Chapter 6  Policy and Procedures for Program Evaluation

Overview

Evaluation of the Colorado Colorectal Screening Program will provide information about patient demographics and clinical outcomes necessary for assessing Program efficacy. Evaluation will also provide information about process outcomes that will measure Program reach, efficiency and quality of services provided. The role of the Evaluation unit is to define clinical and process outcomes of interest and to standardize collection and receipt of these data from all clinic partners. The Evaluation unit will compile Program data, conduct quality control checks, provide feedback to clinic partners and produce regular progress and data quality reports.

I. Data Collection and Submission

Clinic partners are required to collect and submit data for each patient screened through the Program. These data include demographic information, clinical outcomes and process-related outcomes as described below under Minimal Data Elements. A helpful tool for clinics to gather much of the needed data elements is the Evaluation Data Collection Form (see Appendix C or the Program website).

Data is submitted through a web-based data collection system housed at the Colorado Department of Public Health and Environment (CDPHE). This centralized database allows for the standardization of data to be submitted by multiple clinic partners to the Program. Using a centralized system, the Program’s Evaluation staff can perform ‘real time’ data checks, quality control and Program evaluation. Participating clinics are required to use the data system unless they do not have adequate internet access. In this case, clinics may record their data on a paper tracking system that is subsequently provided to the Program by fax or mail.

Although the data system will house individual patient information, including personal health information, no patient identifiers will be accessible by the Program. CDPHE will only provide de-identified data to the Program for evaluation purposes. The Program’s Evaluation staff will work with clinic partners to assure that they have the capacity, in terms of staff, resources and technical support, to collect and submit the necessary data, as well as serve as a resource for Program clinic partners.

Minimal Data Elements: The minimal data elements clinic sites collect and submit to the Program are defined as follows:

Patient Demographic Information:
- Date of birth
- Gender
- Race and ethnicity
- Personal and family history of colon cancer
- Personal and family history of adenomatous polyps
- Specific symptoms at time of screening
- Patient eligibility (insurance and income information)
Clinical Outcomes:
- Type of screen performed (colonoscopy, flexible sigmoidoscopy, CT colonoscopy, barium enema)
- Quality assurance questions (cecum reached, quality of prep)
- Screening outcome (completed, patient refused, patient no show, patient lost to follow up)
- Screening result (negative, positive-biopsied)
- Pathology result (polyp size, histology, # adenomas removed)
- Cancer characteristics (tumor size, histology, location, stage)

Process Related Outcomes:
- Response to outreach efforts (how did clients hear about the program?)
- Screening completion rate: # screened / # appointments scheduled
- Number of patients provided assistance with transportation and translation
- Quality and timeliness of care

II. Explanation of Evaluation Terms

Inadequate Exam
- Any screening exam that was not completed due to poor preparation or not reaching the cecum

Screening Outcome
- Completed: A screen was performed
- Patient refused: Patient refused screening exam
- Patient no show: Patient did not show up for scheduled screening exam
- Patient lost to follow up: Patient cannot be reached

Screening Result
- Negative: Endoscopy without tissue removed and/or polyps identified
- Positive: Endoscopy with polyps detected and/or tissue removed for pathological review

Pathology Result – In cases with multiple biopsies, report the most severe histology. Histologies are listed below in decreasing order of severity (cancer = most severe)
- Cancer: Includes adenocarcinoma, carcinoma, carcinoid tumor, in situ or other neoplasia
- Adenoma/pre-cancerous: Includes adenomatous, villous, tubular, tubulovillous or pre-cancerous finding
- Hyperplastic/benign: Any polyp identified as hyperplastic or benign
- Other/unknown
- No diagnostic abnormality: Biopsy taken of completely normal colon tissue

III. Evaluation

Patient, Clinical, and Process Related Outcomes. Evaluation staff will conduct and report patient demographics and clinical outcomes quarterly for both for internal and external purposes. Data is monitored internally to ensure that the Program is meeting its screening goals and to ensure that it is reaching the target population all across the state. External monitoring ensures
that we are meeting our contractual obligations. Report lengths and details vary depending on the quarter, however, the most in-depth reports consist of three main sections: patient demographics, clinical outcomes and process related outcomes. Reported demographics include the number of patients screened, patients’ gender, the number of people presenting with symptoms at the time of the screen and the number of people screened who have a family history of colon cancer or adenomatous polyps. Included in the reporting of the clinical outcomes are the percent of positive exams and their associated pathology results. The last major report section focuses on the process related outcomes, which includes the number of people who utilized transportation and / or translation services and how they heard about the Program.

**Patient Satisfaction Outcomes.** Evaluation staff will administer an annual mail-based survey in order to measure patient satisfaction with the Program with respect to outreach materials, navigation activities, the screening procedure, and follow-up care. Anonymous surveys will be mailed to a randomly generated sample of patients from all participating clinic partners who were screened through the Program in the previous year. The surveys will be completed and returned to Evaluation staff, who will compile, analyze, and report on the data.

**Provider Satisfaction Outcomes.** An annual on-line survey will be administered in order to measure provider satisfaction with the Program. The goals of the survey are to assess how the Program is received by the providers, areas for improvement, and its ease or difficulty to integrate into clinic systems. A link to the survey will be emailed to all providers, endoscopists, patient navigators, billing staff, and administrative staff that work with, and are actively participating in, the Program. Survey responses will be captured by the on-line survey system and downloaded by the Evaluation staff who will analyze and report on the data.

**Screening Rates.** In order to measure the impact of the Program on state-wide colon cancer screening rates, data from the Behavioral Risk Factor State Survey will be obtained and compared to previous data. Evaluation staff will analyze this data for both the uninsured and the insured populations.

**IV. Data Cleaning**

From time to time a clinic may receive a data cleaning report. Upon receipt of a report, which will include patient id numbers and the field(s) that show a discrepancy, clinics will log into the data system and update the data appropriately after comparing the reported discrepancy to the information found in a patient’s medical record.

**V. Data Audits**

Evaluation staff will conduct annual data audits, either in person or virtually, for all participating clinics. The purpose of the audit is to assure patient eligibility, report clinic specific data entry accuracy rates, track process related improvements over time, and monitor the quality of care provided to patients screened through the Program. From the previous fiscal year, either twenty percent of patients screened or ten patients, which ever is greater, will be randomly selected for audit. Clinic partners audited in person will be asked to provide Evaluation staff access to the patient’s medical chart, including endoscopy and pathology reports, and patient navigation logs in order to compare the data entered into the data system with the data in the patient’s chart. Virtually audited clinic partners will be asked to fax de-identified patient data and consent forms to the coordinating center. Once audits are complete, a detailed report will be generated by the Evaluation staff and provided to the clinic.
**VI. Patient Consent**

Clinics must obtain a signed consent form from all patients who enter the Program (see Appendix D) prior to entering patient data into the data system. This consent form, found in both English and Spanish, allows CDPHE to have access to the patient's identifiable data and for CDPHE to share their de-identified data with the Program. Consent forms do not expire and patients do not need to be re-consented for future exams. Keep the original consent form in the patient's chart for auditing purposes; do not fax the forms to the Program.

For patients who are unwilling to sign a consent form, generic data will be used in the place of patient identifiable data. See Appendix E for instructions on how to enter data for a patient who refuses consent. This allows the Evaluation staff to accurately report screens by ethnicity, gender, symptoms and family history, while respecting the patient's wishes.

**VII. Contacts**

Please visit our website for current Program contacts.

http://colonscreen.coloradocancercenter.org
Figure 6-1: Data Flowchart

**YOUR CLINIC**
1. Screens for patient eligibility
2. If eligible, schedule screening

**ENDOSCOPY PROVIDER**
1. Screens patient
2. Faxes endoscopy report to your clinic

**PATHOLOGY PROVIDER**
1. Analyzes tissue samples
2. Faxes pathology report to your clinic

**YOUR CLINIC**
1. Enters endoscopy report data into data system
2. Enters pathology result data into data system
3. Run reports to view and clean data

**THE DATA**
1. Housed at CDPHE
2. The Program receives weekly data transfers

**Positive Exam**

**Negative Exam**
Appendix C: Evaluation Data Collection Form

Colorado Colorectal Screening Program
Evaluation Data Collection Form

e-CaST ID #

Data from Patient:

<table>
<thead>
<tr>
<th>Name:</th>
<th>Date of Birth: / /</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender: □ Male □ Female</td>
<td></td>
</tr>
</tbody>
</table>

Ethnicity (Use "Unknown" if patient is neither Hispanic or Non-Hispanic White):
□ Hispanic □ Not Hispanic □ Unknown □ Do not want to answer □ Unsure

Race:
□ White □ African American □ Asian
□ Pacific Islander □ American Indian □ Native Hawaiian
□ Alaska Native □ Other □ Client refused to answer
□ Unknown

Enrollment:
Lawfully Present in Colorado-HB 1023 Affidavit on File □ Yes □ No
Insurance Status: No Private Insurance or Medicaid □ Yes □ No
Medicare Part A □ Yes □ No
<250% of Federal Poverty Level □ Yes □ No

How did the patient hear about the program?
□ Brochure/Poster □ Clinic Staff/Physician □ Friend/Family Member □ HealthFair
□ Newspaper Ad □ Radio Ad □ TV Ad □ WWC Event or Staff □ Hotline
□ Other

Primary Contact Info (City, Zip and State will be required but can be taken from client file):
County of Residence: ______________________

Medical History:

Symptoms (list all): ______________________

Family History (mother, father, sibling, child) of Colorectal Cancer?
□ Yes → Who: __________ → Age (earliest dx) __________
□ No
□ Unknown

Family History (mother, father, sibling, child) of adenomatous polyp(s)?
□ Yes → Who: __________ → Age (earliest dx) __________
□ No
□ Unknown

Personal History of polyp(s)?
□ Yes → Age at diagnosis: __________ → Type of Polyp: □ Adenomatous □ Benign □ Other
□ No
□ Unknown

Personal History of Colorectal Cancer?
□ Yes → Age at diagnosis: __________
□ No
□ Unknown

Has or Suspected Genetic Familial Dx (FAP or HNPCC)?
□ Yes □ No □ Unknown

Has Inflammatory Bowel Disease (Crohn's disease or Ulcerative colitis)?
□ Yes □ No □ Unknown

Reason for exam:
□ Screening Only □ Surveillance □ Symptomatic (please list above) □ Positive FIT/FOBT

CRC Primary Care Provider Referral Form Completed and Signed □ Yes □ No
CRC Primary Care Provider Referral Date: __________

Scheduled Exam Date: __________
### Data from Endoscopy Report:

<table>
<thead>
<tr>
<th>Exam date:</th>
<th><strong>/</strong>/___</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of exam:</td>
<td>□ Colonoscopy  □ Sigmoidoscopy  □ Barium Enema</td>
</tr>
<tr>
<td>Exam results:</td>
<td>□ Negative  □ Positive/Biopsied</td>
</tr>
<tr>
<td>Facility:</td>
<td>___________________________</td>
</tr>
<tr>
<td>Endoscopist:</td>
<td>___________________________</td>
</tr>
<tr>
<td>If colonoscopy - was cecum reached?</td>
<td>□ Yes  □ No  □ Unknown</td>
</tr>
<tr>
<td>Quality of Prep for Screen</td>
<td>□ Excellent/Good  □ Adequate/Fair  □ Poor  □ Not Reported</td>
</tr>
</tbody>
</table>

### Data from Pathology Report:

**Important** - If exam is positive, report worst pathology (numbered worst to least where one is worst) and histology (ordered from worst to least).
If adenoma, obtain size of polyp from endoscopy report.
If cancer call CCSP.

- □ Cancer
- □ Adenoma (largest polyp ≥ 1 cm)
- □ Benign/Hyperplastic
- □ Adenoma (largest polyp <1 cm)
- □ Other/Unknown
- □ No Diagnostic Abnormality

| Histology: | ____________ |
| Container Count: | ________ |

If adenoma, # of adenomas removed: ____________
Size of largest adenoma removed (cm): ____________ (from endoscopy report)

High Grade Dysplasia (if HGD not mentioned, then no): □ Yes  □ No

### After screening procedure:

Was transportation provided to patient? □ Yes  □ No
Was translation provided to patient? □ Yes  □ No
Appendix D: Consent Forms

CONSENT FOR USE OF CCSP INFORMATION

By signing this, you give your approval to provide information about your screening test to the Colorado Colorectal Screening Program (CCSP) and the Colorado Department of Public Health and Environment (CDPHE), who stores that information.

- I agree that my doctor and medical personnel who screened me for the Colorado Colorectal Screening Program (CCSP) may share information about my screening test and the results with the Colorado Department of Public Health and Environment (CDPHE).

- CCSP and CDPHE are very careful to keep my information private. They will use my information only for the purpose of the Program. CDPHE will provide general information regarding my screening test, my screening test results and other related information to CCSP. CCSP will use the information to find out how to improve the program. CDPHE will not share my personal information such as name, address and birth date with CCSP.

When I sign this form, I am saying that I understand what this form says and that I agree to it.

___________________________________________
Patient’s Name (please print)

___________________________________________
Patient’s Signature

___________________________________________
Date Signed

___________________________________________
Clinic Staff Member Signature

Clinic Use:

___________________________________________

Patient’s Last Name: _________________________

Patient’s First Name: _________________________

Date of Birth: _____/_____/__________

Colorectal Screening Program Patient ID: ________
CONSENTIMIENTO PARA EL USO DE LA INFORMACIÓN DE CCSP

Al firmar esto, usted otorga su permiso para la entrega de información sobre su prueba de evaluación al Colorado Colorectal Screening Program (CCSP) y al Departamento de Salud y Medio Ambiente de Colorado (Colorado Department of Public Health and Environment o CDPHE), que guarda dicha información.

- Yo estoy de acuerdo en que mi médico y el personal médico que me realizó la evaluación para Colorado Colorectal Screening Program (CCSP) compartan la información sobre la prueba de evaluación y los resultados con el Colorado Department of Public Health and Environment (CDPHE).

- El CCSP y el CDPHE tienen mucho cuidado de mantener la información en forma privada. Ellos utilizarán la información con el solo propósito del programa. El CDPHE ofrecerá información general sobre mi prueba de evaluación, los resultados de la prueba y otra información relacionada al CCSP. El CCSP utilizará la información para saber como mejorar el programa. El CDPHE no compartirá mi información personal como el nombre, domicilio y fecha de nacimiento con el CCSP.

Al firmar esta forma, yo declaro entender la forma y estar de acuerdo con lo expresado en la misma.

Nombre del paciente (letra de molde por favor)

___________________________________________
Firma del paciente

___________________________________________
Fecha en que se firmó

Firma del personal clínico

Clinic Use:

___________________________________________
Apellido del paciente: _________________________
Nombre del paciente: _________________________
Fecha de nacimiento: _____/_____/__________
ID del paciente de la evaluación colorrectal: ________
Appendix E: Instructions on how to Enter a Patient who Refuses Consent

Entering Data While Protecting Patient’s Privacy:

The patient has decided that he/she does not want to share personally identifiable data outside of the clinic. While we understand this, we would still like to collect the same unidentifiable data on these patients as we do on consenting patients. This will allow us to accurately report screens by ethnicity, gender, symptoms and family history, while still respecting the patient’s wishes. In order to assist us in our goal, please enter the patient’s data, as you normally would, using the following for identifiable data:

Name: Deidentified Patient

SSN(last 4): 1234

Date of Birth: 06/30/(year the patient was born)

Primary Phone: 123-456-7891

Address: 123 Main Street
           Denver, Colorado  88888

Please note that the patient must still meet all eligibility requirements.