we stratified over 1000 patients attending three non-complex IBD clinics over 12 months according to disease activity and risk profile. The aim was to offer a choice and subsequently transfer 50% of eligible patients to specialist nurse-led telephone clinics and demonstrate non-inferior satisfaction levels to existing outpatient follow-up. We also sought to ensure there was timely access to a newly established rapid access clinic for patients requiring urgent specialist attention.

A core project team consisting of healthcare professionals, patients and quality improvement scientists met regularly. The team tested and scaled up interventions using ‘Plan-Do-Study-Act’ cycles within the ‘Model for Improvement’ framework and analysed data continuously using statistical process charts.

Results Over 12 months, the average number of eligible patients transferred to telephone clinics rose from 17.6% (42/239) using a questionnaire method to 59.3% (73/123) using active discussion in clinic. Patient satisfaction scores remained high and non-inferior to baseline scores in face-to-face clinics. The median waiting time to be seen in the rapid access clinic was 6.5 days.

Conclusion This is the first published study to report on the successful stratification of patients with IBD based on disease activity and risk of complications to create a more responsive, sustainable and patient-centred model for IBD monitoring.

PROBLEM

Crohn’s disease and ulcerative colitis (inflammatory bowel disease; IBD) are lifelong illnesses, often diagnosed between ages 16 and 35 years, and as the prevalence rises, so does the subsequent demand on outpatient monitoring.1 The National Health Service Five Year Forward View recognised the demand for elective care imposed by long-term illnesses and the need for novel approaches to deliver out-of-hospital (OOH) care.2 The breadth of guidelines from the National Institute for Health and Care Excellence,3 4 the British Society of Gastroenterology5 and the European Crohn’s and Colitis Organisation6 7 define evidence-based management of the disease. However, the implementation of these guidelines is but one dimension to deliver high-quality care. The UK IBD Standards include other determinants of high quality: reducing variation in care, use of information technology (IT), local and patient-centred care delivered by a dedicated IBD team and patient education and support.8

Nationally, other IBD units have reported innovative models of monitoring patients to mitigate the overburden on outpatient resources, for example, virtual clinics9 or online IBD self-management tools (True Colours 1.0, Oxford). Such approaches required a well-maintained registry, empowered patients and significant and costly IT and nurse support. IBD nurse-led telephone clinics were previously reported to be low cost and reduce unnecessary hospital attendance while individualising care10–12 with benefits noted in a paediatric IBD cohort.13 However, they are not universally adopted and may be unsuitable for all patients or services.
At St Mark’s Hospital, Northwest London, there are approximately 7500–10 000 medical IBD consultations per year, delivered by over 15 gastroenterology consultants and five adult IBD clinical nurse specialists (CNS). The hospital serves an adult population of 439,000 with a local annual IBD incidence rate of 17.7/100,000 (R Misra, personal communication) as well as reviewing complex, tertiary and out-of-area referrals.

We proposed to stratify patients with IBD attending three gastroenterology clinics over 12 months (March 2017 to March 2018) by ‘risk status’ and ‘disease activity’. The primary aim was to transfer 50% of eligible patients (those with low risk of complications and in long-term remission) to OOH care within a nurse-led telephone monitoring clinic. Our secondary aims were to offer (1) a rapid access service within 7 days for patients requiring urgent outpatient specialist care, and (2) to record patient-reported satisfaction levels of the new telephone clinic postulating that they would be non-inferior to existing levels at face-to-face clinics.

BACKGROUND

IBD affects over 600,000 people in the UK.1 The condition manifests with periods of remission with intermittent exacerbations, or ‘flare’, of symptoms (e.g., diarrhoea, abdominal pain, rectal bleeding and weight loss). A subset of patients with IBD are prone to disease complications11 such as bowel cancer, or treatment complications, for example, infections, requiring close specialist supervision. However, a significant proportion is at low risk of disease or treatment complications and could be safely monitored more flexibly OOH.

Despite these differences in risk, patients with IBD are traditionally monitored three to six monthly in face-to-face outpatient clinics regardless of their disease activity.15 Cumulative clinic attendance, while in remission with low risk of complications, may displace high-risk or unwell patients who require access to hospital-based specialist services. A previous UK-based study reported that patients were keen to explore alternative non-hospital-based care models, inter alia, telephone and virtual clinics.16

MEASUREMENT

In 2016, prior to this study, a 1-week ‘snapshot’ local service evaluation showed that 94/143 (66%) patients with IBD of all risk profiles attending outpatients were in remission. A considerable proportion reported dissatisfaction with non-clinical aspects, for example, 23/66 (35%) and 18/66 (28%) expressed dissatisfaction with clinic waiting times and car parking arrangements, respectively.

In a 2017 survey, 37/40 (93%) patients with IBD of any risk profile attending face-to-face clinics reported good or very good satisfaction levels with the clinical aspect of their consultation.

Appointment volumes of the newly initiated telephone clinics (from March 2017 to March 2018) and rapid access clinic (RAC) (from June 2017 to December 2017) were monitored to understand their uptake and usage.

The following process measures were selected based on the ease of collection, reliability and relevance:

1. Percentage of outpatient attendances with ‘low risk’ IBD attending index (i.e., latest) and penultimate appointments in remission (‘eligible population’).
2. Percentage of the ‘eligible population’ transferred to nurse-led telephone monitoring clinics.

The following balancing measure was selected:

1. Average time interval from urgent referral to appointment for RAC consultations.

It was not feasible to measure specific outcome measures, for example, mortality, surgery, relapse of symptoms because of the project’s time frame and the long time lag before these outcomes manifest. It was assumed that an improvement in process measures, without an increase in balancing measures or inferior satisfaction scores, would indicate an improvement in the quality and experience of care delivered.

Data on a patient’s risk profile and disease status were collected prospectively from their electronic and paper medical records by a trained project manager and quality assurer by a gastroenterologist. Data were stored on a secure bespoke database (Microsoft Excel) which was updated weekly, with results aggregated and analysed fortnightly.

Clinical information from the index and penultimate clinic appointments were used to define a patient’s disease activity (remission or active) and risk status (low or high).

Operational definitions to determine activity and risk status were agreed among the project team after guided discussions and review of the literature defining clinical remission17 and risk of complications in IBD.18

**Inclusion criteria were defined as:**

1. Age ≥18 years.
2. A confirmed diagnosis of IBD ≥1 year.

**Exclusion criteria were defined as a patient:**

1. Having learning and/or language difficulties.
2. Pregnancy.
3. Currently awaiting investigations of their IBD.
4. Awaiting discussion at an IBD multidisciplinary team meeting.

‘Remission’ was defined as one or more of the following for ≥6 months prior to the index appointment:

1. Mayo Index19 ≤1 or Simple Colitis Clinical Activity Index20 ≤2 (ulcerative colitis).
2. Harvey Bradshaw Index21 ≤3 (Crohn’s disease).
3. No change in IBD medications with no new symptoms reported.
4. Physician documentation of remission status.

‘Low risk of complications’ was defined as having none of the following:

1. On biological medical therapy.
2. On immunomodulatory medications for <12 months or no shared care protocol in place with general practitioner (GP).
3. Family history of bowel cancer in first degree relative, or personal history of IBD-related colonic dysplasia.
4. Primary sclerosing cholangitis.
5. Complex fistulating, strictureing or perianal Crohn’s disease.

Patients were eligible for the offer of a follow-up appointment in a telephone clinic if they met inclusion criteria, had a low risk of complications, were in long-standing remission and met no other exclusion criteria.

**DESIGN**

A project team was formed supported by a service improvement grant, coaching and mentoring from the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care for Northwest London. This consisted of two gastroenterologists, two patient champions, an IBD CNS, a pathway coordinator, a GP/clinical commissioning group lead, a data analyst and two quality improvement scientists. This followed a stakeholder mapping session of over 25 stakeholders working collaboratively to develop an overall ‘action effect diagram’ (see online supplementary file 1). This served as the programme theory to support the desired improvement, helped the team to define their primary and secondary aims and to develop ideas about which interventions to secure them. The ‘Model for Improvement’ and ‘Plan-Do-Study-Act’ (PDSA) methodology was used to document data collection, interventions and analysis. This method supports the iterative planning and study of an action designed to improve a service over a period of time. The team met weekly to use other validated quality improvement methods (eg, process maps—see online supplementary file 2) to codesign interventions and identify the above measures as part of a larger quality improvement programme to improve the quality of care delivered to patients with IBD at St Mark’s Hospital. Meetings also included workforce planning to account for an expected increase in the use of proposed new services and to ensure its sustainability for the future. We have used the Standards for Quality Improvement Reporting Excellence 2.0 guidelines to help shape this report.

The team coproduced the first intervention, a questionnaire to elicit patients’ preferences for outpatient monitoring (face-to-face or OOH monitoring via nurse-led telephone clinics) together with an accompanying patient information sheet (PIS). In total, a maximum of three consultant clinics (consisting primarily of patients with non-complex IBD) were chosen to be studied for feasibility because of the large number of patient data and records that would need analysis. Potentially eligible patients were identified from their clinical patient record and anticipated attendance date. The questionnaire was distributed at the index appointment and completed by patients prior to their consultation. The completed questionnaires were returned to a healthcare assistant for later retrieval and analysis by the pathway coordinator. If they were confirmed eligible according to risk and activity status and had indicated a preference for telephone clinic follow-up, patients were transferred to the telephone clinic post hoc. The team predicted this would be an easy intervention to implement but potentially at risk of low patient uptake.

When transfer rates to telephone clinics were noted to be lower than expected, a second intervention was introduced. This consisted of an information campaign (outpatient posters, clinic room posters for clinicians and departmental staff meeting discussions) highlighting the benefits and inclusion criteria for the new telephone clinics. This raised awareness and facilitated ‘proactive’ discussion regarding patients’ monitoring at the index consultation rather than ‘passively’ through questionnaires. Doctors were encouraged to book telephone follow-up at the end of the consultation when patients accepted and met all the criteria.

Concurrently, a weekly RAC was established, which gave specialist outpatient access to all patients with IBD, including those transferred to the telephone clinics, in the event of a symptom exacerbation requiring urgent review. The team predicted that this service would be popular but could have been at risk of demand outstripping available clinic capacity with a potential increase in waiting time from referral to appointment.

Patient satisfaction of the clinical aspect of their telephone clinic appointment was assessed by a telephone questionnaire (5-point Likert scale; very poor to very good) comparing satisfaction of the first 40 consecutive telephone clinic patients against baseline satisfaction results in regular face-to-face clinics.

**Patient and public involvement**

Two patients were recruited from the St Mark’s Patient Panel and remunerated for their time. Using the 4PI framework, they were involved from the outset at each decision-making stage and invaluably helped codesign measurements and interventions.

**STRATEGY**

**PDSA 1: Questionnaire and PIS design and implementation**

Initially, patient preference for OOH monitoring was surveyed via questionnaires distributed at their index appointment. This allowed an opportunity to explain the role of the new telephone clinics as well as gauge patient interest for OOH monitoring. It also allowed an assessment of (1) variation in preferences depending on the type of clinic attended, and (2) OOH follow-up options (telephone, community and electronic portal), both useful to forward plan staffing and resources.

**Cycle 1**

The first cycle involved creating a double-sided PIS and questionnaire (which underwent 15 revisions in total). These were reviewed and improved via qualitative analysis by the pathway coordinator. If they were confirmed eligible according to risk and activity status and had indicated a preference for telephone clinic follow-up, patients were transferred to the telephone clinic post hoc. The team predicted this would be an easy intervention to implement but potentially at risk of low patient uptake.

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feedback at the weekly project meeting as well as by 13 patients with IBD. The Flesch-Kincaid Reading Ease score was also used to ensure easy readability of the PIS/questionnaire. Key learning points from this cycle were the long time to finalise the wording of the PIS/questionnaire and obtaining early feedback on patient preference for monitoring while in remission. Of 13 patients with IBD surveyed in remission, 46% opted for telephone clinics, validating the project’s aim.

**Cycle 2**
The second cycle involved roll-out of the PIS/questionnaire to 40 patients with IBD attending any general gastroenterology outpatient clinic over a 10-day period to assess the questionnaire’s applicability. The results showed a lower preference for telephone clinic follow-up among complex and joint surgically/medically managed patients. The proportion of patients in remission was similar to previous results of 20/40 (50%), and 11/20 (55%) expressed interest for telephone monitoring. Key learning points included recognising that disease complexity and patients’ perceptions about their disease state affected their preference for OOH follow-up.

**Cycle 3**
This cycle tested the PIS/questionnaire among 65 patients attending three general IBD clinics (ie, non-complex) over a period of 10 days. Rates of response to the questionnaire were low (43%) but in respondents the proportion of those interested in telephone follow-up in remission was over 60%. The learning points from this cycle were that telephone clinic preference continued as predicted, it was feasible and that greater participation/engagement from outpatient staff and adequate resources were required to increase questionnaire response rates.

**PDSA 2: Outpatient information campaign and new mode of offering patients telephone clinic appointments (clinic discussion)**
The testing of interventions in PDSA 1 lasted over 8 months and overall transfer rates of eligible patients were lower than predicted. The team acknowledged time constraints of auxiliary staff in the outpatient department to distribute and collect questionnaires as well as the passive nature of the questionnaire instrument contributed to the low response rate. The patient champions within the project team suggested a new method for identifying and transferring patients, whereby doctors in clinic actively guide discussion regarding follow-up modality.

**Cycle 1**
Two large waiting room posters highlighted the existence of the telephone clinic for eligible patients. Clinician-facing posters explaining the eligibility criteria were posted in each clinic room. This was initially tested, after an initial 5 min briefing discussion, among two general IBD consultants over 2 weeks, with positive feedback about the clarity of the posters and positive verbal feedback from patients.

**Cycle 2**
The intervention was scaled up to include all three consultants’ IBD clinics previously monitored in PDSA 1 over the next 4 months. All were made aware of the eligibility criteria for transferring patients to telephone clinics. The clinic room poster acted as an aid and gave clear instructions on how to document and action their patients’ transfer. The consultants were emailed monthly to inform them of the proportion of eligible patients transferred. Key learning points were that active patient–doctor engagement improved uptake of the telephone clinic and the regular monthly feedback tool was well received to help consultants monitor their own efforts.

**Cycle 3**
Following the above success, it was planned to roll out the intervention to all consultants (n=15) who saw patients with IBD at St Mark’s Hospital. The project team could only monitor performance measures for the three consultants in cycle 2, but the capacity of future available telephone clinic appointments was assessed fortnightly to ensure its sustainability and to guide workforce planning. We reminded consultants about the new telephone clinics at regular multidisciplinary and departmental meetings to help reinforce the transfer of eligible patients as part of routine practice with encouraging clinician feedback.

**PDSA 3: Establishing an RAC**
To ensure that patients with active disease were able to access specialist resources in a timely fashion, the team established an RAC. This was to be used by patients who were newly transferred to telephone clinic follow-up and for the general IBD population at the hospital if their condition warranted urgent specialist attention in the outpatient setting.

**Cycle 1**
The first cycle involved an information campaign directed towards emergency department (ED) staff highlighting the establishment of a new RAC for patients with IBD and a new ‘IBD Hotline’ (mobile phone service) for discussion of all ED patients attending with symptom relapse. Suitable patients were redirected to the RAC, obviating unnecessary admissions to hospital. The initial results were conflicting; ED clinicians fed back they liked the initiative yet the number of calls to the IBD hotline remained low. Key learning points were that eligible patients were still being admitted due to non-awareness of the IBD hotline and attending outside of the hotline’s working hours. Patients frequently called a separate nurse-managed IBD advice line and those requiring specialist review were being directed to the ED. As a new service, referral waiting times to the RAC were predictably low but it was also being underused with several empty slots in the clinic. Waiting times were monitored from the point of referral to review in the RAC over 6 months to ensure its viability and sustainability and to establish a baseline median referral time.
Cycle 2
Acting on the learning points from cycle 1, the nurse-managed IBD advice line also became a source of referral to the RAC, in addition to ED referrers, which increased its utility. The team persisted with regular information campaigns to the ED, including raising awareness among general medical registrars to prevent unnecessary medical admissions.

RESULTS
Over the 12-month period of analysis, the electronic and paper records of 1083 IBD patient attendances were analysed across three non-complex IBD clinics. The aforementioned process measures were grouped and analysed fortnightly via statistical process control charts: p-charts (proportion) and run charts (averages) and monitored for special cause variation. The first 20 data points were used to establish a baseline for the percentage of eligible patients transferred to telephone clinics.

In PDSA 1 (March to November 2017; 8 months) 663 IBD patient attendances were analysed:
- 239/663 (36.0%) patients were eligible for transfer (ie, meeting inclusion/exclusion and eligibility criteria at the index and penultimate clinic appointments).
- 135/239 (56.4%) of these eligible patients returned a questionnaire.
- 42/135 (31.1%) who returned the questionnaire indicated a preference for telephone clinic follow-up and were transferred post hoc.
- 42/239 (17.6%) of the total eligible population were transferred to the telephone clinic.

In PDSA 2 (December 2017 to March 2018; 4 months) 420 IBD patient attendances were analysed:
- 123/420 (29.3%) patients were deemed eligible for transfer.
- 75/123 (59.3%) of the total eligible population were transferred to the telephone clinic after active discussion in clinic.
- The proportion of patients transferred during this phase showed special cause variation with the new intervention considered to have accounted for this as all other contextual elements remained the same (see figure 1).

The percentage of low-risk patients attending penultimate and index outpatient clinic in remission showed special cause variation on the p-chart for the fortnight starting 19 February 2018. More data points would be required to see if this was sustained (see figure 2).

From June 2017 to December 2017 the ‘IBD hotline’ received 97 referrals from the ED and IBD CNS of which 86 were suitable for RAC review:
- On the run chart, the median average waiting time from referral to RAC review was 6.5 days, with no evidence of a change over the measurement period. However, a peak was observed for the fortnight starting on 16 October 2017 due to staff absence but this increase was not sustained (see figure 3).
- A sample questionnaire of 10 patients identified that 70% avoided an ED attendance and 90% were satisfied/very satisfied with the RAC service.

In summary, 362/1083 (33.4%) patients were eligible for transfer. Active clinical discussion regarding follow-up in...
Figure 2 Percentage of outpatients with ‘low risk’ attending index and penultimate appointments in remission. IBD, inflammatory bowel disease; PDSA, Plan-Do-Study-Act.

Figure 3 Average waiting time from referral to Rapid Access Clinic review. PDSA, Plan-Do-Study-Act.

PDSA 2 identified and resulted in, proportionally, more patients transferred to telephone clinics (59.3%) than using the questionnaire method (17.6%). There was no overall increase in our balancing measure of average waiting time from referral to RAC appointment (median 6.5 days) and patient-reported satisfaction rates in the telephone clinics were non-inferior to face-to-face clinics.

LESSONS AND LIMITATIONS

In PDSA 1, the use of questionnaires and explanatory PIS resulted in lower than expected response rates. This was attributable to unforeseen variables (eg, mislaid pens, staff absence with non-distribution of questionnaires).

Furthermore, some patients may have been apprehensive about selecting telephone clinic monitoring without reassurance from their responsible clinician. We also recognised this approach of recording preferences was time consuming, labour intensive and unsustainable in the longer term.

We acknowledge a number of omissions. Recognised outcome measures developed by the International Consortium for Health Outcomes Measurement group such as colorectal cancer development, and hospitalisations and emergency visits for IBD symptoms were not collected as it would have necessitated regular review of clinical records beyond the timescale of the project. Equally, the effect
on waiting times for outpatient clinics was not measured, since these are not routinely collected for patients with IBD, specifically, and would have consumed unjustifiable time to undertake manually. While the overall number of calls to the IBD advice line was logged (over 3000/year), the reason for each call is not automatically recorded and hence could not be used as a balancing measure of calls related to a relapse of symptoms. There were also other factors that mitigated against collection of additional measures. The local IT software changed during the study phase which precluded valid comparison of the impact of our interventions on ED attendances. A cost benefit analysis was outside the remit of this study. The justification for this was that increased overall activity was not anticipated. The team continued to provide care to patients according to their needs and directed them towards relevant healthcare professionals able to support them in managing their condition. However, initial findings from a patient experience questionnaire indicated that the majority of patients (70%) attending the RAC felt that it had prevented an ED attendance.

While the RACs were well received by referring ED and general medical admitting physicians we noted a rise in referral rates from the IBD nurses who receive calls directly from patients. This was unforeseen and reflected a busy nursing team, who would have otherwise managed the patients with verbal advice followed by written advice to their GP. Referrals to the RAC were regularly audited to ensure only patients in whom hospital admission can be avoided or who require urgent face-to-face specialist attention were seen in the clinic.

This study raised several learning points relevant to instigating and maintaining a successful intervention. First, the importance of engaging a wide range of stakeholders, directly and indirectly, responsible for enacting change. When low initial transfer rates were detected, the team sought solutions which were successfully applied. During the second intervention, regular feedback about transfer rates through email communications and verbal updates at departmental meetings helped raise and maintain awareness as well as embed the new interventions into routine practice. While mindful that the Hawthorne effect may have influenced the clinician engagement results, the telephone clinic capacity has been monitored for 6 months following the results reported in this paper, and there were no discernible changes in the way the clinic operated, suggesting ease of utility and sustainability. The team learnt that creating a more responsive and flexible model of healthcare delivery was well received by patients as judged by their high satisfaction scores. This sets the foundation for researching the validity and applicability of alternative OOH models for monitoring, for example, electronic portals or community care follow-up. Whether our improvements can be reproduced in other hospital settings where there may be fewer IBD nurses and specialists able to provide a similar level of care has yet to be investigated.

CONCLUSION
This is the first published quality improvement study to report on the stratification of adult IBD outpatients by risk and disease activity to help guide the setting for outpatient monitoring. At our institution, it has been established that 33% of patients attending non-complex IBD clinics are in long-standing remission with a low risk of complications. With clinician-facilitated discussion nearly 60% of those eligible chose nurse-led telephone clinic monitoring with high non-inferior satisfaction rates compared with existing face-to-face clinics, meeting the aims of the study. Furthermore, establishing IBD referral hotlines and RACs can help create a more responsive patient-centred service, matching patients’ needs to access and resources. Ongoing audits will be undertaken to ensure the nurse-led telephone clinic is sustainable. Further studies are required to determine the generalisability to other IBD units with different staffing levels and to test the applicability of other forms of outpatient monitoring (eg, electronic portals, community clinics).

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Contributors NA conceived the initial design for the study and chaired weekly project meetings with guidance from SB and YA. RKF, NK, AM, AS, SBF, HB, DR and TT helped codeign and implement the interventions with RKF, AM, NK and RM responsible for data collection and analysis. Senior quality improvement and data analysis expertise was provided by SB, YA and TW. All authors critically revised the manuscript and gave their approval for publication.

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