Mixed methods for complex adaptive systems: Reconceiving communication in healthcare delivery research

Simon Craddock Lee, PhD MPH
Associate Professor of Clinical Sciences
Population Science & Cancer Control Program
Harold C. Simmons Comprehensive Cancer Center
University of Texas Southwestern Medical Center
Implementing Interventions along Translational Continuum

- Basic discovery
  - biomedical, behavioral, or epidemiologic factor

- Efficacy
  - optimal conditions

- Effectiveness
  - real-world settings

- Implementation
  - put into practice

- Dissemination
  - distributing information about an intervention

- Practice-based evidence

- Maintenance
  - institutionalization of a program, policy, or practice
Context matters: before, during, after Implementation

Pre-implementation
Baseline

During Implementation

Post-implementation

Mixed methods to assess effects- intended and unintended – and at multiple levels
Conceptual model for intervention adoption

Intervention complexity: episode vs element
Intervention complexity: level of care vs stakeholders
Intervention complexity: user engagement vs degree of tech
Perceptions of identity and interactions

![Bar chart showing estimated marginal means for clinic team and research team in-group and cancer center, with error bars indicating variability. The x-axis represents the teams (Clinic Team and Research Team), and the y-axis represents the level of agreement, ranging from 1 to 7.](image-url)
Each type and transition in care offers opportunities for improvement. Some have been identified in the figure, but within and between types of care, there are interfaces and steps that may be articulated to identify more opportunities. Effectiveness of the process is measured at the patient and population levels based on the outcomes shown. Differences in service delivery and effectiveness across populations are the metrics of disparities (equity).
Embedded intervention study within larger observational design:

A comparative effectiveness trial of benefits, harms, and costs of mailed invitations to:
- Complete and return an enclosed FIT card, or
- Schedule and complete a colonoscopy
CRC Screening is a Process

Type of Care: care delivered to accomplish a specific goal, such as detection, diagnosis, and treatment

Transition: set of steps and interfaces necessary to go from one type of care to another

- FIT
- FIT Kit Distributed
- FIT Kit Returned
- Referral Screening COL
- Apppt Scheduling
- Screening COL Completed
- Transition #1

- Detection
- Performance of Screening
- Results Reporting: Abnormal FIT
- Results Reporting: Normal FIT
- Referral Diagnostic COL
- Apppt Scheduling
- Referral annual FIT
- Transition #2

- Diagnosis
- Performance of Follow-up
- Symptomatic primary care patients
- Non-primary care patients with abnormal test or symptoms
- Diagnostic COL Completed
- Transition #3

- Treatment
- 1st Visit
- Results Reporting: Cancer Detedled
- Adenoma
- Normal COL Elevated Risk
- Normal COL Average Risk
- Normal COL
- Recommend COL surveillance
- Recommend COL

Interface: interactions that link steps and involve transferring information and/or responsibility among patients, providers, and clinic staff

Tiro et al. CEBP 2014; 23(7):1147-58
<table>
<thead>
<tr>
<th>Type of care</th>
<th>The care delivered to accomplish a specific goal of care across the cancer continuum, such as detection, diagnosis, or treatment.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steps of care</td>
<td>Each type of care involves multiple specific activities such as performing the screening test or delivering a dose of chemotherapy.</td>
</tr>
<tr>
<td>Transition</td>
<td>The set of interactions necessary to go from one type of care to another, such as the transition from detection to diagnosis.</td>
</tr>
<tr>
<td>Interface of care</td>
<td>A finer grade of transition where information and responsibility are transferred, such as communicating test results, calling to schedule an appointment, or contact between physicians to communicate details of a referral.</td>
</tr>
</tbody>
</table>
Where are failures in process occurring?

- **Abnormal FIT Result** (n=1,267)
  - 13 Patient refused
  - 22 Colonoscopy not ordered
  - 15 Failure to inform patient of abnormal FIT
  - 16 CRC screening inappropriate

- **Colonoscopy Ordered** (n=1,201)
  - 3 Patient refused
  - 33 Order returned to PCP pending clearance
  - 5 CRC screening inappropriate
  - 66 GI staff inaction

- **Colonoscopy Authorized by GI Lab** (n=1,094)
  - 112 Patient didn’t call

- **Patient called to Schedule Colonoscopy** (n=982)
  - 21 Patient refused
  - 52 Patient no-show or canceled pre-op
  - 2 CRC screening inappropriate
  - 1 Pre-op denied pending labs
  - 23 Pre-op not scheduled

- **Pre-op Completed and Colonoscopy Scheduled** (n=883)
  - 106 Patient no-show or canceled
    - 3 Provider
    - 10 System
    - 14 Unknown
    - 19 Colonoscopy completed after 12 months

**Diagnosis** (Performance of Follow-up)

- Diagnostic Colonoscopy completed within 12 month (n=731)

**Summary:**

- **57% patient-level factors**
- **18% provider-level factors**
- **22% system-level factors**

*Martin et al Am J Medicine, 2016*
Data Collection Phases

Phase 1
- EMR Abstraction to Rank Order Primary Care Clinics on CRC Screening Rates and Focus Deployment of Qualitative Methods

Phase 2
- Document Analysis
- Structured Observation
- Structured Interviews
- Organizational Survey

Phase 3
- Triangulate Findings across Data Collection Methods
- Testing of Hierarchical, Multi-level Models to Identify Influential Patient and Organizational Factors
# CRC Screening Rate at Cohort Entry by clinic, 2010-2011 cohort, N=41,127

<table>
<thead>
<tr>
<th>Clinics¹</th>
<th>% Total Screened</th>
<th>% FIT Screened</th>
<th>% COL/SIG</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community-Based Clinic 1</td>
<td>11.1</td>
<td>5.3</td>
<td>5.8</td>
</tr>
<tr>
<td>Clinic 2</td>
<td>13.0</td>
<td>2.8</td>
<td>10.2</td>
</tr>
<tr>
<td>Clinic 3</td>
<td>17.9</td>
<td>13.1</td>
<td>4.8</td>
</tr>
<tr>
<td>Clinic 4</td>
<td>15.8</td>
<td>11.2</td>
<td>4.6</td>
</tr>
<tr>
<td>Clinic 5</td>
<td>13.0</td>
<td>8.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Clinic 6</td>
<td>19.2</td>
<td>15.5</td>
<td>3.7</td>
</tr>
<tr>
<td>Clinic 7</td>
<td>16.2</td>
<td>11.5</td>
<td>4.7</td>
</tr>
<tr>
<td>Clinic 8</td>
<td>10.7</td>
<td>0.4</td>
<td>10.3</td>
</tr>
<tr>
<td>Academic Clinic 1</td>
<td>14.4</td>
<td>3.0</td>
<td>11.4</td>
</tr>
<tr>
<td>Clinic 2</td>
<td>14.8</td>
<td>1.9</td>
<td>12.9</td>
</tr>
<tr>
<td><strong>Total (Range)</strong></td>
<td><strong>14.6 (10.7-19.2)</strong></td>
<td><strong>8.1 (0.4-15.5)</strong></td>
<td><strong>6.6 (3.7-12.9)</strong></td>
</tr>
</tbody>
</table>

¹ Community-Based Clinic 9 not included in cohort until 2012

Tiro et al (In Press) Pop Health Mgmt
Triangulation of Qualitative Methods

Structured Observation
- Observation of physicians, nurses, lab staff, administrators during usual working activities, including communications with patients and co-workers, EMR data entry.
- 90+ hours at 10 sites

Structured Interviews
- Lead Physicians, Clinical and Administrative Staff at primary care and gastroenterology clinics
- N=32, transcribed and analyzed

Document Analysis
- Analysis of policies, procedures, training manuals, quality reports, lab worksheets, notes from observation, transcripts
- Over 1,000 pages, using Nvivo

Focus: (1) Reporting of FIT Results and (2) Referral for Diagnostic COL
<table>
<thead>
<tr>
<th>Qualitative Method</th>
<th>Rationale for use</th>
<th>Process</th>
<th>Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Document Analysis</strong></td>
<td>Understand development, implementation, and prioritization of CRC screening</td>
<td>Photocopies of documents scanned into database using Optical Character Recognition (OCR)</td>
<td>Identify information that may not be recorded in or easily retrieved from EMR</td>
</tr>
<tr>
<td></td>
<td>Characterize organizational culture, structure, and formal protocols of the CRC screening process, including guideline dissemination and training of care teams</td>
<td></td>
<td>Catalog CRC screening-related policies and protocols</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Identify information disseminated systematically (e.g. via email vs. word of mouth)</td>
<td>Inform chronology of policy implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Inform flowcharts of team members’ roles, responsibilities, relationships, and behaviors across screening steps and interfaces</td>
<td>Validate extent protocols are understood and adhered to, and observe ‘work-arounds’ (deviations)</td>
</tr>
<tr>
<td><strong>Participant Observation</strong></td>
<td>Describe organizational structure, a broad range of clinical and non-clinical care behaviors as they relate to organizational protocols for CRC screening processes</td>
<td>Detailed descriptive field notes transcribed and entered into database</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluate functionality of the system for referring patients with abnormal screening tests</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Semi-structured Interviews</strong></td>
<td>Clarify observations; assess organizational culture (e.g. values, beliefs, and norms)</td>
<td>Audio recordings of interviews and post-interview audio notes by interviewers transcribed and entered into database</td>
<td>Solicit feedback about whether protocols are realistic, effective for optimizing outcomes</td>
</tr>
<tr>
<td></td>
<td>Elucidate decision-making pathways for CRC screening processes at the network- and clinic levels</td>
<td></td>
<td>Solicit feedback on EMR as a barrier and/or facilitator per experience in practice</td>
</tr>
<tr>
<td></td>
<td>Assess perceptions of organizational protocols and practices (e.g. are they compatible with serving safety-net patients?)</td>
<td></td>
<td>Demonstrate degree of concordance between observed behaviors and verbalized understanding of roles and responsibilities.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Clarify processes not easily understood during participant-observation (e.g., values, beliefs)</td>
</tr>
</tbody>
</table>
Structured observation at clinics and structured interviews with teams revealed modification in how FIT kits are distributed:

- adding colored labels to encourage patient writing collection date
- removing mailing envelopes from the kits to encourage in-person return
- providing verbal and/or written instructions re: 10-day return

Implications: Differences may contribute to clinic variation in patient adherence and % of returned samples that staff label as canceled or invalid

Informed additional analyses: Quantify impact of variation on the rate of canceled and invalid results
Structured observation of lab processes, structured interviews with lab supervisors and document analysis revealed loss of key data from returned FIT kits, specifically:

- Collection date, card result, or reason for invalid card are documented on paper, not in Cerner
- EMR set up to only accept certain data from Cerner; lab processing dates only in Cerner

Implications: A lack of systematic data impairs ability to assess frequency of and communicate reasons for invalid samples. Thus, providers using the HER do not know how best to change patient instructions

Informed additional analyses: Use Cerner to quantify the source of delays in reporting FIT results (attributable to patient, lab, or provider behavior) and average time associated with each delay
Structured interviews with PCPs revealed frustration with colonoscopy referral process because many were being delayed or denied “pending further action”.

Structured observation of GI staff revealed a centralized process for triaging referrals; GI staff may delay or deny a referral pending medical clearance for co-morbidity related safety. GI waits for the ordering PCP to resolve. If no action, GI staff close the referral.

Document analysis of GI clinic procedures detailed triage criteria, but not how GI staff communicate these delays and denials.

Implications: Poor coordination between PCP and GI may create delays & drop-offs at COL referral step.

Planned analyses: Quantify whether delays are longer for high-risk, co-morbid patients.
Our findings illuminate why CRC screening rates are low and why diagnostic colonoscopy referrals are delayed.

We pinpointed potential quality improvement intervention targets:

1. facilitating best-practices implementation across clinics;
2. improving laboratory communication to providers about FIT testing and results;
3. creating EHR based alerts to resolve pending colonoscopy referrals.
Settings where health communications occur should be recognized as complex, adaptive systems.

Intervention adoption depends on intervention complexity, including factors highly influenced by context.

Interventions may have impacts on multiple levels, both intended and unintended consequences.

Mixed method designs can enhance assessment of context effects at multiple levels, before, during and after implementation.
# Team Science Acknowledgements

<table>
<thead>
<tr>
<th>UT Southwestern:</th>
<th>UTSW Qualitative Research Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jasmin A. Tiro, PhD</td>
<td>Robin Higashi, PhD</td>
</tr>
<tr>
<td>Amit Singal, MD</td>
<td>Emily Marks, MS</td>
</tr>
<tr>
<td>Celette Sugg Skinner, PhD</td>
<td>Lisa Quirk, MPH</td>
</tr>
<tr>
<td>Ethan Halm, MD MPH</td>
<td></td>
</tr>
<tr>
<td>David E. Gerber, MD MSCS</td>
<td></td>
</tr>
<tr>
<td>John V. Cox, MD</td>
<td></td>
</tr>
<tr>
<td><strong>UT Health School of Public Health</strong></td>
<td></td>
</tr>
<tr>
<td>Bijal A. Balasubramanian, MBBS PhD</td>
<td></td>
</tr>
<tr>
<td>Katelyn Jetelina, PhD</td>
<td></td>
</tr>
<tr>
<td>Jessica Austin, MPH</td>
<td></td>
</tr>
<tr>
<td><strong>Parkland Health &amp; Hospital System:</strong></td>
<td></td>
</tr>
<tr>
<td>Noel Santini, MD</td>
<td></td>
</tr>
<tr>
<td>Donna Persaud, MD, MPH</td>
<td></td>
</tr>
<tr>
<td>Sobha Fuller, RN</td>
<td></td>
</tr>
<tr>
<td><strong>Southern Methodist University</strong></td>
<td></td>
</tr>
<tr>
<td>Austin S. Baldwin, PhD</td>
<td></td>
</tr>
<tr>
<td>Deanna Denman, PhD</td>
<td></td>
</tr>
<tr>
<td><strong>Texas A &amp; M University</strong></td>
<td></td>
</tr>
<tr>
<td>Richard Street, PhD</td>
<td></td>
</tr>
<tr>
<td><strong>U California-Merced</strong></td>
<td></td>
</tr>
<tr>
<td>Deborah Wiebe, PhD</td>
<td></td>
</tr>
<tr>
<td><strong>UTSW Quantitative Analytics Core</strong></td>
<td></td>
</tr>
<tr>
<td>Wendy Bishop, MS</td>
<td></td>
</tr>
<tr>
<td>Joanne Sanders, MS</td>
<td></td>
</tr>
<tr>
<td>Caroline Meijas</td>
<td></td>
</tr>
<tr>
<td><strong>UTSW Research Coordination</strong></td>
<td></td>
</tr>
<tr>
<td>Katharine McCallister</td>
<td></td>
</tr>
<tr>
<td>Claudia Chavez</td>
<td></td>
</tr>
<tr>
<td>Juan Mijares</td>
<td></td>
</tr>
<tr>
<td>Julie Richardson</td>
<td></td>
</tr>
</tbody>
</table>