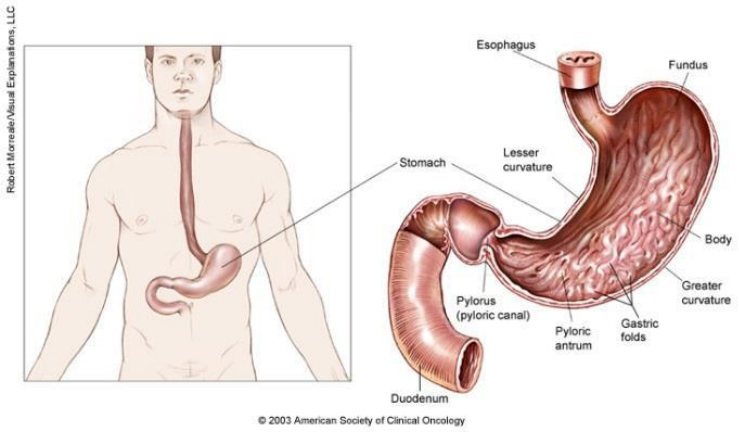
Cancer Association of South Africa (CANSA)

Research • Educate • Support

Fact Sheet on Stomach Cancer

Introduction

The stomach is a muscular, hollow, dilated part of the digestive system which functions as an important organ of the digestive tract of humans, in some animals, including vertebrates, echinoderms, insects (mid-gut), and molluscs. It is involved in the second phase of digestion, following mastication (chewing).



[Picture Credit: Stomach]

The stomach is located between the oesophagus and the small intestine. It secretes protein-digesting enzymes called protease and strong acids to aid in food digestion, (sent to it via oesophageal peristalsis) through smooth muscular contortions (called segmentation) before sending partially digested food (chyme) to the small intestines. The word *stomach* is derived from the Latin *stomachus* which is derived from the Greek word *stomachos*, ultimately from *stoma* (στόμα), "mouth". The words *gastro-* and *gastric* (meaning related to the stomach) are both derived from the Greek word *gaster* (γαστήρ) (Wikipedia).

Stomach Cancer

Stomach cancer, also called *gastric cancer*, is a cancer that starts in the stomach. It occurs when cells in the stomach change and start to grow quickly and in uncontrolled fashion. It can then form a tumour. A malignant tumour is also known as cancer.

Stomach cancer should not be confused with other cancers that can occur in the abdomen, like cancer of the colon (large intestine), liver, pancreas, or small intestine because these cancers may have different symptoms, different outlooks, and different treatments.

Stomach cancers tend to develop slowly over many years. Before a true cancer develops, pre-cancerous changes often occur in the inner lining (mucosa) of the stomach. These early

changes rarely cause symptoms and often go undetected. Cancers starting in different sections of the stomach may cause different symptoms and tend to have different outcomes. The cancer's location can also affect the treatment options.
(American Cancer Society; Irish Cancer Society).

Incidence of Stomach Cancer in South Africa
According to the National Cancer Registry (2012) the following number of stomach cancer cases was histologically diagnosed in South Africa during 2012:

Group - Males 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All males	796	1:177	2,16%
Asian males	46	1:106	5,49%
Black males	294	1:318	2,52%
Coloured males	143	1:77	3,29%
White males	313	1:106	1,56%

Group - Females 2012	Actual No of Cases	Estimated Lifetime Risk	Percentage of All Cancers
All females	427	1:488	1,13%
Asian females	27	1:311	2,46%
Black females	181	1:788	1,09%
Coloured females	70	1:284	1,67%
White females	150	1:261	0,94%

The frequency of histologically diagnosed cases of stomach cancer in South Africa for 2012 was as follows (National Cancer Registry, 2012):

Group - Males 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All males	0	4	21	79	185	221	182	86
Asian males	0	0	0	7	10	12	12	2
Black males	0	3	12	36	83	70	53	16
Coloured males	0	1	2	17	28	46	32	13
White males	0	0	5	16	61	87	81	54

Group - Females 2012	0 – 19 Years	20 – 29 Years	30 – 39 Years	40 – 49 Years	50 – 59 Years	60 – 69 Years	70 – 79 Years	80+ Years
All females	1	5	29	48	67	109	100	54
Asian females	0	0	2	3	7	4	7	1
Black females	1	4	14	30	26	40	38	12
Coloured females	0	0	5	8	15	16	14	9
White females	0	1	6	6	18	46	39	30

N.B. In the event that the totals in any of the above tables do not tally, this may be the result of uncertainties as to the age, race or sex of the individual. The totals for 'all males' and 'all females', however, always reflect the correct totals.

Risk Factors of Stomach Cancer
The following are known risk factors for stomach cancer:

- having a family history of stomach cancer - if a family member has had stomach cancer, it can increase one's risk.
- having an infection of the stomach caused by the bacteria called *Helicobacter pylori*

- having or having had a polyp larger than 2cm in the stomach
- having inflammation and swelling of the stomach for a long time (chronic atrophic gastritis
- *Helicobacter pylori* infection - if these bacteria in the stomach are left untreated, the risk for stomach cancer increases. The risk further increases if the person smoked and has a poor diet as well
- having a history of stomach lymphoma - people who have had a certain type of lymphoma of the stomach known as *mucosa-associated lymphoid tissue (MALT) lymphoma* have an increased risk of getting adenocarcinoma of the stomach. This is probably because MALT lymphoma of the stomach is caused by infection with *H pylori* bacteria
- smoking tobacco products
- age - it is more likely to occur in people over the age of 55
- gender - it is more common in men than women
- smoking tobacco products - people who smoke are twice as likely to develop stomach cancer
- alcohol consumption - alcohol has been declared a Group 1 carcinogen (cancer causing chemical) by the International Agency for Research on Cancer (IARC) in 1988
- diet - a diet low in fresh fruit and vegetables can increase the risk of stomach cancer
- salt intake - a diet high in salt and preservatives can increase the risk of stomach cancer
- chronic gastritis/ulcers/acid reflux - if a person has a history of gastritis, stomach ulcers or acid reflux the risk may increase as well
- Barrett's oesophagus - in this condition, abnormal cells develop in the lining of the lower end of the oesophagus where it joins the stomach. A small number of people with this condition develop stomach cancer
- pernicious anaemia - if the person lacks Vitamin B_{12}, it can cause pernicious anaemia, which affects the lining of your stomach and increases the risk for stomach cancer
- hereditary conditions - these are conditions run in families. For example, if one has small benign growths in one's stomach, it can increase the risk for stomach cancer. These conditions are usually rare
- geography - worldwide, stomach cancer is more common in Japan, China, Southern and Eastern Europe, and South and Central America. This disease is less common in Northern and Western Africa, South Central Asia, and North America
- eating red meat and processed foods - an increased risk for stomach cancer is seen in people with diets that have large amounts of smoked foods, salted fish, red meat, and pickled vegetables. Nitrates and nitrites are substances commonly found in cured meats. It can be converted by certain bacteria, such as *H pylori*, into compounds that have been shown to cause stomach cancer in laboratory animals.
- being overweight or obese - being overweight or obese is a possible cause of cancers of the cardia (the upper part of the stomach nearest the oesophagus) - the link is not yet clear
- having type A blood - blood type groups refer to certain substances that are normally present on the surface of red blood cells and some other types of cells. These groups are important in matching blood for transfusions. For unknown reasons, people with type A blood have a higher risk of getting stomach cancer
- Epstein-Barr (EBV) virus infection – this virus causes infectious mononucleosis. Almost all adults have been infected with this virus at some time in their lives, usually as children or teens. EBV has been linked to some forms of lymphoma. It is also found in the cancer cells of about 5% to 10% of people with stomach cancer. These people tend to have a slower growing, less aggressive cancer with a lower tendency

to spread. EBV has been found in some stomach cancer cells, but it is not yet clear if this virus actually causes stomach cancer

- certain occupations - workers in the coal, metal, nickel refining, rubber, timber and asbestos industries seem to have a higher risk of getting stomach cancer
- inherited cancer syndromes – persons with the following inherited cancer syndromes have a higher risk for stomach cancer:

    - Hereditary diffuse gastric cancer - this inherited syndrome greatly increases the risk of developing stomach cancer. This condition is rare, but the lifetime stomach cancer risk among affected people is about 70% to 80%. Women with this syndrome also have an increased risk of getting a certain type of breast cancer. This condition is caused by mutations (defects) in the *CDH1* gene. Some cancer centres can test for these gene mutations
    - Hereditary non-polyposis colorectal cancer (HNPCC) - HNPCC, also known as *Lynch syndrome*, is an inherited genetic disorder that increases the risk for colorectal cancer. People with this syndrome also have an increased risk of getting stomach cancer (as well as some other cancers). In most cases, this disorder is caused by a defect in either the *MLH1* or *MSH2* gene, but other genes can cause HNPCC, including *MLH3*, *MSH6*, *TGFBR2*, *PMS1* and *PMS2*
    - Familial adenomatous polyposis (FAP) - in FAP syndrome, people get many polyps in the colon and sometimes in the stomach and intestines as well. People with this syndrome are at greatly increased risk for getting colorectal cancer and have a slightly increased risk of getting stomach cancer. It is caused by mutations in the *APC* gene
    - BRCA1 and BRCA2 - people who carry mutations of the inherited breast cancer genes *BRCA1* or *BRCA2* may also have a higher rate of stomach cancer
    - Li-Fraumeni syndrome - people with this syndrome have an increased risk of several types of cancer, including developing stomach cancer at a relatively young age. Li-Fraumeni syndrome is caused by a mutation in the *TP53* gene
    - Peutz-Jeghers syndrome (PJS) - people with this condition develop polyps in the stomach and intestines, as well as in other areas including the nose, the airways of the lungs, and the bladder. The polyps in the stomach and intestines are a special type called *hamartomas*. They can cause problems like bleeding or blockage of the intestines. PJS can also cause dark freckle-like spots on the lips, inner cheeks and other areas. People with PJS have an increased risk of cancers of the breast, colon, pancreas, stomach, and several other organs. This syndrome is caused by mutations in the gene *STK1*

(PubMed Health; Irish Cancer Society; American Cancer Society; National Cancer Institute).

Signs and Symptoms of Stomach Cancer

Signs and symptoms of stomach cancer may include:

- Fatigue
- Bloated feeling after eating
- Feeling full after eating little
- Heartburn
- Indigestion and stomach discomfort

- Nausea which may be mild
- Loss of appetite
- Sensation of food getting stuck in the throat with eating
- Stomach pain
- Vomiting, particularly vomiting up of solid food shortly after eating
- Weight loss
- Diarrhoea or constipation

In cases of more advanced cancer, a patient may present with:

- Discomfort in the upper or middle part of the abdomen
- Blood in the stool (which appears as black, tarry stools)
- Vomiting or vomiting blood
- Presence of blood in the stools
- Black, tarry stools (due to presence of digested blood)
- Unexplained weight loss
- Pain or bloating in the stomach after eating
- Weakness or fatigue associated with mild anaemia (a deficiency in red blood cells)

(Mayo Clinic; National Cancer Institute; MD Anderson Cancer Center;).

Diagnosis of Stomach Cancer

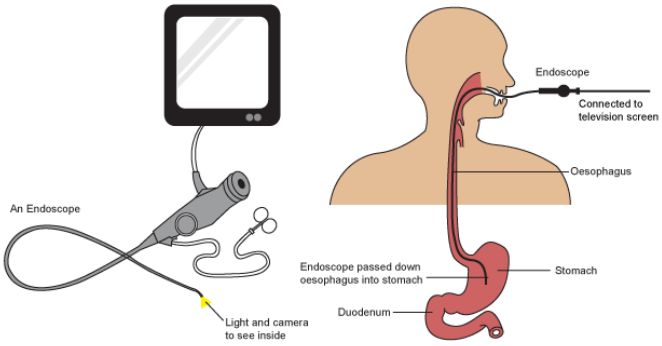
Scientists are not sure exactly what causes stomach cancer. There is a strong correlation between a diet high in smoked, salted and pickled foods and stomach cancer. As the use of refrigeration for preserving foods has increased around the world, the rates of stomach cancer have declined.

In general, cancer begins when an error (mutation) occurs in the DNA of a cell. The mutation causes the cell to grow and divide at a rapid rate and to continue living when normal cells would die. The accumulating cancerous cells form a tumour that can invade nearby structures. And cancer cells can break off from the tumour to spread throughout the body.

In addition to a physical examination, the following tests may be used to diagnose stomach cancer:

- Biopsy - a biopsy is the removal of a small amount of tissue for examination under a microscope. Other tests can suggest that cancer is present, but only a biopsy can make a definite diagnosis. The sample removed from the biopsy is analysed by a pathologist (a doctor who specialises in interpreting laboratory tests and evaluating cells, tissues, and organs to diagnose disease)

[Picture Credit: Endoscopy]



- Endoscopy - this test allows the doctor to see the inside of the body. The patient may be sedated, and the doctor inserts a thin, lighted, flexible tube called a gastroscope or endoscope through the mouth, down the oesophagus, and into

the stomach and small bowel. The doctor can remove a sample of tissue during an endoscopy and check it for evidence of cancer

- Endoscopic ultrasound - this test is similar to an endoscopy, but the gastroscope has a small ultrasound probe on the end that produces a detailed image of the stomach wall. An ultrasound uses sound waves to create a picture of the internal organs. The ultrasound image helps doctors determine how far the cancer has spread into the stomach and nearby lymph nodes, tissue, and organs, such as the liver

- X-ray - an x-ray is a way to create a picture of the structures inside of the body using a small amount of radiation

- Barium swallow - in a barium swallow, a person swallows a liquid containing barium and a series of x-rays are taken. Barium coats the lining of the oesophagus, stomach, and intestines so tumours or other abnormalities are easier to see on the x-ray

- Computed tomography (CT or CAT) scan - a CT scan creates a three-dimensional picture of the inside of the body with an x-ray machine. A computer then combines these images into a detailed, cross-sectional view that shows any abnormalities or tumours. Sometimes, a contrast medium (a special dye) is injected into a patient's vein to provide better detail

- Magnetic resonance imaging (MRI) - an MRI uses magnetic fields, not x-rays, to produce detailed images of the body. A contrast medium may be injected into the patient's vein to create a clearer picture

- Positron emission tomography (PET) scan - a PET scan is a way to create pictures of organs and tissues inside the body. A small amount of a radioactive substance is injected into the patient's body. This substance is absorbed mainly by organs and tissues that use the most energy. Because cancer tends to use energy actively, it absorbs more of the radioactive substance. A scanner then detects this substance to produce images of the inside of the body

- Laparoscopy - a laparoscopy is a minimally invasive surgery in which the surgeon inserts a scope into the abdominal cavity to evaluate spread of the stomach cancer to the lining of the abdominal cavity or liver. This pattern of cancer spread is not detected by CT or PET scan

(Cancer.Net).

Types of Stomach Cancer

The cells that form the tumour determine the type of stomach cancer. The type of cancer cells in the stomach helps determine the treatment options. Types of stomach cancer include:

- Cancer that begins in the glandular cells (adenocarcinoma). The glandular cells that line the inside of the stomach secrete a protective layer of mucus to shield the lining of the stomach from the acidic digestive juices. Adenocarcinoma accounts for the great majority of all stomach cancers

- Cancer that begins in immune system cells (lymphoma). The walls of the stomach contain a small number of immune system cells that can develop cancer. Lymphoma in the stomach is rare.

- Cancer that begins in hormone-producing cells (carcinoid cancer). Hormone-producing cells can develop carcinoid cancer. Carcinoid cancer in the stomach is rare

- Cancer that begins in nervous system tissues. A gastrointestinal stromal tumour (GIST) begins in specific nervous system cells found in your stomach. GIST is a rare form of stomach cancer

Because the other types of stomach cancer are rare, when people use the term 'stomach cancer' they generally are referring to adenocarcinoma.
(Mayo Clinic).

Reducing the Risk for Stomach Cancer
Screening programmes are successful in detecting disease in the early stages in parts of the world where the risk of gastric cancer is high. The value of screening in countries with low rates of gastric cancer is not clear.

The following may help reduce the risk of gastric cancer:
- Do not smoke
- Eat healthy foods rich in fruits and vegetables. Eat at least five (5) portions of vegetables and fresh fruit (in season) every day
- Take medicines to treat reflux disease (heartburn), if it is present
- Take antibiotics if are diagnosed with *H. pylori* infection
- Limit salt intake
- Limit the intake of meat and processed foods
- Limit alcohol intake

(PubMed Health; Life is Beautiful).

Staging of Stomach Cancer
One tool that doctors use to describe the stage is the TNM system developed by the American Joint Committee on Cancer (AJCC). This system judges three factors: the tumour itself, the lymph nodes around the tumour, and if the tumour has spread to the rest of the body. The results are combined to determine the stage of cancer for each person. There are five stages: stage 0 (zero) and stages I through IV (one through four). The stage provides a common way of describing the cancer, so doctors can work together to plan the best treatments.

TNM is an abbreviation for tumour (**T**), node (**N**), and metastasis (**M**). Doctors look at these three factors to determine the stage of cancer:

- How far has the primary tumour extended into the stomach? (Tumour, T)
- Has the tumour spread to the lymph nodes? (Node, N)
- Has the cancer metastasised to other parts of the body? (Metastasis, M)

Using the TNM system, the “T” plus a letter or number (0 to 4) is used to describe how far the tumour has extended into the stomach. Some stages are also divided into smaller groups that help describe the tumour in even more detail.
(Cncer.Net).

Resectable vs Unresectable Stomach Cancer
The AJCC staging system provides a detailed summary of how far a stomach cancer has spread. For treatment purposes, however, doctors are often more concerned about whether the tumour can be removed (resected) with surgery or not.

- Resectable cancers are those the doctor believes can be completely removed during surgery.

- Unresectable cancers cannot be removed completely. This might be because the tumour has grown too far into nearby organs or lymph nodes, it has grown too close to major blood vessels, it has spread to distant parts of the body, or the patient is not healthy enough for surgery.

There is no distinct dividing line between resectable and unresectable in terms of the TNM stage of the cancer but earlier stage cancers are more likely to be resectable.
(American Cancer society).

Prognosis (Outlook)
The prognosis of patients with gastric cancer is related to the extent of the tumour and includes both involvement of lymph nodes and direct extension of the tumour beyond the gastric wall. Tumour grade may also provide some prognostic information.

In localised distal gastric cancer, more than 50% of patients can be cured. The overall survival rate in most patients at 5 years ranges from almost no survival for patients with disseminated disease to almost 50% survival for patients with localised distal gastric cancers confined to resectable regional disease. Even with apparent localised disease, the 5-year survival rate of patients with proximal gastric cancer is only 10% to 15%. Although the treatment of patients with disseminated gastric cancer may result in palliation of symptoms and some prolongation of survival, long remissions are uncommon (National Cancer Institute).

Outlook varies based on how much the cancer has spread by the time of diagnosis. Tumours in the lower stomach are cured more often than those in the higher stomach. Chances of a cure also depend on how far the tumour has invaded the stomach wall and whether lymph nodes are involved.
When the tumour has spread outside the stomach, a cure is often not possible. In this case, the goal of treatment is to improve symptoms (PubMed Health).

Treatment of Stomach Cancer
Once a patient has been diagnosed with cancer and staged, there is a lot to think about before patient and doctors can choose a treatment plan.

The main treatments for stomach cancer are:

- Surgery
- Chemotherapy
- Targeted therapy
- Radiation therapy

Often the best approach uses 2 or more of the above treatment methods.

It is good to have a team of doctors with different specialties involved in the treatment consisting of:

- A gastroenterologist: a doctor who specialises in treatment of diseases of the digestive system
- A surgical oncologist: a doctor who treats cancer with surgery.
- A medical oncologist: a doctor who treats cancer with medicines such as chemotherapy
- A radiation oncologist: a doctor who treats cancer with radiation therapy

Surgery - Surgery to remove the stomach (gastrectomy) is the only treatment that can cure the gastric adenocarcinoma. Radiation therapy and chemotherapy may help. Chemotherapy and radiation therapy after surgery may improve the chance of a cure.

For patients who cannot have surgery, chemotherapy or radiation can improve symptoms and may prolong survival, but will likely not cure the cancer. For some patients, a surgical bypass procedure may relieve symptoms. The goal of surgery is to remove all of the stomach cancer and a margin of healthy tissue, when possible.

Options include:

- Removing early-stage tumours from the stomach lining. Very small cancers limited to the inside lining of the stomach may be removed using endoscopy in a procedure called endoscopic mucosal resection. The endoscope is a lighted tube with a camera that's passed down the throat into the stomach. The doctor uses special tools to remove the cancer and a margin of healthy tissue from the stomach lining.

- Removing a portion of the stomach (subtotal gastrectomy). During subtotal gastrectomy, the surgeon removes only the portion of the stomach affected by the cancer.

- Removing the entire stomach (total gastrectomy). Total gastrectomy involves removing the entire stomach and some surrounding tissue. The oesophagus is then connected directly to the small intestine to allow food to move through your digestive system.
- Surgery to relieve signs and symptoms. Removing part of the stomach may relieve signs and symptoms of a growing tumour in people with advanced stomach cancer. In this case, surgery cannot cure stomach cancer but it can make the person more comfortable.

Surgery carries a risk of bleeding and infection. If all or part of your stomach is removed, you may experience digestive problems.

Chemotherapy - Chemotherapy uses anti-cancer (cytotoxic) drugs to destroy cancer cells. It works by disrupting the growth of cancer cells. The drugs circulate in the bloodstream throughout the body.

For stomach cancer, one may have chemotherapy:

- Before and after surgery
- To reduce or control symptoms in advanced cancer
- To slow an advanced cancer down

One may be given chemotherapy for stomach cancer

- As an injection
- Through a drip into the arm
- Through a pump as a slow continuous infusion
- As tablets

How a patient receives his/her chemotherapy will depend on the particular drug or combination of drugs that are given. The patient may have a combination of drip, injections and tablets.

Chemotherapy before and after surgery - If the patient has stomach cancer that can be removed, he/she is most likely to have chemotherapy both before and after surgery. This is called peri-operative chemotherapy. Chemotherapy helps to reduce the size of the cancer making it easier to remove. It also reduces the chances of the cancer coming back. Chemotherapy does have side effects, and not everyone is fit enough to have it.

Radiation Therapy - Radiation therapy uses high-energy rays or particles to kill cancer cells in a specific area of the body. External beam radiation therapy is the type of radiation therapy often used to treat stomach cancer. This treatment focuses the radiation on the cancer from a machine outside the body. Having this type of radiation therapy is like having an x-ray, except each treatment lasts longer, and the patient usually receives five treatments per week over a period of weeks or months. Following surgery, radiation therapy can be used to kill very small remnants of the cancer that cannot be seen and removed during surgery.

Radiation therapy - especially when combined with certain chemotherapy drugs may delay or prevent cancer from coming back after surgery and may help patients live longer. Radiation therapy can also be used to ease the symptoms of advanced stomach cancer such as pain, bleeding and eating problems.

Side effects from radiation therapy for stomach cancer can include:

- Mild skin problems at the site where the radiation was aimed
- Nausea and vomiting
- Diarrhoea
- Fatigue
- Low blood cell counts

Side effects usually go away within several weeks after treatment is finished. When radiation is given with chemotherapy, side effects are often worse.

Targeted Therapy - Targeted therapy uses drugs that attack specific abnormalities within cancer cells. Targeted drugs are used to treat a rare form of stomach cancer called gastrointestinal stromal tumor. Targeted drugs used to treat this cancer include imatinib (Gleevec) and sunitinib (Sutent).

Gene therapy - Gene therapy is a personalised medicine approach that allows scientists to attack the specific causes of each stomach cancer individually.
(American Cancer Society; PubMed Health; Mayo Clinic; MD Anderson Cancer Center; Cancer Research UK; Da Vinci Surgery).

Changing of Lifestyle after Stomach Cancer Diagnosis
For many people, a diagnosis of cancer helps them focus on their health in ways they may not have thought much about in the past.

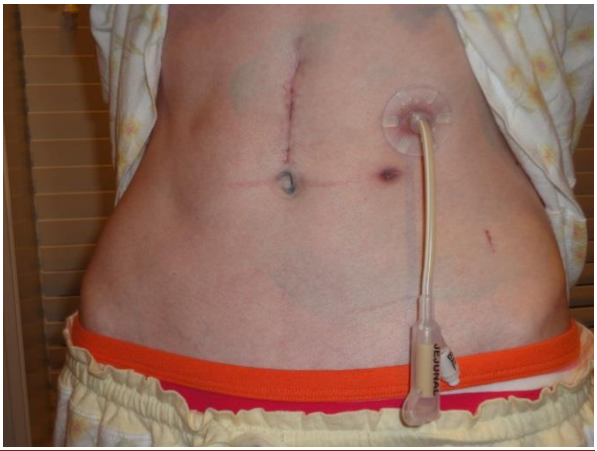
Eating right can be hard for anyone, but it can get even tougher during and after cancer treatment. This is especially true for cancers that affect the digestive tract, such as stomach cancer. The cancer or its treatment can affect how one eats and absorbs foodstuffs. Nausea can be a problem from some treatments. The patient may also lose his/her appetite for a while and lose weight when they do not want to.

During treatment: If losing weight or having trouble eating during treatment, eat what appeals at the time. Patients are advised to eat what they can, when they can. It helps to eat small portions every 2 to 3 hours. Patients are usually referred to a dietician, an expert in nutrition, to assist on how to fight some of the side effects of the treatment.

After treatment: If part or all of the stomach has been removed, the patient might need to eat smaller amounts of food more often. The doctor or nutritionist may also recommend that the patient stays upright for some time after eating. The health care team will help adjust the diet if a particular patient is having problems eating.

Some patients have problems with nausea, diarrhoea, sweating, and flushing after eating. This is called *dumping syndrome*. When part or all of the stomach is removed, the food that is swallowed quickly passes into the intestine, leading to these symptoms after eating. These symptoms often get better over time.

Some people may need nutritional supplements to help make sure they get the nutrition they need. Some people may even need a feeding tube, usually called a *jejunostomy tube (*or *J-tube)*, put into the small intestine. This is done through a small hole in the skin over the abdomen during a minor operation. A J-tube allows liquid nutrition to be put directly into the small intestine to help prevent weight loss and to improve nutrition. Less often, the tube may be placed into the lower part of the stomach instead. This is known as a *gastrostomy tube* or *G-tube*.



[Picture Credit: Jejunostomy]

Other important lifestyle changes include:

- If smoking, quit and get assistance – join the CANSA e-KickButt Programme
- Avoid drinking alcohol
- Limit salt intake
- Prevent being overweight or obese
- Eat a diet rich in vegetables and fresh fruit (in season)
- Avoid a diet rich in smoked, salted and pickled foods

(Life is Beautiful; NoStomachForCancer).

Replace salt in food with the following:

- Garlic powder NOT garlic salt. Garlic powder enhances most cooking and livens it up, from meat to fish to poultry to soups, pastas, stir fry and more

- Fresh ground black pepper is a great salt alternative. There is a huge difference between shaking black pepper and using fresh ground black pepper. Fresh ground black pepper is a more intense and aromatic flavour

- Onion powder NOT onion salt. Be sure to go easy when you first start using it because it is a fairly concentrated taste

- Fresh squeezed lemon juice is a wonderful salt alternative. Fresh squeezed lemon juice is so much better than lemon concentrate

- Lime juice is another salt alternative. Try adding it to water instead of drinking soda or pop. It will give the drink a kick. Lime is also great for making homemade salsa's

- For a crunchier salt alternative, try using unsalted ground sunflower seeds or sesame seeds. It makes great toppings to salads, stir fry and other roasted foods

- For cold deli style salads, try using mustard for notching up the salty taste but reducing the salt and sodium level way down.

- Do not forget about the ‘sweet’. Sweet can add ‘zing’ to foods and cooking also. Try cooking chicken in orange juice and reduced sugar marmalade for wonderful orange chicken! Try using sweetened dried cranberries (such as craisins) to perk up a carrot salad, or other meal. Sweet and sour and tart tastes often satisfy the taste buds and provide a great salt alternative

- Try some of the following herbs and spices: Oregano - a clear winner. In addition to oregano, a number of other herbs are also excellent salt replacements and, in addition, pack a significant antioxidant punch. Among the more familiar, ranked in order, are dill, garden thyme, rosemary and peppermint. Less familiar herbs with comparable antioxidant-power include rose geranium, sweet bay, purple amaranth, winter savoury and Vietnamese coriander

(Life is Beautiful; The World’s Healthiest Foods).

About Clinical Trials

Clinical trials are research studies that involve people. These studies test new ways to prevent, detect, diagnose, or treat diseases. People who take part in cancer clinical trials

have an opportunity to contribute to scientists' knowledge about cancer and to help in the development of improved cancer treatments. They also receive state-of-the-art care from cancer experts.

Types of Clinical Trials

Cancer clinical trials differ according to their primary purpose. They include the following types:

Treatment - these trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer. The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person's immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.

Prevention - these trials test new interventions that may lower the risk of developing certain types of cancer. Most cancer prevention trials involve healthy people who have not had cancer; however, they often only include people who have a higher than average risk of developing a specific type of cancer. Some cancer prevention trials involve people who have had cancer in the past; these trials test interventions that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer

Screening - these trials test new ways of finding cancer early. When cancer is found early, it may be easier to treat and there may be a better chance of long-term survival. Cancer screening trials usually involve people who do not have any signs or symptoms of cancer. However, participation in these trials is often limited to people who have a higher than average risk of developing a certain type of cancer because they have a family history of that type of cancer or they have a history of exposure to cancer-causing substances (e.g., cigarette smoke).

Diagnostic - these trials study new tests or procedures that may help identify, or diagnose, cancer more accurately. Diagnostic trials usually involve people who have some signs or symptoms of cancer.

Quality of life or supportive care - these trials focus on the comfort and quality of life of cancer patients and cancer survivors. New ways to decrease the number or severity of side effects of cancer or its treatment are often studied in these trials. How a specific type of cancer or its treatment affects a person's everyday life may also be studied.

Where Clinical Trials are Conducted

Cancer clinical trials take place in cities and towns in doctors' offices, cancer centres and other medical centres, community hospitals and clinics. A single trial may take place at one or two specialised medical centres only or at hundreds of offices, hospitals, and centres.

Each clinical trial is managed by a research team that can include doctors, nurses, research assistants, data analysts, and other specialists. The research team works closely with other health professionals, including other doctors and nurses, laboratory technicians, pharmacists, dieticians, and social workers, to provide medical and supportive care to people who take part in a clinical trial.

Research Team

The research team closely monitors the health of people taking part in the clinical trial and gives them specific instructions when necessary. To ensure the reliability of the trial's results, it is important for the participants to follow the research team's instructions. The instructions may include keeping logs or answering questionnaires. The research team may also seek to contact the participants regularly after the trial ends to get updates on their health.

Clinical Trial Protocol

Every clinical trial has a protocol, or action plan, that describes what will be done in the trial, how the trial will be conducted, and why each part of the trial is necessary. The protocol also includes guidelines for who can and cannot participate in the trial. These guidelines, called eligibility criteria, describe the characteristics that all interested people must have before they can take part in the trial. Eligibility criteria can include age, sex, medical history, and current health status. Eligibility criteria for cancer treatment trials often include the type and stage of cancer, as well as the type(s) of cancer treatment already received.

Enrolling people who have similar characteristics helps ensure that the outcome of a trial is due to the intervention being tested and not to other factors. In this way, eligibility criteria help researchers obtain the most accurate and meaningful results possible.

National and International Regulations

National and international regulations and policies have been developed to help ensure that research involving people is conducted according to strict scientific and ethical principles. In these regulations and policies, people who participate in research are usually referred to as "human subjects."

Informed Consent

Informed consent is a process through which people learn the important facts about a clinical trial to help them decide whether or not to take part in it, and continue to learn new information about the trial that helps them decide whether or not to continue participating in it.

During the first part of the informed consent process, people are given detailed information about a trial, including information about the purpose of the trial, the tests and other procedures that will be required, and the possible benefits and harms of taking part in the trial. Besides talking with a doctor or nurse, potential trial participants are given a form, called an informed consent form, that provides information about the trial in writing. People who agree to take part in the trial are asked to sign the form. However, signing this form does not mean that a person must remain in the trial. Anyone can choose to leave a trial at any time—either before it starts or at any time during the trial or during the follow-up period. It is important for people who decide to leave a trial to get information from the research team about how to leave the trial safely.

The informed consent process continues throughout a trial. If new benefits, risks, or side effects are discovered during the course of a trial, the researchers must inform the participants so they can decide whether or not they want to continue to take part in the trial. In some cases, participants who want to continue to take part in a trial may be asked to sign a new informed consent form.

New interventions are often studied in a stepwise fashion, with each step representing a different “phase” in the clinical research process. The following phases are used for cancer treatment trials:

Phases of a Clinical Trial

Phase 0. These trials represent the earliest step in testing new treatments in humans. In a phase 0 trial, a very small dose of a chemical or biologic agent is given to a small number of people (approximately 10-15) to gather preliminary information about how the agent is processed by the body (pharmacokinetics) and how the agent affects the body (pharmacodynamics). Because the agents are given in such small amounts, no information is obtained about their safety or effectiveness in treating cancer. Phase 0 trials are also called micro-dosing studies, exploratory Investigational New Drug (IND) trials, or early phase I trials. The people who take part in these trials usually have advanced disease, and no known, effective treatment options are available to them.

Phase I (also called phase 1). These trials are conducted mainly to evaluate the safety of chemical or biologic agents or other types of interventions (e.g., a new radiation therapy technique). They help determine the maximum dose that can be given safely (also known as the maximum tolerated dose) and whether an intervention causes harmful side effects. Phase I trials enrol small numbers of people (20 or more) who have advanced cancer that cannot be treated effectively with standard (usual) treatments or for which no standard treatment exists. Although evaluating the effectiveness of interventions is not a primary goal of these trials, doctors do look for evidence that the interventions might be useful as treatments.

Phase II (also called phase 2). These trials test the effectiveness of interventions in people who have a specific type of cancer or related cancers. They also continue to look at the safety of interventions. Phase II trials usually enrol fewer than 100 people but may include as many as 300. The people who participate in phase II trials may or may not have been treated previously with standard therapy for their type of cancer. If a person has been treated previously, their eligibility to participate in a specific trial may depend on the type and amount of prior treatment they received. Although phase II trials can give some indication of whether or not an intervention works, they are almost never designed to show whether an intervention is better than standard therapy.

Phase III (also called phase 3). These trials compare the effectiveness of a new intervention, or new use of an existing intervention, with the current standard of care (usual treatment) for a particular type of cancer. Phase III trials also examine how the side effects of the new intervention compare with those of the usual treatment. If the new intervention is more effective than the usual treatment and/or is easier to tolerate, it may become the new standard of care.

Phase III trials usually involve large groups of people (100 to several thousand), who are randomly assigned to one of two treatment groups, or “trial arms”: (1) a control group, in which everyone in the group receives usual treatment for their type of cancer, or 2) an investigational or experimental group, in which everyone in the group receives the new intervention or new use of an existing intervention. The trial participants are assigned to their individual groups by random assignment, or randomisation. Randomisation helps ensure that the groups have similar characteristics. This balance is necessary so the researchers

can have confidence that any differences they observe in how the two groups respond to the treatments they receive are due to the treatments and not to other differences between the groups.

Randomisation is usually done by a computer program to ensure that human choices do not influence the assignment to groups. The trial participants cannot request to be in a particular group, and the researchers cannot influence how people are assigned to the groups. Usually, neither the participants nor their doctors know what treatment the participants are receiving.

People who participate in phase III trials may or may not have been treated previously. If they have been treated previously, their eligibility to participate in a specific trial may depend on the type and the amount of prior treatment they received.

In most cases, an intervention will move into phase III testing only after it has shown promise in phase I and phase II trials.

Phase IV (also called phase 4). These trials further evaluate the effectiveness and long-term safety of drugs or other interventions. They usually take place after a drug or intervention has been approved by the medicine regulatory office for standard use. Several hundred to several thousand people may take part in a phase IV trial. These trials are also known as post-marketing surveillance trials. They are generally sponsored by drug companies.

Sometimes clinical trial phases may be combined (e.g., phase I/II or phase II/III trials) to minimize the risks to participants and/or to allow faster development of a new intervention.

Although treatment trials are always assigned a phase, other clinical trials (e.g., screening, prevention, diagnostic, and quality-of-life trials) may not be labelled this way.

Use of Placebos

The use of placebos as comparison or “control” interventions in cancer treatment trials is rare. If a placebo is used by itself, it is because no standard treatment exists. In this case, a trial would compare the effects of a new treatment with the effects of a placebo. More often, however, placebos are given along with a standard treatment. For example, a trial might compare the effects of a standard treatment plus a new treatment with the effects of the same standard treatment plus a placebo.

Possible benefits of taking part in a clinical trial

The benefits of participating in a clinical trial include the following:

- Trial participants have access to promising new interventions that are generally not available outside of a clinical trial.
- The intervention being studied may be more effective than standard therapy. If it is more effective, trial participants may be the first to benefit from it.
- Trial participants receive regular and careful medical attention from a research team that includes doctors, nurses, and other health professionals.
- The results of the trial may help other people who need cancer treatment in the future.

- Trial participants are helping scientists learn more about cancer (e.g., how it grows, how it acts, and what influences its growth and spread).

Potential harms associated with taking part in a clinical trial

The potential harms of participating in a clinical trial include the following:

- The new intervention being studied may not be better than standard therapy, or it may have harmful side effects that doctors do not expect or that are worse than those associated with standard therapy.
- Trial participants may be required to make more visits to the doctor than they would if they were not in a clinical trial and/or may need to travel farther for those visits.

Correlative research studies, and how they are related to clinical trials

In addition to answering questions about the effectiveness of new interventions, clinical trials provide the opportunity for additional research. These additional research studies, called correlative or ancillary studies, may use blood, tumour, or other tissue specimens (also known as 'biospecimens') obtained from trial participants before, during, or after treatment. For example, the molecular characteristics of tumour specimens collected during a trial might be analysed to see if there is a relationship between the presence of a certain gene mutation or the amount of a specific protein and how trial participants responded to the treatment they received. Information obtained from these types of studies could lead to more accurate predictions about how individual patients will respond to certain cancer treatments, improved ways of finding cancer earlier, new methods of identifying people who have an increased risk of cancer, and new approaches to try to prevent cancer.

Clinical trial participants must give their permission before biospecimens obtained from them can be used for research purposes.

When a clinical trial is over

After a clinical trial is completed, the researchers look carefully at the data collected during the trial to understand the meaning of the findings and to plan further research. After a phase I or phase II trial, the researchers decide whether or not to move on to the next phase or stop testing the intervention because it was not safe or effective. When a phase III trial is completed, the researchers analyse the data to determine whether the results have medical importance and, if so, whether the tested intervention could become the new standard of care.

The results of clinical trials are often published in peer-reviewed scientific journals. Peer review is a process by which cancer research experts not associated with a trial review the study report before it is published to make sure that the data are sound, the data analysis was performed correctly, and the conclusions are appropriate. If the results are particularly important, they may be reported by the media and discussed at a scientific meeting and by patient advocacy groups before they are published in a journal. Once a new intervention has proven safe and effective in a clinical trial, it may become a new standard of care.
(National Cancer Institute).

Medical Disclaimer

This Fact Sheet is intended to provide general information only and, as such, should not be considered as a substitute for advice, medically or otherwise, covering any specific situation. Users should seek appropriate advice before taking or refraining from taking any action in reliance on any information contained in this Fact Sheet. So far as permissible by law, the Cancer Association of South Africa (CANSA) does not accept any liability to any person (or his/her dependants/estate/heirs) relating to the use of any information contained in this Fact Sheet.

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