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Quality Improvement in Inflammatory Bowel Disease

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Introduction

In recent decades, research has generated an enormous growth of medical science, technology, and therapeutics. Knowledge from basic research, translational research, randomized clinical trials, and outcomes research has enabled experts in many fields to develop and disseminate evidence-based clinical practice guidelines with recommendations for medical practitioners. Yet health services research suggests that health care could perform a great deal better than it does today. For example, an audit of medical records of 4000 adults in 12 cities in the USA showed that only 55% of recommended preventive, acute, and chronic care was being received [1]. Similar deficits have been observed in ambulatory pediatrics [2]. A study of 3000 hospitals found that only five of ten recommended care measures were provided to a large majority of patients [3]. A report of the Institute of Medicine, Crossing the Quality Chasm, calls for improvements in six dimensions of healthcare performance: Safety, Timeliness, Efficiency, Effectiveness, Equity, and Patient centeredness (STEEEP) [4]. The National Scorecard on U.S. Health System Performance, an assessment of healthcare outcomes, quality, access, equity, and efficiency, found that the U.S. achieves an average score of only 66%. If the U.S. improved performance in key areas, it could save an estimated 100,000–150,000 lives and 50–100 billion dollars annually [5].

Improving the care of patients requires more knowledge; achievement of improvements requires the application of the principles of continuous quality improvement [6, 7]. Quality improvement in health care is the application of knowledge to make changes that result in better care and outcomes.

One of the barriers to quality improvement is unnecessary variation in care. Unnecessary variation, which erodes quality and reliability and adds to costs, is derived in part from habitual differences in practice style that are not grounded in knowledge or reason [8]. Variation makes it impossible to determine if a change in practice results in change in care because small improvements are frequently obscured by the background noise of variation. Quality improvement efforts

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can reduce unnecessary variation; reducing variation is a necessary prerequisite to improve quality. To attain continuous quality improvement in health care, it is necessary to repeatedly measure the processes and outcomes of care and design, implement interventions to improve the processes of care, and re-measure to determine the effect of the interventions [9]. In this chapter, we present an introduction to quality improvement and how it has been applied to pediatric inflammatory bowel disease, with brief discussions of variation in care, the Chronic Illness Care Model, the need for quality improvement, the Improvement Model, the improvement collaborative, the ImproveCareNow Network, next steps/future directions, maintaining improvement, and administrative and funding considerations.

Variation in Care

Inflammatory bowel disease (IBD) is the most common serious chronic gastrointestinal disease afflicting children and adolescents in North America, yet there is currently considerable variation in the way gastroenterologists diagnose and treat IBD [10, 11]. Variation in care can be due to underuse, overuse, or misuse of diagnostic and therapeutic interventions. An example of underuse is failure to obtain small bowel imaging or neglecting to identify and treat growth failure; an example of overuse is unnecessary prolonged prednisone treatment [12]; and an example of misuse is prescribing infliximab to a patient with tuberculosis [13]. While some variations are due to patient needs or preferences, many variations are due to a lack of adherence by practitioners to best practices. Other variations are due to lack of data to guide practice leading to different practice strategies based on anecdotal experience or other non-evidence-based reasons [10]. Standardization of care occurs when physicians agree to provide care in a uniform manner of care appropriate for each patient. This can be evidence based, or in the absence of evidence, can be based on expert opinion or consensus. Standardization of care reduces unnecessary variation and, when combined with systematic studies of planned variations (including randomized studies), can lead to increased knowledge and improved outcomes.

Figure 57.1a is a theoretical example of a wide variation in the number of diagnostic tests performed prior to initiating treatment (labeled Before). When a larger number of tests than average are performed, it could indicate overuse of some tests, while a smaller number than average could indicate underuse. In this example, after a successful quality improvement project leading to less unnecessary variation in care, there is less overuse and less underuse than before, although the average number of tests is the same. Figure 57.1b is a theoretical example of a wide variation and a low percentage of patients at most sites having a skin test for tuberculosis before initiating infliximab therapy (labeled Before). After a successful improvement project, there is less variation and a higher rate of skin testing.

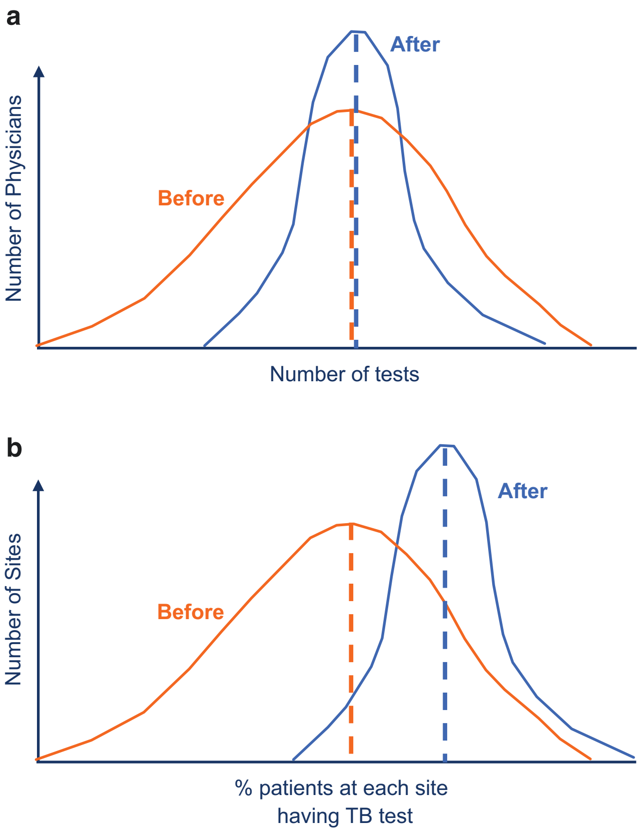


Fig. 57.1 Variation in care. (**a**) Improving quality by decreasing variation. (**b**) Improving quality by shifting distribution

Variation in care has been demonstrated in pediatric IBD [10, 11, 14]. In one study, pediatric gastroenterologists enrolled patients with Crohn disease who were starting treatment with a thiopurine (6-mercaptopurine or azathioprine) or infliximab [11]. Data from 250 patients at 80 sites were examined for variation in diagnostic and therapeutic interventions. Diagnostic studies in which care was uniform-included complete blood count, performed in 100% of patients, erythrocyte sedimentation rate and colonoscopy in 96%, and upper endoscopy in 89%. However, imaging of the small bowel had not been performed in 19%, and a stool test for pathogens had not been performed in 29%. Thiopurine methyltransferase (TPMT) had been measured in 61% of patients before treatment with a thiopurine; in 85%, TPMT was normal. Nonetheless, even when TPMT was normal, 40% of patients received an initial dose of thiopurine that was lower than recommended. Testing for tuberculosis before initiating treatment with infliximab was not documented in 30%. In addition, 36% of severely underweight patients were not receiving a multivitamin supplement, supplemental formula, or tube feeding [14]. The same study also demonstrated widespread inter-center variation in the treatment of newly diagnosed children with Crohn disease, even after adjusting for possible differences in case mix between institutions [14]. Variation in the use of immunomodulators and infliximab in patients with Crohn disease has also been reported [10, 15]. This considerable variation in diagnostic and therapeutic care in pediatric IBD, reflects the presence of underuse, overuse and potentially misuse of interventions that may lead to unintended differences in healthcare costs and outcomes.

Documentation of variation in care has been important in efforts to standardize and improve care in other fields of medicine [3]. For example, the Epidemiologic Study of Cystic Fibrosis demonstrated large variations in practice patterns regarding the prescription of various therapies as well as the fact that a significant proportion of CF patients are not monitored as recommended by the Cystic Fibrosis Foundation (CFF) [16, 17]. In this study, only 58% of patients had quarterly visits to their CF Care Center, 76% had biannual spirometry, 79% had annual airway cultures and 68% had annual chest radiographs [18]. CF Registry reports are now presented in such a way as to reveal practice variation among practice sites, partly in order to motivate an evaluation of this variation and to promote standardization where indicated.

The Chronic Illness Care Model

The Chronic Illness Care Model provides a useful framework for developing changes to the system of IBD care [19–21]. Wagner and colleagues conducted an exhaustive literature review and program assessment to identify the key components of systems of healthcare delivery that result in improved outcomes for patients with chronic illness. Wagner's model includes the following components: family and patient self-management support; decision support; delivery system design; clinical information systems; community resources; and the healthcare organization (Fig. 57.2). Family and patient self-management support includes the methods used by the clinic to increase families' participation in care. Decision support includes the use of care protocols that are integrated into practice systems. The delivery system design component includes the use of planned encounters, clarity in the roles and responsibilities of team members with appropriate training, and the use of regular meetings of the care team to review performance. The clinical information system refers to the ability of caregivers to access data and use registries for care and to provide regular feedback to the team, and also information technology to facilitate scheduling and patient tracking. A prepared proactive practice team interacts with an informed activated patient to improve functional and clinical outcomes.

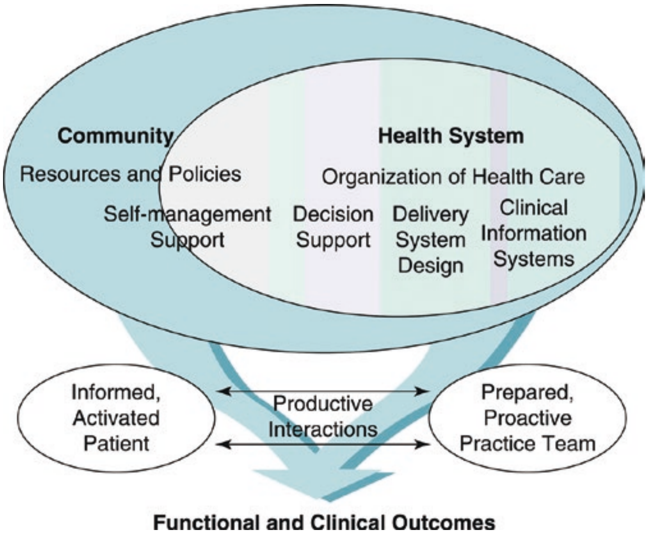


Fig. 57.2 The Chronic Illness Care Model. (Adapted from EH Wagner, *Joint Commission Journal on Quality Improvement* 2001;27:65, by permission)

Improvement science is broadly defined as the science of implementing and testing change. There are many different ways in which improvement science is applied in practice. Each involves the common theme of methodically implementing and testing small changes, and then adopting or rejecting the changes based on the findings of testing [22]. Improvement interventions can range from prospective randomized controlled trials to observational studies [23]. The application of improvement science has led to major advances in quality in the automobile, microchip, and other industries [24–26] which raises the question whether it works in health care or not. Quality improvement interventions utilizing the Chronic Care Illness Model in asthma, congestive heart failure, depression, and diabetes have improved clinical outcomes, processes of care, and quality of life [27]. Studies of controlled trials of interventions that contain at least one element of the Chronic Care Model have demonstrated significant improvements in care [28]. In a cohort study to determine the effect of a specialist nurse on the outcome of 340 patients with IBD, intervention resulted in a 38% reduction in hospital visits, a 19% reduction in hospital length of stay, a 10% increase in patients in remission, and improvement in patient satisfaction [29]. A multi-center randomized controlled trial of a quality improvement project in IBD showed similar results [30]. In the United Kingdom, development of a pediatric IBD service has improved provision of services and access to care for patients [31]. In Australia, the implementation of a dedicated IBD service was associated with a reduction in the use of steroids and opiates as well as a reduction in hospitalizations for IBD [32].

The Need for Quality Improvement in IBD

Have Crohn disease outcomes improved during the last four decades? In a report published in 2004, a structured systematic literature review was performed to evaluate measurable outcomes in Crohn disease. Evaluation of mortality, cancer, disease recurrence, extra-intestinal manifestations, and medication use failed to show consistent evidence for improvement in inflammatory bowel disease outcome during the previous four decades [33]. However; more recent studies have shown decreased mortality in IBD [34], decreased colectomy rate in ulcerative colitis [35], and decreased surgical rates in pediatric Crohn disease within 3 years of diagnosis [36]. Despite advances in research and therapy, the application of knowledge to the improvement of health outcomes and quality of life has lagged. Hospitalization rates for IBD, particularly Crohn disease, increased from 1988 to 2011, contributing to a substantial rise in inflation-adjusted economic burden [37, 38]. Further, even in the era of biologics, the proportion of patients with inflammatory bowel disease not entering remission remains high [39]. Are we optimizing biologic therapies? Are patients with IBD receiving optimal care? A study found that adults with IBD referred for a second opinion often were not receiving optimal medical therapy [40]. There was prolonged use of corticosteroids, failure to use steroid-sparing agents, suboptimal dosing of mesalamine and immunomodulatory medications, inadequate measures to prevent metabolic bone disease, and inadequate screening for colorectal cancer.

A study of the pediatric patients' diagnostic evaluation diagnosed with IBD also identified substantial gaps in small bowel imaging, though this was found to improve over the 5-year course of study [41]. Other evidence indicates a shift toward magnetic resonance imaging and away from ionizing radiation in pediatric IBD [42]. Many pediatric patients diagnosed with Crohn disease had not been tested for intestinal pathogens, had not had imaging of the small intestine, were not receiving a multivitamin supplement, had not been tested for TPMT prior to treatment with a thiopurine, had not been tested for tuberculosis prior to treatment with infliximab, and were receiving suboptimal dosage of medications [11].

Another important aspect of pediatric IBD care needing a quality improvement focus is transition to adult GI care, with the goal of proving comprehensive and uninterrupted care for the adolescent and young adult. The term "transition" refers to the longitudinal process of obtaining the knowledge and skills necessary to care for oneself and one's chronic disease in an adult setting, whereas "transfer" refers to the eventual physical move from pediatric to adult care. Across multiple chronic diseases, it has been demonstrated that poorly managed transitions can result in inappropriate utilization of healthcare resources and adverse health outcomes [43, 44]. The variable (and often complete lack of) transition care processes as well as inconsistent measures of transition readiness in many institutions across the United States continue to put young adults at risk for adverse health outcomes at transition [45–47].

Quality improvement in adult gastroenterology has previously focused on endoscopic procedures [48–56]. More recently, there has been an emphasis on reducing venous thromboembolic events in hospitalized IBD patients [57, 58]. However, the American Gastroenterological Association (AGA) Task Force on Quality in Practice issued a report recommending the formation of an AGA Quality Center to assure uniform documentable excellence in quality of clinical care and GI practice, to support the aims for quality health care set forth by the Institute of Medicine, to identify key quality of care indicators in the treatment of digestive diseases and how they will be measured, to develop programs and tools to assist in implementing evidence-based guidelines and measuring and reporting adherence to quality indicators, and to develop patient education materials to ensure that patients have appropriate expectations regarding high-quality, patient-centered, evidence-based care [59]. In 2011, the AGA developed a set of IBD process measures, approved by the American Medical Association's Physician Consortium for Performance Improvement that focus on transitioning patients to corticosteroid-sparing therapy and preventive care. The AGA subsequently developed a series of quality improvement measures called the Physician Quality Reporting System (PQRS) [60]. The North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) has also developed a set of process measures. In conjunction with measure development, the AGA has also developed the Digestive Health Outcome Registry (DHOR) to help practices develop benchmarking, outcomes measurement, and population management capabilities for patients with IBD [61].

The Improvement Model

The Improvement Model is the foundation of a system for innovation and a framework for developing, testing, and implementing incremental change [62]. The model is based on three questions (Fig. 57.3): What are we trying to accomplish? How will we know that a change is an improvement? What change can we make that will result in improvement? Any approach to improvement must be based on building and applying knowledge. Within the overall framework, the Plan-Do-Study-Act (PDSA) Cycle is a structured application of the scientific method that provides a means to learn rapidly in complex organizational settings. The Plan phase consists of stating the objective of the test, making predictions, and developing a plan to carry out the test. The Do phase consists of carrying out the test, documenting problems and unexpected observations, and beginning an analysis of the data. The Study phase consists of completing the analysis of the data, comparing the test data to predictions, and summarizing what was learned. The Act phase consists of deciding upon and carrying out the changes to be made, and considering what will be the objective of the next cycle. The Improvement Model means applying the principles of using data; developing, testing, and implementing changes; and working collaboratively to bring about improvement in the outcomes of health care (Fig. 57.4). The improvement model can be applied to any aspect of health care.

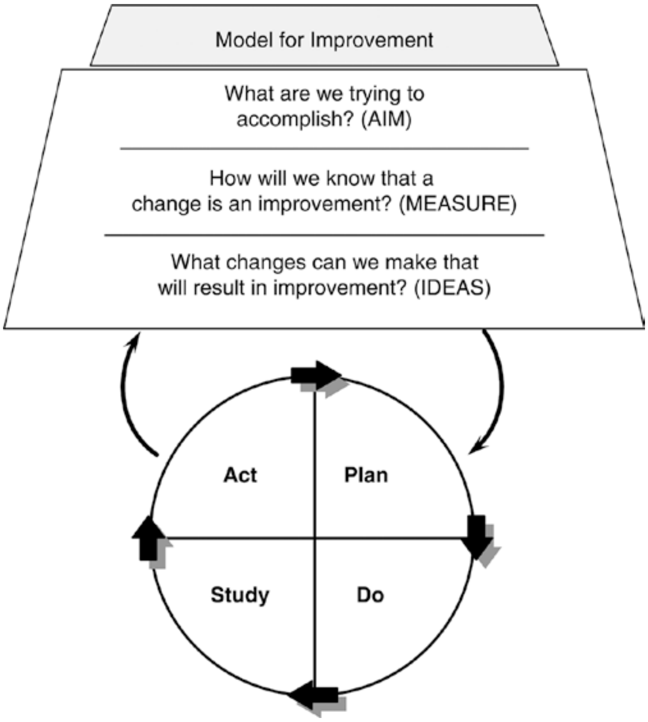
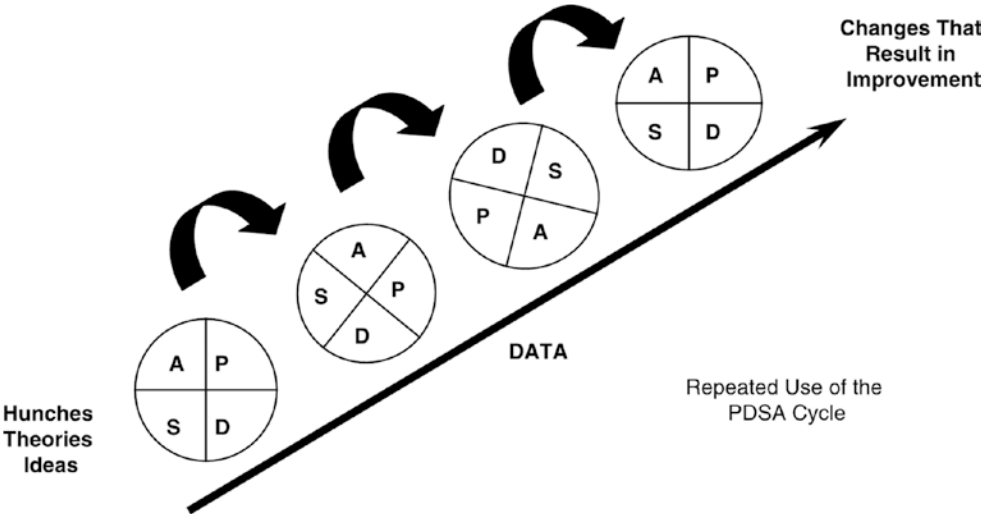


Fig. 57.3 The Improvement Model. (Adapted from Langley, Nolan, Nolan, Norman and Provost [37], page 10, by permission of Jossey Bass)

Fig. 57.4 Repeated use of the Plan-Do-Study-Act cycle. (Adapted from Langley, Nolan, Nolan, Norman and Provost [37], page 9, by permission of Jossey Bass)



Improvement Collaborative

An improvement collaborative is a sequential process in which a group of multidisciplinary teams from different practice sites work intensively together using the principals of improvement science to improve the delivery of care and the quality of life of patients [63, 64]. Improvements consist of redesigning delivery systems to ensure that patients receive recommended care and are not subject to underuse, overuse, or misuse. An improvement collaborative includes three main phases: (1) a design and development phase, in which the aim and measures for the project are developed (see Table 57.1), and changes to be tested are identified and summarized using formal methods for the design of new processes and systems; (2) an implementation phase in which practice sites work together to test and adapt changes in care delivery; and (3) a dissemination phase, where, as changes in the processes of care delivery are tested and reliably achieve desired goals, they are disseminated to other and eventually all pediatric gastroenterology practice sites. Participating sites collect data about their patients' care, share data about the outcomes of care with all of the other sites, identify sites that are performing better, examine reasons for the better performance, set benchmarks for outcomes, and share ideas to enable the other sites to improve their outcomes. Participating sites gather together for conferences to share data and ideas, and then return to their sites to perform PDSA improvement projects there, gathering and sharing new data in an incremental process (Fig. 57.5).

Table 57.1 Measurable outcomes of treatment of pediatric IBD

Disease activity
Remission rate
Interval between relapses
Complication rates (e.g., fistula)
Nutritional status
Growth, final adult height
Days missed from school
Emergency department visits
Hospitalization rate
Hospital length of stay
Surgery
Patient and family satisfaction
Patient quality of life
Adverse drug events (e.g., infusion reactions)
Therapeutic drug monitoring
Surgical complication rate
Objective biomarkers of disease activity: calprotectin, lactoferrin, hemoglobin, erythrocyte sedimentation rate, c-reactive protein, albumin
Procedural assessments: endoscopy, imaging

An IBD improvement collaborative is intended to encourage practices to adopt a more organized approach to IBD care. It is based on models of behavior change and diffusion of innovations in medical practice including involvement of opinion leaders in the medical community, recognition of a performance gap, involving physicians and staff in developing a strategy to make changes to close the gap, compatibility of the intervention with current practice, and reinforcement of positive change [65]. It is designed to identify and address barriers in the way care is delivered in IBD clinics.

This type of systems' intervention is especially important in pediatric IBD clinics because many pediatric IBD practice sites operate within large tertiary medical centers with relatively rigid infrastructures requiring significant and determined effort to change; IBD care is characterized by a complex mixture of preventive and chronic therapeutic interventions; distance and other factors make frequent return visits difficult for many patients, so accidental omission of services and other missed opportunities for care are difficult to recognize and are harder to correct; and the responsibility

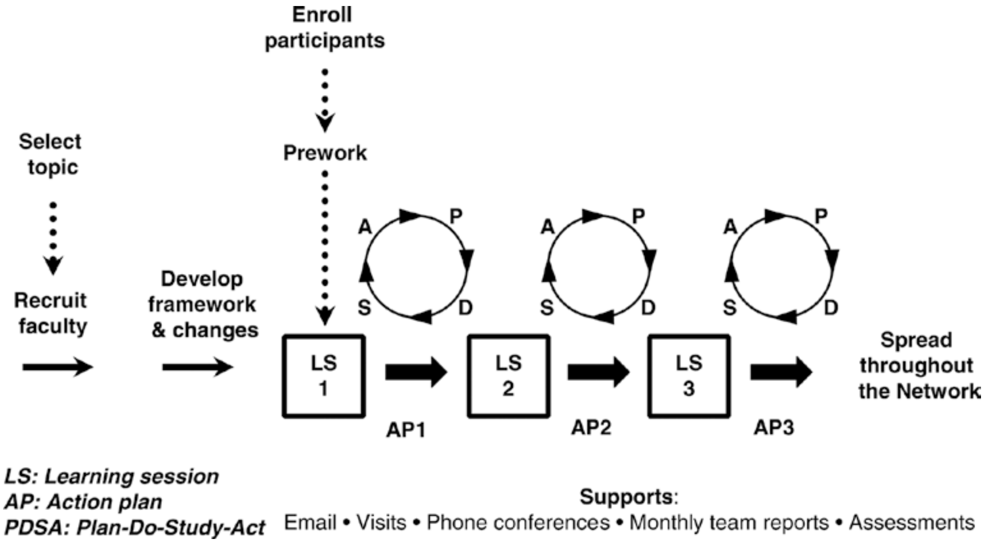


Fig. 57.5 A schematic drawing of the sequence of events in an Improvement Collaborative. (Adapted from a presentation of the Institute for Healthcare Improvement)

for care is shared by multidisciplinary teams and multiple physicians with diverse responsibilities who may overestimate the consistency with which they deliver specific services [66].

The ImproveCareNow Network

The first improvement collaborative in IBD, called ImproveCareNow, was established in early 2007; its global aim is to build a sustainable network of all pediatric gastroenterologists in the US to improve the care and outcomes of children with Crohn disease and ulcerative colitis [67]. In its first 5 years, it grew from 8 to 34 centers, with approximately 300 pediatric gastroenterologists and 10,000 pediatric IBD patients. By 2020, the ImproveCareNow Network grew to 110 centers across 38 states in the US and internationally, including England, Belgium, and Qatar, which include approximately 970 pediatric gastroenterologists and 35,000 patients (www.improvecarenow.org). The six primary drivers of the ImproveCareNow Network are (1) a prepared proactive practice team; (2) accurate diagnosis and disease classification; (3) appropriate drug selection and dosage; (4) adequate nutritional intake; (5) adequate growth monitoring; and (6) informed, activated, and engaged patients and families.

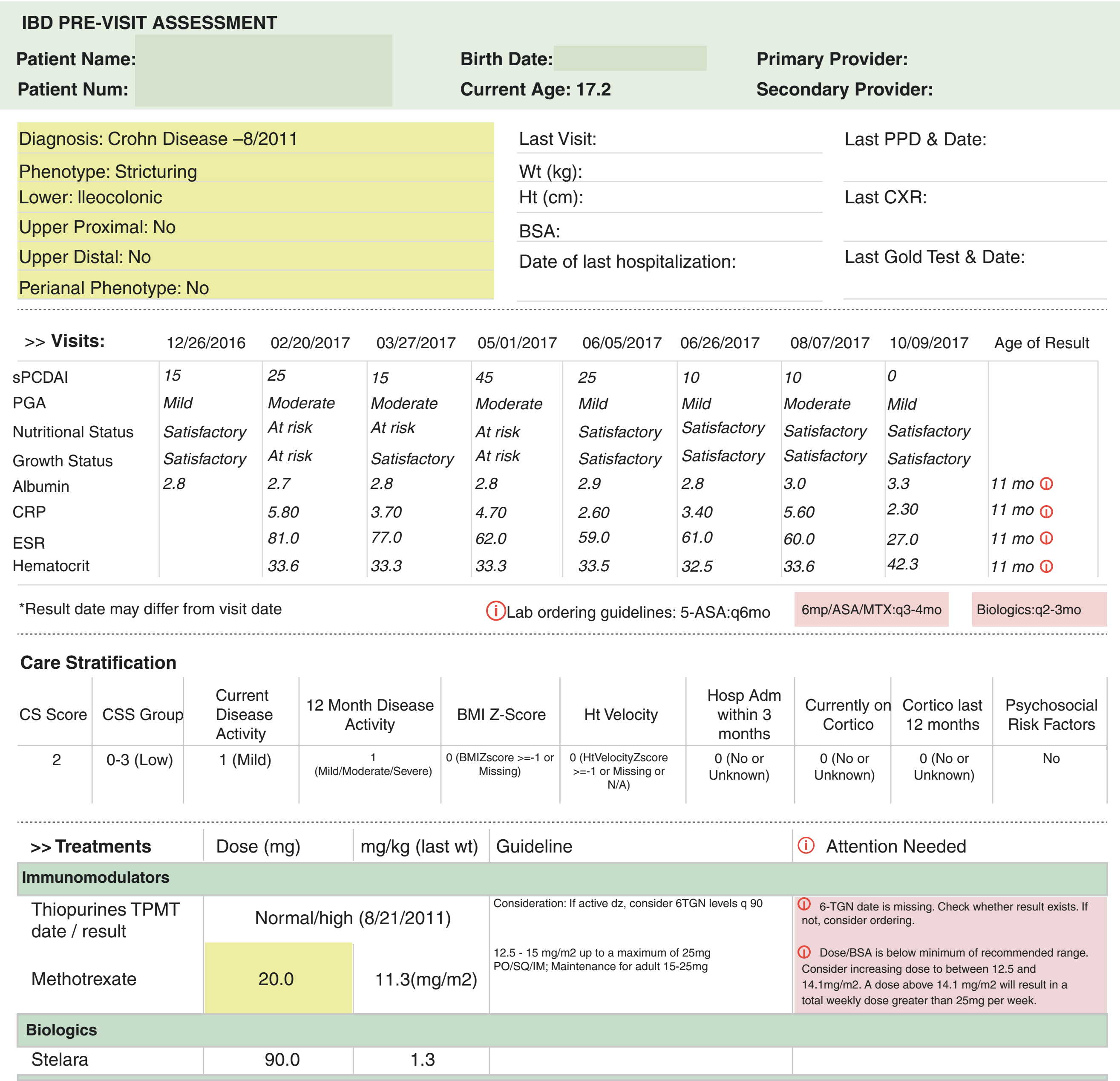
ImproveCareNow developed and implemented five major interventions: (1) enrollment and data quality; (2) consistent reliable care; (3) population management; (4) pre-visit planning; and (5) self-management support. The centers aimed to identify and enroll all of their IBD patient population, collect data from all visits using a standardized template for data elements, and provide complete and accurate data in a timely fashion. ImproveCareNow developed a Model IBD Care Guideline for Consistent Reliable Care, based on an integration of evidence and consensus, and key clinical measures, and process and outcome measures, to monitor the performance at each center and the collaborative as a whole [68]. In addition, algorithms for nutrition and growth were developed.

A population management tool was developed and used to ensure that patients were being seen regularly, and to identify patients who were not receiving model IBD care and who could benefit from for a proactive change in their management. A pre-visit planning checklist was developed and implemented at centers to review important clinical data, to identify and highlight variables that fall outside of protocol guidelines (e.g., drug dosages and results of previous laboratory tests), identify and arrange for needed resources at the time of visit (e.g., pre-ordering laboratory tests; scheduling a dietician), and assist the clinician in preparing an agenda of important issues requiring attention at the visit. In 2011, a systematic program was undertaken to develop tools for patient and family self-management support, including providing patient education, eliciting patient and family priorities for visits, confirming patient understanding of new information, setting and monitoring patient goals collaboratively, and improving adherence.

One of the primary strengths of the ImproveCareNow network is a focus on learning from data. Each participating center receives monthly reports with tables and longitudinal graphs of their performance on the key clinical and data quality measures, and a twice-monthly population management reports. These electronic reports provide both aggregate and individual patient- and visit-level data that can be used to monitor populations of patients and identify subgroups of patients in need of attention or intervention. The reports are used to identify sub-populations of patients with medical issues in need of attention, for example, patients who are on systemic steroids or patients with suboptimal nutritional status. They also are used to identify patients who have outgrown the doses of their medications. The reports can also facilitate failure mode and affect analyses to study problems and gain insights to inform improvement efforts. The reports also include run charts and control charts to help identify special-cause variation when a significant change from baseline has occurred. Centers also have the ability to compare their performance to that of other centers and of the entire network [69].

The data that inform these reports are collected from each patient at each outpatient visit. ImproveCareNow has developed processes by which automated data transfer can be done from electronic medical record systems to populate the data registry. This has reduced the burden of data collection and errors associated with duplicate data entry for many of the participating network sites. For sites without the capability of electronic data transfer, manual data entry is performed. There are numerous quality checks to minimize errors in manual data entry. Data collection includes all the data necessary for calculating the short pediatric Crohn disease activity index (sPCDAI) and the pediatric ulcerative colitis activity index (PUCAI) [70–72].

The ImproveCareNow Network has implemented a process for generating automated pre-visit planning forms that can be automatically generated on demand for each patient (Fig. 57.6). These forms are one-page summary sheets that are pre-populated with patient-specific historical data pulled from the registry. These forms served to streamline the pre-visit planning process for each practice. The automation was part of a larger emphasis on improving the digital architecture of the ImproveCareNow network registry [69].



IBD PRE-VISIT ASSESSMENT

Patient Name:	**Birth Date:**	**Primary Provider:**
Patient Num:	**Current Age: 17.2**	**Secondary Provider:**

Diagnosis: Crohn Disease –8/2011	Last Visit:	Last PPD & Date:
Phenotype: Stricturing	Wt (kg):	
Lower: Ileocolonic	Ht (cm):	Last CXR:
Upper Proximal: No	BSA:	
Upper Distal: No	Date of last hospitalization:	Last Gold Test & Date:
Perianal Phenotype: No		

>> **Visits:**	12/26/2016	02/20/2017	03/27/2017	05/01/2017	06/05/2017	06/26/2017	08/07/2017	10/09/2017	Age of Result
sPCDAI	*15*	*25*	*15*	*45*	*25*	*10*	*10*	*0*	
PGA	*Mild*	*Moderate*	*Moderate*	*Moderate*	*Mild*	*Mild*	*Moderate*	*Mild*	
Nutritional Status	*Satisfactory*	*At risk*	*At risk*	*At risk*	*Satisfactory*	*Satisfactory*	*Satisfactory*	*Satisfactory*	
Growth Status	*Satisfactory*	*At risk*	*Satisfactory*	*At risk*	*Satisfactory*	*Satisfactory*	*Satisfactory*	*Satisfactory*	
Albumin	*2.8*	*2.7*	*2.8*	*2.8*	*2.9*	*2.8*	*3.0*	*3.3*	*11 mo* ⓘ
CRP		*5.80*	*3.70*	*4.70*	*2.60*	*3.40*	*5.60*	*2.30*	*11 mo* ⓘ
ESR		*81.0*	*77.0*	*62.0*	*59.0*	*61.0*	*60.0*	*27.0*	*11 mo* ⓘ
Hematocrit		*33.6*	*33.3*	*33.3*	*33.5*	*32.5*	*33.6*	*42.3*	*11 mo* ⓘ

*Result date may differ from visit date

ⓘLab ordering guidelines: 5-ASA:q6mo 6mp/ASA/MTX:q3-4mo Biologics:q2-3mo

Care Stratification

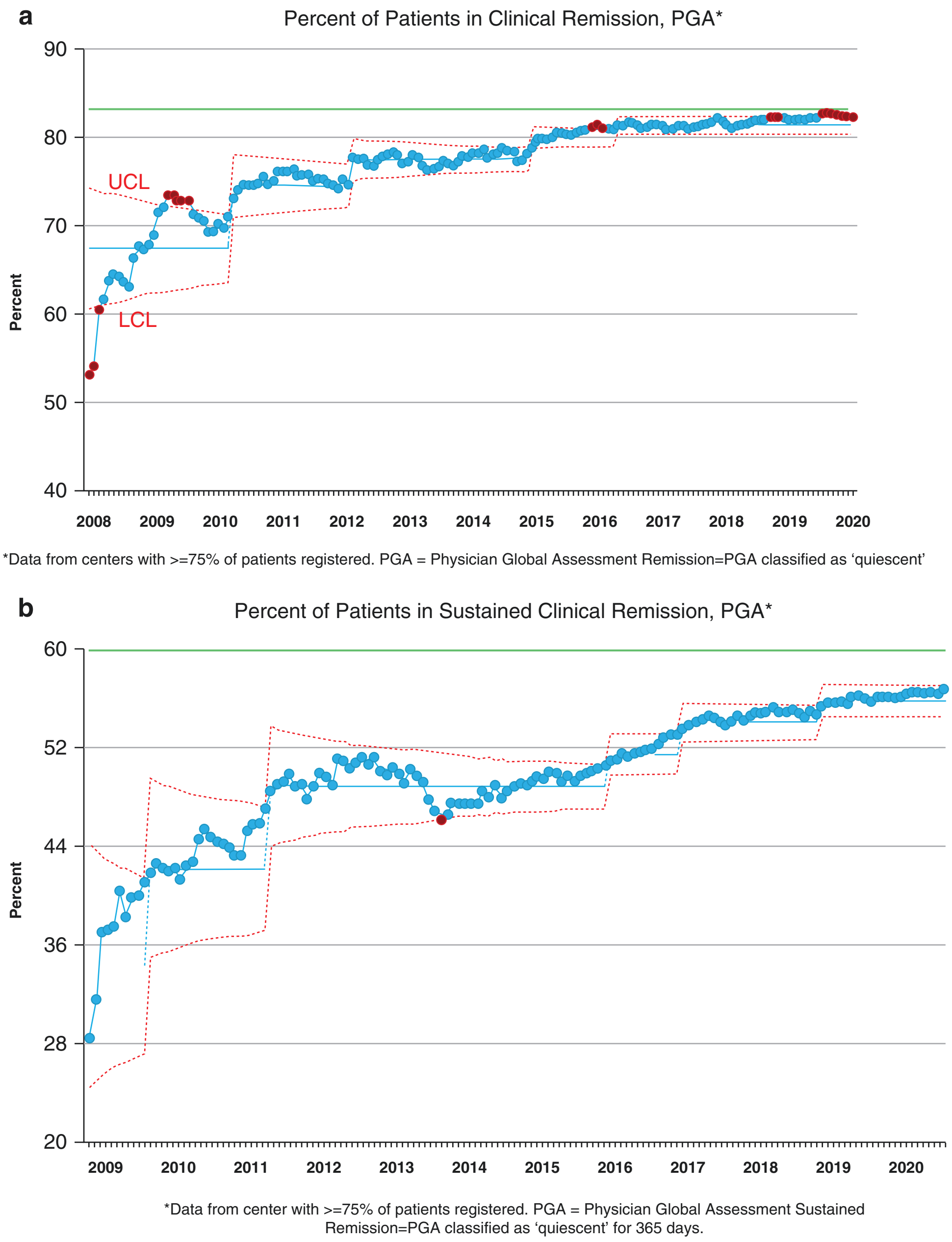
CS Score	CSS Group	Current Disease Activity	12 Month Disease Activity	BMI Z-Score	Ht Velocity	Hosp Adm within 3 months	Currently on Cortico	Cortico last 12 months	Psychosocial Risk Factors
2	0-3 (Low)	1 (Mild)	1 (Mild/Moderate/Severe)	0 (BMIZscore >=-1 or Missing)	0 (HtVelocityZscore >=-1 or Missing or N/A)	0 (No or Unknown)	0 (No or Unknown)	0 (No or Unknown)	No

>> **Treatments**	Dose (mg)	mg/kg (last wt)	Guideline	ⓘ Attention Needed
Immunomodulators				
Thiopurines TPMT date / result	Normal/high (8/21/2011)		Consideration: If active dz, consider 6TGN levels q 90	ⓘ 6-TGN date is missing. Check whether result exists. If not, consider ordering.
Methotrexate	20.0	11.3(mg/m2)	12.5 - 15 mg/m2 up to a maximum of 25mg PO/SQ/IM; Maintenance for adult 15-25mg	ⓘ Dose/BSA is below minimum of recommended range. Consider increasing dose to between 12.5 and 14.1mg/m2. A dose above 14.1 mg/m2 will result in a total weekly dose greater than 25mg per week.
Biologics				
Stelara	90.0	1.3		

Fig. 57.6 Automated pre-visit planning form for one patient pre-populated with data drawn from the ImproveCareNow registry specific to the individual patient. The form includes summary information about the patient's disease phenotype as well as longitudinal data from the last several visits including weight, height, and laboratory information

The first ImproveCareNow report of outcomes was based on a 3-year follow-up of 6 of the initial centers with 1188 patients [73]. Changes in care delivery were associated with an increase in the proportion of visits with complete disease classification, measurement of thiopurine methyltransferase (TPMT) prior to initiation of thiopurines, and patients receiving an initial thiopurine dose appropriate to their TPMT status. There were significant increases in the proportion of Crohn disease (55–68%) and ulcerative colitis (61–72%) patients with quiescent disease (between 2007 and 2015). There was also a significant increase in the proportion of Crohn disease patients not taking prednisone (86–90%). These findings suggest that improvements in the outcomes of patients with Crohn disease and ulcerative colitis were associated with improvements in the process of chronic illness care. Variation in the success of implementing changes suggests the importance of overcoming organizational factors related to quality improvement success. As ImproveCareNow grew and sustained its improvements, the Network was recognized as an exemplar of pediatric collaborative improvement networks [74]. After 7 years, the ImproveCareNow Network outcomes had improved further and the clinical remission rate for children with IBD increased to 77% [75, 76], and by 2020, it was 82% (www.improvecarenow.org, Fig. 57.7a, sustained remission noted in Fig. 57.7b). To further improve outcomes, ImproveCareNow is creating a learning health network in which patients and parents play an integral role in participation and governance of the network and work together with network clinicians and researchers [63].

The adult IBD community has also developed a quality improvement collaborative through the Crohn's and Colitis Foundation, IBD Qorus™, which includes over 50 sites. In 2020, they embarked on a new initiative called Treat to Target to encourage more frequent monitoring to ensure treatment strategies that align a remission-based therapeutic goal with the patient's personal goals regarding quality of life. Thus far, two care pathways have been developed to aid in the recognition and treatment of anemia and nutrition.



*Data from centers with >=75% of patients registered. PGA = Physician Global Assessment Remission=PGA classified as 'quiescent'

*Data from center with >=75% of patients registered. PGA = Physician Global Assessment Sustained Remission=PGA classified as 'quiescent' for 365 days.

Fig. 57.7 (**a**) Improvement in remission rate, based on Physician Global Assessment, of a cohort of patients with Crohn disease in the ImproveCareNow Network from 2008 to 2020. Monthly results for all centers combined are presented as a control chart (Shewhart chart). The center line represents the mean proportion; the dashed upper and lower control limits (UCL and LCL, respectively) reflect the inherent variation in the data and were calculated as ±3 standard deviations of the centerline proportion. The shift in center line indicates a special-cause variation in remission rate. (**b**) Improvement in sustained remission rate from 2009 to 2020

Learning Health Network

A Learning Health Network, as originally conceived by the Institute of Medicine (now the National Academy of Sciences) is a community of clinicians, researchers, other professionals, and patients and families; working together with a focus on improving outcomes; using safe, effective evidence-based care; and providing better care at lower cost [77]. In a Learning Health Network, research is a natural outgrowth of clinical care; new knowledge is generated easier, faster, better, and cheaper. Innovative technology may also be employed so data are available in real time and can be used for clinical, research, and improvement purposes. The key drivers of a successful learning health network—an enhanced registry, improvement science, a robust research infrastructure, and a community of engaged stakeholders—are exemplified by the ImproveCareNow Network [74]. Data obtained at the time of a clinical encounter are analyzed by the enhanced registry and presented for clinical use as pre-visit planning and population management reports [69]. An enhanced registry can also generate a quality performance report that identifies gaps in care, enabling the center improvement teams to identify and focus on specific aspects of its care delivery system applying improvement science methods to improve processes and outcomes. Education and training of each center's improvement team in improvement science are essential to achieve improved care and outcomes. The repository of data is also a gold mine for research enabling retrospective and prospective observational cohort studies of natural history, real-world evidence of clinical care and outcomes, and pragmatic clinical trials. A Learning Health Network can also facilitate the development of new drugs by studies of real-world and long-term effectiveness of drugs; optimizing medication use by clinicians and patients; engaging clinicians and patients to prioritize and design studies; data queries to identify potentially eligible research subjects to facilitate study design and recruitment; conducting prospective drug efficacy studies; and conducting post-market surveillance to monitor for serious adverse events. A registry that is 21 Code of Federal Regulations (CFR) Part 11 compliant and produces Study Data Tabulation Model (SDTM) and Analysis Data Model (AdAM) reports can further contribute to drug development by meeting standards of regulatory agencies. The National Academy of Sciences suggests extensive participation of patients and families in leadership, governance, education, communication, and other operations, which is necessary to optimize the success of a learning health network [78]. A Learning Health Network also provides opportunities for academic and professional advancement, leadership, and career development by enabling research, networking, building collaborations, and providing opportunities for committee involvement and leadership.

Leveraging the power of learning health systems and networks provides opportunities for higher level and more complex interventions to be tested and implemented. For example, the ImproveCareNow Network has developed a series of Learning Labs (i.e., a group of sites focusing on a specific topic or goal such as population management, pre-visit planning, clinical standardization/personalized care, COVID-19 response, and transition to adult care). The movement of clinical practice toward a treat-to-target approach has prompted a Learning Lab (consisting of over 25 centers) to address therapeutic drug monitoring via a care pathway. As part of the design process, a workgroup of clinicians, researchers, patients, and parents reviewed published literature and performed an environmental scan of current practice. This information was then used to develop and implement interventions and measures to address the clinical standardization of therapeutic drug monitoring for anti-TNF alpha therapies, a project still in process.

Maintaining Improvement

In any quality improvement effort, once an improvement is achieved, it must be maintained. Different challenges exist for sustaining an improvement. These range from challenges maintaining consistent error-free data collection, and reminding clinicians to continue reviewing data regularly to updating treatment protocols to remain consistent with the evolving literature. New clinicians require onboarding, and as patients transition from pediatric to adult care, new patient representatives need to be recruited.

Ongoing data monitoring enables centers to detect deterioration in processes or detrimental changes in outcomes. Such data can then allow data analyses to facilitate identifying areas or processes in need of modification in order to return to the prior level of improvement. An example of maintaining improvement includes ensuring that once a center's remission rate improves, they are able to maintain that high level of remission. Some challenges to maintaining a high remission rate include staffing changes; changes in treatment paradigms; availability of new medications; insurance or policy restrictions on access to medications; and the occurrence of pandemics or natural disasters.

Maintaining an updated registry with ongoing monitoring can allow a center to become aware if there is a change in either process measures such as timely data entry, or outcomes such as hospitalization rates or remission rates. Regular population management meetings with review of center-level registry data help the clinicians and staff to detect changes in data. If a particular measurement, such as proportion of patients with adequate nutrition status, has a stable pattern over time, called *common-cause variation*, then if there is a deviation from that rate, it is identified as *special-cause variation*. Detecting special-cause variation provides an opportunity for the team to investigate the circumstances and identify potential reasons for the change.

In order to maintain improvement efforts in clinical practice, such monitoring of data must become an integral part of clinical care. Embedding processes of monitoring data into routine care enables clinicians to keep track of their population of patients and proactively address issues in care as they arise.

Improvement Science in the Business of Health Care

Improvement science and methods can play an important role in the leadership, business, and finances of healthcare systems. QI skills are in effect a problem-solving mindset. Health system leaders value system thinkers who are in a continuous improvement mode to facilitate efficiencies across the system. This mindset allows segmentation of complex clinical and operational issues into aims that can be achieved by application of the model for improvement. The approach of system leaders who use improvement science as a business strategy includes (a) purpose driving the mission and vision of organizations; (b) viewing the organization as a system; (c) a process or system of obtaining information to improve; (d) planning based on the data obtained and integrated with business strategy; (e) managing individual and team improvement activities by carrying out PDSA cycles to implement improvement; and (f) incorporating the perspectives of key stakeholders, such as customers and employees, as well as managers of operational and business units [62].

Improvement science and methods can be leveraged across the health system in both clinical and non-clinical domains. In addition to the clinically focused activities described above, examples in the non-clinical setting include the patient experience, business operations, and system-wide dashboards of key measures of system success.

The Triple Aim of Health Care was conceptualized in 2008 by the Institute for Healthcare Improvement as the simultaneous pursuit of three aims: improving the experience of care, improving the health of populations, and reducing per capita costs of health care [79]. Value in healthcare is quality per unit of cost; higher quality (better outcomes and patient experiences) and lower cost mean higher value. Improvement science methods can be applied to both improving outcomes and reducing unnecessary resource utilization in system and microsystem operations and workflow, as well as in management of population health strategies and complex diseases. Current fee-for-service and volume-based reimbursement models for clinical care delivery lead to excess cost from services that are not necessary. The emerging models of value-based care focus on disease prevention, care coordination, and case management as well as paying providers for improved outcomes and patient experiences within a defined population. The concept of an IBD Medical Home, as championed by Regueiro et al., has shown significant reduction in Emergency Department utilization, as well as increased adherence and improved quality of care [80–83].

Conclusion

While the fundamental purpose of research is to gain knowledge, the goal of quality improvement is to improve care and outcomes. Ultimately knowledge gained through research can be applied to clinical care, and quality improvement can advance care through complementary methods, so both research and quality improvement are necessary to improve outcomes [84, 85]. The road map of translational research begins with basic biomedical science and advances to clinical efficacy knowledge, to clinical effectiveness knowledge and finally to improved healthcare quality and value [86]. Measurement and accountability of healthcare quality and cost, implementation of interventions and healthcare system redesign, and scaling and spread of effective interventions are necessary to transform the healthcare system.

There has been a growing interest in quality of care, particularly in the era of health care reform and its emphasis on performance, accountability, and value in health care [87]. Multiple stakeholders have emerged with strong interests in defining what quality is, how it should be measured, and how the results should be used. These include patients and patient advocacy groups; providers and their professional societies; Medicare, Medicaid, and commercial payers; foundations; certifying boards and credentialing bodies; not-for-profit organizations, notably the National Quality Forum, as well as the National Committee for Quality Assurance; and business consortia such as The Leapfrog Group, an organization which fosters public reporting of healthcare quality and outcomes (hospital quality ratings). The Patient Protection and Affordable Care Act emphasizes quality measurement and requires Medicare to develop mechanisms for Accountable Care Organizations, a delivery model that rewards groups of providers with payments if they can contain costs, improve quality, and assume financial risk for their outcomes. In summary, issues related to quality of care have permeated all areas of healthcare delivery, including training, credentialing, clinical care, access to care, outcomes, documentation, cost, and reimbursement [88]. As the quality landscape continues to change, so too will its impact on the practicing clinician [89].

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