The Commission on Cancer’s National Accreditation Program for Rectal Cancer (NAPRC) and Expected Outcomes

University of Virginia

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Milestones in Rectal Cancer Management

- Description of APR for rectal cancer by Miles
- 1980s: Introduction of the TME
- 1980s: first trials of radiotherapy in rectal cancer
- 1990s-20s: MDT approach for rectal cancer
- 1990’s: Swedish Trial and Dutch TME trial
- 2000s: CR07 and expansion in the use of laparoscopic surgery for rectal cancer

Good quality Surgery remains the corner stone of Rectal Cancer management.
PubMed publications retrieved using “quality of surgery” and “colorectal cancer”

Quality outcomes in Rectal Cancer Surgery

- Survival (the ultimate quality outcome)
- Local Recurrence (linked to survival)
- Quality of Surgery (most readily measurable - linked to local recurrence/survival)
  - TME Grade
  - Resection Margins
  - Lymph Node Yield
- Permanent stoma formation rate
- Long-term quality of Life
Why do we need a national accreditation program?

- **What** surgery is being done?
- **Who** is performing surgery?
- **Where** is surgery being done?
- **Is** treatment evidence-based?
- **Outcomes**?

**USA Rectal Cancer Outcomes**

- Increase in sphincter-preservation rate from 26.9% in 1988 to 48.3% in 2003
- Rate flat after 1999
- Elderly, male, black, Medicaid, low-income zip code predicted colostomy
- "most radical resections for rectal cancer in U.S. hospitals result in a colostomy"

**University of Minnesota Study 2007**

- Nationwide Inpatient Sample
- 20% stratified random sample of U.S. inpatients
- 1988-2003

- 41,631 pts with radical proctectomy
- 16,510 (39.7%) sphincter-sparing
- 25,121 (60.3%) colostomy

Dis Colon Rectum 2007; 50:1119-1127
 Variability in Reconstructive Procedures Following Rectal Cancer Surgery in the United States

- Hospital discharge data from 21 states with county-level place of residence information (2002-04)
- 20,000 proctectomies
- 50% of cases non-restorative (APR)
- Only 20% of counties with colostomy rate <40%

Colostomy Rates

<table>
<thead>
<tr>
<th>Source</th>
<th>Year(s)</th>
<th>n</th>
<th>Country</th>
<th>Tumor distance from anal verge</th>
<th>Colostomy Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norwegian Rectal Cancer Project</td>
<td>1993-1999</td>
<td>2136</td>
<td>Norway</td>
<td>&lt;12 cm</td>
<td>38%</td>
</tr>
<tr>
<td>Dutch Trial</td>
<td>1996-1999</td>
<td>1805</td>
<td>Netherlands/Sweden</td>
<td>&lt;15 cm</td>
<td>32%</td>
</tr>
<tr>
<td>MRC CRO-7</td>
<td>1998-2005</td>
<td>1350</td>
<td>UK/Canada/NZ/SAF</td>
<td>&lt;15 cm</td>
<td>35%</td>
</tr>
<tr>
<td>German Trial</td>
<td>1994-2002</td>
<td>799</td>
<td>Germany</td>
<td>&lt;16 cm</td>
<td>25%</td>
</tr>
<tr>
<td>Trans-Tasman</td>
<td>2001-2006</td>
<td>323</td>
<td>Australia/New Zealand</td>
<td>&lt;12 cm</td>
<td>33%</td>
</tr>
<tr>
<td>AHRQ and OSHPD (CA)</td>
<td>2002-2004</td>
<td>19,912</td>
<td>USA</td>
<td>rectum</td>
<td>50%</td>
</tr>
</tbody>
</table>
11 states’ hospital discharge data 2003-2004 

>7500 proctectomies by 2600 surgeons

40% of surgeons performed ONLY non-restorative procedures (APR) for their rectal cancer patients!
- higher mortality rates (2x) and longer lengths of stay (2 days)

“Restorative” (LAR) surgeons were specialized by virtue of more pelvic pouch and anorectal procedures

CA Office of Statewide Health Planning and Development database 2000-2005
Rectal cancer patients identified by ICD-9 code (154.1)
LAR and APR by CPT code (48.63 and 48.5)
7187 rectal cancer surgeries in 321 hospitals
Hospitals classified as Low (≤30), Medium (31-60), or High (≥60) volume based on number of rectal cancer surgeries performed during the study period
### Hospital Volume

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Low</th>
<th>Medium</th>
<th>High</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yearly case volume (avg)</td>
<td>1-5</td>
<td>6-10</td>
<td>11-24</td>
<td></td>
</tr>
<tr>
<td>Number of hospitals</td>
<td>232</td>
<td>65</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>Number of patients</td>
<td>2364</td>
<td>2666</td>
<td>2137</td>
<td></td>
</tr>
<tr>
<td>Mortality (%)</td>
<td>2.1</td>
<td>1.1</td>
<td>0.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Complications (%)</td>
<td>22</td>
<td>24</td>
<td>20</td>
<td>0.709</td>
</tr>
<tr>
<td>Sphincter preservation (%)</td>
<td>51</td>
<td>55</td>
<td>64</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Length of stay (mean # days)</td>
<td>9.7</td>
<td>9.2</td>
<td>8.8</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

California Office of Statewide Health Planning and Development database (2000-2005)

- **72% of hospitals “low” volume**
- **Only 30% patients treated in “high” volume hospitals**
- **Mortality, colostomy rate, and length of stay higher in low volume hospitals**

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**Consortium for Optimizing the Surgical Treatment of Rectal Cancer**
National Cancer Database (NCDB)

- Hospital-based cancer registry sponsored by the CoC and ACS
- >1 million case reports yearly from ~1500 CoC-member institutions
- Collects data on 70% of all new invasive cancer diagnoses in the U.S. each year

NCDB Rectal Cancer Patients 2013

- N=21,393
  - Approximately 50% of annual U.S. rectal cancer cases
- Number of hospitals=1327
  - Approximately 90% of all CoC-accredited hospitals
- Range of rectal cancer patients treated: 1 to 286
- Median number of patients per hospital: 27
How Experienced is the Typical U.S. Rectal Cancer Hospital?

Answer:

- Not very!
- 70% of hospitals treat fewer than 20 patients/year
- Only 30% of hospitals are “high volume” by common definition
- Only 6% of hospitals treat more than 50 patients/year

Are Most U.S. Rectal Cancer Patients Treated in Higher Volume Centers?

Answer:

- No
- More than half of patients treated in hospitals that see fewer than 30 cases/year
- Only 25% of patients treated in the highest volume centers
Is Treatment Evidence Based?

- NCDB data 2006-2011
- Clinical stage II/III rectal cancer patients (n=30,994)

Examined adherence to evidence-based guidelines for neoadjuvant chemoradiation therapy (NCRT) use based on center type, volume, and geographic location

- Academic, Community, Comprehensive
- Volume: Low (≤10/year), Medium (11-30/year), High (≥31/year)


Is Treatment Evidence Based?

- Adherence to guidelines for NCRT use suboptimal and variable

- Only 74% of stage II/III rectal cancer patients received NCRT (and no improvement over time)

- Significant variation by hospital volume
  - High 78.1% vs. Low 69.4% (p<0.001)
  - 28% of hospitals treated >30 pts/yr

- Significant variation by geography
  - Midwest 76.1% vs. South 70.6% (p<0.001)

- No variation by hospital type

Quality of Surgery/Pathology: Lymph Node Yield

- Minimum of 12 lymph nodes is an internationally-accepted marker for quality of surgery and pathology assessment in rectal cancer*

- NCDB data 2008-2012
  - 53,911/59,653 (90.4%) patients with lymph node yield documented

- Rate of suboptimal lymph node yield (<12) was 35.5%
  - Rate in patients receiving NCRT was 41%
  - Rate in patients treated with surgery alone was 30%


Circumferential Resection Margin (CRM)

- Closest measured distance from outermost edge of tumor or involved lymph node to the mesorectal fascia (<1 mm = “involved”)*

- Powerful prognostic factor for local and distant recurrence and survival**

- Convenient and immediate quality measure for surgical technique and pre-treatment decision-making process

*College of American Pathologists 2011
**Nagtegaal and Quirke. J Clin Oncol 2008;26:303-312
NCDB +CRM data

- NCDB 2010-2011
- Clinical stage I-III
- N=16,619 patients
- 17.2% with +CRM
- Variation by clinical stage and operation type
- No variation by facility type, volume, or NCRT


US Rectal Cancer Care

Low-volume hospitals

Inexperienced providers

High colostomy rates
US Rectal Cancer Care (cont’)

• Suboptimal adherence to evidence-based guidelines for use of neoadjuvant therapy

• Suboptimal surgery

• High rates of +CRM, a surrogate marker for poor oncologic outcomes in rectal cancer patients

• U.S. outcomes are likely inferior to European countries that have instituted national programs to improve quality of rectal cancer care

Fixing the Problem
European Efforts…

Rectal Cancer Standardization
Norwegian Experience

- Early 1990s: TME accepted as the national standard of surgery for rectal cancer
- 1993: Launch of the national *Norwegian Rectal Cancer Project*
- Several surgical workshops on TME technique led by Bill Heald
- Standardization of surgical technique and pathologic assessment
- 1994: establishment of Norwegian Rectal Cancer Registry
  - All rectal cancer registered prospectively
  - Each institution received feedback about their results
- Goal: reduce local recurrence to about 10%
Rectal Cancer Standardization - Norwegian Experience. Has it Worked?

- Implementation of national standard surgical techniques and training, standardized TME techniques
- Increased proportion of patients undergoing TME (78% to 92%)
- Reduced local recurrence and improved survival in the TME group

Wibe et al. Dis Colon Rectum 2002

Rectal Cancer Standardization - Norwegian Experience. Has it Worked?

Risk of local recurrence after rectal cancer surgery

Risk of overall mortality after rectal cancer surgery
Rectal Cancer Standardization
Norwegian Experience- Why has it worked?

- Initiated by the clinicians, not imposed by health – care authorities
- Constant feedback of the results to each clinician and each institution
- Multidisciplinary approach to the project from the onset

Rectal Cancer Centers of Excellence
Swedish Experience

- 1995: establishment of Swedish Rectal Cancer Registry
- The Swedish Rectal cancer project similar to the Norwegian experience
  - Workshops and video demonstration of TME
  - Centralization of rectal cancer treatment to larger units and specialized colorectal surgeons
  - Difference: More use of radiotherapy based on Swedish studies (Stockholm I /II trials)
Swedish Experience
Has it worked?

- 1994-1997: (TME project and introduction of sub-specialization to rectal cancer surgery)
- three surgical/histopathological workshops held at Karolinska Hospital regarding the TME technique and importance of CRM
- Comparison of TME group with Stockholm I and II data
- Decrease the rate local recurrence to 6% with the TME project (p<0.0001)
- Decrease cancer related mortality from 15% to 9% (p<0.002)

Martling AL et al, Lancet 2000

Swedish Experience
Has it worked?

- Centralization of 4 hospitals into 1 CoE
- Local recurrence decreased from 8% to 3.5% (p=0.04)
- 5 year survival increased from 38% to 62% (p=0.003)
- Multivariate analysis: new colorectal unit independent predictor of long-term survival

Khani & Smedh. Colorectal Dis 2010
Rectal Cancer Centers of Excellence
Danish Experience

• 1994: Danish National Rectal Cancer Registry
• National implementation of standards:
  – Total mesorectal excision
  – Improved staging
  – Centralization of care

• Increased 5-year survival from 37% to 51% after new standards

Bulow et al. Colorectal Dis 2010

Danish Experience.
Has it worked?

• Analysis of 10,632 rectal cancer patients
• National implementation of standards:
  – Total mesorectal excision
  – Improved staging
  – Centralization of care
• Increased 5-year survival from 37% to 51% after new standards

Bulow et al. Colorectal Dis 2010
...European Success

- Over two decades the implementation of TME and MDT-focused care has significantly altered rectal cancer outcomes:
  - Lower rates of local recurrence and permanent stoma
  - More patients receiving evidence-based care adhering to accepted guidelines
  - Better recruitment to clinical trials
  - Improved monitoring of standards and outcomes
  - More patients cared for in fewer centers
  - *Rectal cancer outcomes now exceed those for colon cancer*

The UK Rectal Cancer Model

1. Regional MDTs of trained Specialist Providers:
   - Surgeon
   - Radiologist
   - Pathologist
   - Radiation and Medical Oncologists

2. Evidence-Based Protocols for patient care

3. External Audit to confirm adherence to protocols
OSTRiCh Proposal

- Create a national rectal cancer program in US based on already-successful international models:
  - Train and accredit MDT’s at motivated hospitals
  - Establish standards pertaining to defined protocols of patient care and process
  - Prospective data collection to track compliance, quality of care, and outcomes
  - Administered by American College of Surgeons Commission on Cancer (CoC)

“Inclusive”

- Goal: Expand access to high-quality rectal cancer care
**Proposed Standards**

- **Set of 18 Standards** pertaining to program structure and the process of patient care
  - **“Structure Standards”** (5)
    - Creation and Training of Multidisciplinary Team
  - **“Process Standards”** (13)
    - MDT discussions, timing of treatment, imaging, pathology assessment, communication, data submission

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**Quality Improvement**

Feedback to programs on 10 Quality Indicators (QI’s):

<table>
<thead>
<tr>
<th>APR rate</th>
<th>Involved distal resection margin rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anastomotic leak rate</td>
<td>Mesorectal grade rate</td>
</tr>
<tr>
<td>Reoperation rate</td>
<td>Lymph node yield ≥ 12 rate (excluding patients with neoadjuvant therapy)</td>
</tr>
<tr>
<td>30-day mortality rate after surgery</td>
<td>Local recurrence rate</td>
</tr>
<tr>
<td>Involved CRM rate</td>
<td>3-year disease-free survival rate</td>
</tr>
</tbody>
</table>

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Training is Key

- Existing CoE programs did not have central training component

- Rectal Cancer is different
- Skill set is not universally present, but is teachable:
  - Total Mesorectal Excision
  - Pathology assessment
  - MRI protocol and reading
  - Administration and Teamwork

Up, Up, and Away!

CoC National Rectal Cancer Accreditation Program (NRCAP)
OSTRiCh Rectal Cancer Program proposal endorsed by the American College of Surgeon's DROP-C and Board of Regents
June 6, 2014
## Standard 1.1
The institution must be accredited by the American College of Surgeons Commission on Cancer (CoC)

## Standard 1.2
The institution must have a defined Rectal Cancer Multidisciplinary Team (RC-MDT) with a minimum of one named member from each of the following specialties: Surgery, Pathology, Radiology, Medical Oncology, and Radiation Oncology. The RC-MDT meets at least bi-weekly. A member from each of the required specialties attends 50% of the meetings annually.

## Standard 1.3
A Rectal Cancer Multidisciplinary Team (RC-MDT) Patient Coordinator is in place to coordinate all activities of the RC-MDT. A policy and procedure is in place to define patient coordination activity, including, but not limited to, communication with departments within the facility, referring physicians and the patient, patient appointments, and data collection and reporting.

## Standard 1.4
The institution must have a Rectal Cancer Program Leader who is the chair of the Rectal Cancer Multidisciplinary Team (RC-MDT). The Rectal Cancer Program Leader is a required member of the cancer committee and acts as the liaison between the Rectal Cancer Program, the RC-MDT, and the cancer committee. The Rectal Cancer Program Leader reports the finding of monitoring activity to the cancer committee at least annually.

## Standard 1.5
All members of the institution’s RC-MDT complete the prescribed Rectal Cancer Program Training Course (RCP-TC) once within the first survey cycle.
### Standard 2.1
Ninety-five (95) percent of newly diagnosed rectal cancers are confirmed by biopsy prior to treatment. The cancer committee with assistance from the rectal cancer leader performs an annual audit of compliance.

### Standard 2.2
Facility participates in RQRS and submits rectal cancer patient data within 30 days of the patient’s first contact with the facility.

### Standard 2.3
Ninety-five (95) percent of rectal cancer patients are staged (systemic and local tumor) prior to definitive treatment. Systemic staging should be by CT scanning of the chest, abdomen, and pelvis. Local tumor staging should be by rectal cancer-protocol MRI. Staging is discussed and documented at the MDT conference.

### Standard 2.4
Ninety-five (95) percent of MRI staging results for newly diagnosed rectal cancer patients are conveyed by a standardized synoptic report as recommended by ACR.

### Standard 2.5
A CEA level is obtained on all newly diagnosed rectal cancer patients prior to definitive treatment.

### Standard 2.6
**All patients undergo an individualized treatment-planning discussion at a MDT conference prior to definitive treatment**

### Standard 2.7
A pretreatment recommendation summary (TRS) is provided to all newly diagnosed rectal cancer patients and a copy is provided to their referring or primary care physician prior to commencement of therapy.

### Standard 2.8
For previously untreated patients, 90% of patients begin definitive treatment within 30 days of the patient’s initial clinical evaluation at the institution.

### Standard 2.9
Pathology reports using a standardized synoptic format and are issued within two weeks of the definitive surgical resection for ninety-five (95) percent of rectal cancer patients undergoing a definitive surgical resection of the primary tumor at the facility. The pathology reports include all required CAP data items, tumor regression grade, mesorectal grade, and quantitative measurement of CRM in millimeters.

### Standard 2.10
**All patients undergo individualized treatment-outcome discussion at MDT Conference after completion of definitive surgical treatment**

### Standard 2.11
All rectal cancer patients and their referring physician (when other than primary care physician) receive a treatment completion summary and follow up plan within 4 weeks of the treatment completion.

### Standard 2.12
Seventy-five (75) percent of newly diagnosed rectal cancer patients begin recommended adjuvant treatment (if elected by the patient) within 6 weeks of definitive surgical resection of the primary tumor.

### Standard 2.13
The cancer committee working with the rectal cancer program leader develops and implements a continuous quality assurance/quality improvement process and an evaluation of adverse outcomes. Evaluations include activity specified in the standards and performance measures. Identified problems are addressed by the rectal program leadership team to ensure that performance expectations are met.
Education Program

NRCAP Training Course (NRCAP-TC)

Group Training
- Program Administration and Teamwork
- Surgery Training Module (ASCRS)
- Pathology Training Module (CAP)
- Radiology Training Module (ACR)
- MDT Patient Coordinator Training Module

Specialty-specific Training

Implementation

- NRCAP Standards Manual written
- Survey Application Record (SAR) designed
- 6 pilot site surveys completed in March 2016
- Target date for open application is early 2017
www.ostrichconsortium.org