Examining Perceptions of Participation in a Pediatric IBD Collaborative: Analyzing the Integral Features and Activities of ImproveCareNow

By

Thomas M. Runge

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Sue Tolleson-Rinehart, PhD, Advisor and First Reader

Date

Michael Kappelman, MD, Second Reader

Date
Abstract

In 2007, pediatric gastroenterologists from ten practice sites across the U.S. created a quality improvement collaborative, now known as ImproveCareNow, to improve the quality of care provided to children with inflammatory bowel disease. Despite the face validity and great potential of quality improvement collaboratives, investigators do not fully understand how improvement happens, including the variables contributing to quality measures and the necessary components needed to sustain quality improvement. The purpose of this project was to explore perceptions of collaborative participants to identify elements of sustainability. We performed qualitative interviews with 16 ImproveCareNow participants as one method in a triangulated strategy of measuring collaborative participants’ perceptions. We selected informants from a diverse list of practice types and geographic locations, and asked open-ended questions, which we then transcribed and coded. For this master’s paper, I analyzed members’ perceptions of value of, and implementation strategies for, collaborative components like pre-visit planning, patient databases (population management), standardized clinic forms and algorithms, and decision support.

I found that collaborative participants value many system-wide features of collaborative participation, but sites have different paths to implementation, and important features are underdeveloped or under-utilized at some sites. Respondents embraced the potential of population management reports, but noted that data entry burdened clinic flow. Previsit planning was cited as moderately successful, and one site had developed a novel modification of the planning to obviate face-to-face meetings. Standardized clinic templates and decision analysis tools met high expectations for mutual benefit from individual innovation and ingenuity.

Analyzing in-depth interviews of ICN participants is the first step in understanding what health care providers perceive as the value from, benefits of, and challenges to initiating and sustaining collaborative quality improvement activities.
Perspective (Author’s Note)

This master’s paper represents a component of a larger team project that allowed my friend and colleague Erica Peterson and I to utilize qualitative research tools to examine a pediatric IBD quality improvement collaborative. Working together, we were able to assess the perspectives of collaborative participants and explore the literature surrounding quality improvement collaboratives in greater depth than possible had there been just one of us. Therefore, the work completed for the master’s paper and practicum requirements was a collaborative effort itself, in which we both contributed equally at every stage.

Although our master’s project examined the perceptions of participation in a pediatric IBD collaborative, I focused on the practice variation and implementation of key ICN activities, while Erica chose to focus on elements of sustainability of particular ICN activities and the Improve Care Now (ICN) collaborative itself. We hope to present our combined work to the ICN Research Committee in the fall, at which time we will present data from a web-based survey that we constructed. A complete discussion of the derivation and analysis of the survey results, as well as conclusions drawn from collected data, are largely beyond the scope of this project. Still, the in-depth interviews we conducted with health care providers were very engrossing, and allowed us to observe and analyze perspectives of individuals with varying interests and roles in quality improvement. Overall, sustaining quality improvement requires systems change and commitment at all levels of the health care system.
Acknowledgements

This project would not have been possible without the guidance, expertise, and support of our two advisors and readers, Dr. Sue Tolleson-Rinehart and Dr. Mike Kappelman. These two individuals worked extremely hard on this project from the onset, and set a wonderful example for how to focus our research questions, manage our time appropriately, and achieve our goals. Without the direction of these two individuals, we would have taken a substantially different and less fulfilling approach to this project. We would like to thank every member of our policy practicum group who helped us consider many different angles and stay fresh during the spring. We would also like to thank the sixteen physicians, nurse practitioners, and nurses who took their own time to allow us to learn about quality improvement and the ImproveCareNow collaborative. We owe a debt of gratitude to the ImproveCareNow Collaborative, who allowed us to attend their Spring 2010 Learning Session. Finally, I would like to extend my gratitude to my friend in colleague in this project, Erica Peterson, who worked tirelessly with me every step of the way. As a special note to a special mentor in this project, I would like to say that I am deeply envious of future students who will have the privilege of enjoying the most fascinating and delicious combination of the richest food for thought (Health Policy, starring Jervisian Systems) and the richest food for sustenance (raspberry cheesecake brownies) that I have ever experienced.
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Introduction

Inflammatory bowel diseases in pediatric gastroenterology affect many children in the United States. Estimates of those affected range from 30 to 50 per 100,000 children and from 24 to 30 per 100,000 children in the U.S. for Crohn’s and Ulcerative colitis, respectively. Despite published standards of care and high levels of physician training, significant provider- and center-dependent variation exists in many spectra of medical care, and pediatric IBD is no exception. Evidence specific to pediatric IBD helped to broaden and further highlight the importance of quality improvement for chronic illness care, an undertaking begun in earnest following publication of the seminal reports published by the Institute of Medicine, entitled To Err is Human and Crossing the Quality Chasm.

In the mid-1990s, the Institute for Healthcare Improvement developed the Breakthrough Series collaborative model, legitimizing a model for quality improvement and spawning new attempts to reorganize and improve care. Quality improvement collaboratives bring together multidisciplinary teams under the leadership of quality improvement experts. They are designed to complement medical care with common goal-setting, behavioral and psychosocial interventions, and self-management principles to help change the way medical care is delivered. The quality improvement literature suggests that minimizing variations in practice and carefully collecting data on processes of care and outcomes requires multi-level changes to health systems. Implementation of successful interventions like these requires a shift in focus, from short-term acute care to patient-centered chronic care, involving six core areas for improvement as part of the Chronic Care Model: linkages to community resources, self-management support, decision support, delivery system design, clinical information systems, and organization of the health interventions.
Early in 2007, leaders in pediatric IBD and quality improvement experts came together to form the PIDBNet Quality Improvement Collaborative.\textsuperscript{15} for pediatric inflammatory bowel disease. Originally involving 10 sites as an extension of PIBDNet’s studies on variations in pediatric Crohn’s disease, the collaborative, now designated as ImproveCareNow (ICN), currently involves 24 centers. Data collected by the collaborative show a drastically improved rate of Crohn’s remission among enrolled patients. Since early 2008, the proportion of Crohn’s disease patients with disease in remission has progressively increased, from 49% to 64%.

The aim of our project was to explore and assess the perceptions of key participants in this collaborative, through in-depth interviews with key participants in its function, including physicians, nurses, and quality improvement professionals. We sought to place the activities and outcomes targets in an organizational context, exploring the expectations, perceived utility, and obstacles to implementations of key collaborative interventions, while describing the mechanisms of quality improvement at participating sites.

**Methods**

We used the following three methods of analysis to identify and verify perceptions of participation in ICN: (1) in-depth structured interviews, (2) a web-based survey of collaborative participants, and (3) observation of participants at an ICN learning session. This mixed-method analysis allowed us to triangulate our approach to accurately reflect the perceptions and characteristics of ICN collaborative participants. The University of North Carolina IRB reviewed our research protocols and determined that we were exempt from obtaining informed consent.

The sampling strategy used to identify potential respondents combined purposive and chain-referral methods, often used if randomized selection is not appropriate.\textsuperscript{16} We selected respondents based on the heterogeneity of their practice, and used the collaborative database
to identify primary investigators from 10 of ICN’s sites. Some demographic data are presented in Figure 1. Second respondents from selected sites were identified through a reputational process, so that the most involved non-MD participants would be identified. Of the 16 interviews conducted (involving 10 sites), 14 were able to be recorded. One provider did not grant permission for voice recording, and with one interview technical difficulties precluded recording. Completed transcripts were sent to each key respondent.

With our interview being founded upon open-ended questions, construction of our code list was done through an inductive process, based on the responses we received. Interview coding was performed according to a multi-step analytic method similar to that described by Burnard.17 In all, 42,780 words were transcribed, equaling 91 typed pages of interview data. Upon completing all of the interviews and transcriptions, complete copies were distributed to both reviewers. Each reviewer read the transcriptions carefully and took additional notes, seeking to enter the respondent’s “frame of reference.”18

The codebook used to categorize our findings was constructed using a combination of open and selective coding strategies, the former advantageous for coding open-ended interview questions.19 Respondent answers were categorized according to theme, based on the question that was asked. We began with 19 code headings and, constructing a code heading list in an iterative manner, created a final list of 39 code headings. This was done in a cooperative manner by both researchers (see Table 1). Multiple coding can help minimize potential subjective biases when assigning categories to respondent data, and although intensive in nature, can lead to further refinement of coding headings20 allowing for a more elaborate and thorough thematic analysis.21 Analysis of codebook data was based on descriptive statistics, with content analysis based on recurring themes among respondent answers.
We created a short, nine-question survey founded entirely on information from the qualitative interviews. We sought to describe the perceptions of all participants in the collaborative, so we did not construct a sample of these participants, but invited every active participant to participate. Primary investigators at each of 24 sites were contacted and asked to provide a complete list of individuals at their site who are involved in clinical care of patients at that institution, with the understanding that these numbers would vary across sites. We obtained the ICN email contact list from the project manager and supplemented the included email addresses with those obtained from the email query, leading to a total sample of 90 individuals who were invited to participate. New sites were asked only to complete an abbreviated survey, assessing the relative importance of motivational factors for participating in the collaborative. The survey results will be reported and analyzed in a subsequent manuscript.

RESULTS

In general, sites instituted a wide range of activities (see Table 2, Figure 2). Interviewees in general felt that instruction in quality improvement, founded on the principles of Langley and colleagues, was very effective, as were interactions with peers attempting their own Plan-Do-Study-Act cycles. Small tests of change likely encourage active learning of QI methods by trial and error, and clinicians are able to better mold quality improvement into the fabric of their particular clinic, and in previous work researchers have shown that testing changes this way leads to faster improvements. Interviewees seemed to equate a fondness for intra- and inter-team interactions (9 out of 16 interviewees posited interactions and teamwork as primary motivators to join a collaborative) with a different attitude about what quality improvement means. One respondent commented that quality improvement through the collaborative differed strikingly from the version of “quality” that many health providers know, one based on increased
requirements for care, often construed by individuals who do not share the personal and professional concerns of physicians.

**Previsit Planning**

As part of their quality improvement activities, sites participating in ImproveCareNow are asked to conduct previsit assessments of their patients with IBD. Similar previsit work has also been a part of other chronic disease collaboratives. For many sites in our sample, previsit planning occurs in once-weekly or twice-monthly sessions, with meetings composed of health professionals with many different roles. Although this approach is fairly time consuming, discussing the management plan for a patient allows the physician to walk into the exam room with a deeper understanding of the patient’s history, and with a tentative management plan that is much more specific and tailored to each particular patient. According to one respondent, save for standardized clinic intake and recording measures, previsit planning was one of the first things implemented by the collaborative. Intended largely to encourage greater attention to medication dosing and nutrition and growth information, these visits can also be used to obtain needed tests or consultations more quickly than before. Many respondents (83%) mentioned the previsit planning sessions as being an important component of quality improvement work at their site, and their perceptions of purpose and utility of these sessions was largely positive. One respondent described previsit planning sessions as being very successful, especially in comparison to the other patients seen in their gastroenterology practice:

This is the first subset of our total patient population that we’re actually spending some time thinking about in advance of their appointments, which I think is big improvement for us.

As one respondent described, this can shift the focus of the patient’s visit, allowing a physician to focus “more on the problems they have, rather than the general information-gathering that
you typically have with a clinic visit.” One site has monthly sessions, corresponding to a monthly clinic day dedicated solely to IBD patients. For one site, obstacles have prevented regular previsit meetings from occurring. A respondent from this site attributed this to personnel cuts, as well as an unwillingness of other providers to change the way they practice. Another respondent, engaged himself in previsit planning, echoed the latter sentiment, speaking to the difficulty of convincing additional providers to do previsit planning:

But again you need to realize unfortunately it's only when you ask “Has it made an impression?” It's just myself that's giving you that comment. Because as I said the other doctors haven't participated in a large degree in doing this...When I've been away I've said “Can you help me?” When they're there they find it worthwhile, but it's one of those things that kind of goes off they’re radar.

One respondent discussed a previsit planning process that did not involve an actual face-to-face meeting at all, but was structured around a dedicated “previsit planning sheet,” on which pediatric gastroenterology fellows, prior to a visit, can circle whether relevant indicators, such as body weight and medication doses, are in the appropriate range.

**Population Management**

Another significant piece of ICN’s quality improvement intervention is population management. Participating sites enter standardized information for each clinic visit, and this information is stored in a collaborative-wide database. Each month, the collaborative sends updated information back to each site in an Excel spreadsheet (called a “population management report”) that includes information on every patient enrolled in the database, and patients can be sorted by disease activity, nutrition and growth status, as well as the medications they are taking. The collaborative allows sites to identify patients on prednisone or infliximab, and several respondents found this useful.
In general, 92% (11 out of 12) respondents from existing sites mentioned population management in their interviews, and many respondents spoke of the vast potential of this tool to revolutionize patient tracking, especially considering the difficulty of keeping track of patients in-between clinic visits. For many patients, communication with their physicians is often infrequent and erratic. Especially for chronic disease, having a systematic way to track at-risk patients can help fill the gaps between visits. One respondent felt especially strongly how the population management reports help target these patients:

I think…kids who are doing well, or kids that have really have compliant parents, or the kids that are doing really badly, usually come to our attention a lot more quickly, because we see them. But it’s the kids that are doing okay, but may or may not have the most compliant families, that I think collaboratives like this help us sort of remember to target the follow up so that they don’t fall through the cracks. (emphasis added)

Among the sites and respondents we spoke to, the variability in implementation of population management strategies was substantial. Respondents from all seven existing sites discussed some population management reports, but only 3 sites described a standardized process for using it. One respondent gave describes such a process, referring to categorizing his patients through the population management reports as “audits:”

Like we would take our monthly report and look at all the patients who had moderate to severe disease, pull their charts and make sure that there was an active plan in place to try and move them from moderately to severe disease to either remission or at least mild disease

A central theme was that respondents, especially physician respondents, have had very high expectations for the population management report, expectations that frequently have not been met. And for several of the existing sites we interviewed, the process of translating pooled patient information into targeted site-specific quality improvement interventions has been painfully slow. Physician leaders from three existing sites specifically noted a lack of satisfaction with their own use of the tool, up to this point. Certainly a component of this has been an evolving mindset regarding how to best use patient data to make improvements,
especially for the majority of sites with less quality improvement experience. One respondent spoke to the difficulty of deciding what changes to make based on the monthly reports:

The lag time would be that we only recently, only fairly recently, actively used them as a basis for discussion for patient management and to reach out to providers... It took us a little bit of time to figure out how we wanted to approach utilization of the [population management reports]

In addition, information on patients in the population management reports is only as comprehensive as the strategy used to obtain it. Participation of additional care providers in this process entails additional time and effort to complete the required data entry (distinct and in addition to clinical information obtained during a clinic visit) that many other care providers view as a "burden," especially at the beginning of the process, according to one respondent. In addition, one respondent described having to re-educate a physician who was not providing complete data on patients seen in the clinic. Difficulty in changing the habits of other providers, combined with the current lack of a standardized way to ensure complete data are being entered, remain obstacles, according to our interviews.

**Standardized Clinic Templates and Collaborative Interactions**

Many of our interviewees felt that a variety of shared templates and forms play a significant role in quality improvement at their site. Respondents from 5 out of 7 existing sites (71%) mentioned clinic forms as important elements of IBD care at their sites. Respondents perceived these templates as being almost universally successful, for a couple distinct reasons. First, several respondents felt that sharing of useful and clinically useful templates on the extranet allowed them to avoid making the same mistakes through their own de novo development process. Second, peer interactions, sharing, and teamwork aspects were thought to be a major motivating factor for joining a quality improvement collaborative, and these were specifically addressed by a majority (56%) of respondents during their interviews. A theme that emerged from addressing standardized clinic forms was that not only did these forms improve
the completeness of data-gathering, but also addressed a need for busy practitioners: …"To try to maintain uniformity in the evaluation and care of these patients, among providers, and between institutions," in the words of one interviewee.

It is difficult to measure the benefit that sites are able to glean from one another through different interactive activities (e.g., learning sessions, sharing through the extranet, informal conversations with peers) but it is certain that many respondents felt positively about these interactions. The heterogeneity in how different sites attempted to improve care, through site-specific PDSAs and practice level improvements, allows potentially all sites to benefit from one successful effort. If a site can incorporate psychology support into care for their IBD patients, another site can learn how departmental or bureaucratic obstacles were overcome to make it a reality. If a site develops an innovative method for systematically evaluating monthly population management reports, another site can adapt a similar model.

Since different sites engage in specific PDSAs, and the vast majority of investigators are motivated to improve care, the possible successes that sites can have increase as the collaborative expands. For several respondents, actually sharing useful templates via the collaborative extranet represented the best way for less-advanced sites to apply discoveries from more-advanced sites. One respondent described these benefits:

I guess I would simply say this, I think part of the benefit of a collaborative is personal contact. I think that being involved in the process, being involved with other people…significantly helps the process move forward. I think it’s way more than additive; sort of a geometric increase. And so I think [that] when you go through quality improvement you cannot understate the value of interpersonal contact.

**Decision Support**

The ImproveCareNow collaborative has created several important decision aids to help standardize and streamline clinical care of IBD patients. As described by our interview
respondents, these include a nutrition algorithm, model care guidelines, and consistent methods for recording the five components of the “diagnosis bundle,” (BMI, growth status, disease severity, disease phenotype, and nutritional status). The nutrition algorithm groups patients into 3 categories (“satisfactory,” “at-risk,” or “in failure”). Nutrition and growth status in theory can serve as a proxy for disease activity, since chronic inflammatory conditions, if poorly controlled, often cause children to fall off of their age-appropriate growth curves. Several respondents mentioned how little controversy there was surrounding the implementation of this measure, and similarly described the high expectations sites had for this intervention. Every respondent who commented in detail on the nutrition algorithms has found them to be successful, despite the already high expectations.

At the same time, proper use of the nutrition algorithm depends on reliably collecting the pieces of information that determine the category into which a patient falls, and while many sites praised the ability to reliably collect this data now, a not-so-subtle theme underlying respondents’ comments was that before the collaborative, considerable variation precluded being able to reliably use a nutrition algorithm. This sentiment was echoed by respondents from new sites, one of which plainly noted the absence of a systematic way for tracking how often important processes of care like these are followed. Currently, however, ImproveCareNow has clear process-of-care targets for existing sites, designed to increase the consistency of data collection, with “key drivers” necessary to reach those targets. One respondent commented that implementation of electronic medical records was particularly helpful for ensuring that growth status, BMI, disease severity, etc. are documented every visit, simply because blank boxes on the electronic form prompt the physician to ask appropriate questions. Another respondent discussed a protocol through which all new patients are referred to the nutritionist for evaluation, a process that has become fairly well standardized at their site.
Self-Management Support

Self-management is both established component of chronic disease care but also has been a frequent component of previous chronic care collaboratives. In general, half (6 out of 12) respondents from new sites mentioned self-management as an important component of IBD quality improvement. For ImproveCareNow, respondents did not speak of strict requirements or guidelines regarding self-management, but many sites spoke of different approach each has taken to this end, including educational sessions and psychosocial support groups for patients. Accordingly, the approaches taken by different sites have been varied. One site distributes an educational DVD about Inflammatory Bowel Disease to curious and motivated parents. Another respondent discussed adding features such as a patient education day and a parent advocacy group, the former of which was adapted from another collaborative site:

And a couple of the centers had an organized patient education day. And while we have tried to do patient support groups in the past, it never really worked out well...this is one we stole directly from other people. Proudly.

Interestingly, the origins for this patient education day came out as a result of presentations given at a learning session. Having previously tried and failed to successfully implement a patient education day, this respondent took new ideas from these presentations, and constructed a new patient education day that has been more successful. Other sites have been working together more recently to put together an educational workbook

Effect of the Collaborative

In all, 9 out of 12 of interviewees from existing sites felt that improvements were due to the collaborative. In general, supporters felt that reporting data to a centralized database helped hold sites accountable for the care that they give. In addition, interviewees felt that paying attention to detail and learning about quality improvement strategies were tangible benefits of participation in collaborative activities. These supporters seemed to imply that the
ICN provided the tracking capabilities, standardization of process, and self-management strategies, all of which are central components of the chronic care model. When asked for other potential explanations for the increased remission rate seen in the collaborative, responses varied. Three of twelve respondents at existing sites clearly thought ICN was 100% responsible for the outcomes improvement reported by the collaborative. Among the rest of the respondents, three important issues were discussed. Two respondents pointed out that during the course of the collaborative, physicians have begun to move to more powerful medications early in disease course. This suggests that scientific or pharmaceutical improvements, or possibly prescribing habits themselves, could be partially responsible for the increased remission rates. Another respondent raised the issue of standardization of the disease measure. The Physician Global Assessment (PGA) is the current scale for determining if a patient is in remission or has mild, moderate, or severe disease. This scale has a subjective component, and formal methods for rating the severity of disease have not been a part of this collaborative. Lack of standardization of this instrument could be biasing results. Another variable is the lack of standardization of patient entry into the ICN database. There is currently no way to know if there are systematic differences between patients who are enrolled in the database and those who are not. The motivation to increase the fraction of patients in remission, especially among lower performing sites, could play some role in enrolling patients.

**DISCUSSION**

This paper describes a quality improvement collaborative that implemented many practice-level changes. Previsit planning and clinical information systems improvements are common components of similar collaborative interventions, and this has been reported in qualitative analyses done previously. However, this study describes the perceptions
and activities of sites participating in a collaborative that is much more longitudinal in nature than many organizations designed around the Breakthrough Series model, which originally was designed to achieve meaningful change in 12 months.\(^7\)

Our results show that collaborative participants value many of the system-wide features implemented by their sites. However, sites have had differential paths to implementation of certain core features of the collaborative, and at some sites important feature are under-developed or under-utilized. With previsit planning, for example, perceptions and practices among physician leaders varied, as some individuals met regularly and discussed upcoming patients, while others did not meet at all, but relied on mid-level providers to lead the sessions. Since the actual development and implementation of this process seemed to be left up to sites, obstacles to implementation including physician and staff numbers and time may prevent further evolution of this process at some sites.

The self-selection process for participation in ICN eliminates some obstacles that have been experienced by teams engaged in quality improvement in the past. Two notable obstacles discussed in related series include knowledge of change structures and strategies and lack of physician engagement. With ICN, physician leaders are inherently motivated, to do QI or participate in ICN or both. In many cases, the motivation to join the collaborative may be individual rather than institutional, strong leadership is a well-known feature of quality improvement interventions.\(^{29,30}\) In addition, requiring sites to pay yearly dues may make participating individuals more motivated to pursue change.\(^28\) In addition, motivation to engage in quality improvement is abundant among collaborative participants, and learning session attendance In a way, encouraging small tests of change, enables participants to see successes when they occur, and share them with others. The role of peers as both students and teachers of quality improvement was clearly evident at the learning session, and peer-to-peer spread of this nature\(^28\) could be integral in sustaining change.
One aspect that seems to have potential for future success is population management. The literature on clinical information systems for chronic disease unequivocally backs registry and database support as critical for improved outcomes.\textsuperscript{31,32} Allowing physicians to categorize patients based on disease severity, their last visit, and other factors minimizes loss to follow-up and helps sites target at-risk populations, as many interviewees reported. At the same time, construction of a new tool that allows practitioners to track all their patients has been a lofty but often unattainable goal in collaborative interventions.\textsuperscript{24} Developed specifically for the purposes of this collaborative, the database has identified worthwhile targets and outcomes relevant for the patient population. At the same time, duplicity in data entry remains an obstacle to continued success of this instrument. Sites without the ability to hire personnel for data entry will be necessarily limited in the information their report will generate. In addition, some sites do not have the necessary time or resources to design targeted interventions based on the report, even if data entry is complete. These issues remain problematic for the collaborative as a whole, and for individual sites as well.

**CONCLUSION**

In conclusion, collaborative participants have made many important changes to their practice to encourage quality improvement, and the benefits are being seen across the board, from processes of care to outcomes. Data gathering, an essential element of quality improvement in both manufacturing and health care, has allowed site investigators to target specific areas for improvement, and small tests of change have both encouraged continued improvements and helped participants experience quality improvement in a more hands-on way.

Some additional information could be a part of the population management report. This could include: what percent of children have required surgery and what percent are on certain
other medications, so that then the comparability of patients at different sites can be further assessed. Effort and motivation are very difficult to quantify statistically, but from what respondents have said and what we have seen, many sites seem to be encouraged to change and motivated to do so. Self-selection of sites for participation in the collaborative means that The physician global assessment may not be ideally standardized to evaluate if a true increase in remission rates is occurring, and recently a more objective CDAI (Crohn's Disease Activity Index) was developed to address some of these concerns. Another issue is how patients are enrolled in the collaborative. Early on, sicker patients are more likely to be enrolled, since they are seen more often than patients who are well. Early in the collaborative, there was no guideline addressing how often patients should be seen, so it is possible that some healthy patients were not seen for many months, which would bias later remission rates positively.

There are many competing explanations for why the outcomes of IBD patients have improved during this collaborative. We have designed a survey that will assess many aspects of the themes we have uncovered here, in a more quantitative fashion. We hope to have a deeper and more representative set of findings once we have collected and analyzed this data.
<table>
<thead>
<tr>
<th>Factor</th>
<th>Variables</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interviewee</td>
<td>Name, Center, Existing/New site, Type of provider</td>
</tr>
<tr>
<td>General Impression</td>
<td>Improve care for patients, Research opportunities, Interactions, accountability, Leadership, training skills, Developing best practices, Other</td>
</tr>
<tr>
<td>Most Valuable Aspect</td>
<td>Patient tracking, Leadership, Practice standardization, Other</td>
</tr>
<tr>
<td>ICN Activities</td>
<td>Population management, Pre-visit planning, Standardized clinic template, Nutrition &amp; growth algorithm, IBD Clinic, PDSA’s, Multidisciplinary team meetings, Self-management</td>
</tr>
<tr>
<td>Activity Evaluation</td>
<td>Success, Order, Obstacles, Expectations, Implementation, HCP’s involved, Practice standardization, Culture change</td>
</tr>
<tr>
<td>Determining Factors Contributing to Outcomes</td>
<td>Opinion of ICN, Confounders/Other contributors to outcomes, Other factors to be measured</td>
</tr>
<tr>
<td>Obstacles</td>
<td>Budget, Lack of personnel, Creating a culture of CI, Time, Lack of leadership, Infrastructure</td>
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Table 1. Codebook Template
### Table 2: ICN Activities & Description

<table>
<thead>
<tr>
<th>ICN Activities</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>Population management</td>
<td>An interactive program of patient tracking that allows providers to examine care provided to each site’s IBD population across various multiple categories, such as disease severity, nutritional status, and treatment with selected medications</td>
</tr>
<tr>
<td>Pre-visit planning</td>
<td>Process to identify upcoming patient visits and to plan those visits before the patient arrives</td>
</tr>
<tr>
<td>Standardized clinic template</td>
<td>Standardized clinic flow sheets that allow the physician to accomplish a set of goals at a clinic visit</td>
</tr>
<tr>
<td>Nutrition and growth algorithm*</td>
<td>An algorithm developed to assess nutrition and growth status at each patient visit and improve the management of patients with unsatisfactory results.</td>
</tr>
<tr>
<td>IBD Clinic</td>
<td>Implementation of a weekly, bi-weekly, or monthly clinic in which only patients with IBD are seen</td>
</tr>
<tr>
<td>Multidisciplinary team meeting</td>
<td>Team meetings made up of providers from various disciplines to discuss IBD patients. Often includes a physician, nurse practitioner, nurse, dietitian, and others.</td>
</tr>
<tr>
<td>PDSA cycles</td>
<td>Small tests of change particular to each site based on the Plan-Do-Study-Act model</td>
</tr>
<tr>
<td>Self-management*</td>
<td>Tools in the form of workbooks, seminars, CDs or DVDs provided to patients and parents to increase their knowledge of IBD and encourage greater disease management and medication adherence.</td>
</tr>
<tr>
<td>Model IBD Care Guideline*</td>
<td>Guideline developed to standardize diagnosis, disease monitoring, and treatment based on evidence and expert consensus</td>
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### Table 3: Kappa Statistics

<table>
<thead>
<tr>
<th>Question</th>
<th>Kappa</th>
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<tbody>
<tr>
<td>Q1 – General Impression</td>
<td>0.57</td>
</tr>
<tr>
<td>Q2 – Most Valuable Aspect of Participation</td>
<td>0.83</td>
</tr>
<tr>
<td>Q3 – ICN Activity Categorization</td>
<td>0.82</td>
</tr>
<tr>
<td>Q4 – Outcomes Due to Collaborative</td>
<td>1.00</td>
</tr>
<tr>
<td>Q5 – Potential Confounders</td>
<td>0.62</td>
</tr>
</tbody>
</table>
* Includes a site that at the time of the interview had failed to receive adequate funding for a dedicated IBD clinic
Appendix 1: Further Background on Quality Improvement Collaboratives

Origin of Quality Improvement Collaboratives

Promotion of quality assurance in the health care field originated long before the IOM reports *To Err is Human*³³ and *Crossing the Quality Chasm*.⁵ In 1989, Berwick proposed the adoption of *The Theory of Continuous Improvement* in the field of health care.³⁴ However, for years few practitioners took quality improvement seriously because, as Kilo explains, promoters of quality assurance focused on cost control, did not know how to motivate physicians, had unrealistic expectations of health outcomes, and poorly understood the science of improvement.⁷

Nonetheless, Berwick’s goals for improvement in health care³⁵ were the basis for the development of the Institute of Healthcare Improvement’s (IHI) Breakthrough Series (BTS) collaborative model in 1998, which aimed to achieve “unprecedented levels of improved performance in participating organizations in less than 1 year by bringing providers together to understand and drive improvement within a specific topic area” (p. 2).⁷ The IHI developed the collaborative model based on the following principles:

1. A sustained gap exists between knowledge and practice in health care;
2. Broad variation in practice is pervasive;
3. Examples of improved practices and outcomes exist, but they need to be described and disseminated to other organizations;
4. Collaboration between professionals working toward clear aims enables improvement;
5. Health care outcomes are the results of processes; and
6. Understanding the science of rapid cycle improvement can accelerate demonstrable improvement.⁷
The IHI BTS collaborative model offered a framework adaptable for many types of diseases, provider networks, and health organizations. Wilson, Berwick, and Clearly \(^{28}\) summarized the steps in the BTS Collaborative Model, which are presented in Figure A-1. The success or failure of collaborative is dependent on team member interactions, which take place during “learning sessions.” Operating under a Plan-Do-Study-Act model, team members learn improvement techniques, exchange ideas and advice, and generate enthusiasm and commitment to achieving a common goal.\(^{36}\) Learning sessions commonly involve specific instruction on improving selected aspects of care, developing, sharing, and refining data collection and tracking modalities, and reporting results or recent changes at each site.\(^{37}\) After each learning session, team members return to their practice or organization to apply new knowledge and evaluate new outcome measures.\(^{7}\) In between learning sessions, access to a listserv\(^{37}\) or extranet is common, as are monthly conference calls. Some collaboratives also develop and utilize state- and region-based support, offering technical assistance to participating health centers.\(^{38}\) Figure A-2 illustrates the basic framework of the BTS model.

**Figure A-1**

<table>
<thead>
<tr>
<th>Steps in the Breakthrough Series Collaborative Model</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Sponsoring organization identifies topics where a significant gap exists between best and typical practice.</td>
</tr>
<tr>
<td>2. The Institute for Healthcare Improvement (IHI) then assembles an expert panel.</td>
</tr>
<tr>
<td>3. Expert panel prepares a package of ideas for closing the gap.</td>
</tr>
<tr>
<td>4. IHI recruits participating teams to be part of the collaborative.</td>
</tr>
<tr>
<td>5. Participants engage in prework: forming a local improvement team, develop goals and measurements, and characterize current practice.</td>
</tr>
<tr>
<td>6. During a collaborative’s life, usually 6-12 months, teams from participating organizations attend three learning sessions in which they learn about ideas for better practice and improvement methods that they implement between sessions.</td>
</tr>
<tr>
<td>7. Between learning sessions, teams share experiences and maintain contact through such mechanisms as conference calls and internet email listservs while submitting progress reports.</td>
</tr>
<tr>
<td>8. The lessons learned are spread through a national meeting (congress) and reports.</td>
</tr>
</tbody>
</table>
Figure A-2: The Breakthrough Series Model


LS: Learning session

Appendix 2: Limited Systematic Review of Quality Improvement Collaboratives

Introduction

Investigators have identified deficiencies in the safety and quality of health care provided in the U.S. Among recommendations proposed by the Institute of Medicine’s *Crossing the Quality Chasm* is one promoting collaboration among clinicians, institutions, and patients through shared knowledge, free flow of information, evidence based decision making, and transparency of health system processes. In addition, financial rewards linked with clinical outcomes further incentivize adoption of quality improvement methods. Quality improvement collaboratives (QICs) represent one systems-based approach to improve health care quality and patient outcomes.

The purpose of this review is to provide an overview of the literature surrounding QICs, to classify the types of analyses performed on chronic disease QICs, and to appraise the quality of literature examining their effectiveness. First, we will briefly describe the evidence base for QICs. Then, we will report the methods, results, and discussion of a systematic review of studies examining collaboratives specifically focusing on chronic disease. Finally, we will outline suggestions for future research.

Evaluation of the Evidence Base Surrounding QICs

Since the inception of IHI’s BTS collaborative model, various health care systems, organizations, and groups of providers have adopted versions of collaboratives to fit their needs. Improving surgical and critical care outcomes in hospitals were among the first targets of collaboratives. Early quality improvement collaboratives included the Northern New England Cardiovascular Disease Study Group, the US Veterans’ Affairs National Surgical Quality Improvement Program, and the Vermont Oxford Network, which aimed to improve hospital...
mortality associated with coronary artery bypass graft surgery, morbidity and mortality rates after major surgery, and quality of care for very low birth weight infants neonatology survival rates, respectively.

Utilization of collaboratives quickly expanded from hospital-based outcomes to outpatient-based diseases and illnesses. As of 2003, the IHI had conducted collaboratives with over 700 teams working on 23 clinical conditions. In addition, the U.S. Health Resources and Services Administration and the Veterans Health Administration adopted the QIC method. Moreover, adoption of collaboratives expanded beyond the United States. Australia, France, the Netherlands, Norway, Sweden, and the United Kingdom’s National Health Services have developed and implemented variations of collaborative programs.

Numerous studies document the effectiveness of particular quality improvement collaboratives (QICs). Investigators credit the implementation of QICs for reduced inpatient mortality rates associated with coronary artery bypass graft procedures, decreased neonatal infection rates, decreased c-section rates, less costly prescriptive practices, improved patient safety, decreased emergency department waiting times, and improved management of patients with chronic disease. Such studies support the use of quality improvement collaboratives as a viable method for identifying and implementing best practices.

Few studies in the literature conclude that QICs are ineffective, but Landon and colleagues offer one example. They performed a prospective matched pre- and post-interventions study of almost 10,000 HIV-infected patients and found that a multi-institutional quality improvement collaborative did not significantly affect the quality of care.

Other studies sought to identify and explain components of successful collaboratives, which often take the form of informant interviews. Ayers and colleagues used open-ended questions of 18 key informants involved in successful data-driven quality improvement learning
collaboratives in the U.S. and Europe. They identified the following patterns: cultivating trust, attendance to the human dimension, nonlinear development, attendance to organizational culture, integrated philosophy of quality improvement, and a focus on process and outcome measurement to drive change.\textsuperscript{30} Meanwhile, Wilson and colleagues\textsuperscript{28} performed semi-structured interviews with 15 leaders of collaboratives to ascertain the features of effective collaboratives; they identified the following seven critical determinants: sponsorship, topic, ideas for improvements, participants, senior leadership support, preliminary work and learning, and strategies for learning about and making improvements.\textsuperscript{28} However, the internal validity of these studies is questionable because of variation in collaborative frameworks, which targeted a diverse set of medical outcomes and settings, ranging from ambulatory care to critical care units. Similar inconsistencies are rampant in the QIC literature.

**Methods**

We conducted a MEDLINE search to search for literature written about chronic disease QICs published before January 2010. The search algorithm appears in Figure A-3. We used the following MeSH terms: “quality” AND (“cooperative behavior” OR “cooperative” AND “behavior” OR “collaborative”) AND “improvement.” Our 2-person team reviewed the titles and abstracts of articles appearing before January 9, 2010. To obtain additional articles not recovered in our MEDLINE search, we hand-searched references of sentinel articles.

We included studies that were written in English, took place in the U.S., examined collaboratives targeted at one or more chronic diseases, and met the definition of collaborative. In an \textit{ad hoc} manner we defined a quality improvement collaborative (QIC) as “a voluntary network of health care providers in more than one health care system, who agree to share data and information on processes of care for the purpose of improving the quality of care and
patient outcomes.” This definition was based on a pilot search and review, which identified important components of these interventions as including identification of variations in care or deviations from published guidelines, defined, measurable outcomes, a willingness to pursue active information sharing, and collection of data with the intent to study the effectiveness of the intervention. These variables, and others, were also identified in a systematic review of collaboratives by Schouten et al, which helped add a measure of validity to our original search goals and inclusion criteria, for quality improvement collaboratives.48

We excluded articles if the collaboratives took place in the settings of improvement in emergency departments, intensive care units, and primary care practices not focusing on a particular chronic disease. We also excluded articles written about collaboratives focused on organ donation, general preventive measures, medical imaging, surgical interventions, and palliative care.

From abstracts and full-texts of the articles meeting inclusion and exclusion criteria, we extracted the following information: the authors and year of the publication, the disease or medical specialty (i.e. pediatric cardiology, psychiatry, etc.) addressed in the collaborative, the setting of the collaborative participants, and the type of analysis performed by authors. We then classified the types of analyses into the following three broader categories: process and methods, sustainability, and effectiveness. Process and methods included articles written about the need, development, and implementation of quality improvement collaboratives. The category of sustainability included articles that described or identified internal or external resources necessary to sustain the effects of a collaborative. Among these, we also recorded if authors addressed the importance of team work or informatics as necessary components of the collaborative investigated. Finally, the category of effectiveness included articles that evaluated the effectiveness of collaboratives on patient outcomes.
Next, we appraised the quality of studies measuring the effectiveness of QICs. We reviewed the articles classified in the category of *effectiveness* for studies reporting patient-oriented outcomes. We excluded studies evaluating effective components of a collaborative, i.e. teamwork or information technology, and studies examining exclusively non-disease specific outcomes. From the studies meeting these inclusion and exclusion criteria, we extracted the following information: the disease or medical condition addressed by the collaborative, a brief description of the study, the study design, the participants in the analysis, the source of assessment, the outcomes assessed, the methodological status, the duration of follow-up, and the findings. For each study, we appraised the internal validity, external validity, and the clinical utility of the measured outcomes.

**Results**

The MEDLINE search algorithm produced a total of 626 articles, but only 51 met inclusion criteria. A hand-search of pertinent literature yielded five additional articles. Table A-1 details the classification of the 56 articles. Nineteen fell into the category of process/methods, 15 in sustainability, and 22 in effectiveness.

*Categories of Literature*

Process/methods articles focused principally on the formation and evolution of the development of collaboratives. If collaboratives were new to a particular medical field, such as pediatric cardiology or pediatric gastroenterology, investigators published articles outlining the need for a QIC and often detailed an adapted model to suit the goals and needs of the field. Other process/methods articles focused on the implementation of a collaborative or evaluated the implementation by measuring clinic or physician practices.

Articles classified under the categories of sustainability and effectiveness reported various outcomes about collaboratives that had been in operation for at least one year.
general, sustainability articles reported the necessary components to sustain the quality improvement practices initiated because of a collaborative. Some investigators addressed sustainability of a collaborative itself, while others focused on specific components of the QIC. To evaluate which components of a QIC were effective, investigators often conducted qualitative methods, such as interviews with key informants. Six sustainability studies mentioned information technology as a necessary component, while 4 of these specifically evaluate a particular type of technology utilized in the collaborative. Three sustainability studies cited an element of teamwork as an effective QIC component. One study evaluates the cost-effectiveness of implementation of a QIC.

Investigators evaluated a variety of outcomes of collaboratives in studies classified in the category of effectiveness. The outcomes examined are as diverse as the goals for initiation of collaboratives. For instance, some QICs aim to reduce disparities among diabetic patients, while others evaluate physician practices and patient-outcomes.

Unsurprisingly, most collaboratives address common health conditions, such as heart failure, diabetes mellitus, asthma, and depression. QICs focused on HIV and stroke were also common. Unique medical topics included urology and COPD. Pediatric illnesses were also represented in the chronic disease QIC literature. Common pediatric conditions or topics addressed included asthma, inflammatory bowel disease, development disorders, cardiology, and rheumatology.

**Critical Appraisal**

A summary of the systematic review of QIC effectiveness studies is provided in Table A-2. Overall, 13 manuscripts met the inclusion criteria for the systematic review of the effectiveness of QICs. Of these, only 3 studies involved a randomized component in their study design. Five included studies used a comparison group study design,
with selected intervention sites and control sites, not unlike a case-control design. Three studies\textsuperscript{59, 60, 63, 65} used quasi-experimental before-and-after designs, one\textsuperscript{66} used a cross-sectional analysis of a state’s health plans, and two studies\textsuperscript{58, 61} were uncontrolled cross-sectional analyses of a single site participating in a collaborative intervention.\textsuperscript{66}

**Randomized Studies**

Two of the studies featuring a randomized component\textsuperscript{62, 64} used a cluster randomized controlled trial design, randomizing at the practice level to assess the intervention. One study\textsuperscript{60} was designed primarily as a quasi-experimental before-and-after design, but randomized selected centers to either standard or high-intensity collaborative interventions (the latter involving four additional learning sessions and additional provider training). On the whole, none of these randomized trials or arms found that collaborative quality improvement interventions led to improved outcomes.\textsuperscript{60, 62, 64} One study\textsuperscript{62} randomized forty-three practices in greater Detroit, Mich and greater Boston, Mass to participation in a learning collaborative based on Breakthrough Series methodology or standard care. For children with asthma, Homer et al found no significant improvements in asthma process-of-care outcomes, clinical outcomes, or utilization outcomes for individuals randomized to the intervention group.\textsuperscript{62} Another randomized study\textsuperscript{64}, undertaken by Philbin et al, randomized ten hospitals in the upstate New York. Intervention hospitals received an intensive, multifaceted quality improvement intervention consisting of educational sessions, critical pathways, and lectures. The New York research team found no significant improvements in process-of-care markers or clinical outcomes among intervention sites compared to controls. However, a slight, non-significant reduction in hospital length-of-stay was observed among intervention hospitals. The third and final study with a randomized component that fit our inclusion criteria was a study of a diabetes quality
improvement collaborative, undertaken by Chin et al.\textsuperscript{60} Embedded in a longitudinal study looking at the effect of a collaborative quality improvement intervention for, sites treating patients with Type 2 diabetes were randomized to either a high-intensity and standard protocol after 1-2 years of participation. For ACE inhibitor and aspirin use, Chin et al found slightly higher documented rates of compliance.\textsuperscript{60} However, for many other intermediate incomes, and for clinical outcomes measures, there was no significant effect of the higher-intensity intervention.\textsuperscript{60} For several of the intermediate outcomes, including HbA1c levels and systolic blood pressure measurements, control sites out-performed sites that participated in the high-intensity intervention.

**Observational Studies**

The majority of the studies included in our review were observational studies, employing several different designs. The preponderance of observational study designs among our included studies mirrors the predominance of non intervention-based, observational studies in the literature on collaboratives. Four studies\textsuperscript{37, 38, 56, 57} that met inclusion criteria for our report were observational studies molded as case-control studies at the practice level. These studies, offering fewer statistical limitations and theoretically fewer potential confounders and biases in their study design than simple before-and-after studies, represented the most common type of study included in our report. Asch et al studied the effects of a BTS collaborative heart failure outcomes, finding a significant positive effect of collaboratives on counseling and education outcomes, as well as positive effects on rates of ACE inhibitor and lipid-lowering therapy for heart failure patients. However, Asch et al found no improvement in readmission rates for patients at participating sites.\textsuperscript{56} Landon et al, in 2004, published results from a similar assessment of a BTS collaborative, this time concerning HIV treatment and quality. Comparing 44 intervention sites to 25 control clinics primarily on the basis of control of viral load and prevention of opportunistic infections, investigators found no significant differences in outcomes
between the two groups. Although the end result was a lack of significance, the proportion of patients with viral load controlled increased twice as much in the intervention group compared to the control group; these figures were 11.0% improvement (40.7 to 51.7) and 5.4% improvement (44.1 to 49.5), respectively.37

Despite mediocre results in the EQHIV study, another Landon-led research team assessed the effects of collaboratives on management and outcomes of asthma, diabetes, and hypertension.38 Interestingly, for these common chronic diseases, Landon et al found that collaborative participation was associated with improvements in screening, prevention, and disease monitoring, for patients with asthma and diabetes.38 Similar improvements were not seen with hypertension, however. For diabetes and hypertension, there was virtually no effect of collaboratives on clinical outcomes, however. In contrast to these results, Baker et al found that participation in a collaborative for heart failure reported much higher quality of life, satisfaction with medical care, and knowledge of their condition.57 Most importantly, patients in the intervention group utilized less care, in terms of hospitalizations, than those in the control group.57 Despite selection concerns in this study, the utilization outcomes data shows that meaningful improvement likely did occur. The final study comparing “intervention” sites to selected control sites assessed the effects of a quality improvement collaborative on quality of care and outcomes for childhood asthma.63 Comparing nine intervention sites with four control sites, Mangione-Smith et al found significant improvements in process-of-care measures and patient self-management skills. However, small differences in health utilization outcomes between the two groups were not statistically significant, echoing the non-significant findings of this type in several other studies.38,65

Of the remaining studies that fit our inclusion criteria, three employed a before-and-after design, one analyzed variations in care from the perspective of a state health plan, and two studies were uncontrolled studies, reporting results and experiences related to a single site’s
participation in a collaborative. Two of the before-after studies targeted Health Disparities Collaboratives (HDCs). Both of these studies \(^{59, 60}\) studied the effect of collaborative interventions on diabetes care, using a collaborative structure that emphasized involvement of community health centers, combining semi-structured interview data with surveys and reviews of medical records. In these studies, investigators found significant improvements across the board, from process-of-care measures such as HbA1c checks, foot and eye exam referrals, and lipid assessments, as well as HbA1c control, an intermediate outcome that for diabetes serves as a monitor for disease control. Between the two studies the improvement in HbA1c ranged from 0.2\(^{59}\) to 0.45\(^{60}\), although this difference was not significant in either case. The third study with a before-after study design\(^{65}\) actually included control sites for comparison, but the control sites had dramatic differences in location and payer mix compared to intervention sites, so for the purposes of this analysis the study was treated as a time series analysis. Schonlau et al found several significant differences between intervention clinics and control clinics, including several satisfaction and self-management indicators.\(^{65}\) With only 9 included centers, however, the number of utilization outcomes or events (e.g., emergency room visits) was very small, preventing investigators or readers from reaching meaningful conclusions from the results. For example, during the 13 month period of the study, in the intervention group there were 2 emergency visits by patients during the study (according to survey data), compared to a single ED visit among control patients.\(^{65}\)

One study\(^{66}\) that met our inclusion criteria found positive gains attributed to a statewide collaborative for Diabetes quality improvement. Reported from the perspective of Wisconsin-based HMO health plans, Siomos et al found incremental improvements in LDL and HbA1c monitoring, nephropathy screening, and eye exam referrals. However, absent in this study were descriptions of which HMO plans were included for each year of analysis as it varied according to year, and was not explicitly tracked. Nor was there included information on selection of sites,
clear presentation of results, or analysis of findings. The final two studies that met our search criteria had similar validity questions, stemming from incomplete and haphazard reporting of results, no arrangements or discussion of secular trends, and lack of demographic information on included patients or sites. In addition, Benedetti et al and Fox et al presented select information on only one participating center, which drastically limits the validity of these studies. With no substantive discussion of secular trends, the primary purpose of these studies was informative. From an appraisal standpoint, however, these two studies do little to prove that quality improvement collaboratives have a positive, meaningful effect on quality of care and outcomes.

Discussion

The literature on chronic disease QICs is appropriately diverse to coincide with the variety of chronic diseases and conditions and the range of goals QICs seek to address. For instance, the heterogeneity of HIV patients seen at outpatient care facilities may require completely different management strategies from visit to visit. Thus, an HIV collaborative may be less fitted to a rigorously systematic, QIC methodology.

The three categories of process/methods, effectiveness, and sustainability represent the natural evolution of QIC literature. Investigators will continue to report adapted QIC processes and methods for different conditions. Next, collaborative participants must measure patient outcomes and determine what components of the QIC contribute to those outcomes. Finally, identifying and developing methods to sustain quality improvement is crucial. The literature thus far indicates chronic disease QICs are at an early evolutionary stage.

In particular, investigators need to measure consistent patient outcomes to strengthen the evidence of effectiveness of chronic disease QICs. Doing so requires reliable and valid quantitative medical research designs. However, the transition to evaluation of effective QIC
components and how to sustain them likely requires qualitative research methods, which may be a challenge for clinical investigators unfamiliar with such methods.

An appraisal of the chronic disease QIC effectiveness literature reflects poor internal validity. Randomized controlled trials have the greatest potential to maximize internal validity, but they are rare in the literature. We did not find consistent, corroborated evidence proving the effectiveness of collaboratives.

There are several limitations of these studies that both weaken the strength of the results and highlight the difficulties inherent in effectiveness research on quality improvement collaboratives. Unfortunately, conducting assessments of practice-based interventions is quite difficult, especially for the purposes of directing public policy or solidifying a research base that meets commonly referenced reporting standards. Utilization of non-randomized studies, up to this point unofficially, as the primary method for proving the effect of collaboratives on improving the quality of care is fraught with hazard. Put simply, the greater the concern about the methodological quality of some of these studies, the less we know that their results are valid. For example, when only a small fraction of sites participating in a collaborative volunteered to be studied as intervention sites, there were many ways for that sample to be a non-representative one. Leaders at underperforming sites participating in a collaborative, especially with data collection aids, likely were aware of their sites’ relative poor performance, and may not have volunteered for a study because of their own inherent belief that collaboratives are beneficial. Randomization affords the investigator the opportunity to account for both known and unknown confounders, and with special relevance for collaborative-based interventions, has the potential to eliminate biases associated with secular trends. Still, RCTs are not immune to biases, and what follows is a discussion of limitations associated with the randomized studies that analyzed the effectiveness of collaboratives.
In the study by Homer et al\textsuperscript{62}, a much higher percentage of patients enrolled in control sites were on Medicaid. In addition, as reported by the study authors, the risk of contamination in the study was high. This arises from the fact that although 43 sites were randomized at the start of the study, representing the largest sample of clinics included in our review, all forty-three practices were located in one of two geographic areas. In one of the studied regions (Detroit, MI), all of the participating sites, regardless of control or intervention status, were under the same ownership. An unknown dilution factor could have assimilated the medical practice of intervention and control sites that happened to employ the same physicians, but the effect this had is uncertain. In addition, there is no way to ascertain the level of participation or commitment at each site, given that sites were randomized, and some sites with limited investment in the project may have diminished the magnitude of effect at certain sites.

Another randomized study, undertaken by Philbin et al\textsuperscript{64}, randomized 10 practices to either an intensive quality improvement intervention or standard care, for patients with heart failure. This study was exposed to fewer potential biases than the earlier study, primarily due to minimal contamination concerns, but had limitations of its own. First, blinding was not maintained during the study. In addition, as is the case with the other randomized studies, it is difficult to know what effect any secular trends, among the control sites, may have had. Further, as with other randomized study designs analyzing the effect of practice-level interventions, it is very difficult to ascertain the intent or strength commitment of participating clinics and their leaders and practitioners. Leadership is an oft-mentioned component of successful quality improvement and collaborative interventions.\textsuperscript{27, 44} Additionally, although Philbin et al made heart failure the focus of their study, the primary evaluations were carried out from the perspective of acute inpatient diagnosis and treatment, rather than chronic outpatient care.

The final study that included a randomized component in the study design was conducted by Chin et al.\textsuperscript{60} The randomization to either standard-intensity intervention (with no
additional learning sessions) or the high-intensity intervention (attendance at 4 additional
learning sessions) did not give any significant differences between groups. However, there are
several reasons why a true benefit to collaborative interventions might have been missed here.
First, even though the study used randomization, it is vital to note that randomization occurred
1-2 years into the study, at which time all included sites had been participating in the
longitudinal, observational study, attending collaborative learning sessions, and engaging in
quality improvement measures. Thus, a majority of the attainable improvement may have
already been reached by the time of randomization. In addition, as is the case with the vast
majority of studies on collaborative interventions, documentation variation plays as substantial
role in the perceived effectiveness of collaboratives, in many of these study designs. In this
particular study, the high-intensity intervention was associated with less documentation of
diabetes education and exercise counseling. However, additional attention to medication
adjustments and communication may have left less time for counseling in a short clinic visit. Or,
physicians may have continued with counseling but spent less time documenting so in medical
charts. The uncertainty with documentation issues like these clouds a final judgment of
effectiveness of the high-intensity intervention.

The longitudinal study published by Chin et al in 2004 as well as the longitudinal study
(with the embedded randomized component) published in 2007 both are burdened with a
serious validity concern that affects any before-after study of this type. Unlike the more
sophisticated interrupted time series design that employ time series regression models to
reduce unwanted bias in their design, before-after or time-series designs have few defenses
against the risks of secular trends. In a health care environment with increasing awareness of
quality of care and quality improvement, especially since the release of the IOM reports, the
potential effects of secular trends are substantial. During observational studies like these,
unknown and unstudied events can occur at any subset of participating sites, drastically
weakening the ability of readers to make causal inferences about their results.\textsuperscript{68} Internal validity can easily be compromised, especially if studies essentially conduct two-sample t-tests on pre-intervention points and post-intervention points. Doing so gives inaccurate effect sizes if pre-intervention trends are present.\textsuperscript{68}

Certainly, not all observational should be judged equally. Achieving improved quality of care for HIV patients, as discussed in the EQHIV study\textsuperscript{37}, in many ways represents a more difficult challenge than doing so for patients with chronic cardiovascular disorders, such as hypertension or diabetes. At any particular site in the EQUIV study, especially in a non-randomized environment, variation in follow-up, medication adherence, and insurance status, could conceivably have a larger effect on care outcomes than the actual care received in the clinic. Adherence to anti-retroviral medications, for example, is directly correlated to HIV viral load, although adherence could be a confounding variable in a non-randomized study. In addition, socio-economic and demographic characteristics of the patient population, clinic organizational cultures, and financial and regulatory issues make the task considerably more complex.\textsuperscript{69} Landon et al attempted to account for known confounders by matching intervention sites to control sites according to several criteria. Rigorous observational study designs like the EQUIV study can be useful, although currently there is no method for assessing the role of leadership at participating sites. Although it is potentially just as problematic in randomized studies, since sites with strong leadership could all be randomized to control sites, the effect of a quality improvement “champion” or leader at sites participating in a collaborative is universally understood and valued by those with collaborative experience.\textsuperscript{7, 27} Sites without motivated leaders may consistently underachieve compared to centers with strong leadership. Unfortunately leadership is difficult to assess in these studies.

Another problematic issue when analyzing and interpreting the literature on the effectiveness of collaboratives is the almost universal reliance on medical records for data
collection. As discussed previously concerning the randomized intervention undertaken by Chin et al, this problem drastically undermines the ability to draw conclusions from uncontrolled studies\textsuperscript{58, 61}, in which simply increasing documentation in a practice or practices can give the impression that large improvements in care have occurred. But even for more sophisticated studies, determination of statistical significance from medical records alone is troubling. If, for example, a learning session emphasizes preventive counseling and lifestyle changes for heart failure, does finding a higher percentage of patients with “dietary counseling” in their chart indicate quality improvement? For evaluation of prevention and screening measures, an undocumented test or discussion is one that for the purposes of analysis did not occur. Further, in practice-based intervention studies where blinding is seldom performed, an increased emphasis on documentation may falsely create the sense of improvement when the only improvement has been documentation itself.\textsuperscript{57} This apparent effect may be embellished further by investigators who, although they have the best of intentions, are invested in collaborative methods and intrinsically believe in their value. Although not a central point in published guidelines for reporting observational studies\textsuperscript{70}, blinded, dual review is a vital component of systematic reviews and dual review could potentially be used to increase the validity of these types of studies. Such a measure would not eliminate potential biases that can arise from review of medical records, however.

Still, an important distinction about medical record abstraction should be made here, because some endpoints can be reliably taken from medical records. One of the most important uses of medical records is making a determination of definite clinical outcomes, such as MI, stroke, death, or other conditions that are easily defined and reliably documented. However, of the 14 studies we evaluated that analyzed the effect of collaboratives on chronic disease care, only 6 (or 43\%) even collected data on clinical outcomes. Data tables in these articles are filled with satisfaction measures, quality of life indices, and process-of-care targets,
some of which are linked to improved outcomes. However, higher indicators now do not equal improved outcomes in the future. Whereas there can be disagreement among scales and indices when researchers assemble them together to make a clinical judgment, as in a meta-analysis, there is no dispute when studies publish hard, easily defined, concrete outcomes. Of course, improving quality of care is not limited to keeping patients alive, and true quality includes many of these components. In addition, the current medical record abstraction method for data collection in these practice-level interventions is quite useful for some conditions. For instance, heart failure is a condition that arguably is quite better suited to medical record abstraction. For heart failure patients, unlike patients with other medical conditions, utilization outcomes can be used as a proxy measure for disease control. With diabetes mellitus, the pathological processes underlying the disease are often undetectable to afflicted patients, and long-term adverse events like heart attacks, strokes, and peripheral vascular complications are most commonly measured. For heart failure, a poorly controlled patient is a symptomatic one, who will likely present to the hospital with more short-term needs.

**Future Directions**

Despite the hope that collaboratives do improve care enough to lead to improvements in satisfaction, processes of care, and self-management, the evidence linking these changes to improvements in patient outcomes is somewhat underwhelming. With these limitations, however, come opportunities for improvement, and there are other indications that collaboratives may be more successful than the demonstrated evidence currently indicates. For instance, many collaboratives are currently ongoing. Although funding constraints and logistical issues have prevented long-term data collection and analysis for the purposes of publication, these opportunities will increase the future.
Although the literature to date contains some methodological flaws, the sense of cooperation, information-sharing and camaraderie that these interventions can create, both between sites and within sites, is likely already leading to improved care. In a recent study by Bray et al, researchers found that even once a collaborative project with a defined-length of operation ended, many of the quality improvement programs, from infrastructure support, regular meetings to study patient data, and leadership development, remain in place at participating clinics.\textsuperscript{54}

QICs are likely to become more frequent in pediatrics as the American Academy of Pediatrics now requires participation in quality improvement projects. In the Education in Quality Improvement for Pediatric Practice (EQIPP) program, qualified improvement projects help distribute practice-wide data on effectiveness and management.\textsuperscript{71} Enrollment in such a program allows one to receive credit that is required under Maintenance-of-Certification guidelines for Pediatricians. Collaboratives may be beneficial to streamline practices, implement efficient data management strategies, and improve patient tracking, but they are not equally suited to all diseases treated in an outpatient setting. Investigators and researchers must systematically define, through assessments of performance outcomes and medical record audits, which disease processes are more amenable to collaborative interventions and which are less so.

The gaps remaining in the literature must be addressed by subsequent investigators. As mentioned earlier, current medical management of certain chronic diseases is unclear and must be defined. Such a step requires commitment of regulatory agencies and professional medical associations alike. An effort should be made to increase the number of facilities involved in these interventions, to strengthen the ability of statistical techniques to show significant conclusions. In addition, an increased number of included clinics, from various geographic, socioeconomic, and organizational styles, must be approached and included.
Second, key investigators and journal editors must establish standards for research design and methods for evaluating collaboratives to ensure reliable, valid, and comparable findings, which may facilitate future systematic reviews and meta-analyses. Third, sponsoring agencies of QICs need to provide more information regarding the teaching and implementation of collaboratives. The IHI BTS collaborative model provides the most detailed information on collaborative start-up; however, many variants exist. Additionally, BTS collaboratives were designed to last one year or less and offer little direction for providers once a particular collaborative is over.

Finally, quality improvement remains a complex issue in health care. If inconsistent research designs prevent the identification of successful components of QICs, then the components necessary to sustain quality improvement following the completion of a collaborative is less certain. An evidence base for quality improvement itself must be improved. Future research must address concepts regarding the nature of quality problems, quality improvement processes, and the types of research needed to elucidate these processes.

As the push for improved health care processes and patient outcomes continues, quality improvement collaboratives present a popular method to develop best practices, which may shape future payment systems. Collaboration between like-minded physicians can increase camaraderie, facilitate data, speed the adoption of best practices, and most importantly, improve care for patients with chronic disease. However, the research methods to evaluate collaborative interventions require a different mindset, and standards different from those required of a drug trial or biochemical assay. As interventions effecting practices, collaboratives are tests of teamwork, leadership, and commitment. With a renewed emphasis on patient care and best practices, the true effect of these QI interventions remains to be seen. Until then, collaborative interventions may represent some of the most ambitious efforts to change outpatient care delivery for patients with chronic diseases.
Table A-1: Results of Systematic Review Literature Search

<table>
<thead>
<tr>
<th>Article</th>
<th>Year</th>
<th>Medical Topic/Condition</th>
<th>Category</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asch, et al.</td>
<td>2006</td>
<td>Congestive Heart Failure &amp; Diabetic Nephritis</td>
<td>Effectiveness</td>
<td>4 HIV/ETS participating health care organizations &amp; 4 controls</td>
</tr>
<tr>
<td>Balzer, et al.</td>
<td>2005</td>
<td>Heart Failure</td>
<td>Effectiveness</td>
<td>6 health care organizations participating in an HIV ETS collaborative</td>
</tr>
<tr>
<td>Ballard CI et al.</td>
<td>2002</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>22 primary care practices in a network owned by Bayer Health Care System</td>
</tr>
<tr>
<td>Bonham AE et al.</td>
<td>2000</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>108 organizational teams from across the US active in 1 of 4 HIV QIcs</td>
</tr>
<tr>
<td>Chin MH et al.</td>
<td>2007</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>24 health care centers in the Health Disparities Collaborative for 2 years</td>
</tr>
<tr>
<td>Chin MH et al.</td>
<td>2004</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>19 Midwest health centers</td>
</tr>
<tr>
<td>Crein SL et al.</td>
<td>2004</td>
<td>Depression</td>
<td>Effectiveness</td>
<td>37 participating organizations, 22 control sites</td>
</tr>
<tr>
<td>Fox JA et al.</td>
<td>2000</td>
<td>Acute MI &amp; Heart Failure</td>
<td>Effectiveness</td>
<td>5 hospitals in Wichita, KS</td>
</tr>
<tr>
<td>Horner, et al.</td>
<td>2005</td>
<td>Pediatric Asthma</td>
<td>Effectiveness</td>
<td>43 clinics in the greater Detroit &amp; Boston areas</td>
</tr>
<tr>
<td>Johnson DA et al.</td>
<td>2005</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>40 primary care practices in 3 rural states</td>
</tr>
<tr>
<td>Kamarckc EZ et al.</td>
<td>2006</td>
<td>Depression</td>
<td>Effectiveness</td>
<td>26 ethnically &amp; geographically diverse health care organizations</td>
</tr>
<tr>
<td>Landen BE et al.</td>
<td>2004</td>
<td>HIV</td>
<td>Effectiveness</td>
<td>44 intervention clinics &amp; 25 matched control clinics</td>
</tr>
<tr>
<td>Landon, et al.</td>
<td>2007</td>
<td>Diabetes, Asthma, Hypertension</td>
<td>Effectiveness</td>
<td>Community health clinics in the Health Disparities Collaborative</td>
</tr>
<tr>
<td>Mangena-Smith R et al.</td>
<td>2006</td>
<td>Pediatric asthma</td>
<td>Effectiveness</td>
<td>13 primary care clinics</td>
</tr>
<tr>
<td>Methen TP et al.</td>
<td>2004</td>
<td>Hypertension</td>
<td>Effectiveness</td>
<td>17 primary care practices treating Medicare patients</td>
</tr>
<tr>
<td>Olley AR et al.</td>
<td>2000</td>
<td>Acute MI</td>
<td>Effectiveness</td>
<td>18 US &amp; Canadian centers</td>
</tr>
<tr>
<td>Phibun SF et al.</td>
<td>2000</td>
<td>Heart Failure</td>
<td>Effectiveness</td>
<td>10 acute care community hospitals in upstate NY</td>
</tr>
<tr>
<td>Schroll M et al.</td>
<td>2005</td>
<td>Asthma</td>
<td>Effectiveness</td>
<td>6 intervention clinics &amp; 3 matched control sites in an asthma collaborative</td>
</tr>
<tr>
<td>Simonis EE et al.</td>
<td>2006</td>
<td>Diabetes Mellitus</td>
<td>Effectiveness</td>
<td>Managed care plans participating in state diabetes collaborative</td>
</tr>
<tr>
<td>Stockton Roberts S et al.</td>
<td>2006</td>
<td>Stroke</td>
<td>Effectiveness</td>
<td>13 Michigan hospitals in a stroke collaborative</td>
</tr>
<tr>
<td>Swanson KA et al.</td>
<td>2007</td>
<td>Depression</td>
<td>Effectiveness</td>
<td>5 samples of 11 of 108 community-based health care organizations in a national depression collaborative</td>
</tr>
<tr>
<td>Tornquist R &amp; HW Loomis</td>
<td>2007</td>
<td>Heart Failure &amp; others</td>
<td>Process/methods</td>
<td>3 collaborative addressing chronic disease or chronic care</td>
</tr>
<tr>
<td>Travaline A et al.</td>
<td>2006</td>
<td>Pediatric Inflammatory Bowel</td>
<td>Process/methods</td>
<td>N/A</td>
</tr>
<tr>
<td>Britton LF et al.</td>
<td>2008</td>
<td>Pediatric Cystic Fibrosis</td>
<td>Process/methods</td>
<td>1 center of 14 receiving a CF collaborative grant</td>
</tr>
<tr>
<td>Deprin R et al.</td>
<td>2003</td>
<td>COPD</td>
<td>Process/methods</td>
<td>18 primary care clinics in rural Maine</td>
</tr>
<tr>
<td>Fitzgerald C et al.</td>
<td>2006</td>
<td>Psychiatry</td>
<td>Process/methods</td>
<td>11 state mental health services &amp; psych hospitals</td>
</tr>
<tr>
<td>Jenkins KJ et al.</td>
<td>2008</td>
<td>Pediatric Cardiology</td>
<td>Process/methods</td>
<td>Various centers involved in pediatric cardiology collaboratives</td>
</tr>
<tr>
<td>Kristofek RL &amp; HJ Loomis</td>
<td>2007</td>
<td>Pediatric Cardiology-Hypotrophic L</td>
<td>Process/methods</td>
<td>23 ethnically &amp; geographically diverse health care organizations</td>
</tr>
<tr>
<td>Kugler JD et al.</td>
<td>2006</td>
<td>Heart Syndrome</td>
<td>Process/methods</td>
<td>Members of the Joint Council on Congential Heart Disease</td>
</tr>
<tr>
<td>Leleihan KV et al.</td>
<td>2006</td>
<td>Stroke</td>
<td>Process/methods</td>
<td>Members of a national stroke registry</td>
</tr>
<tr>
<td>Mandel HE et al.</td>
<td>2007</td>
<td>Pediatric Asthma</td>
<td>Process/methods</td>
<td>44 pediatric practices in an asthma improvement collaborative</td>
</tr>
<tr>
<td>McEwen DA et al.</td>
<td>2007</td>
<td>HIV</td>
<td>Process/methods</td>
<td>54 intervention HIV clinics vs. 37 control clinics</td>
</tr>
<tr>
<td>Meslin NR JS et al.</td>
<td>2008</td>
<td>Delay/Intelectual Disability</td>
<td>Process/methods</td>
<td>5 clinical genetics practices in Northern New England</td>
</tr>
<tr>
<td>Newton PJ et al.</td>
<td>2008</td>
<td>Heart Failure</td>
<td>Process/methods</td>
<td>N/A</td>
</tr>
<tr>
<td>Pearson KL et al.</td>
<td>2006</td>
<td>CHF, DM, depression, asthma</td>
<td>Process/methods</td>
<td>42 organizations in 5 QCs</td>
</tr>
<tr>
<td>Rosenzweig MB et al.</td>
<td>2006</td>
<td>CHF, DM, asthma</td>
<td>Process/methods</td>
<td>State-sponsored collaborative made up of PCPs of Medicaid patients</td>
</tr>
<tr>
<td>Ruppert CA et al.</td>
<td>2004</td>
<td>Pediatric rheumatology</td>
<td>Process/methods</td>
<td>2 international networks of pediatric rheumatologists</td>
</tr>
<tr>
<td>Schwayman LT et al.</td>
<td>2006</td>
<td>Stroke</td>
<td>Process/methods</td>
<td>N/A</td>
</tr>
<tr>
<td>Segal BE et al.</td>
<td>2006</td>
<td>Heart Failure</td>
<td>Process/methods</td>
<td>2 acute care hospitals in a multi-hospital collaborative</td>
</tr>
<tr>
<td>Sorensen KD et al.</td>
<td>2006</td>
<td>Pediatric Cardiology</td>
<td>Process/methods</td>
<td>2 academic medical centers</td>
</tr>
<tr>
<td>Bray PE et al.</td>
<td>2008</td>
<td>Chronic Diseases</td>
<td>Process/methods</td>
<td>13 primary care sites in NC</td>
</tr>
<tr>
<td>Brownson CA et al.</td>
<td>2007</td>
<td>Diabetes Mellitus</td>
<td>Sustainability</td>
<td>25 diverse health-care teams across the US in a collaborative</td>
</tr>
<tr>
<td>Cole EM et al.</td>
<td>2006</td>
<td>Depression &amp; Congestive Heart Failure</td>
<td>Process/methods</td>
<td>24 patients in a Northeast large not-for-profit provider health system</td>
</tr>
<tr>
<td>Davis E et al.</td>
<td>2002</td>
<td>Various</td>
<td>Sustainability</td>
<td>8 medical groups in TN</td>
</tr>
<tr>
<td>Des S et al.</td>
<td>2006</td>
<td>HIV/ADIS</td>
<td>Sustainability</td>
<td>Cross-section of Ryan White CARE Act funded clinics</td>
</tr>
<tr>
<td>Deva S et al.</td>
<td>2003</td>
<td>Diabetes Mellitus</td>
<td>Sustainability</td>
<td>Primary care clinics in a large VA managed care collaborating with the state public health department</td>
</tr>
<tr>
<td>Fremer M et al.</td>
<td>2006</td>
<td>HIV</td>
<td>Sustainability</td>
<td>9 VA clinics</td>
</tr>
<tr>
<td>Grant RW et al.</td>
<td>2006</td>
<td>Diabetes</td>
<td>Sustainability</td>
<td>14 primary care practices in a multi-hospital health care network</td>
</tr>
<tr>
<td>Gross CI et al.</td>
<td>2006</td>
<td>Chronic Disease Management</td>
<td>Sustainability</td>
<td>38 community-based physician participants</td>
</tr>
<tr>
<td>Hambrick J et al.</td>
<td>2006</td>
<td>Osteoporosis</td>
<td>Process/methods</td>
<td>6 network facilities of the NJ VHA</td>
</tr>
<tr>
<td>Huang ES et al.</td>
<td>2007</td>
<td>Diabetes Mellitus</td>
<td>Sustainability</td>
<td>17 Midwest health care clinics in the Health Disparities Collaborative</td>
</tr>
<tr>
<td>Kibbey MA et al.</td>
<td>2006</td>
<td>Medicaid</td>
<td>Sustainability</td>
<td>Mental health care facility in a VA-academic partnership</td>
</tr>
<tr>
<td>LaBlanch AD et al.</td>
<td>2004</td>
<td>Coronary Artery Disease</td>
<td>Sustainability</td>
<td>24 VA hospitals</td>
</tr>
<tr>
<td>Meyer J et al.</td>
<td>2006</td>
<td>Depression</td>
<td>Sustainability</td>
<td>Psychology clinic at Louisiana State University's Department of Psychology</td>
</tr>
<tr>
<td>Neese DC Jr et al.</td>
<td>2006</td>
<td>Depression</td>
<td>Sustainability</td>
<td>20 primary care clinics in a collaborative</td>
</tr>
</tbody>
</table>

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### Table A-2: Systematic Review Final Inclusions with Quality Ratings

<table>
<thead>
<tr>
<th>Study reference, year</th>
<th>Topic or Condition</th>
<th>Description of Study</th>
<th>Study Design</th>
<th>Participants in Analysis</th>
<th>Source of Measurement</th>
<th>Outcomes</th>
<th>Methodological Status</th>
<th>Duration of Follow-up</th>
<th>Findings</th>
<th>Internal Validity</th>
<th>External Validity</th>
<th>Addresses Obliquely Significant Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ach et al (2009)</td>
<td>Diabetes Mellitus</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Boeher et al (2005)</td>
<td>Diabetes Mellitus</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Borden et al (2004)</td>
<td>Diabetes Mellitus</td>
<td>Evaluation of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Child et al (2004)</td>
<td>Diabetes Mellitus</td>
<td>Evaluation of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Frier et al (2005)</td>
<td>Diabetes Mellitus</td>
<td>Evaluation of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Hamer et al (2005)</td>
<td>Childhood asthma</td>
<td>Analyzing the effect of pharmacological interventions on pulmonary function</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Lender et al (2004)</td>
<td>General/medical care</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Lange et al (2004)</td>
<td>Patients with HIV</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
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<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Varigos et al (2000)</td>
<td>Childhood asthma</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Sustmann et al (2000)</td>
<td>Childhood asthma</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
<tr>
<td>Rubin et al (2000)</td>
<td>Heart failure</td>
<td>Study of 159 patients with T1D treated with BSG</td>
<td>Observational, cross-sectional study</td>
<td>126 (BSG) vs. control</td>
<td>Medical records of patients at baseline and control centers</td>
<td>Baseline measurements: HbA1c, FPG, Podo podathy, Social Health Questionnaire</td>
<td>24 months</td>
<td>Moderate</td>
<td>Poor</td>
<td>Poor</td>
<td>Poor</td>
<td>No significant effect on quality of care.</td>
</tr>
</tbody>
</table>
Appendix 3: Further Methods

Web-Based Survey

We developed a web-based survey designed using Qualtrics Survey Software to validate themes and concepts uncovered in the in-depth interviews and identify new ones by increasing the representative nature of our analysis and the potential for quantitative data analysis by efficiently reaching larger numbers of informed respondents. Surveying all relevant ICN participants, i.e. the entire ICN member population, allowed maximum power of our results.

To capture the entire but limited universe of ICN participants, we asked experts in survey methodology and those with expertise in gastroenterology to review our survey rather than conduct a pilot. Expert reviewers included Anthony Viera (family physician and survey expert) and Greg Randolf (quality improvement expert in clinical settings). We provided the reviewers with a brief introduction of our study and the goals of the survey with an emphasis that to pilot the user groups would sacrifice our universe of participants, and asked them for critical feedback to improve the survey. Once we incorporated experts’ feedback, we asked two ICN members, Sandra Kim, MD, from University of North Carolina-Chapel Hill, and Amy Donegan, NP, from Nationwide Children’s Hospital in Columbus, OH, to evaluate the survey for clarity of questions and response options and ease of completion. We released the final survey to the ICN universe on June 2, 2010, and sent reminders to non-responders weekly for two weeks after the survey release. The final survey is available in Appendix 6.

We uploaded survey results from Qualtrics to an Excel spreadsheet to tabulate descriptive statistics. Response rate was calculated. We quantified themes and concepts addressed by the survey and compared them to those uncovered in the qualitative interviews.
Observation of Participants at an ICN Learning Session

We observed collaborative members at one of ICN's biannual learning sessions in Chicago, IL on April 9-11, 2010. The three-day session included an introductory day-long session for new centers joining the collaborative and two days of learning and research activities for all ICN members. We observed and recorded notes of participant activities as well as their interactions.
Figure A-3: Search Approach for Chronic Disease Collaborative Literature

Inclusion criteria: Articles written about collaboratives targeted at one or more chronic diseases, met the definition of collaborative, took place in the U.S., and written in English. Definition of a collaborative: a voluntary network of health care providers in more than one health care system who agree to share data and information on processes of care for the purposes of improving quality of care and patient outcomes.

Exclusion criteria: Articles about collaboratives (1) in settings of emergency departments, surgery, intensive care units, and general primary care without a specific disease focus; (2) focusing on organ donation, cancer screening, medical imaging, and palliative care.

MEDLINE Advanced Search Terms:
“quality” [all fields] AND (“cooperative behavior” [MeSH Terms] OR “cooperative” [all fields] AND “behavior” [all fields] OR “collaborative” [all fields]) AND “improvement” [all fields]

Limits: “humans” [MeSH Terms] AND English [lang]

Date of Search: January 9, 2010

Yield: 626 articles

51 Articles meeting criteria, +
5 Articles meeting criteria from hand-searched references

Yield: 56 articles

Process/Methods: 19 articles
Effectiveness: 22 articles
Sustainability: 15 articles

Inclusion Criteria: Studies addressing patient-oriented outcomes
Exclusion criteria: Studies evaluating effective components of collaborative, i.e. teamwork or information technology, and studies examining exclusively non-disease specific outcomes.

Yield: 13 articles
Appendix 4: Interview Protocol for Existing Sites

ImproveCareNow (ICN) Pediatric IBD Collaborative: Investigation into the Causes of Outcomes Improvement

Fact Sheet/Interview Protocol/Script for in-depth interviews with key informants at 6 to 10 participating institutions.

[Introductory script, embedding study information and agreement to participate:]

Hello, I am [Erica Peterson/Thomas Runge]. Thank you so much for talking with me today. As you recall, I am one of the two research assistants working with Dr. Michael Kappelman and Dr. Sue Tolleson-Rinehart at the University of North Carolina to help evaluate improvement processes in the ImproveCareNow Collaborative.

I am a medical student who is also earning the Master of Public Health degree at UNC. Drs. Kappelman and Tolleson-Rinehart hope that this study of improvement processes at ICN will also become the subject of my master’s paper, and my fellow student’s master’s paper.

We are interviewing collaborative members. As we mentioned in our initial e-mail message, this interview contains several open-ended questions, and should last around 30 minutes, depending on the time you have to give and what you want to tell me. We ask your permission to record the interview in order to assure we capture all you have to say as accurately as possible. We will be furnishing you with a transcript of your interview, and will welcome any additional information you want to add to that.

The intent of this study is to help the ICN Collaborative measure and understand what its improvement processes are accomplishing. We do intend to use the data to complete two master’s papers, and we will try to publish those papers in the literature. We will, of course, be making all findings available to the ICN Collaborative for its use. You and your institution will be anonymous, but we do wish to use direct quotes from your interview.

The ICN Collaborative Research Committee agrees to support the project, and the UNC IRB has determined that we are exempt. (IRB exemption # 09-2172). Please don’t hesitate to ask any questions about the project – you may contact Dr. Kappelman at Michael_Kappelman@med.unc.edu or Dr. Tolleson-Rinehart at sue@unc.edu.

Before we continue, would you please give me a verbal agree to the statements I’m about to read?

☐ I AGREE to having this interview tape recorded with a digital voice recorder.

☐ I GIVE PERMISSION for the use of direct quotes from this interview for purposes of analysis.
Now we are ready to begin!

1. First, we wanted to ask you your general impression of collaboratives, and what do you think motivates institutions to participate in them?

2. And thinking about ICN particularly, what about participating in it has been most valuable to you as a health care provider who cares for children with IBD.

3. Now we would like to focus on specific ICN quality improvement activities.
   3.a. First, just off the top of your head, can you give me a list of all the activities the ICN has started?

      [If respondent does not understand, say “That is, just whatever comes to mind when you think of the initiatives or practice changes you are involved in because of ICN.”]

   3.b. And which of those things do you think have gone well?

   3.c. And which of those things do you think have not been so successful?

4. The next questions focus on the things YOU and YOUR INSTITUTION have done as a result of your participation in ICN. Could you start by listing the changes that have been made at your institution as a result of the collaborative.

5. To respect your time, we want to focus on what you think have been the most important things you’ve mentioned – the ones you think have been most important in driving improvement at your institution.

In each case, we want to know your institution’s experience.

   5.a. Which of the list you just gave me is the most important thing?

   [do repeat back]

   5.b. For [first thing.], can you describe it in more detail? That is, tell me about how you put it into place at your institution, and how it went?

   [CHECKPOINTS: if they DO NOT mention these things, go back and ask…]
• And when did that happen?
• How long did it take to get it going?
• What did you expect it would produce?
• And about when did you expect to see results from it?
• And where does it stand now? Is it successful and ongoing? Still being implemented? Did it stop?

6. [second thing]
7. [third thing]
8. [fourth thing]

Okay, thank you so much! We are nearly done.

Clearly, your commitment to the collaborative is strong – you have invested time and energy in it. Thanks for telling me about your clinic. We also know from the data that outcomes appeared to have improved. With that understood, we want to ask you to step back and think about how improvement happens in two last questions.

9. First, do you think the outcomes improvement is a result of collaborative activity? [Pause] That is, do you think that the collaborative is already paying dividends, or that it is still too soon to have seen the effects on patient outcomes, or somewhere in between?

10. Thank you for telling me about your clinic. Last, I’d like to ask you are there other changes that have occurred at your institution/center that may have affected outcomes (as measured by the collaborative database)?

   [Can you think of other changes that would have produced these results, such as changes in your center's provider and/or payer mix, leadership, etc.]

Thank you! That ends the interview. We will be sending you a transcript soon! Is there anything else you would like to tell us?
Appendix 5: Interview Protocol for New Sites

ImproveCareNow (ICN) Pediatric IBD Collaborative: Investigation into the Causes of Outcomes Improvement

Fact Sheet/Interview Protocol/Script for in-depth interviews with key informants at 2 to 3 new institutions.

[Introductory script, embedding study information and agreement to participate:]

Hello, I am [Erica Peterson/Thomas Runge]. Thank you so much for talking with me today. As you recall, I am one of the two research assistants working with Dr. Michael Kappelman and Dr. Sue Tolleson-Rinehart at the University of North Carolina to help evaluate improvement processes in the ImproveCareNow Collaborative.

I am a medical student who is also earning the Master of Public Health degree at UNC. Drs. Kappelman and Tolleson-Rinehart hope that this study of improvement processes at ICN will also become the subject of my master’s paper, and my fellow student’s master’s paper.

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Before we continue, would you please give me a verbal agree to the statements I’m about to read?

☐ I AGREE to having this interview tape recorded with a digital voice recorder.

☐ I GIVE PERMISSION for the use of direct quotes from this interview for purposes of analysis.
Now we are ready to begin!

1. First, we wanted to ask you your general impression of collaboratives? What do you think motivates institutions in general to participate in them?

   1.a. And what made you and your institution interested in participating in these kinds of activities?

2. And thinking about your joining ICN particularly, what do you expect will be most valuable to you as a health care provider who cares for children with IBD?

   [That is, what improvements do you hope to see through your participation in ICN?]

3. Now, we would like to focus specifically on quality improvement activities.

   3.a. Are there any particular activities you have already started at your clinic to improve the quality of care for your patients?

   [If yes,]

   3.b. And which of those things do you think have gone well?

   3.c. And which of those things do you think have not been so successful?

4. What are the challenges/obstacles you face in implementing quality improvement activities?

Okay, thank you so much! We are nearly done:

In our final question, we want to ask you to step back and think about how quality improvement happens. As you may know, ICN collects various data, including certain patient outcomes.

5. What factors do you think are important for measuring outcomes improvement?

Thanks for telling me about your clinic and your expectations in participating in ICN. That ends the interview. We will be sending you a transcript soon! Is there anything else you would like to tell us?
Appendix 6: Web-Based Survey

1. We can determine when all sites joined ICN, but we are interested in when YOU think YOUR site became fully engaged in ICN and its activities. Please estimate the year you think your center became fully engaged.
   a) 2007
   b) 2008
   c) 2009
   d) 2010
   e) Our center is not yet fully engaged

2. What types of health professionals are involved with IBD patients in your pediatric IBD program (not necessarily as a part of ICN)? Select all that apply.
   a) Physicians
   b) Mid-level providers (PAs, NPs, etc.)
   c) Nurses
   d) Clinical pharmacists who are assigned to the program
   e) Nurses assistants or medical assistants
   f) Nutritionists, dietitians
   g) Psychologists or psychiatrists
   h) Social workers
   i) Financial counselor
   j) Other: Please specify ___________

3. What best describes you? If you have more than one role, please choose the one that is most applicable right now, to the pediatric IBD program at your center.
   a) I am a physician who cares for patients with IBD
   b) I am a mid-level provider (NP, PA)
   c) I am a pharmacist
   d) I am a nurse
   e) I am a dietitian
   f) I am a research assistant
   g) I am a quality improvement specialist
   h) Other: Please specify ___________

3a. Please estimate what fraction of your total IBD patient population is actively followed in the ICN database (e.g. most visits for these patients are entered)
   a) Less than 20%
   b) Between 20% and 40%
   c) Between 40% and 60%
   d) Between 60% and 80%
   e) More than 80%
   f) Unable to estimate

4. The statements below are a list of things people have told us about why the ICN collaborative is important to them. Please use the slider bars (0-10) below to tell us how important or unimportant each of these things is to YOU and YOUR involvement in ICN. If something does not matter to you AT ALL, please drag the slider bar to zero.
5. As a health care provider, what has been (or what do you expect to be) the SINGLE most valuable aspect of being a member in ImproveCareNow?
   a) Using quality improvement strategies to help patients
   b) Helping health care providers learn leadership skills
   c) Working together and sharing with providers at other centers
   d) An opportunity for research
   e) Developing, agreeing to, and using best practice standards
   f) Other: Please specify __________

6. If you have used any of the following activities, please move the slider bars below to rate each of the following according to HOW VALUABLE THEY ARE to improving the care of IBD patients at your center. If things are NOT VALUABLE at all, please move the slider bar to zero, to make sure your choice registers. If you have NEVER DONE an activity, check the box “Not Applicable.” In the “other” option, if you have no additional comments, please select “Not applicable.”
   a) Standardized IBD Clinic Template
   b) Model Care Guidelines
   c) Nutrition/Growth Algorithms
   d) Dedicated IBD Clinic
   e) Monthly Narrative Reports submitted to ICN
   f) Running small tests of change (PDSAs) at your site
   g) Pre-visit planning
   h) Regular meetings to discuss patients from Population Management Reports (PMR)
   i) Multidisciplinary team meetings, other than those used to discuss PMR
7. ICN provides several services and educational opportunities to its sites. Now we’d like you to rate the value of each of the following. IF YOU HAVE USED any of the following activities, please MOVE the slider bars below to rate each according to HOW VALUABLE THEY ARE to improving the care of IBD patients at your center.
If things are not valuable at all, please move the slider bar to zero, to be sure your choice registers.
If you HAVE NEVER USED an activity, check the box “Not Applicable.”
In the “Other” option, if you have no additional comments, please select “Not applicable.”
   a) Conference calls and webinars
      0 1 2 3 4 5 6 7 8 9 10
   b) Email/Listserv
      0 1 2 3 4 5 6 7 8 9 10
   c) Extranet
      0 1 2 3 4 5 6 7 8 9 10
   d) Monthly data reporting from ICN
      0 1 2 3 4 5 6 7 8 9 10
   e) Population management reports
      0 1 2 3 4 5 6 7 8 9 10
   f) Semi-annual Learning Sessions
      0 1 2 3 4 5 6 7 8 9 10
   g) Other – please describe.
      0 1 2 3 4 5 6 7 8 9 10

8. Below are some potential obstacles to participation in ICN. Please use the slider bars to indicate how challenging these factors are, at your center. If one or more of these is NOT a challenge for your site, please move the slider bar to zero.
If you don’t know or cannot assess, please check the box “Not Applicable.”
In the “Other” option, if you have no additional comments, please select “Not Applicable.”
   a) Financial Costs
      0 1 2 3 4 5 6 7 8 9 10
   b) It takes my time
      0 1 2 3 4 5 6 7 8 9 10
   c) It takes the time of other staff
      0 1 2 3 4 5 6 7 8 9 10
   d) It takes time to see change
      0 1 2 3 4 5 6 7 8 9 10
   e) Clinic restructuring
      0 1 2 3 4 5 6 7 8 9 10
f) Transition to electronic medical records (EMR), or other changes to medical record
   0 1 2 3 4 5 6 7 8 9 10

g) Turnover of specific, key personnel
   0 1 2 3 4 5 6 7 8 9 10

h) Lack of leadership commitment to ICN, or QI in general.
   0 1 2 3 4 5 6 7 8 9 10

i) Difficulty changing the practices of physicians, nurses, and staff
   0 1 2 3 4 5 6 7 8 9 10

j) Other – Please specify.
   0 1 2 3 4 5 6 7 8 9 10

9. Finally, please address the relative effect of each of the variables below on improved patient outcomes in ICN, since 2007. Please MOVE the slider bars below to rate each of the following according to HOW IMPORTANT THEY ARE to improving patient outcomes.
   If things are NOT IMPORTANT at all, please MOVE the slider bar to zero, to be sure your choice registers. If you don't know or cannot assess, please check the box “Not Applicable.”
   In the “OTHER” column, if you have no additional comments, please select “Not Applicable.”

   a) Improved medication management, as a result of scientific or therapeutic advances.
      0 1 2 3 4 5 6 7 8 9 10

   b) Continuing education about IBD, independent of ICN
      0 1 2 3 4 5 6 7 8 9 10

   c) Other secular trends, that is, changes in medicine generally that affect all practices
      0 1 2 3 4 5 6 7 8 9 10

   d) Natural stabilization of the course of disease over time, occurring independent of ICN
      0 1 2 3 4 5 6 7 8 9 10

   e) Other changes in your practice (addition or loss of key physicians, nurses, or other staff)
      0 1 2 3 4 5 6 7 8 9 10

   f) New patient-parent support mechanisms unrelated to ICN
      0 1 2 3 4 5 6 7 8 9 10

   g) Variation in scoring of the PGA (Physician Global Assessment)
      0 1 2 3 4 5 6 7 8 9 10

   h) How patients were entered into the database (i.e., early on, sicker patients more likely to be entered due to frequency of clinic visits compared to healthier patients)
      0 1 2 3 4 5 6 7 8 9 10

   i) The ImproveCareNow collaborative intervention
      0 1 2 3 4 5 6 7 8 9 10

   j) Other – Please specify.
      0 1 2 3 4 5 6 7 8 9 10
REFERENCES


18. Rogers CR. Client-centered therapy. 1951.


