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REVIEW

Are we ready for telemonitoring inflammatory bowel disease? A review of advances, enablers, and barriers

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Abstract

This review summarizes the evidence about telemonitoring in patients with inflammatory bowel disease (IBD). To give an overview of the advances performed, as well as the enablers and barriers which favoured/hindered telemonitoring implementation. We performed a literature search in PubMed, EMBASE, MEDLINE, Cochrane Database, Web of Science and Conference Proceedings. Titles and abstracts published up to September 2022 were screened for a set of inclusion criteria: telemonitoring intervention, IBD as the main disease, and a primary study performed. Ninety-seven reports were selected for full review. Finally, 20 were included for data extraction and critical appraisal. Most studies used telemonitoring combined with tele-education, and programs evolved from home telemanagement systems towards web portals through mHealth applications. Web systems demonstrated patients' acceptance, improvement in quality of life, disease activity and knowledge, with a good cost-effectiveness profile in the short-term. Initially, telemonitoring was almost restricted to ulcerative colitis, but new patient reported outcome measures, home-based tests and mobile devices favoured its expansion to different patients´ categories. However, technological and knowledge advances led to legal, ethical, economical and logistic issues. Standardization of remote healthcare is necessary, to improve the interoperability of systems as well as to address liability concerns and users´ preferences. Telemonitoring IBD is well accepted and improves clinical outcomes at a lower cost in the short-term. Funders, policymakers, providers, and patients need to align their interests to overcome the emerging barriers for its full implementation.

Key Words: Inflammatory bowel disease; Telemedicine; Telemonitoring; Information and

communication technology; Crohn´s disease; Ulcerative colitis

Core Tip: In this review we focus on the advances performed in telemonitoring of patients with inflammatory bowel disease, taking into consideration the elements which enabled its use and how technological achievements led to other barriers for its full implementation. We detail the impact of telemonitoring on health outcomes and its cost-effectiveness. We also describe the advances on new patient-reported outcome measures, home-based tests and wearables which improve the ability to manage new patients´ profiles remotely. However, during the pandemic, e-mail and telephone still represented the main resources used. Then, we describe the emerging barriers which explained the limited application of mature telemonitoring programs.

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INTRODUCTION

Inflammatory bowel disease (IBD) is a group of disorders characterized by the chronic and recurrent inflammation of different segments of the gastrointestinal tract, which usually associates extraintestinal manifestations and complications due to sustained activity. Unlike other chronic pathologies, IBD mainly affects young individuals in their optimal period of personal and professional development. As such, IBD is related to high levels of school absenteeism and work disability[1], interference with social activities, and impaired health-related quality of life (QoL)[2]. Therefore, IBD has a significant medical, social, and financial impact, further increased by the global increase in its incidence and prevalence in recent years[3].

It is suggested that the "treat-to-target" strategy leads to better outcomes[4]. However, in the conventional management of IBD, scheduled outpatient visits show difficulties to address the disease evolution in each patient, with frequent discrepancies between medical practice and guideline recommendations. Furthermore, patients have little involvement in decision-making, and nearly 50% of adults[5] and an even higher percentage of adolescents with IBD[6,7] are nonadherent to treatment. All these factors prevent the effectiveness of traditional interventions in disease control and increase health expenses[8], especially considering that patients with IBD use health care resources more often than patients with other conditions[9].

Nowadays, health systems are facing financial problems, and telemedicine has been proposed as an alternative to provide an efficient and equitable use of health resources. Information and communication technologies (ICTs) have the potential advantages of providing better communication between healthcare providers and patients, as well as educational resources adapted to patients´ needs. On the one hand, communication improvements could overcome limitations of health access in remote areas, also developing telementoring systems and contact between different specialists in centres where multidisciplinary teams are not available. On the other hand, educational elements could favour patients' empowerment and treatment optimization throughout the disease course[10,11], also addressing behavioural and psychological factors related to nonadherence[5].

Telemedicine has been successfully used in other chronic diseases such as congestive heart failure[12,13], diabetes mellitus[14,15] or chronic obstructive pulmonary disease[16,17] and showed excellent acceptance by patients, improvement in health related QoL and a reduction in hospitalizations[12,16,18]. Owing to these positive results, telemedicine systems have been evaluated in patients with IBD, especially in mild to moderate ulcerative colitis (UC)[19,20]. Telemedicine in IBD started with the adaptation of telemonitoring programs previously used in other chronic pathologies[21], but these were subsequently replaced by web and m-health systems, which represented more attractive options to maintain patients adherence to remote follow-up.

Telemonitoring is the main form of telemedicine in IBD. It is based on the provision of health services at a distance, related to diagnosis, treatment, follow-up or education. It is characterized by the structured and continuous monitoring of clinical data that is self-reported by patients in their usual environment, and then sent to health providers. The objective is the early detection and intervention on complications related to the disease itself or its treatment. It usually includes tele-education interventions and shares many features with other domains of use of ICTs in the health-care setting (Figure 1). Web telemonitoring in IBD is safe and reduces the duration of disease flares[22]. Moreover,

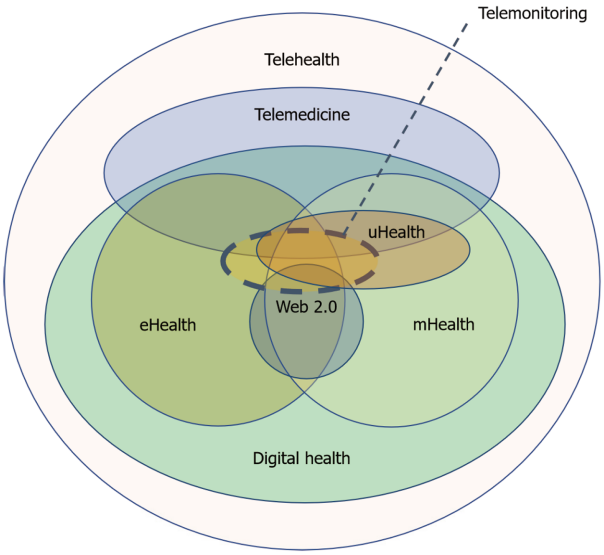

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Figure 1 Telemonitoring in relation to other domains associated with the use of information and communication technologies in the health context.

patients´ empowerment has been related to a reduction in outpatient visits and hospitalizations[23-26], which represent potential cost savings[22,24,27].

The development of more sophisticated telemonitoring programs and point of care (PoC) testing during recent years provided additional value to remote follow-up in the IBD context, improving the ability to cover different patients' profiles more objectively. These advances gained special interest after the advent of coronavirus disease 2019 (COVID-19) outbreak, as distance management offered new elements to overcome healthcare challenges posed during the pandemic[28]. However, telemedicine was represented mainly by telephone and e-mail, previously available in many centres[29,30], but the development of mature telemedicine programs integrated with electronic health records were still the exception, due to a series of remaining barriers.

In this review we focus on the advances performed in telemonitoring of patients with IBD, taking into consideration the elements which enabled its use and how technological achievements led to other barriers for its full implementation. The search strategy is detailed in the Supplementary material.

TELEMEDICINE IN CHRONIC DISEASES

There is a wide heterogeneity of telemedicine programs considering the different types of technological resources used, the different diseases and populations in which they are applied, and the objectives pursued with their use. The variability in the quality and design of the published studies (randomized clinical trials, before-and-after studies, qualitative studies, *etc*.) can partially explain the variable results obtained. Furthermore, in some studies these systems are part of wider interventions, rendering the comparability between programs even more difficult. These factors limit the quality of evidence regarding the efficacy of telemedicine to improve outcomes in chronic diseases.

Despite this, ICTs have been used in a wide range of pathologies, with improvement of patients´ empowerment and with good acceptance[31]. With the aim of giving response to the rise in chronic diseases and multimorbidity worldwide, different projects in Europe have studied the use of telehealth, mainly in diabetes mellitus, cardiovascular diseases, depression, and chronic obstructive pulmonary disease (COPD).

There is moderate evidence about the efficacy of telehealth systems in the improvement of glycaemic control, mainly in terms of HbA1c in patients with type 2 diabetes mellitus. Active telemonitoring including providers´ feedback, as well as tele-education have shown positive results compared with usual practice[14]. In fact, the highest impact was seen in the combination of telemonitoring and tele-education for both patients and providers, allowing for shared decision-making[15].

In patients with heart failure, telemonitoring has been shown to reduce global mortality and hospitalizations compared to usual care[12]. Many telemonitoring systems were part of multidisciplinary programs managed by specialized nurses and incorporated tele-education and action plans before hospital discharge[13]. Interactive monitoring with healthcare providers has also shown to improve blood pressure in hypertensive patients, weight control and lipidic profile[32]. Video consultation and biosensors are especially useful in cardiovascular diseases, with reduced costs compared with other

pathologies[33].

Most digital resources used in the mental health context refer to the application of cognitive behavioural therapy (CBT) in patients with depression. Both traditional and e-Health CBT are effective [34], but its use with telemedicine programs could offer additional advantages, such as better accessibility. However, many studies with psychotherapies show a high rate of nonadherence to follow-up [35]. Similarly, in patients with IBD one clinical trial showed a significant improvement in QoL after 12 wk of self-administered computerized CBT, but this outcome was not maintained at 6 mo, with a high rate of dropouts[36].

In patients with asthma, the use of multiplatform programs combining tele-education, telemonitoring and individualized action plans reduced hospitalizations compared with traditional care, mainly in more severe patients[18]. In patients with COPD, the use of telemedicine also reduces hospitalizations, but without an improvement of global mortality[16]. With the development of mHealth, the use of SMS combined with telephone support is associated with an improvement in respiratory function and QoL in patients with asthma[32], but telemonitoring in COPD has not demonstrated any improvement in these outcomes[17,37]. Telemonitoring of patients with COPD is more expensive due to associated multimorbidity[33].

The use of telemedicine in digestive diseases is more limited, and most studies focused on IBD and irritable bowel syndrome. Unlike other chronic diseases such as diabetes mellitus, IBD implies the consideration of many clinical, biological, endoscopic, and even histologic variables to reach disease control. However, early detection of complications usually requires invasive tests in IBD. The absence of validated tools with adequate cost and accuracy to measure disease activity at a distance have represented an important limitation.

Most studies about telemedicine in IBD have emerged in the last decade. The development of mHealth, the validation of patient reported outcome measures (PROMs), PoC and home-based tests to measure fecal calprotectin (FC) near the patient improved the ability to evaluate more types of patients with IBD at a distance, even in more complex cases.

PROGRAMS FOR TELEMONITORING IBD

The increase in the capacity of data transmission and storage, as well as the evolution of wireless communications provided many resources that are easy to use and adaptable to IBD telemonitoring.

Initially, telemonitoring systems for IBD allowed communication between health centres and patient´s home using computers. Afterwards, the development of web-based systems permitted easy-to-use and cheaper telemonitoring programs. In the last years, mobile devices (Smartphone, Tablet, *etc.*) made it possible to establish the communication process with the patient during his/her daily activities. Furthermore, in other settings (such as cardiovascular diseases) the transmission of continuous physiological data through biotelemetry has evolved with the incorporation of wearables.

In the IBD setting, telemonitoring is a safe, acceptable, and effective option to improve clinical outcomes[38,39], but the results of studies are still variable. In this context, telemonitoring has mainly used programs requiring home installation or web-systems, although e-mail and telephone have supported some of these programs. The main telemonitoring platforms used in IBD are summarized in Table 1.

Home telemanagement systems

The Cross group was the first to apply ICTs in adult patients with IBD, mainly with UC. This research team developed a remote-control system (home automated telemanagement system: HAT system) made up of 3 stations, adapted from a program previously used in self-management of patients with asthma [40]. The Home Unit was made up of a portable computer that collected patients' information (symptoms, adverse effects, medication, *etc.*), and these data were then sent to a decision-support server connected to a provider's PC[21]. The computer created alerts if the values collected in a web portal surpassed pre-established thresholds. Moreover, the HAT system incorporated educative elements.

Different exploratory studies showed good acceptance with the use of this system. In 2 studies with 10 and 23 patients with IBD, all of them considered that the HAT system was simple and increased patients´ knowledge[21,41]. To confirm the acceptability and adherence to follow-up with this program, the authors performed a subsequent study with 25 patients followed-up over 6 mo. Adherence to the weekly questionnaire was 91% and 86% had a prescribed medication adherence over 80%. This good adherence corresponded to a trend towards improvement in disease activity and QoL levels, together with a statistically significant improvement in understanding the disease (P = 0.0015). These good results led to the hypothesis that the HAT system could be feasible for telemonitoring patients with IBD.

Subsequently, the same group designed a randomized clinical trial including 47 patients with mild to moderate UC. Twenty-five patients were controlled with the HAT system and 22 followed usual in-person visits together with educational support and individualized action plans to make groups more comparable[42]. The groups had similar baseline characteristics, except for the use of immunosuppressants in 56% of the study group and 27% of the control group (P = 0.05), which would indicate a

Table 1 Studies of Telemonitoring in inflammatory bowel disease

Ref.	Disease	Type of study	*n*	Application	Outcomes
Cross *et al*[21]	IBD	Noncontrolled, clinical trial	10	Telemonitoring, home unit-server PC provider	Feasible method Excellent patient acceptance
Cross *et al*[113]	IBD	Noncontrolled clinical trial	25	Telemonitoring, home unit-server PC provider	Feasible method Excellent patient acceptance Improvement in QoL, disease activity, and disease knowledge
Cross *et al*[42]	UC	Controlled randomized clinical trial	47	Telemonitoring, home unit-server PC provider	Feasible method Excellent patient acceptance Improvement in QoL
Elkjaer *et al*[115]	UC	Validation study in 2 groups	21	Telemonitoring through the web	Feasible method Excellent patient acceptance
Elkjaer *et al*[22]	UC	Controlled randomized clinical trial	333	Telemonitoring through the web	Feasible method Excellent patient acceptance Improvement in QoL, disease knowledge, and adherence
Pedersen *et al*[10]	CD	Pilot study, controlled	27	Telemonitoring through the web	Feasible and safe method for individualized scheduling of maintenance IFX treatment
Pedersen *et al*[11]	UC	Prospective noncontrolled study	95	Telemonitoring through the web	Feasible and improve adherence to therapy
Torrejón *et al*[56]	IBD	Descriptive, observational, retrospective	1784	Telecare through e-mail, phone calls, fax	Increased telematic contacts and decreased in-person care
Johnson *et al*[27]	IBD	Telemonitoring project	420	A web-guided programme	Effective, safe and cost savings
De Jong *et al*[24]	IBD	Controlled randomized clinical trial	909	Telemonitoring through the web (mHealth)	Reduced outpatient visits and hospitalizations
Carlsen *et al*[43]	IBD	Controlled randomized clinical trial	53	Telemonitoring through the web (mHealth)	Reduced outpatient visits No differences in disease activity, QoL or adherence compared with standard care
Walsh *et al*[112]	UC	Pilot study, non controlled	66	Telemonitoring through the web (mHealth)	Feasible and usable to measure disease activity, QoL and medication use
Del Hoyo *et al*[52]	IBD	Controlled randomized clinical trial	63	Telemonitoring through the web	Higher improvement in disease activity compared to usual care Similar improvement in QoL, social activities and satisfaction between groups
Cross *et al*[25]	IBD	Controlled randomized clinical trial	348	Telemonitoring through the web (mHealth)	Improvement in disease activity and QoL, although not superior to usual care Decrease in hospitalizations and increase in distance contacts
Bilgrami *et al*[48]	IBD	Controlled randomized clinical trial	222	Telemonitoring through the web (mHealth)	No differences in self-efficacy or patient activation compared with standard care
Schliep *et al*[47]	IBD	Controlled randomized clinical trial	217	Telemonitoring through the web (mHealth)	No significant improvement in depressive symptoms or QoL compared with standard care
Heida *et al*[45]	IBD	Controlled randomized clinical trial	170	Telemonitoring through the web, e-mail and telephone	Similar improvement in QoL compared to conventional care Reduction in outpatient visits and societal costs Satisfaction
Linn *et al*[46]	IBD	Controlled randomized clinical trial	160	Telemonitoring through the web or SMS combined with tailored counselling	Improved self-efficacy Satisfaction

Bonnaud *et al* [51]	IBD	Controlled randomized clinical trial	54	Telemonitoring through the web (mHealth)	Significant improvement in QoL A trend to reduce outpatient visits Satisfaction
McCombie *et al*[50]	IBD	Controlled randomized clinical trial	100	Telemonitoring through the web (mHealth) and home-based FC	Non-inferiority of QoL and symptoms Reduced outpatient visits

IBD: Inflammatory bowel disease; UC: Ulcerative colitis; CD: Crohn's disease; QoL: Quality of life

higher level of disease activity in the experimental group. There were no statistically significant differences for improvement of disease activity, treatment adherence, and quality-of-life values between both groups at 12 mo. These results could be related to the small sample size as well as a higher dropout rate in the intervention group, possibly due to the platform design, which required installation and eventual repairs at home.

To avoid these problems, Cross and cols developed web telemonitoring using mobile devices[25].

Web-based systems

In the last decade, telemonitoring systems have progressively evolved with web programs and mHealth solutions. Web applications are less expensive, safe, and feasible in the management of IBD not only in adults but also in adolescents[43-45], and they are associated with a reduction in outpatient visits and hospitalizations[22,24,27,43,45].

A Danish group developed telemonitoring through the web under the concept of "Constant-care". The system was developed through the web http://www.constant-care.dk, which also incorporated an educational centre. These investigators designed a randomized controlled trial with 333 UC patients treated with 5-aminosalicylates (5-ASA) from different hospitals in Denmark and Ireland[22]. The intervention group introduced clinical data and analytic results in the web to guide changes in the follow-up schedule and treatment. This intervention was compared to usual care.

After 12 mo of follow-up, in both the Danish and Irish population 88% of patients showed good acceptance with the web telemonitoring. There was a statistically significant improvement in adherence to treatment after 4 wk and a lower duration of disease flares. This was related to the use of high doses of 5-ASA in 100% of patients from the intervention group in Denmark, who also had improved QoL and disease knowledge. However, these outcomes were not reproduced in the Irish population. Moreover, in the Danish population telemonitoring reduced outpatient and emergency department visits, which led to direct cost-savings of 189 euros per patient-year, but also to an increase of e-mails and telephone contacts.

The use of this web-system in paediatric patients also reduced outpatient visits and school absenteeism, without differences in disease activity, QoL and adherence to treatment compared to the control group[43]. In another study developed in the University of California with a telemonitoring program combined with tele-education, patients followed remotely used less corticosteroids and suffered less hospitalizations and emergency department visits, with cost reductions of 16%[23]. In short, these studies show that web-telemonitoring is feasible, safe and could reduce health costs, although there are reproducibility differences depending on the population in which telemonitoring is applied[19].

Moreover, web-systems have been used to individualize the treatment according to the disease course. In a prospective study with 95 patients with mild to moderate UC, web control allowed the adjustment of 5-ASA doses and improved adherence. This was related with a significant improvement in clinical activity and FC values after 3 mo of follow-up[11]. Telemonitoring has even been used to individualize the treatment schedule with infliximab. After 1 year of follow-up, there were no significant changes in disease activity and QoL, although there was an estimated cost-saving of 699 euros/patient, compared with a historic control group[10].

In the same line and to avoid problems generated with the HAT system in the pioneering studies, the Cross group developed a web system for the management of patients with IBD (TELE-IBD) through text messages. In a randomized clinical trial with 3 parallel groups (TELE-IBD weekly, TELE-IBD every other week and control group) in 3 reference centres for IBD, they included 348 patients who had at least one disease flare in the last 2 years. Seventy-five percent completed the study, with an improvement in disease activity and QoL in the 3 groups, but without a higher improvement in these outcomes, depressive symptoms, or self-efficacy in the web control group, although in another study self-efficacy improved when tailored counselling was associated[46]. Moreover, telemonitoring was associated with a change in the profile of health expenses. Less hospitalizations were seen in the telemonitoring group but with higher use of non-invasive tests and telephone or e-mail[25,47,48].

The largest clinical trial with a telemonitoring program to date was performed with the Dutch web myIBDcoach (http://www.mijnibdcoach.nl). This web allows distance monitoring of disease activity, treatment adherence and side effects, as well as nutritional status, smoking habits, QoL, fatigue, stress,

anxiety and depression. As other platforms, it provides educational elements to improve empowerment. Patients showed good acceptance with its use in a pilot study[49]. In a clinical trial including 909 patients with different disease characteristics, the use of this system reduced outpatient visits and hospitalizations compared to standard care after 12 mo of follow-up[24]. Similarly, a reduction in outpatient visits was also obtained in adolescents[43,45] and in adults who used home-based tests to measure FC[50]. In a pilot study performed in France with the EasyMICI-MaMICI® platform, a reduction in outpatient visits was also associated with a significant improvement in QoL and satisfaction[51].

Our study group evaluated the impact on health outcomes of the telemonitoring web platform TECCU (Telemonitorización de la Enfermedad de Crohn y Colitis Ulcerosa or Telemonitoring of Crohn's Disease and Ulcerative Colitis), as compared to standard care and telephone care. In a 3-arm randomized clinical trial, 63 patients (21 per arm) with complex IBD were managed with each follow-up method over 24 wk. At the end of the study, the percentage of patients in remission was higher in the TECCU group (17/21, 81%) compared to nurse assisted telephone care (14/21, 66.7%) and standard care (15/21, 71.4%). The telemonitoring group had more improvement in disease activity, and this was associated with a larger reduction in FC values. All completers adhered to treatment in the TECCU group, while QoL, social activities, and satisfaction improved in all 3 groups[52].

Telephone and e-mail support in web-systems

Telephone and e-mail are resources attended by both medical doctors and specialized nurses in some IBD units, with high capacity to solve problems at less cost[53-55]. These tools have also been used to coordinate action plans in telemonitoring systems.

In Spain, the Crohn´s and Colitis Care Unit model has been used since 1999 as a multidisciplinary model of continuous care for patients with IBD. This model manages health demands with distance management mainly through telephone or e-mail with the support of a web page, which includes educational elements. The number of users has risen over the years, with a reduction of in-person care [56]. In Illinois, the Sonar Project is based on monthly web monitoring of symptoms in patients with IBD. Nurses exert a central role and use telephone contact for those patients who send results out of normal ranges, and together with medical health providers management adjustments are performed. This system also reduced hospitalizations, emergency visits and costs[57].

Therefore, beyond the use of telephone and e-mail in units which work as centres for resource coordination, telemedicine in IBD is expanding through the use of web and mHealth systems. These include telemonitoring, tele-education and videocalls in some cases. Its application allows the development of projects to provide health resources in remote areas[58,59], mainly with the use of mobile apps and the integration of some of these platforms into the electronic medical records, as is the case of the app HealthPROMISE and mynexuzhealth[60,61]. These models promote collaboration and mentoring between specialists, which could reduce variability in medical practice and modify the structure of future health systems if they demonstrate to be cost-effective.

Cost-effectiveness of telemonitoring IBD

Although many data about cost-savings have been published, they refer almost exclusively to direct costs[22,27], without considering costs of installation and maintenance of platforms or indirect costs.

In the IBD setting, our research group published the first cost-effectiveness and cost-utility analysis of a telemonitoring program compared to telephone and standard care[62,63]. The differences between groups and statistical uncertainty in disease activity, quality-adjusted life-years, and costs were calculated using nonparametric bootstrap estimations. Even though our trial only included 63 patients, we imputed the original dataset 5 times, and the bootstrapping estimations allowed us to extract 1000 random samples (of 21 patients per arm) from each of the 5 imputations, thus generating 5000 bootstrap replications.

We concluded that there is a high probability (79.96%) that the use of the TECCU web platform for telemonitoring complex IBD patients produces a greater improvement in disease activity at a lower societal cost, compared with standard care. Telemonitoring through the TECCU platform saved €2250 per additional patient in remission (95%CI: €–15363 to 11086) *vs* telephone care, and telephone care saved €538 compared with standard care (95%CI: €–6475 to 5303). Moreover, the use of the TECCU platform and telephone care showed an 84% and 67% probability, respectively, of producing a cost saving per additional quality-adjusted life-year (QALY) compared with usual care, even considering the simulations that involved negative incremental QALYs.

With a similar methodology, our results were reproduced by de Jong *et al*[64] who concluded that telemedicine with myIBDcoach is cost-saving and has a high probability of being cost-effective, without a decline in QoL. In this study, telemedicine resulted in lower mean annual costs of €547/patient (95%CI: €1029-2143) without changing quality adjusted life years. At the Dutch threshold of €80000 per quality adjusted life year, the intervention had an increased incremental cost-effectiveness over standard care in 83% of replications.

The authors included all subtypes of IBD, whereas our study with the TECCU platform recruited complex patients with IBD who needed to start immunosuppressants and/or biologic agents. According to our conclusions, the big sample size recruited in this article is useful to confirm our prior results, and

the reproducibility of the favourable cost-effectiveness profile of telemedicine applied in IBD across countries and patients' characteristics. In fact, during the COVID-19 pandemic, similar cost-savings with a higher gain of QALYs have been observed with the use of telemonitoring for IBD in Hong Kong[65].

ENABLERS AND BARRIERS FOR THE IMPLEMENTATION OF TELEMONITORING IN IBD

Unlike the use of ICTs in other fields (streaming entertainment services, grocery delivery, e-banking, *etc.*), telemonitoring interventions deal with a series of barriers which hinder their definitive implementation to reorganize health systems, despite other associated advantages (Table 2)[66-71]. The factors which favoured and limited these changes can be classified in 5 groups: technological, organizational, legal, acceptability and costs[72].

MODELS OF TELEMONITORING IN IBD

Telemonitoring theoretically include three different diagnostic models: patient self-diagnosis, remote providers´ diagnosis and computer-assisted diagnosis. They usually work as triage systems but, beyond diagnostic capabilities, telemonitoring platforms allow for remote management of other aspects such as disease treatment or education. In the IBD setting, they usually combine self-management, remote providers´ management and computer-assisted telemanagement[10,11,21,22,24,25,42,43,45,47,48,50-52].

Patient self-management

Self-management refers to a dynamic, interactive, and daily process in which individuals engage to manage a chronic illness[73]. This process includes the ability to deal with their own symptoms, treatment, physical and social consequences, and lifestyle changes to maintain a satisfactory QoL[74]. In this sense, telemonitoring platforms for IBD have incorporated PROMS and home-based tests that allowed patients to self-report their health status. This information has been even used to guide treatment adjustments by themselves[22].

Resources for patients´ self-management: PROMs, home-based tests and wearable devices

Considering the "treat-to-target" strategy, the Selecting Therapeutic Targets in Inflammatory Bowel Disease (STRIDE) project recognized different evidence and consensus-based recommendations to optimize outcomes in patients with IBD. Among the different targets proposed, clinical remission and endoscopic healing were confirmed in the STRIDE-II actualization, while normalization of serum and fecal markers of inflammation have been determined as short-term targets[4]. There was agreement to evaluate disease remission with clinical indexes, PROMs and endoscopic criteria [or also radiologic criteria in Crohn's disease (CD)].

Usually, endoscopic disease activity has been considered the gold standard to measure inflammation and to consider mucosal healing, but endoscopy is invasive and expensive.

In this sense, with the aim of measuring inflammation non-invasively, different PROMs and PoC tests have been developed over last years. Moreover, some of these tools have been specifically validated for their use in telemedicine programs.

PROMs: A PROM is a measurement of any aspect of a patient's health status that comes directly from the patient, without the interpretation of the patient's responses by healthcare providers and without the need of laboratory tests[75]. PROMs are designed for screening of disease activity, and then they need to be sensitive enough, especially if it implies more false positive results.

The Simple Clinical Colitis Activity Index (SCCAI) has shown a high correlation and good agreement between patient and clinician reported versions[76]. Compared to UC, PROMs used in the context of CD have shown worse correlation with other markers of clinical or endoscopic activity. The Harvey-Bradshaw index (HBI) had high correlation but only moderate agreement between versions registered by the patient or the clinician[77], although a recent version of the HBI self-administered by the patient through a mobile app showed a high percentage of agreement with in-clinic physician assessment, with a remarkably high PPV for remission[78]. Both SCCAI and HBI show good agreement between paper and online versions[78-80], and represent attractive tools for telemonitoring IBD.

Few PROMs have had their correlation with endoscopic activity evaluated. The global assessment of the patient, based on an analogic visual scale about how they felt regarding their UC during the previous 2 d, only showed moderate correlation with endoscopic activity[81]. The subscore of the global medical assessment and the 6-point Mayo index (which includes stool frequency and rectal bleeding) have a high correlation with the whole Mayo index[82]. Moreover, the 6-point Mayo index has an AUC of 0.80 compared to the endoscopic subscore[83].

Recently, the mobile Health Index was validated to monitor IBD activity through mHealth systems. In patients with CD, it showed high correlation and agreement with the Crohn´s Disease Activity Index and the HBI, as well as in patients with UC when it was compared to the partial Mayo index[84]. The

Table 2 Enablers and barriers for the implementation of telemonitoring in inflammatory bowel disease

	Enablers	Barriers
Technological	Adequate support	Lack of EMR integration
	Sufficient training	System maintenance required to avoid malfunction
	Fast internet connections	
	5G network	
Organizational	Continuous monitoring	Multidimensional nature: complex comparability between programmes
	Overcome geographic barriers	
	Safe assistance during COVID-19 pandemic	Lack of robust data: small studies, short-term follow up periods
	Structured data collection	
	Favours experimental studies and epidemiological surveillance	Lack of standardized remote medical practice (Interstate Mecial Licensure compact in the United States)[66]
	Multicentric access to data	Reimbursement limitations
	Telementoring: professional support and education	
Legal		Lack of legal framework[67,68]
		Data security
Acceptability/accessibility	Patient empowerment	Technological knowledge[69-71]; Some demographic factors increase the likelihood of a telematic encounter failure
	Wide use of smartphones	High drop-out rate in some clinical trials
	Wide use of wearable devices	
	Cheap internet plans	
Costs	Potential decrease of direct and indirect costs	High initial investment
		Limited cost-effectiveness data

intraclass correlation coefficient for test-retest reliability was high for CD and for UC. Nevertheless, its agreement with endoscopic scores was poor in CD and moderate in UC.

QoL and absence of disability are other targets of the STRIDE-II initiative. The Inflammatory Bowel Disease Questionnaire (IBDQ) was specifically validated in patients with IBD and has a moderate to high correlation with treatment response and the endoscopic Mayo index. However, their 32 and 36 items versions require a lot of time for their interpretation, so the reduced versions of 9 and 10 questions were subsequently validated[85,86]. On the other hand, the IBD disability index predicts active disease, nonadherence, and treatment with corticosteroids when high disability values are obtained[87]. Finally, health-related fatigue was incorporated in the Monitor IBD At Home index, but it is still not considered a specific target.

Probably the accuracy of PROMs increases when used in combination with FC. Thus, the Monitor IBD At Home index was developed to predict the endoscopic activity in patients with IBD. The association of FC to both the CD and UC versions showed high sensibility and NPV to rule out endoscopic activity[88]. The development of home-based FC tests that can be measured by the patient represent a potential option to measure disease activity in telemonitoring programs.

PoC tests and home-based tests: The use of PoC tests refers to patient specimens assayed at or near the patient with the assumption that test results will be available instantly or in a very short timeframe to assist caregivers with immediate diagnosis and/or clinical intervention[89]. In the IBD setting, the interest has centered on FC, and even though lactoferrin tests have been developed with adequate accuracy[90], FC offers better sensibility at certain cutoffs[90,91].

FC has good correlation with endoscopic activity in both UC[92,93] and CD[94-96]. FC helps to differentiate between functional and inflammatory diseases in patients with digestive symptoms. Moreover, in patients already diagnosed of IBD it allows the evaluation of disease activity, response to treatment, post-surgical recurrence and it predicts relapses after the withdrawal of anti-TNF agents[97,98]. These features, its non-invasiveness and a relative low cost makes FC tests in a useful tool in the diagnosis, monitoring and treatment adjustment in IBD.

Furthermore, the diagnostic accuracy of FC in different clinical scenarios has increased the interest in its use in telemonitoring IBD programs. In line with a patient-centered care and to favour empowerment, during the last years and the COVID-19 pandemic, different home-based FC tests have

been developed as an additional tool for a home-based follow-up[99]. These tests are based on kits that analysed faecal samples through immunochromatography. Then, the results are read with a smartphone camera, and they are sent through a specific app to a server accessible by providers (Figure 2).

Comparison between different home-based FC tests: Three main FC tests have been developed for its use by patients at home: CalproSmart, IBDoc and QuantonCal.

In a recent study, these 3 tests were compared with the ELISA method of the same manufacturer [100]. Considering the importance of obtaining good agreement in the low range of FC values (ruling-out disease activity), IBDoc, QuantonCal and CalproSmart have an 87%, 82% and 76% agreement, respectively, compared with their corresponding ELISA readings.

However, and similarly to its validation study[101], CalproSmart showed a trend to overestimate FC values with a mean bias of +141 μg/g (95%CI: -316 to 598 μg/g), while IBDoc tended to underestimate FC values with a mean bias of -105 μg/g (95%CI: -576 to 366 μg/g). This could generate more false positive results when using CalproSmart, but misclassification in the low (< 250 μg/g), medium (250-500 μg/g) or high (> 500 μg/g) range of FC values with this test showed large differences (*i.e.*, to classify as > 500 with CalproSmart and < 250 with ELISA, and viceversa) in only 2% of measures, compared to 5% in IBDoc and 8% in QuantonCal.

In any case, the error range between FC measured with home-based tests and their corresponding ELISA method was high. This happens especially when FC values are > 500 μg/g. With values ≤ 500 μg/g, differences were also over the acceptable range of 200 μg/g (+/-100 μg/g), but they were not wide enough to induce errors in the interpretation of inflammatory activity. Therefore, home-based tests are considered useful to rule-out inflammation at a distance when FC values are < 500 μg/g, but when values are > 500 μg/g disease activity should be evaluated with other methods.

Home-drug monitoring: Home therapeutic drug monitoring of monoclonal antibodies appears to be an innovative possibility to improve and simplify IBD management. To date, these tests are performed only in some hospital laboratories and results are not immediate. This delay, of months in some cases, impairs drug monitoring and dose adjustment, compromising its utility.

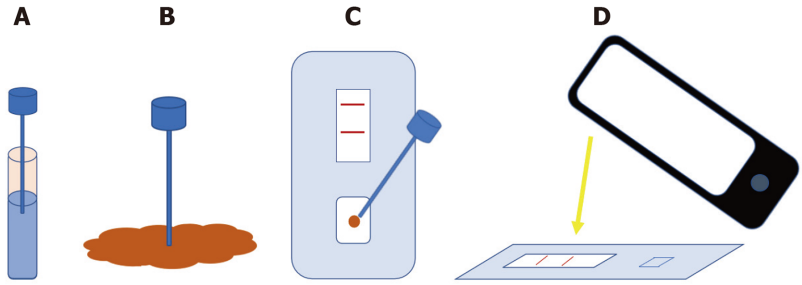
To solve this issue, home drug monitoring using dried blood samples is being evaluated in different inflammatory diseases. The first data were published by Kneepkens *et al*[102] in patients with rheumatic inflammatory diseases. Adalimumab and anti-adalimumab antibodies concentration measurements in finger prick dried blood spots were compared with simultaneous serum measurements. They found that both drug levels and antibody concentrations from the finger prick method correlated well with serum measurements (correlation coefficient > 0.87). However, some disadvantages should be considered, such as loss in precision, workload and elevated costs.

Berends and colleagues did a similar study with 40 IBD patients, comparing infliximab concentrations in dried blood samples and serum. Home-based test infliximab concentrations showed a good correlation (correlation coefficient: 0.671) with serum measurements[103]. This author also published data with adalimumab treatment one year later. A high correlation was found (Pearson's correlation: ≥ 0.96) between dried blood test and venipuncture results when performed at the same time during the outpatient clinic. Moderate correlation (Pearson coefficient = 0.51) was reported between home self-performed finger test and estimated adalimumab concentrations[104]. Larger studies are needed to confirm the reliability, accuracy, and cost effectiveness of home-based testing as a new telemonitoring tool in IBD.

Wearable devices: Wearable devices are electronic gadgets that consumers wear to track health-relevant physiological data to monitor and improve health[105]. IBD patient preferences and interest in wearable technology were evaluated by Hirten and colleagues using a 28-question survey. Four hundred patients completed the survey. Of these, 42.7% reported prior or current use of wearable devices, mainly smart watches (34.5%) and wrist band devices (29.1%). Almost 90% of subjects believed these gadgets could provide important information about their health and 93.8% reported that they would use them if it could help doctors manage their disease[106].

In the last few years, several studies have tried to demonstrate the utility of wearable devices in IBD telemonitoring[107]. The first available data was published by Yvellez *et al*[108] in 2018. They prospectively assessed daily health-related QoL, pain and sleep data using validated indexes through a mobile application and a Fitbit® device. Fitbit® compliance was almost 80%, suggesting this technology is feasible[108]. The Fitbit® device has also been used to predict disease activity. In one study a significant reduction in daily steps has been shown over the week before CRP or FC elevation, but without differences in daily resting heart rate[109]. Two years later, however, Hirten *et al*[110] demonstrated that significant changes in heart rate variability measured using VitalPatch® were observed before the development of symptomatic or inflammatory flare in ulcerative colitis patients.

Step count and sleep monitoring have also been used, not to predict flares but the intent to determine post-operative length of stay. Overall, step count and sleep duration/efficiency did not predict length of stay. However, in a multivariable linear regression model, significant interaction was found between postoperative complications and step count, suggesting that increased physical activity was associated with a reduction in duration of hospital stay[111].



DOI: 10.3748/wjg.v29.i7.1139

Figure 2 Procedure to measure fecal calprotectin at home. A: Extraction buffer; B: Collection of faecal sample; C: Control (C) and test (T) lines appear after application of extracted calprotectin to the sample window; D: A smartphone camera is used to read the result obtained.

Remote providers´ management

All the telemonitoring interventions in IBD reported in this review comprise healthcare providers´ advice. Most systems employ store and forward programs, where nurses acquire a central role in tracking the information received and making contact between patients and specialists to set up healthcare plans. Communication is established through websites, usually with the support of telephone and e-mail, as reported above.

Computer-assisted telemanagement

Computerized systems have been used for telemonitoring IBD and they usually work as a triage system to identify which patients might require further evaluation. Many of them can generate automatic action plans through the integration of different monitorable indicators in decision-making algorithms. In most telemonitoring programs tested thus far, these tools are combined with self-management and the remote providers´ management models seen above.

Telemonitoring systems in IBD are integrated by personal computers or mobile devices used by patients, a decision support server and a website for staff and providers. The website provides an interface to collect data from testing sessions, and these platforms usually generate automated reminders to favour adherence to follow-up. The structure of most eHealth tools in IBD are based on a traffic light system[10,11,22,25,27,43,45,52,112]. Patients usually enter their symptoms in scheduled online controls, mainly in a structured manner through PROMS, but many apps also include a comment box to freely express anything outside the questionnaires. Then, the patient´s status appears as red, yellow or green when disease is highly, moderately active, or quiescent, respectively.

Some systems combine self-reported symptoms with the level of FC in a total inflammation burden score. In fact, recent clinical trials have incorporated FC tests performed by patients at home[45,50,112]. This status is sometimes supplemented with disease activity and QoL graphs[10,11,22]. Depending on the level of alert, simultaneous action plans and email alerts are sent to the participant and providers, who review the information to decide if further management changes are necessary.

Altogether, these new models and resources for patients´ self-management represent advances to reach the implementation of telemonitoring in daily practice, but still some legal, ethical, economical and logistic barriers need to be solved (Figure 3).

DISCUSSION

Telemonitoring is about communication, and the development of faster and wireless systems at a lower cost has supported the use of proactive remote monitoring. As well, the increase in data storage also favoured the incorporation of tele-education in most telemonitoring programs in the IBD setting. However, during the pandemic, e-mail and telephone still represented the main resources used[29,30], while the application of mature telemonitoring programs was the exception. As different enablers encouraged advances of telemonitoring in IBD, many other barriers emerged and hindered its full implementation in daily practice.

Pioneering studies evaluated telemonitoring programs previously used in other chronic diseases[21,42,113,114]. Feasibility and patients´ acceptance of these applications was excellent. Yet, they were not able to clearly demonstrate an improvement in QoL, disease activity, and treatment adherence. These systems were based on remote monitoring through computers, they needed to be adapted to the IBD context and required eventual repairs at home, which were time expensive. Telemonitoring subsequently evolved towards the use of web-based systems, which were cheaper and easy to use. Remote monitoring through the web demonstrated its feasibility and excellent patients' acceptance, with an improvement in QoL, disease activity, and disease knowledge[22,115].

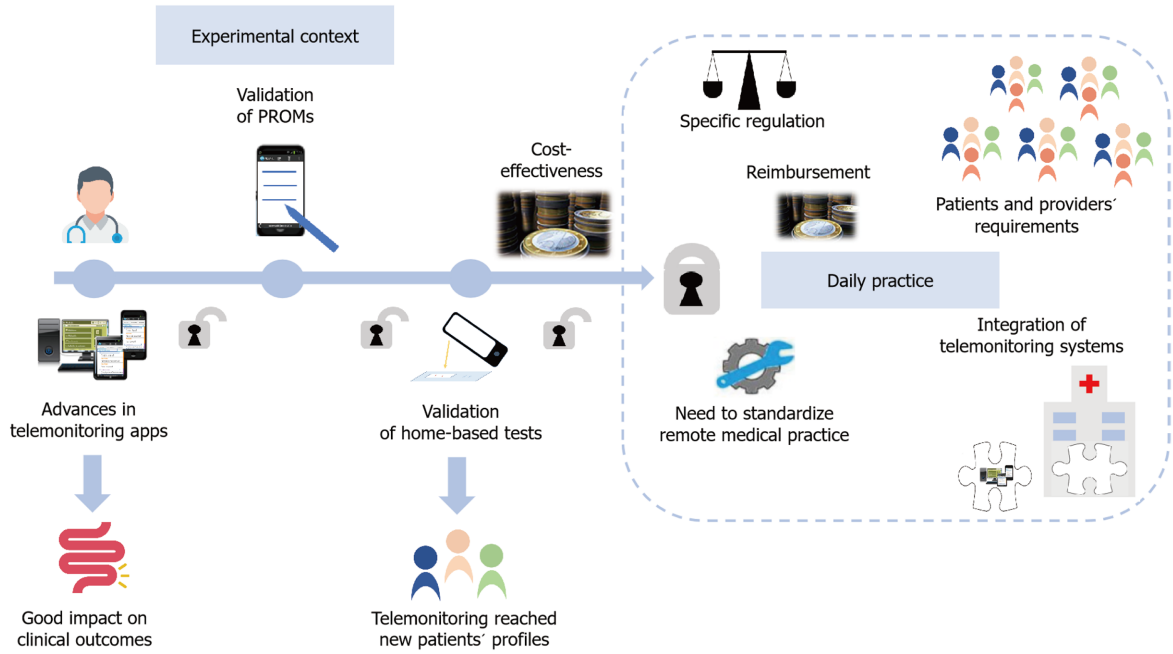


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Figure 3 Advances in telemonitoring of inflammatory bowel disease related to the enablers and barriers for its implementation in daily practice. PROMs: Patient reported outcome measures.

In the last few years, telemonitoring prioritized the use of mHealth resources[24,25,116]. Beyond the improvement in clinical outcomes, mHealth telemonitoring associated cost-savings in outpatient visits and hospitalizations[23-26]. Almost parallel to the mHealth evolution, many PROMs have been validated to self-report disease activity. In line with patient-centered care, empowered patients can use new home-based calprotectin tests, which are accurate enough and useful to rule-out disease activity at low FC values[100,101]. In fact, new home drug monitoring is being developed to measure levels of monoclonal antibodies near the patient[103,104]. Furthermore, the development of mobile devices even enabled the increasing use of wearables to monitor physiological predictors of disease activity and postoperative length of stay[110,111]. These new tools could represent one of the first steps towards ubiquitous Health in IBD, and in a near future machine learning may allow the integration of large data sets in personalized algorithms.

Despite the technological and knowledge advances reached, the effect of telemonitoring on health outcomes is not consistent in different populations and health systems[22,24,25,42,44,45,52]. Initially, remote monitoring was mostly restricted to UC patients, while the design of new apps, PROMs and home-based tests allowed to progressively expand its use to a broad range of patients´ profiles. However, telemonitoring has not been demonstrated to improve QoL or clinical/endoscopic remission in the long-term. In addition, biomarkers in IBD are less accurate compared to other chronic diseases such as diabetes mellitus, and the early recognition of complications in IBD still require invasive tests in many cases.

On the other hand, although telemedicine has been traditionally considered cost-effective, cost-saving data previously published referred almost exclusively to direct costs[22,27]. The implementation of telemonitoring services represents a short-term high initial cost, not only from a technological point of view, but also by changes in the organization of the IBD units. Thus, decision-makers have had difficulties to support the implementation and investment in telemedicine due to a lack of solid evidence so far. In addition, these decisions become even more complicated in areas where reimbursement is an important factor in the setup of clinical activity. In this regard, recent studies suggested a good cost-effectiveness profile of telemonitoring[62-65], even after considering the costs of installation and maintenance of platforms, as well as indirect costs.

The availability of more powerful and cheaper communication tools turned technical challenges into legal, ethical, economical, and logistic issues[28]. To standardize remote medical practice, in the US the Interstate Medical Licensure Compact was created to increase efficiency in multistate licensing of physicians[66] but such a proposal is lacking in Europe. Besides, only a few examples of full integration of telemonitoring programs into electronic medical records are available to date[60,61]. In this sense, interoperability of systems while maintaining the confidentiality of data cannot be guaranteed in many centres. Moreover, the provision of remote health safely also requires a specific European regulation to protect remote medical practice and to lift some existing legal barriers. Finally, to keep adherence to follow-up, it is essential to adapt telemedicine programs according to patients' and providers´ character-

istics, because some demographic factors such as increasing age, commercial insurance status and racial differences increase the likelihood of a telematic encounter failure in some contexts[117].

CONCLUSION

Therefore, telemonitoring IBD is well accepted and improves clinical outcomes at a lower cost in the short-term. The advances performed on new PROMS, home-based tests and wearables improved the ability to manage new patients´ profiles remotely. However, it is still necessary to overcome many legal, ethical, economical and logistic barriers. Funders, policymakers, providers and patients need to align their interests to successfully implement telemonitoring, and further collaborative efforts based on teamwork between centres are essential to help reorganize health systems.

FOOTNOTES

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