THE OFFICIAL PATIENT'S SOURCEBOOK *on*

GASTROINTESTINAL CARCINOID TUMORS

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Dedication

To the healthcare professionals dedicating their time and efforts to the study of gastrointestinal carcinoid tumors.

Acknowledgements

The collective knowledge generated from academic and applied research summarized in various references has been critical in the creation of this sourcebook which is best viewed as a comprehensive compilation and collection of information prepared by various official agencies which directly or indirectly are dedicated to gastrointestinal carcinoid tumors. All of the *Official Patient's Sourcebooks* draw from various agencies and institutions associated with the United States Department of Health and Human Services, and in particular, the Office of the Secretary of Health and Human Services (OS), the Administration for Children and Families (ACF), the Administration on Aging (AOA), the Agency for Healthcare Research and Quality (AHRQ), the Agency for Toxic Substances and Disease Registry (ATSDR), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Healthcare Financing Administration (HCFA), the Health Resources and Services Administration (HRSA), the Indian Health Service (IHS), the institutions of the National Institutes of Health (NIH), the Program Support Center (PSC), and the Substance Abuse and Mental Health Services Administration (SAMHSA). In addition to these sources, information gathered from the National Library of Medicine, the United States Patent Office, the European Union, and their related organizations has been invaluable in the creation of this sourcebook. Some of the work represented was financially supported by the Research and Development Committee at INSEAD. This support is gratefully acknowledged. Finally, special thanks are owed to Tiffany Freeman for her excellent editorial support.

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About ICON Health Publications

In addition to gastrointestinal carcinoid tumors, *Official Patient's Sourcebooks* are available for the following related topics:

- The Official Patient's Sourcebook on Adult Primary Liver Cancer
- The Official Patient's Sourcebook on Anal Cancer
- The Official Patient's Sourcebook on Colon Cancer
- The Official Patient's Sourcebook on Esophageal Cancer
- The Official Patient's Sourcebook on Extrahepatic Bile Duct Cancer
- The Official Patient's Sourcebook on Gallbladder Cancer
- The Official Patient's Sourcebook on Gastric Cancer
- The Official Patient's Sourcebook on Pancreatic Cancer
- The Official Patient's Sourcebook on Rectal Cancer
- The Official Patient's Sourcebook on Small Intestine Cancer

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INTRODUCTION

Overview

Dr. C. Everett Koop, former U.S. Surgeon General, once said, "The best prescription is knowledge."[1] The Agency for Healthcare Research and Quality (AHRQ) of the National Institutes of Health (NIH) echoes this view and recommends that every patient incorporate education into the treatment process. According to the AHRQ:

> Finding out more about your condition is a good place to start. By contacting groups that support your condition, visiting your local library, and searching on the Internet, you can find good information to help guide your treatment decisions. Some information may be hard to find—especially if you don't know where to look.[2]

As the AHRQ mentions, finding the right information is not an obvious task. Though many physicians and public officials had thought that the emergence of the Internet would do much to assist patients in obtaining reliable information, in March 2001 the National Institutes of Health issued the following warning:

> The number of Web sites offering health-related resources grows every day. Many sites provide valuable information, while others may have information that is unreliable or misleading.[3]

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[1] Quotation from **http://www.drkoop.com**.
[2] The Agency for Healthcare Research and Quality (AHRQ): **http://www.ahcpr.gov/consumer/diaginfo.htm**.
[3] From the NIH, National Cancer Institute (NCI): **http://cancertrials.nci.nih.gov/beyond/evaluating.html**.

Since the late 1990s, physicians have seen a general increase in patient Internet usage rates. Patients frequently enter their doctor's offices with printed Web pages of home remedies in the guise of latest medical research. This scenario is so common that doctors often spend more time dispelling misleading information than guiding patients through sound therapies. *The Official Patient's Sourcebook on Gastrointestinal Carcinoid Tumors* has been created for patients who have decided to make education and research an integral part of the treatment process. The pages that follow will tell you where and how to look for information covering virtually all topics related to gastrointestinal carcinoid tumors, from the essentials to the most advanced areas of research.

The title of this book includes the word "official." This reflects the fact that the sourcebook draws from public, academic, government, and peer-reviewed research. Selected readings from various agencies are reproduced to give you some of the latest official information available to date on gastrointestinal carcinoid tumors.

Given patients' increasing sophistication in using the Internet, abundant references to reliable Internet-based resources are provided throughout this sourcebook. Where possible, guidance is provided on how to obtain free-of-charge, primary research results as well as more detailed information via the Internet. E-book and electronic versions of this sourcebook are fully interactive with each of the Internet sites mentioned (clicking on a hyperlink automatically opens your browser to the site indicated). Hard copy users of this sourcebook can type cited Web addresses directly into their browsers to obtain access to the corresponding sites. Since we are working with ICON Health Publications, hard copy *Sourcebooks* are frequently updated and printed on demand to ensure that the information provided is current.

In addition to extensive references accessible via the Internet, every chapter presents a "Vocabulary Builder." Many health guides offer glossaries of technical or uncommon terms in an appendix. In editing this sourcebook, we have decided to place a smaller glossary within each chapter that covers terms used in that chapter. Given the technical nature of some chapters, you may need to revisit many sections. Building one's vocabulary of medical terms in such a gradual manner has been shown to improve the learning process.

We must emphasize that no sourcebook on gastrointestinal carcinoid tumors should affirm that a specific diagnostic procedure or treatment discussed in a research study, patent, or doctoral dissertation is "correct" or your best option. This sourcebook is no exception. Each patient is unique. Deciding on

appropriate options is always up to the patient in consultation with their physician and healthcare providers.

Organization

This sourcebook is organized into three parts. Part I explores basic techniques to researching gastrointestinal carcinoid tumors (e.g. finding guidelines on diagnosis, treatments, and prognosis), followed by a number of topics, including information on how to get in touch with organizations, associations, or other patient networks dedicated to gastrointestinal carcinoid tumors. It also gives you sources of information that can help you find a doctor in your local area specializing in treating gastrointestinal carcinoid tumors. Collectively, the material presented in Part I is a complete primer on basic research topics for patients with gastrointestinal carcinoid tumors.

Part II moves on to advanced research dedicated to gastrointestinal carcinoid tumors. Part II is intended for those willing to invest many hours of hard work and study. It is here that we direct you to the latest scientific and applied research on gastrointestinal carcinoid tumors. When possible, contact names, links via the Internet, and summaries are provided. It is in Part II where the vocabulary process becomes important as authors publishing advanced research frequently use highly specialized language. In general, every attempt is made to recommend "free-to-use" options.

Part III provides appendices of useful background reading for all patients with gastrointestinal carcinoid tumors or related disorders. The appendices are dedicated to more pragmatic issues faced by many patients with gastrointestinal carcinoid tumors. Accessing materials via medical libraries may be the only option for some readers, so a guide is provided for finding local medical libraries which are open to the public. Part III, therefore, focuses on advice that goes beyond the biological and scientific issues facing patients with gastrointestinal carcinoid tumors.

Scope

While this sourcebook covers gastrointestinal carcinoid tumors, your doctor, research publications, and specialists may refer to your condition using a variety of terms. Therefore, you should understand that gastrointestinal carcinoid tumors is often considered a synonym or a condition closely related to the following:

- Adenocarcinoma of the Colon
- Bowel Cancer
- Cancer Colon
- Cancer Intestine
- Cancer of the Colon
- Cancer of the Large Intestine
- Cancer Stomach
- Carcinoma of the Colon
- Colonic Cancer
- Colorectal Cancer
- Digestive Cancer
- Gastric Carcinoma
- Gastrointestinal Cancer
- Intestinal Cancer
- Linitis Plastica
- Non-hodgkins Gastric Lymphoma
- Stomach Cancer
- Stomach Lymphoma, Non-hodgkins Type

In addition to synonyms and related conditions, physicians may refer to gastrointestinal carcinoid tumors using certain coding systems. The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) is the most commonly used system of classification for the world's illnesses. Your physician may use this coding system as an administrative or tracking tool. The following classification is commonly used for gastrointestinal carcinoid tumors:[4]

- 150.0 malignant neoplasm of stomach, cardia
- 151 malignant neoplasm of stomach
- 151.1 malignant neoplasm of stomach, pylorus
- 151.2 malignant neoplasm of stomach, pyloric antrum

[4] This list is based on the official version of the World Health Organization's 9th Revision, International Classification of Diseases (ICD-9). According to the National Technical Information Service, "ICD-9CM extensions, interpretations, modifications, addenda, or errata other than those approved by the U.S. Public Health Service and the Health Care Financing Administration are not to be considered official and should not be utilized. Continuous maintenance of the ICD-9-CM is the responsibility of the federal government."

- 151.3 malignant neoplasm of stomach, fundus of stomach
- 151.4 malignant neoplasm of stomach, body of stomach
- 151.5 malignant neoplasm of stomach, lesser curvature, unspecified
- 151.6 malignant neoplasm of stomach, greater curvature, unspecified
- 151.8 malignant neoplasm of stomach, other specified sites of stomach
- 151.9 malignant neoplasm of stomach, unspecified

For the purposes of this sourcebook, we have attempted to be as inclusive as possible, looking for official information for all of the synonyms relevant to gastrointestinal carcinoid tumors. You may find it useful to refer to synonyms when accessing databases or interacting with healthcare professionals and medical librarians.

Moving Forward

Since the 1980s, the world has seen a proliferation of healthcare guides covering most illnesses. Some are written by patients or their family members. These generally take a layperson's approach to understanding and coping with an illness or disorder. They can be uplifting, encouraging, and highly supportive. Other guides are authored by physicians or other healthcare providers who have a more clinical outlook. Each of these two styles of guide has its purpose and can be quite useful.

As editors, we have chosen a third route. We have chosen to expose you to as many sources of official and peer-reviewed information as practical, for the purpose of educating you about basic and advanced knowledge as recognized by medical science today. You can think of this sourcebook as your personal Internet age reference librarian.

Why "Internet age"? All too often, patients diagnosed with gastrointestinal carcinoid tumors will log on to the Internet, type words into a search engine, and receive several Web site listings which are mostly irrelevant or redundant. These patients are left to wonder where the relevant information is, and how to obtain it. Since only the smallest fraction of information dealing with gastrointestinal carcinoid tumors is even indexed in search engines, a non-systematic approach often leads to frustration and disappointment. With this sourcebook, we hope to direct you to the information you need that you would not likely find using popular Web directories. Beyond Web listings, in many cases we will reproduce brief

summaries or abstracts of available reference materials. These abstracts often contain distilled information on topics of discussion.

While we focus on the more scientific aspects of gastrointestinal carcinoid tumors, there is, of course, the emotional side to consider. Later in the sourcebook, we provide a chapter dedicated to helping you find peer groups and associations that can provide additional support beyond research produced by medical science. We hope that the choices we have made give you the most options available in moving forward. In this way, we wish you the best in your efforts to incorporate this educational approach into your treatment plan.

The Editors

PART I: THE ESSENTIALS

ABOUT PART I

Part I has been edited to give you access to what we feel are "the essentials" on gastrointestinal carcinoid tumors. The essentials of a disease typically include the definition or description of the disease, a discussion of who it affects, the signs or symptoms associated with the disease, tests or diagnostic procedures that might be specific to the disease, and treatments for the disease. Your doctor or healthcare provider may have already explained the essentials of gastrointestinal carcinoid tumors to you or even given you a pamphlet or brochure describing gastrointestinal carcinoid tumors. Now you are searching for more in-depth information. As editors, we have decided, nevertheless, to include a discussion on where to find essential information that can complement what your doctor has already told you. In this section we recommend a process, not a particular Web site or reference book. The process ensures that, as you search the Web, you gain background information in such a way as to maximize your understanding.

CHAPTER 1. THE ESSENTIALS ON GASTROINTESTINAL CARCINOID TUMORS: GUIDELINES

Overview

Official agencies, as well as federally funded institutions supported by national grants, frequently publish a variety of guidelines on gastrointestinal carcinoid tumors. These are typically called "Fact Sheets" or "Guidelines." They can take the form of a brochure, information kit, pamphlet, or flyer. Often they are only a few pages in length. The great advantage of guidelines over other sources is that they are often written with the patient in mind. Since new guidelines on gastrointestinal carcinoid tumors can appear at any moment and be published by a number of sources, the best approach to finding guidelines is to systematically scan the Internet-based services that post them.

The National Institutes of Health (NIH)[5]

The National Institutes of Health (NIH) is the first place to search for relatively current patient guidelines and fact sheets on gastrointestinal carcinoid tumors. Originally founded in 1887, the NIH is one of the world's foremost medical research centers and the federal focal point for medical research in the United States. At any given time, the NIH supports some 35,000 research grants at universities, medical schools, and other research and training institutions, both nationally and internationally. The rosters of those who have conducted research or who have received NIH support over the years include the world's most illustrious scientists and physicians.

[5] Adapted from the NIH: **http://www.nih.gov/about/NIHoverview.html**.

Among them are 97 scientists who have won the Nobel Prize for achievement in medicine.

There is no guarantee that any one Institute will have a guideline on a specific disease, though the National Institutes of Health collectively publish over 600 guidelines for both common and rare diseases. The best way to access NIH guidelines is via the Internet. Although the NIH is organized into many different Institutes and Offices, the following is a list of key Web sites where you are most likely to find NIH clinical guidelines and publications dealing with gastrointestinal carcinoid tumors and associated conditions:

- Office of the Director (OD); guidelines consolidated across agencies available at **http://www.nih.gov/health/consumer/conkey.htm**
- National Library of Medicine (NLM); extensive encyclopedia (A.D.A.M., Inc.) with guidelines available at **http://www.nlm.nih.gov/medlineplus/healthtopics.html**
- National Cancer Institute (NCI); guidelines available at **http://cancernet.nci.nih.gov/pdq/pdq_treatment.shtml**

Among the above, the National Cancer Institute (NCI) is particularly noteworthy. The NCI coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.[6] Specifically, the Institute:

- Supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout this country and abroad through research grants and cooperative agreements.
- Conducts research in its own laboratories and clinics.
- Supports education and training in fundamental sciences and clinical disciplines for participation in basic and clinical research programs and treatment programs relating to cancer through career awards, training grants, and fellowships.
- Supports research projects in cancer control.
- Supports a national network of cancer centers.
- Collaborates with voluntary organizations and other national and foreign institutions engaged in cancer research and training activities.

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[6] This paragraph has been adapted from the NCI: **http://www.nci.nih.gov/**. "Adapted" signifies that a passage has been reproduced exactly or slightly edited for this book.

- Encourages and coordinates cancer research by industrial concerns where such concerns evidence a particular capability for programmatic research.
- Collects and disseminates information on cancer.
- Supports construction of laboratories, clinics, and related facilities necessary for cancer research through the award of construction grants.

The following patient guideline was recently published by the NCI on gastrointestinal carcinoid tumors.

What Are Gastrointestinal Carcinoid Tumors?[7]

Gastrointestinal carcinoid tumors are cancers in which cancer (malignant) cells are found in certain hormone-making cells of the digestive, or gastrointestinal, system. The digestive system absorbs vitamins, minerals, carbohydrates, fats, proteins, and water from the food that is eaten and stores waste until the body eliminates it. The digestive system is made up of the stomach and the small and large intestines. The last 6 feet of intestine is called the colon. The last 10 inches of the colon is the rectum. The appendix is an organ attached to the large intestine.

There are often no signs of a gastrointestinal carcinoid tumor in its early stages. Often the cancer will make too much of some of the hormones, which can cause symptoms. A doctor should be seen if the following symptoms persist: pain in the abdomen, flushing and swelling of the skin of the face and neck, wheezing, diarrhea, and symptoms of heart failure, including breathlessness.

If there are symptoms, a doctor may order blood and urine tests to look for signs of cancer. Other tests may also be done. If there is a carcinoid tumor, the patient has a greater chance of getting other cancers in the digestive system, either at the same time or at a later time.

The chance of recovery (prognosis) and choice of treatment depend on whether the cancer is just in the gastrointestinal system or has spread to other places, and on the patient's general state of health.

[7] The following guidelines appeared on the NCI website on January 30, 2004. The text was last modified in December 2002. The text has been adapted for this sourcebook.

Stages of Gastrointestinal Carcinoid Tumors

Once gastrointestinal carcinoid tumor is found, more tests will be done to find out if cancer cells have spread to other parts of the body. The following stages are used for gastrointestinal carcinoid tumor:

Localized

The cancer is found in the appendix, the colon or rectum, the small intestine, or stomach, but it has not spread to other parts of the body.

Regional

Cancer has spread from the appendix, colon or rectum, stomach, or small intestine to nearby tissues or lymph nodes (small, bean-shaped structures that are found throughout the body that produce and store infection-fighting cells).

Metastatic

Cancer has spread to other parts of the body.

Recurrent

Recurrent disease means that the cancer has come back (recurred) after it has been treated. It may come back in the first place it was found or in another part of the body.

How Gastrointestinal Carcinoid Tumors Are Treated

There are treatments for all patients with gastrointestinal carcinoid tumors. Four kinds of treatment are used:

- Surgery (taking out the cancer)
- Radiation therapy (using high-dose x-rays to kill cancer cells)
- Biological therapy (using the body's natural immune system to fight cancer)

- Chemotherapy (using drugs to kill cancer cells)

Surgery

Depending on where the cancer started, the doctor may take out the cancer using one of the following operations:

- A simple appendectomy removes the appendix. If part of the colon is also taken out, the operation is called a hemicolectomy. The doctor may also remove lymph nodes and look at them under a microscope to see if they contain cancer.
- Local excision uses a special instrument inserted into the colon or rectum through the anus to cut the tumor out. This operation can be used for very small tumors.
- Fulguration uses a special tool inserted into the colon or rectum through the anus. An electric current is then used to burn the tumor away.
- Bowel resection takes out the cancer and a small amount of healthy tissue on either side. The healthy parts of the bowel are then sewn together. The doctor will also remove lymph nodes and have them looked at under a microscope to see if they contain cancer.
- Cryosurgery kills the cancer by freezing it.
- Hepatic artery ligation cuts and ties off the main blood vessel that brings blood into the liver (the hepatic artery).
- Hepatic artery embolization uses drugs or other agents to reduce or block the flow of blood to the liver in order to kill cancer cells growing in the liver.

Radiation Therapy

Radiation therapy uses high-energy x-rays to kill cancer cells and shrink tumors. Radiation may come from a machine outside the body (external radiation therapy) or from putting materials that produce radiation (radioisotopes) through thin plastic tubes in the area where the cancer cells are found (internal radiation therapy).

Chemotherapy

Chemotherapy uses drugs to kill cancer cells. Chemotherapy may be taken by pill, or it may be put into the body by a needle in the vein or muscle. Chemotherapy is called a systemic treatment because the drug enters the bloodstream, travels through the body, and can kill cancer cells outside the digestive system.

Biological Therapy

Biological therapy tries to get the patient's body to fight the cancer. It uses materials made by the body or made in a laboratory to boost, direct, or restore the body's natural defenses against disease. Biological therapy is sometimes called biological response modifier (BRM) therapy or immunotherapy.

Treatment by Type

Treatment of gastrointestinal carcinoid tumor depends on the type of tumor, the stage, and the patient's overall health.

Standard treatment may be considered because of its effectiveness in patients in past studies, or participation in a clinical trial may be considered. Not all patients are cured with standard therapy and some standard treatments may have more side effects than are desired. For these reasons, clinical trials are designed to find better ways to treat cancer patients and are based on the most up-to-date information. Clinical trials are ongoing in most parts of the country for most stages of gastrointestinal carcinoid tumor. To learn more about clinical trials, call the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237); TTY at 1-800-332-8615.

Localized Gastrointestinal Carcinoid Tumor

If the cancer started in the appendix, the treatment will probably be surgery to remove the appendix (appendectomy) with or without removal of part of the colon (hemicolectomy) and lymph nodes.

If the cancer started in the rectum, treatment will probably be simple surgery to remove the cancer, surgery using electric current to burn the cancer away, surgery to remove part of the rectum, or surgery to remove the anus and part

of the rectum. An opening will be made for waste to pass out of the body (colostomy) into a disposable bag attached near the colostomy (colostomy bag).

If the cancer started in the small intestine, the treatment will probably be surgery to remove part of the bowel (bowel resection). Lymph nodes may also be taken out and looked at under the microscope to see if they contain cancer.

If the cancer started in the stomach, pancreas, or colon, the treatment will probably be surgery to remove the organ affected by the cancer and possibly other nearby organs.

Regional Gastrointestinal Carcinoid Tumor

The treatment will probably be surgery to remove the organ affected by the cancer and possibly other nearby organs.

Metastatic Gastrointestinal Carcinoid Tumor

Treatment may be one of the following:

- Surgery to relieve symptoms caused by the cancer. Surgery to freeze and kill the cancer may also be performed.
- Chemotherapy to relieve symptoms caused by the cancer.
- Chemotherapy injected directly into the hepatic artery to block the artery and kill cancer cells growing in the liver.
- Radiation therapy to relieve symptoms caused by the cancer.
- Radioactive substances injected into the cancer to relieve the symptoms caused by the cancer.
- Biological or immunological therapy.

Carcinoid Syndrome

Treatment options for metastatic carcinoid tumor may be one of the following:

- Surgery to remove the cancer.

- Surgery to cut and tie the main artery that goes to the liver (hepatic artery ligation) or injecting chemotherapy into the liver through the hepatic artery to block the artery and kill cancer cells growing in the liver.
- Drugs designed to relieve symptoms caused by the cancer.
- Biological therapy to relieve symptoms caused by the cancer.
- A clinical trial of new combinations of chemotherapy drugs.

Recurrent Gastrointestinal Carcinoid Tumor

The treatment depends on many factors, including where the cancer came back and what treatment the patient received before. Clinical trials are studying new treatments.

To Learn More

Call

For more information, U.S. residents may call the National Cancer Institute's (NCI's) Cancer Information Service toll-free at 1-800-4-CANCER (1-800-422-6237), Monday through Friday from 9:00 a.m. to 4:30 p.m. Deaf and hard-of-hearing callers with TTY equipment may call 1-800-332-8615. The call is free and a trained Cancer Information Specialist is available to answer your questions.

Web Sites and Organizations

The NCI's Cancer.gov Web site (**http://cancer.gov**) provides online access to information on cancer, clinical trials, and other Web sites and organizations that offer support and resources for cancer patients and their families. There are also many other places where people can get materials and information about cancer treatment and services. Local hospitals may have information on local and regional agencies that offer information about finances, getting to and from treatment, receiving care at home, and dealing with problems associated with cancer treatment.

Publications

The NCI has booklets and other materials for patients, health professionals, and the public. These publications discuss types of cancer, methods of cancer treatment, coping with cancer, and clinical trials. Some publications provide information on tests for cancer, cancer causes and prevention, cancer statistics, and NCI research activities. NCI materials on these and other topics may be ordered online or printed directly from the NCI Publications Locator (**https://cissecure.nci.nih.gov/ncipubs**). These materials can also be ordered by telephone from the Cancer Information Service toll-free at 1-800-4-CANCER (1-800-422-6237), TTY at 1-800-332-8615.

LiveHelp

The NCI's LiveHelp service, a program available on several of the Institute's Web sites, provides Internet users with the ability to chat online with an Information Specialist. The service is available from Monday - Friday 9:00 AM - 10:00 PM Eastern Time. Information Specialists can help Internet users find information on NCI Web sites and answer questions about cancer.

Write

For more information from the NCI, please write to this address:

National Cancer Institute
Office of Communications
31 Center Drive, MSC 2580
Bethesda, MD 20892-2580

About PDQ

PDQ Is a Comprehensive Cancer Database Available on Cancer.gov

PDQ is the National Cancer Institute's (NCI's) comprehensive cancer information database. Most of the information contained in PDQ is available online at Cancer.gov (**http://cancer.gov**), the NCI's Web site. PDQ is provided as a service of the NCI. The NCI is part of the National Institutes of Health, the federal government's focal point for biomedical research.

PDQ Contains Cancer Information Summaries

The PDQ database contains summaries of the latest published information on cancer prevention, detection, genetics, treatment, supportive care, and complementary and alternative medicine. Most summaries are available in two versions. The health professional versions provide detailed information written in technical language. The patient versions are written in easy-to-understand, non-technical language. Both versions provide current and accurate cancer information.

The PDQ cancer information summaries are developed by cancer experts and reviewed regularly. Editorial Boards made up of experts in oncology and related specialties are responsible for writing and maintaining the cancer information summaries. The summaries are reviewed regularly and changes are made as new information becomes available. The date on each summary ("Date Last Modified") indicates the time of the most recent change.

PDQ Contains Information on Clinical Trials

Before starting treatment, patients may want to think about taking part in a clinical trial. A clinical trial is a study to answer a scientific question, such as whether one treatment is better than another. Trials are based on past studies and what has been learned in the laboratory. Each trial answers certain scientific questions in order to find new and better ways to help cancer patients. During treatment clinical trials, information is collected about new treatments, the risks involved, and how well they do or do not work. If a clinical trial shows that a new treatment is better than one currently being used, the new treatment may become "standard."

Listings of clinical trials are included in PDQ and are available online at Cancer.gov (**http://cancer.gov/clinical_trials**). Descriptions of the trials are available in health professional and patient versions. Many cancer doctors who take part in clinical trials are also listed in PDQ. For more information, call the Cancer Information Service at 1-800-4-CANCER (1-800-422-6237); TTY at 1-800-332-8615.

More Guideline Sources

The guideline above on gastrointestinal carcinoid tumors is only one example of the kind of material that you can find online and free of charge. The remainder of this chapter will direct you to other sources which either

publish or can help you find additional guidelines on topics related to gastrointestinal carcinoid tumors. Many of the guidelines listed below address topics that may be of particular relevance to your specific situation or of special interest to only some patients with gastrointestinal carcinoid tumors. Due to space limitations these sources are listed in a concise manner. Do not hesitate to consult the following sources by either using the Internet hyperlink provided, or, in cases where the contact information is provided, contacting the publisher or author directly.

Topic Pages: MEDLINEplus

For patients wishing to go beyond guidelines published by specific Institutes of the NIH, the National Library of Medicine has created a vast and patient-oriented healthcare information portal called MEDLINEplus. Within this Internet-based system are "health topic pages." You can think of a health topic page as a guide to patient guides. To access this system, log on to **http://www.nlm.nih.gov/medlineplus/healthtopics.html**. From there you can either search using the alphabetical index or browse by broad topic areas. Recently, MEDLINEplus listed the following as being relevant to gastrointestinal carcinoid tumors:

- Other guides

  Anal and Rectal Diseases
  http://www.nlm.nih.gov/medlineplus/analandrectaldiseases.html

  Bone Cancer
  http://www.nlm.nih.gov/medlineplus/bonecancer.html

  Brain Cancer
  http://www.nlm.nih.gov/medlineplus/braincancer.html

  Breast Cancer
  http://www.nlm.nih.gov/medlineplus/breastcancer.html

  Cancer
  http://www.nlm.nih.gov/medlineplus/cancer.html

  Cancer Alternative Therapy
  http://www.nlm.nih.gov/medlineplus/canceralternativetherapy.html

  Carcinoid Tumors
  http://www.nlm.nih.gov/medlineplus/carcinoidtumors.html

  Colonic Diseases
  http://www.nlm.nih.gov/medlineplus/colonicdiseases.html

Colonic Polyps
http://www.nlm.nih.gov/medlineplus/colonicpolyps.html

Colorectal Cancer
http://www.nlm.nih.gov/medlineplus/colorectalcancer.html

Digestive Diseases
http://www.nlm.nih.gov/medlineplus/digestivediseases.html

Esophageal Cancer
http://www.nlm.nih.gov/medlineplus/esophagealcancer.html

Hodgkin's Disease
http://www.nlm.nih.gov/medlineplus/hodgkinsdisease.html

Intestinal Cancer
http://www.nlm.nih.gov/medlineplus/intestinalcancer.html

Lung Cancer
http://www.nlm.nih.gov/medlineplus/lungcancer.html

Lymphoma
http://www.nlm.nih.gov/medlineplus/lymphoma.html

Ovarian Cancer
http://www.nlm.nih.gov/medlineplus/ovariancancer.html

Pancreatic Cancer
http://www.nlm.nih.gov/medlineplus/pancreaticcancer.html

Stomach Cancer
http://www.nlm.nih.gov/medlineplus/stomachcancer.html

Stomach Disorders
http://www.nlm.nih.gov/medlineplus/stomachdisorders.html

Within the health topic page dedicated to gastrointestinal carcinoid tumors, the following was recently recommended to patients:

- General/Overviews

  Stomach Cancer
  Source: Mayo Foundation for Medical Education and Research
  http://www.mayoclinic.com/invoke.cfm?id=DS00301

- Diagnosis/Symptoms

  How Is Stomach Cancer Diagnosed?
  Source: American Cancer Society
  http://www.cancer.org/docroot/cri/content/cri_2_4_3x_how_is_sto

mach_cancer_diagnosed_40.asp?sitearea=cri

How Is Stomach Cancer Staged?
Source: American Cancer Society
http://www.cancer.org/docroot/cri/content/cri_2_4_3x_how_is_stomach_cancer_staged_40.asp?sitearea=cri

Upper Endoscopy
Source: National Digestive Diseases Information Clearinghouse
http://digestive.niddk.nih.gov/ddiseases/pubs/upperendoscopy/index.htm

Upper GI Series
Source: National Digestive Diseases Information Clearinghouse
http://digestive.niddk.nih.gov/ddiseases/pubs/uppergi/index.htm

- Treatment

  Gastric Cancer (PDQ): Treatment
  Source: National Cancer Institute
  http://www.cancer.gov/cancerinfo/pdq/treatment/gastric/patient/

- Specific Conditions/Aspects

  Stomach Polyps
  Source: Mayo Foundation for Medical Education and Research
  http://www.mayoclinic.com/invoke.cfm?id=AN00133

  What Should You Ask Your Doctor about Stomach Cancer?
  Source: American Cancer Society
  http://www.cancer.org/docroot/cri/content/cri_2_4_5x_what_should_you_ask_your_physician_about_stomach_cancer_40.asp?sitearea=cri

- From the National Institutes of Health

  What You Need to Know about Stomach Cancer
  Source: National Cancer Institute
  http://www.cancer.gov/cancerinfo/wyntk/stomach

- Latest News

  Celebrex Suppresses Stomach Cancer, in Rats
  Source: 02/13/2004, Reuters Health
  http://www.nlm.nih.gov//www.nlm.nih.gov/medlineplus/news/fullstory_16062.html

- Organizations

  American Cancer Society
  http://www.cancer.org/

  National Cancer Institute
  http://www.cancer.gov/

- Prevention/Screening

  Gastric Cancer (PDQ): Prevention
  Source: National Cancer Institute
  http://www.cancer.gov/cancerinfo/pdq/prevention/gastric/patient/

  Gastric Cancer (PDQ): Screening
  Source: National Cancer Institute
  http://www.cancer.gov/cancerinfo/pdq/screening/gastric/patient/

  Stomach Cancer Questionnaire
  Source: Harvard Center for Cancer Prevention
  http://www.yourcancerrisk.harvard.edu/hccpquiz.pl?func=d_start&cancer_list=Stomach

  What Are the Risk Factors for Stomach Cancer?
  Source: American Cancer Society
  http://www.cancer.org/docroot/cri/content/cri_2_4_2x_what_are_the_risk_factors_for_stomach_cancer_40.asp?sitearea=cri

- Research

  Do We Know What Causes Stomach Cancer?
  Source: American Cancer Society
  http://www.cancer.org/docroot/cri/content/cri_2_4_2x_do_we_know_what_causes_stomach_cancer_40.asp?sitearea=ped

  What's New in Stomach Cancer Research and Treatment?
  Source: American Cancer Society
  http://www.cancer.org/docroot/cri/content/cri_2_4_6x_whats_new_in_stomach_cancer_research_and_treatment_40.asp?sitearea=cri

- Statistics

  What Are the Key Statistics for Stomach Cancer?
  Source: American Cancer Society
  http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_ar

e_the_key_statistics_for_stomach_cancer_40.asp?sitearea=

You may also choose to use the search utility provided by MEDLINEplus at the following Web address: **http://www.nlm.nih.gov/medlineplus/**. Simply type a keyword into the search box and click "Search." This utility is similar to the NIH search utility, with the exception that it only includes materials that are linked within the MEDLINEplus system (mostly patient-oriented information). It also has the disadvantage of generating unstructured results. We recommend, therefore, that you use this method only if you have a very targeted search.

The Combined Health Information Database (CHID)

CHID Online is a reference tool that maintains a database directory of thousands of journal articles and patient education guidelines on gastrointestinal carcinoid tumors and related conditions. One of the advantages of CHID over other sources is that it offers summaries that describe the guidelines available, including contact information and pricing. CHID's general Web site is **http://chid.nih.gov/**. To search this database, go to **http://chid.nih.gov/detail/detail.html**. In particular, you can use the advanced search options to look up pamphlets, reports, brochures, and information kits. The following was recently posted in this archive:

- **Screening and Surveillance for Colorectal Cancer**

  Source: Arlington Heights, IL: American Society of Colon and Rectal Surgeons. 1999. 2 p.

  Contact: Available from American Society for Colon and Rectal Surgeons (ASCRS). 85 West Algonquin Road, Suite 550, Arlington Heights, IL 60005. (800) 791-0001 or (847) 290-9184. E-mail: ascrs@fascrs.org. Website: www.fascrs.org. PRICE: Full-text available online at no charge; bulk copies available.

  Summary: Colorectal cancer is known as a silent disease because many people do not develop symptoms such as bleeding or abdominal pain until the cancer is difficult to cure. The simplest screening test for colon and rectal cancer is testing of the stool (feces) to detect tiny amounts of invisible blood; this is called fecal occult blood testing. However, only about 50 percent of cancers and 10 percent of polyps bleed enough to be detected by this test. This brochure describes other screening approaches for colon and rectal cancer. Written in a question and answer format, the brochure describes flexible sigmoidoscopy, colonoscopy, and barium enema. The brochure also discusses why testing should be done, when

and how often testing should be done, risk factors and high risk groups, and who performs screening and surveillance tests. The brochure describes the work of colon and rectal surgeons, who treat benign and malignant conditions, perform routine screening examinations, and surgically treat problems when necessary. The brochure includes the contact information for the American Society of Colon and Rectal Surgeons (www.fascrs.org).

- **ACG Recommendations on Colorectal Cancer Screening for Average and Higher Risk Patients in Clinical Practice**

  Source: Arlington, VA: American College of Gastroenterology. 200x. 25 p.

  Contact: Available from American College of Gastroenterology. 4900 B South 31st Street, Arlington, VA 22206-1656. (703) 820-7400. Fax (703) 931-4520. PRICE: Single copy free.

  Summary: This booklet outlines the preferred colorectal cancer screening recommendations of the American College of Gastroenterology (ACG) and presents an update of the ACG position on screening as outlined by the Agency for Healthcare Policy and Research (AHCPR). The AHCPR's recommendations presented a menu of options for screening average risk persons. These options have similar cost-effectiveness ratios, however, there are substantial differences between the various options regarding their effectiveness, initial costs, and to a lesser degree, risk. The ACG continues to endorse the AHCPR guideline. The update recommendation as presented in the booklet is meant to reflect trends in the rapidly changing perceptions of colorectal cancer prevention strategies among clinical gastroenterologists in both academic and private practice. The preferred screening strategy for persons over age 50 at average risk for colorectal cancer is colonoscopy every 10 years. An alternative strategy for this population (used when resources, expertise, or reimbursement for screening colonoscopy are not available) is flexible sigmoidoscopy every 5 years plus annual fecal occult blood testing. The booklet outlines other screening strategies include barium enema, and CT (computed tomography) and magnetic resonance (MR) colonography (also called virtual colonoscopy). The booklet then discusses screening for people in high risk categories, including those with a personal or family history of familial adenomatous polyposis, hereditary nonpolyposis colorectal cancer, and strong family history of colon cancer. The booklet includes extensive tables that summarize the information and guidelines presented in the text. 2 figures. 4 tables. 142 references.

- **Women and Colorectal Cancer: What are the Facts?**

  Source: Bethesda, MD: Foundation for Digestive Health and Nutrition. 1999. 6 p.

  Contact: Available from Foundation for Digestive Health and Nutrition. 7910 Woodmont Avenue, Suite 610, Bethesda, MD 20814-3015. (301) 222-4002. Fax (301) 222-4010. E-mail: info@fdhn.org. Website: www.fdhn.org. PRICE: Full-text available online at no charge.

  Summary: This brochure discusses colorectal cancer in women. Although commonly mistaken as a man's disease, colorectal cancer is the third leading cause of cancer death in women. However, colorectal cancer is preventable and, if detected early, it is curable in men and women. Getting tested for colorectal cancer even when no symptoms are present (screening) can reduce the risk of developing the disease by up to 75 percent. The brochure describes how colorectal cancer develops, risk factors, symptoms, prevention, diagnostic tests (fecal occult blood test, flexible sigmoidoscopy, colonoscopy, barium xray), and treatment strategies. The brochure concludes by encouraging women to get screened for colorectal cancer, noting that Medicare and most other insurance providers now pay for these diagnostic tests. The brochure is illustrated with photographs of women in everyday settings. The brochure includes information about the Foundation for Digestive Health and Nutrition (www.fdhn.org) and the Society for the Advancement of Women's Health Research (www.womens-health.org).

- **Colorectal Cancer Screening: Early Detection**

  Source: San Ramon, CA: Health Information Network, Inc. 1996. 14 p.

  Contact: Available from HIN, Inc. 231 Market Place, Number 331, San Ramon, CA 94583. (800) HIN-1121. Fax (925) 358-4377. Website: www.hinbooks.com. PRICE: $1.95 suggested list price; professional and bulk discounts available. Order number 206. ISBN: 1885274629.

  Summary: This brochure provides readers with basic information about screening for colorectal cancer. The brochure defines a screening test as a type of medical examination that may find cancer early, before it causes symptoms or pain. Colorectal cancer is cancer in any part of the large intestine, which includes the colon and rectum. Colorectal cancer is one of the most curable types of cancer, with a success rate of over 90 percent when found in its early stages. Written in language that is easy to read, the brochure covers the anatomy of the colon and rectum, the nature of cancer, risk factors for colorectal cancer, screening tests for colorectal cancer (fecal occult blood test, flexible sigmoidoscopy, colonoscopy, barium enema with air contrast examination, and digital rectal

examination), symptoms of colorectal cancer, and patient followup. The brochure provides the addresses and phone numbers of the American Cancer Society and the National Cancer Institute. A brief glossary of terms is also included.

- **Talk about colorectal cancer with your health care provider**

  Source: Washington, DC: National Alliance for Hispanic Health. [2002]. 4 pp.

  Contact: Available from National Alliance for Hispanic Health, 1501 16th Street, N.W, Washington, DC 20036-1401. Telephone: (202) 387-5000 / fax: (202) 797-4353 / e-mail: info@hispanichealth.org / Web site: http://www.hispanichealth.org/. Available at no charge; also available from the Web site at no charge.

  Summary: This brochure, available in both English and Spanish, describes colorectal cancer, explains why screening is important for Hispanics, explains how screening for colorectal cancer can be performed, offers information on who should be screened, and provides contact information for low-cost screening alternatives.

- **Follow Up Evaluation After Surgery for Colorectal Cancer: Questions and Answers**

  Source: Arlington Heights, IL: American Society of Colon and Rectal Surgeons. 1996. 4 p.

  Contact: Available from American Society of Colon and Rectal Surgeons. 85 West Algonquin Road, Suite 550, Arlington Heights, IL 60005. (800) 791-0001 or (847) 290-9184. Fax (847) 290-9203. E-mail: ascrs@fascrs.org. Website: www.fascrs.org. PRICE: Full-text available online at no charge; Single copy free; bulk copies available.

  Summary: This patient education brochure provides information about patient follow-up evaluations after surgery for colorectal cancer. Written in a question and answer format, the brief brochure discusses the reasons why follow-up evaluations are crucial, the recommended length of a followup program, what to expect at a followup visit, and the importance of screening close family members who are at increased risk for colon and rectal cancer.

The National Guideline Clearinghouse™

The National Guideline Clearinghouse™ offers hundreds of evidence-based clinical practice guidelines published in the United States and other

countries. You can search their site located at **http://www.guideline.gov** by using the keyword "gastrointestinal carcinoid tumors" or synonyms. The following was recently posted:

- **2000 update of recommendations for the use of tumor markers in breast and colorectal cancer: clinical practice guidelines of the American Society of Clinical Oncology**

  Source: American Society of Clinical Oncology - Medical Specialty Society; 1997 (revised 2001 Mar); 14 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=2746&nbr=1972&string=Cancer+AND+colon

- **ACR Appropriateness Criteria for pre-treatment staging of colorectal cancer**

  Source: American College of Radiology - Medical Specialty Society; 1996 (revised 1999); 8 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=2400&nbr=1626&string=Bowel+AND+cancer

- **ACR Appropriateness Criteria for screening for colorectal cancer**

  Source: American College of Radiology - Medical Specialty Society; 1998; 7 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=2413&nbr=1639&string=Bowel+AND+cancer

- **American Gastroenterological Association medical position statement: hereditary colorectal cancer and genetic testing**

  Source: American Gastroenterological Association - Medical Specialty Society; 2001 April 18; 3 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3057&nbr=2283&string=Bowel+AND+cancer

- **Colorectal cancer screening**

  Source: Institute for Clinical Systems Improvement - Private Nonprofit Organization; 1995 May (revised 2002 Jun); 45 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3406&nbr=2632&string=Bowel+AND+cancer

- **Colorectal cancer screening and surveillance: clinical guidelines and rationale-update based on new evidence**

  Source: American College of Gastroenterology - Medical Specialty Society; 1997 February (revised 2003 Feb); 48 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3686&nbr=2912&string=Bowel+AND+cancer

- **Management of colorectal cancer. A national clinical guideline**

  Source: Scottish Intercollegiate Guidelines Network - National Government Agency [Non-U.S.]; 2003 March; 47 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3724&nbr=2950&string=Bowel+AND+cancer

- **Prevention and screening of colorectal cancer**

  Source: Finnish Medical Society Duodecim - Professional Association; 2002 April 27; Various pagings

  http://www.guideline.gov/summary/summary.aspx?doc_id=3397&nbr=2623&string=Bowel+AND+cancer

- **Preventive health care, 2001 update: colorectal cancer screening**

  Source: Canadian Task Force on Preventive Health Care - National Government Agency [Non-U.S.]; 2001; 2 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=2894&nbr=2120&string=Bowel+AND+cancer

- **Recommended colorectal cancer surveillance guidelines by the American Society of Clinical Oncology.**

  Source: American Society of Clinical Oncology - Medical Specialty Society; 1999 April (revised 2000 Oct); 10 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=1885&nbr=1111&string=Bowel+AND+cancer

- **Screening for colorectal cancer: recommendations and rationale**

  Source: United States Preventive Services Task Force - Independent Expert Panel; 1996 (revised 2002 Jul); 13 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3285&nbr=2511&string=Bowel+AND+cancer

- **Surgical treatment of cancer of the colon or rectum**

  Source: Society for Surgery of the Alimentary Tract, Inc - Medical Specialty Society; 1996 (revised 2000); 5 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=2168&nbr=1394&string=Bowel+AND+cancer

- **Use of irinotecan (Camptosar, CPT-11) combined with 5-fluorouracil and leucovorin (5FU/LV) as first-line therapy for metastatic colorectal cancer**

  Source: Practice Guidelines Initiative - State/Local Government Agency [Non-U.S.]; 2001 October 23 (updated online 2003 Feb); 20 pages

  http://www.guideline.gov/summary/summary.aspx?doc_id=3763&nbr=2989&string=Bowel+AND+cancer

Healthfinder™

Healthfinder™ is an additional source sponsored by the U.S. Department of Health and Human Services which offers links to hundreds of other sites that contain healthcare information. This Web site is located at **http://www.healthfinder.gov**. Again, keyword searches can be used to find guidelines. The following was recently found in this database:

- **Gastric Cancer (PDQ®): Treatment**

  Summary: Based on information in the PDQ summary for health professionals on gastric (stomach) cancer, this patient resource presents facts about current treatment of stomach cancer by cancer stage.

  Source: National Cancer Institute, National Institutes of Health

  http://www.healthfinder.gov/scripts/recordpass.asp?RecordType=0&RecordID=6194

- **Stomach (Gastric) Cancer Home Page**

  Summary: This web site links patients, health care professionals, and the general public to a range of topics related to stomach cancer, including diagnosis, screening, treatment, disease management, coping

  Source: National Cancer Institute, National Institutes of Health

  http://www.healthfinder.gov/scripts/recordpass.asp?RecordType=0&RecordID=6195

- **What You Need To Know About™ Stomach Cancer**

  Summary: Patient information about stomach cancer, including detection/screening, staging, treatment options, treatment side effects and research.

  Source: National Cancer Institute, National Institutes of Health

  http://www.healthfinder.gov/scripts/recordpass.asp?RecordType=0&RecordID=6193

The NIH Search Utility

After browsing the references listed at the beginning of this chapter, you may want to explore the NIH search utility. This allows you to search for documents on over 100 selected Web sites that comprise the NIH-WEB-SPACE. Each of these servers is "crawled" and indexed on an ongoing basis. Your search will produce a list of various documents, all of which will relate in some way to gastrointestinal carcinoid tumors. The drawbacks of this approach are that the information is not organized by theme and that the references are often a mix of information for professionals and patients. Nevertheless, a large number of the listed Web sites provide useful background information. We can only recommend this route, therefore, for relatively rare or specific disorders, or when using highly targeted searches. To use the NIH search utility, visit the following Web page: **http://search.nih.gov/index.html**.

Additional Web Sources

A number of Web sites that often link to government sites are available to the public. These can also point you in the direction of essential information. The following is a representative sample:

- AOL: **http://search.aol.com/cat.adp?id=168&layer=&from=subcats**

- Family Village: **http://www.familyvillage.wisc.edu/specific.htm**
- Google: **http://directory.google.com/Top/Health/Conditions_and_Diseases/**
- Med Help International: **http://www.medhelp.org/HealthTopics/A.html**
- Open Directory Project: **http://dmoz.org/Health/Conditions_and_Diseases/**
- Yahoo.com: **http://dir.yahoo.com/Health/Diseases_and_Conditions/**
- WebMD®Health: **http://my.webmd.com/health_topics**

Vocabulary Builder

The material in this chapter may have contained a number of unfamiliar words. The following Vocabulary Builder introduces you to terms used in this chapter that have not been covered in the previous chapter:

Fat: Total lipids including phospholipids. [NIH]

Feces: The undigested residue of food and other forms of waste matter and alimentary refuse discharged from the bowel during defecation. [NIH]

Genetics: The biological science that deals with the phenomena and mechanisms of heredity. [NIH]

Hereditary: Of, relating to, or denoting factors that can be transmitted genetically from one generation to another. [NIH]

Lymphoma: Tumor of lymphatic tissue. [NIH]

Pancreatic cancer: Cancer of the pancreas, a salivary gland of the abdomen. [NIH]

Specialist: In medicine, one who concentrates on 1 special branch of medical science. [NIH]

Wheezing: Breathing with a rasp or whistling sound. It results from constriction or obstruction of the throat, pharynx, trachea, or bronchi. [NIH]

CHAPTER 2. SEEKING GUIDANCE

Overview

Some patients are comforted by the knowledge that a number of organizations dedicate their resources to helping people with gastrointestinal carcinoid tumors. These associations can become invaluable sources of information and advice. Many associations offer aftercare support, financial assistance, and other important services. Furthermore, healthcare research has shown that support groups often help people to better cope with their conditions.[8] In addition to support groups, your physician can be a valuable source of guidance and support. Therefore, finding a physician that can work with your unique situation is a very important aspect of your care.

In this chapter, we direct you to resources that can help you find patient organizations and medical specialists. We begin by describing how to find associations and peer groups that can help you better understand and cope with gastrointestinal carcinoid tumors. The chapter ends with a discussion on how to find a doctor that is right for you.

Associations and Gastrointestinal Carcinoid Tumors

As mentioned by the Agency for Healthcare Research and Quality, sometimes the emotional side of an illness can be as taxing as the physical side.[9] You may have fears or feel overwhelmed by your situation. Everyone has different ways of dealing with disease or physical injury. Your attitude, your expectations, and how well you cope with your condition can all

[8] Churches, synagogues, and other houses of worship might also have groups that can offer you the social support you need.
[9] This section has been adapted from **http://www.ahcpr.gov/consumer/diaginf5.htm**.

influence your well-being. This is true for both minor conditions and serious illnesses. For example, a study on female breast cancer survivors revealed that women who participated in support groups lived longer and experienced better quality of life when compared with women who did not participate. In the support group, women learned coping skills and had the opportunity to share their feelings with other women in the same situation.

In addition to associations or groups that your doctor might recommend, we suggest that you consider the following list (if there is a fee for an association, you may want to check with your insurance provider to find out if the cost will be covered):

- **David G. Jagelman Inherited Colorectal Cancer Registries**

  Telephone: (216) 444-6470 Toll-free: (800) 998-4785

  Fax: (216) 445-6935

  Email: mcganne@cc.ccf.org

  Background: Established in 1978, the David G. Jagelman Inherited **Colorectal Cancer** Registries is a not-for-profit academic medical center recognized as a National Referral Center and an international resource for diseases of the colon and rectum. Dedicated to identifying, educating, and serving affected individuals, the organization has an educational division, a research institute, and a hospital and outpatient clinic. The organization offers risk assessments and appropriate screening tests; maintains computerized registries of affected individuals and those who may be at risk (e.g., for Familial Adenomatous Polyposis, Hereditary Nonpolyposis **Colorectal Cancer,** and Familial Colon Cancer). It suggests surveillance protocols and reviews surgical options for affected individuals. David G. Jagelman Inherited **Colorectal Cancer** Registries also provides a variety of educational and support materials including brochures, pamphlets, articles, and a newsletter called 'Family Matters.'.

- **Intestinal Multiple Polyposis and Colorectal Cancer Registry**

  Telephone: (717) 788-3712

  Fax: (717) 788-4046

  Email: user291524@aol.com

  Background: The Intestinal Multiple Polyposis and **Colorectal Cancer** Registry, also known as IMPACC, is a not-for-profit self-help service organization that was established in 1986. The purpose of the group is to provide information and support to people affected by Multiple Polyposis or Hereditary **Colorectal Cancer,** their families, and their physicians. Multiple Familial Polyposis is a group of rare inherited

conditions of the gastrointestinal system characterized by benign growths (adenomatous polyps) lining the mucous membrane of the intestine. Because such growths have high malignant potential, affected individuals may potentially develop **cancer of the colon** and/or rectum. The Registry promotes ongoing medical research into the causes, treatment, and prevention of these disorders. IMPACC also offers a variety of services including genetic counseling, referrals to appropriate avenues of treatment, and a quarterly newsletter.

- **Johns Hopkins Hereditary Colorectal Cancer Registry**

  Telephone: (410) 955-3875 Toll-free: (888) 772-6566

  Fax: (410) 614-9544

  Email: hccregistry@jhmi.edu

  Web Site: www.hopkikns.org

  Background: The Johns Hopkins Hereditary **Colorectal Cancer** Registry is a research organization that maintains a registry of families affected by different forms of Hereditary **Colorectal Cancer** including Hereditary Colon Cancer, Familial Adenomatous Polyposis, Hereditary Nonpolyposis **Colorectal Cancer,** Juvenile Polyposis, and Peutz-Jeghers Syndrome. Established in 1973, the Registry currently includes hundreds of families affected by these disorders. Interested individuals are offered the opportunity to participate in ongoing research studies. The Registry also offers educational materials to people affected by hereditary forms of colon cancer, their families, and physicians.

- **M. D. Anderson Cancer Center Hereditary Colorectal Cancer Registry**

  Telephone: (713) 792-2828 Toll-free: (800) 472-4376

  Fax: (713) 745-1163

  Email: hcc-editor@mdacc.tmc.edu

  Web Site: http://www3.mdanderson.org/depts/hcc/registries.htm

  Background: The University of Texas M.D. Anderson Cancer Center Hereditary **Colorectal Cancer** Registry is a registry organization dedicated to evaluating families in which there is a suspected or confirmed risk of a hereditary **colorectal cancer** syndrome. Established in 1988, the registry stafRegistry's staff makes arrangements to obtain necessary risk assessment, tests, procedures, or treatments at M.D. Anderson. Genetic testing and counseling are performed on appropriate families in order to identify persons at high risk for hereditary **colorectal cancer.** Individuals and their family members can also be evaluated for

eligibility for other ongoing studies such as chemoprevention and psychosocial studies. Educational materials include a periodic newsletter entitled 'Hereditary Colon Cancer Newsletter,' a guide entitled 'Johns Hopkins Guide for Patients and Families: Familial Adenomatous Polyposis (FAP),' and 'Hereditary Non-Polyposis Colon Cancer: A Guide for Patients and Families.' Program activities include genetic counseling, educational programs, and referrals.

Finding Associations

There are a several Internet directories that provide lists of medical associations with information on or resources relating to gastrointestinal carcinoid tumors. By consulting all of associations listed in this chapter, you will have nearly exhausted all sources for patient associations concerned with gastrointestinal carcinoid tumors.

The National Cancer Institute (NCI)

The National Cancer Institute (NCI) has complied a list of national organizations that offer services to people with cancer and their families. To view the list, see the NCI fact sheet online at the following Web address: **http://cis.nci.nih.gov/fact/8_1.htm**. The name of each organization is accompanied by its contact information and a brief explanation of its services.

The National Health Information Center (NHIC)

The National Health Information Center (NHIC) offers a free referral service to help people find organizations that provide information about gastrointestinal carcinoid tumors. For more information, see the NHIC's Web site at **http://www.health.gov/NHIC/** or contact an information specialist by calling 1-800-336-4797.

DIRLINE

A comprehensive source of information on associations is the DIRLINE database maintained by the National Library of Medicine. The database comprises some 10,000 records of organizations, research centers, and government institutes and associations which primarily focus on health and

biomedicine. DIRLINE is available via the Internet at the following Web site: **http://dirline.nlm.nih.gov/**. Simply type in "gastrointestinal carcinoid tumors" (or a synonym) or the name of a topic, and the site will list information contained in the database on all relevant organizations.

The Combined Health Information Database

Another comprehensive source of information on healthcare associations is the Combined Health Information Database. Using the "Detailed Search" option, you will need to limit your search to "Organizations" and "gastrointestinal carcinoid tumors". Type the following hyperlink into your Web browser: **http://chid.nih.gov/detail/detail.html**. To find associations, use the drop boxes at the bottom of the search page where "You may refine your search by." For publication date, select "All Years." Then, select your preferred language and the format option "Organization Resource Sheet." By making these selections and typing in "gastrointestinal carcinoid tumors" (or synonyms) into the "For these words:" box, you will only receive results on organizations dealing with gastrointestinal carcinoid tumors. You should check back periodically with this database since it is updated every 3 months.

The National Organization for Rare Disorders, Inc.

The National Organization for Rare Disorders, Inc. has prepared a Web site that provides, at no charge, lists of associations organized by specific diseases. You can access this database at the following Web site: **http://www.rarediseases.org/search/orgsearch.html**. Type "gastrointestinal carcinoid tumors" (or a synonym) in the search box, and click "Submit Query."

Cancer Support Groups[10]

People diagnosed with cancer and their families face many challenges that may leave them feeling overwhelmed, afraid, and alone. It can be difficult to cope with these challenges or to talk to even the most supportive family members and friends. Often, support groups can help people affected by cancer feel less alone and can improve their ability to deal with the uncertainties and challenges that cancer brings. Support groups give people

[10] This section has been adapted from the NCI: **http://cis.nci.nih.gov/fact/8_8.htm**.

who are affected by similar diseases an opportunity to meet and discuss ways to cope with the illness.

How Can Support Groups Help?

People who have been diagnosed with cancer sometimes find they need assistance coping with the emotional as well as the practical aspects of their disease. In fact, attention to the emotional burden of cancer is sometimes part of a patient's treatment plan. Cancer support groups are designed to provide a confidential atmosphere where cancer patients or cancer survivors can discuss the challenges that accompany the illness with others who may have experienced the same challenges. For example, people gather to discuss the emotional needs created by cancer, to exchange information about their disease—including practical problems such as managing side effects or returning to work after treatment—and to share their feelings. Support groups have helped thousands of people cope with these and similar situations.

Can Family Members and Friends Participate in Support Groups?

Family and friends are affected when cancer touches someone they love, and they may need help in dealing with stresses such as family disruptions, financial worries, and changing roles within relationships. To help meet these needs, some support groups are designed just for family members of people diagnosed with cancer; other groups encourage families and friends to participate along with the cancer patient or cancer survivor.

How Can People Find Support Groups?

Many organizations offer support groups for people diagnosed with cancer and their family members or friends. The NCI fact sheet *National Organizations That Offer Services to People with Cancer and Their Families* lists many cancer-concerned organizations that can provide information about support groups. This fact sheet is available at **http://cis.nci.nih.gov/fact/8_1.htm** on the Internet, or can be ordered from the Cancer Information Service at 1–800–4–CANCER (1–800–422–6237). Some of these organizations provide information on their Web sites about contacting support groups.

Doctors, nurses, or hospital social workers who work with cancer patients may also have information about support groups, such as their location, size, type, and how often they meet. Most hospitals have social services departments that provide information about cancer support programs. Additionally, many newspapers carry a special health supplement containing information about where to find support groups.

What Types of Support Groups Are Available?

Several kinds of support groups are available to meet the individual needs of people at all stages of cancer treatment, from diagnosis through follow-up care. Some groups are general cancer support groups, while more specialized groups may be for teens or young adults, for family members, or for people affected by a particular disease. Support groups may be led by a professional, such as a psychiatrist, psychologist, or social worker, or by cancer patients or survivors. In addition, support groups can vary in approach, size, and how often they meet. Many groups are free, but some require a fee (people can contact their health insurance company to find out whether their plan will cover the cost). It is important for people to find an atmosphere that is comfortable and meets their individual needs.

Online Support Groups

In addition to support groups, commercial Internet service providers offer forums and chat rooms for people with different illnesses and conditions. WebMD®, for example, offers such a service at their Web site: **http://boards.webmd.com/roundtable**. These online self-help communities can help you connect with a network of people whose concerns are similar to yours. Online support groups are places where people can talk informally. If you read about a novel approach, consult with your doctor or other healthcare providers, as the treatments or discoveries you hear about may not be scientifically proven to be safe and effective.

The Cancer Information Service[11]

The Cancer Information Service (CIS) is a program of the National Cancer Institute (NCI), the Nation's lead agency for cancer research. As a resource for information and education about cancer, the CIS is a leader in helping

[11] This section has been adapted from the NCI: **http://cis.nci.nih.gov/fact/2_5.htm**.

people become active participants in their own health care by providing the latest information on cancer in understandable language. Through its network of regional offices, the CIS serves the United States, Puerto Rico, the U.S. Virgin Islands, and the Pacific Islands.

For 25 years, the Cancer Information Service has provided the latest and most accurate cancer information to patients and families, the public, and health professionals by:

- Interacting with people one-on-one through its Information Service,
- Working with organizations through its Partnership Program,
- Participating in research efforts to find the best ways to help people adopt healthier behaviors,
- Providing access to NCI information over the Internet.

How Does the CIS Assist the Public?

Through the CIS toll-free telephone service (1–800–4–CANCER), callers speak with knowledgeable, caring staff who are experienced at explaining medical information in easy-to-understand terms. CIS information specialists answer calls in English and Spanish. They also provide cancer information to deaf and hard of hearing callers through the toll-free TTY number (1–800–332–8615). CIS staff have access to comprehensive, accurate information from the NCI on a range of cancer topics, including the most recent advances in cancer treatment. They take as much time as each caller needs, provide thorough and personalized attention, and keep all calls confidential.

The CIS also provides live, online assistance to users of NCI Web sites through LiveHelp, an instant messaging service that is available from 9:00 a.m. to 7:30 p.m. Eastern time, Monday through Friday. Through LiveHelp, information specialists provide answers to questions about cancer and help in navigating Cancer.gov, the NCI's Web site.

Through the telephone numbers or LiveHelp service, CIS users receive:

- Answers to their questions about cancer, including ways to prevent cancer, symptoms and risks, diagnosis, current treatments, and research studies;
- Written materials from the NCI;
- Referrals to clinical trials and cancer-related services, such as treatment centers, mammography facilities, or other cancer organizations;

- Assistance in quitting smoking from information specialists trained in smoking cessation counseling.

What Kind of Assistance Does the CIS Partnership Program Offer?

Through its Partnership Program, the CIS collaborates with established national, state, and regional organizations to reach minority and medically underserved audiences with cancer information. Partnership Program staff provide assistance to organizations developing programs that focus on breast and cervical cancer, clinical trials, tobacco control, and cancer awareness for special populations. To reach those in need, the CIS:

- Helps bring cancer information to people who do not traditionally seek health information or who may have difficulties doing so because of educational, financial, cultural, or language barriers;
- Provides expertise to organizations to help strengthen their ability to inform people they serve about cancer; and
- Links organizations with similar goals and helps them plan and evaluate programs, develop coalitions, conduct training on cancer-related topics, and use NCI resources.

How Do CIS Research Efforts Assist the Public?

The CIS plays an important role in research by studying the most effective ways to communicate with people about healthy lifestyles; health risks; and options for preventing, diagnosing, and treating cancer. The ability to conduct health communications research is a unique aspect of the CIS. Results from these research studies can be applied to improving the way the CIS communicates about cancer and can help other programs communicate more effectively.

How Do People Reach the Cancer Information Service?

- To speak with a CIS information specialist call 1–800–4–CANCER (1–800–422–6237), 9:00 a.m. to 4:30 p.m. local time, Monday through Friday. Deaf or hard of hearing callers with TTY equipment may call 1–800–332–8615.
- To obtain online assistance visit the NCI's Cancer Information Web site at **http://cancer.gov/cancer_information** and click on the LiveHelp link between 9:00 a.m. and 7:30 p.m. Eastern time, Monday through Friday.

- For information 24 hours a day, 7 days a week call 1–800–4–CANCER and select option 4 to hear recorded information at any time.
- Visit NCI's Web site at **http://cancer.gov** on the Internet.
- Visit the CIS Web site at **http://cancer.gov/cis** on the Internet.

Finding Cancer Resources in Your Community[12]

If you have cancer or are undergoing cancer treatment, there are places in your community to turn to for help. There are many local organizations throughout the country that offer a variety of practical and support services to people with cancer. However, people often don't know about these services or are unable to find them. National cancer organizations can assist you in finding these resources, and there are a number of things you can do for yourself.

Whether you are looking for a support group, counseling, advice, financial assistance, transportation to and from treatment, or information about cancer, most neighborhood organizations, local health care providers, or area hospitals are a good place to start. Often, the hardest part of looking for help is knowing the right questions to ask.

What Kind of Help Can I Get?

Until now, you probably never thought about the many issues and difficulties that arise with a diagnosis of cancer. There are support services to help you deal with almost any type of problem that might occur. The first step in finding the help you need is knowing what types of services are available. The following pages describe some of these services and how to find them.

- **Information on Cancer.** Most national cancer organizations provide a range of information services, including materials on different types of cancer, treatments, and treatment-related issues.
- **Counseling.** While some people are reluctant to seek counseling, studies show that having someone to talk to reduces stress and helps people both mentally and physically. Counseling can also provide emotional support to cancer patients and help them better understand their illness. Different types of counseling include individual, group, family, self-help

[12] Adapted from the NCI: **http://cis.nci.nih.gov/fact/8_9.htm**.

(sometimes called peer counseling), bereavement, patient-to-patient, and sexuality.

- **Medical Treatment Decisions.** Often, people with cancer need to make complicated medical decisions. Many organizations provide hospital and physician referrals for second opinions and information on clinical trials (research studies with people), which may expand treatment options.
- **Prevention and Early Detection.** While cancer prevention may never be 100 percent effective, many things (such as quitting smoking and eating healthy foods) can greatly reduce a person's risk for developing cancer. Prevention services usually focus on smoking cessation and nutrition. Early detection services, which are designed to detect cancer when a person has no symptoms of disease, can include referrals for screening mammograms, Pap tests, or prostate exams.
- **Home Health Care.** Home health care assists patients who no longer need to stay in a hospital or nursing home, but still require professional medical help. Skilled nursing care, physical therapy, social work services, and nutrition counseling are all available at home.
- **Hospice Care.** Hospice is care focused on the special needs of terminally ill cancer patients. Sometimes called *palliative care*, it centers around providing comfort, controlling physical symptoms, and giving emotional support to patients who can no longer benefit from curative treatment. Hospice programs provide services in various settings, including the patient's home, hospice centers, hospitals, or skilled nursing facilities. Your doctor or social worker can provide a referral for these services.
- **Rehabilitation.** Rehabilitation services help people adjust to the effects of cancer and its treatment. Physical rehabilitation focuses on recovery from the physical effects of surgery or the side effects associated with chemotherapy. Occupational or vocational therapy helps people readjust to everyday routines, get back to work, or find employment.
- **Advocacy.** Advocacy is a general term that refers to promoting or protecting the rights and interests of a certain group, such as cancer patients. Advocacy groups may offer services to assist with legal, ethical, medical, employment, legislative, or insurance issues, among others. For instance, if you feel your insurance company has not handled your claim fairly, you may want to advocate for a review of its decision.
- **Financial.** Having cancer can be a tremendous financial burden to cancer patients and their families. There are programs sponsored by the government and nonprofit organizations to help cancer patients with problems related to medical billing, insurance coverage, and reimbursement issues. There are also sources for financial assistance, and

ways to get help collecting entitlements from Medicaid, Medicare, and the Social Security Administration.

- **Housing/Lodging.** Some organizations provide lodging for the family of a patient undergoing treatment, especially if it is a child who is ill and the parents are required to accompany the child to treatment.
- **Children's Services.** A number of organizations provide services for children with cancer, including summer camps, make-a-wish programs, and help for parents seeking child care.

How to Find These Services

Often, the services that people with cancer are looking for are right in their own neighborhood or city. The following is a list of places where you can begin your search for help.

- The hospital, clinic, or medical center where you see your doctor, received your diagnosis, or where you undergo treatment should be able to give you information. Your doctor or nurse may be able to tell you about your specific medical condition, pain management, rehabilitation services, home nursing, or hospice care.
- Most hospitals also have a social work, home care, or discharge planning department. This department may be able to help you find a support group, a nonprofit agency that helps people who have cancer, or the government agencies that oversee Social Security, Medicare, and Medicaid. While you are undergoing treatment, be sure to ask the hospital about transportation, practical assistance, or even temporary child care. Talk to a hospital financial counselor in the business office about developing a monthly payment plan if you need help with hospital expenses.
- The public library is an excellent source of information, as are patient libraries at many cancer centers. A librarian can help you find books and articles through a literature search.
- A local church, synagogue, YMCA or YWCA, or fraternal order may provide financial assistance, or may have volunteers who can help with transportation and home care. Catholic Charities, the United Way, or the American Red Cross may also operate local offices. Some of these organizations may provide home care, and the United Way's information and referral service can refer you to an agency that provides financial help. To find the United Way serving your community, visit their online

directory at **http://www.unitedway.org** on the Internet or look in the White Pages of your local telephone book.

- Local or county government agencies may offer low-cost transportation (sometimes called para-transit) to individuals unable to use public transportation. Most states also have an Area Agency on Aging that offers low-cost services to people over 60. Your hospital or community social worker can direct you to government agencies for entitlements, including Social Security, state disability, Medicaid, income maintenance, and food stamps. (Keep in mind that most applications to entitlement programs take some time to process.) The Federal government also runs the Hill-Burton program (1–800–638–0742), which funds certain medical facilities and hospitals to provide cancer patients with free or low-cost care if they are in financial need.

Getting the Most From a Service: What To Ask

No matter what type of help you are looking for, the only way to find resources to fit your needs is to ask the right questions. When you are calling an organization for information, it is important to think about what questions you are going to ask before you call. Many people find it helpful to write out their questions in advance, and to take notes during the call. Another good tip is to ask the name of the person with whom you are speaking in case you have follow-up questions. Below are some of the questions you may want to consider if you are calling or visiting a new agency and want to learn about how they can help:

- How do I apply [for this service]?
- Are there eligibility requirements? What are they?
- Is there an application process? How long will it take? What information will I need to complete the application process? Will I need anything else to get the service?
- Do you have any other suggestions or ideas about where I can find help?

The most important thing to remember is that you will rarely receive help unless you ask for it. In fact, asking can be the hardest part of getting help. Don't be afraid or ashamed to ask for assistance. Cancer is a very difficult disease, but there are people and services that can ease your burdens and help you focus on your treatment and recovery.

Finding Doctors Who Specialize in Cancer Care[13]

One of the most important aspects of your treatment will be the relationship between you and your doctor or specialist. All patients with gastrointestinal carcinoid tumors must go through the process of selecting a physician. A common way to find a doctor who specializes in cancer care is to ask for a referral from your primary care physician. Sometimes, you may know a specialist yourself, or through the experience of a family member, coworker, or friend.

The following resources may also be able to provide you with names of doctors who specialize in treating specific diseases or conditions. However, these resources may not have information about the quality of care that the doctors provide.

- Your local hospital or its patient referral service may be able to provide you with a list of specialists who practice at that hospital.
- Your nearest National Cancer Institute (NCI)-designated cancer center can provide information about doctors who practice at that center. The NCI fact sheet *The National Cancer Institute Cancer Centers Program* describes and gives contact information, including Web sites, for NCI-designated cancer treatment centers around the country. Many of the cancer centers' Web sites have searchable directories of physicians who practice at each facility. The NCI's fact sheet is available at **http://cis.nci.nih.gov/fact/1_2.htm** on the Internet, or by calling the Cancer Information Service (CIS) at 1–800–4–CANCER (1–800–422–6237).
- The American Board of Medical Specialties (ABMS) publishes a list of board-certified physicians. The *Official ABMS Directory of Board Certified Medical Specialists* lists doctors' names along with their specialty and their educational background. This resource is available in most public libraries. The ABMS also has a Web site that can be used to verify whether a specific physician is board-certified. This free service is located at **http://www.abms.org/newsearch.asp** on the Internet. Verification of a physician's board certification can also be obtained by calling the ABMS at 1–866–275–2267 (1–866–ASK–ABMS).
- The American Medical Association (AMA) provides an online service called AMA Physician Select that offers basic professional information on virtually every licensed physician in the United States and its possessions. The database can be searched by doctor's name or by

[13] Adapted from the NCI: **http://cis.nci.nih.gov/fact/7_47.htm**.

medical specialty. The AMA Physician Select service is located at **http://www.ama-assn.org/aps/amahg.htm** on the Internet.

- The American Society of Clinical Oncologists (ASCO) provides an online list of doctors who are members of ASCO. The member database has the names and affiliations of over 15,000 oncologists worldwide. It can be searched by doctor's name, institution's name, location, and/or type of board certification. This service is located at **http://www.asco.org/people/db/html/m_db.htm** on the Internet.
- The American College of Surgeons (ACOS) Fellowship Database is an online list of surgeons who are Fellows of the ACOS. The list can be searched by doctor's name, geographic location, or medical specialty. This service is located at **http://web.facs.org/acsdir/default.htm** on the Internet. The ACOS can be contacted at 633 North Saint Clair Street, Chicago, IL 60611–3211; or by telephone at 312–202–5000.
- Local medical societies may maintain lists of doctors in each specialty.
- Public and medical libraries may have print directories of doctors' names, listed geographically by specialty.
- Your local Yellow Pages may have doctors listed by specialty under "Physicians."

The Agency for Healthcare Research and Quality (AHRQ) offers *Your Guide to Choosing Quality Health Care*, which has information for consumers on choosing a health plan, a doctor, a hospital, or a long-term care provider. The Guide includes suggestions and checklists that you can use to determine which doctor or hospital is best for you. This resource is available at **http://www.ahrq.gov/consumer/qntool.htm** on the Internet. You can also order the Guide by calling the AHRQ Publications Clearinghouse at 1–800–358–9295.

If you are a member of a health insurance plan, your choice may be limited to doctors who participate in your plan. Your insurance company can provide you with a list of participating primary care doctors and specialists. It is important to ask your insurance company if the doctor you choose is accepting new patients through your health plan. You also have the option of seeing a doctor outside your health plan and paying the costs yourself. If you have a choice of health insurance plans, you may first wish to consider which doctor or doctors you would like to use, then choose a plan that includes your chosen physician(s).

The National Comprehensive Cancer Network (NCCN) Physician Directory lists specialists who practice in the NCCN's 19 member institutions across

the U.S. To access the directory, go to **http://www.nccn.org/** and click on "Physician Directory". To use this service, you will be required to scroll to the bottom of the page and select "I agree." Enter your search criteria and select "Find" at the bottom of the page. To obtain more information on a physician or institution, contact the institution's Physician Referral Department or the NCCN Patient Information and Referral Service at 1-888-909-NCCN or **patientinformation@nccn.org**.

If the previous sources did not meet your needs, you may want to log on to the Web site of the National Organization for Rare Disorders (NORD) at **http://www.rarediseases.org/**. NORD maintains a database of doctors with expertise in various rare diseases. The Metabolic Information Network (MIN), 800-945-2188, also maintains a database of physicians with expertise in various metabolic diseases.

Selecting Your Doctor[14]

When you have compiled a list of prospective doctors, call each of their offices. First, ask if the doctor accepts your health insurance plan and if he or she is taking new patients. If the doctor is not covered by your plan, ask yourself if you are prepared to pay the extra costs. The next step is to schedule a visit with your chosen physician. During the first visit you will have the opportunity to evaluate your doctor and to find out if you feel comfortable with him or her. Ask yourself, did the doctor:

- Give me a chance to ask questions about gastrointestinal carcinoid tumors?
- Really listen to my questions?
- Answer in terms I understood?
- Show respect for me?
- Ask me questions?
- Make me feel comfortable?
- Address the health problem(s) I came with?
- Ask me my preferences about different kinds of treatments for gastrointestinal carcinoid tumors?
- Spend enough time with me?

[14] This section has been adapted from the AHRQ: **www.ahrq.gov/consumer/qntascii/qntdr.htm**.

Trust your instincts when deciding if the doctor is right for you. But remember, it might take time for the relationship to develop. It takes more than one visit for you and your doctor to get to know each other.

Working with Your Doctor[15]

Research has shown that patients who have good relationships with their doctors tend to be more satisfied with their care and have better results. Here are some tips to help you and your doctor become partners:

- You know important things about your symptoms and your health history. Tell your doctor what you think he or she needs to know.
- It is important to tell your doctor personal information, even if it makes you feel embarrassed or uncomfortable.
- Bring a "health history" list with you (and keep it up to date).
- Always bring any medications you are currently taking with you to the appointment, or you can bring a list of your medications including dosage and frequency information. Talk about any allergies or reactions you have had to your medications.
- Tell your doctor about any natural or alternative medicines you are taking.
- Bring other medical information, such as x-ray films, test results, and medical records.
- Ask questions. If you don't, your doctor will assume that you understood everything that was said.
- Write down your questions before your visit. List the most important ones first to make sure that they are addressed.
- Consider bringing a friend with you to the appointment to help you ask questions. This person can also help you understand and/or remember the answers.
- Ask your doctor to draw pictures if you think that this would help you understand.
- Take notes. Some doctors do not mind if you bring a tape recorder to help you remember things, but always ask first.

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[15] This section has been adapted from the AHRQ: **www.ahrq.gov/consumer/qntascii/qntdr.htm**.

- Let your doctor know if you need more time. If there is not time that day, perhaps you can speak to a nurse or physician assistant on staff or schedule a telephone appointment.
- Take information home. Ask for written instructions. Your doctor may also have brochures and audio and videotapes that can help you.
- After leaving the doctor's office, take responsibility for your care. If you have questions, call. If your symptoms get worse or if you have problems with your medication, call. If you had tests and do not hear from your doctor, call for your test results. If your doctor recommended that you have certain tests, schedule an appointment to get them done. If your doctor said you should see an additional specialist, make an appointment.

By following these steps, you will enhance the relationship you will have with your physician.

Finding a Cancer Treatment Facility[16]

Choosing a treatment facility is another important consideration for getting the best medical care possible. Although you may not be able to choose which hospital treats you in an emergency, you can choose a facility for scheduled and ongoing care. If you have already found a doctor for your cancer treatment, you may need to choose a facility based on where your doctor practices. Your doctor may be able to recommend a facility that provides quality care to meet your needs. You may wish to ask the following questions when considering a treatment facility:

- Has the facility had experience and success in treating my condition?
- Has the facility been rated by state, consumer, or other groups for its quality of care?
- How does the facility check and work to improve its quality of care?
- Has the facility been approved by a nationally recognized accrediting body, such as the American College of Surgeons (ACOS) and/or the Joint Commission on Accredited Healthcare Organizations (JCAHO)?
- Does the facility explain patients' rights and responsibilities? Are copies of this information available to patients?

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[16] Adapted from the NCI: **http://cis.nci.nih.gov/fact/7_47.htm**. At this Web site, information on how to find treatment facilities is also available for patients living outside the U.S.

- Does the treatment facility offer support services, such as social workers and resources to help me find financial assistance if I need it?
- Is the facility conveniently located?

If you are a member of a health insurance plan, your choice of treatment facilities may be limited to those that participate in your plan. Your insurance company can provide you with a list of approved facilities. Although the costs of cancer treatment can be very high, you have the option of paying out-of-pocket if you want to use a treatment facility that is not covered by your insurance plan. If you are considering paying for treatment yourself, you may wish to discuss the potential costs with your doctor beforehand. You may also want to speak with the person who does the billing for the treatment facility. In some instances, nurses and social workers can provide you with more information about coverage, eligibility, and insurance issues.

The following resources may help you find a hospital or treatment facility for your care:

- The NCI fact sheet *The National Cancer Institute Cancer Centers Program* describes and gives contact information for NCI-designated cancer treatment centers around the country.
- The ACOS accredits cancer programs at hospitals and other treatment facilities. More than 1,400 programs in the United States have been designated by the ACOS as Approved Cancer Programs. The ACOS Web site offers a searchable database of these programs at **http://web.facs.org/cpm/default.htm** on the Internet. The ACOS can be contacted at 633 North Saint Clair Street, Chicago, IL 60611–3211; or by telephone at 312–202–5000.
- The JCAHO is an independent, not-for-profit organization that evaluates and accredits health care organizations and programs in the United States. It also offers information for the general public about choosing a treatment facility. The JCAHO Web site is located at **http://www.jcaho.org** on the Internet. The JCAHO is located at One Renaissance Boulevard, Oakbrook Terrace, IL 60181–4294. The telephone number is 630–792–5800.
- The JCAHO offers an online Quality Check service that patients can use to determine whether a specific facility has been accredited by the JCAHO and view the organization's performance reports. This service is located at **http://www.jcaho.org/qualitycheck/directry/directry.asp** on the Internet.

- The AHRQ publication *Your Guide To Choosing Quality Health Care* has suggestions and checklists for choosing the treatment facility that is right for you.

Additional Cancer Support Information

In addition to the references above, the NCI has set up guidance Web sites that offers information on issues relating to cancer. These include:

- Facing Forward - A Guide for Cancer Survivors: **http://www.cancer.gov/cancer_information/doc_img.aspx?viewid=cc93a843-6fc0-409e-8798-5c65afc172fe**
- Taking Time: Support for People With Cancer and the People Who Care About Them: **http://www.cancer.gov/cancer_information/doc_img.aspx?viewid=21a46445-a5c8-4fee-95a3-d9d0d665077a**
- When Cancer Recurs: Meeting the Challenge: **http://www.cancer.gov/cancer_information/doc_img.aspx?viewid=9e13d0d2-b7de-4bd6-87da-5750300a0dab**
- Your Health Care Team: Your Doctor Is Only the Beginning: **http://cis.nci.nih.gov/fact/8_10.htm**

Vocabulary Builder

The following vocabulary builder provides definitions of words used in this chapter that have not been defined in previous chapters:

Growth: The progressive development of a living being or part of an organism from its earliest stage to maturity. [NIH]

Hospice: Institution dedicated to caring for the terminally ill. [NIH]

Joint: The point of contact between elements of an animal skeleton with the parts that surround and support it. [NIH]

Outpatient: A patient who is not an inmate of a hospital but receives diagnosis or treatment in a clinic or dispensary connected with the hospital. [NIH]

Protocol: The detailed plan for a clinical trial that states the trial's rationale, purpose, drug or vaccine dosages, length of study, routes of administration, who may participate, and other aspects of trial design. [NIH]

CHAPTER 3. CLINICAL TRIALS AND GASTROINTESTINAL CARCINOID TUMORS

Overview

Very few medical conditions have a single treatment. The basic treatment guidelines that your physician has discussed with you, or those that you have found using the techniques discussed in Chapter 1, may provide you with all that you will require. For some patients, current treatments can be enhanced with new or innovative techniques currently under investigation. In this chapter, we will describe how clinical trials work and show you how to keep informed of trials concerning gastrointestinal carcinoid tumors.

What Is a Clinical Trial?[17]

Clinical trials involve the participation of people in medical research. Most medical research begins with studies in test tubes and on animals. Treatments that show promise in these early studies may then be tried with people. The only sure way to find out whether a new treatment is safe, effective, and better than other treatments for gastrointestinal carcinoid tumors is to try it on patients in a clinical trial.

[17] The discussion in this chapter has been adapted from the NIH and the NEI: **http://www.nei.nih.gov/health/clinicaltrials%5Ffacts/index.htm**.

What Kinds of Clinical Trials Are There?

Clinical trials are carried out in three phases:

- **Phase I.** Researchers first conduct Phase I trials with small numbers of patients and healthy volunteers. If the new treatment is a medication, researchers also try to determine how much of it can be given safely.
- **Phase II.** Researchers conduct Phase II trials in small numbers of patients to find out the effect of a new treatment on gastrointestinal carcinoid tumors.
- **Phase III.** Finally, researchers conduct Phase III trials to find out how new treatments for gastrointestinal carcinoid tumors compare with standard treatments already being used. Phase III trials also help to determine if new treatments have any side effects. These trials--which may involve hundreds, perhaps thousands, of people--can also compare new treatments with no treatment.

How Is a Clinical Trial Conducted?

Various organizations support clinical trials at medical centers, hospitals, universities, and doctors' offices across the United States. The "principal investigator" is the researcher in charge of the study at each facility participating in the clinical trial. Most clinical trial researchers are medical doctors, academic researchers, and specialists. The "clinic coordinator" knows all about how the study works and makes all the arrangements for your visits.

All doctors and researchers who take part in the study on gastrointestinal carcinoid tumors carefully follow a detailed treatment plan called a protocol. This plan fully explains how the doctors will treat you in the study. The "protocol" ensures that all patients are treated in the same way, no matter where they receive care.

Clinical trials are controlled. This means that researchers compare the effects of the new treatment with those of the standard treatment. In some cases, when no standard treatment exists, the new treatment is compared with no treatment. Patients who receive the new treatment are in the treatment group. Patients who receive a standard treatment or no treatment are in the "control" group. In some clinical trials, patients in the treatment group get a new medication while those in the control group get a placebo. A placebo is a harmless substance, a "dummy" pill, that has no effect on gastrointestinal carcinoid tumors. In other clinical trials, where a new surgery or device (not

a medicine) is being tested, patients in the control group may receive a "sham treatment." This treatment, like a placebo, has no effect on gastrointestinal carcinoid tumors and does not harm patients.

Researchers assign patients "randomly" to the treatment or control group. This is like flipping a coin to decide which patients are in each group. If you choose to participate in a clinical trial, you will not know which group you will be appointed to. The chance of any patient getting the new treatment is about 50 percent. You cannot request to receive the new treatment instead of the placebo or sham treatment. Often, you will not know until the study is over whether you have been in the treatment group or the control group. This is called a "masked" study. In some trials, neither doctors nor patients know who is getting which treatment. This is called a "double masked" study. These types of trials help to ensure that the perceptions of the patients or doctors will not affect the study results.

Natural History Studies

Unlike clinical trials in which patient volunteers may receive new treatments, natural history studies provide important information to researchers on how gastrointestinal carcinoid tumors develops over time. A natural history study follows patient volunteers to see how factors such as age, sex, race, or family history might make some people more or less at risk for gastrointestinal carcinoid tumors. A natural history study may also tell researchers if diet, lifestyle, or occupation affects how a disease or disorder develops and progresses. Results from these studies provide information that helps answer questions such as: How fast will a disease or disorder usually progress? How bad will the condition become? Will treatment be needed?

What Is Expected of Patients in a Clinical Trial?

Not everyone can take part in a clinical trial for a specific disease or disorder. Each study enrolls patients with certain features or eligibility criteria. These criteria may include the type and stage of disease or disorder, as well as, the age and previous treatment history of the patient. You or your doctor can contact the sponsoring organization to find out more about specific clinical trials and their eligibility criteria. If you are interested in joining a clinical trial, your doctor must contact one of the trial's investigators and provide details about your diagnosis and medical history.

If you participate in a clinical trial, you may be required to have a number of medical tests. You may also need to take medications and/or undergo

surgery. Depending upon the treatment and the examination procedure, you may be required to receive inpatient hospital care. Or, you may have to return to the medical facility for follow-up examinations. These exams help find out how well the treatment is working. Follow-up studies can take months or years. However, the success of the clinical trial often depends on learning what happens to patients over a long period of time. Only patients who continue to return for follow-up examinations can provide this important long-term information.

Recent Trials on Gastrointestinal Carcinoid Tumors

The National Institutes of Health and other organizations sponsor trials on various diseases and disorders. Because funding for research goes to the medical areas that show promising research opportunities, it is not possible for the NIH or others to sponsor clinical trials for every disease and disorder at all times. The following lists recent trials dedicated to gastrointestinal carcinoid tumors.[18] If the trial listed by the NIH is still recruiting, you may be eligible. If it is no longer recruiting or has been completed, then you can contact the sponsors to learn more about the study and, if published, the results. Further information on the trial is available at the Web site indicated. Please note that some trials may no longer be recruiting patients or are otherwise closed. Before contacting sponsors of a clinical trial, consult with your physician who can help you determine if you might benefit from participation.

- **Adjuvant Hepatic Arterial Infusion and Combination Chemotherapy in Treating Patients With Resectable Hepatic Metastases From Colorectal Cancer**

  Condition(s): Colon Cancer; liver metastases; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Memorial Sloan-Kettering Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Hepatic arterial infusion uses a catheter to deliver chemotherapy directly to the liver. Chemoprotective drugs such as dexamethasone may protect normal cells from the side effects of chemotherapy. Combining more than one chemotherapy drug and giving them after surgery may kill any remaining tumor cells. PURPOSE: Phase I trial to study the effectiveness of combining adjuvant hepatic arterial infusion with

[18] These are listed at **www.ClinicalTrials.gov**.

combination chemotherapy in treating patients who have resectablehepatic (liver) metastases from **colorectal cancer.**

Phase(s): Phase I

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00059930

- **Antineoplaston Therapy in Treating Patients With Colon Cancer**

  Condition(s): stage IV colon cancer; recurrent colon cancer; adenocarcinoma of the colon

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Burzynski Research Institute

  Purpose - Excerpt: RATIONALE: Antineoplastons are naturally occurring substances found in urine. Antineoplastons may inhibit the growth of cancer cells. PURPOSE: Phase II trial to study the effectiveness of antineoplaston therapy in treating patients with colon cancer.

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00003486

- **Antineoplaston Therapy in Treating Patients With Metastatic or Unresectable Colon Cancer**

  Condition(s): stage IV colon cancer; recurrent colon cancer; adenocarcinoma of the colon

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Burzynski Research Institute

  Purpose - Excerpt: RATIONALE: Antineoplastons are naturally occurring substances found in urine. Antineoplastons may inhibit the growth of cancer cells. PURPOSE: Phase II trial to study the effectiveness of antineoplaston therapy in treating patients with metastatic or unresectable colon cancer.

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00003485

- **Capecitabine and Irinotecan in Treating Patients With Locally Advanced, Recurrent, or Metastatic Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Hoffmann-La Roche

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combining capecitabine and irinotecan in treating patients who have locally advanced, recurrent, or metastaticcolorectal cancer.

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00022698

- **Celecoxib, Leucovorin, Fluorouracil, and Oxaliplatin in Treating Patients With Metastatic Colorectal Cancer**

  Condition(s): Stage IV rectal cancer; stage IV colon cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum; recurrent rectal cancer; recurrent colon cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): GERCOR

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as leucovorin, fluorouracil, and oxaliplatin, use different ways to stop tumor cells from dividing so they stop growing or die. Celecoxib may stop the growth of **colorectal cancer** by stopping blood flow to the tumor and by blocking the enzymes necessary for tumor cell growth. Combining chemotherapy with celecoxib may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combining celecoxib with leucovorin, fluorouracil, and oxaliplatin in treating patients who have metastatic **colorectal cancer.**

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00072553

- **Combination Chemotherapy and Oblimersen in Treating Patients With Advanced Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): San Antonio Cancer Institute; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. Oblimersen may increase the effectiveness of chemotherapy by making tumor cells more sensitive to the drugs. PURPOSE: Phase I/II trial to study the effectiveness of combining oxaliplatin, fluorouracil, and leucovorin with oblimersen in treating patients who have unresectable, metastatic, or recurrentcolorectal cancer.

  Phase(s): Phase I; Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00055822

- **Combination Chemotherapy and Radiation Therapy in Treating Patients With Stage III or Stage IV Colorectal Cancer, Other Refractory Cancer, or Metastatic Cancer of Unknown Primary Origin**

  Condition(s): adult solid tumor; carcinoma of unknown primary; childhood solid tumor; Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): St. Jude Children's Research Hospital; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Radiation therapy uses high-energy x-rays to damage tumor cells. Combining more than one chemotherapy drug with radiation therapy may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combination chemotherapy and radiation therapy in treating patients who have stage III or stage IV **colorectal cancer,** other refractory cancer, or metastaticcancer of unknown primary origin.

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00004005

- **Combination Chemotherapy in Treating Patients With Colon Cancer**

  Condition(s): adenocarcinoma of the colon; stage II colon cancer; stage III colon cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Groupe Regional d'Etudes du Cancer Colorectal

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. It is not yet known which schedule of chemotherapy is most effective in treating colon cancer. PURPOSE: Randomizedphase III trial to compare different schedules of chemotherapy using carboplatin with fluorouracil and leucovorin in treating patients who have stage IIB or stage III colon cancer.

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00046995

- **Combination Chemotherapy in Treating Patients With Liver Metastases from Colorectal Cancer**

  Condition(s): Colon Cancer; liver metastases; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Cancer and Leukemia Group B; National Cancer Institute (NCI); Eastern Cooperative Oncology Group

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more cancer cells. It is not yet known which chemotherapy regimen is more effective for metastatic **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of intrahepaticfloxuridine, leucovorin, and dexamethasone with that of systemicfluorouracil and leucovorin in treating patients who have unresectableliver metastases from **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00002716

- **Combination Chemotherapy in Treating Patients With Unresectable Liver Metastases from Colorectal Cancer**

  Condition(s): Colon Cancer; liver metastases; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Memorial Sloan-Kettering Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Cryosurgery kills cancer cells by freezing them. Combining more than one chemotherapy drug with cryosurgery and giving drugs in different ways may kill more tumor cells. PURPOSE: Phase I trial to study the effectiveness of intrahepatic and intravenouscombination chemotherapy with or without cryosurgery in treating unresectableliver metastases from **colorectal cancer.**

  Phase(s): Phase I

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00008294

- **Combination Chemotherapy in Treating Patients With Unresectable Metastatic Colorectal Cancer**

  Condition(s): stage IV colon cancer; Stage IV rectal cancer; recurrent colon cancer; recurrent rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Medical Research Council

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. It is not yet known which regimen of combination chemotherapy is more effective for advanced **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of fluorouracil combined with leucovorin and either irinotecan or oxaliplatin in treating patients who have unresectablemetastatic **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00008060

- **Combination Chemotherapy With or Without Celecoxib in Treating Patients With Metastatic Colorectal Cancer**

  Condition(s): adenocarcinoma of the colon; adenocarcinoma of the rectum; stage IV colon cancer; Stage IV rectal cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): EORTC Gastrointestinal Tract Cancer Cooperative Group

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy such as irinotecan, capecitabine, leucovorin, and fluorouracil use different ways to stop tumor cells from dividing so they stop growing or die. Celecoxib may stop the growth of **colorectal cancer** by stopping blood flow to the tumor. It is not yet known which combination chemotherapyregimen with or without celecoxib is more effective in treating metastatic **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of two combination chemotherapy regimens with or without celecoxib in treating patients who have metastatic **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00064181

- **Conventional Surgery Compared With Laparoscopic-Assisted Surgery in Treating Patients With Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Medical Research Council

  Purpose - Excerpt: RATIONALE: Laparoscopic-assisted surgery is a less invasive type of surgery for **colorectal cancer** and may have fewer side effects and improve recovery. It is not yet known if undergoing conventional surgery is more effective than laparoscopic-assisted surgery for **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of conventional surgery with that of laparoscopic-assisted surgery in treating patients who have **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00003354

- **Epothilone D as Second-Line Treatment for Patients With Advanced or Metastatic Refractory Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Memorial Sloan-Kettering Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy such as epothilone D work in different ways to stop tumor cells from dividing so they stop growing or die. PURPOSE: Phase II trial to study the effectiveness of epothilone D as second-line therapy in treating patients who have advanced or metastaticrefractorycolorectal cancer.

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00077259

- **Erlotinib and Combination Chemotherapy in Treating Patients With Metastatic or Locally Advanced Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Sidney Kimmel Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Erlotinib may stop the growth of tumor cells by blocking the enzymes necessary for tumor cell growth. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining erlotinib with combination chemotherapy may kill more tumor cells. PURPOSE: Phase I trial to study the effectiveness of combining erlotinib with fluorouracil, leucovorin, and oxaliplatin in treating patients who have metastatic or locally advancedcolorectal cancer.

  Phase(s): Phase I

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00060411

- **First-line treatment of metastatic colorectal cancer with oxaliplatin/5-FU/leucovorin plus PTK787/ZK 222584 or placebo**

  Condition(s): Colorectal Neoplasms; Colonic Neoplasms; Rectal Neoplasms

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Novartis Pharmaceuticals

  Purpose - Excerpt: To compare treatment with oxaliplatin/5-FU/leucovorin plus PTK787/ZK 222584 versus oxaliplatin/5-FU/leucovorin plus placebo in patients with **colorectal cancer** that has spread to other organs and are seeking first chemotherapy treatment

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00056459

- **Floxuridine, Dexamethasone, and Irinotecan After Surgery in Treating Patients With Liver Metastases From Colorectal Cancer**

  Condition(s): Colon Cancer; liver metastases; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Memorial Sloan-Kettering Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as floxuridine, dexamethasone, and irinotecan, use different ways to stop tumor cells from dividing so they stop growing or die. Hepatic arterial infusion uses a catheter to deliver chemotherapy directly to the liver. Combining more than one drug and giving them in different ways may kill any tumor cells remaining after surgery. PURPOSE: Phase II trial to study the effectiveness of irinotecan combined with hepatic arterial infusion with floxuridine and dexamethasone after surgery in treating patients who have liver metastases from **colorectal cancer.**

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00003753

- **Fluorouracil and Leucovorin Plus Either Irinotecan or Oxaliplatin With or Without Cetuximab in Treating Patients With Previously Untreated Locally Advanced or Metastatic Adenocarcinoma of the Colon or Rectum**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Cancer and Leukemia Group B; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as fluorouracil, leucovorin, irinotecan, and oxaliplatin, work in different ways to stop tumor cells from dividing so they stop growing or die. Monoclonal antibodies such as cetuximab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Combining more than one drug with monoclonal antibody therapy may kill more tumor cells. It is not yet known which combination chemotherapyregimen is more effective with or without cetuximab in treating locally advanced or metastaticadenocarcinoma (cancer) of the colon or rectum. PURPOSE: Randomizedphase III trial to compare the effectiveness of combining fluorouracil and leucovorin with either irinotecan or oxaliplatin with or without cetuximab in treating patients who have locally advanced or metastatic **cancer of the colon** or rectum.

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00077233

- **Fluorouracil, Leucovorin, and Irinotecan in Treating Patients With Recurrent or Refractory Metastatic Unresectable Colorectal Cancer**

  Condition(s): stage IV colon cancer; Stage IV rectal cancer; recurrent colon cancer; recurrent rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is currently recruiting patients.

  Sponsor(s): GERCOR

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as fluorouracil, leucovorin, and irinotecan, use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one chemotherapy drug may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combining fluorouracil and leucovorin

with irinotecan in treating patients who have recurrent or refractorymetastaticunresectablecolorectal cancer.

Phase(s): Phase II

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00075595

- **Fluorouracil, Phenylbutyrate, Indomethacin, and Interferon Gamma in Treating Patients With Advanced Colorectal Cancer**

  Condition(s): stage IV colon cancer; Stage IV rectal cancer; recurrent colon cancer; recurrent rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Mount Sinai Medical Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Interferon-gamma may interfere with the growth of tumor cells and slow the growth of the tumor. Combining more than one drug with interferon-gamma may kill more tumor cells. PURPOSE: Phase I/II trial to study the effectiveness of combining fluorouracil with phenylbutyrate, indomethacin, and interferon-gamma in treating patients who have stage IV **colorectal cancer.**

  Phase(s): Phase I; Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00002796

- **Gefitinib and Combination Chemotherapy in Treating Patients With Advanced or Recurrent Colorectal Cancer**

  Condition(s): stage IV colon cancer; Stage IV rectal cancer; recurrent colon cancer; recurrent rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Abramson Cancer Center at University of Pennsylvania Medical Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Biological therapies such as gefitinib may stop the growth of tumor cells by blocking the enzymes necessary for tumor cell growth. Drugs used in chemotherapy use different ways to

stop tumor cells from dividing so they stop growing or die. Combining gefitinib with fluorouracil, leucovorin, and irinotecan may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combining gefitinib with fluorouracil, leucovorin, and irinotecan in treating patients who have advanced or recurrentcolorectal cancer.

Phase(s): Phase II

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00052585

- **Gefitinib and Combination Chemotherapy in Treating Patients With Advanced Solid Tumors or Colorectal Cancer**

  Condition(s): stage IV colon cancer; Stage IV rectal cancer; recurrent colon cancer; recurrent rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Stanford University; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Biological therapies such as gefitinib may interfere with the growth of tumor cells and slow the growth of the tumor. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug with gefitinib may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of gefitinib and oxaliplatin combined with leucovorin and fluorouracil in treating patients who have advanced solid tumors or **colorectal cancer.**

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00025142

- **Genetic Study of Familial Factors in Patients With Colon Cancer**

  Condition(s): adenocarcinoma of the colon; stage I colon cancer; stage II colon cancer; stage III colon cancer; stage IV colon cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Cancer and Leukemia Group B; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Genetic studies may help in understanding the genetic processes involved in the development of

some types of cancer. PURPOSE: Clinical trial to study the cancer-related genes in patients who have colon cancer or adenomatouspolyps.

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00055848

- **Genetic Study of Young Patients With Colorectal Cancer**

  Condition(s): Colon Cancer; hereditary non-polyposis colon cancer (hMSH2, hMLH1, hPMS1, hPMS2); Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): American College of Surgeons; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Identifying genemutations (microsatellite instability) may allow doctors to plan effective treatment for patients who develop **colorectal cancer** at an early age. PURPOSE: Genetictrial to determine the significance of gene mutations in helping predict the outcome of treatment in patients who develop stage I, stage II, or stage III **colorectal cancer** at an early age.

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00044967

- **Hepatic Arterial Infusion Plus Chemotherapy in Treating Patients With Colorectal Cancer Metastatic to the Liver**

  Condition(s): Colon Cancer; liver metastases; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): North Central Cancer Treatment Group; National Cancer Institute (NCI); National Surgical Adjuvant Breast and Bowel Project (NSABP)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Giving the drugs in different combinations and different ways may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of hepatic arterial infusion plus chemotherapy in treating patients who have **colorectal cancer** metastatic to the liver.

  Phase(s): Phase II

  Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00026234

- **Hepatic Arterial Infusion With Floxuridine and Systemic Irinotecan After Surgery in Treating Patients With Hepatic (Liver) Metastases From Colorectal Cancer**

  Condition(s): stage IV colon cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum; Stage IV rectal cancer; liver metastases

  Study Status: This study is currently recruiting patients.

  Sponsor(s): American College of Surgeons; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy such as floxuridine and irinotecan use different ways to stop tumor cells from dividing so they stop growing or die. Hepatic arterial infusion uses a catheter to deliver chemotherapy directly to the liver. Combining more than one drug and giving them in different ways may kill any tumor cells remaining after surgery. PURPOSE: Phase II trial to study the effectiveness of systemic irinotecan and hepatic arterial infusion with floxuridine after surgery in treating patients who have hepatic (liver) metastases from **colorectal cancer.**

  Phase(s): Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00063960

- **High-Dose Fluorouracil With or Without Leucovorin Compared With Standard Fluorouracil Plus Leucovorin Following Surgery in Treating Patients With Stage III Colon Cancer**

  Condition(s): stage III colon cancer; adenocarcinoma of the colon; mucinous adenocarcinoma of the colon

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Robert Roessle Klinik; EORTC Gastrointestinal Tract Cancer Cooperative Group; Federation Francophone de Cancerologie Digestive; Grupo Espanol Tratamiento Tumores Digestivos

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. It is not yet known which chemotherapy regimen is more effective for colon cancer. PURPOSE: Randomizedphase III trial to study the effectiveness of high-dose fluorouracil with or without leucovorin

compared with standard-dose fluorouracil plus leucovorin following surgery in treating patients who have stage III colon cancer.

Phase(s): Phase III

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00004150

- **Leucovorin and Fluorouracil With or Without Oxaliplatin Compared to Capecitabine With or Without Oxaliplatin in Treating Patients With Metastatic Colorectal Cancer**

  Condition(s): Colon Cancer; Quality of Life; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): National Cancer Research Institute (NCRI); Medical Research Council

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as leucovorin, fluorouracil, capecitabine, and oxaliplatin, use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug may kill more tumor cells. It is not yet known whether leucovorin and fluorouracil with or without oxaliplatin is more effective than capecitabine with or without oxaliplatin in treating patients who have metastaticcolorectal cancer. PURPOSE: Randomizedphase III trial to compare the effectiveness of leucovorin and fluorouracil with or without oxaliplatin with that of capecitabine with or without oxaliplatin in treating patients who have metastatic **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00070213

- **LMB-9 Immunotoxin in Treating Patients With Advanced Pancreatic, Esophageal, Stomach, Colon, or Rectal Cancer**

  Condition(s): Colorectal Cancer; Esophageal Cancer; Gastric Cancer; Pancreatic Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): University of Freiburg; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: LMB-9 immunotoxin can locate tumor cells and kill them without harming normal cells. This may be an effective treatment for advanced pancreatic, esophageal, stomach, colon or rectal

cancer. PURPOSE: Phase I trial to study the effectiveness of LMB-9 immunotoxin in treating patients who have advanced pancreatic, esophageal, stomach, colon, or rectal cancer.

Phase(s): Phase I

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00010270

- **Monoclonal Antibody Therapy and/or Vaccine Therapy in Treating Patients With Locally Advanced or Metastatic Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Onyvax

  Purpose - Excerpt: RATIONALE: Monoclonal antibodies can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Vaccines made from cancer cells may make the body build an immune response to kill colorectal tumor cells. PURPOSE: Phase I/II trial to study the effectiveness of monoclonal antibody therapy and/or vaccine therapy in treating patients who have locally advanced or metastatic **colorectal cancer.**

  Phase(s): Phase I; Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00007826

- **Neoadjuvant Radiation Therapy and Capecitabine in Treating Patients With Stage III or Stage IV Colorectal Adenocarcinoma**

  Condition(s): stage III colon cancer; stage IV colon cancer; stage III rectal cancer; Stage IV rectal cancer; adenocarcinoma of the rectum; adenocarcinoma of the colon

  Study Status: This study is currently recruiting patients.

  Sponsor(s): GERCOR

  Purpose - Excerpt: RATIONALE: Radiation therapy uses high-energy x-rays to damage tumor cells. Drugs used in chemotherapy, such as capecitabine, use different ways to stop tumor cells from dividing so they stop growing or die. Combining radiation therapy with chemotherapy before surgery may shrink the tumor so that it can be removed. PURPOSE: Phase II trial to study the effectiveness of neoadjuvant

radiation therapy combined with capecitabine in treating patients who are undergoing surgery for stage III or stage IV colorectaladenocarcinoma.

Phase(s): Phase II

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00075556

- **Ondansetron With or Without Dexamethasone to Prevent Vomiting in Patients Receiving Radiation Therapy to the Upper Abdomen**

  Condition(s): Endocrine Cancer; female reproductive cancer; Gastrointestinal Cancer; nausea and vomiting; Quality of Life

  Study Status: This study is currently recruiting patients.

  Sponsor(s): National Cancer Institute of Canada

  Purpose - Excerpt: RATIONALE: Antiemetic drugs may help to reduce or prevent vomiting in patients treated with radiation therapy. It is not yet known if ondansetron is more effective with or without dexamethasone in preventing vomiting caused by radiation therapy. PURPOSE: Randomizedphase III trial to compare the effectiveness of ondansetron with or without dexamethasone in preventing vomiting in patients with cancer who are receiving radiation therapy to the upper abdomen.

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00016380

- **Oxaliplatin and Bevacizumab (Avastin(tm)) With Either Fluorouracil and Leucovorin or Capecitabine in Treating Patients With Advanced Colorectal Cancer**

  Condition(s): adenocarcinoma of the colon; adenocarcinoma of the rectum; recurrent colon cancer; stage IV colon cancer; recurrent rectal cancer; Stage IV rectal cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Prologue Research International

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as oxaliplatin, fluorouracil, leucovorin, and capecitabine, use different ways to stop tumor cells from dividing so they stop growing or die. Combining more than one drug and giving them in different combinations may kill

more tumor cells. Monoclonal antibodies, such as bevacizumab (Avastin(tm)), can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. It is not yet known which regimen is more effective in treating advanced **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of oxaliplatin and bevacizumab combined with either fluorouracil and leucovorin or capecitabine in treating patients who have metastatic or recurrent **colorectal cancer.**

Phase(s): Phase III

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00062426

- **Oxaliplatin, Fluorouracil, and Leucovorin With or Without PTK787/ZK 222584 in Treating Patients With Refractory or Recurrent Metastatic Colon or Rectal Cancer**

  Condition(s): adenocarcinoma of the rectum; adenocarcinoma of the colon; stage IV colon cancer; recurrent colon cancer; Stage IV rectal cancer; recurrent rectal cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Jonsson Comprehensive Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as oxaliplatin, fluorouracil, and leucovorin, use different ways to stop tumor cells from dividing so they stop growing or die. PTK787/ZK 222584 may stop the growth of tumor cells by stopping blood flow to the tumor. It is not yet known whether combination chemotherapy is more effective with or without PTK787/ZK 222584 in treating colon or rectal cancer. PURPOSE: Randomizedphase III trial to compare the effectiveness of combining oxaliplatin, fluorouracil, and leucovorin with or without PTK787/ZK 222584 in treating patients who have refractory or recurrentmetastatic colon or rectal cancer.

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00068679

- **PV701 in Treating Patients With Advanced or Recurrent Peritoneal Cancer**

  Condition(s): Endocrine Cancer; female reproductive cancer; Gastrointestinal Cancer; thorax and respiratory cancer; unclassified and other cancer

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Memorial Sloan-Kettering Cancer Center; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: PV701 may be able to kill tumor cells while leaving normal cells undamaged. PURPOSE: Phase I trial to study the effectiveness of PV701 in treating patients who have advanced or recurrentovarian epithelial, fallopian tube, primaryperitoneal, colorectal, or other cancer found primarily within the peritoneal cavity.

  Phase(s): Phase I

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00055705

- **Treatment of patients with previously treated metastatic colorectal cancer with oxaliplatin/5FU/LV and PTK787 or placebo**

  Condition(s): Colorectal Neoplasms; Colonic Neoplasms; Rectal Neoplasms

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Novartis Pharmaceuticals

  Purpose - Excerpt: To compare treatment with oxaliplatin/5-FU/leucovorin plus PTK787/ZK 222584 versus oxaliplatin/5-FU/leucovorin plus placebo in patients with **colorectal cancer** that has spread to other organs and whose disease has worsened after treatment with irinotecan.

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00056446

- **Vaccine Therapy in Treating Patients With Cancer of the Gastrointestinal Tract**

  Condition(s): Gastrointestinal Cancer

Study Status: This study is currently recruiting patients.

Sponsor(s): University of Texas; National Cancer Institute (NCI)

Purpose - Excerpt: RATIONALE: Vaccines may make the body build an immune response to kill tumor cells. PURPOSE: Randomizedphase II trial to compare the effectiveness of two different vaccines in treating patients who have cancer of the gastrointestinal tract.

Phase(s): Phase II

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00012246

- **Vaccine Therapy in Treating Patients With Stage II or Stage III Colon Cancer That has Been Removed During Surgery**

  Condition(s): stage II colon cancer; stage III colon cancer; adenocarcinoma of the colon

  Study Status: This study is currently recruiting patients.

  Sponsor(s): Intracel

  Purpose - Excerpt: RATIONALE: Vaccines made from a patient's white blood cells and tumor cells may make the body build an immune response to kill tumor cells. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Combining vaccine therapy with chemotherapy may kill more tumor cells. PURPOSE: Phase I/II trial to study the effectiveness of vaccine therapy combined with leucovorin and fluorouracil in treating patients who have undergone surgery to completely remove stage II or stage III colon cancer.

  Phase(s): Phase I; Phase II

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00016133

- **Combination Chemotherapy Plus Cetuximab in Treating Patients With Liver Metastases from Colorectal Cancer**

  Condition(s): liver metastases; stage IV colon cancer; Stage IV rectal cancer; adenocarcinoma of the colon; adenocarcinoma of the rectum

  Study Status: This study is not yet open for patient recruitment.

Sponsor(s): North Central Cancer Treatment Group; National Cancer Institute (NCI)

Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die. Monoclonal antibodies such as cetuximab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Combining chemotherapy with cetuximab may kill more tumor cells. PURPOSE: Phase II trial to study the effectiveness of combination chemotherapy plus cetuximab in treating patients who have unresectablelivermetastases from **colorectal cancer.**

Phase(s): Phase II

Study Type: Interventional

Contact(s): see Web site below

Web Site: http://clinicaltrials.gov/ct/show/NCT00056030

- **Combination Chemotherapy With or Without Bevacizumab in Treating Patients With Locally Advanced, Metastatic, or Recurrent Colorectal Cancer**

  Condition(s): Colon Cancer; Rectal Cancer

  Study Status: This study is not yet open for patient recruitment.

  Sponsor(s): Southwest Oncology Group; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Drugs used in chemotherapy, such as oxaliplatin, leucovorin, fluorouracil, and capecitabine, use different ways to stop cancer cells from dividing so they stop growing or die. Monoclonal antibodies such as bevacizumab can locate tumor cells and either kill them or deliver tumor-killing substances to them without harming normal cells. Combining chemotherapy with monoclonal antibody therapy may kill more tumor cells. It is not yet known which combination chemotherapyregimen with or without bevacizumab is more effective in treating **colorectal cancer.** PURPOSE: Randomizedphase III trial to compare the effectiveness of two combination chemotherapy regimens with or without bevacizumab in treating patients who have locally advanced, metastatic, or recurrent **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00070122

- **Octreotide in Preventing Diarrhea in Patients Receiving Chemotherapy for Colorectal Cancer**

  Condition(s): Colon Cancer; Diarrhea; Rectal Cancer

  Study Status: This study is not yet open for patient recruitment.

  Sponsor(s): University of Rochester; National Cancer Institute (NCI)

  Purpose - Excerpt: RATIONALE: Octreotide may be effective in preventing or controlling diarrhea in patients who are receiving chemotherapy for **colorectal cancer.** It is not yet known whether octreotide is more effective than standard treatment for diarrhea. PURPOSE: Randomizedphase III trial to compare the effectiveness of octreotide with that of standard therapy in preventing diarrhea in patients who are receiving chemotherapy for **colorectal cancer.**

  Phase(s): Phase III

  Study Type: Interventional

  Contact(s): see Web site below

  Web Site: http://clinicaltrials.gov/ct/show/NCT00052975

Benefits and Risks[19]

What Are the Benefits of Participating in a Clinical Trial?

If you are interested in a clinical trial, it is important to realize that your participation can bring many benefits to you and society at large:

- A new treatment could be more effective than the current treatment for gastrointestinal carcinoid tumors. Although only half of the participants in a clinical trial receive the experimental treatment, if the new treatment is proved to be more effective and safer than the current treatment, then those patients who did not receive the new treatment during the clinical trial may be among the first to benefit from it when the study is over.
- If the treatment is effective, then it may improve health or prevent diseases or disorders.
- Clinical trial patients receive the highest quality of medical care. Experts watch them closely during the study and may continue to follow them after the study is over.

[19] This section has been adapted from ClinicalTrials.gov, a service of the National Institutes of Health:
http://www.clinicaltrials.gov/ct/gui/c/a1r/info/whatis?JServSessionIdzone_ct=9jmun6f291.

- People who take part in trials contribute to scientific discoveries that may help other people with gastrointestinal carcinoid tumors. In cases where certain diseases or disorders run in families, your participation may lead to better care or prevention for your family members.

The Informed Consent

Once you agree to take part in a clinical trial, you will be asked to sign an "informed consent." This document explains a clinical trial's risks and benefits, the researcher's expectations of you, and your rights as a patient.

What Are the Risks?

Clinical trials may involve risks as well as benefits. Whether or not a new treatment will work cannot be known ahead of time. There is always a chance that a new treatment may not work better than a standard treatment. There is also the possibility that it may be harmful. The treatment you receive may cause side effects that are serious enough to require medical attention.

How Is Patient Safety Protected?

Clinical trials can raise fears of the unknown. Understanding the safeguards that protect patients can ease some of these fears. Before a clinical trial begins, researchers must get approval from their hospital's Institutional Review Board (IRB), an advisory group that makes sure a clinical trial is designed to protect patient safety. During a clinical trial, doctors will closely watch you to see if the treatment is working and if you are experiencing any side effects. All the results are carefully recorded and reviewed. In many cases, experts from the Data and Safety Monitoring Committee carefully monitor each clinical trial and can recommend that a study be stopped at any time. You will only be asked to take part in a clinical trial as a volunteer giving informed consent.

What Are a Patient's Rights in a Clinical Trial?

If you are eligible for a clinical trial, you will be given information to help you decide whether or not you want to participate. As a patient, you have the right to:

- Information on all known risks and benefits of the treatments in the study.
- Know how the researchers plan to carry out the study, for how long, and where.
- Know what is expected of you.
- Know any costs involved for you or your insurance provider.
- Know before any of your medical or personal information is shared with other researchers involved in the clinical trial.
- Talk openly with doctors and ask any questions.

After you join a clinical trial, you have the right to:

- Leave the study at any time. Participation is strictly voluntary. However, you should not enroll if you do not plan to complete the study.
- Receive any new information about the new treatment.
- Continue to ask questions and get answers.
- Maintain your privacy. Your name will not appear in any reports based on the study.
- Know whether you participated in the treatment group or the control group (once the study has been completed).

What about Costs?

In some clinical trials, the research facility pays for treatment costs and other associated expenses. You or your insurance provider may have to pay for costs that are considered standard care. These things may include inpatient hospital care, laboratory and other tests, and medical procedures. You also may need to pay for travel between your home and the clinic. You should find out about costs before committing to participation in the trial. If you have health insurance, find out exactly what it will cover. If you don't have health insurance, or if your insurance company will not cover your costs, talk to the clinic staff about other options for covering the cost of your care.

What Questions Should You Ask before Deciding to Join a Clinical Trial?

Questions you should ask when thinking about joining a clinical trial include the following:

- What is the purpose of the clinical trial?
- What are the standard treatments for gastrointestinal carcinoid tumors? Why do researchers think the new treatment may be better? What is likely to happen to me with or without the new treatment?
- What tests and treatments will I need? Will I need surgery? Medication? Hospitalization?
- How long will the treatment last? How often will I have to come back for follow-up exams?
- What are the treatment's possible benefits to my condition? What are the short- and long-term risks? What are the possible side effects?
- Will the treatment be uncomfortable? Will it make me feel sick? If so, for how long?
- How will my health be monitored?
- Where will I need to go for the clinical trial? How will I get there?
- How much will it cost to be in the study? What costs are covered by the study? How much will my health insurance cover?
- Will I be able to see my own doctor? Who will be in charge of my care?
- Will taking part in the study affect my daily life? Do I have time to participate?
- How do I feel about taking part in a clinical trial? Are there family members or friends who may benefit from my contributions to new medical knowledge?

Clinical Trials and Insurance Coverage[20]

As you consider enrolling in a clinical trial, you will face the critical issue of how to cover the costs of care. Even if you have health insurance, your coverage may not include some or all of the patient care costs associated with

[20] Adapted from the NCI:
http://www.cancer.gov/clinical_trials/doc_header.aspx?viewid=1d92be79-8748-4bda-8005-2a56d332463b.

a clinical trial. This is because some health plans define clinical trials as "experimental" or "investigational" procedures.

Because lack of coverage for these costs can keep people from enrolling in trials, the National Cancer Institute is working with major health plans and managed care groups to find solutions. In the meantime, there are strategies that may help you deal with cost and coverage barriers. This section answers frequently asked questions about insurance coverage for clinical trial participation and directs you to additional information resources.

The material here is mainly concerned with treatment clinical trials, since other types of trials (prevention, screening, etc.) are newer and generally not covered by health insurance at all. However, this guide may become more relevant for prevention and other types of trials as these trials grow more common.

If you do not have any health insurance, you may find this section helpful for understanding some of the costs that trials involve.

What Costs Do Trials Involve? Who Is Usually Responsible for Paying Them?

There are two types of costs associated with a trial: patient care costs and research costs.
Patient care costs fall into two categories:

- Usual care costs, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, etc., which occur whether you are participating in a trial or receiving standard treatment. These costs have usually been covered by a third-party health plan, such as Medicare or private insurance.
- Extra care costs associated with clinical trial participation, such as the additional tests that may or may not be fully covered by the clinical trial sponsor and/or research institution.

The sponsor and the participant's health plan need to resolve coverage of these costs for particular trials.

Research costs are those associated with conducting the trial, such as data collection and management, research physician and nurse time, analysis of results, and tests purely performed for research purposes. Such costs are usually covered by the sponsoring organization, such as NCI or a pharmaceutical company.

Criteria Used by Health Plans to Make Reimbursement Decisions about Trials

Health insurance companies and managed care companies decide which health care services they will pay for by developing coverage policy regarding the specific services. In general, the most important factor determining whether something is covered is a health plan's judgment as to whether the service is established or investigational. Health plans usually designate a service as established if there is a certain amount of scientific data to show that it is safe and effective. If the health plan does not think that such data exist in sufficient quantity, the plan may label the service as investigational.

Health care services delivered within the setting of a clinical trial are very often categorized as investigational and not covered. This is because the health plan thinks that the major reason to perform the clinical trial is that there is not enough data to establish the safety and effectiveness of the service being studied. Thus, for some health plans, any mention of the fact that the patient is involved in a clinical trial results in a denial of payment.

Your health plan may define specific criteria that a trial must meet before extending coverage, such as the following:

Sponsorship

Some plans may only cover costs of trials sponsored by organizations whose review and oversight of the trial is careful and scientifically rigorous, according to standards set by the health plan.

Trial Phase and Type

Some plans may cover patient care costs only for the clinical trials they judge to be "medically necessary" on a case-by-case basis. Trial phase may also affect coverage; for example, while a plan may be willing to cover costs associated with Phase III trials, which include treatments that have already been successful with a certain number of people, the plan may require some documentation of effectiveness before covering a Phase I or II trial.

While health plans are interested in efforts to improve prevention and screening, they currently seem less likely to have a review process in place

for these trials. Therefore, it may be more difficult to get coverage for the care costs associated with them.

Some plans, especially smaller ones, will not cover any costs associated with a clinical trial. Policies vary widely, but in most cases your best bet is to have your doctor initiate discussions with the health plan.

Cost "Neutrality"

Some health plans may limit coverage to trials they consider cost-neutral (i.e., not significantly more expensive than the treatments considered standard).

Lack of Standard Therapy

Some plans limit coverage of trials to situations in which no standard therapy is available.

Facility and Personnel Qualifications

A health plan may require that the facility and medical staff meet specific qualifications to conduct a trial involving unique services, especially intensive therapy such as a bone marrow transplant (high-dose chemotherapy with bone marrow/ stem cell rescue).

Clinical Trials and Medicare Coverage

For up-to-date information about Medicare coverage of clinical trials, go to the Web site for the Centers for Medicaid & Medicare (**http://www.hcfa.gov/coverage/8d.htm**; formerly the Health Care Financing Administration). As of January 2001, the following information was accurate[21]:

[21] On June 7, 2000, Present Clinton announced that Medicare would revise its payment policy to reimburse the routine patient care costs of clinical trials. The announcement is available for public viewing at the following Web address: **http://www.cancer.gov/clinical_trials/doc.aspx?viewid=320DD013-BA7A-4177-A000-2011089F34A0**.

What Will Medicare Pay?

- Anything normally covered is still covered when it is part of a clinical trial. This includes test, procedures, and doctor visits that are ordinarily covered.
- Anything normally covered even if it is a service or item associated with the experimental treatment. For example, Medicare will pay for the intravenous administration of a new chemotherapy drug being tested in a trial, including any therapy to prevent side effects from the new drug.
- Anything normally covered even if it resulted from your being in the clinical trial. For example, a test or hospitalization resulting from a side effect of the new treatment that Medicare would ordinarily cover.

What Costs Are Not Covered?

- Investigational items or services being tested in a trial. Sponsors of clinical trials often provide the new drug free, but make sure you ask your doctor before you begin.
- Items or services used solely for the data collection needs of the trial.
- Anything being provided free by the sponsor of the trial.

What Kinds of Clinical Trials Are Covered?

NCI's Cancer Information Service has provided a fact sheet for Medicare beneficiaries at the following Web site: **http://cis.nci.nih.gov/fact/8_14.htm**. In general, cancer treatment and diagnosis trials are covered if:

- They are funded by the National Cancer Institute (NCI), NCI-Designated Cancer Centers, NCI-Sponsored Clinical Trials Cooperative Groups and all other Federal agencies that fund cancer research. Other trials may be eligible for coverage and doctors can ask Medicare to pay the patients' costs. Ask your doctor about this before you begin.
- They are designed to treat or diagnose your cancer.
- The purpose or subject of the trial is within a Medicare benefit category. For example, cancer diagnosis and treatment are Medicare benefits, so these trials are covered. Cancer prevention trials are not currently covered.

Increasing the Likelihood of Insurance Coverage for Trials[22]

There are several steps you can follow to deal with coverage issues up front when deciding to enter a clinical trial. Along the way, enlist the help of family members and your doctor or other health professionals. You may find the following checklist useful:

Understand the Costs Associated with the Trial

Ask your doctor or the trial's contact person about the costs that must be covered by you or your health plan. Are these costs significantly higher than those associated with standard care? Also, inquire about the experience of other patients in the trial. Have their plans paid for their care? Have there been any persistent problems with coverage? How often have the trial's administrators been successful in getting plans to cover patient care costs?

Understand Your Health Plan

Be sure you know what's in your policy; request and carefully review the actual contract language. If there's a specific exclusion for "experimental treatment," look closely at the policy to see how the plan defines such treatment and under what conditions it might be covered. If it is not clearly defined, call the plan's customer service line, consult their Web site, and/or write to them. Ask for specific information about clinical trials coverage.

Work Closely with Your Doctor

Talk with your doctor about the paperwork he or she submits to your health plan. If there have been problems with coverage in the past, you might ask your doctor or the hospital to send an information package to the plan that includes studies supporting the procedure's safety, benefits, and medical appropriateness. This package might include:

- Publications from peer-reviewed literature about the proposed therapy that demonstrate patient benefits;

[22] This section has been adapted from the NCI:
http://www.cancer.gov/clinical_trials/doc_header.aspx?viewid=1d92be79-8748-4bda-8005-2a56d332463b&docid=0df4397a-eccb-465f-bd33-a89e7a708c46.

- A letter that uses the insurance contract's own language to explain why the treatment, screening method, or preventive measure should be covered;
- Letters from researchers that explain the clinical trial;
- Support letters from patient advocacy groups.

Be sure to keep your own copy of any materials that the doctor sends to your health plan for future reference.

Work Closely with Your Company's Benefits Manager

This person may be helpful in enlisting the support of your employer to request coverage by the health plan.

Give Your Health Plan a Deadline

Ask the hospital or cancer center to set a target date for the therapy. This will help to ensure that coverage decisions are made promptly.

Know Your Rights[23]

A number of state governments are addressing the question of whether insurance companies ought to cover the costs associated with patients' participation in clinical trials. Lack of such coverage is a significant barrier to many patients who might otherwise benefit from enrolling in a trial. Lack of coverage also makes it harder for researchers to successfully conduct trials that could improve prevention and treatment options. Information on State initiatives and legislation concerning cancer-related clinical trials is available at **http://www.cancer.gov/ClinicalTrials/insurancelaws**. By conducting your own research and learning about your rights, you may increase the likelihood that your insurance company will cover the costs of a trial.

If Your Insurance Claim Is Denied after the Trial Has Begun

If a claim is denied, read your policy to find out what steps you can follow to make an appeal. In "What Cancer Survivors Need to Know about Health

[23] Adapted from Cancer.gov: **http://www.cancer.gov/ClinicalTrials/insurancelaws**.

Insurance", the National Coalition for Cancer Survivorship suggests that you and your doctor demonstrate to the health plan that:

- The therapy is not just a research study, but also a valid procedure that benefits patients;
- Your situation is similar to that of other patients who are participating in clinical trials as part of a covered benefit;
- Possible complications have been anticipated and can be handled effectively.

You also may wish to contact your state insurance counseling hotline or insurance department for more help, or write your state insurance commissioner describing the problem.

Where Else Can I Turn for Assistance?

It's never easy to deal with financial issues when you or a loved one faces cancer. Unfortunately, costs can present a significant barrier to clinical trials participation. The range of insurance issues and health plan contracts makes it impossible to deal with all of them here. You may wish to consult this partial list of publications, organizations, and Web sites for more information:

Publications

What Cancer Survivors Need to Know about Health Insurance
National Coalition of Cancer Survivorship
1010 Wayne Avenue, 5th floor
Silver Spring, MD 20910
(301) 650-8868
http://www.cansearch.org/

Cancer Treatments Your Insurance Should Cover
The Association of Community Cancer Centers
11600 Nebel Street, Suite 201
Rockville, MD 20852
(301) 984-9496
http://www.accc-cancer.org/main2001.shtml

The Managed Care Answer Guide
Patient Advocate Foundation

739 Thimble Shoals Boulevard, Suite 704
Newport News, VA 23606
(757) 873-6668
E-mail: **ndepaf@pinn.net**

1998 Guide to Health Insurance for People with Medicare, The Medicare Handbook
Medicare Helpline: 1-800-444-4606
Health Care Financing Administration: **http://www.hcfa.gov/**
New Medicare site: **http://www.medicare.gov/**

Assistance Programs

Candlelighters Childhood Cancer Foundation
Ombudsman Program
910 Woodmont Avenue, #4607
Bethesda, MD 20814
(301) 657-8401; 1-800-366-2223 (toll-free)
E-mail: **info@candlelighters.org**
http://www.candlelighters.org
The Ombudsman Program helps families of children with cancer and survivors of childhood cancer resolve a range of problems, including insurance coverage difficulties. Local groups appoint a Parent Advocate who works with the treatment center on behalf of families.

Medical Care Management Corporation
5272 River Road, Suite 650
Bethesda, MD 20816-1405
(301) 652-1818
email: mcman@mcman.com
http://www.mcman.com/
Working for a range of clients, including health plans, employers, and patients, MCMC conducts independent, objective reviews of high-technology medical care cases to assist in decision-making. While it does charge for its services, MCMC also offers a volunteer program for those who cannot afford to pay.

More Information Resources

OncoLink
A service of the University of Pennsylvania Cancer Center.
http://www.oncolink.com/
In addition to general cancer information, this web site features a section on financial information for patients. Among the topics: viatical settlements, life insurance, a glossary of financial and medical terms, and news about billing and insurance.

American Association of Health Plans
1129 20th Street, NW, Suite 600
Washington, DC 20036-3421
(202) 778-3200
http://www.aahp.org/
The Web site section "For Consumers" includes a fact sheet on clinical research that describes various health plans' efforts to support research initiatives and collaborate with academic health centers and universities.

Health Insurance Association of America
555 13th Street, NW
Washington, DC 20004
(202) 824-1600

- Home page: **http://www.hiaa.org/**
- Consumer Information: **http://www.hiaa.org/consumer/**
- Insurance Counseling Hotlines by State: **http://www.hiaa.org/consumer/insurance_counsel.cfm**
- State Insurance Departments: **http://www.hiaa.org/consumer/state_insurance.cfm**

Government Initiatives to Expand Insurance Coverage for Trials[24]

The good news is that there has been a recent effort in the U.S. to assure clinical trials coverage, with NCI involved in several new initiatives as described below:

[24] Adapted from the NCI:
http://www.cancer.gov/clinical_trials/doc_header.aspx?viewid=1d92be79-8748-4bda-8005-2a56d332463b&docid=d8092601-daf9-4794-8536-3be2712eb6b9.

NCI-Department of Defense Agreement

An innovative 1996 agreement between NCI and the Department of Defense (DoD) has given thousands of DoD cancer patients more options for care and greater access to state-of-the-art treatments. Patients who are beneficiaries of TRICARE/CHAMPUS, the DoD's health program, are covered for NCI-sponsored Phase II and Phase III clinical treatment trials. NCI and DoD are refining a system that allows physicians and patients to determine quickly what current trials meet their needs and where they are taking place.

NCI-Department of Veterans Affairs Agreement

A 1997 agreement with the Department of Veterans Affairs provides coverage for eligible veterans of the armed services to participate in NCI-sponsored prevention, diagnosis, and treatment studies nationwide. For additional information, see the VA/DoD Beneficiaries Digest Page at **http://www.va.gov/cancer.htm**.

Midwest Health Plans Agreement

Some NCI Cooperative Groups have reached agreements with several insurers in Wisconsin and Minnesota to provide more than 200,000 people with coverage. This coverage is allocated for patient care costs if they participate in a cooperative group-sponsored trial.

Pediatric Cancer Care Network

This network, a cooperative agreement among the Children's Cancer Group, the Pediatric Oncology Group, and the Blue Cross Blue Shield System Association (BCBS) nationwide, will ensure that children of BCBS subscribers receive care at designated centers of cancer care excellence and may promote the enrollment of children in Cooperative Group clinical trials.

Keeping Current on Clinical Trials

Various government agencies maintain databases on trials. The U.S. National Institutes of Health, through the National Library of Medicine, has developed ClinicalTrials.gov to provide patients, family members, and

physicians with current information about clinical research across the broadest number of diseases and conditions.

The site was launched in February 2000 and currently contains approximately 5,700 clinical studies in over 59,000 locations worldwide, with most studies being conducted in the United States. ClinicalTrials.gov receives about 2 million hits per month and hosts approximately 5,400 visitors daily. To access this database, simply go to their Web site (**www.clinicaltrials.gov**) and search by "gastrointestinal carcinoid tumors" (or synonyms).

While ClinicalTrials.gov is the most comprehensive listing of NIH-supported clinical trials available, not all trials are in the database. The database is updated regularly, so clinical trials are continually being added. The following is a list of specialty databases affiliated with the National Institutes of Health that offer additional information on trials:

- For clinical studies at the Warren Grant Magnuson Clinical Center located in Bethesda, Maryland, visit their Web site: **http://clinicalstudies.info.nih.gov/**
- For clinical studies conducted at the Bayview Campus in Baltimore, Maryland, visit their Web site: **http://www.jhbmc.jhu.edu/studies/index.html**
- For cancer trials, visit the National Cancer Institute: **http://cancertrials.nci.nih.gov/**

General References

The following references describe clinical trials and experimental medical research. They have been selected to ensure that they are likely to be available from your local or online bookseller or university medical library. These references are usually written for healthcare professionals, so you may consider consulting with a librarian or bookseller who might recommend a particular reference. The following includes some of the most readily available references (sorted alphabetically by title; hyperlinks provide rankings, information and reviews at Amazon.com):

- **A Guide to Patient Recruitment : Today's Best Practices & Proven Strategies** by Diana L. Anderson; Paperback - 350 pages (2001), CenterWatch, Inc.; ISBN: 1930624115; **http://www.amazon.com/exec/obidos/ASIN/1930624115/icongroupinterna**

- **A Step-By-Step Guide to Clinical Trials** by Marilyn Mulay, R.N., M.S., OCN; Spiral-bound - 143 pages Spiral edition (2001), Jones & Bartlett Pub; ISBN: 0763715697; **http://www.amazon.com/exec/obidos/ASIN/0763715697/icongroupinterna**
- **The CenterWatch Directory of Drugs in Clinical Trials** by CenterWatch; Paperback - 656 pages (2000), CenterWatch, Inc.; ISBN: 0967302935; **http://www.amazon.com/exec/obidos/ASIN/0967302935/icongroupinterna**
- **Extending Medicare Reimbursement in Clinical Trials** by Institute of Medicine Staff (Editor), et al; Paperback 1st edition (2000), National Academy Press; ISBN: 0309068886; **http://www.amazon.com/exec/obidos/ASIN/0309068886/icongroupinterna**
- **Handbook of Clinical Trials** by Marcus Flather (Editor); Paperback (2001), Remedica Pub Ltd; ISBN: 1901346293; **http://www.amazon.com/exec/obidos/ASIN/1901346293/icongroupinterna**

Vocabulary Builder

The following vocabulary builder gives definitions of words used in this chapter that have not been defined in previous chapters:

Consultation: A deliberation between two or more physicians concerning the diagnosis and the proper method of treatment in a case. [NIH]

Monoclonal: An antibody produced by culturing a single type of cell. It therefore consists of a single species of immunoglobulin molecules. [NIH]

Thorax: A part of the trunk between the neck and the abdomen; the chest. [NIH]

PART II: ADDITIONAL RESOURCES AND ADVANCED MATERIAL

ABOUT PART II

In Part II, we introduce you to additional resources and advanced research on gastrointestinal carcinoid tumors. All too often, patients who conduct their own research are overwhelmed by the difficulty in finding and organizing information. The purpose of the following chapters is to provide you an organized and structured format to help you find additional information resources on gastrointestinal carcinoid tumors. In Part II, as in Part I, our objective is not to interpret the latest advances on gastrointestinal carcinoid tumors or render an opinion. Rather, our goal is to give you access to original research and to increase your awareness of sources you may not have already considered. In this way, you will come across the advanced materials often referred to in pamphlets, books, or other general works. Once again, some of this material is technical in nature, so consultation with a professional familiar with gastrointestinal carcinoid tumors is suggested.

CHAPTER 4. STUDIES ON GASTROINTESTINAL CARCINOID TUMORS

Overview

Every year, academic studies are published on gastrointestinal carcinoid tumors or related conditions. Broadly speaking, there are two types of studies. The first are peer reviewed. Generally, the content of these studies has been reviewed by scientists or physicians. Peer-reviewed studies are typically published in scientific journals and are usually available at medical libraries. The second type of studies is non-peer reviewed. These works include summary articles that do not use or report scientific results. These often appear in the popular press, newsletters, or similar periodicals.

In this chapter, we will show you how to locate peer-reviewed references and studies on gastrointestinal carcinoid tumors. We will begin by discussing research that has been summarized and is free to view by the public via the Internet. We then show you how to generate a bibliography on gastrointestinal carcinoid tumors and teach you how to keep current on new studies as they are published or undertaken by the scientific community.

Federally Funded Research on Gastrointestinal Carcinoid Tumors

The U.S. Government supports a variety of research studies relating to gastrointestinal carcinoid tumors and associated conditions. These studies are tracked by the Office of Extramural Research at the National Institutes of

Health.[25] CRISP (Computerized Retrieval of Information on Scientific Projects) is a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other institutions. Visit CRISP at **http://crisp.cit.nih.gov/crisp/crisp_query.generate_screen**. You can perform targeted searches by various criteria including geography, date, as well as topics related to gastrointestinal carcinoid tumors and related conditions.

For most of the studies, the agencies reporting into CRISP provide summaries or abstracts. As opposed to clinical trial research using patients, many federally funded studies use animals or simulated models to explore gastrointestinal carcinoid tumors and related conditions. In some cases, therefore, it may be difficult to understand how some basic or fundamental research could eventually translate into medical practice.

The National Library of Medicine: PubMed

One of the quickest and most comprehensive ways to find academic studies in both English and other languages is to use PubMed, maintained by the National Library of Medicine. The advantage of PubMed over previously mentioned sources is that it covers a greater number of domestic and foreign references. It is also free to the public.[26] If the publisher has a Web site that offers full text of its journals, PubMed will provide links to that site, as well as to sites offering other related data. User registration, a subscription fee, or some other type of fee may be required to access the full text of articles in some journals.

To generate your own bibliography of studies dealing with gastrointestinal carcinoid tumors, simply go to the PubMed Web site at **www.ncbi.nlm.nih.gov/pubmed**. Type "gastrointestinal carcinoid tumors" (or synonyms) into the search box, and click "Go." The following is the type

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[25] Healthcare projects are funded by the National Institutes of Health (NIH), Substance Abuse and Mental Health Services (SAMHSA), Health Resources and Services Administration (HRSA), Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDCP), Agency for Healthcare Research and Quality (AHRQ), and Office of Assistant Secretary of Health (OASH).

[26] PubMed was developed by the National Center for Biotechnology Information (NCBI) at the National Library of Medicine (NLM) at the National Institutes of Health (NIH). The PubMed database was developed in conjunction with publishers of biomedical literature as a search tool for accessing literature citations and linking to full-text journal articles at Web sites of participating publishers. Publishers that participate in PubMed supply NLM with their citations electronically prior to or at the time of publication.

of output you can expect from PubMed for "gastrointestinal carcinoid tumors" (hyperlinks lead to article summaries):

- **A case-control study of use of postmenopausal female hormone supplements in relation to the risk of large bowel cancer.**
  Author(s): Prihartono N, Palmer JR, Louik C, Shapiro S, Rosenberg L.
  Source: Cancer Epidemiology, Biomarkers & Prevention : a Publication of the American Association for Cancer Research, Cosponsored by the American Society of Preventive Oncology. 2000 April; 9(4): 443-7.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10794491&dopt=Abstract

- **A phase II trial of homoharringtonine and caracemide in the treatment of patients with advanced large bowel cancer.**
  Author(s): Witte RS, Lipsitz S, Goodman TL, Asbury RF, Wilding G, Strnad CM, Smith TJ, Haller DG.
  Source: Investigational New Drugs. 1999; 17(2): 173-7.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10638488&dopt=Abstract

- **A selective policy in follow-up for bowel cancer.**
  Author(s): Ross PJ, Cunningham D.
  Source: Lancet. 1998 June 20; 351(9119): 1891-2.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9652702&dopt=Abstract

- **A selective policy in follow-up for bowel cancer.**
  Author(s): Renehan A, O'Dwyer ST.
  Source: Lancet. 1998 June 20; 351(9119): 1891.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9652701&dopt=Abstract

- **Age, cohort and period effects on large bowel cancer incidence.**
  Author(s): Levi F, La Vecchia C.
  Source: European Journal of Cancer Prevention : the Official Journal of the European Cancer Prevention Organisation (Ecp). 2002 December; 11(6): 515-7.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12457101&dopt=Abstract

- **Antibodies against gastrointestinal carcinoid tumors in IDDM.**
  Author(s): Miettinen A, Holthofer H, Kontiainen S, Miettinen M, Andersson LC.
  Source: Diabetes. 1989 May; 38(5): 667-9.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2469610&dopt=Abstract

- **Aspirin for bowel cancer: an old friend finds a new role.**
  Author(s): Featherstone C.
  Source: Lancet. 1997 August 9; 350(9075): 418.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9289594&dopt=Abstract

- **Bowel cancer. Positive expectations for improvements in outcomes.**
  Author(s): Semmens JB, Platell C.
  Source: Aust Fam Physician. 2001 June; 30(6): 539-45.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11458580&dopt=Abstract

- **Bowel cancer: watching over the family.**
  Author(s): Macrae F.
  Source: Journal of Gastroenterology and Hepatology. 1995 May-June; 10(3): 337-8.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7548814&dopt=Abstract

- **Cancer chemoprevention through interruption of multistage carcinogenesis. The lessons learnt by comparing mouse skin carcinogenesis and human large bowel cancer.**
  Author(s): Marks F, Furstenberger G.
  Source: European Journal of Cancer (Oxford, England : 1990). 2000 February; 36(3): 314-29. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10708932&dopt=Abstract

- **Changes in colorectal cancer during a 20-year period: an extended report from the multi-institutional registry of large bowel cancer, Japan.**
  Author(s): Kotake K, Honjo S, Sugihara K, Kato T, Kodaira S, Takahashi T, Yasutomi M, Muto T, Koyama Y.
  Source: Diseases of the Colon and Rectum. 2003 October; 46(10 Suppl): S32-43.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=14530656&dopt=Abstract

- **Charity recommends introduction of screening programme for bowel cancer.**
  Author(s): Iles A.
  Source: Bmj (Clinical Research Ed.). 2003 September 20; 327(7416): 642.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=14500430&dopt=Abstract

- **Chemotherapy of metastatic bowel cancer.**
  Author(s): Ross PJ, Cunningham D.
  Source: Br J Hosp Med. 1996 March 6-19; 55(5): 263-6. Review. No Abstract Available.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8777518&dopt=Abstract

- **Cigarette smoking in relation to risk of large bowel cancer in women.**
  Author(s): Newcomb PA, Storer BE, Marcus PM.
  Source: Cancer Research. 1995 November 1; 55(21): 4906-9.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7585528&dopt=Abstract

- **Clinical study of 81 gastrointestinal carcinoid tumors.**
  Author(s): Sabback MS, O'Brien PH.
  Source: Southern Medical Journal. 1979 April; 72(4): 386-90.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=432675&dopt=Abstract

- **Clinicopathologic characteristics of large bowel cancer developing after radiotherapy for uterine cervical cancer.**
  Author(s): Shirouzu K, Isomoto H, Morodomi T, Ogata Y, Araki Y, Kakegawa T.
  Source: Diseases of the Colon and Rectum. 1994 December; 37(12): 1245-9.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7995152&dopt=Abstract

- **Commentary: the rough world of nutritional epidemiology: does dietary fibre prevent large bowel cancer?**
  Author(s): Lawlor DA, Ness AR.
  Source: International Journal of Epidemiology. 2003 April; 32(2): 239-43.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12714543&dopt=Abstract

- **Confusion about secondary prevention for bowel cancer: resolving issues at the front line.**
  Author(s): Young GP.
  Source: The Medical Journal of Australia. 1999 February 1; 170(3): 102-3.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10065118&dopt=Abstract

- **COX-2 in large bowel cancer: a one-sided story.**
  Author(s): DuBOIS RN.
  Source: Gut. 1999 November; 45(5): 636-7.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10517891&dopt=Abstract

- **Current thinking on screening for large bowel cancer.**
  Author(s): Winter A, Pickford I.
  Source: The Practitioner. 1994 October; 238(1543): 700-4. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7991486&dopt=Abstract

- **Declining the offer of flexible sigmoidoscopy screening for bowel cancer: a qualitative investigation of the decision-making process.**
  Author(s): McCaffery K, Borril J, Williamson S, Taylor T, Sutton S, Atkin W, Wardle J.
  Source: Social Science & Medicine (1982). 2001 September; 53(5): 679-91.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11478546&dopt=Abstract

- **Delay in seeking advice for symptoms that potentially indicate bowel cancer.**
  Author(s): Cockburn J, Paul C, Tzelepis F, McElduff P, Byles J.
  Source: American Journal of Health Behavior. 2003 July-August; 27(4): 401-7.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12882434&dopt=Abstract

- **Diabetes mellitus and risk of large bowel cancer.**
  Author(s): Nelson R, Persky V, Davis F.
  Source: Journal of the National Cancer Institute. 1997 August 20; 89(16): 1232-3.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9274920&dopt=Abstract

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  Author(s): Weiderpass E, Gridley G, Nyren O, Ekbom A, Persson I, Adami HO.
  Source: Journal of the National Cancer Institute. 1997 May 7; 89(9): 660-1.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9150194&dopt=Abstract

- **Different beta-catenin immunoexpression in carcinoid tumors of the appendix in comparison to other gastrointestinal carcinoid tumors.**
  Author(s): Barshack I, Goldberg I, Chowers Y, Horowitz A, Kopolovic J.
  Source: Pathology, Research and Practice. 2002; 198(8): 531-6.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12389996&dopt=Abstract
- **Distribution of colorectal adenomas: implications for bowel cancer screening.**
  Author(s): Nicholson FB, Korman MG, Stern AI, Hansky J.
  Source: The Medical Journal of Australia. 2000 May 1; 172(9): 428-30.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10870535&dopt=Abstract

- **Do bowel cancer patients participate in treatment decision-making? Findings from a qualitative study.**
  Author(s): Sanders T, Skevington S.
  Source: European Journal of Cancer Care. 2003 June; 12(2): 166-75.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12787015&dopt=Abstract

- **Does digestibility of meat protein help explain large bowel cancer risk?**
  Author(s): Silvester KR, Cummings JH.
  Source: Nutrition and Cancer. 1995; 24(3): 279-88.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8610047&dopt=Abstract

- **Eating meat more than 10 times a week almost doubles chances of bowel cancer.**
  Author(s): Sweet M.
  Source: Bmj (Clinical Research Ed.). 2002 June 29; 324(7353): 1544.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12092604&dopt=Abstract

- **Effect of a surgical training programme on outcome of rectal cancer in the County of Stockholm. Stockholm Colorectal Cancer Study Group, Basingstoke Bowel Cancer Research Project.**
  Author(s): Martling AL, Holm T, Rutqvist LE, Moran BJ, Heald RJ, Cedemark B.
  Source: Lancet. 2000 July 8; 356(9224): 93-6.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10963244&dopt=Abstract

- **Effect of age, period of diagnosis and birth cohort on large bowel cancer incidence in a well-defined French population, 1976-1995.**
  Author(s): Mitry E, Benhamiche AM, Couillault C, Roy P, Faivre-Finn C, Clinard F, Faivre J.
  Source: European Journal of Cancer Prevention : the Official Journal of the European Cancer Prevention Organisation (Ecp). 2002 December; 11(6): 529-34.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12457104&dopt=Abstract

- **Expression of tumor-associated polymorphic epithelial mucin and carcinoembryonic antigen in gastrointestinal carcinoid tumors. Implications for immunodiagnosis and immunotherapy.**
  Author(s): Moyana TN, Xiang J.
  Source: Cancer. 1995 June 15; 75(12): 2836-43.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7539715&dopt=Abstract

- **Faecal neutral sterols and bile acids in patients with adenomas and large bowel cancer: an ECP case-control study. European cancer prevention.**
  Author(s): Roy P, Owen RW, Faivre J, Scheppach W, Saldanha MH, Beckly DE, Boutron MC.
  Source: European Journal of Cancer Prevention : the Official Journal of the European Cancer Prevention Organisation (Ecp). 1999 October; 8(5): 409-15.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10548396&dopt=Abstract

- **Familial giant hyperplastic polyposis predisposing to colorectal cancer: a new hereditary bowel cancer syndrome.**
  Author(s): Jeevaratnam P, Cottier DS, Browett PJ, Van De Water NS, Pokos V, Jass JR.
  Source: The Journal of Pathology. 1996 May; 179(1): 20-5.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=8691339&dopt=Abstract

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  Author(s): Geiger D, Mpinga E, Steves MA, Sugarbaker PH.
  Source: Diseases of the Colon and Rectum. 1998 July; 41(7): 910-3.
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  Author(s): Habal N, Sims C, Bilchik AJ.
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  Author(s): Eller R, Frazee R, Roberts J.
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  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2058850&dopt=Abstract

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  Author(s): Postlethwait RW.
  Source: Postgraduate Medicine. 1966 October; 40(4): 445-54. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=5331449&dopt=Abstract

- **Gastrointestinal carcinoid tumors: an analysis of 104 cases.**
  Author(s): Clements JL Jr, Hixson GL Jr, Berk RN, Dodds WJ, Goldstein H.
  Source: The Mount Sinai Journal of Medicine, New York. 1984 July-August; 51(4): 351-9.
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  Author(s): Memon MA, Nelson H.
  Source: Diseases of the Colon and Rectum. 1997 September; 40(9): 1101-18. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=9293943&dopt=Abstract

- **Gastrointestinal carcinoid tumors: long-term prognosis for surgically treated patients.**
  Author(s): Soreide JA, van Heerden JA, Thompson GB, Schleck C, Ilstrup DM, Churchward M.
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  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11038218&dopt=Abstract

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  Author(s): Chapman PD, Burn J.
  Source: Cytogenetics and Cell Genetics. 1999; 86(2): 118-24. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10545701&dopt=Abstract

- **Hereditary colorectal cancer: keeping it in the family--the bowel cancer story.**
  Author(s): McGrath DR, Spigelman AD.
  Source: Internal Medicine Journal. 2002 July; 32(7): 325-30. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12088352&dopt=Abstract

- **Home bowel cancer tests and informed choice--is current information sufficient?**
  Author(s): Howard K, Salkeld G.
  Source: Aust N Z J Public Health. 2003 October; 27(5): 513-6.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=14651396&dopt=Abstract

- **Identifying and managing patients at low risk of bowel cancer in general practice.**
  Author(s): Thompson MR, Heath I, Ellis BG, Swarbrick ET, Wood LF, Atkin WS.
  Source: Bmj (Clinical Research Ed.). 2003 August 2; 327(7409): 263-5. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=12896939&dopt=Abstract

- **Identifying patients at low risk of bowel cancer: personal or familial risk factors need to be mentioned.**
  Author(s): O'Riordan MM.
  Source: Bmj (Clinical Research Ed.). 2003 October 11; 327(7419): 871; Author Reply 871-2.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=14551120&dopt=Abstract

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  Author(s): Stachura J, Pietron M, Nowak K, Rudzki Z, Nowak W.
  Source: Folia Histochem Cytobiol. 1989; 27(4): 227-31.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=2635675&dopt=Abstract
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  Author(s): Sokmensuer C, Gedikoglu G, Uzunalimoglu B.
  Source: Hepatogastroenterology. 2001 May-June; 48(39): 720-3.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11462912&dopt=Abstract

- **Informal out-patient discussions with patients following surgery for large bowel cancer: are they beneficial?**
  Author(s): Broughton M, Doulton G, Topham C, Marks C.
  Source: European Journal of Cancer Care. 1995 June; 4(2): 57-62.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7599872&dopt=Abstract

- **Interactions of familial and hormonal risk factors for large bowel cancer in women.**
  Author(s): Newcomb PA, Taylor JO, Trentham-Dietz A.
  Source: International Journal of Epidemiology. 1999 August; 28(4): 603-8.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10480684&dopt=Abstract

- **Interpreting precursor studies: what polyp trials tell us about large-bowel cancer.**
  Author(s): Schatzkin A, Freedman LS, Dawsey SM, Lanza E.
  Source: Journal of the National Cancer Institute. 1994 July 20; 86(14): 1053-7. Review.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=7802771&dopt=Abstract

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  Author(s): Thomas RJ, Spigelman AD, Armstrong BK.
  Source: The Medical Journal of Australia. 1999 September 20; 171(6): 284-5.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10560439&dopt=Abstract

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  Author(s): Richman S, Adlard J.
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  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11964327&dopt=Abstract

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  Author(s): Jones PF.
  Source: The British Journal of Surgery. 1995 December; 82(12): 1700.
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  Author(s): Franceschi S.
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  Author(s): Abbasciano V, Bianchi MP, Trevisani L, Sartori S, Gilli G, Zavagli G.
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  Source: Journal of the National Cancer Institute. 1995 July 19; 87(14): 1067-71. Erratum In: J Natl Cancer Inst 1995 September 20; 87(18): 1416.
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  Author(s): Gray B, Van Hazel G, Hope M, Burton M, Moroz P, Anderson J, Gebski V.
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  Author(s): Jacobson JS, Neugut AI.
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  Source: Journal of Epidemiology and Community Health. 1996 December; 50(6): 640-4.
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  Author(s): Seglenieks A, Black RB.
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  Source: Breast Cancer Research and Treatment. 1999 February; 53(3): 271-7.
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  Author(s): Dietz AT, Newcomb PA, Marcus PM, Storer BE.
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  Author(s): Ashenafi S.
  Source: Ethiop Med J. 2000 October; 38(4): 277-82.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=11125502&dopt=Abstract

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  Author(s): Wichmann MW, Muller C, Lau-Werner U, Strauss T, Lang RA, Hornung HM, Stieber P, Schildberg FW.
  Source: Langenbeck's Archives of Surgery / Deutsche Gesellschaft Fur Chirurgie. 2000 July; 385(4): 271-5.
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  Source: The Australian and New Zealand Journal of Surgery. 1998 February; 68(2): 101-2.
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  Author(s): Isbister WH.
  Source: Bmj (Clinical Research Ed.). 1999 July 31; 319(7205): 317.
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- **Training in large bowel cancer surgery: observations from three prospective regional United Kingdom audits.**
  Author(s): Aitken RJ, Thompson MR, Smith JA, Radcliffe AG, Stamatakis JD, Steele RJ.
  Source: Bmj (Clinical Research Ed.). 1999 March 13; 318(7185): 702-3.
  http://www.ncbi.nlm.nih.gov:80/entrez/query.fcgi?cmd=Retrieve&db=PubMed&list_uids=10074013&dopt=Abstract

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  Author(s): Josefson D.
  Source: Bmj (Clinical Research Ed.). 2002 July 20; 325(7356): 124.
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  Author(s): Hough DR, Chan A, Davidson H.
  Source: Cancer. 1983 June 15; 51(12): 2206-8. Review.
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  Author(s): Wood LF.
  Source: Nursing Standard : Official Newspaper of the Royal College of Nursing. 1999 January 6-12; 13(16): 16.
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- **Whole-body 18F dopa PET for detection of gastrointestinal carcinoid tumors.**
  Author(s): Hoegerle S, Altehoefer C, Ghanem N, Koehler G, Waller CF, Scheruebl H, Moser E, Nitzsche E.
  Source: Radiology. 2001 August; 220(2): 373-80.
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Vocabulary Builder

Nihilism: The delusion of non-existence. [NIH]

Resolving: The ability of the eye or of a lens to make small objects that are close together, separately visible; thus revealing the structure of an object. [NIH]

CHAPTER 5. PATENTS ON GASTROINTESTINAL CARCINOID TUMORS

Overview

You can learn about innovations relating to gastrointestinal carcinoid tumors by reading recent patents and patent applications. Patents can be physical innovations (e.g. chemicals, pharmaceuticals, medical equipment) or processes (e.g. treatments or diagnostic procedures). The United States Patent and Trademark Office defines a patent as a grant of a property right to the inventor, issued by the Patent and Trademark Office.[27] Patents, therefore, are intellectual property. For the United States, the term of a new patent is 20 years from the date when the patent application was filed. If the inventor wishes to receive economic benefits, it is likely that the invention will become commercially available to patients with gastrointestinal carcinoid tumors within 20 years of the initial filing. It is important to understand, therefore, that an inventor's patent does not indicate that a product or service is or will be commercially available to patients with gastrointestinal carcinoid tumors. The patent implies only that the inventor has "the right to exclude others from making, using, offering for sale, or selling" the invention in the United States. While this relates to U.S. patents, similar rules govern foreign patents.

In this chapter, we show you how to locate information on patents and their inventors. If you find a patent that is particularly interesting to you, contact the inventor or the assignee for further information.

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[27]Adapted from The U. S. Patent and Trademark Office:
http://www.uspto.gov/web/offices/pac/doc/general/whatis.htm.

Patents on Gastrointestinal Carcinoid Tumors

By performing a patent search focusing on gastrointestinal carcinoid tumors, you can obtain information such as the title of the invention, the names of the inventor(s), the assignee(s) or the company that owns or controls the patent, a short abstract that summarizes the patent, and a few excerpts from the description of the patent. The abstract of a patent tends to be more technical in nature, while the description is often written for the public. Full patent descriptions contain much more information than is presented here (e.g. claims, references, figures, diagrams, etc.). We will tell you how to obtain this information later in the chapter. The following is an example of the type of information that you can expect to obtain from a patent search on gastrointestinal carcinoid tumors:

- **Chromosome I8Q loss and prognosis in colorectal cancer**

  Inventor(s): Hamilton; Stanley (Lutherville, MD), Kinzler; Kenneth W. (Baltimore, MD), Vogelstein; Bert (Baltimore, MD)

  Assignee(s): The Johns Hopkins University (baltimore, Md)

  Patent Number: 5,702,886

  Date filed: October 5, 1994

  Abstract: To examine the status of chromosome 18q, polymorphic genetic markers and DNA from formalin-fixed, paraffin-embedded tumors are employed. DNA from normal tissue is used as a comparison. The status of chromosome 18q is prognostic of the survival among stage II and stage III **colorectal cancer** patients.

  Excerpt(s): This invention was partially supported by grants (CA-35494, CA-47527, and CA-62924) from the National Cancer Institute. The U.S. government retains certain rights in this invention.... With about 150,000 cases and 60,000 deaths annually, **colorectal cancer** is one of the commonest causes of death from cancer in the United States..sup.1 Currently, determining prognosis and selecting patients for postoperative adjuvant therapy rely mainly on pathological and clinical staging. The TNM system--T for primary tumor, N for regional lymph node involvement, and M for metastases--developed by the Union Internationale Contre Cancer (UICC) is one of the two major staging systems currently in use..sup.2,3 Patients with TNM stage I cancer (Dukes' stage A: tumor confined within the bowel wall, with no lymph-node metastasis) usually have a normal life span, whereas patients with stage IV disseminated disease have a very poor survival rate. However, predicting outcome in patients with intermediate stages is difficult.

Patients with stage II **colorectal cancer** (Dukes'0 stage B: tumor extending through the bowel wall, without lymph-node metastasis) have a five-year survival rate of about 70 percent, and those with stage III disease (Dukes' stage C: regional lymph-node metastasis) have a rate of only 40 to 50 percent..sup.4 Adjuvant therapy improves the outcome in subgroups of patients, but it leads to substantial morbidity..sup.5-9 Better means of formulating the prognosis in patients with **colorectal cancer** would improve the selection of patients for adjuvant chemotherapy and radiation therapy.... Colorectal cancers result from the accumulation of several distinct genetic alterations involving the K-ras oncogene on chromosome 12 and tumor-suppressor genes on chromosomes 5, 17, and 18..sup.10-12 The short arm of chromosome 17 (17p) and the long arm of chromosome 18 (18q) are frequently lost in colorectal tumors. This observation led to the discovery that inactivation of the p53 and DCC gene (located on chromosomes 17p and 18q, respectively) probably contributes to the neoplastic transformation of colorectal epithelial cells..sup.13,14 Although studies of the biochemical mechanisms underlying the development of **colorectal cancer** are just beginning, the genes involved in this process have the potential to serve as markers in diagnosis and prognosis.

Web site: http://www.delphion.com/details?pn=US05702886__

- **Colorectal chemoprotective composition and method of preventing colorectal cancer**

  Inventor(s): McCracken; John D. (Redlands, CA), Wechter; William J. (Redlands, CA)

  Assignee(s): Loma Linda University Medical Center (loma Linda, Ca)

  Patent Number: 5,955,504

  Date filed: March 13, 1995

  Abstract: A composition for use in preventing **colorectal cancer** and other neoplastic diseases includes an enantiomerically stable R-NSAID or a pharmaceutically acceptable salt thereof in an amount effective to elicit a chemoprotective effect. The composition is substantially free of the S-enantiomer of the R-NSAID. Therapeutic use of the composition is accompanied by reduced adverse side effects.

  Excerpt(s): The present invention relates to compositions and methods useful in the prevention of colorectal and other gastrointestinal epithelial cancers.... Cancer of the colon is common in the western world and is an important cause of morbidity and mortality, having an incidence of about 5% in the U.S. population. As with other types of cancers, cancers of the

gastrointestinal tract, including colon cancer, are characterized by abnormal development in cell proliferation and differentiation in the gastrointestinal tract.... The gastrointestinal tract, including the rectum and colon, is lined with epithelial cells which have a high proliferation rate. The lining of the colon, in particular, made up of columnar rows of epithelial cells, is characterized by a series of indentations or crypts. Epithelial cells in the bottom regions of the crypts proliferate and move upward toward the tops of the crypts. In the normal colon, the proliferation region of the large intestine normally occupies the basal or deeper three-quarters of the crypts. A relationship has been observed between the expansion of cell proliferation zones to the upper regions of the crypts and colon cancer. See M. Lipkin, "Biomarkers of Increased Susceptibility to Gastrointestinal Cancer: New Application to Studies of Cancer Prevention in Human Subjects," Cancer Research, Vol. 48, pp. 235-245 (Jan. 15, 1988).

Web site: http://www.delphion.com/details?pn=US05955504__

- **Compositions that specifically bind to colorectal cancer cells and methods of using the same**

  Inventor(s): Barber; Michael T. (Paoli, PA), Parkinson; Scott J. (Philadelphia, PA), Pearlman; Joshua M. (Philadelphia, PA), Schulz; Stephanie (West Chester, PA), Waldman; Scott A. (Ardmore, PA)

  Assignee(s): Thomas Jefferson University (philadelphia, Pa)

  Patent Number: 6,120,995

  Date filed: August 7, 1997

  Abstract: A unique transcription product, CRCA-1, and alternative translation products generated thereform, are disclosed. The transcript and its translation products are markers for colorectal cells. Screening and diagnostic reagents, kits and methods for metastasized **colorectal cancer** are disclosed as are reagents, kits and methods for identifying adenocarcinomas as colorectal in origin. Compounds, compositions and methods of treating patients with metastasized **colorectal cancer** and for imaging metastasized colorectal tumors in vivo are disclosed. Compositions and methods for delivering active compounds such as gene therapeutics and antisense compounds to colorectal cells are disclosed. Vaccines compositions and methods of for treating and preventing metastasized **colorectal cancer** are disclosed.

  Excerpt(s): The present invention relates to in vitro diagnostic methods for detecting **colorectal cancer** cells, to kits and reagent for performing such methods. The present invention relates to compounds and methods

for in vivo imaging and treatment of colorectal tumors. The present invention relates to methods and compositions for making and using targeted gene therapy, antisense and drug compositions. The present invention relates to prophylactic and therapeutic anti-colorectal cancer vaccines and compositions and methods of making and using the same.... Colorectal cancer is the third most common neoplasm worldwide. The mortality rate of newly diagnosed large **bowel cancer** approaches 50% and there has been little improvement over the past 40 years. Most of this mortality reflects local, regional and distant metastases.... Surgery is the mainstay of treatment for **colorectal cancer** but recurrence is frequent. **Colorectal cancer** has proven resistant to chemotherapy, although limited success has been achieved using a combination of 5-fluorouracil and levamisole. Surgery has had the largest impact on survival and, in some patients with limited disease, achieves a cure. However, surgery removes bulk tumor, leaving behind microscopic residual disease which ultimately results in recrudescence.

Web site: http://www.delphion.com/details?pn=US06120995__

- **Detection of inherited and somatic mutations of APC gene in colorectal cancer of humans**

  Inventor(s): Albertsen; Hans (Salt Lake City, UT), Anand; Rakesh (Cheshire, GB2), Carlson; Mary (Salt Lake City, UT), Groden; Joanna (Salt Lake City, UT), Hedge; Philip John (Cheshire, GB2), Joslyn; Geoff (Salt Lake City, UT), Kinzler; Kenneth (Baltimore, MD), Markham; Alexander (Cheshire, GB2), Nakamura; Yusuke (Tokyo, JP), Thliveris; Andrew (Salt Lake City, UT), Vogelstein; Bert (Baltimore, MD), White; Raymond L. (Salt Lake City, UT)

  Assignee(s): Japanese Foundation for Cancer Research Cancer Institute (tokyo, Jp), The John Hopkins University (baltimore, Md), University of Utah (salt Lake City, Ut), Zeneca Limited (cheshire, Gb2)

  Patent Number: 5,648,212

  Date filed: August 12, 1994

  Abstract: Methods are provided for assessing mutations of the APC gene in human tissues and body samples. APC mutations are found in familial adenomatous polyposis patients as well as in sporadic **colorectal cancer** patients. APC is expressed in most normal tissues. APC is a tumor suppressor.

  Excerpt(s): The invention relates to the area of cancer diagnostics and therapeutics. More particularly, the invention relates to detection of the germline and somatic alterations of wild-type APC genes. In addition, it

relates to therapeutic intervention to restore-the function of APC (adenomatous Poliposis Coli) gene product.... In order to fully understand the pathogenesis of tumors, it will be necessary to identify the other suppressor genes that play a role in the tumorigenesis process. Prominent among these is the one(s) presumptively located at 5q21. Cytogenetic (Herrera et al., Am J. Med. Genet., Vol. 25, p. 473 (1986) and linkage (Leppert et al., Science, Vol. 238, p. 1411 (1987); Bodmer et al., Nature, Vol. 328, p. 614 (1987)) studies have shown that this chromosome region harbors the gene responsible for familial adenomatous polyposis (FAP) and Gardner's Syndrome (GS). FAP is an autosomal-dominant, inherited disease in which affected individuals develop hundreds to thousands of adenomatous polyps, some of which progress to malignancy. GS is a variant of FAP in which desmoid tumors, osteomas and other soft tissue tumors occur together with multiple adenomas of the colon and rectum. A less severe form of polyposis has been identified in which only a few (2-40) polyps develop. This condition also is familial and is linked to the same chromosomal markers as FAP and GS (Leppert et al., New England Journal of Medicine, Vol. 322, pp. 904-908, 1990.) Additionally, this chromosomal region is often deleted from the adenomas (Vogelstein et al., N. Engl. J. Med., Vol. 319, p. 525 (1988)) and carcinomas (Vogelstein et al., N. Engl. J. Med., Vol. 319, p. 525 (1988); Solomon et al., Nature, Vol. 328, p. 616 (1987); Sasaki et al., Cancer Research, Vol. 49, p. 4402 (1989); Delattre et al., Lancet, Vol. 2, p. 353 (1989); and Ashton-Rickardt et al., Oncogene, Vol. 4, p. 1169 (1989)) of patients without FAP (sporadic tumors). Thus, a putative suppressor gene on chromosome 5q21 appears to play a role in the early stages of colorectal neoplasia in both sporadic and familial tumors.... Although the MCC gene has been identified on 5q21 as a candidate suppressor gene, it does not appear to be altered in FAP or GS patients. Thus there is a need in the art for investigations of this chromosomal region to identify genes and to determine if any of such genes are associated with FAP and/or GS and the process of tumorigenesis.

Web site: http://www.delphion.com/details?pn=US05648212__

- **Hybridoma CT43 producing a monoclonal antibody to a novel mucin epitope which correlates with the presence of colorectal cancer**

  Inventor(s): Brown; Joseph P. (Seattle, WA)

  Assignee(s): Genetic Systems Corporation (redmond, Wa)

  Patent Number: 5,459,043

  Date filed: December 3, 1992

Abstract: The present invention relates to a novel monoclonal antibody reactive with human colorectal mucin antigen. More particularly, the antibody of the invention is a murine monoclonal antibody, CT43, reactive with a novel antigenic determinant on much antigen highly correlated with human **colorectal cancer.** The antigenic determinant found by the CT43 has been characterized as neuraminidase and proteinase K resistant, periodate sensitive and unreactive with the glycoconjugates of Table 2. Methods are provided for the detection and quantitation of the CT43 antigenic determinant and its correlation with **colorectal cancer.** CT43, and CT66 specific for the sialylated Lewis a and Lewis a antigen have been deposited with the American Type Culture Collection, as accession numbers ATCC HB 10217 and ATCC HB 10218, deposited Sep. 6, 1989.

Excerpt(s): This invention relates to the hybridoma cell line CT43 which produces a monoclonal antibody reactive with mucins, particularly a novel epitope on mucin molecules associated with **colorectal cancer** malignancies. Monoclonal antibody CT43 and other antibodies specific for the epitope recognized by CT43 are useful in the detection and treatment of human cancers, particularly **colorectal cancer.**... The diagnosis of **colorectal cancer** is currently based upon clinical findings, detection of blood in fecal samples, and a correlation with high level of certain carcinoma- associated mucin antigens in tissue, blood, or serum samples detected by the binding of certain monoclonal antibodies. Examples of monoclonal antibodies which have been reported to recognize antigens associated with gastrointestinal or **colorectal cancer** include CA 19-9 (Magnani, J. L. et al. supra), CCK061 (European Patent Application, EP200464) and a monoclonal antibody specific for carcinoembryonic antigen (1116NS-3d), U.S. Pat. No. 4,349,528). In vitro diagnostic methods for detecting the presence of cancer cells or other cancer cells producing small intestine mucin antigens and/or large intestine mucin antigen and monoclonal antibodies useful therein are disclosed by Linnane (PCT Publication WO 86/00414). Many other malignant conditions are also detected, in addition to colorectal carcinoma (e.g., stomach, gall bladder, malignant lymphoma and acute lymphocytic leukemia). Diagnostic tests based on each of the antigens recognized by the above antibodies fail to have a high correlation with colorectal carcinoma, particularly in its early stages, resulting in high numbers of false positive results. The only truly reliable method to date is biopsy of potentially malignant growths. Monoclonal antibodies such as CEA or CA 19- 9 are used in conjunction with other diagnostic methods or in post-therapy survey for cancer recurrance.... The present invention provides a monoclonal antibody that is highly reactive with mucin epitopes associated with human **colorectal cancer.** More specifically, the

novel antibody of the invention, designated CT43, is a murine monoclonal antibody that binds a novel epitope on the membrane of colorectal carcinoma cells and also on mucin molecules found in human sera of patients suffering from **colorectal cancer.** The novel mucin epitope is characterized as being neuraminidase and proteinase K resistant, periodate sensitive and unreactive with many known, naturally occuring glycoconjugates.

Web site: http://www.delphion.com/details?pn=US05459043__

- **Medicinal compositions for treating colorectal cancer**

  Inventor(s): Goto; Takeshi (Ibaraki, JP), Tanida; Norifumi (Ibaraki, JP), Tomizawa; Naoko (Ibaraki, JP)

  Assignee(s): Hisamitsu Pharmaceutical Co., Inc. (saga, Jp)

  Patent Number: 6,620,834

  Date filed: April 15, 2002

  Abstract: Medicinal compositions for **colorectal cancer** to be administered to the large intestine by taking advantage of preparations disintegrating in the large intestine, characterized by containing a cyclooxygenase inhibitor and an HMG-CoA reductase inhibitor. These compositions are appropriate for inhibiting the postoperative liver metastasis and recurrence of **colorectal cancer.**

  Excerpt(s): The invention relates to a pharmaceutical composition to be administered to the large intestine for treating a **colorectal cancer.**... In cancer therapy the surgical treatment is the mainstream at present. However, in order to improve the performance of the surgical treatment further, an ancillary use of chemotherapy is indispensable. Since cases of cancer metastasis to the liver or lung due to a hemokinetic metastasis from, in particular, the **colorectal cancer** is frequently observed, a postoperative ancillary chemotherapy has become essential. For the chemotherapy aiming to inhibit the postoperative metastasis and recurrence of cancer, usually an oral anticancer agent represented by 5-fluorouracil is mainly used. In case of using such an anticancer agent expecting the metastasis inhibition or recurrence prevention, a medicine-taking period for one year or more is necessary, though the present situation is that the medication is compelled to be abandoned owing to the development of a strong digestive tract disorder or a systemic side effect such as a severe myelosuppression. Therefore, naturally there is limitation for achieving the above object only by the chemotherapy mainly using an anticancer agent.... Further, in case of making the chemotherapy aim to prevent especially the postoperative liver

metastasis of **colorectal cancer,** it is important to carry out a drug delivery from the mesenteric vein to the portal in a metastasis route of cancer cells and to maintain a drug concentration in the portal blood.

Web site: http://www.delphion.com/details?pn=US06620834__

- **Method for colorectal cancer prognosis and treatment selection**

  Inventor(s): Ross; Jeffrey S. (New Lebanon, NY)

  Assignee(s): Albany Medical College (albany, Ny)

  Patent Number: 6,322,986

  Date filed: January 18, 2000

  Abstract: A method predicting the outcome, and prognosis and indicating treatment for patients afflicted with **colorectal cancer** by determining whether the number of copies of HER-2/neu gene in cancer cells from the patient exceeds four by in-situ hybridization. Patients having cells with five or more copies of the HER-2/neu gene are to be treated more aggressively or in combination with an anti-HER-2/neu antibody.

  Excerpt(s): The present invention relates to predicting the outcome and selecting preferred treatments for **colorectal cancer** by DNA analysis.... Colorectal cancer is a common cancer in the developed world and is a major cause of cancer death. The disease is diagnosed in about 129,400 people and is responsible for nearly 56,600 deaths per year in the United States alone. Traditional therapies for **colorectal cancer** include surgery, radiation therapy, and chemotherapy, with 5-fluorouracil, levamisole, leucovorin or semustine (methyl CCNU) being the preferred chemotherapeutic agents for colorectal adenocarcinoma.... After surgery or other treatment the ability to predict recurrence and to treat the patient appropriately becomes problematic. Post-surgical treatments have numerous undesired side effects which one wishes to avoid if possible. Conversely, failure to adequately treat any residual tumor cells may result in recurrence of the cancer. Pathological stage, clinical stage, patient age, various protein markers and cell proliferation index are each indicative of the aggressiveness of the cancer and prognostic of eventual outcome. Examples of such indicators may be found in Cohn et al, Cancer 79:233-44 (1997), Finkelstein et al, Cancer 71(12):3827-3838 (1993), Harrison et al, Human Pathology 26(1):31-38 (1995), Furuta et al, Clinical Cancer Research 4:21-29 (1998), Tanigawa et al, Cancer Research 57:1043-1046 (1997), Ropponen et al, Cancer Research 58:342-347 (1998), Wielenga et al, Cancer Research 53:4754-4756 (1993), Halter et al, Modern Pathology 5(2):131-134 (1992), Tanabe et al, Lancet, 341:725-726 (1993), Lanza et al,

Anatomic Pathology 105(5):604-612 (1996), Graham et al, Modern Pathology 3(3):332-335 (1990), Engel et al, The American Journal of Surgical Pathology 20(10):1260-1265 (1996), Suzuki et al, Gastroenterology 109:1098-1104 (1995), Morrin et al, Gut 35:1627-1631 (1994) and Nakamori et al, Gastroenterology 106:353-361 (1994).

Web site: http://www.delphion.com/details?pn=US06322986__

- **Method of diagnosing and monitoring colorectal cancer**

  Inventor(s): Holmes; Stephen D. (Great Chishill, GB2), Kirkpatrick; Robert B. (King of Prussia, PA), Robbins; David (King of Prussia, PA)

  Assignee(s): Smithkline Beechum Corporation (king of Prussia, Pa)

  Patent Number: 5,726,061

  Date filed: October 8, 1996

  Abstract: Methods of screening for **colorectal cancer** by measuring levels of HC gp-39 are provided. Methods of monitoring patients with **colorectal cancer** are also provided. In addition, kits for detection of HC gp-39 useful in screening for and monitoring of **colorectal cancer** in a patient are provided.

  Excerpt(s): Colorectal cancer is a leading cause of death in the western hemisphere. It is currently the second most common neoplasm, as well as the second leading cause of death due to cancer, in the United States. Risk factors for **colorectal cancer** include familial and genetic factors, and may include low levels of physical activity, alcohol consumption, high dietary intake of fat and meat and low intake of fiber and vegetables. Age also appears to be a significant risk factor as less than 2% of the cases occur in people under 40 years of age. The risk of **colorectal cancer** in a patient 50 years of age is 18 to 20 times that in a patient 30 years of age and the risk doubles about every 7 years thereafter.... The prognosis of **colorectal cancer** is directly related to the stage at which the cancer is detected. When detected early, either as an adenoma or wherein the tumor is confined to the bowel wall, the cancer can be treated effectively with a greater than 90%, five-year survival rate. However, in later stages, **colorectal cancer** spreads to local and regional lymph nodes, with the most common distant metastatic sites being the liver and the lung, thus making methods of treatment much less effective.... The World Health Organization in Geneva Switzerland has outlined certain requirements for determining when screening for a specific disease might be beneficial. First, the disease is a major cause of morbidity and/or mortality. Second, the treatment must be effective and risks of screening low. Third, the test must be both efficacious and cost-effective. Fourth, the test must have

high sensitivity and specificity. Finally, the test must be acceptable to the general population and to the physicians who implement the screening. **Colorectal cancer** clearly meets these requirements. In fact, there are several tests currently being recommended by the American Cancer Society for colorectal screening, i.e., flexible sigmoidoscopy and fecal occult blood tests. Digital rectal examination has also been suggested. Wayne et al. Arch. Fam. Med., 1995, 4, 357-366.

Web site: http://www.delphion.com/details?pn=US05726061__

- **Method of preparing activated killer monocytes for treating colorectal cancer**

  Inventor(s): Stevenson; Henry C. (Kensington, MD)

  Assignee(s): The United States of America AS Represented by the Department of Health (washington, Dc)

  Patent Number: 5,093,115

  Date filed: June 20, 1988

  Abstract: The present invention discloses a method of preparing activated killer monocytes for treating **colorectal cancer.** Activated killer monocytes are prepared in serum free medium in polypropylene containers.

  Excerpt(s): The present invention is related generally to cancer therapy. More particularly, the present invention is related to monitoring in cancer patients the tumoricidal activity of purified human monocytes cultured in suspension in a serum-free medium.... Mononuclear phagocytes (monocytes) in their various forms have been shown to participate in many critical phases of the mammalian immune response. Monocytes and macrophages are known to be essential for the initiation of immune responses by virtue of their ability to process antigen (Rosenthal, New Engl. J. Med. 303, 1153. 1980), and for their ability to secrete soluble factors such as interleukin 1 (IL-1), colony stimulating factor (CSF), interferon (IFN) and prostaglandin E (PGE) which allow them to function as immunoregulators for a number of immune responses (Epstein, Biology of Lymphokines; Academic Press, NY, pp. 123-152. 1979; Stevenson, The Reticuloendothelial System. A Comprehensive Treatise, Vol. VI: Plenum Press, NY, pp. 79-91. 19882). In addition, monocytes are known to play critical role as final effector cells in humoral immunity by virtue of the fact that these cells secrete complement components (Nathan, et al, New England J. Med. 303, 623. 1980) and are capable of mediating cytotoxic functions. In addition to antibody-dependent cellular cytotoxicity (ADCC) (Poplack, et al, Blood 48, 890. 1976), activated killer

monocytes (AKM) are known to be potent killers of tumor cells (Stevenson, et al, Artificial Organs 112, 128. 1988).... Assessment of the in vitro function of human monocytes and AKM has been hampered by a number of technical and theoretical problems. First, monocytes constitute a very low proportion of the cells in human peripheral blood (generally less than 5%); thus, obtaining large numbers of them has been quite difficult. In addition, very few techniques have emerged which allow for the large-scale isolation of purified populations of human monocytes by negative selection; instead, generally small numbers of rather impure monocytes are isolated on gradients such as Percoll (Hester, et al., 1981) or cells of higher purity are obtained by adhering them onto plastic or glass labware by positive selection (Werb, J. Exp. Med. 147, 1695. 1978).

Web site: http://www.delphion.com/details?pn=US05093115__

- **Method of screening for colorectal cancer**

  Inventor(s): Mashiba; Shinichi (Kyoto-fu, JP), Uchida; Kazuo (Hyogo-ken, JP)

  Assignee(s): Ikagaku Co., Ltd. (kyoto, Jp)

  Patent Number: 5,552,292

  Date filed: November 10, 1994

  Abstract: The invention provides a new method for screening for **colorectal cancer** by measurement of the level of lactoferrin or myeloperoxidase in feces. Particularly, a screening test method for **colorectal cancer** by measurement of the level of lactoferrin or myeloperoxidase in feces by immunoassay and by measurement of the level of whole-sized lactoferrin by immunoassay utilizing monoclonal antibody.

  Excerpt(s): In various kinds of gastrointestinal tract diseases such as inflammatory gastrointestinal disorders and **gastrointestinal cancer,** intestinal chronic bleeding is observed in inflammation neoplasia at the mucous membrane, or protein leaking in gastrointestinal tract is observed due to permeability disorder of capillary blood vessel or pressure raise of lymphoduct.... In order to diagnose the gastrointestinal tract diseases, the fecal occult blood test method has most been used for screening of gastrointestinal tract diseases with bleeding, especially for mass screening of **colorectal cancer.**... Among the fecal occult blood test, the guaiac method is the most widely used and the method utilizes the peroxidase activity of the heme in hemoglobin, hence not only human hemoglobin in feces, but also hemoglobin from animal and fish meat or special vegetable is detected by this method. Since human hemoglobin is not detected

specifically by the Guaiac method, subjects are required to follow a special diet in order to prevent the occurrence of false positive results. Moreover, it has been difficult to increase the sensitivity of this method.

Web site: http://www.delphion.com/details?pn=US05552292__

- **Method of treating or inhibiting colonic polyps and colorectal cancer**

  Inventor(s): Discafani-Marro; Carolyn M. (Cortlandt Manor, NY), Frost; Philip (Morris Township, NJ)

  Assignee(s): American Cyanamid Company (madison, Nj)

  Patent Number: 6,432,979

  Date filed: August 9, 2000

  Abstract: This invention provides a method of treating or inhibiting colonic polyps or treating or inhibiting **colorectal cancer** in a mammal in need thereof which comprises administering to said mammal an NSAID and an EFGR kinase inhibitor.

  Excerpt(s): This invention relates to the use of a combination of an NSAID and a epidermal growth factor receptor (EGFR) kinase inhibitor in the treatment and inhibition of colonic polyps and **colorectal cancer.**... Colonic Polyps occur in both a familial pattern (familial adenomatous polyps; FAP) and sporadically. FAP afflicts approximately 25,000 patients in the US; while it is estimated that sporadic adenomatous polyps (SAP) occur in approximately 2 million people per year in the US alone. All these patients are at risk for developing **adenocarcinoma of the colon.**. In the case of FAP, that risk is virtually 100% and these patients usually undergo a colectomy at an early age. Patients with sporadic polyps are treated with polypectomy and require periodic colonoscopic examination because of their inherent risk of developing recurrent polyps. In fact, parents and siblings of these patients are also at increased risk for developing **colorectal cancer.**... The genetic basis for FAP has been linked to the presence of mutations in the APC gene. Similar APC mutations have been found in patients with sporadic polyps. Biochemically, the APC mutation occurs in conjunction with the increased expression of cyclooxygenase enzymes, particularly COX-2. These enzymes are essential for the production of prostenoids, (prostaglandin's; (PG's)) that mediate a number of functions in the bowel including motility, vascular tone, angiogenesis and mucosal protection. PG's are also purported to discourage apoptosis and this is proposed as an explanation for polyp formation.

  Web site: http://www.delphion.com/details?pn=US06432979__

- **Methods of diagnosing colorectal cancer, compositions, and methods of screening for colorectal cancer modulators**

  Inventor(s): Gish; Kurt C. (San Francisco, CA), Mack; David (Menlo Park, CA), Wilson; Keith E. (Redwood City, CA)

  Assignee(s): Eos Biotechnology, Inc. (south San Francisco, Ca)

  Patent Number: 6,294,343

  Date filed: November 9, 1999

  Abstract: Described herein are methods that can be used for diagnosis and prognosis of **colorectal cancer.** Also described herein are methods that can be used to screen candidate bioactive agents for the ability to modulate **colorectal cancer.** Additionally, methods and molecular targets (genes and their products) for therapeutic intervention in colorectal and other cancers are described.

  Excerpt(s): The invention relates to the identification of expression profiles and the nucleic acids involved in **colorectal cancer,** and to the use of such expression profiles and nucleic acids in diagnosis and prognosis of **colorectal cancer.** The invention further relates to methods for identifying and using candidate agents and/or targets which modulate **colorectal cancer.**... Colorectal cancer is a significant cancer in Western populations. It develops as the result of a pathologic transformation of normal colon epithelium to an invasive cancer. There have been a number of recently characterized genetic alterations that have been implicated in **colorectal cancer,** including mutations in two classes of genes, tumor-suppressor genes and proto-oncogenes, with recent work suggesting that mutations in DNA repair genes may also be involved in tumorigenesis. For example, inactivating mutations of both alleles of the adenomatous polyposis coli (APC) gene, a tumor suppressor gene, appears to be one of the earliest events in **colorectal cancer,** and may even be the initiating event. Other genes implicated in **colorectal cancer** include the MCC gene, the p53 gene, the DCC (deleted in colorectal carcinoma) gene and other chromosome 18q genes, and genes in the TGF-.beta. signalling pathway. For a review, see Molecular Biology of **Colorectal Cancer,** pp238-299, in Curr. Probl. Cancer, September/October 1997.... Imaging of **colorectal cancer** for diagnosis has been problematic and limited. In addition, dissemination of tumor cells (metastases) to locoregional lymph nodes is an important prognostic factor; five year survival rates drop from 80 percent in patients with no lymph node metastases to 45 to 50 percent in those patients who do have lymph node metastases. A recent report showed that micrometastases can be detected from lymph nodes using

reverse transcriptase-PCR methods based on the presence of mRNA for carcinoembryonic antigen, which has previously been shown to be present in the vast majority of colorectal cancers but not in normal tissues. Liefers et al., New England J. of Med. 339(4):223 (1998).

Web site: http://www.delphion.com/details?pn=US06294343__

- **Prevention and treatment of colorectal cancer by 6-fluoroursodeoxycholic acid (6-FUDCA)**

  Inventor(s): Capuano; Leonard Robert (Parsippany, NJ), Gibson; Joyce Corey (Harding Township, NJ)

  Assignee(s): Novartis AG (basel, Ch)

  Patent Number: 6,426,340

  Date filed: October 6, 2000

  Abstract: Methods for the prevention and treatment of **colorectal cancer** are provided. Specifically, the method relates to the administration of an effective adenoma or microadenoma preventing amount of 6-fluoroursodeoxycholic acid (6-FUDCA) or a pharmaceutically acceptable salt or pharmaceutically acceptable conjugate thereof to a mammal in need of such treatment. The methods find general use in the prevention of the formation of secondary bile acids, the reduction of deoxycholic acid, and the protection against cytotoxic effects of other bioacids and carcinogens.

  Excerpt(s): The invention relates to the treatment and prevention of precancerous cell formation in the colon in those patients at risk for developing such precancerous cells. It also relates to preventing recurrence of such cell formation in those having been treated for **cancer of the colon.**.... Cancer of the colon is a common and deadly disease in the Western world. Genetic predisposition plays an important role, but exposure to substances that initiate and promote cancer is essential for a malignant tumor to develop. Bile acids have been implicated as important cancer-promoting agents.... In the normal colon mucosa, epithelial cells line crypt along the mucosal wall. Those epithelial cells which line the colon exposed surface and approximately the upper 2/3 of the crypt are normally non-proliferating, while those lining the lower 1/3 of the crypts are proliferating. As the proliferating cells migrate toward the upper portion of the crypt they transform and lose their proliferative ability. Ultimately the oldest cells are shed from the colon surface in the normal functioning of the colon. However, when the proliferating epithelial cells are induced to retain their proliferative capacity after reaching the upper 1/3 of the crypt, the normal process may go awry and

microadenomas form. The proliferating cell, now at the surface of the colon continues to proliferate and a polyp develops.

Web site: http://www.delphion.com/details?pn=US06426340__

- **Screening test for early detection of colorectal cancer**

  Inventor(s): Chociej; Jacek (43 Valleywoods Rd. #89, Toronto, CA), Kandel; Gabor P. (430 Heath St. East, Toronto, CA), Krepinsky; Jiri J. (810 Srigley Street, Newmarket, CA), Yeung; Ka Sing (810 Srigley St., Newmarket, CA)

  Assignee(s): None Reported

  Patent Number: 5,416,025

  Date filed: August 31, 1994

  Abstract: A method for detecting the presence of neoplasia or **cancer of the colon** or rectum, which method comprises obtaining a sample of colorectal mucus from the rectum of a patient; treating the sample with Schiff's reagent and screening for neoplasia or **cancer of the colon** or rectum based upon the coloration produced in the sample by the treatment. The method is rapid, simple, inexpensive and provides a screening test for **colorectal cancer** which does not give a high percentage of false positive and false negative results. A screening test kit is provided.

  Excerpt(s): This invention relates to a simple screening test for **colorectal cancer.** Specifically, a method is described whereby a **colorectal cancer** marker is detected in rectal mucus obtained by digital rectal examination. More particularly, this marker is detected in the mucus deposited on a support using Schiff's reagent.... Colorectal carcinoma is the second most frequent cause of cancer mortality in men and women, causing nearly one third of all malignancy-related deaths in North America. It has been estimated that ultimately as many as 6% of Canadians and Americans will develop malignancy in the lower bowel, and over 50% of them will die within 5 years of diagnosis. Because there are no realistic prospects of significantly improving the cure rate once the cancer has spread beyond the bowel wall, many authorities believe that **colorectal cancer** can be controlled only by preventive measures (1).... Primary prevention, i.e. averting the development of the tumour by altering biological risk factors, is not yet feasible since so little is understood of the etiology of the disease. Alternatively, secondary preventive measures, i.e. detection at an asymptomatic, treatable state, would be possible should an effective screening test be available. Indeed, neoplasms of the lower bowel have the characteristics that make them a suitable candidate for the

development of a screening test. This is because i) it is a common cause of cancer-related deaths, and ii) whereas once the stage of true cancer is reached, leading to symptoms, the mortality rate is over 50%, removal of bowel neoplasms at its earliest, asymptomatic stage can be done by non-surgical endoscopic polypectomy, without any significant risk. Moreover, it requires at least four to six years before an adenomatous polyp reaches the cancer stage, so there is ample opportunity to detect these neoplasms at their treatable stage. Recent clinical studies document a decrease in mortality from **colorectal cancer** screening, as predicted by these theoretical considerations. The problem to-date has been that polyps can be reliably detected only by endoscopy.

Web site: http://www.delphion.com/details?pn=US05416025__

- **Treatment of pain and colorectal cancer with dipeptoids of.alpha.-substituted Trp-Phe derivatives**

  Inventor(s): Aranda; Julian (Vorstetter, DE), Horwell; David C. (Foxton, GB2), Pritchard; Martyn C. (Swavesey, GB2), Richardson; Reginald S. (Haverhill, GB2), Roberts; Edward (Wood Ditton, GB2)

  Assignee(s): Warner-lambert Company (morris Plains, Nj)

  Patent Number: 5,580,896

  Date filed: May 22, 1995

  Abstract: This invention relates to the treatment of pain and inhibiting the growth of **colorectal cancer** with dipeptoids of.alpha.-substituted Trp-Phe derivatives.

  Excerpt(s): Agents acting at central cholecystokinin (CCK) receptors induce satiety (Schick, Yaksh and Go, Regulatory Peptides 14:277-291, 1986). They are also expected to act as analgesics (Hill, Hughes and Pittaway, Neuropharmacology 26:289-300, 1987), and as anticonvulsants (MacVicar, Kerrin and Davison, Brain Research, 406:130-135, 1987).... Reduced levels of CCK-peptides have been found in the brains of schizophrenic patients compared with controls (Roberts, Ferrier, Lee, Crow, Johnstone, Owens, Bacarese-Hamilton, McGregor, O'Shaughnessey, Polak and Bloom. Brain Research 288, 199-211, 1983). It has been proposed that changes in the activity of CCK neurones projecting to the nucleus accumbens may play a role in schizophrenic processes by influencing dopaminergic function (Totterdell and Smith, Neuroscience 19, 181-192, 1986). This is consistent with numerous reports that CCK peptides modulate dopaminergic function in the basal ganglia and particularly the nucleus accumbens (Weiss, Tanzer, and Ettenberg, Pharmacology, Biochemistry and Behaviour 30, 309-317, 1988; Schneider,

Allpert and Iversen, Peptides 4, 749-753, 1983). It may therefore be expected that agents modifying CCK receptor activity may have therapeutic value in conditions associated with disturbed function of central dopaminergic function such as schizophrenia and Parkinson's disease.... The CCK peptides are widely distributed in various organs of the body including the gastrointestinal tract, endocrine glands, and the nerves of the peripheral and central nervous systems. Various biologically active forms have been identified including a 33-amino acid hormone and various carboxyl-terminus fragments of this peptide (e.g., the octapeptide CCK26-33 and the tetrapeptide CCK30-33). (G. J. Dockray, Br. Med. Bull., 38 (No. 3):253-258, 1982).

Web site: http://www.delphion.com/details?pn=US05580896__

Patent Applications on Gastrointestinal Carcinoid Tumors

As of December 2000, U.S. patent applications are open to public viewing.[28] Applications are patent requests which have yet to be granted (the process to achieve a patent can take several years). The following patent applications have been filed since December 2000 relating to gastrointestinal carcinoid tumors:

- **4-(4'-HYDROXYPHENYL) AMINO-6,7-DIMETHOXYQUINAZOLINE TO PREVENT DEVELOPMENT OF COLORECTAL CANCER**

  Inventor(s): Uckun, Fatih M.; (White Bear Lake, MN)

  Correspondence: Merchant & Gould PC; P.o. Box 2903; Minneapolis; MN; 55402-0903; US

  Patent Application Number: 20020183340

  Date filed: May 14, 2002

  Abstract: The present invention is directed to a method of preventing the development or recurrence of **colorectal cancer** in a mammal comprising adminstering to the mammal an effective cancer preventive amount of 4(4'-hydroxyphenyl)-amino-6,7-dimethoxyquinazoline or a pharmaceutically acceptable salt thereof.

  Excerpt(s): This application is being filed as a PCT International Patent application in the name of Parker Hughes Institute, a U.S. national corporation, (applicant for all countries except US), and Fatih M. Uckun, a U.S. citizen (applicant for US only), on Nov. 14, 2000, designating all countries.... The present invention relates to quinazoline compounds,

[28] This has been a common practice outside the United States prior to December 2000.

compositions and therapeutic methods for the treatment of cancers by administering quinazoline compounds.... Currently, there is a need for methods useful for preventing the development or recurrence of cancer in mammals. Quinazoline compounds have been suggested as useful compounds in the treatment of cell growth and differentiation characterized by activity of the human epidermal growth factor receptor type2 (HER2). See, for example, Myers et.al., U.S. Pat. No. 5,721,237. Some quinazoline derivatives have been suggested as useful as anti-cancer agents for the treatment of specific receptor tyrosine kinase-expressing cancers, especially those expressing epithelial growth factor (EGF) receptor tyrosine kinase. See, for example, Barker et. al., U.S. Pat. No. 5,457,105. It is generally taught that quinazolines exert their anti-tumor effects via tyrosine kinase inhibition. However, while some quinazoline compounds inhibit the growth of tumor cells, such as brain tumor cells, others with equally potent tyrosine kinase inhibitory activity fail to do so (Naria et.al., 1998, Clin.Cancer Res. 4:1405-1414; Naria et.al., 1998, Clin. Cancer Res. 4:2463-2471).

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Colorectal cancer diagnostics**

  Inventor(s): Wang, Yixin; (San Diego, CA)

  Correspondence: Audley A. Ciamporcero Jr.; Johnson & Johnson; One Johnson & Johnson Plaza; New Brunswick; NJ; 08933-7003; US

  Patent Application Number: 20030186302

  Date filed: March 21, 2003

  Abstract: A method of assessing the presence or absence of **colorectal cancer** or the likely condition of a person believed to have **colorectal cancer** is conducted by analyzing the expression of a group of genes. Gene expresson profiles in a variety of medium such as microarrays are included as are kits that contain them.

  Excerpt(s): This application claims the benefit of U.S Provisional Application No. 60/368,798 filed on Mar. 29, 2002.... This invention relates to diagnostics and prognostics for **colorectal cancer** based on the gene expression profiles of biological samples.... Colorectal cancer is a heterogenous disease, consisting of tumors thought to emerge through three major molecular mechanisms: 1) mutations in the adenomatous polyposis coli (APC) gene, or the.beta.-catenin gene, combined with chromosomal instability, 2) mutations in DNA mismatch repair genes, such as MLH1, MSH2, PMS1, PMS2 and MSH6, associated with microsatellite instability and mutations in genes containing short repeats,

and 3) gene silencing induced by hypermethylation of the promoter regions of tumor suppressor genes. The genetic complement of individual colorectal cancers is likely to include different combinations of genetic instability, specific mutations, and gene silencing. Chromosomal instability (CIN) is a common feature of cancers in general. It implies an aneuploid phenotype, in which whole chromosomes or large parts of them are being lost or gained. Microsomal instability (MIN) is found in diploid tumors with an increased mutation rate in short repeats. Both forms of genetic instability are common in **colorectal cancer.**

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Compositions and methods for diagnosing, monitoring, staging, imaging and treating stomach cancer**

  Inventor(s): Chen, Sei-Yu; (Foster City, CA), Hu, Ping; (San Ramon, CA), Macina, Roberto A.; (San Jose, CA), Pluta, Jason; (Mountain View, CA), Recipon, Herve E.; (San Francisco, CA)

  Correspondence: Licata & Tyrrell P.c.; 66 E. Main Street; Marlton; NJ; 08053; US

  Patent Application Number: 20020068307

  Date filed: March 30, 2001

  Abstract: The present invention provides polynucleotides and polypeptides which are diagnostic markers for **stomach cancer.**. In addition, antibodies immunospecific for these markers are provided. Vectors, hosts cells and methods for producing these markers, as well as methods and tools for using these markers in detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating **stomach cancer** are also provided.

  Excerpt(s): This application claims the benefit of priority from U.S. Provisional Application Serial No. 60/193,095, filed Mar. 30, 2000.... This invention relates, in part, to newly identified polynucleotides and polypeptides encoded thereby, as well as methods for producing and using these polynucleotides and polypeptides. Antibodies which are immunospecific for these polypeptides are also described. Expression of the newly identified polynucleotides and levels of the polypeptides encoded thereby are upregulated in or specific to **stomach cancer** tissue. These new polynucleotides and polypeptides, referred to herein as **Stomach Cancer** Specific Genes or SSGs are believed to be useful in assays for detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating cancers, particularly **stomach cancer.**.... Cancer of the stomach, also referred to as gastric cancer, is difficult to diagnose in

early stages and can be in the stomach for a long time, growing to a large size before symptoms arise. In the early stages of cancer of the stomach, an individual may experience indigestion and stomach discomfort, a bloated feeling after eating, mild nausea, loss of appetite or heartburn. In more advanced stages of **stomach cancer,** there may be blood in the stool, vomiting, weight loss or more severe pain.

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Compositions and methods for the treatment of colorectal cancer**

  Inventor(s): Govindarajan, Rangaswamy; (Little Rock, AR), Zeitlin, Andrew; (Basking Ridge, NJ)

  Correspondence: Pennie & Edmonds Llp; 1667 K Street NW; Suite 1000; Washington; DC; 20006

  Patent Application Number: 20020035091

  Date filed: May 14, 2001

  Abstract: This invention relates to compositions comprising thalidomide and irinotecan, which can be used in the treatment or prevention of **colorectal cancer.** The invention also relates to methods of treating or preventing **colorectal cancer** which comprise the administration of thalidomide and irinotecan to a patient in need of such treatment or prevention. The invention further relates to methods of reducing or avoiding adverse side effects associated with the administration of irinotecan which comprise the administration of thalidomide to a patient in need of such reduction or avoidance.

  Excerpt(s): This invention relates to pharmaceutical compositions comprising thalidomide and irinotecan, to methods of treating **colorectal cancer,** and to methods of reducing or avoiding adverse effects of irinotecan.... Cancer is characterized primarily by an increase in the number of abnormal cells derived from a given normal tissue, invasion of adjacent tissues by these abnormal cells, or lymphatic or blood-borne spread of malignant cells to regional lymph nodes and to distant sites (metastasis). Clinical data and molecular biologic studies indicate that cancer is a multistep process that begins with minor preneoplastic changes, which may under certain conditions progress to neoplasia.... Pre-malignant abnormal cell growth is exemplified by hyperplasia, metaplasia, or most particularly, dysplasia (for review of such abnormal growth conditions, see Robbins and Angell, 1976, Basic Pathology, 2d Ed., W. B. Saunders Co., Philadelphia, pp. 68-79). Hyperplasia is a form of controlled cell proliferation involving an increase in cell number in a tissue or organ, without significant alteration in structure or function. As

but one example, endometrial hyperplasia often precedes endometrial cancer. Metaplasia is a form of controlled cell growth in which one type of adult or fully differentiated cell substitutes for another type of adult cell. Metaplasia can occur in epithelial or connective tissue cells. Atypical metaplasia involves a somewhat disorderly metaplastic epithelium. Dysplasia is frequently a forerunner of cancer, and is found mainly in the epithelia; it is the most disorderly form of non-neoplastic cell growth, involving a loss in individual cell uniformity and in the architectural orientation of cells. Dysplastic cells often have abnormally large, deeply stained nuclei, and exhibit pleomorphism. Dysplasia characteristically occurs where there exists chronic irritation or inflammation, and is often found in the cervix, respiratory passages, oral cavity, and gall bladder.

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Development of immuno-PCR for serological diagnosis of gastric carcinoma**

  Inventor(s): Ren, Jun; (Xian, CN)

  Correspondence: Knobbe Martens Olson & Bear Llp; 620 Newport Center Drive; Sixteenth Floor; Newport Beach; CA; 92660; US

  Patent Application Number: 20020132233

  Date filed: January 16, 2001

  Abstract: Methods of detecting carcinoma-associated antigens in patient sera have been discovered. Aspects of the invention utilize single determinant immuno PCR to detect the presence or absence of a tumor associated antigens (e.g., gastric carcinoma-associated antigen MG7-Ag) in human sera. In some embodiments, a biotinylated monoclonal antibody (e.g., MG7-Ab), an avidin linker, and a biotinylated DNA are employed. The methods described herein allow for the early diagnosis of cancers, including, but not limited to, **gastric carcinoma** and cancers of the liver, colon, breast, uterus, and lung that display a tumor associated antigen. Some embodiments can be used to detect cancers at an early stage, to screen large populations of individuals for various cancers, diagnose the reoccurrence of cancer after surgery, and determine whether an individual suffers from metastasis.

  Excerpt(s): This invention concerns the detection of carcinoma-associated antigens in a biological sample. Embodiments include compositions and methods for the early diagnosis of cancer and metastasis.... Gastric carcinoma is one of the most significant malignancies causing morbidity and mortality in China and other Asian counties. Since **gastric carcinoma** is largely asymptomatic, early diagnosis is rarely possible. Only at a late

stage of **gastric carcinoma** is this malady realized largely because the symptoms of **gastric carcinoma,** including vomiting, reduction of body weight, stomach ache and blood-vomiting, are brought to the attention of a wary clinician.... At the early stage of **gastric carcinoma,** the carcinoma cells are located at the gastric mucosa, submucosa in the inner wall of stomach. When **gastric carcinoma** is detected at this early stage, surgical intervention is possible and the five year survival rate can be up to 90%. Thus, early diagnosis is of great importance in improving survival.

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **EBV-infected stomach cancer cell line**

  Inventor(s): Miyazawa, Yukihasa; (Tokyo, JP), Okinaga, Kota; (Tokyo, JP), Tajima, Masako; (Tokyo, JP), Takanashi, Masakatsu; (Tokyo, JP), Takeshima, Toshio; (Tokyo, JP)

  Correspondence: Birch Stewart Kolasch & Birch; PO Box 747; Falls Church; VA; 22040-0747; US

  Patent Application Number: 20010044148

  Date filed: June 18, 2001

  Abstract: An EBV strain infecting epithelial cells and a **stomach cancer** cell line cancerated by EBV are established to clarify the mechanism of canceration of epithelial cells into **stomach cancer** by EBV and to develop a chemotherapeutic agent for **stomach cancer** cancerated by EBV. Further, a **stomach cancer** cell line stably producing EBV-related antigens is established to develop a diagnostic drug for **stomach cancer** cancerated by EBV. According to the present invention, GTC-4 cell line was established through culture of **stomach cancer** tissues. GTC-4 produced the EBV strain infecting epithelial cells and simultaneously produced EBV-related antigens stably in the supernatant.

  Excerpt(s): The present invention relates to a method of establishing an EBV-infected **stomach cancer** cell line from **stomach cancer** tissues infected with EBV, as well as EBV infecting cultured epithelial cells.... EBV (Epstein-Barr Virus) is a DNA virus belonging to the family human herpes virus. When adult persons are first infected with it, infectious mononucleosis (IM) occur, but in Japan, the majority of persons are first infected latently with the virus at the infant stage, and through the life, latent infection continues. Accordingly, this virus has been suspected to be that causing many diseases including various cancers and autoimmune diseases, but there are many features unrevealed except that the connection with Barrkit [phonetic] lymphoma in Africa (Epstein M A, Barr Y M, Lancet Vol. 1:252-253, 1964) and upper pharyngeal cancer in the

southern part of China (Pathnabathan R. et al., New Engl. J. Med. 333(11):693-698, 1995) was proven.... In recent years, an EBV gene was detected in **stomach cancer** cells (Shousha S. et al., J. Clin. Pathol. 47:695-698, 1994) and further the EBV gene was found to be monoclonal (Imai S. et al., Proc. Natl. Acad. Sci. USA, 91:1931-1935, 1994), and since it was suggested that the EBV gene may be involved in the canceration process, it came to be thought that EBV is involved in at least a part of stomach cancers.

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Method of diagnosing, monitoring, staging, imaging and treating gastrointestinal cancer**

  Inventor(s): Macina, Roberto A.; (San Jose, CA), Piderit, Alejandra; (Concepcion, CL), Sun, Yongmng; (San Jose, CA)

  Correspondence: Licata & Tyrrell P.c.; 66 E. Main Street; Marlton; NJ; 08053; US

  Patent Application Number: 20020042088

  Date filed: March 9, 2001

  Abstract: The present invention provides new methods and agents for detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating **gastrointestinal cancer.**.

  Excerpt(s): This application claims the benefit of priority from U.S. Provisional application Ser. No. 60/188,061, filed Mar. 9, 2000.... This invention relates, in part, to newly developed assays and compositions for detecting, diagnosing, monitoring, staging, prognosticating, imaging and treating cancers, particularly gastrointestinal cancers including stomach, small intestine and colon cancer.... Cancer of the colon is the second most frequently diagnosed malignancy in the United States, as well as the second most common cause of cancer death. Colon cancer is a highly treatable and often curable disease when localized to the bowel. Surgery is the primary treatment and results in cure in approximately 50% of patients. However, recurrence and metastases following surgery is a major problem and often is the ultimate cause of death.

  Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Noninvasive detection of colorectal cancer and other gastrointestinal pathology**

  Inventor(s): Nair, Padmanabhan P.; (Ellicott City, MD)

  Correspondence: Mishrilal L. Jain; 11620 Masters Run; Ellicott City; MD; 21042; US

  Patent Application Number: 20010024801

  Date filed: January 8, 2001

  Abstract: A method for isolating viable, biologically substantially pure exfoliated fecal colonocytes at normal ambient temperature is described. Immunocoprocytes and inflammatory cells indicative of certain gastrointestinal conditions and a noninvasive method for detecting **colorectal cancer** are set forth. Composition of transport and suspension media for isolation of colonocytes are detailed.

  Excerpt(s): The present invention is related to isolated colonocytes enabling early noninvasive detection of **colorectal cancer** and other gastrointestinal diseases. More particularly, the present invention is related to isolated, biologically substantially pure and viable immunocoprocytes and nonepithelial cells of lymphoid origin obtained from a small fecal sample. The invention is further related to providing a transport medium and a dispersion or suspension medium for isolating viable colonocytes from a fecal sample at normal ambient temperature and a method for detecting colorectal and other gastrointestinal pathology employing the isolated colonocytes of the present invention. The isolated colonocytes also allow the study and determination of other anomalous conditions, symptoms, disorders or pathological conditions.... A common gastrointestinal malignancy in humans is **colorectal cancer.** It has been estimated that **colorectal cancer** accounts for approximately 14% of all cancer-related deaths in men and women in the United States and its incidence continues to be high (Boring et al, CA Cancer J. Clin. 1994; 44:7-26). Early detection is a critical factor in successful treatment of this cancer, as it is in the treatment of other malignancies.... Screening approaches to detection of colon and colorectal tumors are presently based on the use of (a) fecal occult blood test (FOBT), (b) flexible sigmoidoscopy, (c) double contrast barium enema, and (d) colonoscopy. Among these screening tests only FOBT, which is based on a relatively high probability of bleeding from colorectal tumors, is noninvasive, simple and relatively inexpensive. However, frequent false positive and false negative results of the FOBT considerably limit its specificity and sensitivity. Other procedures are expensive and invasive. Hence, there is a clear need for providing a simple, noninvasive, reliable and inexpensive

method for detecting **colorectal cancer,** gastrointestinal (GI) tract diseases and other pathological conditions.

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Novel methods of diagnosing colorectal cancer, compositions, and methods of screening for colorectal cancer modulators**

  Inventor(s): Gish, Kurt C.; (San Francisco, CA), Mack, David; (Menlo Park, CA), Wilson, Keith E.; (Redwood City, CA)

  Correspondence: Flehr Hohbach Test; Albritton & Herbert Llp; Four Embarcadero Center, Suite 3400; San Francisco; CA; 94111-4187; US

  Patent Application Number: 20020042067

  Date filed: May 8, 2001

  Abstract: Described herein are methods that can be used for diagnosis and prognosis of **colorectal cancer.** Also described herein are methods that can be used to screen candidate bioactive agents for the ability to modulate **colorectal cancer.** Additionally, methods and molecular targets (genes and their products) for therapeutic intervention in **colorectal cancer** are described.

  Excerpt(s): The invention relates to the identification of expression profiles and the nucleic acids involved in **colorectal cancer,** and to the use of such expression profiles and nucleic acids in diagnosis and prognosis of **colorectal cancer.** The invention further relates to methods for identifying and using candidate agents and/or targets which modulate **colorectal cancer.**... Colorectal cancer is a significant cancer in Western populations. It develops as the result of a pathologic transformation of normal colon epithelium to an invasive cancer. There have been a number of recently characterized genetic alterations that have been implicated in **colorectal cancer,** including mutations in two classes of genes, tumor-suppressor genes and proto-oncogenes, with recent work suggesting that mutations in DNA repair genes may also be involved in tumorigenesis. For example, inactivating mutations of both alleles of the adenomatous polyposis coli (APC) gene, a tumor suppressor gene, appears to be one of the earliest events in **colorectal cancer,** and may even be the initiating event. Other genes implicated in **colorectal cancer** include the MCC gene, the p53 gene, the DCC (deleted in colorectal carcinoma) gene and other chromosome 18 q genes, and genes in the TGF-.beta. signalling pathway. For a review, see Molecular Biology of **Colorectal Cancer,** pp238-299, in Curr. Probl. Cancer, September/October 1997.... Imaging of **colorectal cancer** for diagnosis has been problematic and limited. In addition, dissemination of tumor cells (metastases) to locoregional lymph nodes is

an important prognostic factor; five year survival rates drop from 80 percent in patients with no lymph node metastases to 45 to 50 percent in those patients who do have lymph node metastases. A recent report showed that micrometastases can be detected from lymph nodes using reverse transcriptase-PCR methods based on the presence of mRNA for carcinoembryonic antigen, which has previously been shown to be present in the vast majority of colorectal cancers but not in normal tissues. Liefers et al., New England J. of Med. 339(4):223 (1998).

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Novel methods of diagnosis of metastatic colorectal cancer, compositions and methods of screening for modulators of metastatic colorectal cancer**

  Inventor(s): Mack, David H.; (Menlo Park, CA), Markowitz, Sanford David; (Pepper Pike, OH)

  Correspondence: Townsend and Townsend and Crew, Llp; Two Embarcadero Center; Eighth Floor; San Francisco; CA; 94111-3834; US

  Patent Application Number: 20030235820

  Date filed: February 27, 2002

  Abstract: Described herein are methods and compositions that can be used for diagnosis and treatment of metastatic **colorectal cancer.** Also described herein are methods that can be used to identify modulators of metastatic **colorectal cancer.**

  Excerpt(s): The present application is related to U.S. S No. 60/272,206, filed Feb. 27, 2001, U.S. S No. 60/281,149, filed Apr. 2, 2001, and U.S. S No. 60/284,555, filed Apr. 17, 2001, all of which are herein incorporated by referenced in their entirety.... The invention relates to the identification of nucleic acid and protein expression profiles and nucleic acids, products, and antibodies thereto that are involved in metastatic **colorectal cancer;**; and to the use of such expression profiles and compositions in diagnosis and therapy of metastatic **colorectal cancer.** The invention further relates to methods for identifying and using agents and/or targets that inhibit metastatic **colorectal cancer.**... Cancer of the colon and/or rectum (referred to as "colorectal cancer") are significant in Western populations and particularly in the United States. Cancers of the colon and rectum occur in both men and women most commonly after the age of 50. These develop as the result of a pathologic transformation of normal colon epithelium to an invasive cancer. There have been a number of recently characterized genetic alterations that have been implicated in **colorectal cancer,** including mutations in two classes of genes, tumor-

suppressor genes and proto-oncogenes, with recent work suggesting that mutations in DNA repair genes may also be involved in tumorigenesis. For example, inactivating mutations of both alleles of the adenomatous polyposis coli (APC) gene, a tumor suppressor gene, appears to be one of the earliest events in **colorectal cancer,** and may even be the initiating event. Other genes implicated in **colorectal cancer** include the MCC gene, the p53 gene, the DCC (deleted in colorectal carcinoma) gene and other chromosome 18q genes, and genes in the TGF-.beta. signaling pathway. For a review, see Molecular Biology of **Colorectal Cancer,** pp. 238-299, in Curr. Probl. Cancer, September/October 1997; see also Willams, **Colorectal Cancer** (1996); Kinsella & Schofield, Colorectal Cancer: A Scientific Perspective (1993); Colorectal Cancer: Molecular Mechanisms, Premalignant State and its Prevention (Schiniegel & Scholmerich eds., 2000); Colorectal Cancer: New Aspects of molecular Biology and Their Clinical Applications (Hanski et al., eds 2000); McArdle et al., **Colorectal Cancer** (2000); Wanebo, **Colorectal Cancer** (1993); Levin, The American Cancer Society: **Colorectal Cancer** (1999); Treatment of Hepatic Metastases of **Colorectal Cancer** (Nordlinger & Jaeck eds., 1993); Management of **Colorectal Cancer** (Dunitz et al., eds. 1998); Cancer: Principles and Practice of Oncology (Devita et al., eds. 2001); Surgical Oncology: Contemporary Principles and Practice (Kirby et al., eds. 2001); Offit, Clinical Cancer Genetics: Risk Counseling and Management (1997); Radioimmunotherapy of Cancer (Abrams & Fritzberg eds. 2000); Fleming, AJCC Cancer Staging Handbook (1998); Textbook of Radiation Oncology (Leibel & Phillips eds. 2000); and Clinical Oncology (Abeloff et al., eds. 2000).

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **NOVEL MUTATIONS IN HUMAN MLH1 AND HUMAN MSH2 GENES USEFUL IN DIAGNOSING COLORECTAL CANCER**

  Inventor(s): LING, JESSICA C.; (BENSALEM, PA), LIN-GOERKE, JUILI LILLIAN; (SPRING CITY, PA), ROBBINS, DAVID; (STEVENSON RANCH, CA)

  Correspondence: Jane Massey Licata; 66 E Main Street; Marlton; NJ; 08053

  Patent Application Number: 20010044936

  Date filed: October 22, 1999

  Abstract: Variant human MLH1 and MSH2 genes are provided. Methods of using these variant genes to diagnose hereditary non-polyposis **colorectal cancer** (HNPCC) and/or determine a patient's susceptibility to developing HNPCC are also provided. Methods and compositions for

identifying new variant MLH1 of MSH2 genes are also provided. In addition, experimental models for hereditary non-polyposis **colorectal cancer** comprising these variant genes are provided.

Excerpt(s): This application claims the benefit of U.S. provisional application Ser. No. 60/105,180, filed Oct. 22, 1998.... Colorectal cancer (CRC) is one of the most common fatal cancers in developed countries, and the worldwide incidence is increasing. The United States and the United Kingdom are high incidence countries, with an estimated 133,500 new cases and 55,300 deaths (Parker et al. CA Cancer J. Clin. 1996 46:5-27) in the United States and 30,941 cases and approximately 17,000 deaths in the United Kingdom (HMSO UK Cancer Registry Data). The population lifetime risk is 1 in 25 in the United States and Northern Europe and thus represents a significant public health issue (Sharp et al. Cancer Registration Statistics Scotland 1981-1990, Information and Statistics Division, The National Health Service in Scotland, Edinburgh (1993)). Identification of people who are predisposed to the disease would allow targeting of effective preventative measures with the aim of reducing the considerable cancer related mortality (Burke et al. J. Am. Med. Ass'n. 1997 227:915-919).... One group of people with a very high **colorectal cancer** risk are those who carry germline mutations in genes that participate in DNA mismatch repair. hMSH2 (Fishel et al. Cell 1993 75:1027-1038; Leach et al. Cell 1993 75:1215-1225; U.S. Pat. No. 5,591,826) and hMLH1 (Bronner et al. Nature 1994 368:258-261; Papadopoulos et al. Science 1994 263:1625-1629; PCT Publication No. WO 95/20678, published on Aug. 3, 1995) are the two genes most commonly involved in heredity predisposition to CRC, but mutations in hPMS1 and hPMS2 also occur in a minority of cases (Nicolaides et al. Nature 1994 371:75-80). Such mutations are usually associated with marked familial aggregation of colorectal, uterine and other cancers constituting the clinically defined autosomal dominant syndrome of hereditary non-polyposis **colorectal cancer** (HNPCC) (Lynch et al. Gastroenterology 1993 104:1535-1549; Liu et al. Nature Med. 1996 2:169-174; Wijnen et al. Am. J. Hum. Genet. 1995 56:1060-1066; Mary et al. Hum. Mol. Genet. 1994 3:2067-2069; Nystrom-Lahti et al. Nature Med. 1995 1:1203-1206). However, an appreciable proportion of patients who have early onset **colorectal cancer** but who do not fulfill pragmatic criteria for HNPCC (Vasen et al. Dis. Colon Rectum 1991 34:424-425) also carry mismatch repair gene mutations (Liu et al. Nature Med. 1995 2:169-174; Dunlop et al. Br. Med. J. 1997 314:1779-1780). Thus, restricting genetic testing to individuals from families fulfilling HNPCC criteria is likely to exclude a significant fraction of gene carriers in the general population. However, screening unselected patients with sporadic cancer represents an enormous workload and may provide a

very low yield of mutation carriers (Liu et al. Nat. Med. 1995 1:348-352; Tomlinson et al. J. Med. Genet. 1997 34:39-42).

Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

- **Nutritious supplemental composition for suppression against onset of large intestinal cancer and manufacturing method thereof**

  Inventor(s): Iwasaki, Teruaki; (Sapporo-shi, JP)

  Correspondence: Mckee, Voorhees & Sease, P.l.c.; 801 Grand Avenue; Suite 3200; Des Moines; IA; 50309-2721; US

  Patent Application Number: 20020172667

  Date filed: September 13, 2001

  Abstract: In view of an acknowledgement that keeping a healthy body is a fundamental matter for overcoming cancer, it is an object of the present invention to provide composition containing well-balanced nutrition, having an effect to suppress the mutagenesis substances, having no sub-action even if the composition is continued to be taken as nutritious supplemental substance and capable of promoting healthy state. There are provided a nutritious supplemental composition for suppression against large **intestinal cancer** and its manufacturing method in which dietary fiber in a range of 15 wt % to 30 wt % in respect to a total amount of composition is contained in the dried koji fine powder including dead fungi of Aspergillus while keeping a capability of catalysis of groups of enzyme produced by Aspergillus.

  Excerpt(s): This invention relates to a nutritious supplemental composition for suppression against onset of large **intestinal cancer** in which it shows a superior suppression against onset of large **intestinal cancer.**.... In particular, in the present invention, rice bran is heated with steam, Aspergillus, Aspergillus oryzae strain, for example, is mixed with the rice bran, they are cultivated and ripened to make rice bran koji, Aspergillus is annihilated, and the enzyme groups produced by Aspergillus are changed into the dried koji fine powder of dried powder under a state in which a proper capability of catalysis of enzyme itself is not lost.... Either dietary fiber aiming at removal of mutagen or plant protein acting as nutritious element is contained in it and the present invention relates to the nutritious supplemental composition for suppression against onset of large **intestinal cancer** and its manufacturing method.

  Web site: http://appft1.uspto.gov/netahtml/PTO/search-bool.html

Keeping Current

In order to stay informed about patents and patent applications dealing with gastrointestinal carcinoid tumors, you can access the U.S. Patent Office archive via the Internet at the following Web address: **http://www.uspto.gov/patft/index.html**. You will see two broad options: (1) Issued Patent, and (2) Published Applications. To see a list of issued patents, perform the following steps: Under "Issued Patents," click "Quick Search." Then, type "gastrointestinal carcinoid tumors" (or synonyms) into the "Term 1" box. After clicking on the search button, scroll down to see the various patents which have been granted to date on gastrointestinal carcinoid tumors.

You can also use this procedure to view pending patent applications concerning gastrointestinal carcinoid tumors. Simply go back to the following Web address: **http://www.uspto.gov/patft/index.html**. Select "Quick Search" under "Published Applications." Then proceed with the steps listed above.

Vocabulary Builder

Adenocarcinomas: A malignant tumor of the epithelial cells of a gland which typically metastasizes by way of the lymphatics. [NIH]

Consumption: Pulmonary tuberculosis. [NIH]

Cytotoxicity: Quality of being capable of producing a specific toxic action upon cells of special organs. [NIH]

Diploid: Having two sets of chromosomes. [NIH]

EBV: A DNA virus of the herpes group discovered in cultures of Burkitt's lymphoma cells. EBV is the cause of infectious mononucleosis, and it has an integration site on human chromosome 14. [NIH]

Effector: It is often an enzyme that converts an inactive precursor molecule into an active second messenger. [NIH]

Endoscopic: A technique where a lateral-view endoscope is passed orally to the duodenum for visualization of the ampulla of Vater. [NIH]

Epitope: A molecule or portion of a molecule capable of binding to the combining site of an antibody. For every given antigenic determinant, the body can construct a variety of antibody-combining sites, some of which fit almost perfectly, and others which barely fit. [NIH]

Hybridoma: A hybrid cell resulting from the fusion of a specific antibody-

producing spleen cell with a myeloma cell. [NIH]

Initiation: Mutation induced by a chemical reactive substance causing cell changes; being a step in a carcinogenic process. [NIH]

Linkage: The tendency of two or more genes in the same chromosome to remain together from one generation to the next more frequently than expected according to the law of independent assortment. [NIH]

Lymphatic: The tissues and organs, including the bone marrow, spleen, thymus, and lymph nodes, that produce and store cells that fight infection and disease. [NIH]

Lymphokine: A soluble protein produced by some types of white blood cell that stimulates other white blood cells to kill foreign invaders. [NIH]

Mononuclear: A cell with one nucleus. [NIH]

MRNA: The RNA molecule that conveys from the DNA the information that is to be translated into the structure of a particular polypeptide molecule. [NIH]

Nerve: A cordlike structure of nervous tissue that connects parts of the nervous system with other tissues of the body and conveys nervous impulses to, or away from, these tissues. [NIH]

Nucleus: A body of specialized protoplasm found in nearly all cells and containing the chromosomes. [NIH]

Promoter: A chemical substance that increases the activity of a carcinogenic process. [NIH]

Reductase: Enzyme converting testosterone to dihydrotestosterone. [NIH]

Schizophrenia: A mental disorder characterized by a special type of disintegration of the personality. [NIH]

Specificity: Degree of selectivity shown by an antibody with respect to the number and types of antigens with which the antibody combines, as well as with respect to the rates and the extents of these reactions. [NIH]

Therapeutics: The branch of medicine which is concerned with the treatment of diseases, palliative or curative. [NIH]

Transcriptase: An enzyme which catalyses the synthesis of a complementary mRNA molecule from a DNA template in the presence of a mixture of the four ribonucleotides (ATP, UTP, GTP and CTP). [NIH]

Translation: The process whereby the genetic information present in the linear sequence of ribonucleotides in mRNA is converted into a corresponding sequence of amino acids in a protein. It occurs on the ribosome and is unidirectional. [NIH]

Vector: Plasmid or other self-replicating DNA molecule that transfers DNA between cells in nature or in recombinant DNA technology. [NIH]

Vitro: Descriptive of an event or enzyme reaction under experimental investigation occurring outside a living organism. Parts of an organism or microorganism are used together with artificial substrates and/or conditions. [NIH]

CHAPTER 6. BOOKS ON GASTROINTESTINAL CARCINOID TUMORS

Overview

This chapter provides bibliographic book references relating to gastrointestinal carcinoid tumors. You have many options to locate books on gastrointestinal carcinoid tumors. The simplest method is to go to your local bookseller and inquire about titles that they have in stock or can special order for you. Some patients, however, feel uncomfortable approaching their local booksellers and prefer online sources (e.g. **www.amazon.com** and **www.bn.com**). In addition to online booksellers, excellent sources for book titles on gastrointestinal carcinoid tumors include the Combined Health Information Database and the National Library of Medicine. Once you have found a title that interests you, visit your local public or medical library to see if it is available for loan.

Book Summaries: Online Booksellers

Commercial Internet-based booksellers, such as Amazon.com and Barnes & Noble.com, offer summaries which have been supplied by each title's publisher. Some summaries also include customer reviews. Your local bookseller may have access to in-house and commercial databases that index all published books (e.g. Books in Print®). The following have been recently listed with online booksellers as relating to gastrointestinal carcinoid tumors (sorted alphabetically by title; follow the hyperlink to view more details at Amazon.com):

- **Gastrointestinal Carcinoid Tumors: Histogenetic, Histochemical, Immunohistochemical, Clinical and Therapeutic Aspects (Progress in**

Histochemistry an) by Erik Wilander, et al; ISBN: 0895742837; http://www.amazon.com/exec/obidos/ASIN/0895742837/icongroupinterna

Chapters on Gastrointestinal Carcinoid Tumors

Frequently, gastrointestinal carcinoid tumors will be discussed within a book, perhaps within a specific chapter. In order to find chapters that are specifically dealing with gastrointestinal carcinoid tumors, an excellent source of abstracts is the Combined Health Information Database. You will need to limit your search to book chapters and gastrointestinal carcinoid tumors using the "Detailed Search" option. Go directly to the following hyperlink: **http://chid.nih.gov/detail/detail.html**. To find book chapters, use the drop boxes at the bottom of the search page where "You may refine your search by." Select the dates and language you prefer, and the format option "Book Chapter." By making these selections and typing in "gastrointestinal carcinoid tumors" (or synonyms) into the "For these words:" box, you will only receive results on chapters in books.

General Home References

In addition to references for gastrointestinal carcinoid tumors, you may want a general home medical guide that spans all aspects of home healthcare. The following list is a recent sample of such guides (sorted alphabetically by title; hyperlinks provide rankings, information, and reviews at Amazon.com):

- **Cancer: 50 Essential Things to Do** by Greg Anderson, O. Carl Simonton; Paperback - 184 pages; Revised & Updated edition (August 1999), Plume; ISBN: 0452280745; **http://www.amazon.com/exec/obidos/ASIN/0452280745/icongroupinterna**
- **Cancer Encyclopedia -- Collections of Anti-Cancer & Anti-Carcinogenic Agents, Chemicals, Drugs and Substances** by John C. Bartone; Paperback (January 2002), ABBE Publishers Association of Washington, DC; ISBN: 0788326791; **http://www.amazon.com/exec/obidos/ASIN/0788326791/icongroupinterna**
- **Cancer Sourcebook: Basic Consumer Health Information About Major Forms and Stages of Cancer** by Edward J. Prucha (Editor); Library Binding - 1100 pages, 3rd edition (August 1, 2000), Omnigraphics, Inc.; ISBN: 0780802276;

http://www.amazon.com/exec/obidos/ASIN/0780802276/icongroupinterna

- **Cancer Supportive Care: A Comprehensive Guide for Patients and Their Families** by Ernest H. Rosenbaum, M.D., Isadora Rosenbaum, M.A.; Paperback - 472 pages (November 5, 1998), Somerville House Books Limited; ISBN: 1894042115; **http://www.amazon.com/exec/obidos/ASIN/1894042115/icongroupinterna**
- **Cancer Symptom Management: Patient Self-Care Guides (Book with CD-ROM for Windows & Macintosh)** by Connie Henke Yarbro (Editor), et al; CD-ROM - 264 pages, 2nd Book & CD-Rom edition (January 15, 2000), Jones & Bartlett Publishing; ISBN: 0763711675; http://www.amazon.com/exec/obidos/ASIN/0763711675/icongroupinterna
- **Diagnosis Cancer: Your Guide Through the First Few Months** by Wendy Schlessel Harpham, Ann Bliss Pilcher (Illustrator); Paperback: 230 pages; Revised & Updated edition (November 1997),.W. Norton & Company; ISBN: 0393316912; **http://www.amazon.com/exec/obidos/ASIN/0393316912/icongroupinterna**
- **The Human Side of Cancer: Living with Hope, Coping with Uncertainty** by Jimmie C. Holland, M.D., Sheldon Lewis; Paperback - 368 pages (October 2, 2001), Quill; ISBN: 006093042X; **http://www.amazon.com/exec/obidos/ASIN/006093042X/icongroupinterna**

CHAPTER 7. MULTIMEDIA ON GASTROINTESTINAL CARCINOID TUMORS

Overview

Information on gastrointestinal carcinoid tumors can come in a variety of formats. Among multimedia sources, video productions, slides, audiotapes, and computer databases are often available. In this chapter, we show you how to keep current on multimedia sources of information on gastrointestinal carcinoid tumors. We start with sources that have been summarized by federal agencies, and then show you how to find bibliographic information catalogued by the National Library of Medicine. If you see an interesting item, visit your local medical library to check on the availability of the title.

Video Recordings

Most diseases do not have a video dedicated to them. If they do, they are often rather technical in nature. An excellent source of multimedia information on gastrointestinal carcinoid tumors is the Combined Health Information Database. You will need to limit your search to "video recording" and "gastrointestinal carcinoid tumors" using the "Detailed Search" option. Go directly to the following hyperlink: **http://chid.nih.gov/detail/detail.html**. To find video productions, use the drop boxes at the bottom of the search page where "You may refine your search by." Select the dates and language you prefer, and the format option "Videorecording (videotape, videocassette, etc.)." By making these selections and typing "gastrointestinal carcinoid tumors" (or synonyms) into the "For these words:" box, you will only receive results on video productions. The

following is a typical result when searching for video recordings on gastrointestinal carcinoid tumors:

- **Screening for Colorectal Cancer: An Easy Step to Save Your Life**

  Source: Bethesda, MD: Foundation for Digestive Health and Nutrition. 1999. (videorecording).

  Contact: Available from Foundation for Digestive Health and Nutrition. 7910 Woodmont Avenue, Suite 610, Bethesda, MD 20814-3015. (301) 222-4002. Fax (301) 222-4010. E-mail: info@fdhn.org. Website: www.fdhn.org. PRICE: Full-text available online at no charge; contact organization for print copies.

  Summary: Although highly treatable if detected early, colorectal cancer is the second leading cause of death by cancer in the United States, accounting for 140,000 new cases and approximately 55,000 deaths each year. This patient care video is produced by the Foundation for Digestive Health and Nutrition (FDHN). The FDHN, created by the American Gastroenterological Association, develops funds for research to explore causation, prevention, improved treatments or potential cures for digestive and liver diseases, and conducts public education initiatives supporting its mission. This video is intended for the general public and demonstrates through animation and testimonies of three real patients that cancer screening saves lives. The video depicts how these individuals are now enjoying their families and their lives again because of the educated decisions that they made about colorectal cancer screening. The National Cancer Institute estimates 80-90 million people are considered at risk because of age or other factors. Viewers are encouraged to talk to their doctor about colorectal cancer screening if: they are age 50 or older (men and women are equally at risk); they or a family member has a history of colorectal cancer; or they or a family member has suffered from a chronic inflammatory bowel disease, such as ulcerative colitis and Crohn's disease. To receive a free brochure on colorectal cancer, call the Foundation for Digestive Health and Nutrition information line at 1-866-337-FDHN. For more information about cancer, call the American Cancer Society at 1-800-ACS-2345.

CHAPTER 8. PHYSICIAN GUIDELINES AND DATABASES

Overview

Doctors and medical researchers rely on a number of information sources to help patients with their conditions. Many will subscribe to journals or newsletters published by their professional associations or refer to specialized textbooks or clinical guides published for the medical profession. In this chapter, we focus on databases and Internet-based guidelines created or written for this professional audience.

NIH Guidelines

For the more common diseases, The National Institutes of Health publish guidelines that are frequently consulted by physicians. Publications are typically written by one or more of the various NIH Institutes. For physician guidelines, commonly referred to as "clinical" or "professional" guidelines, you can visit the following Institutes:

- Office of the Director (OD); guidelines consolidated across agencies available at **http://www.nih.gov/health/consumer/conkey.htm**
- National Institute of General Medical Sciences (NIGMS); fact sheets available at **http://www.nigms.nih.gov/news/facts/**
- National Library of Medicine (NLM); extensive encyclopedia (A.D.A.M., Inc.) with guidelines: **http://www.nlm.nih.gov/medlineplus/healthtopics.html**
- National Cancer Institute (NCI); guidelines available at **http://www.cancer.gov/cancerinfo/list.aspx?viewid=5f35036e-5497-4d86-8c2c-714a9f7c8d25**

In this chapter, we begin by reproducing one such guideline for gastrointestinal carcinoid tumors:

What Are Gastrointestinal Carcinoid Tumors?[29]

Many carcinoid tumors behave like benign tumors and can be treated and often cured, especially in early stages.[30] The occurrence of metastasis from carcinoid tumor relates directly to the size of the primary tumor (lesions 1 centimeter or less rarely metastasize; lesions greater than 2 centimeters frequently metastasize). They are classified as neuroendocrine or amine precursor uptake and decarboxylation tumors. Rarely, they may be a part of the multiple endocrine neoplasia syndrome type 1. These usually slow-growing tumors may arise from various sites, although the appendix, small bowel, and rectum account for over 90% of surgical cases occurring in the gastrointestinal tract. Small bowel carcinoids may occur in multiple sites in the same patient. Symptoms may be chronic, suggesting partial obstruction or intussusception. Carcinoid tumors, except those originating in the rectum, produce a variety of endocrine substances, the most frequent of which are serotonin (5-hydroxytryptamine) and kallikrein (an activator of bradykinin release). The diagnosis of carcinoid syndrome (carcinoid tumor with distant metastases) is aided by demonstrating elevated 24-hour urinary 5-hydroxyindoleacetic acid levels. This test is not useful in diagnosis of carcinoids at a curable stage, except in some rare cases in which the tumor arises from a site outside of the gastrointestinal tract such as the lung.[31] Blood chromogranin A assay may also be a useful, though non-specific,

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[29] The following guidelines appeared on the NCI website on January 30, 2004. The text was last modified in November 2003. The text has been adapted for this sourcebook.

[30] Moertel CG: An odyssey in the land of small tumors. Journal of Clinical Oncology 5(10): 1503-1522, 1987.

[31] Kulke MH, Mayer RJ: Carcinoid tumors. New England Journal of Medicine 340(11): 858-868, 1999.

Mani S, Modlin IM, Ballantyne G, et al.: Carcinoids of the rectum. Journal of the American College of Surgeons 179(2): 231-248, 1994.

Moertel CG, Weiland LH, Nagorney DM, et al.: Carcinoid tumor of the appendix: treatment and prognosis. New England Journal of Medicine 317(27): 1699-1701, 1987.

Martin JK, Moertel CG, Adson MA, et al.: Surgical treatment of functioning metastatic carcinoid tumors. Archives of Surgery 118(5): 537-542, 1983.

Moertel CG: Treatment of the carcinoid tumor and the malignant carcinoid syndrome. Journal of Clinical Oncology 1(11): 727-740, 1983.

Delcore R, Friesen SR: Gastrointestinal neuroendocrine tumors. Journal of the American College of Surgeons 178(2): 187-211, 1994.

confirmatory test for carcinoid or neuroendocrine tumors.[32] Primary carcinoids of the extrapelvic colon are uncommon, typically present with metastatic disease, and have a poor prognosis.[33] Patients with carcinoid tumor are at increased risk for synchronous or metachronous second malignancies. The most common site for a second primary malignancy is the gastrointestinal tract.[34]

The relatively rare malignant carcinoid syndrome (flush, diarrhea, bronchoconstriction, cardiac valvular lesions, arthropathy, and telangiectasia) relates to the release of endocrine substances, but precise pharmacologic mechanisms are still unclear. Because of efficient hepatic metabolism of vasoactive amines, the carcinoid syndrome rarely occurs in the absence of liver metastases. Exceptions are circumstances where venous blood from large tumor masses drains directly into the systemic circulation (for example, pulmonary and ovarian primaries, and pelvic or retroperitoneal involvement by metastatic or locally invasive small bowel carcinoids or extensive bone metastases).

Surgical resection is the standard curative modality. If the primary tumor is localized and resectable, 5-year survival rates are excellent (70%-90%). Even in patients with distant metastasis, the disease is usually very indolent with median survivals of 2 years or more. For such patients, excellent palliation may be achieved by bypass surgery, or resection of large hepatic metastases that may produce the carcinoid syndrome. Radiation therapy has a minor role in patients with regionally unresectable disease and may palliate the pain of bone metastasis. Patients with carcinoid syndrome can usually be effectively palliated by injections of somatostatin analogue 2 to 3 times a day. A long- acting somatostatin analogue that can be given as an injection once a month, with equivalent efficacy, is now available.[35]

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[32] Roberts LJ, Anthony LB, Oates JA: Disorders of vasodilator hormones: carcinoid syndrome and mastocytosis. In: Wilson JD, Forster DW, Kronenberg HM, et al.: Williams Textbook of Endocrinology. Philadelphia; W.B. Sanders Company, 9th ed., 1998, 1711-1731.

[33] Spread C, Berkel H, Jewell L, et al.: Colon carcinoid tumors: a population-based study. Diseases of the Colon and Rectum 37(5): 482-491, 1994.

Modlin IM, Sandor A: An analysis of 8305 cases of carcinoid tumors. Cancer 79(4): 813-829, 1997.

[34] Gerstle JT, Kauffman GL, Koltun WA: The incidence, management, and outcome of patients with gastrointestinal carcinoids and second primary malignancies. Journal of the American College of Surgeons 180(4): 427-432, 1995.

[35] Rubin J, Ajani J, Schirmer W, et al.: Octreotide acetate long-acting formulation versus open-label subcutaneous octreotide acetate in malignant carcinoid syndrome. Journal of Clinical Oncology 17(2): 600-606, 1999.

Patients with symptomatic metastatic carcinoid disease are appropriate candidates for clinical trials examining combination chemotherapy, since single-agent standard chemotherapy provides minimal palliation. However, chemotherapeutic drug combinations occasionally do offer long-lasting (in excess of 1 year) palliation. In patients with the carcinoid syndrome, palliation is sometimes obtained with pharmacologic agents that suppress production or block the action of vasoactive amines; of particular interest is a somatostatin analogue.[36] Some patients benefit from the use of interferon alfa. Toxic effects associated with interferon treatment that frequently outweigh therapeutic gains can occur in some patients, but these effects are reversible once treatment has been discontinued and usually do not occur with smaller doses. Anecdotal reports of biologic activity indicate that some patients may respond to combined octreotide and interferon alfa treatment.[37] Patients with asymptomatic metastases that cannot be resected for cure will often remain symptom-free for long periods of time.

Cellular Classification

There is no histologic difference between carcinoids arising in various sites or between metastasizing and nonmetastasizing lesions. Carcinoid tumors are neuroendocrine tumors composed of uniform, round, or polygonal cells. Immunohistochemistry reveals the presence of neuron-specific enolase (NSE) and chromogranin. Electron microscopy shows neurosecretory granules. Morphologic features suggesting malignancy (cellular pleomorphism, hyperchromatic nuclei, necrosis, high mitotic activity) can occasionally be seen. Such cases are designated as atypical carcinoids and usually have an aggressive clinical course. Carcinoids are classified by their embryologic relationship to the foregut (the anterior part of the alimentary canal, from the mouth to the intestine or to the entrance of the bile duct), midgut (the middle part of the alimentary canal, from the stomach or entrance of the bile duct to or including the large intestine), or hindgut (the posterior part of the alimentary canal, including the rectum and sometimes the large intestine), which is correlated with clinical behavior and the secretion or nonsecretion of various neuroendocrine peptides. Proximal carcinoids may secrete histamine-like peptides causing a pink flush and bronchoconstriction. Peptide secretions of midgut carcinoids cause a cyanotic (purplish) flush,

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[36] Gorden P, Comi RL, Maton PN, et al.: Somatostatin and somatostatin analogue (SMS 201-995) in treatment of hormone-secreting tumors of the pituitary and gastrointestinal tract and non-neoplastic diseases of the gut. Annals of Internal Medicine 110(1): 35-50, 1989.

[37] Frank M, Klose KJ, Wied M, et al.: Combination therapy with octreotide and alpha-interferon: effect on tumor growth in metastatic endocrine gastoenteropancreatic tumors. American Journal of Gastroenterology 94(5): 1381-1387, 1999.

diarrhea, and hypotension. Hindgut carcinoids usually do not secrete syndrome-producing peptides.

There is no accepted staging system for carcinoid tumors.

Treatment Option Overview

The designations in PDQ that treatments are "standard" or "under clinical evaluation" are not to be used as a basis for reimbursement determinations.

Localized Gastrointestinal Carcinoid Tumor

Appendiceal Carcinoids

For appendiceal carcinoid tumors less than 1.5 centimeters in greatest diameter, appendectomy is adequate treatment with cure rates of essentially 100%.[38] No follow-up management is required if the tumor is confined within the wall of the appendix. Tumors 1.5 to 2 centimeters in diameter can be treated by simple appendectomy or more aggressive surgical treatment. Tumors 2 centimeters or greater in diameter are less common, but must be considered malignant. Invasion of the mesoappendix does not alter prognosis, but invasion of the cecum mandates more extensive resection. When right hemicolectomy is performed, a lymphadenectomy, as performed for colon cancer, is appropriate.

Rectal Carcinoids

For rectal carcinoid tumors 1 centimeter or less in diameter, simple fulguration or local excision is adequate treatment. Cure rates of essentially 100% may be anticipated, and no follow-up management is required.[39]

Tumors 2 centimeters or larger should be considered malignant and should be treated by an appropriate cancer operation, but sphincter-preserving procedures are preferred when possible. Otherwise, standard therapy includes abdomino-perineal resection.

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[38] Roggo A, Wood WC, Ottinger LW: Carcinoid tumors of the appendix. Annals of Surgery 217(4): 385-390, 1993.

[39] Mani S, Modlin IM, Ballantyne G, et al.: Carcinoids of the rectum. Journal of the American College of Surgeons 179(2): 231-248, 1994.

Tumors 1 to 2 centimeters in diameter can be treated either by local excision or by more radical resection. The decision should be based on actual size of the tumor, extent of invasion, and necessity for abdominal perineal resection versus a sphincter-preserving resection, and estimated operative risk. If local excision is elected, the patient should be carefully followed.

Small Bowel Carcinoids

For small bowel carcinoid tumors less than 1 centimeter in diameter, conservative local resection is sufficient. For tumors greater than 1 centimeter in diameter, excision of a wedge of mesentery containing regional nodes is indicated.[40] Patients with tumors 1.5 to 2 centimeters or larger are at risk for recurrence; however, a standard surveillance program has not been established. A search for multiple primary lesions should be made in all patients with small bowel carcinoids.

Gastric, Pancreatic, and Colon Carcinoids

Carcinoids of other sites in the gastrointestinal tract are rare. Optimal management of localized disease is aggressive surgical resection, although carcinoid tumors of the stomach and colon are typically less often localized than those in other gastrointestinal sites.[41]

Regional Gastrointestinal Carcinoid Tumor

Carcinoid tumors with gross regional lymphatic metastasis or local extension should be treated by aggressive surgical resection. If all visible malignant disease can be removed, long-term survival rates will be excellent.[42] However, late recurrences (after 5 or 10 years) do occur, implying the need for prolonged follow-up.

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[40] Moertel CG: An odyssey in the land of small tumors. Journal of Clinical Oncology 5(10): 1503-1522, 1987.

[41] Spread C, Berkel H, Jewell L, et al.: Colon carcinoid tumors: a population-based study. Diseases of the Colon and Rectum 37(5): 482-491, 1994.
Maurer CA, Baer HU, Dyong TH, et al.: Carcinoid of the pancreas: clinical characteristics and morphological features. European Journal of Cancer 32A(7): 1109-1116, 1996.

[42] Moertel CG: An odyssey in the land of small tumors. Journal of Clinical Oncology 5(10): 1503-1522, 1987.

There is no known effective surgical adjuvant treatment and none should be attempted except as part of a clinical trial.

If the regional disease is found to be unresectable, palliative surgery, such as partial resection, cryoablation, radiofrequency ablation, or hepatic artery chemoembolization should be considered. Treatment should be customized for each patient depending on the growth of the tumor and/or development of symptoms since some patients with asymptomatic, unresectable disease will frequently have many months or even years of comfortable life with no further treatment.

Metastatic Gastrointestinal Carcinoid Tumor

Since carcinoid tumors are frequently indolent in growth, and asymptomatic, not all patients require treatment of metastatic disease at diagnosis. A period of observation may allow for a decision to be made concerning optimal supportive care or antitumor treatments.

Treatment options for distant metastasis:

- Surgical treatment
- Chemotherapy
- Chemoembolization
- Radiation therapy
- 131I-MIBG
- Biological modification (immunotherapy)

Surgical Treatment

Surgical treatment may frequently provide effective palliation (even in the presence of known distant metastasis with or without malignant carcinoid syndrome), particularly through bypass or palliative resection of obstructing small bowel tumors. Heroic attempts at surgical debulking, however, are not indicated except for hepatic resection in patients with the carcinoid syndrome (see section on carcinoid syndrome). Although liver metastases are usually multiple and neither bulky nor clustered, multiple wedge resections, cryosurgery, or radiofrequency ablation of the lesions can be considered in patients with carcinoid syndrome.

Chemotherapy

Although activity with a variety of single agents and drug combinations has been reported (fluorouracil, doxorubicin, dacarbazine, cyclophosphamide, fluorouracil + streptozocin, and etoposide + cisplatin[43]), response rates seldom exceed 30%. Complete responses are uncommon. Duration of response is usually short, although occasional remissions lasting a year or more have been noted. Otherwise, there is little evidence that chemotherapy contributes to patient survival. Chemotherapy should be used only for palliation in symptomatic patients who should be included in clinical trials aimed at developing new, more effective treatment. Continuous infusion of agents such as floxuridine into the hepatic artery has not been prospectively tested in large series of patients.

Chemoembolization

Hepatic artery infusion with fluorouracil, doxorubicin, mitomycin, or cisplatin, combined with embolization of the hepatic artery with collagen fibers or other material (i.e., gelfoam, lipiodol, or poly vinyl alcohol) has been reported to decrease tumor bulk of liver metastases from carcinoid tumors by 50% or more in as many as 60% of patients.[44] Palliative embolizations that prove effective may be repeated if symptoms return.

Radiation Therapy

The role of radiation therapy in the management of carcinoid tumor with distant metastasis is restricted to symptomatic palliation.[45] Although the tumor persists, painful bone metastases can be palliated.

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[43] Moertel CG, Kvols LK, O'Connell MJ, et al.: Treatment of neuroendocrine carcinomas with combined etoposide and cisplatin. Evidence of major therapeutic activity in the anaplastic variants of these neoplasms. Cancer 68(2): 227-232, 1991.

[44] Diaco DS, Hajarizadeh H, Mueller CR, et al.: Treatment of metastatic carcinoid tumors using multimodality therapy of octreotide acetate, intra-arterial chemotherapy, and hepatic arterial chemoembolization. American Journal of Surgery 169(5): 523-528, 1995.

[45] Schupak KD, Wallner KE: The role of radiation therapy in the treatment of locally unresectable or metastatic carcinoid tumors. International Journal of Radiation Oncology, Biology, Physics 20(3): 489-495, 1991.

131I-MIBG

Therapeutic doses of iodine-131-labeled metaiodobenzylguanidine (MIBG) and unlabeled MIBG have been evaluated, with reduction of symptoms found in preliminary studies.[46]

Biological Modification (Immunotherapy)

Low-dose interferon alfa and octreotide, alone and in combination, have been reported to have activity.[47]

Carcinoid Syndrome

Treatment options associated with metastatic carcinoid tumor:

Surgical Treatment

Surgery may sometimes be of considerable value in the patient who has large or extensive hepatic metastases involving surgically accessible areas of the liver (single or multiple). Recurrent hepatic metastases (after previous resection) should be considered for resection if the lesions are placed in an area where resection can be done with minimal morbidity. Alternate non-resection surgical ablative techniques include cryosurgery, radiofrequency ablation, and percutaneous alcohol injections. For very carefully selected patients with indolent disease and symptomatic carcinoid heart disease, valve replacement may be indicated.

Hepatic Artery Ligation or Embolization

For patients with bulky or symptomatic hepatic metastases, hepatic artery ligation or embolization can cause substantial tumor necrosis. Toxic effects of embolization are frequent and can be severe, especially if the entire liver is

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[46] Taal BG, Hoefnagel CA, Valdes Olmos RA, et al.: Palliative effect of metaiodobenzylguanidine in metastatic carcinoid tumors. Journal of Clinical Oncology 14(6): 1829-1838, 1996.

[47] Oberg K: Advances in chemotherapy and biotherapy of endocrine tumors. Current Opinion in Oncology 10(1): 58-65, 1998.

Oberg K: Carcinoid tumors: current concepts in diagnosis and treatment. Oncologist 3(5): 339-345, 1998.

treated at one time. Reactions may be attenuated if multiple treatment sessions are possible at intervals of several weeks or months. These include abdominal pain, fever, nausea and transient worsening of the syndrome. However, many patients have subsequent symptomatic relief.[48] Such treatment may also be given in conjunction with systemic chemotherapy in selected patients.[49] Intra-arterial chemotherapy via the hepatic artery can cause regression of lesions in selected patients. These regressions tend to be durable as long as treatment is continued.

Pharmacologic Management

Somatostatin analogue (octreotide) has been demonstrated to relieve symptoms of malignant carcinoid syndrome in the great majority of patients, with significant reduction of 5-hydroxyindoleacetic acid (5-HIAA) levels. Tumor reduction is rarely seen.[50]

Patients benefit from specific pharmacologic interventions that either suppress production of vasoactive amines or block their peripheral effects. These agents include cyproheptadine and H2-receptor blockers.

Monoamine oxidase inhibitors and adrenergic agonists are drugs to be specifically avoided in these patients since they will exacerbate the syndrome by inhibiting serotonin degradation or producing carcinoid syndrome crisis.

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[48] Carrasco CH, Charnsangavej C, Ajani J, et al.: The carcinoid syndrome: palliation by hepatic artery embolization. American Journal of Roentgenology 147(1): 149-154, 1986.
Moertel CG, May GR, Martin JK, et al.: Sequential hepatic artery occlusion (HAO) and chemotherapy for metastatic carcinoid tumor and islet cell carcinoma (ICC). Proceedings of the American Society of Clinical Oncology 4: 80, 1985.

[49] Moertel CG, Johnson CM, McKusick MA, et al.: The management of patients with advanced carcinoid tumors and islet cell carcinomas. Annals of Internal Medicine 120(4): 302-309, 1994.

[50] Kvols LK, Moertel CG, O'Connell MJ, et al.: Treatment of the malignant carcinoid syndrome: evaluation of a long-acting somatostatin analogue. New England Journal of Medicine 315(11): 663-666, 1986.
Kvols LK, Martin JK, Marsh HM, et al.: Rapid reversal of carcinoid crisis with a somatostatin analogue. New England Journal of Medicine 313(19): 1229-1230, 1985.
Gorden P, Comi RL, Maton PN, et al.: Somatostatin and somatostatin analogue (SMS 201-995) in treatment of hormone-secreting tumors of the pituitary and gastrointestinal tract and non-neoplastic diseases of the gut. Annals of Internal Medicine 110(1): 35-50, 1989.
Kvols LK: The carcinoid syndrome: a treatable malignant disease. Oncology (Huntington NY) 2(2): 33-40, 1988.

Interferon Alfa Preparations

Interferon alfa preparations may have a role in controlling symptoms of the carcinoid syndrome or in arresting tumor growth.[51] These benefits have generally been transient and accompanied by toxic effects that frequently outweigh therapeutic gains,[52] although interferon alfa has been reported to re-induce symptom control in patients who have failed octreotide.[53] The combination of interferon alfa and continuous- infusion fluorouracil has demonstrated antitumor and/or antihormonal activity and, similar to other drug regimens, can provide useful palliation.[54] Combination of interferon alfa and octreotide has also been reported to have activity.[55]

Chemotherapy Combinations

Protocols using chemotherapy combinations should be considered for symptomatic patients.[56]

Recurrent Gastrointestinal Carcinoid Tumor

The prognosis for any treated carcinoid patient with progressing, recurring, or relapsing disease is poor. Deciding on further treatment depends on many factors, including the prior treatment, site of recurrence, as well as individual patient considerations. Attempts at re-resecting slow growing tumors (e.g., repeat or multiple liver resections) are worthy of consideration after extensive evaluation, since successful further reduction of tumor volume may provide long-term palliation. Recurrence in any single site may also be potentially resectable. Clinical trials are appropriate and should be considered when possible.

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[51] Oberg K, Norheim I, Lind E, et al.: Treatment of malignant carcinoid tumors with human leukocyte interferon: long-term results. Cancer Treatment Reports 70(11): 1297-1304, 1986.

[52] Moertel CG, Rubin J, Kvols LK: Therapy of metastatic carcinoid tumor and the malignant carcinoid syndrome with recombinant leukocyte A interferon. Journal of Clinical Oncology 7(7): 865-868, 1989.

[53] Tiensuu Janson EM, Ahlstrom H, Andersson T: Octreotide and interferon alfa: a new combination for the treatment of malignant carcinoid tumours. European Journal of Cancer 28(10): 1647-1650, 1992.

[54] Andreyev HJ, Scott-Mackie P, Cunningham D, et al.: Phase II study of continuous infusion fluorouracil and interferon alfa-2b in the palliation of malignant neuroendocrine tumors. Journal of Clinical Oncology 13(6): 1486-1492, 1995.

[55] Oberg K: Advances in chemotherapy and biotherapy of endocrine tumors. Current Opinion in Oncology 10(1): 58-65, 1998.

[56] Moertel CG: An odyssey in the land of small tumors. Journal of Clinical Oncology 5(10): 1503-1522, 1987.

NIH Databases

In addition to the various Institutes of Health that publish professional guidelines, the NIH has designed a number of databases for professionals.[57] Physician-oriented resources provide a wide variety of information related to the biomedical and health sciences, both past and present. The format of these resources varies. Searchable databases, bibliographic citations, full text articles (when available), archival collections, and images are all available. The following are referenced by the National Library of Medicine:[58]

- **Bioethics:** Access to published literature on the ethical, legal and public policy issues surrounding healthcare and biomedical research. This information is provided in conjunction with the Kennedy Institute of Ethics located at Georgetown University, Washington, D.C.: **http://www.nlm.nih.gov/databases/databases_bioethics.html**
- **HIV/AIDS Resources:** Describes various links and databases dedicated to HIV/AIDS research: **http://www.nlm.nih.gov/pubs/factsheets/aidsinfs.html**
- **NLM Online Exhibitions:** Describes "Exhibitions in the History of Medicine": **http://www.nlm.nih.gov/exhibition/exhibition.html**. Additional resources for historical scholarship in medicine: **http://www.nlm.nih.gov/hmd/hmd.html**
- **Biotechnology Information:** Access to public databases. The National Center for Biotechnology Information conducts research in computational biology, develops software tools for analyzing genome data, and disseminates biomedical information for the better understanding of molecular processes affecting human health and disease: **http://www.ncbi.nlm.nih.gov/**
- **Population Information:** The National Library of Medicine provides access to worldwide coverage of population, family planning, and related health issues, including family planning technology and programs, fertility, and population law and policy: **http://www.nlm.nih.gov/databases/databases_population.html**
- **Cancer Information:** Access to caner-oriented databases: **http://www.nlm.nih.gov/databases/databases_cancer.html**

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[57] Remember, for the general public, the National Library of Medicine recommends the databases referenced in MEDLINE*plus* (**http://medlineplus.gov/** or **http://www.nlm.nih.gov/medlineplus/databases.html**).

[58] See **http://www.nlm.nih.gov/databases/databases.html**.

- **Profiles in Science:** Offering the archival collections of prominent twentieth-century biomedical scientists to the public through modern digital technology: **http://www.profiles.nlm.nih.gov/**
- **Chemical Information:** Provides links to various chemical databases and references: **http://sis.nlm.nih.gov/Chem/ChemMain.html**
- **Clinical Alerts:** Reports the release of findings from the NIH-funded clinical trials where such release could significantly affect morbidity and mortality: **http://www.nlm.nih.gov/databases/alerts/clinical_alerts.html**
- **Space Life Sciences:** Provides links and information to space-based research (including NASA): **http://www.nlm.nih.gov/databases/databases_space.html**
- **MEDLINE:** Bibliographic database covering the fields of medicine, nursing, dentistry, veterinary medicine, the healthcare system, and the pre-clinical sciences: **http://www.nlm.nih.gov/databases/databases_medline.html**
- **Toxicology and Environmental Health Information (TOXNET):** Databases covering toxicology and environmental health: **http://sis.nlm.nih.gov/Tox/ToxMain.html**
- **Visible Human Interface:** Anatomically detailed, three-dimensional representations of normal male and female human bodies: **http://www.nlm.nih.gov/research/visible/visible_human.html**

While all of the above references may be of interest to physicians who study and treat gastrointestinal carcinoid tumors, the following are particularly noteworthy.

The NLM Gateway[59]

The NLM (National Library of Medicine) Gateway is a Web-based system that lets users search simultaneously in multiple retrieval systems at the U.S. National Library of Medicine (NLM). It allows users of NLM services to initiate searches from one Web interface, providing "one-stop searching" for many of NLM's information resources or databases.[60] One target audience for the Gateway is the Internet user who is new to NLM's online resources and does not know what information is available or how best to search for it. This

[59] Adapted from NLM: **http://gateway.nlm.nih.gov/gw/Cmd?Overview.x**.

[60] The NLM Gateway is currently being developed by the Lister Hill National Center for Biomedical Communications (LHNCBC) at the National Library of Medicine (NLM) of the National Institutes of Health (NIH).

audience may include physicians and other healthcare providers, researchers, librarians, students, and, increasingly, patients, their families, and the public.[61] To use the NLM Gateway, simply go to the search site at **http://gateway.nlm.nih.gov/gw/Cmd**. Type "gastrointestinal carcinoid tumors" (or synonyms) into the search box and click "Search." The results will be presented in a tabular form, indicating the number of references in each database category.

Results Summary

Category	Items Found
Journal Articles	1006
Books / Periodicals / Audio Visual	9
Consumer Health	883
Meeting Abstracts	2
Other Collections	7
Total	1907

HSTAT[62]

HSTAT is a free, Web-based resource that provides access to full-text documents used in healthcare decision-making.[63] HSTAT's audience includes healthcare providers, health service researchers, policy makers, insurance companies, consumers, and the information professionals who serve these groups. HSTAT provides access to a wide variety of publications, including clinical practice guidelines, quick-reference guides for clinicians, consumer health brochures, evidence reports and technology assessments from the Agency for Healthcare Research and Quality (AHRQ), as well as AHRQ's Put Prevention Into Practice.[64] Simply search by "gastrointestinal carcinoid tumors" (or synonyms) at the following Web site: **http://text.nlm.nih.gov**.

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[61] Other users may find the Gateway useful for an overall search of NLM's information resources. Some searchers may locate what they need immediately, while others will utilize the Gateway as an adjunct tool to other NLM search services such as PubMed® and MEDLINEplus®. The Gateway connects users with multiple NLM retrieval systems while also providing a search interface for its own collections. These collections include various types of information that do not logically belong in PubMed, LOCATORplus, or other established NLM retrieval systems (e.g., meeting announcements and pre-1966 journal citations). The Gateway will provide access to the information found in an increasing number of NLM retrieval systems in several phases.

[62] Adapted from HSTAT: **http://www.nlm.nih.gov/pubs/factsheets/hstat.html**.

[63] The HSTAT URL is **http://hstat.nlm.nih.gov/**.

[64] Other important documents in HSTAT include: the National Institutes of Health (NIH) Consensus Conference Reports and Technology Assessment Reports; the HIV/AIDS

Coffee Break: Tutorials for Biologists[65]

Some patients may wish to have access to a general healthcare site that takes a scientific view of the news and covers recent breakthroughs in biology that may one day assist physicians in developing treatments. To this end, we recommend "Coffee Break," a collection of short reports on recent biological discoveries. Each report incorporates interactive tutorials that demonstrate how bioinformatics tools are used as a part of the research process. Currently, all Coffee Breaks are written by NCBI staff.[66] Each report is about 400 words and is usually based on a discovery reported in one or more articles from recently published, peer-reviewed literature.[67] This site has new articles every few weeks, so it can be considered an online magazine of sorts, and intended for general background information. You can access Coffee Break at **http://www.ncbi.nlm.nih.gov/Coffeebreak/**.

Other Commercial Databases

In addition to resources maintained by official agencies, other databases exist that are commercial ventures addressing medical professionals. Here are some examples that may interest you:

- **CliniWeb International:** Index and table of contents to selected clinical information on the Internet; see **http://www.ohsu.edu/cliniweb/**.
- **Medical World Search:** Searches full text from thousands of selected medical sites on the Internet; see **http://www.mwsearch.com/**.

Treatment Information Service (ATIS) resource documents; the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (SAMHSA/CSAT) Treatment Improvement Protocols (TIP) and Center for Substance Abuse Prevention (SAMHSA/CSAP) Prevention Enhancement Protocols System (PEPS); the Public Health Service (PHS) Preventive Services Task Force's *Guide to Clinical Preventive Services*; the independent, nonfederal Task Force on Community Services *Guide to Community Preventive Services*; and the Health Technology Advisory Committee (HTAC) of the Minnesota Health Care Commission (MHCC) health technology evaluations.

[65] Adapted from **http://www.ncbi.nlm.nih.gov/Coffeebreak/Archive/FAQ.html**.

[66] The figure that accompanies each article is frequently supplied by an expert external to NCBI, in which case the source of the figure is cited. The result is an interactive tutorial that tells a biological story.

[67] After a brief introduction that sets the work described into a broader context, the report focuses on how a molecular understanding can provide explanations of observed biology and lead to therapies for diseases. Each vignette is accompanied by a figure and hypertext links that lead to a series of pages that interactively show how NCBI tools and resources are used in the research process.

PART III. APPENDICES

ABOUT PART III

Part III is a collection of appendices on general medical topics which may be of interest to patients with gastrointestinal carcinoid tumors and related conditions.

APPENDIX A. RESEARCHING YOUR MEDICATIONS

Overview

There are a number of sources available on new or existing medications which could be prescribed to patients with gastrointestinal carcinoid tumors. While a number of hard copy or CD-Rom resources are available to patients and physicians for research purposes, a more flexible method is to use Internet-based databases. In this chapter, we will begin with a general overview of medications. We will then proceed to outline official recommendations on how you should view your medications. You may also want to research medications that you are currently taking for other conditions as they may interact with medications for gastrointestinal carcinoid tumors. Research can give you information on the side effects, interactions, and limitations of prescription drugs used in the treatment of gastrointestinal carcinoid tumors. Broadly speaking, there are two sources of information on approved medications: public sources and private sources. We will emphasize free-to-use public sources.

Your Medications: The Basics[68]

The Agency for Health Care Research and Quality has published extremely useful guidelines on how you can best participate in the medication aspects of gastrointestinal carcinoid tumors. Taking medicines is not always as simple as swallowing a pill. It can involve many steps and decisions each day. The AHCRQ recommends that patients with gastrointestinal carcinoid tumors take part in treatment decisions. Do not be afraid to ask questions and talk about your concerns. By taking a moment to ask questions early,

[68] This section is adapted from AHCRQ: **http://www.ahcpr.gov/consumer/ncpiebro.htm**.

you may avoid problems later. Here are some points to cover each time a new medicine is prescribed**:**

- Ask about all parts of your treatment, including diet changes, exercise, and medicines.
- Ask about the risks and benefits of each medicine or other treatment you might receive.
- Ask how often you or your doctor will check for side effects from a given medication.

Do not hesitate to ask what is important to you about your medicines. You may want a medicine with the fewest side effects, or the fewest doses to take each day. You may care most about cost, or how the medicine might affect how you live or work. Or, you may want the medicine your doctor believes will work the best. Telling your doctor will help him or her select the best treatment for you.

Do not be afraid to "bother" your doctor with your concerns and questions about medications for gastrointestinal carcinoid tumors. You can also talk to a nurse or a pharmacist. They can help you better understand your treatment plan. Feel free to bring a friend or family member with you when you visit your doctor. Talking over your options with someone you trust can help you make better choices, especially if you are not feeling well. Specifically, ask your doctor the following:

- The name of the medicine and what it is supposed to do.
- How and when to take the medicine, how much to take, and for how long.
- What food, drinks, other medicines, or activities you should avoid while taking the medicine.
- What side effects the medicine may have, and what to do if they occur.
- If you can get a refill, and how often.
- About any terms or directions you do not understand.
- What to do if you miss a dose.
- If there is written information you can take home (most pharmacies have information sheets on your prescription medicines; some even offer large-print or Spanish versions).

Do not forget to tell your doctor about all the medicines you are currently taking (not just those for gastrointestinal carcinoid tumors). This includes

prescription medicines and the medicines that you buy over the counter. Then your doctor can avoid giving you a new medicine that may not work well with the medications you take now. When talking to your doctor, you may wish to prepare a list of medicines you currently take, the reason you take them, and how you take them. Be sure to include the following information for each:

- Name of medicine
- Reason taken
- Dosage
- Time(s) of day

Also include any over-the-counter medicines, such as:

- Laxatives
- Diet pills
- Vitamins
- Cold medicine
- Aspirin or other pain, headache, or fever medicine
- Cough medicine
- Allergy relief medicine
- Antacids
- Sleeping pills
- Others (include names)

Learning More about Your Medications

Because of historical investments by various organizations and the emergence of the Internet, it has become rather simple to learn about the medications your doctor has recommended for gastrointestinal carcinoid tumors. One such source is the United States Pharmacopeia. In 1820, eleven physicians met in Washington, D.C. to establish the first compendium of standard drugs for the United States. They called this compendium the "U.S. Pharmacopeia (USP)." Today, the USP is a non-profit organization consisting of 800 volunteer scientists, eleven elected officials, and 400 representatives of state associations and colleges of medicine and pharmacy. The USP is located in Rockville, Maryland, and its home page is located at **www.usp.org**. The USP currently provides standards for over 3,700 medications. The resulting

USP DI® Advice for the Patient® can be accessed through the National Library of Medicine of the National Institutes of Health. The database is partially derived from lists of federally approved medications in the Food and Drug Administration's (FDA) Drug Approvals database.[69]

While the FDA database is rather large and difficult to navigate, the Phamacopeia is both user-friendly and free to use. It covers more than 9,000 prescription and over-the-counter medications. To access this database, simply type the following hyperlink into your Web browser: **http://www.nlm.nih.gov/medlineplus/druginformation.html**. To view examples of a given medication (brand names, category, description, preparation, proper use, precautions, side effects, etc.), simply follow the hyperlinks indicated within the United States Pharmacopeia (USP).

Of course, we as editors cannot be certain as to what medications you are taking. Therefore, we have compiled a list of medications associated with the treatment of gastrointestinal carcinoid tumors. Once again, due to space limitations, we only list a sample of medications and provide hyperlinks to ample documentation (e.g. typical dosage, side effects, drug-interaction risks, etc.). The following drugs have been mentioned in the Pharmacopeia and other sources as being potentially applicable to gastrointestinal carcinoid tumors:

Capecitabine

- **Systemic - U.S. Brands:** Xeloda
  http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/203548.html

Carmustine

- **Systemic - U.S. Brands:** BiCNU
  http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202117.html

Fluorouracil

- **Systemic - U.S. Brands:** Adrucil
  http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202245.html

[69] Though cumbersome, the FDA database can be freely browsed at the following site: **www.fda.gov/cder/da/da.htm**.

Irinotecan

- **Systemic - U.S. Brands:** Camptosar
  http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/203051.html

Leucovorin

- **Systemic - U.S. Brands:** Wellcovorin
  http://www.nlm.nih.gov/medlineplus/druginfo/uspdi/202321.html

Commercial Databases

In addition to the medications listed in the USP above, a number of commercial sites are available by subscription to physicians and their institutions. You may be able to access these sources from your local medical library or your doctor's office.

Reuters Health Drug Database

The Reuters Health Drug Database can be searched by keyword at the hyperlink: **http://www.reutershealth.com/frame2/drug.html**.

Mosby's GenRx

Mosby's GenRx database (also available on CD-Rom and book format) covers 45,000 drug products including generics and international brands. It provides prescribing information, drug interactions, and patient information. Information can be obtained at the following hyperlink: **http://www.genrx.com/Mosby/PhyGenRx/group.html**.

PDR*health*

The PDR*health* database is a free-to-use, drug information search engine that has been written for the public in layman's terms. It contains FDA-approved drug information adapted from the Physicians' Desk Reference (PDR) database. PDR*health* can be searched by brand name, generic name, or indication. It features multiple drug interactions reports. Search PDR*health* at **http://www.pdrhealth.com/drug_info/index.html**.

Other Web Sites

A number of additional Web sites discuss drug information. As an example, you may like to look at **www.drugs.com** which reproduces the information in the Pharmacopeia as well as commercial information. You may also want to consider the Web site of the Medical Letter, Inc. which allows users to download articles on various drugs and therapeutics for a nominal fee: **http://www.medletter.com/**.

Drug Development and Approval

The following Web sites can be valuable resources when conducting research on the development and approval of new cancer drugs:

- FDA Home Page: Search for drugs currently in development or those which have been recently approved by the FDA.
  http://www.fda.gov/
- Cancer Liaison Program: Answers questions from the public about drug approval processes, cancer clinical trials, and access to investigational therapies.
  http://www.fda.gov/oashi/cancer/cancer.html
- Center for Drug Evaluation and Research
  http://www.fda.gov/cder/
- Drug Approvals by Cancer Indications (Alphabetical List)
  http://www.fda.gov/oashi/cancer/cdrugalpha.html
- Drug Approvals by Cancer Indications (Cancer Type)
  http://www.fda.gov/oashi/cancer/cdrugind.html
- Electronic Orange Book of Approved Drug Products
  http://www.fda.gov/cder/ob/default.htm
- Guidance Documents for Industry: Contains an archive of documents describing FDA policies on specific topics.
  http://www.fda.gov/cder/guidance/index.htm
- Industry Collaboration: Provides information to industry on the process for getting new drugs into clinical trials.
  http://ctep.cancer.gov/industry/index.html
- Investigator's Handbook: Provides information to investigators on specific procedures related to clinical trial development.
  http://ctep.cancer.gov/handbook/index.html

- Questions and Answers About NCI's Natural Products Branch: A fact sheet that describes the functions of this branch, which collects and analyzes specimens of plant, marine, and microbial origin for possible anticancer properties.
  http://cis.nci.nih.gov/fact/7_33.htm

Understanding the Approval Process for New Cancer Drugs[70]

Since June 1996, about 80 new cancer-related drugs, or new uses for drugs already on the market, have been approved by the U.S. Food and Drug Administration (FDA), the division of the U.S. Department of Health and Human Services charged with ensuring the safety and effectiveness of new drugs before they can go on the market. (The FDA maintains an annotated online list of drugs approved for use with cancer since 1996.) Some of these drugs treat cancer, some alleviate pain and other symptoms, and, in one case, reduce the risk of invasive cancer in people who are considered high-risk. The FDA relied on the results of clinical trials in making every one of these approvals. Without reliable information about a drug's effects on humans, it would be impossible to approve any drug for widespread use.

When considering a new drug, the FDA faces two challenges:

- First, making sure that the drug is safe and effective before it is made widely available.
- Second, ensuring that drugs which show promise are made available as quickly as possible to the people they can help.

To deal with these challenges, the FDA maintains a rigorous review process but also has measures in place to make some drugs available in special cases. This aim of this section is to acquaint you with the drug approval process and point you to other resources for learning more about it.

The Role of the Federal Drug Administration (FDA)

Approval is only one step in the drug development process. In fact, the FDA estimates that, on average, it takes eight and a half years to study and test a new drug before it can be approved for the general public. That includes early laboratory and animal testing, as well as the clinical trials that evaluate

[70] Adapted from the NCI:
http://www.cancer.gov/clinical_trials/doc_header.aspx?viewid=d94cbfac-e478-4704-9052-d8e8a3372b56.

the drugs in humans. The FDA plays a key role at three main points in this process:

- Determining whether or not a new drug shows enough promise to be given to people in clinical trials
- Once clinical trials begin, deciding whether or not they should continue, based on reports of efficacy and adverse reactions
- When clinical trials are completed, deciding whether or not the drug can be sold to the public and what its label should say about directions for use, side effects, warnings, and the like.

To make these decisions, the FDA must review studies submitted by the drug's sponsor (usually the manufacturer), evaluate any adverse reports from preclinical studies and clinical trials (that is, reports of side effects or complications), and review the adequacy of the chemistry and manufacturing. This process is lengthy, but it is meant to ensure that only beneficial drugs with acceptable side effects will make their way into the hands of the public. At the same time, recent legislative mandates and streamlined procedures within the FDA have accelerated the approval of effective drugs, especially for serious illnesses such as cancer. In addition, specific provisions make some drugs available to patients with special needs even before the approval process is complete.

From Lab to Patient Care

By law, the Food and Drug Administration (FDA) must review all test results for new drugs to ensure that products are safe and effective for specific uses. "Safe" does not mean that the drug is free of possible adverse side effects; rather, it means that the potential benefits have been determined to outweigh any risks. The testing process begins long before the first person takes the drug, with preliminary research and animal testing.

If a drug proves promising in the lab, the drug company or sponsor must apply for FDA approval to test it in clinical trials involving people. For drugs, the application, called an Investigational New Drug (IND) Application, is sent through the Center for Drug Evaluation and Research's (CDER) IND Review Process; for biological agents, the IND is sent to the Center for Biologics Evaluation and Research (CBER). Once the IND is approved by CDER or CBER, clinical trials can begin.

If the drug makes it through the clinical trials process—that is, the studies show that it is superior to current drugs—the manufacturer must submit a

New Drug Application (NDA) or (for biological agents) a Biologics License Application (BLA) to the FDA. (Biological agents, such as serums, vaccines, and cloned proteins, are manufactured from substances taken from living humans or animals.) This application must include:

- The exact chemical makeup of the drug or biologic and the mechanisms by which it is effective
- Results of animal studies
- Results of clinical trials
- How the drug or biologic is manufactured, processed, and packaged
- Quality control standards
- Samples of the product in the form(s) in which it is to be administered.

Once the FDA receives the NDA or BLA from the manufacturer or developer, the formal New Drug Application Review Process or Biologics/Product License Application Review Process begins.

For an overview of the entire process from start to finish, see the CDER's visual representation of The New Drug Development Process: Steps from Test Tube to New Drug Application Review, which is available for public viewing at the following Web address: **http://www.fda.gov/cder/handbook/develop.htm**.

Speed versus Safety in the Approval Process

The FDA's current goal is that no more than ten months will pass between the time that a complete application is submitted and the FDA takes action on it. But the process is not always smooth. Sometimes FDA's external advisory panels call for additional research or data. In other cases, the FDA staff asks for more information or revised studies. Some new drug approvals have taken as little as 42 days; other more difficult NDAs have spent years in the approval process.

Setting Priorities

The order in which NDAs are assessed by the FDA is determined by a classification system designed to give priority to drugs with the greatest potential benefits. All drugs that offer significant medical advances over existing therapies for any disease are considered "priority" drugs in the

approval process. NDAs for cancer treatment drugs are reviewed for this status primarily by the Division of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research (CDER). For Biologic License Applications (vaccines, blood products, and medicines made from animal products), the Center for Biologics Evaluation and Research (CBER) provides additional regulation and oversight.

Expert Advice

The FDA relies on a system of independent advisory committees, made up of professionals from outside the agency, for expert advice and guidance in making sound decisions about drug approval. Each committee meets as needed to weigh available evidence and assess the safety, effectiveness, and appropriate use of products considered for approval. In addition, these committees provide advice about general criteria for evaluation and scientific issues not related to specific products. The Oncologic Drugs Advisory Committee (ODAC) meets regularly to provide expert advice on cancer-related treatments and preventive drugs.

Each committee is composed of representatives from the research science and medical fields. At least one member on every advisory committee must represent the consumer perspective.

Final Approval

As the FDA looks at all the data submitted and the results of its own review, it applies two benchmark questions to each application for drug approval:

- Do the results of well-controlled studies provide substantial evidence of effectiveness?
- Do the results show the product is safe under the conditions of use in the proposed labeling? In this context, "safe" means that potential benefits have been determined to outweigh any risks.

Continued Vigilance

The FDA's responsibility for new drug treatments does not stop with final approval. The Office of Compliance in the Center for Drug Evaluation and Research (CDER) implements and tracks programs to make sure manufacturers comply with current standards and practice regulations.

CDER's Office of Drug Marketing, Advertising, and Communication monitors new drug advertising to make sure it is truthful and complete. At the Center for Biologic Evaluation and Research, biologics are followed with the same vigilance after approval. And through a system called MedWatch, the FDA gets feedback from health professionals and consumers on how the new drugs are working, any adverse reactions, and potential problems in labeling and dosage.

Online FDA Resources

The following information from the FDA should help you better understand the drug approval process:

- Center for Drug Evaluation and Research: **http://www.fda.gov/cder/handbook**
- From Test Tube to Patient: New Drug Development in the U.S. – a special January 1995 issue of the magazine FDA Consumer: **http://www.fda.gov/fdac/special/newdrug/ndd_toc.html**
- Milestones in U.S. Food and Drug Law History: **http://www.fda.gov/opacom/backgrounders/miles.html**
- Drug Approvals for Cancer Indications: **http://www.fda.gov/oashi/cancer/cdrug.html**

Getting Drugs to Patients Who Need Them

Clinical trials provide the most important information used by the FDA in determining whether a new drug shows "substantial evidence of effectiveness," or whether an already-approved drug can be used effectively in new ways (for example, to treat or prevent other types of cancer, or at a different dosage). The FDA must certify that a drug has shown promise in laboratory and animal trials before human testing can begin. The trials process includes three main stages and involves continuous review, which ensures that the sponsor can stop the study early if major problems develop or unexpected levels of treatment benefit are found. As with all clinical trials, benefits and risks must be carefully weighed by the researchers conducting the study and the patients who decide to participate.

Not everyone is eligible to participate in a clinical trial. Some patients do not fit the exact requirements for studies, some have rare forms of cancer for which only a limited number of studies are underway, and others are too ill

to participate. Working with the NCI and other sponsors, the FDA has established special conditions under which a patient and his or her physician can apply to receive cancer drugs that have not yet been through the approval process. In the past, these special case applications for new drugs were grouped under the name "compassionate uses." More recently, such uses have expanded to include more patients and more categories of investigational drugs.

Access to Investigational Drugs

The process of new drug development has many parts. In the United States, until a drug has been approved by the FDA, it can generally be obtained only through several mechanisms: enrollment in a clinical trial studying the drug, an expanded access program or special exemption/compassionate use programs. For more information about investigational drugs, go to **http://cis.nci.nih.gov/fact/7_46.htm** to view the NCI's fact sheet entitled "Access to Investigational Drugs: Questions and Answers".

"Group C" Drugs

In the 1970s, researchers from the NCI became concerned about the lag between the date when an investigational drug was found to have anti-tumor activity and the time that drug became available on the market. Working with the FDA, the NCI established the "Group C" classification to allow access to drugs with reproducible activity. Group C drugs are provided to properly trained physicians who have registered using a special form to assure that their patient qualifies under guideline protocols for the drug. Each Group C drug protocol specifies patient eligibility, reporting methodology, and drug use. Not only does Group C designation (now called Group C/Treatment INDs) speed new drugs to patients who need them most, but the process also allows the NCI to gather important information on the safety as well as activity of the drugs in the settings in which they will be most used after final FDA approval. Drugs are placed in the Group C category by agreement between the FDA and the NCI. Group C drugs are always provided free of charge, and the Health Care Financing Administration provides coverage for care associated with Group C therapy.

Treatment INDs

In 1987, the FDA began authorizing the use of new drugs still in the development process to treat certain seriously ill patients. In these cases, the process is referred to as a treatment investigational new drug application (Treatment IND). Clinical trials of the new drug must already be underway and have demonstrated positive results that are reproducible. The FDA sets guidelines about what constitutes serious and life-threatening illnesses, how much must already be known about a drug's side effects and benefits, and where physicians can obtain the drug for treatment. For many seriously ill patients, the risks associated with taking a not-yet-completely proven drug are outweighed by the possible benefits.

Accelerated Approval

"Accelerated approval" is the short-hand term for the FDA's new review system which, in the 1990s, has been used to ensure rapid approval while at the same time putting new safeguards into place. Accelerated approval is based on "surrogate endpoint" judgments: FDA can grant marketing approval to drugs and treatments that, according to certain indicators, prove they are likely to have beneficial effects on a disease or condition, even before such direct benefits have been shown clinically. Accelerated approval does NOT mean that additional clinical trials are not needed or that FDA stops gathering information about the effects of the drug; a follow-up study is required to demonstrate activity by more conventional endpoints.

Researching Orphan Drugs

Orphan drugs are a special class of pharmaceuticals used by patients who are unaffected by existing treatments or with illnesses for which no known drug is effective. Orphan drugs are most commonly prescribed or developed for "rare" diseases or conditions.[71] According to the FDA, an orphan drug (or biological) may already be approved, or it may still be experimental. A drug becomes an "orphan" when it receives orphan designation from the Office of

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[71] The U.S. Food and Drug Administration defines a rare disease or condition as "any disease or condition which affects less than 200,000 persons in the United States, or affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug." Adapted from the U.S. Food and Drug Administration: **http://www.fda.gov/opacom/laws/orphandg.htm**.

Orphan Products Development at the FDA.[72] Orphan designation qualifies the sponsor to receive certain benefits from the U.S. Government in exchange for developing the drug. The drug must then undergo the new drug approval process as any other drug would. To date, over 1000 orphan products have been designated, and over 200 have been approved for marketing. Historically, the approval time for orphan products as a group has been considerably shorter than the approval time for other drugs. This is due to the fact that many orphan products receive expedited review because they are developed for serious or life-threatening diseases.

The cost of orphan products is determined by the sponsor of the drug and can vary greatly. Reimbursement rates for drug expenses are set by each insurance company and outlined in your policy. Insurance companies will generally reimburse for orphan products that have been approved for marketing, but may not reimburse for products that are considered experimental. Consult your insurance company about specific reimbursement policies. If an orphan product has been approved for marketing, it will be available through the normal pharmaceutical supply channels. If the product has not been approved, the sponsor may make the product available on a compassionate-use basis.[73]

Although the list of orphan drugs is revised on a daily basis, you can quickly research orphan drugs that might be applicable to gastrointestinal carcinoid tumors using the database managed by the National Organization for Rare Disorders, Inc. (NORD), located at **www.rarediseases.org**. Simply go to their general search page and select "Orphan Drug Designation Database." On this page (**http://www.rarediseases.org/search/noddsearch.html**), type "gastrointestinal carcinoid tumors" or a synonym into the search box and click "Submit Query." When you see a list of drugs, understand that not all of the drugs may be relevant. Some may have been withdrawn from orphan status. Write down or print out the name of each drug and the relevant contact information. From there, visit the Pharmacopeia Web site and type the name of each orphan drug into the search box on **http://www.nlm.nih.gov/medlineplus/druginformation.html**. Read about each drug in detail and consult your doctor to find out if you might benefit

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[72] The following is adapted from the U.S. Food and Drug Administration: **http://www.fda.gov/orphan/faq/index.htm**.

[73] For contact information on sponsors of orphan products, contact the Office of Orphan Products Development (**http://www.fda.gov/orphan/**). General inquiries may be routed to the main office: Office of Orphan Products Development (HF-35); Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; Voice: (301) 827-3666 or (800) 300-7469; FAX: (301) 443-4915.

from these medications. You or your physician may need to contact the sponsor or NORD.

NORD conducts "early access programs for investigational new drugs (IND) under the Food and Drug Administration's (FDA's) approval 'Treatment INDs' programs which allow for a limited number of individuals to receive investigational drugs before FDA marketing approval." If the orphan product about which you are seeking information is approved for marketing, information on side effects can be found on the product's label. If the product is not approved, you or your physician should consult the sponsor.

The following is a list of orphan drugs currently listed in the NORD Orphan Drug Designation Database for gastrointestinal carcinoid tumors or related conditions:

- **L-leucovorin (trade name: Isovorin)**
  http://www.rarediseases.org/nord/search/nodd_full?code=195
- **Leucovorin (trade name: Leucovorin calcium)**
  http://www.rarediseases.org/nord/search/nodd_full?code=317
- **Leucovorin calcium (trade name: Wellcovorin)**
  http://www.rarediseases.org/nord/search/nodd_full?code=333
- **L-leucovorin (trade name: Isovorin)**
  http://www.rarediseases.org/nord/search/nodd_full?code=426
- **Interferon alfa-2a (recombinant) (trade name: Roferon-A)**
  http://www.rarediseases.org/nord/search/nodd_full?code=532
- **Fluorouracil (trade name: Adrucil)**
  http://www.rarediseases.org/nord/search/nodd_full?code=708

Contraindications and Interactions (Hidden Dangers)

Some of the medications mentioned in the previous discussions can be problematic for patients with gastrointestinal carcinoid tumors--not because they are used in the treatment process, but because of contraindications, or side effects. Medications with contraindications are those that could react with drugs used to treat gastrointestinal carcinoid tumors or potentially create deleterious side effects in patients with gastrointestinal carcinoid tumors. You should ask your physician about any contraindications,

especially as these might apply to other medications that you may be taking for common ailments.

Drug-drug interactions occur when two or more drugs react with each other. This drug-drug interaction may cause you to experience an unexpected side effect. Drug interactions may make your medications less effective, cause unexpected side effects, or increase the action of a particular drug. Some drug interactions can even be harmful to you.

Be sure to read the label every time you use a nonprescription or prescription drug, and take the time to learn about drug interactions. These precautions may be critical to your health. You can reduce the risk of potentially harmful drug interactions and side effects with a little bit of knowledge and common sense.

Drug labels contain important information about ingredients, uses, warnings, and directions which you should take the time to read and understand. Labels also include warnings about possible drug interactions. Further, drug labels may change as new information becomes available. This is why it's especially important to read the label every time you use a medication. When your doctor prescribes a new drug, discuss all over-the-counter and prescription medications, dietary supplements, vitamins, botanicals, minerals and herbals you take as well as the foods you eat. Ask your pharmacist for the package insert for each prescription drug you take. The package insert provides more information about potential drug interactions.

A Final Warning

At some point, you may hear of alternative medications from friends, relatives, or in the news media. Advertisements may suggest that certain alternative drugs can produce positive results for patients with gastrointestinal carcinoid tumors. Exercise caution--some of these drugs may have fraudulent claims, and others may actually hurt you. The Food and Drug Administration (FDA) is the official U.S. agency charged with discovering which medications are likely to improve the health of patients with gastrointestinal carcinoid tumors. The FDA warns patients to watch out for[74]:

- Secret formulas (real scientists share what they know)

[74] This section has been adapted from **http://www.fda.gov/opacom/lowlit/medfraud.html**.

- Amazing breakthroughs or miracle cures (real breakthroughs don't happen very often; when they do, real scientists do not call them amazing or miracles)
- Quick, painless, or guaranteed cures
- If it sounds too good to be true, it probably isn't true.

If you have any questions about any kind of medical treatment, the FDA may have an office near you. Look for their number in the blue pages of the phone book. You can also contact the FDA through its toll-free number, 1-888-INFO-FDA (1-888-463-6332), or on the World Wide Web at **www.fda.gov**.

General References

In addition to the resources provided earlier in this chapter, the following general references describe medications (sorted alphabetically by title; hyperlinks provide rankings, information and reviews at Amazon.com):

- **Antifolate Drugs in Cancer Therapy (Cancer Drug Discovery and Development)** by Ann L. Jackman (Editor); Hardcover: 480 pages; (March 1999), Humana Press; ISBN: 0896035964; **http://www.amazon.com/exec/obidos/ASIN/0896035964/icongroupinterna**
- **Consumers Guide to Cancer Drugs** by Gail M. Wilkes, et al; Paperback - 448 pages, 1st edition (January 15, 2000), Jones & Bartlett Publishing; ISBN: 0763711705; **http://www.amazon.com/exec/obidos/ASIN/0763711705/icongroupinterna**
- **Patient Education Guide to Oncology Drugs (Book with CD-ROM)** by Gail M. Wilkes, et al; CD-ROM - 447 pages, 1st edition (January 15, 2000), Jones & Bartlett Publishing; ISBN: 076371173X; **http://www.amazon.com/exec/obidos/ASIN/076371173X/icongroupinterna**
- **The Role of Multiple Intensification in Medical Oncology** by M. S. Aapro (Editor), D. Maraninchi (Editor); Hardcover (June 1998), Springer Verlag; ISBN: 3540635432; **http://www.amazon.com/exec/obidos/ASIN/3540635432/icongroupinterna**

Vocabulary Builder

The following vocabulary builder gives definitions of words used in this chapter that have not been defined in previous chapters:

Compassionate: A process for providing experimental drugs to very sick patients who have no treatment options. [NIH]

Contraindications: Any factor or sign that it is unwise to pursue a certain kind of action or treatment, e. g. giving a general anesthetic to a person with pneumonia. [NIH]

APPENDIX B. FINDING MEDICAL LIBRARIES

Overview

At a medical library you can find medical texts and reference books, consumer health publications, specialty newspapers and magazines, as well as medical journals. In this Appendix, we show you how to quickly find a medical library in your area.

Preparation

Before going to the library, highlight the references mentioned in this sourcebook that you find interesting. Focus on those items that are not available via the Internet, and ask the reference librarian for help with your search. He or she may know of additional resources that could be helpful to you. Most importantly, your local public library and medical libraries have Interlibrary Loan programs with the National Library of Medicine (NLM), one of the largest medical collections in the world. According to the NLM, most of the literature in the general and historical collections of the National Library of Medicine is available on interlibrary loan to any library. NLM's interlibrary loan services are only available to libraries. If you would like to access NLM medical literature, then visit a library in your area that can request the publications for you.[75]

[75] Adapted from the NLM: **http://www.nlm.nih.gov/psd/cas/interlibrary.html**.

Finding a Local Medical Library

The quickest method to locate medical libraries is to use the Internet-based directory published by the National Network of Libraries of Medicine (NN/LM). This network includes 4626 members and affiliates that provide many services to librarians, health professionals, and the public. To find a library in your area, simply visit **http://nnlm.gov/members/adv.html** or call 1-800-338-7657.

Medical Libraries in the U.S. and Canada

In addition to the NN/LM, the National Library of Medicine (NLM) lists a number of libraries with reference facilities that are open to the public. The following is the NLM's list and includes hyperlinks to each library's Web site. These Web pages can provide information on hours of operation and other restrictions. The list below is a small sample of libraries recommended by the National Library of Medicine (sorted alphabetically by name of the U.S. state or Canadian province where the library is located)[76]:

- **Alabama:** Health InfoNet of Jefferson County (Jefferson County Library Cooperative, Lister Hill Library of the Health Sciences), **http://www.uab.edu/infonet/**
- **Alabama:** Richard M. Scrushy Library (American Sports Medicine Institute)
- **Arizona:** Samaritan Regional Medical Center: The Learning Center (Samaritan Health System, Phoenix, Arizona), **http://www.samaritan.edu/library/bannerlibs.htm**
- **California:** Kris Kelly Health Information Center (St. Joseph Health System, Humboldt), **http://www.humboldt1.com/~kkhic/index.html**
- **California:** Community Health Library of Los Gatos, **http://www.healthlib.org/orgresources.html**
- **California:** Consumer Health Program and Services (CHIPS) (County of Los Angeles Public Library, Los Angeles County Harbor-UCLA Medical Center Library) - Carson, CA, **http://www.colapublib.org/services/chips.html**
- **California:** Gateway Health Library (Sutter Gould Medical Foundation)
- **California:** Health Library (Stanford University Medical Center), **http://www-med.stanford.edu/healthlibrary/**

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[76] Abstracted from **http://www.nlm.nih.gov/medlineplus/libraries.html**.

- **California:** Patient Education Resource Center - Health Information and Resources (University of California, San Francisco), **http://sfghdean.ucsf.edu/barnett/PERC/default.asp**
- **California:** Redwood Health Library (Petaluma Health Care District), **http://www.phcd.org/rdwdlib.html**
- **California:** Los Gatos PlaneTree Health Library, **http://planetreesanjose.org/**
- **California:** Sutter Resource Library (Sutter Hospitals Foundation, Sacramento), **http://suttermedicalcenter.org/library/**
- **California:** Health Sciences Libraries (University of California, Davis), **http://www.lib.ucdavis.edu/healthsci/**
- **California:** ValleyCare Health Library & Ryan Comer Cancer Resource Center (ValleyCare Health System, Pleasanton), **http://gaelnet.stmarys-ca.edu/other.libs/gbal/east/vchl.html**
- **California:** Washington Community Health Resource Library (Fremont), **http://www.healthlibrary.org/**
- **Colorado:** William V. Gervasini Memorial Library (Exempla Healthcare), **http://www.saintjosephdenver.org/yourhealth/libraries/**
- **Connecticut:** Hartford Hospital Health Science Libraries (Hartford Hospital), **http://www.harthosp.org/library/**
- **Connecticut:** Healthnet: Connecticut Consumer Health Information Center (University of Connecticut Health Center, Lyman Maynard Stowe Library), **http://library.uchc.edu/departm/hnet/**
- **Connecticut:** Waterbury Hospital Health Center Library (Waterbury Hospital, Waterbury), **http://www.waterburyhospital.com/library/consumer.shtml**
- **Delaware:** Consumer Health Library (Christiana Care Health System, Eugene du Pont Preventive Medicine & Rehabilitation Institute, Wilmington), **http://www.christianacare.org/health_guide/health_guide_pmri_health_info.cfm**
- **Delaware:** Lewis B. Flinn Library (Delaware Academy of Medicine, Wilmington), **http://www.delamed.org/chls.html**
- **Georgia:** Family Resource Library (Medical College of Georgia, Augusta), **http://cmc.mcg.edu/kids_families/fam_resources/fam_res_lib/frl.htm**
- **Georgia:** Health Resource Center (Medical Center of Central Georgia, Macon), **http://www.mccg.org/hrc/hrchome.asp**

- **Hawaii:** Hawaii Medical Library: Consumer Health Information Service (Hawaii Medical Library, Honolulu), **http://hml.org/CHIS/**
- **Idaho:** DeArmond Consumer Health Library (Kootenai Medical Center, Coeur d'Alene), **http://www.nicon.org/DeArmond/index.htm**
- **Illinois:** Health Learning Center of Northwestern Memorial Hospital (Chicago), **http://www.nmh.org/health_info/hlc.html**
- **Illinois:** Medical Library (OSF Saint Francis Medical Center, Peoria), **http://www.osfsaintfrancis.org/general/library/**
- **Kentucky:** Medical Library - Services for Patients, Families, Students & the Public (Central Baptist Hospital, Lexington), **http://www.centralbap.com/education/community/library.cfm**
- **Kentucky:** University of Kentucky - Health Information Library (Chandler Medical Center, Lexington), **http://www.mc.uky.edu/PatientEd/**
- **Louisiana:** Alton Ochsner Medical Foundation Library (Alton Ochsner Medical Foundation, New Orleans), **http://www.ochsner.org/library/**
- **Louisiana:** Louisiana State University Health Sciences Center Medical Library-Shreveport, **http://lib-sh.lsuhsc.edu/**
- **Maine:** Franklin Memorial Hospital Medical Library (Franklin Memorial Hospital, Farmington), **http://www.fchn.org/fmh/lib.htm**
- **Maine:** Gerrish-True Health Sciences Library (Central Maine Medical Center, Lewiston), **http://www.cmmc.org/library/library.html**
- **Maine:** Hadley Parrot Health Science Library (Eastern Maine Healthcare, Bangor), **http://www.emh.org/hll/hpl/guide.htm**
- **Maine:** Maine Medical Center Library (Maine Medical Center, Portland), **http://www.mmc.org/library/**
- **Maine:** Parkview Hospital (Brunswick), **http://www.parkviewhospital.org/**
- **Maine:** Southern Maine Medical Center Health Sciences Library (Southern Maine Medical Center, Biddeford), **http://www.smmc.org/services/service.php3?choice=10**
- **Maine:** Stephens Memorial Hospital's Health Information Library (Western Maine Health, Norway), **http://www.wmhcc.org/Library/**
- **Manitoba, Canada:** Consumer & Patient Health Information Service (University of Manitoba Libraries), **http://www.umanitoba.ca/libraries/units/health/reference/chis.html**

- **Manitoba, Canada:** J.W. Crane Memorial Library (Deer Lodge Centre, Winnipeg), **http://www.deerlodge.mb.ca/crane_library/about.asp**
- **Maryland:** Health Information Center at the Wheaton Regional Library (Montgomery County, Dept. of Public Libraries, Wheaton Regional Library), **http://www.mont.lib.md.us/healthinfo/hic.asp**
- **Massachusetts:** Baystate Medical Center Library (Baystate Health System), **http://www.baystatehealth.com/1024/**
- **Massachusetts:** Boston University Medical Center Alumni Medical Library (Boston University Medical Center), **http://med-libwww.bu.edu/library/lib.html**
- **Massachusetts:** Lowell General Hospital Health Sciences Library (Lowell General Hospital, Lowell), **http://www.lowellgeneral.org/library/HomePageLinks/WWW.htm**
- **Massachusetts:** Paul E. Woodard Health Sciences Library (New England Baptist Hospital, Boston), **http://www.nebh.org/health_lib.asp**
- **Massachusetts:** St. Luke's Hospital Health Sciences Library (St. Luke's Hospital, Southcoast Health System, New Bedford), **http://www.southcoast.org/library/**
- **Massachusetts:** Treadwell Library Consumer Health Reference Center (Massachusetts General Hospital), **http://www.mgh.harvard.edu/library/chrcindex.html**
- **Massachusetts:** UMass HealthNet (University of Massachusetts Medical School, Worchester), **http://healthnet.umassmed.edu/**
- **Michigan:** Botsford General Hospital Library - Consumer Health (Botsford General Hospital, Library & Internet Services), **http://www.botsfordlibrary.org/consumer.htm**
- **Michigan:** Helen DeRoy Medical Library (Providence Hospital and Medical Centers), **http://www.providence-hospital.org/library/**
- **Michigan:** Marquette General Hospital - Consumer Health Library (Marquette General Hospital, Health Information Center), **http://www.mgh.org/center.html**
- **Michigan:** Patient Education Resouce Center - University of Michigan Cancer Center (University of Michigan Comprehensive Cancer Center, Ann Arbor), **http://www.cancer.med.umich.edu/learn/leares.htm**
- **Michigan:** Sladen Library & Center for Health Information Resources - Consumer Health Information (Detroit), **http://www.henryford.com/body.cfm?id=39330**

- **Montana:** Center for Health Information (St. Patrick Hospital and Health Sciences Center, Missoula)
- **National:** Consumer Health Library Directory (Medical Library Association, Consumer and Patient Health Information Section), **http://caphis.mlanet.org/directory/index.html**
- **National:** National Network of Libraries of Medicine (National Library of Medicine) - provides library services for health professionals in the United States who do not have access to a medical library, **http://nnlm.gov/**
- **National:** NN/LM List of Libraries Serving the Public (National Network of Libraries of Medicine), **http://nnlm.gov/members/**
- **Nevada:** Health Science Library, West Charleston Library (Las Vegas-Clark County Library District, Las Vegas), **http://www.lvccld.org/special_collections/medical/index.htm**
- **New Hampshire:** Dartmouth Biomedical Libraries (Dartmouth College Library, Hanover), **http://www.dartmouth.edu/~biomed/resources.htmld/conshealth.htmld**
- **New Jersey:** Consumer Health Library (Rahway Hospital, Rahway), **http://www.rahwayhospital.com/library.htm**
- **New Jersey:** Dr. Walter Phillips Health Sciences Library (Englewood Hospital and Medical Center, Englewood), **http://www.englewoodhospital.com/links/index.htm**
- **New Jersey:** Meland Foundation (Englewood Hospital and Medical Center, Englewood), **http://www.geocities.com/ResearchTriangle/9360/**
- **New York:** Choices in Health Information (New York Public Library) - NLM Consumer Pilot Project participant, **http://www.nypl.org/branch/health/links.html**
- **New York:** Health Information Center (Upstate Medical University, State University of New York, Syracuse), **http://www.upstate.edu/library/hic/**
- **New York:** Health Sciences Library (Long Island Jewish Medical Center, New Hyde Park), **http://www.lij.edu/library/library.html**
- **New York:** ViaHealth Medical Library (Rochester General Hospital), **http://www.nyam.org/library/**
- **Ohio:** Consumer Health Library (Akron General Medical Center, Medical & Consumer Health Library), **http://www.akrongeneral.org/hwlibrary.htm**

- **Oklahoma:** The Health Information Center at Saint Francis Hospital (Saint Francis Health System, Tulsa), **http://www.sfh-tulsa.com/services/healthinfo.asp**
- **Oregon:** Planetree Health Resource Center (Mid-Columbia Medical Center, The Dalles), **http://www.mcmc.net/phrc/**
- **Pennsylvania:** Community Health Information Library (Milton S. Hershey Medical Center, Hershey), **http://www.hmc.psu.edu/commhealth/**
- **Pennsylvania:** Community Health Resource Library (Geisinger Medical Center, Danville), **http://www.geisinger.edu/education/commlib.shtml**
- **Pennsylvania:** HealthInfo Library (Moses Taylor Hospital, Scranton), **http://www.mth.org/healthwellness.html**
- **Pennsylvania:** Hopwood Library (University of Pittsburgh, Health Sciences Library System, Pittsburgh), **http://www.hsls.pitt.edu/guides/chi/hopwood/index_html**
- **Pennsylvania:** Koop Community Health Information Center (College of Physicians of Philadelphia), **http://www.collphyphil.org/kooppg1.shtml**
- **Pennsylvania:** Learning Resources Center - Medical Library (Susquehanna Health System, Williamsport), **http://www.shscares.org/services/lrc/index.asp**
- **Pennsylvania:** Medical Library (UPMC Health System, Pittsburgh), **http://www.upmc.edu/passavant/library.htm**
- **Quebec, Canada:** Medical Library (Montreal General Hospital), **http://www.mghlib.mcgill.ca/**
- **South Dakota:** Rapid City Regional Hospital Medical Library (Rapid City Regional Hospital), **http://www.rcrh.org/Services/Library/Default.asp**
- **Texas:** Houston HealthWays (Houston Academy of Medicine-Texas Medical Center Library), **http://hhw.library.tmc.edu/**
- **Washington:** Community Health Library (Kittitas Valley Community Hospital), **http://www.kvch.com/**
- **Washington:** Southwest Washington Medical Center Library (Southwest Washington Medical Center, Vancouver), **http://www.swmedicalcenter.com/body.cfm?id=72**

APPENDIX C. YOUR RIGHTS AND INSURANCE

Overview

Any patient with gastrointestinal carcinoid tumors faces a series of issues related more to the healthcare industry than to the medical condition itself. This appendix covers two important topics in this regard: your rights and responsibilities as a patient, and how to get the most out of your medical insurance plan.

Your Rights as a Patient

The President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry has created the following summary of your rights as a patient.[77]

Information Disclosure

Consumers have the right to receive accurate, easily understood information. Some consumers require assistance in making informed decisions about health plans, health professionals, and healthcare facilities. Such information includes:

- ***Health plans.*** Covered benefits, cost-sharing, and procedures for resolving complaints, licensure, certification, and accreditation status, comparable measures of quality and consumer satisfaction, provider

[77]Adapted from Consumer Bill of Rights and Responsibilities: **http://www.hcqualitycommission.gov/press/cbor.html#head1**.

network composition, the procedures that govern access to specialists and emergency services, and care management information.

- ***Health professionals.*** Education, board certification, and recertification, years of practice, experience performing certain procedures, and comparable measures of quality and consumer satisfaction.
- ***Healthcare facilities.*** Experience in performing certain procedures and services, accreditation status, comparable measures of quality, worker, and consumer satisfaction, and procedures for resolving complaints.
- ***Consumer assistance programs.*** Programs must be carefully structured to promote consumer confidence and to work cooperatively with health plans, providers, payers, and regulators. Desirable characteristics of such programs are sponsorship that ensures accountability to the interests of consumers and stable, adequate funding.

Choice of Providers and Plans

Consumers have the right to a choice of healthcare providers that is sufficient to ensure access to appropriate high-quality healthcare. To ensure such choice, the Commission recommends the following:

- ***Provider network adequacy.*** All health plan networks should provide access to sufficient numbers and types of providers to assure that all covered services will be accessible without unreasonable delay -- including access to emergency services 24 hours a day and 7 days a week. If a health plan has an insufficient number or type of providers to provide a covered benefit with the appropriate degree of specialization, the plan should ensure that the consumer obtains the benefit outside the network at no greater cost than if the benefit were obtained from participating providers.
- ***Women's health services.*** Women should be able to choose a qualified provider offered by a plan -- such as gynecologists, certified nurse midwives, and other qualified healthcare providers -- for the provision of covered care necessary to provide routine and preventative women's healthcare services.
- ***Access to specialists.*** Consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan.

- ***Transitional care.*** Consumers who are undergoing a course of treatment for a chronic or disabling condition (or who are in the second or third trimester of a pregnancy) at the time they involuntarily change health plans or at a time when a provider is terminated by a plan for other than cause should be able to continue seeing their current specialty providers for up to 90 days (or through completion of postpartum care) to allow for transition of care.
- ***Choice of health plans.*** Public and private group purchasers should, wherever feasible, offer consumers a choice of high-quality health insurance plans.

Access to Emergency Services

Consumers have the right to access emergency healthcare services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity--including severe pain--such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

Participation in Treatment Decisions

Consumers have the right and responsibility to fully participate in all decisions related to their healthcare. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators. Physicians and other health professionals should:

- Provide patients with sufficient information and opportunity to decide among treatment options consistent with the informed consent process.
- Discuss all treatment options with a patient in a culturally competent manner, including the option of no treatment at all.
- Ensure that persons with disabilities have effective communications with members of the health system in making such decisions.
- Discuss all current treatments a consumer may be undergoing.
- Discuss all risks, benefits, and consequences to treatment or nontreatment.

- Give patients the opportunity to refuse treatment and to express preferences about future treatment decisions.
- Discuss the use of advance directives -- both living wills and durable powers of attorney for healthcare -- with patients and their designated family members.
- Abide by the decisions made by their patients and/or their designated representatives consistent with the informed consent process.

Health plans, health providers, and healthcare facilities should:

- Disclose to consumers factors -- such as methods of compensation, ownership of or interest in healthcare facilities, or matters of conscience -- that could influence advice or treatment decisions.
- Assure that provider contracts do not contain any so-called "gag clauses" or other contractual mechanisms that restrict healthcare providers' ability to communicate with and advise patients about medically necessary treatment options.
- Be prohibited from penalizing or seeking retribution against healthcare professionals or other health workers for advocating on behalf of their patients.

Respect and Nondiscrimination

Consumers have the right to considerate, respectful care from all members of the healthcare industry at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality healthcare system. To assure that right, the Commission recommends the following:

- Consumers must not be discriminated against in the delivery of healthcare services consistent with the benefits covered in their policy, or as required by law, based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.
- Consumers eligible for coverage under the terms and conditions of a health plan or program, or as required by law, must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Confidentiality of Health Information

Consumers have the right to communicate with healthcare providers in confidence and to have the confidentiality of their individually identifiable healthcare information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

Complaints and Appeals

Consumers have the right to a fair and efficient process for resolving differences with their health plans, healthcare providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review. A free copy of the Patient's Bill of Rights is available from the American Hospital Association.[78]

Patient Responsibilities

Treatment is a two-way street between you and your healthcare providers. To underscore the importance of finance in modern healthcare as well as your responsibility for the financial aspects of your care, the President's Advisory Commission on Consumer Protection and Quality in the Healthcare Industry has proposed that patients understand the following "Consumer Responsibilities."[79] In a healthcare system that protects consumers' rights, it is reasonable to expect and encourage consumers to assume certain responsibilities. Greater individual involvement by the consumer in his or her care increases the likelihood of achieving the best outcome and helps support a quality-oriented, cost-conscious environment. Such responsibilities include:

- Take responsibility for maximizing healthy habits such as exercising, not smoking, and eating a healthy diet.
- Work collaboratively with healthcare providers in developing and carrying out agreed-upon treatment plans.
- Disclose relevant information and clearly communicate wants and needs.

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[78] To order your free copy of the Patient's Bill of Rights, telephone 312-422-3000 or visit the American Hospital Association's Web site: **http://www.aha.org**. Click on "Resource Center," go to "Search" at bottom of page, and then type in "Patient's Bill of Rights." The Patient's Bill of Rights is also available from Fax on Demand, at 312-422-2020, document number 471124.

[79] Adapted from **http://www.hcqualitycommission.gov/press/cbor.html#head1**.

- Use your health insurance plan's internal complaint and appeal processes to address your concerns.
- Avoid knowingly spreading disease.
- Recognize the reality of risks, the limits of the medical science, and the human fallibility of the healthcare professional.
- Be aware of a healthcare provider's obligation to be reasonably efficient and equitable in providing care to other patients and the community.
- Become knowledgeable about your health plan's coverage and options (when available) including all covered benefits, limitations, and exclusions, rules regarding use of network providers, coverage and referral rules, appropriate processes to secure additional information, and the process to appeal coverage decisions.
- Show respect for other patients and health workers.
- Make a good-faith effort to meet financial obligations.
- Abide by administrative and operational procedures of health plans, healthcare providers, and Government health benefit programs.

Choosing an Insurance Plan

There are a number of official government agencies that help consumers understand their healthcare insurance choices.[80] The U.S. Department of Labor, in particular, recommends ten ways to make your health benefits choices work best for you.[81]

1. Your options are important. There are many different types of health benefit plans. Find out which one your employer offers, then check out the plan, or plans, offered. Your employer's human resource office, the health plan administrator, or your union can provide information to help you match your needs and preferences with the available plans. The more information you have, the better your healthcare decisions will be.

2. Reviewing the benefits available. Do the plans offered cover preventive care, well-baby care, vision or dental care? Are there deductibles? Answers to these questions can help determine the out-of-pocket expenses you may

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[80] More information about quality across programs is provided at the following AHRQ Web site:
http://www.ahrq.gov/consumer/qntascii/qnthplan.htm.

[81] Adapted from the Department of Labor:
http://www.dol.gov/dol/pwba/public/pubs/health/top10-text.html.

face. Matching your needs and those of your family members will result in the best possible benefits. Cheapest may not always be best. Your goal is high quality health benefits.

3. Look for quality. The quality of healthcare services varies, but quality can be measured. You should consider the quality of healthcare in deciding among the healthcare plans or options available to you. Not all health plans, doctors, hospitals and other providers give the highest quality care. Fortunately, there is quality information you can use right now to help you compare your healthcare choices. Find out how you can measure quality. Consult the U.S. Department of Health and Human Services publication "Your Guide to Choosing Quality Health Care" on the Internet at **www.ahcpr.gov/consumer**.

4. Your plan's summary plan description (SPD) provides a wealth of information. Your health plan administrator can provide you with a copy of your plan's SPD. It outlines your benefits and your legal rights under the Employee Retirement Income Security Act (ERISA), the federal law that protects your health benefits. It should contain information about the coverage of dependents, what services will require a co-pay, and the circumstances under which your employer can change or terminate a health benefits plan. Save the SPD and all other health plan brochures and documents, along with memos or correspondence from your employer relating to health benefits.

5. Assess your benefit coverage as your family status changes. Marriage, divorce, childbirth or adoption, and the death of a spouse are all life events that may signal a need to change your health benefits. You, your spouse and dependent children may be eligible for a special enrollment period under provisions of the Health Insurance Portability and Accountability Act (HIPAA). Even without life-changing events, the information provided by your employer should tell you how you can change benefits or switch plans, if more than one plan is offered. If your spouse's employer also offers a health benefits package, consider coordinating both plans for maximum coverage.

6. Changing jobs and other life events can affect your health benefits. Under the Consolidated Omnibus Budget Reconciliation Act (COBRA), you, your covered spouse, and your dependent children may be eligible to purchase extended health coverage under your employer's plan if you lose your job, change employers, get divorced, or upon occurrence of certain other events. Coverage can range from 18 to 36 months depending on your situation. COBRA applies to most employers with 20 or more workers and

requires your plan to notify you of your rights. Most plans require eligible individuals to make their COBRA election within 60 days of the plan's notice. Be sure to follow up with your plan sponsor if you don't receive notice, and make sure you respond within the allotted time.

7. HIPAA can also help if you are changing jobs, particularly if you have a medical condition. HIPAA generally limits pre-existing condition exclusions to a maximum of 12 months (18 months for late enrollees). HIPAA also requires this maximum period to be reduced by the length of time you had prior "creditable coverage." You should receive a certificate documenting your prior creditable coverage from your old plan when coverage ends.

8. Plan for retirement. Before you retire, find out what health benefits, if any, extend to you and your spouse during your retirement years. Consult with your employer's human resources office, your union, the plan administrator, and check your SPD. Make sure there is no conflicting information among these sources about the benefits you will receive or the circumstances under which they can change or be eliminated. With this information in hand, you can make other important choices, like finding out if you are eligible for Medicare and Medigap insurance coverage.

9. Know how to file an appeal if your health benefits claim is denied. Understand how your plan handles grievances and where to make appeals of the plan's decisions. Keep records and copies of correspondence. Check your health benefits package and your SPD to determine who is responsible for handling problems with benefit claims. Contact PWBA for customer service assistance if you are unable to obtain a response to your complaint.

10. You can take steps to improve the quality of the healthcare and the health benefits you receive. Look for and use things like Quality Reports and Accreditation Reports whenever you can. Quality reports may contain consumer ratings -- how satisfied consumers are with the doctors in their plan, for instance-- and clinical performance measures -- how well a healthcare organization prevents and treats illness. Accreditation reports provide information on how accredited organizations meet national standards, and often include clinical performance measures. Look for these quality measures whenever possible. Consult "Your Guide to Choosing Quality Health Care" on the Internet at **www.ahcpr.gov/consumer**.

Medicare and Medicaid

Illness strikes both rich and poor families. For low-income families, Medicaid is available to defer the costs of treatment. The Health Care Financing Administration (HCFA) administers Medicare, the nation's largest health insurance program, which covers 39 million Americans. In the following pages, you will learn the basics about Medicare insurance as well as useful contact information on how to find more in-depth information about Medicaid.[82]

Who Is Eligible for Medicare?

Generally, you are eligible for Medicare if you or your spouse worked for at least 10 years in Medicare-covered employment and you are 65 years old and a citizen or permanent resident of the United States. You might also qualify for coverage if you are under age 65 but have a disability or End-Stage Renal disease (permanent kidney failure requiring dialysis or transplant). Here are some simple guidelines:

You can get Part A at age 65 without having to pay premiums if:

- You are already receiving retirement benefits from Social Security or the Railroad Retirement Board.
- You are eligible to receive Social Security or Railroad benefits but have not yet filed for them.
- You or your spouse had Medicare-covered government employment.

If you are under 65, you can get Part A without having to pay premiums if:

- You have received Social Security or Railroad Retirement Board disability benefit for 24 months.
- You are a kidney dialysis or kidney transplant patient.

Medicare has two parts:

- Part A (Hospital Insurance). Most people do not have to pay for Part A.
- Part B (Medical Insurance). Most people pay monthly for Part B.

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[82] This section has been adapted from the Official U.S. Site for Medicare Information: **http://www.medicare.gov/Basics/Overview.asp**.

Part A (Hospital Insurance)

Helps Pay For: Inpatient hospital care, care in critical access hospitals (small facilities that give limited outpatient and inpatient services to people in rural areas) and skilled nursing facilities, hospice care, and some home healthcare.

Cost: Most people get Part A automatically when they turn age 65. You do not have to pay a monthly payment called a premium for Part A because you or a spouse paid Medicare taxes while you were working.

If you (or your spouse) did not pay Medicare taxes while you were working and you are age 65 or older, you still may be able to buy Part A. If you are not sure you have Part A, look on your red, white, and blue Medicare card. It will show "Hospital Part A" on the lower left corner of the card. You can also call the Social Security Administration toll free at 1-800-772-1213 or call your local Social Security office for more information about buying Part A. If you get benefits from the Railroad Retirement Board, call your local RRB office or 1-800-808-0772. For more information, call your Fiscal Intermediary about Part A bills and services. The phone number for the Fiscal Intermediary office in your area can be obtained from the following Web site: **http://www.medicare.gov/Contacts/home.asp**.

Part B (Medical Insurance)

Helps Pay For: Doctors, services, outpatient hospital care, and some other medical services that Part A does not cover, such as the services of physical and occupational therapists, and some home healthcare. Part B helps pay for covered services and supplies when they are medically necessary.

Cost: As of 2001, you pay the Medicare Part B premium of $50.00 per month. In some cases this amount may be higher if you did not choose Part B when you first became eligible at age 65. The cost of Part B may go up 10% for each 12-month period that you were eligible for Part B but declined coverage, except in special cases. You will have to pay the extra 10% cost for the rest of your life.

Enrolling in Part B is your choice. You can sign up for Part B anytime during a 7-month period that begins 3 months before you turn 65. Visit your local Social Security office, or call the Social Security Administration at 1-800-772-1213 to sign up. If you choose to enroll in Part B, the premium is usually taken out of your monthly Social Security, Railroad Retirement, or Civil

Service Retirement payment. If you do not receive any of the above payments, Medicare sends you a bill for your part B premium every 3 months. You should receive your Medicare premium bill in the mail by the 10th of the month. If you do not, call the Social Security Administration at 1-800-772-1213, or your local Social Security office. If you get benefits from the Railroad Retirement Board, call your local RRB office or 1-800-808-0772. For more information, call your Medicare carrier about bills and services. The phone number for the Medicare carrier in your area can be found at the following Web site: **http://www.medicare.gov/Contacts/home.asp**. You may have choices in how you get your healthcare including the Original Medicare Plan, Medicare Managed Care Plans (like HMOs), and Medicare Private Fee-for-Service Plans.

Medicaid

Medicaid is a joint federal and state program that helps pay medical costs for some people with low incomes and limited resources. Medicaid programs vary from state to state. People on Medicaid may also get coverage for nursing home care and outpatient prescription drugs which are not covered by Medicare. You can find more information about Medicaid on the HCFA.gov Web site at **http://www.hcfa.gov/medicaid/medicaid.htm**.

States also have programs that pay some or all of Medicare's premiums and may also pay Medicare deductibles and coinsurance for certain people who have Medicare and a low income. To qualify, you must have:

- Part A (Hospital Insurance),
- Assets, such as bank accounts, stocks, and bonds that are not more than $4,000 for a single person, or $6,000 for a couple, and
- A monthly income that is below certain limits.

For more information, look at the Medicare Savings Programs brochure, **http://www.medicare.gov/Library/PDFNavigation/PDFInterim.asp?Language=English&Type=Pub&PubID=10126**. There are also Prescription Drug Assistance Programs available. Find information on these programs which offer discounts or free medications to individuals in need at **http://www.medicare.gov/Prescription/Home.asp**.

NORD's Medication Assistance Programs

Finally, the National Organization for Rare Disorders, Inc. (NORD) administers medication programs sponsored by humanitarian-minded pharmaceutical and biotechnology companies to help uninsured or under-insured individuals secure life-saving or life-sustaining drugs.[83] NORD programs ensure that certain vital drugs are available "to those individuals whose income is too high to qualify for Medicaid but too low to pay for their prescribed medications." The program has standards for fairness, equity, and unbiased eligibility. It currently covers some 14 programs for nine pharmaceutical companies. NORD also offers early access programs for investigational new drugs (IND) under the approved "Treatment INDs" programs of the Food and Drug Administration (FDA). In these programs, a limited number of individuals can receive investigational drugs that have yet to be approved by the FDA. These programs are generally designed for rare diseases or disorders. For more information, visit **www.rarediseases.org**.

Additional Resources

In addition to the references already listed in this chapter, you may need more information on health insurance, hospitals, or the healthcare system in general. The NIH has set up an excellent guidance Web site that addresses these and other issues. Topics include:[84]

- Health Insurance: **http://www.nlm.nih.gov/medlineplus/healthinsurance.html**
- Health Statistics: **http://www.nlm.nih.gov/medlineplus/healthstatistics.html**
- HMO and Managed Care: **http://www.nlm.nih.gov/medlineplus/managedcare.html**
- Hospice Care: **http://www.nlm.nih.gov/medlineplus/hospicecare.html**
- Medicaid: **http://www.nlm.nih.gov/medlineplus/medicaid.html**
- Medicare: **http://www.nlm.nih.gov/medlineplus/medicare.html**
- Nursing Homes and Long-Term Care: **http://www.nlm.nih.gov/medlineplus/nursinghomes.html**

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[83] Adapted from NORD: **http://www.rarediseases.org/programs/medication**.

[84] You can access this information at http://www.nlm.nih.gov/medlineplus/healthsystem.html.

- Patient's Rights, Confidentiality, Informed Consent, Ombudsman Programs, Privacy and Patient Issues: **http://www.nlm.nih.gov/medlineplus/patientissues.html**
- Veteran's Health, Persian Gulf War, Gulf War Syndrome, Agent Orange: **http://www.nlm.nih.gov/medlineplus/veteranshealth.html**

ONLINE GLOSSARIES

The Internet provides access to a number of free-to-use medical dictionaries and glossaries. The National Library of Medicine has compiled the following list of online dictionaries:

- ADAM Medical Encyclopedia (A.D.A.M., Inc.), comprehensive medical reference: **http://www.nlm.nih.gov/medlineplus/encyclopedia.html**
- MedicineNet.com Medical Dictionary (MedicineNet, Inc.): **http://www.medterms.com/Script/Main/hp.asp**
- Merriam-Webster Medical Dictionary (Inteli-Health, Inc.): **http://www.intelihealth.com/IH/**
- Multilingual Glossary of Technical and Popular Medical Terms in Eight European Languages (European Commission) - Danish, Dutch, English, French, German, Italian, Portuguese, and Spanish: **http://allserv.rug.ac.be/~rvdstich/eugloss/welcome.html**
- On-line Medical Dictionary (CancerWEB): **http://www.graylab.ac.uk/omd/**
- Technology Glossary (National Library of Medicine) - Health Care Technology: **http://www.nlm.nih.gov/nichsr/ta101/ta10108.htm**
- Terms and Definitions (Office of Rare Diseases): **http://rarediseases.info.nih.gov/ord/glossary_a-e.html**

Beyond these, MEDLINEplus contains a very user-friendly encyclopedia covering every aspect of medicine (licensed from A.D.A.M., Inc.). The ADAM Medical Encyclopedia can be accessed via the following Web site address: **http://www.nlm.nih.gov/medlineplus/encyclopedia.html**. ADAM is also available on commercial Web sites such as Web MD (**http://my.webmd.com/adam/asset/adam_disease_articles/a_to_z/a**) and drkoop.com (**http://www.drkoop.com/**). Topics of interest can be researched by using keywords before continuing elsewhere, as these basic definitions and concepts will be useful in more advanced areas of research. You may choose to print various pages specifically relating to gastrointestinal carcinoid tumors and keep them on file.

Online Dictionary Directories

The following are additional online directories compiled by the National Library of Medicine, including a number of specialized medical dictionaries and glossaries:

- Medical Dictionaries: Medical & Biological (World Health Organization): **http://www.who.int/hlt/virtuallibrary/English/diction.htm#Medical**
- MEL-Michigan Electronic Library List of Online Health and Medical Dictionaries (Michigan Electronic Library): **http://mel.lib.mi.us/health/health-dictionaries.html**
- Patient Education: Glossaries (DMOZ Open Directory Project): **http://dmoz.org/Health/Education/Patient_Education/Glossaries/**
- Web of Online Dictionaries (Bucknell University): **http://www.yourdictionary.com/diction5.html#medicine**

GASTROINTESTINAL CARCINOID TUMORS GLOSSARY

The following is a complete glossary of terms used in this sourcebook. The definitions are derived from official public sources including the National Institutes of Health [NIH] and the European Union [EU]. After this glossary, we list a number of additional hardbound and electronic glossaries and dictionaries that you may wish to consult.

Adenocarcinomas: A malignant tumor of the epithelial cells of a gland which typically metastasizes by way of the lymphatics. [NIH]

Attenuated: Strain with weakened or reduced virulence. [NIH]

Compassionate: A process for providing experimental drugs to very sick patients who have no treatment options. [NIH]

Consultation: A deliberation between two or more physicians concerning the diagnosis and the proper method of treatment in a case. [NIH]

Consumption: Pulmonary tuberculosis. [NIH]

Contraindications: Any factor or sign that it is unwise to pursue a certain kind of action or treatment, e. g. giving a general anesthetic to a person with pneumonia. [NIH]

Cytotoxicity: Quality of being capable of producing a specific toxic action upon cells of special organs. [NIH]

Davidson: Light seen through the pupil when a light source is held in the mouth. [NIH]

Diploid: Having two sets of chromosomes. [NIH]

EBV: A DNA virus of the herpes group discovered in cultures of Burkitt's lymphoma cells. EBV is the cause of infectious mononucleosis, and it has an integration site on human chromosome 14. [NIH]

Effector: It is often an enzyme that converts an inactive precursor molecule into an active second messenger. [NIH]

Endoscopic: A technique where a lateral-view endoscope is passed orally to the duodenum for visualization of the ampulla of Vater. [NIH]

Epitope: A molecule or portion of a molecule capable of binding to the combining site of an antibody. For every given antigenic determinant, the body can construct a variety of antibody-combining sites, some of which fit almost perfectly, and others which barely fit. [NIH]

Epstein: Failure of the upper eyelid to move downward on downward

movement of the eye, occurring in premature and nervous infants. [NIH]

Fat: Total lipids including phospholipids. [NIH]

Feces: The undigested residue of food and other forms of waste matter and alimentary refuse discharged from the bowel during defecation. [NIH]

Genetics: The biological science that deals with the phenomena and mechanisms of heredity. [NIH]

Gould: Turning of the head downward in walking to bring the image of the ground on the functioning position of the retina, in destructive disease of the peripheral retina. [NIH]

Growth: The progressive development of a living being or part of an organism from its earliest stage to maturity. [NIH]

Hereditary: Of, relating to, or denoting factors that can be transmitted genetically from one generation to another. [NIH]

Hospice: Institution dedicated to caring for the terminally ill. [NIH]

Host: Any animal that receives a transplanted graft. [NIH]

Hybridoma: A hybrid cell resulting from the fusion of a specific antibody-producing spleen cell with a myeloma cell. [NIH]

Initiation: Mutation induced by a chemical reactive substance causing cell changes; being a step in a carcinogenic process. [NIH]

Jefferson: A fracture produced by a compressive downward force that is transmitted evenly through occipital condyles to superior articular surfaces of the lateral masses of C1. [NIH]

Joint: The point of contact between elements of an animal skeleton with the parts that surround and support it. [NIH]

Linkage: The tendency of two or more genes in the same chromosome to remain together from one generation to the next more frequently than expected according to the law of independent assortment. [NIH]

Lymphatic: The tissues and organs, including the bone marrow, spleen, thymus, and lymph nodes, that produce and store cells that fight infection and disease. [NIH]

Lymphokine: A soluble protein produced by some types of white blood cell that stimulates other white blood cells to kill foreign invaders. [NIH]

Lymphoma: Tumor of lymphatic tissue. [NIH]

Mitotic: Cell resulting from mitosis. [NIH]

Modification: A change in an organism, or in a process in an organism, that is acquired from its own activity or environment. [NIH]

Monoamine: Enzyme that breaks down dopamine in the astrocytes and microglia. [NIH]

Monoclonal: An antibody produced by culturing a single type of cell. It therefore consists of a single species of immunoglobulin molecules. [NIH]

Mononuclear: A cell with one nucleus. [NIH]

MRNA: The RNA molecule that conveys from the DNA the information that is to be translated into the structure of a particular polypeptide molecule. [NIH]

Nerve: A cordlike structure of nervous tissue that connects parts of the nervous system with other tissues of the body and conveys nervous impulses to, or away from, these tissues. [NIH]

Nihilism: The delusion of non-existence. [NIH]

Nucleus: A body of specialized protoplasm found in nearly all cells and containing the chromosomes. [NIH]

Outpatient: A patient who is not an inmate of a hospital but receives diagnosis or treatment in a clinic or dispensary connected with the hospital. [NIH]

Pancreatic cancer: Cancer of the pancreas, a salivary gland of the abdomen. [NIH]

Promoter: A chemical substance that increases the activity of a carcinogenic process. [NIH]

Protocol: The detailed plan for a clinical trial that states the trial's rationale, purpose, drug or vaccine dosages, length of study, routes of administration, who may participate, and other aspects of trial design. [NIH]

Reductase: Enzyme converting testosterone to dihydrotestosterone. [NIH]

Resolving: The ability of the eye or of a lens to make small objects that are close together, separately visible; thus revealing the structure of an object. [NIH]

Schizophrenia: A mental disorder characterized by a special type of disintegration of the personality. [NIH]

Specialist: In medicine, one who concentrates on 1 special branch of medical science. [NIH]

Specificity: Degree of selectivity shown by an antibody with respect to the number and types of antigens with which the antibody combines, as well as with respect to the rates and the extents of these reactions. [NIH]

Therapeutics: The branch of medicine which is concerned with the treatment of diseases, palliative or curative. [NIH]

Thorax: A part of the trunk between the neck and the abdomen; the chest. [NIH]

Transcriptase: An enzyme which catalyses the synthesis of a complementary mRNA molecule from a DNA template in the presence of a mixture of the four ribonucleotides (ATP, UTP, GTP and CTP). [NIH]

Translation: The process whereby the genetic information present in the linear sequence of ribonucleotides in mRNA is converted into a corresponding sequence of amino acids in a protein. It occurs on the ribosome and is unidirectional. [NIH]

Vector: Plasmid or other self-replicating DNA molecule that transfers DNA between cells in nature or in recombinant DNA technology. [NIH]

Vitro: Descriptive of an event or enzyme reaction under experimental investigation occurring outside a living organism. Parts of an organism or microorganism are used together with artificial substrates and/or conditions. [NIH]

Wheezing: Breathing with a rasp or whistling sound. It results from constriction or obstruction of the throat, pharynx, trachea, or bronchi. [NIH]

General Dictionaries and Glossaries

While the above glossary is essentially complete, the dictionaries listed here cover virtually all aspects of medicine, from basic words and phrases to more advanced terms (sorted alphabetically by title; hyperlinks provide rankings, information and reviews at Amazon.com):

- **The Cancer Dictionary** by Roberta Altman, Michael J., Md Sarg; Paperback - 368 pages, 2nd Revised edition (November 1999), Checkmark Books; ISBN: 0816039542; **http://www.amazon.com/exec/obidos/ASIN/0816039542/icongroupinterna**
- **Dictionary of Medical Acronymns & Abbreviations** by Stanley Jablonski (Editor), Paperback, 4th edition (2001), Lippincott Williams & Wilkins Publishers, ISBN: 1560534605, **http://www.amazon.com/exec/obidos/ASIN/1560534605/icongroupinterna**
- **Dictionary of Medical Terms : For the Nonmedical Person (Dictionary of Medical Terms for the Nonmedical Person, Ed 4)** by Mikel A. Rothenberg, M.D, et al, Paperback - 544 pages, 4th edition (2000), Barrons Educational Series, ISBN: 0764112015, **http://www.amazon.com/exec/obidos/ASIN/0764112015/icongroupinterna**
- **A Dictionary of the History of Medicine** by A. Sebastian, CD-Rom edition (2001), CRC Press-Parthenon Publishers, ISBN: 185070368X, **http://www.amazon.com/exec/obidos/ASIN/185070368X/icongroupinterna**

- **Dorland's Illustrated Medical Dictionary (Standard Version)** by Dorland, et al, Hardcover - 2088 pages, 29th edition (2000), W B Saunders Co, ISBN: 0721662544, **http://www.amazon.com/exec/obidos/ASIN/0721662544/icongroupinterna**
- **Dorland's Electronic Medical Dictionary** by Dorland, et al, Software, 29th Book & CD-Rom edition (2000), Harcourt Health Sciences, ISBN: 0721694934, **http://www.amazon.com/exec/obidos/ASIN/0721694934/icongroupinterna**
- **Dorland's Pocket Medical Dictionary (Dorland's Pocket Medical Dictionary, 26th Ed)** Hardcover - 912 pages, 26th edition (2001), W B Saunders Co, ISBN: 0721682812, **http://www.amazon.com/exec/obidos/ASIN/0721682812/icongroupinterna/103-4193558-7304618**
- **Melloni's Illustrated Medical Dictionary (Melloni's Illustrated Medical Dictionary, 4th Ed)** by Melloni, Hardcover, 4th edition (2001), CRC Press-Parthenon Publishers, ISBN: 85070094X, **http://www.amazon.com/exec/obidos/ASIN/85070094X/icongroupinterna**
- **Stedman's Electronic Medical Dictionary Version 5.0 (CD-ROM for Windows and Macintosh, Individual)** by Stedmans, CD-ROM edition (2000), Lippincott Williams & Wilkins Publishers, ISBN: 0781726328, **http://www.amazon.com/exec/obidos/ASIN/0781726328/icongroupinterna**
- **Stedman's Medical Dictionary** by Thomas Lathrop Stedman, Hardcover - 2098 pages, 27th edition (2000), Lippincott, Williams & Wilkins, ISBN: 068340007X, **http://www.amazon.com/exec/obidos/ASIN/068340007X/icongroupinterna**
- **Stedman's Oncology Words** by Beverly J. Wolpert (Editor), Stedmans; Paperback - 502 pages, 3rd edition (June 15, 2000), Lippincott, Williams & Wilkins; ISBN: 0781726549; **http://www.amazon.com/exec/obidos/ASIN/0781726549/icongroupinterna**
- **Tabers Cyclopedic Medical Dictionary (Thumb Index)** by Donald Venes (Editor), et al, Hardcover - 2439 pages, 19th edition (2001), F A Davis Co., ISBN: 0803606540, **http://www.amazon.com/exec/obidos/ASIN/0803606540/icongroupinterna**

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