Identifying quality improvement targets to facilitate colorectal cancer screening completion

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ABSTRACT

The colorectal cancer (CRC) screening process involves multiple interfaces (communication exchanges and transfers of responsibility for specific actions) among primary care and gastroenterology providers, laboratory, and administrative staff. After a retrospective electronic health record (EHR) analysis discovered substantial clinic variation and low CRC screening prevalence overall in an urban, integrated safety-net system, we launched a qualitative analysis to identify potential quality improvement targets to enhance fecal immunochemical test (FIT) completion, the system's preferred screening modality. Here, we report examination of organization-, clinic-, and provider-level interfaces over a three-year period (December 2011–October 2014).

We deployed in parallel 3 qualitative data collection methods: (1) structured observation (90+ hours, 10 sites); (2) document analysis (n > 100); and (3) semi-structured interviews (n = 41) and conducted iterative thematic analysis in which findings from each method cross-informed subsequent data collection. Thematic analysis was guided by a conceptual model and applied deductive and inductive codes.

There was substantial variation in protocols for distributing and returning FIT kits both within and across clinics. Providers, clinic and laboratory staff had differing access to important data about FIT results based on clinical information system used and this affected results reporting. Communication and coordination during electronic referrals for diagnostic colonoscopy was suboptimal particularly for co-morbid patients needing anesthesia clearance.

Our multi-level approach elucidated organizational deficiencies not evident by quantitative analysis alone. Findings indicate potential quality improvement intervention targets including: (1) best-practices implementation across clinics; (2) detailed communication to providers about FIT results; and (3) creation of EHR alerts to resolve pending colonoscopy referrals before they expire.

1. Introduction

Colorectal cancer (CRC) screening delivery is a complex process involving multiple interfaces (communication exchanges and transfers of responsibility for specific actions) among primary care and gastroenterology (GI) teams and pathology laboratory staff to transition patients through detection to diagnostic resolution or treatment (Tiro et al., 2014; Zapka et al., 2010). Recent quantitative analyses of electronic health record (EHR) data from an integrated safety-net healthcare system discovered: substantial clinic variation and low CRC screening prevalence overall (Tiro et al., In Press), and individual-, provider-, and system-level factors associated with delays in follow-up to positive fecal immunochemical tests (FIT) (Chubak et al., 2016). But these studies have fallen short of identifying key drivers that underlie such differences.

Prior studies have found significant variation in timely follow-up of abnormal fecal-based tests (occult blood or immunochemical) (Powell et al., 2009; Pruitt et al., 2014). Most relied on patient-level

Table 1
Qualitative methods, processes, rationales, and objectives.

Qualitative method, process	Rationale for use	Objectives
Document analysis (100+ documents). Photocopies of policies, protocols, training materials, etc. scanned into database using Optical Character Recognition (OCR)	•Understand development, implementation, and prioritization of CRC screening •Characterize organizational culture, structure, and formal protocols of the CRC screening process, including guideline dissemination and training of care teams	•Identify information that may not be recorded in or easily retrieved from HER •Catalog CRC screening-related policies and protocols •Inform chronology of CRC screening policy implementation •Identify information that may be disseminated systematically (e.g. via email vs. word of mouth)
Participant observation (90+ hours). Detailed descriptive field notes transcribed and entered into database	•Describe organizational structure, a broad range of clinical and non-clinical care behaviors as they relate to organizational protocols for CRC screening processes •Evaluate functionality of the system for referring patients with abnormal screening tests	•Inform flowcharts that depict team members' roles, responsibilities, relationships, and behaviors across range of CRC screening steps and interfaces •Validate extent to which protocols are understood and adhered to, and observe 'work-arounds' (deviations)
Semi-structured interviews (*n* = 41). Audio recordings of interviews and post-interview audio notes by interviewers transcribed and entered into database	•Clarify observations; assess organizational values, beliefs, and norms •Elucidate decision-making pathways for CRC screening processes at the network- and clinic levels •Assess perceptions of organizational protocols and practices (e.g. are they compatible with serving safety-net patients?)	•Solicit feedback about whether protocols are realistic and effective for optimizing CRC outcomes •Solicit feedback about the value of EHR as a barrier and/or facilitator to CRC screening based on experience in practice •Demonstrate degree of concordance between observed behaviors and participants' verbalized understanding of roles and responsibilities •Clarify processes not easily understood during participant-observation (e.g., values, beliefs)

quantitative data from clinical information systems (Singh et al., 2009a; Weiss et al., 2013). Few have studied challenges in screening care delivery (O'Malley et al., 2015), particularly referral of patients with abnormal fecal tests for diagnostic colonoscopy (Hudson et al., 2007; Partin et al., 2015).

Investigators partnered with the healthcare system to understand how to optimize processes within and across clinics to enhance FIT, the preferred screening modality of the system. Here, we report on an analysis that deployed 3 qualitative data collection methods to identify targets for quality improvement in FIT delivery and follow-up of abnormal results.

2. Methods

2.1. Setting

This study was conducted with data from the Parkland-UT Southwestern PROSPR Colorectal Research Center. Patients, providers, and staff were from the Parkland Health & Hospital System (Parkland), an integrated, safety-net system including a hospital, specialty clinics, and 12 primary care clinics serving primarily uninsured, low income residents of Dallas County. Nine clinics are based in low-income neighborhoods, two academic clinics adjacent to the hospital train internal/family medicine residents, and one clinic cares for employees. Based on system feasibility and capacity, Parkland's policy adopted FIT as the primary screening modality for patient at average risk for CRC (American Cancer Society, 2015). Parkland distributes a 3-sample FIT kit consisting of: flushable tissue for sample collection, 3 collection cards, 3 applicator sticks, and a return mailing envelope; English-language instructions are printed on the inside of the kit. All clinics use Epic electronic health record (EHR) system (Verona, WI) to document care delivery activities. Laboratory staff document pathology results in Cerner (Kansas City, MO) which are electronically linked to Epic.

2.2. Preliminary data

This qualitative report is part of a large explanatory, sequential, mixed-method study to inform a quality improvement initiative for Parkland. The first phase quantitatively analyzed EHR data to describe clinic-level variation in CRC screening rates and survey of providers and staff to document use of evidence-based practice across the 12 primary care clinics (Tiro et al., In Press). Although clinics varied in their patient population's recent CRC screening prevalence (range: 10.7 to 19.2%) and preferred modality (FIT versus colonoscopy), all clinics had uniformly sub-optimal rates of screening. Per Health People 2020, recent screening adherence was 40% below the target goal. Drawing from those EHR data, we identified 5 neighborhood clinics and 1 academically-affiliated clinic with the highest and lowest FIT prevalence estimates to further examine behaviors of the primary care team that might impact screening process completion. We focused on FIT delivery because the safety-net system leaders decided to prioritize offering FITs over colonoscopies due to constrained resources. In this qualitative report, we have focused on communication and coordination of roles and responsibilities around FIT distribution and result reporting among patients, primary care and specialty providers, laboratory staff, and administrative staff.

2.3. Data collection

Our conceptual model of the CRC screening process in community settings guided our initial deductive approach to qualitative data collection and analysis (Tiro et al., 2014). Following an explanatory, sequential design (Fetters et al., 2013), three qualitative data collection methods (structured observation, document analysis, semis-structured interviews) were conducted in parallel and iterative analysis facilitated identification of emergent findings that were explored further in subsequent data collection (Table 1). We focused on how providers (primary care and specialty) and staff (nurses, laboratory personnel, and clerks) understood their roles and implemented processes related to distributing FITs, reporting results, and referring patients with abnormal FITs for diagnostic colonoscopy. We were particularly interested in interfaces— "handoffs" in which team members had to communicate information and transfer responsibility for specific actions such as notifying a provider about an unsatisfactory FIT result or placing an electronic referral for a colonoscopy. Our design allowed us to iteratively sample newly identified "targets"—other team members who had a designated role in the FIT screening process. For example, after interviewing a provider or staff member and learning about their protocol, we evaluated (and assessed the existence of) institutional documents to train staff in similar roles on the described protocol. We also observed how interviewees documented their activities in the EHR and who was the receiving party notified electronically.

Data were collected by 6 qualitative scientists and scientific research staff: 3 conducted observations, 2 conducted interviews, and 4

participated in analysis. Two quantitative scientists and a physician investigator participated in data analysis and interpretation to enhance validity and reduce bias (Thurston et al., 2008; Thurmond, 2001). Staff met weekly with the senior qualitative investigator to review field notes and analyses. Decisions about subsequent data collection targets and appropriate modes of data collection (i.e. further observation, interviews or document review) were made collectively by the investigator team. Data were collected over a three-year period (December 2011–October 2014). Study procedures were approved by the UT Southwestern Medical Center Institutional Review Board (STU102011–070), in conjunction with Parkland Office of Research Administration. Study participants provided verbal informed consent.

2.3.1. Structured observations

Our structured observations began by capturing all care team members' activities in the central gastrointestinal (GI) lab to understand how patients with abnormal FITs referred for diagnostic colonoscopy were processed. Then, we traced patient referral paths back to the primary care clinics. There, we investigated how primary care teams distributed FITs, communicated with laboratory personnel about FIT results, and placed electronic referrals for diagnostic colonoscopies following an abnormal FIT result. Trained research staff shadowed care team members over several months in direct patient care activities, use of clinical information systems (triaging referrals, pathology reporting), and communication within and across primary care, GI, and pathology teams (scheduled quality improvement meetings, consultations) (Monahan and Fisher, 2010). The team used standard field note templates based on our conceptual model to annotate observations and emerging concerns. As observation progressed, we identified practice norms and patterns, how and what data are recorded in the EHR and pathology clinical information system, and performance expectations. When feasible, we clarified observations during opportunistic verbal exchanges with team members. Observations provided insight on whether clinic operations reflected organizational policies and protocols, or represented "work-arounds" (opportunistic deviations from established protocols) of the screening process (Halbesleben et al., 2008; Singh et al., 2009b). In addition to detailed fieldnotes of observations, we generated process maps depicting CRC screening steps and interfaces across the system.

2.3.2. Document analysis

We compiled and analyzed all Parkland materials describing policies and protocols to implement and evaluate the CRC screening process. In addition to asking care team members during observation and interviews, we systematically searched the Parkland intranet for training protocols and other documents, by clinical service line (e.g. GI Lab) and key word (e.g. colorectal, screening test). Materials included administrative documents (policies, proposals, and project reports), position descriptions, organizational charts, training materials, written communications, budgets, and patient billing documents. When possible, documents were digitally recorded and transformed into text using Optical Character Recognition software (otherwise recreated through transcribed field notes) for analysis (Meyen, 2008).

2.3.3. Semi-structured interviews

We purposively sampled key actors (e.g. lead physician, site administrator, nurses) from the 6 selected primary care clinics. We also iteratively sampled additional interviewees from multiple points along our conceptual model (Tiro et al., 2014) based on emergent data. Overall, we interviewed 41 individuals from the 6 primary care clinics, all 6 clinic-affiliated pathology laboratories, both GI clinics, and 3 centralized departments (appointment scheduling, financial counseling, and health information management). Interviewees included 6 lead physicians, 5 lead nurses, 5 lab supervisors, 4 other clinicians, 10 clinic site administrators and unit managers, 9 patient financial services and scheduling staff, and 2 health information managers. Following our

conceptual model, we developed a general interview guide reflecting key clinical steps (e.g. FIT screening, FIT processing, diagnostic colonoscopy referral), then tailored additional domains of inquiry based on each interviewee's relevant roles and responsibilities (e.g. lab supervisor vs. lead physician vs. financial counselor; see Appendix). Interview questions probed participants' understanding of the CRC screening process, communication through clinical information systems, differences between referring patients for diagnostic versus screening colonoscopy, team member roles, and quality metrics. We solicited feedback about factors at different levels (organizational, clinic, provider) that may account for patient drop-offs or delays in care. Interviews lasted 45–60 min, over 1–2 sessions, enabling investigators to compare notes, follow up on themes raised by other interviewees, and confirm and clarify elements of the earlier interview (i.e. member-checking). All interviews were audio-recorded and transcribed verbatim by professional vendor; participants received a $15 honorarium.

2.4. Data analysis

As data were collected, we conducted thematic analysis of all structured observation fieldnotes, interview transcripts, documents (~1000 pages) using NVivo 9.0 (QSR International, Australia). First, investigators and research staff used the CRC screening process model (Tiro et al., 2014) to develop a deductive coding scheme that reflected: 1) transitions between detection, diagnosis, and treatment, and 2) steps and interfaces among individual team members and sites. In an iterative coding process, we examined actual utterances, expressions and concepts against participant characteristics, documents, and site codes to identify relationships and link codes to the conceptual model (Fereday and Muir-Cochrane, 2006). We met weekly to identify and interpret findings, and inductively revise the coding schema accordingly, resolving discrepancies by consensus (Cohen and Crabtree, 2008). Iterative analysis across sources further enabled identification of "work-arounds" and informed refinement of the interview guides for subsequent administration (Thurmond, 2001; Brown et al., 2015).

3. Results

Thematic analysis identified challenges to optimal CRC screening delivery during 3 key clinical activities in the screening process model: (Tiro et al., 2014) FIT kit distribution and return; (Zapka et al., 2010) transfer of FIT result data across clinical information systems, and (Tiro et al., In Press) communication and coordination during colonoscopy referral following abnormal FIT, particularly for complex patients with comorbid conditions.

3.1. FIT kit distribution and return

FIT kit distribution and return method varied substantially within and across clinic sites. Some variation resulted from 'work-arounds' while other differences stemmed from more systematic efforts at quality improvement in individual clinics. Opportunistic feedback from providers and pathology lab managers about common reasons for invalid FIT results enabled individual clinics to modify their kits before distribution. For instance, some clinics used highlighting or bright labels to call attention to important elements such as writing in the date of sample collection. However, there were no systematic efforts to consolidate this feedback to inform trans-clinic quality improvement initiatives.

Although patients could return FIT kits by mail, some clinics encouraged patients to return kits in person at the clinic lab to prevent loss or postal system delays. Clinics were concerned about delays because laboratories were required to reject kits if time window between sample collection and laboratory receipt exceeded manufacturer guidelines and CLIA regulations. Therefore, to discourage delays due to mailed return, some clinics removed the return envelope before distributing kits. Return instructions were not printed on the kits; rather,

they were provided verbally and in the after-visit summary, a separate document given to patients. Despite availability of Epic *SmartPhrases* (standardized language), kit return instructions were not systematically generated and content varied within and across teams and clinics.

Notably, the manufacturer-assembled kit only included English instructions. Some clinics did not provide written instructions in Spanish; others had Spanish instructions in the after-visit summary. One provider reported inserting Spanish instructions into the kit if she felt the patient did not fully understand her verbal instructions. Document comparison of her Spanish instructions with the manufacturer version revealed divergent explanations about the importance of FIT.

Although we found quality assessment and improvement efforts in several different clinics, many efforts were neither informed by nor shared with other clinics. For example, following receipt of a sub-optimal CRC screening quality metric score based on the health system's quality improvement/assurance analysis of EHR data, one clinic reported conducting a thorough review of their FIT distribution and return process. The clinic site leaders (administrator, provider, nursing, pathology lab) met with the Medical Director to review procedures and devise a quality improvement plan including:

- Removal of return mailing envelopes;
- Application of date stickers to collection cards;
- Verbal instruction by the provider and nurse;
- Simplification of instructions to suit safety-net patients' literacy level; and
- Revision of the FIT flowchart to reflect sequential activities of each team member.

However, we found this plan was never shared with lead physicians of the other clinics. Consequently, local improvement processes were unable to rise to the level of system best practices despite initial distribution of clinic screening rates.

3.2. Transfer of result data across clinical information systems

Key information regarding the frequency and reasons for invalid FIT results were not systematically available to primary care teams. The only test result data available to clinical providers in the EHR were number of cards tested and overall test result. However, lab staff documented multiple data elements on paper and/or in their pathology information system, including collection dates, each card's individual test result, and reasons for invalid results. Overall result was determined as follows:

(a) If ≥1 card was positive then overall result was positive;

(b) If ≥1 card could be processed and none were positive, then overall result was negative; and

(c) If all 3 cards could not be processed, then overall result was invalid.

The FIT manufacturer provides no guidance regarding clinically appropriate follow-up if fewer than 3 cards are processed. Sensitivity and specificity estimates required 3 valid cards (Allison et al., 2007). Parkland's policy allows providers to use clinical judgment about whether to repeat the FIT or accept the screening result if < 3 valid cards are processed. Providers and lab managers understood this policy but expressed uncertainty about exercising it given their lack of access to detailed result information.

3.2.1. Communication and coordination during colonoscopy referral

A third challenge was communication and care coordination between primary care and GI teams during colonoscopy referral, particularly for patients for whom colonoscopy with moderate "conscious" sedation may be contraindicated (e.g. hypertension, COPD) (American Society of Anesthesiologists, 2002). GI staff triaged colonoscopy referrals based on patient age, family or prior medical history, co-morbidities, and severity of symptoms. Some of these triage criteria require

additional documentation in the EHR by primary care providers (e.g., symptoms reported do not meet direct access criteria, medical clearance from specialists for high-risk co-morbid patients). In such cases, the GI nurse manager "denies" the referral in the EHR, pending further action, with free text notes explaining actions required for referral resubmission. However, some primary care providers were unaware of or failed to respond to the "denied" referral. If the ordering provider took no action or if GI staff could not reach the specialist for additional documentation, the referral would expire in the EHR by default after 12 months. The EHR lacked a standard process to identify and notify team member(s) responsible for resolving 'denied' referrals.

4. Discussion

Our multi-level approach identified: (Tiro et al., 2014) practice variation within and across clinics in FIT kit distribution and return method, (Zapka et al., 2010) incomplete transfer of key FIT result data across clinical information systems, and (Tiro et al., In Press) sub-optimal communication and coordination during diagnostic colonoscopy referrals. Results illustrate how sequential activities of different provider teams rarely evolved into consistent, coordinated action across the integrated system to enable patients to complete the complex CRC screening process (Brown et al., 2015; Weaver et al., 2013).

Our results contribute to the quality improvement literature by moving beyond patient- and provider-perceived barriers to identify how lack of documentation and coordination of quality improvement efforts across clinics within this integrated system hampered systematic implementation of "best practices." (Halbesleben et al., 2008) Our systematic analysis revealed where and why communication failures occurred between team members and identified potential targets for practice change intervention. For example, redesigning health information technology to accommodate more comprehensive data transfer across clinical information systems could enhance consistency of communication among clinicians and staff (O'Malley et al., 2015).

In our study, pathology staff did not systematically share key clinical outcome and process data with primary care teams due to continued reliance on paper documentation and data elements that could not be transferred from the pathology database to the EHR. Without information on the frequency and reasons for invalid FIT results, primary care teams lacked information that could help them improve patient education during FIT distributions and prevent invalid results; (Feufel et al., 2010) this knowledge gap constrained design of quality improvement efforts. Unfortunately, use of multiple clinical information systems, as we found in pathology and primary care, make interoperability a major obstacle to meaningful use of health information technology.

In addition, our data highlight how safety-net systems sometimes choose less patient-centered policies due to limited resources. Requiring patients to return FIT kits in person is challenging for patients lacking their own transportation; however, safety-net system leaders had to balance this concern against structural constraints: FITs are currently processed at each clinic and all mail is received at a central office then distributed to each clinic. System leadership was concerned that FIT kits would get lost in the mail or that transit time would delay laboratory processing after the 14-day window required by manufacturer guidelines and CLIA rules. Currently, there are no federal or state programs to support CRC screening costs; thus, Parkland could only use county tax funds to support this preventive service. Redesign of central laboratory process was not feasible during the study window, according to system leaders.

While EHR alerts can strengthen primary care-specialty interfaces, we found breakdowns in the referral process persist for other reasons (Singh et al., 2011). Prevalence of co-morbid patients requiring clearance from specialty providers for diagnostic colonoscopy will continue to pose systemic challenges to healthcare systems. Prior studies found negative associations between co-morbidities and CRC screening

completion (Bazargan et al., 2009). Our results suggest this association is due not only to lack of patient follow up but also to shortfalls in care team members' efforts to communicate necessary protocols to obtain medical clearance. Inadequate attention to communication and EHR documentation practices among providers increases medical errors and may also contribute to delays in screening completion and abnormal follow-up.

Information technology-driven quality reports could improve communication between primary care and specialists (O'Malley and Reschovsky, 2011). Routine reports extracted from the pathology clinical information system would enable primary care clinic leaders to quantify various sources of delays in FIT result reporting. Time stamps calculating average time associated with each delay type could inform intervention targets (patient, provider or laboratory staff) (Murphy et al., 2014). Administrators could also generate EHR reports to determine whether delays in diagnostic colonoscopy scheduling and completion are longer for high-risk co-morbid patients needing clearance. These reports could be distributed to a case manager for routine outreach and navigation (Myers et al., 2008; Raich et al., 2012).

Our analysis of the CRC screening process emphasize how actors across primary and specialty care, in fact, constitute a multi-team system (Smith and Toonen, 2007; Mathieu and Marks, 2001). Our findings highlight how team member roles, responsibilities, and communication patterns are critical to successfully improve FIT distribution and transition to diagnostic colonoscopy for those with abnormal results (Zapka et al., 2010; Taplin et al., 2010). To be effective, multi-team systems need protocols that ensure "closed-loop communication," so that information is sent, received, confirmed, and acknowledged between parties (Weaver et al., 2013; Singh et al., 2008; Salas et al., 2009; Bunnell et al., 2013). Future research should explore how the addition of mid-level staff (e.g. clinical nurse specialists, nurse practitioners, physician assistants) to care teams could expedite colonoscopy referrals following an abnormal FIT (Hudson et al., 2007; Shaheen et al., 2000), particularly for co-morbid patients (Bayliss et al., 2014).

4.1. Limitations

Few healthcare organizations have resources to support the intensive time and staffing effort of our design. However, our approach may inform rapid cycle quality improvement efforts to address process targets. Our study identified process challenges in a large, integrated safety net setting; challenges may differ for systems serving insured, higher health-literacy populations. Problematic interface between primary and specialty care is likely even higher in settings that do not share a common EHR. Future research should examine these challenges in small group practices or other loosely affiliated clinical networks (Messina et al., 2009).

5. Conclusion

FIT result reporting involves multiple care teams, interfaces, and points of communication. Our qualitative findings supplement an earlier quantitative EMR-based analysis and illuminate why CRC screening rates are low and why diagnostic colonoscopy referrals are delayed. We pinpointed potential quality improvement intervention targets: (Tiro et al., 2014) facilitating best-practices implementation across clinics; (Zapka et al., 2010) improving laboratory communication to providers about FIT testing and results; and (Tiro et al., In Press) creating EHR-based alerts to resolve pending colonoscopy referrals. Organizations that systematically apply both quantitative and qualitative data can better identify intervention targets to improve delivery of screening in real-world settings.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.pmedr.2018.01.004.

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