Telemanagement of Inflammatory Bowel Disease

Raymond K. Cross
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Editors

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Foreword

History is punctuated with the dramatic innovations that have changed the way entire populations live and work. Think about the invention of the printing press. The Industrial Revolution. The Internet Age. Each of these revolutions involved the introduction of disruptive new technologies that enabled people to do things they could hardly imagine before.

I believe that we are living through such a revolution right now in health care. The combination of communication technologies, new medical devices, the Internet, and powerful analytic capabilities has converged to create entirely new ways of delivering health care. Telemedicine, virtual health care, mobile health—whatever you choose to call it—is presenting unequalled opportunities to improve access and quality, while reducing cost.

Never before have we had the chance to create truly patient-centered health-care systems at a cost we can afford.

Health-care providers have begun to realize this potential, and as a result, telemedicine is erupting in pockets all over the globe. Where I live, here in Ontario, we have created one of the largest telemedicine networks in the world, the Ontario Telemedicine Network, to connect providers, patients, and families over our vast geography. Last year, 488,000 patient teleconsultations were performed in the province, eliminating distance and travel as a barrier to care and providing unparalleled access. As we continue to grow, we continually look for new and better ways to leverage technology to enhance care delivery and engage patients.

This book represents a sentinel example of a "new and better way." Patients with inflammatory bowel disease (IBD) need specialized expertise and ongoing, consistent expert advice and self-management support that is—simply said—a scarce resource. Telemedicine is the only practical way to reach out to all those affected by the disease to provide the support they need, when and where they need it. With tremendous pressure to provide a higher quality of care and reduce the costs of care, telemedicine is an absolute necessity for these long-term patients.

Drs. Cross and Watson with their colleagues have put it all in one place, combining evidence with their substantial practical experience to provide a comprehensive guide to the future of IBD management. Using teleconsultation, telemanagement, telemonitoring, and telementoring, this book paints a picture of how technology enables new and better models of care delivery and patient empowerment.

This is the best practice of the future, delivered now.

Edward M. Brown, MD

Preface

Springer International Publishing AG, Raymond K. Cross, Andrew R. Watson, and contributing authors have developed the first edition of Telemanagement of Inflammatory Bowel Disease to provide a comprehensive summary of telemedicine in the care of patients with inflammatory bowel disease (IBD).

The field of IBD, comprising Crohn's disease (CD) and ulcerative colitis (UC), has changed dramatically in the last 15 years. Increasing use of immune suppressants, development of biologic therapies, including anti-tumor necrosis α agents and anti-integrin agents, and clinical research on optimization of existing therapies has resulted in greater expectations for treatment. Indeed, expectations for treatment are evolving beyond improvement in bowel symptoms to achieve steroid-free clinical remission, biologic remission, and mucosal healing. Advances in surgical techniques and in particular minimally invasive techniques are leading to faster recovery, less postoperative adhesions, and a new diagnostic modality—exploratory laparoscopy. Reaching these more stringent outcomes is associated with fewer flares of disease, decreased hospitalizations, decreased complications, and decreased surgeries.

Unfortunately, despite advances in care, a significant proportion of patients experience suboptimal outcomes. Barriers to successful treatment outcomes include, but are not limited to, access to specialist IBD care, adverse effects of drug therapy, nonadherence, psychosocial comorbidities, inadequate monitoring, poor provider adherence to published guidelines, lack of education, and patient–provider discordance. Telemedicine approaches including telephone triage/education, telemonitoring, teleconsultation, teleconferences, and disease tracking through mobile applications have shown promise in improving outcomes further and for chronic disease management in patients with IBD. With the significant advances in the consumer electronics market and the maturation of telemedicine, access to patients, caregivers, and information has never been easier. The trend to a more technologically empowered health-care system and consumer is rapidly increasing. Therefore, telemedicine offers a consumer friendly and potent new model of care to enable the treatment of one of the most challenging subsets of chronic diseases, IBD.

This textbook provides a comprehensive, state-of-the art review of this field, and will serve as a valuable resource for medical and surgical clinicians, trainees, allied health professionals, industry and clinical researchers with an interest in telemedicine applications in IBD. The book will review barriers to successful outcomes in patients with IBD and offer a rationale for how self-management and telemedicine approaches can improve care in chronic illnesses such as IBD. A summary of the impact of telemedicine in other chronic illnesses will launch additional topics focused on the use of telemedicine in patients with IBD. This review will include a summary of the burden of telephone encounters in patients with IBD, characteristics of frequent callers to the office, outcomes associated with high telephone use, and strategies to provide education via telephone encounters to patients with IBD. We will also summarize prior literature on implementation of teleconsultation in research and clinical practice as well as mobile applications used to track symptoms, quality of life, diet, and medication use in IBD. We will also summarize recent randomized, clinical trials that have evaluated telemonitoring and patient self-management on clinical outcomes in patients with IBD. This review will also discuss a recently created teleconference, IBD Live, which was developed to facilitate complex multidisciplinary care across institutions and to improve provider education in IBD care. Considerable details will be provided surrounding system requirements, legal, regulatory, and ethical issues related to use of telemedicine applications. Lastly, the review will offer future directions for use of telemedicine applications in the care of patients with IBD and other chronic illnesses in the changing marketplace.

The intersection of chronic disease management, virtualized health care via telemedicine, and the most sophisticated medical/surgical treatments is paramount to treating complex patients and stabilizing the escalating health-care cost in our country. This book captures a paramount example of the deployment of telemedicine for this purpose.

This book would not have been possible without the outstanding dedication of the contributing authors and the editorial staff at Springer. We are deeply grateful for their efforts.

We hope that you find Telemanagement of Inflammatory Bowel Disease in implementing or enhancing use of telemedicine applications as part of your clinical practice. If you have any comments or feedback on ways we can improve this book, please contact us at rcross@medicine.umaryland.edu or watsar@upmc.edu.

Sincerely,

Raymond K. Cross,
M.D., M.S.
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Chapter 1
Barriers to Successful Outcomes in Patients with Inflammatory Bowel Diseases

Robin Ligler and Sara Horst

Definitions of Successful Outcomes

Before embarking on discussion of obstacles in the care of inflammatory bowel disease (IBD) patients, it is important to establish appropriate endpoints for their care. For ulcerative colitis (UC), the disease can be deemed cured after colectomy; however, most patients with UC do not need or desire surgery. Therefore, goals include inducing and retaining remission with medication and/or surgical intervention. For Crohn's disease (CD), neither medical nor surgical therapy is curative and goals also include inducing and retaining remission. Practice guidelines from the American College of Gastroenterology (ACG) note that the overall goal of care for patients with CD is remission that can include clinical remission, endoscopic remission, or surgical remission. Clinical remission is further defined to include a patient who has no symptoms and is not on steroids [1]. In UC, endpoints in care include remission of symptoms, reduction in need for long-term corticosteroids, and minimization of cancer risk [2].

In research trials, remission is often defined on the basis of a composite index such as the Mayo Clinic Score (MCS) or Modified Baron Score (MBS) in UC or the Crohn's Disease Activity Index (CDAI) in CD [3]. Some indices unfortunately do not combine clinical and endoscopic findings, can be time consuming, and the usefulness of these composite indices in clinical care can be limited. There is a developing concept that our goals for therapy in IBD should be based on resolution of symptoms as well as resolution of inflammation of the mucosa. Damage of the

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Table 1.1 Inflammatory bowel disease (IBD) quality measures eligible for Physician Quality Reporting System (PQRS) reporting, 2014

Measure description
Documentation of IBD type, anatomic location, and activity
Percentage of patients prescribed corticosteroid-sparing therapy
Bone loss assessment in patients who have been on corticosteroid therapy
Influenza immunization
Pneumococcal immunization
Testing for latent tuberculosis before starting anti-TNF therapy
Assessment of hepatitis B virus status before starting anti-TNF therapy
Tobacco use screening and counseling for cessation in tobacco users

anti-TNF anti-tumor necrosis factor

intestinal epithelial cells disrupts the intestinal barrier function, and this has been shown to be a factor in the pathogenesis of IBD [4]. Studies on mucosal healing have been undertaken, and mucosal healing has been shown to predict sustained clinical remission as well as resection-free survival [5].

Day-to-day determination of remission and success of IBD treatment in clinical practice is left up to the practitioner; however, in the USA, there are systems in place that hold practitioners accountable for some of their outcomes. A group of more specific endpoints in IBD has been determined by the Centers for Medicare and Medicaid Services (CMS) with help from the American Gastroenterological Association (AGA). The CMS Physician Quality Reporting System (PQRS) defines eight quality measures that are eligible for reporting to CMS. These measures are listed in Table 1.1 and range from documenting IBD type, activity, and anatomic location to immunizations and evaluation for corticosteroid-related iatrogenic bone loss [6]. It is important to note that these indicators of quality of care in IBD do not only involve disease-specific treatment but also revolve around prevention of overall health complications for the patient. Providers who reported to the PQRS in 2012−2014 were eligible for a 0.5% incentive bonus on reimbursements for Medicare Part B patients [7]. Importantly, in 2015, there will also be a "payment adjustment" of −1.5% for Medicare Part B reimbursements for providers who do not satisfactorily report data [8]. Overall, it is important to consider these types of endpoints when managing IBD patients and subsequently determining suboptimal outcomes.

Patient-Related Barriers to Success

Patients are complex human individuals, and IBD is a complex disease process. Therefore, it is no surprise that specific patient components can contribute to undesired outcomes in IBD. Taking these issues into account is important when treating patients and predicting patients' needs.

Because IBD is such an intricate disease process, it is a priority to teach patients about their disease. Ideally this education should occur during office visits with the provider and/or staff. Unfortunately, it has been shown that patients do not know as much about their IBD as providers would expect or hope. In a study of 70 newly diagnosed IBD patients who underwent a 30 min consultation with a nurse providing education on medication adverse events, medication names, and medication administration, patients only recalled 52.6 % of information initially and 53.8 % of information after 3 weeks [9]. This confirms that it is prudent to provide continued education to patients during every encounter. Even with education, patients can glean erroneous information about their disease and medications. For example, when 165 patients with established IBD were asked to complete a survey regarding the risks and benefits of the anti-tumor necrosis factor (anti-TNF) medication, infliximab, patients were found to overestimate the benefit of infliximab and to not know or underestimate the risks of infliximab including the lymphoma risk. When asked on the survey to indicate whether they would take a hypothetical drug (with same risks of infliximab), the majority indicated they would not take it and 30 % of these patients actually had taken infliximab or were taking it at the time of the survey [10]. Although much medical information is readily available on the Internet, several studies have shown widely varying quality of information available [11–13]. For example, a recent systematic review found that when a Google search was performed for "Crohn's disease" and "Ulcerative colitis," a marked variation of the quality of information was found, and high-quality websites were often low on the list of websites generated, making it more difficult for patients to find and discern correct information [12]. Therefore, it is important for physicians and teams to provide patients with high-quality Internet resource tools for patients.

Common mistakes made by physicians in educating patients include the framing effect, numeracy, and relying on verbal labels [14]. The framing effect refers to the choice providers make to present information in a certain format. This format can influence a patient's decision. For example, presenting a relative risk statistic in regard to an adverse drug reaction versus presenting absolute terms to a patient can affect the patient's decision to be adherent to the medication. Physicians also assume a patient's ability to understand numbers. For example, a physician often assumes that a patient has the ability to interpret the term "0.2 %" to be 2 in 1000 people; however, this may not always be the case. This can lead to altered patient perception of risk and subsequent changes in adherence. Finally, providers tend to rely on verbal labels such as "very common" and "very rare" when explaining disease and consequences. Patients often do not interpret the actual meaning of this and should be counseled in more specific terms. Tools to help educate patients appropriately include always providing absolute risk numbers, avoiding small percentages, focusing on shorter time intervals (as opposed to lifetime risk), and rounding numbers [7]. Overall, education of patients has been shown to be best presented by the use of decision aids [15]. A decision aid is a balanced presentation of particular treatment options that can be as simple as a paper presentation or as complex as a video. An

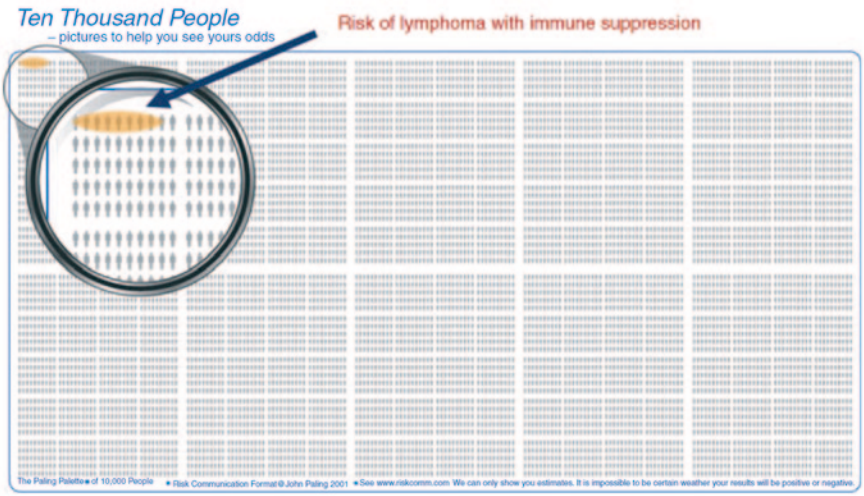

Fig. 1.1 Decision aid in explaining risks of lymphoma in inflammatory bowel disease (IBD) therapy. (Adapted from Ref. [70] with permission)

example of a decision aid is presented in Fig. 1.1. The picture displays the risks of lymphoma and certain IBD treatments. It illustrates 10,000 silhouettes of individual people and highlights nine of these silhouettes to illustrate the numerical risk of 4–9 per 10,000 patients who may develop lymphoma. The goal of using a decision aid is to enhance the physician–provider discussion. The educated patient in turn is then better able to participate in shared decision-making, which is simply the process of including patients in their medical decisions. Patients want to be involved in decision-making. When 1061 IBD patients were asked how important it is for them to be involved in medical decisions, 98 % responded that it was important [16].

When involving patients in their care, it is important to estimate a patient's acceptance of risk as this will translate to their perception of their disease in the context of their entire life. Risk is the probability of an event occurrence and the consequence if it occurs. It is incumbent on the practitioner to disclose these risks to patients prior to starting treatment and patient's acceptance of these risks will affect their willingness to comply with therapy. When assessing middle-aged and older patients, gastroenterologists have an overall higher acceptance of risk than their patients, so it is important to keep the practitioner bias in check when prescribing and discussing therapy [17]. In assessing patient's views on medication risks, studies have shown that patients are willing to accept a higher level of risk if they perceive a greater benefit from therapy. It is very important to delineate the risk compared to benefit ratio. For example, discussing the high percentage of steroid-free remission using anti-TNF therapy in a patient with CD can help the patient understand why a medication is recommended despite the risks of therapy. In one recent clinical trial by Colombel et al. [18], greater than 50 % patients were in steroid-free remission on azathioprine and infliximab. This is compared to the extremely rare risk of a complication such as lymphoma (4–6 in 10,000 patients per year). Patients also tend to be more risk averse to unfamiliar risks. For example, in a web-based survey of 600 CD patients who were presented with a series of tasks to determine their maximum acceptable risk of side effects including sepsis, lymphoma, progressive multifocal leukoencephalopathy (PML) in exchange for remission or response, the survey found that patients were more risk averse to adverse events such as PML which were less familiar to them than sepsis or lymphoma [19]. Risk assessment in IBD includes discussions about surgery as well as medications. Bewtra et al. [20] explored patient preferences for surgical and medical therapy in 300 UC patients and found that patients were willing to accept a high risk of complications (including lymphoma and infection risk) from medical therapy to avoid surgery with an ostomy. If the surgery would not involve an ostomy (ileoanal anastomosis), patients considered surgery equivalent to incompletely effective medical therapy.

Studies evaluating if demographic factors including race and socioeconomic status have consistently altered outcomes in IBD such as medical therapy utilization, utilization of surgery, and medication adherence have not been conclusive. In a recent review of 40 studies on this matter, authors concluded that surgical care utilization was the only significant category affected by patients' race [21]. In a large population study using the National Inpatient Sample, Nguyen et al. [22] discovered that when compared to Caucasians, minorities were much less likely to undergo bowel resection for active disease. Specifically, African Americans were 32 % less likely to undergo bowel resection, Hispanics were 30 % less likely to undergo surgery, and Asians were 69 % less likely to pursue an operation. There are conflicting data in regard to medication utilization between different races. In the review, race was a predictor of medical therapy utilization, albeit less drastic [21]. Caucasians were treated more overall with immunomodulators and anti-TNF medications, but the reasons for this were not explored. In contrast, a recent study of over 26 million office visits in the USA for patients with IBD that examined race and use of immunomodulators and anti-TNFs found no evidence of disparities over a 13-year time period [23]. In regard to medication adherence, multiple studies have shown that minorities are less likely to adhere to their medication regimen due to decreased trust in their provider, younger age, and perceived improvement in disease [21]. Racial differences between patients' knowledge and perceptions also exist and minorities have been found to have lower IBD-specific knowledge and perceived greater intrusiveness of IBD on their lives compared with Caucasians [21]. Socioeconomic status such as race has not been shown to consistently affect outcomes in IBD. In the abovementioned study by Nguyen et al. [22] regarding bowel resection for CD, patients with Medicaid coverage were 48 % less likely to undergo bowel resection than privately insured patients, and CD patients with an income below the median were associated with 29 % increased risk of in-hospital mortality. Contrasting this, a French study of 200 patients with CD failed to show differences in disease severity recurrence, steroid use, infliximab use, and immunomodulator use across deprived and non-deprived populations [24].

Depression and anxiety are common in patients with IBD. Prevalence ranges from 11 to 41 % in different cohort assessments [25–27]. Depression in IBD is most common in younger, female patients and in patients with pain and functional limitations [26]. Anxiety is associated with more severe disease, flares, being disabled or unemployed, and socioeconomic deprivation [27]. When gaging nonadherence to treatment and poor outcomes in IBD, psychiatric disease is often shown to be an associated factor. For example, when asked about adherence and reasons for nonadherence, a survey of 1600 IBD patients performed by Nahon et al. [28] revealed that factors associated with nonadherence were being a smoker, having concerns related to their treatment, anxiety, and moodiness. In a review of adherence to oral medications in IBD, psychiatric factors including depression, chronic stress, or a psychiatric diagnosis were consistently associated with nonadherence [29]. Finally, in patients with CD on infliximab, depression was shown to be a risk factor for lower remission rate and a need for earlier re-treatment with the anti-TNF [30]. Outcomes including surgical utilization are also affected by psychiatric diagnoses of depression or anxiety. When looked at directly, CD patients with a diagnosis of depression or anxiety were 28 % more likely to require surgery than patients without these diagnoses [31]. It is therefore important to assess for depression and anxiety in clinical practice and provide support and referral for these diseases if they coexist in the IBD patient.

Patient Adherence

Medication Adherence

Promoting adherence in the IBD patient population is a challenge for health-care providers and nonadherence is certainly a contributor to poor outcomes in IBD. Nonadherent adults are 5.5 times more likely to experience a flare of their disease than their adherent counterparts [32]. Patient adherence is defined as "the extent to which a person's behavior coincides with medical or health advice" [33]. Exploring patient adherence in IBD patients involves examining medication adherence, adherence to screening and surveillance colonoscopy, and strategies to improve adherence.

Adherence to medications in IBD consists of patient compliance with taking oral medications as well as injectable therapies or medications given by infusion. Nonadherence to oral medications ranges from 7 to 72 % with the majority of assessments reporting a 30–45 % nonadherence rate [29]. Specifically for aminosalicylate medications (5-ASAs, 5-aminosalicylic acids), adherence ranges from 50 to 68 % [34]. Much investigation has been undertaken to identify predictive factors of patient nonadherence to 5-ASA medication as this is one of the mainstays of treatment in IBD. When asked to identify barriers to adherence to taking 5-ASA, patients responses aligned into themes including competing priorities, social stigma, refill inconvenience, cost, doubts about efficacy or need for daily medication, side effects, size of the pill, and frequency of administration [35]. When evaluating adherence to 5-ASAs during the first 3 months of therapy, predictors of lower persistence with therapy included psychiatric diagnoses, mail order prescription of the index prescription, female gender, and co-pay amount. In this same population of patients, at 12 months, predictors of lower persistence with therapy included more comorbid illnesses, patients who received a mail order prescription for a 90-day supply, and patients who were hospitalized for a gastrointestinal (GI) condition [36]. Taking these predictors into account with prescribing 5-ASAs can help to target and improve nonadherence rates. For example, it may be helpful to investigate a patient's co-pay and provide hard copy or local prescription for the index prescription of the drug. It is also important to provide consistency in prescribing for patients taking 5-ASAs as there are many formulations of ASA medications. In a large study in the UK, when patients were switched between two different formulations of 5-ASA, these switches led to a 3.5-fold greater risk of relapse in disease [37]. The thiopurine drug class, consisting of the oral drugs 6-mercaptopuine and azathioprine, is another common and effective therapy for both CD and UC. Adherence rates for the thiopurine drug class have been reported to be 50–93 % [38]. In a study of 144 patients with IBD in England, nonadherence with thiopurines was associated with younger age, lower socioeconomic status, and depression [39]. These factors mirror factors for nonadherence with the 5-ASA class of drugs.

Anti-TNF therapy has become the mainstay of treatment for moderate-to-severe CD and UC. The most commonly used drugs in this class for IBD currently are adalimumab, infliximab, certolizumab pegol, and golimumab. Infliximab is given via an intravenous infusion while adalimumab, certolizumab pegol, and golimumab are administered via self-injection. Overall adherence to the anti-TNFs adalimumab and infliximab has been shown in a recent review to be 82.6 % [40]. For both drugs, factors associated with overall nonadherence were female gender, active smoking, and having anxiety or self-reported moodiness. When looking at adalimumab alone, the adherence rate was 83.1 % and predictors of nonadherence were every-other-week dosing, syringe use (vs. preloaded pen), prescription by an internist (vs. a gastroenterologist), use of retail pharmacy (vs. a specialty pharmacy), and being a new user [40]. Translating these predictors into clinical practice means that when prescribing adalimumab, it may be important to provide patients with medication reminders, preloaded pens, and specialized education for the new user. Infliximab seems to be an easier anti-TNF for which to measure adherence as patients are required to report to an infusion center to receive the drug. In 2006, Kane et al. [41] assessed adherence to induction and maintenance infliximab in 274 patients (greater than 1000 scheduled infliximab infusions) over 1 year as well as patient characteristics associated with nonadherence. Only 4 % of the infusion appointments were classified as "no-show" appointments in this group making the adherence rate 96 %. This differs from reported rates in other studies of 30–70 % [40]. Risk factors for nonadherence in Kane's study [41] were patients who were female, had Medicaid, and patients who had gone >18 weeks from their initial infusion. Kane et al. [42] then evaluated adherence to maintenance therapy alone in 571 patients with CD on infliximab. The nonadherence rate was 34.3 % over 1 year. Risk factors for nonadherence to maintenance infliximab included patients with recent hospitalizations. A cost analysis of adherent and nonadherent patients with CD on maintenance infliximab in this study showed that all-cause medical costs by nonadherent patients were 81 % greater [42]. In clinical practice, therefore, when prescribing infliximab, it is important to consider closer monitoring of patients > 18 weeks into their therapy and patients with recent hospitalizations.

Measuring adherence to medication regimens for patients in itself is difficult to accomplish. Adherence can be monitored via self-report, tablet counts at clinic visits, pharmacy records, analysis of drug metabolites, and even electronic monitoring systems. All of these methods have their own flaws; however, overall an objective approach to measuring adherence is preferred. In one study of 60 UC patients, electronic monitoring systems were used to evaluate adherence to 5-ASA medications and compared to self-report and tablet counts. The medication event monitoring system records the date and time of bottle cap openings and uploads the data to the physician. Over the 12-month study period, self-reported adherence was 89.3 %, tablet count adherence was 96.7 %, and electronic adherence was 89.2 % [43]. Taking this into account, it is likely important to incorporate some sort of medication adherence measure into clinic visits with IBD patients.

Patient Adherence to Health Maintenance

Not only medication adherence is important but also preventative care is extremely important for patients. For example, patients with UC and CD who have extensive or left-sided colitis are at increased risk for developing colorectal cancer. The AGA has published guidelines regarding surveillance colonoscopy in an attempt to detect early neoplastic lesions. Current guidelines advise a screening colonoscopy at a maximum of 8 years after the onset of IBD symptoms with multiple biopsy specimens obtained throughout the colon to assess true microscopic extent of inflammation [44]. Patients with extensive or left-sided UC are recommended to start surveillance 1–2 years after the initial screening, endoscopy, and after two negative examinations, this interval may be extended to every 1–3 years. Patients with UC and primary sclerosing cholangitis are recommended to have yearly screening starting at diagnosis of UC. IBD patient compliance with screening and surveillance colonoscopy has not been studied extensively. In an older study, Woolrich et al. [45] followed 121 patients with UC for 7 years. Seven patients developed cancer over this time and two of the seven patients had been noncompliant with colonoscopy recommendations. These patients had quiescent disease, and the authors concluded that asymptomatic patients were likely to have decreased adherence with screening and surveillance recommendations. In a larger and more recent cohort study involving three tertiary IBD centers, 400 patients with IBD were followed, and 25 % of patients were found to be nonadherent to recommendations for surveillance colonoscopy [46]. The majority of patients (80 %) were aware of the recommended interval. When asked why they did not follow the recommendation, they identified logistics, stress, health perception, and the procedure itself as reasons for postponing.

Another important preventative care measure in patients with IBD involves vaccinations. Often, IBD patients are immunosuppressed, and there are clear current guidelines regarding appropriate vaccinations (more details given below in the Sect. 1.5). Unfortunately, patients with IBD who are on immunosuppressive medications often are not getting correct vaccinations. A recent large national Internet-based cohort survey of patients with IBD in the Crohn's and Colitis Foundation of America (CCFA) Partners program was evaluated regarding vaccination status and beliefs [47]. Vaccination rates in this patient population remained suboptimal. Of the population, 81.5 % had received the influenza vaccine, but only 42.6 % had received the pneumococcal vaccine. Only 3.5–19.1 % had received counseling about the avoidance of live vaccinations while on immunosuppression. Patients with a primary care physician and who were on immunosuppression were more likely to get the influenza vaccine. Of the patients who avoided the vaccine, concerns about side effects, effectiveness, and worsening their IBD were cited as reasons for refusal. Those who refused the vaccine had a lower education level, were younger, and were not immunosuppressed.

Factors Associated with Improving Patient Adherence

Enhancing the patient–provider relationship can influence adherence, and therefore, cultivating this relationship should be a top priority. A prospective study of 153 IBD patients showed that 2 weeks after a clinic visit, 41 % of patients were nonadherent to a medication and that 81 % of these patients were intentionally nonadherent. Physician–patient discordance was one of the factors associated with intentional nonadherence [48]. The therapeutic relationship can be cultivated by giving time for patients to discuss concerns and ask questions. Physicians should not over- or underestimate patient understanding and use open questions during encounters. Interventions to improve adherence have been studied and can be grouped into broad categories including educational strategies, behavioral interventions, multifaceted interventions, and finally individual assessment [49].

Educational intervention has been studied in adult populations and aims to achieve patient "buy in" in regard to their disease. Patients do not know as much about their disease as physicians believe. In a study by Martin et al. [50] of 100 IBD patients, 62 % of UC patients and 78 % of CD patients reported feeling insufficiently informed about their disease in regard to etiology, diet, symptoms, treatments, treatment risks, cancer, and cancer risk. This makes educational intervention an attractive area for improving adherence. For example, a group of 70 IBD patients underwent a total of 12 h of instruction over 4 weeks by a gastroenterology nurse practitioner. Their adherence was compared to a standard care group of patients who had received educational pamphlets and physician education only. The educated group demonstrated a trend towards improved adherence over time [51].

Behavioral interventions with patients and providers can promote adherence by attempting to improve the logistics of taking a medication and by providing cognitive therapy. In regard to 5-ASAs, simplifying a regimen from multiple doses to daily dosing initially improves adherence as shown by Kane et al. [52] who studied adults with UC. At 3 months, there was 100% adherence in the daily dosed group versus 70% in the multiply dosed group. Cognitive behavioral therapy in IBD has not been specifically evaluated, however, potentially can be implemented to improve behavioral patterns to support adherence and alter thinking patterns that support nonadherence [49]. Practically speaking, providing patients with simple behavior interventions such as reminder systems (visual or auditory) and pillbox use can also improve adherence.

Multicomponent interventions are package interventions that combine strategies to enhance adherence. These are valuable in that they give patients the "best shot" at improving adherence; however, separating out specific interventions within the package that improve adherence can be difficult. For example, Cross et al. [53] intervened on UC patients with the UC Home Automated Telemanagement (HAT) program which consisted of providing patients with education, feedback on symptoms, self-management, and follow-up phone contact to change regimens based on symptoms. Adherence in the intervention group was higher at 12 months. Another example of packaged intervention comes from a web-based intervention developed by Elkjaer et al. [54]. UC patients were provided with disease-specific web-based education, feedback, and medication adjustment based on symptoms and additional interaction with providers via electronic messaging in the intervention group. Over 4 weeks, adherence to 5-ASAs was improved by an average of 37% compared to the standard care group. There were also less outpatient clinic visits in the intervention group which translated into calculated monetary savings.

More recent strategies for improving adherence focus on the individual rather than assessing risk factors across large populations. Figure 1.2 displays the emerging concept of individualized assessment of nonadherence [55]. After assessment of the

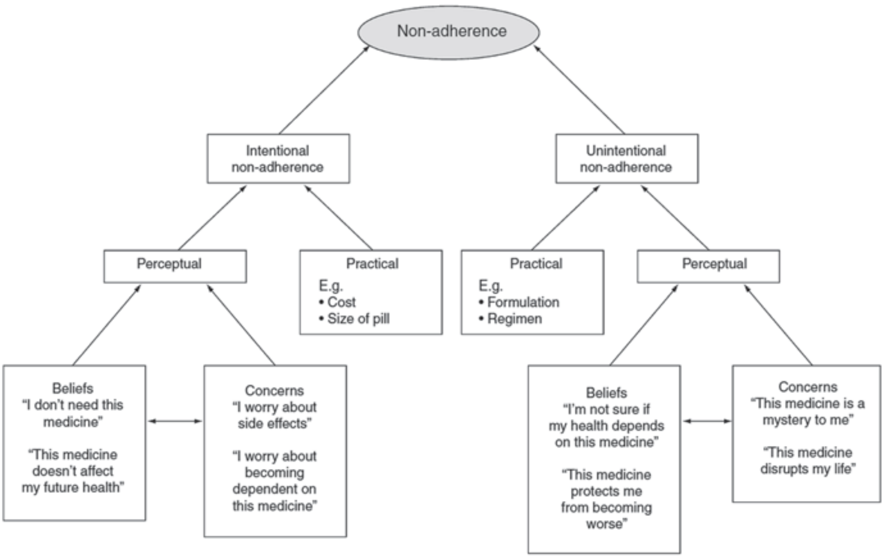

Fig. 1.2 Emerging concepts in nonadherence. (Adapted from Ref. [55] with permission)

individual attitudes and beliefs of a patient, the physician can then focus interventions on the underlying causes for nonadherence and hopefully improve outcomes.

Improving Quality of Care in IBD: A Physician and Community Effort

Successful outcomes in patients with IBD encompass much more than patient adherence. It also involves preventative care which has been increasingly recognized by gastroenterologists, societies, and health-care systems as an area of importance. There is an increasing emphasis on "quality of care" in chronic diseases, and this includes IBD. Quality of care, as defined by the Institute of Medicine, is "The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [56]. The concept of the "Triple Aim" in the area of quality of care involves believing that providing quality care will lead to improved individual outcomes, an overall improvement of health in the population, and reduced costs [57]. To interpret this into clinical practice, it is useful to assess concrete elements of quality, which are quality of care indicators. These indicators have been modeled in the Donabedian model into three categories: structural indicators (context in which care is delivered), process of care indicators (transactions between patients and providers), and outcomes indicators (effects of care on patients and populations) [58]. Specific examples of quality of care indicators in IBD include the measureable elements providers can report to CMS, which are listed in Table 1.1. Unfortunately, physicians often fail to give quality care. A 2005 study by Reddy et al. [59] evaluated 67 IBD patients who were getting care from a gastroenterologist and then sought a second opinion at a tertiary care hospital. Investigators found that many patients were not getting recommended therapy or appropriate medication dosing. In the previously mentioned National Inpatient Sample study, besides looking at race and surgical utilization, authors also investigated geographical patterns of care. Variation between colectomy rates was found. The northeast had lower colectomy rates than other regions of the country [22]. This may signify differences in practice patterns versus failure of providers to recommend appropriate surgical care. Because variation of care exists in the USA, it is possible that some of these variations could be leading to suboptimal care and outcomes within the IBD population.

The IBD community is working very hard to improve quality of care within IBD, and multiple societies are supporting initiatives. The AGA, as mentioned at the beginning of this chapter, has worked with the National Quality Strategy (NQS) framework to develop the quality indicators that have been incorporated into federal programs such as the PQRS. The CCFA has also initiated a quality improvement program with the hopes to integrate the program into both community and academic practices [7]. The CCFA first supported an initiative to identify the ten most important quality indicators in IBD [60]. Many of the measures are similar to the indicators reportable in the PQRS that were developed with the AGA and the NQS framework.

The quality indicators in Table 1.1 are goals that every practitioner should strive to achieve in IBD care. Vaccinating IBD patients is extremely important, and unfortunately, many IBD patients are not being vaccinated appropriately [61]. A survey of almost 1000 patients with IBD found vaccination rates for vaccines including zoster, human papilloma virus (HPV), meningococcal, pneumococcal, varicella, hepatitis B, and hepatitis A below 50 %, with the exception of the influenza vaccine which had a vaccination rate around 80 % [47]. Many patients with IBD are on corticosteroids, immunomodulators, and/or biologics, and use of these medications places this population at increased risk for infection. These patients are also considered to have altered immunocompetence, and this label may cause errors in physician recommendation for immunization. The Centers for Disease Control (CDC) has clear recommendations for immunization in patients with altered immunocompetence, including those on immunosuppression [62]. These patients should be given vaccines based on the Adult Immunization Schedule with a few important caveats. Unfortunately, gastroenterologists often have poor knowledge in regard to the appropriate vaccination guidelines for patients, as demonstrated in recent studies [63, 64]. For example, IBD patients receiving immunosuppressive agents should receive yearly inactivated influenza vaccine and should not receive the live intranasal influenza vaccine as live vaccines are contraindicated in patients who are immunosuppressed [61]. A recent survey showed nearly one third of gastroenterologists would mistakenly have recommended a live vaccine to a patient on immunosuppressive medications [64]. These patients should also receive vaccination for prevention of streptococcal pneumonia. As of 2012, the Advisory Committee on Immunization Practices at the Centers for Disease Control recommends that the vaccination should extend beyond the pneumococcal polysaccharide vaccine (PPSV23) and that the pneumococcal 13-valent conjugate (PCV13) vaccine should be administered as well, both are inactivated [65]. The abovementioned survey revealed that one half of gastroenterologists would withhold inactivated vaccines in their immunosuppressed patients. Therefore, it is important for gastroenterologists who care for patients with IBD to be adequately informed of the correct vaccine guidelines and ensure this is correctly discussed with the patient. Often, the patient will look to their gastroenterologist to help with these preventative care measures. There are other important vaccine caveats to remember as well. HPV vaccination is recommended by the CDC for females and males aged 9–26, and administration should be emphasized in the appropriate population of IBD patients on immunosuppression as immunosuppression can increase the risk of cervical dysplasia. In IBD patients who are not currently on immunosuppressive medications, it is important to think ahead and plan vaccinations if they are going to receive or expected to receive immunosuppression at any point during their disease course. Specifically, it is important to think about the zoster vaccine. This vaccine is currently approved for those over age 50 and recommended by the CDC for all patients over age 60. It is a live vaccine so it cannot be given to patients on immunosuppression. The biologic must not be started for a minimum of 1–3 months after the vaccine is given [61].

Another example of a quality of care component in IBD is regarding bone health, again an area not directly related to the gastrointestinal tract, but deemed an important component of quality of care. Patients with IBD have a higher risk of osteoporosis and fracture [66]. The etiology of bone disease is thought to be complex including factors such as corticosteroid use as well as increased bone resorption from inflammatory cytokines and decreased osteocyte viability [67]. The AGA published a position statement in 2003 [68] recommending a dual energy x-ray absorptiometry (DEXA) scan for postmenopausal women, men >50, patients with prolonged corticosteroid use, patients with a history of fracture associated with low trauma, and hypogonadism. They also recommended considering DEXA in IBD patients with risks such as use of methotrexate (MTX), cyclosporine, poor nutritional status, low body weight, smoking, excess alcohol use, and risk of falling. Some data are starting to emerge that in patients with IBD and low bone mineral density, medical therapy may be improving patient outcomes. A meta-analysis and systematic review showed that bisphosphonate therapy in this population was effective and well tolerated and reduced the risk of vertebral fractures [69].

It is important for gastroenterologists who routinely care for patients with IBD to understand that quality of care now extends beyond medications and into overall health including vaccine-related, bone health-related, smoking cessation, and cancer screening-related issues. It is important to educate patients, and now, increasingly, ensure that appropriate documentation regarding these health issues is recorded. There are increasing options to assist gastroenterologists and health-care teams in ensuring their patients are adherent to quality of care guidelines. For example, authors have generated worksheets to help practitioners ensure patients are getting the appropriate preventative care and that this is recorded properly. In an area of electronic medical record, many practitioners are adding documentation of items such as vaccine history and colon cancer screening into their patient's chart routinely to ensure it has been addressed appropriately. Gastroenterology societies have developed tools to help practitioners document and follow their adherence to quality of care guidelines. For example, the AGA along with the ACG and the American Society of Gastrointestinal Endoscopy (ASGE) has developed slides and webinars available to help practitioners navigate through the new quality reporting system in the USA, available on their website (http://www.gastro.org/practice/practice-management/aga-think-tank/preparing-gi-ascs). Also, qualified clinical data registries (QCDRs) have been developed as new reporting mechanisms for PQRS, an example has been developed through the GI Quality Improvement Consortium (GIQuIC), a project recently taken over by the ACG and ASGE (http://giquic.gi.org/pqrs.asp). All of these measures and more will help practitioners and health-care teams ensure patients are getting appropriate preventative and current standard of care to hopefully improve outcomes in patients with IBD.

Conclusion

Many factors are associated with barriers to successful outcomes in patients with IBD. Patient's understanding of their disease and risks and benefits associated with medications is very important and an issue that physicians and teams can continue to work on to improve. Patient medication adherence can be a huge hindrance to appropriate care in IBD and many often widely varying factors are associated with this. It can make improving patient adherence difficult, but several strategies can be considered, including education, behavioral interventions, multifaceted interventions, and finally individual assessments. Also, successful outcomes in IBD are no longer being measured simply by medication adherence. Preventative care has become a large component of quality in IBD as society and health care systems have shifted to focus on the comprehensive care of each patient. Physicians are increasingly becoming aware of the importance of preventative health assessments in patients with IBD, including things like vaccine-related issues, bone health, cancer prevention, and smoking cessation education. Improving physician awareness of preventative care, patient education, and documentation of these issues are increasingly important caveats as successful outcomes in IBD continue to evolve. Physicians, health-care teams, and patients will continue to work together to lead to successful outcomes in IBD.

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Chapter 2
Experience with Telemedicine Systems in Chronic Illness: What Can We Learn

Jessica A. Briscoe and Sandra M. Quezada

Introduction

The American Telemedicine Association describes telemedicine as the use of electronic transmission of medical information from one place to another to help improve patient care [1]. The devices and applications used for exchange of information have evolved significantly as society becomes increasingly more technologically advanced. Examples range from simple telephone monitoring to remote electronic monitoring devices or mobile phones transmitting data over a secure Internet server [1]. Health management and interventions through telemedicine have been examined not only in the context of provider-to-patient communication but also through provider-to-provider scenarios. There is an extensive body of research evaluating the role of telemedicine in clinical practice. With a steady growth in the elderly population, and vast increase in the health-care burden of chronic disease coupled with physician shortage, there is a need for enhanced and innovative methods for monitoring and managing patients [2]. Many postulate that telemedicine can help enhance long-term management of chronic diseases and thereby reduce the financial burden of care while improving outcomes.

Telemedicine interventions date back to the late 1950s. A Nebraska group utilized interactive television (IATV) for telepsychiatry consultation from an academic center to a remote psychiatric hospital [3]. These early methods were not sustainable, however, and with the conversion to digital technology and creation of the World Wide Web, telemedicine interventions became a more viable option with increased opportunity for its use in clinic practice [3]. Modern technology now allows for the use of smartphone data collection and transmission via Bluetooth to a secure Internet server for remote review by clinicians. In addition, videoconferencing for provider-to-provider teleconsultation and applications for patient self-management

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and empowerment are also a present reality. Telemedicine has been studied in several chronic diseases, and the data suggest that incorporation of this technology improves outcomes, quality of life, and could potentially decrease health-care cost in the future [4]. This chapter will review the current literature on the use of telemedicine in the context of management for several chronic diseases including asthma, chronic obstructive pulmonary disease (COPD), diabetes, heart failure (HF), hypertension (HTN), inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and hepatitis C.

Telemedicine and Chronic disease

Asthma

The Center for Disease Control (CDC) estimates that over 18 million adults in the USA have a diagnosis of asthma—incurring over 14 million physician office visits, more than 1 million emergency room (ER) visits, and billions of dollars in health-care costs [5]. Standard treatment strategies are aimed at reducing exacerbations, improving patient functional status, and preventing death [5, 6]. Management challenges encompass medication nonadherence and poor patient recognition of symptoms leading to delays in seeking medical care [7]. The goal of telemedicine is to improve patient education concerning their disease pathology, increase medication adherence, and prevent unnecessary hospitalizations, ER visits, and absenteeism of work/school [6, 7]. A 2009 non-blinded randomized study conducted in the Netherlands by van der Meer et al. utilized an Internet-based self-management (IBSM) model in addition to usual care and compared results to usual care alone [8]. Study participants included 200 patients with a diagnosis of asthma, age 18–50 years old, with at least a 3-month prescription of inhaled corticosteroids. The IBSM comprised a web-based profile in which patients reported symptoms electronically on a daily basis and completed an Asthma Control Questionnaire (ACQ) that was submitted weekly via their personal password-protected page. The Internet group received instant weekly feedback based on their ACQ for step-up or step-down treatment strategies. After a 12-month monitoring period, this study showed a significant improvement of quality of life, symptom-free days, lung function, and overall asthma control in the Internet group as compared to usual care [8].

In 2011, Mclean et al. performed a Cochrane review of 21 randomized control trials (RCTs) that evaluated telehealth management strategies of asthma. Interventions included provider phone calls, text messages, video conferencing, or other Internet monitoring. The studies evaluated various endpoints including quality of life, ER visits, hospital admissions, medication administration technique, peak flow recordings, and symptoms. They found no significant difference in quality of life or ER visits. However, there was a statistically significant reduction in hospital admissions in patients that received telehealth services evidenced by a relative risk ratio of 0.25 [9]. The authors do acknowledge that in many of the studies, patients that were randomized to control arms received “enhanced face-to-face care,” as opposed to standard care, which could diminish the apparent effect of the intervention [9].

Morrison et al. performed a systematic review in 2014 of articles that explored telemedicine in asthma management via interventions through the use of tablets/smartphones, computers, or a “purpose built electronic device,” as compared to usual care [6]. Of the studies included, usual care ranged from no intervention to enhanced care with multiple face-to-face teaching sessions and in some cases intermittent use of the intervention [6]. They evaluated ten review articles, including 19 unique RCTs, which included children and adults less than age 65. Primary outcomes in these studies included quality of life, activity limitations, lung function, medication use, and symptoms [6]. They determined that telemedicine techniques might be useful in improving medication compliance, patient knowledge and awareness, quality of life, and function. However, many of the studies used enhanced usual care as previously mentioned, which could confound the gravity of the effect of telehealth interventions in these studies. The authors also noted that exact mechanisms of technology use were vague and many studies did not discuss cost-effectiveness, patient accessibility, or socioeconomic status. Recognizing the limitations of the available data, telemedicine interventions certainly show promise in the chronic management of asthma; however, more studies are needed to determine its true impact and cost-effectiveness [6].

Chronic Obstructive Pulmonary Disease

COPD is defined by the American Thoracic Society as “a preventable and treatable disease state characterized by airflow limitation that is not fully reversible [10].” In 2010, the National Heart, Lung, and Blood Institute (as cited in *CHEST*) projected that COPD would incur approximately $29.5 billion in direct health-care costs in the USA annually, generating a substantial financial burden on the American population [11]. A hallmark of the disease course in patients with COPD is exacerbation of symptoms leading to decompensation requiring ER evaluation and treatment, medical or intensive care admission for management, and a resultant negative impact on the patient’s quality of life [11, 12]. There have been several studies and initiatives which incorporate telehealth monitoring for COPD patients. McLean et al. reviewed ten randomized control clinical trials that implemented telehealth strategies for COPD management in 2011. Primary endpoints evaluated over a 12-month period included number of ER visits, quality of life (measured by the St. George’s Respiratory Questionnaire [13]), number of COPD exacerbations, and death [14]. This review concluded that the use of telemedicine is associated with a significant reduction in ER visits (odds ratio 0.27), hospital admissions (odds ratio 0.46), and improvement in quality of life [14]. There was no statistical difference in mortality rates among groups.

In contrast, a randomized, multicenter, researcher-blinded study conducted by Pinnock et al. in 2013 reported no difference in outcomes with telemedicine management, including the number of exacerbations, quality of life, or hospital admissions [15]. This UK-based study included 256 patients diagnosed with COPD, with 128 patients randomized to telemedicine or standard care. Patients within the intervention arm had a home telemonitoring system installed with instructions on recording symptoms and pulse oximetry. A remote team would monitor electronically and provide treatment advice based on a standardized algorithm. After a year of monitoring and data collection, they concluded there was no significant clinical difference in telemedicine monitoring and usual care for chronic COPD management [15].

In 2014, Tabak et al. conducted a randomized pilot study that implemented a telehealth program based on four points of monitoring which included web-based exercise programs, an electronic activity monitor and smartphone for activity goals, online self-management modules instructing patients on how to treat exacerbations, and web-based teleconsultation options providing a venue for patients to ask questions of a physiotherapist [12]. Interventions were centered on improving physical activity and modifying behaviors. Out of 29 patients, 15 were randomized to the intervention group and 14 patients to usual care. While no clinical differences were demonstrated, the study was limited by a small sample size and high dropout rate of the control group. Despite this, there was a reported increase in patient satisfaction in the telehealth group.

Currently, the data on telehealth strategies in COPD management are largely inconclusive [12, 15, 16]. Many studies had small sample sizes, short duration of follow-up, and lack of standardization of telehealth methods resulting in insufficient evidence to support clinical use of telemedicine in COPD management [16]. Further research with larger RCTs is necessary before telehealth can be instituted into standard clinical practice for COPD long-term management.

Diabetes

Diabetes is a chronic disease that affects billions worldwide. The CDC estimates that approximately 29 million Americans have diabetes, of which about 8 million are undiagnosed [17]. Those affected experience significantly increased morbidity and mortality due to effects on multiple organ systems. In addition, diabetes contributes to substantial financial costs totaling over $200 billion in the USA alone [17–19]. Several studies support telemedicine management in diabetes evidenced by improved glycemic control demonstrated through a reduction in hemoglobin A1c (Hgb A1c).

Marcolino et al. performed a meta-analysis of 15 studies in 2013 aimed at determining the effectiveness of telehealth management in addition to usual care in type 1 and type 2 diabetics. Interventions ranged from nursing phone calls to full home telemonitoring devices that could transmit blood glucose values and blood pressure measurements to medical personnel [19]. They found a significant reduction in Hgb A1c, with a greater reduction in the first 6 months as compared to the 1-year follow-up. Secondary points included low-density lipoprotein (LDL) and blood pressure monitoring; however, no significant reduction was noted in these outcomes. A greater reduction of Hgb A1c was noted in the subgroup analysis for type 1 diabetics, which could be associated with age, as these patients tended to be younger and more technologically savvy, as opposed to the type 2 population [19].

In a meta-analysis by Zhai et al. in 2014, a statistically significant reduction in Hgb A1c was demonstrated among type 2 diabetic patients in the telemedicine intervention groups. They analyzed 35 RCTs, 19 of which employed an Internet-based module for telemonitoring. The remaining studies used telephone-based interventions [20]. The absolute reduction in Hgb A1c was actually reported to be small. Moreover, a slightly higher absolute reduction of A1c was noted in the studies that used telephone-based models (calls or text messages) in addition to usual care, as opposed to the use of Internet-based modules. The mean age of study participants in the trials included ranged from 42.5 to 70.8 years in the intervention groups and 42.3–70.9 years in the control group [20]. It is not clear why there was a difference between telephone and Internet-based modules; however, age could be a factor given that type 2 diabetic patients are typically older and more likely to be familiar with telephone-based communication compared to web-based methods.

Cassimatis et al. conducted a meta-analysis that reviewed the effect of telehealth interventions not only in terms of glycemic control but also examined dietary adherence, physical activity, and medication compliance in patients with type 2 diabetes [21]. Telehealth interventions utilized in the studies consisted of scheduled telephone calls from trained staff in addition to diabetes education, and one study also used periodic cell phone video messages on diabetes self-care topics. Glycemic control, physical activity, and dietary compliance were significantly improved in the telehealth groups [21].

Overall, current data suggest that implementation of telemedicine strategies in patients with type 1 and type 2 diabetes improves glycemic control, physical activity, and adherence to dietary restrictions [19–21]. However, although many studies report a statistically significant reduction in A1c, the actual reduction was less than 1% in many of the studies reviewed; thus, the clinical relevance of these interventions has yet to be determined and warrants further investigation [21]. Cost-effectiveness was rarely addressed in these studies, and thus the data available are not widely applicable to draw a definitive conclusion in terms of overall economic effect.

Heart Failure

The American Heart Association reports that approximately half of all patients with HF will die within 5 years of diagnosis [22]. As a result, significant research efforts have been dedicated to the optimization of its management, producing several landmark trials delineating treatment regimens that reduce morbidity and mortality. As with any chronic disease, patients with HF are prone to exacerbation of symptoms, prompting investigation into the role of telehealth management implementation. Goldberg et al. published an RCT in 2003, which included 280 patients and reported a 56.2% reduction in mortality at 6 months within the intervention group that utilized a telemonitoring system (AlereNet system). However, no significant difference in hospitalization rates was found [23].

In 2010, *The New England Journal of Medicine* published the Tele-HF trial, a large, multicenter RCT aimed at evaluating the effectiveness of telemonitoring in HF patients [24]. Over 1600 patients underwent randomization, and 826 were included in the intervention group. In addition to usual care, these patients received a Pharos Tel-Assurance device that gave them access to an automated phone messaging system to record their daily symptoms. The results were reviewed by clinicians every weekday, and any unusual symptoms prompted the clinician to call the patient and recommend further intervention if deemed necessary. The remaining patients included in the usual care group were given regular physician follow-up, HF educational material, and a scale for weight monitoring. Overall, the median age of study participants was 61, and over 70% of participants had an ejection fraction less than 40% with largely New York Heart Association (NYHA) class II and III symptom manifestations [24]. After 6 months of evaluation, there was no statistically significant difference found in time to readmission for HF, all-cause readmission, number of readmissions, hospital days, or mortality. It should be noted that the adherence rate in the telemonitoring group dropped from ~90% in the first week to ~50% by week 26, which is comparable to "real-life" adherence rates [24]. Additionally, no difference was noted in subgroup analyses including NYHA class, gender, age (<65 or ≥65), race, or ejection fraction. A German trial, TIM-HF, published in 2011, used mobile devices for blood pressure, weight, and electrocardiogram (EKG) monitoring and also found no difference in all-cause mortality in "remote telemedical management," [25] as opposed to usual care.

A meta-analysis by Clark et al. reviewed 13 studies in 2011 that evaluated the effectiveness of telemedicine in HF management. Out of the studies evaluated, 10 used mortality as a primary endpoint, and 5 of these showed a reduction in mortality favoring telehealth monitoring [26]. These studies consisted of a reasonable study group size of at least greater than 80 patients [23, 26]. Overall, the meta-analysis showed no difference in hospitalization rates with the use of telehealth monitoring, although the power to detect a difference may have been limited by a significant drop in admission rates in the beginning of the study period, although this eventually tapered off. Patients in the telemonitoring groups were reported to have significant improvement in quality of life, as measured by the Minnesota Living with Heart Failure and Short Form questionnaires [26–28].

In 2014, Feltner et al. reviewed 47 trials regarding the use of transitional care strategies in the management of HF which included home visits, structured telephone support, telemonitoring, and clinic-based follow-up. A significant reduction in morality and HF-specific hospital admission rates was identified over the 6-month study period in patients that received structured telephone support [29]. Overall, the data for the use of telehealth strategies in HF management have not demonstrated reproducible improvements in hospitalizations and readmission rates in this population. However, the possibility of mortality benefit and improvement in quality of life using telehealth warrants more investigation in this area. Standardization of techniques employed will be necessary to gain conclusive information.

Hypertension

HTN affects approximately 32.5 % adults over the age of 18 in the USA [30]. It has been well documented that uncontrolled HTN is associated with significantly increased cardiovascular risk and morbidity/mortality related to end-organ damage [31]. It has been identified as the "silent killer," battled by primary care clinicians every day. Blood pressure values fluctuate with stress, anxiety (white coat HTN), pain, and discomfort; therefore, in-office readings may not provide the most accurate depiction of blood pressure control, thus establishing a specific role for home blood pressure monitoring and telehealth interventions [31].

Abudagga et al. reviewed 15 studies on this topic, including ten RCTs, with a range of telemonitoring devices including self-blood pressure monitoring and phone reporting, blood pressure monitoring devices that link to web-based technologies accessible by clinicians, and 24 ambulatory devices [31]. Study durations ranged from 8 weeks to 2 years, and participant mean ages ranged from 51 to 76. The authors concluded that telemonitoring resulted in significant improvement of blood pressure, with reductions in systolic blood pressure by at least 10 points in six of the studies reviewed. Unfortunately, there are several limitations to these studies. Compliance with use of the monitoring devices was noted to decline over time, medication compliance was not addressed and could not be adequately assessed in many studies, and cost-effectiveness was largely not studied. Four of the aforementioned investigations addressed quality of life as a secondary end point and noted no significant difference [31]. A 2010 systematic review by Pare et al. on telemanagement of chronic diseases that included 17 HTN studies, also reported that research favors improvement in HTN management with the use of telehealth technology evidenced by reduction in systolic and diastolic blood pressure [4].

As previously mentioned, uncontrolled HTN negatively affects various disease processes, significantly impacting morbidity. The relationship between HTN control and diabetes and how it correlates with risk reduction is well documented, and current guidelines support more intensive control in this group of patients with these chronic diseases [32]. A Canadian study published in 2012 included 110 diabetic patients who were randomized to self-care support, that is, telemonitoring ($n = 55$) or control ($n = 55$). This study utilized 24 ambulatory devices that submitted blood pressure data over Bluetooth to a smartphone. Patients in the intervention group, in addition to usual care and regular follow-up, received electronic messages alerting them if their blood pressure was in the target range, and if values were outside the range, they would be prompted to contact their clinician. Subjects were monitored for 1 year. In this study, telemonitoring was associated with a mean decrease of 7.1 mmHg in systolic pressure compared to controls ($p < 0.005$). Furthermore, 51 % participants in the self-monitoring group reached their target blood pressure of < 130/80 as compared to 31 % of control subjects [33].

The data regarding telemonitoring, as related to HTN management, support the notion that these interventions are efficacious in reducing blood pressure. Of the literature reviewed, little data speak to the cost-effectiveness of these strategies. In an outpatient Scottish study in 2013, the clinical benefit of telemonitoring in blood pressure management was also confirmed, but with an associated significant increase in cost as compared to usual care [34]. That said, the duration of the study was brief (6 months) and cannot speak to future, long-term implications regarding decreased health-care costs as a result of risk reduction from improved blood pressure control.

Inflammatory Bowel Disease

IBD encompasses two disease entities, Crohn's disease and ulcerative colitis (UC). It is estimated that 1.4 million Americans suffer from IBD [35]. The disease course includes periods of remission and times of exacerbation, which can be extremely distressing to patients and diminish their quality of life. [36]. Multiple treatment regimens are available; however, medication noncompliance is a recurrent challenge in this population, resulting in high rates of relapse and increased health-care resource utilization [36]. Cross et al. published a pilot study in 2007 that included 25 patients to evaluate the feasibility of Home Automated Telemanagement (HAT) utilization [37]. Patients were required to do weekly self-testing in the form of a symptom diary via multiple-choice testing on a secure server. Data alerts were set to notify clinicians based on symptom scoring. In addition to self-monitoring, their software also included educational facts related to their disease from the Crohn's and Colitis Foundation, with related follow-up questions. This study reported 91 % of patients were complaint with the technology. The authors noted a decrease in the clinical disease activity using the Harvey Bradshaw Index [38] as well as a decrease in serologic inflammatory markers at 6 months follow-up. An improvement in quality of life was also reported, demonstrated by an overall increase in IBD-specific quality of life scores as measured by the Short Inflammatory Bowel Disease Questionnaire (SIBDQ) [37, 39].

In 2010, Elkjaer et al. conducted a study that utilized a web-based self-management and treatment approach as opposed to standard of care for 12 months [40]. The study was based in Ireland and Denmark and included 333 patients with mild to moderate UC. Only 135 patients completed the study. In the Danish arm, web subjects were more adherent with acute treatment, demonstrated improved knowledge of their disease and quality of life. There was no difference in disease activity, flare rates, or hospitalizations between the groups; however, intervention patients experienced shorter duration of relapses than the control patients. In the Irish arm, the results were similar; however, there was no difference in quality of life between groups, and the relapse rate was higher in the web group than controls. Web group patients underwent fewer routine and urgent visits; conversely, web group patients generated more emails and telephone calls. Overall, it was determined that web-based telemanagement strategies improved adherence to acute treatment and quality of life and decreased the amount of clinic visits [40].

Cross et al. published an RCT, UC HAT, in 2012 that included 47 UC patients, randomized to telemanagement ($n=25$) or best available care (BAC, $n=22$); only 14 patients in the HAT group and 18 in the BAC group completed the study. This study population was 66 % female and 53 % Caucasian. The intervention group received HAT monitoring, consisting of weekly recording of symptoms and medications which prompted a customized action plan based on symptoms [41]. Participants were monitored for 1 year. While the study revealed no difference in adherence, quality of life, or disease activity, there was a significant improvement in disease specific quality of life [41] in the HAT group as compared to the BAC group after adjusting for baseline differences between the groups.

A 2012 study by Penderson et al. investigated the efficacy of web-based monitoring of disease activity in Crohn's patients for individualized scheduling of infliximab (IFX) maintenance therapy [42]. They enrolled 27 patients, 17 of whom completed 52 weeks and 6 patients who completed 26 weeks of follow-up. The study subjects recorded their disease symptoms weekly via a web-based portal, and their symptoms were graded using a standardized scale. Based on symptom scores, patients were instructed whether or not to contact their physician for an IFX infusion. They found that 50 % of the patients were able to tolerate longer intervals (> 8 weeks) between infusions, 36 % required shorter durations (< 8 weeks), and only 10 % continued IFX infusions every 8 weeks. This study concluded that web-based monitoring is safe and effective for patient-based scheduling of IFX [42]. Additionally, Penderson et al. further investigated this concept in a 2014 study evaluating UC patients and web-based mesalazine treatments [43]. The study included patients with mild to moderate UC. Eighty six participants completed 3 months of web-based mesalazine therapy. Mesalazine treatment was individualized based on a disease activity index, which was a composite of clinical symptoms and fecal calprotectin levels. Use of the web application was associated with decreased disease activity scores and lower fecal calprotectin levels despite dose reduction in 88 % of patients at week 12. They concluded that web-based methods of treatment improve adherence to treatment and offer individualized care [43].

A 2014 meta-analysis reviewed six RCTs regarding the efficacy of telemedicine or remote management in IBD [44]. Three trials used telemanagement strategies [40, 41], and the remainder used patient self-guided management strategies and open-access clinics. The authors concluded that in all studies reviewed, there are trends toward improvement in quality of life in the intervention groups and that there was a significant decrease in the number of clinic visits [44]. These results show promise for the use of telemedicine in IBD management and suggest its use can yield more cost-effective management. Further investigation is warranted to assess the effects of telemedicine on adherence, hospitalization rates, disease activity, and management.

Irritable Bowel Syndrome

IBS is a functional gastrointestinal disorder that has been shown to significantly decrease the quality of life in affected patients [45]. There is no current diagnostic test to confirm the diagnosis, but rather a clinical diagnosis is made with a standardized evaluation of symptoms guided by the Rome III criteria, which includes abdominal pain and changes in stool frequency and consistency [45]. This syndrome is not associated with increased mortality risk; however, it incurs over 15 billion dollars in health-care cost due patient distress and impairment. Treatment is aimed largely at symptom management, utilizing pharmacologic and psychological methods [45].

Telemedicine has not been widely studied in this population, but available data show promise for web technology utilization. Enak et al. used a web-based questionnaire to collect data on symptoms and quality of life in IBS patients [46]. This study allowed open-access to their evaluation form through a unique website and demonstrated that web-based data collection was feasible in this patient population, yielding data that were comparable to other methods. In 2010, Ljotsson et al. developed an Internet-based cognitive behavioral therapy (CBT) model and aimed to investigate its effectiveness in patients with IBS [47]. Study participants consisted of 85 self-referred patients, randomized to the treatment group ($n=42$) versus control ($n=43$), with a diagnosis of IBS based on Rome II criteria. Participants were excluded that described symptoms that would warrant a clinical workup for organic causes including <2 years of IBS, rapid weight loss, bloody diarrhea, diarrhea-predominant IBS without endoscopic workup, or severe psychiatric illness [47]. Patients in the treatment group received a 10-week, 5-step, web-based CBT-protocol that included mindfulness strategies and examined the psychological effects of IBS. Twenty-nine of the 42 patients in the treatment group completed all five steps. Patients randomized to the control group were given access to an online forum (separate from the treatment group) where general discussions regarding IBS were held weekly. Control subjects were also allowed to contact a student therapist if they desired; however, they were not given any CBT-based therapy [47]. Patients who received the web-based CBT treatment were noted to have a significant improvement of symptoms measured by the Gastrointestinal Symptoms Rating Scale for IBS (GSRS-IBS) [48] and improvement in quality of life as measured by the Irritable Bowel Syndrome Quality of Life Instrument (IBS-QOL) [49].

Overall, the investigation of telemedicine methods in the IBS population is limited; however, preliminary studies incorporating web-based technology show promise for future management efforts. Additional investigation in this area is warranted as this disease contributes to significant health-care costs, high economic burden due to nonproductivity and missed workdays, and the significant social impact on quality of life in those affected.

Hepatitis C

Hepatitis C is a viral infection that affects approximately 130 million people worldwide [50]. Chronic infections can lead to cirrhosis and hepatocellular carcinoma. This disease poses a major public health issue and financial burden producing an estimated US$11 billion in health-care costs and upwards of US$50 billion in projected cost due to loss of productivity from disability and death [51]. In developed countries it is often transmitted via injection drug use, high-risk sexual practices, and transfusion prior to screening efforts [50]. The developing world continues to struggle with transmission through contaminated blood products and medical equipment [50]. Antiviral regimens have been shown to sustain viral load suppression and reduce the risk of progression to cirrhosis and hepatocellular carcinoma, but with the dynamic evolution of antiviral therapy and the complexities of its management, these patients are often referred to tertiary academic centers, and access to care remains a significant obstacle. As described below, telemedicine has provided a means to connect providers in rural areas to specialists and improve access to care and overall management of hepatitis C patients in these underserved areas.

Project Extension for Community Healthcare Outcomes (ECHO) based out of University of New Mexico School of Medicine, utilizes a videoconferencing network that connects primary providers in rural areas to an interdisciplinary team including gastroenterology and infectious disease specialists, pharmacists, social workers, and psychiatrists [51]. Once a new partnership is established with a rural clinic, telemedicine experts install local unique hepatitis C virus (HCV) management software developed by the Liver Research Institute in Denver, CO. Clinicians participate in an orientation and training at the university [51]. Upon completion of training, rural clinicians participate in weekly telemedicine conferences, presenting patients in a case-based manner and discussing treatment options. A survey from 29 providers participating in the project demonstrated that the program increased their knowledge of the management of hepatitis C, 92 % felt competent in management practices, and many listed the availability of a specialist as a major benefit [51].

A 2012 Australian study by Nazareth et al. showed that telehealth clinics were equivalent to face-to-face management for the treatment of hepatitis C [52]. Researchers set up telehealth clinics in rural Australia, operated remotely by nurse practitioners (NP). Patients referred by general practitioners met the following inclusion criteria: non-pregnant and non-breastfeeding adult patients over age 18 with compensated disease. NP provided consultation, treatment initiation, and follow-up via videoconferencing technology. Fifty rural patients were referred and started treatment with pegylated interferon and ribavirin. After treatment for 4 years, there was no significant difference in sustained virological response (SVR) in the telemonitoring group when compared to face-to-face care. Rosario et al. performed a retrospective study in 2013 on 80 HCV patients treated via telemedicine in California. This study also demonstrated that HCV patients can be safely managed by telemonitoring as opposed to face-to-face management as demonstrated by equivalent SVR in both treatment and control groups [53]. Current data suggest that telehealth strategies can improve access to care and provider competence of HCV management, telemedicine management is not inferior to face-to-face management, and this evidence shows that this technology can be utilized in the future to address the burden of disease worldwide.

Conclusion

Telemedicine incorporates the use of technology to enable clinicians to remotely manage medical illness. Current telehealth technology has evolved over the last 40 years to include smartphones, videoconferencing, web-based tools and applications [1]. The use of this technology is postulated to optimize patient care while concurrently decreasing health-care costs and economic burden. In this chapter, we have qualitatively reviewed current literature evaluating the application of telemedicine in various chronic disease states. In asthma, studies show that telemedicine can decrease the number of hospital visits and improve medication compliance and lung function [6–9]. The literature regarding telemedicine management of COPD is generally inconclusive but shows promise for reduction in ER visits, hospital admissions, and improving quality of life [12, 14–16]. In diabetes, studies collectively support telemedicine strategies for the improvement of glycemic control as evidenced by absolute reduction in Hgb A1c, although in many studies the degree of A1c reduction was not clinically significant [19–21]. The data are conflicting concerning the use of telemonitoring in chronic HF management. Overall, no significant difference is reported in hospitalization rates; however, some studies do recognize a significant mortality benefit in the telemedicine treatment groups [23, 26]. Telemonitoring intervention improves blood pressure control in chronic HTN management [4, 31, 34]. Initial data regarding the role of telemedicine in IBD reveal that these methods may improve quality of life and reduce provider visits [40–41, 44]. Conversely, the role of telemedicine in managing IBS has yet to be determined; however, initial studies show web-based CBT can improve quality of life and symptom control [47]. Multiple studies support the effectiveness of telemedicine via physician-to-physician and clinician-to-patient models in the management of Hepatitis C, extending the scope of practice and reaching underserved populations in rural areas [51–53]. The impact of telemedicine in the chronic disease processes reviewed in this chapter is summarized in Table 2.1.

While the overarching message in the existing literature supports the use of telemedicine in chronic disease management, there are some limitations in these studies, including small sample sizes, high dropout rates, lack of standardization of interventions which limits the determination of effect size and generalizability, and lack of cost-benefit analyses. The concept of age and technological awareness must be taken into consideration when assessing telemedicine systems as many of the patients with chronic illnesses grew up in a technological era that predates smartphone and web-based applications; thus, current interventions may need to be tailored accordingly due to limited scope of comprehension to help increase

Table 2.1 The outcomes of telemedicine in the management of chronic disease

Chronic disease	Study	Outcomes
Asthma	Morrison et al. [6]	Improved medication adherence, function, QOL
	van der Meer et al. [8]	Improved QOL, symptom-free days, asthma control
	McLean et al. [9]	Reduction in hospital admissions
COPD	Tabak et al. [12]	No difference in behavior modification or physical activity
	McLean et al. [14]	Reduction in ER visits and hospital admissions Improved QOL
	Pinnock et al. [15]	No difference in exacerbations, QOL, or hospital admissions
Diabetes	Marcolino et al. [19]	Reduction in Hgb A1c
	Zhai et al. [20]	Reduction in Hgb A1c
	Cassimatis et al. [21]	Improved Hgb A1c, physical activity, and dietary compliance
CHF	Goldberg et al. [23]	Reduction in mortality No difference in hospitalization rates
	Chaudhry et al. [24]	No difference in readmission rates, hospital days, or mortality
	Koehler et al. [25]	No difference in all-cause mortality
	Clark et al. [26]	No difference in hospitalization rates Improved QOL
	Feltner et al. [29]	Reduced mortality and HF hospitalization rates
HTN	Pare at al. [4]	Reduction in systolic and diastolic blood pressure
	AbuDagga et al. [31]	Reduction in systolic blood pressure No difference in QOL
	Logan et al. [33]	Reduction in systolic blood pressure
IBD	Cross et al. 2007 [37]	Decreased disease activity Improved quality of life Increased IBD knowledge
	Elkjaer et al. [40]	Improved adherence to acute treatment Improved QOL Decreased duration of relapses Decreased routine in urgent visits Increase in emails and telephone calls
	Cross et al. 2012 [41]	Improved disease activity Improved disease-specific QOL
	Huang et al. [44]	Improved QOL Decreased clinic visits
	Penderson et al. 2012 [42]	Individualized IFX treatment can be achieved without worsening clinical outcomes
	Penderson et al. [43]	Decreased disease activity scores Decreased fecal calprotectin levels Individualized approach to treatment resulted in decreased dose of mesalazine
IBS	Ljotsson et al. [47]	Improved symptoms and QOL
Hepatitis C	Arora et al. [51]	Improved physician competency and specialized resources
	Nazareth et al. [52]	No difference in treatment outcomes compared to face-to-face care
	Rosario et al. [53]	Equivalent SVR in treatment and control groups

COPD chronic obstructive pulmonary disease, *CHF* congestive heart failure, *HF* heart failure, *HGB* hemoglobin, *HTN* hypertension, *IBD* inflammatory bowel disease, *IBS* irritable bowel syndrome, *IFX* infliximab, *QOL* quality of life, *SVR* sustained viral response acceptance of the technology and retention rates. Provider-to-provider utilization of telemedicine has resulted in improved evidence-based practice and thus widens the scope of practice to reach the underserved. Further research, using large-scale RCTs, evaluating telemedicine in management of chronic diseases is warranted to further define its role in chronic disease management and its economic impact. As technology continues to evolve into more user-friendly applications, this may help decrease dropout rates and increase interest in telemedicine applications, both among patients and providers.

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Chapter 3
Telephone Encounters in Inflammatory Bowel Disease (IBD) Care: Burden, Risk Factors, and Opportunities for Intervention

Claudia Ramos Rivers, Benjamin H. Click and David G. Binion

Introduction: Telephone Communication in Health care and IBD

Telephone communication has become a central component of modern life in the USA. A study from the Pew Research Center's Internet & American Life Project recently reported that more than 90 % of the American adults own a cellphone; on average, each person spends 162 min per day on their phone [1]. In parallel with the growing importance, telephone communication in daily life has been the expansion of it as an integral part of health care in the USA. This is especially true for the spectrum of health-care telephone communication involving chronic illness, including inflammatory bowel disease (IBD).

The major forms of IBD, Crohn's disease (CD) and ulcerative colitis (UC), are most commonly diagnosed in young adults and characterized by lifelong incurable illness and chronic inflammatory damage of the gastrointestinal tract. The importance of telephone communication in the care of IBD has been in part driven by the young age demographic of these patients, the acuity and severity of their symptoms, and the rising cost of IBD care (which necessitates insurance authorizations for more expensive biologic agents). The telephone communication in the care of IBD in the USA is multidirectional, involving communication among patients, health-care providers, pharmacies, and payors (health-care insurers).

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Despite the central importance of telephone communication in chronic disease care, including IBD, there is surprisingly limited information regarding the spectrum of this activity. Our IBD Center at University of Pittsburgh Medical Center (UPMC) undertook a multiyear project to understand the spectrum and nature of telephone communication in the care of patients with CD and UC. Here, we highlight the frequency and characteristics of telephone encounters in the setting of IBD and potential novel uses of surveying telephone activity to optimize patient care. The rationale of this study was twofold. To quantify the volume of telephone calls being handled by the IBD center's nursing staff for the purpose of generating data to support health-care resource allocation on the part of hospital and clinic administration. This initial part of the study included categorizing phone calls coming into and out of the center and the parties involved in the calls (i.e., patients, pharmacies, and insurers). The second rationale was to perform an in-depth characterization of the reasons contributing to telephone activity in the IBD center, with a specific focus on the patient-specific characteristics, which corresponded with the increasing telephone communications. This granular analysis of telephone encounters recorded in the electronic medical record (EMR) provided insight into the patient characteristics of those individuals who called frequently and their more complex clinical patterns.The patterns of telephone activity acted as an "early warning mechanism" of patients who are at risk for future deterioration and needing to access more expensive emergency department (ED) and hospital care. Finally, patterns of telephone activity functioned as an agnostic phenotyping strategy, identifying a subgroup of heterogeneous patients with high levels of health-care utilization, which was driven by refractory inflammation, chronic pain, and difficulty coping with chronic illness [2].

The patterns of telephone activity can function as a proxy of disease severity, specifically how individual patients experience chronic illness and their ability to cope with these challenges. Thus, a surveillance of patterns of telephone activity would identify individuals who could be targeted for intervention, with the hope of improving their health status prior to needing rescue treatment in the hospital.

Telephone Communication in IBD: Clinical Burden

There is surprisingly limited information regarding the frequency and distribution of telephone calls in the delivery of health care and more specifically in the management of chronic illness. Published literature on the nature of telephone activity in health care has focused on the use of telephone communication, specifically between patients and nurses, as a strategy to avoid clinic encounters, reduce the length of hospital admission, and more recently as a component of telemanagement of chronic illness [3–6]. Telephone communication between patients and providers in between office visits provides opportunity to react to emerging problems early, with the hope of preventing the need for ED use and hospitalization, both of which would signify late intervention and further clinical deterioration.

Given the widespread availability of mobile phones, particularly in the young adult population, which is the major age demographic for IBD, the ability of patients to communicate with the health-care system is more commonplace now than ever previously, yet a characterization of the volume of this activity was not readily available, specifically regarding IBD.

The initial studies sought to characterize the volume of telephone calls that were handled by an IBD center nursing staff in the care of patients with IBD (i.e., CD and UC). The IBD Center at UPMC Presbyterian Hospital began a prospective evaluation of telephone activity in the care of IBD patients in 2009. The UPMC IBD Center is a tertiary referral clinic currently staffed by nine physicians dedicated to IBD care, ten nurses, three mid-level providers, as well as dedicated secretarial and scheduling administrative support. In the UPMC IBD Center, nursing staff handles the majority of incoming and outgoing telephone communication. Nurses kept track of every phone call either made or received at the IBD center. This included not only successful telephone communication but also unanswered calls and answering machine messages both retrieved and left by the nursing staff. We chose to make a complete tally of telephone activity, as attempts to include only specific subgroups were felt to be arbitrary.

The telephone calls were prospectively recorded on a daily basis. Given that the center was expanding throughout this time period, from three clinical attendings in the first half of 2009 to six physicians in 2010, there was a reasonable assumption and expectation that there would be a progressive increase in call volume from January to December. Over the course of a 2-year time period, there were more than 54,000 calls handled by the nursing staff. However, the actual pattern of telephone activity was variable, with call volume increasing and decreasing throughout the year. On an average, there was a monthly call volume of approximately 2000 phone calls. There were no annual patterns of peak or low telephone activity on a monthly or seasonal basis.

In addition to tracking the sheer number of telephone calls handled during routine work hours during this first part of the study, the nursing staff was asked to track the reason for the individual telephone call.

Categories for telephone calls were subjectively created, which included (1) patients calling into the center for questions/reporting clinical status, (2) nurses calling out of the center with plans/resolution of clinical issues, (3) refill requests, (4) insurance authorization, and (5) requests for the completion of forms. Over the 2 years, 44 % of the telephone calls were categorized as problem and/or follow up, 25 % were resolution and/or plans, 12 % were refill requests, 10 % were insurance authorizations, and the remaining were form completion and record requests.

There was a growing appreciation that telephone communication was not limited to direct contact with patients. Additional communication occurred between health-care providers, pharmacies, allied health-care providers including visiting nurse association, and payors. Contacting payors is an essential component in the delivery of IBD care, as it is mandatory to obtain preauthorization coverage for prescriptions and invasive diagnostic tests, both of which are frequently employed in IBD care. Negotiating with payors for preauthorization for biologic therapy and other prescriptions became a rising concern during the 2009 time period to the present in our center, and data on the burden of this activity required by nursing staff was lacking.

Analysis of the telephone activity handled by IBD center nursing staff demonstrated that subjective categories for annual patterns and characteristics of telephone activity recorded during the 2-year time period were essentially identical, despite the fact that new and additional nursing personnel were added to the IBD center during this time period. This internal validation of the categorization patterns suggested that the spectrum of telephone activity handled by the IBD center nurses was stable.

The most frequent type of telephone activity handled by the IBD center nurses was responses to patients who were calling into the center, which accounted for half of all telephone calls. Nurses calling patients with information/follow-up plans were an additional quarter of the total telephone activity. Thus, direct communication between nurses and patients accounted for three quarters of telephone activity in our IBD center. It is also important to note that attempts to communicate between nurses and patients involved significant “back and forth” between patients and the nursing staff, as missed calls and answering machine messages were approximately half of the telephone activity.

Telephone Communication in IBD: Risk Factors

In addition to characterizing telephone calls handled by the IBD center’s nursing staff, we sought to determine the contributing clinical factors associated with these calls. In order to determine these distinct clinical factors associated with telephone activity, we utilized a consented natural history registry, which has been maintained at the UPMC Presbyterian Hospital from 2001 to the present. These consented IBD patients have been tracked in a prospective longitudinal natural history registry linked to stable EMR-based data retrieval. Data are housed in a Health Insurance Portability and Accountability Act of 1996 (HIPAA)-compliant server, and the raw data are transformed into patterns of metadata, which are typically organized into annual patterns. This Institutional-Review-Board-approved registry was initiated in parallel with the National Institutes of Health IBD genetics discovery effort at the University of Pittsburgh School of Medicine and UPMC, and has been maintained and curated to the present time.

The telephone encounters are logged into the EMR prospectively. For our analysis, we focused on telephone encounters handled by gastroenterology. After calculating the median number of telephone encounters logged into the EMR on an annual basis, categories of annual telephone encounters were created [2, 7]. Patients were then categorized based on the following annual pattern of telephone encounters per year: 0–1 low telephone encounters (e.g., LTE), 2–5 annual telephone encounters, 6–10 annual telephone encounters, and >10 annual telephone encounters (high telephone encounters). When patients were stratified based on annual patterns of telephone activity, the distribution was skewed, as 14 % of patients accounted for 53 % of all telephone encounter volume, with more than ten phone calls per year per patient.[2, 8]

The initial analysis of telephone encounters in the care of IBD focused on overall relationships of this form of health-care interaction compared to clinic visits. On an average, there was double the number of telephone encounters than clinic appointments.

The majority of phone calls occurred during office hours, with only 2.7 % of the phone calls occurring after hours. [9]

Telephone Calls as a Severity Index

Till date, there is no standardized measure to evaluate the progress or deterioration of an IBD patient or the disease's impact on their life. Measuring telephone calls activity throughout a year provides a mechanism to stratify patient's disease severity.

When IBD patients were stratified according to their annual telephone activity, those who called more than ten times a year had higher rates of inflammation; measured by erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP) elevation as well as corticosteroid prescriptions compared to those who called either one or zero times [2, 7, 8] (Fig. 3.1).

Furthermore, high-frequency calling was associated with higher levels of abdominal pain measured by the sub-score of the Short inflammatory bowel disease questionnaire (SIBDQ; question 4), prescription opiate use, and neuropsychiatric comorbidity when compared to those who called less frequently [2, 8, 10, 11] (Fig. 3.1).

High-frequency callers had overall lower quality of life measured by an SIBDQ total score < 50 when compared to the IBD patients who only called 0–1 times a year (Fig. 3.1). Increased telephone encounter frequency was associated with significantly higher health-care utilization as patients who called more than ten times a year had a higher rate of ED visits and hospital admissions (Fig. 3.1) [2, 8, 12–14]. High-frequency callers that were admitted to the hospital displayed more complex and severe symptoms; they showed an overlap of abdominal pain, increased inflammation, and psychiatric comorbidities compared to those who called fewer times.

Similar to more frequent calling, after-hours calling was significantly associated with increased abdominal pain, poor quality of life, elevated CRP, elevated ESR, and higher rates of prednisone use (Fig. 3.2). Furthermore, after-hours callers had higher overall health-care utilization including ED visits, hospital admissions, clinic visits, and increased number of daytime telephone calls (Table 3.1). [9, 15]

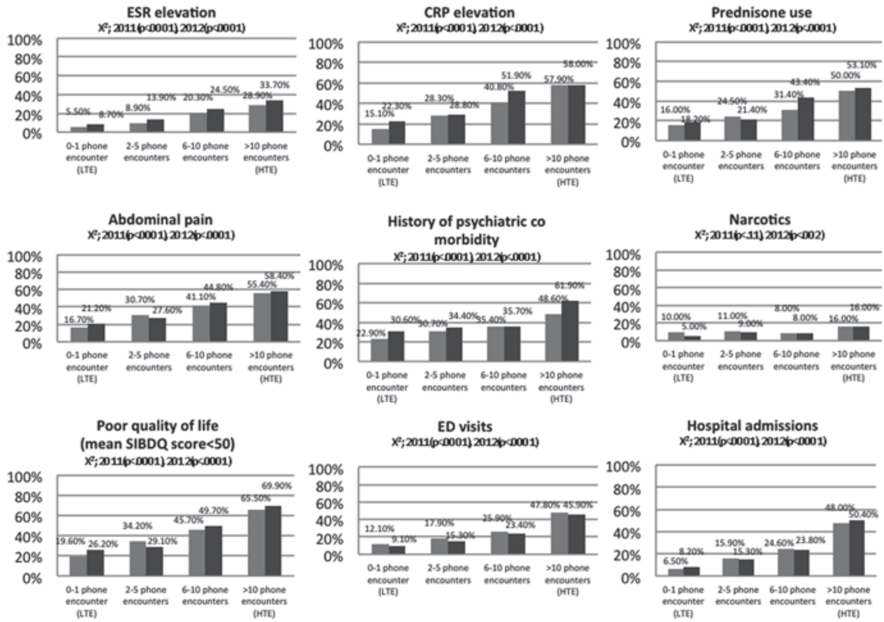

Fig. 3.1 Characteristics of telephone activity 2011–2012. (High frequency telephone encounters in patients with IBD were associated with increased *CRP* C-reactive protein and *ESR* erythrocyte sedimentation rate elevation, prednisone and narcotic use, abdominal pain, psychiatric comorbidity, poor quality of life, *ED* emergency department visits, and hospital admissions during 2011 (●) and 2012 (●))

Telephone Communication in IBD: Opportunities for Intervention

Telephone Call Frequency as a Predictor of Short-Term Health-Care Utilization

The organization of phone calls into clusters showed that increased telephone activity (more than eight phone calls) over 30 days was associated with increased rates of ED use and/or hospitalization over the next 12 months compared to those with only one telephone encounter. Therefore, patients with increased acute telephone activity may serve as a signal to providers of impending deterioration and patients may benefit from an urgent clinic visit and possibly a change in management. [2]

Telephone Calls as a Predictor of Health-Care Charges

In an effort to quantify health-care utilization in a single measure, financial charge data were obtained and categorized for a large group of IBD patients enrolled in the

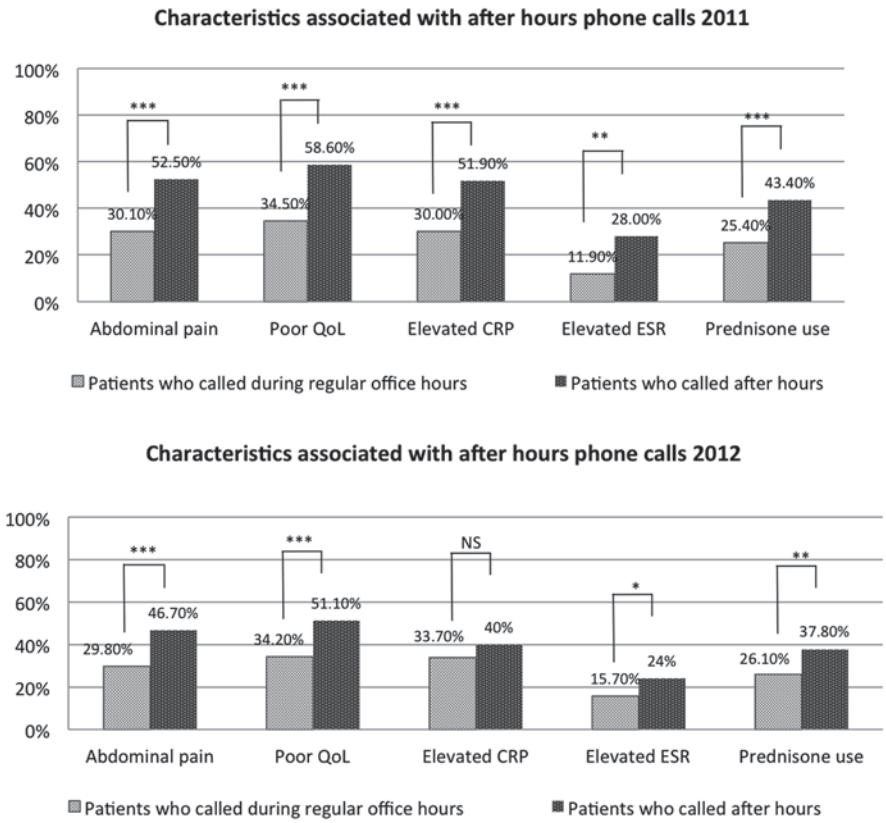

Fig. 3.2 Characteristics of after-hours telephone activity 2011–2012. (Patients who called after hours reported more abdominal pain, lower quality of life, higher rates of *CRP* C-reactive protein and *ESR* erythrocyte sedimentation rate elevation and increased use of prednisone for both years. $^*P<0.05$, $^{**}P<0.01$, $^{***}P<0.001$)

Table 3.1 Health-care utilization of patients who called during office hours and after hours

	2011			2012		
	Patients who called during regular office hours	Patients who called after hours	*P* value	Patients who called during regular office hours	Patients who called after hours	*P* value
Clinic visits	2.39 ± 1.9	4.83 ± 3.8	0.0001	2.55 ± 3.05	3.87 ± 4.2	0.0001
Phone calls during office hours	4.56 ± 5.3	16.93 ± 17.07	0.0001	4.04 ± 5.5	11.8 ± 12.5	0.0001
ED visits	0.39 ± 1.4	1.49 ± 4.7	0.0001	0.43 ± 1.6	2.19 ± 6.3	0.0001
Hospital admissions	0.29 ± 0.8	0.98 ± 1.6	0.0001	0.3 ± 0.97	1.22 ± 2.4	0.0001

ED emergency department

Table 3.2 Linear regression of telephone call frequency to predict total and future expenditures (natural log transformed)

Predictor year(s) (# telephone encounters)	Outcome(s) (total charges)	Coefficient	*P* value
2009–2011	2009–2011	0.024	<0.0001
2009	2010	0.037	0.02
	2011	0.013	0.28
2010	2011	0.054	<0.0001

UPMC IBD registry. Charges were categorized by inpatient hospital charges and professional service charges. Hospital charges included fees for room and board, administrative, medication, laboratory, diagnostic testing, and procedures that occurred when admitted to the hospital. Professional service charges included physician or specialized personnel fees for surgery, anesthesia, endoscopy, radiology, pathology, outpatient laboratory testing, outpatient diagnostic tests or procedures (e.g., echocardiogram, bronchoscopy), ED physician services, sex-specific health care (e.g., mammogram, prostate biopsy), and outpatient clinic visits. Finally, a summative total charge category was created by combining the professional service and inpatient related charges. The financial charges were compared to telephone encounter's frequency. Telephone encounter's count over 3 years was significantly associated with higher total charges over the same period (Table 3.2). Furthermore, telephone encounters in the first year were predictive of future expenditures over the following year. Therefore, increased telephone encounter frequency is associated with significantly higher health-care spending and is also a significant predictor of future spending. These findings mirror the aforementioned short-term health-care utilization patterns. There was a subgroup of patients who had consistently high telephone activity over the time frame of the study, and these patients accounted for a disproportionate allotment of all health-care charges.

Summary and Conclusions

In conclusion, telephone communication in the management of IBD is essential. There is a spectrum of telephone activity among the IBD population, and the increased telephone activity can be used as a surrogate marker of both disease activity and a consistent high health-care utilization subpopulation [16]. Given the time delay between increased telephone activity and risk of hospitalization, this period may represent an opportunity for possible intervention to prevent expensive health-care utilization.

As the cost of IBD care continues to rise among a heterogeneous population of patients, telephone communication represents a potential opportunity for health-care cost reduction [14]. Potential opportunities for intervention could include pilot programs of tracking phone calls with an alarm threshold to schedule an outpatient visit in order to prevent hospital admission[17]. Conversely, for those IBD patients with long-term quiescent or stable disease, the implementation of annual phone visits with a provider could represent another measure to help reduce the financial burden of IBD [18, 19]. It is important to acknowledge the under recognized and unreimbursed effort that is made by clinic support staff in the management of phone calls such that opportunities for intervention must account for these facets of clinic structure.

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Chapter 4
Teleconsultation in the Care of Patients with IBD

Andrew R. Watson

Introduction

Teleconsultation simply is the use of live video to see patients remotely, and represents the origins of telemedicine. The initial telemedicine trials as we know them today, and the basis for many large telemedicine programs started with live video clinics done at remote and typically rural settings [1]. When video teleconferencing became suitable for healthcare, patients could be seen at a distance with suitable fidelity. The rationale behind this was access to healthcare, as many times patients were not able to drive or could not afford to drive or driving was not an option due to geography, such as clinics in remote Alaska, rural America, or during inclement weather. In other words, telemedicine grew up and developed into teleconsultations.

Today, two of the largest programs in North America are based on teleconsultations-Avera and the Ontario Telemedicine Network [2, 3]. The most northern aspects of the province of Ontario are not accessible by road, and therefore telemedicine is naturally fit especially for subspecialty care.

The other reason why teleconsultation became a favorable method of practicing telemedicine is because providers did not have to travel. Physicians in essence run a small business, and therefore have to travel to access different patient referral basins. Travel meant less time in clinic, fewer patients booked, and fewer procedures performed. Therefore, the "windshield time" is the wasted time and inefficient and also not cost-effective. Telemedicine created a high degree of efficiency and began to cut down on provider travel and was thus more cost-effective.

Inflammatory bowel disease (IBD) adds a third dimension beyond geography and provider travel. Patients suffering with IBD have multiple confabulating factors that make travel impossible or difficult, and make urban clinics inaccessible. For one thing, patients with IBD can have disabling diarrhea, urgency to move the

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bowels, incomplete evacuation, and in cases of ulcerative colitis (UC) have to move their bowels multiple times an hour. Patients may stop eating the day before just to drive the clinic. Therefore, travel is not just about geography and provider convenience, but it is complicated by bowel function and inability to access toilets. Nausea and vomiting in the case of severe IBD are likewise disabling. Patients can also have difficulty taking extensive time off work as IBD can lead to medical absences, traveling a half day for clinic means more personal time off (PTO). Patients can have difficulties finding childcare. Patients can have difficulties paying for tolls, parking, and meals when traveling. In total, there is a fundamental assumption in healthcare that travelling is something that patients will do, and the setting of IBD this is not the case, and therefore patients may skip clinic visits, and lose access to healthcare. Teleconsultations represent a solution to these challenges.

The last reason why teleconsultations are valuable for patients with IBD is that the most complex patients demand subspecialty medical homes, the multiple subcomponents of the medical home are not readily available in real time or in typical face-to-face medicine. The ability to provide teleconsultations to complete the array of medical home participants/components is a significant advance in healthcare via technology and more specifically telemedicine.

Teleconsultations Defined

Teleconsultation is a live two-way audio video conference between a physician and a patient and nurse who are at a remote location. Traditionally, the subspecialist physician is in urban location/tertiary hospital. The patient and nurse are typically located in a rural health care facility and most commonly a rural hospital. As technology evolves, and video broadband becomes a commodity, these classic locations are being expanded to include medical office buildings, the home, mobile applications, and rural nonhospital locations. The expense of setting up video connectivity and the hardware end-points described below meant that the traditional urban doctor and rural patient/nurse was the model. Regardless, this is a doctor to nurse and patient live video conference.

The nurse at the remote location will place the patient in a room, they will gather information, such as a medical list/vital signs and send it via fax or scan or electronic health record (EHR) to the urban physician. During this process vital signs are taken, initial questions are answered, and if this is the patient's first time for telemedicine an overview is provided. The urban doctor will connect video in a point-to-point fashion using live video teleconferencing and will speak to both the nurse and the patient together.

The interaction with the nurse and patient answers basic and then more patient centric questions akin to a routine face-to-face encounter. The physician will have a dialogue with the patient and complete the history of present illness, confirm the chief complaint, and dive into significant details about the past medical history, past surgical history, family history, social history, and lifestyle factors. During this process the patient can ask questions, provide information, and if the family is in the room they will interact with the telemedicine physician in the same fashion as in person. By the end of this process, the subjective component of the examination is completed.

The next part of the examination is the objective part whereby the nurse examines the patient's serving as a proxy for the urban physician. Traditionalists describe the art of medicine as laying hands on the patient, in this new model of care the objective examination is the art of telemedicine. The urban physician observes carefully as the nurse examines the patient and describes the findings. Lymph nodes, tenderness of the abdomen, peripheral edema, and the expression of pus from wounds can all be described and simultaneously observed. There is an art to this that is learned through experience and careful attention. Video fidelity is critical during this process, because a grainy or frozen picture may significantly negatively impact the observation.

To augment this component of the objective examination, digital medical peripherals can be attached to the rural endpoint. This can include a digital stethoscope that will listen to high-pitched bowel sounds in the setting of a Crohn's obstruction, or a high definition wound camera to capture a peripheral lesion, such as pyoderma or note the drainage from a recent surgical incision. Other peripherals can include a laryngoscope looking for mouth ulcers, a blood pressure cuff, and an EKG that could provide a preoperative cardiac clearance. These medical peripherals are rapidly advancing and reaching a commoditize price that makes their prevalence larger, and hence the capabilities of the rural telemedicine clinics more sophisticated [4].

In most teleconsultation clinics physicians have access to radiology and laboratory data to complete the examination of the patient. Just like a face-to-face visit, physicians will consider the aggregated sum of data and then render an opinion. A clear assessment and plan is generated and given to the patient and the nurse at the remote location. A treatment plan can include ePrescribing to the patient's pharmacy, ordering additional diagnostic studies, such as a computerized tomography (CT) scan at the remote hospital, or it may involve discussing surgical options for more complicated cases. A comprehensive and effective examination is thus completed.

One of the main limitations of this process is examination of the patient's abdomen and the rectal examination. Subtle findings of fullness from a nest of Crohn's fistulas in the right lower quadrant, lateral tenderness on the rectal examination from an early fistula, or lateralizing colitis secondary to inflammation are subtle findings that may not be fully appreciated when you dissociate the expert watching the exam from the hands conducting an examination. This is why in many situations having an expert handle teleconsultation especially in more complex cases is an absolute necessity. Experts typically can pick up on very subtle findings by watching the nurse conduct examination. This also highlights the importance of the remote nurse who is conducting the examination. In almost all cases, the urban physician has the ability to discuss how they examine patients and the types of patients they expect to see with the remote nurse ahead of time. Many rural telemedicine clinics strive to use nurses who have specific skill sets in tele-examination so they can convey the necessary information. When nurses examine the patients, they typically speak aloud about what they are feeling, hearing, and seeing. This is a change from typical face-to-face visits, as physicians do not typically speak out loud and describe the data they are generating and accruing in real time.

At the end of the teleconsultation, all participants have the ability to interact and summarize the findings and plan. This is exactly same as a face-to-face clinic. Many times the remote nurse is responsible for ensuring the scheduling is coordinated for tests, such as laboratory studies or radiographic. If the teleconsultation is not taking place in a rural hospital, the nurse will almost certainly know the local environment and be able to help coordinate the necessary care. If the nurse is unavailable or unable to do this, frequently the urban physician has two options which are to have a nurse on the urban location watch the entire examination and coordinate care, or the urban physician can transfer the video call to a nurse and have them complete the necessary aspects of scheduling. This requires more sophisticated technology and provider savvy as they must initiate a three-party video call and then exit the call dropping it back to a two-party call between the urban nurse in the rural nurse/patient. With experience, this becomes a highly efficient way for urban physicians to see large numbers of patients leveraging multiple locations simultaneously.

Teleconsultations can be used for all types of patient visits, including preoperative visits, postoperative visits, new patient visits, inpatient rounding, and medical home type activities. As long as the patient has access to a secure video network and a nurse who can serve as the remote presenter, teleconsultations can serve any role for the care of the simple and complex-IBD patients.

Technology

The technology behind teleconsultations is reliant upon video teleconferencing hardware and software and in the rural setting typically a large screen display with attached peripherals.

The original model for teleconsultations relied upon practitioner carts which were vendor specific and required significant bandwidth. These carts had microphones, large screens, medical peripherals, and had the ability to dial each other point-to-point. This meant that the urban practitioner and the rural nurse needed to have the ability and know how to dial IP addresses or access a global address book of names. In the last 2 years, the maturation of hardware has enabled the urban practitioners to use commonplace standard hospital desktops or home computers with cheap USB cameras in lieu of the vendor specific cards. The calls are now brokered through central conferencing hardware the makes the process more seamless and more user-friendly. It also makes them more resilient to IT network outages, changes and router configuration, and software upgrades.

The rural or remote setting still requires a practitioner cart with the attached peripherals. The peripherals that were listed above are usually hardwired into this cart and require the nurse to manually switch between them. The maintenance, cleaning, and installation of these peripherals fall upon the remote hospital or facility and requires IT support.

In the past, consultations could be conducted with 512K video stream, and 768K was preferable. Nowadays, a 1 or 2 Meg video stream is the norm and with modern video codecs, high-definition images are becoming commonplace. The sophistication of rural broadband and the capacity of wireless long-term evolution (LTE) networks has led to much better video fidelity, and hence safer and more effective teleconsultations especially in the setting of IBD were subtle findings are critical to understand.

Network speeds are critically important as delays in network transmission lead to two significant challenges. One is the video picture becoming out of sync with the audio stream, which means that the patient is watching a physician talk and yet the audio is not heard until 1 or 2 s later. Secondly, the video can freeze or become pixelated or become jittery, which is equally as distracting as audio and video dissociation. These technical challenges can undermine patient and nurse confidence in a teleconsultation. They are much less commonplace now in the setting of advanced cellular and broadband technologies.

There is little doubt that as fields, such as telemedicine and remote patient monitoring advance, the spectrum of peripherals available will increase in the ease-of-use will simultaneously increase and become mostly patient self-service based.

Operations Behind a Teleconsultation

Performing a teleconsultation has multiple logistical concerns specific to the separation of the provider and patient. The greatest operational challenges lie in the IT space as described above, as the remote telemedicine endpoint needs to have access to broadband and medical peripherals. But there are additional considerations specific to teleconsultations.

The room itself must have two key features for a teleconsultation to be effective. First, having the room with no windows and closed blinds is critical, because the urban physician needs to see the patient clearly to adequately supervise a remote examination. In the setting of bright light from a light fixture or sun coming in through a window can make the patient disappear in the eyes of the camera or make the video image blurry. This is akin to looking into the bright sun and losing depth of vision. Therefore, careful consideration must be taken to the direction that the camera is facing and where the patient is located in relationship to light sources.

The other key consideration is ambient noise that can come from outside the room or from within the room. If the door is open, the sensitive microphones of the telemedicine endpoint can pick up patients talking in the hallway, electric doors opening or closing, or equipment moving down a hallway. This can leave the urban physician having to repeat themselves multiple times to get a question answered. Furthermore, small activities within the remote room, such as a patient opening a soda can, or someone unwrapping food can sound like loud windstorms or very distracting noises at the urban physician side. Care must be taken to minimize unnecessary noise during the teleconsultation. Another classic example of this is a physician's cell phone going off during the consultation that is projected and amplified to the patient and the near side. This could be both alarming and distracting.

Another key consideration is the workflow of the clinic especially when multiple patients are being seen. Physicians in the urban setting need to have a way of knowing when a patient is in the room and ready for a teleconsultation. Just connecting at random can lead to intrusive video connectivity while a patient is changing or makes the physician having to connect multiple times before the patient is ready. Modern telemedicine systems are able to interface with electronic health records and provide situational awareness about the status of the patients akin to normal face-to-face clinics. This makes clinics more efficient, and leads to an overall elevation and satisfaction.

Documentation of the teleconsultation can be on a local urban system that generates a printed report that is then faxed or digitally sent to the remote location. In more sophisticated settings the urban physician has access to the remote electronic health record and can dictate directly into it or into the remote dictation system. File transfers between software systems is also possible and effective.

The last major operational consideration is IT support when a telemedicine teleconsultation runs into technical troubles. This is a unique situation as compared to a face-to-face encounter. There needs to be a clear single number to dial so that immediate resolution is available for a broken remote endpoint, lost network connectivity, or a necessary hardware reset. Remote patients and nurses have high expectations and typically are not familiar with these events. If there is an absolute failure, it may be necessary for the patient to come back at another time, or a later day, or even have to drive into an urban setting and be seen later on that same day. This possibility is typically provided in writing in advance of the telemedicine clinic.

Outcomes from Teleconsultations

Teleconsultations are measured in a variety of fashions most of which are short-term, that have significant implications for long-term patient outcomes. As was recently published in the *New England Journal of Medicine,* longitudinal care of patients using telemedicine remains to be fully proven [5].

Provider systems using teleconsultations traditionally defined success based on the number of consultations conducted and patient satisfaction survey scores. To bring about large-scale teleconsultation activity requires significant operational efficiency and urban physician engagement. Therefore, as provider systems raise the numbers into the thousands and tens of thousands and that time hundreds of thousands it represents the success of the clinical and operational marriage. Patients are also surveyed at the end of the encounter and by and large the satisfaction surveys are based on the experience and convenience, these are typically very favorable [6].

When presented with significantly less travel in typically free parking there is no wonder satisfaction survey results are so favorable.

More advanced programs will measure technological success in terms of the absence of reported IT failures, the use of multiple endpoints, highly efficient mobility, and background software updates. As telemedicine becomes just “medicine” and the IT becomes invisible this is a tremendous success.

Patient success and outcomes aside from satisfaction surveys are less visible but very important. Avoided time off work, not paying for gasoline for extensive travel, not having to pay for child care, not having to pay for meals while traveling, not paying for parking, and not paying for tolls can add up to a range between $100 and 250 and greater depending on the degree of plurality. Between the islands of Hawaii or the most rural aspects of Alaska this figure can be much greater due to avoid airfare [7].

Providers likewise can view outcomes in terms of less travel, more patient seen, more procedures performed, more operations performed, and more efficiency in clinic for patients are being roomed simultaneously in a tele-clinic and a face-to-face clinic. Windshield time is in effect hemorrhaging money for a provider and administration.

The most important outcome is the clinical outcome. A teleconsultation clinic should be as good as a face-to-face clinic. With an experienced physician and experienced nurse presenter this should not be a problem. Failure to recognize the surgical complication, not escalating medical therapy, inappropriate ePrescribing to date has not been seen with the use of teleconsultations. In many ways, we see that rural patients are more likely to skip clinic visits, and therefore create gaps in care when they do not have the ease of access as is provided by teleconsultations. This is very difficult to measure, and hard to quantify, but at some point it simply makes sense and tertiary providers see this on a regular basis when patients cancel clinic appointments due to inclement weather or the most complex patients failed to show up as they cannot drive or do not have someone that will drive them. This last point is perhaps the greatest and most significant and hardest to quantify outcome of a teleconsultation clinic.

The longitudinal care of a patient that is cared for using teleconsultation and most likely in combination with face-to-face encounters has yet to be studied. Clearly, this cannot be a blinded prospective trial. Furthermore, when the model of the medical home was created, there was a baseline assumption that the patient would be seen face-to-face by all subcomponents of the medical home. Clearly, it is impossible for all medical home providers to see the patients in real time face-to-face together. But, with teleconsultations this could become a reality, or in a modified form with the patient seen in sequence by all providers on the same day and in series. This could be a significant advance over face-to-face medicine and represent the greatest clinical outcome. This will need to be studied and evaluated as telemedicine continues to expand.

As the era of telemedicine remote monitoring evolves, it is currently still in its infancy, satisfaction surveys and remote biometrics will feed into teleconsultations and significantly augment their accuracy and completeness. This will only enhance the outcomes and in particular the longitudinal care of IBD patients.

Moving forward, the success of teleconsultations will be dependent upon the success of the medical home in managing complex-IBD patients. The use of psychotherapy, care managers, nutritionist, G. I. medicine, IBD surgeons, and pharmacists will be the core of the medical home team. Without a substantial investment in clinical time and resources, it will be impossible for this diverse array of skill sets to be together in real time. Therefore, teleconsultation has the ability to truly impact the coordination of care, the cost of care, the cost of pharmaceuticals, and the longitudinal outcomes of the IBD patient population. In particular, the hot spotting super utilization by an extreme subset will be the most likely target for effective utilization teleconsultation.

Risks and Limitations

There are multiple and classic limitations and risks that are associated with teleconsultations. One of the greatest limitations is the ability to bill for traditional fee for service encounters. Currently, almost half of the states in the USA are mandating third-party payer reimbursement for telemedicine. Furthermore, Center for Medicare and Medicaid Services (CMS) is close to dropping its rural health professional shortage area restriction for the practice of telemedicine. There are areas of urban underserved populations as well as the typical definitions of rurality, which limit the expansion and utilization of tele-consults in the setting of IBD patients and tele-consults in general. As accountable care organizations and risk bearing entities make their entry into healthcare, teleconsultations will become less dependent upon fee-for-service billing and more valuable as a care coordination and risk mitigation strategy.

State licensure continues to evolve, the recent Federation of State Medical Boards' ruling opens the door for a more seamless practice of teleconsultations and telemedicine in general. This means that urban settings—such as Pittsburgh that serve West Virginia, Ohio, Maryland, in Pennsylvania—can seamlessly serve the patient population using teleconsultations. At the current moment, a provider in Pittsburgh is unable to practice telemedicine in Ohio without a telemedicine license in Ohio. Strangely, patients who drive from Ohio can be seen in a face-to-face fashion in Pittsburgh without the Pittsburgh provider having an Ohio license.

Medical malpractice has not dominated the telemedicine landscape today, and there has not been any significant expansion in this arena yet. At some point telemedicine malpractice should logically reach the same level as typical face-to-face encounter malpractice claims. On one hand you could expect that the logistics and slight limitations of telemedicine could lead to a higher rate of malpractice. On the other hand, one might see remote and rural settings facing malpractice claims by not offering telemedicine access to urban experts especially in the setting of IBD.

Diseases, such as IBD are some of the most complex and the most expensive in the USA.

Summary

In conclusion, teleconsultations represent the consumer electronics market entering healthcare. It is only natural that patients and providers start to utilize video in healthcare much like we use video for Skype calls or Face Time calls. As innovative technologies, such as the Apple watch and other consumer grade peripherals start to gather biometric data, teleconsultations will be augmented with datasets representing longitudinal biometric parameters and treatment successes. The expansion of cellular networks in the same fashion will allow for more efficient expansion of teleconsultations to remote rural as well as home-based encounters. The most complex-IBD patients who are most likely to be the super utilizers will now be accessible at home for more frequent and coordinated care. There is no doubt this will impact the longitudinal care from a clinical and financial standpoint.

Teleconsultations in general represent the origin of telemedicine as we know it today, and telemedicine has evolved in many diverse ways, such as patient portals, remote monitoring, and in-patient telemedicine, but the standard teleconsultation is the most powerful way to interact with and treat IBD patients over the long term and in a coordinated fashion. Many of the limitations the traditionally hampered teleconsultations appear to be going away, therefore we would expect the future in rapid expansion of this new model of care throughout the USA regardless of geography in caring for IBD patients.

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Chapter 5
Self-Management Techniques in IBD

Laurie Keefer and Sunanda Kane

Introduction

Lifelong management of inflammatory bowel diseases (IBDs) encompasses a range of medical and surgical approaches designed to maintain disease remission and optimize quality of life, including acute symptom management (flares), flare prevention/maintenance of remission, colon cancer surveillance, monitoring of comorbidity, and the consequences of complex medication regimens [1, 2]. The irony of this modestly effective approach to IBD is that, irrespective of the strength of an IBD care team, an individual will still likely spend less than 3 h per year obtaining care or in communication with their provider(s) [3] and the rest of the time managing uncomfortable and embarrassing symptoms, disability and functional impairment, complicated medication regimens, demanding lifestyle changes, and coordination of medical care and health insurance on his/her own [4, 5]. In other words, *everyone with IBD self-manages, however well or poorly that management might be*.

In a changing health-care climate in which national priorities of reducing costs and improving quality focus largely on prevention of health episodes in which health-care costs are highest (reducing readmissions), incentivizing collaborative care, patient education, and transparency (meaningful use) and emphasizing patient and provider responsibility for long-term outcomes [6], effective patient self-management is more important than ever.

In this chapter, we (1) define self-management and discuss the unique features of IBD which make self-management particularly challenging, (2) describe the role of self-management support, including health-technology-enabled support, on health

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outcomes in IBD, and (3) discuss the importance of social-cognitive theory in the development and implementation of self-management support for IBD, including the types of techniques and constructs which fit within this model.

Defining Self-Management

Self-management is a behavior that cannot be avoided—rather, it is one which operates on a continuum of healthy to maladaptive. The goal of self-management is to engage in a set of behaviors that allows one to maintain emotional and physical wellness in the setting of chronic disease over time. "Good Self-Managers" have been characterized by Dr. Kate Lorig, a pioneer in this area as "individuals with chronic diseases who make informed choices, adapt new perspectives and generic skills that can be applied to new problems as they arise, practice new health behaviors, and maintain or regain emotional stability" [7].

Self-management of chronic illness is characterized according to the degree to which someone can effectively engage in three interrelated tasks: (1) medical management (medication adherence, decision-making, disease knowledge, patient–provider relationship or communication), (2) preserving or creating meaningful life roles in context of the limitations a disease presents, and (3) acknowledging and managing the emotional or psychological impact of chronic disease. Within each of these self-management tasks, there are five core skills that determine one's success—these include (a) problem-solving, (b) decision-making, (c) resource utilization, (d) forming a collaborative relationship with a health-care provider, and (e) taking action/implementing change (Fig. 5.1; [7]).

The Self-Management Challenge in IBD

Not surprisingly, the majority of self-management interventions in IBD are based on the task of medical management and the skills of problem-solving, resource utilization, and decision-making. However, self-management is more complex than this. Indeed, the risk of flare as well as the efficacy and dosing of medications required to induce and sustain remission is directly influenced by self-management behaviors, including adhering to medication [4, 8–20], managing stress and psychological well-being [21–30], coping [29, 31, 32], managing the patient–physician relationship [10, 15, 33–36], smoking [37, 38], and maintaining relevant disease knowledge [35, 39–41]. There are several reasons why self-management of IBD is such a challenge:

1. IBD differs from many chronic diseases in that, even when patients are optimized medically and "doing everything right," disease flares can still occur.
2. Because the majority of patients are diagnosed between the ages of 15 and 35, they cycle for decades with periods of acute symptom management (disease

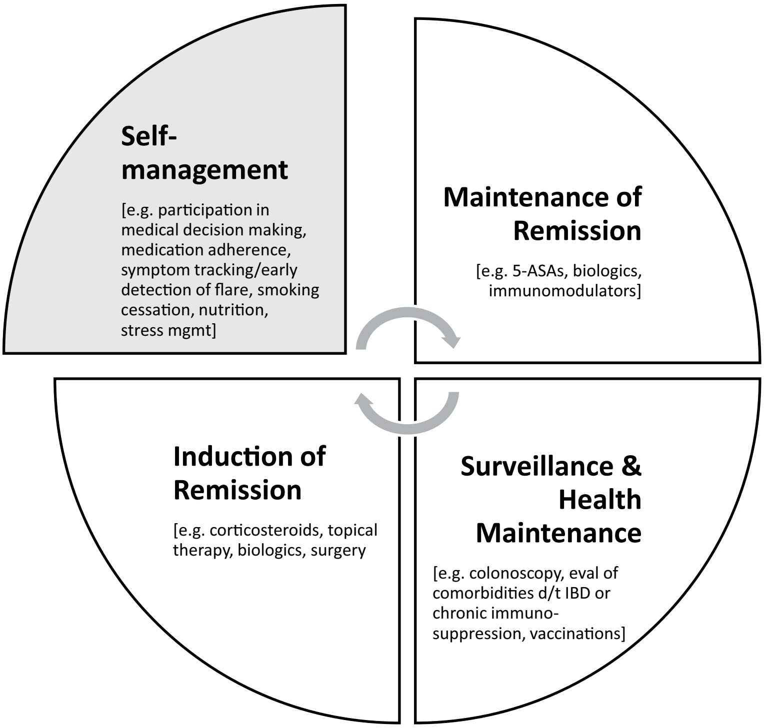

Fig. 5.1 Components of effective inflammatory bowel disease *(IBD)* management

flare), flare prevention (maintenance medication), cancer/risk surveillance, and lifestyle modification (Fig. 5.2).

3. Disease parameters, psychological well-being, and quality of life are directly affected by where a patient fits in terms of flare versus remission [42], their current treatment regimen (e.g., corticosteroid use) [43], and access to quality care [44].
4. In addition to shifts in disease course and cycle, as patients age with the disease and meet developmental milestones, there are critical shifts in social support (e.g., young adults moving out of the home with caregivers), financial resources, stressors, comorbidity, and self-management skills are readily impacted [45].
5. IBD symptoms themselves (fatigue, urgent diarrhea) affect one's ability to engage in complex disease management behaviors such as coordinating care across providers, especially if a patient is receiving treatment across different hospitals and emergency departments, making decisions based on evidence and nonphysician recommendations (e.g., online resources), deciphering test results, storing and organizing medications over multiple settings, and implementing behavior change in multiple contexts [46].

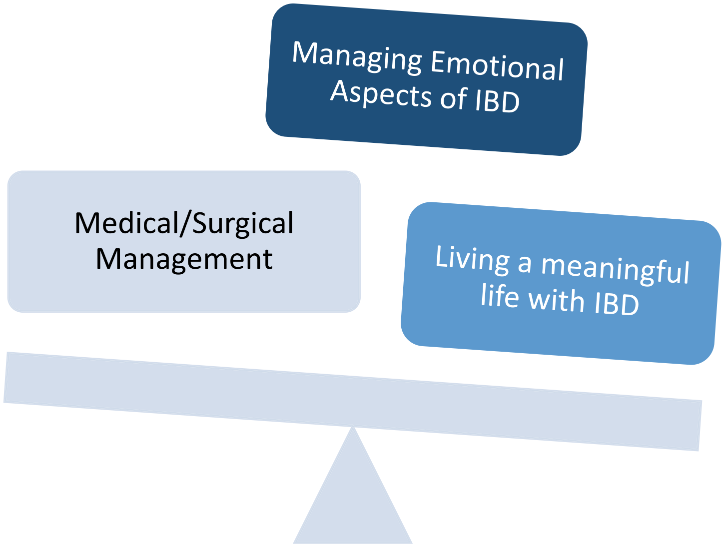

Fig. 5.2 Primary tasks of effective self-management

6. Self-management skills are further complicated by sociocultural barriers, including access to care, health literacy, social support, language, and access to online information [46].

Unfortunately, not all patients are successful in all aspects of self-management. Indeed, IBD patients who have difficulty adapting to disease-related demands report more bowel and systemic symptoms, more pain, less engagement in activities, higher perceived stress, an emotional representation of illness, and higher health-care use [41].

Self-Management Support

Strong self-management skills and high patient engagement lead to healthy outcomes in IBD [13, 47]. Self-management support or the use of behavioral tools and techniques to foster skills building and self-efficacy, when properly administered, can dramatically improve health outcomes [48]. Self-management programs that address a patient's chronic disease in context can ultimately improve the efficacy of treatment through improved disease knowledge, improved communication, increased adherence, better self-monitoring, less health-harming behaviors (smoking), and better self-care [49]. As such, when treatments are more effective, outcomes improve quality of life, decreasing disability, reducing need for surgery shortening flare course, and decreasing health-care costs [50]. Figure 5.3 represents a model linking self-management support to health outcomes.

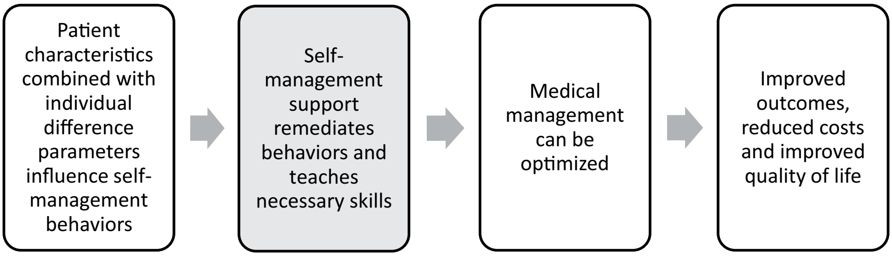

Fig. 5.3 Relationship between self-management support and outcomes

Effective self-management is based on the accomplishment of tasks and building of skills over the entire course of a disease. Again, the core skills that determine one's self-management success include (a) problem-solving, (b) decision-making, (c) resource utilization, (d) forming a collaborative relationship with a health-care provider, and (e) taking action/implementing change [7]. For most individuals, developing and refining these skills requires varying degrees of self-management support over time. Indeed, optimizing self-management support has been an increasing focus of governmental and health-care organizations, described in the famous "Crossing the Quality Chasm" report from the Institute of Medicine [51], and as implemented in patient-centered medical homes and mandated in the Patient Accountability and Affordability HealthCare Act (H.R. 3590, 2009).

Self-management support programs are typically problem based, meaning they identify and promote the development of skills that solve a critical aspect of disease management. Tools or programs which support skills such as improving medication adherence, increasing disease knowledge, implementing decision-support tools, or optimizing communication between patients and providers are all problem-focused ways in which IBD self-management can be readily supported. For a review of self-management/education programs in IBD, see C. Barlow et al. [52].

Self-Management Support Through Psychotherapy

Most self-management support programs in IBD and other diseases focus primarily on the core task of medical management, with less emphasis on preserving or creating a meaningful life or managing the psychological impact of the disease. The exception to this is the use of psychotherapy in patients with IBD. A review of 18 behavioral trials for IBD demonstrated that brief, problem-focused psychotherapies such as cognitive-behavior therapy may actually show promise with respect to reducing pain, fatigue, relapse rate and, hospitalization and improving medication adherence [53]. This notion is supported by the work of Knowles and colleagues, who point out that if psychotherapies are grouped according to their theoretical approach, skills-based interventions for IBD tend to have slightly better impact [54]. More traditional psychological interventions, a.k.a. "talk therapy" which have the potential to affect self-management tasks 2 (meaningful life) and 3 (psychological impact) in addition to medical management, have also been employed in IBD with mixed results—unfortunately, many of these programs did not address disease-specific concerns [50–57] or limited their scope to IBD patients with frank depression or anxiety [54, 57, 58].

Self-Management Support Through Health Technology

Chronic disease research suggests that the degree to which patients can fully engage in their health care is determined by the extent to which they can access culturally, linguistically appropriate information directly relevant to their specific disease state or concern at the exact time they are looking for it [55–62].

Mobile and web-enabled self-management solutions can drastically reduce the environmental barriers for a wider overall reach, heighten the cost-saving economic impact of chronic illness self-management programs, and address accessibility factors associated with disease outcomes, including the timeliness and pertinence of both support and disease information. By providing these, tailored to the individual, mobile self-management solutions are limited in access only by one's ability to connect to the Internet [63].

Health information technology in the form of online support groups, social networks, and education platforms are adopted and used by a modest subset of IBD patients demonstrating patient interest and potential or perceived benefit [47]. As we discussed previously, the self-management demands of IBD are long term and constantly changing, which makes it difficult to keep content and tools relevant. Table 5.1 lists examples of health information technology (IT) self-management tools.

Social-Cognitive Theory and Self-Management Support for IBD

While traditional self-management programs targeting a single problem can be quite effective, self-management support initiatives may be better suited to approaches which integrate the complex interactions between the thoughts, feelings, and behaviors that accompany IBD (patient modifiers) and the physical and environmental demands the disease presents (disease modifiers). Social-cognitive theory can be readily leveraged for the development of self-management support tools for IBD. In this model, knowledge about the importance of a skill is a necessary but not sufficient way to promote health behavior change. Rather, individual perception (perceived risk, trust in medical provider), motivation, skills, and the environment are all important contributors to a patient's ability to adapt to ever-changing disease-related demands (Fig. 5.4; [69]).

Table 5.1 Common categories of problem-based online disease self-management tools

Medical advice/disease knowledge
Online conversations cover a wide spectrum of health-care and lifestyle topics and serve as a place where personal information is freely shared and important decisions about treatment options are openly discussed. While physicians who provide answers to questions posed by patients online may have their best interests in mind, the unstructured and uncontrollable nature of online discussion may result in incomplete portrayals of patient and disease profiles and render patients susceptible to inappropriate, potentially detrimental, and/or suboptimal recommendations. Foundation-sponsored patient education websites (e.g., www.ibdetermined.org) target a relatively small subset of highly motivated, high health-literate patients [64] who do not require the tailored, specialized structure and motivational components which consider individual lifestyle, disease characteristics, and personal preferences to foster effective disease self-management [47]
Social-support tools
Online peer support networks provide reported social and emotional benefit to patients [65, 66] and potentially provide insight into beneficial disease self-management practices, but the uncontrolled nature of peer-to-peer interaction and unknown agendas of website users also puts patients at risk for exposure to inaccurate information and could undermine the collaborative decision-making process between doctor and patient
Symptom-tracking tools
There are now over 5000 medical applications available to download from various web and mobile application stores, and the number continues to rise as health-care digitization continues [67]. One IBD example is from the Crohn's and Colitis Foundation of America (CCFA), who released the web- and mobile-enabled app "GI Buddy" in January 2013, which features a set of tools focused on different tracking activities. While the barriers to access are low in this format, motivation to continually engage with these applications is lacking
Decision-support tools
Decision-support tools are developed in an effort to make complex medical information (e.g., on biologics and dual therapies) easier to understand, allowing patients to make informed medical decisions in line with their personal preferences for treatment [68]

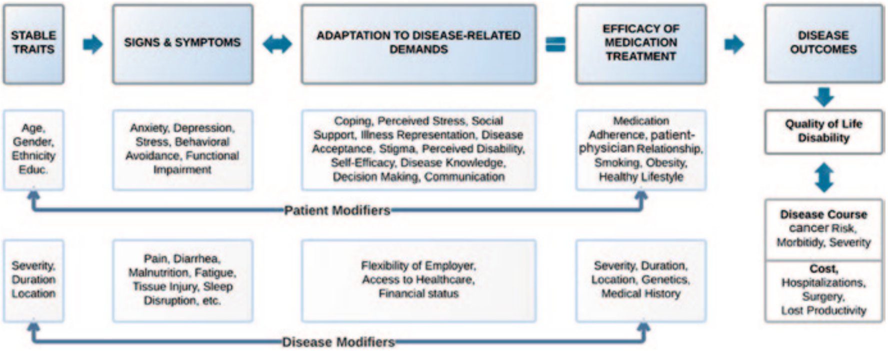

Fig. 5.4 Social cognitive model of inflammatory bowel disease *(IBD)*. Interventions that target the dynamic interactions between these variables have the potential to improve the efficacy of treatment and thereby impact disease outcomes

Social-Cognitive Techniques

Social-cognitive theory carries with it a set of behavior change techniques, which are applicable to chronic disease self-management. These techniques can be classically thought of as either respondent or operant in nature.

Respondent techniques are based on principles of classical conditioning and target the physiological responses (e.g., arousal, vasovagal symptoms, and immune function) to aversive stimuli (e.g., stress, injection phobias). Progressive muscle relaxation, guided imagery, breathing retraining, and hypnotherapy are all examples of respondent-based interventions. These are often used to promote coping, emotional well-being, and reduced physiological arousal associated with disease-specific tasks (e.g., anxiety around ostomy, needle-injection phobias, difficulty swallowing pills). Techniques such as mindfulness-based stress reduction and relaxation-based therapies can be particularly helpful when patients have IBD with chronic abdominal pain not linked to intestinal inflammation or if they have concurrent irritable bowel syndrome, as these techniques simultaneously target the brain-gut axis, pain catastrophizing, and other key aspects of functional gastrointestinal (GI) motility and pain disorders [70–72]. Similarly, hypnotherapy for ulcerative colitis seems to have a positive effect on the immune-inflammatory response [73] and may prolong maintenance of remission [74, 75].

Operant techniques are based on principles of instrumental conditioning [76]. These techniques work to diminish the cognitive-affective and environmental contingencies that maintain negative health behaviors and to promote and reinforce acquisition and implementation of healthy behaviors. Operant-based interventions foster change through the direct manipulation of personal consequences. For example, if a behavior change (improved adherence) leads to a favorable outcome (maintaining remission), an individual will be more likely to engage in that behavior going forward (positive reinforcement). If a behavior change (improved adherence) is associated with the removal/reduction of an aversive stimulus (ability to taper off of corticosteroids), an individual will be less likely to forget to take his/her medicine (negative reinforcement). If a behavior (smoking) leads to an unfavorable outcome (flare), a person will be less motivated to engage in that behavior (punishment).

For example, in the “Project Management for Crohn’s Disease” study [77], patients were asked to identify a single health behavior which undermined the efficacy of his/her treatment. Skills training was provided individually over six weekly sessions to 16 adults with quiescent Crohn’s disease (CD) and mirrored project management methodology, including viewing CD as a project that could be managed, allocating personal resources to disease management (e.g., assertiveness around saying no, choosing which aspects of their life they valued most, etc.), self-monitoring of progress, removing barriers, consulting with experts (nutritionist, personal trainer, smoking cessation support group), and risk management. Another 12 adults with quiescent CD underwent treatment as usual. While the sample size was small and results were preliminary, the project management outperformed usual care in each target domain—Inflammatory Bowel Disease Questionnaire (IBDQ) total score, IBDQ bowel and systemic subscales, IBD self-efficacy, and perceived stress.

In another operant learning-based self-management support program focused on fatigue in IBD [78], 29 patients with quiescent CD and high fatigue scores were randomized to solution-focused therapy (SFT), problem-solving therapy positive control group, or treatment as usual. SFT was administered in the form of five sessions over 12 weeks and offered a wide range of self-management skills focused on helping a patient make a behavior change around fatigue. SFT improved fatigue ratings in more than 85 % of patients and was superior to both control groups.

Telemanagement approaches are particularly conducive to operant techniques as reinforcement and punishment feedback can be readily translated into online formats (acquiring or losing points/tokens/badges, being able to move to a new level) [79–81].

Disease Self-Efficacy

The final characteristic of effective self-management programs, also a main component of social-cognitive theory, is that they build self-efficacy. Self-management support programs promoting self-efficacy have been linked to healthy disease outcomes in cancer [82], multiple sclerosis [83], heart disease [84], diabetes [85], and to long-lasting health behavior change [86].

Self-efficacy occurs when an individual’s perception of his or her ability to adopt new health behaviors improves as he or she encounters new experiences that affect his or her thoughts and beliefs [87]. Self-efficacy is determined by the degree of success or mastery an individual believes he or she has with a specific behavior change. However, self-efficacy is also strongly influenced by reinforcement from key people (e.g., spouse, physician, nurse, psychologist) and the ability to self-regulate any physical or emotional discomfort associated with a behavior change. Self-efficacy can be acquired in IBD and may be one of the most important predictors of successful adaptation to disease-related demands [41, 88].

There are three ways to foster self-efficacy: (1) personal experience, (2) vicarious experience (peer support, testimonials), and (3) in the presence of supportive environmental contingencies (clear reinforcers). Again, telemanagement approaches can readily garner support for all three learning techniques (Table 5.2).

In a large, randomized controlled trial of self-management-based training, 700 IBD patients were followed over 1 year after receiving either self-management training or nothing and at the end of 1 year; self-managing patients were found to have higher confidence in their ability to cope with their condition, which predicted improved quality of life, health service resource use, and patient satisfaction [89]. Similar results have been found in other studies [90] as well as with adolescents, particularly in the context of transition care [91, 92].

Conclusion

In this chapter, we discussed the unique self-management skills of IBD patients in the context of social-cognitive theory. The bottom line is that when self-management support focuses on disease-specific problems (fatigue, adherence), it can be very effective. However, as described from a social-cognitive framework, the challenges in promoting optimal self-management in IBD are quite complex and poorly understood.

Limitations in Our Understanding

There are a few obstacles to widespread dissemination of self-management support tools for IBD. First, heterogeneity across disease status leads to serious gaps in the promotion and implementation of patient self-management support tools, with individual patient characteristics interacting with disease characteristics to add complexity to the medical decision-making process. Because patients differ by diagnosis (Crohn's, ulcerative colitis, indeterminate colitis, etc.), anatomical location (small bowel, colon, both small bowel and colon, upper gastrointestinal tract, left-sided colon, pancolitis, etc.), disease behavior (inflammatory, fibrostenotic, fistulizing), severity (mild, moderate, severe), individual response to treatments, presence and type of extraintestinal manifestations, surgical history, and genetic contribution of IBD [93, 94], medical decision-making support tools must be quite sophisticated and customized.

Second, viewing IBD self-management behaviors as a singular construct may result in inaccurate assessment of the patient's self-management need or problem. For example, a patient who has an injection phobia and therefore misses doses of their

Table 5.2 Social-cognitive theory applied to inflammatory bowel disease (IBD) self-management need

A 33-year-old, married female patient with peri-anal CD for the past 5 years, is told by her gastroenterologist (GE) that her disease has progressed to the point where her temporary ostomy should be converted to a permanent one. Social-cognitive theory predicts that the patient would be most likely to follow recommendations and be successful if she:
Holds positive outcome expectations: The patient trusts her gastroenterologist's recommendation (or has received a second opinion consistent with her doctor's) for surgical treatment and is 80 % confident she will feel better once this is done
Learns about others' experiences: One of the nurses in her surgeon's office puts her in contact with another young, married woman who has also recently had a permanent ostomy for similar reasons and is doing great
Acquires the skills necessary: The patient signs up for an ostomy class run by the surgery nurses to better understand how to order the supplies she needs, how to maintain the wound, purchase underwear, swimsuits, and lingerie that hide the bag, etc.
Immediately experiences positive effects: Within 2 weeks postsurgically, the patient feels more energy than she has in years and has stopped experiencing foul-smelling drainage from her rectum. She thinks she may be ready for sexual intercourse again
Receives positive reinforcement over time: One year postsurgically, the patient applies for and receives a promotion at work. The patient reports that she was able to do this because of the confidence she has gained since having the permanent ostomy. The patient gets pregnant while her disease is in remission and has a healthy baby boy
Has high self-efficacy: Based on her experiences to date, the patient is now confident she can successfully perform the skills necessary to manage the ostomy and anything that might come her way IBD-wise in the future

CD Crohn's disease

biologic may be highly adherent to his/her oral medications. Providing a patient with a text reminder to take medication may seem on the surface to help with an adherence to a biologic but may be largely ineffective. *Context is critical to the application of self-management tools and such tools should not be applied in isolation*.

Disease heterogeneity and chronicity limits the utility of "kitchen-sink" self-management programs; it is difficult enough to engage patients in self-management programs given the profound lifestyle and behavior changes often indicated, but nearly impossible without any clear, personally relevant, disease-altering incentives. The challenges of managing IBD change over time and require new or modified skills as the disease progresses, meaning that onetime exposure to self-management training is inadequate and possibly even detrimental if a behavior that was at one time adaptive, later interferes with optimal management. Future research in this area is needed to meet the quality recommendations for chronic disease care.

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Chapter 6
Mobile Applications for Patients with Inflammatory Bowel Disease

Ashish Atreja and Praneet Wander

Currently, more than two thirds of Americans now have smartphones [1]. Americans are also increasingly tech-laden, with an average of four devices per person; a third of them have a tablet versus just 5% 2 years ago [1]. With increased use of smartphones, tablets and access to high-speed data networks, more patients are able to use mobile applications (apps) than ever before. There are also federal initiatives to promote access of digital technology to low-income population. Since 1985, many low-income patients qualify for the LifeLine assistance program (http://www.fcc.gov/lifeline) that provides free smartphones and free monthly airtime. Recent review of literature indicates that a majority of patients at all socioeconomic levels have smartphone or Internet access [2].

The majority of patients using the Internet have reported using it for health-care needs. A similar pattern is seen with the use of mobile apps with majority of patients having smartphones report using mobile apps for health needs ranging from health information search to wellness to managing their diseases [3]. Inflammatory bowel disease (IBD) is a chronic condition of the bowel that affects over 1.8 million people in the USA. Although the incidence of IBD is rising, the precise cause of the disease remains unknown. Medical treatment for IBD has improved significantly in recent years; however, current efforts are largely symptom related and preventative rather than curative. Irrespective of the strength of a patient's care team or treatment plan, the majority of patients with gastrointestinal (GI) conditions spend less than a few hours per year in communication with their provider(s). The remainder of the year is spent in "self-management." Indeed, the dominance of self-management is evident in outcomes: The risk of a flare, as well as the efficacy and dosing of

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the medications required to induce and sustain remission, is directly influenced by patient behaviors that take place outside a health-care setting, and which we often do not adequately assess or track (e.g., adherence to medication, stress levels, depression, health literacy, and smoking) [4]. As a result, IBD patients have to cope with a lifelong condition in which there are commonly remissions and relapses. This quality makes IBD patients the ideal candidates to target for improved self-management when it comes to longitudinal care and mobile apps can be a valuable tool to support this.

This chapter provides a synopsis of the common mobile apps available in Apple iTunes and/or Google Play stores that are relevant to patients with IBD along with an in-depth qualitative review of some representative apps from each of the following categories: general purpose, health education, symptom tracking, collaborative disease management, and miscellaneous. The ranking, price, and synopsis are mainly derived from iTunes and Google Play stores. Special permission is taken for figures of representative apps.

General Purpose Apps

There are many apps that help to address some of the common needs for patients with chronic GI diseases. While some of these may not be specifically designed for patients with IBD per se, they can still provide some common resources or tools that can be useful for IBD care. Some of the common apps in this category are:

Bathroom Scout

iPhone—$0.99

Android—3.8 Stars—Free

Patients with IBD and other GI diseases have a need to be aware of nearest restroom wherever they go.

The Bathroom Scout can show the closest toilet on satellite view—and lead patients there turn by turn, if necessary. With a database of more than a million public bathrooms around the world, this app can give some added confidence to patients when they are on the go. Plus, the more people that use Bathroom Scout, the better it will become, as users are able to rate facilities and add new locations.

CareZone

iPhone—4.5 Stars—Free

Patients and caregivers of patients with chronic diseases need to stay organized and in charge of various aspects of disease management.

CareZone is a free family organizer app created with the caregiver in mind. It's especially useful for patients with chronic diseases or if someone is caring for more than one person. It helps keep track of doctor appointments, medications, and other important details so that the information is always at your fingertips. A dual password system helps keep sensitive information from prying eyes, but allows one to share account with the people they trust. Patients and caregivers can also set up a voice mail broadcast to up to 100 people.

Colonoscopy Prep Assistant

iPhone—2.5 Stars—Free

Android—3.1 Stars—Free

Patients with IBD undergo regular colonoscopy for cancer surveillance or for assessment of mucosal response. The day before a colonoscopy requires attention to detail that can easily be missed with paper-based instructions.

Colonoscopy prep assistant (and other similar apps) helps patients to remember detail instructions for colonoscopy store the date of the last procedure. Once procedure is scheduled, the app prompts patients at preset intervals when it's time to take action again. The running timekeeper lets patients know how much total prep time they have left.

Livestrong Calorie Tracker

iPhone—4.5 Stars—Free

Android—2.8 Stars—Free

Patients with IBD have dietary challenges and inability to gain weight especially when disease is not in control.

Livestrong's Calorie Tracker (like many other nutrition wellness apps) is designed to keep track of calories and exercise, and it's also a valid way for patients with IBD to monitor their diet. A vast database of foods and restaurant items allows patients to easily learn more about the food they are about to eat so that they can make sensible decisions. The app also calculates the number of calories patients is likely to burn and keeps patients on track with weight and fitness goals. Patients can also access support groups and forums to help them in their quest for better health.

Lisa's Diet

Price: Free

Iphone: Rating: unavailable

This is another popular diet logging app for patients which helps to log the food the patients eat and thus possible their correlation with symptoms. It helps to self-discover one's own food intolerances and maintain a healthy diet.

Health Education Apps

Patients with IBD have a lot of unmet needs especially with respect to access to trustworthy health information around topics related to diagnosis, follow-up, medications, and decisions related to surgeries or interventions. While there are many apps that include health education content, the following apps are specifically focused on providing relevant health education content for IBD patients.

AnswersIn Crohn's Disease

Price: $3.99

This app contains videos from Professor Owen Epstein who is a leading specialist in the condition. These have been made in the University College London Business (UCLB). The videos are interactive interviews describing each aspect of the condition. These include: introduction, clinical features, investigations, management, further management, surgery, and perianal disease. There are summaries provided with each interview. These are helpful for doctors, nurses, and patients.

AnswersIn Ulcerative Colitis

Price: $3.99

Rating:

An app with videos by Professor Owen Epstein, produced in association with the UCLB describing the highlights of the disease. They are based on the latest British Society of Gastroenterology Guidelines. These videos covering multiple topics including: clinical features, investigations, educating the patient, assessing severity, mild/moderate disease, severe disease, and surgery.

Crohn's Disease by AZoMedical

Price: Free

It provides regularly updated information and news on Crohn's disease. It provides authentic information about the disease to health-care professionals, scientists, engineers, and technologists.

Ulcerative Colitis Information

Price: Free

It provides complete information about ulcerative colitis diseases. It covers all relevant topics about the disease to improve knowledge. Some of the features include: how to prevent yourself from ulcerative colitis, definition, description of disease and symptoms sign, causes and risk factors, preparing for appointment, tests and it also emphasizes on lifestyle and home remedies, internal medical disorders, congenital and inherited disorders and drugs used for treatment.

Living with Crohn's Disease

Price: Free

This app provides basic information about the disease. It helps to answer general questions about the disease that arise in any individuals mind. Every individual with Crohn's disease faces similar problems and this app helps to answer those questions. To list a few: What happens with inflammation of the bowels? Also describes signs and symptoms, common complications, different types of diagnosis and treatment. Also helps with simple cures and lifestyle changes and to manage stress and coping with the emotional factors.

Crohn's Disease and Symptoms

Price: Free

Rating: not available

It is an educational app which covers all important aspects about the disease. Provides information on how to prevent yourself from Crohn's disease, definition, description, causes, risk factors, diagnosis, and treatment.

Inform Health

iPhone—not ranked—Free (requires PIN)

Android—5 Stars—Free (requires PIN)

This is a mobile app developed at Sinai AppLab at Mount Sinai Medical Center, New York and includes IBD health education content categorized into multimedia videos, drug information, conditions, or images (see Figs. 6.1 and 6.2).

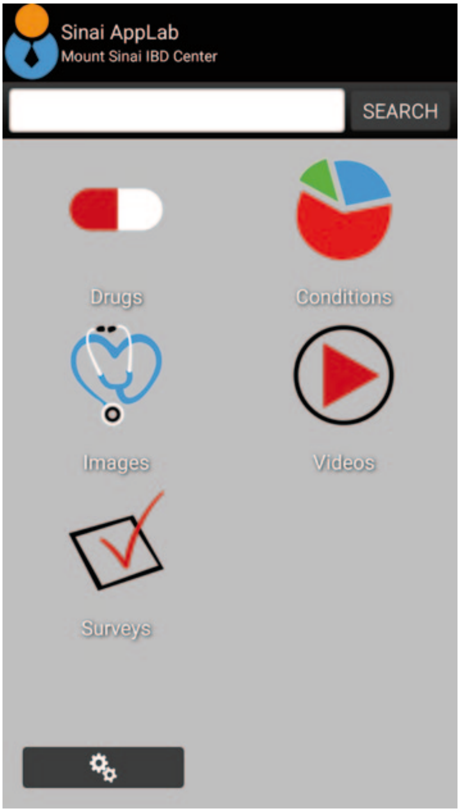

Fig. 6.1 It shows health education content category in InformHealth app category

Symptom Tracking Apps

Unlike some other chronic diseases like hypertension and diabetes, which are asymptomatic for most part, IBD flares are typically symptomatic. There are many apps in the market that allow IBD specific symptoms to be tracked through electronic diaries or e-diaries like functionalities. Some of the commonly used apps in this category are:

GI Monitor

iPhone—4.5 Stars—Free

Android—3.9 Stars—Free

GI Monitor was designed by a patient who wanted his physician to access accurate information about his symptoms. With real-time symptom tracking, GI Monitor allows to find the links between dietary or lifestyle choices and symptoms, or between symptoms and treatments that work. It provides functionality to sync the data across multiple platforms and provide printed reports to physicians.

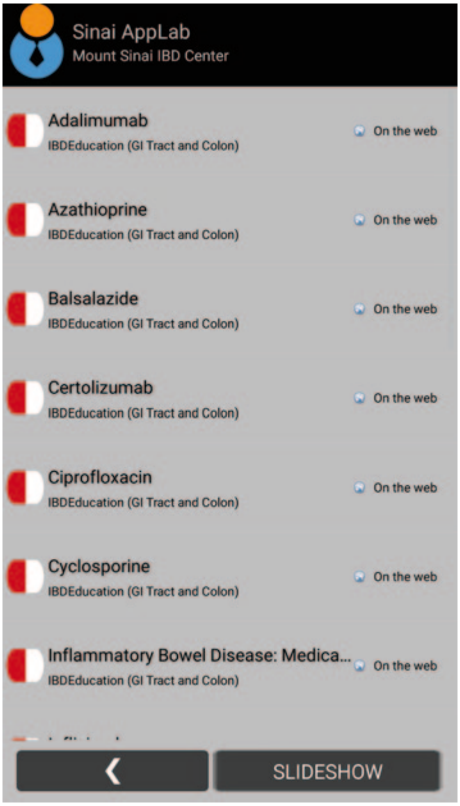

Fig. 6.2 It shows content listing in "drugs" content category in InformHealth app category

PoopTime

iPhone—4.5 Stars—$0.99

PoopTime allows gamification of the time on the bathroom. PoopTime keeps track of bathroom time and, just for kicks, tells how much money patients earned while sitting there. It even keeps a running total! "Poop facts" and "poop jokes," plus options for sharing on Facebook and Twitter, make for something rather unique to occupy patients' bathroom time.

Poo Log

iPhone—3.5 Stars—$0.99

Android—3.6 Stars—$0.99

The app is based on the book, "What's Your Poo Telling You?" by Josh Richman and Anish Sheth, MD. With a timer, a daily log, and useful graph features, patients can learn from their poo. There's also a fair amount of trivia, interesting factoids, and useful information. Poo Log is a handy tool with a humorous twist.

myIBD—sickkids'

iPhone—3 Stars—Free

Android—2.6 Stars—Free

The Hospital for Sick Children created this app for patients to get a better handle on symptoms for IBD. It's fast and easy to record details about symptoms, appetite, and trips to the bathroom. Patients can view their information as text or in graph form at any time. The app is convenient and also includes educational content.

My Pain Diary

iPhone—4.5 Stars—$2.99

Android—4.4 Stars—$4.99

My Pain Diary is a convenient method of logging level of pain at the moment it happens. By keeping track of related events, patients might be able to pinpoint pain triggers and learn which treatments ease your pain. Patients can use this app to find out if their pain is affected by weather, activities, or diet. With color-coded calendars and interactive graphs, they will have more information to go on than ever before.

GI Buddy

iPhone—3.5 Stars—Free

Android—3.2 Stars—Free

Chronic illnesses require lots of cooperation between patients and their doctors. Having the information patients need at their fingertips puts them in a better position to manage their IBD. To address this unmet need, the Crohn's & Colitis Foundation of America developed GI Buddy (www.ccfa.org/gibuddy).

The overarching goals of GI Buddy were to

- Provide patients with an interactive tool to monitor their disease management in order to better understand their disease and communicate effectively with their health-care team to make more informed health decisions.
- Serve as an empowering resource between patients and their disease to provide hope and encourage them to take action to better manage their disease.

GI Buddy allows users to log many factors that may be impacting their Crohn's disease or ulcerative colitis, like symptoms they have experienced, missed doses of treatments, foods they have eaten, and their overall well-being. GI Buddy can be accessed from an Internet desktop portal or by mobile application (iPhone and Android) in order to conveniently input variables in real time (see Fig. 6.3 a, b). Patients must be 13 years or older to utilize GI Buddy.

Fig. 6.3 **a**, **b** It show trackers and customizable reports in GIBuddy app (courtesy of Crohn's & Colitis Foundation of America)

GI Buddy allows users to

- Track symptoms
- Stay on top of treatment regimens
- Log foods that are eaten
- Monitor overall well-being, including stress and exercise
- Generate reports to help see trends
- Keep track of questions for health-care team
- Access Charmin's Sit-or-Squat public restroom locator

Customizable Reports

Logged information is charted (daily, weekly, monthly, or annual graphs) and placed into customizable reports that can be printed and used for personal use or forwarded to the patient's physician, allowing users to easily

- Gain a greater understanding of their disease symptoms
- See how IBD impacts their lives
- Identify potential triggers

Since its launch in November 2012, *GI Buddy* has had over 20,000 downloads. It has been very well-received by patients and professionals, with a 4-star rating on iTunes.

User Feedback

Annual user surveys and/or focus groups are conducted to ensure satisfaction with *GI Buddy* and to identify ways to enhance the tool. In 2013, over 81 % of users were "very satisfied" or "satisfied" with *GI Buddy* overall.

Quality Improvement and Collaborative Disease Management Apps

IBD Circle

iPhone—Free (invite only)

Android—Free (invite only)

IBD CIRCLE is a free application provided for patients of Brigham and Women's Hospital and currently requires a specific invitation by care team.

This app provides a wide range of tools and educational materials for patients and their families including:

- A Symptom Diary as well as journals for lifestyles and nutrition, and a detailed quality of life (QOL) index to help patients track trends in their own health.
- A Medical Content Library specifically for patients with Crohn's disease and ulcerative colitis and a detailed glossary—both with pictures, images, and videos, and multimedia materials.
- The app features a meditations section with podcasts to use for sessions at home.
- The app has an inbox for messaging and reminders.

UCLA eIBD App

iPhone—Free (locked with a PIN)

Android—5.0 Stars—Free (locked with a PIN)

The public portion of the UCLAeIBD application invites patients to learn about UCLA value-based care program. Patients can also learn about our e-research programs, program patient testimonials, and get to know the UCLA IBD team. The signed in portion of the UCLAeIBD application is designed specifically for enrolled patients at the UCLA Center for IBD. Once enrolled, patients will be able to perform a variety of tasks that include:

- Check current and historical VQ®
- Contact health-care team
- View individualized Care Program: Tight Control Scenario
- Complete home care
- View upcoming labs, clinic visits, scheduled home care, and procedures
- Review and confirm IBD medication

HealthPromise App

iPhone—Free (locked with a PIN)

Android—5.0 Stars—Free (locked with a PIN)

HealthPROMISE is a cloud-based patient-reported outcome (PRO) and decision-support platform developed at Sinai AppLab, Icahn School of Medicine at Mount Sinai. Patients track their QOL and symptoms, and providers can use the visual data in real time (integrated with electronic health records (EHRs)) to provide better care to their entire patient population (Figs. 6.4 and 6.5) . HealthPROMISE addresses unique challenges to improve quality and outcomes for patients with a chronic disease like IBD. In addition to measuring QOL, the app tracks quality indicators that our group has helped develop and validate using multi-stakeholder input from patients with IBD, caregivers, nurses, and physicians [5]. The quality indicators identified through this widely accepted methodology includes both process (e.g., medication administration) and outcome (e.g., hospitalizations) measures for IBD [6].

The HealthPROMISE app is currently undergoing pragmatic randomized control trial at Mount Sinai, New York [7] and is being implemented in routine care at the

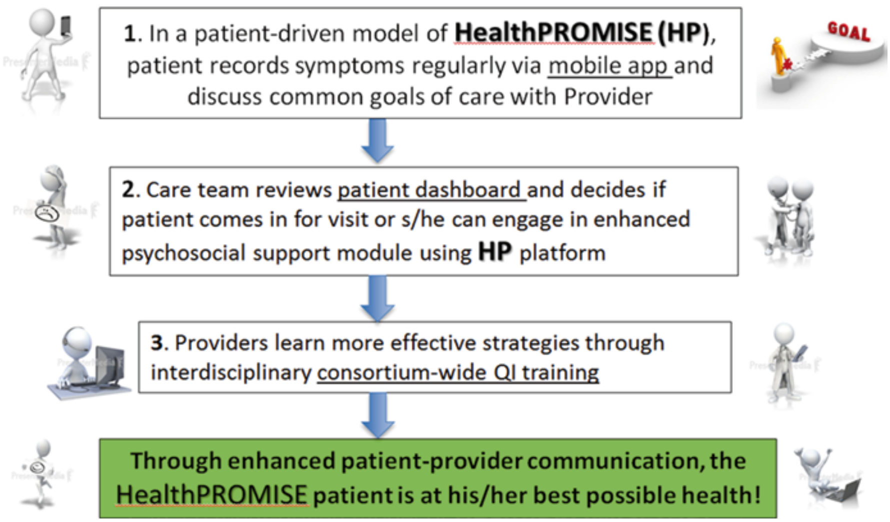

Fig. 6.4 It shows three main features of the HealthPROMISE platform: Patient app, provider dashboard and consortium-wide quality improvement training

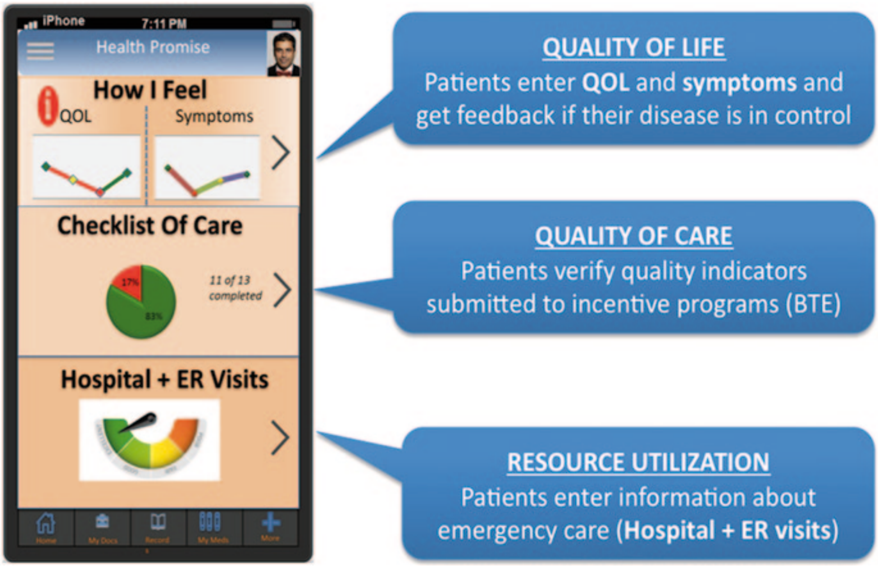

Fig. 6.5 Existing HealthPROMISE 1.0 app: Patient decision support. Patients enter data through app, get immediate feedback through quality report card that visually shows trend in QOL, quality of care and resources

University of Pittsburgh Medical Center, Northwestern University medical center, University of Miami and Johns Hopkins University Medical Center.

Miscellaneous Apps

MyCrohnsandColitisTeam Mobile

iPhone—Free

Android—4.5 stars, Free

This is a social network app exclusively dedicated to those living with Crohn's or colitis. This helps people with the same disease to stay connected and share with others who best understand the problems associated with the disease. It allows individuals to uploads photos, post updates, provide support, and find people with the same disease.

Personal Health Record Apps

In addition to above-mentioned apps, there are many tethered and non-tethered personal health record (PHR) apps such as MyChart, which allow patients access to their own medical charts including medications, preventive reminders, upcoming appointments, lab results and enable secure communication with their providers. While these apps are available in general to all patients in a given health-care system, they do provide some continuity of care in patients with chronic diseases such as IBD.

Conclusions

There are many apps currently available for patients with IBD with various features including general resources mapping, health education, symptom tracking and collaborative disease management. Only a minority of apps are led by providers or health-care organizations. While some of these apps are now widely utilized, up to this date there is a paucity of published evidence in as to whether utilization of these apps can lead to improvement in process metrics (such as patient knowledge or experience) or outcome metrics for patients with IBD. Future studies should include measures of efficacy of health outcomes such as disease activity, medication adherence and health-care resource utilization that are relevant to patients with IBD as well as return on investment (ROI) metrics that are relevant to providers and health-care executives.

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Chapter 7
Telemonitoring and Self-Care in Patients with IBD

Johan Burisch and Pia Munkholm

Results obtained by home-monitoring of inflammatory bowel disease (IBD) support the physician or nurse consultation obtained at an out-patient clinic or through telephone or e-mail. EHealth has shown to influence the time to remission by screening for disease activity visualized in a simple traffic light. Furthermore, eHealth increases patient adherence and their health-related quality of life (HRQoL). However, it has yet to be proven if this personalized telemedicine self-care approach will decrease surgery and hospitalization rates as well as direct and indirect costs in the long-term.

The Copenhagen criteria for self-care in IBD using eHealth of IBD implies a Crohn's disease (CD) or ulcerative colitis (UC) patient being enabled during education to perform screening for disease activity and responding adequately to the traffic light colors red, yellow, and green, thereby increasing compliance and adherence as well as self-initiating topical 5-ASA therapy if needed.

The education of the IBD patient touches five disease-specific objectives: (1) general IBD knowledge, (2) medication and influence of adherence, (3) anatomy and maximum extent of disease in the bowel, (4) complications and alarm symptoms, (5) diet including the importance of iron, D-vitamin, calcium, and B12 vitamin supplementation. Furthermore, education is provided in the eHealth system, www.Constant-Care.dk, related disease activity scores, and fecal calprotectin (FC) home testing. The eHealth system cumulates data automatically, subsequently presenting patients with a total inflammatory burden score visualized as a traffic light.

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Self-Care Definitions

> Give a man a fish and he will feed himself for a day-
> Teach a man to fish and he will feed himself for life

Self-care has been defined by the World Health Organization (WHO) as a generic concept [1] and is what people do for themselves to establish and maintain health, prevent and deal with illness. It is a broad concept encompassing:

- hygiene (general and personal)
- nutrition (type and quality of food eaten)
- lifestyle (sporting activities, leisure etc.)
- environmental factors (living conditions, social habits, etc.)
- socioeconomic factors (income level, cultural beliefs, etc.)
- self-medication

Definitions of "Self-care" or self-management are overlapping and not yet been defined and validated internationally in IBD. We have developed the Copenhagen definition of self-care in eHealth of IBD: "Self-care implies a CD or UC patient being empowered and enabled to perform screening for disease activity as well as responding adequately to alarm symptoms and the three traffic light colors of red (Aggressive disease activity), yellow (mild to moderate disease activity), and green (remission)."

Self-care ensures high patient adherence and supports self-initiated topical treatment with therapy (i.e., aminosalicylates [5-ASA]) if needed [2].

Prior to self-care the IBD patient has been educated in the patient education center in five disease-specific objectives: (1) general IBD knowledge, (2) medication and influence of adherence, (3) anatomy and maximum extent of disease in the bowel, (4) complications, (5) diet including the importance of iron, D-vitamin, calcium and B12 vitamin supplementation. Furthermore, patients receive education in the eHealth system, www.Constant-Care.dk, related disease activity scores (e.g., the Harvey-Bradshaw index (HBI) [3] or simple clinical colitis activity index (SC-CAI) [4]), and FC home-testing [5]. The eHealth system cumulates data automatically, subsequently presenting patients with a total inflammatory burden scoring (Fig. 7.1) [6, 7].

Advancement in socioeconomics that implies growing patient empowerment, resulting from improved educational levels and greater access to information, combined with increased individual interest in personal health, is resulting in growing demand for direct participation in the health care decisions.

Self-medication usually accounts for herbs and over the counter medicine but has in recent years also involved prescribed IBD medicine as suppositories and enemas [2, 6, 7] and web app guidance of short-term dosage escalation of systemic 5-ASA for less than 30 days [2]. However, no matter how much individualized guidance is received electronically; one must not forget that these solutions are only supportive of consultations at the provider's office.

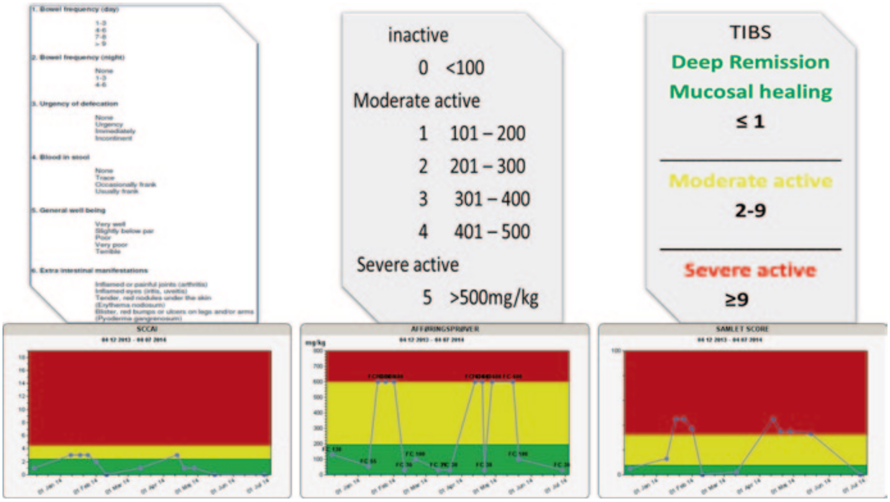

Fig. 7.1 Total inflammation burden scoring appears as a traffic light consisting of a rational sum of symptoms score and calprotectin carried out at home in this case by a ulcerative colitis (UC) patient, www.constant-care.dk. (Data from Vinding KK [5] and Elkjaer M, Burisch J, Avnstrøm S, et al. Development of a Web-based concept for patients with ulcerative colitis and 5-aminosalicylic acid treatment. Eur J Gastroenterol Hepatol 2010;22:695–704. doi:10.1097/MEG.0b013e32832e0a18)

Tools for Telemonitoring

Whether in the conventional out-patient setting or in eHealth, the aims of disease monitoring are the same: the optimization of treatment for highly refined disease control and the maintenance of remission. In order to prevent bowel damage, reduce long-term disability and maintain normal quality of life in IBD patients; mucosal healing has in recent years emerged as an important therapeutic endpoint [8]. However, several aspects of monitoring—such as the distinction between IBD and noninflammatory conditions, assessment of disease activity and severity, and outcome of therapy—remain challenging for physicians in both out-patient and eHealth settings, as no single gold standard test exists. Physicians must instead rely on a combination of symptoms and diagnostic tests (e.g., biomarkers, cross-sectional imaging, and endoscopy) in order to make clinical decisions.

In telemonitoring, most of these diagnostic tools either are not feasible as they are invasive, time consuming, or for some other reason require hospital attendance, thus making disease assessment problematic. Ideally, tests for disease activity or patient-reported outcomes (PROs), such as quality of life and fatigue, should be quick and easy to perform and be possible to carry out by the patients themselves while at home. In the following, some of these tests will be briefly described.

Biomarkers for Telemonitoring

Relying exclusively on presenting clinical manifestations (e.g., using clinical disease activity indices) for treatment strategies is rarely successful in modifying the course of IBD, and telemonitoring can therefore not rely on the monitoring of symptoms alone. Clinical disease activity indices are nonspecific and do not correlate well with endoscopic activity [9]. Conventional blood tests (including hemoglobin, C-reactive protein, and erythrocyte sedimentation) are used frequently in the diagnostics and disease assessment of IBD. However, the sensitivity of these tests is insufficient to detect intestinal inflammation [10], limiting their use in telemonitoring.

Currently, FC is the most suitable biomarker for intestinal inflammation to be used for telemonitoring. FC is a noninvasive biomarker found in stool that can detect histological inflammation despite endoscopic remission [11–13]. Calprotectin levels in patients with sustained deep remission during treatment with infliximab remained very low (median <40 mg/kg at all time points). Patients who flared had significantly higher FC levels (median >300 mg/kg) 3 months before the flare. Two consecutive FC measurements of >300 mg/kg within a 1-month interval were identified as the best predictor of flare (61.5 % sensitivity and 100 % specificity) [14]. FC constitutes about 60 % of the total protein in the cytosol of neutrophil granulocytes and levels correlate with the influx of neutrophils into the intestine [15]. Importantly, FC is stable in feces for up to 7 days at room temperature and can be accurately measured in small stool samples by several commercially available enzyme-linked immunosorbent assays (ELISAs) [16–19]. Recently, smart phone tests for FC have been developed, thus offering the possibility for home analysis of FC by patients [5, 20]. Home-testing of FC takes 18 min to carry out (Fig. 7.2) and has surprisingly high sensitivity and specificity. Coefficient of variation was between 4 and 12, with less than 10 being considered a useful and fair laboratory test [5].

Of particular interest for the telemonitoring IBD patients is the ability of FC to differentiate IBD from irritable bowel syndrome (IBS) [21–23], assess IBD activity, and predict a relapse [14, 24, 25]. IBD patients often report symptoms referable to the gastrointestinal (GI) tract, without objective evidence of ongoing disease activity and 25–50 % of the IBD patients in clinical remission have symptoms compatible with a diagnosis of IBS [26]. A meta-analysis of the diagnostic precision of FC in distinguishing between IBD and non-IBD found that using a cutoff level of 50 μg/g gave a pooled sensitivity of 89 % and pooled specificity of 81 %. Even higher diagnostic precision was reported for a cutoff value of 100 μg/g [27]. FC can therefore be used to prevent excessive treatment of IBS-like symptoms and reduce the need for endoscopy [28].

Furthermore, FC is able to differentiate well between active and inactive IBD. FC correlates significantly with endoscopic disease activity [10; 12, 29] and normalization of FC levels is a surrogate marker for mucosal healing [30, 31]. In UC, FC correlates with disease extent and disease severity [12]. FC is also able to differentiate endoscopically inactive disease from mild, moderate, and severely active disease [11]. In CD, FC also correlates with endoscopic disease activity [29, 30]. In a study of 126 patients with IBD (87 patients with CD and 39 patients with UC),

Fig. 7.2 Home monitoring of fecal calprotectin (FC) using a smartphone can be performed in 15 min by patients. (Data from Vinding KK [5])

FC > 250 µg/g gave a sensitivity of 71 % and a specificity of 100 % (PPV 100 %, NPV 47 %) for active mucosal disease activity in UC. The same study also found that in CD, FC ≤250 µg/g predicted endoscopic remission with 94 % sensitivity and 62 % specificity (PPV 49 %, NPV 97 %) [12]. A recent meta-analysis combined the results of 13 studies on the diagnostic accuracy of FC in differentiating between patients with active IBD and those in remission; it found that a cutoff of 250 µg/g in IBD resulted in a pooled sensitivity of 80 % and a specificity of 82 % [32].

Finally, increasing levels of FC can predict clinical relapse in CD and UC patients, especially for colonic and ileocolonic CD. A meta-analysis used data from six prospective studies investigating the predictive ability of FC and found a pooled sensitivity and specificity of FC to predict relapse of quiescent IBD of 78 and 73 %, respectively [33]. FC cutoff values ranged from 150 to 250 µg/g.

Thus, FC is a reliable biomarker for intestinal inflammation. Periodic testing of FC for guidance of IBD treatment and disease monitoring—especially with FC testing being compatible with eHealth solutions that can be used in the patient's home [5]—is a promising alternative to current standard care [34].

Patient-reported Outcomes (PROs) in Telemedicine

PROs capture the patient's illness experience in a structured format and may help the physicians to better understand symptoms from the patient's perspective [35]. PROs measure any aspect of health directly reported by the patient (e.g., physical, emotional, or social symptoms) and may help to direct care and improve clinical outcomes [36]. Currently, the US Food and Drug Administration (FDA) is moving away from using disease activity indices as clinical trial endpoints and towards

PROs when assessing the patient's experience of symptoms and objective measures of disease [37].

The ultimate PRO is improvement in HRQoL. HRQoL is a subjective measure of a person's physical and psychological well-being and represents a patient's assessment of how a particular disease or intervention has affected their life. Patients with IBD experience an impaired HRQoL when compared with a healthy background population [38–40]. Disease course and activity [41, 42], perceived quality of care delivered, and the individual's psychological status and social support [43, 44], are important factors affecting HRQoL.

Several different instruments exist for the assessment of HRQoL in IBD [45]. Disease-specific questionnaires for HRQoL—derived from and validated in the relevant disease groups—are the most sensitive indicators of change over time or with treatment. Generic instruments, on the other hand, are used to show similarities or differences among groups or populations; however, they may not be sensitive to changes over time or subsequent to treatment in groups of patients with specific diseases [46]. Until recently, most eHealth trials have used the disease-specific Inflammatory Bowel Disease Questionnaire (IBDQ) [47, 48], with or without the generic short form (SF-36 or SF-12) [49] questionnaire. The IBDQ instrument comprises 32 items that measure the following broad domains: physical health, psychological health, social relationships, and environment. The patient's answers are scored on a seven-point Likert scale, in which "7" corresponds to the highest level of functioning. A cumulative score above 170 points represents good QoL, with scores ranging from 32 to 224. The s-IBDQ is a shorter version of the original instrument (comprised only ten questions, but representing all four domains) that may be more convenient for use in the clinical setting as well as in eHealth applications. The range of scores of the SIBDQ is 10–70 points with a score of 50 comparable to 170 in IBDQ [48, 50].

The SF-36 is a generic HRQoL questionnaire containing 36 items. Thirty-five of the items are grouped into eight multi-item scales: physical function, social function, role limitations due to physical problems, role limitations due to emotional problems, energy/vitality, mental health, bodily pain, and general health perception. It also contains a one-item measure of self-evaluated change in health status (health transition) over the previous year. For each question, the raw score is coded and transformed into a percentage, with 0 indicating the least favorable possible health status and 100 indicating the most favorable. The 12-Item SF-12 is a short form survey derived from the SF-36 instrument and developed to reduce respondent burden while achieving minimum standards of precision for purposes of group comparisons involving multiple health dimensions [49, 51].

Telemonitoring Systems

Different approaches to telemonitoring of IBD patients have been tested in clinical trials. While some have used Internet communication for distance consultations between patients and physicians or between physicians [52, 53], the most innovative systems have implemented the regular monitoring of patient-reported symptoms and PROs.

The home telemanagement in UC (UC HAT) [54] system has been developed to aid patients with self-managed care through remote clinical monitoring of symptoms, HRQoL, and adherence to therapy. This system is comprised a patient unit (laptop and electronic weighing scale for weekly self-testing), a decision support server, and a web-based clinician portal. It also includes an integrated disease-specific education curriculum. Besides recording the data, the system is able to send alerts to the clinician portal-based on remarkable responses, thereby enabling each side to act accordingly. The mobile Health PROMISE Platform [55] is a newly developed PRO and decision support platform. Using the application, patients can track their HRQoL (e.g., sIBDQ) and symptoms, and providers can use the visual data in real time, integrated with eHealth records, to provide better care to their entire patient population.

The Constant Care application [2, 56–59], on the other hand, combines web-based disease monitoring with an eHealth algorithm that actively provides treatment advice and is able to aid patients in treatment adherence and individual dosing of medication. It consists of a patient education package (eLearning and educational video clips further illustrating the information contained on the website, medication, and the study conditions) and a web-based disease monitoring package. Using the disease monitoring package, patients are able to record their disease activity as well as their FC levels, the latter being measured using a smart phone application and home testing kit of FC. Based on these results, disease activity is visualized according to a "traffic light" system of green, yellow, or red color, to illustrate inflammatory activity. The Constant Care application then directs individualized treatment for the patient (Fig. 7.1). The administrator part of the web application, which is only accessible to the investigators, allows the treating physician to monitor the patients.

A promising validated mobile Health Index for remote monitoring of IBD disease activity revealed good receiver operating characteristic (ROC) curves and will in future be tested for usability and feasibility in clinical practice [60]. Web applications in eHealth care have to follow the rules of the European Union (EU) and nationally for database constructions, and to protect the patients by anonymous data registration, login, and unique password [61]. Conformité Européenne (CE) marking is mandatory in the EU in accordance with regulation for database [62].

Web Applications Hosted by Healthcare Platforms

Many systems systems exists among which Epic offers an integrated suite of health care software and their applications support functions related to patient care, including registration and scheduling; clinical systems for doctors, nurses, emergency personnel, and other care providers; systems for lab technologists, pharmacists, and radiologists; and billing systems for insurers.

Due to the Office of the National Coordinator for Health Information Technology, sharing health data from other software is possible as rules were produced in a 10-year vision and agenda to achieve healthcare interoperability in 2014.

EPIC provides electronic records systems for many academic medical centers in the USA. In Europe, EPIC has been installed in several countries including the UK, the Netherland, and Denmark. In Denmark, installation of EPIC is in progress at a cost of 840,000,000 DKK (Approx. 140,000,000$) [63] in all hospitals in the capital region and whole of the Zealand where the capital Copenhagen is situated covering with its 2.5, 5 million people about 1/2 of the Danish population. A feature in the Epic system is the possibility for telemedicine applications to be integrated into the electronic record system. In Denmark this feature will be included 2016 in accordance with the overall ambition to make telemonitoring available for all patients with chronic diseases.

Ehealth Influencing Natural Disease Course of IBD

Mucosal healing is a goal of treatment that minimizes bowel damage in CD and UC [64–66]. Mucosal healing has no clear definition but can imply remission by clinical scoring, surrogate endpoint markers such as CRP or FC, histopathological remission or even immunological remission as assessed by the tumor necrosis factor (TNF) levels in mucosa biopsy specimens [67]. Telemonitoring has been shown to detect symptoms of a flare sooner than standard care resulting in less time in relapse (Fig. 7.3) [6, 7]. In a large eHealth trial in UC, time to remission was reduced to a median of 17 days using monthly or on-demand eHealth screening using clinical activity index compared to 77 days in the standard care group [2].

A diminished inflammation burden or area under the activity curve is achieved by screening for disease activity with the total inflammation burden score (TIBS) as an accumulation of disease activity and FC (Fig. 7.4).

Future Aspects

The advantages of eHealth applications and telemonitoring are obvious, and include giving the patient quick and easy access to medical care and providing them with more individualized treatment. Furthermore, self-management strategies promote patient engagement and empowerment, support patient adherence to treatment, and represent a unique opportunity for a selected group of patients with IBD that require life-long follow-up and treatment. Physicians can access a large clinical population, as well as patients in rural and remote areas. Patients with less aggressive disease courses or in maintenance of remission can be followed-up primarily using eHealth, thus unburdening practitioners by allowing for better and more effective allocation of their time.

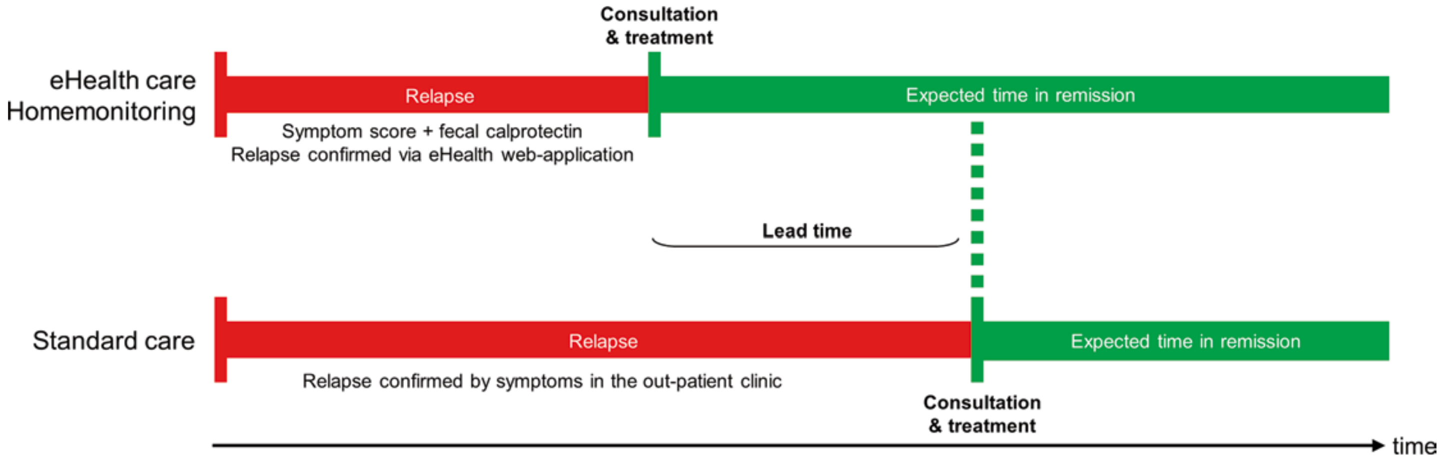

Fig. 7.3 Lead time in eHealth home-monitoring by patients is influencing time to obtain remission. Future long-term trials will show if there is a change of disease course as consequence of optimization and control of disease damage. (Adapted from Burisch J, Munkholm P. The epidemiology of inflammatory bowel disease (IBD). Scand J Gastroenterol 2015;50:942–51 with permission)

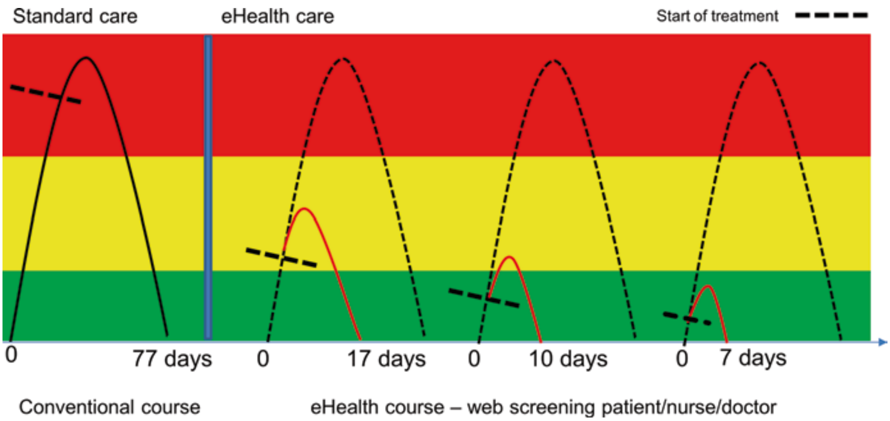

Fig. 7.4 Standard care verses eHealth webcare shows a decreased total inflammation burden scoring, appearing in the traffic light colors, consisting of a rational sum of symptoms score, and calprotectin. The screening by home testing catches the relapse early on and individualize the medical therapy in accordance resulting in shorter time in relapse. (Data from Elkjaer M [2]; Elkjaer M. [6]; Pedersen N. [7]; Pedersen N [57]; Pedersen N [58]; Pedersen N [59])

Yet the potential of eHealth lies beyond the mere practical advantages. EHealth in IBD patients has made it possible to transfer knowledge about disease course patterns gained from epidemiological studies of inception cohorts [68–70] into clinical practice. In recent years, eHealth has been introduced as an important "adjuvant" to medical therapy that can improve adherence to medication among IBD patients [2], time in remission [2, 59], and HRQoL [2, 6]. A recent meta-analysis showed that distance management (including telemedicine and web-based intervention) significantly decreases the number of clinic visits and can improve quality of life in certain groups of patients [71]. Furthermore, eHealth disease management was validated in another meta-analysis of telemedicine in IBS and IBD. Generally speaking, improvement of HRQoL, adherence to therapies, knowledge about the disease, reduction of healthcare costs for IBD, and quicker time to remission, were all shown [72].

Using these methods, guidance and medication adjustment can be provided immediately and the patients are able to recognize their own disease course pattern, thus improving the short-term disease course [2, 60]. By integrating self-monitoring and/or self-treatment in IBD care, it is anticipated that the burden of inflammation, as well as time to remission, can be improved and, potentially, the long-term disease course of IBD changed for the better.

In Denmark, the first steps for integrating eHealth with daily clinical care have already been taken. A large trial using the clinically-integrated home monitoring platform (KIH) on patients with diabetes, chronic obstructive pulmonary disease, and IBD, as well as pregnant women, is ongoing and is in the evaluation stage. In the North Zealand Hospital, Denmark, integration of the Constant Care application with the files of IBD patients continues, as does work to create an eHealth nurse outpatient clinic for patients with mild-moderate disease. Furthermore, home blood testing (e.g., Ferritin, hemoglobin and CRP for iron deficiency anemia in IBD patients or adverse events such as liver function tests and complete blood counts for patients treated with azathioprine) is being tested in order to expand the possibilities of telemonitoring and self-care to include additional aspects of IBD care. EPIC health platform from EPIC, Verona, Wisconsin has been implemented in the USA and Europe and in 2016 in Denmark in the capital region and the island of Zealand covering about 50 % of the Danish population. A feature in the Epic system is telemedicine, which will be implemented in 2016 in the electronic files that patients and health care providers will have access to.

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Chapter 8
Teleconferences to Facilitate Multidisciplinary Care and Education in IBD

Julia B. Greer and Miguel D. Regueiro

Background

The medical and surgical management of inflammatory bowel disease (IBD) patients necessitates the coordination of multiple medical disciplines [1, 2]. Patients with Crohn's disease and ulcerative colitis often experience comorbid illnesses and medical complications for which consultation with outside academic centers is sought. Recent technological advancements have significantly improved the ability of physicians to interact remotely. Intra-institutional videoconferences that include specialists from disciplines such as medicine, surgery, pathology, and radiology are often held to discuss patient management. More recently, teleconferencing between major academic and clinical centers is being used to help care for IBD patients. These team interactions increase physicians' knowledge base and therapeutically benefit patients by sharing ideas about superior as well as novel pathways of care.

In previous decades, primary care physicians, pediatric and adult gastroenterologists, and surgeons provided almost all of the care that IBD patients required. Nevertheless, the number of newly diagnosed and prevalent IBD cases has grown in a steadfast fashion in the Western world over the years, while rates have also been increasing as less-developed countries become more industrialized [3, 4]. In parallel, comprehension of the pathophysiology and management of Crohn's disease and ulcerative colitis has increased. Adding to the treatment armamentarium of accepted therapies are newer biologically active pharmaceuticals. At many academic centers, standard surgical procedures are gradually being replaced with more direct approaches and advanced techniques. The result has been a paradigm shift to provide

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Table 8.1 Health-care professionals involved in the care of IBD patients

Colorectal surgeons[a]	Neurologists/pain specialists
Dermatologists	Nutritionists[a]
Dietitians[a]	Obstetricians/gynecologists
Emergency medicine physicians	Occupational therapists
Endocrinologists	Oncologists
Enterostomal nurse therapists[a]	Pathologists[a]
Family practitioners	Pediatric gastroenterologists[a]
Gastroenterologists[a]	Pediatricians
Geneticists	Physical therapists
Hematologists	Psychiatrists[a]
Hepatologists	Psychologists[a]
Hospitalists[a]	Pulmonologists
Immunologists	Radiologists[a]
Infectious disease specialists	Rheumatologists
Internists	Social workers
Intestinal transplant surgeons	Surgical oncologists[a]
Nephrologists	TPN nurses

[a] Regular participants in IBD LIVE

comprehensive and individualized IBD patient care. To that end, a substantial number of specialists are often involved in the care of IBD patients (Table 8.1) [5–7].

The majority of health-care workers have direct contact and interaction with IBD patients. Other physicians, such as pathologists and radiologists, make patient assessments by sharing the results of diagnostic testing. A myriad of cross-disciplinary information is required to care for IBD patients, especially those whose disease has followed a complicated course. Guidance and expert opinions from outside institutions are often sought either by phone consultation between the treating and consulting physician or by having the patient physically travel to another medical center for care. Each type of outside consultation has its drawbacks, whether it is due to insufficient information for giving advice via the phone or the substantial time demands and financial expenses of travel, as well as minimal out-of-network insurance coverage for many patients.

Physicians who practice at academic centers routinely share information about a given IBD patient through direct consultation and patient evaluation. Within an institution, more generalized education about specific IBD-related illnesses and their complications is considered and frequently debated at weekly grand round sessions. On a larger scale, gastroenterologists attend regional and national conferences to present their data and explore new insights about IBD. Although these meetings are a great source of information for IBD specialists, their infrequency significantly restricts their ability to a superior means of interacting with peers at outside institutions. The teleconference, specifically the videoconference, may provide a way to diminish the prevailing limitations of distance consultation and infrequent educational meetings.

The purpose of telemedicine is to communicate electronically to exchange medical information between separate sites to improve the clinical health status of one or more patients. Telemedicine has grown to comprise a great range of information and telecommunication methods [8]. Teleconferencing has become very popular among physicians and other researchers because of the ability to include multiple team members in a discussion. Teleconference has long been favored in surgical morbidity and mortality sessions because it allows satellite academic campuses to be included in patient presentation and dialogue [9].

The early form of teleconferencing was typically limited to voice only conversations. Although the cost is fairly low, drawbacks of audio only teleconferencing include the lack of preparation or attentiveness of certain members of the call, particularly those who are less involved in the case discussion. Additionally, some members of the teleconference are not able to participate in each session, due to clinical duties or scheduling conflicts. Teleconferences involving large groups of participants make it difficult to identify some speakers or to be cognizant of who is speaking. Finally, audio teleconferences do not allow for the presentation of physical findings or imaging studies.

The transmission of images in conjunction with telephone discussion dates back to the 1930s, when the invention of the television led to the establishment of analog videophone communication [10]. In this era, for instance, the German post office network connected Berlin with other German cities using coaxial cables [11]. Today, videoconferencing is becoming such a common means of interinstitutional communication that some people hypothesize that travel may soon be unnecessary [12]. Videoconferencing encompasses live audio and video streaming.

In the treatment of IBD patients, this form of live and active communication embodies a successful implementation of a telemedicine system. Videoconferencing allows a slide show to be presented to multidisciplinary physicians and physician trainees, highlighting the most salient features of the patient's clinical course. Relevant photos demonstrating imaging and endoscopic studies, displaying skin or stoma lesions, or describing assessments of other extraintestinal disease manifestations are often shown to the group. Videoconference participants view the presentation in real time and are able to provide valuable interpretation and feedback about key issues in each case.

We recently established a formal, multi-institutional IBD videoconference that geographically links discrete medical institutions and physicians by using interactive live video streaming [13]. The idea for this conference came from gastroenterologist Miguel D. Regueiro, M.D. and surgeon Andrew Watson, M.D. MLitt, who both practice at the University of Pittsburgh Medical Center. For several years prior to the development of the videoconference, there had been a weekly "in person" multidisciplinary conference that included the pediatric gastroenterologists. When the pediatric hospital of Pittsburgh relocated several miles from the adult hospital, the challenge arose of linking to the pediatricians. This continuing medical education (CME)-accredited IBD case conference has expanded nationally and is now known as The inflammatory bowel disease live interinstitutional and interdisciplinary videoconference education (IBD LIVE). IBD LIVE brings together clinicians from a variety of disciplines to discuss challenging IBD patients where management decisions could benefit from outside consultation and discussion. Each quarter, selected cases from the IBD LIVE series are published in the journal *Inflammatory Bowel Diseases*. The conference was developed and has grown exponentially over the course of 4 years. We believe that IBD LIVE is the first IBD videoconference of its kind and we will describe various important aspects of this program in subsequent sections.

The core technology used in a videoconferencing system is digital compression of audio and video streams in real time. Certain equipment is needed to conduct a successful videoconference, including a digital network (Internet Protocol [IP] or Integrated Services Digital Network [ISDN]), video input (camera or webcam), video output (computer monitor, projector, or television), audio input (microphone), audio output (system speakers), means of data transfer (local area network [LAN] or the Internet), and a computer that initiates and maintains data linkage via the network, unites all of the components, and performs the compressing and decompressing of data.

Technology

Videoconferencing technology in our series is typically provided by an information technology (IT) specialist at each participating medical institution along with an IT specialist at a videoconferencing company. Prior to having a new institution participate in the conference, an information technologist is identified at the new site in addition to an appropriately sized room that contains appropriate videoconferencing equipment. A site certification should be performed to check connectivity; audio and video quality check is conducted to ensure that the transmission rate and most effective equipment are available. Throughout the live video streaming, each site works with conference specialists to advance slides, adjust and mute sites, and change display screens so that the other groups can see each speaker. Standard IP connectivity through hardwired endpoints supports the teleconference.

Example of an IBD Videoconference

Regular participants in our multi-institutional and multidisciplinary IBD videoconference include pediatric and adult gastroenterologists, surgeons, pathologists, radiologists, and trainees from any of these fields. Specialists from dermatology, nutrition, intestinal transplant, hepatology, psychiatry, rheumatology, infectious disease, and the ostomy care team frequently attend when a case involves their care or consultation. The primary aims of our videoconference are enhancing the understanding of (1) the natural course of Crohn's disease and ulcerative colitis; (2) medical treatments available for IBD; (3) surgical options, including their risks and benefits, used in the management of ulcerative colitis and Crohn's disease patients; and (4) the pathophysiology and etiology of immune-mediated inflammatory bowel diseases. Prior to each conference, an e-mail is sent to all participants requesting physician submission of pertinent cases.

The IBD LIVE course director selects two cases per conference. The radiologist and pathologist assigned to the case review radiographs and histopathology, respectively. For a videoconference to progress smoothly, audio and visual features must be well coordinated so that transitions between slides and participating groups can be seamless. The moderator is responsible for summarizing the recommendations for the presenter and, when possible, providing a consensus statement. Our conferences are archived so that they can be viewed in the future by an unlimited number of health-care providers. The cases are also being presented quarterly in the journal *Inflammatory Bowel Disease.* Fellows and other trainees are invited to attend the conference as it provides them with information that is highly pertinent to their clinical education. Additionally, the trainees are asked to present cases and, when selected, serve as author on the case publication. Not only does this provide the trainee with the opportunity to present at a national conference, it also serves as a valuable learning experience in the preparation of a peer-reviewed manuscript.

The conference lasts 1 h and the time is allocated equally between the two cases. The director ensures that all cases and materials are de-identified and in compliance with CME standards by the University of Pittsburgh Medical Center (UPMC). The moderator of each session is responsible for keeping the case presentation within its allotted time frame and for facilitating participant discussion. Each case is generally presented in the format of a PowerPoint slide set, beginning with the introduction and review of the case, including laboratory and imaging results, as needed, and followed by a discussion by interested members from any participating institution. The moderator provides a summary of the case and consensus recommendations once the discussion has ended.

In 2002, our multidisciplinary weekly IBD conference began. As of 2010, the conference attendees receive CME. The conference was initially designed to provide a forum by which UPMC physicians from various specialties could discuss the management of some of their most complex patients with IBD. Children's Hospital of Pittsburgh of UPMC relocated to a site 5 miles from the adult hospitals (UPMC Presbyterian and Montefiore) in 2009; thereafter, the first videoconference was initiated using the UPMC telecommunication's bridge for video feed. In 2010, the University of Maryland joined, quickly followed by Penn State Hershey Medical Center and the IBD LIVE series was launched.

Today, numerous medical centers participate in the IBD LIVE videoconference (Figs. 8.1 and 8.2, Table 8.2), including UPMC Presbyterian Hospital, UPMC Children's Hospital, University of Maryland at Baltimore, Penn State Hershey Medical Center, Yale New Haven Hospital, Dartmouth-Hitchcock Medical Center, Yale Bridgeport Hospital, Brown University Miriam Hospital, Emory University, Allegheny Health Network, Rhode Island Hospital, Hunter Holmes McGuire VA Medical Center (Richmond Virginia), Boston Medical Center, UPMC Mercy Hospital, and Geisinger Medical Center. Medical students, interns, residents, and fellows from

Fig. 8.1 Screenshots of IBD LIVE series members interacting during a case discussion

each discipline attend and trainees often present cases. Due to the complexity of care of these patients, attendance by physicians in other disciplines is common. There has been a steady increase in sites and participants over the course of many years. The videoconferences have been interactive and informative in managing these difficult cases.

The following cases are a sample of those that have been presented at the IBD LIVE videoconferences. They may serve as examples of the topics pertinent to caring for IBD patients that can easily be covered in a technologically advanced, multidisciplinary collaborative fashion. The cases are not meant to represent full presentations, but to provide an overview of the educational format and opportunities within an IBD videoconference.

Fig. 8.2 Institutions involved in the IBD LIVE series including (*clockwise from top*) Yale New Haven Hospital, Emory University, Penn State Hershey Medical Center, University of Maryland, Baltimore, Children's Hospital of the University of Pittsburgh Medical Center (UPMC), University of North Carolina Health Care, Yale Bridgeport Hospital, Dartmouth-Hitchcock Medical Center, Brown University Miriam Hospital, and UPMC Presbyterian Hospital (*center*)

Table 8.2 Institutions currently participating in IBD LIVE

UPMC Presbyterian Hospital
Children's Hospital of UPMC
University of Maryland at Baltimore
Penn State Hershey Medical Center
Yale New Haven Hospital
Dartmouth-Hitchcock Medical Center
Yale Bridgeport Hospital
Allegheny Health Network
University of North Carolina Health Care
Brown University Miriam Hospital
Geisinger Medical Center
Emory University
Rhode Island Hospital
Boston Medical Center
Hunter Holmes McGuire VA Medical Center
UPMC Mercy Hospital

UPMC University of Pittsburgh Medical Center

Example 1: Education

A 47-year-old male was first diagnosed with left-sided ulcerative colitis in 2000 and initially treated with mesalamine and intermittent systemic steroids until 2005. From 2005 to 2008, he had one flare that resolved with rectal mesalamine. During a flare in 2009, 6-mercaptopurine (6-MP) was initiated but was stopped after 6 months because it was ineffective. Oral mesalamine and rectal mesalamine were also of no help. He was then prescribed recurrent steroid tapers and became steroid-dependent to keep his disease in remission. In June of 2010, he was tried on balsalazide and rectal hydrocortisone without effect. In November of 2010, the patient was started on methotrexate 25 mg once weekly plus folic acid and hydrocortisone foam. From December 2010 to April 2014, he only received methotrexate 25 mg/week. He recently completed his second marathon and he feels great. He is happy that his colitis is under control and does not want to change anything although he now has an accumulative dose of methotrexate of about 4 g. Consideration is being given to lowering the dose to 15 mg per week. However, the data that we have on methotrexate, including long-term effects, is almost exclusively among Crohn's disease patients.

Videoconference Topics Discussed What is the role of methotrexate in IBD? Is methotrexate an effective medication for ulcerative colitis? When is it appropriate to lower the dose of a medication that may have long-term health risks? Are there other treatment options for ulcerative colitis that can be considered when most drug therapies have failed?

Example 2: Shared Decision-making (Gastroenterology, Surgery, Oncology)

The patient is a 58-year-old woman who was diagnosed with Crohn's disease at 24 years of age. She has been treated intermittently with antibiotics, mesalamine, and short courses of systemic corticosteroids. Her history is remarkable for stage I infiltrating lobular breast carcinoma diagnosed 10 years ago for which she underwent bilateral mastectomy and adjuvant hormonal therapy. Eight years ago, colonoscopy demonstrated a proximal "pinhole opening" colonic stricture with ulcerations (Fig. 8.3). Random colonic and stricture biopsies revealed chronic active colitis with noncaseating granulomas but no dysplasia. Imaging performed 7 years ago suggested the patient had a subclinical small bowel obstruction. She was referred to a surgeon but decided against stricturoplasty or resection. The following year, she developed refractory anemia and underwent a workup for a hematologic malignancy that was unremarkable.

The patient noted more frequent postprandial epigastric pain, nausea, bloating, and loose bowel movements approximately 4 years ago. A small bowel series demonstrated two jejunal strictures and a 16–20 cm long ileal stricture. The patient underwent an ileocecectomy and resection of the jejunal strictures. At surgery, a

Fig. 8.3 "Pinhole opening" colonic stricture with ulcerations observed during colonoscopy

large mass was seen at the proximal jejunum that had bulky adenopathy extending to the base of the mesentery. Some nodes could not be resected. Pathology indicated that the tumor was invasive adenocarcinoma that was categorized as stage IV after a chest computed tomography (CT) was positive for thoracic lymph nodes. She was treated with 12 cycles of folinic acid fluorouracil oxaliplatin (FOLFOX). Serial positron emission tomography/computed tomography (PET/CT) scans have not demonstrated signs of cancer recurrence.

She now presents with progressively worse postprandial epigastric discomfort, bloating, weight loss, and intermittent nausea. Recent CT scan shows a new distal ileal stricture with neo-terminal ileum thickening and adjacent fat stranding. Endoscopically, there is evidence of active Crohn's disease with stenosis in the distal ileum. Of note, she has never been treated with immunomodulators or biologics.

Videoconference Topics Discussed Is it safe to use immunomodulators or biologic medications to treat an IBD patient with a history of cancer or with an active cancer? What is the best approach for treating a patient with long-standing enteric Crohn's disease who has undergone surgery for small bowel adenocarcinoma but remains symptomatic and has evidence of small bowel strictures?

Example 3: Pediatric IBD, Medication Compliance

This is a 15-year-old boy with ulcerative colitis that has manifested as left-sided disease as well as pancolitis. At initial diagnosis, both his lab and stool studies were normal. He has had a slowly progressive course with increasing symptoms of bloody diarrhea, arthralgias, and fatigue. He has not been compliant with any of the medications prescribed, including balsalazide, budesonide, and 6-MP. At his most recent office visit, the patient's mother stated that he was fatigued and that his eyes looked yellow. His liver function tests (LFTs) were normal but his total bilirubin was three times the upper limit of normal and for the first time he had a drop in his hemoglobin to 9.4 (normal 14–17 g/dL). His ESR had jumped up to 62 (normal for males 1–15 mm/h). His gastroenterologist felt that this might be Gilbert's disease. Colonoscopy showed only focal active colitis in the cecum and mild rectosigmoid inflammation.

However, 2 days following colonoscopy, he presented with worsening bloody diarrhea, dizziness, blurred vision, joint pain, and excessive fatigue. His hemoglobin was 8.6 (normal 14–17 g/dL) and he had a haptoglobin below 15 (normal 50–150 mg/dL). Both total bilirubin and lactate dehydrogenase (LDH) were elevated to 3.2 (normal 0.3–1.2 mg/dL); his LDH was high at 324 (normal 60–100 units/L), and he had a positive antibody screen. Based on his peripheral smear, there was a strong indication of hemolysis. He was diagnosed with secondary autoimmune hemolytic anemia. For his hemolytic anemia, the patient took prednisone 100 mg/day for 1 week and is currently on 50 mg/day. He is doing well, especially from his colitis perspective where he has only two stools per day. The medical literature on ulcerative colitis and hemolytic anemia is sparse; broad recommendations go anywhere from medicines such as infliximab to a surgical total colectomy.

Videoconference Topics Discussed Is there any established relationship between IBD and hemolytic anemia? What are some future treatment options for this young patient with ulcerative colitis that will not put him at risk for hemolytic anemia? What are some effective methods of managing a young patient whose family is against the use of medication?

Example 4: Education (IBD Mimics)

This is a 65-year-old white female who was diagnosed with irritable bowel syndrome when she was in her 20s. About a decade later, she reported having more frequent diarrhea with abdominal cramping. Colonoscopy with biopsy revealed that she had a lymphocytic, microscopic colitis. In the early 2000s, the patient was diagnosed with chronic variable immune deficiency (CVID) following a workup for symptoms that included some gastrointestinal symptoms. She receives regular treatment with intravenous immunoglobulin (IVIG). Over the past couple of years, she has had more frequent bloody diarrhea and her endoscopic findings are suggestive of ulcerative colitis. She has done well on mesalamine, although she has had three episodes of *Clostridium difficile* colitis during the past 2 years that were treated successfully with oral vancomycin. Of note, she has congenital asplenism and she has a history of purified protein derivative (PPD) positivity that was never treated with appropriate medication.

The patient recently had another flare with increasing diarrhea and some blood in her stool. She has lost about 6 pounds but lacks other constitutional symptoms. This time she was *C. difficile* negative. Giardia, microsporidia, and other pathogens were not found. Her most recent colonoscopy findings remained consistent with moderate to severe ulcerative colitis. Terminal ileal biopsies showed some focal active ileitis without chronic changes or aphthous ulcerations. There was mild disease with some architectural changes compatible with IBD in the right colon. The left colon and rectum had severe disease with ulcers. The transverse colon was spared.

Her current medications include 4.8 g/day of mesalamine and 3 mg of budesonide, which is the highest dose that she tolerates without experiencing easy bruising. She takes loperamide as needed. Her physical exam was unremarkable, aside from mild discomfort to deep palpation of her left lower quadrant. She was slightly anemic and her inflammatory markers were modestly elevated but other lab tests, including her LFTs, were normal**.**

Videoconference Topics Discussed What is the best way to differentiate an immunodeficiency from IBD? In the setting of an immunodeficiency such as CVID, what are some effective tactics for managing IBD?

Example 5: Transfer of Care?

A 39-year-old Caucasian female with an 11-year history of Crohn's disease was transferred to our care for further diagnosis and treatment. The patient had been in long-term remission on 6-MP until this past year when she had two flares of bloody diarrhea that did not fully resolve with extended release budesonide and repeated corticosteroid tapers. Since that time, she was noted to have pancytopenia that her providers attributed to the antibiotic metronidazole that she was taking for a urinary tract infection. Endoscopically, she was shown to have chronic active colitis. She was later admitted to an outside hospital for fever, lethargy, and altered mental status.

Abdominal CT scan showed severe pancolitis without abscess or perforation. Subsequent flexible sigmoidoscopy demonstrated severe diffuse colitis with ulcerations. Biopsies were consistent with severe Crohn's colitis without notable cytomegalovirus (CMV) inclusions; however, immunostained histologic specimens were positive for CMV. She was started on IV ganciclovir for approximately 1 week and then was switched to oral ganciclovir to complete 14 days of treatment. She was discharged on oral steroids and mesalamine. Polymerase chain reaction (PCR) for CMV performed at the outside institution was negative. The patient continued to complain of bloody diarrhea, weight loss, and lethargy. She was referred to our institution at which time she was noted to be hemodynamically stable and afebrile, with mild left-sided abdominal tenderness.

When tested at our institution, her platelet and white cell count had normalized but she had a hemoglobin of 10 g/dl (normal 12–15 g/dl), an erythrocyte sedimentation rate (ESR) of 100 (normal for females 1–25 mm/h), and her previously normal CRP was elevated to 5.3. CMV PCR was positive with 30,882 CMV copies/mL. Numerous colonic biopsies demonstrated CMV intranuclear and intracytoplasmic inclusions. It is noteworthy to add that the IBD service had recently seen a man with an incidental finding of a single CMV intranuclear inclusion on histology. This man had no signs or symptoms of active CMV infection and the CMV inclusion was deemed to be an 'incident bystander' of no clinical consequence.

Videoconference Topics Discussed What do you do with patients who have CMV in the setting of IBD? How do you treat them? Should immunosuppression be discontinued or is it necessary for IBD treatment? Are biologics safe in CMV? What is the role of surgery in these patients?

Example 6: Multidisciplinary Care, Dermatology

This 19-year-old male was diagnosed with ulcerative pancolitis at the age of 4. He has a past history of lip and oral lesions as well as kidney stones. He was a secondary nonresponder to infliximab and underwent a colectomy and ileal pouch anal anastomosis around age 7 for poorly controlled disease. His physicians thereafter noted active disease in the pouch and proximal to the pouch inlet, as well as a stricture. He was subsequently diagnosed with small bowel Crohn's disease and required a loop ileostomy that then was converted to an end ileostomy in 2008. When this young man came into our care the past year, he was underweight, malnourished, and pale with stoma ulcerations and an enterocutaneous fistula. Endoscopically and radiographically, he was found to have fistulizing Crohn's disease.

Since this time, he has had a number of small bowel resections and two fistula takedowns. He has about 250 cm of small bowel remaining. Following resection, he was placed on adalimumab and he did well clinically for a period of time. At follow-up, there were no signs of active disease endoscopically or on cross-sectional imaging. He recently developed acute onset of this recurrent lip swelling and blisters as well as oral and buccal aphthae. He is not taking any medications that are associated with angioedema. Additionally, he has no urticaria, genital ulcerations, or other types of rashes. The lip swelling responds to systemic corticosteroids. We referred him to dermatology.

Videoconference Topics Discussed What types of oral and facial lesions are known to occur in patients with Crohn's disease? Is there a relationship between skin lesions and any medications outside of the anti-tumor necrosis factor agents (TNFs)? Similarly, are any of the newer biologics, such as vedolizumab, associated with these lesions? Can diet play a role and, if so, are there any dietary modifications that might help to clear up these lesions and avoid future outbreaks?

Example 7: Multidisciplinary Care, Colorectal Surgery, and Small Bowel Transplant

The patient is a 52-year-old woman with medically refractory Crohn's disease and high ileostomy output. She was diagnosed with Crohn's disease at age 18 and following a 9-month course of steroids, she maintained a 16-year remission. She underwent an ileocecal resection 17 years after her initial diagnosis. Since that time she has had a stricturoplasty and three anastomotic resections currently leaving her with a diverting loop ileostomy. Disease improvement was not achieved with 6-MP, azathioprine, or 5-ASA and she experienced reactions to anti-TNFs and methotrexate. While corticosteroids improved her Crohn's symptoms, long-term low-dose prednisone induced avascular necrosis of the feet that required surgery, including a fusion. Most recently, she has had perianal involvement, including a perianal fistula treated with drainage and seton placement. She has had two successive perianal abscesses that required antibiotics and incision and drainage, respectively. On recent ileoscopy, there was no evidence of Crohn's disease. MRI was notable for hepatic ductal abnormalities. She was recently admitted to the hospital twice for dehydration and labs indicate that she is hypokalemic, anemic, and has elevated LFTs.

Neither octreotide nor total parenteral nutrition (TPN) has helped to decrease her ileostomy output significantly. She remains on TPN and is not tolerating oral nutrition well. Her current symptoms include nausea, malaise, and lightheadedness. Ustekinumab has been approved but not yet started. Insurance approval for teduglutide is pending.

Videoconference Topics Which types of therapies have been used to help a patient increase intestinal absorption and limit fluid losses? Are there medications outside of traditional IBD drugs that might help her to maintain proper hydration and decrease ostomy output? What are the surgical options for this patient? Are there any dietary modifications that might help her?

Example 8: Risk–Benefit Considerations

A 49-year-old man with no significant medical history was admitted to the hospital with a 1 week history of watery diarrhea 8–10 times a day with diffuse abdominal pain, urgency, and tenesmus. The patient had quit smoking 3 weeks prior to admission. Lab studies demonstrated an elevated creatinine and slightly elevated INR as well as hypokalemia and hypoalbuminemia. Stool studies were negative for pathogens, including *C. difficile* toxin but showed elevated fecal leukocytes. The patient's CRP was elevated to 4.3 mg/dL (normal 0.0–1.0 mg/dL).

Sigmoidoscopy showed diffuse colitis with friable tissue and deep ulcerations to the proximal sigmoid colon. A non-contrast computed tomography (CT) scan revealed diffuse colonic thickening, greatest in the sigmoid, without evidence of toxic megacolon or perforation. Biopsy provided no evidence of small bowel disease. Additionally, there were no granulomas, and rectal biopsies show no evidence of cytomegalovirus or other viral infection. Overall, the picture presented was of a patient with chronic ulcerative colitis. The patient was started on infliximab with good clinical and endoscopic response. However, he lost his insurance and reported significant financial difficulties with paying for any medication.

Videoconference Topics Discussed Can recommending that a patient reinitiate cigarette smoking be a therapeutic means of controlling ulcerative colitis? What does the medical literature show in regards to achieving colitis remission after smoking cigarettes in a previous smoker? Under which circumstances could it be considered appropriate to recommend smoking a small number of cigarettes to control ulcerative colitis symptoms and limit disease progression?

Discussion

Multidisciplinary, multisite videoconferences such as IBD LIVE allow physicians caring for IBD patients to participate in management discussions across a wide geography without the burdens of traveling. IBD videoconferences are an invaluable collaborative, educational experience that results in shared decision-making. They provide "real time" information that positively impacts patient care and improves patient outcomes. The cases are often discussed in the IBD LIVE series are some of the most complex patients who are high utilizers of the health-care system. These patients often have a difficult disease course, spending significantly more time in the emergency department and in the hospital than the majority of IBD patients. It is common for them to have undergone numerous surgeries. Rare patients, such those with as an immunodeficiency in the setting of IBD, are likely to have been seen by very few practitioners. The ability to share effective treatments for these less common conditions is invaluable information to be shared with peers in this group experience.

Teleconferences have been used for decades as a means of educating health-care professionals in remote settings, such as rural areas [14]. They are currently being evaluated as a health education tool in less developed nations [15]. In addition to CME, teleconferences are now being used for patient management in multiple sclerosis and patient support in breast cancer as well as internationally for trauma patients [16–19]. Although videoconferencing plays a significant role in the physician side of telemedicine, it has not yet become widespread multi-institutionally. The IBD LIVE videoconference platform may be an appropriate model for medical education of the future.

Some of the benefits of multisite video teleconferences are the ability of health-care providers to take part in a CME-eligible interdisciplinary discussion that can improve the quality of patient care and increase medical knowledge without having to travel from their academic institution. Not only does this avoid the expense and inconvenience of travel, it means that physicians will not be absent from their valuable clinical obligations. Compared to a hospital-based consultation, the IBD LIVE sessions bring together multiple specialists from numerous institutions, offering the opportunity for a detailed dialogue and exchange of viewpoints.

Each involved center and the individual participants make these types of conferences a success. More experienced IBD specialists are able to share their knowledge with each other, as well as with junior faculty and trainees. Additionally, thought leaders from larger institutions may be able to exchange ideas and information with those from smaller academic centers, contributing their valuable insight and management experience. Presenting and discussing some of the most challenging situations that are encountered in IBD patient care leads to knowledge transfer and serves as a platform for investigating novel or creative therapies. Participants often continue to discuss the cases after the conference meeting, and may provide follow-up on management decisions and patient outcomes. Patient referrals sometimes occur as the result of the conference, when particular therapies are available at an outside institution. Additionally, the videoconferences have fostered collaborative research experiences between centers.

New communication and digital technology has allowed for more extensive institutional and educational access. Multiparty IBD videoconferencing such as ours is now webcasting, which permits any site to access and view the conference. Anyone watching and listening to this webcast can e-mail, text, or electronically post questions to the moderator. A broader audience is therefore capable of posing questions about each particular case. A virtual library was created recently in which our IBD LIVE sessions will be archived so that participants can view them at a later time and receive CME credit. In the near future, we hope to have mobile devices such as tablets, notebooks, and smart phones configured to show the live video feed so that the videoconference can be experienced in just about any geographical locations.

The ultimate goal of any health-care-related videoconference is to improve health and ensure better long-term outcomes for patients. Multi-institutional IBD videoconferencing can positively impact patient care and outcomes through actively sharing ideas and fostering multi-institutional research. As videoconferencing gains popularity in various fields of medicine, its expeditious growth and success in IBD shows that it has limitless potential for clinical education.

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Chapter 9
System Requirements for Delivery of Telemedicine Services

John Kornak

With the lack of medical students heading into the healthcare field, the access to quality specialists continues to decrease as is the case of physicians providing the needed level of care for diseases like Crohn's, colitis, and inflammatory bowel disease (IBD). Patients are performing local, nationwide, and even international website searches to find specialists in their field who can provide both the needed level of care and follow-up care at a distance using technologies such as telemedicine. Telemedicine continues to grow in popularity for health systems, hospitals, specialists, account care organizations (ACOs), and even start-up companies that can provide both the technical platform via cloud technology and access to specialists. In years past, Internet access, bandwidth speed, and wireless were all very cumbersome and expensive but this has changed significantly in the last 5 years. The telemedicine technical platform requirements have become less complex and the ability to use consumer grade equipment like laptops, tablets, and smartphones is on the rise. The cost of purchasing, leasing, and even renting a video solution via software as a service (SaaS) platform has decreased to drive the increased adoption for creating a telemedicine program using the consumer electronics market technologies. In this section, the system requirements will be reviewed to build a telemedicine program for the delivery of telemedicine services.

Scope of Work

A telemedicine program is only as good as the foundation that has been created around the scope of work on how the program will be organized and delivered to the patients. In this manner, the administrative and clinical leadership teams should create a scope of work around how the program will be delivered, funded, and ul-

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timately staffed by internal or external specialists. Senior management must define operational policies and deliver strategic aims of the program, as well as clearly define roles and responsibilities for everyone who will be involved in direct contact with the patient population [1]. A typical mechanism of attaining the scope of a program is creating a concept sheet or a scope of work document. Many organizations have an information technology (IT) department that have certain standards in place around project management and documentation. A scope of work document may already be available for a project, but with a telemedicine program, there is more than just IT requirements that have to be detailed. See Fig. 9.1 for suggested questions that should be included into a telemedicine concept sheet or scope of work.

Once the telemedicine concept has been outlined in the document and all parties have agreed on the program, a project charter should be developed to spell out the telemedicine program, a contact list of all involved participants, a project plan to show tasks and delivery dates, risks and concerns if the project is not delivered on time, and finally the project charter will need to have sign-off from senior leadership, departmental administration, physicians, and finally the telemedicine department. The funding or budget component of the scope of work must be worked out before the program moves too far. Without the necessary funding or finance department agreeing to allocate capital funds for the program, the telemedicine program should only be considered in a conceptual phase. Depending on the structure of the program, the finance department may require a split-funded program or fully departmental-funded approach. This will all be something that must be agreed upon prior to any major progress on program development.

Types of Telemedicine Services

Once the telemedicine concept has been properly documented for the telemedicine department to review internally, a separate meeting should take place with the physician or administrative leader who is requesting the telemedicine program to review the concept and to figure out what is the most appropriate type of service to embark upon since a "one-size-fits-all" technology is rarely appropriate for every concept.

The delivery of remote health services is used for a variety of purposes:

- *Specialist referral services* typically involve a specialist assisting a general practitioner in rendering a diagnosis. This may involve a patient "seeing" a specialist over a live, remote consult or the transmission of diagnostic images and/or video along with patient data to a specialist for viewing later.
- *Direct patient care* such as sharing audio, video, and medical data between a patient and health professional for use in rendering a diagnosis, treatment plan, prescription, or advice. This might involve a patient located at a remote clinic, a physician's office, or home.
- *Remote patient monitoring* uses devices to remotely collect and send data to a monitoring station for interpretation. Such "home telehealth" applications might include using telemetry devices to capture specific vital sign or other biometric

Telemedicine Consult Concept Sheet

Please complete the following sections for your proposed Telemedicine Consult project:

Name of the program:

Department/Section/Person Requestor:

Please describe the proposed telemedicine project by completing the following:

1. Intent of the program?
2. Funding source for IT equipment (webcams, microphones, headsets) and support?
3. Optimal Time Line for starting program?
4. Patient population/Organ system (if applicable)?
5. Anticipated documentation, records, and/or data collection?
6. Expected goals for the program?
7. Expected administrative process for how a patient schedules a video consultation?
8. How many providers (physicians, nurses, data coordinators, etc.) do you anticipate participating in the video program, at 1 time?
9. Do you anticipate in having multiple video calls taking place at the same time? Or dispersed pending availability in electronic medical record scheduling?
10. Do you anticipate to bill for reimbursement for these teleconsults? What is your financial model for long-term sustainability of the program?

Fig. 9.1 Telemedicine consult concept sheet

data, such as blood pressure, glucose, electrocardiogram (ECG), and weight. Such services can be used to supplement the use of visiting nurses and other payer-led supportive services.

- *Medical education and mentoring*, which range from the provision of continuing medical education credits for health professionals and special medical education

seminars for targeted groups to interactive expert advice provided to another professional performing medical procedure. This can range from video teleconference meetings to surgical telementoring for complex Crohn's cases.
- *Consumer medical and health information* includes the use of the Internet for consumers to obtain specialized health information and online discussion groups to provide peer-to-peer support [2].

Most programs may involve a specialist referral service or direct patient care service; there could be a combination of one, two, or even three services depending upon the concept and end result that has been presented by the physician or administrative leader.

Technology Audit and Assessment

The biggest concern around technology and telemedicine has been the lack of knowledge if the physical equipment is onsite and installed in a particular location or for public clinical use. It is the "you don't know what you don't know" type of mentality. A technology audit should be conducted on the entire campus or healthcare setting to see what types of equipment are in use as well as what can be utilized for a telemedicine program. The audit should be documented in a spreadsheet so that it lists all manufacturers, model numbers, current firmware version, current Internet Protocol (IP) addresses, main point of contact to book the room or equipment, and any other details about the equipment or conference room. Figure 9.2 is an example of what a typical audit spreadsheet should catalog during the inventory process. This process limits the challenge of multivendor complexity seen with disconnected purchasing and deployment of various vendors.

If the conference room is used for standard audio meetings including content sharing and slide presentations but does not have any videoconferencing capabilities, this room should not be used for any potential telemedicine consults unless the budget will fund the necessary technology for the room. If the room has the necessary video technology, it should be reviewed for setup, configuration, and ease of use with a particular focus on microphone placement and audio challenges. All equipment, no matter if in a conference room or mobile equipment, should be easy for nontechnical people to use [3]. This is where the simplistic approach comes in because if the equipment is too difficult to use, it will not be used for anything including telemedicine.

Conference room design impacts the quality of the telemedicine services and it should not be overlooked during the development of a telemedicine program. Good telemedicine room design will accomplish two major functions: it will create the visual and audio clarity and accuracy that is necessary to support clinical examination and diagnosis from a distance and a connection between the patient and the remote provider sites where the patient–clinician interaction, not the technology, is the focal point. The patient and provider's location should ensure privacy to prevent any unauthorized access or distractions to take away from the virtual consultation—in

Hospital	Dept/Location	Room or Mobile System	Video V-LAN	Conference Room Status	Manufacturer	Firmware #	Serial #	Admin Passcode	H.323	IP	Contact Person	Contact Phone #

Fig. 9.2 Technology audit spreadsheet

particular, windows with bright light and loud noises from hallways or mechanical doors.

The challenge in creating a telemedicine room is to integrate the technology into the regular flow of an examination and to reproduce the images at the consulting clinician site with clarity and accuracy. There are a number of aspects to consider when designing a telemedicine examination room. The most important design considerations are room location, room size, placement of equipment/furniture, electrical and telecommunications connections, lighting, acoustics, and wall color. Since most patient sites will be adapting an existing room for telemedicine, it is important to select the best possible fit and to budget, if necessary, for room modifications [4]. A well-created telemedicine room assessment guide should be developed, including all of the necessary design considerations, and should be utilized during any type of construction reviews with all of the necessary impacted parties.

Telemedicine Infrastructure: Videoconferencing/ Collaboration Systems

Once a telemedicine audit has been performed, the telemedicine department should be able to get a sense of what type of technology is currently being deployed and utilized across the network. If a telemedicine audit renders a long list of consult or conference rooms that have been enabled with videoconferencing, the telemedicine department should work with the physicians providing the teleconsult service to see if this approach would be the best for the program along with adding in desktop videoconferencing for the physicians and a model solution for patients. Patients should be given a clear hardware and software solution that requires little to no investment or a bring your own device (BYOD) strategy. If the patients have a device that is capable of using the software for a teleconsult, this will be a much desired solution since there will not be a large expense. The complexity of the telemedicine infrastructure is one of the factors that either grows the adoption of a telemedicine program or fundamentally challenges it [5].

Traditional videoconferencing solutions are equipped with a type of video codec for compression and transmission of video. The following are a few of the more popular video protocols that are being used today over the Internet:

- *H.323*—This is the technical standard for videoconferencing compression standards that allow different equipment to interoperate via the IP.
- *SIP*—This is a technical protocol for signaling and controlling multimedia communication sessions like internet telephony for voice/video calls as well as instant messaging via the IP.
- *H.264*—This is a video compression format that was created to provide good video quality at lower bit rates than previous video protocols which is used by Blu-ray.

- *H.265*—This is a high efficiency video coding protocol which doubles the data compression ratio at the same level of video quality.
- *webRTC*—A newer free, open protocol that provides browsers and mobile application with real-time communication (RTC) capabilities via simple application program interfaces (APIs) to perform voice calling, video chat, and P2P file sharing without any internal or external plugins [6].

For more information on the telemedicine and telehealth standards along with definitions of some of the common terms, see Appendix 10.1 and 10.2 at the end of the chapter [7].

During the telemedicine audit, if a very old, archaic technology is no longer under support warranty or cannot be placed under any type of support contract, a short-cycle telemedicine strategy session is imperative. A roadmap of how to put a cohesive solution in place and who is going to be funding this initiative will need to be decided upon during program development. If an entire videoconferencing solution needs to be purchased and will be available for clinicians and administrators, a telemedicine executive planning committee should be formed with the top leaders in the organization driving telemedicine adoption to put the standards in place. If the remote specialist does not want to wait for a larger initiative to be funded and installed by the telemedicine and IT departments, they may want to purchase or lease a cloud-based videoconferencing solution that is rapidly becoming commoditized.

Cloud-based solutions typically come in two different models: hosted within customer's location for security and privacy sake, or at the vendor's site for a better scalabilty and less expense. The second model is called a "software as a service" model or SaaS. Most cloud-based vendors operating as a truly virtual model will price their solutions based on the number of participants in a telemedicine consult as well as if the remote specialist needs audio and video as well as interoperability to H.323 or SIP endpoints, mobile/tablet solution, as well as far-end camera control (FECC). A cloud-based solution can be a much more reasonable investment for a provider or even a smaller remote specialist group. It can be expanded as the telemedicine program grows with more remote specialists and patients, as well as the exchange of collaborative efforts between customer and vendor to expand the cloud-based platforms, electronic medical record interface, and other possibilities.

The most important aspects to remember when selecting the proper technology to use for your telemedicine consult solution are:

1. What is the current clinical workflow?
2. How will the current clinical workflow change with telemedicine?
3. What solutions are available that are easy to use for both clinicians and patients?
4. What is the return on investment (ROI) of the solution?
5. Invest in a large videoconferencing solution or a cloud-based SaaS solution?
6. What is the support model for the teleconsultation service program?

While the technology is typically the most talked about and most desired solution from the clinical environment, the scope of the program must be clearly defined of which how a technical solution using video will be implemented to enhance, *not replace*, the clinician-to-patient relationship.

Interoperability

Most of the original plain old telephone service (POTS) and integrated services digital network (ISDN) videoconferencing systems were originally built to communicate among other videoconferencing systems on the same network. This is an example of a closed-network program that relied on a great deal of security and privacy, which is a topic that will be discussed later in this chapter. For the government and military, this solution works and everyone else who wants to communicate with them needs to have interoperable solutions that scale down to these levels. This level of scalability is also known as interoperability. While most federal government and military videoconferencing infrastructure solutions are not always used for telemedicine purposes, the same level of security and privacy for the patient should be kept to the same standard as well as being able to provide interoperable infrastructure video solutions that are flexible and cost-effective. This issue goes back to the building of a telemedicine infrastructure that can be scaled for one or multiple programs by a tiered approach.

Most videoconferencing systems or even off-the-shelf components are adequate for their intended function, but being able to add new features tends to be costly and time-consuming. The closed-network designs from one vendor may not be able to communicate or talk the same video language to another vendor [8]. In order to provide an interoperable video solution for remote specialists, patients, and many of the telemedicine programs, the telemedicine infrastructure must be designed and built with virtual bridges to handle the necessary video protocols from one system to another. These virtual bridges can be very expensive to purchase after the original video infrastructure has been implemented; so it is very important to consider interoperable codecs when making the initial purchase. If the virtual bridge must be purchased after the telemedicine design, a proper technology requirements document should be presented to the finance team for consideration of this capital investment.

Another possible solution to the interoperability problems of a telemedicine program is adding a middleware solution (possible software and network engineering) to act as the glue that enables incompatible systems to talk among each other [9]. This can be accomplished by purchasing a middleware software solution to be added to the current environment. Another possibility is leasing a solution from a third-party vendor who has already built this into their cohosted environment. A final optional solution would be to find a third-party vendor who can host an entire interoperable solution in the cloud for a per month fee.

Interoperability among the most recognizable videoconferencing infrastructures is one of the main factors that has limited the early adoption and expansion of telemedicine. Remote specialists experience frustration when they try to perform a telemedicine consult with a patient who does not have either the proper software or hardware. Patients experience frustration when the remote specialist's office does not relay the proper information about the telemedicine software/hardware or cannot complete the consultation without having a technical person guide them through the controls of the system. In order to grow telemedicine programs and their popularity, a telemedicine department must be able to provide an interoperable solution that is cost-effective, not time-consuming, and can work on any technical platform without any problems.

Network Connectivity

The connection between remote specialist and patient should appear as if everyone was in the same room together. In order to provide this type of appearance, the telemedicine equipment should be connected at the highest, acceptable network speed as well as to the most reliable connection—wired at all times if possible and wireless when needed using mobile carts, tablets, and smartphones. Reliability of the networks and the telemedicine connections must be kept at the highest regard since the remote specialists and patients will be surveyed on their telemedicine experience. The most common delivery mechanisms for remote healthcare and data delivery are dependent on the reliability of the network. The list below is the most common delivery mechanisms:

- *Network programs*—Also known as closed-network programs, these link tertiary care hospitals and clinics with outlying clinics and community health centers in rural or suburban areas through either hub-and-spoke or integrated network systems. The links may use dedicated high-speed lines or the Internet for telecommunication links between sites. It is estimated that there are 200 telemedicine networks in the USA involving close to 3500 medical and healthcare institutions throughout the country.
- *Point-to-point connections*—Using private networks are used by hospitals and clinics that deliver services directly or contract out (outsourced) specialty services to independent medical service providers at ambulatory care sites.
- *Health provider to the home connections*—This involves connecting primary care providers, specialists, and home health nurses with patients over single-line phone-video systems for interactive clinical consultations. Such services can also be extended to a residential care center, such as nursing homes and assisted living facility.
- *Direct patient to monitoring center*—Links are used for pacemaker, cardiac, pulmonary, or fetal monitoring and related services and provide patients the ability to maintain independent lifestyles.
- *Web-based e-health patient service sites*—These provide direct consumer outreach and services over the Internet [10].

Most health systems and hospitals have preferred to outfit an examination room or conference room with the necessary equipment and to use a wired data connection for the remote specialists to communicate with their patients. Examination and conference rooms can be designed with standard-based videoconferencing systems or off-the-shelf high-definition webcams and headsets just as long as the wired data connection has been set up on the local area network (LAN) with the proper network speed. The elimination of audio feedback or video jitter is among what is typically seen via pixelated images or the sound from a person not matching their mouth movements. The networks of most health systems and hospitals are also set up with quality of services (QOS) network protocol to provide the most reliable network experience without sacrificing network speed.

As technology has advanced over the years, many people have set up their own home personal wireless networks to provide portability and accessibility of their laptops and tablets. These wireless networks, while acceptable but not the most preferred connection type, must be robust enough to allow the video and audio traffic from a telemedicine consultation to be communicated to the remote specialists in an acceptable manner. If the patient is utilizing a smartphone or cellular-enabled tablet and using their data plan for connectivity, a mock telemedicine event using this technology should be tested prior to the actual telemedicine consult to verify that remote specialist acceptance of the network connection. If the remote specialist requires a more reliable connection, the patient may need to find a wireless access point in their area or direct the patient to reschedule the telemedicine service when they have a more reliable and robust network. In turn, if the remote specialist is on call and is in the midst of traveling, they need to provide a reliable network connection and a secure location to the patient so that they are seen and heard over their mobile device. Being able to provide the most reliable and trusted network connection will enhance the telemedicine experience for both the remote specialist and the patient. Reliability in network connectivity will also help increase the use and adoption of telemedicine for remote specialists and patients, which will hopefully be reflected in telemedicine survey results.

Network Bandwidth

When a patient's survey is returned and they state that the best part about the telemedicine consult was that they felt like they were in the same room as the remote specialist, a large amount of this is credited to the network bandwidth that is supplied to the network. The video hardware that is being used for the telemedicine experience should be isolated from the rest of the traffic on the network. In a small office with little to no IT staff, this might be very difficult, but in a hospital environment this is very feasible. With the amount of equipment on a hospital network, the networking team should be able to build a video network to isolate the traffic off so that it does not collide with all of the other computers, wireless phones, and even the mobile carts that are deployed throughout the hospital.

The higher the transmission speed is, the better performance on the network will be seen on the telemedicine consult. For optimal evaluations, a minimum of 768 Kbps transmission speed is needed for the video system; however, many telemedicine consults have functioned at 384 Kbps [11]. Many telemedicine programs base their network bandwidth speeds on preexisting practice standards as described by the governing body of telemedicine, that is, the American Telemedicine Association (ATA). Per the ATA, the minimum bandwidth for adequate bandwidth, resolution, and speed for a clinical consultation is 384 Kbps in both downlink and uplink directions. They also state in their practice guidelines that the resolution should be set at a minimum of 640 × 360 and have a speed at 30 frame per second [16]. When possible to troubleshoot network issues found during a previous telemedicine consult, network test tools should be utilized for troubleshooting. These network test tools will run any number of bandwidth algorithms to test dropped packets, network jitter, audio issues, or to detect any issues that might be compromising the network.

In the event of any network deactivations or emergency management protocols, there should be a downtime procedure set in place for both the remote specialist and the patient. This downtime procedure should be documented for the remote specialist and their care team as well as provided to the patient in paper and electronic form and provided to all prior to telemedicine consultation. For remote specialists and care team troubleshooting, an audio line can be utilized to walk through troubleshooting steps or possibly implementing a remote desktop software to take control of the needed equipment. The downtime procedure should have the necessary phone numbers and support staff identified for normal business hours and after-hours support. [12].

Security and Privacy

Privacy and confidentiality, much like in the banking industry, has always been a concern in healthcare where patient health information (PHI) has been and will continue to be a concern for health systems, their clinicians, and the patients. With the advancements in technology over the years, the use of encryption software has been able to protect information from unauthorized access. The encryption software is located at both ends of the telemedicine communication and effectively encodes the video, sound, and data during transmission and reconstitutes the information at the other end. Even if someone were able to intercept the transmission, the software would prohibit anyone but an authorized user from reconstructing the encrypted video, sound, and data [13].

The privacy and confidentiality requirements for clinical and healthcare organizations to follow are properly outlined by the Health Insurance Portability and Accountability Act (HIPAA) as well as other applicable state and local laws. As with an in-person office visit, a provider must document in the patient's medical record either on paper or electronically the visit. Accessing the patient's medical record should follow standard HIPAA privacy provisions. For those providers or telemedicine departments utilizing a third-party vendor for an electronic medical record (EMR) or videoconferencing solution, a business associate agreement (BAA) should be executed as stipulated under the HIPAA Act of 1996 and the HITECH Act of 2009. When it comes to security and privacy, the encryption standard should include FIPS 140-2, known as the Federal Information Processing Standard (FIPS) as well as the American Encryption Standard (AES) [14].

Most healthcare organizations have a department(s) specializing in network connectivity and security. These departments should be included during the telemedicine program development so that the necessary precautions are put in place to protect all parties. Videoconferencing systems, computers, and mobile devices should also be encrypted by either software running locally on the device to secure the connection or by logging into a virtual private network (VPN) with the proper credentials to use the telemedicine software and hardware. The authentication process of entering a unique username and password should be a requirement to the technical architecture as well as setting up timeout thresholds when the software programs lay in an idle state. Devices should be configured to utilize an inactivity timeout function that requires a passphrase to access the device after timeout threshold has been exceeded. This timeout should not exceed 15 min mode [15]. The use of generic usernames and passwords should not be allowed nor endorsed by the telemedicine department for ease of use by the providers.

Patients should be educated about the technologies available to use regarding computer and mobile device security, as well as be informed about the privacy and security options. Videoconferencing privacy features should be available to both the provider and the patient. Privacy features should include audio muting, video muting, and the ability to easily change from public to private audio mode [16]. If a provider is sending out a "click to join" e-mail to the patient, the provider should have the ability to assign a passcode for the patient as well as the "lock" or secure the teleconsult to only those required to participate in the session. This will ensure that the proper patient has entered the teleconsult as well as to prevent previous or future teleconsults happening without the provider's knowledge. At the end of a teleconsult, the provider should have the ability to disconnect all parties from the session.

Providers, using mobile devices to perform the teleconsult visit with their patient, should keep devices in their possession when traveling or in an uncontrolled environment. Providers should have the capability to remotely disable or wipe their mobile device in the event it is lost or stolen [17]. The organization's mobile device governing body should educate and deploy a mobile device management (MDM) solution. A MDM solution provides the loading of appropriate and warranted applications to the user's job description as well as deactivating or remotely wiping the device for security purposes. While this might deter some providers of receiving a free device from an organization and using their own device, the MDM solution should provide peace of mind to the provider and information technology group who must support and upkeep these devices.

Patient Documentation/Patient Portal

As stated earlier in this chapter, a provider must document the teleconsult visit as if the patient participated in an in-person visit. Most healthcare organizations are planning or have already transitioned to an EMR and are even allowing patients to view their records online, modify their own demographic data, upload radiology images, and even communicate electronically over a secure e-mail system via a patient portal. The patient portal provides further involvement of the patient in their own healthcare as well as the ability to review the provider's notes and the exact treatment plan. Patients should be advised of security risks of attempting to upload information from mobile devices. As described above in the Security and Privacy section, patients are also required to authenticate their user credentials and must accept the same timeout thresholds.

During a telemedicine consult, the telemedicine physician should work off a checklist to assure that the collection of all needed information from the patient has been received and recorded within the patient's EMR. In a typical hub and spoke telemedicine program, a remote site uses a provided patient documentation checklist to capture and record all of the patient's information prior to the telemedicine consult start so that the remote specialist has all required information prior to evaluating the patient. This will assure the most informative package of information is provided to the remote specialist so that the best diagnosis can be offered to the patient. As telemedicine systems and health information systems continue to merge, it will become easier to integrate these checklists and required patient demographic fields into the software interfaces for the telemedicine system as well as a referring provider will be able to assemble all the necessary information and transmit it to the consulting provider instantly [18].

While telemedicine has its own barriers with technology and risk, there is an even larger barrier with providers and healthcare systems allowing patients to access their own information. The patient has the right to see their EMR and now these patient portals are providing the necessary gateway regardless of provider acceptance. Many organizations have to provide this patient portal access because of meaningful use (MU). At the current time, while the Veterans Administration nationwide is on a single EMR platform, VistA, many hospitals and healthcare systems are running different EMRs; some interoperate or communicate with each other and some are silo solutions. For more information on patient documentation, patient portals, and MU, it would be best for those providers and clinicians to connect with their information technology departments that support these areas.

Recording/Archiving

Security and privacy has already been discussed in this chapter, but the topic of recording and archiving these consults is another area of concern when it comes to telemedicine that must be addressed early during a telemedicine program creation. Many years ago, physicians who were just starting to use videoconferencing for telemedicine services could use videocassette recorders (VCRs) to tape their conferences with other physicians. Some sessions were recorded for teaching purposes for residents or incoming students to understand how patients would react to the use of video during an examination. These sessions would also be recorded for legal purposes so that if a patient were to ever come back and sue the physician for malpractice, the physician would be able to pull a recording to provide to their legal counsel for assistance in the court proceedings. As technology has changed and evolved, VCRs were replaced by compact disc (CD) burners, and now they have been replaced by content sharing servers.

In today's evolving world of telemedicine, hospitals and health systems are averse to any potential leak of PHI. The legal counsels and compliance departments are concerned about malpractice based on a recording that the patient has no knowledge ever took place. Any clinical user taking part in a recorded session will need to announce their name, position, and intention of why they are taking part in the consult as well as getting the verbal and written consent from the patient that they are approving the recording of their telemedicine consult.

Clinicians and patients should discuss any intention to record a telemedicine consult, how this session is to be stored and how privacy will be protected. Recording should be encrypted for maximum security. Recording should be streamed to protect from accidental or unauthorized file sharing and/or transfer. The physician may also want to discuss his or her policy with regard to the patient sharing portions of this information with the general public. Written agreements pertaining to this issue can protect both the patient and the clinicians. If consults are recorded, the recordings should be stored and archived in a secure location. Access to these recordings should only be granted to authorized users [19].

Mock Training Events

The success of a telemedicine program will rely on minimizing failure, reducing the difficulties in providing technical support, and constantly testing the hardware and software. It is important to achieve a high level of reliability and performance. Reliability and performance should be approximately 99% or better to attract and retain physicians and patients satisfied that telemedicine is a viable process for delivering medical care. It is often difficult to regain credibility with either physicians or patients if the systems or networks perform unreliably [20]. Not only should a working model for delivering telemedicine support be developed, but also the clinical end users should perform mock events to test the hardware, software, video speed, and the reliability of their physical location among their own team as well as those identified patients.

The physician champion identified to run the telemedicine program and their administrative staff should take the lead on identifying dates and times when the mock events should be scheduled within the organization. Departmental technical staff, if identified as hardware resources, should also take part in the mock training events so that they are available to identify, troubleshoot, and resolve the hardware or software. Administrative staff identified to communicate with the patients should be provided the necessary set of instructions, weblinks, documentation, and e-mail templates by the telemedicine support team for testing purposes. Once all the information has been gathered and received operational approval, a select number of patients should be identified as "beta-testers" who can follow installation and testing documentation provided by the telemedicine team.

A week prior to the actual telemedicine consult, the administrative staff should schedule a mock training event with the patient to test the installation and any configuration of the software (unless a telemedicine device is provided to the patient for home use). During this mock event, the administrative staff should communicate with the patient and verify video and audio on both sides to see if the patient can see and hear the end user communicating with them. If the hardware and software allow for FECC, the testing of remote pan-tilt-zoom (PTZ) functions should be tested and communicated by the telemedicine technical team. Once the mock event between administrative staff member and patient is concluded and everyone signs off that audio and video were successful, the telemedicine physician or clinical end user who will be contacting the patient for a telemedicine consult should perform the same mock training event with their hardware and software setup. All results of administrative, clinical, and patient testing should be recorded in a checklist and provided back to the telemedicine technical team for further troubleshooting and potential custom documentation edits. The constant testing and retesting with the three groups identified will build reliability and accuracy for the successful launch and proliferation of the telemedicine program.

Video Etiquette for Remote Specialists and Patients

During a teleconsultation session, both the provider and patient locations are considered a patient examination room regardless of the location's intended use. The room should be of sufficient size to accommodate not only the patient and/or family member/significant other who is participating in the teleconsultation but also the necessary equipment. The room should be safe, adequately lit, have minimal external noise, and provide comfortable seating. The room should be designed with audio and visual privacy and be able to accommodate posture and movement visualization. Pagers, cell phones (unless being used as the device for the teleconsultation), and other electronic devices that could cause a disturbance should be turned off if remaining in the room or removed from the room during the length of the teleconsultation.

For the provider, the telemedicine room should be in a quiet location, minimizing exposure to home or office noise, busy corridors, stairwells, parking lots, waiting rooms, restrooms, or other sources of house (i.e., children and/or pets). Such noise can be picked up by microphones which can make it difficult for the patient to hear. Rooms without windows are better for quality image transmission with less camera glare. Rooms with windows should have shared or blinds to reduce the light and glare. The environment needs to be designed to enhance the quality of the video and audio interactions and to accommodate the equipment that might not normally be in an examination room [21].

The California Telemedicine and eHealth Center (CTEC) have created a Telemedicine Room Design Program Guide that addresses many of the current video etiquette and environmental concerns regarding teleconsultation. In this guide, they have discussed the need to integrate the technology into the regular flow of an examination room and to reproduce the images at the patient's site with clarity and accuracy. They focused much attention in their guide to addressing the following aspects: location, placement of equipment and furniture, electrical and telecommunications connections, lighting, acoustics, and wall color. Rather than trying to recreate the wheel on a telemedicine program and how to change the culture within an organization, a recommendation would be to perform research on video etiquette and environment concerns before creating custom documentation for a telemedicine program. Another recommendation would be to download the Telemedicine Room Design Program Guide document and adapt it to a clinical program since it seems to address many known and unknown areas. The location of this document download is: http://www.telehealthresourcecenter.org/sites/main/files/file-attachments/09-0824-2_ctec_program_guide-room_design_w_cm_edits.pdf. An example of the CTEC's Telemedicine Room Assessment and Design Worksheet is included in Appendix 10.3 for reference.

Telemedicine Deployment and Management

The mission of the telemedicine program should be driven by clinical leadership but the deployment and management of that program should be a collective effort including the clinical and technical leadership from the telemedicine team. Since telemedicine is considered to be a new way of delivering medicine, the implementation of a new program may change the workflow of existing practices. Planned and sensitive change management is therefore central to the successful introduction of telemedicine services. Other critical success factors include the organization of hub and remote sites (otherwise known as "spokes"), data collection and performance indicators, development plans, and marketing communication [22].

All telemedicine conceptual ideas should be vetted through a Telehealth Executive Committee in which the clinical leadership presents the idea, provides a current volume of patient that could be affected by a telemedicine program, funding for the needed hardware for the program, discussion on reimbursement and credentialing areas, and, lastly, how the clinical program envisions the program to impact their current patient population. The Telehealth Executive Committee should provide critique to the clinical program and ask any questions before making their recommendations to approve the program to move into development stage. The telemedicine program should operate with the current telemedicine technology that has been deployed across the health system or hospital to leverage the return on investment. Any additional equipment needed for the program will need to be recommended to the telemedicine team for evaluation before agreeing to include them into the operation of the telemedicine program. Once approval of the telemedicine program has been reached, the telemedicine team can move this program into development stage.

The telemedicine team and the clinical champion will need to develop a project plan including all steps and responsible parties who need to be assigned tasks within this project plan. The telemedicine team will assign a project manager to manage the project plan, schedule weekly meetings with all parties, set up testing and training plans, and ultimately give the "thumbs-up" on when the program has reached 100%assigned task completion making it ready to move to the "go live" stage. While the telemedicine program might be ready for "show time," the clinical champion who created the idea must get the approval from the clinical chairperson to move the project from concept into production. They will need to verify that all billing, credentialing, and malpractice issues have been resolved prior to recruiting the first round of patients to be evaluated using telemedicine.

Once the program has moved into a "live" status, the telemedicine team will use collected data and surveys to perform some monthly management meetings with the clinical champions. The required information will be disseminated among the group to review and discuss how to resolve challenging situations, as well as to review if the program has met the clinical champions' goals. Monthly and quarterly management meetings and check-ins should be scheduled so that strategic goals are continued to being met, as well as program expansion can be considered for other services lines.

Support Structure

The support and upkeep of a telemedicine program is very important to the success and longevity to both the end users and the patients. The technology will require infrastructure support, repair service, and preventive maintenance, as well as a training and marketing to all stakeholders. Ongoing technology maintenance and repair is often best managed through an in-house technical support center [23]. A technical support group should have the ability to create custom documentation for any end user to follow, either clinical or a regular patient, in order to step through the installation of software as well as testing with the technical or end user community. The documentation should be created in layman's terms to avoid any confusion from those following the step-by-step instructions.

The in-house technical support center should have a mechanism in place to receive incoming phone calls, the ability to open service tickets, as well as a the funding to repair and replace broken or out of service equipment in a timely fashion. When technical support resources are limited, the ability to cross train internal "super users" or the technical staff of another department should also be included in program development. When the clinical users and patients require technical support for mock events and during actual teleconsults, the program must include a matrix level of support that can be included in the program creation. Any telemedicine programs that also requires after hours or 24-7-365 support, an on-call schedule must be created so that a dedicated technical and clinical support team can provide the needed support in a timely manner. If additional technical or clinical support resources are needed to provide support to the program, a special operational budget request should be delivered to the financial team requesting these funds. If the request is denied due to lack of operational budget, the required resource costs, either daily or on-call after hours, should be paid for by the department that is setting up the telemedicine program. These additional resources will help drive adoption of telemedicine in the department as well as provide satisfaction to the clinical telemedicine team members and those patients utilizing the solution.

Telemedicine Program Go-Live

A clearly identifiable go-live date is needed to be established by the telemedicine team project manager during the development of the project plan. While this date can be changed anytime during the project, a firm date should be established during the program. A proof of concept or pilot project in telemedicine has been created by many organizations but they have never moved past the pilot stage. Recurrent pilot programs that are never moved into major products are due to many issues like: reimbursement, rurality, remote site technical issues, staff turnover, lack of patient interest, adoption issues, risk of malpractice, and security concerns.

The go-live tasks should be clearly identified in the project plan including assigned responsible parties who will be available both onsite for clinical champion and administrative support as well as the support structure to assist patients from their remote offices. Since many of these telemedicine programs are being offered during normal office hours, the ability of having technical and clinical support from the telemedicine team should be identified during a pre-go-live meeting with the clinical leaders. If the go-live and the go-live date need to be adjusted for some clinical or administrative reasoning, this change should be echoed during the program development meeting and cleared by the telemedicine team.

Telemedicine Survey/Data Analytics

Telemedicine has numerous participants, each with unique needs and expectations. Patients desire effective and compassionate care that precedes in as expeditious a manner as possible. Primary caregivers desire effective consultation but are also interested in the time spent preparing and presenting a case. Consultants are concerned about the duration of the visit and quality of presentation. The system collectively is concerned with cost-effectiveness and patient-management issues. A complete assessment of telemedicine satisfaction must have all perspectives in mind [24]. Since all telemedicine programs learn from each other, the program must survey all participants to get their feedback on the effectiveness of the telemedicine consult.

Conference ID: 1202177329899177
Conference Name: rcross@ummc002.vidyo.umm.edu

Call ID	User ID	Display Name	Direction	End Point Type	Tenant	Join Time	Leave Time	Duration	Router ID	Gateway ID	Gateway Prefix
13517	nmiller	Nicole Miller	O	D	UMMC-IBD	25:00.0	42:00.0	17	CPBSAJXHD5ZR8A58S399M9WSBCEERGXJ1 EDMC2G6E3P6V00VR0001		
13516	Guest	John Kornak-h4iMYYIcBrcWCAxp	O	G	UMMC-IBD	10:00.0	42:00.0	32	CPBSAJXHD5ZR8A58S399M9WSBCEERGXJ1 EDMC2G6E3P6V00VR0001		
13515	rcross	Dr. Raymond Cross	O	D	UMMC-IBD	05:00.0	42:00.0	37	CPBSAJXHD5ZR8A58S399M9WSBCEERGXJ1 EDMC2G6E3P6V00VR0001		

Fig. 9.3 Example of analytical reporting log for a telemedicine consult

For the patient, they should be asked if the consult is what they expected out of the program. The survey should address the effectiveness of patient's overall medical care, any technical limitations during mock events or actual visit, and any fears concerning patient privacy and security. Finally, the patient should provide any timeliness or inconvenience of the teleconsult visit with the standard in-person visit at the hospital or clinic. The physician or clinical end user should also be surveyed on many of the same factors that are explained above about the patient. In addition, they should be asked if the visits were helpful or more harmful to the patient as well as address any patient consent concerns. The clinical end user should also be asked if future teleconsults would decrease the number of in-person consultations by a certain percentage freeing up more clinic time for new patients to be seen by the staff. Examples of patient and provider surveys are located below in Appendix 10.4 at the end of this chapter.

As for data analytics and recordkeeping, the same methodology should apply for a telemedicine consult as with a hospital or clinical networking topology. The telemedicine support team should be able to provide a tracking report or a log of when the telemedicine consults took place, who joined the telemedicine video call, if they joined from within the hospital/clinic or from the outside world, when the participants started and ended their video session, and finally a figure of how many minutes the video consults lasted with the attendees.

Figure 9.3 below provides an example of a typical reporting log for a telemedicine consult.

The use of this report or log can be used to correlate survey results back to a particular session, show ROI of the video technology for future or expansion of telemedicine program, or to provide to a network security team or legal counsel if patient privacy were to come in question or possibly a malpractice lawsuit. Surveys and reporting logs should be backed up and archived in a safe and secure location for any potential server outages or data loss. Also the reporting process should take place on a weekly, monthly, and annual process and presented to the clinical end users for validation of metrics and to discuss survey results.

Marketing a Telemedicine Program

The success and further adoption of a telemedicine program should be published so that the results can encourage others to enter the telemedicine space. With the data analytics and patient surveys, it would best to use this data to market a telehealth program to a group of physicians or other patients after a reasonable amount of time (i.e., 3–6 months of data is best for marketing and promoting a new telemedicine program). The patients from your successful telemedicine program launch can provide accounts to marketing or public affairs departments so that articles can be written on how the telemedicine program have benefited them and that no anticipated adverse patient privacy consequences exist [25]. The public affairs department should also consider sending a video crew to the patient's house to capture their reaction of a first time teleconsultation on video for internal website marketing.

The clinical champions should also be interviewed to address any questions or concerns regarding technical feasibility, ROI, and lastly if they suffered financially or lost personal prestige by migrating away from tradition face-to-face consults. For both patients and other clinical leaders, they can be swayed to try something new for their own healthcare if they see or hear about other people's experiences. This marketing plan could potentially help motivate others to enter into the world of telemedicine and create a new experience for their patients to receive better access to care via the electronic age of the Internet.

Summary

Over the course of this chapter, there has been a discussion on terminology and methodology necessary to set up a technical telemedicine platform. For a newcomer to telemedicine, the discussion shows that setting up a telemedicine platform can be very challenging since most of the program development is not just concentrating on the technology that enables a telemedicine program. Technology is usually only about 20 % of the program. The remainder of a telemedicine program tends to deal with current clinical workflows and protocols and how a telemedicine program can fit into these current workflows and protocols. There are many tips available on how to create a successful telemedicine program but Nirav Desai, the CEO and Founder of Hands On Telehealth, LLC, said it best in his e-Book [26] which describes 10 secrets to drive success in a telemedicine program:

1. Have a strategy
2. Dedicate resources
3. Ensure clinical satisfaction
4. Keep it simple
5. Identify and develop champions
6. Foster consistent use
7. Provide ongoing training
8. Measure and assess performance
9. Setup repeatable processes
10. Always be marketing

While system requirements, technology, interoperability, network bandwidth, privacy and security, cloud-based solutions, SaaS, and other areas covered within this chapter are important to the program architecture and program development of a telemedicine program, the primary objective of the program is not to replace a face-to-face relationship between physician and patient. The program goal must be to provide better access to patient care when and where the patient needs it with the proper clinical resources and specialists.

Telemedicine should be viewed as part of a diversified approach to the new models of providing medical care. As telemedicine continues to evolve, legislative and regulatory safeguard maturation will increase efficiency, cut costs, and help assure that medical care delivered via telemedicine networks meets the standards of "in-person" medical care. Telemedicine is not a total solution to shortages of primary care physicians and specialists, but it has demonstrated the potential to address factors that affect physicians' decisions regarding practice as well as to extend, geographically, care through mid-level health personnel. Once these potential contributions to the resolution of the problem are adequately demonstrated and continue to satisfy that delivery medical care via telemedicine is equal to that delivered in person, telemedicine will become an essential and constant factor in the delivery of medical care in the USA [27].

Appendix 10.1: Existing Digital Imaging Standards

This is not meant to be a comprehensive list of all existing standards, but rather provides a description of the standards most relevant to the practice of telemental health.

International Telecommunications Union (ITU-T) The International Telecommunications Union (ITU-T) has established a series of standards (H.300) for VTC. It includes such sections as the H.320 series for circuit-switched, $n \times 64$ (i.e., ITU-T); the H.323 series: packet-switched/network, IP; and the H.324: plain old telephone service (POTS).

Session Initiation Protocol (SIP) The Internet Engineering Task Force RFC 3261 also applies to VTC. SIP is a text-based protocol for initiating interactive communication sessions between users, including voice, video, chat, and virtual reality.

JPEG/TIF/WAV Some of the most common compression methods used for still images include the following. The method used depends on the achievable compression ratio and the number and types of artifacts created during compression. Lossless compression allows for the reconstruction of the exact original data prior to compression without any loss of information. Lossy compression refers to methods that lose data once the image has been compressed and uncompressed. The level of compression and method used affects the amount of data lossand whether or not it is visually perceptible. The type and level of compression may vary depending on the type of examination. Different compression algorithms will achieve different compression ratios with varying degrees of artifacts. The choice of compression method and level should be reviewed periodically for each image and examination type, to insure that artifacts are not perceptible. It should be noted that lossy compression can affect the colors in an image.

- *JPEG (2000)*: JPEG 2000 uses wavelet technology that allows an image to be retained without any distortion or loss. File extensions for JPEG 2000 are either. jp2 or.j2c (for traditional JPEG it is either.jpg or.jpeg).
- *TIF*: Tagged Image File Format is used for formatting and compressing images. It can be lossy or lossless. The file extension for TIF is.tiff or.tif.
- *WAV*: It is a method of compression using wavelets transforms (mathematical functions that divide data based on frequency components). There are a variety of file extensions depending on the wavelet method used. It can be lossy or lossless.

Health Level Seven (HL7) Health Level Seven (HL7) is one of the several American National Standards Institute (ANSI) Standards Developing Organizations (SDOs) operating in the healthcare arena. HL7s domain is clinical and administrative data.

United Sates Health Insurance Portability & Accountability Act (US HIPAA) The United Sates Health Insurance Portability & Accountability Act (US HIPAA) of 1996 (Public Law 104–191) calls for improved efficiency in healthcare delivery by standardizing electronic data interchange, and the protection of confidentiality and security of health data through setting and enforcing standards. It has rules for:

- Standardization of electronic patient health, administrative and financial data
- Unique health identifiers for individuals, employers, health plans, and healthcare providers
- Security standards protecting the confidentiality and integrity of "individually identifiable health information," past, present, or future.

JCAHO The Joint Commission evaluates and accredits nearly 15,000 healthcare organizations and programs in the USA. It is an independent, not-for-profit organization, and is a standards-setting and accrediting body in healthcare. Since 1951, it has maintained state-of-the-art standards that focus on improving the quality and safety of care provided by healthcare organizations. The Joint Commission's comprehensive accreditation process evaluates an organization's compliance with these standards and other accreditation requirements. Its accreditation is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards. To earn and maintain the Joint Commission's Gold Seal of Approval™, an organization must undergo an on-site survey by a Joint Commission survey team at least every 3 years. (Laboratories must be surveyed every 2 years.)

Appendix 10.2: Telemedicine/Telehealth Glossary

The following is a list of terms and definitions that are commonly used in telemedicine and telehealth. The list was assembled for the purpose of encouraging consistency in employing these terms in ATA related documents and resource materials.

The list is not all-inclusive and may be augmented by specialty areas as deemed appropriate.

Application Service Provider (ASP): An ASP hosts a variety of applications on a central server. Customers are charged a fee to access applications over secure Internet connections or a private network. This means that they do not need to purchase, install, and maintain the software themselves; instead they rent the applications they need from their ASP. Even new releases, such as software upgrades, are generally included in the price.

Asynchronous: This term is sometimes used to describe store and forward (S&F) transmission of medical images or information because the transmission typically occurs in one direction in time. This is the opposite of synchronous (see below).

Authentication: A method of verifying the identity of a person sending or receiving information using passwords, keys, and other automated identifiers.

Bandwidth: A measure of the information carrying capacity of a communications channel; a practical limit to the size, cost, and capability of a telemedicine service.

Bluetooth wireless: Bluetooth is an industrial specification for wireless personal area networks (PANs). Bluetooth provides a way to connect and exchange information between devices, such as mobile phones, laptops, PCs, printers, digital cameras, and video game consoles over a secure, globally unlicensed short-range radio frequency. The Bluetooth specifications are developed and licensed by the Bluetooth Special Interest Group.

Broadband: Communications (e.g., broadcast television, microwave, and satellite) capable of carrying a wide range of frequencies; refers to transmission of signals in a frequency-modulated fashion, over a segment of the total bandwidth available, thereby permitting simultaneous transmission of several messages.

Clinical information system: Relating exclusively to the information regarding the care of a patient, rather than administrative data, this hospital-based information system is designed to collect and organize data.

CODEC: Acronym for coder-decoder. This is a videoconferencing device (e.g., Polycom, Tandberg, Sony, Panasonic, etc.) that converts analog video and audio signals to digital video and audio code and vice versa. CODECs typically compress the digital code to conserve bandwidth on a telecommunications path.

Compressed video: Video images that have been processed to reduce the amount of bandwidth needed to capture the necessary information so that the information can be sent over a telephone network.

Computer-based patient record (CPR): An electronic form of individual patient information that is designed to provide access to complete and accurate patient data.

Data compression: A method to reduce the volume of data using encoding to reduce image processing, transmission times, bandwidth requirements, and storage space requirements. Some compression techniques result in the loss of some information, which may or may not be clinically important.

Diagnostic equipment (scopes, cameras and other peripheral devices): Diagnostic equipment is a hardware device not part of the central computer (e.g., digitizers, stethoscope, or camera) that can provide medical data input to or accept output from the computer.

Digital camera (still images): A digital camera is typically used to take still images of a patient. General uses for this type of camera include dermatology and wound care. This camera produces images that can be downloaded to a PC and sent to a provider/consultant over a network.

Digital Imaging and Communication in Medicine (DICOM): A standard for communications among medical imaging devices; a set of protocols describing how images are identified and formatted that is vendor-independent and developed by the American College of Radiology and the National Electronic Manufacturers Association.

Disease management: A continuous coordinated healthcare process that seeks to manage and improve the health status of a carefully defined patient population over the entire course of a disease (e.g., CHF and DM). The patient populations targeted are high-risk, high-cost patients with chronic conditions that depend on appropriate care for proper maintenance.

Distance learning: The incorporation of video and audio technologies, allowing students to "attend" classes and training sessions that are being presented at a remote location. Distance learning systems are usually interactive and are a tool in the delivery of training and education to widely dispersed students, or in instances in which the instructor cannot travel to the student's site.

Distant site: The distant site is defined as the telehealth site where the provider/specialist is seeing the patient at a distance or consulting with a patient's provider. (CMS) Others common names for this term include—hub site, specialty site, provider/physician site, and referral site. The site may also be referred to as the consulting site.

Document camera: A camera that can display written or typed information (e.g., lab results), photographs, graphics (e.g., ECG strips) and in some cases X-rays.

Electronic data interchange (EDI): The sending and receiving of data directly between trading partners without paper or human intervention.

Electronic patient record: An electronic form of individual patient information that is designed to provide access to complete and accurate patient data, alerts, reminders, clinical decision-support systems, links to medical knowledge, and other aids.

Encryption: A system of encoding data on a Web page or e-mail where the information can only be retrieved and decoded by the person or computer system authorized to access it.

Firewall: Computer hardware and software that block unauthorized communications between an institution's computer network and external networks.

Full-motion video: This describes a standard video signal that allows video to be shown at the distant end in smooth, uninterrupted images.

Guideline: A statement of policy or procedures by which to determine a course of action, or give guidance for setting standards.

H.320: This is the technical standard for videoconferencing compression standards that allow different equipment to interoperate via T1 or ISDN connections.

H.323: This is the technical standard for videoconferencing compression standards that allow different equipment to interoperate via the IP (see below).

H.324: This is the technical standard for videoconferencing compression standards that allow different equipment to interoperate via POTS.

Health level 7 Data Communications Protocol (HL7): This communication standard guides the transmission of health-related information. HL7 allows the integration of various applications, such as bedside terminals, radiological imaging W stations, hospital census, order entries, and patient accounting, into one system.

HIPAA: Acronym for Health Information Portability Act.

Home healthcare and remote monitoring systems: Home healthcare is care provided to individuals and families in their place of residence for promoting, maintaining, or restoring health; or for minimizing the effects of disability and illness, including terminal illness. In the Medicare Current Beneficiary Survey and Medicare claims and enrollment data, home healthcare refers to home visits by professionals including nurses, physicians, social workers, therapists, and home health aides. Using remote monitoring and interactive devices allows the patient to send in vital signs on a regular basis to a provider without the need for travel.

Informatics: The use of computer science and information technologies to the management and processing of data, information, and knowledge.

Integrated Services Digital Network (ISDN): This is a common dial-up transmission path for videoconferencing. Since ISDN services are used on demand by dialing another ISDN-based device, per minute charges accumulate at some contracted rate and then are billed to the site placing the call. This service is analogous to use the dialing features associated with a long distance telephone call. The initiator of the call will pay the bill. ISDN permits connections up to 128 Kbps.

Interactive video/television: This is analogous with videoconferencing technologies that allow for two-way, synchronous, interactive video and audio signals for the purpose of delivering telehealth, telemedicine, or distant education services. It is often referred to by the acronyms—ITV, IATV, or VTC (video teleconference).

Internet Protocol: The Internet Protocol (IP) is the protocol by which data is sent from one computer to another on the Internet. Each computer on the Internet has at least one address that uniquely identifies it from all other computers on the Internet. IP is a connectionless protocol, which means that there is no established connection between the end points that are communicating. The IP address of a videoconferencing system is its phone number.

Interoperability: Interoperability refers to the ability of two of more systems* to interact with one another and exchange information in order to achieve predictable results (*refers to more than technical systems) (Bergman, Ulmer and Sargious, 2001). There are three types of interoperability: human/operational; clinical; and technical (Canadian Society for Telehealth, 2001). Interoperability refers to the ability of two or more systems (computers, communication devices, networks, software, and other information technology components) to interact with one another and exchange data according to a prescribed method in order to achieve predictable results (ISO ITC-215).

ISDN Basic Rate Interface (BRI): This is an ISDN interface that provides 128 k of bandwidth for videoconferencing or simultaneous voice and data services.

Multiple BRI lines can be linked together using a multiplexer (see below) to achieve higher bandwidth levels. For instance, a popular choice among telehealth networks is to combine three BRI lines to provide 384 k of bandwidth for videoconferencing. It should be noted that BRI services are not available in some rural locations. One should check with their telecommunications providers on the availability of BRI service before ordering videoconferencing equipment that uses this type of service.

ISDN Primary Rate Interface (PRI): This is an ISDN interface standard that operates using 23, 64 k channels and one 64 k data channel. With the proper multiplexing equipment the ISDN PRI channels can be selected by the user for a video call. For instance if the user wants to have a videoconference at 384 k of bandwidth then they can instruct the multiplexer to use channels one through six (6×64 k = 384 k). This is important because the user typically pays charges based on the number of 64 k channels used during a videoconference. The fewer channels used to obtain a quality video signal the less expensive the call.

JCAHO: Acronym for Joint Commission on Accreditation of Healthcare Organizations.

Lossless: A format of data compression, typically of an order of less than 2:1, in which none of the original data information is lost when the image is reproduced.

Lossy: A process of data compression at a relatively high ratio, which leads to some permanent loss of information upon reconstruction.

Medical/nursing call center: A call center is a centralized office that answers incoming telephone calls from patients. Such an office may also respond to letters, faxes, e-mails, and similar written correspondence. Usually staffed by nurses, call centers provide basic health information and instructions to callers but do not provide an official diagnosis of conditions or prescribe medicine. Call centers act as an initial triage point for patients.

Mobile telehealth: The provision of healthcare services with the assistance of a van, trailer, or other mobile unit in which the healthcare provider might provide patient services at a distance from a normal medical facility. Services may also be provided through mobile technologies that allow a mobile vehicle equipped with medical technologies to attach to an existing healthcare facility, such as mobile CT, MRI, or teledentistry.

Multiplexer (MUX): A device that combines multiple inputs (ISDN PRI channels or ISDN BRI lines) into an aggregate signal to be transported via a single transmission path.

Multi-point Control Unit (MCU): A device that can link multiple videoconferencing sites into a single videoconference. An MCU is also often referred to as a "bridge."

Multi-point teleconferencing: Interactive electronic communication between multiple users at two or more sites which facilitates voice, video, and/or data transmission systems: audio, graphics, computer, and video systems. Multi-point teleconferencing requires a MCU or bridging device to link multiple sites into a single videoconference.

Network integrators: Organizations specializing in the development of software and related services that allows devices and systems to share data and communicate to one another.

Originating site: The originating site is where the patient and/or the patient's physician is located during the telehealth encounter or consult (CMS). Other common names for this term include—spoke site, patient site, remote site, and rural site.

Patient examination camera (video): This is the camera typically used to examine the general condition of the patient. Types of cameras include those that may be embedded with set-top videoconferencing units, handheld video cameras, gooseneck cameras, camcorders, etc. The camera may be analog or digital depending upon the connection to the videoconferencing unit.

Peripheral devices: Any device that is attached to a computer externally, that is, Scanners, mouse pointers, printers, keyboards; and clinical monitors, such as pulse oximeters, weight scales, are all examples of this.

Pharmacy solutions: The use of electronic information and communication technology to provide and support comprehensive pharmacy services when distance separates the participants.

POTS: Acronym for plain old telephone service.

Presenter (patient presenter): Telehealth encounters require the distant provider to perform an examination of a patient from many miles away. In order to accomplish that task an individual with a clinical background (e.g., LPN, RN, etc.) trained in the use of the equipment must be available at the originating site to "present" the patient, manage the cameras and perform any "hands-on" activities to successfully complete the examination. For example, a neurological diagnostic examination usually requires a nurse capable of testing a patient's reflexes and other manipulative activities. It should be noted that in certain cases, such as interview-based clinical consultations such as Telemental Health or Nutrition Services, that a licensed practitioner such as an RN or LPN, might not be necessary, and a non-licensed provider such as support staff, could provide telepresenting functions.

Regional Health Information Organization (RHIO): RHIO and Health Information Exchange (HIE) are often used interchangeably. RHIO is a group of organizations with a business stake in improving the quality, safety, and efficiency of healthcare delivery. RHIOs are the building blocks of the proposed National Health Information Network (NHIN) initiative at the Office of the National Coordinator for Health Information Technology (ONCHIT).

Router: This device provides an interface between two networks or connects sub-networks within a single organization. It routes network traffic between multiple locations and it can find the best route between any two sites. For example, PCs or H.323 videoconferencing devices tell the routers where the destination device is located and the routers find the best way to get the information to that distant point.

Standard: A statement established by consensus or authority, that provides a benchmark for measuring quality, that is aimed at achieving optimal results (NIFTE Research Consortium, 2003).

Store and forward (S&F): S&F is a type of telehealth encounter or consult that uses still digital images of a patient for the purpose of rendering a medical opinion or diagnosis. Common types of S&F services include radiology, pathology, dermatology, and wound care. Store and forward also includes the asynchronous transmission of clinical data, such as blood glucose levels and ECG measurements, from one site (e.g., patient's home) to another site (e.g., home health agency, hospital, and clinic).

Switch: A switch in the videoconferencing world is an electrical device that selects the path of the video transmission. It may be thought of as an intelligent hub (see hub above) because it can be programmed to direct traffic on specific ports to specific destinations. Hub ports feed the same information to each device.

Synchronous: This term is sometimes used to describe interactive video connections because the transmission of information in both directions is occurring at exactly the same period.

System/network integration: The use of software that allows devices and systems to share data and communicate to one another.

T1/DS1: A digital carrier or type of telephone line service offering high-speed data, voice, or compressed video access in two directions, with a transmission rate of 1.544 Mbps. T3/DS3: A carrier of 45 Mbps.

Transmission control protocol/Internet protocol (TCP/IP): The underlying communications rules and protocols that allow computers to interact with each other and exchange data on the Internet.

Telecommunications providers: An entity licensed by the government (the Federal Communications Commission in the USA) to provide telecommunications services to individuals or institutions.

Teleconferencing: Interactive electronic communication between multiple users at two or more sites which facilitates voice, video, and/or data transmission systems such as: audio, graphics, computer, and video systems.

Telehealth and telemedicine: Telemedicine and telehealth both describe the use of medical information exchanged from one site to another via electronic communications to improve patients' health status. Although evolving, telemedicine is sometimes associated with direct patient clinical services and telehealth is sometimes associated with a broader definition of remote healthcare services.

Telematics: The use of information processing based on a computer in telecommunications, and the use of telecommunications to permit computers to transfer programs and data to one another.

Telementoring: The use of audio, video, and other telecommunications and electronic information processing technologies to provide individual guidance or direction. An example of this help may involve a consultant aiding a distant clinician in a new medical procedure.

Telemonitoring: The process of using audio, video, and other telecommunications and electronic information processing technologies to monitor the health status of a patience from a distance.

Telepresence: The method of using robotic and other instruments that permit a clinician to perform a procedure at a remote location by manipulating devices and receiving feedback or sensory information that contributes to a sense of being present at the remote site and allows a satisfactory degree of technical achievement. For example, this term could be applied to a surgeon using lasers or dental hand pieces and receiving pressure similar to that created by touching a patient so that it seems as though she/he is actually present, permitting a satisfactory degree of dexterity.

Teleradiology and picture archiving and communications systems (PACs): The electronic transmission of radiological images, such as X-rays, CTs, and MRIs, for the purposes of interpretation and/or consultation. Digital images are transmitted over a distance using standard telephone lines, satellite connections, or local area networks (LANs). Teleradiology also is beginning to include the process of interfacing with the hospital information systems/radiology information systems (HIS/RIS) in the transport of digital images. PACs provide centralized storage and access to medical images over information systems.

Ultrasound: A device that uses high-frequency sound waves to examine structures inside the body. It can rapidly detect tumors and other abnormalities, often right in the physician's office.

Universal Service Administrative Company (USAC): The Universal Service Administrative Company administers the Universal Service Fund (USF), which provides communities across the country with affordable telecommunication services. The Rural Health Care Division (RHCD) of USAC manages the telecommunications discount program for healthcare.

Videoconferencing systems: Equipment and software that provide real-time, generally two-way transmission of digitized video images between multiple locations; uses telecommunications to bring people at physically remote locations together for meetings. Each individual location in a videoconferencing system requires a room equipped to send and receive video.

Videoconferencing: Real-time, generally two-way transmission of digitized video images between multiple locations; uses telecommunications to bring people at physically remote locations together for meetings. Each individual location in a videoconferencing system requires a room equipped to send and receive video.

Wi-Fi: Originally licensed by the Wi-Fi Alliance to describe the underlying technology of wireless local area networks (WLAN) based on the IEEE 802.11 specifications. It was developed to be used for mobile computing devices, such as laptops, in LANs, but is now increasingly used for more services, including the Internet and VoIP phone access, gaming, and basic connectivity of consumer electronics, such as televisions and DVD players, or digital cameras. (Wikipedia)

Appendix 10.3: Telemedicine Room Assessment and Design Worksheet

Type of Telemedicine Room: ❒ Patient exam ❒ Remote clinician ❒ Education/classroom

What type of clinical services will be provided: ____

____

Are there any special spaces or lighting considerations related to the services: ________________

____

Name of room selected for assessment: ____

Room Location:

Yes No
❒ ❒ Quiet
❒ ❒ Easily accessible
❒ ❒ Minimal exposure to office and outside noise
❒ ❒ Close to regular clinic operations

Room Size:

Identify the equipment that will be needed in this room.

❒ Telemedicine unit – specify size: _____
❒ Exam table
❒ Patient chair
❒ Other chairs – number: _____
❒ Work table
❒ Desk
❒ Computer
❒ Specialized lighting – specify type: _____
❒ Peripheral equipment
❒ Telephone
❒ Fax machine
❒ How many people does the room need to accommodate: _____

Yes No
❒ ❒ Room is large enough to accommodate needed equipment with adequate room for the patient presenter to comfortably move around

Equipment Placement:

Yes No
❒ ❒ Placement of plugs and lines will not interfere with movement or create hazard
❒ ❒ Camera can be placed to provide full view of patient
❒ ❒ Camera can be placed to create eye to eye contact
❒ ❒ Scopes and peripherals can be easily accessible

Modifications that will be required: ____

____

Estimated cost of modifications: ____

Lighting:

Yes No
❒ ❒ No windows in the room
❒ ❒ If the room has windows, can shades or blinds mitigate impact of lighting
❒ ❒ If the room has windows, can the exam table be placed to avoid backlighting
❒ ❒ Lighting provides adequate direct and indirect lighting
❒ ❒ Direct light source shines diagonally toward the patient
❒ ❒ Supplemental lighting adequate
❒ ❒ Full spectrum light bulbs are needed

Modifications that will be required:____

____

Estimated cost of modifications:____

Room Color:

Yes No
❒ ❒ Paint color is appropriate for telemedicine
❒ ❒ Paint finish is flat

Modifications that will be required:____

____

Estimated cost of modifications:____

Acoustics:

Yes No
❒ ❒ Room has minimal outside noise
❒ ❒ Room does not echo
❒ ❒ Equipment noise levels are minimal
❒ ❒ Facility license requirements allow modifications

Modifications that will be required:____

____

Estimated cost of modifications:____

Clean and Uncluttered Room:

Yes No
❒ ❒ Area is clear of clutter

Total estimated cost for room modifications:____

Appendix 10.4: Patient and Referring Healthcare Provide Satisfaction Surveys

Patient Survey

Name (OPTIONAL): ______________________ **Date:** _____________ **Site:** ___________

Instructions:

Please rate the following on a scale of 1 to 6 where **1** = strongly disagree, **2** = disagree, **3** = neither agree or disagree, **4** = agree, **5** = strongly agree

Survey Questions:	**Disagree⟶Agree**				
1. I could see the doctor/nurse practitioner/nurse clearly during the telemedicine visit.	**1**	**2**	**3**	**4**	**5**
2. I had no trouble hearing the doctor when he/she spoke to me.	**1**	**2**	**3**	**4**	**5**
3. I was able to speak freely with the doctor and ask questions.	**1**	**2**	**3**	**4**	**5**
4. The doctor was able to ask me questions.	**1**	**2**	**3**	**4**	**5**
5. The doctor seemed to understand my problem.	**1**	**2**	**3**	**4**	**5**
6. I was comfortable with and understood what the doctor told me about my complaint.	**1**	**2**	**3**	**4**	**5**
7. The camera and other equipment embarrassed me or made me feel uncomfortable.	**1**	**2**	**3**	**4**	**5**
8. A telemedicine visit makes receiving care more accessible (for example, I don't have to drive as far, I can get the appointment more easily).	**1**	**2**	**3**	**4**	**5**
9. I would prefer a telemedicine visit now rather than waiting for a face-to-face appointment with the same doctor.	**1**	**2**	**3**	**4**	**5**
10. I would have traveled to another city to see a specialist if I had not used telemedicine.	**1**	**2**	**3**	**4**	**5**
11. Traveling to another hospital would cut into my work or school time.	**1**	**2**	**3**	**4**	**5**
12. Traveling would affect my wages for that time.	**1**	**2**	**3**	**4**	**5**
13. I would experience other inconveniences in traveling (for example, travel arrangements, family, work, etc.)	**1**	**2**	**3**	**4**	**5**
14. I would prefer a face-to-face visit with the specialist rather than a teleconsultation with a specialist.	**1**	**2**	**3**	**4**	**5**
15. This telemedicine visit was as good as face-to-face encounter.	**1**	**2**	**3**	**4**	**5**
16. Overall, I am satisfied with telemedicine.					

Additional Comments:

Referring Health Care Provider: Real-Time Consultation

Name: ______________________ **Date:** ____________________ **Specialty:** _____________

Patient Name: ___________________

Instructions:

Please rate the following on a scale of 1 to 6 where **1** = strongly disagree, **2** = disagree, **3** = neither agree or disagree, **4** = agree, **5** = strongly agree

Survey Questions:	**Disagree⟶Agree**				
1. The quality of the image (focus, visual resolution, magnification was acceptable.	**1**	**2**	**3**	**4**	**5**
2. The quality of the audio was acceptable.	**1**	**2**	**3**	**4**	**5**
3. The consultant's inability to touch the patient seemed to impair diagnosis.	**1**	**2**	**3**	**4**	**5**
4. The telemedicine clinical exam appeared to provide sufficient information.	**1**	**2**	**3**	**4**	**5**
5. The consultant seemed to understand the problem.	**1**	**2**	**3**	**4**	**5**
6. I am confident in the consultant's diagnosis/advice.	**1**	**2**	**3**	**4**	**5**
7. In this case, the consultant changed my diagnosis and treatment.	**1**	**2**	**3**	**4**	**5**
8. I could communicate adequately with the consultant.	**1**	**2**	**3**	**4**	**5**
9. The consultant seemed to communicate will with the patient.	**1**	**2**	**3**	**4**	**5**
10. The patient seemed comfortable and able to communicate well with the consultant.	**1**	**2**	**3**	**4**	**5**
11. The technology (the normal operation of the instrument rather than any problems encountered) distracted me from the consultation.	**1**	**2**	**3**	**4**	**5**
12. Technical difficulties made this process too time-consuming.	**1**	**2**	**3**	**4**	**5**
13. Overall, the system was easy to use.	**1**	**2**	**3**	**4**	**5**
14. Using telemedicine takes longer than face-to-face consult.	**1**	**2**	**3**	**4**	**5**
15. Telemedicine improves clinical efficiency.	**1**	**2**	**3**	**4**	**5**

Additional Comments:

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Chapter 10
Legal, Regulatory, and Ethical Issues in the Use of Telemedicine

Marc T. Zubrow, Anita K. Witzke and H. Neal Reynolds

Introduction

The imperative for expanded deployment and utilization of telemedicine includes: expanded health-care access due to the Affordable Care Act (ACA) [1, 2], physician shortages and maldistribution [3–6], patient-centered medical home (PCMH) models driving expanded responsibilities [7, 8] (see Fig. 10.1), shared risk programs [9], pay-4-performance strategies such as the loss of reimbursement for congestive heart failure readmission within 30 days [10], or need to improve return on investment (ROI) and efficiencies [11–13]. The imperative has fueled a 315 % growth in telemedicine investment [14] yielding the fastest growing segment in digital health.

The political landscape driving telemedicine forward versus the evolving barriers to expansion of telemedicine are significant. On the one hand, during 2013, 15 state medical boards and state legislatures considered proposals to revise standards for telemedicine suggesting high level of interest [15]. On the other hand, some states are imposing standards for the practice of telemedicine that are higher or more cumbersome than the practice of face-to-face medicine. Some have considered requiring an initial face-to-face encounter prior to any telemedicine encounters in order to qualify for reimbursement mostly in a direct to consumer-type model, which could effectively challenge emergent stroke telemedicine, most of the tele-ICU activity, emergent cardiac consultation, etc. Similar requirements have been

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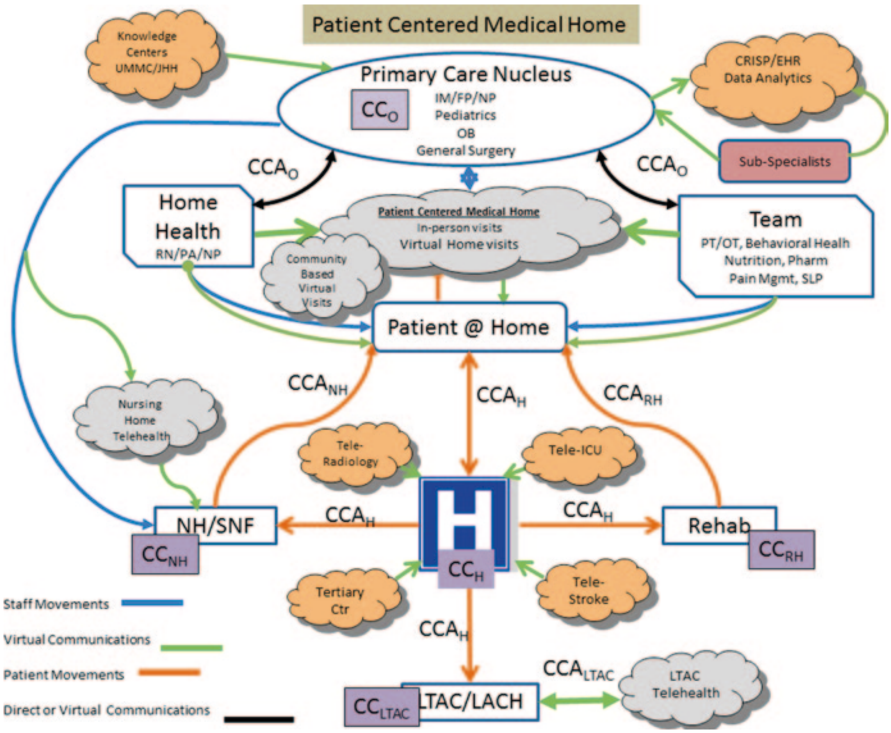

Fig. 10.1 Concept diagram of a fully developed patient-centered medical home (PCMH) to include Multiple telemedicine applications. *Clouds* represent existing remote technology *(orange)* or future applications *(gray)*. *Green lines* represent "virtual" movements via telemedicine communications. CC_o care coordinator office, CC_H care coordinator hospital, CC_{NH} care coordinator nursing home, CC_{LTAC} care coordinator long-term acute care hospital, *CCAo*, CCA_H, CCA_{NH}, $CCA_{RH}l$, $CCA_H CCA_{LTAC}$, ("A" represents actions performed by the respective care coordinators), *IM* internal medicine, *FP* family practice, *OB* obstetrics and gynecology, *RN* registered nurse, *PA* physician's assistant, *NP* nurse practitioner, *PT* physical therapy, *OT* occupational therapy, *SLP* speech language pathologist, *NH* nursing home, *SNF* skilled nursing facility

proposed for establishing "physician–patient relationship" prior to any telemedicine encounters with a similar impact upon emergent consultations. If such regulations were to be implemented, large telemedicine networks, such as tele-ICU programs, where the physician may never meet the patient face-to-face, would be impossible. Similarly, certain state medical boards have considered requiring very complex and demanding patient consent for telemedicine, far in excess of what is done with traditional face-to-face medicine. Furthermore, some states have mandated a tele-presenter be with the patient and require a subsequent face-to-face encounter after the telemedicine encounter. All of the above act as barriers to *intra*state practice of telemedicine in certain states. Medical licensure remains the primary barrier to *inter*state practice of medicine which may be changing with the new Federation of State Medical Board (FSMB) ruling in favor of license sharing between states. How states choose to adopt and implement this remains to be seen.

The American Telemedicine Association (ATA) has published the "State Telemedicine Gap Analysis: Physician Practice Standards and Licensure" in 2014 [15]. This document should be consulted for the specific limitations and requirements in each state. Other than licensure issues, which are discussed later, several issues are noted in the ATA gap analysis.

- Tele-presenter required to be on-site: six states
- About half of the USA requires a pre-, post-, or intra-event face-to-face visit
- About seven states require some form of patient consent
- Regarding nuances of licensure requirement, essentially *every* state has at least one barrier to interstate practice of telemedicine when the physician does not already have full state licensure. Options available to the State Medical Boards to facilitate interstate practice of telemedicine include accepting physician-to-physician consultations without licensure, full reciprocity or reciprocity of bordering states, and/or conditional or limited telemedicine licenses limited to telemedicine

Clearly, it is a fluid time in the regulatory atmosphere surrounding telemedicine. The following sections are designed to educate the reader regarding ethics, regulatory, medical legal aspects, practical administrative aspects, legislative, licensure, and reimbursement issues. We will also review barriers to the growth and expansion of telemedicine: known, potential, and future.

General Principles of Patient Management

Several basic principles must be considered when using telemedicine technologies such as fundamental ethical principles, establishment of the patient–physician relationship, patient privacy, confidentiality, and informed consent (informed decision-making). Furthermore, when using either asynchronous (not in real time: see appendix) or synchronous (occurring in real time: see appendix) telecommunication systems to exchange information, consult, or provide direct care, additional procedures may be required to ensure that the telemedicine encounter is both ethically sound and functional. It is imperative when providers embark on using technology in the management of patients, the following is considered:

- Is the telemedicine/telecommunication process *ethically* sound for a particular patient and/or situation?
- When is the *patient–physician relationship* established?
- Is the patient *information kept private*, confidential, and secure before, during, and after a telemedicine encounter?
- What *delivery model* and treatment methods are best for meeting the patient's care needs?
- How and when is *informed consent* obtained?

Ethical Principles

Ethical principles applicable to traditional in-person encounters apply equally for the telemedicine evaluation and management of patients including *non-maleficence, beneficence, fidelity, justice*, and *patient autonomy* [16, 17]. In general, as stated by the FSMB, "there should be parity of ethical and professional standards whether care is rendered face-to-face or remotely" [18]. The accepted definitions of each ethical principle with relevant discussion related to the application in telemedicine are presented as follows:

- *Non-maleficence (do no-harm) and beneficence (do good)*:
  - *Non-maleficence*: It requires that a procedure or therapy do no harm to the patient involved, to others, or to society in general. If there is a risk of harm, the risk versus benefit must be understood and judged generally in favor of benefit.
  - *Beneficence*: Procedures and therapeutics be provided with the intent of doing good for the patient. This implies that, health-care providers are capable of doing good and therefore, must maintain the skills and knowledge necessary to provide net benefit.

The FSMB in their Model Guidelines for State Medical Boards Appropriate Regulation of Telemedicine [19] has opined that "*the evaluation, treatment recommendations when made via telemedicine technologies will be held to the same standards of practice as when making the same evaluations during traditional in person encounters*." Specifically, when the technology is appropriate for the care being provided and provides benefit, and the provider maintains the necessary skills, concepts of non-maleficence and beneficence are met. Generally, telemedicine would not be appropriate for performance of surgical procedures in today's landscape but could be appropriate for remote monitoring and proctoring during surgical procedures, if needed. Telemedicine is highly appropriate for tele-mental health or any of the disease states characterized by review of symptomatology and provision of advice. In highly monitored environments, such as the intensive care unit, where decisions are largely made based upon monitoring data, risk of harm would parallel on-site care and yet be fully translatable to the remote environment while providing benefit by early preemptive interventions. Telemedicine would be ethically appropriate for "store-and-forward" interventions such as tele-dermatology, tele-pathology, or teleradiology where direct provider-to-patient interaction is typically limited. In these examples, the telemedicine patient receives beneficence by increased access to specialty care, increased timely care yet no perceived enhancement of risk.

- *Justice (be fair)*: Health care must be fairly distributed, scarce resources allocated and competing needs, rights, and obligations be fairly considered, and conflicts with established legislation resolved while upholding existing laws. Risks, burdens, and benefits of new or experimental treatments must be distributed equally among all groups. Fundamentally, telemedicine reduces barriers to health care to include distance, time, and/or burdens of travel. The principle of justice is, therefore, well served via telemedicine through improved distribution of health care and reductions in the disparities of health care. With wide application of telemedicine, those living in rural areas could enjoy similar health care to those in the major metropolitan areas. Disparities in the distribution of specialists, such as gastroenterologists with unique intellectual expertise, can be largely mitigated.

- *Patient autonomy (patient choice)*: The patient (or patient's legitimate surrogate) must maintain autonomy of thought, intention, and action when making decisions regarding health care. This implies that the patient has mental "capacity" and/or the surrogate is rational without external motives. With telemedicine, the patient maintains full autonomy and can always opt out of the interaction with the rare exceptions of telestroke cases. In some cases, where extensive informed consent is mandated, autonomy is greater than the face-to-face encounters, which do not require such level of prior informed consent. There are certain situations, such as the tele-ICU, where that patient may not be interactive and surrogate not available. However, most of these environments have global informed consent at time of admission. To complete informed consent, patients should be given the risks and benefits of the tele-encounter.
- *Fidelity (patient first)*: Fidelity [20] requires care providers to maintain the patient's trust and confidence by keeping their patients' interests first in their mind above all others. The principle of fidelity is upheld through the relationship established between the patient and the physician with telemedicine technologies. The care provider is able to attend to patients' needs more frequently and more on the patients' terms (such as from their home), satisfying patient fidelity.

Ultimately, the basic ethical foundations to medicine are to be applied independent of how the medical service is delivered or advice provided. A simple telephone call between a care provider and patient, store-and-forward interpretation of a radiograph, an emailed image of a skin lesion, or a full face-to-face real-time audio-video all must be founded in the same underlying ethical principles.

Patient–Physician (Provider) Relationship

The American Medical Association (AMA) [21] emphasizes the importance of establishing the patient–physician relationship as a core aspect of medical ethics. Certain technologies have challenged the medical community in defining the process of how and when a patient–physician relationship is established. Therefore, before engaging in any forms of telemedicine, it is crucial to have knowledge and follow any current international, national, state, and specialty practice standards for establishing the patient–physician relationship.

According to the Council on Medical Services [22] of the AMA, this relationship can be established in-person *or* with real-time audiovisual equipment [23]. However, the 2014 ATA *State Telemedicine Gap Analysis* [15] reported that certain states mandate physician practice standards for telemedicine that are very stringent requiring the patient–physician relationship be established through an in-person exam or a visit *prior* to any telemedicine encounters. Furthermore, some states may require a separate in-person visit for prescribing medications while other aspects such as consultation may not. The ATA has developed operational and specialty guidelines to direct providers to current best practices and resources [24].

Miller [25] reported in a review of 38 studies, the use of telemedicine elicited a high degree of satisfaction regarding physician communication, and supported its use in establishing patient-centered relationships. Others [26] have cautioned that quality of and methodology(s) used for interactions between the physician and the patient should be evaluated to ensure communication is open and clear. As it may be difficult to communicate when face-to-face, so it may also be difficult when done so remotely. As a consequence of the seeming disarray between the states and to foster wider adoption to telemedicine/telehealth, the FSMB recently proposed "Model Guidelines for State Medical Boards Appropriate Regulation of Telemedicine" [19]. These guidelines are provided as a template for a more unified approach to growing telemedicine. The following are several specific points from the guidelines:

- The FSMB guidelines support a consistent standard of care and scope of practice independent of the delivery tool enabling physician-to-patient communications.
- The "physician–patient relationship" can be established during a telemedicine encounter and would not necessarily have been established before an encounter. But in doing so, the physician should:

  Verify the identity and location of the patient to the extent possible
  The physician should disclose his/her identity and credentials
  Obtain the patients consent, written or verbal after disclosing the technology and limitations (FSMB language is silent on the value of video recording verbal consents)

- The remote care provider must arrange for follow-up and develop a mechanism for transfer of information from the telemedicine encounter to follow-up medical personnel when necessary.
- A mechanism should be established to arrange or refer patients for emergency care in the event where such care is needed.

Information Exchange and Patient Privacy

The Health Insurance Portability and Accountability Act (HIPAA) [27] of 1996 charged Department of Health and Human Services (HHS) to establish regulations for electronic data transmission and security standards. Embedded in these rules are privacy regulations with regard to patient information being transmitted electronically that went into effect in 2003. The general foundation is that the same "laws and regulations governing on-site patient health-care records" apply to telemedicine providers [18, 19]. And, since telemedicine is not static, consideration should be given to how patient information is exchanged *before, during, and after* a telemedicine encounter. All entities in the chain of patient information exchange must address local security concerns by maintaining a secure server, having unique individual passwords with access set up on a need-to-know basis and timed automatic return to screen savers. Additionally, these safeguards should be internally and continuously audited with random checks to ensure users are compliant. Because of the complexity of HIPAA, there remains the real risk of "horror stories" related to unintended HIPAA violations [28].

Compliance with these regulations requires that the patients be informed that their data is being sent electronically to a remote site. In addition, HIPAA establishes that the federal regulations will supersede state regulations when there is regulatory conflict although practitioners will remain subject to the state regulations. The HIPAA laws have evolved like many federal regulations. Under the recent potential threats of an international outbreak of ebola, HHS issued a recent bulletin on "HIPAA Privacy in Emergency Situations" [29] allowing for much more liberal exchange of personal health information (PHI) when there is a national threat.

Simple and practical guidelines would suggest that the provider conducting audiovisual telemedicine encounters should do so in a private room where passersby and other health-care workers cannot see or overhear. The patient should be made aware of any additional persons in the audience at the distant site.

Both synchronous and asynchronous encounters must follow regulatory standards for encryption. Encryption [30] is the coding of the transmitted information to minimize the chances of unauthorized individuals understanding the information. Furthermore, decryption tools (technology for reversing the coding) should be stored on a device or location separate from where the data are being encrypted. The National Institutes of Standards and Technology (NIST) has provided encryption guidelines for both Personal Health Information (PHI) "in motion" during transmission and information "at rest" or information "in storage" [31].

Telehealth resource centers [32] are an excellent resource for providers to access operational, legal and regulatory, training, and program development tool kits to ensure that the telemedicine environment is both ethical and functional. Telehealth resource centers are regional centers of expertise to help with operational and logistical issues associated with the safe practice of telemedicine.

Informed Consent

Although telemedicine technology is available in many forms, the technology may not be the right fit for all situations. "*Informed Consent*" should begin with the care provider determining whether the patient is comfortable with and has the ability to use the technology required during the telemedicine encounter. In some cases, the patient may simply need assistance at the "originating site" from a nurse or other medical personnel converting a bad-fit situation into a good-fit situation.

The FSMB (2014) in their *Model Policy for the Appropriate Use of Telemedicine* recommends support of patient autonomy by obtaining and maintaining informed consent [19]. Informed consent includes the patient's right to make decisions in accordance with the 1990 congressional Patient Self-Determination Act (PSA) [33, 34].

According to FSMB, at a minimum, informed consent should include the following:

(note: significant overlap with physician–patient relationship as noted previously)

- Identification of the patient.
- Identification of the physician and the physician's credentials.
- Types of interaction permitted using telemedicine technologies (e.g., prescription refills, appointment scheduling, patient education, virtual examination, therapeutics, etc.).
- The patient agrees that the physician determines whether or not the condition being diagnosed and/or treated is appropriate for a telemedicine encounter.
- Details on security measures taken with the use of telemedicine technologies, such as encryption, password-protected screen savers and data files, or utilizing other reliable authentication techniques as well as potential risks to privacy notwithstanding such measures.
- Hold harmless clause for information lost due to technical failures.
- *Requirement for expressing patient's consent to forward patient-identifiable information to a legitimate third party*.

In addition, the patient should be informed and give consent to any audio or video recording of the tele-encounter. Furthermore, written policies and procedures should be created to outline privacy, all health-care personnel who will process information, hours of operations, types of electronic transmissions, archival and retrieval of information, and quality oversight [18]. *The authors of this chapter do not necessarily endorse all the FSMB requirements and judge some elements to be excessive.*

Regulatory

Telemedicine is directly and indirectly regulated by a variety of national and state regulatory agencies. The Center for Medicare and Medicaid Services (CMMS) [35, 36] has set general guidelines for eligibility, established acceptable providers and locations, and limited billing codes for Medicare-related telemedicine encounters (see section "Coding for Reimbursement for Telemedicine Services"). The Food and Drug Administration (FDA) [37, 38] has established regulations for nondrug, medical devices to include a rating and classification system for medical device data systems (MDDS) and medical information storage and communications Devices (i.e., picture archiving systems for radiology) (Table 10.1).

Generally, devices used for telemedicine monitoring are MDDS Class I which are defined as devices that store, transfer, or display information without modifying the information.

Table 10.1 Federal Food and Drug Administration classification of medical monitoring devices

Device type	Classification
Medical device data systems (MDDS)	Class I
Medical information storage and communications devices	Class I
Picture archiving systems for radiology (PACS)	Class II
Nurse call systems	Class II
Active patient monitoring	Class II or III
Clinical decision support	Probably Class II

Class I: "Low Risk" device, Class II: "Moderate Risk" device, Class III: "High Risk" device

The Joint Commission (JC) [39] has focused primarily on the interaction of medical staff and the hospital. The Agency for Healthcare Research and Quality (AHRQ) with its "Health Information Portfolio," via granting opportunities is promoting a national "*strategy to put information technology to work in health care by developing secure and private electronic health records for Americans, and making health information available electronically when and where it is needed*" [40]

Ultimately the AHRQ is developing quality indicators to measure telemedicine projects. The positive granting opportunities countered by potentially burdensome quality monitoring obligations could impact a beginning telemedicine programs. Finally, the HHS, primarily via the Health Resources Services Administration (HRSA) [41], aims to increase the utilization of telehealth to improve the care of underserved primarily through developmental initiatives such as:

- Promoting partnerships between HRSA, other federal/state agencies, and private sector for the creation of telehealth projects.
- Administering telehealth grant programs such as telehealth resource centers.
- Providing technical assistance.
- Evaluating the use of telehealth technologies and programs.
- Developing telehealth policy initiatives to improve access to quality health services.
- Promoting knowledge exchange about "best telehealth practices."

While HRSA works primarily on the developmental side of telemedicine, each grant will have its incumbent reporting obligations.

Credentialing and Privileging

The rules for credentialing at Medicare facilities are primarily determined by CMMS. In 2008, CMMS established independent rules for telemedicine credentialing that required each individual physician engaged in the practice of telemedicine to be independently and fully credentialed at each hospital where the care was being delivered. Prior to the CMMS ruling, telemedicine credentialing could follow the Joint Commission (JC) rules that allowed for credentialing by proxy. In 2009, the JC revised their rules for telemedicine to fall more in line with those of CMMS mandating that all practitioners be completely credentialed at each facility where the care is being delivered without the use of credentialing by proxy. Subsequently, in 2011, the CMMS reversed its position, issuing the current rules which allow for credentialing by proxy under the following circumstances:

- The originating hospital (site where the patient is located) can rely on distant site (where the care provider is located) for credentialing and privileging.
- The distant site must be a Medicare-participating hospital or telemedicine entity.
- There must be written agreements between the originating and distant entity establishing the practice agreement: Memorandum of Understanding (MOU).
- The distant Medicare-participating hospital or entity must ensure Medicare compliance.
- The distant site must provide a list of privileges for all of the providers to the originating site.
- The distant site practitioner must hold an active license to practice medicine in the originating site's state.
- The originating hospital must maintain an internal review of the practitioners' performance, reporting all adverse events to the distant site.

From the hospital perspective, credentialing can significantly inhibit development and maintenance of a new telemedicine service. Smaller hospitals reliant upon limited medical staff offices may find processing a sudden onslaught of applications daunting ultimately delaying initiation of telemedical services. Additionally, the telemedicine-related credentialing may also add significant personnel requirements or overhead costs to the local hospital. Beyond the initial credentialing, the medical staff office will need to manage the work load of biannual reappointments.

When initiating a new telemedicine program, telemedicine credentials and delineation of privileges (DOP) may not exist at a specific facility. Development of policy [42], credentials, and DOP could require a medical staff by-law's change or amendment before the credentialing process may proceed, again adding expense and delay to start of a telemedicine program. Knowledgeable medical personnel or direct consultation with the telemedicine vendor/organization will be required to specify the DOP [43, 44] and render the DOP consistent with the hospital DOP format.

Since telemedicine physicians are generally not local, the telemedicine-privileged physicians cannot be required to serve on local hospital committees, take emergency room call, may not be available for on-site interviews, and unable to attend the minimum required number of medical staff meetings. Consequently, telemedicine privileges may require a significant deviation from the usual standards required of full-time staff. Allowances in requirements are necessary but can cause consternation and resistance to change from existing staff members. Other considerations include medical staff application fees and yearly staff dues. Since the remote telemedicine staff may arguably participate differently with the hospital, there may be room to negotiate these fees or at the very least budget for the fees when designing a telemedicine program.

Compliance

Authorization for payment of telemedicine services was initiated in 1997 with the Balanced Budget Act [45]. Imbedded within that law was a directive to Medicare to initiate reimbursement for certain specific telemedicine services. Reimbursement for telemedicine was expanded in the year 2000 via the Medicare, Medicaid, and SCHIP Program Benefits Improvement Act [46]. With the foundation laid for payment of telemedicine services, issues of fraud and abuse were raised [47]. For instance, concerns about violations of the "Anti-Kickback-Law" have been raised but no in-fact violations have been reported to date. But the law continues to evolve [48] and subtle violations could easily go unnoticed by a program administrator. Specifically, the Anti-Kick Back-Law states:

> it is illegal to "knowingly and willfully" offer or pay "remuneration" directly or indirectly, overtly or covertly, in cash or in kind to "induce" a person to (1)"refer" a person to someone for the furnishing (or arranging for the furnishing) of any item or service for which payment may be made under a federal health care program; (2) "purchase" or "order" any item or service for which payment may be made under a federal health care program; or (3) "arrange for or recommend" purchasing or ordering any item or service for which payment may be made under a federal health care program.

Violations of the Anti-Kickback- law could be as obscure and subtle as a physician accepting an e-venture offer to establish a free website. This could be construed as "in-kind remuneration" and therefore a violation of Anti-Kickback-Law. The "Ethics in Patient Referral Act" [49], commonly known as the Stark law (or Stark I and Stark II as the law evolved), was passed in 1989 which disallowed physicians from referring Medicare patients to clinical labs in which they had financial interest. This law has gone under multiple evolutions [50] and continues to evolve. As there seems to be little or no case law pertaining to self-referral neither within telemedicine networks nor specific telemedicine-related language in the law, it is easy to imagine that a financially vested individual could easily violate the spirit of Stark law within physician-owned telemedicine systems.

In 1890, the US Congress passed the Sherman Act (a comprehensive charter of economic liberty aimed at preserving free and unfettered competition) followed by the Federal Trade Commission Act and the Clayton Act. These combined create the "Antitrust Laws" designed to "protect the process of competition for the benefit of consumers" [51]. Regarding the impact of the Antitrust Laws on telemedicine, the following was extracted verbatim, from the Telehealth Resource Center website [52].

> Telemedicine networks that provide equipment to remote underserved community sites at less than fair-market value to promote the development of services and referral patterns in underserved communities may risk being challenged for violating anti-trust as well as Stark laws if such actions create a monopoly. Generally, however, merely possessing monopoly power, significant market power, or a high market share is not in and of itself evidence of anticompetitive behavior. A violation of the Sherman Anti-trust Act occurs when a person with monopoly or market power engages in unfair or predatory conduct, with the intent to harm competitors and maintain or extend monopoly power.

Antitrust, with the possibility of price fixing, restraint of trade, and the creation of monopolies are all possible legal entanglements. The reader is advised to seek advice from the regional telehealth resource centers (Centers named as: *California, Heartland, Mid-Atlantic, Great Plains, North East, Northwest, South Central, and Pacific Basin Telehealth Resource Centers*) [53].

Liability and Malpractice

The legal principle of *Lex loci delecti commissi (the state in which the injury occurred or the state with the most ties to the issues involved has jurisdiction)* applies to telemedicine services and is the primary determinant of where a malpractice case is adjudicated [54]. While some practitioners may feel that risk of liability is high when delivering care via telemedicine technologies, there is considerable uncertainty about the real risk of liability since the existing case law is very low. In fact, according to the Center for Telehealth and e-Health Law, the majority of malpractice suites center upon prescription writing over the Internet [55] rather than negligent care [56]. There has been litigation arising from the remote review of radiographs with incorrect diagnosis arising from "*the lack of clinical or contextual information when making interpretations*." Conceptually, the same concern about lack of clinical or contextual information could easily apply to any branch of telemedicine [57].

Several theories have been proposed to explain the low frequency of case law such as: (1) unclear doctor–patient relationship and therefore where does the liability land, (2) the standard of care is maintained with very careful and legible documentation, (3) telemedicine services may be an overlay or additional service on top of the primary care and provide safety net thereby reducing errors, and (4) telemedicine facilitates the access to subspecialists thereby improving the quality of care.

Independent of the above, generally, liability is defined as what a reasonable and prudent physician would do in similar circumstances [58]. However, it is uncertain whether technological innovations of telemedicine could change these standards. In particular, standards of care often refer to the comparison of a care provided *in the same community or under similar circumstances* [59]. With the relative removal of regionalism, the health-care providers of telemedicine may be held to the highest of national/international standards for care.

Telemedicine is not immune to the usual liabilities such as physician omission, inappropriate commissions or negligence of other medical or nonmedical employees (IT staff). However, liabilities unique to telemedicine services include hardware malfunction with inability to deliver services, software failure with lost data, inappropriate use of protected health information by employees, or loss of the patient's personal and/or medical information through hackers or equipment failure.

Solutions to these problems include:

- Redundant or backup hardware systems
- Alternative modalities of care in the event of hardware failure (an on-site alternative care provider)

- Alternatives when communications systems are interrupted such as alternative/redundant communications lines with two parallel data circuits, use of telephone lines, use of the Internet, etc.
- Real-time data backup at a safe, independent, and remote storage site
- High-level encryption for all transmitted and received data
- All email performed within the system and 100 % exclusion of the use of private emails from within the system
- Regular and scheduled compliance course requirement with certification. The course should cover Antitrust, Stark laws, Anti-Kickback-Laws, and privacy concerns

Relationship with Local Caregiver Team

Although the practice of telemedicine is: (1) legal, (2) recognized by state and national regulatory agencies, (3) reimbursed by a high proportion of health insurance companies, (4) reimbursed by most State Medicaid programs, (5) has some federal Medicare reimbursement, (6) supported by various national medical societies, acceptance by local health-care providers is highly variable. In fact, resistance from local health-care providers may be the rate-limiting step to a program's acceptance. Telemedicine challenges local physician and nursing autonomy, generates suspicion that "Big-Brother is Watching," and is often countered by the erroneous assertions that patients and families will not accept this form of care delivery. Questions of who is the captain of the ship and who gets called and for what particular issue arise if there are not clear rules and delineations established with the inception of any program. Folded into the mix is the perceived or real potential of loss of professional billing revenue from the local physicians and advance practitioners. Therefore, thorough implementation work with community care providers is absolutely paramount, it must be transparent, inclusive, and honest. Addressing the loss of revenue openly by redirecting staff to other more productive ventures can be helpful.

Medical Licensure

Despite considerable effort to achieve national medical licensure [60–62], the USA continues with parochial control of medical licenses by individual states under Article X of the US Constitution.

The powers not delegated to the USA by the Constitution, nor prohibited by it to the states, are reserved to the states, respectively, or to the people [63]. This includes the states authority to regulate activities that affect the health, safety, and welfare of their citizens including the practice of healing arts within their borders. In an effort to promote the development of telemedicine, the FSMB proposed proper use of the Internet and the development of an Interstate Licensure Compact [64], including an overview with eight essential principles [65] and model language for medical boards [66]. Two of the key "principles" for the Interstate Licensure Compact include the following:

- The practice of medicine occurs *where the patient is located at the time of the physician–patient encounter* requiring the physician to be under the jurisdiction of the State Medical Board where the patient is located.
- Any physician practicing in the state will be known by, and *under the jurisdiction of, the State Medical Board where the patient is located* and the practice occurs.

To date, the efforts by the FSMB have been recognized and applauded by a bipartisan group of the US senators [67]. As of 2015, there are nine states with legislation introduced to participate in the Interstate Licensure Compact (TX, WY, UT, NB, SD, MN, IA, OK,&; VT). Sources, in addition to the ATA, include the FSMB [68] for up-to-date information on legislative initiatives.

Otherwise, despite efforts by the Federal Senator Tom Udall (D-NM) and Representative Mike Thompson (D-Ca) to introduce legislation for national medical licensure, broad-based acceptance of out-of-state providers is limited to the Indian Health Service [69] and Military personnel [70].

Professional Billing and Reimbursement

There are three primary sources of reimbursement: private payers (Commercial Payers), Medicaid, and Medicare. The aim of this section is to review and offer advice to sources of specific information for reimbursement.

Private Payer and Medicaid Reimbursement

Briefly, the private payers and Medicaid are under state regulations with wide variation from state-to-state resulting in a baffling "*patchwork*" of differing allowances and restrictions. A state that mandates "reimbursement" from either private payers or Medicaid may, in fact, have full, unrestricted reimbursement or extremely limited reimbursement. The American Telemedicine has recently published the "State Telemedicine Gap Analysis Coverage and Reimbursement" [71]. Key variables from state-to-state include:

- Parity: Private and Medicaid reimbursement should be "in parity" with face-to-face services. That is, professional services are reimbursed the same dollar amount for telemedicine versus face-to-face services. Of those states providing general telemedicine coverage, only 15 states mandate full parity from private payers for telemedicine services.
- State employee health plans: The vast majority (over 80 %) of states exclude state employees for coverage via telemedicine/telehealth.

- Regional Restrictions: In the past, much of telemedicine reimbursement was limited to rural areas of a state. There is a rapid trend toward removing regional limitations. Under State Medicaid Regulations, 82 % of states have no regional restriction.
- Health provider-type restrictions: There is a wide and baffling array of limitations on provider types. Of the reviewed 25 ± provider types, 24 states accepted less than 9 health provider types and 3 states allowed only physicians.
- Structural and technological limitations: There has been a rapid movement away from the limited hub-and-spoke process to include store-and-forward, remote-patient monitoring, and open architecture designs. However, almost 60 % of states currently are scored very low due to limitations to "synchronous telemedicine" or no coverage at all.
- Originating site restrictions: The evolution is away from limitations such as only accepting hospitals or FQHCs now to supporting home monitoring although not universally yet

In summary, there is a wide spectrum of allowances and restrictions such that the interested party must seek final word from their State Medical Board and review the information provided by the ATA. The National Conference of State Legislators [72] has developed the following visual describing the current status of telemedicine coverage (see Fig. 10.2). Of note, this 2015 map has evolved favorably regarding the regulatory environment for telemedicine in the USA since 2013.

Medicare Payments for Telemedicine

As mentioned previously, partial Medicare reimbursement for telehealth services was authorized in the Balanced Budget Act of 1997 [44]. The narrow scope of reimbursement prompted efforts toward expansion and revision via the Benefits Improvement and Protection Act of 2000 [45], which enhanced the scope of reimbursement yet maintained substantial limitations on geographic location, originating sites, and eligible telehealth services. Ultimately, the uncertainty centers around determining if a patient or situation will satisfy federal qualifying regulations [73]. Once determining that the process meets CMMS/Medicare requirements, there are only about 69 CMMS-authorized codes related to Telehealth reimbursement [74].

Four general criteria must be met to satisfy reimbursement requirements for telehealth services through the Medicare system. Additionally, the Federal government has imposed an additional "Current Procedural Terminology (CPT)" code: The HCPCS system [75].

1. Medicare patient's originating site region (where the patient is located) must be in a:
   - Rural health professional shortage area [76, 77]
   - A county outside of a metropolitan statistical area [78]

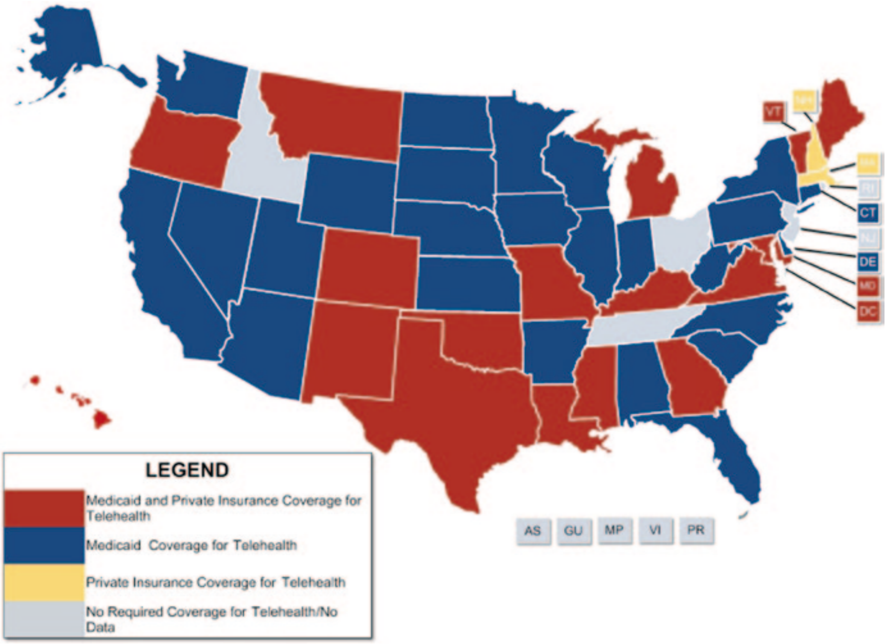

Fig. 10.2 Map of the USA where telehealth services are presented as "No required Coverage for TeleHealth *(light blue)*, "Private Insurance Coverage for Telehealth" only *(yellow)*, "Medicaid Coverage for Telehealth" only *(dark blue)* and combined "Medicaid and Private Insurance Coverage for Telehealth" *(maroon)*. (From the National Conference of State Legislatures. http://www.ncsl.org/research/health/state-coverage-for-telehealth-services.aspx. Accessed 26 Jan 2015 with permission)

2. The "originating site" must be in one of the following categories: (note: Home not included)
   - Physician's or practitioner's office
   - Acute care hospital
   - Critical Access Hospitals [79]
   - Rural Health Clinics [80]
   - Federally Qualified Health Centers [81]
3. Telemedicine/telehealth providers at the "distant site" must be either: (note: R.N. not included)
   - Physicians
   - Nurse practitioners or physician assistants
   - Nurse midwives
   - Clinical nurse specialists
   - Clinical psychologists or clinical social workers
   - Registered dietitians or nutrition professionals
4. Minimum technology includes: (note store-and-forward not included)
   - Real-time interactive audio and video system
   - Asynchronous "store-and-forward" technology is permitted only in federal telemedicine demonstration programs conducted in Alaska or Hawaii

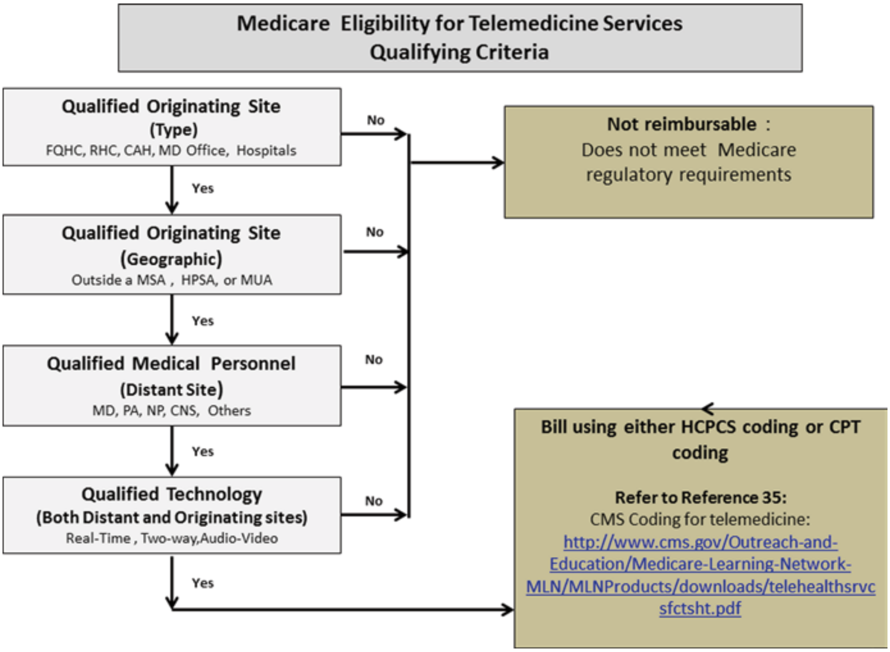

Fig. 10.3 Overview of the Medicare structure required for successful reimbursement for a bona fide Medicare patient provided telemedicine services in the ICU. Note federal regulations do not support 99291 or 99292 billing codes. Other codes may provide some reimbursement through the Medicare system but not at the level of 99291 and/or 99292. *FQHC* Federally Qualified Health Center, *RHC* Rural Healthcare Center, *CAH* Critical Access Hospital, *MSA* metropolitan statistical area, *HPSA* health professional shortage area, *MUA* medically underserved area, *MD* medical doctor, *PA* physician's assistant, *NP* nurse practitioner, *CNS* clinical nurse specialist, *HCPCA* Healthcare Common Procedural Coding System, *ICU* intensive care unit

Overview of the process to qualify for reimbursement under the Medicare system is presented graphically in Fig. 10.3.

Under the pressure of the ACA and need for greater efficiency, the CMMS will come under ever greater pressure to increase coverage and decrease limitations for reimbursement of telemedicine services. As of 2014, a bill [82] in "Discussion Document" format: "*To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes*" is being considered by the US House of Representatives. Specifics of this 400-page document include:

- The Secretary (of Health) shall implement a methodology to provide for coverage and payment for a telehealth service … to include store-and-forward technology.
- Such methodology… would reduce (or would not result in any increase in) net program spending under this title.
- States should collaborate, through the use of State Medical Board compacts, to create common licensure requirements for providing telehealth services in order to facilitate multistate practices.

The current Discussion Document is already meeting with criticism suggesting likelihood of failure unless amended [83], but does give the current appetite of the congress for change in this arena.

Coding for Reimbursement for Telemedicine Services

In general, for private payers or Medicaid, coding for telemedicine services will be the same as for on-site, hands-on care with the exception that billing codes will have the "GT" modifier added. The "GT" modifier indicates that services were provided "*via interactive audio and video telecommunications systems*" and for Medicare beneficiaries, certifying that the "*beneficiary was present at an eligible originating site when the telehealth service was furnished*." By contrast, CMMS has established a coding system separate and distinct from the CPT codes that does not require the GT modifier.

Future Reimbursement Models for Telemedicine Services

All the discussions about fee-for-service and reimbursement via the three categories of payers may be rendered moot with the development of "global reimbursement" [84], "bundled payment schemes" [85], "Total Patient revenue" [86] "Pay-for-Performance" [87] and "Accountable-Care-Organizations" [88]. Of note, despite the apparent value of telemedicine for the support and promotion of the accountable care organizations (ACOs) or bundled payment schemes, telehealth technologies are not currently supported by CMMS for this application

Conclusion

Regarding the ethics of telemedicine, it is judged that, in general, telemedicine is highly consistent with the basic tenants of ethical medicine. There remains some uncertainty about how and when a physician–patient relationship is, in fact, established, and due to the impact on physician medical licensure this remains a sensitive issue. Informed consent is still evolving with one extreme being the excessive and inhibitory guidelines from the FSMB and from certain states. The regulatory environment is complex as noted with many federal and state regulatory agencies involved. But, more than the number and complexity of the regulatory structure is the ever-present and on-going evolution and interpretation of laws. Finally, in regards to reimbursement, there has been significant progress getting reimbursement from all payers (except the federal government) under the traditional fee-for-service system. With the constant evolution and metamorphosis of health-care reimbursement, many of the controversies and inconsistencies described will likely become irrelevant in the near future. But the authors believe that the new reimbursement systems should, by necessity, drive the development of telemedicine much more than the prior fee-for-service system. However, the payor/reimbursement process for these programs must mature and be inclusive of telemedicine services.

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Appendix 13.1

In order to understand telemedicine/telehealth, the reader must speak "the language." The following represents some important lexicon necessary to read the literature.

Asynchronous Telecommunications Activities take place outside of real time such as "store-and-forward" data or image exchange. Examples include e-mail communications, radiographic image interpretation, and delayed image review such as skin lesions or pathology specimens.

Store-and-Forward Technology Information, which could be graphical, images, or photographs, is transmitted electronically, and is interpreted in a delayed fashion. Typical applications of store-and-forward include radiography, dermatology, pathology, and retinal scans for ophthalmology.

Synchronous Telecommunications It is real-time, two-way audio-video communications. Activities take place in real time such as real-time two-way audio-video communications, telephone calls, or direct conversations.

Telemedicine The practice of medicine using electronic communications, information technology, or other means between a care provider in one location and a patient in another location with or without an intervening health-care provider.

Originating Site Defined by the federal government as the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Generally defined as "where the patient is located," therefore defining which state medical licensure will apply and under which State Medical Board.

Distant Site Where the clinician is located providing the telemedicine services. Could be same state where the patient is located (originating site) or other remote state.

Health Resources Services Administration (HRSA) "Federal agency for improving access to health care by strengthening the health care workforce, building healthy communities and achieving health equity. HRSAs programs provide health care to people who are geographically isolated, economically or medically vulnerable" [52].

Health Professional Shortage Area (HPSA) Geographic area or populations lacking sufficient health care. HPSAs designated by HRSA based on census tracts, townships, or counties. Designations are made for primary care, dental, and mental health. A geographic area will be designated as having a shortage of primary medical care professionals if the following three criteria are met:

a. The area is a rational area for the delivery of primary medical care services.
b. One of the following conditions prevails, having a population- to- full-time-equivalent primary care physician ratio of at least 3500:1 or the area has a population- to- full-time-equivalent primary care physician ratio of less than 3500:1 but greater than 3000:1 and unusually high needs for primary care services or insufficient capacity of existing primary care providers.
c. Primary medical care professionals in contiguous areas are overutilized, excessively distant, or inaccessible to the population of the area under consideration.

Metropolitan Statistical Area (MSA) A geographical region comprising a relatively high population density, at least 50,000. An MSA is neither a legally incorporated city nor a legal administrative entity such as a state or county.

Critical Access Hospital (CAH)

- Located in a state with a rural health plan with a State Flex Program for Medicare (Includes all states except CT, MD, DE, NJ, and RI)
- Located in a rural area or “treated as rural”
- Provide 24 × 7 × 365 services which may be on-site staff or on-call staff
- 25 or less beds
- Average length of stay (LOS) < 96 h
- Located more than 35 miles ground transportation from the nearest full-service hospital

Rural Health Clinic (RHC)

- Located in a nonurbanized area as defined by the US Census Bureau
- Qualify as a HRSA shortage area
- Employ either NPs or PAs
- Provide certain minimum diagnostic services and studies
- Have an established relationship with a local hospital
- Stock medications and biologicals for medical emergencies
- Not an FQHC
- Meet certain administrative requirements

Federally Qualified Health Centers (FQHC)

- The main purpose of the FQHC program is to enhance the provision of primary care services in underserved urban and rural communities
- Received a grant from the federal government Public Health Service (PHS)
- Has been a FQHC as of 1/1990 or
- Has been providing native American tribe or tribal health services as of 10/1/1991

Medically Underserved Area/Medically Underserved Population (MUA/MUP)

- HRSA-defined area as medically underserved areas/medically underserved populations are areas or populations designated by HRSA as having too few primary care providers, high infant mortality, high poverty, and/or high elderly population.

Healthcare Common Procedural Coding System (HCPCS) [57]

- The HCPCS is divided into two principle subsystems, referred to as level I and level II of the HCPCS. Level I of the HCPCS comprises CPT, maintained by the AMA. Level II of the HCPCS is a standardized coding system used primarily to identify products, supplies, and services not included in the CPT codes, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies.

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Chapter 11
Future Directions in Telemedicine Applications for Inflammatory Bowel Disease (IBD)

Welmoed K. van Deen and Daniel W. Hommes

Introduction

Health care costs are exploding globally and are a burden on the economy. Many reforms in the past have aimed to control spending, but results have been insufficient. Furthermore, quality and costs are not always correlated [1], which can only be worsened by health care reforms that purely focus on costs. The current idea is that health care reforms should focus on health value—the combination of health outcomes and costs—rather than on costs or quality alone [2]. This concept is called value-based health care (VBHC), and many centers are progressively implementing VBHC concepts in their care practice. Key components for VBHC implementation are the ability to measure outcomes and cost reliably and compare those to others, and to have the ability to improve care processes according to the measured results [3]. We think that telemedicine—and in particular electronic—and mobile health (mHealth) systems can be a key component to support durable changes in care delivery.

Traditionally, health-care systems have been organized around symptomatic care where patients seek help from their physician whenever they have complaints. However, systems are moving more and more toward prevention-oriented and connected care that are focused on retaining health rather than treating sickness. This shift will obviously dramatically change the role of physicians as well; instead of the doctor prescribing medication, the doctor will increasingly function as a health coach. Even there, the care giver does not need to be a doctor per se; many clinics have introduced the nurse coordinator for chronic disease management. By staying connected to patients, monitoring and early intervention can be practiced much more efficiently than in the traditional disconnected care model. In the case of inflammatory bowel diseases (IBD), in addition to treating flares, the focus will need

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to be on continuous disease monitoring and full patient participation. This can be achieved partly through enhanced patient education for which there need to be a reward mechanism in place, and partly through introducing telemedicine solutions to ensure that patients will *stay* connected to their caregiver.

The area of telemedicine offers features that could be attractive for the purpose of patient connectivity and disease control. Having messaging, phone, monitoring tools, diagnostics and even (preventative) treatments available at your fingertips will not only allow for those changes to happen but will also empower patients to *make* these changes happen. Comprehensive information technology (IT) systems can facilitate care coordination and communication between different participants in the care system (e.g., physicians, nurses, patients), facilitate monitoring and education, and support general wellness and preventive approaches. Indeed, mHealth technologies are rapidly gaining ground though the maximum potential is still far from achieved. According to a 2014 PriceWaterhouseCoopers report on mHealth there are four main barriers for adoption of mHealth: (1) the medical culture, which is very resistant to change; (2) the size and complexity of the health systems; (3) regulation; and (4) perverse incentives for the different participants in the health-care system [4].

With the field of VBHC gaining more interest, payment reforms to reward value are slowly emerging as well. These payment reforms incentivize higher quality and lower costs [3]. These reforms will remove the perverse incentives in the current system and will force providers to think about innovative ways to improve quality and decrease costs in care. This creates an opening toward the introduction and integration of mHealth into medical practices. Progress is made in the regulatory field as well. The US Food and Drug Administration (FDA) recently released a draft guidance document describing their vision on the regulation of mHealth applications (apps), on February 9, 2015 [5]. This document is meant to provide clarity for mHealth app developers to understand when their product is considered a Wellness app and when it would be considered a medical device and falls under FDA regulation. The European Union (EU) released a similar set of guidelines in 2012 to clarify when medical software and applications are regulated as medical devices [6].

The question remains where telemedicine has the largest potential and what the future of telemedicine looks like. In the next paragraphs we present our vision on the future use of telemedicine. We focus on different areas with large potential in this field: (1) communication, (2) accessible information and education, (3) diagnostics and monitoring, (4) wellness, and (5) data analytics and personalized medicine. We describe the telemedicine model currently implemented at University of California, Los Angeles (UCLA) and summarize next steps to be taken in order to fully achieve the maximum potential of telemedicine to increase patient value.

Communication

Patient–Provider Communication In chronic disease management, office visits are traditionally scheduled by the provider and are frequently influenced by provider availability. Upon symptoms, patients can request an appointment which will be scheduled depending on the urgency and physician availability. Usually this will be within days or weeks during which there usually is no medical attention or intervention and patients are left at their own devices. As a consequence, patients often visit emergency departments (EDs). Needless to say that this drives up costs substantially even though this could have been largely prevented through enhanced connectivity.

It has been reported that IBD patients experience scheduled follow-up visits when “doing well” as unnecessary and inconvenient [7]. In this study 19 out of 20 selected patients were in favor of the use of telemedicine. In addition self-management was thought to be a good approach to a group of patients, though not all patients felt comfortable to self-manage their disease. This underlines the need to move toward more accessible, on-demand care, which can all be enabled by the use of telemedicine systems. Because telemedicine services can be independent of the location of both the physician and the patient, a global physician network could facilitate the availability of on demand care for 24 h per day.

In non-acute settings, telemedicine has the benefit to provide asynchronous care which can be delivered by the patient’s own health-care provider. Where a health-care provider traditionally needs to be available at the same time as the patient to communicate effectively, in the modern world patients can communicate through secure channels such as chat, or text messaging which does not require two people to be available at the exact same time and can be very effective in treatment plans.

Patient–Patient Communication Social media also offers benefit to patients. The use of social networking sites (e.g., Facebook, PatientsLikeMe), blogs, and discussion forums have been shown to improve psychological, social, and cognitive health in pain management [8]. Furthermore, social media encourages patients to adapt a more healthy lifestyle. A recent study showed that the use of a Facebook social support group to log and share daily activity was effective to increase physical activity in young women [9].

Provider–Provider Communication Telemedicine also enables the removal of geographic barriers for provider–provider interaction. Real-time consultations can be done using videoconference, and similarly, peer-education can be done through videoconferencing. Furthermore, with the use of online education technologies, asynchronous education using online platforms becomes more widely available as well. For IBD, the IBD Live Inter-institutional and Interdisciplinary Videoconference Education (LIVE) series have been described. IBD LIVE is a case-conference in which up to 11 centers and 74 participants have participated per conference. Gastroenterologists, surgeons, pathologists, and radiologists all participate and all patient documentation is reviewed prior to the conference and presented during the conference. This approach was conceived as a great way to disseminate knowledge about difficult IBD cases, and disease management was changed for all presented cases [10]. These approaches increase multidisciplinarily, make specialty care more widely available, and enhance coordination of care between different providers. Before such efforts were undertaken travel or peer-to-peer limited phone calls were the only way to interact which limited collaboration on challenging cases and the rapid dissemination of new treatment concepts.

Diagnostics and Monitoring

Point of care tests for simple lab tests such as urine dipsticks or hemoglobin or glucose fingerpick tests have been readily available for many years. Technological possibilities in this field are rapidly improving. A recent study showed the feasibility of running an enzyme-linked immunosorbent assay (ELISA) using a smartphone accessory to test for multiple infectious diseases. Using the smartphone's battery as power source and the audio-jack to transfer data to the smartphone a reliable ELISA can be performed [11]. The photo-camera of the device can also be used for diagnostic purposes, ranging from the use of photographs for remote assessment of dermatologic lesions, to the use of the camera to interpret lab tests. A new calprotectin test to be used by patients was recently developed and tested, which uses an immunochromatographic rapid test for calprotectin. Stool is placed on the test cassette, and results can be "read" by taking a picture of the cassette. Using image processing the result is interpreted and sent to a server. This approach for home-testing was shown to be feasible [12] and results were comparable to conventional ELISA tests [13].

However, the predictive value of many existing biomarkers is limited [14] and the search for more reliable biomarkers is ongoing. Micro RNAs (miRNAs) seem to be promising targets for new biomarker development and several serum miRNAs have been implied to be associated with disease activity in IBD [15, 16]. When both the development of new biomarkers for disease activity and the development of new techniques for home testing rapidly progress, this clearly shows large potential for the future of telemedicine.

Self-testing can be used to either self-monitor or even self-manage a chronic disease. In both scenarios the patient is trained to do use a point-of-care device to test a certain marker. In a self-monitoring setting this information is transferred to a health-care provider who interprets the test and adjusts the treatment plan accordingly. In a self-management setting the patient interprets the results and adjusts the treatment plan accordingly, without intervention of a health-care practitioner [17]. These differences in the use of remote disease management affect the way patients [7], physicians [18], and regulatory agencies such as the FDA [5] evaluate the device.

Many companies have already developed point of care devices for weight, electrocardiogram (EKG), blood pressure, blood glucose, or symptom monitoring [19,20]. These devices can then transmit those results to a health-care practitioner for further management. These devices facilitate care but still require active patient participation. Ideally monitoring should switch from active to passive, in which the patient is tracked automatically, which could increase consistency and reliability of the data. Toilets that automatically measure weight, hydration, temperature, tissue perfusion, EKG, and urine sugar have been developed [21]. For IBD automated tracking of newly developed stool or urine biomarkers might help detect disease activity at an early stage and thus enable early treatment plan modification or early and more effective intervention.

In a similar way sensors can be implemented in the living location. Because many patients carry their mobile device on them most of the day, location and movement data can be tracked directly through mobile devices. Implants offer another possibility. For cardiac patients with pacemakers and implantable cardioverter-defibrillator, for example, several companies already offer home-monitoring options [22]. The rapid evolution of the sensor field offers tremendous potential for IBD patients in the near future.

Accessible Information and Education

Because more information is becoming available online, there are many more possibilities for patients to become more educated about their disease. However, there is large variation in the quality of information available online about IBD, and the content of only 4% of the assessed websites used language that had acceptable readability levels [23]. This shows that improvement is warranted in this field but the potential is real.

The success of chronic disease management is strongly dependent on the patient's disease behavior. Behavioral interventions are therefore thought to be of great value in chronic disease management. However, in order to adapt behavioral changes, social, institutional, and cultural environments are of large importance. Education is more effective when delivered in a personalized, contextual, and interactive manner rather than in a one-directional, "one-size-fits-all" message [24]. Artificial intelligence (AI) techniques are thought to enhance the effectiveness of health communication and improve patient engagement and participation. This includes the provision of timely, relevant, actionable, and patient-specific information [25]. *In short, patients want to get and digest information when and where they please, not based on the traditional convenience of our health-care system.*

Dynamic information can be displayed based on the patients' specific interests. A recent study from Mayo clinic showed the possibility of using search engine data to identify areas of interest to patients. By mapping 10 million search queries related to cardiovascular disease into 17 categories, patients' interests were identified [26]. By expanding these techniques to individual patients, personalized education becomes possible.

The addition to gamification elements in online education is also thought to have beneficial effects. Gamification includes the use of trophies, leaderboards, points and levels, challenges, and social engagement loops [27]. In a recent study in the field of rheumatoid arthritis it was shown that patients that had access to educational content with gamification features spent more time on the website then patients with access to educational content without gamification. Also physical activity increased in those patients [28].

Incorporation of all the components of AI, personalization, and gamification in educational material will support a patient-driven and more effective learning environment. Higher patient empowerment and disease knowledge will most likely result in better disease behavior and increased adherence, which in turn lead to better disease control and improvements in patient's quality of life. This is truly an organic approach to chronic disease management.

Wellness

At this moment a wide range of general wellness apps are available in the iTunes and Google Play store. The general health apps range from apps that stimulate healthy behavior such as physical activity, healthy diet or smoking cessation, to apps that aim to improve mental health, or apps that focus on medication self-management [29]. These apps can be used in a wide range of patients, though specific adjustments can and should be made based on the patients' disease. When personalization approaches will be more readily available, individualized activation programs can be offered to patients. Interactivity [30], gamification, and peer interaction [27] have shown beneficial results on behavior modification in the wellness field as well. It is not expected that informing patients about the availability of wellness apps will have a significant impact on their health. In contrast to passive wellness offerings, health systems will have to integrate wellness into their care delivery. Incentivizing patients for active participation is likely to enhance outcomes.

Data Analytics and Personalized Medicine

Large amounts of health data are increasingly becoming available from electronic health records (EHRs), genetic datasets, and imaging data. These large datasets are thought to be the bridge toward personalized medicine, by comparing new patients to patients with very similar characteristics. This can facilitate (1) validation of existing medical treatments, (2) choosing a therapy targeted to the individual, and (3) a focus on prevention [31]. Data collected through telemedicine systems will be another source of big data through collection of data on symptoms, through monitoring devices, and by geo-location data. Remote monitoring in particular will add a large subset to the big-data warehouse. When interoperability between different systems and applications increases, this will only enhance the current possibilities. Predicting which patients are at risk for a disease flare based on patterns in their geolocation, movement, app use, and mobile phone use in general will only be one of the many possibilities.

The UCLA Model

The UCLA Center for IBD has launched a VBHC program in February 2012. The developed program is specifically focused on IBD, but the same infrastructure is currently being used to create VBHC programs for other chronic diseases. The program is based on the ideas of VBHC; care coordination, outcome and cost measurements, and general wellness improvement are therefore an integral part of the program.

The UCLA IBD Center's IT infrastructure is built around an online provider portal behind a firewall, and a patient application that communicates with the database using a web server that is connected with the mobile application using an application program interface (API). All interactions with the system are web based and use secured communications channels. The data are collected in a HIPAA secure database that allows identified access for treating physicians; anonymized data is available in a separate part of the database—the data warehouse—for research and big data analysis (Fig. 11.1).

Care is organized in evidence-based coordinated care pathways based on the patient's current disease state (i.e., active versus remission) and medication regimen. Based on guidelines, relevant literature, and consensus statements, ten pathways were developed; five 6-week scenarios for patients with active diseases (Fig. 11.2a), and five annual scenarios for patients in remission (Fig. 11.2b). Each pathway has a predefined number of clinic visits, electronic visits (e-Care), and lab sets (Table 11.1). Whenever the physician switches the scenario on using the provider interface, a care pathway is automatically generated (Fig. 11.2c). The pathways can be modified according to the physician's discretion. Standard operating procedures (SOPs) are included in the pathway, as well as a reference cost model (Fig. 11.2d; [32]).

Outcome measurements are collected routinely and include assessment of level of disease control, quality of life, and productivity at work, school, or home. During clinic visits, validated questionnaires are used for collection of patients' outcomes data. For disease control the Harvey–Bradshaw Index [33] is collected for Crohn's disease (CD) and the partial Mayo score [34] for ulcerative colitis (UC). For quality

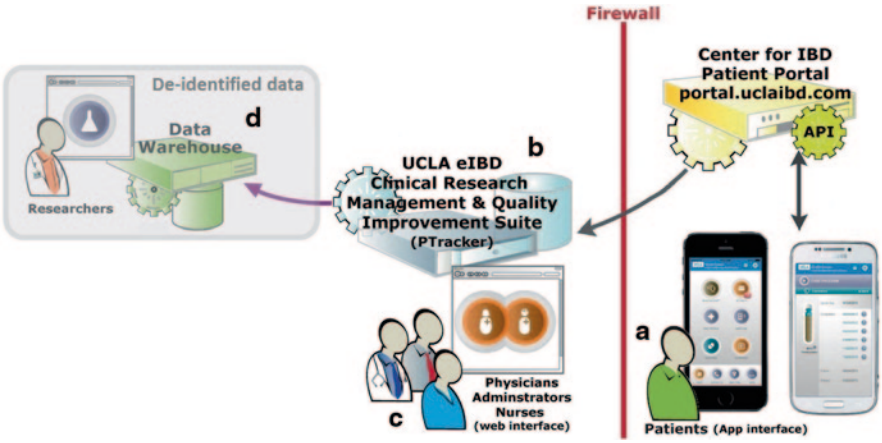

Fig. 11.1 The general information technology (IT) infrastructure of the University of California, Los Angeles (UCLA) value-based health care (VBHC) program. Patients use a mobile application (**a**) which is connected to the database (**b**) using an application program interface *(API)* and web server through secure communication channels. The provider portal (**c**) is inside the firewall and gives care providers access to patients' data. A de-identified version of the database is available in the data-warehouse, which can be utilized for research purposes. (**d**)

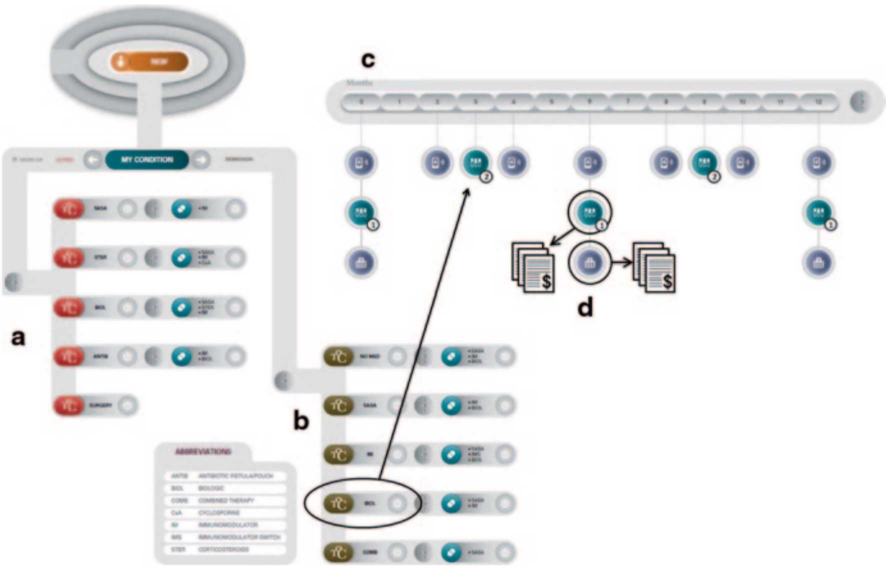

Fig. 11.2 Coordinated care pathway architecture as implemented at the University of California, Los Angeles (UCLA) Center for Inflammatory Bowel Diseases. Care scenarios designed based on the patients' treatment regimens and current disease states (i.e. active (**a**) versus inactive (**b**) were implemented and include scheduled clinic visits, lab tests, and e-health contacts (**c**). Standard operating procedures (SOPs) are included in the pathways and a reference cost model was developed (**d**). (Adapted with permission from UCLA Health Center for Inflammatory Bowel Diseases Key Performance Report 2013)

Table 11.1 Evidence-based care pathways designed based on the patient's disease state and treatment regimen

Care scenario	Total duration	Labs[a]	Office visit	Home care
Remission induction antibiotics	6 weeks	Week 0+6 set 1	Week 0+6	Every 2 weeks
Remission induction 5ASA/SPS				
Remission induction steroids				
Remission induction biologics				
Maintenance 5ASA/SPS	Continuous	Yearly set 1	Yearly	Every 2 months
Maintenance no medication				
Maintenance immunomodulator	Continuous	Every 3 months alternate set 1 and 2	2x/year	Every 2 months
Maintenance combo				
Maintenance biologics	Continuous	2x/year set 1	2x/year	Every 2 months

[a] Lab set 1 is used for disease activity assessment (CBC, CMP, ESR/CRP). Lab set 2 is used for monitoring of side effects of immunomodulator therapy (CBC, CMP)

CRP C-reactive protein, *ESR* erythrocyte sedimentation rate, of life assessment, patients fill out the short IBD questionnaire [35] (sIBDQ), and for work productivity assessment the work productivity and impairment questionnaire [36] (WPAI). For monitoring of disease control at home—which enables care providers both to detect relapses as well as to measure outcomes—short four-question questionnaires consisting of just patient reported outcomes (PROs) were developed: the mHealth index (mHI) for UC (mHI-UC) and CD (mHI-CD) [37]. These questionnaires were specifically developed to be implemented in a mobile application (Fig. 11.3). To monitor costs, a charge-model was implemented which shows real-time changes in encountered charges whenever procedures are added or removed from the pathway.

We aimed to include the five relevant aspects of telemedicine in our IT system as well. (1) To enhance communication a messaging functionality was included in the platform. Patients can send messages to their care coordinator 24 h/day, and will receive a response within 24 h on business days. In the initial version only patient–provider communication was included. To further enhance communication and support effective care coordination, a provider–provider messaging system was developed as well. (2) The developed mHIs are used for home monitoring and automated messages are sent to the care coordinators whenever the score indicates disease activity. (3) For educational purposes an IBD specific educational program was developed. This program includes five educational modules covering different aspects of IBD diagnosis, treatment, and management. Every module ends with a test question. Furthermore, a glossary was included in this section of the app,

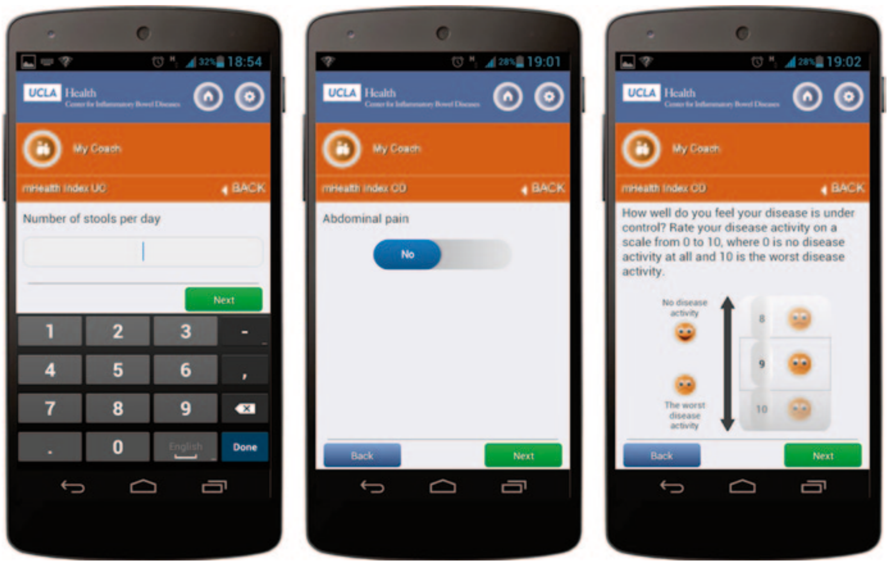

Fig. 11.3 Three examples of mobile health index (mHI) questions as implemented at the UCLA eIBD patient-facing mobile application

which enables patients to look up specific topics of interest. (4) For enhancement of general wellness in IBD patients six 6-week wellness programs were developed tailored towards IBD: fitness, yoga, meditation, diet, and acupressure modules were developed, as well as a 6-week e-behavioral antinational therapy (eBAT) program for patients suffering from anxiety and depression. Lastly, (5) all data is accessible in a de-identified fromat for research purposes. This enables us to identify patterns in the collected data and improve care over time.

Recently, first outcomes of this program were presented and preliminary results show encouraging data. UCLA IBD patients were compared to a matched control group using insurance claims data from a major California insurer. Significantly, less corticosteroid use was observed in the UCLA IBD group (12 vs. 31 %, $p = 0.03$) and numerically more methotrexate (1 vs. 6 %, not significant (NS)) and adalimumab (15 vs. 21 %, NS) use. Furthermore, patients in the UCLA IBD group had 1.3–3.4 times more frequent biomarker testing ($p < 0.001$), and 89 % fewer hospitalizations and 75 % fewer ED visits (NS) [38].

Next Steps

In future efforts telemedicine systems need to fully optimize the five components discussed in this chapter. Major advances can still be achieved by fully optimizing potential for communication, education, remote monitoring, and encouraging general wellness. Future research will have to show the most effective ways to improve these potentially important areas of telemedicine systems. Furthermore, the collected data can majorly advance health care by opening the way toward personalized medicine.

However, to fully utilize the potential of telemedicine for improving value in health care some major hurdles still need to be overcome. Interoperability is still a major challenge but this represents a broader challenge within health care and is not limited to IBD per se. Different applications and EHRs use different data formats and moreover, not all developers allow interconnectivity yet with other applications and certainly there is no large scale interconnection between telemedicine and EHRs.

Changing the medical culture is another hurdle. In order to fully utilize the potential of telemedicine and mHealth systems, all participants in the health care chain need to be fully on board and appropriately incentivized. Current physician incentives mostly focus on delivering volume rather than quality. However, new payment systems which reward value rather that quantity are gaining ground and will encourage participants to change current practices and thus adopt telemedicine. Because telemedicine offers a major potential to improve quality and reduce overall costs, this seems to be a promising opportunity.

Conclusion

In conclusion, the entire health system will have to transform from a volume-based, disconnected, and fragmented care model toward a value-based, connected, and co-ordinated care model. Telemedicine offers the potential to support all those changes and increase care efficiency overall. The full potential of telemedicine is far from achieved but many innovations are emerging throughout the world.

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