

Monitoring biologics in inflammatory bowel disease (IBD) using the Patients Know Best electronic portal: pilot study of uptake, acceptability and outcomes

Abstract

Background: The number of inflammatory bowel disease (IBD) patients on biologics in the UK is increasing; this and the expansion of available drugs have contributed to delays in delivering treatment. E-health applications, such as the Patients Know Best (PKB) personal online healthcare record system, can improve efficiency of patient management in stable IBD. This pilot study aimed to explore the uptake, acceptability and outcomes of PKB in the management of patients starting biologics. **Methods:** IBD patients prescribed biologics were invited to register and trained online. The authors measured the number of new starters, PKB registrants, time intervals to treatment and the nature of online activity. Patients using the application received an evaluation questionnaire 6 months after enrolment. **Results:** Out of 40 patients newly started on biologics, 33 years were included, with a mean (SD) age of 44.3 (13.3) years. The mean time interval from decision to treatment administration was 82.7 days (44.0). Ten patients raised at least one issue on PKB; 45 new issues were raised, mostly relevant to active disease (18/45), adverse events of treatments (6/45) and the funding application process (5/45)—39 were resolved online. Of patients, 16 answered the questionnaire, and 11 found it at least somewhat helpful. More training was requested. **Conclusions:** The use of PKB did not accelerate the process of drug administration. However, patients engaged with the use of the platform, several issues were raised and most of these were resolved electronically. Regular training and individual treatment plans for patients starting biologics may optimise PKB's use for long-term monitoring.

Biological therapies, also known as biologics, are recognised treatments for a number of inflammatory conditions. In inflammatory bowel disease (IBD), four biologic drugs are licensed for the management of Crohn's disease (CD) and ulcerative colitis (UC) (Table 1) (National Institute for Health and Care Excellence (NICE), 2010; 2015a–c). In the UK, NICE approval, greater availability and earlier commencement of biologics—alongside an increasing incidence of IBD—have contributed to an increasing adoption of these drugs in clinical practice (NICE, 2010; 2015; Royal College of Physicians (RCP), 2015).

In most hospitals, biologics are commissioned through a funding application process on an individual basis, resulting in a significant administrative burden for healthcare professionals. National data indicate a significant delay of 6 months from the decision to initiate therapy to first treatment administration (Lee, 2016). At St Mark's Hospital, this time interval was 10–14 weeks; moreover, 172 patients initiated or switched to a new biologic treatment over the course of a year. As IBD is a lifelong condition, biologic treatment is rarely withdrawn (Kennedy, 2016). Patients who lose response to

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Key words

- Biologics
- E-health
- Inflammatory bowel disease
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- Self-management

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one biologic agent may be switched to another (Feagan, 2013), and, as new biologics are licensed, a cumulative burden is placed on hospital services (Amiot, 2015).

The increase in biologic prescriptions may also pose a challenge for the effective monitoring of treatment, in the context of prevailing demands for gastroenterology outpatient clinic appointments. It has been shown that IBD patients use the internet to talk with other patients and exchange experiences about their disease activity and treatment (Tshuma et al, 2012). With the rapid expansion of smartphones and tablets among patients, a number of web-based applications have been developed to assist with the self-management of a number of chronic conditions, including IBD (Con et al, 2016). The use of electronic web-based management systems in patients with IBD has been shown to improve adherence to medication (Pedersen, 2015). In Denmark, the application of electronic portals for patients on biologic treatment showed improvement in treatment outcomes and individualisation according to disease activity, as well as a reduction of overall costs (Pedersen, 2015). These observations were supported by a systematic review and meta-analysis of six randomised controlled trials and nine observational studies (Jackson et al, 2016). In the UK, an IBD-specific e-health application, My IBD Portal, has been developed, and its role is being investigated.

Patients Know Best

Patients Know Best (PKB) is an online patient-centered personal healthcare record system. It was developed to involve patients in their care, by providing a secure forum for patients to interact with healthcare professionals without the need to travel to hospital. It facilitates interactions with a patient's health network, remote consultations and active self-management through shared

care plans. It allows patients to obtain a copy of their healthcare information from different sources and collate it in one place to share with whomever they choose; the data sources can be entered by the patient, a clinician or an interface with existing clinical record systems. PKB is safe, secure and password-protected, lying within the NHS N3 secure network (RCP, 2016a).

PKB has been successful in offering care in a wide range of disciplines, including HIV. At St Mark's Hospital, it is routinely used for patients who require parenteral nutritional support at home, who reported it to be very helpful (Ambrose et al, 2014). When Luton and Dunstable Hospital applied PKB to IBD patients in remission, it reduced the cost of patient management by £69 000 over 1 year (Johnson et al, 2013).

Aims and objectives

This pilot study explores the uptake, acceptability and value of PKB as a self-management tool for patients with IBD who have been prescribed biologic therapy. In order to determine PKB's future sustainability and application to other situations, the study aims to assess its:

- Uptake among patients
- Acceptability
- Ease of use
- Success in reducing delays in drug administration
- Safety in early reporting and management of adverse effects.

Methods

Recruitment

Invitations to register with PKB were sent to all patients at St Mark's Hospital with a confirmed diagnosis of IBD who were prescribed biologic drugs over a 6-month period. Patients who were switching biologic therapy or undergoing dose escalation were excluded.

Patients were given an information sheet about how to use PKB, along with a link to an information video, and were encouraged to use the application to facilitate the biologics funding application process and their ongoing care. The patients were to complete their personal applications and disease activity scores on the biologic funding application form that was sent to them through PKB and then upload it on the portal, where it would be accessible to the IBD team. The patients were also able to use the portal to contact the IBD team for any queries regarding disease activity or care,

Table 1. Biologics licensed in inflammatory bowel disease

| Drug | Function | Licensed in |
|-------------|--------------------------------|-------------------------|
| Ustekinumab | Monoclonal antibody | Crohn's disease (CD) |
| Golimumab | Anti-TNF | Ulcerative colitis (UC) |
| Adalimumab* | Anti-TNF | CD and UC |
| Infliximab* | Anti-TNF | CD and UC |
| Vedolizumab | Gut-selective integrin blocker | CD and UC |

*Biosimilars available

and the messages would be answered by the IBD nurse or IBD physician. As this was a pilot study, there were no any additional human resources dedicated to the supervision of the application. The IBD nurses and physicians would regularly log on to the application in order to answer patient queries. At 6 months after enrolment with the application, all registered patients were invited to participate in a survey.

Survey

The survey was undertaken through a web-based questionnaire, created using Survey Monkey. The questions were generated based on previous use of PKB in other conditions, such as intestinal failure (Ambrose et al, 2014). The questions followed a structured response format and covered frequency and pattern of use and overall satisfaction with the application. The response format included dichotomous, five-point Likert responses, ranging from strongly disagree to strongly agree, while the interval response was formatted on a scale of 1–10, and the multi-option format was expressed as a number of preferred options. The questionnaire ended with questions in unstructured response format, where patients were given the option to add comments. Data was collected through a research company, MGES. The results were collated anonymously.

Data collection

Patients' demographic and disease-specific data were collected by the investigators by reviewing their records on the hospital's electronic clinical information system. This included mean age, diagnosis, disease duration and extent of disease using Montreal classification (Silverberg et al, 2005). In addition, the time interval between decision to start therapy and first treatment administration was recorded. This was used to extract two time intervals: firstly from the decision to start until funding approval, secondly from funding approval to first treatment administration. Data collected from the PKB platform included the number and nature of discussions raised by the patients and the efficiency of the application in helping resolve queries. Patient satisfaction was measured through structured questions on the patient questionnaire.

Data analysis

All data relevant to the outcome measures were recorded on an Excel spreadsheet and subsequently

transferred to the Statistical Package for Social Sciences (SPSS). The SPSS spreadsheet was used to produce the mean (SD) of the outcome variables.

Results

Study population

There were 48 patients registered with PKB between December 2015 and June 2016. Of these, 15 were excluded from the study analysis, with six not on biologics, five already on biologics long term, two not receiving treatment, one being paediatric and having been initiated on biologics as an inpatient without following the standard funding-application process. From a total of 40 patients who were initiated on biologics within the recruitment period, 33 were included in the study (Figure 1).

Demographic data

From the 33 included patients, 20 had an underlying diagnosis of CD, and 13 had an underlying diagnosis of UC. The mean (SD) age of the patients was 44.3 (13.3) years. The mean (SD) disease duration was 180 (139) and 159 (91) months for CD and UC respectively.

Among UC patients, four had extensive colitis (E3), four had left-sided colitis (E2) and 5 had distal colitis (E1), according to the Montreal classification. Among CD patients, 13 of 20 were diagnosed between 17–39 years of age, 17 had ileocolonic involvement, 10 had penetrative disease and 8 had perianal involvement. Of

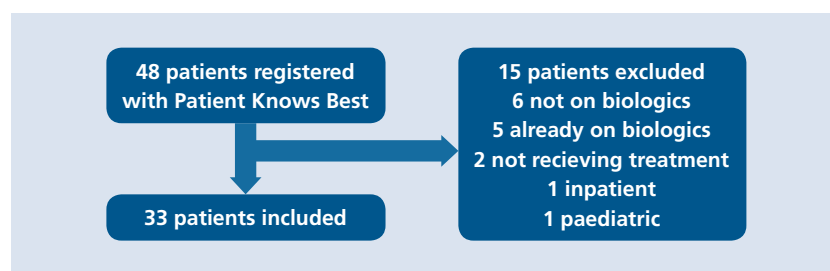


Figure 1. Study population

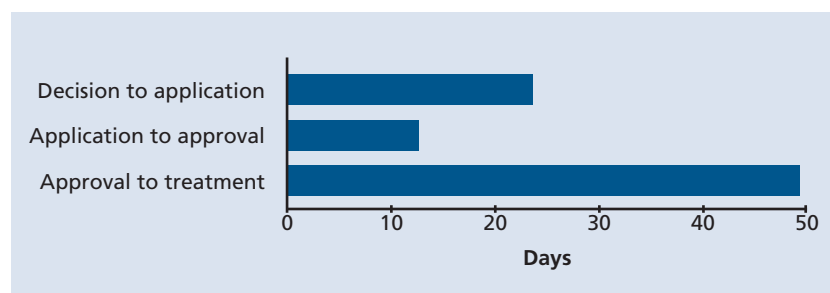


Figure 2. Time intervals between drug funding application, approval and treatment

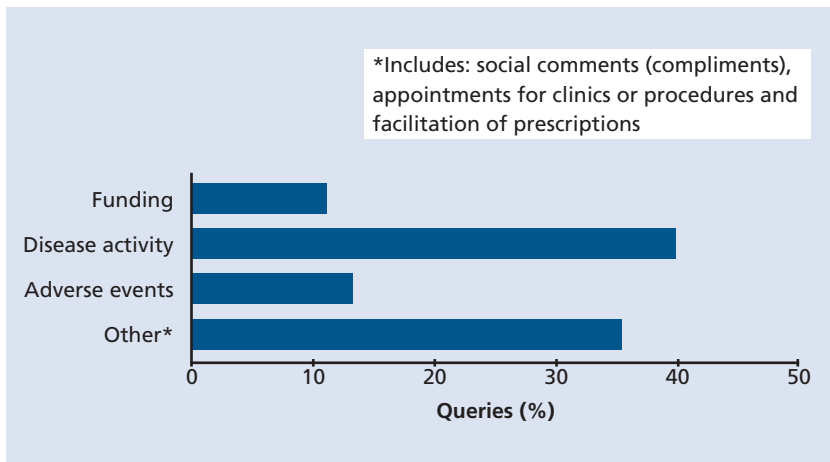


Figure 3. Nature of patient queries

Box 1. Key points of patient feedback (n=16)

- 11/16 patients found Patients Know Best (PKB) to be at least somewhat useful
- 3/16 patients found PKB to be very useful
- 8/16 patients reported to use PKB less frequently than once a month

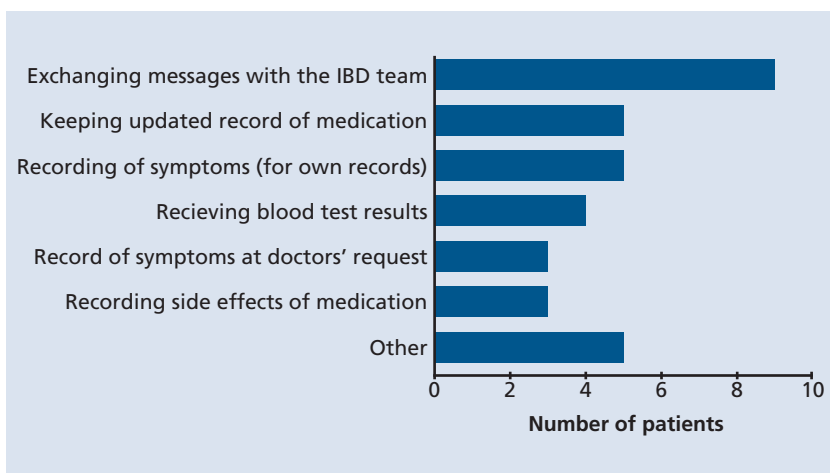


Figure 4. Functions used by patients according to patient survey

Box 2. Patient comments on Patients Know Best

Positive

- Able to ask questions without taking up clinic time
- Helped me to highlight delays with my treatment directly to my consultant
- I can be in contact with my IBD team even when abroad, which is fantastic
- I've been able to request prescriptions via PKB rather than having to travel to the clinic
- Just being able to communicate with your team is a lifeline especially when you live far away; having your medical letters scanned and uploaded and also keeping a record of your medications is invaluable—it's just such a better way of keeping track of everything in one place—absolutely brilliant

Needs improving

- Would be good for someone to explain fully how it works
- I don't think I have the time or energy to enter every little thing myself
- I didn't have any explanation of how to use it, I've had to teach myself
- I think the system has potential but at the moment only works at a very basic level

the 20 patients with CD, 11 had undergone at least one previous small- or large-bowel resection.

Biologic drug therapy: time intervals in funding application and drug administration

The mean (SD) time interval between the decision to treat a patient with biologics and the submission of funding application was 23.8 (23.6) days. The mean (SD) time interval between funding application receipt at CCG and funding approval was 12.9 (17.2) days. The mean (SD) interval from funding approval to the first drug administration was 49.8 (29.0) days. The mean (SD) total time from decision date and administration date of biologic drug was 82.7 (44.0) days (Figure 2).

Uptake and activity

From 40 new starters, 33 registered with the platform. Ten patients (10/33) who registered with PKB for this study raised at least one issue with healthcare professionals on the PKB forum. The mean (SD) number of electronic queries was 1.36 (3.7) per patient, ranging from a minimum of 0 to a maximum of 19 new discussions. In total, 45 new discussions/queries were raised by 10 patients. The majority of queries (39/45) were resolved online. The nature of queries was diverse: 6 (11.1%) were related to funding application or approval, 18 (40%) to disease activity, 6 (13.3%) were related to treatment adverse events and 16 (35.5%) to other issues such as appointments for procedures or clinical reviews (Figure 3)

Acceptability and patient experience

Out of the overall 48 patients, 16 responded to the questionnaire anonymously. The majority of the responders (13 out of 16) reported use of PKB for a period between 0 and 4 months with a frequency of <1 per month in 50% (8/16). Overall, 11 out of 16 patients (69%) reported that PKB was at least somewhat useful. Of these, Three patients found it very useful (Box 1).

The patients mainly used PKB as a secure way to communicate with their clinical team (8/16), to maintain a record of their medication (5/16), as a useful consistent symptom diary (5/16), to monitor their blood results (4/16) and to record and report adverse events relevant to their treatment (3/16) (Figure 4). On the comments section patients were supportive of the new application but also critical. The ease of communication with

IBD healthcare professionals has been very well received. The main points of criticism have been the possible delays in answering queries, the time that needs to be spent by the patients in order to update their record and the fact that more training may be required for patients in order to use PKB effectively (Box 2).

Discussion

This is the first reported pilot study exploring an electronic platform for the targeted management of IBD patients on biological treatments in the UK.

Delays were found between the time a clinical decision to prescribe therapy was made and the actual administration of therapy, with a mean of 82.7 days; this delay was similar to local data captured a year previously. Although PKB did not improve treatment delay, it did reveal what process step was responsible for it. Prior to the study, the team predicated that the key step delaying therapy would be the wait between submitting a funding application and receiving a funding approval response; however, it was observed that the main delay occurred after funding had been approved. There are three plausible reasons, which can be addressed in the future:

- A growing demand for biologics (RCP, 2016b) has imposed significant pressure on the timeframe of IBD service delivery
- Guidelines recommend screening prior to administration of therapy and pre-emptive treatment with anti-tuberculosis medication for latent tuberculosis
- For patients with perianal CD, examination under anaesthesia and drainage of possible perianal collections must be performed prior to treatment initiation.

It is noteworthy that patients who are prescribed biologics have either severe, refractory or complicated disease, and a 3-month delay in treatment can lead to further complications. Careful patient selection, robust and audited screening pathways and the use of electronic resources to improve communication within the multidisciplinary team and with patients are avenues worth of further exploration to improve service delivery.

Overall, there was good uptake and activity with the electronic platform among IBD patients recently starting biologic therapy: 82.5% (33/40) of patients enrolled, and their overall feedback was positive. Registered patients engaged with

this e-health application for several aspects of their disease management. In the study, this application was mainly used as a portal of safe communication between patients and their health professionals in order to discuss issues regarding their disease activity, treatments and procedures. Although there was significant variability in the engagement, the majority of patients found it at least somewhat useful. The cause of this variability is unclear, as the survey was undertaken anonymously, and many patients failed to respond to the survey overall. It could be speculated that patients with mild disease activity would need it less than those with more active disease. Also, since all patients included in this study had been newly initiated on biologics, the rigorous baseline support provided by the IBD nurses over the phone and in the infusion suite may have been enough to answer possible patient queries regarding treatment. Baseline IT literacy can affect engagement, and the intensity of training may need to be adjusted to meet every patient's needs. It is of note that patients commented on the IBD team not always answering queries in a timely manner. The wider use of PKB would be an additional service, and it is vital that adequate resources are allocated for its support in order to build further trust among patients.

Interestingly, the majority of issues raised over the portal were resolved online, absolving the need for a clinic appointment. Patient engagement and the ability of this application to resolve queries suggest that it may be a viable tool for monitoring patients in the future. Further questions need to be asked of the patients who received therapy but failed to register with the platform in order to understand and select patients best suited for this portal.

Previous studies indicated that e-health applications improve adherence to medication, reduce the cost of administration of biologic therapies and reduce demands on outpatient

CPD reflective questions

- In what ways could applications like Patients Know Best (PKB) improve the overall management of inflammatory bowel disease (IBD) patients on biologics?
- What factors that would make using PKB more or less feasible for monitoring IBD patients in different clinical settings?
- What are the possible risks and disadvantages of using e-health applications to monitor IBD patients?

services (Pedersen, 2015; Jackson et al, 2016). E-health applications can even direct patients towards successful modification or self-initiation of treatment in order to effectively self-manage, and it has been shown that this approach may shorten the duration of a disease flares (Elkjaer, 2012). The degree of patient engagement experienced in this cohort of patients suggests that PKB could be used for IBD patients as a tool for self-management. The findings from this study can be applied more broadly. First of all, PKB could be used as a standard way of monitoring and self-management in less-complicated IBD patients on conventional treatments where the implementation of self-management is more safe and realistic. PKB could also be used to monitor most of the chronic conditions that share common patterns of disease course and treatment with IBD but fall under other specialties, such as dermatology or rheumatology.

Conclusion

Overall, PKB showed perceived benefits for clinical management. Patients were able to easily update their healthcare team on their clinical condition and report adverse events, which could then be managed promptly. In future, these could be linked to an electronic yellow-card reporting scheme. For wider successful adoption of PKB to monitor biologic therapies, users need to be confident with its use, as well as its limitations, so as not to compromise safety. Given the breadth of the platform, regular scheduled and progressive training modules directed at variable needs and abilities of the user are critical for wider adoption and have the potential to reduce unnecessary hospital visits. Although enhanced access to therapy was not shown, the introduction of the Blueteq High Cost Drug System nationally is anticipated to address the issues with drug funding (NHS England, 2015).

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Declaration of interest *The authors have no conflicts of interest to declare*

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