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Population Health Management for Inflammatory Bowel Disease

Parambir S. Dulai[1]*, Siddharth Singh[1,2]*, Lucilla Ohno-Machado[2], William J. Sandborn[1]

[1]Division of Gastroenterology, University of California at San Diego; [2]Health System Department of Biomedical Informatics, University of California at San Diego

*Contributed equally as first authors

Corresponding Author:
Parambir S. Dulai, MD
University of California at San Diego
Division of Gastroenterology
9500 Gilman Dr.
La Jolla, CA 92093

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ABSTRACT

Inflammatory bowel diseases (IBD) are chronic and impose significant, multi-dimensional burdens on patients and healthcare systems. The increasing prevalence of IBD will only worsen this problem globally—population health management (PHM) strategies are needed to increase quality of care and population health outcomes while reducing healthcare costs. We discuss the key components of PHM in IBD. Effective implementation of PHM strategies requires accurate identification of at-risk patients and of key areas of variability in care. Improving outcomes of the at-risk population requires implementation of a multi-component chronic care model designed to shift delivery of ambulatory care from acute, episodic, and reactive encounters, to proactive, planned, long-term care. This is achieved through team care of an activated patient with the help of remote monitoring, clinical information systems and integrated decision support, with accompanying changes in delivery systems. Performance measurement is integral to any PHM strategy. This involves developing and implementing meaningful metrics of different phases of quality of IBD care and measuring them efficiently using modern clinical information systems. Such an integrated framework of PHM in IBD will facilitate the delivery of high-value care to patients.

Crohn's disease (CD) and ulcerative colitis (UC) are inflammatory bowel diseases (IBD) characterized by chronic relapsing and remitting courses requiring ongoing adjustments in therapy and constant interactions with the healthcare system. The prevalence of IBD is estimated to be over 3 million persons in the US and Europe, and the incidence of IBD is increasing worldwide among developed and developing countries.[1] IBD ranks as one of the top 5 most expensive GI conditions, with direct costs estimated to exceed $6 billion dollars per year in the US alone.[2, 3] IBD patients also have significant indirect costs through social and psychological impacts from their chronic disease state, which negatively affect their overall quality of life, and create substantial burdens to caregivers and communities.[4]

Similar to most chronic diseases, 25%–30% of IBD patients account for over 80% of total IBD healthcare burden,[5-7] and psycho-socioeconomic, disease, and treatment determinants of health are the primary drivers for variability in care, expenditure, and outcomes.[3] An important and emerging concept within the field of IBD is population health management (PHM) – coordination of care at a macro level to improve outcomes and effectively manage clinical and financial risks for a defined group of individuals.[8] Although conceptually important, the operationalization of PHM for IBD will require a multi-step process across various healthcare platform domains. In this review we discuss the key components to a successful PHM strategy for IBD.

POPULATION HEALTH MANAGEMENT

The core principles of PHM are to shift from volume to value by improving the quality of care delivered, improving population health outcomes, and reducing healthcare costs (a triple aim).[8, 9] This triple aim can be broken down into actionable components (adapted from National Quality Strategy for Improvement in Health Care)[10]:

1. Make care safer by reducing harm caused in the delivery of care
2. Ensure providers, patients, families, and communities are engaged as partners
3. Promote effective communication and coordination of care
4. Promote the most effective, risk-stratified, prevention and treatment practices

To achieve these aims, healthcare systems will need to first identify high-risk populations, drivers of cost, and variability in care within their specific populations (**Figure 1**).

IDENTIFYING HIGH RISK POPULATIONS, VARIATIONS IN CARE, AND FACTORS THAT AFFECT COST

The most important component of an effective PHM strategy is the application of an operational improvement methodology, such as Lean Six Sigma, which includes collaborative efforts to reduce error, remove waste, and improve performance, by ensuring consistent delivery of desired results, with a focus on patient experience. The first step in this process is to define the population, deficits and care, and drivers of cost.

Patients with IBD can be categorized as well patients who require minimal health care interactions, so the focus should be on maintaining their health (primary prevention); patients at risk for complications in the immediate or near future, so the focus should be expedited management to avoid progression or recurrence (secondary prevention), and patients who already have disease-related complications. Patients can transition between the 1st and 2nd health states, but disease-related complications are a terminal health state and the focus is to decrease the impact of ongoing illness, prevent recurrence of complications, and improve their ability to function and maintain quality of life (tertiary prevention). Health systems should consider objectives for each health state, focus on identifying triggers for transitions between health states, and optimizing the care of patients at risk for developing complications to reduce the population level impact of IBD.

Patients at risk can be identified through an evaluation of known principal determinants, drivers, and predictors of IBD health and healthcare expenditure (**Figure 2**).[10-29] The greatest degree of variability in care for these patients occurs in: diagnosis and management of acute disease flares (delay in initial IBD diagnosis or diagnosis of an acute disease flare due to lack of access or lack of guideline-congruent care), prevention of complications (inappropriate use of ineffective therapy without adequate risk stratification and prognostication through prediction modeling, delay in use of effective therapy resulting in loss of window of opportunity, fragmentation of healthcare resulting in inadequate communication, interruption of therapy), and minimization of treatment-related risks (inadequate understanding of differential risks with therapies promoting inappropriate use). These determinants could serve as triggers for PHM systems to identify subpopulations and healthcare interactions at greatest need for optimized coordinated care.

CHRONIC CARE MODELS (CCMs) TO IMPROVE CONSISTENCY OF DELIVERY

Once identified, at-risk populations would benefit from multi-component CCMs designed to shift from acute, episodic, and reactive encounters, to proactive, planned, and individualized long-term care. The goals of a CCM are to meet the needs of patients and providers, while

enhancing the ability to co-produce high quality evidence-based care.[30, 31] These goals can be achieved through the 6 related components of a CCM (see **Table 1)**. CCMs have been shown to improve the overall quality of care delivered in other chronic health conditions (i.e. diabetes, congestive heart failure, asthma, and chronic obstructive pulmonary diseases) by improving patient satisfaction and function, adherence to guideline recommended care, and most importantly, clinical outcomes through reductions in unplanned healthcare utilization, hospitalizations, disease related complications, and mortality.[32] Below are examples of IBD-focused PHM strategies that are active:

1. **IBD Specialty Medical Home**: Some large centers, particularly where the health market is dominated by a single payor, have developed IBD specialty medical homes in which the gastroenterologist assumes the principal role in care to safeguard against unnecessary medications and testing, unplanned emergency department visits, and hospitalizations. The medical home is composed of group medical visits with behavioral health experts, social workers, nurse practitioners, and dietitians, and are conducted under one roof during a single office visit, with close follow up through telemedicine and use of community resources. This IBD medical home is being tested for a subset of high need, high cost patients within the University of Pittsburgh Medical Center healthcare plan and provides the framework for other healthcare organizations to adopt the patient centered medical home model for IBD.[33] The University of California at Los Angeles has similarly introduced a comprehensive, integrated approach to value-based care in IBD with the development of a value quotient (patient value divided by provider costs). Through a tightly controlled and coordinated multi-disciplinary team with robust IT infrastructure, use of remote monitoring (of disease control and quality of life), and patient self management through mobile health tools, this model has demonstrated decreased healthcare utilization, fewer surgeries, decreased chronic steroid use, and reduced costs.[34, 35] Project Sonar, a community practice based IBD specialty home, is a joint venture between Illinois Gastroenterology Group and Blue Cross Blue Shield Illinois. The cloud-based program developed by SonarMD integrates monthly patient reported symptoms and quality of life information with clinical data in an electronic medical record to provide comprehensive, real-time information to physicians and patients on health status. Additionally, it provides point of care clinical decision support to physicians through access to the American Gastroenterology Association (AGA) CD and UC care pathways,[30, 31] and integrates patient information with objective information to create a Sonar score, which predicts risk of disease relapse and facilitates proactive patient engagement. In a preliminary study of 152 patients with CD, Kosinski et al observed over a 50% decline in

hospitalization and emergency department visits, and 11% decline in healthcare costs, over a 10-month period (as compared to the period immediately preceding implementation of this platform).[36] This specialty-based intensive medical home also provides insight into cost normalization,[36] and the ability to implement a shared savings model which is central to the development of IBD specific Accountable Care Organizations.[9, 37]

2. **Collaborative Learning Health Systems**: Although IBD specialty homes have demonstrated value with cost reduction and improvement in outcomes, particularly for a subset of high-need, high-cost patients, these are difficulty to implement at a national and international level, given the intensive resources needed. For most patients with IBD, who are not high consumers, alternative more readily accessible strategies of PHM may be helpful. Learning health systems represent a cyclic framework which harnesses the collective experiences of patients and uses their aggregated data to generate new evidence to inform future shared decision making for a given population. IBD Qorus is a learning health system collaborative through the Crohn's and Colitis Foundation which focuses on studying the impact of a coproduction model (in which both patients and providers contribute data) on patient outcomes across 30 academic and community gastroenterology practices caring for approximately 20,000 adults with IBD.[38] Co-production models offer distinct advantages over IBD specialty homes, particularly in resource-limited countries, as the level of engagement and infrastructure can be tailored to local needs and resource availability. The visualization of at-risk patients and physician or system-level performance metrics can be personalized based on drivers of cost to that specific region or country or local guideline recommendations and availability of alternative therapies (i.e. biosimilars). IBD Qorus provides a framework for this model in adults, but a similar IBD-focused pediatric learning health system, ImproveCareNow, has been shown to increase patient engagement and follow up and improve outcomes.[39-42]
3. **Remote Monitoring and Telehealth:** With improvements in technology, there has been a resurgence of telehealth, which has advanced from simply increasing access for patients with acute conditions to providing convenience and services for patients with chronic and episodic conditions.[43] In a recent pragmatic randomized trial in the Netherlands, de Jong et al compared a telemangement system, MyIBDCoach, to standard of care. MyIBDCoach involves telemonitoring through a web-based platform, with patient-tailored information, a personal care plan, and accessibility to an IBD nurse. During this 12 month trial enrolling over 900 patients, the authors demonstrated a reduction in outpatient and inpatient healthcare use, and improved patient-reported quality of care, with the MyIBDCoach.[44] In

another randomized trial of 333 patients with mild–moderate ulcerative colitis treated with mesalamine in Denmark and Ireland, Elkjaer et al observed that tight disease monitoring, intensive patient education and personalized treatment strategies delivered through a web-based platform, Constant-Care, resulted in an improvement of patient empowerment, quality of life, and medication adherence, and a reduction in outpatient visits and relapse duration compared with usual care.[45]

These examples provide a framework for opportunities to implement CCMs. The most effective delivery of healthcare will likely be through a combination of CCM features that target areas of greatest variability or needs specific to each healthcare system and population. This is of particular importance on the international level where significant variations exist in healthcare system models, payors, and costs.

MEASURING PERFORMANCE AND REDEFINING METRICS

Important components of an effective PHM strategy are performance measurement, tracking, and analysis. To assist providers in delivering high-quality, high-value care, the Institute of Medicine developed quality measures and metrics that can be used for reimbursement decisions in IBD (Physician Quality Reporting System). Although these indicators are important, and should be addressed by all PHM strategies, they do not capture or provide recommendations to achieve uniformity or consistency with healthcare delivery or treatment outcomes. To further expand on these measures, the AGA and the Crohn's and Colitis Foundation have developed IBD-specific quality indicators that address various facets of IBD care, from disease activity assessment (documenting disease type, location, and activity), to primary (smoking cessation, vaccinations, infection screening, cancer surveillance), secondary (venous thromboembolism prophylaxis, minimization of corticosteroid use, immunosuppressive use, bone loss screening), and tertiary (timing of surgical referral, quality of life and disability assessment) preventive measures.[25] As defined, these measures risk spending considerable effort focusing on what is measurable, rather than measuring what makes a difference in outcomes. Remaining limitations include an absence of more objective performance metrics that are known to affect treatment and disease outcomes, and our inability to accurate capture and share performance metrics among populations.

Potentially important measures that are not being adequately captured include:

1. **Assessing disease activity and achieving mucosal healing:** AGA and Crohn's and Colitis Foundation IBD quality measures include metrics on the assessment of clinical

disease activity and severity, and on the proportion of patients who have achieved steroid-free clinical remission for >12 months. These metrics carry inherent limitations because they do not provide ongoing information to providers to help improve the probability of achieving key endpoints known to improve IBD health outcomes.[46, 47] Mucosal healing is an important treatment target given the association between achieving mucosal healing and reducing the risk of disease related complications (hospitalization, cancer, surgery). Treatment strategies have now shifted towards achieving mucosal healing through treat to target algorithms.[47-49] A retrospective review associated frequent assessment of endoscopic disease activity (within 26 weeks of treatment initiation or adjustment) with increased probability of achieving mucosal healing (odds ratio, 2.35).[50] A cluster-randomized trial (Enhanced Algorithm for Crohn's Treatment Incorporating Early Combination Therapy, REACT2) is nearing completion; it will definitively evaluate the importance of this endpoint and the effects of frequent endoscopic assessments on long-term outcomes (hospitalization, surgery, disease related complications).[47]

2. **Achieving target biologic drug concentrations**: Another potentially important metric that is not being captured is the frequency with which providers assess drug concentrations and adjust therapy. Drug clearance varies among individuals, based on clinical and pharmacokinetic factors, and there is a clear association between serum concentrations of tumor necrosis alpha antagonists and outcomes of patients with IBD (remission, mucosal healing, colectomy).[51] With biologic therapy accounting for a significant proportion of IBD-related healthcare costs, drug optimization is an important treatment goal. A randomized trial demonstrated that trough concentration-based guidance of dose resulted in more efficient use of the biologic, with a nearly 30% reduction in cost for a subset of patients with high drug concentrations.[52]

Analogous to the quality metrics of simply measuring microalbuminuria or hemoglobin A1c for diabetes, PHM systems can consider that if these assessments occur in IBD (i.e. checking for mucosal disease activity through endoscopy or biomarkers, and measuring drug concentrations), then providers will adjust therapies until endpoints or therapeutic targets are achieved (i.e. mucosal healing or biomarker normalization, target drug concentrations).[48] These are two potential metrics for consideration in PHM, and evidence-based metrics with prospective studies supporting their value will need to be identified.

An important limitation to tracking any performance measure is the ability to accurately validate and share data. Of the 21 measures included in the AGA and the Crohn's and Colitis Foundation recommendations, 11 could not be assessed using claims-based data and 10 were at risk for misclassification due to coding error.[25] This finding indicates the importance of Health IT platforms and the application of novel techniques to implement and measure PHM strategies. Natural language processing (NLP)[53, 54] has been used successfully to develop clinical decision support tools for colonoscopy surveillance intervals and monitoring of provider performance (i.e. adenoma detection rate),[55-60] as well as to identify patients with cirrhosis who would benefit from preventive services (i.e. hepatocellular carcinoma screening).[61] Although early work in IBD involved the use NLP for patient identification,[62] phenotype classification,[63] and for differentiating surveillance from non-surveillance colonoscopies,[64] the application of NLP for performance measurement and tracking is still in its infancy. Furthermore, there are still concerns and barriers related to the tradeoffs between individual and institutional privacy and the societal benefits of sharing clinical data, and to the practical challenges of harmonizing data across several institutions to build predictive models and decision support systems.[65-70]

Strategies for Resource-limited Settings

With increasing global incidence and prevalence of IBD, particularly in newly industrialized nations, the burden of IBD will continually rise. As our knowledge on the epidemiology and natural history of IBD in these countries builds, resource-adaptive and culturally sensitive PHM strategies would be warranted. With limited access to specialists, let alone IBD specialists in these regions, provider education through development of regional clinical guidelines and clinical decision support tools, development of timely referral and access mechanisms through integrated care, remote monitoring strategies, as well as development of patient self-management and well-informed widespread community resources, would be important. The use of expensive biologic medications may be cost prohibitive, and engaging national governments to inform optimal health policies would be critical. At the same time, a careful and systematic assessment of risks–benefit and cost effectiveness of interventions, such as treat to target, etc. would be warranted. For example, although intensive and repeated endoscopic monitoring for CD may not be feasible, use of stool-based biomarkers may be a reasonable alternative.

FUTURE DIRECTIONS

Significant progress has been made in improving the quality of care delivered to IBD patients, but gaps remain. Beside systematic and accurate risk stratification strategies, or implementation

of innovative care delivery models and ongoing monitoring of key quality metrics, factors that merit prospective evaluation in promoting PHM include integration of IT and clinical information systems with omics' and precision medicine to build tools that identify and predict provider trends in healthcare delivery and treatment. It will also be important to evaluate trends in healthcare use and adherence, determine risk of disease progression for individual patients, and predict response to therapy. These factors could help patients avoid ineffective therapies, which increase the likelihood of poor outcomes (i.e. surgery),[71-73] identify patients most likely to benefit from highly effective therapeutic interventions early in the disease course,[74-77] and created personalized decision support tools for patients at risk for high healthcare utilization and providers at risk for variability in care.[78]

We have outlined the essential components of an effective PHM strategy and actionable items for healthcare systems to consider when implementing these strategies for IBD patients. Consideration will need to be given on the individualization of PHM strategy aspects to local needs and resources, and the integration of information technology platforms.

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Element of CCM	Examples and Potential Impact	IBD Qorus	Project Sonar	IBD Medical Home
Self-Management Support (empower patients to manage their health)	• Counselling for self-management, including written treatment plans, tailored education, skills training • Mobile health applications, to track symptoms, improve adherence to therapy, identify potential triggers • Structured self-management programs which assist participants in making their own disease management choices to reach self-selected goals (though goal-setting; use of cognitive symptom management, stress- and pain- reduction techniques; psychosocial support)	++	+	+
Clinical Information Systems (organize data to facilitate care)	• Proactive care planning to identify patients at highest risk of complications and healthcare needs • Automated timely updates on patients' clinical status outside of healthcare system	++	+++	+
Clinical Decision Support (facilitate care consistent with evidence, and sensitive to patient preferences)	• Electronic health record-integrated, point-of-care, clinical decision support tools, based on clinical guidelines	+++	+++	-
Delivery System Design (assure effective, efficient, and individualized, healthcare delivery)	• Pre-planned personalization of clinic visits to suit patient-provider needs • Multi-disciplinary team visit (physician, psychiatrist, dietician, social worker, etc.) • Effective utilization of non-clinical staff to improve workflow and patient experience • Telehealth for remote monitoring and distance management	+	++	+++
Health Care Organization (culture focused on high-quality, high-value care)	• Organizational support for continuous improvement and implementation of components of chronic care models • Incentivize quality improvement	-	+	+++
Community Resources (access to services needed in community)	• Social networks to provide peer support and share experiences with other patients • Regular referral and encouragement to participate in useful community resources • Partnerships between medical practices and community organizations to develop and support needed services	-	-	+

Table 1. Components of a Chronic Care Model, and illustrative examples how current population health management interventions in IBD are utilizing different elements

Figure 1: Population Health Management Components and Strategy in IBD

IT: Information technology; PHM: population health management; AGA: American Gastroenterology Association; CCF: Crohn's and Colitis Foundation; PRO: Patient Reported Outcomes; NLP: Natural Language Processing

Figure 2: Determinants of IBD Health, Variations in Care, and Future Considerations

IBD: Inflammatory bowel disease; Chromo: chromoendoscopy or other dye-based surveillance techniques; C. Diff: Clostridium difficile; CMV: cytomegalovirus; VTE: venous thromboembolism; TPMT: thiopurine methyltransferase test; AZA: azathioprine; 6MP: 6-mercaptopurine; TB: tuberculosis; Hep B: hepatitis B; Anti-TNF: anti-tumor necrosis factor

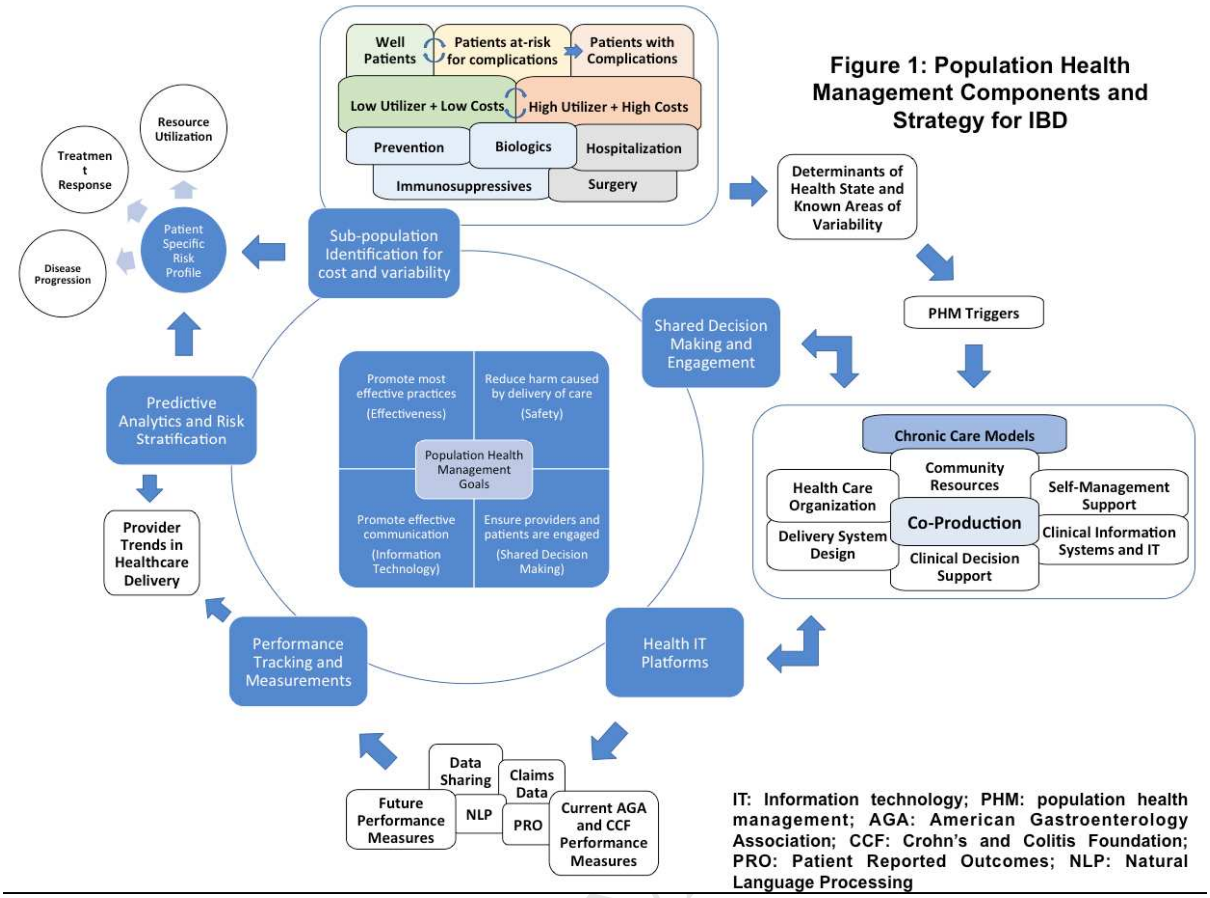

Figure 1: Population Health Management Components and Strategy for IBD

IT: Information technology; PHM: population health management; AGA: American Gastroenterology Association; CCF: Crohn's and Colitis Foundation; PRO: Patient Reported Outcomes; NLP: Natural Language Processing

Social Determinants	Known Areas of Variability in IBD Care	Areas in Need of Research

• Lower disease related knowledge
• Lower socioeconomic status
• Public or uninsured patients (access to care)
• Younger patients (increased healthcare utilization)
• Psychiatric illness
Disease Determinants
• Disease location, phenotype, and severity
• Prior IBD-related hospitalization or surgery
• Anemia and Malnutrition
• Multiple comorbid conditions
• Older patients (increased risk of complications)
Treatment Determinants
• Need for total parenteral nutrition (TPN)
• Chronic use of corticosteroids or narcotics
• Delayed use or non-adherence to biologics
• Low volume centers without IBD expertise
	• Prevention
	  • Vaccinations (Influenza, Pneumonia)
	  • Smoking cessation and counseling
	  • Colorectal cancer screening/surveillance
	  • Intervals, number of biopsies and method of assessment (i.e. chromo)
	  • Timing of referral for surgery
	• Acute flares
	  • Testing (C. Diff; CMV in steroid refractory)
	  • Confirming disease activity and severity
	  • Hospitalized Flares
	  • VTE prophylaxis use
	  • Gastroenterology consultation
	  • Escalation to 2nd line therapy
	• Use of immunosuppressants and biologics
	  • Testing for TPMT before AZA or 6MP use
	  • Testing for TB and Hep B before anti-TNF use
	  • Use of corticosteroid-sparing therapy and testing for bone loss in chronic steroid users
		• Mucosal healing
		  • Ascertainment and validation of surrogate measures (frequency of endoscopic assessment)
		  • Assessment of provider variability and impact on IBD-related outcomes
		• Biologic drug concentrations
		  • Ascertainment of drug concentration testing
		  • Understanding of target biologic concentrations
		  • Validation as surrogate measure of achieving target drug concentrations
		  • Assessment of provider variability in testing and impact on treatment success with biologics
		• Predictive analytics: Integration of information systems with omics' and precision medicine
		  • Provider patterns in healthcare delivery
		  • Patient trends in healthcare utilization
		  • Risk profile for disease progression and response to therapies