BIOMARKER TESTING - IMPACT ON TREATMENT

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BACKGROUND

The American Recovery and Reinvestment Act of 2009 (ARRA) provided the Agency for Healthcare Research and Quality (AHRQ) with $300 million to improve healthcare outcomes by providing evidence that would assist patients and providers with medical decision making. The Centers for Disease Control and Prevention (CDC) created Specialized Cancer Registries to enhance data collection within the National Program of Cancer Registries (NPCR). The Rhode Island Cancer Registry (RICR) was one of the 10 central cancer registries selected to take part in the Comparative Effectiveness Research (CER) project. Selection was based on the history of high quality data collection and implementable plans to enhance data collection. The central cancer registries selected were: Alaska, California, Colorado, Florida, Idaho, Louisiana, New Hampshire, North Carolina, Rhode Island and Texas. These states are geographically diverse, have different racial and ethnical makeup and range from rural to urban.

The objective of the CER project was to develop a dataset that could be used by researchers to improve cancer care. The dataset was based on existing cancer registry data. Included were patient characteristics, tumor characteristics and first course of treatment data. The dataset was expanded to include information on biomarker testing, detailed treatment information and data items that recorded why treatment was not given or stopped. CER focused on newly diagnosed cancers of the breast, colon, rectum as well as chronic myelogenous leukemia (CML). An additional goal was to expand data sources and increase the use of electronic reporting. In addition, data sources were to be expanded with increased use of electronic reporting. The impact of biomarker testing on treatment and survival were also reviewed. The CER project involved collecting the expanded dataset for the diagnosis year 2011. Treatment data collection was limited to one year after the date of diagnosis. A limited number of eligible cases could not be added due to late submission and interstate data exchange.

The RICR was one of seven states selected to take part in the extension of the CER project through the Patient Centered Outcome Research (PCOR) Project. The states selected to take part in the PCOR project enrolled previously missed cases, completed the collection of treatment data beyond one year post diagnosis and conducted active and passive follow-up to document vital status, cancer status and co-morbid conditions.

METHODOLOGY

With the goal of enhanced surveillance over time, RICR staff created a database that includes all data items found in the standard NAACCR format as well as the additional CER project data items. Newly diagnosed cancer cases of the breast, colon, rectum as well as CML diagnosed in 2011 were added to the database. This database was used to monitor completeness, timeliness, perform quality control and to conduct follow-up during the CER and PCOR projects. Active and passive follow-up continue. RICR staff added cases of breast, colon and rectum diagnosed in 2012 and on and expanded passive and active follow-up activities to include these years. While it was impossible to collect the detailed information involved in the original CER project, the standard NAACCR format contains extensive diagnostic and treatment information as well as follow-up information. The RICR conducts annual death clearance and NDI linkage to improve survival data.

Follow-up activities identified clinical, diagnostic and treatment information that was not submitted in the original case report. RICR files were revised to include the additional information.

The decision was made to focus on HER2 testing and the use of Biological Response Modifiers (BRM) to treat breast cancer patients. Collaborative Stage Site Specific Factor 15 was used to identify these cases. This included patients diagnosed with invasive breast cancer that were HER2 positive with positive lymph nodes, HER2 positive without lymph node spread that are ER/PR negative or with a tumor size greater than 2cm, less than 35 years of age, with a grade of 2 or 3.

A coding change occurred when Herceptin (Trastuzumab) was reclassified as a biologic response modifier (BRM). In the past, Herceptin (Trastuzumab) was coded as a chemotherapy agent. While the new coding schema was available for 2012 and 2013, CER coding criteria required BRM to be coded as chemotherapy. RICR staff visually reviewed CER case reports of patients included in this project to identify HER2 positive cases. A coding change was made to the project database to identify HER2 positive patients treated with Herceptin (Trastuzumab) to facilitate observation while central cancer registry files remain pristine with established coding conventions.

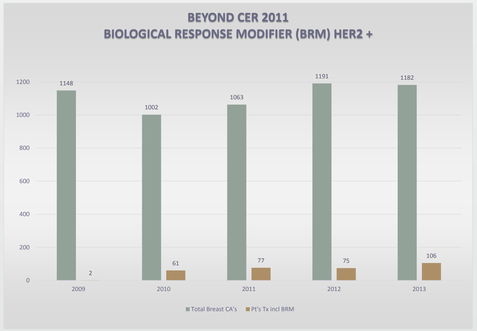
KRAS testing is used to identify patients with advanced (SEER 7) colorectal cancer who might benefit when treated with a specific chemotherapy regiment. Site Specific Factor 9 was used to identify these patients. This group included patients found to be KRAS Wild Type normal, not expressed or negative.

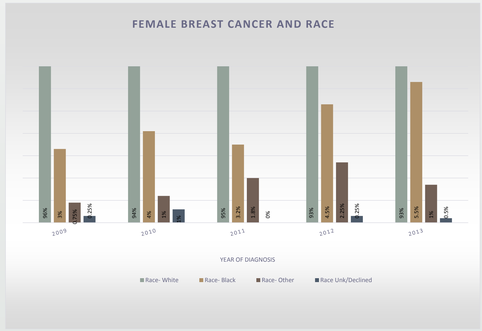
OBJECTIVES

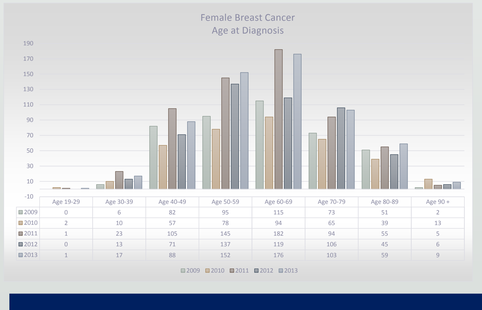
The decision was made to focus on three questions that related to biological response modifiers and their use in providing guidance is determining treatment.

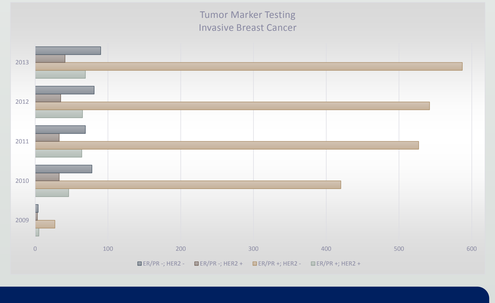
- Are colorectal cancer patients receiving KRAS testing and what are the effects on treatment decisions?
- Are women diagnosed with breast cancer being tested for HER2 and what are the effects on treatment decisions?
- Are patients diagnosed with rectal cancer being treated with radiation therapy?
- Has treatment guided by the results of biomarker testing improved survival?

BREAST CANCER

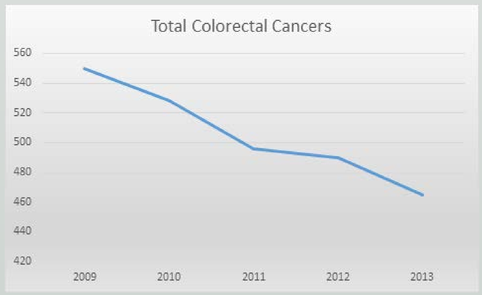


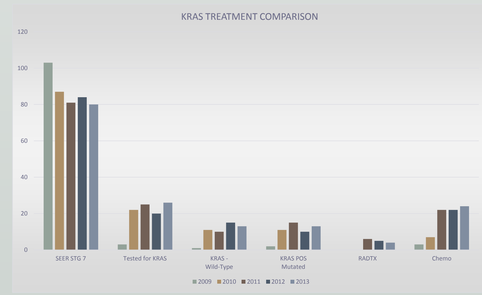




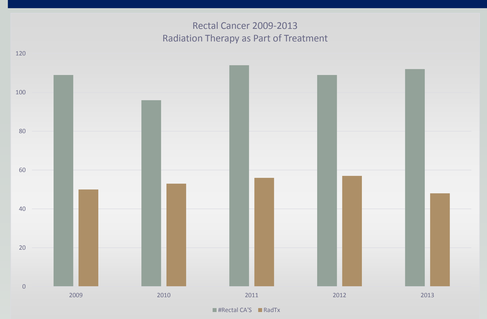


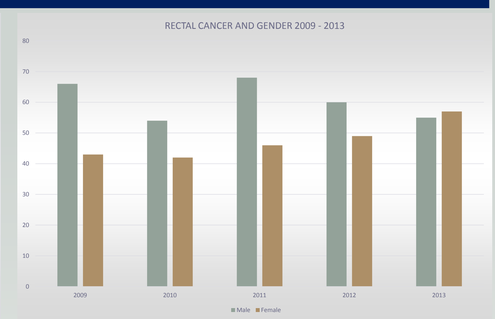
COLORECTAL CANCER





RECTAL CANCER





BARRIERS

- In Rhode Island, the state's acute care hospitals continue to be the center for the diagnosis and treatment of cancer. All freestanding radiation therapy centers report electronically to the central cancer registry. Historically the Rhode Island Cancer Registry (RICR) collected update information electronically on vital status, cancer status and cause of death. However participation in the CER and PCOR projects revealed that all first course of treatment information was not included in the case report submitted to the RICR. Additional treatment information was obtained through aggressive follow-up activities including the review of source documents by RICR staff at Rhode Island acute care hospitals and one hospital cancer center in a neighboring state.
- Barriers include:
- Herceptin (Trastuzumab) required recoding
- Case reports lack sufficient text to support coding changes
- Documentation required RIRC staff to review source documents at reporting facilities and to conduct active follow-back
- Treatment data was found to be incomplete when originally reported

FINDINGS

- There has been an increase in the breast cancer patients who are found to be ER/PR positive and HER2 negative
- There has been a steady Increase in the number of breast cancer cases treated with Biological Response Modifiers
- There has been an increase in the percentage of breast cancer cases identified as black with a corresponding decline in unknown or declined after 2011
- There is no discernable pattern or trends that involve the age of breast cancer patients at the time of diagnosis
- There has been a steady decline in the number of colorectal cancers which is reflected in the decline of patients diagnosed with advanced SEER Summary Stage 7
- KRAS testing has remained relatively steady. There has been a slight decline in the colorectal cases treated with radiation therapy while treatment with chemo therapy has remained the same for the final 3 years of this project
- There was a gradual increase in the use of radiation therapy to treat rectal cancers in the first 4 years of this project
- There has been a slight decline in the number of males diagnosed with rectal cancer while there has been a slight increase in the number of females

CONCLUSIONS

- There has been an increase in the use of biomarker testing and in using the results of the testing to determine treatment of breast and colorectal cancer patients in Rhode Island
- An electronic update process can supply the most recent vital status, cancer status and date last seen as well as improve the completeness of treatment data
- Active follow-up that involves contacting providers as well as acute care hospitals in Rhode Island and other states can be implemented with the proper programming tools.

Lessons Learned:

The long term goal of the RICR was to develop an early case capture process for all cancer sites and implement active and passive follow-up on cancer. Our involvement in the CER and PCOR projects shows that this is possible. The CDC/NPCR should engage and support a number of central cancer registries to develop an early case capture and follow-up process with the eventual goal of implementing rapid case reporting and follow-up process that all states could use.